

Pharmaceuticals and Personal Care Products: Science and Policy Challenges for EPA

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How is EPA involved

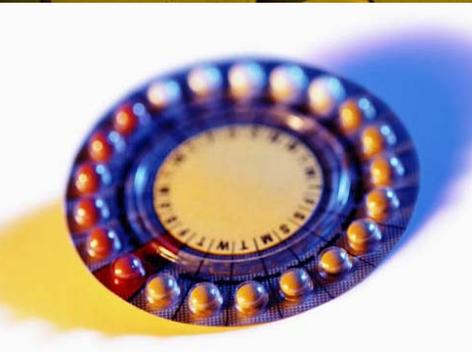
- EPA is concerned about pharmaceuticals and personal care products (PPCPs)
- EPA activities related to PPCPs
 - Screening and analytical methods
 - Partnerships (local, regional, national)
 - ORD Laboratory research
- PPCP Network
- Grants

What is an Endocrine Disruptor?

- An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.

(IPCS/WHO, 2002)

Classes of Suspected/Potential EDCs



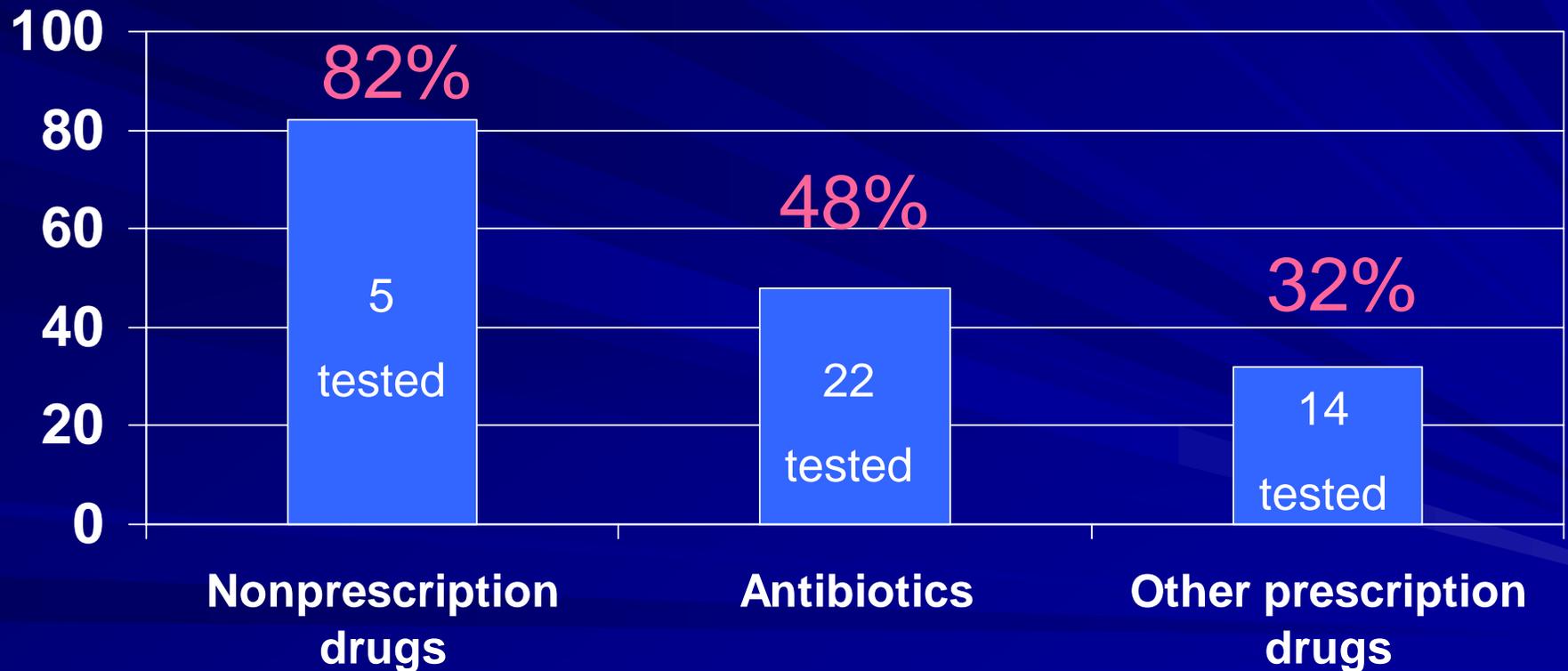
Effluents
Flame Retardants
Fungicides
Herbicides
Insecticides
Metals
Pharmaceuticals
Phenols
Plasticizers
PAHs
Soy Products
Surfactants

STW, pulp & paper mills
PBDEs
Vinclozolin
Atrazine
Methoxychlor
Tributyltin
Ethinyl Estradiol
Bisphenol A
Phthalates
PCBs, dioxin
Genistein
Alkylphenol
Ethoxylates



