2013 Pharmaceutical Waste Stewardship Summit
MEETING SUMMARY
June 11, 2013 – Milwaukee, WI

Attendees
More than 80 people participated in the 2013 Pharmaceutical Waste Stewardship Summit, the majority attended in person in Milwaukee, and a few others dialed in. Participants included state and local government officials, representatives of the waste management industry, non-profit advocacy organizations, academic institutions, pharmacists, and pharmacy association professionals. The meeting was organized and facilitated by the Product Stewardship Institute (PSI) in collaboration with the University of Wisconsin Extension. Those attending came from Arizona, California, Illinois, Indiana, Iowa, Michigan, Minnesota, Nebraska, New York, Ohio, Washington, and Wisconsin.

Meeting Materials
The meeting summary, handouts, presentations, final agenda, and participant list are posted on PSI’s website: [www.productstewardship.us/pharmaceuticalsummit2013](http://www.productstewardship.us/pharmaceuticalsummit2013). The PowerPoint presentation should be consulted for details when reviewing this summary.

Meeting Outcomes
There was agreement that the Great Lakes region, as well as many other parts of the country, have made great progress in addressing the issue of pharmaceutical waste over the last few years. A growing number of collection sites have sprung up throughout the region, helped in part by valuable partnerships with local law enforcement and pharmacies to serve as collection sites. However, despite a growing coalition of government officials, public health and environmental advocates, the lack of sustainable funding for take-back initiatives continues to be the greatest barrier in establishing a comprehensive solution to managing unused medications. Although some stakeholders felt that pursuing a producer responsibility approach was the necessary next step, others felt it was important to focus on increasing voluntary collections, at least until a more comprehensive solution can be reached. Attendees noted other challenges, including the slow process of finalizing DEA regulations for controlled substances, and a lack of public awareness and communication about how to properly dispose of unused medications. (See the “Call to Action & Next Steps” section below for proposed strategies to address these issues.)

General Takeaways

- Lack of funding for voluntary pharmaceutical take-back programs continues to hinder pharmaceuticals stewardship.
- Uncertainty regarding final DEA rule and requirements for future collections obstructs progress.
- Growing partnerships and diverse coalitions in support of pharmaceutical take-back, particularly among public health advocates.
- Take-back collection locations at law enforcement are not ideal (and are generally not as convenient as pharmacy collection locations).
- Lack of public awareness of current options for properly disposing of unused medications.

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Introduction
Milwaukee Mayor Tom Barrett welcomed meeting attendees and expressed support for product stewardship solutions for pharmaceutical waste, including requiring pharmaceutical companies to establish a program to properly dispose of leftover and expired medications. Mayor Barrett highlighted the importance of proper pharmaceutical disposal for the City of Milwaukee and the country. David Spakowicz, Director of the Division of Criminal Investigation at the Wisconsin Department of Justice, also provided an introduction to meeting attendees, highlighting the importance of proper pharmaceutical disposal in addressing the growing problem of opiate and heroine abuse in the state. PSI’s Scott Cassel then welcomed participants to the meeting and provided a brief overview of the day’s events.

Update on the Great Lakes Pharmaceutical Stewardship Project
Steve Brachman from the University of Wisconsin Extension (UWEX) and Barb Bickford from the Wisconsin Department of Natural Resources (DNR) described the Great Lakes Regional Initiative project on pharmaceutical stewardship and provided an update on the current status of this project.

Accomplishments:
1. Medicine Mail-Back Program: This four month pilot project can serve as a model for future programs.
2. Pharmaceutical Waste Working Group (PWWG): This group partners with the State Council on Alcohol and Other Drug Abuse and works on both pharmaceutical disposal and reduction issues.
3. Regional dialogues have been held on pharmaceutical waste stewardship efforts.
4. Model public policies have been developed, such as “Key Elements of Pharmaceutical Collection and Disposal Programs,” which is a vision document developed by PSI, which also developed model legislation for pharmaceuticals EPR.
5. A website of interactive tools was created to help healthcare facilities reduce pharmaceutical waste, [http://www.uwm.edu/SHWEC/pharmaceuticalwaste/](http://www.uwm.edu/SHWEC/pharmaceuticalwaste/).
6. There is an increased public awareness in collaboration with groups such as the Pharmacy Society of Wisconsin.

