Reuse and Emerging Contaminants of Concern

Dave Clark, P.E.
Mike Murray, Ph.D.
Glen Boyd, Ph.D.

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HDR

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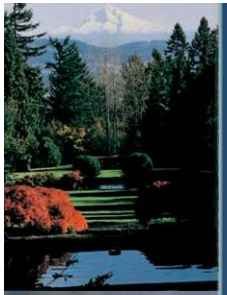
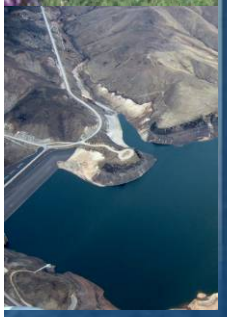
Presentation Overview

- What are ECOC, PPCPs, EDCs?
- Occurrence in Environment
- Wastewater Treatment
- Reuse
- Source Control
- Conclusions and Recommendations

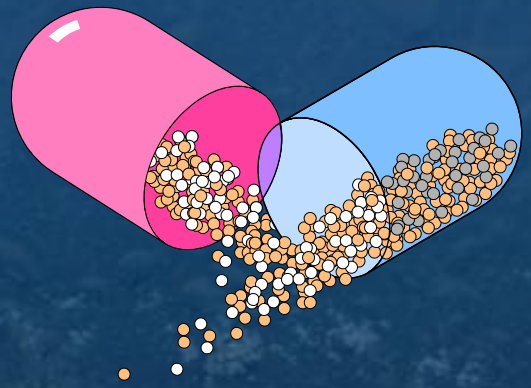


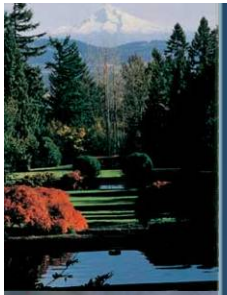


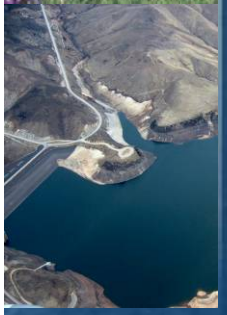
Emerging Contaminants of Concern

- Emerging contaminants of concern (ECOC) are defined as those chemicals that are not commonly monitored, but have been shown to occur in the environment and may have the potential to represent an ecosystem or public health risk

- *Pharmaceuticals and Personal Care Products (PPCPs)*
- *Endocrine Disrupting Chemicals (EDCs)*







A Tongue-in-cheek Guide to Emerging Contaminants of Concern

- Generally have long and unpronounceable names

No one is sure what their presence means

  - So everyone assumes it has got to be bad

- Practically unlimited in number
  - No sooner do you get a handle on one, another pops up

- Improving analytical methods only make it worse

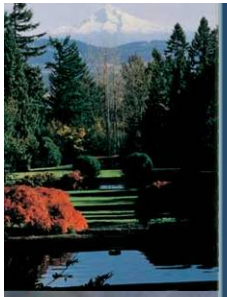
- Guaranteed to keep regulators (and researchers) busy for years to come

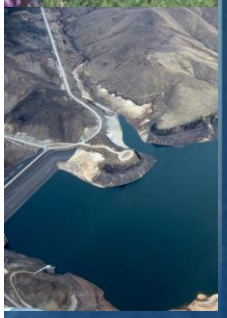
So what is an Emerging Contaminant of Concern? If it quacks like a duck…

- Present at trace concentrations
  - Typically part per trillion
  - At or near detection level
- Heath effects data lacking at concentrations of interest
  - Frequently adverse effects at concentrations several magnitudes higher than occurrence
- Pathways and magnitude of exposure uncertain
- Regulatory framework lacking

Pharmaceuticals and Personal Care Products (PPCPs)

- PPCPs comprise a very broad, diverse collection of thousands of chemical substances, including prescription and over-the-counter therapeutic drugs, fragrances, cosmetics, sun-screen agents, diagnostic agents, biopharmaceuticals, and many others.
- Any product consumed by individuals for personal health or cosmetic reasons
- Not new, analytical instrumentation now allows us to see ppb and ppt range



