

Medications in the Water Supply

June 24, 2010

Texas Federation of Drug Stores
National Association of Chain Drug Stores

Who We Are

- National Association of Chain Drug Stores
 - represents 154 chain pharmacies nationally
 - 25 chain pharmacies in Texas
- Texas Federation of Drug Stores
 - represents 14 chain pharmacies in Texas

Who We Are

- Highly regulated
 - Drug Enforcement Administration (DEA)
 - Food & Drug Administration (FDA)
 - Centers for Medicare & Medicaid (CMS)
 - Texas State Board of Pharmacy (TSBP)
 - Texas Department of Safety (DPS)
 - Texas Health & Human Services Commission (HHSC)
 - Texas Department of Health Services (DHS)

Proper Disposal of Drugs within the Supply Chain

- Community pharmacies return saleable & non-saleable products not dispensed to patients to wholesale distributors or reverse distributors
- Wholesale distributors and reverse distributors either redistribute or properly destroy the products
- Drugs within the supply chain are properly disposed of - these products are not the source of medications in the water supply

Two Components To Consider

- Education of the Consumer Regarding Proper Disposal
- Actual Return Process for the Appropriate Discarding of the Unused Medications

Pharmacies are concerned with the potential introduction of a hazardous waste product in a pharmacy

Programs to Help Consumers Dispose of Unused Medication

- Question at hand is how to help consumers, who find themselves with unused prescription and over-the-counter (OTC) medications for a variety of reasons, such as changes in drug therapy, expired products or poor medication adherence, how to appropriately dispose of unused medications.

Key Principles for Return and Disposal of Consumers' Unused Drugs

- Protect Patient Health and Safety:
 - Maintain a physical separation between pharmacies and locations that take back consumers' unused drugs.
- Use Safe and Effective Systems
 - Provide consumers with a safe and effective way to return their unused drugs such as a mail back program using prepaid envelopes or state municipal waste collection systems.
- Ensure Necessary Funding
 - Establish feasible funding sources such as through drug manufacturers or state hazardous waste resources.

Added Consideration – Limitations on What Pharmacies Can Do

- Federal restrictions on take-back of Controlled Substances (CDS)
 - DEA does not permit pharmacies to take back CDS from consumers - this would violate the federal Controlled Substances Act and regulations
 - Only authorized law enforcement officials acting in their official capacity may take back CDS from consumers
- States laws restrict handling and take-back of unused drugs

Varying Policy Options for Helping Consumers Dispose of Unused Drugs

- Finding a workable means for consumers to dispose of unused and expired drugs is receiving attention at both the national and state levels
- Varying policy options to address the issue have been proposed

White House



- Office of National Drug Control Policy
 - Updated guidelines for disposal of drugs not labeled to be flushed
 - Mix drugs with undesirable substances
 - Seal in non-descript impermeable containers
 - List of 27 drug products that should be flushed

Varying State Approaches

- Pre-paid mail back envelopes
- Consumer education programs
- Limited pilot programs or collection events held in community settings involving law enforcement as a key component, as part of waste management collection events or at police departments
- Some of the better approaches include...

District of Columbia

- Consumer Education Program
 - Board of Pharmacy to design public education program on appropriate disposal of unused drugs
 - Retail pharmacies to provide consumers with program information
- Drug disposal program
 - Mayor to develop drug disposal program, such as mail-back program, pursuant to recommendations of Board of Pharmacy
 - Program will enable consumers to dispose of unused drugs, including CDS

Maine

- Public Law 2003, Chapter 679
 - “Unused Pharmaceutical Disposal Program” administered by Maine DEA (voluntary pilot program)
- Pilot – EPA grant \$150,000
- Mail Back –
 - Mailers available at participating pharmacies in 4 counties
- Educational campaign
 - Environmental hazards from improper storage/disposal of unused drugs
- Inventory types & quantities of drugs returned

Indiana

- Household Hazardous Waste Grant Program
 - Funding through Hazardous Substances Response Trust Fund and Solid Waste Management Fund
 - Includes funding for pharmaceutical waste
 - Consumers can drop off unused medicines at solid waste management facilities or appropriate locations

Texas Pharmacies

- Implement New Law – HB 19
 - For certain prescription drugs, requires pharmacy to place on container label or include in accompanying prescription information by January 1, 2011

***“Do not flush unused medications
or pour down a sink or drain”***

Texas Pharmacies

- Raise consumer awareness of community collection programs
- Provide guidance to consumers on the appropriate way to disposed of unused drugs as recommended by the FDA

Final Thoughts

- Pharmacy recognizes that there must be a mechanism in place for consumers to properly dispose of their unused medications, both to prevent incidences of drug diversion and misuse and to minimize the impact of unused products on the environment
- As we work to create a program in Texas, it is paramount that the program be designed to facilitate proper drug disposal in a manner that serves public health and safety interests and meets environmental goals.

