Proceedings of the
Roundtable Discussion on Managing Unused Pharmaceuticals in NYS
May 15, 2008

Welcome & Introduction

Judith Enck, Deputy Secretary for the Environment, Office of Governor Patterson

Judith Enck welcomed a crowd of approximately 120 stakeholders and described pharmaceutical waste as an important issue that is a threat to our environment. She believes that there is sufficient evidence to support an immediate end to flushing of unused pharmaceuticals, and charged the group with developing an action plan to address pharmaceuticals in water.

Nancy Kim, NYS DOH Center for Environmental Health

Nancy Kim described the multiple ways in which DOH intersects with the issue of proper disposal of pharmaceuticals and their impact on the state's waters. The agency regulates medical facilities, has regular interactions with the medical community, and also regulates the state's drinking water supplies. Ms. Kim described a DOH study, conducted with DEC and other partners, in which four waste water treatment plants in the NYC watershed were tested. In each case, pharmaceuticals were present in the WWTP effluent, but little indication of the presence of pharmaceuticals was found downstream. She echoed Judith Enck's sentiments that this issue needs immediate attention and that it is prudent for the state to build its understanding of pharmaceuticals in the wastestream.

Octavia Conerly, Office of Water, US EPA

Ms. Conerly provided an overview of EPA's approach to the issue of pharmaceuticals in water. She highlighted several key points:

- Strengthening scientific knowledge: EPA is collecting data on the presence of pharmaceuticals in water, the tissue of aquatic organisms, and biosolids. To help address areas of uncertainty, the White House Committee on the Environment and Natural Resources has created an interagency work group, chaired by EPA, FDA and USGS, on Pharmaceuticals in the Environment, to develop a federal research strategy.
- Improving public understanding: EPA is documenting and communicating the risks to human and aquatic life posed by pharmaceuticals in water.
- Building partnerships: EPA is working with the states, other federal agencies and stakeholders to address this and other emerging contaminants.
- Utilizing regulatory tools when warranted: If necessary and appropriate, the agency will utilize its regulatory authority to help address this issue.

Scott Stoner & Ken Kosinski, Division of Water, NYS DEC

DEC staff provided an overview of the issue of pharmaceuticals in the state's waters. Key points included:

- Pharmaceuticals are one class of many largely unregulated contaminants of emerging concern; there are few if any water quality standards for pharmaceuticals.
- 225 million prescriptions per year are written in NYS alone.
- Sources of pharmaceuticals in the state's waters are diverse and include flushing unused medications in homes and institutions, water discharges from manufacturing facilities, and the passage of medications through the human body.
- The effects of long-term low-level exposure to pharmaceuticals in water supplies, for both aquatic and human life, are of concern.
- An end-of-pipe (e.g., at the waste water treatment plant) removal strategy for pharmaceuticals is not practical; source control is a better alternative.
- DEC has formed an internal working group (that includes NYS DOH), and an inter-agency working group with NYS DOH and NYSED to develop strategies to reduce the discharge of pharmaceuticals into water; the agency is also working with US EPA, USGS and the New England Interstate Water Pollution Control Commission on regional and national strategies.

Panel Discussion: Managing pharmaceuticals generated by households

James Giglio, NYS DOH, Bureau of Narcotics Enforcement
Andrea Person, NYS Board of Pharmacy
Thomas Lauro, Commissioner, Westchester County Department of Facilities
Nick Anastas, MA Department of Environmental Protection
Joe Fiscella, Westchester/Rockland Society of Pharmacists
Will Perry, Public Health, Seattle & King County
Mary Hendrickson, Capital Returns, WI (by telephone)

Resa Dimino, NYS DEC, Moderator and Harold Evans, NYS DEC, Facilitator

The panel discussion began with a description by each agency of the regulatory context for managing unused pharmaceuticals generated by households.

