



Pharmaceutical Disposal Advisory Group Meeting, January 26th, 2010

Facilitator/Chairman:

Elston Johnson

Manager, Public Drinking Water Section

Water Supply Division, Office of Water

TCEQ



Purpose of Today's Meeting



- So we're all on the same page moving forward:
 - To introduce the topic of pharmaceuticals
 - To explain goals and scope of SB-1757
 - To define intent of Pharmaceutical Disposal Advisory Group
- Mostly presentation-based today
- Opportunity for discussions toward end

Today's Agenda



- 9:00 - 9:10am: Welcome (10 mins)
- 9:10 - 9:40am: Pharmaceuticals 101 (30 mins)
- 9:40 - 10.30am: Stakeholder Introductions (50 mins)
- 10:30 - 10:50am: Break (20 mins) – Room E254
- 10:50 - 11:10am: Scope/goals of Senate Bill 1757 project (20 mins)
- 11:10 - 11:30am: Goals of Advisory Group (20 mins)
- 11:30 - 11:40am: Questionnaire (10 mins)
- 11:40 - 12:25pm: Questions and discussion (45 mins)
- 12:25 - 12:30pm: Next meeting and adjourn



Pharmaceuticals 101

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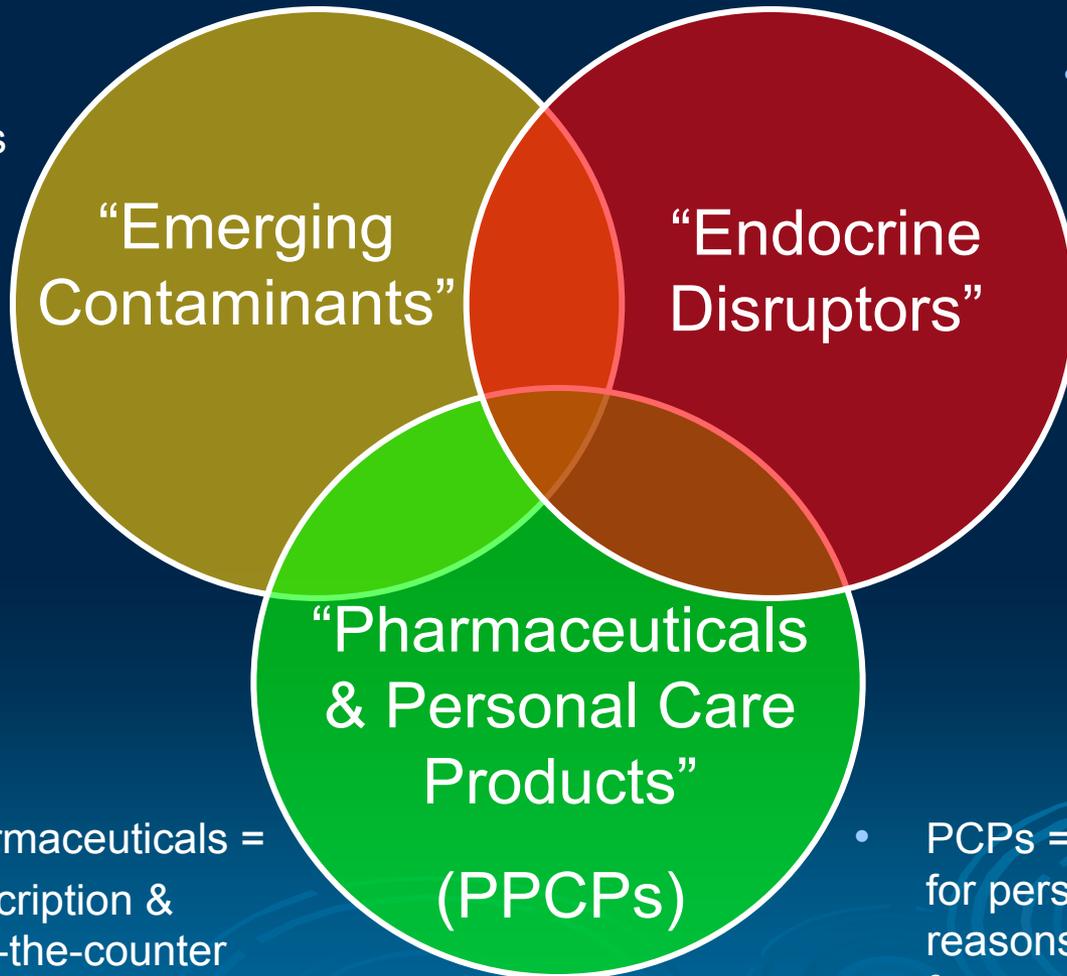


Outline

- What are Pharmaceuticals?
- **Categories of Pharmaceuticals**
- Typical Disposal Options
- **Sources in the Environment**
- Sources in Wastewater Stream
- **Removal of Pharmaceuticals via Treatment**
- Occurrence Data
- **Ecological and Human Health Impacts**
- Water-Related Regulations
- **Public Health/Safety Aspects**
- Current Data Gaps



Current Buzzwords



- Unregulated
- New contaminants or
- Existing contaminants only now detected (better analytical sensitivity)

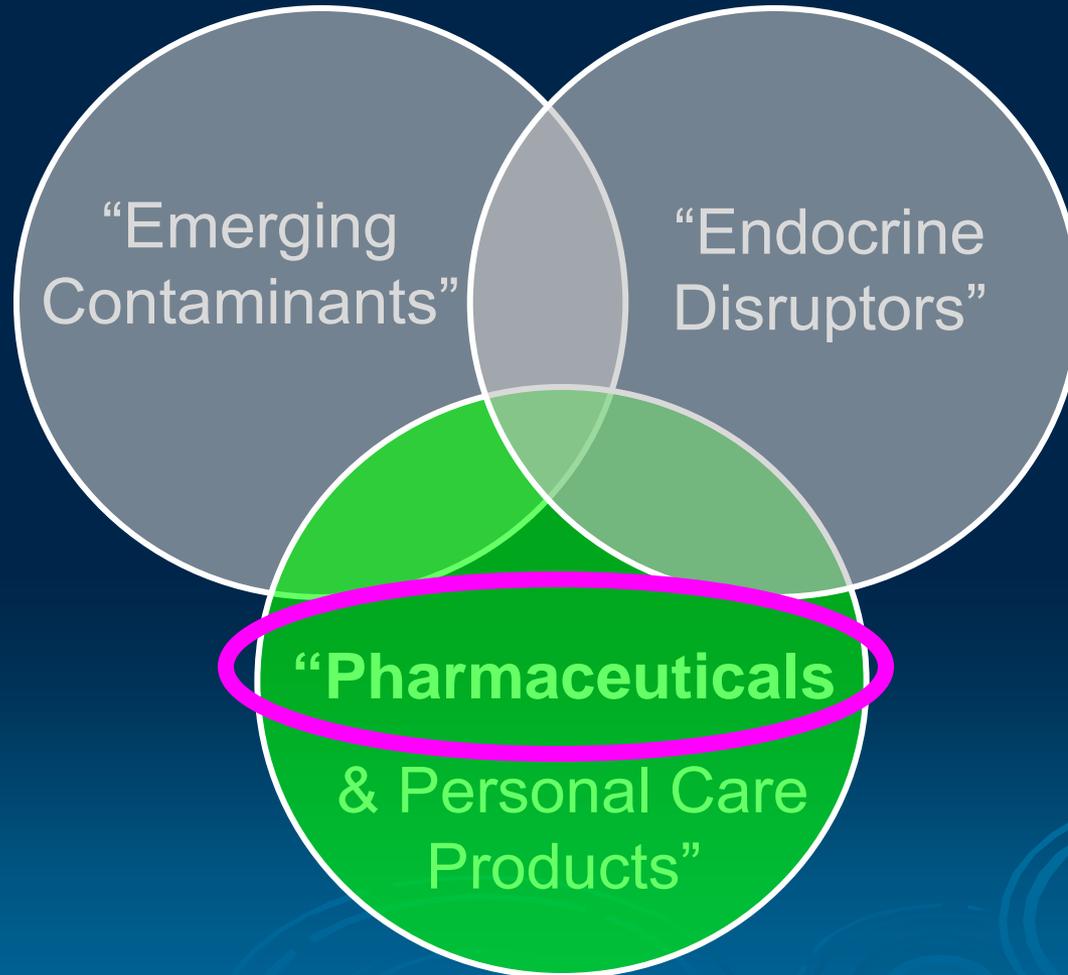
- Substances that impact endocrine systems of animals (Endocrine system regulates all biological process in body – e.g. reproductive, hormone, brain development, nervous system)

