



**Waste Pharmaceuticals National Dialogue
Stakeholder Meeting #1
Meeting Summary
Sacramento, CA
June 19-20, 2008**

ATTENDEES

The meeting was attended by over 80 participants, with another 34 registered to participate via a conference call dial-in number over the course of the two-day meeting. The final participant list is on the PSI website at:

<http://www.productstewardship.us/PharmaceuticalMeetingSacramentoCA>.

MEETING MATERIALS

This meeting summary, final agenda, PowerPoint presentations, and other materials are at <http://www.productstewardship.us/PharmaceuticalMeetingSacramentoCA>. **The PowerPoint presentations should be consulted for details when reviewing this summary.** Unless otherwise specified, comments made under the heading of a presentation are those of the presenter. This summary is intended to provide a brief overview of the key points discussed at the meeting.

WELCOME AND INTRODUCTIONS

Scott Cassel (PSI) opened the meeting by welcoming the group and thanking the CA Integrated Waste Management Board (CIWMB) for hosting the meeting. CIWMB Board Member Rosalie Mulé welcomed the group by highlighting the importance of the issue in California. Scott recognized the meeting sponsors, including Waste Management, EXP Pharmaceuticals, and 20 other companies and government agencies (local and state).

OVERVIEW OF PSI DIALOGUE PROCESS

Scott Cassel presented general information about PSI and the national dialogue process, as well as the expectations of PSI as the facilitator and participants as representatives of their various agencies, organizations, and companies with authority to negotiate on their behalf. He also outlined the anticipated “road map” of four national dialogue meetings, with each meeting intended to build on the previous one so that the four meetings form a single process that results in joint agreements. Scott presented a definition of “consensus” and spoke about the importance of each stakeholder participating in good faith.

PRESENTATIONS

A Pharmaceutical Industry Perspective, Leslie Wood (PhRMA)

Leslie Wood, Director of State Policy for PhRMA, gave her presentation just prior to departing for a flight. She later provided the following summary.

Leslie Wood, Director of State Policy for the Pharmaceutical Research and Manufacturers of America (PhRMA), described to the Product Stewardship Institute on June 19, 2008, PhRMA's position on the issue of pharmaceuticals in the water. In addition, she described research and other work conducted by the Pharmaceuticals in the Environment (PIE) Task Force at PhRMA. When the first reports of trace amounts of pharmaceuticals in the environment were issued, PhRMA convened the PIE TF of science experts who take a scientific approach to studying this issue. PhRMA and independent researchers have found that there is no discernible evidence of adverse human health effects due to trace amounts of pharmaceuticals in the environment. In fact, pharmaceuticals are the most studied chemical compounds regarding potential effects on humans.

From studies on unused medicines, it can be derived that normal use and excretion of metabolized drugs accounts for approximately 90 percent of the trace amounts of medicines detected in the environment. On average, pharmaceuticals in the environment are detected at 18 parts per trillion. A part per trillion is about one second in 32,000 years or one penny per \$10 billion.

Because the traces of pharmaceuticals in the environment are mostly due to human use, take-back programs do not address the source. In addition, there are no regulations under the Controlled Substance Act for patients to return controlled medicines. PhRMA also is greatly concerned that aggregating unused medicines in communities could increase the risk of drug diversion. From its science, PhRMA believes that disposal of unused medicines in landfills is protective of the environment. To that end, we are partners with the American Pharmacists Association and US Fish and Wildlife Service on SMARxT Disposal™. The consumer outreach program is designed to educate American consumers about the proper disposal of unused medicines through the current household trash disposal infrastructure.

With regard to drug abuse, PhRMA worked with DARE America to develop a curriculum for middle and high school age adolescents about the dangers of drug abuse and misuse. PhRMA also works with the Partnership for a Drug Free America on the issue of drug abuse. PhRMA also believes it is important to address why patients have leftover medicines. For example, a recent RAND study published in the Annals of Internal Medicine found that 50% of all quality problems in the use of medicines was accounted for by underuse. PhRMA also has several programs in place that advocate the importance of medicine compliance and patient safety.