Lessons Learned:
1. The slow progress of finalizing the DEA regulations is impeding progress in pharmaceutical waste stewardship efforts.
2. Determining destruction options for pharmaceutical waste is an ongoing challenge.
3. Public safety trumps environmental concerns as a rationale for pharmaceutical waste stewardship.
4. There is broad public support for pharmaceutical stewardship initiatives.

Next Steps:
1. Expand destruction options.
2. Raise consumer awareness.
3. Centralize data.
4. Reduce pharmaceutical waste at the source.
5. Expand pharmaceutical stewardship coalitions.
6. Create new funding options.

Scott Cassel also shared highlights from PSI’s report to Wisconsin DNR (co-authored with UWEX) on the effectiveness of drug collection efforts in Wisconsin. (The report is available at [http://dnr.wi.gov/topic/healthwaste/pharm.html](http://dnr.wi.gov/topic/healthwaste/pharm.html) under the “Department Study” tab.) Only 2% of pharmaceutical waste is currently being collected in Wisconsin despite the extensive take-back programs. The low collection rate is due to the fact that there are not enough participating pharmacies.
and other collection sites to allow for the convenience levels that would increase the collection rate. A collector of pharmaceutical wastes in Wisconsin said that the pharmacies that are currently participating in a take-back program do not have the capacity to collect more than they do. Dave Galvin of the King County Local Hazardous Waste Management program in Washington noted that collection sites at law enforcement offices are insufficient; to ensure high collection rates, participation from every pharmacy should be required. There was consensus that these convenience gaps are due to limited funding.

**Regional Roundtable on Drug Take-Back Programs in the Great Lakes**

Officials from six state government agencies and one local government in the Great Lakes states gave short presentations on the current status of drug take-back efforts in their states, as well as the successes they have seen and the challenges they have faced (see the summary handout for more detail). Some of the general themes that emerged from this discussion are listed below.

**Challenges**
- Limited funding.
- Cost of transportation to destruction facilities.
- Many unknowns with pending DEA regulations.
- Lack of statewide data in states other than Wisconsin.
- Lack of public awareness and confused messaging about the risks of improper medicine disposal and existing take-back options.
- Lack of a comprehensive system for convenient drug take-back collection.
- Varied state disposal regulations.

**Successes**
- Partnerships with local law enforcement to serve as take-back collection sites.
- Increasing number of collection sites throughout the region.
- Wisconsin’s pharmaceutical report gives all states a better estimate of the quantities of drugs being discarded.
- NY law requires retail pharmacies to display a “don’t flush” notice.
- IL passed a law to impose a $20 fee on drug-related offenses to establish a reserve to contribute funding for future drug take-back programs.

**Options for Increasing Local Take-Backs**
- State/federal collection program.
- State/federal EPR for pharmaceuticals.
- Tax incentives for sites participating in take-back programs.
- Outreach & education materials.
- Address the misperception that EPR legislation would require retailers to collect medications.

In the ensuing discussion, John Waffenschmidt of Covanta Energy responded to concerns about the continuation of pharmaceutical incineration at waste-to-energy plants. John expects the Covanta “Prescription for Safety” program to continue at least for another 2-3 years as many people within the company see its value as a public service. John Storlie (CB&I) highlighted the challenge for retail pharmacies to comply with varied regulations on the state/county level, and also mentioned the Notice of Data Availability (NODA) on reverse logistics that will be released this summer by the Environmental Protection Agency (EPA). John wants to make sure that people comment on the NODA and keep pressure on its release.

**Examining Producer Responsibility Approaches from the Local, State, and Federal Levels**

PSI’s Scott Cassel kicked off this session with a general overview of existing pharmaceuticals waste stewardship policies and EPR legislation in the U.S. As part of this overview, Scott defined the terms...
“product stewardship” and “extended producer responsibility,” as agreed upon by the national stakeholder process led by PSI, the Product Policy Institute (PPI), and CPSC.

**Product Stewardship** is the act of minimizing health, safety, environmental and social impacts, and maximizing economic benefits of a product and its packaging throughout all lifecycle stages. The producer of the product has the greatest ability to minimize adverse impacts, but other stakeholders, such as suppliers, retailers, and consumers, also play a role. Stewardship can be either voluntary or required by law.

