

Pharmaceuticals in the Environment PhRMA Initiatives

NACWA Pretreatment Meeting

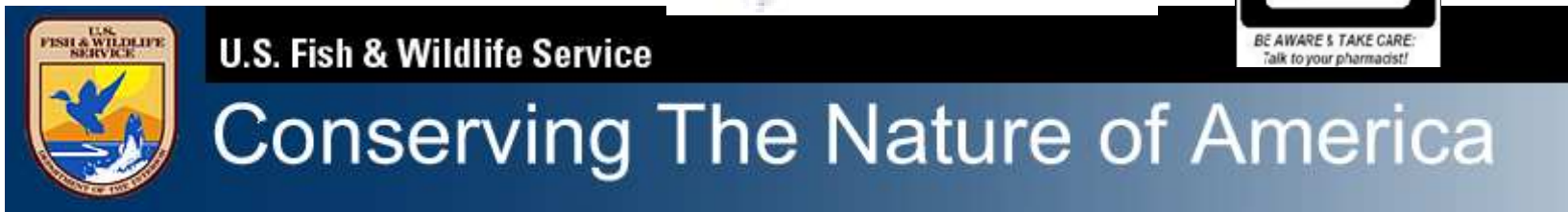
November 15, 2007
Denver, Colorado

Virginia L. Cunningham, Ph.D.
GlaxoSmithKline

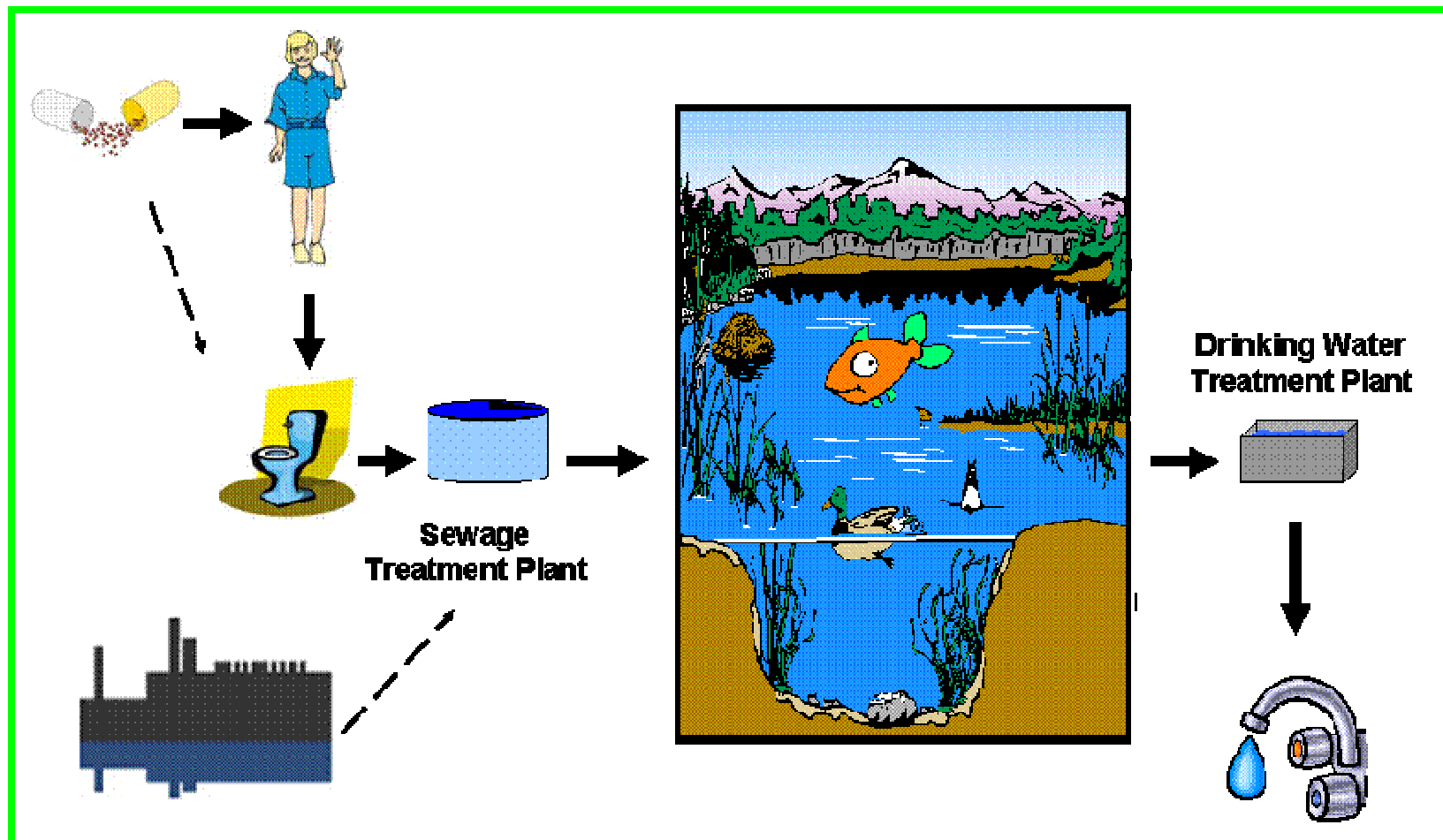
PhRMA PIE Task Force

The logo for the Pharmaceutical Research and Manufacturers of America (PhRMA). It features the word "PhRMA" in a bold, serif font. The "Ph" is stylized