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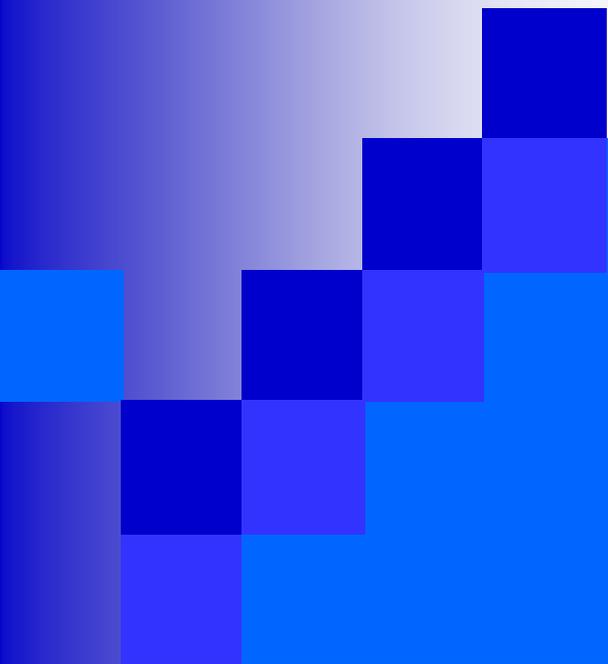
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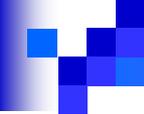
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Overview of Unused Medicine Disposal

Prepared for the Texas Commission on
Environmental Quality's Pharmaceutical Disposal
Advisory Group

June 24, 2010

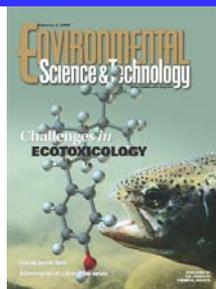


Understanding pharmaceuticals in water & the impacts of unused medicine disposal

- Our work is focused in three areas
 - Human Health
 - Aquatic Life
 - Unused Medicine Disposal
 - Peer reviewed published studies.
 - PhRMA member company environmental experts goal is to apply the same level of scientific rigor to pharmaceuticals in water that we apply in other areas of our business
 - Working with external stakeholders
-

Publications

■ Screening Analysis



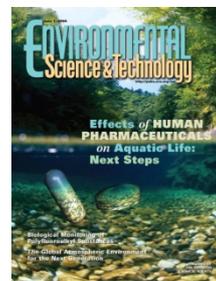
■ Human Health Effects

Environ. Sci. Technol. XXXX, xxx, 000-000

Derivation of an Aquatic Predicted No-Effect Concentration for the Synthetic Hormone, 17 α -Ethinyl Estradiol

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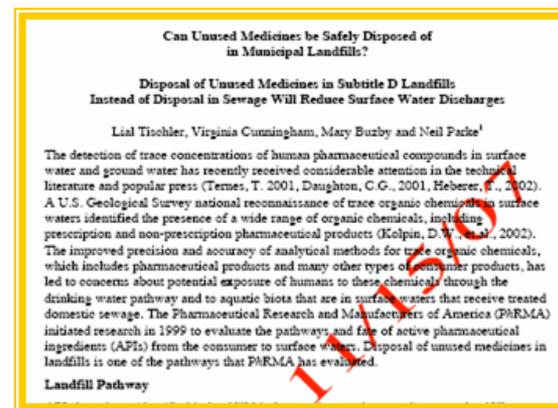
Received March 3, 2008. Revised manuscript received June 26, 2008. Accepted July 15, 2008.