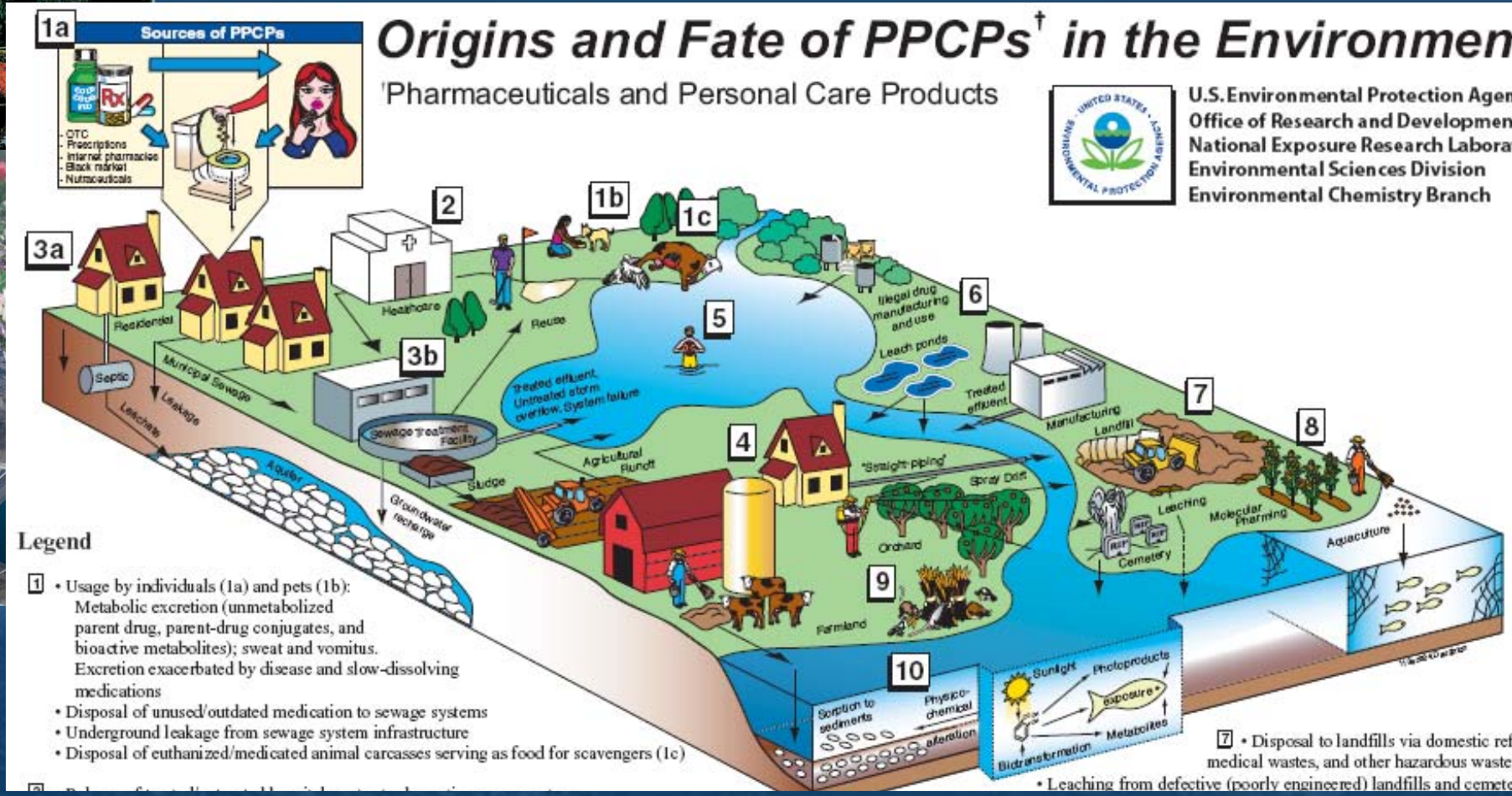


Occurrence in the Environment

Origins and Fate of PPCPs† in the Environment

†Pharmaceuticals and Personal Care Products

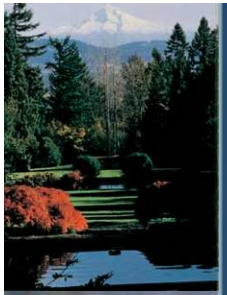
U.S. Environmental Protection Agency
Office of Research and Development
National Exposure Research Laboratory
Environmental Sciences Division
Environmental Chemistry Branch

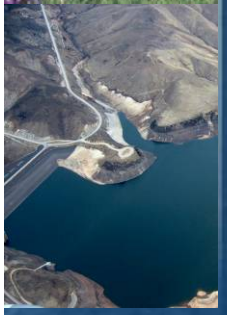


Legend

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)

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





Pharmaceuticals and Personal Care Products (PPCPs)

- Peer-reviewed papers reporting measurable levels of PPCPs in waters (soils)
  - Municipal effluents
  - Surface, ground and drinking water
- Levels are typically low (ng-µg/L)
- Potential Concern – chronic, developmental or reproductive effects in aquatic organisms due to biological activity of PPCPs (Datson et al., 2003)

ENVIRONEWS
Forum

We should no longer think of water as a gift of nature but an industry which needs investment.
Thawat Vichaidiji, Thai water official
quoted in the *Bangkok Post*, 17 March 1991

WATER POLLUTION

Drugged Drinking Water

Drugs and personal care products that are excreted from or washed off the body naturally end up in the sewage that flows into sewer systems and septic tanks, but where do they go from there? Scientists are beginning to monitor the extent of pharmaceutical and personal care products (PPCPs) in the aquatic environment and their consequences. What they're finding is that, through leaching from septic tanks and escaping intact through sewage treatment processes, some of these substances are ending up back in the drinking water.

Germany has been at the forefront of PPCP monitoring. Studies conducted there during the past 10 years confirmed the presence of PPCPs in treated and untreated sewage effluent, surface water, groundwater, and drinking water. Most commonly found were anti-inflammatory and pain-killing drugs, cholesterol-lowering drugs, anticonvulsants, and sex hormones from oral contraceptives. Samples from 40 German rivers and streams turned up residues of 21 different PPCPs, according to a report presented at the March 2000 American Chemical Society meeting in San Francisco, California, by Thomas Ternes, a chemist at the Institute for Water Research and Water Technology in Wiesbaden.

Researchers worldwide have discovered more than 60 different PPCPs in water sources, according to Christian Daughton, chief of the Environmental Chemistry Branch of the U.S. Environmental Protection Agency (EPA) Environmental Sciences Division in Las Vegas, Nevada. In addition to the drugs noted above, the list includes antineoplastics, beta-blockers, bronchodilators, lipid regulators, hypnotics, antibiotics, antiseptics, X-ray contrast agents, sunscreen agents, caffeine, and fragrances such as synthetic musks. Most PPCPs are detected at concentrations ranging from parts per trillion to parts per billion, and originate in treated and untreated sewage, says Daughton, who coauthored an article on PPCPs in the December 1999 issue of *EHP Supplements*.

North American researchers are just beginning to look at the issue of PPCPs. Studies presented at the June 2000 Emerging Issues Conference sponsored by the National Ground Water Association, held in Minneapolis, Minnesota, indicate that the problem exists here, too. For example, environmental scientist Chris Metcalfe of Trent University in Peterborough, Ontario, detected the drugs aspirin, ibuprofen, indomethacin, bezafibrate (a cholesterol regulator), and carbamazepine (an anticonvulsant) in 10 pre- and post-treatment samples from sewage treatment plants in eastern Canada. The sewage treatment process in place removed some drugs that were easily biodegradable or more amenable to removal by activated charcoal, degradative microbes, or sand filtration, but others were resistant to degradation.

Metcalfe is just beginning to analyze the effects of cholesterol-lowering drugs, estrogens, and anticonvulsants on fish in the Great Lakes. All three drug types can potentially interfere with normal reproduction and development in fish living downstream from sewage treatment plants. His laboratory studies show that estrogen compounds at parts-per-trillion exposures feminize male fish and disrupt the development of the circulatory system, eyes, and bladder. He says it's too soon to know whether PPCPs adversely affect wild fish populations.

In one of the first studies in the United States to report the occurrence of drugs in drinking water, environmental engineer Glen Boyd had his students at Tulane University in New Orleans, Louisiana, sample water from the Mississippi River, a local lake, and city tap water. Their preliminary experiment targeted the pain reliever naproxen, the sex hormone estrone, and clofibric acid, a major bioactive metabolite from certain anticholesterol drugs. All three were detected at varying concentrations in most of the samples. "The big unknown," says Boyd, "is whether PPCPs present a health concern now or in the future." He notes that, although the number of peer-reviewed papers on the topic is limited, government agencies concerned with water quality in the United States and professional organizations serving the water and wastewater communities are beginning to acknowledge PPCPs as an emerging environmental issue.