A Government Perspective, Dave Galvin (King County, WA)

In his presentation, Dave Galvin of King County, Washington, outlined issues related to the disposal of waste pharmaceuticals as expressed by the media, government officials, and others. These concerns include environmental health concerns from pharmaceuticals found in drinking water, impacts on aquatic species from pharmaceuticals in waterways, and drug misuse or abuse. He emphasized that, while the amount of any one drug detected in the water may be small, the cumulative impacts on aquatic or other species are unknown. He also emphasized that the issues regarding poisonings and abuse/diversion are substantial enough to warrant better systems to

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manage unused medicines regardless of the debate about the significance of pharmaceuticals found in the environment.

Pharmaceuticals of greatest concern owing to practical considerations (such as take-back logistics) include those that would designate as “hazardous waste” and/or those listed as “controlled substances” by the U.S. Drug Enforcement Administration (DEA). Dave acknowledged that drugs enter the environment through use (excretion) *and* disposal, although he stated that a significant amount of pharmaceuticals go unused, and medication use per capita is increasing rapidly. Additionally, the number of poisonings due to pharmaceutical exposure and the abuse of prescription drugs are rising. He stated that these problems cannot be solved by disposing of unused pharmaceuticals in the solid waste stream because people and animals can still intentionally or accidentally consume the drugs throughout the waste management process, and unmetabolized pharmaceuticals may be released to the environment in landfill leachate (before or after treatment). Dave said that he and many other government officials believe that pharmaceutical take-back programs are, therefore, essential to reduce drug poisonings and abuse, and that government agencies should not bear the primary responsibility for financing these take-back programs and other initiatives. Dave advocated for a product stewardship approach that included manufacturers being responsible for financing collections, as is done in British Columbia, Canada.

A Pharmacist’s Perspective, Shirley Reitz (Group Health Cooperative)

Shirley Reitz of Group Health Cooperative expressed the need for drug take-back programs based on statistics from a survey done in King County, Washington, which found that citizens are generally willing to bring their unused medications to a collection location if convenient. The national problem of teen prescription drug abuse and addiction, along with findings that prescription drugs are the substance most likely to cause death, make this problem pressing. Group Health pharmacy locations across Washington have started pilot projects for secure collection at pharmacies and safe disposal methods using a tracking system. Shirley does not believe that pharmacies should be responsible for financing take-back programs, even though they do contribute staff time for program implementation.

U.S. EPA Perspective, Alexis Strauss (Region 9) and Virginia Thompson (Region 3)

Alexis Strauss described the U.S. Environmental Protection Agency’s (U.S. EPA) 4-pronged approach related to pharmaceuticals and personal care products, as well as other non-endocrine disruptors:

- 1) Strengthen scientific knowledge
- 2) Improve public understanding and risk perception
- 3) Build partnerships for stewardship
- 4) Use regulatory tools.

Alexis indicated that EPA supports take-back programs to reduce the incidence of accidental poisonings and drug abuse, and EPA Region 9 has been an enthusiastic supporter of California’s *No Drugs Down the Drain* campaign. Harold Zenick, EPA Director of the National Health and Environmental Effects Research Laboratory, is coordinating research on this issue. The EPA has begun to study pharmaceutical disposal practices at health care facilities. EPA is also commissioning a National Academy of Sciences report of the potential risk to human health posed by low levels of pharmaceutical residues in drinking water. The Academy is set to advise EPA in January 2009 on methods for screening and prioritizing pharmaceuticals.

Virginia Thompson described the EPA Region 3 pharmaceuticals workgroup which integrates Region 3 Field Office programs, the Philadelphia Department of Water, and other utilities and states in the region. In addition, the workgroup coordinates with other organizations (including PhRMA) and some pharmaceutical companies. The group is developing a pilot project to identify data collection efforts related to the disposal of unused medications in the long-term care setting. Virginia reported that the Potomac Partnership in Washington, DC found intersex fish during its research. Kroger is interested in providing drug take-back at its retail locations, but prefers a national approach to a state-by-state roll-out. EPA Region 3 also held a one-day Summit with excelleRX, a hospice medication provider.

At the annual biosolids symposium at the University of California-Davis on October 1-2, 2008, particular attention will be given to the presence of pharmaceutical products in biosolids.

As questions about DEA's regulations on collecting controlled substances were raised, Scott read an excerpt of a recent letter sent by DEA to the National Association of Chain Drug Stores. DEA is in the process of revising its regulations and will issue a Notice of Proposed Rulemaking as part of a public comment period. The letter is posted on the PSI website, at <http://www.productstewardship.us/RelatedPharmaceuticalsInitiatives>.

