Pharmaceuticals and Personal Care Products in Wastewater

Presentation to:

Regional Wastewater Reclamation Advisory Committee

August 21, 2008

PPCPs in the Environment

Arizona Daily Star

Tiny amounts of drugs found in well

Tucson Water says pharmaceuticals, disinfectants pose no risk to customers

By Rob O'Dell

ARIZONA DAILY STAR

Trace amounts of mood-stabilizing drugs, chemicals ingested before fetuses, disinfectants and antibiotics were found in a Tucson Water drinking-water well in Marana near Continental Ranch, city officials said Monday.

The chemicals, the traces of which are so small that they are expressed as parts per billion, were uncovered in "testing" by Tucson Water conducted once every three years. The testing is above and beyond the mandatory testing required under federal and state law.

Tucson Water spokesman Mark Bejarano said the discretionary testing for the pharmaceuticals was conducted because of national and local reports about trace amounts of pills people take and personal-care products they use showing up in drinking water.

The trace amounts of the chemicals pose no health risks to water customers, Bejarano said, noting that it would require a customer to drink more than a million gallons of water to build up enough of the chemicals to constitute a medical dose of the drugs the city found.

There currently are no water-quality standards for the chemicals Tucson Water found in the well, which included:

• Carbamazepines, an anti-convulsant and mood-stabilizing drug used for treating epilepsy and bipolar disorder.

• Lopromidol, a chemical injected into the body for use in X-rays as a contrast to better show a patient's condition.

• Sulfamethoxazole, an antibiotic often used to treat urinary tract infections.

• Triclosan, an antibacterial agent used as a disinfectant or antiseptic in consumer products.

The city tested for dozens of chemicals at one time, finding the four substances at the Marana well. The other samples tested were the parts where Central Arizona Project water from the Colorado River is blended into the city's drinking-water system. No pharmaceuticals were found there.

Finding the trace amounts of chemicals led to Tucson Water submitting a recommendation to City Manager Mike Hein that the city expand its discretionary "testing" adding them once every three years as an annual program.

Hein approved the change, and he also requested Tucson Water to expand the number of wells it would test throughout its service area.

"Since we found some, I thought it would be prudent to expand the area" where we are looking for the chemicals, Hein said.

Mark Shaffer, communications director for the Arizona Department of Environmental Quality, said the state has no standards yet for these chemicals. "That's probably coming, but it's still early in the game," he said.

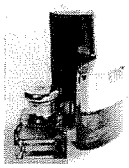
The city tested the two locations because they were the most likely places where trace amounts of personal-care products and endocrine-disrupting compounds from pills would be found in the water supply.

- What are PPCPs?
- How do they get into the environment?
- What is the concern?
- Should I be concerned?
- How can PPCPs levels be reduced?

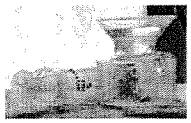
What are PPCPs?

