

# Consumer Rx Take-Back Programs: Challenges & Solutions



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# Issues

The public's desire to provide safe disposal options for unwanted medications is increasing

Regulatory barriers

Environmental

Controlled substances

Question of sustainable funding



# Drugs in Drinking Water & Healthcare Pharmaceutical Waste

## March 9, 2008

5-month inquiry discovered that drugs were detected in the drinking water supplies of 24 major metropolitan areas

## September 14, 2008

Majority of 5,700 hospitals and 45,000 long-term care facilities flush unwanted drugs down the drain and do not document amounts according to EPA survey

Extrapolation of data from 14 representative facilities in Minnesota yielded an estimated total volume of 250 million pounds of drug waste annually, including packaging

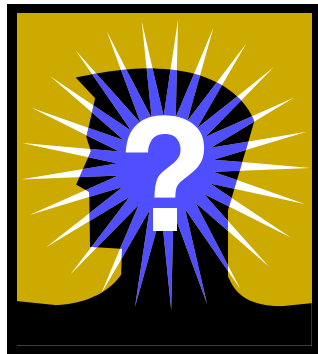
## April 19, 2009

U.S. manufacturers, including major drugmakers, have legally released at least 271 million pounds of pharmaceuticals into waterways that often provide drinking water





# Species at Risk



# Effects of Chronic Exposure to Prozac

- Developmental delays, forelimb formation, tail resorption
- Increased time to metamorphosis
- Increased mortality

Black, MC; Rogers, ED;  
Henry, RB. Endocrine Effects  
Of Selective Serotonin Reuptake  
Inhibitors (SSRIs) on Aquatic  
Organisms



Control



38 ppb Prozac



# Pending Legislation

## Safe Drug Disposal Act of 2009

Introduced into the House on February 25, 2009: HR 1191

Introduced into the Senate on June 24, 2009: S 1336

To amend the Controlled Substances Act to provide for the disposal of controlled substances by ultimate users and care takers through State take-back disposal programs

To amend the Federal Food, Drug and Cosmetic Act to prohibit recommendations on drug labels for the disposal by flushing

## Secure & Responsible Drug Disposal Act of 2009

Introduced into the House on March 5, 2009: HR 1359

Introduced into the Senate on June 18, 2009: S. 1292

To amend the Controlled Substances Act to enable consumer take-back programs



# Defining Success

**What makes medication collection and treatment programs successful?**

- 1) Accessible**
- 2) Easy**
- 3) Cost Effective**
- 4) Sustainable**





# Accessible

Programs must be accessible to a variety of ultimate users.

## 3 models

- Community Take-Back

Typically one-day events

- Mail back

For non-mobile populations

- Pharmacy Kiosk

Permanent



# Easy

Programs and operating procedures must be easy for ultimate users and collection staff.

- **Law enforcement involvement**
  - Currently required by Controlled Substances Act (CSA)
- **Simple sorting process**
  - Controlled vs. Non-controlled

## Federal CSA rule change

- Could allow for additional forms of pharmacy take-back



# Cost Effective

Collection and treatment programs must show value for dollars spent.

- Non-hazardous waste disposal
- Waste-to-Energy
- Medical Waste Incineration



Federal exclusion for household-generated hazardous wastes. Each state decides position on consumer-generated drug waste that would otherwise meet the definition of a hazardous waste.



# Sustainable

## *Product Stewardship*



# What is Product Stewardship?

Shared responsibility for the end-of-life management for products which are deemed hazardous to human health or the environment

Includes changes in product design and production, changes in consumer behavior, and decisions regarding cost of proper disposal

Often involves competing agendas and differences of opinion as to what entity bears which costs and responsibilities

Primary historical reference: Scott Cassel, Ex Dir, Product Stewardship Institute,  
<http://www.productstewardship.us/>



# What Has Worked(Relatively) Well: Battery Recycling

Portable Rechargeable Battery Association

Established Rechargeable Battery Recycling  
Corporation (RBRC) in 1995

Management of recovery and recycling of nickel-  
cadmium (NiCd) batteries

First national, industry-wide producer  
responsibility program in US

Ni-Cd batteries comprised less than 0.1% of MSW  
but accounted for 75% of cadmium content



# What Could Be Done Better?

In spite of public education, many consumers unaware of program

Inherent in voluntary program are “free riders,” companies that do not support the program but benefit from the take-back efforts