- <u>DEC</u>: DEC's primary role with regard to pharmaceuticals is the regulatory oversight of management, collection and disposal of pharmaceuticals from households and institutions. Pharmaceutical waste can fall into three categories—those that are hazardous waste under the Resource Conservation and Recovery Act (RCRA), or Regulated Medical Waste (RMW) under the Part 360 regulations, or solid waste. However, households are exempt from any RCRA and RMW regulations. Therefore, pharmaceuticals from households are considered solid waste.

- <u>DOH Bureau of Narcotics Enforcement (BNE)</u>: BNE is responsible for ensuring that controlled substances are not diverted from their intended distribution path (manufacturer to pharmacist to patient) to accidental or intentional misuse. While BNE must approve the methods that hospitals and institutions use to destroy controlled substances, the methods that patients use to dispose of unwanted or unneeded controlled substances is unregulated.

- NYS Education Department Board of Pharmacy: The Board regulates pharmacists and therefore has oversight over the dispensing and supply chain management of pharmaceuticals. The board does not have any official oversight over homeowners or their practices, but would have a role in approval of return programs for unused pharmaceuticals if pharmacists or pharmacies were involved. State law currently prohibits pharmacists from accepting controlled substances from a patient to whom they have already been dispensed.

The panel then discussed collection program options for safely managing unused pharmaceuticals generated by households. Options included incorporating pharmaceuticals collection in Household Hazardous Waste Collection days (Westchester County), mail back programs for unused pharmaceuticals (ME & WI), and return-to-clinic/pharmacy (King County, WA).

Westchester County HHW Collections:

In Spring 2008, Westchester County began to include the collection of pharmaceuticals in their 12 household hazardous waste collection days. Program highlights include:

- A police officer was present at all collections to accept controlled substances, as per DEA/BNE requirements; the officer maintained custody of the controlled substances and other pharmaceuticals, drove them to the county's waste to energy facility and witness their destruction.
- DEC provided a variance to the waste to energy facility to enable it to accept pharmaceuticals which may contain some materials classified as hazardous waste under RCRA.
- Members of the Westchester Society of Pharmacists volunteered at the events to accept, sort and categorize the pharmaceuticals collected.
- The first of the 12 collection days generated two 55-gallon drums of pharmaceuticals.

Wisconsin Mail Back Collections:

Reverse distributor Capital Returns is working with two counties in Wisconsin to implement a pilot mail-back program for unused pharmaceuticals. In this program, consumers are provided a 1-800 number to request a mail-back envelope for their unused medications. The program does not currently accept controlled substances, but rather is informing callers with controlled substances on proper disguising and disposal through residential waste. The program is funded by grants from US EPA and the State of Wisconsin. Outreach and promotional efforts include free media in newspapers and television as well as distribution of posters, flyers and other informational materials.

King County, WA Return to Clinic/Pharmacy

After several years of research, partnership building, and program development King County, Washington launched a pilot drop-off program for unused pharmaceuticals in 2007. The program was motivated not only by environmental concerns, but also by a sharp rise in deaths by unintentional poisoning and prescription drug abuse.

Initially rolled out in one HMO's chain of clinics, the program is now being expanded to include retail pharmacies as return sites. A powerpoint presentation on the program is available at [insert web link here]. Key elements of the program include:

- A convenient network of 27 drop-off sites;
- A specially designed drop-off box that does not allow the unused medications to be retrieved unless two authorized, key-holding program administrators are present;
- Staff sort through materials to ensure proper handling; reverse distributor disposes of materials collected;
- Protocols secure enough to safely handle controlled substances (despite the lack of DEA approval to handle such materials at this point);
- Signs to identify materials that are and are not accepted in the program; 97 percent compliance with program requirements, with mercury thermometers being the most common contaminant; and
- A website (www.medicinereturn.com), brochures distributed by pharmacies, and other promotional materials to encourage participation.

Key lessons from this pilot project include:

- Any separation makes it time consuming;
- A system that requires a pharmacist be present is costly;
- Programs need to be streamlined and take advantage of existing infrastructure;
- Sustainable funding is an issue; legislation is required to develop, implement, and fund a long-term take back program, British Columbia has such a program and achieves a 98 percent return rate;
- Strong partnerships and endorsements from all stakeholders are key;
- Relative to the cost of return in the program, the real cost is the waste of valuable, usable medications; and
- Education and outreach is key for all sectors, including consumers, agencies, businesses, and legislators.