Prescription Medications

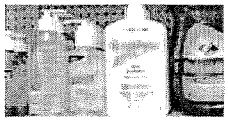
Nonprescription Medications



Cosmetics & Fragrances

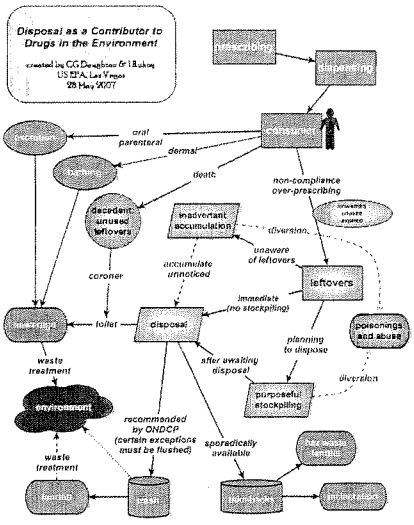


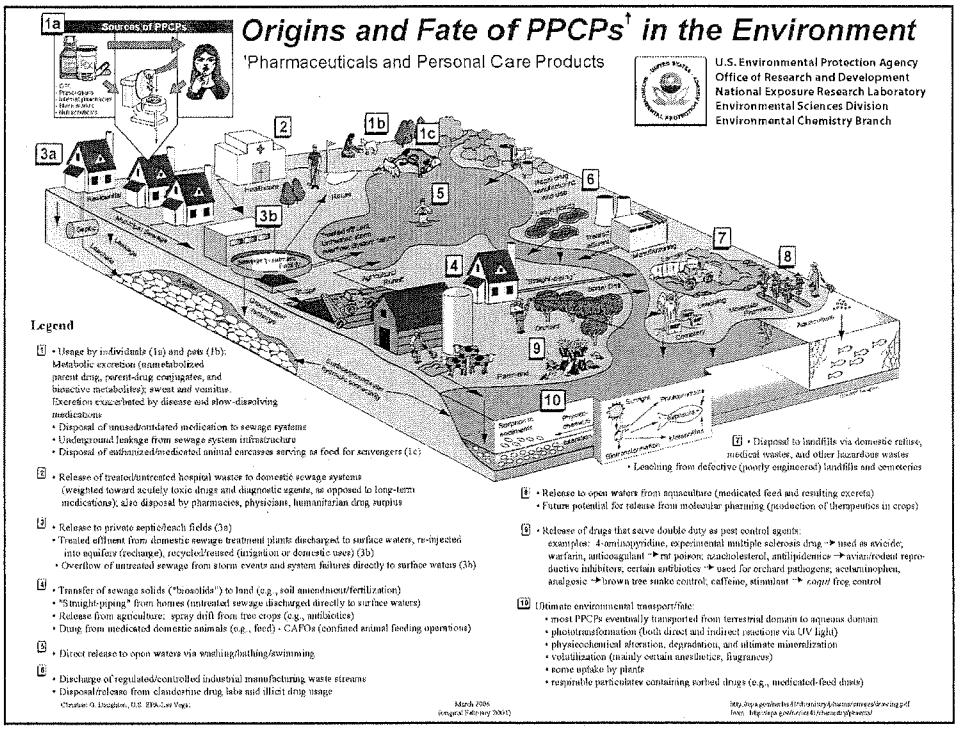
Illicit Drugs



Soaps, Cleaners, Sunscreens, Lotions, etc.

Mechanisms of Disposal



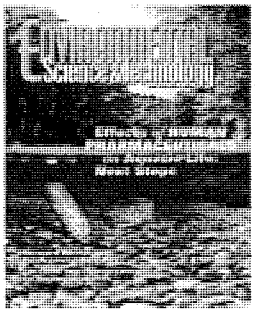


Why the Recent Concern?