The long-term outcome of humans ingesting subtherapeutic doses of numerous drugs as well as any dose at all of substances not meant to be ingested remains a major unaddressed issue. "In areas of water scarcity, we'll see more and more reuse of treated sewage to meet drinking water needs," predicts Daughton, thereby increasing the likelihood that PPCPs will end up in drinking water. Extensive monitoring of the occurrence of PPCPs and their concentration trends over time is required to ensure safe water supplies in the future. Then toxicologists need to determine if the kinds and amounts of PPCPs that occur affect people and other living creatures. This subject will require collaboration between the Food and Drug Administration and the EPA, says Daughton, since the former usually does not address environmental concerns and the latter generally does not deal with drug issues.

–Carol Potera

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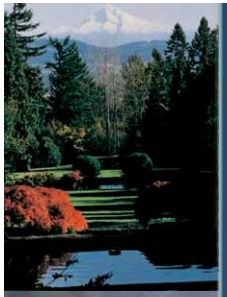
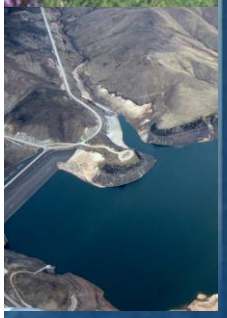
VOLUME 108 | NUMBER 10 | October 2000 • Environmental Health Perspectives

Ref: *Env. Health Persp.*, Oct 2000.

Tadpole Development

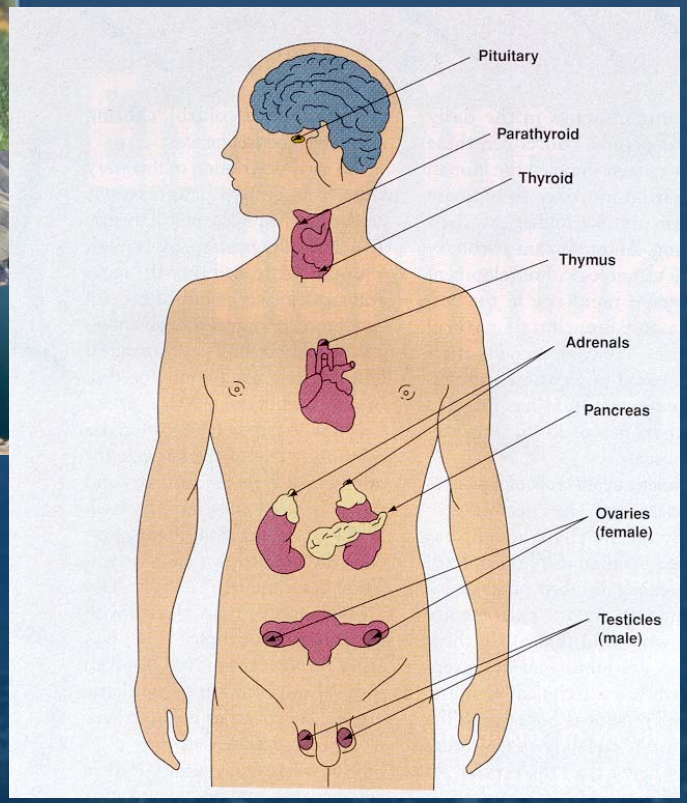
Two tadpoles after 57 days of development in the lab. The one on the right, which has yet to sprout limbs, was exposed to (at unknown levels) Prozac.





Wastewater Treatment

Endocrine Disrupting Chemicals (EDCs)



<u>Endocrine Disruptor</u> – an exogenous substance or mixture that alters functions of the endocrine (hormone) system and consequently causes adverse health effects.

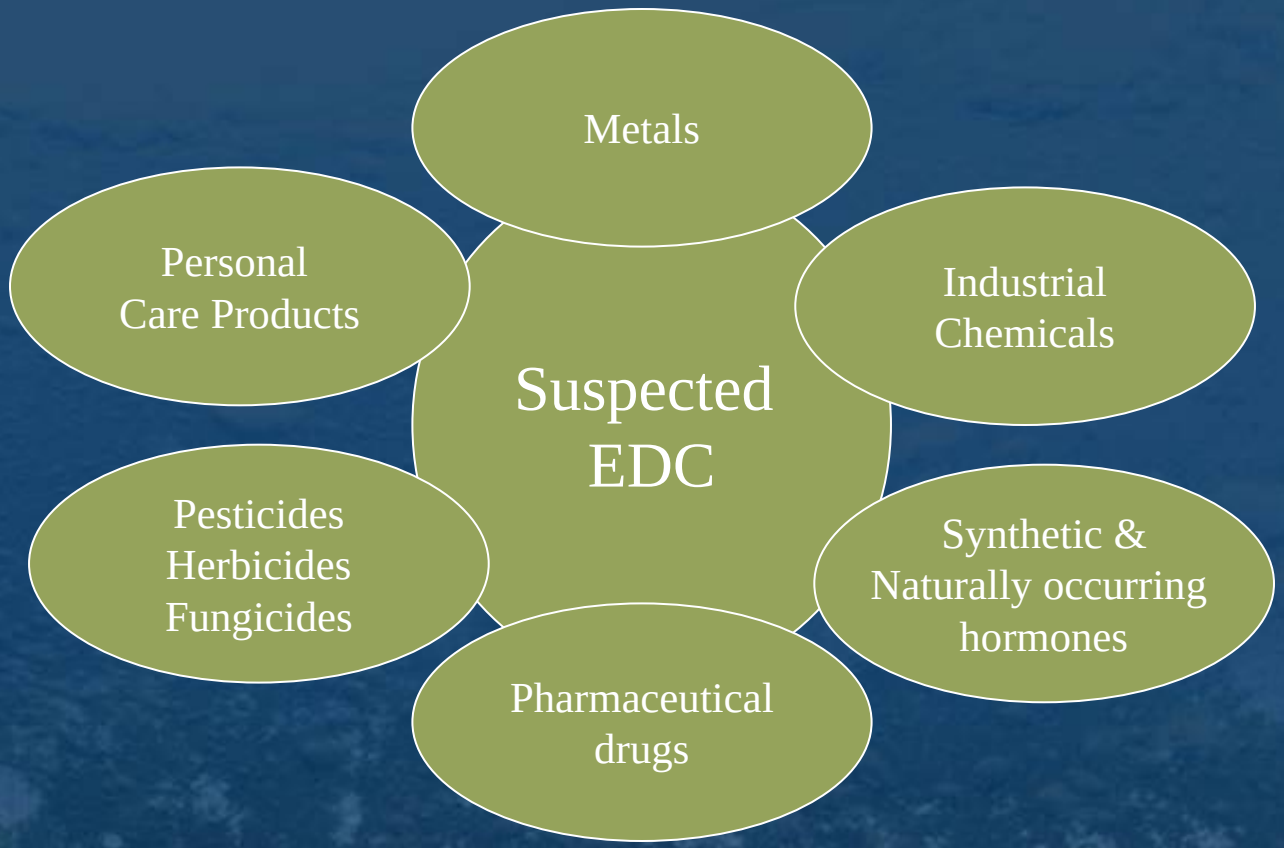
<u>Dose-Response Relationship</u>

- **EDCs mimic or antagonize natural hormones**
- **Low-dose effects - controversial**
- **Timing of exposure is critical**

Trussel, R. 2001. *JAWWA* 93(2):58-65

WHO. 2002. *Global Assessment of EDCs*.