with a large, bold "P" and a smaller "h". The "RMA" is in a standard serif font. The logo is positioned at the bottom right of the slide, with a horizontal line extending from the left edge of the slide to the "P" and another horizontal line extending from the "A" to the right edge of the slide.

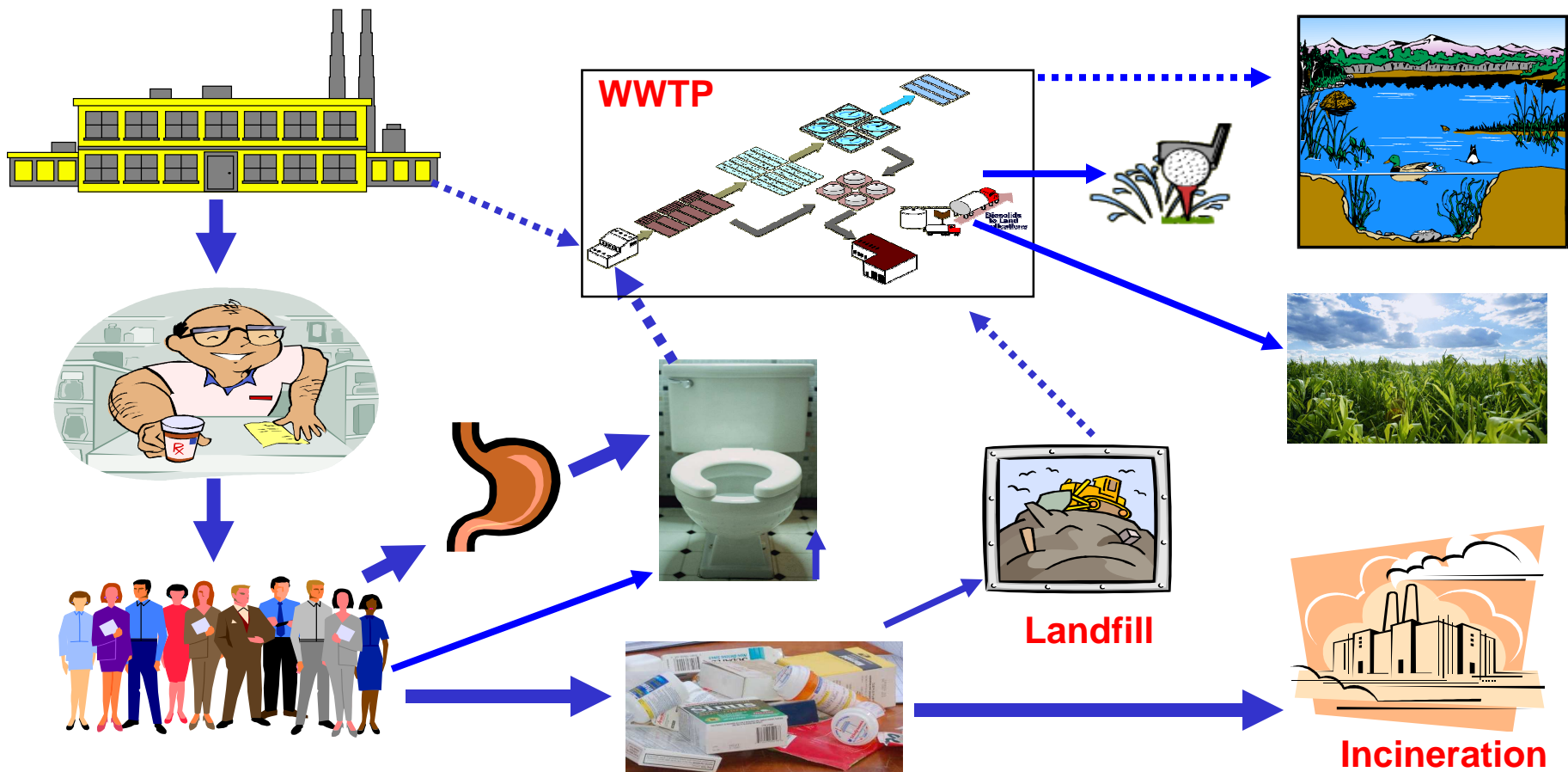
Management of Unused Medicines is of interest to a broad range of stakeholders