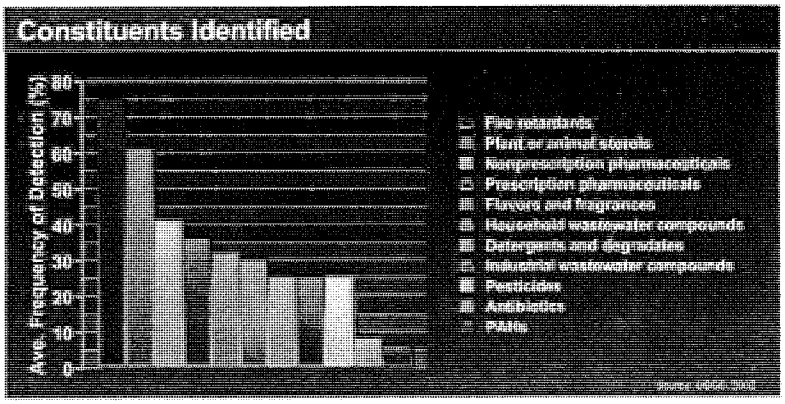
1999 - 2000 Stream Study

2002 Effluent Study

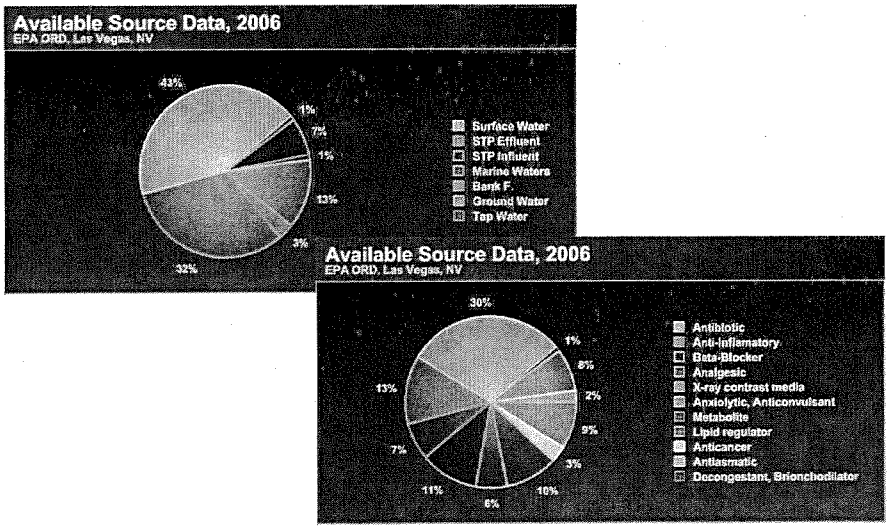
2006 Effects Study



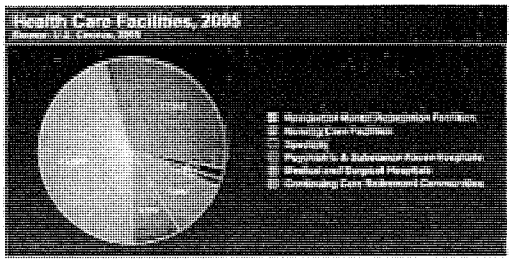
What They Found



Pharmaceutical Partitioning



Putting it all into Perspective



	Arizona	United States
Retail Prescriptions Filled at Pharmacies	*54,602,733*	*3,309,155,973*
At a cost of:	*$2,866,871,055*	*$192,041,120,674*
Retail Prescriptions Filled at Pharmacies per Capita	*9*	*11*
• Age: 0-18	*3*	*4*
• Age 19-64	*9*	*11*
• Age 65+	*20*	*28*
• Male	*7*	*9*
• Female	*11*	*14*

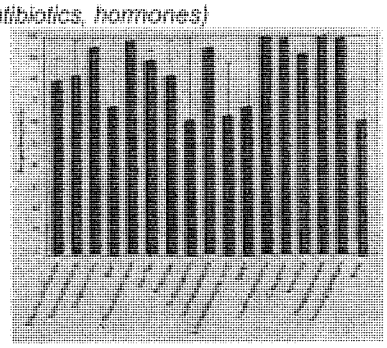
Source: Verispan, 2006

Wastewater Treatment

- No single treatment technology will remove all PPCPs or disinfection byproducts.
- Recent WERF studies have demonstrated that conventional secondary treatment removes over 90% of many compounds.
- 2004 Black & Veatch study demonstrated complete biodegradation of select PPCPs can be achieved with adequate SRT and/or HRT in an activated sludge system.
- Optimization of the activated sludge process should be considered prior to expensive treatment options.
- Upgrading existing activated sludge basins to increase SRT will result in complete removal of many compounds.