■ Hormone

■ Environmental Assessment

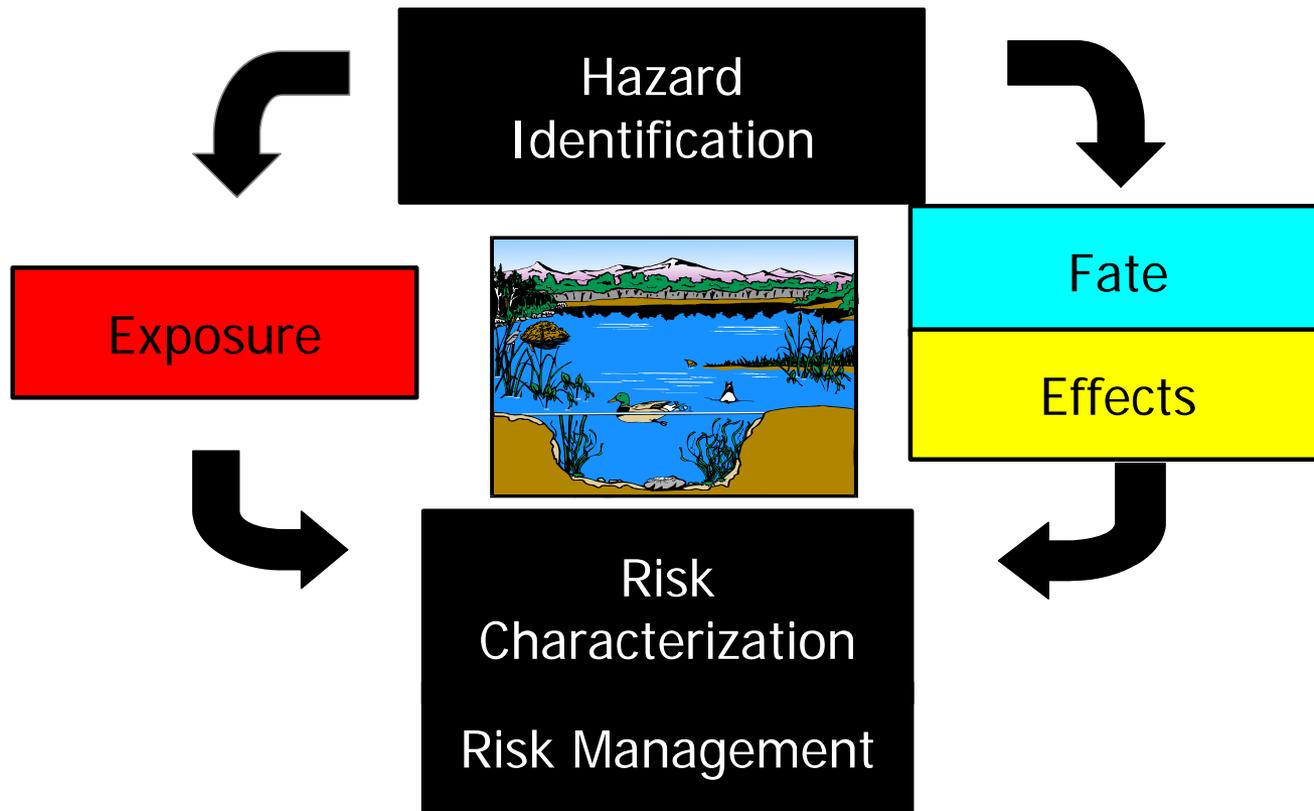
■ Landfill



Collaborations



A science based approach is needed to evaluate the significance of pharmaceuticals detected





Findings of our work - **Human Health**

Results of human health assessment indicate that residues of pharmaceuticals in water present no appreciable risk to human health



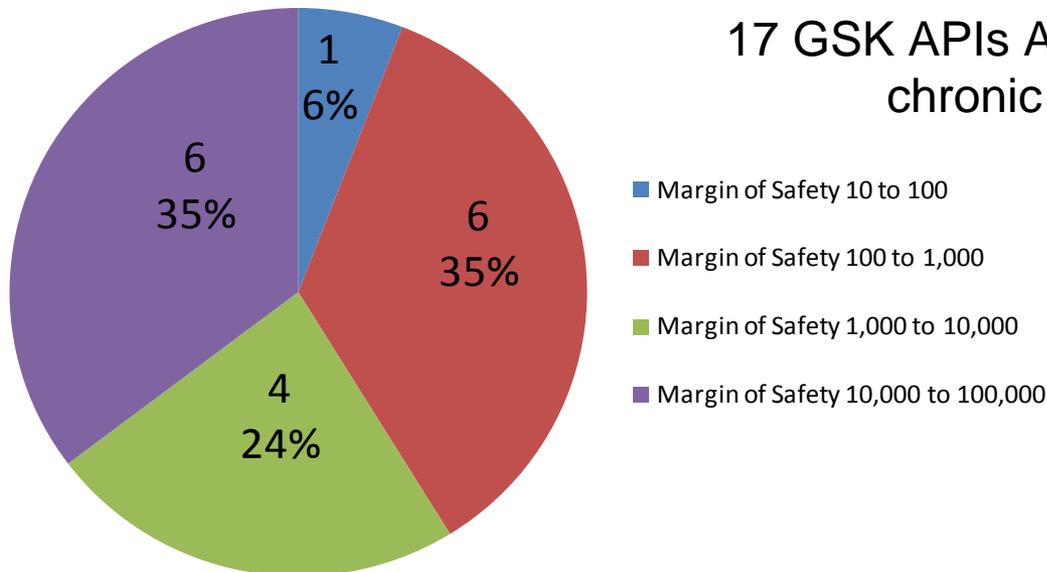
100,000 years to get a single
200mg ibuprofen tablet

Safety factor of 19,000 for
Carbamazepine



Findings of our work – Aquatic Life

- Concentrations of pharmaceuticals in typical environmental settings are not high enough to cause the effects that can be observed in experimental settings.
- The science underpinning measuring aquatic life impacts is still under active development (*PhRMA* members are participating).



Predicted Environmental Concentration



Environmental Toxicology and Chemistry, Vol. 28, No. 12, pp. 2725–2732, 2009

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Printed in the USA

0730-7268/09 \$12.00 + .00

Pharmaceuticals and Personal Care Products in the Environment Hazard/Risk Assessment

