Snohomish County

Grant No. G0800005

GRANT TITLE: Northwest Straits: MRC Year 6 Administration and Action Projects

TASK NO: 4.1 Pharmaceutical Take-Back Education and Research

(___) ANNUAL REPORT (January 1 – December 31)
(___) WORK PLAN
(___) PROGRESS REPORT No. 1 ☐ No. 2 ☐ No. 3 ☐
(___) FINAL PROGRESS REPORT
(___) PROJECT COMPLETION REPORT
(XX) SUMMARY REPORT Year 1 ☑ Year 2 ☐
(___) TECHNICAL REPORT

PERIOD COVERED: July 1, 2007 – June 30, 2008

DATE SUBMITTED: June 15, 2008

This report was funded in part through a cooperative agreement with the National Oceanic and Atmospheric Administration.

# SUMMARY REPORT

## Task Title: TASK NO: 4.1 Pharmaceuticals from Households: A Return Mechanism

### Project Sponsors

- Snohomish County Marine Resources Committee (MRC)
- Snohomish County Solid Waste Management Division
- Washington State Board of Pharmacy
- Washington State Department of Ecology (DOE)
- Washington State Department of Social and Health Services
- King County Local Hazardous Waste Management Program
- Pacific Northwest Pollution Prevention Resource Center (PPRC)
- Washington Citizens for Resource Conservation (WCRC)
- Group Health Cooperative
- Seattle and King County Public Health
- Interagency Resource for Achieving Cooperation (IRAC)
- Northwest Product Stewardship Council

### Project Funders

- Bartell Drug Company
- Group Health Cooperative
- National Oceanic and Atmospheric Administration (NOAA)
- North American Hazardous Materials Management Association (NAHMMA)
- Northwest Product Stewardship Council
- Northwest Straits Commission
- Snohomish County Public Works
- Snohomish County Marine Resources Committee
- WA Department of Ecology/Solid Waste & Financial Assistance Program

### Project Background

Household pharmaceutical wastes are detectable at low but environmentally significant levels in the streams, lakes and other tributary surface waters that flow in Puget Sound. Scientists are beginning to link pharmaceutical contaminants in surface water to biological effects on the endocrine systems of hundreds of freshwater, estuarine and marine species. The detection of pharmaceutical compounds stems from a variety of sources, but one significant contributor is the direct disposal of waste pharmaceuticals to the sewer or the landfill.

In addition to concerns about environmental impacts, there is some concern about social impacts. When these unwanted medications are left in the home, they may increase opportunities for drug abuse, diversion, teen “pharming” and accidental poisonings.

The Washington PH:ARM (Pharmaceuticals from Households: A Return Mechanism) Coalition has initiated the first phase in a pilot take-back program to collect unwanted household medical waste. Beginning in October 2006, the PH:ARM Coalition has established the take-back program in 25 Group Health Cooperative clinical pharmacies in 6 counties within a 13 month period.

The PH:ARM Coalition envisions an eventual statewide medicine return program available at all pharmacies that is managed and funded by pharmaceutical manufacturers.

**Project Objectives (Bulleted list)**

Our objectives were to facilitate PH:ARM's mission to create a simple, low-cost and secure take-back system to collect unwanted medications from households and small quantity sources. This program will provide a mechanism for the return of any and all unwanted pharmaceuticals from households including pharmaceutical pills, capsules and tablets, vitamins, medicated ointments, cough syrups, antibiotics, and inhalers that are either over-the-counter, prescribed or controlled substances. Efforts are being directed toward establishing continuous year round locations at local pharmacies and nursing homes that is ultimately funded by pharmaceutical manufacturers. This effort will reduce pharmaceutical pollution in Puget Sound and other waters, while improving public safety.

Specific objectives under this grant included:

- Develop a list of key stakeholders for the use of the PH:ARM Coalition.
- Disseminate information on medicinal disposal, the pilot pharmaceutical take-back program in WA, and educational/stakeholder
- Convene a one-day workshop on establishing a Medicine Take-Back Program in Washington State
- Engage manufacturers in the process of developing the program.
- Build stakeholder support for the medicine take-back program.
- Promote legislation that can be supported by all stakeholders involved.

**Project Implementation (Who did the work, when and where)**

*Workshop Planning*

In October, the Snohomish County MRC staff began researching and building a database of stakeholders for the "Medicine Take Back" program. They compiled a list of over 1,000 contacts which included stakeholders from pharmaceutical manufacturers, distributors, retailers, healthcare insurers, practitioners and facilities such as HMOs, medical clinics, assisted care, and hospice (See Attachment 1.1). It also included social and civic organizations, government and educational entities, plus interested nonprofits, professionals and citizens.

In December, the list was transferred to the Pacific Northwest Pollution Prevention Resource Center (PPRC) to take over duties of database manager. Their Communications Specialist continued to add contact information for new stakeholders up until the workshop, and will continue to do so as this Take Back Program develops.

The one-day invitation-only workshop event was scheduled for April 18th, 2008 from 8:00am – 4:30pm. Chris Betchley, Temporary Associate Planner for the Marine Resources Program, secured the Seattle Airport Marriot facilities for the workshop. Workshop package included the main event room, five additional breakout rooms, meals (breakfast, lunch, and snacks), parking and twenty additional hotel rooms at reduced rates for out of town guests.

In January, the PH:ARM Coalition chose 150 stakeholders from the database that they wanted represented at the workshop. An e-mail invitation was developed by the Snohomish County Graphics Department, and was sent off in March (See Attachment 3.4). By the deadline, the team had received only 50 RSVPs. The WCC IP Marine Resources Program Assistant, Amy Johnson, was recruited to call the invited individuals who had not registered yet to inquire if they received the invitation, and to remind them about the event. As a result, approximately 50 more invitees registered for the event.

*Workshop Event*

Over 80 individuals attended the workshop representing a diverse set of interests, including environmental groups, state legislators, pharmaceutical manufacturer lobbyists, and healthcare professionals (See Attachment 6.1). It was the first opportunity for all the stakeholders to come together and share ideas, concerns, and updates on the PH:ARM Pilot Project. Each participant was given a packet of information that included the agenda along with educational materials and copies of all the PowerPoint presentations (See Attachment 5).

The morning of the workshop was spent briefing the participants on the issues and status of the PH:ARM Pilot Project, with presentations by the Coalition and partners, as well as the pharmaceutical manufacturers. During the afternoon, key breakout groups were formed and discussed focus questions for gathering support and ideas for next steps:

- If we are completely successful in establishing a state-wide medicine take-back program, how will the world be different?
- What will it take for you to support a manufacturer-funded medicine take-back program?
- What are the next steps needed to bring about a state-wide medicine take-back program?
- How can groups in this room collaborate to bring this about?

- What are you and your organization willing to do, to contribute to this effort?

The workshop ended with a report-back on the results of the breakout sessions, and a discussion about next steps for the PH:ARM Pilot Project.

*Workshop Analysis and Evaluation*

Adele Barilleaux of Snohomish County Solid Waste compiled and transcribed the notes from the breakout sessions and the action sheets into an Excel spreadsheet (See Attachment 4.1) for ease of reviewing. Cathy Buller of Pacific NW Pollution Prevention Resource Center (PPRC) summarized the highlights of the findings into key actions (See Attachment 4.2).

**Discussion (Did you meet the planned objectives? If not, why not?)**

As of April 2008, more than 7,500 pounds of consumer-packaged drugs have been collected. Bartell Drugs opened its first collection site, and will soon expand to 10 collection sites around Puget Sound. Two boarding/nursing homes will also begin accepting unwanted medicines soon.

The database served as contact information for key stakeholders to allow for easy dispersal of education materials and other stakeholder opportunities. It was effective in deciding not only which key stakeholders should attend the workshop, but also in determining who is missing from the list.

The one-day workshop was very successful, and a lot of actionable next steps came out of it. Sego Jackson from Snohomish County Solid Waste noted that he was impressed by the networking and breakout planning that had been done even during lunch. There was a lot of excitement from all stakeholder interests to get these issues worked out. An important objective was to engage manufacturers in this process, and by bringing them to the table at the workshop and allow them to present, we effectively let their perspectives and concerns surface.

When the participants were asked specifically what types of things they or their organization would be willing to do, we received a lot of positive feedback. Most participants were willing to assist with outreach and education to the public, drug companies, legislators, etc, and some were also willing to support legislation and researching funding sources for a long-term program. For more information about the types of feedback and support the workshop received, see attached summary sheet compiled by PPRC (See Attachment 4.2).

**Recommendations (Do you have recommendations for the next year's implementation or to others doing similar work?)**

The Snohomish County MRC should continue supporting the establishment of a permanent "Medicine Take Back" program for unwanted household medicines in Washington State. We also encourage the NWSC to support legislation in 2009 for the Secure Medicine Return Bill (see attached).

Information on proper disposal of these unwanted household medicines and available take-back locations should be included in our outreach programs to the citizens of Snohomish County. An opportunity that the NWSC and other MRCs should also take advantage of is environmental-focused education/outreach efforts. Currently, most of the messaging for this take-back program is focusing on the safety/abuse issue, and not targeting the environmental messaging. However, initial survey results (completed by WCRC and funded by private foundations; See Attachment 1.4) indicate 76% of respondents stated that protecting the environment is a benefit to returning unwanted medications. Because of this response, it is likely that the public will support an environmental message.

**Resources/References**
See Attachments

**Attachments (On CD)**
1. Database Contact List (Folder)
   1.1. ContractMatrixReport.pdf

2. Educational and PR Materials (Folder)
   2.1. Medicine Return Website (Folder of PDFs)
   2.2. MedicineReturnBrochure.pdf
   2.3. MedicineReturnPressRelease.pdf
   2.4. PHARM survey report May07.pdf
   2.5. PHARMProdStewPresentation.pdf
   2.6. SecureMedicineReturnLegislationFactSheet.pdf
   2.7. UnwantedMedicationsPrimer07.pdf

3. Workshop Invitations and Agendas (Folder)
   3.1. Agenda.pdf
   3.2. Don't Forget To Register.pdf
   3.3. Register Now.pdf
   3.4. Save the Date.pdf

4. Workshop Notes and Summaries (Folder)
   4.1. PHARMWkshopBreakoutandActionNotes.pdf
   4.2. PrelimWorkshopSummary_BreakoutandActionNotes.pdf

5. Workshop Packet Materials (Folder)
   5.1. BreakoutSessionsQuestions_worksheet.pdf
   5.2. IssuesandStatus_GalvinPresentation.pdf

5.3. PharmManufacturerInterests_handout.pdf
5.4. PharmManufacturerRetailerInterests_Finan_and_WoodPresentation.pdf
5.5. TakeBackModels_StitzhalPresentation.pdf
5.6. TakebackModelsBC_handout.pdf
5.7. TakebackModelsBC_MacdonaldPresentation.pdf
5.8. TakeBackModelsBC_powerpoint.pdf
5.9. TakeBackModelsOregon_handout.pdf
5.10. UpcomingActionSteps_ReplyForm.pdf
5.11. WAmedicinereturnlegislation_MelePresentation.pdf
5.12. WAPharmPilotProgressReport_handout.pdf
5.13. WAPharmPilotProject_CompiledPresentations.pdf
5.14. WAPharmPilotSummary_handout.pdf

6. Workshop Sign-In Sheet (Folder)
   6.1. Ph_armSignInSheet.pdf

# Medicine Take-Back Workshop

April 18, 2008
Sea-Tac Marriott

Establishing a Return Program for Household Drugs

**8:00 am** **REGISTRATION/CHECK-IN**

**8:30 am** **WELCOME AND OPENING REMARKS**
Cheri Grasso, Local Hazardous Waste Management Program in King County
Representative Tami Green, R.N., University Place

**8:45 am** **OVERVIEW: ISSUES, STATUS**
Dave Galvin, Local Hazardous Waste Management Program in King County

**9:10 am** **PERSPECTIVES ON NEED FOR HOUSEHOLD MEDICINE RETURN**
Caleb Banta-Green, University of Washington Alcohol and Drug Abuse Institute
Ken Butti, LOTT Alliance (Lacy-Olympia-Tumwater-Thurston County)
Chris Johnson, Washington State Attorney General's Office
Shirley Reitz, Group Health Cooperative
Leslie Ann Rose, Citizens for a Healthy Bay

**9:40 am** **PHARMACEUTICAL MANUFACTURER AND RETAILER INTERESTS**
Dan Connolly, Bartell Drug Company, Assistant Vice-President, Pharmacy
Doug Finan, GlaxoSmithKline, Director of Environmental Health & Safety
Leslie Wood, Pharmaceutical Research and Manufacturers of America (PhRMA) Director: State Policy

**10:15 am** **MORNING BREAK**

**10:35 am** **TAKE-BACK PROGRAM MODELS**
David Stitzhal, Northwest Product Stewardship Council
Brock Macdonald, Executive Director, Recycling Council of British Columbia

**11:10 am** **REPORT BACK ON WASHINGTON PH:ARM PILOT PROJECT**
Cathy Buller, Pacific Northwest Pollution Prevention Resource Center (PPRC)
Shirley Reitz, Group Health Cooperative
Stan Jeppesen, Washington Board of Pharmacy
Alice Chapman, Local Hazardous Waste Management Program in King County
Eva Dale, Washington Citizens for Resource Conservation (WCRC)
Will Perry, Public Health – Seattle and King County

**12:10 pm** **LUNCH (provided)**

**1:10 pm** **WASHINGTON PHARMACEUTICAL RETURN LEGISLATION**
Suellen Mele, Washington Citizens for Resource Conservation
Representative Dawn Morrell, R.N., Puyallup

**1:45 pm** **BREAKOUT SESSIONS: ESTABLISHING A LONG-TERM MEDICINE TAKE-BACK PROGRAM**
Facilitator: Sego Jackson, Snohomish County Public Works

**2:45 pm** **AFTERNOON BREAK**

**3:00 pm** **HIGHLIGHTS FROM BREAKOUT GROUPS**
Facilitator: Sego Jackson, Snohomish County Public Works

**3:45 pm** **UPCOMING ACTION STEPS**
PH:ARM Team Representatives

**4:20 pm** **CLOSING REMARKS**
Representative Dawn Morrell, R.N., Puyallup
Dave Galvin, Local Hazardous Waste Management Program in King County

# Medicine Take-Back Workshop *sponsors*

## The Medicine Take-Back Workshop is brought to you by a coalition of representatives and advisors from:

- **Bartell Drug Company**
- **Group Health Cooperative**
- **Interagency Resource for Achieving Cooperation (IRAC)**
- **Local Hazardous Waste Management Program in King County**
- **Northwest Product Stewardship Council**
- **Pacific Northwest Pollution Prevention Resource Center (PPRC)**
- **Public Health - Seattle and King County**
- **Snohomish County Public Works Solid Waste**
- **Washington Board of Pharmacy**
- **Washington Citizens for Resource Conservation (WCRC)**
- **Washington Department of Ecology**
- **Washington Department of Social and Health Services**

## Financial support for the Medicine Take-Back Workshop has been provided by:

- **Bartell Drug Company**
- **Group Health Cooperative**
- **National Oceanic and Atmospheric Administration (NOAA)**
- **North American Hazardous Materials Management Association (NAHMMA)**
- **Northwest Product Stewardship Council**
- **Northwest Straits Commission**
- **Snohomish County Public Works Solid Waste**
- **Snohomish County Marine Resources Committee**
- **Washington Department of Ecology/Solid Waste and Financial Assistance Program**

# Medicine Take-Back Workshop *green practices*

## Seattle Marriott SeaTac Hotel green practices include:

- Recycling of paper, bottles and cans
- Use or donation of unserved food and composting of food scrap
- Use of durable tableware rather than disposable
- Replenishment of refreshments only as needed to prevent food waste
- Recycling kitchen oil for biodiesel fuel
- Water served in pitchers rather than plastic bottles

## Other Workshop Green Practices include:

- Invitations sent electronically rather than printed
- Folders and handouts printed on recycled stock
- Reusable name tag holders (please return yours as you leave)

With all the recent media coverage on pharmaceuticals found in drinking water *now is the time* to gather key stakeholders in Washington State to start talking about what it will tatke to create an effective statewide take-back program for household drugs. Don't miss out on the opportunity to have your voice heard!


***Register Now!***
***Friday, April 18, 2008***
***Seattle Vicinity, Washington***

You have been selected to attend a free invitation-only, participatory workshop to establish a return program for unwanted household drugs throughout Washington State.

Join key stakeholders to:
- Examine issues
- Strengthen partnerships
- Review results/lessons from pilot project
- Discuss next steps to establish a secure, long-term medicine take-back program

**Register** now to reserve your seat. You will receive additional information after registering.

Please join us April 18th for a workshop to address the residential drug disposal dilemma and determine the next action steps in establishing a secure take-back system for Washington State.

This invitation-only, one-day workshop is being planned by a consortium of key health, government, environmental and citizen groups concerned with the impacts of improper residential drug disposal. Drugs that accumulate in our medicine cabinets can contribute to accidental poisonings and possible diversion, which can lead to abuse. Much of the unwanted medicine that is flushed down toilets or thrown in the trash will end up in our surface or ground water, potentially harming our environment.

Because space is limited, we want to ensure the participation of interested, thoughtful representatives from key stakeholder groups. You have been chosen as an invitee. If you are unable to attend or have a colleague or contact that you think would be a good contributor to the workshop, please send an e-mail with the pertinent contact information to takeback@pprc.org.

Watch for additional emails with more information to come.

**Invited Guests, Register Now!**

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If you would like your name removed from future e-mail lists, please send an email to takeback@pprc.org.

Information on Medicine Take-Back issues and the current Washington State pilot program can be found at www.medicinereturn.com.

# Why Return Unwanted Medicines?

**1.** Your home is safer. Help protect children and the elderly from the most common cause of accidents. Storing unwanted medications puts everyone in your home at risk.

**2.** Proper and safe disposal of unwanted medications prevents theft and other misuse.

**3.** When you return your medications for proper disposal, you are protecting local waters and aquatic life.

The **Medication Take-Back Program** is available at participating pharmacies. To locate a participating pharmacy, call **1-800-732-9253** or visit **www.MedicineReturn.com.**

This Program is only available during pharmacy hours of operation.