Massachusetts—Education & Green Chemistry

The MA Department of Environmental Protection is working to develop an approach to pharmaceuticals collection, but has also approached the issue from a pollution prevention point of view. As such, the state has a public education campaign aimed at eliminating the flushing of pharmaceuticals and fostering safe disposal. The state is promoting "green chemistry" strategies to develop medications that break down more quickly in the environment once they pass through the human body. MA officials are closely watching a Sweedish program that created an environmental classification for pharmaceuticals that is promoted to pharmacists, physicians, researchers and the public. The classification gives a numerical score based on the environmental impact of the pharmaceuticals (more information is available at http://www.dnsy.se/lfm/In_English/)

Highlights of the Discussion of managing pharmaceuticals generated by households

Price Chopper return program: Locally, Price Chopper held a 2-week pilot program during which their pharmacies in the Capital District accepted unused medications. Many of the returns to the store were mail orders or 90-day supplies of medications that the patient did not need or could not use.

Reuse: Several stakeholders and panelists discussed the social and economic costs of the wasting of unused and often expensive medications. Medicine redistribution programs would ensure that these valuable pharmaceuticals are provided to the indigent and others in need. The pharmaceutical industry does have some redistribution programs. However, medicine reuse programs are generally not allowed under NYS legislation and regulations.

Topical pharmaceuticals: Certain topicals, like Lindane, are hazardous yet designed to be washed out and therefore enter the waste water supply. Industry representatives noted that that chemical is no longer used; EPA has a water quality standard for Lindane.

What are the options for immediate actions?

- Smart prescribing: begin with samples or short-term prescriptions to ensure no contraindications and less waste.
- "Don't Flush" education: on prescription labels, in pharmacy postings, inserts in water bills, etc. Note: this requires developing alternative disposal methods.
- Mail Back Programs: BNE stated a preference for mail-back as a convenient, secure and effective means of handling unused medications.
- Household Hazardous Waste Collections: We should continue to encourage HHW programs to incorporate pharmaceuticals collection, however, these programs are too inconvenient to provide a long-term solution that will ensure that unwanted medications are not misused.

Product Stewardship: Product Stewardship is the extension of the producer/manufacturer's responsibility for a product throughout its entire life cycle, including production, distribution and ultimate end-use or disposal. This approach has been used to safely manage other problematic and hazardous waste materials including electronics, paint and household hazardous waste. British Columbia and several European countries have pharmaceutical take back programs funded through a legislatively-created stewardship system. The Product Stewardship Institute (of which NYS DEC is a member) is launching a national stakeholder dialogue to develop a stewardship system that can reduce the environmental impacts of unused pharmaceuticals. The first of four dialogue meetings was held in June, 2008. For more information on pharmaceutical product stewardship see
http://www.productstewardship.us/displaycommon.cfm?an=1&subarticlenbr=181

Veterinary Pharmaceuticals: The role of veterinary pharmaceuticals in the overall environmental problem is undefined, but important to consider in policy options moving forward.

Panel Discussion: Managing pharmaceuticals generated by institutions

Mary Ellen Hennessy, NYS DOH, Division of Primary and Acute Care Services
Judith Mooney, NYS DOH, Division of Long Term Care

Andrea Person, NYS Board of Pharmacy
Dr. Russell Mankes, Albany Medical Center
Charlotte Smith, PharmEcology Associates, LLC
Nancy Leveille, New York State Health Facilities Association
Holly Vaughn, Fort Hudson Nursing Center

Resa Dimino, NYS DEC, Moderator and Harold Evans, NYS DEC, Facilitator

Like the morning panel, the discussion of managing pharmaceuticals generated by hospitals and institutions began with an overview of the regulatory context in these settings.