Some Chemicals From These Groups are Potential EDCs



What Are The Concerns?

- WEF Congressional Briefing March 23, 2007
  - Ed Ohanian, EPA Office of Water
    - Fish Tissue Study of 37 Pharmaceuticals in Discharges From 5 Plants – Dec 2007
    - Study of Discharges of 10 Plants -- 2008
    - Biosolids Study of 75 Compounds – Dec 2008
- Dana Kolpin, Chief USGS Toxic Substances Hydrology Program
  - USGS has "definitive" evidence from laboratory experiments in Boulder, Colo…….. that chemical compounds found in pesticides, agricultural runoff, stormwater runoff, household detergents, and drugs *that pass through wastewater treatment plants are responsible for "feminizing" male fish downstream of such plants*.

'Intersex' fish found off Calif. coast

LOS ANGELES — Scientists have discovered sexually altered fish off the Southern California coast, raising concerns that treated sewage discharged into the ocean contains chemicals that can affect an animal's reproductive system.

Nearly a billion gallons of treated sewage are released into the Pacific Ocean every day through three underwater pipelines off Huntington Beach, Playa del Rey and Palos Verdes Peninsula.

Male fish producing eggs; is pollution to blame?

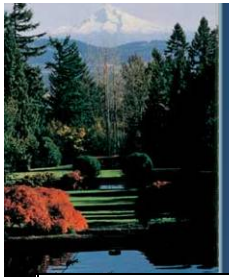
The Washington Post

WASHINGTON — Abnormally developed fish, possessing both male and female characteristics, have been discovered in the Potomac River in Washington, D.C., and in tributaries across the region, federal scientists say — **raising alarms that the river is tainted by pollution that drives hormone systems haywire.**

Mechanisms of EDC Removal

- Adsorption
- Biological Degradation
- Transformation/Degradation
- Volatilization

- Key Factors in EDC Removal
  - Physical/Chemical Properties of EDCs
  - Temperature
  - Sludge Age
  - Treatment Process
  - Influent Concentrations
  - Acclimation time
  - Concentration of Co-metabolites
  - Hydraulic Retention Time



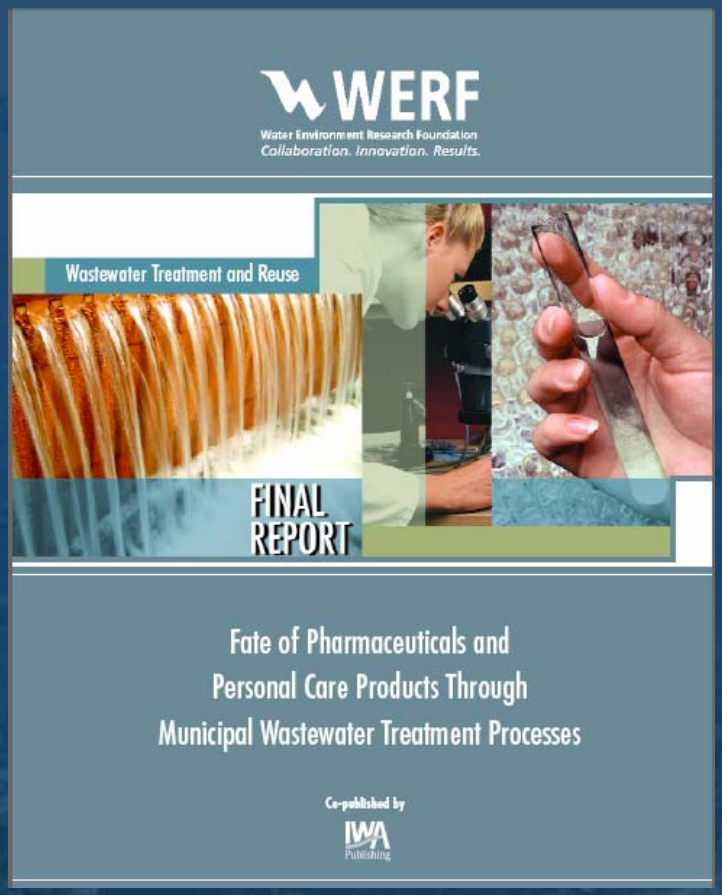
Liquid Stream Wastewater Treatment Process Effectiveness

Treatment Process	Parameter	Removal Efficiency	References and Comments
• Secondary Treatment (Activated Sludge, Trickling Filter, MBR)	Naproxen Estrogens Sulfonamides, macrolides, and trimethoprim	Low removal 77% to ?90% Incomplete removal	• Metcalfe et al., 2003 low removal of naproxen with short HRT • Joss et al. (2004) observed >90% removal estrogens (estrone, estradiol, and ethinylestradiol) in activated sludge, and 77% estrone and ?90% estradiol in fixed bed reactor. • Göbel et al. (2005) found removal of sulfonamides, macrolides and trimethoprim incomplete activated sludge treatment
• Disinfection (Cl_2)	Naproxen, phenols, aromatic ether and amine-containing pharmaceuticals	Oxidation and formation of rxn products	• Boyd et al. (2005) showed that synthetic waters containing elevated concentrations of naproxen were oxidized by free chlorine and formed disinfection products • Recent research aimed at characterizing transformation kinetics and identifying reaction products with chlorine (Gallard and von Gunten, 2002
• Disinfection (Ozone)	Pharmaceuticals, PPCPs	Effective removal	• Huber et al. (2005) showed that many pharmaceuticals in wastewater can be effectively oxidized with • Other studies reported by Zwiener and Frimmel (2000); Ternes et al. (2003); Huber et al. (2003).
• Effluent Filtration (Membrane)			• Heberer et al. (2002); Nghiem and Schäfer (2002).

