



Welcome

to the Pharmaceutical Disposal Advisory Group Meeting, March 24th, 2010

We will begin promptly at 9:00am.

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Teleconference dial-in number: 1-866-456-0016

Room ID: \* 9751955 \*

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LiveMeeting Log-in:

URL:

https://www.livemeeting.com/cc/tceq_state_tx_us/join?id=PharmStudy3&role=attend&pw=PharmAttend3

Meeting ID: PharmStudy3

Entry Code: PharmAttend3



Elston Johnson

Manager, Public Drinking Water Section
Water Supply Division
Office of Water
TCEQ



Attendees at TCEQ Office



- Thank you for coming!
- Food and drinks are not allowed in this room
- Restrooms down the hall
- Microphones available (wave down TCEQ staff)
- Please announce your name before speaking

LiveMeeting Attendees



- Please mute phone during presentations.
- Un-mute to speak.
- Please announce your name before speaking.
- You can also ask a question using LiveMeeting – Click on “Q&A”, type your question in the box and submit.

Today's Agenda



- 9:00 - 9:15: Welcome & Introductions
- 9:15 - 9:30: Revisit Terminology
- 9:30 - 10:45: Open discussion about current methods of disposal of unused pharmaceuticals
- **10:45 - 11:00: Break (15 mins)**
- 11:00 - 11:30: Frequently asked questions
- 11:30 - 12:00: Final discussion about current methods
- *12:00 - 12:30: If time permits: Introduce alternative methods of disposal*



Re-cap of SB1757 Objectives

- (1) the methods currently used in Texas (by consumers, health care providers, and others);
- (2) alternative methods used, including methods used in other states; and
- (3) the effects on public health and the environment of the various methods used for that purpose.
- (4) The report must also provide an analysis of the feasibility of implementing the recommended disposal methods on a statewide basis.

Revisiting Terminology - Pharmaceuticals



- Pharmaceutical = Drug
 - Medications
 - Prescription drugs & over the counter
 - Veterinary medications
- Dangerous Drug ~ Prescription Drug
 - Except that DD includes devices and “Drugs” do not
 - Title 6 HSC Chapter 483
- API = Active Pharmaceutical Ingredient
 - *“Any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product”*

Revisiting Terminology - Pharmaceuticals



- Controlled Substances:
 - Specific list of substances
 - Strict handling requirements
 - Only represents about 5-10% of pharmaceuticals dispensed
- Hazardous Waste:
 - Specific list of substances or any of the 4 hazardous characteristics
 - Strict disposal requirements
 - Only represents about 10-20% of pharmaceuticals in hospitals



Revisiting Terminology

- “Unused”



- **Unwanted/unneeded: Once dispensed to patients**
 - Symptoms cured (leftover meds unneeded)
 - Patient discontinued because experienced reaction
 - Changed prescription (former dosage drugs leftover)
 - Patient died (or discharged)
 - Patient non-adherence
- **Unwanted/unneeded: Not dispensed to patients**
 - Solid dose non-administered drugs (e.g. only half a pill required)
 - Non-administered or partially used liquid
 - Too much drawn up in syringe, some remains in syringe
 - Not all liquid dispensed from pre-manufactured (pre-filled) syringe
 - Leftover fluid in pre-filled IV bag
- **Expired drugs:**
 - Passed “used-by” date

Revisiting Terminology

- Waste References



- Drug becomes a “waste” when it is discarded (for disposal or processing).
- “Disposal”: Waste goes directly to landfill (or ultimate disposal location).
- “Processing”: Waste is redirected to intermediate facility, prior to disposal.

Revisiting Terminology - Water/Wastewater



- WWTP = Wastewater Treatment Plant
 - Domestic or industrial
 - ‘Domestic’ could be private or public/municipal
- POTW = Publicly Owned Treatment Works
 - i.e. a municipal WWTP



Open Discussion about Current Methods of Disposal





Potential Discussion Topics

- How do Long-Term Care Facilities operate?
- How does Reverse Distribution operate?
 - Are pharmacies & health-care facilities **required** to have a reverse distribution program?
- Rural versus urban Texas
 - the health-care provider perspective?
 - the consumer perspective?
- What is being autoclaved, by whom?
 - What are the pros/cons?



Potential Discussion Topics

- Where are gaps/issues in the rules from your perspective?
- What would you change with the current set-up for disposing of unused pharmaceuticals if you could?
- If disposal practices have changed, why have they changed?
- How do you determine success in your profession regarding current methods of disposing of pharmaceuticals?





Potential Discussion Topics

- What about this project makes you cautious or concerned?
- What drug distribution systems are primarily used in Texas?
 - Retail pharmacies, mail-order, internet pharmacies? Any data?
 - How does the distribution impact quantities of unused drugs?
- Other data availability?
 - Biggest contributors of unused pharmaceuticals?
 - Quantity unused prescription vs. OTC?
 - Controlled vs. other prescription dispensed?
 - Unused/disposed: Liquid vs. solid?





Potential Discussion Topics

- Education Strategies:
 - How are nurses and pharmacists currently trained to dispose of unused pharmaceuticals?
 - What other education strategies have been employed for disposal?
- Have labeling or sorting practices changed and has that made a difference in how much goes expired or unused?
- Costs of disposal methods
- Other issues/questions?