USGS Stream Survey

Frequency of Detection by Drug Class



Relevant Legislation

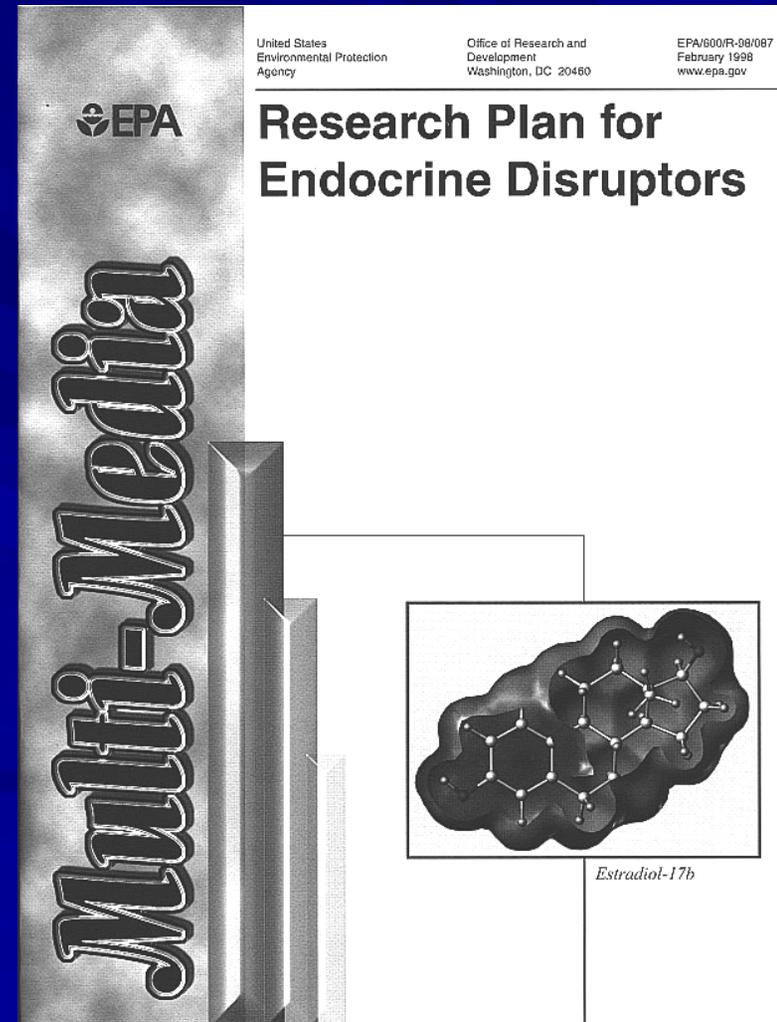
- Clean Water Act (CWA)
 - *Ambient Water Quality Criteria & Standards*
 - *Human Health & Aquatic Life*
 - *Risk-Based (only)*

- Safe Drinking Water Act (SDWA)
 - *Drinking Water Standards & Health Advisories*
 - *Human Health*
 - *Risk (MCL-G) & Treatment Technology (MCL) - based*