Solids Stream Treatment Process Effectiveness

Treatment Process	Parameter	Removal Efficiency	References and Comments
• Anaerobic Digestion	EDCs	Possible increase in estrogenic activity	• Holbrook et al. (2002) reported increase in estrogenic activity • Andersen et al. (2003) reported an increase in natural estrogen concentrations in the water and sludge phases from a mesophilic anaerobic
• Aerobic Digestion	EDCs	Possible increase in estrogenic activity	• Holbrook et al. (2002) reported an observed increase in estrogenic activity

WERF Fate of Pharmaceuticals and Personal Care Products Through Municipal Wastewater Treatment Processes



- PPCP Removals
  - 6 Activated Sludge Plants
  - 2 MBR Pilot Plants

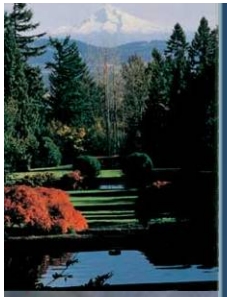
WERF Fate of Pharmaceuticals and Personal Care Products Through Municipal Wastewater Treatment Processes

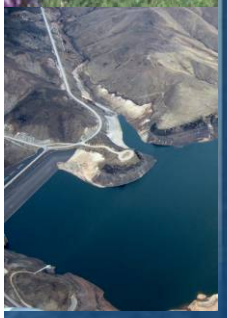
- Key Study Findings
  - Increased SRT Enhanced Removal of Majority of PPCPs
  - SRT Required for >80% Removal is Compound Specific
    - Many in Range SRT 5 to 15 Days
    - Complete Removal of Most with SRT>10 Days
  - Long SRT for 80% Removal of Some PPCPs
    - Galaxolide, Musk Ketone, Tri(chloroethyl) Phosphate
- To Achieve Good Results for Most Compounds, a Second Barrier Might be Necessary
- No Obvious Advantage of MBR over CAS for Similar SRT
  - Micro and Ultra Filtration Membranes Cannot Remove PPCP Molecules 100 Times Smaller Than Pore Size of Membranes
- No PPCPs Detected Following Reverse Osmosis Treatment

MBR vs Conventional Activated Sludge (CAS)

- Estrogenic Steroid Removals
  - E1 (metabolite of E2)
  - E2 (natural estrogen)
  - EE2 (synthetic estrogen)
- Enhanced MBR Removals
  - 99% Removal E1 and E2
  - 90% Removal EE2
- Lower Conventional Activated Sludge Removals
  - 90% Removal E1 and E2
  - ~59% to 82% Removal EE2
- Select Pharmaceuticals
- No Removal in MBR or CASf
  - Carbamazepine (anti-epileptic drug)
  - AMDOPH (metabolite of an analgesic)
- MBR 30% Removal vs CAS 15%
  - Phenazone (analgesic), Propyhenazone, and FAA (metabolite)
- MBR Conclusions
  - Allows Retention and Cultivation of Slow-growing Metabolic Specialists
  - Adaptation Period of ~5 Months Required

Zuehlke, et al, "Long-Term Comparison of Trace Organics Removal Performances Between Conventional and Membrane Activated Sludge Processes," Water Environment Research, Vol. 78, No. 13, December 2006





Reuse

Reuse and Emerging Contaminants of Concern

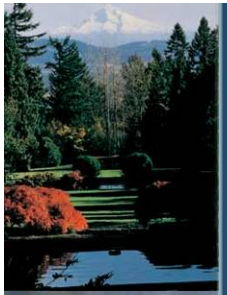
- Most common wastewater reuse in Idaho is irrigation (agricultural lands, golf courses, parks)
- Slow rate systems, applied during the growing season
- Fate and transport of ECOC in the soil system?

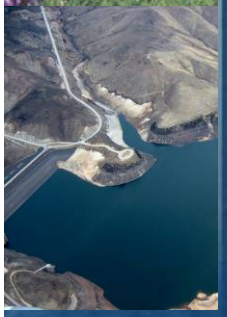
Reuse and Emerging Contaminants of Concern

- Reuse studies looking at ECOC
  - *Presence and Distribution of Wastewater-Derived Pharmaceuticals in Soil Irrigated with Reclaimed Water*. Kinney et al., 2006, Environmental Toxicology and Chemistry, Vol. 25, No. 2, pp 317-326

Colorado Study (Kinney et al, 2006)

- Medium size Front Range city
- Sprinkler irrigated reclaimed water from single source.
- Investigated 3 locations: City Hall lawn; Golf course; treatment facility lawn
- Reclaimed water (Class A): coagulation and filtration, disinfection with chlorine





Soils

Table 1. Soil characteristics by depth for the three field sites (CO, USA)

Location	Density (g/cm)	Organic carbon (%)	Clay (%)[a]	Silt (%)[a]	Sand (%)[a]	Soil pH[b]
City hall (3)[c]						
0–5 cm	0.52	0.877	2.46	19.7	76.1	6.5
5–10 cm	1.24	0.465	4.47	31.9	55.3	7.9
10–15 cm	1.54	0.057	7.92	49.9	40.8	7.9
15–20 cm	1.64	0.061	8.76	60.8	29.7	7.9
20–25 cm	1.65	0.042	9.94	63.6	26.2	7.9
25–30 cm	1.80	0.083	9.61	62.4	27.5	8.2
Golf course (4)						
0–5 cm	0.50	0.364	4.45	27.8	62.4	6.0
5–10 cm	1.34	0.199	13.2	83.9	2.8	8.0
10–15 cm	1.39	0.157	8.81	58.7	32.4	7.9
15–20 cm	1.50	0.199	9.4	62.6	27.7	7.9
20–25 cm	1.71	0.116	23.6	76.1	0.0	7.9
25–30 cm	1.75	0.094	17.3	82.5	0.0	7.8
Reclaimed water facility (2)						
0–5 cm	0.83	0.205	3.47	27.7	66.2	7.5
5–10 cm	0.97	0.191	5.99	39.0	54.8	7.9
10–15 cm	1.64	0.038	5.07	35.6	59.2	7.8
15–20 cm	1.67	0.027	5.58	33.0	55.2	8.3
20–25 cm	1.71	0	5.29	37.8	56.4	8.3
25–30 cm	1.75	0.040	5.03	35.9	59.1	8.2

[a] Percentage of the total soil material.
[b] In a 1:1 soil solution.
[c] Values in parentheses are the typical water frequency (d/week) during the majority of the irrigation season.