EXPOSURE ASSESSMENT OF 17 α -ETHINYLESTRADIOL IN SURFACE WATERS OF THE UNITED STATES AND EUROPE

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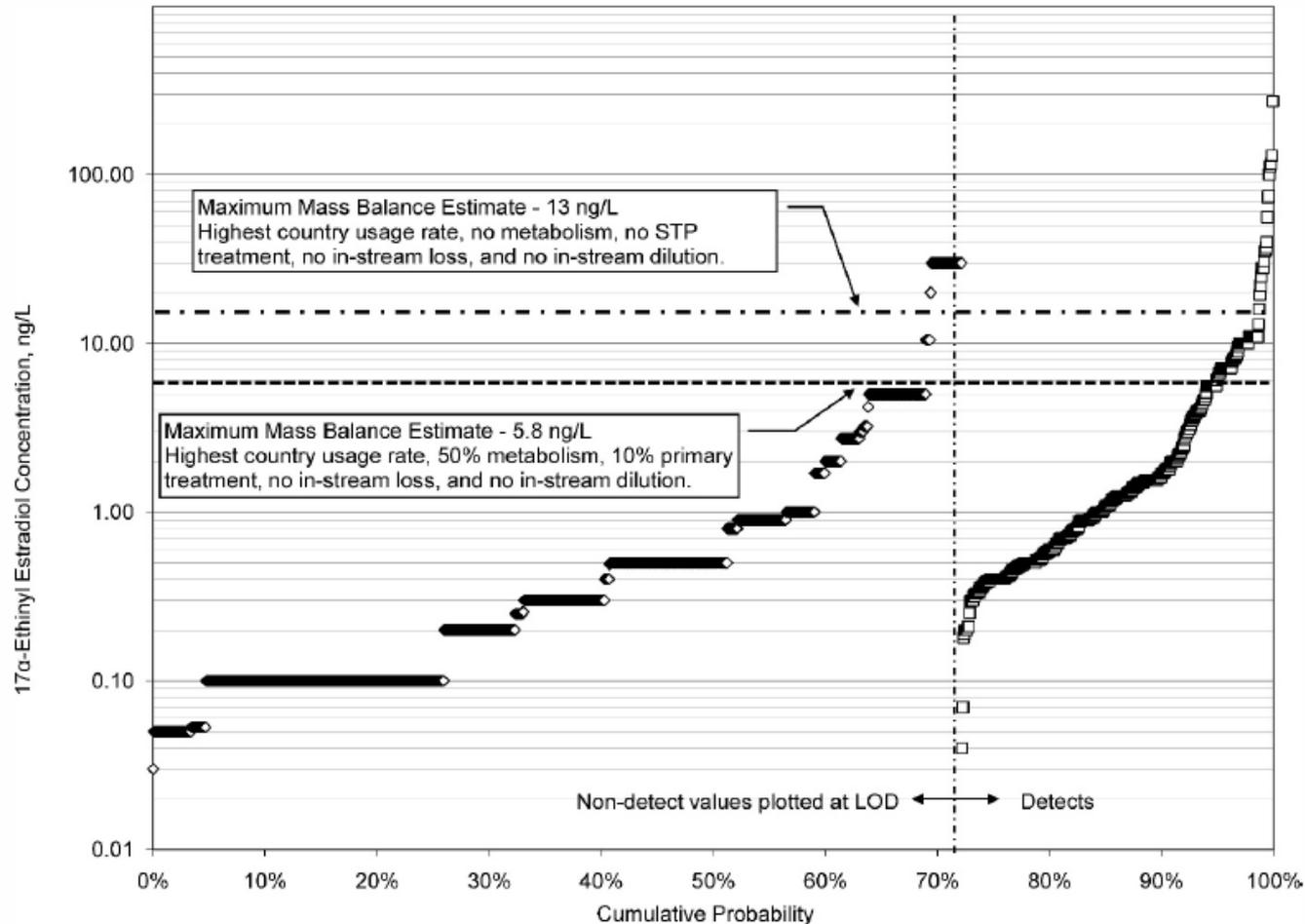
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(Received 2 December 2008; Accepted 21 April 2009)