USEPA's ED Research Plan

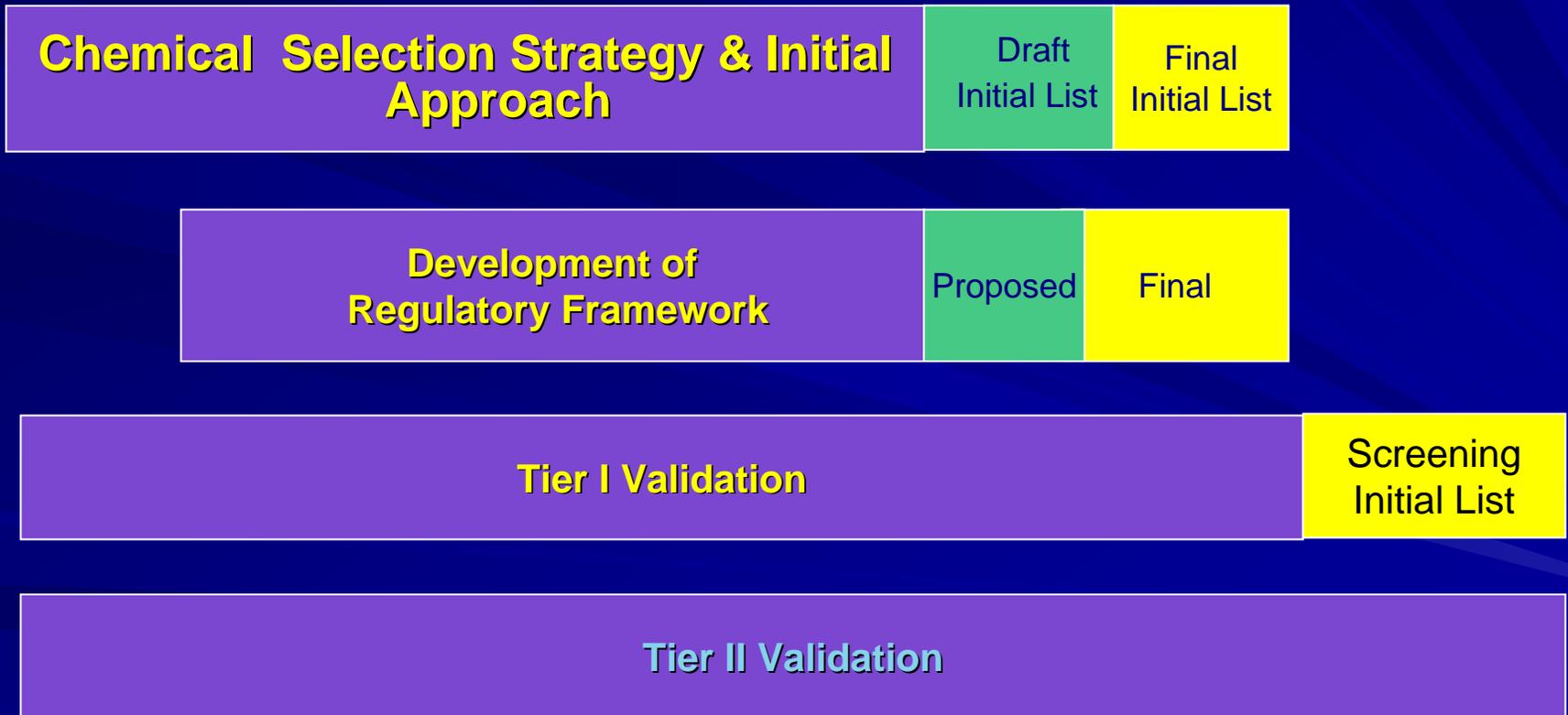
Long-term Research Goals

1. Understand the basic science
2. Determine the extent of the problem
3. Support USEPA's endocrine disruptors screening program (EDSP)



EDSP Timeline

2000 2001 2002 2003 2004 2005 2006 2007 2008



Regulation of EDCs under SDWA

- **USEPA identifies contaminants that may adversely affect public health and occur in drinking water with a frequency and at levels that pose a threat to public health.**
 - **Candidate Contaminant List (CCL)**
 - **Approximately 50 chemicals**
 - **Every five years, must decide to regulate (or not) at least five chemicals**
 - **CCL3 is currently being developed**
 - **Unregulated Contaminant Monitoring Regulation (UCMR)**
 - **Limited to 30 chemicals in any five year cycle**
 - **UCMR2 is currently being planned**

OW PPCP Related Work Underway

- **Workgroup involvement**
 - *EPA staff participating on PPCPs Interagency workgroups; newly formed PPCP Network within EPA*
- **PPCP Literature Database**
 - *Updating database of peer-reviewed literature*
 - *Over 400 citations and summaries*
 - *Searchable by keyword, author, title*
- **Draft Pharmaceuticals in the Environment (PiE) Strategy**
- **Draft website www.epa.gov/ppcp**

OW PPCP Related Work Underway

■ Nonylphenol Aquatic Life Criteria

- *Decreased Reproduction is basis for chronic criterion*
- *Fresh acute/chronic criteria 28 ug/L/ 6.6 ug/L*
- *Salt acute/chronic criteria 7.0 ug/L/ 1.7 ug/L*
- *Final: 2006*

■ POTW study

- **Currently ongoing study looking at fish effects from wastewater treatment plant effluent across the country**

Addressing Regulatory Hurdles

- Resource Conservation and Recovery Act (RCRA)
 - EPA may amend ‘universal waste rule’ to include pharmaceuticals
- Drug Enforcement Agency (DEA) regulations under the Controlled Substances Act
 - Pharmaceuticals that are controlled substances can only be received by law enforcement

Bay Area Regional Pharmaceutical Take-Back Event

- 1 week event at 39 locations
- 1500 residents participated
- 3,634 lbs of medicines disposed
- Previous disposal practices showed $\frac{1}{2}$ of participants used the trash, and $\frac{1}{4}$ of them put them in the sewer system
- Long term disposal solution needed

EPA Grant money

- \$300,000 awarded to University of Maine and Area Resources for Community and Human Services in St. Louis, MO to plan and implement pilot mail-back and take-back pharmaceutical disposal programs

What Have We Learned?

- Emerging contaminants/PPCPs are not currently regulated in surface or drinking waters.
- However, there is a high level of interest concerning ECs (particularly EDCs and PPCPs) among federal scientists and regulators.
- Even without pressing water regulations, good disposal protocols can minimize the ECs released into the environment.
- We must continue to work together to explore opportunities and find answers

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