Pharmaceutical compounds primarily enter the environment through normal patient use



Unused medicines can contribute to the amounts of medicines found in the environment



However, landfill disposal of unused medicines does not constitute a significant contribution to wastewater treatment influents as compared to patient use of the medicines

API	Patient Use API to WWTP kg/year	Flushed API Mass (kg/yr) 10% of Sold	Total kg/year to WWTP	POTW influent µg/l
Acetaminophen	4,609,807	569,112	5,178,919	116.88
Albuterol Sulfate	899	357	1,256	0.03
Cimetidine	21,591	4,998	26,589	0.60
Ciprofloxacin	68,437	8,544	76,981	1.74
Codeine	12,227	1,510	13,737	0.31
Digoxin	173	23	196	0.00
Diltiazem	5,375	14,930	20,304	0.46
Doxycycline	29,506	3,278	32,784	0.74
Enalaprilat	625	77	702	0.02
Erythromycin-H ₂ O	57,855	6,428	64,283	1.45
Fluoxetine	1,119	1,243	2,362	0.05
Gemfibrozil	158,367	23,153	181,520	4.10
Ibuprofen	204,975	103,523	308,498	6.96
Lincomycin	296	33	328	0.01
Metformin	1,438,098	159,789	1,597,887	36.06
Norfloxacin	2,260	270	2,530	0.06
Oxytetracycline	28	3	31	0.00
Paroxetine metabolite	17,527	1,947	19,474	0.44
Ranitidine	84,952	10,042	94,994	2.14
Sulfamethoxazole	33,954	31,439	65,393	1.48
Sulfathiazole	369	48	418	0.01
Tetracycline	61,712	6,857	68,569	1.55
Trimethoprim	49,304	6,445	55,749	1.26
Warfarin	288	400	688	0.02

If 10% of medicines sold are land-filled with household trash, on average, 0.9% of the POTW influent load of pharmaceuticals is due to unused medicine disposal to landfill.

99.1% of influent load is due to patients taking medicines

Flushing of unused medicines is a more significant source than landfill disposal when compared to patient use of the medicines

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If 10 % of medicines sold are flushed to the sewer, on average, 21% of influent load to POTWs is due to unused medicine disposal to the sewer.

