Unwanted Pharmaceuticals: Overview & Legislative Update

Presentation to the 2016 New York State Association of Reduction, Reuse and Recycling (NYSAR3) Conference

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1. Why Pharmaceuticals Matter
2. Reuse
3. The DEA Rule
4. Extended Producer Responsibility (EPR) Laws
5. What You Can Do
80 % of U.S. streams and waterways tested by USGS have traces of pharmaceuticals.

Source: US Geological Survey, 2002

Traces of pharmaceuticals found in drinking water of at least 46 million Americans

Source: Associated Press, 2008

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Emerging Contaminants
Dangerous and unregulated

Growing Body of Evidence of Harm to Organisms

Tadpoles on Prozac (right) develop more slowly into frogs than tadpoles in control groups (left).

Developmental delays could threaten tadpoles who live in seasonal pools and puddles.

http://researchmagazine.uga.edu/summer2005/prozac02.htm

Photos: Emily Rogers & Marsha Black. Used w Permission.
The pharmaceutical drug diclofenac has caused a catastrophic crash of vulture populations.

Gyps vulture, Pakistan.

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Extreme Human Hazard!

27 chemotherapy drugs are extremely hazardous. Cytotoxic, genotoxic, carcinogenic, mutagenic &/or teratogenic.

“There is no safe level of exposure.” OSHA

For at least 48 hours after receiving chemotherapy, a person’s excretions (urine, feces, vomit, saliva and sweat) contain dangerous levels of the drug!

Rhode Island came close to passing a law to regulate them.

More info: http://www.cytotoxicsafety.org/
Pathways to the Environment:

1. Excretion

Humans, pets, and livestock excrete drugs, both unchanged and as active metabolites.

Photo © Mishka Henner, used w/permission
2. Wastewater discharge

Consumers:
Toilet & Trash (via leachate)

Manufacturers
Public Awareness is Growing

Rx Directions:
FILL THIS CONTAINER WITH TAP WATER;
DRINK TWICE DAILY
Pharmaceuticals: Not Just An Emerging Environmental Contaminant

Unwanted pharmaceuticals in homes leads to other problems:
Opioid Addiction Crisis

Illegal Diversion

Prescription medications are abused more than cocaine, heroin, & methamphetamines combined!
In 2011, accidental overdoses surpassed car accidents as the leading cause of accidental death in U.S.

Majority from Rx.

1797 deaths in NYS (2009)!

Still Climbing!

2009 NYS: 9.2 per 100K pop.
< national: 12.8 per 100K

1 death every 14 minutes

Source: National Vital Statistics System
Cost of Unwanted Pharmaceuticals

Illegal Diversion:
Fuels the Opioid Epidemic
Cost to society: $55.7 Billion in 2007 [CDC]

Accidental Overdose:
Leading Cause of Accidental Death
Cost to treat poisonings in 2000 estimated at $26 billion. Loss of life: much↑

Environmental Contamination:
Long Term Consequences
Costs: unknown

Total Cost to Society: Huge!
New York may soon become the 39 state to allow medications to be donated for “reuse.”

S5903A, introduced by Hannon, passed the Senate & Assembly. Cuomo needs to sign.
600 tons of expired, damaged, or inappropriate medicines were donated for one post-tsunami event, 2004

Contrary to WHO guidelines and standards, 70% of donated medicines were labeled in languages other than English or Indonesian

“Donated medicines have created more problems than benefits.”
DEA’s Take Back Initiative

Interim Solution

12 Events

Popularity Growing

[Total Pounds Per Collection Up 3X]

Total Collected: 3,209 tons

Collected in Tompkins Co.
(one day events + 9 kiosks) from 2010-2016:
7 tons!
Take Back Made Easier

DEA prohibits viewing contents (except law enforcement) +
Contents may contain hazardous materials +
DOT requires special labeling/handling of hazardous materials

= Road Block to Participation!

Now, DOT has an exemption for material from collection events.
NYS DEC is also removing regulatory hurdles:
Part 360 permits and HazWaste disposal requirements.

Destination: Incineration
Convenience Crucial; DEA Rule (2014) Opens Door

Pharmacy Kiosks

Mailers

Law Enforcement Kiosks

Drive-thru & walk in events

A few communities send officers, by request, to do home collections!

Pharmacy Collection = low per pound cost

Mailers = convenient for homebound and rural, moderate per pound cost

Home disposal pouches = high per pound cost

Note: CT, HI, MN, MO and MS still have rules that prohibit take back.
Sustainable Funding
Product Stewardship vs. EPR

- Product stewardship
- Manufacturer ("producer") responsibility
- Other government regulatory programs
- Voluntary programs
- Mandatory programs (e.g., EPR)

Graphic courtesy of the Product Stewardship Institute
EPR state laws in the U.S.

2000

2016

Product Categories
- Primary Batteries
- Rechargeable Batteries

Approximate Cost for Pharmacy Collection:
- $400/year/pharmacy;
- 1 cent/prescription;
- $2-5/pound

Pharmaceuticals Need EPR

Only a small percent of pharmacies take back controlled substances.
Cost is a major barrier to participation.

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In the
Supreme Court of the United States

Pharmaceutical Research and Manufacturers
of America; Generic Pharmaceutical
Association; Biotechnology Industry
Organization,

Petitioners,

v.

County of Alameda, California; Alameda County
Department of Environmental Health

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Ninth Circuit

Petition for Writ of Certiorari

DENIED
Pharmaceutical EPR Programs

in Canada: 4
in Europe: 15
in Mexico: 22 (of 31) States

France established in 1993
British Columbia established in 1996
Manitoba established in 2011
Hungary established in 2005
Portugal established in 2001
Spain established in 2003

in U.S.: MA & VT, 10 Counties, 2 Cities
(Cook Co., Illinois (pop.>5 million) passed on 10/28/16)
NY Assemblyman Engelbright has proposed bills.
PhARMA  Pharmaceutical industry’s largest trade group

MyOldMeds “educational” program in lieu of EPR laws:

• Advocates in-home trash disposal
• Claims existing take-back sufficient, only need public awareness
• Preempts/Opposes EPR legislation with direct lobbying and grassroots canvassing:
  • Falsely claiming EPR will cost consumers more
  • Falsely claiming EPR less environmental
• Disrupt implementation of EPR programs by delaying process:
  • After causing delays & missed deadlines, label programs “failures”

Example in L.A. County (CA):
  Chair of Board of Supervisors said,
  “We’ve wasted a lot of time … people are dying.
  It’s time that we really start to hold some people responsible.”

“People Start Pollution. People can stop it.” 1971
Reduce: Prescribing Guidelines; Samples; Oversight helps prevent abuse (doctor shopping, pill mills)

Reuse: Ask Governor Cuomo to sign S5903A into law.

Safe Disposal:
1. Support One Day Events
2. Encourage Pharmacies to become take back locations.
3. Lobby for Regulation of Chemotherapy Drugs
4. Fight for local, state, and federal EPR legislation

Everyone wants safe, convenient disposal options. Your efforts will be appreciated!
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http://www.healthyouth.org/medication-disposal.php