Conventional Treatment

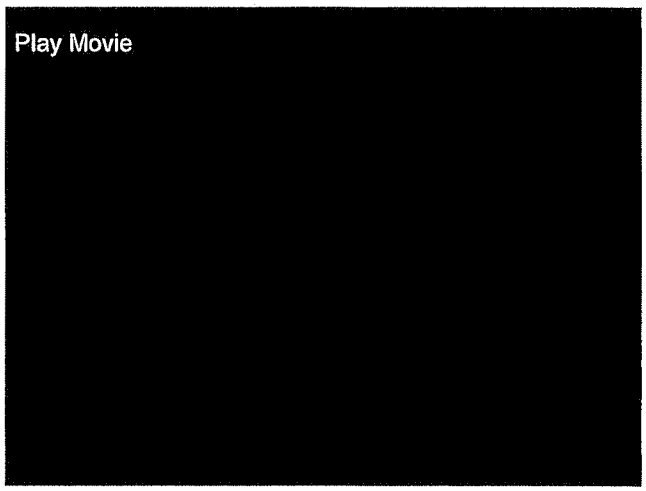
- Typical nutrient removal SRT of 10-20 days is effective removal *(antibiotics, anti-inflamatories, hormones and lipid regulators)*
- SRT has little or no impact *(anticonvulsants and Beta Blockers)*
- HRT <12 hours provides effective removal *(antibiotics, hormones)*
- HRT 12 – 25 hours provides effective removal *(anti-inflamatories and lipid regulators)*
- HRT has little or no impact *(contrast media, anticonvulsants)*



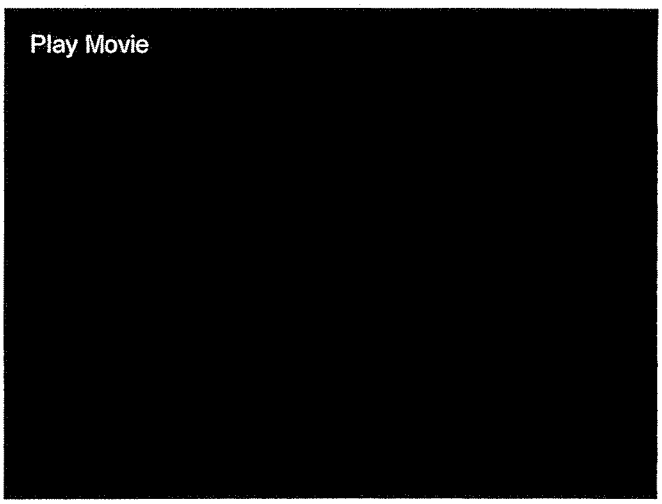
Unused Medications

- PhRMA estimates that 3% of all prescribed medications go unused
- A recent British survey indicates that:
  82% of antibiotics go unused
  50% of antidepressants go unused
  50% of beta-blockers go unused
  20% of pain medications go unused

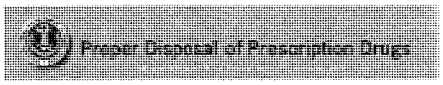
Unused Medications



Unused Medications



Federal Disposal Guidelines



Federal Guidelines:

1. Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
2. 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.
3. Flush prescription drugs down the toilet *only* if the label or accompanying patient information specifically instructs doing so (see box).
4. 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.