DISCUSSION OF ISSUE STATEMENT, PROJECT FOCUS, PROJECT GOALS

Scott Cassel presented an issue statement, project focus, and project goals, all of which had been circulated for review prior to the meeting (available on the PSI meeting website at the URL above). The ensuing discussion highlighted the importance to many in the group of including a source control/reduction approach, including responsible prescription practices. Some revisions to the issue, focus, and goals were suggested.

During the discussion of the *issue statement*, the following ideas were shared about the relative importance of different aspects of the issue:

- Consumer disposal options must be safe, practical, and convenient. Ultimate disposal must be considered as well.
- "Water sources" of all kinds are the concern, although the public's focus has been on drinking water.
- There is no wastewater treatment technology that removes pharmaceuticals from the water completely.
- The expiration date of a medication is based on an average, so some products may be still be "good" after that date. Some Boards of Pharmacy mandate an expiration date. There are a number of confounding variables, such as temperature, that impact the effectiveness of a drug.
- The use of pharmaceuticals on animals, particularly livestock, should be considered in a later phase of this project.
- The small amount of pharmaceuticals that are "controlled substances" can only be taken back by law enforcement personnel, and this is not a sustainable solution.

DRAFT Dialogue Focus (discussed at meeting)

This project will focus on unwanted or waste pharmaceutical products from households, long-term care facilities (e.g., nursing homes and hospice care), and other similar generation sources from which waste pharmaceuticals may be treated as household waste (e.g., schools, cruise ships, hotels, and pet care facilities). The project will specifically address the proper management of unused pharmaceuticals that typically enter the municipal solid waste stream, municipal wastewater, or residential septic systems. The project will not focus on personal care products or non-pharmaceutical endocrine disruptors. It will not focus on problems related to the use of pharmaceuticals, although the impacts of dispensing and use practices that are relevant to the generation of unwanted and waste pharmaceuticals will be explored.

The following clarifications were offered on the *focus* of the dialogue:

- Source reduction should be included.
- We should be clear that we are considering branded, generic, and over the counter drugs in this project.

DRAFT Dialogue Goals (discussed at meeting)

1. Evaluate the need for a nationally coordinated system for the management of unwanted/waste pharmaceuticals that allows for multiple solutions to reflect local/regional differences.
2. Increase the safe, legal, and environmentally-protective management of unwanted/waste pharmaceuticals through the development of best management practices.

The following changes were made to the Dialogue Goals:

- The goal should be to “develop” a nationally-coordinated system, not to evaluate the need for one.
- The PH:ARM project group in Washington came up with a definition for an “effective” collection program that may be useful to this group.

DISCUSSION OF POTENTIAL AREAS OF JOINT RESEARCH

Scott Cassel presented several potential areas of joint research for the group’s consideration. The potential joint research areas emphasized improving a shared understanding of different aspects of the overall issue.

Potential Areas of Joint Research (discussed at meeting)

1. Quantity and type of waste/unwanted medications.
2. Extent of accidental poisonings, overdoses, thefts, diversions, and deaths attributable to waste/unwanted medications in the home.
3. Percentage of pharmaceuticals in home storage attributable to normal use vs. waste/unwanted medications.
4. Percentage of pharmaceuticals entering waterways attributable to excretion vs. other pathways.
5. Impact on aquatic species and potential impact on human health.
6. Reasons and attitudes behind household storage and disposal practices/preferences.

The following comments were offered:

- What is the dollar value of waste/unwanted medications?
- To what extent are pharmaceuticals reaching landfill leachate?

- There are also safety issues with home disposal in the garbage besides landfill leachate.
- “Disposal” should cover disposal practices in the home and the ultimate treatment/disposal of the waste.
- Why do people hold on to waste medications?
- What are the relative impacts of different drugs, as in the Swedish rating system based on ecotoxicity?

DISCUSSION OF POTENTIAL SOURCE REDUCTION STRATEGIES

Waste Reduction and Pharmaceuticals, Eva Dale (Washington Citizens for Resource Conservation)

Eva Dale discussed the importance of knowing which drugs become waste most frequently and why, which allows her organization to prioritize efforts to reduce waste and eco-toxicity of pharmaceuticals (source reduction). Suggestions about how to achieve these goals include using smaller initial doses, eco-toxicity ratings, and individualized dosages based on body weight. These strategies may help solve the problem of pharmaceuticals in the environment prior to the need for disposal.