**Extended Producer Responsibility (EPR)** is a mandatory type of product stewardship that includes, at a minimum, the requirement that the producer’s responsibility for their product extends to post-consumer management of that product and its packaging.

- Alameda County Supervisor Nate Miley discussed Alameda County’s first-in-the-nation pharmaceuticals EPR ordinance, and the legal challenge it currently faces. Supervisor Miley explained that passing an ordinance through the Board of Supervisors appeared to be less challenging than a citizen ballot initiative would have been. In responding to questions, Supervisor Miley explained that the ordinance does not mandate anything of consumers. The Pharmaceutical Researchers and Manufacturers of America (PhRMA) has sued Alameda County in response to the pharmaceuticals EPR ordinance, claiming that it violates the U.S. Constitution’s Interstate Commerce Clause by increasing costs for consumers outside of Alameda County by incurring costs on the national producers selling into the county. There is consensus that the results of this hearing will have broad implications for EPR policy. A summary judgment hearing for the Alameda County lawsuit was held in federal court on August 1, 2013 in San Francisco, where the judge did not issue a ruling at the hearing.

- Heidi Sanborn of the California Product Stewardship Council discussed current efforts to pass statewide pharmaceutical EPR legislation. SB 727, introduced by Senator Hanna-Beth Jackson, is similar to the Alameda County ordinance. It is an EPR cost internalization model that establishes convenience standards and requires clear and concise messaging.

- Margaret Shield provided an overview of the King County, Washington, Board of Health’s process for considering an EPR approach for pharmaceuticals. She noted that there is currently insufficient financing and promotion to ensure successful collection programs around the country. In May 2013, King County proposed a rule and regulation for industry-funded household pharmaceutical collections. The proposed rule and regulation was opened up for stakeholder input at multiple public meetings and so far all stakeholders are supportive of the proposed rule except for PhRMA. Like the Alameda County and California models, this is a cost-internalization model, with review by the Public Health Department.

**Stakeholder Roles in Implementing Take-Back Programs and Impact of the Proposed Drug Enforcement Administration (DEA) Rule**

Stefanie Wnuck from PSI provided a general overview of the proposed DEA rule, highlighted a few provisions PSI’s network supported, and noted current requirements that may increase costs for operating take-back programs and/or impact program convenience. Charlotte Smith from PharmEcology Services at Waste Management described some of the potential implications for stakeholders involved in operating drug take-back programs and outlined some concerns with DEA’s proposed rule. Problematic requirements on reverse distributors imposed by the proposed DEA rule include documentation, the requirement that reverse distributors must destroy a pharmaceutical package within 14 days, staff presence for transportation and destruction, as well as inventory and reporting procedures. Charlotte also mentioned the lack of other disposal alternatives for long-term care facilities as another concern. In closing, Charlotte referenced WM’s extensive comments submitted as the primary method of communicating with the DEA, noting that it has been difficult to engage and share information on current practices with the DEA.
Representatives of various stakeholder groups involved in pharmaceutical waste issues gave brief presentations to describe their current role, and how this role may be impacted by the DEA rule. Some of the general themes that emerged from this discussion are listed below. Please consult the slide deck for further detail on each state’s programs.

- **State law enforcement:** David Spakowicz from the Wisconsin State Department of Justice spoke of the effective collaboration between DEA and the Wisconsin Attorney General. Wisconsin’s DEA take-back collection days have the second highest collection rate in the country. David said that he expects the implementation of the proposed DEA regulations to reduce these collection numbers for the one-day events, and that he still thinks it would be a good idea to continue having these events at least once a year.

- **Local law enforcement:** Paul Milbrath, the Jefferson County Sheriff in Wisconsin, mentioned that two of the biggest issues for law enforcement conducting collections are storage and sorting. Participating law enforcement sites are already running out of storage space. He hopes that DEA will continue to allow local law enforcement to sort on-site under the supervision of trained pharmacists to reduce the amount of drugs to be managed as controlled substances.

- **Local government:** Bill Leonard, from Hennepin County Environmental Services in Minnesota, provided a brief history of how the county’s take-back program transitioned from holding one day collection events to setting up permanent drop boxes by partnering with law enforcement. He also noted that the current collection program in Hennepin County will not be too significantly impacted by the DEA regulations.