- Pharmaceuticals = prescription & over-the-counter drugs

- PCPs = products used for personal & cosmetic reasons (soaps, fragrances, sunscreen, insect repellent)



Our Focus is on Pharmaceuticals Only



What are Pharmaceuticals?



- Prescription drugs
- Over-the-counter medications
- Veterinary drugs (pets & livestock)
- Definition explained more later in “SB1757 Scope” presentation



Main Categories of Pharmaceuticals



- (1) “Controlled Substances”
- (2) “Hazardous” Pharmaceuticals
- (3) Non-hazardous non-controlled Pharmaceuticals
- (4) Pharmaceuticals in Households

Main Categories of Pharmaceuticals



- (1) “Controlled Substances”
 - Specific list of substances (Schedule I-V)
 - Regulated under Federal Controlled Substances Act (US DoJ-DEA) and Texas Controlled Substances Act (Texas Dept of Public Safety)
 - Strict rules related to handling & documentation
- (2) “Hazardous” Pharmaceuticals
 - Includes:
 - Listed substances (U- and P- lists); or
 - Characteristically hazardous waste (any of: ignitable, corrosive, reactive and/or toxic).
 - Regulated under Resource Conservation and Recovery Act (RCRA)- through TCEQ in Texas.
 - Strict rules for generation, transportation, treatment, storage & disposal

Main Categories of Pharmaceuticals



- **(3) Non-Hazardous Non-Controlled Pharmaceuticals:**
 - Some prescription & over-the-counter
 - When not contained in household, considered “Special Waste” for regulation purposes.
- **(4) Households/end users:**
 - Pharmaceuticals in households (and other lodging eg. hotels) are not regulated under other categories, until centrally collected.



Typical Disposal Methods

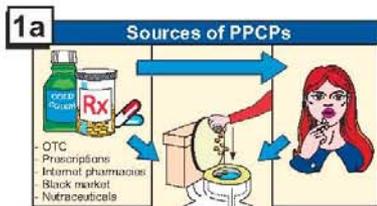


- Common Methods for Intentional Disposal :
 - (1) Deposit in trash → Municipal Solid Waste (MSW) landfill
 - (2) Hazardous-Waste Landfill
 - (3) Incineration
 - (4) Treat in autoclave with med waste → to MSW landfill
 - (5) Return to manufacturer (certain entities, certain cond.)
 - (6) “Take-Back” Programs (eg. mail-back, collection events, drop-boxes/kiosks)
 - (7) Flush down drain



Sources of Pharmaceuticals in Environment



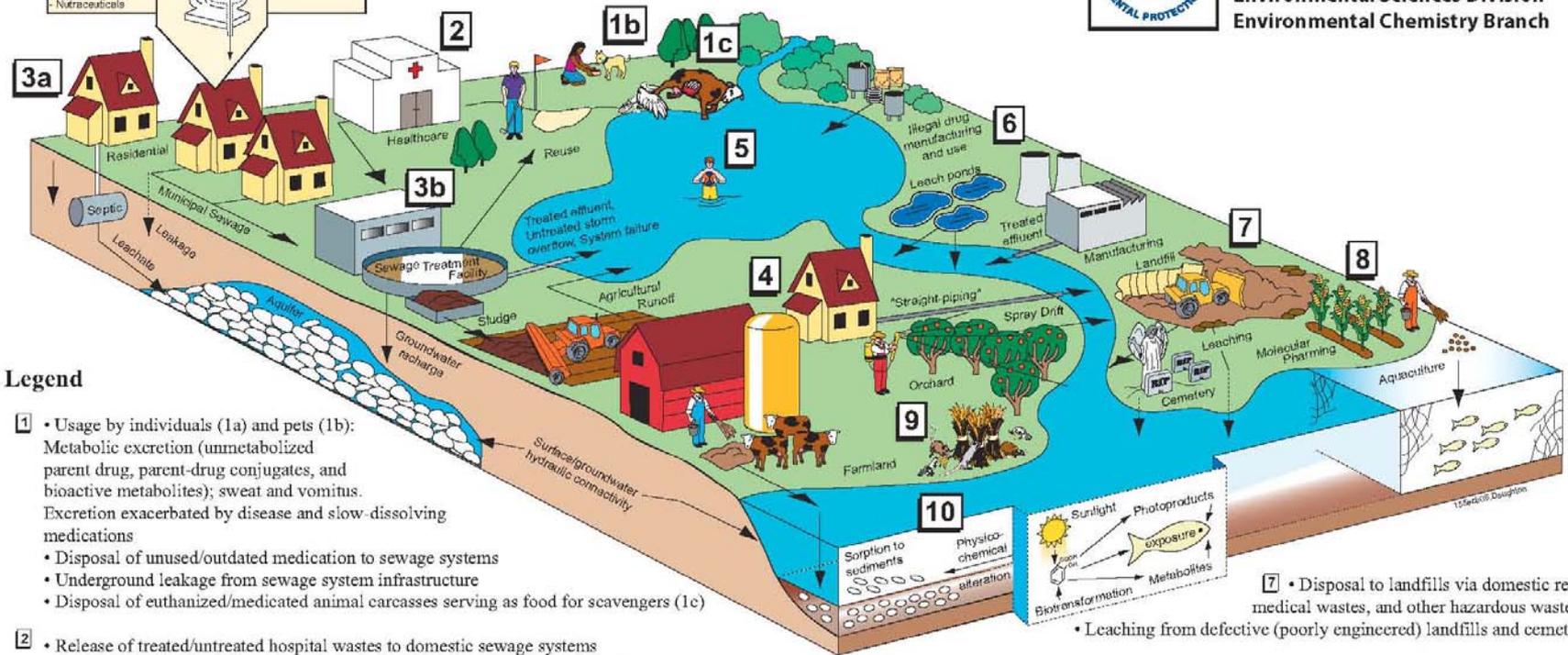


Origins and Fate of PPCPs[†] in the Environment

[†]Pharmaceuticals and Personal Care Products



U.S. Environmental Protection Agency
Office of Research and Development
National Exposure Research Laboratory
Environmental Sciences Division
Environmental Chemistry Branch