All Measured Environmental Concentrations

EU and US Data

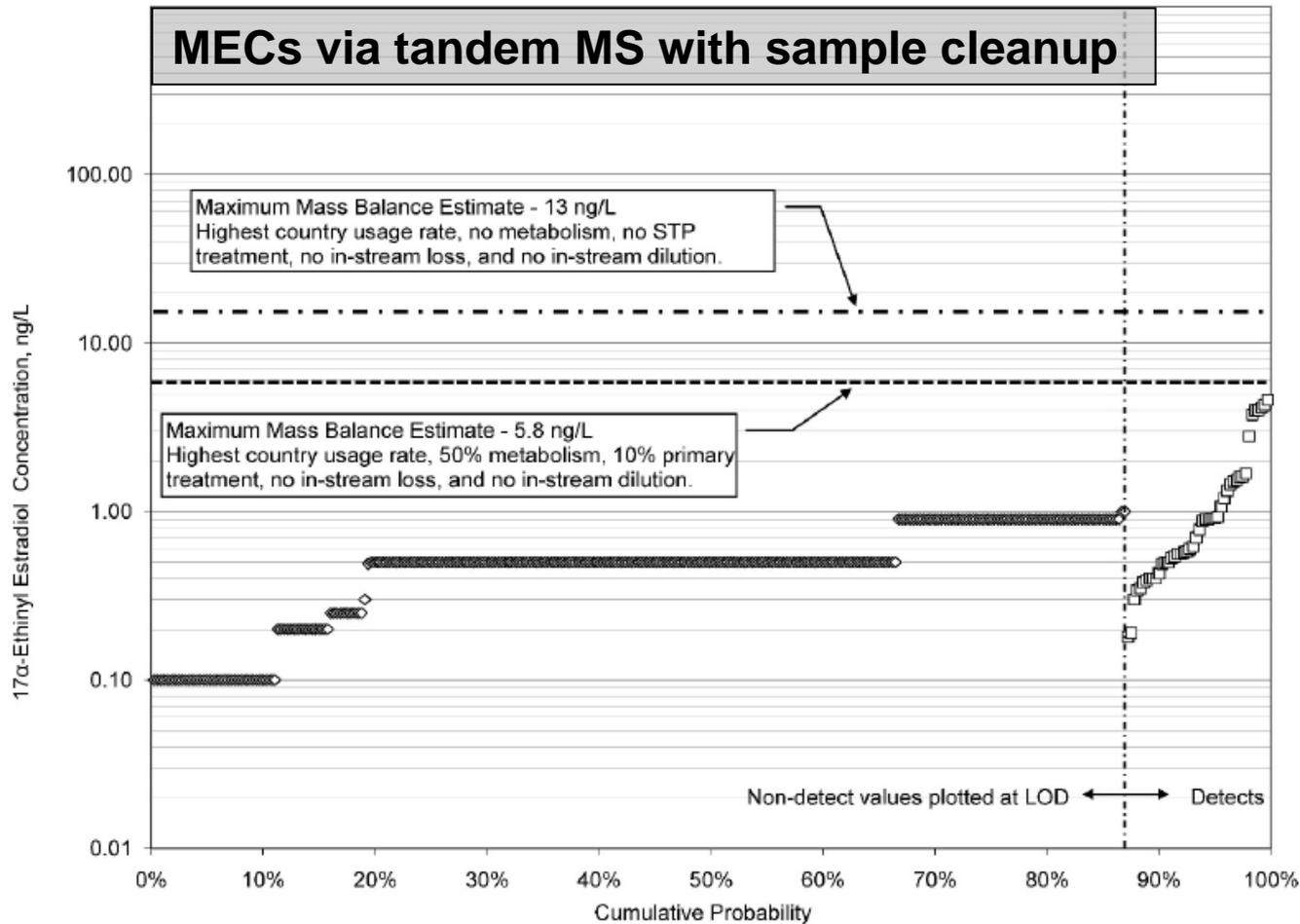


How Analytical Methods Can Effect Reported Concentrations of EE2

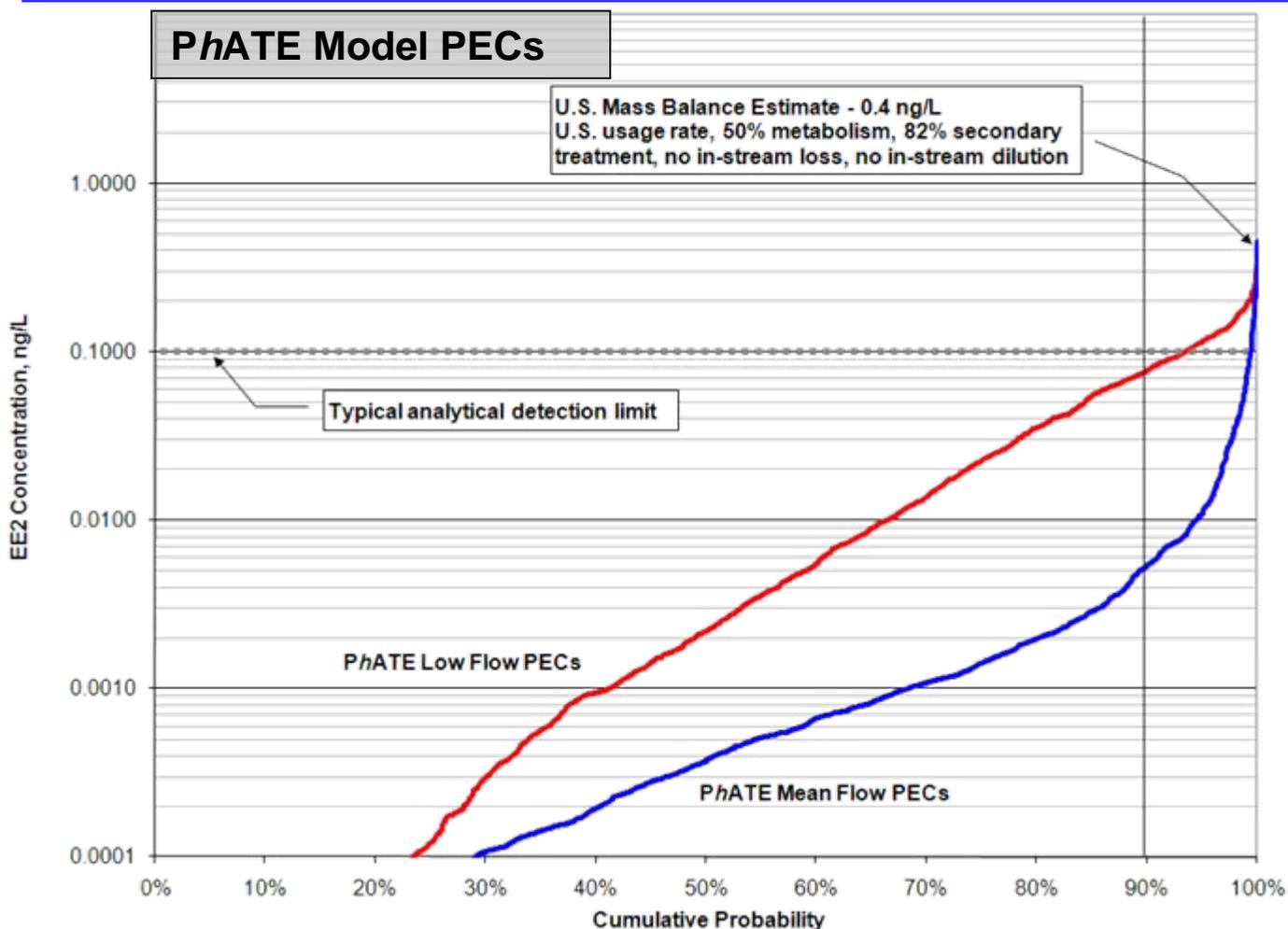
- Single MS can overestimate EE2 concentrations due to overlap of EE2 peak in the chromatogram with an unknown impurity.
 - Results of international round robin test of 8 labs reporting results for EE2 in wastewater:
 - Mean value of 1.38 ng/L using tandem MS
 - Single stage LC/MS resulted in a slightly overestimated value of 3.4 ng/L
 - Single stage MS resulted in an outlier value of 50 ng/L
-