*Ask your pharmacist additional questions about medication use or disposal procedures.*

For more information, please visit **www.MedicineReturn.com** or call **1-800-732-9253**


This program is made possible by:

- Bartell Drugs
- Group Health Cooperative
- Group Health Community Foundation
- Interagency Resource for Achieving Cooperation (IRAC)
- Local Hazardous Waste Management Program in King County
- Northwest Product Stewardship Council
- Pacific NW Pollution Prevention Resource Center
- Public Health – Seattle & King County
- Puget Sound Action Team
- Seattle Public Utilities
- Snohomish County Solid Waste Division
- The Russell Family Foundation
- Washington Citizens for Resource Conservation
- Washington State Department of Ecology
- Washington State Department of Social and Health Services – Aging and Disability Services Administration Project Advisor
- Washington Board of Pharmacy (Project Advisor)

*Printed on 100% post-consumer recycled, chlorine-free paper*

*Illustrations: Shannon Leahy • Design: EcoChica Design*

Printed: 5/15/07


# Return Unwanted Medications

## for Free & Safe Disposal

### Protect your family

Returning unwanted medications makes your home safer.

### Protect our community

Proper and safe disposal prevents theft and other misuse of medications.

### Protect our environment

Flushing or throwing away medications puts our waterways and aquatic life at risk.

Take it BACK Network

# How to Return Your Unwanted Medicines

**1.** Gather your unwanted medications. See list to the right to find out which items can be returned. Leave items in the original containers. Mark out any personal information if you wish.

**2.** Bring medications to a participating pharmacy. To locate a participating pharmacy call **1-800-732-9253** or go to www.MedicineReturn.com

**3.** Deposit medications into the secure bin marked for "medication return".

*Cleaning out your medicine cabinet will help avoid mistakes.*


## What Can You Return For Safe Disposal?

### Return: YES!

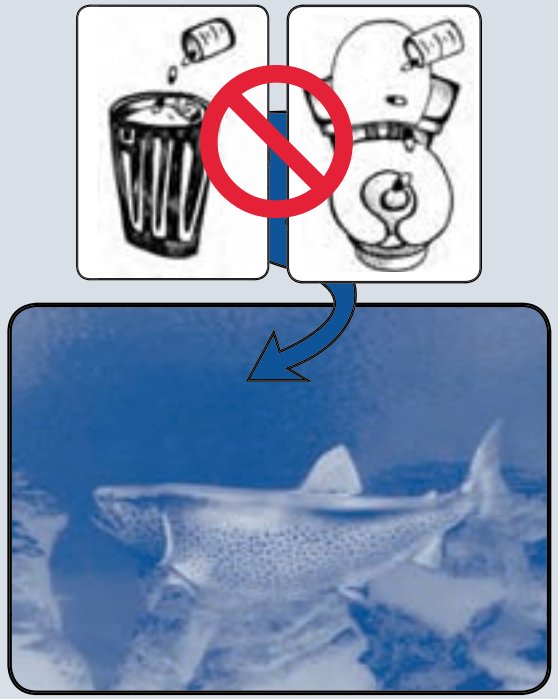
- ☑ Prescription medications
- ☑ Over-the-counter medications
- ☑ Medication samples
- ☑ Medications for pets
- ☑ Vitamins
- ☑ Medicated ointments/lotions
- ☑ Inhalers
- ☑ Liquid medication in glass or leak-proof containers

### Return: NO!

- ⦸ Needles
- ⦸ Thermometers
- ⦸ Narcotics (controlled substances)
- ⦸ IV bags
- ⦸ Bloody or infectious waste
- ⦸ Personal care products
- ⦸ Business waste
- ⦸ Empty containers
- ⦸ Hydrogen peroxide
- ⦸ Aerosol cans

## Medications and The Environment

Medications enter the water when they are flushed down toilets and sinks or put into the garbage or when humans and animals pass drugs through their bodies.



Pollutants from medications have been found in the Puget Sound and waterways nationwide. These chemicals could impact aquatic organisms or degrade water quality.

Contact: Chloe Birnel
Telephone: (206) 352-2050
Cell Phone: (206) 330-8566
Email: cbirnel@pprc.org

FOR IMMEDIATE RELEASE

UNWANTED MEDICINES COULD BE PUTTING YOUR FAMILY, COMMUNITY AND ENVIRONMENT AT RISK

Legislators, Pharmacists, Health Advocates: Something Must Be Done to Ensure Safe Disposal of Unwanted Medicines

Drug abuse.

Accidental poisonings.

Contaminated drinking water.

All three were hot topics at Washington State's **Medicine Take-Back Workshop** held Friday, April 18th in Seattle. Participants represented a wide variety of stakeholder groups including pharmaceutical manufacturers, state legislators, government hazardous and solid waste programs, pharmacists, and clean water/environmental advocates concerned about the risks resulting from improper drug disposal in households.

The workshop was put on by the coalition behind Washington's multi-county **Medicine Return Pilot Program**: the nation's largest pharmacy-based household pharmaceutical return program. Over the past year and a half this program has collected and securely disposed of over 8,000 pounds of unwanted medicines from its 26 participating pharmacy locations in King, Kitsap, Pierce, Snohomish, Spokane and Thurston counties.

As the end of the pilot program's funding draws near, supporters are keen to continue and expand the medicine return service to all of Washington's 1,300 pharmacies. A long-term statewide manufacturer-funded program is the solution.

While speaking at the workshop, State Representative Dawn Morrell of Puyallup explained her personal connection to the issues at hand: "*As a nurse and grandmother I am acutely aware of the need for safer and easier methods to dispose of unwanted medicines*."

Morrell noted that she is "*fully committed to sponsoring state legislation in 2009 to create a secure, statewide, manufacturer-funded household medicine return system*."

"*It's easy to see why so many people take an interest in this issue*," continued Morrell. "*No one wants their loved ones to be at risk for accidental poisonings. No one wants their unused drugs to be misused. And certainly no one wants contaminated water. Yet all three of these things can occur when household pharmaceuticals are disposed of improperly*."

Before the Medicine Return Pilot Program there was no easy answer to these concerns. Over the last year and a half the pilot program has proven to be a safe, effective, and convenient way for residents near participating pharmacies to dispose of unwanted medicines.

Rep. Morrell went on to add "*I look forward to the day when I can say this program is available at all 1,300 pharmacies in Washington State*."

To learn more about the Medicine Return Pilot Program or to locate your nearest drop-off location, visit www.medicinereturn.com.

The household medicine return pilot program is the result of efforts by a coalition of local and state governments, businesses and non-profits known as the **PH:ARM Team** (Pharmaceuticals from Households: A Return Mechanism).

**###**

If you'd like more information about this topic, or to schedule an interview with any of the PH:ARM Team members please contact Chloe Birnel at (206) 352-2050 or email Chloe at CBirnel@pprc.org. Additional information, including materials from the recent workshop can be found at www.medicinereturn.com.

*The PH:ARM Team is a coalition of representatives and advisors from:*

Bartell Drug Company
Group Health Cooperative
Interagency Resource for Achieving Cooperation (IRAC)
Local Hazardous Waste Management Program in King County
Northwest Product Stewardship Council
Pacific Northwest Pollution Prevention Resource Center (PPRC)
Public Health – Seattle & King County
Snohomish County Public Works/Solid Waste Division
Washington Board of Pharmacy
Washington Citizens for Resource Conservation
Washington State Department of Ecology
Washington State Department of Social and Health Services

# Medicine Return Pilot Program

## 2007 Pharmacy Evaluation prepared for PH:ARM
### Surveys of Participating Group Health Pharmacies

Findings

May 2007

**Washington Citizens for Resource Conservation**

## Summary of Surveys

**Evaluation Objectives:**

1. Pharmacy staff satisfaction with the take-back pilot program.
2. Customer satisfaction with the take-back program, future-use plans and how customers learned about the program.
3. Interest expressed in pharmacy display and educational materials.

**Evaluation Methods:**

1. Pharmacy staff online survey sent to all Group Health participating pharmacy staff.
2. Group Health pharmacy patient self-administered written survey at four select participating pharmacy locations.
3. In-pharmacy observations of pharmacy customer behavior, performed just prior to setting up patient surveys.

**Summary of Pharmacist Survey Results**

WCRC surveyed pharmacy staff at the seven Group Health locations currently participating in the Medicine Return Program. We contracted with Cunningham Environmental Services to assist in developing survey questions. There was a 54% response rate (68 individuals responded out of 125 possible staff members). They were given just less than one week to respond and offered an incentive of entering into a drawing for a $50 gift certificate to Amazon.com.

We found:

The Medicine Return Project generally demands little time of pharmacy staff.

- 69% of staff have spent less than one hour in the last six months on program maintenance, inquiries, etc.
- Only 3% have spent more than ten hours in the last six months on the program.

Most of the pharmacy staff members think the program is effective.

- 69% think the program is extremely or very effective
- 94% think the program is somewhat, very, or extremely effective
- No respondents think the program is not at all effective.

Pharmacy staff members generally are not yet telling very many patients about the program.

- 50% have told ten or fewer patients about the program in the last six months.
- On average, pharmacy staff have each told 19.4 patients about the program in the last six months. (Calculation based on median value for categorical range response).

On the whole, comments received by staff from the patients have been very positive.

- 76% of respondents stated comments were very positive
- 95% stated comments were somewhat or very positive
- No respondents stated comments were negative.

To improve the program, pharmacy staff want larger collection containers but also suggest more publicity and changes to the signage.

- 56% of respondents want bigger internal collection containers
- 47% suggest better or more publicity within Group Health
- 28% suggest changes be made to the instructions posted on the container

**Summary of Patient Survey**

WCRC surveyed pharmacy patients at four select Group Health locations currently participating in the Medicine Return Program. We contracted with Cunningham Environmental Services to assist in developing survey questions. The surveys were self-administered with nine questions. There was a 41% return rate (400 surveys were put out and 162 were returned). Clinics were surveyed for one week and patients were offered an incentive of a drawing for a $50 gift card to Fred Meyer.

We found:

Perception of environmental impact:

- 46% of respondents that chose “protecting the environment” as the main benefit of the program had previously thought (before hearing about the program) that disposing to drain or garbage was either “not at all harmful” or “not very harmful”.
- “Protecting the environment” was the most chosen main benefit of the program while only 1% of respondents selected “there are no benefits”.
- 76% of respondents chose “protecting the environment” as a benefit (main or additional) of returning medicines.

Patient support of the program:

- 53% said they were either “extremely likely” or “very likely” to return medicines in the next six months.
- 13% of respondents have already used the program.
- When asked for additional comments or questions, 39 of the 47 responses indicated that this program is a good idea and there were no negative comments.
- When asked about benefits to having this program, zero customers chose “I don’t think there are any benefits”.

Outreach efforts:

- 44% learned about the program through Group Health brochures or signage (note: this result conflicts with results of observation portion of evaluation below and pharmacy staff survey above).
- 10% learned about the program through a Group Health publication
- Some were already aware of the program from outreach methods outside of Group Health (4% Media and 6% word of mouth).
- 45% of respondents learned about the program for the first time when completing the survey.

**Observations**

Observations were made in four of the participating clinics: Silverdale, Olympia, Redmond, and Everett (same clinics used for patient surveys) just prior to the start of the patient survey. Clinics were observed for short amounts of time (30 minutes to one hour each) to determine the best placement of surveys and secondarily to watch for pharmacy patient response to posters, drop box signage, and brochures. No interactions with patients occurred for these observations.

We found:

Two of the four clinics did not have brochures.

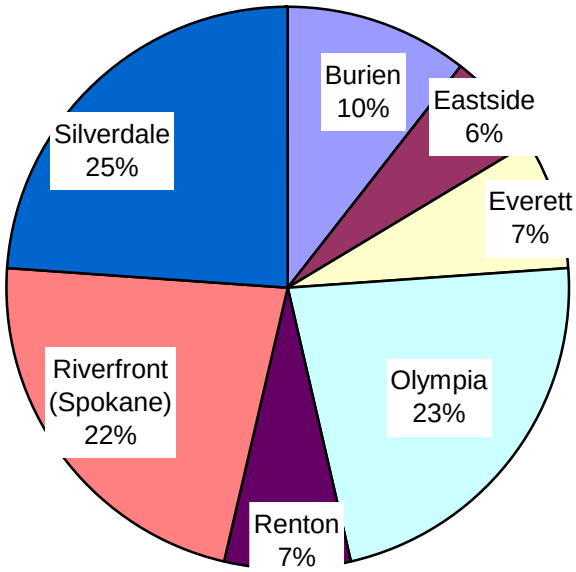
Pharmacy patients did not seem to notice the brochures, poster, or drop box. Of the more than 100 patients observed in the pharmacies, not a single person noticeably picked up a brochure or stopped to read the poster or drop box sign.

## Group Health Pharmacy Staff Survey Results

The following are the results of 68 surveys completed online (out of 125 pharmacy staff) during May 3 – 9, 2007 through surveymonkey.com.

**1. Which pharmacy do you work in?**

| | Response Total |
|---|---|
| Burien Medical Center Pharmacy | 7 |
| Eastside Primary Care Pharmacy | 4 |
| Everett Hospital and Specialty Center Pharmacy | 5 |
| Olympia Medical Center Pharmacy | 15 |
| Renton Medical Center Pharmacy | 5 |
| Riverfront (Spokane) Medical Center Pharmacy | 15 |
| Silverdale Medical Center Pharmacy | 16 |
| | |
| Total Respondents | 67 |
| (skipped this question) | 1 |

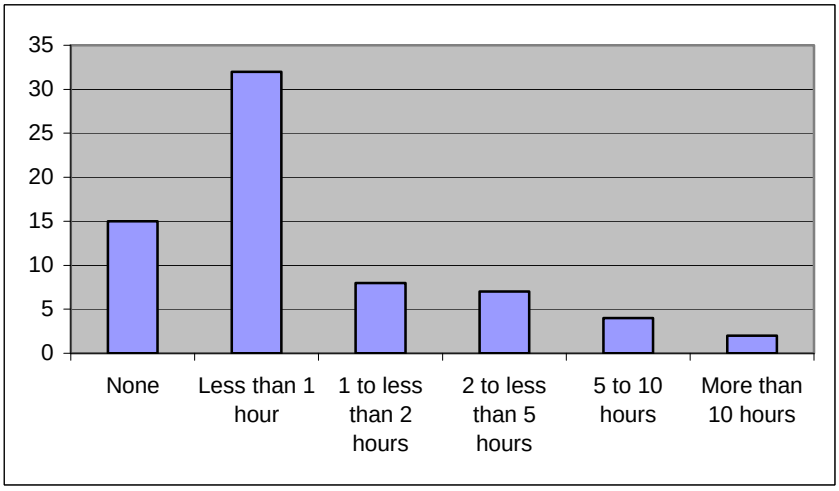



**2. How many days per week on average do you work at this pharmacy?**

| Days per week | Response Total |
|---|---|
| 1 | 5 |
| 2 | 1 |
| 2.5 | 3 |
| 3 | 4 |
| 4 | 9 |
| 5 | 46 |
| | |
| Total Respondents | 68 |
| (skipped question) | 0 |

**3. Approximately how much time have you personally spent on the Medicine Return Pilot Project since it began? This includes checking the container switching out the buckets making phone calls and handling staff and patient questions and comments.**

| | Response Total |
|---|---|
| None | 15 |
| Less than 1 hour | 32 |
| 1 to less than 2 hours | 8 |
| 2 to less than 5 hours | 7 |
| 5 to 10 hours | 4 |
| More than 10 hours | 2 |
| | |
| Total Respondents | 68 |
| (skipped question) | 0 |

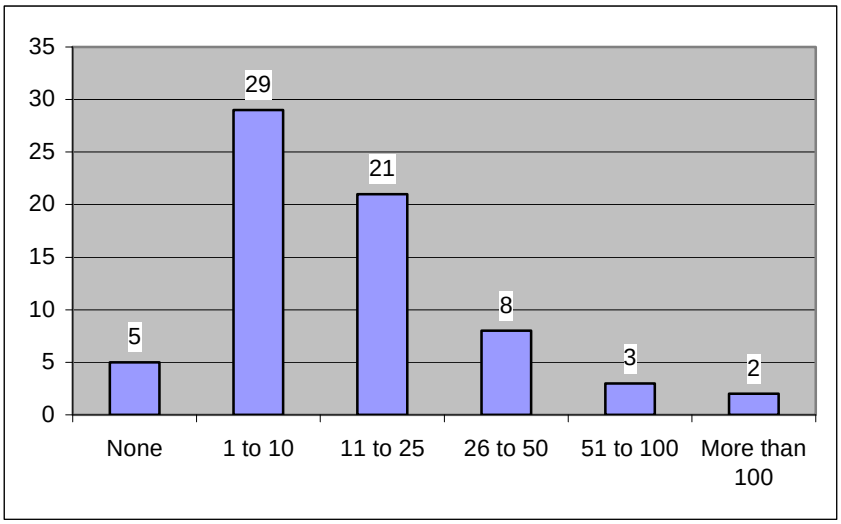


**4. Have the tasks you performed for the Medicine Return Pilot Project detracted from your regular tasks at the pharmacy?**

| | Response Total |
|---|---|
| Yes | 8 |
| No | 46 |
| | |
| Total Respondents | 54 |
| (skipped this question) | 14 |

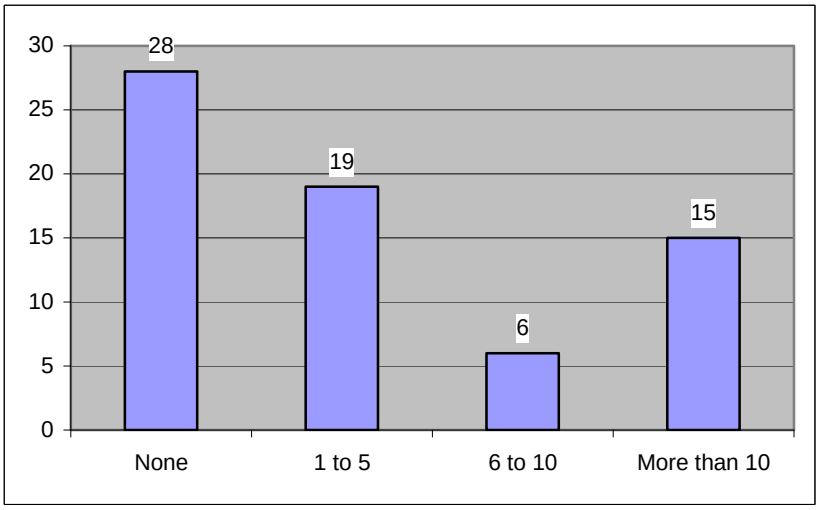
**5. Since the dropbox was installed in your pharmacy waiting area approximately how many patients have you told about the Medicine Return Pilot Project?**

| | Response Total |
|---|---|
| None | 5 |
| 1 to 10 | 29 |
| 11 to 25 | 21 |
| 26 to 50 | 8 |
| 51 to 100 | 3 |
| More than 100 | 2 |
| | |
| Total Respondents | 68 |
| (skipped this question) | 0 |




