Northwest Product Stewardship Council

2008 Pharmaceuticals Subcommittee Issue Paper
April 2008

Subcommittee Members: David Stitzhal (NWPSC), Alice Chapman and Cheri Grasso (Local HW Mgmt Program in King Co.), Will Perry (Public Health Seattle & King Co.), Eva Dale and Suellen Mele (WCRC), Stan Jeppesen (WA Board of Pharmacy), Cathy Buller (PPRC), Emma Johnson (Dept. of Ecology), Todd Henry (DSHS), Shirley Reitz (Group Health Cooperative), Dan Connelly (Bartells), Sego Jackson (Snohomish County Solid Waste Management Division)

The Issue

Pharmaceuticals are a ubiquitous environmental pollutant found at very low levels (parts per trillion, or ng/L) in surface waters, streams, septic tanks, tap water and waste water effluent. While levels found are far below the recommended prescription dose, it is unknown if continual exposure to such pollution could induce long-term effects in humans. Some drugs, their metabolites, or the synergistic effects of drug mixtures in water have been found to affect aquatic organisms both in the environment and in laboratory studies.

Pharmaceuticals end up in these water bodies because of human excreta, animal excreta, and disposal of unwanted or expired medications. Conventional wastewater treatment is not able to eliminate the majority of pharmaceutical compounds.

Pharmaceuticals in the environment are now frequently detectable. A 2002 U.S. Geological Survey (USGS) study found Organic Wastewater Contaminants (OWCs), including many pharmaceutical and personal care product contaminants, in 80 percent of 139 streams sampled in 30 states (Koplin, 2002). In Washington State, a screening analysis conducted in a tertiary wastewater treatment plant effluents and nearby wells and creeks in the Sequim-Dungeness area detected 16 organic wastewater contaminants (OWCs) in the effluent samples. 9 of 11 samples (82%) contained pharmaceutical drugs. Significantly, only 24 chemicals were analyzed for, while 95 chemicals were analyzed for in the USGS study (WSDOE Environmental Assessment Program, 2004).

While pollution from excreta and disposal of drugs has occurred as long as humans have used them, we are now facing accelerating drug sales, use, and waste.

- The average prescription rate in Washington State was 8.5 prescriptions per capita in 2005, totaling 53.6 million retail prescriptions (Henry J. Kaiser Foundation, 2007).
- The number of prescriptions in the US purchased increased 71% (from 2.1 billion to 3.6 billion) from 1994 to 2005, compared to a US population growth of 9%. The average number of retail prescriptions per capita increased from 7.9 in 1994 to 12.4 in 2006 (Henry J. Kaiser Foundation, 2007).
- PhRMA, the drug manufacturer's association, reported that sales of 23 active ingredients (representing a typical sampling of drugs) totaled approximately 22 million lbs (Tischler, 2006).
- Patients fail to comply with their doctor's initial prescriptions 2 to 20 percent of the time. Some of the non-compliance is not taking medication correctly or not finishing it, leaving some as waste (Perri, 2008).

Why address the disposal issue for medications?

While solutions (such as reducing the quantities of prescriptions or alternative wastewater treatments) will be needed to reduce the presence of medications and their metabolites in the environment, there is an obvious and immediate need to prevent disposal of unused medications to the sewer and garbage. This is one source of these chemicals in the environment that can be addressed now.

- A June 2005 survey completed in King County and Seattle showed that:
  - 36.5 % of residents typically disposed of pharmaceuticals to the trash.
  - 29.4% or residents typically disposed of pharmaceuticals to the sink or toilet (KCLHWMP, 2005).

- SoundStats conducted a telephone survey of King County residents in January 2006, on current disposal practices for unwanted or expired medicines. The survey found that King County residents are actively using or planning to use only a third of the medicines they have in their households in the next six months (WCRC, 2006).

Nationwide, medications are the most common poison exposure category and rising drug abuse is a serious concern. Both may be related to improper storage or disposal of unwanted medications in people's homes.