Legend

- Usage by individuals (1a) and pets (1b): Metabolic excretion (unmetabolized parent drug, parent-drug conjugates, and bioactive metabolites); sweat and vomitus. Excretion exacerbated by disease and slow-dissolving medications
 - Disposal of unused/outdated medication to sewage systems
 - Underground leakage from sewage system infrastructure
 - Disposal of euthanized/medicated animal carcasses serving as food for scavengers (1c)
- Release of treated/untreated hospital wastes to domestic sewage systems (weighted toward acutely toxic drugs and diagnostic agents, as opposed to long-term medications); also disposal by pharmacies, physicians, humanitarian drug surplus
- Release to private septic/leach fields (3a)
 - Treated effluent from domestic sewage treatment plants discharged to surface waters, re-injected into aquifers (recharge), recycled/reused (irrigation or domestic uses) (3b)
 - Overflow of untreated sewage from storm events and system failures directly to surface waters (3b)
- Transfer of sewage solids ("biosolids") to land (e.g., soil amendment/fertilization)
 - "Straight-piping" from homes (untreated sewage discharged directly to surface waters)
 - Release from agriculture: spray drift from tree crops (e.g., antibiotics)
 - Dung from medicated domestic animals (e.g., feed) - CAFOs (confined animal feeding operations)
- Direct release to open waters via washing/bathing/swimming
- Discharge of regulated/controlled industrial manufacturing waste streams
 - Disposal/release from clandestine drug labs and illicit drug usage
- Disposal to landfills via domestic refuse, medical wastes, and other hazardous wastes
 - Leaching from defective (poorly engineered) landfills and cemeteries
- Release to open waters from aquaculture (medicated feed and resulting excreta)
 - Future potential for release from molecular pharming (production of therapeutics in crops)
- Release of drugs that serve double duty as pest control agents: examples: 4-aminopyridine, experimental multiple sclerosis drug → used as avicide; warfarin, anticoagulant → rat poison; azacholesterol, antilipidemics → avian/rodent reproductive inhibitors; certain antibiotics → used for orchard pathogens; acetaminophen, analgesic → brown tree snake control; caffeine, stimulant → *coqui* frog control
- Ultimate environmental transport/fate:
 - most PPCPs eventually transported from terrestrial domain to aqueous domain
 - phototransformation (both direct and indirect reactions via UV light)
 - physicochemical alteration, degradation, and ultimate mineralization
 - volatilization (mainly certain anesthetics, fragrances)
 - some uptake by plants
 - respirable particulates containing sorbed drugs (e.g., medicated-feed dusts)

Sources of Pharmaceuticals in Environment



WASTEWATER PATHWAY

- Treated Wastewater discharge into:
 - surface waters (rivers)
 - groundwater (re-injected into aquifers or recharge/leaching from irrigation)
- Untreated discharge from WWTP failures & storm overflows
- Untreated releases from septic sys.

DIRECT RELEASE TO SURFACE WATER

- “Straight piping” (untreated sewage from homes to surface waters)
- Untreated discharges from illegal drug producers
- Treated discharges from pharmaceutical manufacturers
- Spray drift
- Aquaculture (release of medicated feed & excreta)

TERRESTRIAL TO AQUATIC PATHWAY

- Leaching from :
 - land application of biosolids
 - defective landfills (eg. poorly constructed and/or maintained)
 - cemeteries (medicated bodies)
- Leaching/runoff from farmland (dung from medicated livestock, sprayed pharms)



Major Sources of Pharmaceuticals in Wastewater

Medicines **consumed** &
not completely
metabolized
(or metabolized into
other forms)



Major: Excretion
Minor: Sweat & vomit

Intentional disposal of
unused drugs
(flushed down toilet
or sink)



Pharmaceuticals enter wastewater stream
(WWTP or septic systems)



Removal of Pharmaceuticals via Treatment



- **Conventional** WWTPs not designed to remove pharmaceuticals (but they tend to remove some).
- Some information exists on the removal of pharmaceuticals from WWTPs under **innovative** treatment technologies.
 - Eg. nanofiltration, reverse osmosis, ozone, UV, and combinations.
- Depending on treatment used, removal efficiencies range **1%-100%**.
 - Generally, innovative treatments remove more pharmaceuticals.
 - Limited number of WWTPS employ innovative treatment technologies in Texas.

Removal of Pharmaceuticals via Treatment



- **Some** pharmaceuticals are removed **more easily than others** under the **same treatment** processes.
 - Eg: Complete elimination of 17-ethinylestradiol, but only 20-60% removal efficiency for others (incl. ibuprofen) and carbamazepine was not removed at all (Carballa et al., 2007).
- Consequently, **pharmaceuticals may remain in water** at variable concentrations **after WW treatment**
- → Pharmaceuticals could **discharge to surface water** (rivers, lakes) and become our **future drinking water sources**.
- → **Aquatic organisms** may be **exposed**
- **DWTPs** have **similar issues** as WWTPs with removing pharmaceuticals.

Occurrence Data (Water)



- Significant amounts of **research** (and media attention) around the world studying the occurrence of pharmaceuticals in water
- In USA, **significant national** studies were undertaken by USGS 1999-2002, plus countless private and government studies since then.
- Studies **confirmed** pharmaceuticals (& other emerging contaminants) **do occur** in US waterbodies (**at low concentrations**).



Occurrence Data (Water)



- USGS National Stream Reconnaissance 1999/2000:
 - 139 streams tested for 'emerging contaminants'; 30 States
 - **50% streams** contained **7 or more** of the chemicals
 - Pharmaceuticals **acetaminophen** and **codeine** were found in **24%**, and **11%** of samples, respectively.
 - Steroids and hormones were also commonly found in surface waters, with **17-ethinyl estradiol** (estrogen hormone) found in **16% of samples** analyzed.
 - **Antibiotics** were found in over **10%** of samples analyzed.
 - See Kolpin et. al. 2002.