**6. Since the dropbox was installed in your pharmacy waiting area approximately how many patients have you observed putting an unacceptable item in it?**

| | Response Total |
|---|---|
| None | 28 |
| 1 to 5 | 19 |
| 6 to 10 | 6 |
| More than 10 | 15 |
| | |
| Total Respondents | 68 |
| (skipped this question) | 0 |

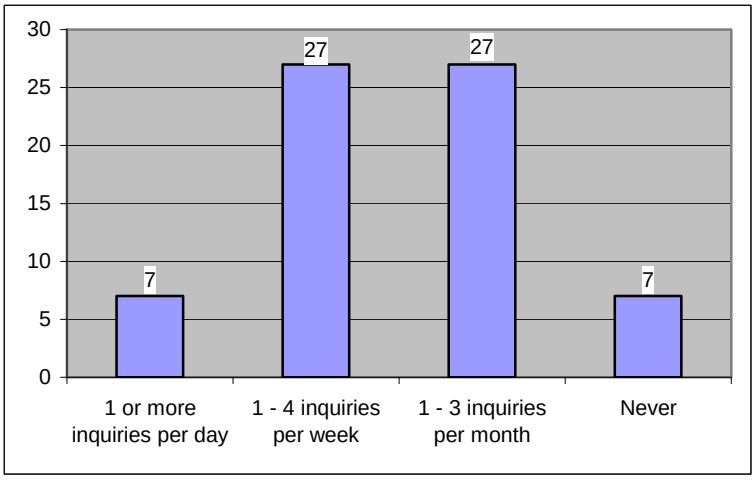


**7. What specific suggestions do you have to deter patients from putting unacceptable items in the dropbox?** (edited)

- Why not a running video on top of the box of what is acceptable to dispose of?
- bigger and bolder signage and brochure to state contraband items.
- A sign that read: The lab is able to take used syringes in sharp containers.
- it is still unclear as to whether we are accepting meds from non ghc customers
- MORE EDUCATION EITHER BY SIGNAGE OR THRU HANDOUTS
- "Possibly putting larger signs on the front of the container to remind patients that there are certain things we do not accept. "
- SIGNS WITH BIG LETTERS
- " My suggestion would be what is accetpable and what is unacceptable...a diaagram or picture. If they need assistance or have a question have them see one of our staff, that is always available."
- Like the airport--use photos/drawings of unacceptable items
- A sign that detail exactly what they can and cannot put in it.
- Bigger signage
- More graphics and less wording on the sign. Our home recycling company has a very clear visual of DO's and DO NOT's.
- posted sign is clear.
- needles and garbage they think it is a trash can
- Move it closer to the pharmacy windows
- None
- Clear signage with pictures.
- Jumping out from behind the door and saying NO! Bad girl (or boy)! and smacking them in the nose with a newspaper.
- no needles
- "since I only work there once each week, I was not aware of anyone putting unacceptable items in there, I hadn't heard any feedback. If/when cameras are installed out in the lobby, I wonder if that will make any kind of difference"
- The only thing I can think of if this is a major problem is for the box to be in the pharmacy and we collect materials from the pt. And I guess this isn't really an option.
- Larger and more clear signage. NOT garbage disposable. What products are NOT acceptable.
- call hazordous waste
- I think they will put what they want in there and ignore the signs.
- None at this time
- "If they are unsure at all about whether the items are unacceptable for the dropbox, they are encouraged to take a ticket and ask a technician or pharmacist, before depositing the items. "
- posting a ' no hazardous waste' sign on the dropbox
- put it in closer view of the pharmacy
- N/A
- make the wording more clear on the box on what is not acceptable. We also find lots of injectables in there
- "bigger, clearer signs of what's not allowed"

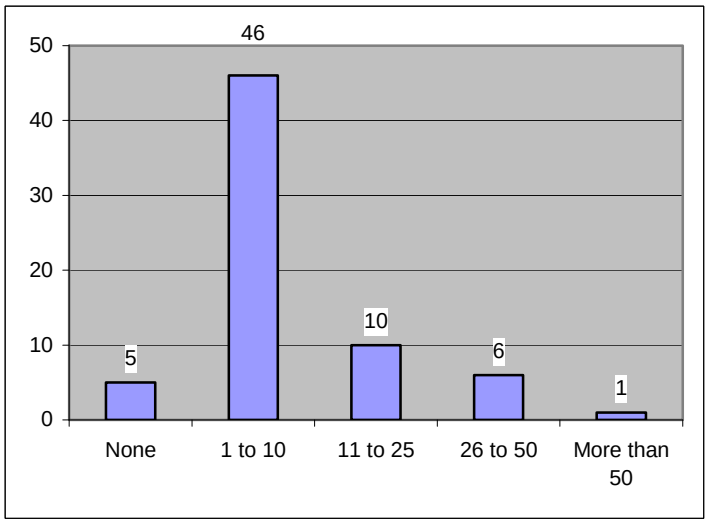
**8. How often in the last 6 months or so have patients at this pharmacy asked you general questions about how to safely dispose of unwanted or expired medicines? (In responding don't include specific questions about the Medicine Return Pilot Program).**

| | Response Total |
|---|---|
| Frequently (1 or more inquiries per day) | 7 |
| Occasionally (1 to 4 inquiries per week) | 27 |
| Rarely (1 to 3 inquiries per month) | 27 |
| Never | 7 |
| | |
| Total Respondents | 68 |
| (skipped this question) | 0 |




**9. Since the medicine dropbox was installed approximately how many patients have initiated questions or comments with you specifically about the Medicine Return Program?**

| | Response Total |
|---|---|
| None | 5 |
| 1 to 10 | 46 |
| 11 to 25 | 10 |
| 26 to 50 | 6 |
| More than 50 | 1 |
| | |
| Total Respondents | 68 |
| (skipped this question) | 0 |




**10. Would you say that on the whole the comments from the patients have been:**

| | Response Total |
|---|---|
| Very positive | 48 |
| Somewhat positive | 12 |
| Neutral - neither positive nor negative | 3 |
| Somewhat negative | 0 |
| Very negative | 0 |
| Mixed - both positive and negative | 0 |
| | |
| Total Respondents | 63 |
| (skipped this question) | 5 |

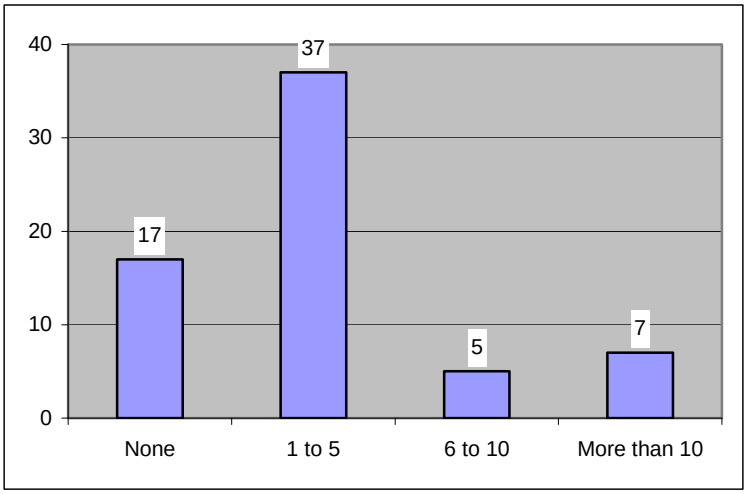
**11. What were the types of comments or questions that patients have about the program? (Check all that apply)**

| | Response Total |
|---|---|
| Patients like the program | 50 |
| The directions are unclear about which medicines are accepted | 16 |
| Patients want to know why certain medicines are not accepted | 23 |
| Concerns about privacy | 19 |
| Questions about how or where the medicines in the dropbox are disposed | 30 |
| Other (please specify) | 6 |
| | |
| Total Respondents | 63 |
| (skipped this question) | 5 |

- Mostly if syringes can be dispensed there.
- box needs to be a brighter color
- what they should do with unacceptable items
- can I put supplements and products from other pharmacies in?
- patients are anxious for the box to come to Poulsbo, that's where i work most of the time
- pt's wanting to know what to do with medications that are not acceptable to drop off in dropbox.

**12. Since the medicine dropbox was installed approximately how many patients have asked you whether a particular item can be put in the dropbox?**

| | Response Total |
|---|---|
| None | 17 |
| 1 to 5 | 37 |
| 6 to 10 | 5 |
| More than 10 | 7 |
| | |
| Total Respondents | 66 |
| (skipped question) | 2 |




**13. How effective do you think the current program is in getting unused and expired medicines out of people's homes and out of waste streams that can pollute the environment?**

| | Response Total |
|---|---|
| Extremely effective | 17 |
| Very effective | 29 |
| Somewhat effective | 17 |
| Not very effective | 4 |
| Not at all effective | 0 |
| | |
| Total Respondents | 67 |
| (skipped this question) | 1 |

**14. Based on your observations and interactions with patients what parts of the program are working very well?** (edited)

- Very visible to staff and patients and lots of great compliments about having a program like this to get rid of those unwanted meds they no longer need
- Availability of easy drop box (un-manned
- "The attention for this disposal concept has been overwhelming, we are getting meds from non-group health members and outside communities. "
- "The location of the box is visible, which is very helpful. I have seen both patients and medical staff use the box
- "By giving people a place to discard unused or expired meds, instead of dumping in the water supply or landfill
- PATTIENT'S I HAVE ENCOUNTERD WERE APRRECIATIVE OF THE PROGRAM.
- Awarness of patients that they have a place to dispose of meds. I think the visibility of the drop box in the pharmacy encourages to clean there meds out at home and bring them in.
- The information that we have Med box available to the consumer.
- "No complaints, just questions regarding the specifics. So, all of it appears to be working well. "
- patients knowing how to safely and effectively dispose of medications
- I think the program overall is working rather well.
- "The word is out, the drop box is filled to capacity quite often."
- "Just the fact that we have a disposal bin in Kitsap County is huge--pt's outside of GHC know about it and are using it, I am sure."
- Location of the drop box in the pharmacy lobby.
- RE #13: impossible to ascertain what fraction of unused medication in the community is going down the toilet vs. what is gong in the box - probably a small fraction going in the box. People are generally lazy. RE #14: boxing up and shipping is relatively easy.
- they are glad that we have this so they don't have to flush there meds
- They can dispose of meds without anyone else involed
- "ease of disposal, convenient location"
- It is being used more often because customers are slowly becoming aware of it.
- "anyone may drop off, more work off line "
- "I think patients really like this program, so many of them don't want to put there meds down the toilet or in the garbage and are concerned about the safety of those practices. Patients are waiting for the boxes in more clinics now."
- It's hard to say because I don't collect the materials. But I think it is a good thing for all pharmacies to do.
- Providing a disposal place for patients who have been accumulating drug and not knowing what to do with it.
- Very convenient for patients to bring to GHC Pharmacy
- patients are actually using it and more than willing to do so
- People use it when they know it's available. Even non-gh pt.s are coming in because it was advertised.
- "They like to drop them off rather than throw them away, for privacy reasons and/or environmental reasons."
- having the drop box accessable it great and an added value to our facility
- "I think it was a great idea to promote the dropbox by giving the waiting patients the brochure regarding the dropbox. Many patients did not even notice it in the waiting area previously, of it they did, they didn't know what it was. "
- All parts seem to be working well.
- encourages them to get rid of unused meds
- "i work U.C. silverdale 2 days/7 weeks. Few people will make the effort, but having the opportunity to do this is very important to some people."
- They are happy to have a place to dispose of their meds.
- patients think it's a good idea. Keeping folks from flushing their meds down the toilet is a great idea.
- The service of having a process available where patients can safely dispose of their meds. We get empty buckets timely. Efficient/easy process for returning full buckets. Available point persons if we have any questions/concerns.

**15. Based on your observations and interactions with patients and Group Health staff what improvements do you think can be made to the Medicine Return Pilot Project? (Check all that apply)**

| | Response Total |
|---|---|
| Changes to the container design | 14 |
| Bigger internal collection container (bucket) | 38 |
| Changes in the placement of the container | 7 |
| Changes to the informational brochure | 6 |
| Changes to the instructions posted on the container | 19 |
| Better or more publicity within Group Health | 32 |
| Better or more publicity outside of Group Health | 17 |
| None | 4 |
| Other (please specify) | 11 |
| | |
| Total Respondents | 68 |
| (skipped this question) | 0 |

- main thing is container needs to be bigger. We have to empty our bins 2-3 times per week on average
- post around the clinics and and urgent care
- not have doc dump bags of meds into container
- "Buckets that seal easier, less security on handlings keys"
- just don't know
- patients have had a difficult time finding where to open the dropbox for disposal.
- very difficult to seal the inner bucket for return; something other than the closure it has now which requires really hammering it with the mallet
- more locations
- available at all sites

**16. What specific recommendations can you make to improve the program?** (edited)

- "a smoother or efficient way for staff to prep the disposal of the containers. At this point, it seems too many steps, papers to fill out
- Clearer instructions on how to discard items that are not to be put in the box.
- "A larger bucket would be a bettet option. I personally am distracted from my job when I am told by coworkers,staff etc that the bucket is full. I have to stop what I'm doing, track down the other person with the key, wait for that person to finish his job, change the buckets,pound the bucket, fax the paper work and search for a gray container to put it it."
- "If this is to be for the whole community (not just ghc) the container size needs to be much larger. We have to change almost daily when there is public info given out about it. It just takes time to change and when that happens daily, it's lost time. The container swap system seems to take too long. We sometimes have to wait 3-4 days to get new buckets, as our existing bucket is running over."
- MORE EDUCATION & LARGER BIN
- make buckets easier to close/seal.
- It should be larger. Lots of patients bring in their deceased family members meds and that already fills up the bucket.
- having a bigger bin and sign so patients can be more aware that its there
- Make the lids easier to seal

- Place more disposal bins throughout the clinic. Change to buckets that don't require stomping and pounding on the lids. Get bigger buckets that can be sealed and shipped directly without needing a gray tote.
- "Improved safety for the technicians is vital. Sharps are not supposed to be put in these bins, but they still are!!!"
- none i like it the way it is but i think that we need to get a sign to put over it to say what it is
- Advertise it more in mailings to patients
- "Make the container more visable instead of hiding it in a corner. More brochures, posters, handouts to clarify what meds are to be place in the container. Also give patients information on what to do with the meds that cannot go into the container. "
- signage could be better
- "I know there are reasons why this is only a pilot and that it will take some time before these are approved at all the clinics (hopefully), but there is real patient interest in having more available"
- "bigger container, more advertisement and clearer signs."
- None. Seems to be working well.
- "A larger container, most definetly. It gets filled up really fast. We have a lot of non-GHC members bringing meds because they read/heard about it. "

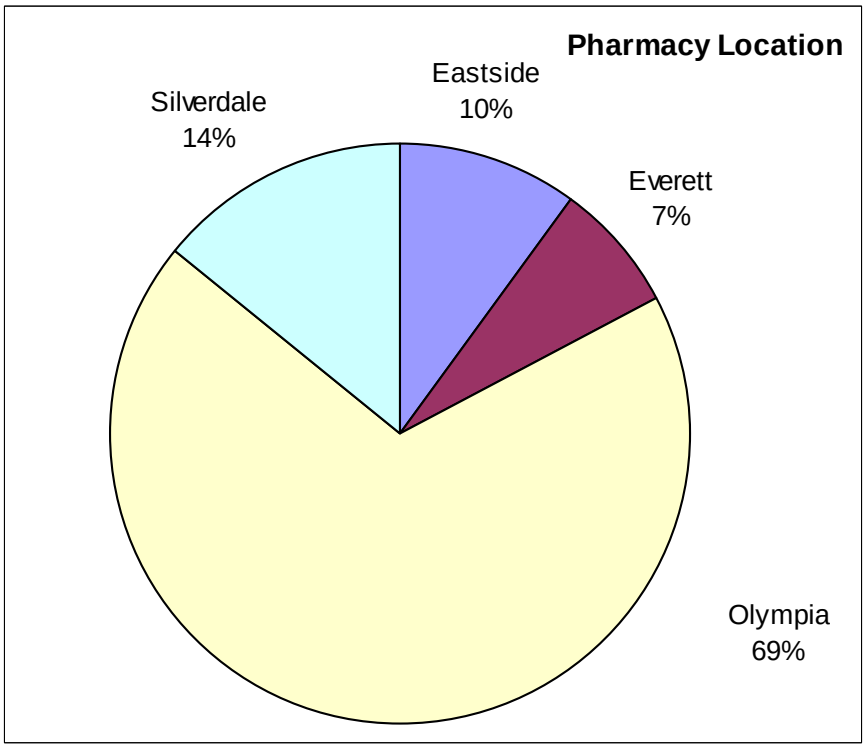
### 17. Do you have any other comments about the program?

- Great patient/community service.
- "The program as a whole, I think is great! What a great way to clean up peoples left over and expired meds! The containers and buckets need to be larger if we will serve the greater community."
- make the bin a brighter color that people can spot right away. Also it could use a bigger bucket that's inside of it.
- "Great Program, just needs to be expanded and bigger containers used. With bigger containers, there would be room for more signage about what not to put in container. Also, it would be nice to have something attached to the container that would hold pamphlets on the project for the patients to pick up."
- GREAT PROGRAM. WISH IT COULD BE STATEWIDE
- We love it!! Now we don't have to worry about contaminating ourselves or utilizing man hours to process.
- Good effort. Worthy cause.
- I think it is a great program.
- lot of off line work
- So glad we have this up & running - so much better for our environment!! Way to go green!!
- Great program that patients appreciate very much
- I think this should be available at all pharmacies and nursing homes.
- "no, the program is great"
- A Great program in support of protecting our environment.