79% of influent load is due to patients taking medicines

Average Estimated Influent Difference Between Take Back and Household Trash Disposal is:

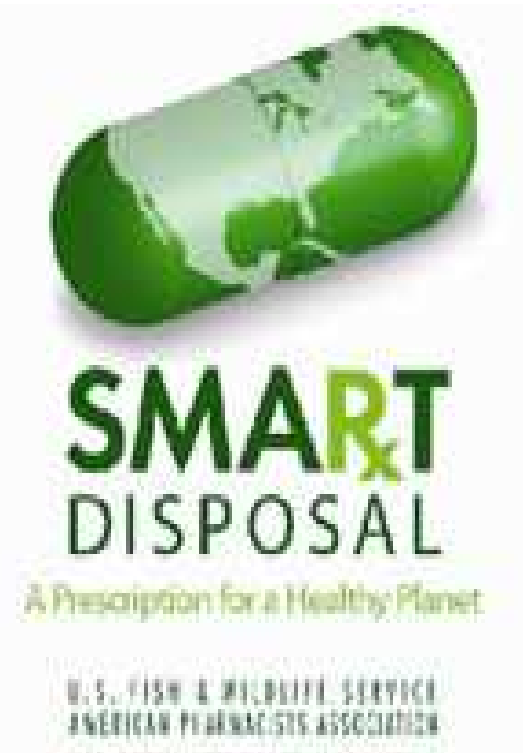
Concentration - 0.3 part per trillion

Percent of Influent Load From Unused Medicines Flushing - 0.28%

	Average % of Influent Load From Unused	Average Influent Concentration Change From Current in µg/l
Current	10.34%	
Take Back	0.66%	0.896%
Household Trash	0.93%	0.897%

Drain disposal generally should be avoided

"The U.S. Fish and Wildlife Service, the American Pharmacists Association (APhA) and PhRMA are joining forces to help protect our nation's fish and aquatic resources from improper disposal of medication. As part of the effort - dubbed "SMARxT DISPOSAL" - the USFWS and the APhA will work to publicize the potential environmental and health impacts of unused medications when they are flushed into our nation's sewer systems."



Office of Drug Control Policy

Federal Guidelines for proper disposal of prescription drugs

February 20, 2007



Proper Disposal of Prescription Drugs

Office of National Drug Control Policy February 2007

Federal Guidelines:

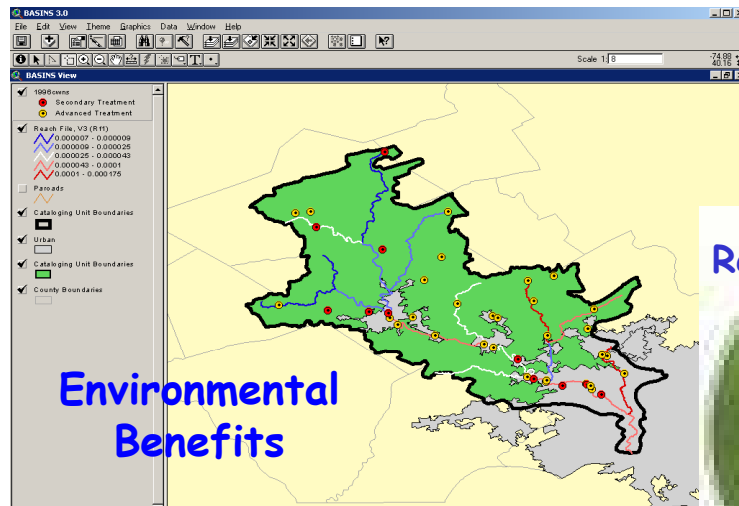
- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
- Mixing prescription drugs with an undesirable substance, like used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Flush prescription drugs down the toilet *only* if the label specifically instructs doing so.
- 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.