Occurrence Data (Water)



- USGS Untreated Drinking Water Study 2001:
 - In **25 States** & **Puerto Rico**
 - Samples in 25 **GW** & 49 **SW** untreated sources drinking water
 - At least 1 “emerging contaminant” was detected in **96%** of samples
- Among the most **frequently** detected chemicals:
 - In surface water: **cotinine** (nicotine metabolite), and **1,7-dimethylxanthine** (caffeine metabolite)
 - In groundwater: **carbamazepine** (anti-epileptic drug), and 1,7-dimethylxanthine.
- Overall, detections were more common in surface water sites than from groundwater sites.
- See Focazio et al., 2008

Occurrence Data (Water)



- Most pharmaceuticals detected were at the parts per billion or parts per trillion level (very low).
- Keep in mind that those pharmaceuticals detected in water (and other aspects of env) have resulted from **targeted** monitoring.
 - Targeted chemicals
 - Targeted locations (those more likely to contain those chemicals eg. urban, sometimes effluent-dominated surface water).
- There may be other pharmaceuticals of potential concern that have not been targeted or identified yet with available analytical methods.

Occurrence Data - Texas



- Some pharmaceutical occurrence data exist in TX waters:
 - **South-central Texas WWTP influent /effluent study:**
 - Most pharmaceuticals were completely removed (the exception of carbamazepine, an anti-epileptic) as a result of WW treatment.
 - None detected in treated drinking water supply.
 - A hospital contributed 12 emerging contaminants to the WWTP.
 - **North Texas DWTP raw/treated study:**
 - A number of pharmaceuticals detected in raw water entering DWTPs.
 - However, no pharmaceuticals (with the exception of an anti-anxiety drug) were found above detection limits in the treated (finished) drinking water.

Occurrence Data - Texas



- **Fish tissue** studies conducted in **effluent-dominated** rivers in North Texas
 - **Trinity River** in Dallas part of national pilot study:
 - Among **fish liver** samples, the antidepressant norfluoxetine was **detected** in 4 of the 6 fish liver composite samples collected from the Trinity River.
 - Also detected sertraline (antidepressant) and diphenhydramine (antihistamine) in fish liver samples from Trinity River.
 - See Ramirez et *al.*, 2009



Human-Health Impacts

- **No evidence of adverse health effects to humans**
 - Studies show negligible to no appreciable risk to humans associated with the exposure to pharmaceuticals via drinking water (Schwab et al., 2005).
 - Margin between exposure via drinking water & the daily therapeutic dose is at least 3 orders of magnitude (Webb et al., 2003).
- Concerns of antibiotic-resistance in humans
 - More research required



Ecological Impacts



- Ecological impacts of exposure to pharmaceuticals have **been observed**.
- Well documented study is the **feminization of fish**:
 - Chronic exposure of fathead minnow to low concentrations of synthetic estrogen led to feminization of fish population
 - 7-year study resulted in near extinction of the fish sp. in Canadian lake

Ecological Impacts

- Several other ecological impacts observed:
 - Reduced predator behaviors
 - **Developmental delays** (eg. tadpoles exposed to prozac that don't grow limbs)



- These impacts may inhibit **species survival**
- Note that aquatic life are **continuously exposed**.
- **Plants** can also uptake and store pharmaceuticals contained in soil pore water.

Water-Related Regulations



- TCEQ and the EPA currently have no rules or policies in place to address 'emerging contaminants'.
- Both agencies are reviewing the issue and expect to be able to address the problem in the future.



Wastewater Regulations



- **Effluent analyses** for approx 150 pollutants are required during the **permitting process** for WW treatment facilities with a permitted/proposed flow of ≥ 1 MGD, or facilities with an approved pretreatment program.
 - A **screening** procedure is performed
 - That may result in **effluent limits and/or monitoring requirements** for pollutants that **exceed** the criteria (found in 30 TAC Chapt. 307).
 - A **few** of these pollutants are **used** in **pharmaceutical manufacturing** but are not pharmaceuticals themselves.

Drinking Water Regulations



- **No** pharmaceuticals listed in the Primary or Secondary **National Drinking Water Regulations**.
- However, **10 pharmaceuticals** are listed on the **Contaminant Candidate List 3 (CCL3)** – used by EPA to help determine if chemicals should be regulated in future.

Public Health/Safety Aspects



- Substance Abuse/Diversion Issues
- Safety (poisoning) Issues

Public Health/Safety Aspects



- Amount of **pharmaceuticals in US households** has **increased** for many **reasons**:
 - Ease of **access** (eg. internet pharmacies)
 - **Aging** population
 - **Automatic refill** option (refilled without any action by patient)
 - High **cost-effectiveness** of buying **large quantities** of non-prescription drugs
 - **Large quantities** filled through **mail order** (eg. 90 days supply minimum)
 - Reduced costs of medication due to **generic** switches
 - **Free samples** from physician

Public Health/Safety Aspects



- Prescription drug USE:
 - 1999-2000 National Study:
 - 44% of Americans taking 1 or 2 prescription drugs (during the prior month)
 - 84% Americans 65 or older taking 1 or 2 prescription drugs
- Prescription drug ABUSE:
 - National Institute on Drug Abuse 2009 Survey:
Among 12th-graders, 8 of the 13 most commonly abused drugs (excluding tobacco and alcohol) were prescription or over-the-counter medications.

Public Health/Safety Aspects



- Results from 2008 **National** Survey on Drug Use & Health:
 - **Non-medical users** of prescription-type psychotherapeutic drugs were asked **how they obtained the drugs**:
 - **Over half** of the nonmedical users of prescription-type pain relievers, tranquilizers, stimulants, and sedatives aged 12 or older said they got the drugs they used most recently **"from a friend or relative for free."**
 - **5.4 percent** took them from a friend or relative without asking.

Public Health/Safety Aspects



- The **storage of unused pharmaceuticals** in households and other locations, or the improper disposal of them, **can lead to many issues**:
 - It facilitates the abuse of the pharmaceuticals by those the medicines were not intended for (“**diversion**”)
 - Potential accidental **poisonings** (infants, elderly, pets etc.)
 - **Expired** medications can sometimes be **less effective** and/or their **toxicity can increase**, leading to possible poisonings.
 - Accumulating multiple drugs can lead to increased chances of adverse **drug reactions**.
 - Facilitates using stored meds at a later date for an illness for which they were **not intended** (**delaying appropriate evaluation** and medical treatment).
 - Accumulating drugs can also increase the chance of **burglary**.

Public Health/Safety Aspects



- Therefore a major **public safety goal** related to the use and disposal of unused pharmaceuticals is to “**get them out of the house**”.
- **Remove them** from the household and other places that people or animals may find/look for them, and **dispose of them in safe locations**, or **destroy them so they are not usable**.



Some Data Gaps



- Lack of information about the effect of long-term exposure to low concentrations of pharmaceuticals in water supplies on human health
- Synergistic effects: Questions about the effect of multiple pharmaceuticals on human health (as opposed to studies investigating the impact of single pharmaceuticals)
- Limited analytical methods to understand the proportion of pharmaceuticals in WWTPs as a result of intentional disposal vs excretion.
- Many other questions....