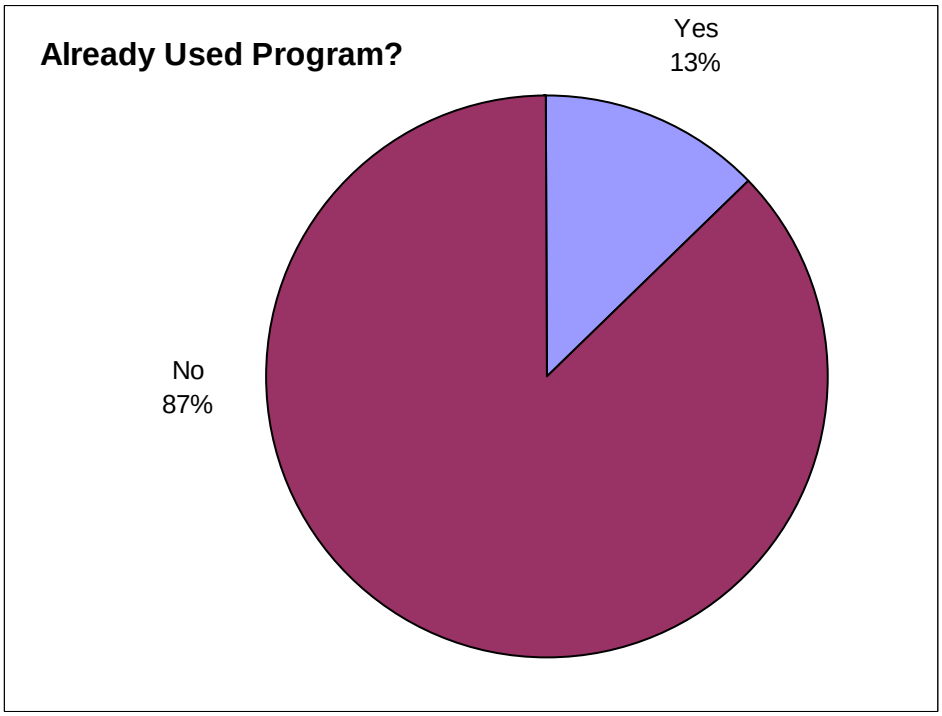
## Group Health Patient Survey Results

Number of patients surveyed=162, survey dates: April 23 - 30, 2007

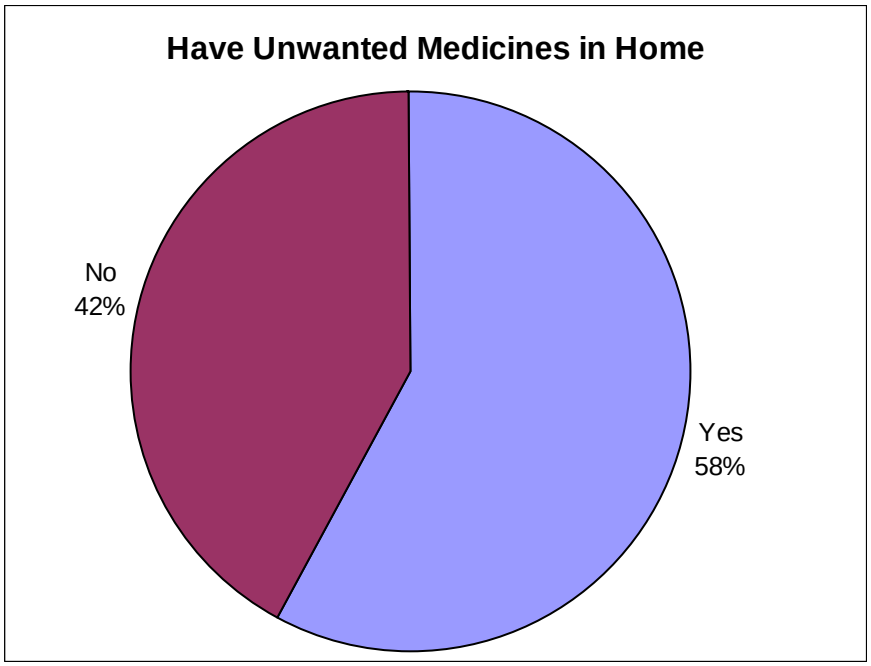
1. Pharmacy where survey was completed.



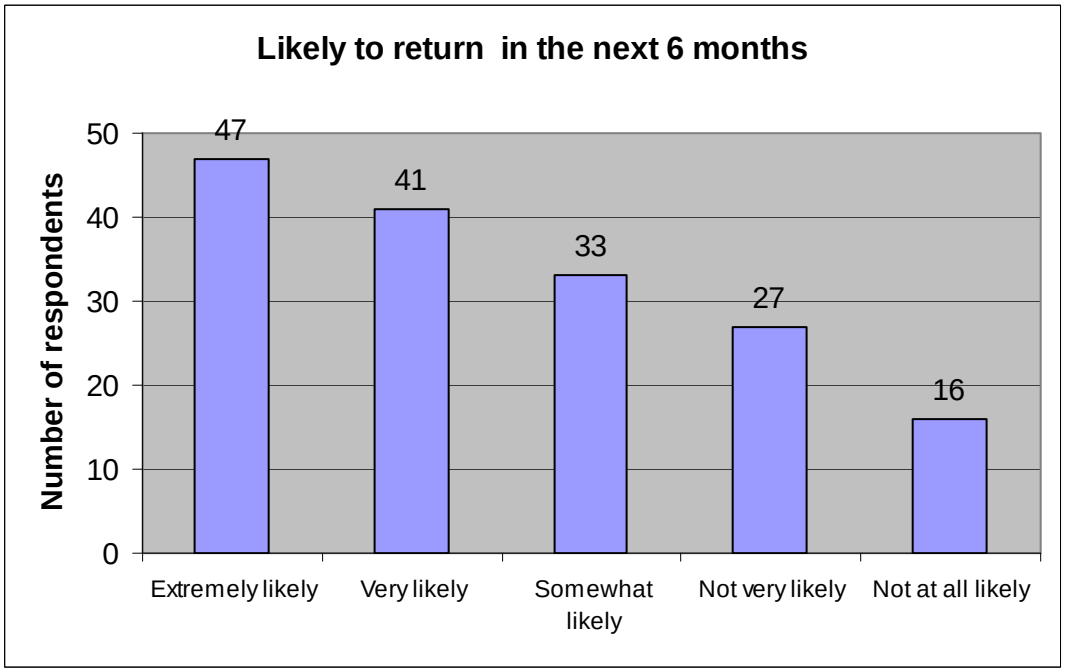

2. Have you disposed of unwanted medicines in the medication return dropbox located in the Group Health pharmacy?



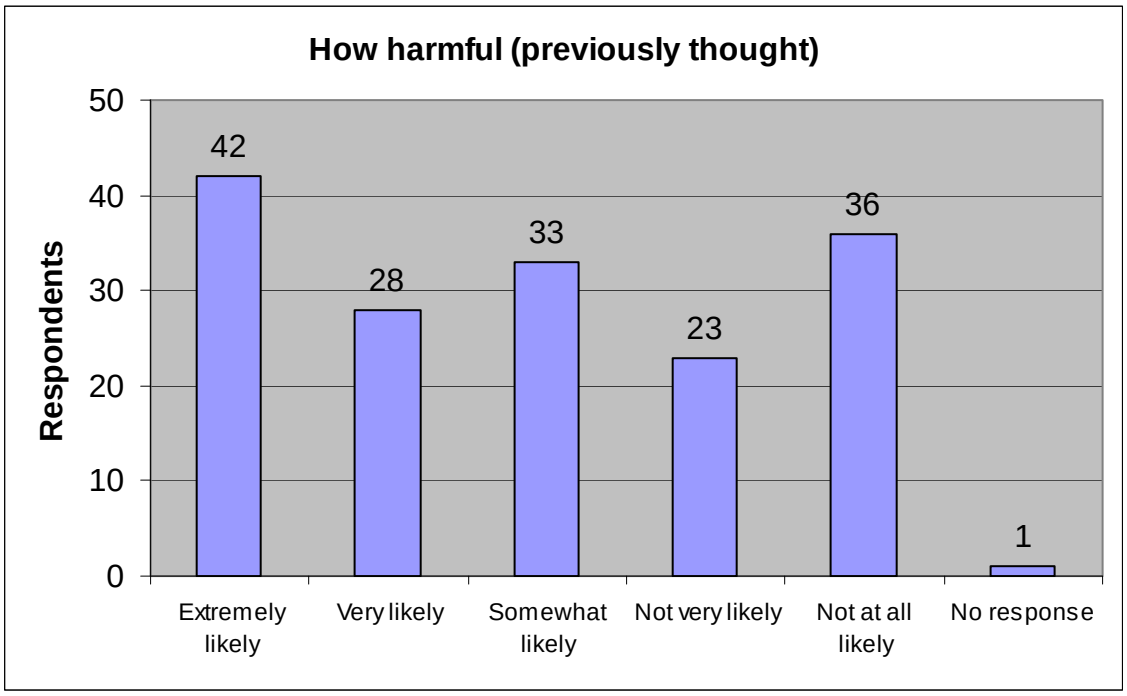
3. Do you currently have leftover or expired unwanted medicines in your home?



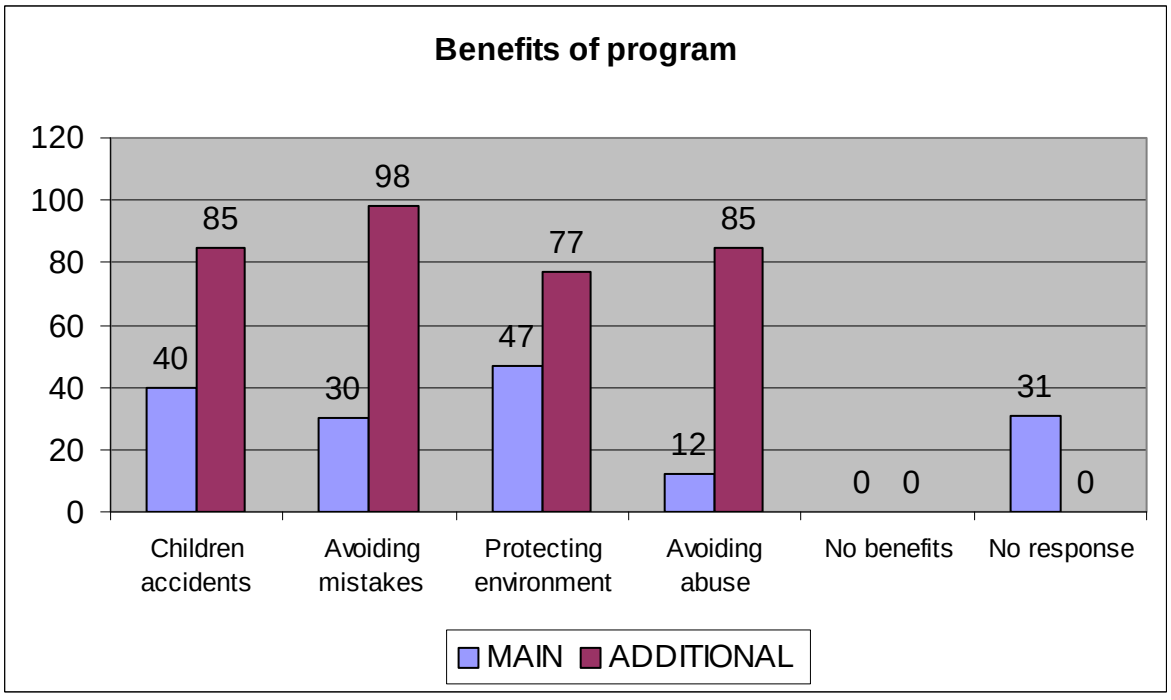

4. How likely are you or another household member to bring your unwanted medicines to the dropbox in the next 6 months?



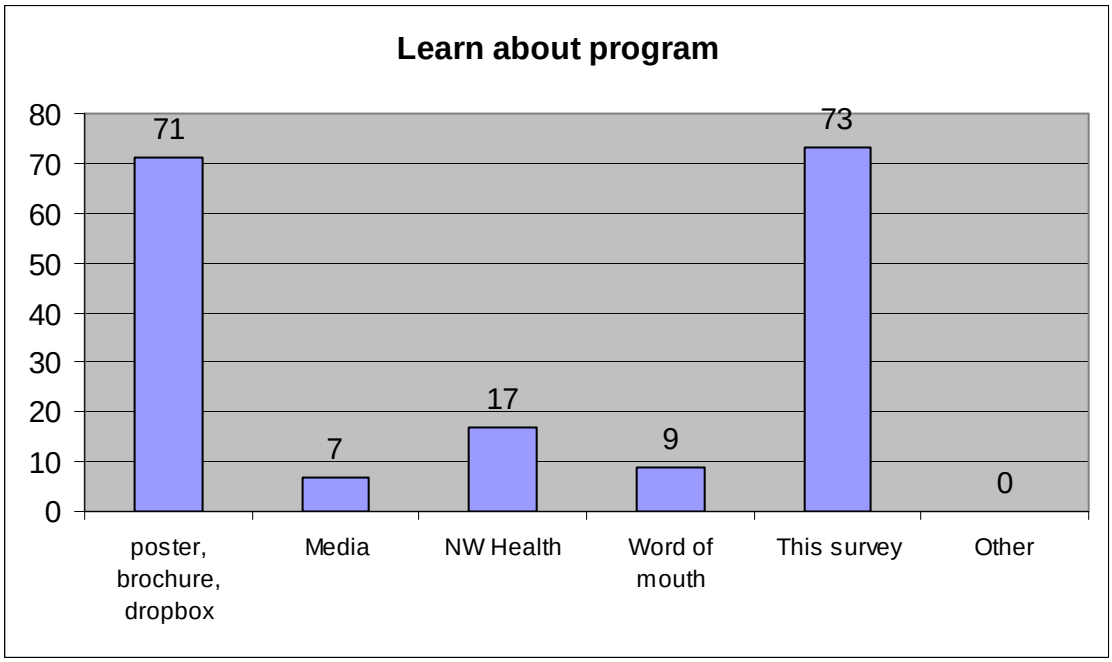
5. Before hearing about the Medicines Return Program, how harmful to the environment did you think it was to put unused medications down the drain or in the garbage?



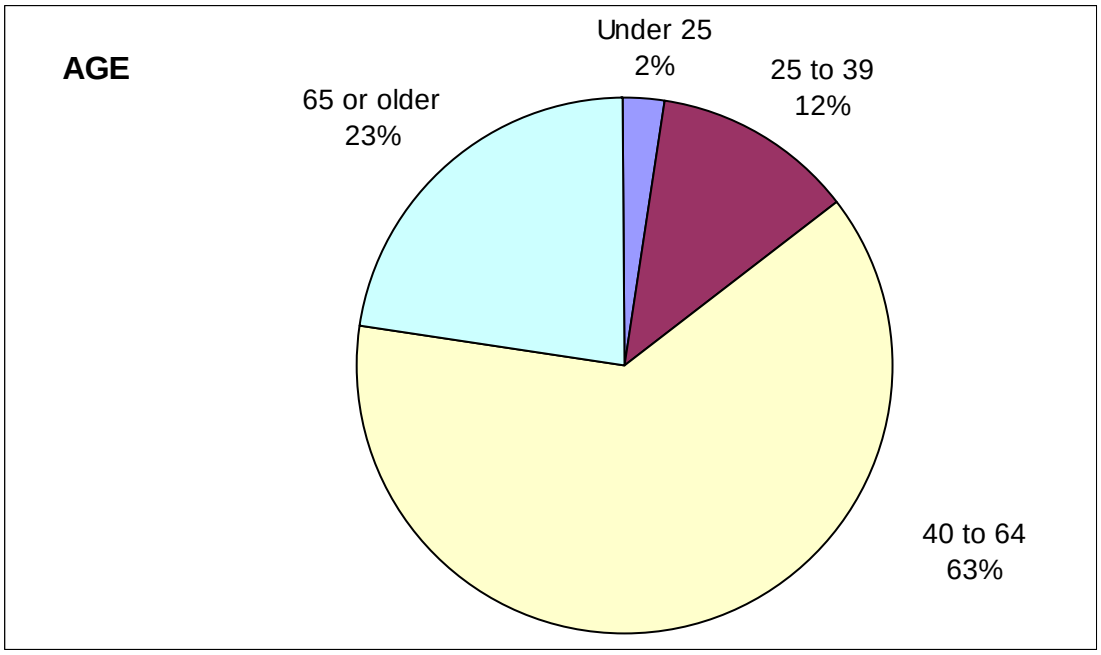

6. What do you believe is the main benefit of using the pharmacy dropbox for disposing your unwanted medicines? (Check one)
7. Do you believe there are any additional benefits of using the pharmacy dropbox for disposing your unwanted medicines? (Check all that apply)



8. How did you learn about the medicines return service offered at this Group Health pharmacy? (Check all that apply)

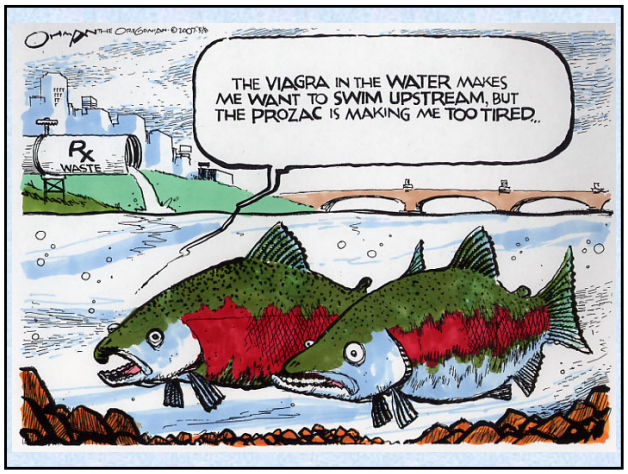



9. What is your age?



10. We welcome your comments or questions:

- This is a great way to educate and to get people's attention! I hope a lot of people benefit as much as I did.
- You are all awesome!
- A helpful addition to GH service. I've used it 3 times already.
- GH does remarkably well in doing what is right for the environment.
- Do you take flea medications used for cats?
- I think it's a great program and needs to be continued!
- Don't have kids or pets. I like to have the extra medicines in case I run out I could use expired ones since are often still somewhat effective.
- We usually take all medicines prescribed.
- Good idea.
- Usually use up prescriptions - didn't know about the Redicines Return Program.
- Am glad this box is here.
- Great idea
- The misinformation I've heard about the disposal of medicine was very confusing. This is great.
- Good info.
- Good program
- Can you donate meds to doctors who volunteer abroad?
- Thank you for bringing this to my attention. Would have never thought about it.
- Wonderful idea!
- "Education of dangers would be welcomed. Any scientific statistics, studies to prove your thesis?"
- Great program! Thanks.
- This is a good thing!
- I get excellent advice from GH pharmacists. Very much appreciated. Thank you!
- Thank you for this program. I was extremely unclear on what to do with old meds.
- A super service!
- Great service.
- Wonderful service.
- It's an excellent idea.
- Thank you for starting this program - will you be offering non-GH patients to use the dropbox?
- Great idea!
- I have been flushing them - never thought about any of this before - am glad to see it!
- I like this way of disposing old medicines.
- This is an excellent service that I hope will be retained.
- "I've never really thought much about this. It's a great idea, program."
- I just saw the box at my last visit - I think it's a great idea!
- "Website should mention program stats, and disposal process."
- Where is the box?
- An excellent program which I will take advantage of.
- Thank you for the drop box. I will feel safer getting rid of medications this way.
- I appreciate the conern of Group Health for their patients.
- What a wonderful idea!
- Overall Group Health is great.
- Great idea!
- Thanks
- You are doing a good job doing this survey. Many people do not know about this.
- Kudos to you all
- Really helpful! I don't hear that from other hospitals!
- This was wonderful. I had no idea this was a service you offered.