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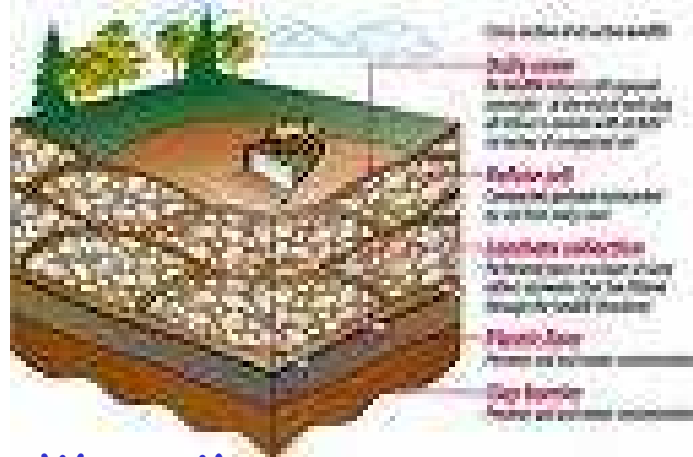


www.WhiteHouseDrugPolicy.gov

Decisions on how to manage unused medicines need to consider all available information



Environmental Benefits



Waste Management Infrastructure



Regulatory Requirements



Other Options And Benefits



Environmental Costs

Infrastructure improvements may be a more effective approach to address PPCP concerns

CHARACTERIZING THE PASSAGE OF PERSONAL CARE PRODUCTS THROUGH WASTEWATER TREATMENT PROCESSES

Joan Oppenheimer and Roger Stephenson
MWH
300 N Lake Ave, Suite 1200
Pasadena, CA 91101

Treatment Occurrence			
	Bin T1 Excellent Removal	Bin T2 Moderate Removal	Bin T3 Poor Removal
Bin O1 ¹ Infrequent	Methyl-3-phenylpropionate	Octylphenol	TCEP Triphenylphosphate
Bin O2 Variable		Ethyl-3-phenylpropionate	BHA DEET Musk Ketone
Bin O3 Frequent	Caffeine Ibuprofen Oxybenzone Chloroxylenol Methylparaben Benzyl Salicylate 3-Phenylpropionate Butylbenzyl Phthalate Octylmethoxycinnamate	Triclosan Benzophenone ²	Galaxolide

Reduction of unused medicines at specific sources could reduce the generation of unused medicines and may be a more effective than community based take-back programs

Pharmacies

- Most unused medicines returned for credit

Hospitals

- Use their pharmacies to return for credit
- Unreturnables:
 - Ordinary IV → drain
 - Chemo IV → HW
 - Pills → Medical Waste

Long Term Care Facilities

- Source of 34% (1.5 MM lbs) of unused
- 7% to 13% wastage
- Typical disposal practice is flushing down the drain

Individuals

- Source of 66% (2.8 MM lbs) of unused
 - 2 to 3% wastage
 - Typical disposal
- | | US | UK & Canada
w/ take back |
|-----------------|-----------|---|
| Trash | 50% | 50% |
| Drain | 30% | 10% |
| Pharmacy | | 20% |

Certain elements of how to manage unused medicines disposal are clear

- Drain disposal generally should be avoided
- Dialogue among all interested stakeholders is needed
- Disposal alternatives should be evaluated based on assessments of all their potential environmental impacts
- Take-back pilot programs
 - Need to understand the types and amounts of medicines being collected, participation rates, management of regulatory compliance issues, program costs, funding sources, final disposal, obstacles and potential alternative solutions

In conclusion...

- The industry is committed to assessing the significance of pharmaceuticals in the environment using science- based approaches.
- The human health assessment indicates that pharmaceuticals in drinking water for the compounds investigated to date present no appreciable risk to human health.
- The industry is evaluating published data on aquatic life impacts and formulating an approach to assess the potential for impacts to ecosystems.
- The industry is continuing to research sources of unused medicine, to identify options for their disposal and to participate in discussions with stakeholders on these issues.



PhRMA

New Medicines. New Hope.

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