Summary



- Pharmaceuticals can enter the environment in many ways.
 - One significant mechanism is through the wastewater stream (excretion or intentional flushing).
- WWTPs may not remove all pharmaceuticals from the water before being discharged into surface waters. These may then be our future DW sources. DWTP may also not remove all.
- We do not currently regulate pharmaceuticals in WW or DW.

Summary



- Studies suggest no adverse health effect of consuming pharmaceuticals in the concentrations that have been found in surface waters (our potential DW sources).
- However some questions remain about the effect of multiple pharmaceuticals at low concentrations on humans.
- Ecological impacts of the exposure to pharmaceuticals have been observed, especially in aquatic species that are continually exposed to chemicals in the water.
- While an environmental viewpoint may be to consider eliminating flushing of pharmaceuticals as a means of disposal, the public health/safety viewpoint aims to remove them from the household so that they can't be accessed by unintended users.



Stakeholder Introductions



Stakeholders



- **State Government**
 - Department of Aging and Disability Services (DADS)
 - Department of Public Safety of the State of Texas (DPS)
 - Department of State Health Services (DSHS)
 - Texas Facilities Commission
 - Texas Parks and Wildlife Department
 - Texas State Board of Pharmacy
- **Federal Government**
 - U.S. Dept of Justice, Drug Enforcement Administration, Houston Field Division
 - United States Environmental Protection Agency - Region 6
- **Local Government**
 - City of Arlington
 - City of Austin
 - City of Dallas
 - City of Denton
 - City of Houston
 - City of Round Rock
 - Ford Bend County (Household Hazardous Waste Program)
 - Harris County (Public Health and Environmental Services)
 - Texas Municipal League
- **Community Group**
 - Texas Campaign for the Environment



- **Health-Care Providers:**
 - Texas Ambulance Association
 - Texas Assisted Living Association
 - Texas Association for Home Care
 - Texas Association of Community Health Centers
 - Texas Association of Homes and Services for the Aging
 - Texas Dental Association
 - Texas Health Care Association
 - Texas Healthcare Association
 - Texas Hospitals Association
 - Texas Medical Association
 - Texas Organization of Rural & Community Hospitals
 - Texas Panhandle Poison Center
 - Texas Veterinary Medicine Association
 - M. D. Anderson Cancer Center

- **Medical Waste Processing:**
 - Inmar-Reverse Logistics
 - PharmEcology
 - Sharps Compliance Inc.
 - Stericycle, Inc.
 - Texas Association of Healthcare Facilities Management
 - Texas Disposal Systems
 - Texas Solid Waste Association of North America
 - WM Healthcare Solutions
 - WNWN International



- **Pharmacies & Pharmacists:**
 - National Association of Chain Drug Stores
 - Texas Federation of Drug Stores
 - Texas Pharmacy Association
 - Texas Pharmacy Association Academy of Compounding Pharmacists
 - Texas Pharmacy Business Council
 - Texas Society of Health-System Pharmacists
- **Pharmaceutical Manufacturers**
 - Allergan, Inc.
 - Astellas Pharma
 - AstraZeneca
 - Eisai Pharmaceuticals
 - Eli Lilly USA, LLC
 - Genentech
 - Merck & Co., Inc.
 - Merial Ltd.
 - Pharmaceutical Research and Manufacturers of America (PHRMA)
 - sanofi-aventis U.S.
- **Regional Councils:**
 - Alamo Area Council of Governments
 - Brazos Valley Council of Governments
 - Capital Area Council of Governments
 - Houston-Galveston Area Council
 - North Central Texas Council of Governments





- **Water Utility-Related Groups:**
 - Association of Water Board Directors (Texas)
 - AECOM
 - Lower Colorado River Authority
 - San Antonio Water System
 - Texas Assn of Clean Water Agencies
 - Texas Section American Water Works Association
 - Texas Water Conservation Association
 - Water Environment Assn of Texas

- **Ranchers & Farmers:**
 - Independent Cattlemen's Association of Texas
 - Texas and Southwestern Cattle Raisers Association
 - Texas Association of Dairymen
 - Texas Cattle Feeders Association
 - Texas Farm Bureau
 - Texas Poultry Federation
 - Texas Pork Producers

- **Educational Institutions:**
 - Baylor University
 - Texas A&M Health Science Center
 - Texas State University - San Marcos
 - Texas Tech University, Civil and Environmental Engineering
 - Texas Water Resources Institute
 - University of North Texas
 - University of Texas Medical Branch





SB-1757 Project – Scope and Goals

**Texas Commission on Environmental Quality
Pharmaceutical Disposal Advisory Group Meeting
January 26th, 2010**



Overview



- SB-1757 Task
- Stakeholders
- General Intent
- Specific objectives
- Clarifications
 - SB-1757 will/will not...
 - Definitions of Pharmaceutical & Unused

Senate Bill 1757 Project



- Passed in 81st Legislative Session, 2009
- TCEQ shall study and make recommendations regarding the methods to be used by **consumers**, health care **providers**, and **others** for disposing of unused pharmaceuticals so that they do not enter a wastewater system.
- Report due to legislature December 1, 2010

Suggested Stakeholders



- In conducting the study, the TCEQ may solicit input from:
 - (1) the Health and Human Services Commission;
 - (2) the Department of Public Safety of the State of Texas;
 - (3) pharmaceutical manufacturers;
 - (4) pharmacies;
 - (5) health care providers, including home health care providers;
 - (6) hospitals;
 - (7) clinics;
 - (8) long-term care facilities;
 - (9) entities that engage in medical waste processing and handling;
 - (10) solid waste management service providers;
 - (11) local governments;
 - (12) ranchers and farmers;
 - (13) end users of medication;
 - (14) water utilities and other water suppliers;
 - (15) the United States Postal Service;
 - (16) the United States Environmental Protection Agency; and
 - (17) any other entity the commission considers necessary.



Major Sources of Pharmaceuticals in Wastewater

Medicines **consumed** &
not completely
metabolized
(or metabolized into
other forms)



Major: Excretion
Minor: Sweat & vomit

Intentional disposal of
unused drugs
(flushed down toilet
or sink)

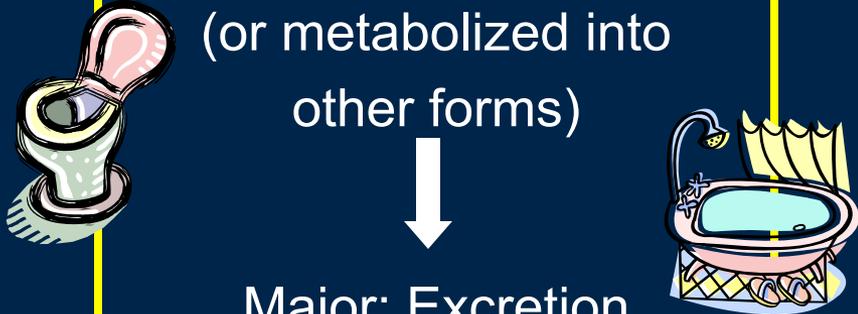


Pharmaceuticals enter wastewater stream
(WWTP or septic systems)

General Intent of SB-1757



Medicines **consumed** & **not completely metabolized** (or metabolized into other forms)



Major: Excretion
Minor: Sweat & vomit

A diagram showing a toilet on the left and a bathtub on the right. A large white arrow points downwards from the text to a final summary box.