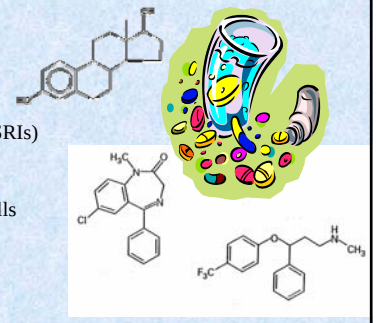




## Overview

- Issue overview \
  - Drugs 101
  - Public health and safety
  - Pharms in environment
  - No legal options to flushing
- British Columbia Program
- Washington State Pilot
- Oregon Stakeholder Process and Recommendations

## Pharmaceuticals

- Antibiotics
- Anti-inflammatories
- Beta-blockers
- Anti-depressants (SSRIs)
- Steroids
- Hormones, estrogen replacements, BC pills
- Chemotherapeutics
- Stimulants
- Etc.



## Pharmaceuticals (cont'd)

- Wide range of biologically-active chemicals
- Three classes by sale/ regulation:
  - Over The Counter
  - Prescription (or "Legend")
  - Controlled Substances
- Some designate as hazardous waste

## Pharmaceuticals (cont'd)

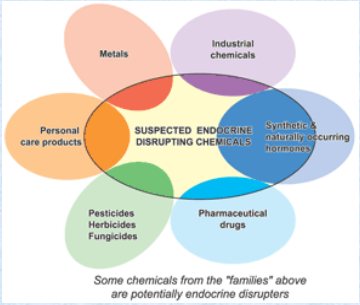
- **Controlled Substances** – regulated by the Federal Drug Enforcement Administration due to potential for abuse
  - Schedule I – illegal drugs (ex., heroin, LSD)
  - Schedule II – morphine, OxyContin, codeine, Demerol, Ritalin, amphetamines
  - Schedule III – Tylenol with codeine, Vicodin
  - Schedule IV – benzodiazepines, Valium, Darvon
  - Schedule V – codeine cough syrups

## What is an endocrine disruptor?

An endocrine disruptor is a synthetic chemical that when absorbed into the body either mimics or blocks hormones and disrupts the body's normal functions.

This disruption can happen through altering normal hormone levels, halting or stimulating the production of hormones, or changing the way hormones travel through the body, thus affecting the functions that these hormones control.

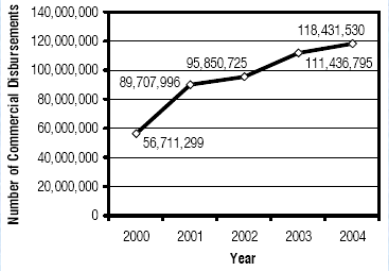
## Endocrine Disrupting Chemicals vs. Pharmaceuticals




*Some chemicals from the "families" above are potentially endocrine disrupters*

## Drug sales have skyrocketed

Sales have more than doubled in last 5 yrs



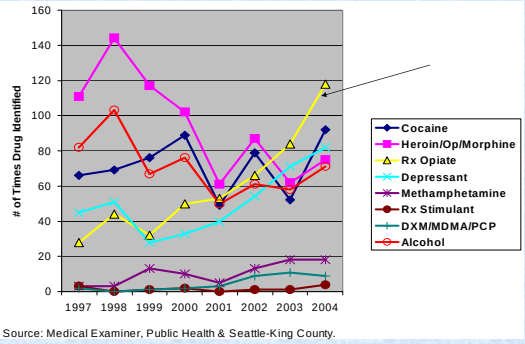

(Ref: National Drug Intelligence Center, 2005, via Ilene Ruhoy, 2006)

## Pharms present poisoning and abuse hazards

- Most homes have many medicines on the shelves
- Common source of childhood poisonings
- Common source of teenage and adult abuse

## Drug Abuse (cont'd)

Drug Involved Deaths, King County



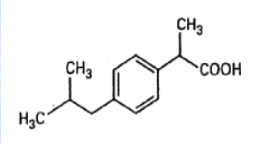

Source: Medical Examiner, Public Health & Seattle-King County.

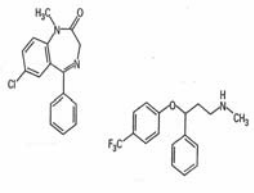
## Pharms enter the environment through use and disposal

- Probably most result from use, passing through us un-metabolized, then going through wastewater treatment systems
- Unused/unwanted quantities could be huge, as much as 50% of many prescriptions (80% for antibiotics)
- Common/historical recommendation was to flush

## Pharms are showing up in the environment

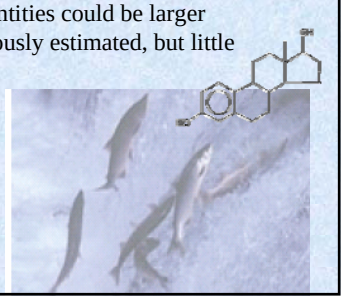
- Ibuprofen, valium, prozac, antibiotics, steroids, hormones
- Found in 80% of U.S. streams tested by USGS
- Not sure of significance: "presence without relevance"



## Pharms in the environment (cont'd)

- Antibiotics, hormones, anti-depressants are receiving the most attention.
- Unused/unwanted quantities could be larger contributor than previously estimated, but little data exist (key gap)
- Flushing has been accepted disposal method up to now
- Continual inputs create "pseudo-persistence"



## Pharms in the environment (cont'd)

- Bioassays of antidepressants are showing some sub-lethal effects at environmentally-relevant levels.
- Boulder Creek, CO, study: 50:50 female:male ratio upstream, 90:10 downstream; ethynyl-estradiol measurably higher downstream.
- Male fish are producing eggs in the Potomac River, as well as in many other locations.

## Pharms are present in wastewater treatment systems

- EPA, USGS and other studies are finding pharmaceuticals in all systems sampled
- 5-POTW study in NE found 38 pharms: naproxen, ibuprofen, acetaminophen, …
- 10-POTW study in U.S. found 78 of 110, found pharms in effluents and downstream

## Pharms are present (cont'd)

- Sequim study by Ecology:
  - 2 tertiary effluents sampled, plus nearby streams and wells.
  - Found 16 of 24 compounds in effl.: acetaminophen, carbamazepine, cimetidine, codeine, cotinine, diltiazem, hydrodocone, ketoprofen, metformin, paraxanthine, salbutamol, sulfamethoxazole, trimethoprim, estrone. Also caffeine and nicotine.
  - Metformin (antihyperglycemic) found at unusually high levels in nearby streams and wells as well as effluent.

## Summary of the Concern

- Lots of unused drugs in people's homes
- Poisoning and abuse concerns
- Low compliance = high accumulations
- Left-overs are often flushed
- Pharms are showing up in the environment
- No safe, legal, environmentally- acceptable disposal options

## No Safe Options Available

- Currently no safe and secure alternative to flushing.
- Problems with disposal as garbage
  - Access: pets, children, abusers, workers
  - Pharmaceuticals move through landfill leachate
  - Not technically legal in some places: Sno Co
- Problems with disposal at HHW facilities

## No Safe Options Available

- Problems with disposal at HHW facilities
  - Inadequate convenience to effectively address problem.
  - Not legal or endorsed by Drug Enforcement Agency or Board of Pharmacy.
  - Security and diversion issues.

## No Safe Options Available

- DEA likes idea of disposal at Sheriff's offices
- Numerous problems
  - Ineffectual
    - Estimate 285 lbs. of controlled substances captured throughout WA if this were put in place
    - Estimate 7,300 lbs. of controlled substances captured throughout WA if pharmacy take-back put in place
  - Burden on agencies
  - Relies on public, not private, funding

## Who is Having the Disposal Problem?

- Especially:
  - Residents
  - Residential Care Facilities
  - Schools (unclaimed meds at end of year)
  - Hospice
  - Hospitals (have some options)
  - Users of veterinary supplies
  - People and facilities associated with someone using medications: cruise ships, etc.

## Product Stewardship Solution: Return to Pharmacy

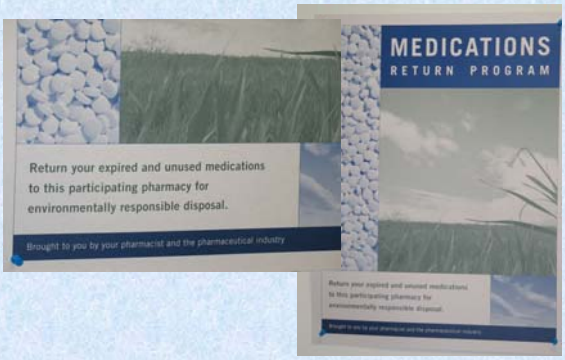
- Drugs returned to pharmacies for safe, secure destruction as hazardous waste (HHW incineration, landfilling or other process)
- Might be coupled with a mailer program.
- Pharmaceutical manufacturers finance and manage system.

## Closest Model: British Columbia

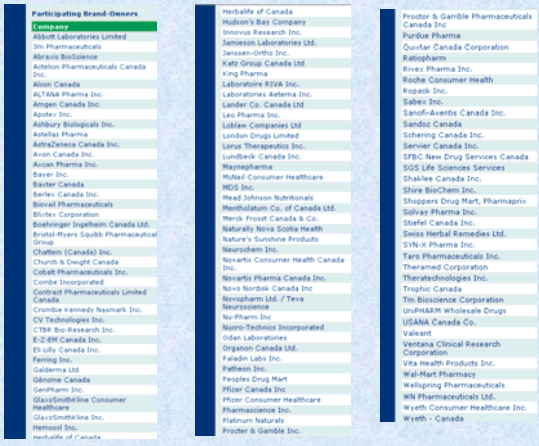
- Pharmaceutical manufacturers finance and manage through a "third party organization"
- Over 800 pharmacies voluntarily participate
- 52,800 lbs. collected in 2004
- Cost:
  - $170,000/ year
  - $3.25 per lb.

## British Columbia Program

## British Columbia Program








## B.C. Medication Cost Increases

- None: absorbed as cost of doing business

*"The Medications Return Program does not pass on or show separately the cost of the program to the consumer."*

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## Developing a Washington Drug Take Back Program

- PH:aRM Pilot

## Key PH:ARM Team and Advisors

**Local Governments**

- Local Governments in King County
  - Public Health - Seattle & King County
  - Local Hazardous Waste Management Program in King County
  - Interagency Resource for Achieving Cooperation
  - Seattle Public Utilities
- Snohomish County Solid Waste Management Division

**State Agencies**

- Washington State Board of Pharmacy
- Washington State Department of Ecology
- Washington State Department of Social and Health Services- Aging and Disability Services

**Non Profits**

- Pacific Northwest Pollution Prevention Resource Center
- Northwest Product Stewardship Council
- Washington Citizens for Resource Conservation

**Private Sector**

- Bartell Drugs
- Group Health Cooperative …and many other Interested Parties

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## Basic Tenets for Success

- Safe and secure system (secure collection, transport, destruction)
- Low-cost and financially sustainable
- Effective (high volume recovered)
  - Easily accessible & user friendly
  - Ongoing and widely available
- Government regulates and oversees the on-going program but does not fund and manage it. This should be left to the private sector.

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## Meeting the Public's Needs

- It should be as easy to properly dispose of medications as it is to purchase them.
- Public comfort with solution is key to success.
- January 2006 SoundStats Survey showed that:
  - *74% of respondents said that they would be willing or very willing to properly dispose of unwanted medicines if a convenient location is offered.*
  - *84% of respondents indicated a local pharmacy would be the most convenient location to dispose of unused or expired medicines.*
  - *4% said they would be willing to use sheriff or police office, 5% said special collection event, 2% said public hazardous waste facility.*

*Source: SoundStats Survey of King County Households (2006, WCRC)*

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## PH:ARM Pilot

- Began November 2006.
- Initially launched with 7 Group Health locations. Expanding to 24.
- Will initially launch at several Bartell Drug Pharmacies in 2007. Expand to 54.
- Address adult care and others locations later in 2007.
- Pilot planned to run for 2 years.
- Work toward state-wide product stewardship system before pilot ends.
- Awaiting waiver from DEA.

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## First Prototype: Metal Drop Box

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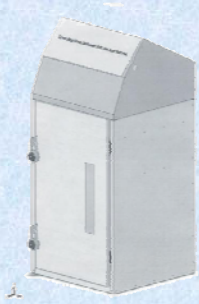
## Second Generation Metal Drop Box



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## Prototype: Plastic Toter


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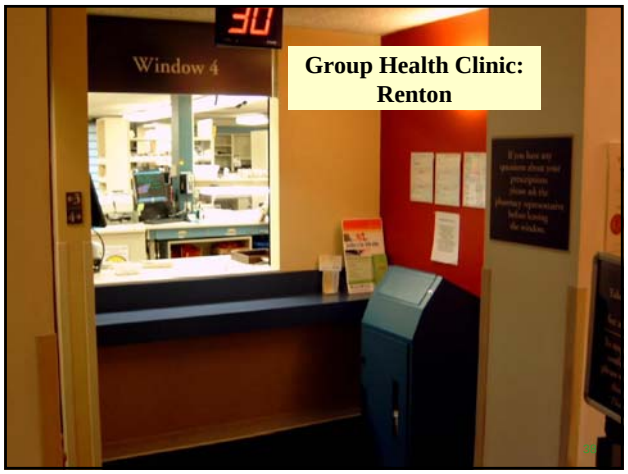


**Group Health Clinic: Renton**


**Group Health Clinic: Burien**

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## Group Health Decal


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## Group Health Flier


41

## Bartell Drug Poster (program pending)


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## Double Locked Container Can Only be Opened with Two People

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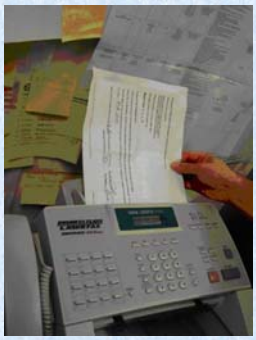
## Bucket Closed with Lock Lid Under Double Witness

44

## Each Bucket Has Unique Tracking Number and Security Tag

45

## Each Bucket Is Carefully Tracked



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## Buckets are Returned to Pharmacy Distribution Center, Recorded, and Placed in Locked Cage

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## When Enough Buckets Have Accumulated, They Will Be Picked-up For Secure, Witnessed Destruction

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## Developing an Oregon Drug Take Back Program

- Stakeholder group process
  - Graduate student for research
- Funded by
  - ACWA
  - Oregon Water Utilities Council
  - Oregon DEQ

## Developing an Oregon Drug Take Back Program

- Broad Stakeholder Group
  - Oregon Board of Pharmacy
  - Oregon DEQ
  - ACWA
  - Pharmacists Association
  - PhRMA
  - Oregon Water Utilities Council
  - Lane County P2 Team
  - Environmental public interest groups
  - DEA
  - Others…

## Goals for Oregon Program

- Legal under Federal Drug Enforcement Administration regulations
  - Controlled substances
    - Chain of custody and tracking requirements
- Simple and understandable for public
- Affordable
- Statewide

## Developing an Oregon Drug Take Back Program

- Stakeholder Group
  - Meeting since October
  - Recommendations likely completed in July

## Options for an Oregon Program

- Pharmacy collection – no mailer
  - Drop controlled drugs at law enforcement
- Pharmacy collection with mailer
  - Mail back controlled drugs
- Collection at law enforcement agencies
  - Similar to existing program in Clark County
- Mail to Oregon State Police
- Mail to Reverse Distributor
- Product Stewardship Model

## Funding Options

- Solid waste disposal fees
- Pharmaceutical fees
- Mix of solid waste and pharmaceutical fees
- Tax on water utilities
- State General Fund
- Industry funded

## Recommendations

- Product stewardship model
  - Drug manufacturers (including generic) and over the counter
  - Develop and fund best program
    - Likely mail back/pharmacy drop-off combination
  - Might need 2009 Oregon legislation to ensure participation
    - Want to work with industry

## If costs were passed on to patients:

- What if manufacturers DID allocate program costs to only prescriptions at retail pharmacies in OR?
  - cost increase of 2 cents per prescription ($.0238)
  - annual increase in costs of 22 cents per capita for prescription medications
  - $487.60 worth of meds would then cost $487.82
- But costs would also be spread over mail-order prescriptions and over the counter drugs, reducing the per prescription numbers above.

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## What Can You Do?

