

# State Product Stewardship Initiatives: Industry Implications



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# Pharmaceutical Life Cycle Management: The Perfect Storm



Growing environmental awareness

Increasing focus on environmental regulations

Efforts to “green” the manufacturing and supply processes

Calls for “Green Chemistry”

Public health issues: ODs and poisonings

Cost containment through waste reduction

# 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Primary historical reference: Scott Cassel, Ex Dir,  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



# Historical Process

Government agencies/non-profits engage in discussions with manufacturers/retailers

Initial resistance of manufacturers to internalizing end-of-life costs into product price

Promotion of end-of-life fees

Slow movement towards the middle by both sides, resulting in greater responsibility taken by manufacturers and more flexibility by government



# Learning from the Past

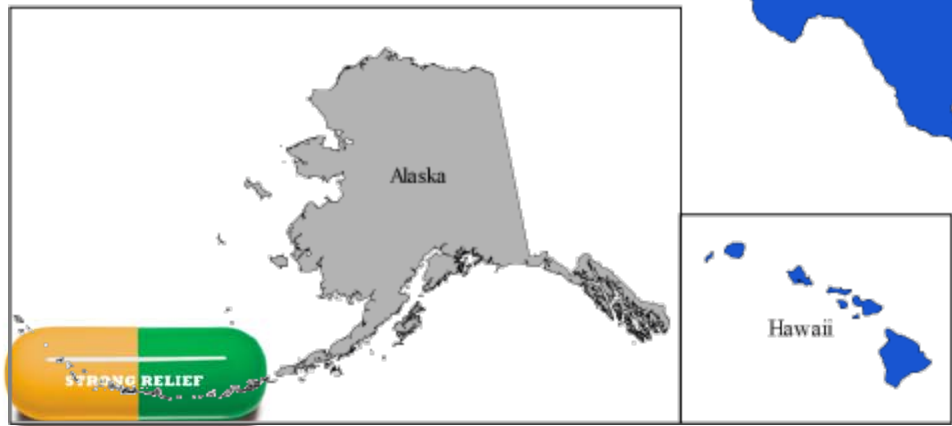
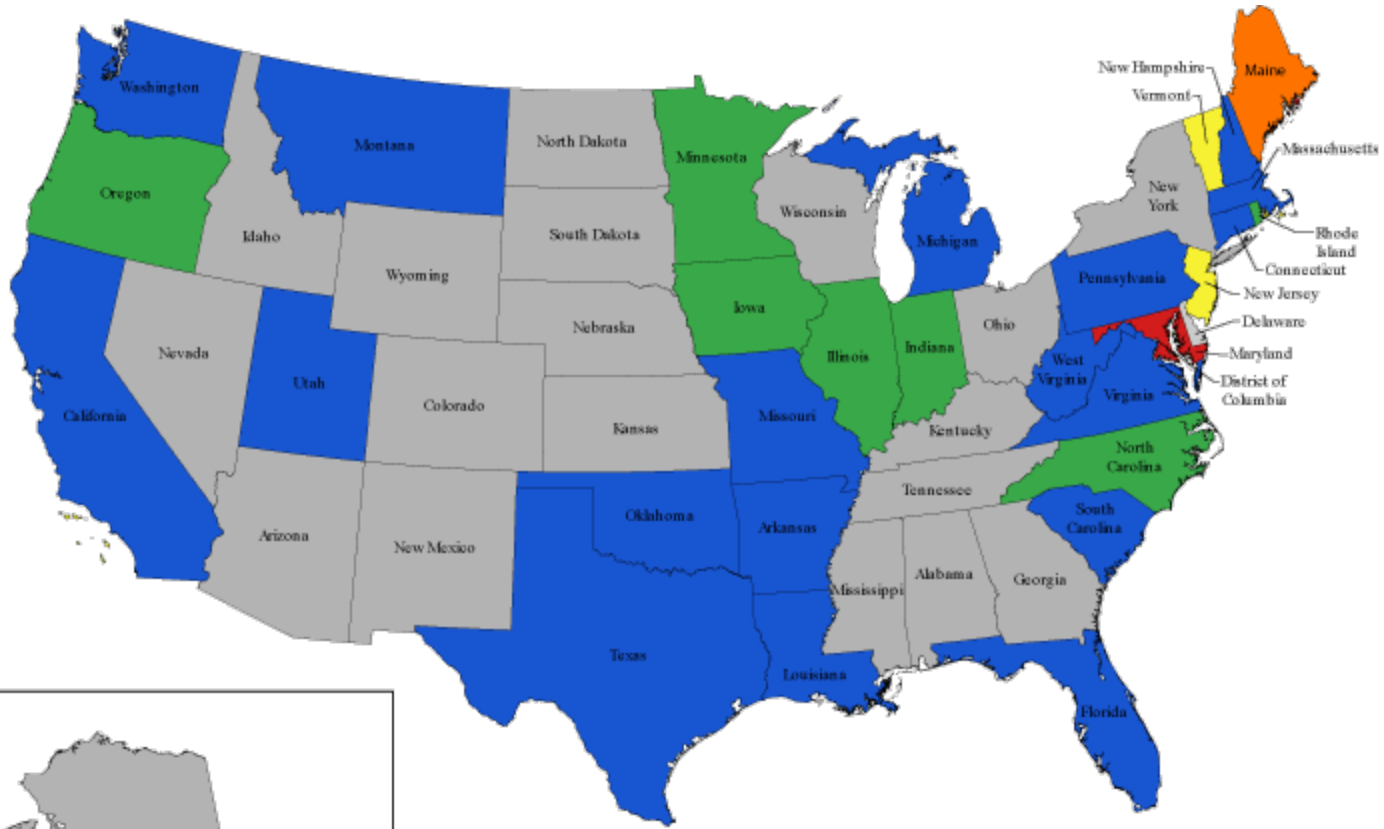
State legislative efforts are an important mechanism for moving issues forward nationally