~~Intentional disposal of unused drugs (flushed down toilet or sink)~~



~~↓~~

A diagram showing a hand dropping pills into a toilet. The entire diagram is crossed out with a large red 'X'. A red 'X' is also placed over a white arrow pointing downwards from this box.

FEWER pharmaceuticals enter wastewater stream

Pharmaceutical Removal/Reduction from Wastewater



TWO APPROACHES

TREATMENT APPROACH

Remove the pharmaceuticals AFTER they've entered the wastewater system

Requires improved WW treatment tech

PREVENTION APPROACH

Prevent/reduce the amount entering to wastewater system

Consider alternative (non-flush) disposal programs

Objectives



- Specifically, TCEQ shall consider:
 - (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.

Objectives



(1) the methods currently used in Texas
(by consumers, health care
providers, and others);

- TCEQ has formed the Pharmaceutical Disposal Advisory Group to help address this question





WHO

Disposes?

Regulates/controls?

May be impacted
by changes?

WHAT & HOW (Ideally)

What and how much should
be disposed of?

How should they be
Disposed of?

Authorizations/permits required?

WHAT & HOW (Reality)

What, and how much, is
actually disposed of?

How are they actually
disposed of by each group?

WHY

What factors impact
disposal practices/choices?

Benefits/constraints
of ideal/actual methods



Objectives



- (2) alternative methods used, including methods used in other states;



Consumers

Pros and cons of landfill disposal,
mail-back, drop-boxes
& collection events?
What education strategies
have been implemented?

Providers

Have they implemented:
Staff education?
Sorting/rotation/labeling practices?
Reverse distribution?
Guidance documents?

Rule/regs

What rules have been proposed/
passed in other States?
Rules additions/amendments?
Permit requirements
(WW discharge, waste generation)?
Product stewardship
requirements?

Objectives



- (3) the effects on public health and the environment of the various methods used for that purpose.



Impact on
aquatic
ecosystems

Impact on
attitudes &
practices
(consumers &
providers)

Impact on
public health
(safety,
diversion)

IMPACTS

We must consider the impact
of disposal practices on:

Impact on
quantity & type of
pharmaceuticals
entering wastewater

Impact on quantity
& type of
pharmaceuticals
In drinking water

Impact on landfill
deposition practices

Impact on
sludge disposal

Impact on
health care industry
(eg. med. costs)

Objectives



- (4) An analysis of the feasibility of implementing the recommended disposal methods on a statewide basis.



Community desires

What do they want?
What are they willing
to do now & future?

Resources &
Partnerships
Required

(\$ and manpower from
govt., health providers,
municipalities and
other sanitary districts)

Consider how health-care
staff are educated?

Feasibility Considerations

Rural and urban
communities in Texas

What will it take for recommendations
to be successful across Texas?

What role does Texas
govt. need to have
to ensure feasibility?

Fill gaps or add to
Texas Health & Safety Code
to make implementation
feasible?

How will we assess
ongoing feasibility as
current/alternative disposal
methods are employed?



Some Clarifications



- SB-1757 Will/Will Not
- Definition of Pharmaceutical
- Definition of Unused





Scope Clarification: SB-1757...



WILL	WILL NOT
Consider pharmaceuticals.	Consider Personal Care Products (eg. shampoo, DEET).
Intend to address known current and alternative disposal methods, and make recommendations at the end of this project.	Advocate any alternative disposal program at the beginning of this project.
Be making recommendations.	Be promulgating new rules as part of this study.
Consider all of Texas (rural and urban communities).	Only consider disposal methods in large communities or municipalities.
Address consumers and health-care providers and other parties involved in disposal of pharmaceuticals.	Only consider households.
Use data to make decisions where possible.	Use opinions to make decisions.



Definition of Pharmaceutical



- Can include:
 - “**Drug**” as defined in Texas regulations
 - Title 6, Texas Health and Safety Code (Texas Food, Drug and Cosmetic Act) §431.002 (14) and § 481.002 (16)
 - **Prescription** medications
 - Over-the-counter (**OTC**) medications
 - **Veterinary** medications
 - Can also include “**Controlled substances**”
 - Title 6, Texas Health and Safety Code § 481.002 (5)
 - Can also include “**Dangerous drugs**”
 - Title 6, Texas Health and Safety Code § 483.001 (2)
 - Can also include “**Hazardous Wastes**”
 - Title 30, Texas Administrative Code, § 335.1 (69)
 - Solid and liquid pharmaceuticals (liquid eg. IV fluids)
 - Unwanted drugs and/or expired drugs



Definition of Pharmaceutical



- Using the plain and ordinary meaning of the term, we consider a **pharmaceutical as a “drug”** and is defined as:
- A substance, other than a device or a component, part, or accessory of a device, that is:
 - (A) **recognized as a drug in certain lists** (the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or a supplement to either pharmacopoeia or the formulary); OR
 - (B) **intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals**; OR
 - (C) intended to **affect the structure or function** of the body of **man or animals** but is **not food**; OR
 - (D) intended for use as a **component of a substance described by (A), (B), or (C)**.
- Drug definition from Title 6, Texas Health and Safety Code, Chapters 431 and 481.

Definition of Pharmaceuticals



- **Examples:**

- Things that help us live healthier/longer lives!
- Analgesics
- Anti-inflammatory
- Anti-anxiety
- Antihistamines
- Antibiotics
- Anti-depressants
- Anti-convulsives
- Antibacterials
- Anti-coagulants
- Anti-diabetics
- Anti-seizure drugs
- Lipid regulators & beta-blockers (heart-related)
- Hormones (eg. thyroid, birth control)
- Steroids
- Anti-neoplastic agents (used in cancer treatment)
- Stimulants (eg. caffeine if defined as drug, not food)
- Anaesthetics
- Diagnostics (eg. X-ray contrast media)

Definition of Pharmaceuticals



- **Excludes**

- Devices or instruments, or components of these, that administer pharmaceuticals
- Food
- Dietary supplements that are not approved “drugs” (by the US Food and Drug Administration)
- Empty containers

- **Examples:**

- Vitamins, minerals and herbs
- Caffeine when it is considered (consumed as) a food.

