

# The Dilemma of Waste Pharmaceuticals

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# Let's set the stage

- In US # prescriptions increased 71% (from 2 billion to 3.42 billion) from 1993 to 2006 while population only increased about 14%.
- Sales of OTCs increased >60% in 1990s.
- Age 65+ =13% population but 34% scrips.  
(average 40 scripts/yr., others 11.8/yr.)
- Approximately 50% of all manufactured medications are sold in the US.
- WHO studies find only 50% adherence.
- Nobody knows amounts excreted vs. amounts dumped.

# And it will continue to grow..

- Expanding population;
- Aging population;
- More prescriptions being written;
- Shift to generics;
- New drug choices;
- New uses for existing drugs;
- Increased public advertising (growing 50% annually since 1997);
- New target age groups (e.g. antidepressants for children).

# Interested Parties

- Environmental professionals: concerned about fate and effects on environment and resident organisms.
- Health professionals: accidental poisonings and attempted suicides; inappropriate dosing; potential impacts on human health from envir. contamination. Poor adherence may cost US \$177 billion/year and is associated with 40% of nursing home admissions.
- Law enforcement: diversion and associated crimes.
- Government: waste management costs; wasted health care dollars; increased health care costs; costs associated with environmental degradation; increased law enforcement costs.

# Interested Parties

Pharmaceutical companies and health insurance companies.

# Product Stewardship

- Definition: "Product stewardship" is a principle that directs all participants involved in the life cycle of a product to take shared responsibility for the impacts to human health and the natural environment that result from the production, use, and end-of-life management of the product.
- The greater the ability of a party to influence the life cycle impacts of a product, the greater the degree of that party's responsibility.
- Stakeholders typically include manufacturers, retailers, consumers, and government officials.

# Maine Examples of Product Stewardship

- Returnable bottle law
- Mercury Auto Switch law
- Manufacturer responsibility for E-waste
- Mercury Thermostat Incentive law

Will pharmaceuticals be next?

# Product Stewardship Programs

## British Columbia:

- Voluntarily started by the pharmaceutical industry in 1996. 44,092 lbs/'06. 4 m pop.
- Consumer takes unwanted meds to any of 800+ participating pharmacies.
- Paid for by industry.

Alberta: Similar program to BC.

Ottawa: Retail take-back and financing.

# Product Stewardship Programs

## European Union:

- 11 EU countries have stewardship programs.
- Serve 90% of European citizens.
- Returns are to local pharmacies.
- More than half funded by pharmaceutical industry or retail pharmacies. Rest funded by government at some level.

# Product Stewardship Programs

## Australia

- Ongoing, permanent program since 1998.
- Collection at pharmacies.
- Collected 696,241 lbs. in 2005.
- US \$ 737,000 costs in 2005.
- Serves 21 million people.
- Funded by Australian government which is discussing product stewardship w/ manufacturers.

# In the United States

- Collection pilots and events happening in limited locations without involvement of manufacturers but some with pharmacy chains.
- Washington's PH:ARM - pharmacy collection in secure 'mailboxes'. Modeled after B.C. program. '06-08. Data gathering to put forth a stewardship model.
- Clark Co., Wa – drop off controlled substances at 4 police stations, non-controlled at pharmacies.
- San Fran East Bay – 2006 week long collection at 38 sites. 1500 participants disposed of almost 3700 lbs. or 2.45 lbs/person.

# Maine's Pilots

- Maine first in US to pass legislation authorizing a mail-in program. Pilot planning has started with funding from EPA and legislature.
- Pre-paid mailers at pharmacies by 12/07.
- Meds sent to ME DEA for consolidation and disposal.
- ME DEP working with ME DEA on disposal through haz. waste incineration.
- Pilot through 2009.

# Maine Collections

- Largest one –day event is in mid-coast area, started by a local hospital.
- 4 collection events in mid-coast since 11/’05.
- Collections at 4 locations, over a 4 hour period, collecting over 420 lbs. + 10 gallons controlled.
- Average about 2-3 lbs/participant or household.  
Cost \$4.50/lb. for haz. waste disposal.
- Last time collected over 5500 c.s pills

# Maine Collections

- Successful legal single event collections require a team that includes law enforcement, medical professionals including a pharmacist, waste specialists.
- Controlled must be segregated from non-controlled unless law enforcement is willing to dispose of all materials collected.

# ??Questions??

- How do pharmaceuticals rank on the list of significant environmental contaminants?
- What potential volume could be recovered through collection?
- Who pays? Sustainable financing.
- How to solve the regulatory barriers to collection (DEA rules on controlled substances).
- Do we need to change the FDA threshold for triggering an envir. assessments? (1ppb Expected Environmental Concentration – 1ppt EU proposed)

# What does the future hold?

- Expand the dialogue to all parties.
- Continue and expand research in potential environmental impacts.
- Improve drug design and delivery systems.
- Improve dispensing practices and patient compliance.

# What does the future hold?

- Fully develop collection models: mail-in; one day; at pharmacy.
- Develop model product stewardship legislation.
- Solve the regulatory barriers presented by the Controlled Substances Act.