Concentrations (ng/L)

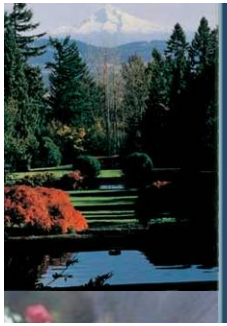
Pharmaceutical	May 14, 2003	July 16, 2003	September 16, 2003	Water solubility (mg/L)[a]	Log K_{ow}[a]
Cotinine	16.5 (2.47)[b]	61.8 (6.97)	22.3 (2.70)	9.99×10^5	0.07
Salbutamol	11.4 (0.17)	ND[c]	6.71 (0.36)	1.43×10^4	0.64
Cimetidine	ND	ND	ND	9.38×10^3	0.40
Acetaminophen	8.1 (2.24)	65.3 (8.83)	33.8 (8.42)	1.4×10^4	0.46
1, 7-Dimethylxanthine	64.5 (9.04)	ND	57.0 (29.8)	—[d]	—
Trimethoprim	42.0 (6.95)	1.77 (0.25)	1.96 (0.16)	400	0.91
Diltiazem	4.61 (0.76)	7.43 (2.29)	2.17 (0.22)	465	2.79
Fluoxetine	5.40 (0.88)	1.23 (0.35)	1.73 (0.31)	60.3	4.05
Warfarin	73.4 (17.9)	ND	ND	17	2.60
Gemfibrozil	93.6 (14.7)	ND	ND	—	4.77
Caffeine	9.72 (1.45)	1.97 (3.41)	17.2 (3.68)	2.1×10^4	−0.07
Sulfamethoxazole	59.2 (10.7)	ND	2.61 (0.19)	610	0.89
Dehydronifedipine	3.58 (0.71)	3.30 (0.95)	1.24 (0.08)	—	—
Codeine	58.7 (8.90)	ND	27.9 (3.16)	9.0×10^3	1.19
Thiabendazole	72.7 (8.14)	5.67 (0.35)	13.9 (0.74)	50	2.47
Diphenhydramine	72.1 (9.50)	38.4 (10.2)	10.1 (0.76)	3.06×10^3	3.27
Erythromycin	177 (29.1)	611 (88.3)	154 (24.13)	1.44	3.06
Carbamazepine	71.8 (10.9)	93.6 (25.2)	43.1 (1.10)	17.7	2.45
Miconazole	ND	ND	0.33 (0.31)	—	6.25

[a] Solubility and log K_{ow} data from Syracuse Research Corporation (http://www.syrres.com/esc).

[b] Values in parentheses are the standard deviation for the given compound on that collection date (n = 3).

[c] Not detected.

[d] Values not given.

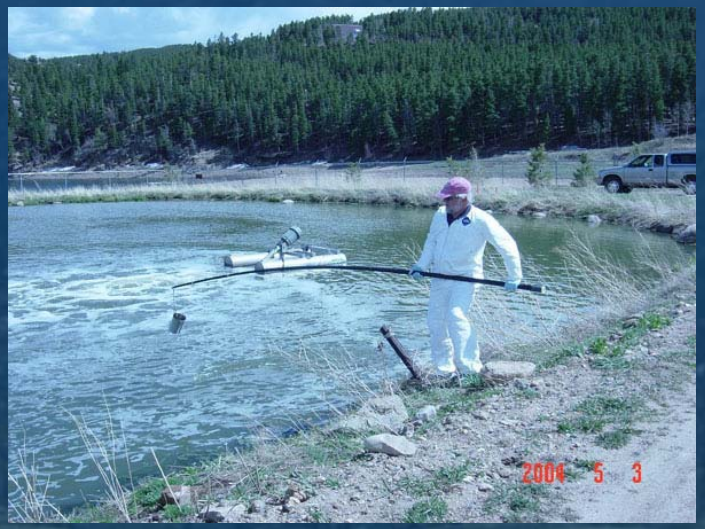


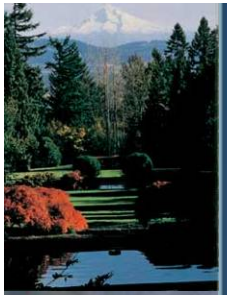
Integrated Mass 0-30 cm City Hall (ng)

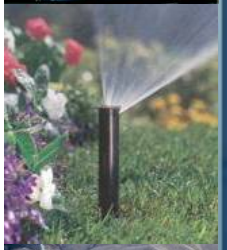
Pharmaceutical	Preirrigation (April 1, 2003)	First postirrigation (June 2, 2003)	June 16, 2003	July 16, 2003	August 19, 2003	September 16, 2003	Total no. of detections
Cotinine	85.2	0	169	133	10.2	0	14
Salbutamol	0	166	176	0	0	0	4
Cimetidine	47.7	0	0	39.6	0	0	2
Acetaminophen	399	326	283	394	830	1,640	15
1,7-Dimethyixanthine	0	0	490	0	1,640	0	2
Trimethoprim	3.11	31.6	60.0	19.8	5.90	21.5	8
Diltiazem	6.23	0	8.89	0	0	0	3
Fluoxetine	109	147	376	23.9	122	249	31
Warfarin	15.8	0	0	2,770	0	0	7
Gemfibrozil	264	0	0	0	0	0	3
Caffeine	0	22.7	32.8	162	260	317	8
Sulfamethoxazole	52.7	282	260	0	138	332	13
Dehydronifedipine	43.6	0	9.46	75.7	19.7	13.7	16
Codeine	0	0	0	0	0	0	0
Thiabendazole	39.3	32.4	29.0	64.7	35.9	350	17
Diphenhydramine	30.5	0	67.9	33.9	49.7	0	18
Erythromycin	2,750	3,690	4,600	1,860	4,380	6,270	36
Carbamazapine	193	278	380	257	401	549	31
Miconazole	19.6	20.7	64.8	0	45.9	13.5	11

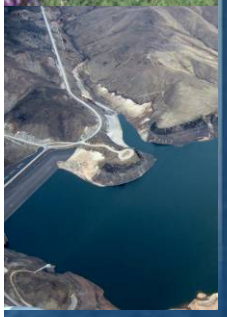
Colorado Study

- Use of Reclaim water can result in presence and accumulation of pharmaceuticals in soil
- Some are mobile (30 cm)
- Additional studies needed to determine leaching
- Soil organic matter controlling factor in retention



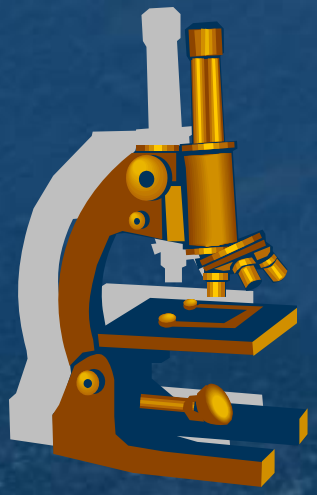






Colorado Study

- Unknown if existence of pharmaceuticals at concentrations observed pose a risk to human or environmental health.