State of the art MECs only

EU and US Data



US Predicted Environmental Concentrations



90% of Segments
low flow = 0.075ng/l
avg flow = 0.005ng/l

Effluent Dominated
= 0.2ng/l

Predicted No-Effect Concentration

Environ. Sci. Technol. 2008, 42, 7046–7054

Derivation of an Aquatic Predicted No-Effect Concentration for the Synthetic Hormone, 17 α -Ethinyl Estradiol

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*Johnson & Johnson, New Brunswick, New Jersey; Pfizer, New York, New York;
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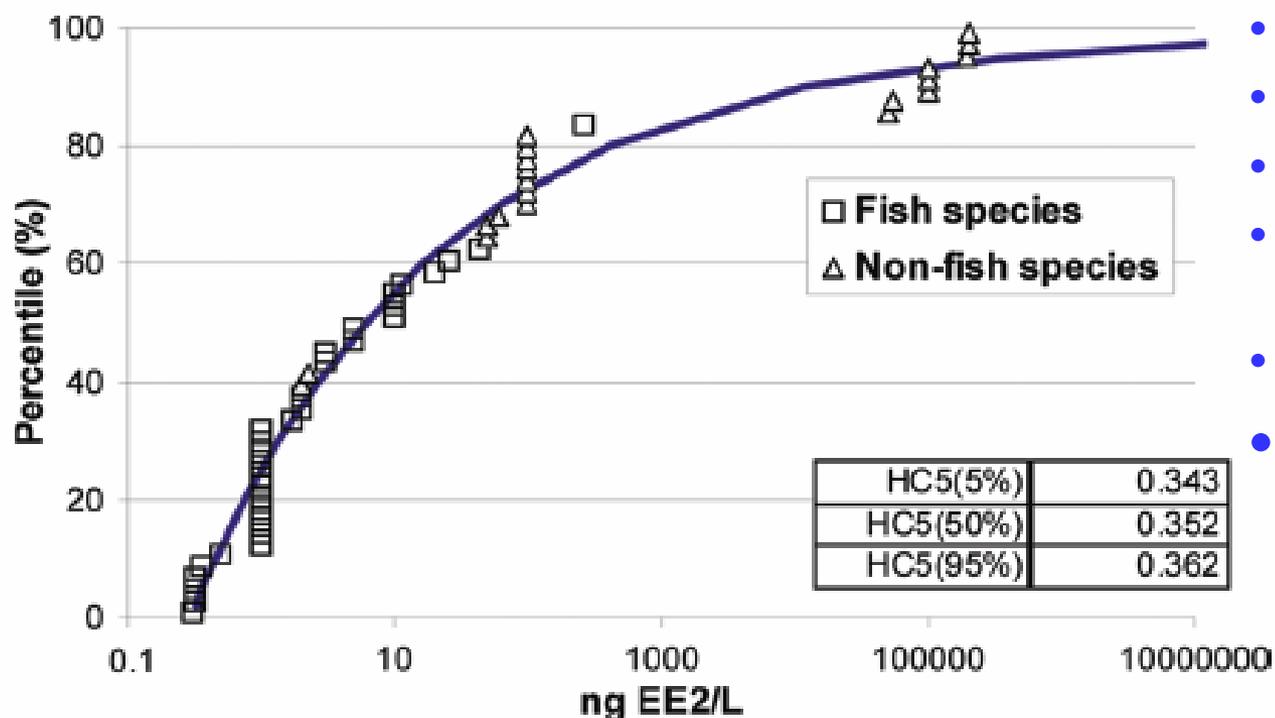
PhACT Tool Review – 60 Aquatic NOECs