The Centers for Disease Control reported that:

- 71.2% of poisoning suicides were caused by drugs—both legal and illegal (2003)
- Most nonfatal, poison-related suicide attempts involved prescription drugs (2003)
- Drugs caused 94.3% of the unintentional and undetermined poisoning deaths (2003)
- Poisonings led to $26 billion in medical expenses and made up 6% of the economic costs of all injuries in the United States (2000) (CDCP, 2007).

The National Center on Addiction and Substance Abuse found that:

- The number of Americans who abuse controlled prescription drugs has nearly doubled from 7.8 million in 1992 to 15.1 million in 2003. Prescription drug abuse among teens has more than tripled during that time (CASA, 2005)
- One in 10 teens reports having abused Over-The-Counter cough medicines to get high (CHPA, 2008).

The NWPSC Position

NWPSC believes that waste pharmaceuticals present both a public safety and environmental hazard if no secure disposal option exists. Take-Back programs can effectively reduce the amount of drug waste improperly disposed and stored in people's homes.

The NWPSC also believes that the most effective and most equitable provider of these programs are those with the most influence over the product. Typically, manufacturers are in this position, but retailers, wholesalers, healthcare organizations, and consumers may also have a critical role to play in providing a solution to this problem.

There are many successful and cost-effective examples of manufacturer stewardship in pharmaceuticals, including British Columbia, Australia, Prince Edward Island, France, Italy, and several other European countries. A manufacturer-funded program launched in October 1996 in British

Columbia, Canada serves a population of 4 million. 800+ pharmacies collected **44,092 lbs** of waste medicine in 2006 (Iverson, 2006). Extrapolating the B.C. collection data to Washington State, with a population of 6.2 million, a similar program could collect **66,000 lbs** per year for proper disposal.

Manufacturers (and by extension, consumers) are the most equitable funder of product take-back programs; such management costs should not be borne by taxpayers or garbage utility ratepayers.

- Of the 2006 average retail prescription price of $68.26, the manufacturer received 78% of the cost, the retailer received 19%, and the wholesaler received 3% (Henry J. Kaiser Family Foundation, 2007).

- From 1995 to 2002, pharmaceutical manufacturers were the nation's most profitable industry. They ranked 3rd in 2003 and 2004, 5th in 2005, and in 2006 they ranked 2nd, with profits (return on revenues) of 19.6% (Henry J. Kaiser Family Foundation, 2007).
    - $2.8 billion was spent in Washington to purchase 53.6 million prescriptions (Henry J. Kaiser Family Foundation, 2005).
    - $15.4 billion was spent on over-the-counter medication and/or personal care products nationwide, excluding Wal-Mart (CHPA, 2006).

By managing their products at end-of-life, manufactures can obtain significant data to inform product redesign. In the case of pharmaceuticals, such data can help inform prescribing practices, patient compliance rates, and possibly drug formulation.

Proposed Solution/Recommendations

Pharmaceuticals from Households: A Return Mechanism (PH:ARM) is currently testing a system in which pharmacies and long-term care facilities will collect household waste pharmaceuticals. Existing wholesaler/ distributors will provide the transportation, consolidation, and delivery to the eventual goal of a compliant hazardous waste incinerator. (Due to DEA regulatory barriers, the PH:ARM team cannot yet access this incinerator and is using a waste-to-energy plan on pilot basis.)

The pilot hopes to develop a model where pharmacies play a key operational role in capturing end-of-life pharmaceuticals to benefit their customers and the community. A mandatory part of the PH:ARM project is to dissolve the regulatory barriers of the Drug Enforcement Administration (DEA). DEA rules prohibit the collection of certain controlled substance drugs (a class of prescription drugs) by anyone other than a law enforcement officer. The DEA has yet to respond to a PH:ARM request that they offer a practical solution for states desiring to allow cost-effective product take-back programs to occur. Letters of support have been received from over 20 organizations and individuals including the Governor of Washington and the Attorney General to support our request.

Other PH:ARM goals include:

- Helping other states develop product stewardship solutions, such as Oregon, North Carolina, New York, and many others.
- Exploring long-term financing relationships with manufacturers in coordination with the Product Stewardship Institute.
- Working with legislators and stakeholders to develop product stewardship framework legislation that could implement a viable, low-cost, safe and secure, and statewide program for consumers with pharmaceutical waste.