Definition of Unused



- Remember: TCEQ shall study and make recommendations regarding the methods to be used for disposing of unused pharmaceuticals so that they do not enter a wastewater system.
- So what does **unused** mean?
- Unused can include:
 - **Unwanted** drugs
 - Symptoms cured (leftover meds unneeded)
 - Discontinued because experienced reaction
 - Changed prescription (former dosage meds leftover)
 - Patient non-adherence
 - Patient died
 - **Expired** drugs

TCEQ Developed a Study Team:



- **Elston Johnson (Public Drinking Water)**
 - E: eljohnso@tceq.state.tx.us P: 512-239-0990
- **Eric Beller (Municipal Solid Waste)**
 - E: ebeller@tceq.state.tx.us P: 512-239-1177
- **Clyde Bohmfalk (Water Quality Planning)**
 - E: cbohmfal@tceq.state.tx.us P: 512-239-1315
- **Angela Curry (Toxicology)**
 - E: acurry@tceq.state.tx.us P: 512-239-1306
- **Thomas Harrigan (Wastewater Permits)**
 - E: tharriga@tceq.state.tx.us P: 512-239-4521
- **Shannon Herriott (Pollution Prevention & Ed.)**
 - E: sherriot@tceq.state.tx.us P: 512-239-6543
- **Jeff Horvath (Strategic Planning)**
 - E: jhorvath@tceq.state.tx.us P: 512-239-1901
- **Jessica Huybregts (Public Drinking Water)**
 - E: jhuybreg@tceq.state.tx.us P: 512-239-4709
- **Daniel Ingersoll (Env. Law)**
 - E: dingerso@tceq.state.tx.us P: 512-239-3668



Intent of Pharmaceutical Disposal Advisory Group

Texas Commission on Environmental Quality
Pharmaceutical Disposal Advisory Group Meeting
January 26th, 2010

Overview



- Re-cap of SB-1757 Objectives
- Intent of Advisory Group
- Clarifications (will/will not...)
- Advisory Group Meetings
 - General info and Record-keeping
 - Decision-making
 - Proposed Topics
 - Attendance
 - Contacts



Objectives



- Specifically, TCEQ shall consider:
 - (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.



Intent of Advisory Group

- To provide a **forum** for **TCEQ** to **gather** appropriate and sufficient **information** to understand the:
 - **methods** currently used in Texas to dispose of unused pharmaceuticals;
 - **amount and type** of unused pharmaceuticals currently disposed of via various disposal methods;
 - **factors driving** disposal practices;
 - **regional differences** in disposal practices;
 - **desires** of consumers, the health-care industry and others for alternative disposal methods; and
 - knowledge gaps.

Intent of Advisory Group



- To provide an **opportunity** for **stakeholders** to **convey** their experiences (good and bad) regarding the current methods of disposing of unused pharmaceuticals.



Intent of Advisory Group



- We want to know and understand from you:
 - **advantages** of the **current** methods;
 - **challenges** of the **current** methods;
 - **perceived gaps** in regulations or guidelines that make compliance or non-flush disposal difficult;
 - what practices stakeholders are **willing** to **change** and **why**, with regards to disposal; and
 - what **alternative** methods have been used in the past and what worked well/poor;
 - the **costs** of various disposal options;
 - the education, manpower, money and other **resources** that would make recommended disposal choices feasible throughout Texas.

Intent of Advisory Group



- TCEQ chose to **target** key stakeholder **associations** that can reach a number of groups/individuals who have some role in disposing of unused pharmaceuticals.
- **Examples:**
 - Texas Hospitals Association
 - Texas Federation of Drug Stores
 - Various Councils of Governments

Intent of Advisory Group



- TCEQ also invited/welcomed those who may not dispose of pharmaceuticals but who:
 - have **interest** in this topic because outcomes **may impact** their operations;
 - or have or may be interested in performing **studies**/research related to this topic;
 - or they may just want to **stay informed** of how Texas is approaching this topic.
- Examples:
 - Wastewater and drinking water utilities

Clarification - Advisory Group will/will not:



WILL	WILL NOT
Spend the first meeting ensuring attendees understand the scope and goals of the project and Advisory Group.	Be a TCEQ vs. stakeholder venue! We will make sure that future meetings involve more discussions and possibly a workshop style format.
Endeavour to capture information from all stakeholder groups.	Only consider certain stakeholder groups.
Provide input so that TCEQ can formulate strategies/recommendations and write the report to the legislature.	Write the report to the legislature.
Request respectful communication and interaction between stakeholders.	Tolerate disrespectful behavior, lobbying or marketing of products at this venue.
Address questions and issues directly related to SB1757 objectives.	Have the time to get off-topic. (Items may need to be flagged as potential issues and we may have time to discuss those later.)
Use data to make decisions where possible – some will be obtained through a questionnaire (more on that later).	Use opinions to make decisions.

Advisory Group Meetings



- **Monthly**, January through June 2010.
- All meetings will be at TCEQ Austin office.
 - **LiveMeeting** services will be provided at each meeting for anyone interested.
- Room for February meeting will probably change (to facilitate better interaction).
- **Webpage** lists upcoming meeting information, including dates, agendas and past meeting minutes.
- http://www.tceq.state.tx.us/permitting/water_supply/pdw/pdagroup

Record Keeping



- Attendees will be asked to **sign in** at all meetings.
- To reduce paper usage, all **correspondence** will be made **via email**, unless requested otherwise.
- Within 1 week following a meeting, the TCEQ Study Team will prepare **draft meeting minutes** and send for **review**.
- Stakeholders will have **1 week** to **comment** on minutes and propose changes.
 - Responses should be provided to Jessica Huybregts via **email**.
- Agreed-upon **changes** will be noted to the group at the **following meeting**.
- Minutes will be considered final after review by TCEQ Study Team, and then **posted on the webpage** in a portable document format (pdf).

Decision-making



- This advisory group will be an **information gathering** and **discussion forum**.
- It's **unlikely** that attendees will be asked to cast votes for decision-making purposes.
- However should voting occur, voting rights will be limited to the named SB1757 stakeholders only.
- Additionally, we will be **seeking advice and input** from stakeholder groups; we **will not seek consensus** on issues on behalf of all stakeholders.

Advisory Group Meeting Topics



- Each meeting will have a specific topic.
- *Potentially:*
 - January: Define objectives and scope.
 - February: Discussion of current disposal practices
 - March: Complete discussion of current disposal options and introduce alternative disposal practices
 - April: Discussion of alternative disposal practices
 - May: Feasibility Considerations
 - June: Summarize findings and final considerations.

Attendance



- TCEQ wants to make sure that we capture all relevant information so that we can provide an accurate, thorough report to the legislature.
- We thank you all for your willingness to be involved in this effort.
- We request you attend all meetings where possible (or via LiveMeeting). If you cannot attend, please provide an appropriate replacement.
- If, after now understanding the scope and goals of this Advisory Group, you decide that you would no longer like to be involved, please just let Jessica know.

Contacts



- Contact Jessica Huybregts for Advisory Group questions/feedback:
 - Email: jhuybreg@tceq.state.tx.us
 - Phone 512-239-4709



Introduction to Questionnaire

Texas Commission on Environmental Quality
Pharmaceutical Disposal Advisory Group Meeting
January 26th, 2010

Overview



- Purpose of Questionnaire
- Groups of Respondents
- Examples of Questions
- Format
- Schedule
- Opportunity to Volunteer

Purpose of Questionnaire



- To collect a **baseline** set of information documenting:
 - **how** health-care facilities/providers, consumers and others are currently disposing of unused pharmaceuticals in Texas;
 - **how much** of **what** is being disposed of via the various disposal practices; and
 - **why** certain disposal practices are chosen.