Data Collection from Green Pharmacy Campaign, Joel Kreisburg (Teleosis Institute)

Joel Kreisburg from the Teleosis Institute outlined the type of data collected from the Green Pharmacy Campaign. Pharmaceuticals were found to enter the environment from people disposing of medicines in the garbage or flushing them down the toilet, but primarily through excretion. Collection sites participating in the Green Pharmacy Pilot project in the Bay Area provided educational information for the public and health professionals. From this collection, the Bay Area group was determined the types and quantities of drugs collected, why drugs were collected, and from where the drugs came. Joel suggests that these data can help refine and implement pharmaceutical stewardship.

Potential Source Reduction Strategies (discussed at meeting)

1. Modify prescribing practices to avoid excess medications (samples to try, small initial doses, identify potential allergies/drug reactions upfront).
2. Educate consumers about taking all medications as prescribed.
3. Modify reimbursement formulas and sales that currently encourage prescription of larger doses.

The following comments were offered on the potential source reduction strategies listed above:

- Insurers and third party payers should be educated about the impacts of their administrative preference for dispensing larger amounts of drugs at one time.
- What are the root causes of excess medications?
- Since health care is increasingly taking place in homes, education should focus there.
- This group should consider translating the Swedish toxicity rating system to the U.S., which might provide an impetus for people to take unwanted drugs to a collection location.
- This group is primarily state and local government officials without medical expertise; it is important that medical professionals make recommendations related to patient care.
- A Minnesota focus group of pharmacists developed three potential solutions to the problem of unwanted/waste medications.

DISCUSSION OF POTENTIAL COLLECTION AND DISPOSAL OPTIONS

Overview of Collection and Disposal, David Stitzhal (Full Circle Environmental and Northwest Product Stewardship Council)

David described four options for pharmaceutical collection:

- (1) One-day/short-term collection events. There are many problems with this type of collection including the necessary presence of law enforcement officials, unpredictability, high cost, and inconvenience.
- (2) Collection by law enforcement (controlled substances). Some issues with this form of collection are inconvenience, uncomfortable atmosphere, a small amount of medications collected, hard to reproduce, and keeping track of all medications.
- (3) Mail-back collection, which has been used in Maine. Mail-backs have high costs without permanent financing; one suggestion is for pharmacies to provide mailers.
- (4) Household hazardous waste collection. Already implemented in many communities, these programs are inconvenient, sparse, have irregular hours, expensive, funded by taxpayers, cannot accept controlled substances, and are not secure.

Some pharmacies have conducted pharmaceutical take-back programs, although there are no uniform procedures for such collections. The most important aspects of a successful collection program are convenience, security, a wide range of drugs accepted (including controlled substances), and a sustainable financing mechanism.

PH:ARM Project, Sego Jackson (Snohomish County, WA)

Sego discussed the details of PH:ARM, a program for the safe disposal of pharmaceuticals based on collection at pharmacy locations. The key factors of success identified by the PH:ARM project group are safety, security, financial sustainability, convenience, funding by the private sector, and government assistance to oversee the process. The PH:ARM pilot program began in November 2006 at seven Group Health Cooperative locations. Today, there are 24 Group Health collection sites and a small but growing number of Bartell's Drugs pharmacies participating as well. The pilot program plans to run for two years, after which it is intended by its founders to transition to a producer responsibility model. The collection box is a metal drop box, which has proven to be secure, effective, and easily tracked. After return to the pharmacy distribution center, the pharmaceuticals are picked up and destroyed.

Reverse Distribution, Mark Harvey (EXP Pharmaceuticals)

Mark Harvey described the rationale behind reverse distribution. Reverse distributors receive potentially creditable pharmaceutical products from pharmacies and return them for credit to manufacturers. Obstacles preventing more efficient drug take back programs using reverse distributors include the DEA regulations (which restrict who can collect controlled substances), the U.S. Postal Service (which would need to change its domestic mail manual to allow for waste pharmaceuticals to be sent via U.S. mail), and state and local regulatory agencies, which may or may not regulate waste pharmaceuticals once collected from consumers. Pharmaceuticals collected can include or exclude controlled substances, and programs can be of two types: drop-off or mail-back. The benefits of drug take back programs include reduced teen "pharming," increased safety for patients, children, and the elderly, and less environmental impact.