- Get your organization to endorse the Oregon Drug Take Back Stakeholders final report recommendations
  - Likely available the end of July

## Product Stewardship Solution

- Provides good customer service and responsible corporate stewardship
- Uses relationships that already exist between manufacturers, DEA, pharmacies, distributors, and other regulatory agencies
- Leverages private sector know how and internal resources and priorities

## Resources

**Post Consumer Pharmaceutical Stewardship Association**
(info on BC Medication Return Program)
www.medicationsreturn.ca

**British Columbia Program including 2005 Report** (gov site)
http://www.env.gov.bc.ca/epd/epdpa/ips/meds/index.html

**Washington PH:aRM Pilot**
http://www.medicinereturn.com/

**Oregon Association of Clean Water Agencies (OR Process)**
www.oracwa.org

**Kaiser Family Foundation**
http://statehealthfacts.org/cgi-bin/healthfacts.cgi?

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**WASHINGTON MEDICINE TAKE-BACK WORKSHOP APRIL 18, 2008 SEATTLE, WASHINGTON**
**Breakout Session notes - groups 1-5 and 8**

| ***What will it take for support?*** | ***Next steps?*** | ***How can groups collaborate?*** | ***What are you willing to do?*** | ***Extra Discussion*** |
|---|---|---|---|---|
| ***GROUP #1*** | | | | |
| Min. sot for local gov | Legislation with time frame and deadline | Be infor source for community | Educate public (Earth Ministry) | Need for funding for science |
| Make accessable for citizens | National dialogue Re: DEA permit | Be openminded about other options/programs such as Smart RX | Continue progress (Group Health) | Testing/studies need to be done before new pharmacuticals approved by FDA |
| Show science behind policy/claims | Build support of public | Look at a National/streamline program or systems | Respond & Reply but won't be contributing (BOP) | |
| Better waste reduction methods | Consumer awareness/participation | Get Haz Waste programs educated | Provide assistance, support education (local HazWaste, Tacoma) | |
| More info on mechanics of $ support | Residue issues with DEA then state legislation | Increase dialogue with manufacturers and other stakeholders | Work on gaining support from company (Kaiser Perm.) | |
| (for manufacturers) | Challenge DEA's authority. Act now and then let them regulate | Dialogues continue | Can't give political support but will provide data | |
| Include controlled substances | Work cooperatively with manufacturers | Collaborate with water and environmental federation | Continue program they are working on (PhRMA) | |
| Works for phamacys | Show how this will solve problem | Dialogue on science to ensure the problem is addressed | Lobby support, education resources (city of Bellingham) | |
| Take into account abuse prevention | Educate all parties and get input so you do bill right | City as conduits of info - communicate with stakeholders and constituents | Work at National level. Explore options with DEA (EPA) | |
| Link with local haz waste facilities/cities to provide info | Frame issue as not only environmental but also health and safety | PhARMA engages in open dialogue - makes sure good decision is made, look at a variety of answers - ie - education ,SMARxT program | Educate ratepayers & work on National level (Lake Haven Utility Dist. ) | |
| Way to report back to public | What is best disposal method | Raise public awareness | Outreach to their constituents/communities | |
| Collection process includes security | Pass legislation with dates in place | Raise dialogue between manfu and stakeholders | BOP will not be able to actively influence because they are prohibited from doing so | |

| | | | | |
|---|---|---|---|---|
| Easy to explain and access | National dialogue re: DEA permit | Silos | Back up the proactive groups - support it | |
| Enforcement of participation for all manufacturers/distributors | Build support of legislation | Dialogue | KP has lots of interest - can start to gain support within their org. | |
| Already fully supported | Build comsumer awareness | Network with local utilities and local env. agencies/water & env. federation | Montana BOP - provide info to public, identify sources of funding | |
| Minimize local gov. cost | Get DEA issues resolved, then state legislation put in place | Agree on the science and then make sure answer actually solves the problem | Study issue further, connected to APHA & US Fish and Wildlife program | |
| Comprehensive including CS/accessible to pts. | Follow through with 2008 legislation | | OR BOP apply accupunctual stimulus to DEA to help them understand the importance | |
| See the science that this will be helpful/more responsibility | If state programs are exempt then put the on us | | Lobbying support for legislation ,educational resources | |
| Want to see the mechanics of a manfr. funded take back - how do you levy costs - how do you allocate costs, do chem manfact. pay more? | On DEA to prove that they have authority | | Explore conversations between EPA/DEA | |
| Must collect CS, has to work for pharmacies without drain on their resources | Develop a program that is acceptable to PhARMA, collaborative science is telling us that take back may not solve the problem | | Public Awareness - letters/door hangers, update rate payers | |
| City municipality must buy into it;city is a conduit of information | Educate all parties and develop the right bill | | Concern about need for hard sciences - take many, many $$ and many years - by that time, significant damage will have occurred | |
| Comprehensive, accessible, sustainable, data collected to be report back, secures collection process, adequate destruction. Basic info about type of meds coming back that can affect upstream dispensing | Frame what the issue is for the citizens of the state accounting for public health, public safety, etc. - counteract PhARMA statistics | | | |
| Easy to explain, easy to access | What is best way to dispose of meds, Carbon footprint, etc. | | | |
| Full participation of all mauf. | | | | |

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|---|---|---|---|---|
| Control costs of medication, destruction | | | | |
| Control costs of medication, destruction | | | | |
| Controls on it to ensure that materials, get to appropriate destruction | | | | |
| Issue of generics/drugs manuf outside of country | | | | |
| Solution that can be applied across the region - ie - Dr/WA | | | | |
| ***What will it take for support?*** | ***Next steps?*** | ***How can groups collaborate?*** | ***What are you willing to do?*** | ***Extra Discussion*** |
| ***GROUP #2*** | | | | |
| Keep it simple | Legislation (collaboration) | Fed's State componets (treat the same) Transp. Regulations to consider even if state program - may have Fed roadblock need way to collaborate | Pt. education effort to take Rx (no unused drugs) Does not over prescrib | |
| There is bigger problems out there | Controlled substances | Can DEA provide waivers to allow state programs | County education on Pharm waste | |
| Flush? Landfill? Incinerate? Manufacturers want to know the best way. Know best practices. | Making DEA job easier | WA ST Env. Health Director AARP not on list | Drug comp. education on disposal | |
| One answer may not fit all | Want manufacturer buy-in (better if "you're driving the bus") | Not just ecology issue | Look for greener final disposal (commercially available) | |
| Need to know handled properly as Haz Waste | Legisl. In parallel with science/research (=more participation) | Lots of hoops for phamacy's to jump through | Stericycle- Check option | |
| Cost effective | OTC coming in to retailers | All meds handled as HHW | | |
| Pay small fee per share to pay for program | How to fund research? Do jointly with drug comp. Steering group lead U of Mich. All agree to what data says? Is this the best thing to do? Easiest? Envir. Impacts of Takeback (trucking etc.) | Meds incinerated with other materials- makes all ash haz waste | | |
| Know manuf. Disposal has least env. Impact (may change over time) | Agree on how to measure impact | Work together to lobby agencies to make it easier | | |
| Participation rates we can expect | Address problem of people waste | Coop research | | |
| How much unused meds are out there? | | Pharmacy proactive with legislators | | |
| No cost to consumer | | Policy options (collab. Discuss.) | | |
| | | Cong work with WA & others | | |
| | | Oregon work with WA | | |

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|---|---|---|---|---|
| | | Health dist work with agencies - keep informed | | |
| | | Give Group Health grant (from drup manuf) breakdown by type of drug | | |
| | | Provide tech assistance State Dept Board of Pharm. | | |
| | | Coll. With Univ/research to measure effects | | |
| ***What will it take for support?*** | ***Next steps?*** | ***How can groups collaborate?*** | ***What are you willing to do?*** | ***Extra Discussion*** |
| ***GROUP #3*** | | | | |
| Convenience - location | DEA | Can provide forum to collaborate | Will beat table: negotiate, ideas | |
| DEA issue - big deal to resolve | Negot. Multiagency | Considering a pilot like GHS's | Where is personal responsibility? Wise use focus, vs max purchaes - free disp. | |
| Outreach as a key of program so its real | Producer support | Sr. Orgs. Can assist with outreach | Use market forces to improve whole system | |
| Mailback role - can support via UPS, also support non-mailback | Long-term funding if no producer supp. Avail. | Local gov. can assist with outreach | Is pt compliance a separate issue from disposal? | |
| Negotiate multiagency issues, eg: nursing homes, BOP/Ecology/Etc. | Thorough assessment of pilot | USPS - more collaboration like with Maine;resource to solution | Upstream work - how much marketing - free samples of Ambien - no way! In people mag. | |
| Ok to move forward w/out DEA issue or others all resolved, better to move | Find the players, follow the chain, practical focus | Bill analysis - action | There will always be waste drugs | |
| Easier disposal | Enforcement necessary | Inform public/local councils ~ issue updates | Will pay deposit for drug at POS | |
| | Legislation- WA & OR, engage stakeholders - several meetings - negotiate with PH Mfrs | Talk, interesting & unexplored questions remain - focus group, whee is most convenient? To who? What builds compliance in real world? | Foreign chemical in our body - like to reduce personal drug use. | |
| | Don't pre-suppose product stew. as the answer, start with an open-ended soln. | Joint exploration of options | Many upstream issues - all need addressing. | |
| | Agree on goals, then soln. | ME program-fewer middlemen? More recycling? | | |
| | Consumer needs - convenient, easy, free | Include nat'l perspective | | |

| | | | | |
|---|---|---|---|---|
| | Concern~study as using up resources/stall tactic | Find most eff. Xportation, of other models for waste | | |
| | Making Phrma responsible brings them to table | Broad perspective is best. Ultimate drug container to facilitate drug recyclers | | |
| | | | | |
| ***What will it take for support?*** | ***Next steps?*** | ***How can groups collaborate?*** | ***What are you willing to do?*** | ***Extra Discussion*** |
| ***GROUP #4*** | | | | |
| Support the manuf. effort | Legislature specific on what is to be done | Keep groups talking | Stay in touch-help with task force approach | |
| Logical step -source control - pollution prevention makes lots of good sense | Bring in manuf. Participation. | Subgroups dealing with individual issues and obstacles - concerted effort towards solutions. | Get Fed Leg involved - should state make contact with Fed agency? | |
| Convince others to support | Look into DEA-who to talk to for firm answers | Good communications strategy start networks. List serves build enthusiasm to do the work | Tell others, raise awareness | |
| Support with reservation over metabolized sources that still need dealing with. Stewardship best way to deal with problem | State and Fed. Barriers - bring people together to fix it. | Emphasis on including more manuf. and stakeholders. | DOE supports | |
| Equity & efficiency plus customer service - what cost shifts to consumer? (important part of education costs of program) | Cost of program estimate | Get regulatory folks together to look at barriers | Continue to look into issues | |
| Understand barriers to program | Responsibility of prescribers - BMP | Need a model for barriers, TIB model from consumers- then we can address the barriers | | |
| Understand role of gov. expansion to deeper issue-ie; recycle med. Bottles | Ask about real need for individual perscrip. | | | |
| Idea: separate packaging from meds. Benefit: ID gone in recyle process such as shredding, grinding - do it on the spot. Require consumer to remove labels | Involvement of manuf - they need to be on board too. | | | |
| Look at this as only 1st step, don't review pilot as the way to go for manuf. | Follow legisla. work done with specific obstacles | | | |
| More fair distribution of business participation | Have collection sites on board and ready | | | |
| No cost to counties | Better and smaller packages | | | |

| | | | | |
|---|---|---|---|---|
| Manuf. % based on the actual product sold into the state - their responsibility | | | | |
| ***What will it take for support?*** | ***Next steps?*** | ***How can groups collaborate?*** | ***What are you willing to do?*** | ***Extra Discussion*** |
| ***GROUP #5*** | | | | |
| See more than I site - multiple per rural and smaller communities | Complete backing in state of WA. Leg. Exec branch-help in funding? | Patient education - pharm can pplay that role, doctors, pharmacists. Etc. can be educated too | Sit back - see how pilot goes - Thurston Co. Have facilities et up - outreach ability "infrastructure" mobile waste collection event" - have means but want to see pilot. | |
| Lesser or non-cost push to patients. Manuf. pay, but make sure independent pharmacies don't have hidden costs. | Successful legislation - continue support for locals | Companies interested in being involved - funding and support? | Kaiser has talked about it - willing to create program but waiting - DEA hurdle, pharmacists liable if put in position without DEA approval. Want to get there. | |
| Private citizen realization that Leg. Has no funding, recession? Manuf. Not funding-concerned no funding available. | Hear more discussion at end of chain - haz waste disposal mechanism - tech parameters, access to facility? Need to determine. Wcrc-doing that at Bartell's. Reg framework created for whole incineration process? Haz waste could work - controlled sub concern, what's happening with that now? | Bring manufacturers together | Welcome support and testimony for HB - Manuf funding | |
| Make sure long term funding | ID broad rep. -potential coalition: members, hospitals, elder care, nursing (health care related). Names-what other people. Need commitments from end users - support endorse and educate. | Ask what they want out of it (vendors and retailers) ex: large chains know need prescrip monitoring - ask what they want to see - best practices? Make it easier on them - listen, bring them in. | In the past pharmacy/safety issue - DOH support recently - injury preventon - board of Pharmacy - diversion/poisoning really is a public health issue | |
| Insurance environ. Protective way | Statewide - two sets of circumstances - Moses Lake (or Selah) vs Seattle - where to take in rural communities? What about volunteer pharms - don't participate | Need to listen pharm companies - keep out of waste stream, prevent dispensing to dead people - trial medications? Reduce #'s? Take seriously upstream issues - bring pharm companies to table. | Attorney General - continue advocating, board stratecy - educate, prevent, law enforcement, multi pronged approach. Ensure proper safety disposal boxes | |

| | | | | |
|---|---|---|---|---|
| System as simlple as possible, lower regulatory involvement | Lots of messaging before grant funds run out. Tech knowledge, diverse disciplines - talking points developes educate/engage public | Adherence to drugs - pharm. "goal" | Help with messaging - SnoCo very proactive, law enforcement | |
| Won't lead on issue - DOH will be lead: client happy with outcome -baselines-accurately capture return rate-determining actual values in waste stream-Fed and State law followed - supported by industry and vendors. | Show why it's a compelling issue. Unanswered questions need addressing. Lay groundwork - should be prioritized. | | | |
| | WA leader in environ. Bills. Toxic toys - manuf. Need to be involved immediately | | | |
| | Pull in public support - example: programs that pay for patients who can't afford. Make a bigger topic now. Patients put pressure on industry/organizations. | | | |
| ***What will it take for support?*** | ***Next steps?*** | ***How can groups collaborate?*** | ***What are you willing to do?*** | ***Extra Discussion*** |
| ***GROUP #8*** | | | | |
| Simple not much time | Get a law passed | Concise outreach communication development | State waste agreement includes this waste stream | |
| Let professionals do what they do best | Press coverage | "Cleansweep program involvement" | Education | |
| This just makes sense | Lobby - legislative areas | Dialogue = industry in a collaborative way | | |
| Is anything really free? | Canada example | Involve disposal side | | |
| Appropriate Manf. Funded program becomes mainstream. | Mfr. Example | DEA need to hear from all side | | |
| | Retail RX peer pressure | | | |
| | Cookie cutter approach | | | |

# PRELIMINARY SUMMARY: Breakout Session Notes, and Action Steps

as of June 5, 2008

**MEDICINE TAKE-BACK WORKSHOP: Establishing a Return Program for Household Drugs**

APRIL 18, 2008 8am-4:30pm SEA-TAC MARRIOTT

## Breakout Session Notes

From facilitated discussions among workshop participants

What will it take for you to support a manufacturer-funded take-back program?

- Manufacturer cost estimates, funding
- Data/science on pilots, risks, volumes
- Ability to take controlled substances
- Keep it simple
- Waste reduction efforts
- Work on excretion issues, source reduction
- Assure long-term funding

What are specific next steps needed to bring about a state-wide medicine take-back program?

- Resolve DEA issues
- Legislation
- Long-term funding
- National dialogue
- Manufacturer collaboration, participation
- Science/research, including PH:ARM pilot assessment
- Measure impacts
- Deal with excretion, waste
- Best mgmt practices (BMPS): prescription reduction
- Expand collection sites/partners, have them ready-to-go
- More support, coalition from other partners: elder care, nursing homes, etc.
- Consumer education and support
- Lots of messaging, communication, press coverage

How can groups in this room collaborate to bring this about?

- Manufacturer dialogues
- National perspective
- Science, communication
- Not just an environmental issue
- Local utilities, water, environmental federations
- More partners – e.g., env'l health, AARP
- Legislation
- DEA waiver request
- Solutions – e.g., USPS or transportation regulations
- Forums: public & stakeholder discussions
- Build/support networks with communications, list serve, issue updates to local gov't & public
- Public awareness, patient education
- Upstream waste reduction

What are you and your organization willing to do, to contribute to this effort?

- Educate public, drug companies, legislators
- Assist PH:Arm team
- Seek support
- DEA discussion/national level
- Study science
- Lobby
- Check disposal alternatives
- Wait for pilot results
- Stress safety/risk message & partners
- Help with messaging

## Summary of Action Steps

As noted by workshop participants and (see asterisks) workshop planners

Outreach:

- Presentations to stakeholders and interested parties*
- Report back to my organization
- Address unused medicine disposal in DARE and Poison Control Center messages
- Website updates, press releases, op-ed pieces*
- Final report on pilot project*

Long-Term program:

- Circulate information on pilot project and long-term objectives*
- National coordination: pharm return interests*
- Get pharm manufacturer funding to support Group Health and other collection site partners*
- Look for new collection partners and opportunities

Policy/Legislation:

- Collect personal &professional "stories of need" for safe medicine return*
- Endorse legislation (and seek endorsements from others)*
- Work on DEA changes to Controlled Substances Act*
- Do policy research

Stakeholders:

- Engage with health care interests*
- Involve others in creating, supporting a long-term solution*
- Seek support from other stakeholders (e.g., health care organizations)
- Follow-up meetings (separately) with regulators, manufacturers, pharmacists, local/state gov't*

Solutions:

- Work on source reduction*
- Check into Rotary drug re-use programs
- Use HHW facilities to collect unused meds


***Register Now!***
***Friday, April 18, 2008***
***Seattle Vicinity, Washington***

You have been selected to attend a free invitation-only, participatory workshop to establish a return program for unwanted household drugs throughout Washington State. Space is limited. Register now.

Join key stakeholders to:
- Examine issues
- Strengthen partnerships
- Review results/lessons from pilot project
- Discuss next steps to establish a secure, long-term medicine take-back program

**Register** now to reserve your seat. You will receive additional information after registering.

Please join us April 18th for a workshop to address the residential drug disposal dilemma and determine the next action steps in establishing a secure take-back system for Washington State.

This invitation-only, one-day workshop is being planned by a consortium of key health, government, environmental and citizen groups concerned with the impacts of improper residential drug disposal. Drugs that accumulate in our medicine cabinets can contribute to accidental poisonings and possible diversion, which can lead to abuse. Much of the unwanted medicine that is flushed down toilets or thrown in the trash will end up in our surface or ground water, potentially harming our environment.