- DEC: Roughly 5% or less of the pharmaceuticals typically generated in a hospital or institutional setting are classified as hazardous under RCRA and therefore regulated by the DEC and required to be disposed of as hazardous waste. Additionally, about 3% of pharmaceuticals are classified as regulated medical waste (RMW) by DEC and required to be disposed of in an approved RMW facility.
- DOH BNE: Hospitals and institutions are required to ensure destruction of controlled substances by: returning them to the manufacturer; returning them to a DEA registered handler/disposal facility; or destroying them on-site through a BNE approved method.
- DOH Adult Care Facilities: DOH recommends flushing unused pharmaceuticals (both controlled and non-controlled substances) in most adult care facilities. While some pharmaceuticals can be returned through reverse distribution, that option is only accessible for facilities with in-house pharmacies and for patients that are not on Medicare.

The panel then discussed best practices for managing pharmaceuticals, as well as the current state of practice in hospital and institutional settings.

Best Practices for Institutional Pharmaceuticals Management – Charlotte Smith, PharmEcology

Hospitals and institutions currently use a variety of methods to manage their unused pharmaceuticals including regulated medical waste (RMW), hazardous waste, and flushing in wastewater. While it may seem reasonable to include pharmaceuticals in the RMW stream, much RMW is no longer incinerated, but instead sent to an autoclave for sterilization prior to landfilling; with pharmaceuticals this would result in very clean, but still biologically active pharmaceuticals being sent for disposal. Incineration is a well accepted management method for pharmaceuticals.

Best practices for pharmaceuticals management include:

- Identify RCRA hazardous pharmaceuticals and manage those as hazardous waste
- Segregate chemotherapy waste (usually in yellow containers) and manage in an RMW incinerator
- Develop a new stream (white container with a blue top) for all currently unregulated pharmaceuticals (90% of the stream) and dispose of through a service provider (e.g., Stericycle, Clean Harbors, Viola, etc.)

State of practice in Long Term Care – Holly Vaughn, Fort Hudson Nursing Home

Currently, the most common practice to manage pharmaceuticals in a nursing home or long-term care facility is to flush, as recommended by the NYS DOH. Controlled and non-controlled substances are gathered and tracked through separate systems, but both streams are ultimately flushed. Many nursing homes are unaware that some medications are considered by the state and federal government to be hazardous waste. While alternative management systems exist, such as services provided by disposal companies, they are costly and lacking a mandate or a strong education program, unlikely to gain administrative support.

The return of unused or expired medications through reverse distributors is not as widespread as it once was. While some pharmaceuticals are still handled through that system, certain third party insurance providers and Medicare Part D do not allow for reverse distribution because they have not agreed upon a credit mechanism for the returned medications.

Writing shorter-term prescriptions would help to reduce the amount of waste in long-term care facilities. Unfortunately, Hospice care is the only type of institution that can get a partial supply of medications due to stringent pharmacy regulations.

State of Practice in Hospitals - Nancy Leveille, New York State Health Facilities Association

There is less waste of pharmaceuticals in a hospital setting than a nursing home/long-term care facility since hospitals have in-house pharmacies and tend to dispense medication by the individual dose. (In long-term care prescriptions are written directly to the patient for 30 or 90 days.) However, hospital pharmacies generate expired medications and under Medicare Part D, those cannot be managed through reverse distribution.

Hospitals must have approved destruction methods for controlled substances, along the lines of the options laid out by BNE. The most common currently approved on-site destruction method is flushing.

Albany Medical Center Pilot Project –Dr. Russell Mankes

Albany Medical Center has launched a two-year pilot program to establish best practices for pharmaceuticals management and educate the staff to achieve strong compliance with the program. Key program elements include:

- Collect baseline data on how pharmaceuticals were handled prior to the program and what needs to be changed
- Educate clinical staff on the methods to properly handle pharmaceuticals and the importance of doing so
- Collect, sort and properly manage the unused pharmaceuticals at the medical center.