Gaining the acceptance and participation of the industry involved is a win-win for industry and the public

Corporate leadership is vital for a successful program



# Extended Producer Responsibility Laws



- Zero Laws
- One Law
- Two Laws
- Three Laws
- Four Laws
- Five Laws



Courtesy Product Stewardship Institute October 2009



# What Has Worked(Relatively) Well: Battery Recycling

Portable Rechargeable Battery Association

Established Rechargeable Battery Recyclign  
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



# Why Batteries?

RBRC prompted by 8 state laws with take-back requirements for rechargeable batteries

Growing interest in Europe to ban Cd

Passage of comprehensive legislation in MN and NJ

Battery industry sought federal legislation to facilitate

Mercury-Containing and Rechargeable Battery Management Act (“The Battery Act”)

Made the Universal Waste Rule immediately effective in all states





# 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



# Drug Take-back Pioneers: Charting Unknown Territory

How much consumer-generated drug waste occurs annually?

What percentage of drugs dispensed is wasted?

How much residual, historical waste is in the system that needs to be “flushed” out

What is the most efficient method for collecting/processing drug waste

How does efficiency correlate with convenience?

What will the costs of each system be?

Who should incur the costs?



# 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



# Reasons for Retailers & Manufacturers to Participate

Competitive Advantage: perceived as being “green” and leaders in sustainability efforts

Reduction of Business Risk: getting out in front of multiple state legislative efforts to support a mutually agreed upon federal effort

Company Leadership: Bold decision to lead  
Wal-Mart’s packaging scorecard initiative  
Home Depot’s Eco Options label program  
Whole Foods’ Whole Trade Guarantee



# Reverse Distribution: Wholesale/Retail Success Story

Drug manufacturers have been “buying back” expired drugs for many years

Development of reverse distribution industry in late 1980's, early 1990's accelerated and streamlined the process