Because space is limited, we want to ensure the participation of interested, thoughtful representatives from key stakeholder groups. You have been chosen as an invitee. If you are unable to attend or have a colleague or contact that you think would be a good contributor to the workshop, please send an e-mail with the pertinent contact information to takeback@pprc.org.

Watch for additional emails with more information to come.

**Invited Guests, Register Now!**

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Information on Medicine Take-Back issues and the current Washington State pilot program can be found at www.medicinereturn.com.


## *Save the Date*

***Friday, April 18, 2008***
***Seattle, Washington***

Attend a free invitation-only, participatory workshop to establish a return program for unwanted household drugs throughout Washington State.

Join key stakeholders to:
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Check your email for more information to come. Online registration will be available in February.

Please join us April 18th for a workshop to address the residential drug disposal dilemma and determine the next action steps in establishing a secure take-back system for Washington State.

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Watch for additional e-mails for more information to come.

If you would like your name removed from future e-mail lists, please send an email to takeback@pprc.org

Information on Medicine Take-Back issues and the current Washington State pilot program can be found at www.medicinereturn.com.

Related legislation (HB 2600) has just been prefiled for the 2008 Washington legislative session. For a summary of the proposed legislation visit http://wastenotwashington.org/HB2600summary.pdf. If your organization would like to sign on to the bill's growing list of endorsers, please contact Will Perry by email at William.Perry@kingcounty.gov or by phone at (206) 263-8477.

# SHB 3064
# Secure Medicine Return

## Concerns

Medicines save lives. When we are left with expired or unwanted drugs, however, there is growing concern that they be handled in a protective and safe manner. Drugs that accumulate in our medicine cabinets can contribute to accidental poisonings and illegitimate access that can lead to abuse. Much of the unwanted medicine that is flushed down toilets or thrown in the trash will end up in our surface or ground waters, potentially impacting aquatic organisms.

- **Accidental Poisonings**: Accidental poisonings increased 345% from 1990, most of them from medications. (Source: Unintentional Poisoning/Overdose Deaths in Washington, 6-12-07, Department of Health)
- **Drug Abuse**: Over half of the people using prescription drugs for nonmedical reasons obtained them from a friend or relative for free. (Source: National Survey On Drug Use and Health, 2006)
- **Our Environment**: Septic systems and wastewater and sewage treatment are not effective in eliminating the majority of medicines. Organic wastewater contaminants, including medicines, were found in 80% of 139 streams sampled in 30 states. (Source: U.S. Geological Survey, 2002)

## Solution

The legislation will result in a cost-effective medicine return program that is convenient, safe and secure for residents throughout the state. Drug companies will pay for and implement "product stewardship programs" for the collection, transportation and disposal of unwanted drugs from residential sources, removing them from harm's way.

## Key Advantages

- Provides **effective collection** of unwanted medicines. In 2006, an industry-run and financed program in British Columbia collected 44,000 pounds of medicines at over 850 participating pharmacies. That program has operated for more than 10 years and is funded by an association of over 100 drug companies as a "cost of doing business."
- Provides an **easy and safe** return program for residents throughout the state. Residents want and will use a safe way to dispose of their unwanted drugs. A pilot project at limited locations here in Washington is safely collecting 1.5 pounds per day per pharmacy of unwanted drugs from people's homes.
- **No charge to residents** when returning medicines. The law will have negligible, if any, impacts on the price of medicines.
- **No new costs to local governments.**
- Medicine return becomes **part of doing business** for the producers, and the law will level the playing field by requiring that all producers participate.

**Contact information:**

**Suellen Mele, Washington Citizens for Resource Conservation: 206.856.4761**
**Cheri Grasso, Local Hazardous Waste Management Program in King County: 206.291.5004**

## How It Will Work

- The legislation will establish a free, convenient and safe return program for expired and unwanted medicines from residential sources, including prescription and over-the-counter drugs.

- By January 1, 2010, producers (drug companies) will establish and pay for a product stewardship program for the collection, transportation, and disposal of the medicines. Producers can meet this requirement independently or by coordinating with other producers.

- The program must be available to residents in every county of the state. The program will also be available to residential sources such as hospice services, nursing homes, boarding homes, and schools.
- Producers will determine how best to securely and conveniently collect the drugs. Retailers are not required to provide collection locations. However, based on the experience of a pilot project currently operating in Washington and a British Columbia program operating since 1996, it is expected that many pharmacies will be eager to become collection locations for a program provided by producers.
- Producers will set their own recovery goals for the first three years of the program. After that time, the Board of Pharmacy will set and enforce recovery rates.
- Medicines collected by a product stewardship program must be disposed at a properly permitted hazardous waste facility. If packaging delivered into the program along with unwanted medicines is then separated from the unwanted medicines, the program will maximize recycling of that packaging.
- Producers will inform the public about their program and prepare outreach materials for use by pharmacies and others. Pharmacies will also provide information to customers describing where and how to return unwanted drugs.
- To ensure secure handling of the medicines, the product stewardship programs will be reviewed, overseen, and enforced by the Board of Pharmacy. Producers must submit a product stewardship plan to the Board for approval, and must also submit annual reports. The Board will review plans in consultation with the Department of Ecology.

**Supported by:**

**WA State Pharmacy Association · Bartell Drugs · Group Health · WA Food Industry**
**Senior Citizens' Lobby · Children's Alliance · Breast Cancer Fund · League of Women Voters of WA**
**Yakima County · King County · Local Hazardous Waste Management Program in King County**
**Thurston County · Coalition for Clean Water · WA Association of Sheriffs and Police Chiefs**
**WA State Nurses Association · WA State Association of Occupational Health Nurses**
**WA State Hospice and Palliative Care Organization · Assoc. of Advanced Practice Psychiatric Nurses**
**WashPIRG · Environment Washington · WA Organic Recycling Council**
**WA Citizens for Resource Conservation · Sierra Club Cascade Chapter · People for Puget Sound**

# Disposal of Medications from Residential Consumers

## Issues, barriers, and opportunities

**Compiled by:**
Pharmaceuticals from Households:
A Return Mechanism (PH:ARM) Pilot Team

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Interagency Resource for Achieving Cooperation (IRAC), Local Hazardous Waste Management Program in King County, Snohomish County Solid Waste Management Division, Public Health- Seattle & King County, Northwest Product Stewardship Council, Washington Citizens for Resource Conservation, the Pacific Northwest Pollution Prevention Resource Center, Washington State Department of Ecology, Department of Social and Health Services, and the Washington State Board of Pharmacy.

**October 12, 2005, revised December 14, 2007**

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# Table of Contents

## Purpose of this Document

This document frames the issue of unwanted medicines disposal for decision makers and stakeholders. Our goals are:

- To clarify and explore frequently raised issues.
- To establish a common framework of understanding, thus allowing the development of effective policy recommendations and programs for proper drug disposal.

This document briefly provides:

- A background of scientific evidence and the regulatory framework related to waste consumer pharmaceuticals;
- A discussion of the current barriers to implementing an efficient and effective collection program;
- An overview of necessary components for successful medicine returns programs.

## Pharmaceuticals Background

**Why prevent improper disposal of waste residential medicines?**

Poisoning and abuse remain the most acute human health concerns related to left-over and unwanted medicines in people's homes.

Poisoning

Disposal to the household trash or improper storage may contribute to the risk of accidental poisonings. According to the Washington State Department of Health, nine children die each year from poisoning, 465 are hospitalized, and 3,490 visit the doctor.[1] Of 24 child poisoning deaths from 1999 to 2001, 16 were due to medications[2], or approximately 5 per year. Unintentional poisoning[3] death rates in Washington increased 345% between 1990 and 2004, from 2.3 to 10.2 per 100,000 people.[4]

Nationwide, medications are the most common poison exposure category. The Centers for Disease Control[5] 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).

Abuse

Rising drug abuse is a serious concern which may be related to improper storage or disposal of unwanted medications in people's homes:

- 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 [6]

- One in 10 teens reports having abused Over-The-Counter cough medicines to get high.[7]
- In 2006 abuse of prescription pain killers ranked second—only behind marijuana—as the Nation's most prevalent illegal drug problem. Much of this abuse appears to be fueled by the relative ease of access to prescription drugs[8].

Assistant Surgeon General Eric Broderick, D.D.S., M.P.H., the Substance Abuse and Mental Health Services Administration Acting Deputy Administrator, stated that:

"…70 to 80 percent of those 12 years or older said they got their drugs from a friend or relative… Parents and other caregivers should ***store their prescription drugs carefully and dispose of any unused drugs*** before they can fall into the wrong hands."[9]

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**Are pharmaceuticals present in the environment?**

Due to new assessment tools, pharmaceuticals are now being detected in water and soil by scientists worldwide. 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.[10]

A 1999 summary of research from the EPA's National Exposure Research Laboratory cites that "Excluding the antibiotics and steroids, over 50 distinct pharmaceuticals and personal care products or metabolites (from more than 10 broad classes of therapeutic agents or personal care products) have been identified in sewage treatment effluent or in environmental samples (mainly surface and ground waters); representative classes include analgesics/anti-inflammatories, antineoplastics, antiseptics, beta-blocker (antihypertensives), 2-sympathomimetics (bronchodilators), lipid regulators and bioactive metabolites, musks (synthetic nitro and polycyclics; also reduced metabolites of nitro musks), anti-psychotics, sun screen agents, and X-ray contrast media.[11].

In Washington state, a screening analysis conducted in tertiary wastewater treatment plant effluents and nearby wells and creeks in the Sequim-Dungeness area of northwest Washington detected 16 organic wastewater contaminants (OWCs) in the effluent samples. In the Sequim study, 9 of 11 samples (82%) contained pharmaceutical drugs. Significantly, the Washington state analysis was limited to only 24 chemicals, whereas the USGS study tested for 95 chemicals. [12]

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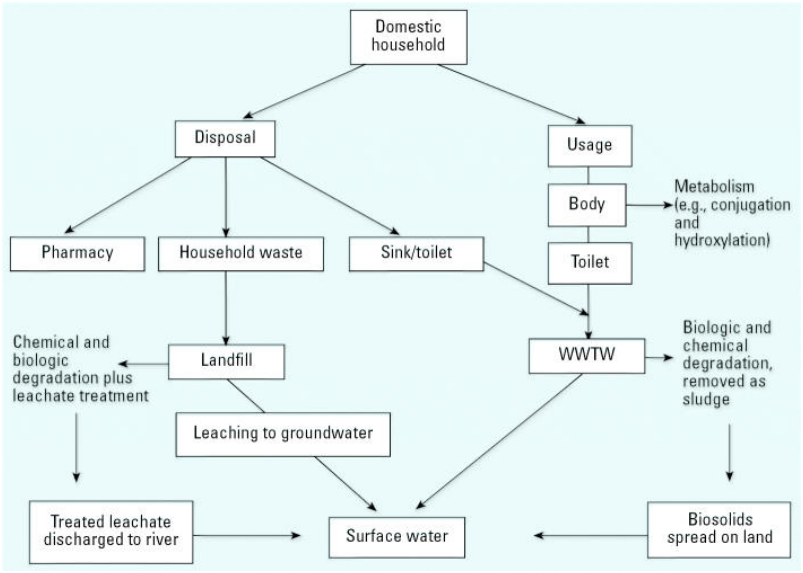
**How do pharmaceuticals enter the**

Pharmaceuticals and OWCs have been found primarily in effluent and surface water, and emerging research indicates the presence of pharmaceutical chemicals in biosolids and soil.[13]

**environment?**

Residential, commercial, and agricultural pharmaceuticals can follow various pathways to the environment, described in the illustration below.[14]




1) Excretion: A large percentage of a drug or its metabolites can be excreted following human and livestock consumption.[15] The portion of the substances that is excreted follows sewage, septic or surface runoff pathways to wastewater or into sludge (biosolids). Topical medicine products are eventually washed off and can enter the wastewater system.
2) Direct Disposal: Unused pharmaceuticals are typically disposed of to the septic tank, sewer or landfill. About one third (33%) of the pharmaceuticals prescribed in Germany and one quarter (25%) in Austria are disposed of in household waste or down the drain.[16]
3) Reclaimed Water and Land Application: Pharmaceuticals contained in wastewater sludge can be applied to agricultural land as fertilizer, which could leach into groundwater[17]. A USGS study showed that soils samples from land irrigated with reclaimed water contained 19 different pharmaceuticals[18].

Problems:

When discharged to the sewer, pharmaceuticals end up at wastewater treatment plants that offer primary, secondary or tertiary treatment levels. Most conventional wastewater treatment cannot effectively eliminate all pharmaceutical compounds.[19] Some treatment technologies are available for organic wastewater contaminants[20], but thus far they have been cost and space prohibitive in large waste water applications.[21] Pharmaceuticals discharged to septic tanks may also enter the environment when pumped material is disposed or from seepage into groundwater or soil.

Landfill leachate may also contain pharmaceutical contaminants. Often this leachate is sent to the same wastewater treatment systems that receive residential wastewater. Traces of pharmaceuticals have been detected in landfill leachate[22], so disposal of pharmaceuticals at engineered landfills may merely postpone pollution of surface water and ground water.[23] In Germany, barbiturate use peaked more than 3 decades ago, yet drugs are still being detected in surface water and groundwater in Germany at several micrograms per liter. No barbiturate was degraded biotically or abiotically. Researchers suggested the source of barbiturates as old landfills or contaminated sites, rather than excretion via WWTPs.[24]

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**Why is there concern about pharmaceuticals in the environment?**

"A particularly troublesome environmental pollution scenario is one resulting in continual but unnoticed biochemical effects on organisms — effects that accumulate so slowly that major change is not detectable until their cumulative level finally cascades to irreversible change. One possible example fitting this scenario, starting with subtle, unnoticed effects and culminating with outward change, could be manifested by the continual exposure of aquatic organisms to the complex spectrum of pharmaceuticals that can persist in the treated effluent from sewage facilities.[25]"

The emerging concern about pharmaceutical pollution is the *widespread detection and number* of low-level Organic Wastewater Contaminants (OWCs) found in the 2002 US Geological Survey study samples. An average of seven OWCs and as many as 38 OWCs were found in individual water samples. Most pharmaceuticals degrade in the environment, but have a quality of pseudo-persistence due to the continual release of the contaminants via use, excretion, and disposal.

Little is known about the potential interactive effects (such as synergistic or antagonistic toxicity) that may occur from complex mixtures of OWCs in the environment.[26] However, researchers are starting to suspect that hormones and medicines in the water may be responsible for effects on wildlife including:

- Endocrine disruption among male fish exposed to municipal wastewater, including feminization, sluggish activity or reduced appetite.[27]
- Antibiotic resistant bacteria in surface waters based on the occurrence of antibiotics in wastewater.[28]
- Antibiotics may reduce the growth of aquatic plants.[29]

A recent study by the University of Minnesota demonstrated that corn, potato and lettuce can uptake antibiotics into their leaves and plant tissue from animal manure applied to soil. Concentrations in plant tissue also increased as the amount of antibiotics present in the manure increased. From 9 to 13 million kg of antibiotics are used in livestock

operations in the US annually.[30]

**How common is prescription use in Washington state, the U.S. and the world?**

Pharmaceutical use in the general population is common and growing, meaning that more often than not, households are dealing with leftover drugs. The average prescription rate in Washington was 9 prescriptions per capita per year in 2006, totaling 56.8 million retail prescriptions in Washington state. [31] The national average was 11 per capita per year for 2006, totaling 3.3 billion retail prescriptions.[32] From 1994 to 2004, the number of prescriptions purchased increased 68% (from 2.1 billion to 3.5 billion), as the U.S. population grew only 12% over the same period[33].

This trend is also in evidence on a global basis. Worldwide, the pharmaceutical industry is forecasted to more than double to $1.3 trillion by 2020.[34]

**What is the total quantity of waste pharmaceuticals?**

There are a variety of estimations of the volume of waste pharmaceuticals being stored or disposed of by consumers. A recent study completed by the EPA estimated that 17.9 metric tons of medicine is disposed of annually to the sewage system by the deceased population alone.[35]

The following illustration used in a 2005 presentation by PhRMA, the U.S. brand owner pharmaceutical manufacturer association. The total weight of unused pharmaceuticals in the U.S. is estimated based on four different estimates of total unused prescriptions[36].

**The quantity of unused medicines depends on the assumptions used.**

| Number of Prescriptions | Weight of (Non-Hospital and Clinic) Prescriptions |
|---|---|
| 3.4 billion | Pills: 40.0 MM lbs.<br>Pills & containers: 143.0 MM lbs. |

| % (Non-Hospital or Clinic) Prescriptions Unused | | | |
|---|---|---|---|
| 20 % | 10 % | 5 % | Best Est. % |
| 28.6 MM lbs | 14.3 MM lbs | 7.2 MM lbs | 4.3 MM lbs |

By weight of pills and containers

Based on blended individual and LTCF "wastage" rates

One study of older adults (65 and older) conducted in 1999 approximates the value of wasted medications to be 2.3% of the total medications

prescribed. If the subjects in this research are representative of the elderly population in the U.S., the value of wasted medications could top one billion dollars each year[37].

PhRMA, estimates 3% of product sold is wasted nationwide[38]. This figure contrasts the estimated 25-33% waste rate noted in studies from Germany and Austria of pharmaceuticals disposed of either to a landfill/incineration or into the wastewater system[39].

PhRMA reported that sales of 23 active ingredients (representing a typical sampling of drugs) totaled approximately 22 million lbs.[40] If the 25% wastage rate from Germany and Austria is accurate, 5.5 million pounds of pharmaceuticals are disposed per year nationwide from sale of these 23 active ingredients.

**How do consumers currently dispose of waste medication?**

A survey completed in 1996 showed that 63% of the U.S. population disposed of medication in the past.[41] The following table from a study done in the Eastern U.S. estimates the fate of unused pharmaceuticals by source prior to disposal.[42] About two thirds of unused pharmaceuticals are generated by individuals. Another third originates at long term care facilities.