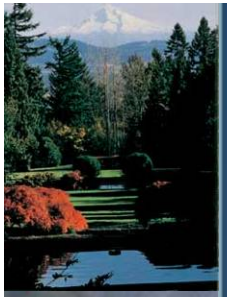
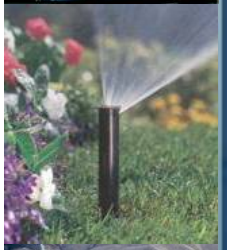
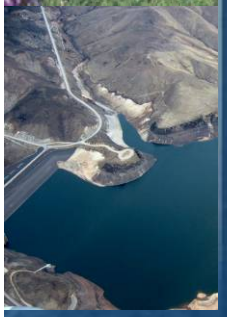


Aquatic versus Soil System

Parameter	Aquatic (river)	Soil System
Organic Carbon	4 mg/L	40,000 mg/Kg
Microbial Populations	1 X 10^{7} cells/L	1 X $10^{10\text{-}12}$ cells/g
Residence Time	1 to 20 days	Years to decades
Pathways	Microbial decomposition Abiotic reactions Photolysis Small to moderate sorption Low to moderate oxygen transfer	Microbial decomposition Abiotic reactions Pytoremediation Substantial sorption High oxygen transfer Highly buffered system

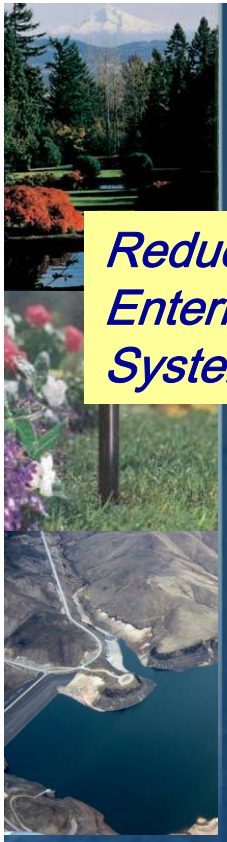
Phenol toxic to m/o 0.001 to 0.2 mg/L in aquatic system

Phenol at 200 mg/L no toxic effect m/o in soils

Source Control

Source Control for EDCs



Reduce Quantities Entering Collection System

Water Reclamation Facility

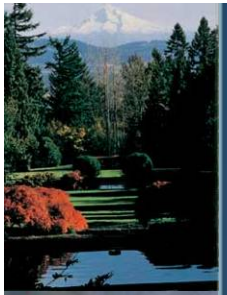
River

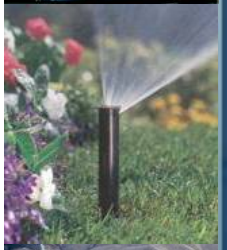
Reuse

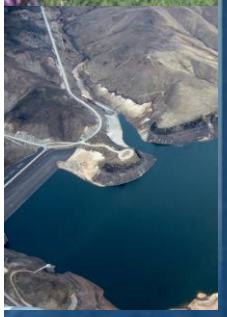
- Urban Irrigation
  - •Parks, Schools, Fairgrounds
- Industrial Reuse
  - •Paper Mill, Rock Crushing, Concrete
- Groundwater Recharge
  - • Surface Percolation
- Wetlands Restoration
  - •Creation, Restoration, Enhancement
- Other
  - •Agricultural Land, Poplar Farms

Pharmaceutical Collection Programs - Benefits and Challenges

- Public Education
  - Foster Understanding of Water Quality Impacts
  - Reduce Medications Flushed to Sewer
  - Disposal Information on Medication Containers
- Provide Collection Programs
  - Collection Bins in Retail Pharmacies
  - Household Pharmaceutical Collection Days
- "Green Guide for Healthcare“
  - Design, Construction, Operation BMPs based on LEED System
- Broad Group of Stakeholders
  - Wastewater Utility
  - Solid Waste Utility
  - Health Care Industry
    - Pharmacies, Hospitals, Nursing Homes, Extended Care Facilities
  - Law Enforcement
- DEA Regulations to Eliminate Drug Diversions
  - Prescription Controlled Substances
  - Closed System Manufacturers, Distributors, Pharmacies, and Physicians – ***But Not Patients***
- RCRA Challenges to Managing Pharmaceutical Wastes
  - Epinephrine, Warfarin, Lindane, and 9 Chemotherapy Agents Classified as Hazardous Waste







White House Guidelines for *Proper Disposal of Prescription Drugs – Feb 2007*

Proper Disposal of Prescription Drugs

Office of National Drug Control Policy — February 2007

Federal Guidelines:

- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
- Mixing prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Flush prescription drugs down the toilet *only* if the label or accompanying patient information specifically instructs doing so (see box).
- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.

The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:

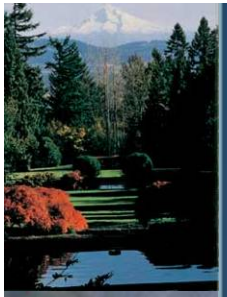
Actiq (fentanyl citrate)
Daytrana Transdermal Patch (methylphenidate)
Duragesic Transdermal System (fentanyl)
OxyContin Tablets (oxycodone)
Avinza Capsules (morphine sulfate)
Baraclude Tablets (entecavir)
Reyataz Capsules (atazanavir sulfate)
Tequin Tablets (gatifloxacin)
Zerit for Oral Solution (stavudine)
Meperidine HCl Tablets
Percocet (Oxycodone and Acetaminophen)
Xyrem (Sodium Oxybate)
Fentora (fentanyl buccal tablet)

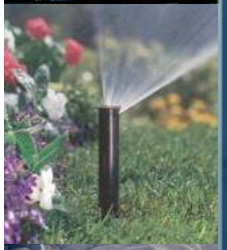
Note: Patients should always refer to printed material accompanying their medication for specific instructions.