Consider mandatory federal program with increasing performance goals to enable manufacturers to factor in costs as data is generated



# What Makes Drug Collection So Problematic?

Hundreds of manufacturers/repackagers

Consumer does not often have choice of products/brands

Difficult to separate by origin

“Bring only those drugs manufactured by ABC drug manufacturer”

Controlled substance and other regulatory issues

Concerns regarding diversion/safety

Multiple distribution systems: retail pharmacy, mail-order, internet pharmacy, multi-national sources





# Impact on Manufacturers

Have a stake in reducing drug waste if costs of disposal must be built in to cost structure

Potential reduction in sampling/move to vouchers

Encouragement of lower introductory prescription limits/options

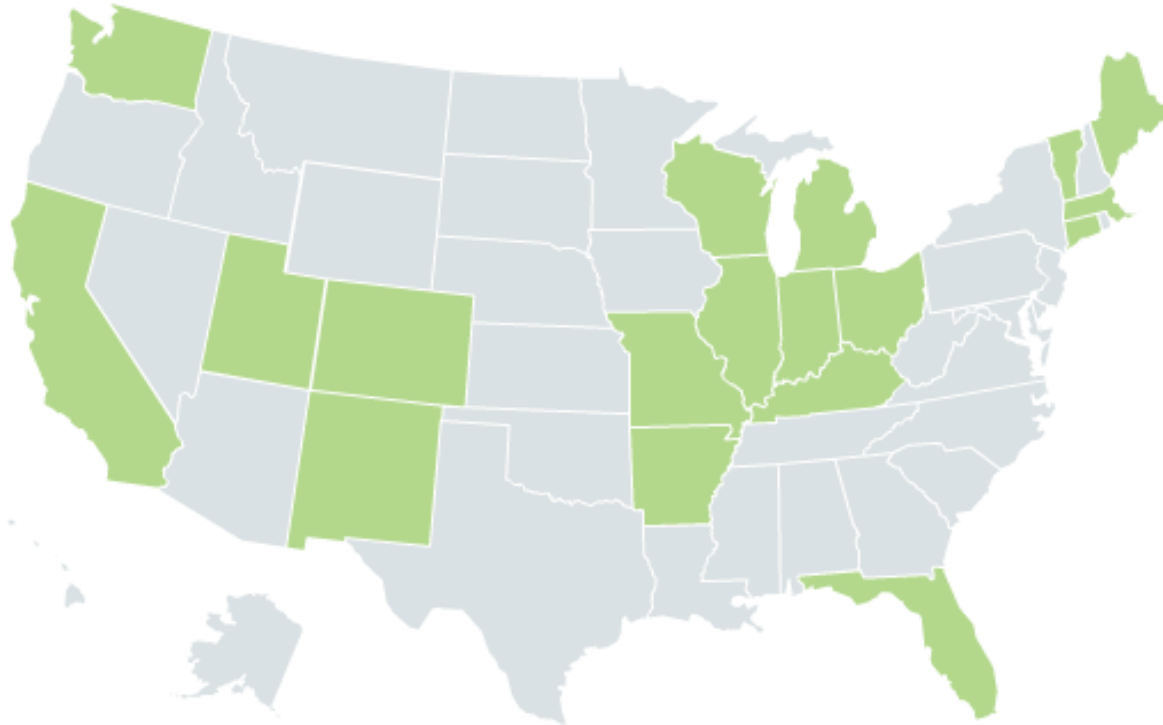
Application of business process to increase efficiencies in take-back efforts

Economies of scale emerge



# Current State Take-back Efforts

Communities across the country are exploring options for collecting and disposing unused medications from consumers.



[www.takebacknetwork.com](http://www.takebacknetwork.com)

presented by

The Product Stewardship Institute



# Common Elements: General Consensus

Must accept all OTC, RX drugs; some include veterinary

Manufacturer or Importer; retailer not included

Target audience: consumers, including long term care facilities, other residential treatment centers, hospice

Plan Required of Manufacturer(s): Renewal times differ

Flexibility: Urban and rural/mail-back required in some; collection in cities of 10,000+ in others



# Finding a Way Forward

Determine cost efficiency for 3 scenarios:

Community take-back

Pharmacy kiosk

Individual mailback

Define cost efficiency

By individual? by family unit?

By prescription? By pound?

Seek federal legislation which allocates funding based on agreed upon parameter

Sales into the market?

Volume into the market?



# Questions?

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