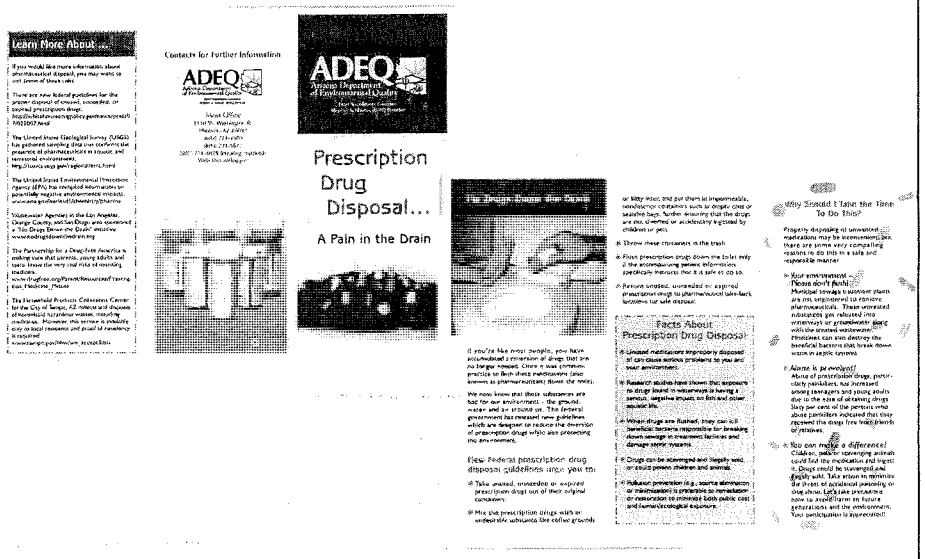
The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:

- 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.

www.WhiteHouseDrugPolicy.gov

ADEQ Position



Controlled Substances Act

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

APR 3 2008

Kevin N. Nicholson, R.Ph., JD
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Pharmacy Regulatory Affairs
National Association of Chain Drug Stores
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Alexandria, Virginia 22313-1480

Dear Mr. Nicholson:

This correspondence is in response to your letter dated April 16, 2008, in which you requested the Drug Enforcement Administration (DEA) policy regarding "take-back" prescription disposal programs as they relate to controlled substances, so that you may share that policy with members of the National Association of Chain Drug Stores (NACDS) members.

A primary mission of DEA is to prevent, detect, and investigate the diversion of legitimate controlled substances while ensuring their availability for medical and scientific purposes. The DEA must weigh the benefits of efficiently destroying unwanted controlled substances with the associated risks encountered if improper handling results in the diversion of the surrendered unwanted controlled substances into the illicit market.

The DEA is aware of the concept of pharmaceutical "take-back" disposal programs. As noted by many news reports, the hazards of prescription medications making their way into the environment are a health risk of which we all must be cognizant. However, the development of efficient, secure, and environmentally-sound protocols to collect unwanted controlled substances from consumers is a significant and complex matter and many scenarios for collecting and destroying these controlled substances are not supported by the Controlled Substances Act (CSA) and its implementing regulations.

The CSA and its implementing regulations establish a closed system of distribution for controlled substances which requires those individuals or firms desiring to handle controlled substances to be registered with DEA. This closed system facilitates an accurate accounting of all controlled substances from their manufacture through and including their dispensation. This closed system reduces the potential for diversion of controlled substances from these registrants because of the audit trail and the ability of this system to detect excessive, suspicious and unusual orders/shipments. The ultimate user is a non-registrant, and there are no provisions in the CSA to allow a DEA registered pharmacy to acquire controlled substances from a non-registrant.

The regulations do, however, authorize law enforcement officials to handle controlled substances when acting in the course of his or her official duties (Title 21 Code of Federal Regulations § 1301.24). Thus, the regulations permit end users to surrender their unused or unwanted pharmaceutical controlled substances to a law enforcement entity for disposal, if permitted by the state. However, many law enforcement organizations do not want the responsibility or expense of disposing of unwanted pharmaceutical controlled substances and have therefore, not implemented take-back programs for this purpose.

To correct this matter, DEA is drafting regulations to permit ultimate users to surrender their controlled substances for destruction via other methods. Once the DEA has completed drafting these regulations, they will be published as a Notice of Proposed Rulemaking in the Federal Register and made available for public comment. DEA would welcome any additional comments from you and/or NACDS members during that public comment period.

We hope that the information provided will assist you and NACDS members in responding to take-back drug disposal proponents. Please contact me at (202) 307-7297 if I may further assist you in this matter.

Sincerely,

Mark W. Caverly
Chief, Liaison and Policy Section
Office of Diversion Control