Potential Collection and Disposal Strategies (discussed at meeting)

1. Develop consensus on best management practices for safe disposal from the home (either long-term or interim).
2. Develop best practices for collection locations, including ultimate disposal.
3. Identify existing, or develop new, demonstration projects to collect data on the relative costs, logistics, and performance of mail-back and/or collection at various locations.
4. Develop unified and consistent messaging regarding the safe and environmentally sound disposal of waste pharmaceuticals (may be based on lessons learned).
5. Evaluate performance of existing and potential future collection programs.

The following comments were offered on the potential strategies listed above:

- Collection options should consider regional differences, such as urban and rural areas.
- Why does the U.S. DEA trust the U.S. Postal Service to handle unwanted/waste drugs (controlled substances) when pharmacists and local governments are not allowed to do so without law enforcement?
- Collecting data on the type/manufacturer of medications from return programs is possible and may be important, but it will add cost.
- Data on whether collecting in a retail pharmacy increases sales would be useful. Perhaps pharmacies that are about to start collection efforts could do a before/after analysis to show what, if any, impact collection has on sales.
- What is the environmental impact of transporting materials collected?
- What is the impact of deputizing collection facilities on the potential reach and effectiveness of a collection program?

DISCUSSION OF REGULATORY ISSUES

Drug Enforcement Issues Related to Collection/Reverse Distribution, David Stitzhal (Full Circle Environmental and Northwest Product Stewardship Council; presentation prepared by Stan Jeppesen, WA Board of Pharmacy)

Regulatory barriers pertaining to the Northwest's pharmaceutical return program (known as PH:ARM) stem from regulations administered by the U.S. Department of Transportation, U.S. EPA, Regional Air Board Permitting Agencies, U.S. Postal Service, and U.S. DEA. The DEA is responsible for implementation of regulations under the Controlled Substances Act, which states that patients can only transfer controlled substances to a law enforcement official. It is silent on the issue of pharmaceutical waste and take-back programs. To address DEA's concerns, PH:ARM designed a secure collection container with no personnel necessary at the time of collection. The system allows for, but does not require, disposed materials to be tracked. PH:ARM requested a waiver from DEA to collect controlled substances, but did not receive one. The disposal of controlled substances through the U.S. Postal Service also requires a waiver.

Potential Regulatory Strategies (discussed at meeting)

1. Change DEA regulations to facilitate collection of waste/unwanted pharmaceuticals from consumers.
2. Change the Controlled Substances Act to allow for the return of controlled substances.

The following comments were offered on the potential strategies listed above:

- In order to become a DEA registrant, a company or other entity must undergo an investigation of the facility and their security officers. Currently, only certain entities can be registrants, such as pharmacies, doctors, and wholesalers.
- When drugs collected are considered hazardous under the Resource Conservation and Recovery Act (RCRA) and transported across state lines, Department of Transportation regulations take effect. This requires additional documentation.
- The Prescription Drug Marketing Act could allow manufacturers to arrange for the collection and disposal of sample drugs they distribute.

INFORMATION EXCHANGE ON FINANCING SYSTEMS FOR THE MANAGEMENT OF WASTE PHARMACEUTICALS

European Examples, David Stitzhal (Full Circle Environmental and Northwest Product Stewardship Council)

David Stitzhal described programs in Spain and France. The Spain Integrated Waste Management System's take-back program accepts all medications (including packaging) at pharmacies nationwide under a program managed by a manufacturer-financed product stewardship organization since 2002. In France, pharmacies, manufacturers, and wholesalers collaborate on a medicine and packaging take-back funded entirely by industry. Established in 1995, the association that runs the program educates consumers through leaflets when medicines are sold, along with various other advertisements.

Canadian Model, Ginette Vanasse (Post Consumer Pharmaceutical Stewardship Association)

Ginette Vanasse described the Post Consumer Pharmaceutical Stewardship Association, which helps pharmaceutical and self-care health product industries achieve stewardship solutions. The program operates in British Columbia, where it is free to those returning their medications to pharmacies. Pharmacy participation is completely voluntary. The association also does much work to advertise and promote its programs. The responsibility to fund the program falls on companies with a registered trademark or the licensee of a trademark (including both brand-name and generic).

Consumers return their drugs to pharmacies, and the pharmacy contacts the program administrator when a container is full for pick up. The program records the quantity of pharmaceuticals collected, and pharmaceuticals are stored until they are incinerated. The program has succeeded in getting Canadians to return their unused or expired medications.