TABLE 1. Summary of Available Reproductive NOECs for 17 α -Ethinyl Estradiol (EE2)

test species	reproductive end point	duration (days)	NOEC (ng EE2/L)	LOEC ^a (ng EE2/L)	VTG NOEC ^a (ng EE2/L)	ref	Klimisch code ^a
<i>D. magna</i>	reproduction	21	387 000 ^b			25	
<i>D. magna</i>	reproduction	21	100 000 ^b			28	
<i>S. subspicatus</i> ^c	Biomass	3	54 000			28	
<i>D. subspicatus</i>	Biomass	3	<100 000			Länge, 2002	
<i>D. subspicatus</i>	Growth Rate	3	<100 000			Länge, 2002	
<i>Brachionus</i> <i>calyciflorus</i>	No. of females	3	202 000			52	
<i>S. crystalline</i>	reproduction	3generations	100 000			29	
<i>Ceriodaphnia</i> <i>reticulate</i>	reproduction	3generation	200 000			29	
<i>Nicotra spinipes</i>	reproduction	18	50 000			37	
	Fecundity, sex ratio,						
<i>Tisbe battagliai</i>	development	21	> 100 000 ^d			53	
<i>Gammarus pulex</i>	Sex ratio, pop size	100	100			54	
<i>Hyalella azteca</i>	reproduction	273	100			55	
<i>Potamopyrgus</i> <i>antipodarum</i>	Embryo production	63	100			10	
<i>Marisa cornuarietis</i>	Imposex, oogenesis	180	50 ^e			56	
<i>Lymnaea stagnalis</i>	Not specified	21	100			57	
<i>L. stagnalis</i>	Egg masses	70	50			57	
	Emergence, sex ratio,						
	egg prod and						
<i>Chironomus riparius</i>	viability	30	100 ^f			58	
<i>Strongylocentrotus</i>							

TABLE 1. Continued

Species Sensitivity Distribution



- at least 10 NOEC entries
- across at least 8 taxa
- most sensitive endpoint
- SSD = Best Fit model through the data points
- HC5 is the 5th percentile
- **PNEC = 0.35ng/L**

FIGURE 1. Species sensitivity distribution for 17 α -ethinyl estradiol, based on all available reproductive NOECs.

PEC/PNEC Ratios

- *Ph*A TE - 90% of stream segments at low flow
 - $0.075(\text{ng/l})/0.35(\text{ng/l}) = \mathbf{0.21}$
- *Ph*A TE - 90% of stream segments at average flow
 - $0.005(\text{ng/l})/0.35(\text{ng/l}) = \mathbf{0.014}$
- *Ph*A TE – Effluent dominate stream segments
 - $0.2(\text{ng/l})/0.35(\text{ng/l}) = \mathbf{0.57}$

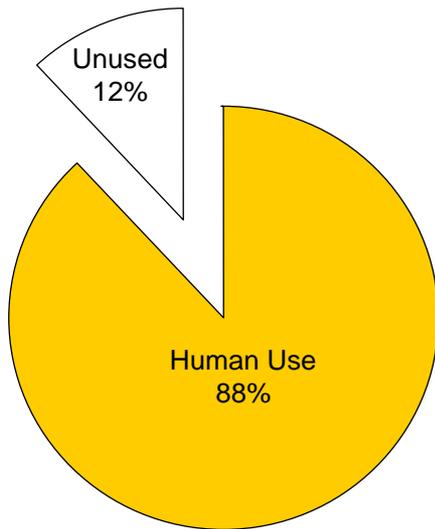
NOTE: PEC/PNEC Ratios < 1 are considered protective of aquatic life



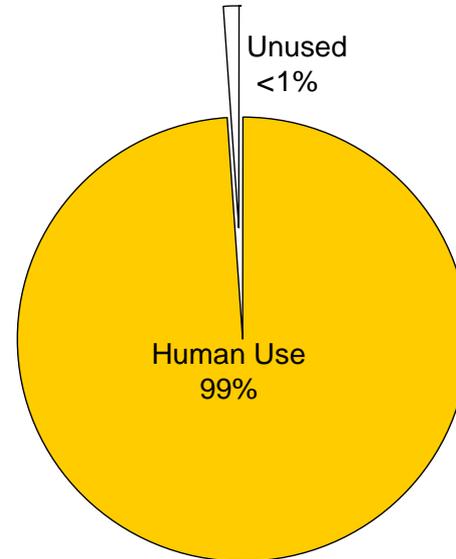
Findings of our work – **Unused Medicine**

- **The main source of pharmaceuticals in the environment is patient use.**
 - **Disposal in landfills is effective and environmentally acceptable.**
 - **Flushing should be avoided, when possible.**
 - **Take back for incineration is not the most effective product stewardship approach**
 - **Long term care facilities (LTCF) will require different approaches than the general public**
-

Landfill Study Results



All unused flushed



All unused to landfill

* Assumes 10% of medicine is unused

Leachate Concentrations

PhRMA Model compared to Maine measured concentrations

	Hatch Hill Landfill, Augusta Primexpond III	Bath Municipal Landfill Leach-MH	Brunswick Municipal Landfill MH-P1	Median of Three Landfills	PhRMA Predicted at 15% Unused Leachate Concentration	PhRMA Predicted at 10% Unused Leachate Concentration	PhRMA Predicted at 5% Unused Leachate Concentration
Parameter Name	Conc. [ng/L]	Conc. [ng/L]	Conc. [ng/L]	Conc. [ng/L]	Conc. [ng/L]	Conc. [ng/L]	Conc. [ng/L]
Acetaminophen	117,000	2,750		59,875	57,000	38,000	19,000
Albuterol	604	27	88	88	1,400	1,000	500
Cimetidine	25	149	60	60	200	200	100
Ciprofloxacin	269			269	753,900	502,600	251,300
Diltiazem	20		11	15	100	100	<100
Enalapril	41	3	3	3	681,000	454,000	227,000
Erythromycin-H2O	2,990	31	289	289	<100	<100	<100
Gemfibrozil	172	151	277	172	73,900	49,200	24,600
Ibuprofen	23,200	21,900	11,600	21,900	383,200	255,400	127,700
Lincomycin	64	73	278	73	<100	<100	<100
Metformin	14,800			14,800	57,400	38,200	19,100
Norfloxacin	449			449	2,382,500	1,588,300	794,200
Sulfathiazole	37		255	146	<100	<100	<100

