



PSI PHARMACEUTICALS INITIATIVE PROSPECTUS

What is the Problem?

Pharmaceutical products save lives, ease pain and suffering, and enhance quality of life. As more people enjoy the benefits of pharmaceuticals, and as pharmaceuticals are used increasingly in treating farm animals and pets, more pharmaceuticals are becoming waste. Waste pharmaceuticals are prescription and over-the-counter medications that consumers have purchased or otherwise obtained but they no longer need, either because the pharmaceutical has passed its expiration date, the consumer has chosen not to complete a course of treatment, or the consumer has died. Waste pharmaceuticals pose four types of potential threats: they can enter the environment and impact aquatic organisms and potentially drinking water, and they can contribute to accidental poisonings and drug abuse.

Who is Involved?

PSI is working with over 400 stakeholders interested in the disposal of waste pharmaceuticals. We share information with these stakeholders and invite them to participate in PSI's National Dialogue on Waste Pharmaceuticals. Dialogue participants and supporters include:

Government

- ⇒ U.S. Environmental Protection Agency, Food and Drug Administration, Office of National Drug Control Policy (observers), Congressional offices of Jay Inslee (D-WA) and James Moran (D-VA)
- ⇒ State agencies from Arkansas, California, Connecticut, Florida, Idaho, Iowa, Minnesota, Missouri, New York, Oklahoma, Oregon, Utah, Virginia, Wisconsin, Washington
- ⇒ Over 20 local government entities from California, King County & Snohomish County (WA) and Metro Regional Government (OR), Western Lake Superior Sanitary District (MN)

Companies

- ⇒ Pharmaceutical companies, including Alkermes, AstraZeneca, BD Medical, GlaxoSmithKline, Hoffman La-Roche, Johnson & Johnson, King Pharmaceuticals, Pfizer, Inc., Schering-Plough
- ⇒ Waste industry, including Capital Returns, Inc., Enserv West, LLC, EXP Pharmaceuticals, Integrated Waste Control LLC, PharmWaste Technologies, Sharps Compliance, Inc., Stericycle, Veolia Environmental Services, Waste Management
- ⇒ Consultancies & other companies, including Avalere Health, LLC, Earth 911, Full Circle Environmental, PharmEcology Associates, Spurgin & Associates

Environmental & Public Health Groups

- ⇒ National groups, including American Water Works Association, Clean Water Action, Healthcare Without Harm, Natural Resources Defense Council, National Association of Clean Water Agencies, National Association of Drug Diversion Investigators, National Safety Council, Teleosis Institute
- ⇒ Local, state, or regional groups, including Alliance for the Great Lakes, California Product Stewardship Council, Minnesota Technical Assistance Program, Northwest Product Stewardship Council, Save the Bay, Washington Citizens for Resource Conservation

What is the Project Goal and Focus?

- ⇒ Develop and implement a nationally coordinated system for the safe, practical, legal, and environmentally protective management, collection, and disposal of waste pharmaceuticals.
- ⇒ Identify and implement strategies to reduce the amount of pharmaceuticals that become waste.

This project is focused on household-generated pharmaceutical wastes, whether from residences, schools, cruise ships, pet care, or some long-term care facilities.

PRODUCT STEWARDSHIP

Product stewardship directs all participants in the lifecycle of a product to take responsibility for reducing the impacts to the environment and human health caused by the production, use, and end-of-life management of that product.

PSI

The Product Stewardship Institute (PSI) is a national environmental institute with membership from 45 states, 70 local governments, and over 45 businesses, environmental groups, and organizations that establishes cooperative agreements to reduce the health and environmental impacts from consumer products. We work with state and local government agencies to partner with waste firms, manufacturers, retailers, environmental groups, federal agencies, and other key stakeholders. The mission of PSI is to pursue initiatives to ensure that all those involved in the lifecycle of a product share responsibility for reducing its health and environmental impacts.

What is the Process for the National Dialogue ?

Action Plan Development Spring 2005 - Spring 2008	Project Summary and Action Plan	In Spring 2005, local government agencies provided initial funding for PSI to conduct the first phase of a national dialogue on waste pharmaceuticals. PSI developed a Project Summary as a tool to solicit input from a diverse stakeholder group. Using information obtained from over 30 stakeholder interviews, PSI developed a Draft <i>Product Stewardship Action Plan</i> , which contains a problem statement, project goals and focus, key issues, and potential solutions. It also provides a comprehensive summary of activities related to pharmaceuticals management in the U.S. and around the world, including pilot projects.
Dialogue Phase 1: June - October 2008	Meeting #1 June 19-20 Sacramento, CA Workgroups: ⇒ Research ⇒ Collection & Disposal ⇒ Regulations ⇒ Source Reduction	PSI designed and facilitated the first national dialogue meeting with over 120 representatives from state, local, and federal government; manufacturers; public health and environmental and organizations; and the waste management industry. Following the meeting, four workgroups convened to develop and implement joint strategies to resolve key research questions; overcome regulatory barriers to collection of waste pharmaceuticals; develop recommendations for best practices for collection and disposal (both from the home and from collection points); and reduce the quantity and toxicity of waste pharmaceuticals. This phase of the dialogue was funded by EXP Pharmaceuticals, Waste Management, and over 20 local and state agencies, organizations, and companies.
Dialogue Phase 2: November 2008 - Spring/ Summer 2009	Meeting #2 December 2-3 Washington, DC <i>The workgroups from the previous phase will continue.</i>	Over 120 participants convened again, this time with new participation from federal agencies and national organizations. Participants discussed issues and next steps related to estimating the how many pharmaceuticals go unused, collaborative strategies to reduce this amount, key issues related to the relative benefits and costs of trash disposal as compared to take-back programs, federal regulatory barriers to cost-effective take-back programs, and clear and consistent messaging to the public on drug disposal. Meeting #2 of the dialogue was funded by King Pharmaceuticals.
Dialogue Phase 3: Summer/Fall 2009	Meeting #3 To be scheduled when funding is secured.	PSI is currently seeking funding for this phase of the dialogue.
Dialogue Phase 4: Fall/Winter 2009 - 2010	Meeting #4 To be scheduled when funding is secured.	PSI is currently seeking funding for this phase of the dialogue.

What Funding is Still Needed?

PSI seeks funds to (1) Advocate to change the Controlled Substances Act to reduce regulatory barriers and costs associated with safe drug disposal; (2) Work with federal, state, and local governments and other groups to develop a consistent message on disposal options; (3) Study the quantity, type, dollar value, and percentage of prescription and over-the-counter drugs that go unused (this information will help in planning take-back programs and targeting source reduction efforts); (4) Convene a *Pharmaceutical Source Reduction Summit* to develop collaborative strategies to reduce the amount of pharmaceuticals that become waste; and (5) Develop best practices for drug take-back program operations.

To contribute funding to this project, please contact Scott Cassel at scott@productstewardship.us or 617.236.4822.

CONTACT INFORMATION

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