In response to questions, Ginette provided the following additional information:

- In Canada, there is no parallel to the Controlled Substances Act.
- Pharmacists serve as collection points because they are familiar with handling drugs.
- Collection data are kept in terms of weight, not type of pill.
- 93.4% of pharmacies in British Columbia are participating voluntarily. The pharmacists' association was a key player in launching the program.

Oregon’s Pharmaceutical Initiative, Janet Gillaspie (OR Association of Clean Water Agencies) and Abby Boudouris (OR Department of Environmental Quality)

Janet Gillaspie described Oregon’s drug take back model. The stakeholder group held workshops, conducted research, and recommended potential solutions and funding mechanisms. Suggestions included a solid waste disposal fee (paid to municipal and industrial landfills, incinerators, and energy recovery facilities), pharmaceutical outlet fees (paid to retail pharmacies – manufacturers, wholesalers, and reverse distributors), or a combination of the two. Other funding options include financing by the State General Fund, a surcharge on wastewater or drinking water utility bills, a fee on each prescription, or a product stewardship approach, where industries fund and operate the program.

STRATEGIES AND NEXT STEPS

Four workgroups were developed to address the strategies listed below.

Issue Area	Strategies
WORKGROUP #1: Joint Research/ General	Quantity, type, and dollar value of waste/unwanted medications.
	What are the impacts of take back programs? (Do they reduce teen “pharming,” poisonings, etc.?)
	What are the best available technologies for destruction and disposal?
	What sites in the country accept waste pharmaceuticals and what are the GHG implications of transportation to these facilities?
	What actions are necessary to allow hazardous waste incinerators to accept controlled substances (e.g., deputization)?
WORKGROUP #1: Joint Research: Diversion/poisonings	Extent of abuse/diversions and accidental poisonings attributable to waste/unwanted medications in the home.
	Percentage of pharmaceuticals in home storage attributable to normal use vs. waste/unwanted medications.
	What is the cost to society of accidental poisonings from waste pharmaceuticals?
	Do collection events present an opportunity for diversion?
WORKGROUP #1: Joint Research: Environment	Percentage of pharmaceuticals entering waterways attributable to excretion vs. other pathways.
	Impact on aquatic species and potential impact on human health.
	To what degree are pharmaceuticals present in leachate and what risks do they represent?
	Are pharmaceutical residuals found in landfill leachate, and are they expected to increase or decrease over time?
WORKGROUP #1: Joint Research: Behavior and Education	What are the reasons and attitudes behind household storage and disposal practices and preferences?
	What is the average consumer willing to do to dispose of their waste pharmaceuticals “properly”?
WORKGROUP #2: Source Reduction	Modify prescribing practices to avoid the excess purchase of medications (e.g., vouchers for samples to try, small initial doses, ID potential allergies/drug interactions up front)
	Educate consumers about taking all medications as prescribed

Issue Area	Strategies
	Work with physicians and insurance companies to encourage the use of smaller doses when possible
	Develop ecotoxicity rating as used in Sweden to reduce impacts of pharmaceuticals on water even after excretion.
WORKGROUP #3: Collection and Disposal	Develop consensus on best management practices for safe disposal from the home (either long-term or interim).
	Summarize protocols for collecting waste medications under different scenarios, including ultimate disposal.
	Identify existing or develop demonstration programs to collect data on the relative costs, logistics, and performance of mail-back and/or collection through various locations.
	Develop unified and consistent messaging regarding the safe and environmentally sound disposal of waste pharmaceuticals.
	Consider options to reduce the cost of mail-back programs (e.g., packaging, return distance, etc.)
	Develop strategies for engaging retail pharmacies in collecting waste medications (e.g., share lessons learned from retail pharmacies successfully collecting; increased consumer sales among pharmacies collecting, etc.).
WORKGROUP #4: Regulations	Work with DEA through public comment period or other process on Controlled Substances Act regulations that impact collection programs
	Work with Congressional delegations to advocate for change to Controlled Substances Act such that collection programs would be possible
	Clarify RCRA barriers to collection programs (collection location reaching generator status, whether materials collected from households are included, etc.)
	Brief the presidential transition team on the issue
	Review Prescription Drug Marketing Act language providing for manufacturers to arrange for the disposal of sample drugs
	Review Controlled Substances Act language to determine section that allows for companies to accept drug returns.

Meeting #2

PSI will identify a location and venue for the second meeting to be held in Washington, DC. The meeting will be sponsored by King Pharmaceuticals.