In the Albany Medical Center program, clinical staff are trained to place all unused pharmaceuticals in a collection container (white with a blue top). The contents of those containers are later sorted by trained staff who identify hazardous and controlled substances and manage them accordingly. AMCs approved method of destruction for controlled substances

involves placing/dissolving the controlled substances in a waste solvent generated by the hospital that is then managed as a hazardous waste.

The results of the program indicate that more than 90 percent of unused pharmaceuticals are unregulated, but those include some of the medications of greatest concern in our water—antibiotics, antipsychotics, endocrine disruptors, mood elevators, etc. Approximately 5 percent of unused pharmaceuticals are controlled substances and 4.4 percent are considered hazardous under RCRA . (For more detail on the AMC project, see a powerpoint presentation at …web address here.) Focusing on the 90 percent that is unregulated will capture most of the environmental concern.

Proper management of pharmaceuticals in a hospital or institutional setting is complicated by competing and sometimes unclear regulations promulgated by NYS and US EPA. An appropriate sorting system with trained staff is critical, but expensive.

Highlights of Discussion on Hospital and Institutional Pharmaceutical Waste Management

Regulatory Clarity: Harmonizing the regulations of various agencies (DOH, DEC, EPA, DOT, DEA) would ease the compliance burden on hospitals and institutions. In addition, clarifying when regulations apply would help—i.e., when is a long term care facility a home (and therefore exempt from RCRA/DEC regulations) and when is it an institution?

Education: Educating the medical community on the importance of eliminating the disposal of pharmaceuticals in the waste water system is critical to achieving behavioral change. Administrators must become aware of why it is necessary and important for them to invest in proper management. Clinical care staff must be trained on proper handling and management techniques. Many stakeholders and roundtable participants, including the NY Nurses Association, volunteered to aid in an outreach and education effort. Participants suggested adding pharmaceutical waste training to continuing education program, or requiring it through the Joint Commission of Accreditation.

Proper disposal: DEC and other roundtable participants stressed that incineration is the proper disposal method for otherwise unregulated pharmaceutical waste.

Product Stewardship: A product stewardship program (described earlier) would solve the single largest barrier to proper management of unused pharmaceuticals – cost. In this type of program, the cost would be bourne by the manufacturer. In the British Columbia system, the stewardship program is run by an industry-established organization that allocates the program costs to individual companies using an agreed upon formula.

Medicare Part D: Revising Medicare Part D so that it allowed for crediting of expired medication through reverse distribution would have a positive impact on the unused pharmaceuticals disposal problem. The state should support such change at the federal level.

The extent of the problem: There was some debate about how much of the pharmaceuticals in the water supply are the result of flushing, versus excretion through the human body. The

pharmaceutical industry claims that 90 percent of the medicines in water are a result of human excretion, though no studies have been provided. The industry also claims that risk to humans have not been proven. As per the directive from Governor Patterson's Office, New York State's position is that given the potential risk, precaution is warranted. Such a position dictates that we take whatever actions necessary to prevent the discharge of pharmaceuticals to our waters.

Overview and Next Steps

Develop an Inter-Agency Work Group that includes all the relevant state agencies to address the issues raised, including:

- providing regulatory clarity
- issuing guidance on proper management
- developing and implementing education and outreach programs and
- advocating for legislative and regulatory changes at the state and federal level, including product stewardship, changes to Medicare D rules, and prohibiting flushing of medications

Education Program: Develop alternatives to flushing unused pharmaceuticals and educate key constituencies, including health practitioners, administrators, consumers, municipalities, etc.

Green Chemistry: Create pharmaceuticals that break down more readily once they've passed through the human body.

Research: Continue to build our knowledge base on the presence of pharmaceuticals in the natural environment and the environmental and public health risks associated with them.

Sewage Treatment Technology: Even the most advanced waste water treatment technology in use in the state, in the NYC watershed, does not effectively remove pharmaceutical contaminants. A recent DEC study found that the state faces a $36 billion price tag for necessary sewage treatment upgrades, even without addressing these materials. However, the state should continue to monitor and support research to develop technologies to address this and other emerging contaminants.