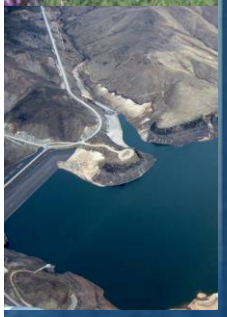
Office of National Drug Control Policy
ONDCP, Washington, D.C. 20503
p (202) 395-6618 f (202) 395-6730

www.WhiteHouseDrugPolicy.gov

- *The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:*
  - Actiq (fentanyl citrate)
  - Daytrana Transdermal Patch (methylphenidate)
  - Duragesic Transdermal System (fentanyl)
  - OxyContin Tablets (oxycodone)
  - Avinza Capsules (morphine sulfate)
  - Baraclude Tablets (entecavir)
  - Reyataz Capsules (atazanavir sulfate)
  - Tequin Tablets (gatifloxacin)
  - Zerit for Oral Solution (stavudine)
  - Meperidine HCl Tablets
  - Percocet (Oxycodone and Acetaminophen)
  - Xyrem (Sodium Oxybate)
  - Fentora (fentanyl buccal tablet)







NACWA Response to White House Guidelines for *Proper Disposal of Prescription Drugs – May 2007*

NACWA

May 2, 2007

John P. Walters
Director
White House Office of National Drug Control Policy (ONDCP)
750 17th St. NW
Washington, DC 20503

Dear Mr. Walters,

The National Association of Clean Water Agencies (NACWA) appreciates the efforts of your office to improve the handling and disposal of unused prescription drugs, including the recent issuance of new federal disposal guidelines in February. Your work with the Department of Health and Human Services (HHS) and the U.S. Environmental Protection Agency (EPA) to develop the guidelines is clearly a step in the right direction toward reducing prescription drug diversion for illicit use as well as protecting the environment. NACWA does, however, have several major concerns with the current version of the guidelines.

NACWA represents the interests of nearly 300 public wastewater treatment agencies. NACWA's members are responsible for ensuring the wastewater from their respective communities is appropriately treated before being discharged to the Nation's waters. As stewards of the water environment, NACWA's members are actively exploring new and innovative ways to reduce the quantity of unused prescription drugs that make there way into the sewer system. NACWA believes that your office's guidelines, as currently drafted, will result in unnecessary quantities of prescription drugs entering the environment and fails to take full advantage of the numerous unused drug collection programs that many of the Nation's municipalities have established.

NACWA's major concern is that the federal guidelines continue to advise that certain prescription drugs be flushed into the sewer system. NACWA understands that the Food and Drug Administration (FDA) has specifically identified a short list of drugs that the Administration believes can only be safely disposed of in the sewer system. Unfortunately, at the same time that FDA, ONCDP, HHS, and EPA are recommending flushing for certain drugs, EPA and other regulatory agencies at the federal and state level are conducting efforts that may ultimately require NACWA's members to install additional equipment or take other action to remove these same drugs from their wastewater effluent.

National Association of Clean Water Agencies
1816 Jefferson Place, NW
Washington DC 20036-2505
p 202.833.2672 f 202.833.4657
www.nacwa.org · info@nacwa.org

Clearly, preventing illicit drug use must be a national priority, but NACWA feels strongly that there are better ways of managing prescription drugs without resorting to disposal in the sewer system. Instead, a long-term, sustainable approach relying on convenient, on-going collection of unused drugs, utilizing specialized disposal as appropriate (e.g., hazardous waste incineration) needs to be explored. If the federal government as a whole has concluded that there is a true public benefit to flushing certain prescription drugs, then the entire federal government, including EPA, must understand the impracticality of pursuing standards and permit requirements for any of these substances at this time. Absent an alternative disposal method that is federally endorsed and widely available, the current policy direction will only result in a wasteful expenditure of local resources to remove these substances from wastewater.

NACWA's other concerns with the new federal guidelines are outlined below.

1. NACWA understands that the government may have some trepidation regarding a wholesale endorsement of local or regional take-back programs. Nevertheless, many of NACWA's members have spent thousands of dollars to 'do the right thing' to ensure that these drugs, which have historically not been their responsibility, do not end up in the environment. The federal government should do more to ensure take-back programs are more prominently recognized as a real and viable option for many communities. Several collection programs in the San Francisco Bay Area and in the State of Washington are very mature and could serve as models for a more coordinated approach. ***Revising the guidelines to list these types of collection programs as the top option available for disposal would be a good start.***

2. If the ONDCP and the FDA continue to believe that flushing certain prescription drugs is the only option, the wording should be changed to indicate that flushing should be a last resort and that it only applies to the drugs listed in the guidelines. NACWA appreciates the fact that ONDCP has changed the way the guidelines appear on its website to include the list of drugs the FDA believes should be flushed. Still, ***even with the FDA "flush list" incorporated into the guidelines, NACWA believes that the flush option will be used as a default for all drugs not just those on the list– the path of least resistance for most Americans and the one with the most negative environmental impacts.***

3. NACWA's final concern with the current guidelines is the recommendation to take unused prescription drugs out of their original containers. NACWA understands the reasoning for this, but for many take-back programs, the original containers and labeling are very helpful for classifying drugs and ensuring that control substances are handled properly. ***NACWA suggests a revision to the guidelines to ensure these drugs can be properly classified by take-back program managers.***

Thank you for considering our concerns. We would be happy to meet with you or your staff if you have any questions. Please contact me at 202/833-9106 if you would like to discuss further.

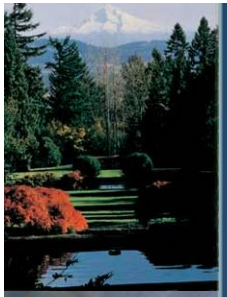
Sincerely,

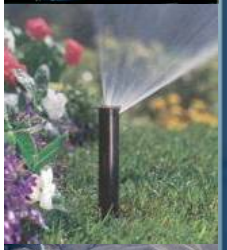
Chris Hornback
Senior Director, Regulatory Affairs

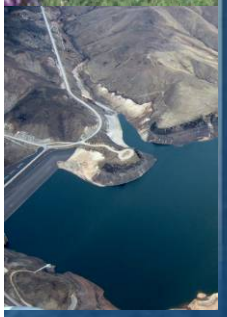
cc: Ephraim King, Director, Office of Science and Technology, Office of Water, EPA
Jim Hanlon, Director, Office of Wastewater Management, Office of Water, EPA

Oregon Senate Bill 737

- Passed House June 26, 2007
  - Vote of 51 to 8 with 1 Excused
  - Will Take Effect Immediately Upon Governor's Signing
- Focus on Pollutant Reduction
- Phase 1
  - Oregon Department of Environmental Quality (DEQ)
  - Assess Persistent Pollutants in Environment
  - Create Priority list of Most Harmful
  - Identify Best Means to Reduce at Source
- Phase 2
  - Major Municipal Dischargers
  - *Develop Pollutant Reduction Plans Based on Source Prevention*
    - Pharmaceutical Collection Programs
    - Removing Mercury in Schools
    - Legacy Pesticide Collection







Conclusions and Recommendations