PH:ARM's Mission:
To create a simple, low-cost and secure take-back system to collect unwanted medications from household sources. The system will operate year round at local pharmacies and nursing homes, and

will be funded by pharmaceutical manufacturers. The local system is designed to be expanded state and nationwide. Our goal is to prevent pharmaceutical pollution while improving public safety

Subcommittee Next Steps/Timeline

Between 2007 and December 2008, PH:ARM plans to

- Expand the pilot to 80-100 pharmacy and long term care sites in 2008;
- Gain access to hazardous waste incineration for all HHW drug waste collected by the program;
- Fully fund the pilot;
- Obtain a waiver to federal rules which prohibit the collection of controlled substances by anyone other than a law enforcement officer;
- Introduce a product stewardship-focused study bill or product stewardship implementation bill for safe and secure household waste pharmaceutical disposal;
- Inventory and sample the type, amount, and brand of drugs being returned to the pilot program;
- Explore alternatives to incineration; and
- Engage manufacturers in a long-term funding solution for proper disposal of pharmaceutical waste.

References

Centers for Disease Control and Prevention (CDCP). (2007). Poisoning in the US: Fact Sheet. Retrieved February 11, 2008 from www.cdc.gov/ncipc/factsheets/poisoning.htm

Consumer Healthcare Products Association (CHPA). (2008). OTC Retail Sales—1964-2006. Retrieved February, 11 2008 from www.chpa-info.org/ChpaPortal/PressRoom/Statistics/OTCRetailSales.htm

Consumer Healthcare Products Association (CHPA). (2008). Stop Cough Medicine Abuse. Retrieved February 11, 2008 from www.chpa-info.org/ChpaPortal/ForConsumers/Cough_Med_Abuse/Stop_Cough_Med_Abuse.htm

Iverson, Paul. Conversation. BC Residuals Management Group. 7, July 2006.

King County Local Hazardous Waste Management Program (KCLHWMP). (2005). DNR Behavior Survey.. Retrieved on February 11, 2008 from http://www.govlink.org/hazwaste/publications/UnwantedMedicationsPrimerFinal_Oct24_06.pdf

Koplin, D.W., et al. (2002). Pharmaceuticals, hormones, and other organic wastewater contaminants in U.S. streams, 1999-2000--A national reconnaissance. Environmental Science and Technology, 36, 1202-1211.

Henry J. Kaiser Family Foundation. (2007). State Health Facts. Retrieved February 11, 2008 from http://statehealthfacts.org/profilecat.jsp?rgn=49&cat=5

Henry J. Kaiser Family Foundation. (2007). State Health Facts. Retrieved February 11, 2008 from http://www.kff.org/rxdrugs/3057.cfm

Henry J. Kaiser Family Foundation. (2005). Washington: Total Retail Sales for Prescription Drugs filled at Pharmacies. Retrieved February 27, 2007 from http://statehealthfacts.org.

National Center on Addiction and Substance Abuse (CASA). (2005). Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S. Retrieved February 11, 2008 from www.casacolumbia.org/supportcasa/item.asp?cID=12&PID=138

Perri, Matthew III. (2008). Pharmacy Care and Medication Compliance. Retrieved February 11, 2008 from

www.rx.uga.edu/main/home/phrm3900/htdocs/comp_art.htm

Tischler and Kocurek. (2006). Potential Releases of Unused Medicines in Subtitle D Landfill Leachate.

Washington Citizens for Resource Conservation (WCRC). (2006). SoundStats Survey of King County Households. Retrieved February 11, 2008 from http://www.wastenotwashington.org/Pharmsurvey.pdf

Washington State Department of Ecology (WSDOE) Environmental Assessment Program. (2004). Results of a Screening Analysis for Pharmaceuticals in Wastewater Treatment Plant Effluents, Wells, and Creeks in the Sequim-Dungeness Area. (AHCPR Publication No. 04-03-051). Jonson, A., B. Carey, and S. Golding. Retrieved February 11, 2008 from http://www.ecy.wa.gov/biblio/0403051.html