Reverse distributors initially reviled and mistrusted by some manufacturers

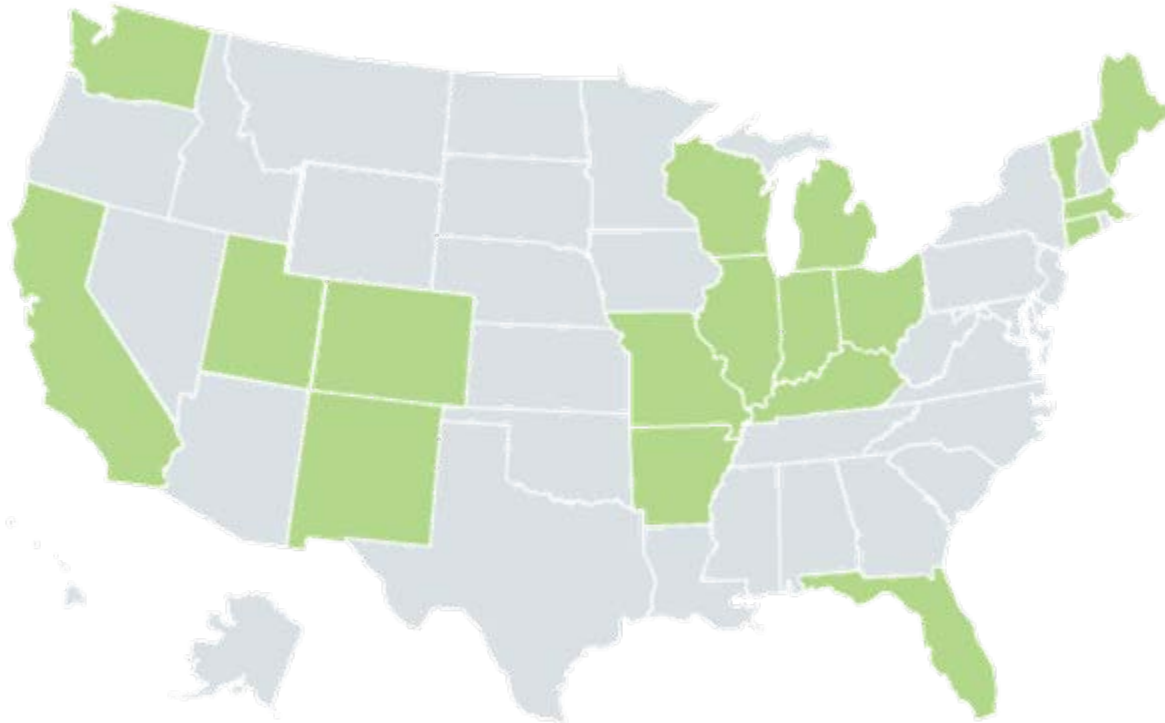
Many manufacturers now embrace and out-source, resulting in cost reductions and economies of scale

Greater visibility and ability to reduce outdate generation by pharmacies/wholesalers



# 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



# Proposed Product Stewardship Bills

Florida: HR 1357, SB 2650

Maine: HP0557, LD 821

Minnesota: HR 1217

Oregon: SB 598

Washington State: HR 1165, SB 5279 (duplicate)

None have passed to date – only a matter of time





# 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



# Common Elements: General Consensus

- Manufacturer(s) must cover all costs;  
administrative fee may also be levied by state;  
No fee allowed at time of collection
- Must include either recovery goals first 3 years  
(lbs/capita) or other evaluation program
- Must accept all unwanted covered products  
regardless of who produced them
- Annual report (3 of 5 require)
- Educational outreach required; toll-free number &  
website (3 of 5)



# Common Elements: General Consensus

State Oversight: Varying degrees, with WA State the most highly defined

Pharmacy Responsibilities: Must publicize (3 of 5)

Performance Standards: Required (4 of 5)

Policies & Procedures/Track/Trace/Security:  
(3 of 5)

Stewardship Organization: To administer and track participation (2 of 5)



# Common Elements: Lack of Consensus

Required Destruction Technologies:

Maine, Minnesota, Washington: Require  
Hazardous waste or superior technology

Florida, Oregon: Hazardous waste or other  
incineration



# 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?



# What's Needed: Product Stewardship Model Language

States are clearly adopting language from each other  
Washington State, Maine, Minnesota very influential

Suggested Action Item:

- Draft model language that retains much of the acceptable common elements

- Involve industry in dialog

- Move the discussion to federal legislation with some state flexibility

Use federal act to move hazardous pharmaceuticals into  
Universal Waste Rule (UWR) in tandem with EPA



# The Maine Declaration?

First mandatory 15-day introductory prescription for selected drugs as compared to 90 day automatic fill by mail-order pharmacies

“The Maine Declaration”

Support for limited first-time prescriptions on selected drugs based on returns data

No co-pay so consumer is not penalized

Track data – system may pay for itself



# Discussion





# References

Handbook on Household Hazardous Waste, edited by Amy D. Cabaniss; Chapter 7, Product Stewardship by Scott Cassel, PSI. Government Institutes, 2008

Product Stewardship Institute

<http://www.productstewardship.us/>