- Agenda Items. Meeting #2 will focus on regulatory issues, and include reports from all workgroups.
- Missing Stakeholders. The group identified stakeholders who were not present at the first meeting but who they felt should attend the second meeting. PSI contacted many of these groups prior to the first meeting, but will need the concerted effort of the full dialogue group to contact these groups and strongly encourage them to attend the 2nd meeting.

Workgroups

The following four workgroups were established to conduct additional research and initiate other efforts between the first and second meetings. The workgroups correspond to the issue areas

shown in the table above. Each workgroup will develop its priorities, identify resources needed, develop a work plan (including timeline), and present the results of its efforts at Meeting #2.

<p><u>Joint Research:</u></p> <p>Cynthia Lane, <i>American Water Works Association</i> Lisa Huff, <i>U.S. Environmental Protection Agency</i> Catherine Zimmer, <i>University of Minnesota</i> Joel Kreisberg, <i>The Teleosis Institute</i> Alice Chapman, <i>Local Hazardous Waste Management Program in King County, WA</i> Adrian Simmons, <i>OK Department of Environmental Quality</i> David Trindell, <i>Hoffmann-La Roche Inc. (Roche)</i></p>	<p><u>Source Reduction:</u></p> <p>Diana Phelps, <i>CA Department of Toxic Substances Control</i> Virginia Thompson, <i>U.S. Environmental Protection Agency – Region 3</i> Eva Dale, <i>Washington Citizens for Resource Conservation</i> Anna Gilmore Hall, <i>Health Care Without Harm</i> Laurie Tenace, <i>FL Department of Environmental Protection</i> Catherine Zimmer, <i>University of Minnesota</i> Joel Kreisberg, <i>The Teleosis Institute</i> Mary Hendrickson, <i>Capital Returns</i> Lyn Smirl, <i>BC Ministry of Environment</i></p>
<p><u>Collection/Disposal:</u></p> <p>Jennifer Jackson, <i>East Bay Municipal Utility District, CA</i> Theresa Stiner, <i>IA Department of Natural Resources</i> Bill Turpin, <i>Waste Management, Inc.</i> Catherine Zimmer, <i>University of Minnesota</i> Marty Strauss, <i>City of Sacramento, CA</i> Offad Vallejo, <i>Becton-Dickinson Medical</i> Kim Stevenson, <i>Veolia Environmental Services</i> Mark Harvey, <i>EXP Pharmaceutical Services Corp.</i> Bruce Thompson, <i>Stericycle</i> Sharon Newton, <i>City of San Jose, CA</i> Luther St. James, <i>U.S. Environmental Protection Agency</i> Jack McGurk, <i>Sharps Compliance</i> Andria Ventura, <i>Clean Water Action/Clean Water Fund</i> Sego Jackson, <i>Snohomish County, WA</i> Veronica Blette, <i>U.S. Environmental Protection Agency, Office of Water</i> Mary Hendrickson, <i>Capital Returns</i> Jennifer Volkman, <i>MN Pollution Control Agency</i> Lyn Smirl, <i>BC Ministry of Environment</i></p>	<p><u>Regulations:</u></p> <p>David Stitzhal, <i>Full Circle Environmental, Inc.</i> Virginia Thompson, <i>U.S. Environmental Protection Agency – Region 3</i> Jennifer Jackson, <i>East Bay Municipal Utility District, CA</i> Anna Gilmore Hall, <i>Health Care Without Harm</i> Phil Bobel, <i>City of Palo Alto, CA</i> Sharon Siler, <i>Avalere Health LLC</i> Virginia Strom-Martin, <i>Sonoma County Water Agency, CA</i> Melody LaBella, <i>Central Contra Costa Sanitary District & HHW Collection Facility</i> Jack Price, <i>FL Department of Environmental Protection</i> Catherine Zimmer, <i>University of Minnesota</i> Alexis Strauss, <i>U.S. Environmental Protection Agency</i> Abby Boudouris, <i>OR Department of Environmental Quality</i> Robert Ellis, <i>EXP Pharmaceutical Services Corp.</i> Bruce Thompson, <i>Stericycle</i> Cookie Quandt, <i>Long's Drug Store</i> Andria Ventura, <i>Clean Water Action/Clean Water Fund</i> Sego Jackson, <i>Snohomish County, WA</i> Mary Hendrickson, <i>Capital Returns</i> Lyn Smirl, <i>BC Ministry of Environment</i></p>