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Frequently Asked Questions



FAQs



- If there are no known adverse human health impacts from being exposed to low levels of pharmaceuticals in our environment/drinking water, why should we consider attempting to reduce pharmaceuticals entering WWTPs and our water supplies?
 1. Insufficient data (→ adopt precautionary principle):
 - We do not understand the potential health effects of long-term chronic ingestion of low concentrations through drinking water.
 - The effect of multiple pharmaceuticals on human health (synergistic impacts) are not often studied.

FAQs



- 2. There is evidence that aquatic species may be impacted by the presence of pharmaceuticals in surface water bodies.
- 30 TAC Chapter 307 : TEXAS SURFACE WATER QUALITY STANDARDS
- §307.1. General Policy Statement.
- It is the policy of this state and the purpose of this chapter to maintain the quality of water in the state consistent with public health and enjoyment, propagation and protection of terrestrial and aquatic life, operation of existing industries, and economic development of the state....

FAQs



- What proportion of pharmaceuticals that eventuate at a WWTP are due to excretion vs. intentional flushing?
 - Limited data available & analytical methods.
 - Some quote 75%-97% is due to excretion.
 - We're still looking for the peer-reviewed literature references that quote those numbers.

FAQs



- If, say, only 20% of drugs in WWTPs are attributable to intentional flushing, then why even consider an anti-flush message? Some potential arguments:
 1. It's something we can directly impact now
 - Impacting the 80% due to excretion would be a difficult task requiring investment e.g. re-formulating drugs
 2. Community perception/desires & public health/safety:
 - Even if levels in drinking water are negligible, people don't want to impact aquatic organisms & the environment.
 - Consumers may not want to flush (or trash) drugs. If so, they may hold on to them waiting for other options which becomes a safety issue.
 3. Magnitude of the problem: eliminating 20% *may* be a worthwhile effort – we must address this.

FAQs



- **Magnitude of Unused Drugs in Texas:**
- 233 million prescriptions filled in Texas in 2008, dispensed from retail pharmacies only
- EPA's Health Services Industry study states that approx. 3% of all purchased medications reach their expiration date before they are used.
 - If we assume people don't use expired drugs, that's almost **7 million prescriptions that would expire and require disposal in 1 year in Texas.**
 - Data suggests that 10-35% of medications in the household requiring disposal are flushed → **that's 700,000 – 2.45 million prescriptions flushed in Texas per year.**
- Could it make a difference to our water bodies if we stopped 700,000 prescriptions being flushed per year in Texas?
- Could it impact public health?

FAQs



- Do landfills contribute pharmaceuticals to the groundwater?
 - EPA 2002 study on 54 landfills suggested that API transfer to groundwater from correctly designed/constructed landfills is negligible.
 - Landfills are permitted and designed with multiple barriers to prohibit movement of contaminants (geomembrane liner, clay liner and leachate collection system).
 - Older landfills without those design measures no longer receive new waste.
 - USGS work presented at February meeting suggests there may be impacts at their research site in OK.
 - But more data/research required.

FAQs



- Do landfills in Texas send their leachate to WWTP or do they treat their own leachate?
 - Many discharge collected leachate to a POTW.
 - Some re-circulate it back in to the landfill.

FAQs



- Does landfill leachate contain pharmaceuticals?
 - Limited data.
 - Recent Maine Dept. of Env Protection study of the leachate from 3 lined landfills:
 - The landfills were chosen because they receive little or no sludge from POTWs (but do receive significant quantities of household waste).
 - Study confirmed detection of 40 PPCP compounds or their breakdown products in leachate.
 - Leachate from all 3 landfills detected 20 compounds (some pharmaceuticals), but all detects were at very low concentrations (detection limit at the nanograms per liter level).

FAQs



- Does landfill leachate contribute pharmaceuticals to surface water bodies (assuming leachate is treated at a WWTP and WWTP effluent is discharged to surface water)?
 - 2007 PhRMA study suggested 99.9% of releases of API into surface water would be due to patient excretion, not landfill disposal.
 - Study does not address the potential impact of biosolids applied to the landfill.



Final discussion about current methods of disposal



Ultimate Disposal Options



- Sewer
- Landfill
- Processing - treated medical waste, incineration



Next Meeting



- Discuss alternative approaches in detail.
- Consider how these alternative approaches may work in Texas and impact public health and environment.
- Overview some legislation proposed or passed around country.

Resources Before Next Meeting



- EPA Health Care Industry Study Interim Report:
<http://www.epa.gov/waterscience/ppcp/hcioutreach.pdf>
- Information about proposal to add Pharmaceuticals to Universal Waste Rule:
<http://www.epa.gov/epawaste/hazard/wastetypes/universal/pharm.htm#1>

Closing



- Thank you for your attendance and valuable discussions
- Next meetings:
 - April 22nd, May 25th, June 24th.



Closing



- Agenda for March meeting & minutes for this meeting on website by **April 7th**.
- Provide questions/comments on meeting format, discussion topics etc. to Jessica
 - **jhuybreg@tceq.state.tx.us**
- http://www.tceq.state.tx.us/permitting/water_supply/pdw/pdagroup