- **Pharmacy Association:** Tom Engels, from the Pharmacy Society of Wisconsin, discussed the Wisconsin Pharmacy Quality Collaborative. This program received a $4 million grant from the Center for Medicare and Medicaid Services, (CMS) in the largest grant ever awarded to a pharmacy organization in the U.S. This program aims to control costs and ensure that consumers understand how to properly use and dispose of their medications, through education and information-sharing efforts. CMS estimates that the full implementation of this program statewide will save over $20 million in health care costs over the next three years, with over half of the projected savings to occur within the state’s Medicaid program. Tom Engels also noted that pharmacists are very supportive of participating in drug take-back if there is funding to cover their costs.

- **Drug Abuse Prevention Advocate:** Russ Jenson from Dane County’s MedDrop Program and the Safer Communities Coalition in Wisconsin discussed the role of this advocacy organization has played in operating drug take-back collection programs.

- **Pharmaceutical Destruction:** John Waffenschmidt from Covanta Energy discussed the role of the waste-to-energy company in destroying unused pharmaceuticals. The company’s pharmaceutical disposal program, “Prescription for Safety,” began in 2010 in collaboration with PSI and the state of New York with the aim of reducing groundwater contamination. It was then rolled out as a national initiative. Covanta’s program has collected over 865,000 pounds of medications so far, a number which is projected to reach one million by the end of 2013. John highlighted the importance of the household hazardous waste exemption as key in allowing Covanta’s pharmaceutical destruction program to operate in different states. He also noted the need for a sustainable funding mechanism to expand take-back programs. In addition, John expressed concern that the proposed DEA rule does not recognize the possibility of thermal destruction for pharmaceutical waste.
Call to Action & Next Steps for the Great Lakes Region

Many stakeholders felt that pursuing a producer responsibility approach is the necessary next step and therefore the political dynamics of support and opposition for pharmaceutical EPR legislation were discussed at length. Participants noted that both Republicans and Democrats across the country have been supportive of pharmaceutical stewardship solutions. Various strategies for laying the groundwork for legislation were discussed, and are listed below.

Strategies for laying the groundwork for a producer responsibility solution for pharmaceuticals:

- Build coalitions to increase the diversity of key supporters of EPR for pharmaceuticals
  - Identify a local or state “champion” who can rise above opposition pressures and is well versed in the issue.
  - Reach out to drug abuse prevention and public health advocates to help spread the message and increase support for a producer responsibility solution.
  - Identify stakeholder groups that have significant influence over key legislators and educate those groups about pharmaceutical waste and risks of improper disposal.
  - Identify and develop partnerships with powerful players in each state (e.g. key committee chairs).
  - Continue to expand partnerships with law enforcement.
  - Establish partnerships with pharmacy associations and pharmacy schools.
  - Educate and mobilize shareholders to increase pressure on pharmaceutical companies.
- Coordinate consistent outreach and education efforts
  - Develop targeted media outreach where a national campaign is coordinated with local and state specific messaging.
  - Continue general outreach and education on the benefits of product stewardship and EPR for pharmaceuticals.
  - Simplify the message for EPR for pharmaceuticals.
- Increase coordinated data collection and analysis
  - Conduct research on impacts of improper pharmaceutical disposal and obtain state-specific data (e.g. overdoses/poisonings/drug abuse and associated health care costs, drug crime law enforcement costs, impacts of proposed legislation on drug costs).
  - Prepare strong and fully supported arguments to demonstrate the extent of the problem and the need for a sustainable solution.
- Continue to track and share updates on legislative actions at the local level in Alameda and King County as well as the progress of the DEA regulations.

Participants also proposed additional suggestions for programs that could be effective strategies to address issues of pharmaceutical waste:

- Anthony Pudlo from the Iowa Pharmacists Association highlighted a legislated drug repository program in Iowa that allows drugs collected in a controlled environment (often long-term care facilities) to be repurposed and redistributed to patients in need.
- Charlotte Smith from WM suggested the possibility of seeking funding from CMS for education about proper drug usage as well as a drug take-back program.
- Respondents to the Attendee Survey after the Summit suggested greater coordinated efforts to educate about how to develop and implement local medicine collection programs.