Purpose of Questionnaire



- Questionnaire chosen so that we have some data to support claims.
- Some national reports and reviews exist but little, if any, detail provided about Texas.



Questionnaire Respondents



- We are developing different questionnaires appropriate to each stakeholder type.
 - (1) Public Health-Care Providers
 - (2) Veterinary Care Providers
 - (3) Pharmacies/Pharmacists
 - (4) Waste Disposal Operations, Reverse Distributors
 - (5) Pharmaceutical Manufacturers
 - (6) Ranchers and Farmers
 - (7) End user/consumers
 - (8) Water Utilities
 - (9) Local Governments
 - (10) In-home care providers

Examples of Questions



- Health Care Providers: (similar for vet care questionnaire)
 - Do you **separate** various waste types at your facility into different containers? Which categories?
 - What **proportion** of pharmaceuticals entering your facility are **unused and disposed** of?
 - How **often** do you dispose of unused pharmaceuticals?
 - **Why** were the pharmaceuticals **not used**?
 - How does your facility **determine how** to dispose of each type of pharmaceutical waste?
 - **How does** your facility **dispose** of **each type** of pharmaceutical?
 - Are there any disposal practices that your facility does not use because they are **unavailable** or subject to restrictions?
 - What **factors** impact your **decision** to dispose of unused pharmaceuticals in a certain way?

Examples of Questions



- Health Care Providers (cont.):
 - Are there any **alternatives** for disposing of unused pharmaceuticals that you **have tried in the past** but that were discontinued? Why were they discontinued?
 - Are there any unused pharmaceuticals disposal methods your facility **would like to be involved** in (but are not currently)?
 - **Why** would you like to use those alternative disposal methods?
 - What **factors are inhibiting** you from adopting those alternative disposal methods?
 - Does your facility **communicate** disposal practices for unused pharmaceuticals to **staff**? If so, **how**?
 - **LTCFs**: Are you a **DEA/DPS registrant**? (Controlled Substances)
 - What **county** is your facility located in?

Examples of Questions



- Pharmacists/Pharmacies:
 - Some similar questions, some different
 - Do you **have** unused pharmaceuticals in your operation?
 - What are the **reasons** for having unused pharmaceuticals at your operation?
 - **How** do you **dispose** of **each type** of unused pharmaceutical?
 - **How often** do you dispose of unused pharmaceuticals?
 - What are the main **reasons** for **choosing** those disposal methods?
 - Have your disposal **practices changed**? **Why**?
 - **Would you like to change** your methods of disposing of any type of unused pharmaceutical? Which ones? **Why**?
 - What **factors inhibit** you disposing of unused pharmaceuticals in that way?
 - What do you perceive as the **main advantages** for how you **currently** dispose of unused pharmaceuticals?
 - Other **education/training/resource** questions.....

Examples of Questions



- **Solid Waste Management Groups & Reverse Distributors:**
 - Some similar questions, some different
 - **How** do you **dispose** of various types of pharmaceutical wastes you collect?
 - **How often**.....
 - What are the **reasons** for choosing the disposal method?
 - For local govt/county: have you collected unused pharmaceuticals at an **organized event**? **How** did you **dispose** of them?
 - Others.....
- **Pharmaceutical Manufacturers**
 - Some similar questions, some different
 - Do you **accept** unused pharmaceuticals from various entities?
 - What **quantity** of unused pharmaceuticals do you **accept** from those entities? (ranges offered)
 - What **quantity** of unused pharmaceuticals do you **generate** as a **result** of **manufacturing**? (ranges offered)
 - **Why** are the pharmaceuticals **unused**?
 - **How** do you **dispose** of various types of pharmaceutical wastes?
 - What are the **reasons** for **choosing** the disposal method?
 - Others.....

Examples of Questions



- **Ranchers and Farmers:**
 - What **proportion** of your pharmaceuticals are **unused**?
 - **Why** are they left unused?
 - **Are** the unused pharmaceuticals **disposed** of? **How**...?
 - What are the **reasons** for **choosing** the disposal method?
 - Others.....
- **End Users/Consumers**
 - **Do you have** unused pharmaceuticals in your **household**?
 - **Why** are the pharmaceuticals **unused**?
 - **Where** did you **obtain** your pharmaceuticals from?
 - **Do you usually dispose** of unused pharmaceuticals?
 - **How** do you **dispose** of your unused pharmaceuticals?
 - What are the **reasons** for **choosing** the disposal method?
 - Have you **changed** your disposal methods? If so, for **what reasons**?
 - What would be the **most convenient way of disposing** of unused pharmaceuticals?
 - Others.....

Questionnaire Format



- Check-boxes with multiple options provided
- Space to expand on ‘other’.
- Very limited number of open-ended questions.
- Designed to take < 1 hour to complete.
- Base responses on practices conducted in 2009, unless otherwise noted.
- Format will either be internet-based, or as another digital format (excel, word etc.) or on paper – **please provide your input on this during discussion session**

Schedule



- TCEQ will aim to provide questionnaires to volunteers by late-February.
- We will ask for them to be completed within 3 weeks.

Volunteers



- We would like volunteers from both **urban** and **rural** areas, and in **small** and **large** operations.
- Volunteers filling out forms should be the relevant **onsite** director of **operations** (related to disposal of pharmaceuticals).
- We are asking **associations** represented in Advisory Group to **approach their members** about completing the questionnaires.

Volunteers



- We would like **at least 10** questionnaires completed for **each** of the following **groups**:
 - Veterinary Care Providers
 - Pharmacies/Pharmacists
 - Pharmaceutical Manufacturers
 - Waste Disposal Operations and Reverse Distributors
 - Ranchers and Farmers
- We would like **at least 10** questionnaires completed for **each** of the **sub-groups** of Public Health Care Providers:
 - Hospitals
 - Clinics
 - Long Term Care Facilities
 - Hospice and Home-care
- Once we decide how to reach end-users/consumers, we would like many volunteers.

Volunteers



- Please contact TCEQ ASAP to confirm your involvement, either by:
 - committing to complete the questionnaire yourself; or
 - committing to forward questionnaire to your members to complete.
- Please confirm your involvement today or provide specific names of volunteers by February 5th latest.
- Contact: Jessica Huybregts
 - Email (preferred): jhuybreg@tceq.state.tx.us
 - Phone: 512-239-4709



Questions for your Consideration



- Any **other groups** of volunteers we should target?
- Any **ideas** on how to reach “**end-users/ consumers**”?
- Any **other questions** you think should be addressed to help us fulfill our objectives?
- Preferred **format**?

Closing



- Thank you for your attendance/interest
- Next meeting: **February 26th, 2010 @TCEQ**
- Topic: Discussion of **current** disposal practices
- Agenda for Feb meeting & minutes for this meeting on website by **Feb 12th**.
- Please **RSVP** (attend in person or LiveMeeting) by **Feb 5th** to: Jessica Huybregts <jhuybreg@tceq.state.tx.us>