A Product Stewardship Approach to the Unused Medicine Issue (general public)

1. Don't generate the waste in the first place



Reuse



Recycle

Patient safety dictates that any medicine dispensed to the general public that goes unused be disposed

4. Dispose

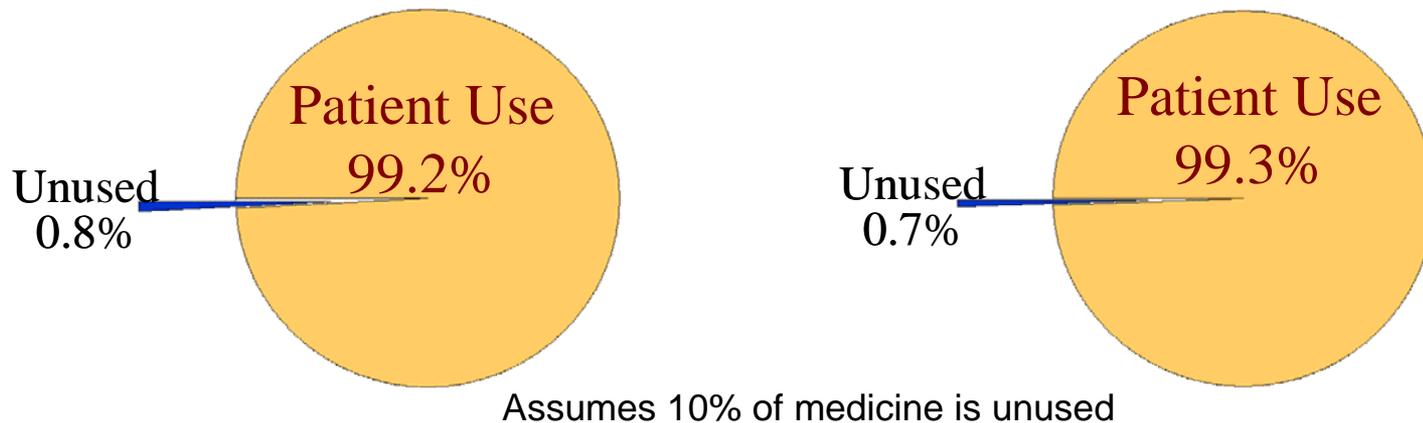
Proper Disposal – last in the hierarchy

Disposal options for US consumers

- ⊘ drain disposal *
- ✓ household trash disposal
- ✓ collection for incineration

7

ation



* FDA advises drain disposal for a very few medicines

SMAR_xT DISPOSAL™

A National Public Awareness and Partnership Campaign
Promoting Responsible Consumer Medication Disposal to Ensure Healthy Aquatic Ecosystems



SMART DISPOSAL

A Prescription for a Healthy Planet



American Pharmacists Association®
Improving medication use. Advancing patient care.

PhARMA

smarxtdisposal.net

A Product Stewardship Approach to the Unused Medicine Issue

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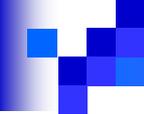
Reuse



Recycle

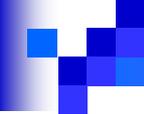
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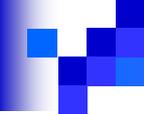
Source Reduction – first in the hierarchy

- Educate patients to take all medicine as directed.
 - Educate patients & health care professionals on how to address the reasons why medicines go unused - Reason cited most often
 - The medication has been changed
 - side effects
 - not solving the problem.
 - The patient feels they no longer need the medication (patient non-compliance)
 - The medicine has expired (especially OTC)
-



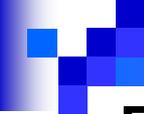
Drug Abuse & Poisoning

- Prompt disposal is the key
 - the Federal drug disposal guidelines clearly indicate that trash disposal is effective
 - Just as likely to occur with active medicine
 - safeguard all medicine in the home (active prescriptions, OTC products or awaiting disposal)
-



European Take Back Programs

- Started for different reasons
 - Europe doesn't have US rules on MSW landfills
 - Some are funded by manufacturers some are not
 - Typically get participations less than 20%
 - Have not shown any reduction in concentrations of pharmaceuticals in water
 - Have not shown any reductions in drug abuse or poisonings
-



Recommendations for a Public Education Campaign

- Education Should Concentrate On
 - Don't flush unused medicine
 - The proper way to safeguard all of the medicines under their control
 - Adherence and other ways to reduce the amount of medicine that goes unused
 - How to properly dispose of unused medicine in household trash
-

Recommendations for Residential Unused Medicine Disposal

- Household trash disposal is environmentally friendly and meets all DEA & EPA requirements.
 - The scientific data does not support the need to develop an new program to take back & incinerate unused medicine
 - People that don't feel comfortable with household trash disposal should be encouraged to take advantage of existing programs & infrastructure
 - Household hazardous waste collection
 - Law enforcement evidence disposal programs
-