**Unused medicines management practices vary depending on who holds the unused medicine.**

| Pharmacies | Hospitals |
|---|---|
| • Most unused medicines returned for credit | • Use their pharmacies to return for credit<br>• Unreturnables:<br>- Ordinary IV → drain<br>- Chemo IV → HW<br>- Pills → Medical Waste |

| Long Term Care Facilities |
|---|
| • Source of 34% (1.5 MM lbs) of unused medicines<br>• 4% to 10% wastage<br>• Typical disposal practice is flushing down the drain |

**Individuals**

• Source of 66% (2.8 MM lbs) of unused medicines

| | Pittsburgh | Ontario |
|---|---|---|
| **Trash** | 54% | 31% |
| **Drain** | 35% | 46% |
| **Keep** | 7% | |
| **Pharmacy** | | 17% |

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.[43]

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 only a third of King County residents are actively using or planning to use the medicines they have in their households in the next six months.[44]

**What's the difference between over-the-counter drugs, prescription drugs, and controlled substances?**

Over-the-counter (OTC) drugs are products that consumers can buy without a prescription. Prescription (or legend) drugs require a prescription from a doctor, and are dispensed by a pharmacist. Some legend drugs are called 'scheduled drugs' or 'controlled substances,' and are categorized into Schedules I-V by the US Drug Enforcement Administration (DEA) according to their beneficial use and addiction potential. Many of these controlled substances are legally prescribed to patients, commonly for pain control, such as codeine. Schedule I drugs are illegal.

**Are pharmaceuticals considered hazardous waste? Aren't they a beneficial consumer product?**

Many pharmaceuticals have ingredients with characteristics that cause them to 'designate' as hazardous waste when disposed. To designate means to either be a federally-regulated (under RCRA – Resource Conservation and Recovery Act) or state-regulated hazardous waste (under the Dangerous Waste Regulations WAC 173-303). Federally-regulated hazardous wastes include lists of certain discarded chemical products or manufacturing/industrial processes or wastes with hazardous characteristics (ignitability, corrosivity, reactivity or toxicity). Washington State has additional criteria for toxicity and persistence that make other pharmaceuticals 'designate.'

Hazardous waste regulations apply to pharmaceuticals as soon as a business makes a decision that they are waste and no longer a product. It is important to note that **pharmaceutical waste generated by households is exempt** from the state Dangerous Waste and the federal RCRA rules.[45] However, local jurisdictions responsible for municipal waste management may disallow household hazardous waste from regular solid waste, septic, or sewer disposal routes[46], as in the case of Snohomish County, Kitsap County, and the City of Seattle. Many cities and counties have goals to prevent and remove pharmaceuticals from both wastewater and solid waste streams.

A study from 1996 showed that, for medications that are not returnable: 15% were incinerated; 17% were directed to hazardous waste handlers; and 68% were disposed to solid waste or the toilet[47].

## Why the Current System Needs Modification

**Can hazardous waste disposal companies accept waste**

Yes, though these companies need special permits to do so. Currently, hazardous waste transporters pick up hazardous waste and deliver it to sites permitted for hazardous waste treatment, storage, and disposal (TSDFs).[48] Medicine waste can be handled by these businesses with the

**pharmaceuticals from consumers?**

following two conditions:

1) Handling pharmaceuticals or waste pharmaceuticals requires a license from the Washington Board of Pharmacy.
2) Disposal service companies cannot accept any end-user controlled substances returned to a pharmacy take-back program without federal permission (such as a waiver to DEA regulations).

---

**Can pharmaceuticals be collected at municipal household hazardous waste facilities or events?**

Municipal household hazardous waste facilities and events are not licensed by the Washington State Board of Pharmacy, or the DEA, to handle medications. Such facilities do not have capability to take the necessary precautions or the desire to handle a material that would make them a potential target of drug seekers (by the public or the site staff).

In addition, there are limited numbers of household hazardous waste (HHW) facilities, typically one per county, which makes them generally inconvenient. In comparison, there are numerous pharmacies (1,300+ statewide) found in any given community. Many consumers would not think of taking waste pharmaceuticals to a hazardous waste facility—but are naturally inclined to take waste pharmaceuticals back to their convenient local pharmacy. In a SoundStats survey completed in 2006, 2% reported they considered a municipal waste facility convenient, and 5% said they considered a special collection event convenient.[49]

---

**Can waste consumer medications currently be returned through pharmacies?**

Yes and no. There are two distinct barriers to the return of a consumer's medications to a pharmacy:

1) Federal DEA rules do not currently allow for the return of end-user controlled substances to a pharmacy.
2) Federal Resource Conservation and Recovery Act (RCRA) rules do not allow the take-back of **waste** household pharmaceuticals through a pharmacy's pharmaceutical take-back provider (called a reverse distributor, see next section) because reverse distributors are not permitted to accept waste without the applicable regulatory controls for waste management, according to a 1991 EPA memo.[50]

The first barrier cannot be eliminated *unless* the DEA grants a local program wavier or changes the Controlled Substances Act (which is the reason for the detailed waiver request made by the PH:ARM team in March 2007).

The second barrier can be eliminated if the reverse distributor meets one or more of the following conditions: they can be classified as an exempt "take-back" location (for Washington State household hazardous waste only)[51], a hazardous waste transporter (subject to a 10-day storage limit), or a solid waste transporter (a 'G-certificate' issued by the Utilities and Transportation Commission in Washington). The Washington UTC generally issues one G-permit for a single territory of service.

**Can the pharmacy's waste and waste medications from consumers be put into the same disposal system?**

Household waste, if combined with business waste, would lose its exemption from Federal RCRA hazardous waste rules. Though small quantity generators (SQGs) have streamlined compliance requirements compared to regulated generators,[52] they are not exempt from the requirements to designate and count their hazardous waste. In some situations, adding an additional quantity of pharmaceutical waste may place a pharmacy above the Small Quantity Generator[53] volume limit for hazardous waste and extremely hazardous waste, such as epinephrine.

Therefore, segregating patient & consumer returns and business waste is critical to remain in compliance with environmental laws.

Alternatively, the US EPA is looking to develop universal waste rules which would eliminate counting and designation requirements, allowing business and household waste to commingle. That rule change will take several years.

## Reverse Distributors

**What is a reverse distributor (RD)?**

A reverse distributor (RD) is a business that manages certain pharmaceuticals typically shipped from a licensed pharmacy. The RD then makes the determination of whether the pharmaceutical is "product" or "waste", thereby becoming the generator of the waste (rather than the original business generator). The RD may accept expired or unusable product, but only product that has not already been designated as waste.

If the product has been designated as business 'hazardous waste,' Federal RCRA rules require the waste to be handled by a hazardous waste treatment, storage or disposal facility. [54] Business waste must be designated by type of hazardous waste and counted by the original business generator. RD's provide some credit (for business waste only) when a valued product is ultimately returned to the manufacturer.

**Can a reverse distributor collect controlled substance waste for destruction?**

DEA regulations permit the collection of *a pharmacy's* controlled substances (CS) by a licensed reverse distributor (RD) for the return of the pharmaceuticals to the manufacturer or for destruction. RDs are still required to keep detailed records of all controlled substances that change hands on Forms 222 and 41. However, RDs cannot currently accept controlled substances from end-users without a DEA waiver from regulations, even if all accounting procedures are in place.[55]

The DEA allowed RDs in Kentucky to take-back controlled substance pharmaceuticals from long term care facilities. A similar proposal was also made by Washington state in 2005 to do the same, but the DEA has

stated that expansion of the Kentucky program will not be considered.

## Medicine Return Programs

**What are the reasons to collect waste household medicines?**

- Pharmaceuticals present both a public safety and environmental hazard if no secure disposal option exists.
- Data generated by the collection program can be used in educational efforts to reduce waste in both pharmaceutical use and prescription writing.
- A collection system decreases the environmental pollution from solid waste landfills and waste water treatment discharge.
- Separate collection helps communicate the environmental impact of this waste stream to the responsible parties: consumers, retailers, and manufacturers.
- A simple collection system can be modeled after other take-back programs for light bulbs, computers, thermometers, batteries, and oil.

**What is the expected quantity of waste medicines that could be collected in a pharmacy-based take-back program?**

The EPA Workshop on Pharmaceuticals in the Environment held in 1995 looked at the results of other consumer product take-back programs to attempt to gauge what the capability of a drug take back program could be. They determined that in general the success rate was under 20% of total products sold with exceptions being lead acid and rechargeable batteries[56]. There were 53.8 million retail prescriptions sold in Washington state in 2006.[57] If the take-back program follows the success rates of some of the other products, the eventual yield could be 10% (5.38 million prescriptions per year) to 20% (10.8 million prescriptions per year). That is an equivalent of 63,000 lbs to 127,000 lbs annually in Washington State, using a conversion rate of 0.0118 lbs of pill weight per prescription. [58]

A pharmacy-based take-back program launched in October 1996 in British Columbia, Canada serves a population of 4 million with 800+ pharmacies and collected **44,092 lbs** of waste medicine in 2006.[59]

Extrapolating the B.C. collection data to Washington state, with a population of 6.2 million, a statewide program based on the BC program could collect **66,000 lbs** per year for proper disposal.

Current collection volumes from the PH:ARM pilot at Group Health Cooperative between October, 2006 and September 2007 showed sites collecting an average of 1.5 lbs per pharmacy per day. If the average collection rate continues, a statewide program could collect **600,000+ lbs** of medications per year (6 days a week at 1,300 pharmacies), excluding long term care facilities.

In addition, there appears to be a ramp-up effect as visitors to

pharmacies develop awareness of the program and begin to bring in medications. The latest screening collected 1.5 lbs per day, or three times more than the collection rates at the beginning of the program which only yielded 0.5 lb per day. Time will be needed to determine whether the higher rates will continue or whether they will level off.

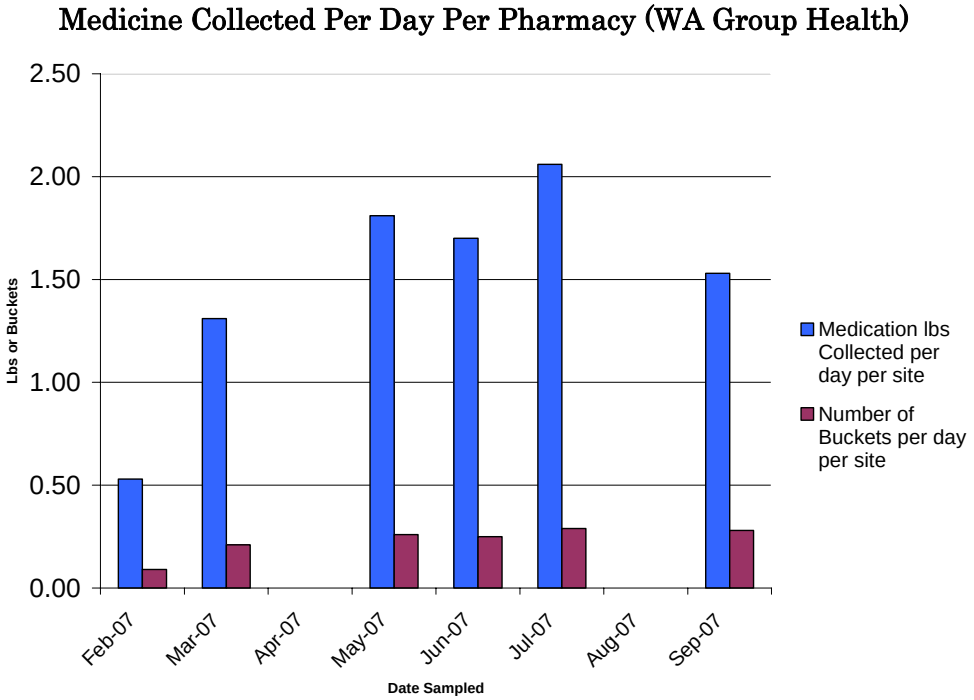


**Figure 1 PH:ARM Pilot Program Generation Rates measured February 2007 to September 2007. Collection began October 2006.**

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**What is the anticipated composition of medications collected in a pharmacy take-back program?**

Though there are thousands of drugs on the market, fifty of the best selling drugs in 2001 accounted for 44.4%of total outpatient retail drug sales, and should be indicative of the variety of waste returned. The remaining 9,482 drugs accounted for 55.6% of total sales.[60]

Based on data from other collection programs,[61] PH:ARM estimated the general composition of the collected pharmaceutical waste (by weight) to be:

- Inhalers 0-1%
- Chemotherapy drugs 0-0.1%
- High toxicity drugs (Epinephrine) 0-0.5%
- Inert packaging 10-20%
- Lindane (zero to trace)
- Low toxicity drugs (includes antibiotics) 50-75%
- Preparations with alcohol (e.g. cough syrup) 0-2%
- Thimerosol (zero to trace)
- Vitamins (1-5%)

**Could a law enforcement- based collection program work?**

The DEA has suggested police and sheriff offices as potential collection locations. While these agencies can offer a high level of security, law enforcement locations are generally inconvenient and intimidating for the general public to dispose of medications. In the SoundStats survey, 4% considered a law enforcement location to be convenient. [62]

While some sheriff offices (e.g. Clark County) are willing to act as collection locations, many police organizations, including the Washington Association of Sheriffs and Police Chiefs, support non- police officer dependent types of collection due to the cost, storage, or inventory requirements of providing this service.

**Could a periodic community collection program work?**

Periodic collection sends an inconsistent message to the community about proper behavior regarding storage and disposal, and could lead to increased home poisoning incidents (by requiring longer term storage of unused medications). Additionally it is difficult to create lasting, beneficial behavior change in a population that lacks on-going access to services.

A program based on periodic collection events also may artificially create 'a crisis of scarcity,' thereby encouraging a flood of medications coming in at once. This increases overhead and management costs.[63] Finally, the inconvenience to customers reduces overall participation in the program.

**Could a mail-back program work?**

A mail-back program may work well because of the rise in internet sales of pharmaceuticals and the high convenience level of this approach. This may also be an expensive approach, as the Oregon stakeholder group estimated a cost $3.40 per 0.5 lb mailer.[64] Another barrier is the current US postal code regarding mailing controlled substances. There are also restrictions on air transport of certain hazardous materials by the US Department of Transportation.

Maine is currently working on a mail-back program for controlled substances (resulting from 2004 legislation), but implementation of a program has thus far been halted by the Federal DEA and the Controlled Substances Act.

According to US Mail Publication 52[65]:

**483.1 Controlled Substances**

If the distribution of a controlled substance is unlawful under 21 USC 801 or any implementing regulation in 21 CFR 1300, then the mailing of the substance is also unlawful under 18 USC 1716.

Controlled substances and drugs that contain controlled substances are

acceptable in the domestic mail only under the following conditions:

a. For mailable controlled substances, generally both the sender and addressee must meet either of the following conditions:
   (1) Be registered with the Drug Enforcement Administration (DEA).
   (2) Be exempted from DEA registration, such as military, civil defense, and law enforcement personnel, in performing official duties.

b. For prescription medicines containing mailable narcotic drugs (controlled substances), only a pharmacist or medical practitioner, etc., who dispenses the medicine may mail such substances to the patients under their care.

**483.6 Return of Prescription Drugs**

Mailers may use merchandise return service to return prescription drugs for purposes of drug recalls; voluntary manufacturer withdrawals; and dispensing errors such as incorrect drug, dosage, or strength, as permitted by 21 CFR 1307.12 or other applicable law. The mailpiece must be addressed to the manufacturer or its registered agent. Manufacturers or their registered agents must furnish mailing containers to their customers for the purpose of mailing back the identified drugs. Manufacturers or their registered agents must use merchandise return service (see DMM 507.9.0) with First-Class Mail or Priority Mail for these mail pieces. Manufacturers or their agents continue to be responsible for maintaining records in compliance with any regulation of the Drug Enforcement Administration and/or the Food and Drug Administration.

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**What are the key elements of PH:ARM's proposed take-back program?**

- Waste household medicines will be as easy to return as they are to purchase (for example, via a pharmacy, or via mail back).
- Collection of waste medicine is offered on an on-going basis at statewide pharmacies.
- Unwanted over-the-counter (OTC), prescription and controlled substances from consumers would be collected in the same system (because consumers don't distinguish among these categories).
- Collection and consolidation of waste consumer pharmaceuticals will use existing business infrastructure, such as wholesaler/ distributor supply chains, reducing costs for handling, permitting, and transportation.
- The pharmacies offering a collection program will not take official possession of the drugs. The pharmacies will only provide collection sites and assist in the security for the pharmaceuticals.
- Waste medicines are thrown away by the consumer, so the material would be considered 'household' waste, and not generated

by the pharmacy.
- No specific inventory of the pharmaceutical waste placed inside the waste collection containers would be required because it is household hazardous waste. Volumes collected will be tracked as part of the program.
- All waste collected will be considered irretrievable by the consumer after disposing of the medication.
- Shipping of waste containers from pharmacies to central consolidation locations and to the site of ultimate destruction will be documented. New technology, such as embedded radio frequency tags could facilitate and expedite this tracking.
- Collection at pharmacies, if done in a cost-effective manner, should not impact the retail price of consumer medicines.

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**Why is a pharmacy-based pharmaceutical return program a preferred collection model?**

The 2006 SoundStats Survey found that three-quarters (74%) of King County respondents said they would be willing to properly dispose of their unused or expired medicines by returning them to a convenient location. Local pharmacies were chosen as the most convenient location to dispose of unused or expired medicines by 84% of the respondents. Four in five (80%) respondents stated that they are likely to return their unused or expired medicines to their local pharmacy if a secure drop box was set up there for this purpose.[66]

Reasons to pursue pharmacy locations as take-back sites include:

- Collecting this waste through conveniently located pharmacies is anticipated to maximize collection of residential consumer pharmaceutical waste.
- Local retailers and clinics are already interested and willing to participate when regulations allow them (if easy, inexpensive, and low risk).[67]
- It capitalizes on the level of trust already present in the pharmaceutical industry, and presents an opportunity for the industry to promote individual and community health.
- It is an opportunity for pharmacies to provide additional customer service.
- It links environmental consciousness and community service with the pharmaceutical industry in the mind of the customer.
- It allows for a secure, low-cost and efficient return mechanism that uses existing business infrastructure.
- The diversion risk is minimized because collection is located at a site that already handles pharmaceuticals, with professional staff familiar with the risks and hazards of pharmaceuticals, and the ethic and security measures in place to prevent diversion.
- Costs of the program are born by the producers and users of the product, rather than by all taxpayers.
- It increases public safety.

**What do the secure collection boxes being piloted in pharmacy locations look like?**

A prototype of a secure drop-box for collection in a pharmacy is shown below. The double-locked and bolted container would be within eyesight of the pharmacist counter. The consumer would deposit medications in their original packaging.

One design is a steel container with a 5 gallon bucket or a 14 cubic inch box inside. A new prototype is in development.

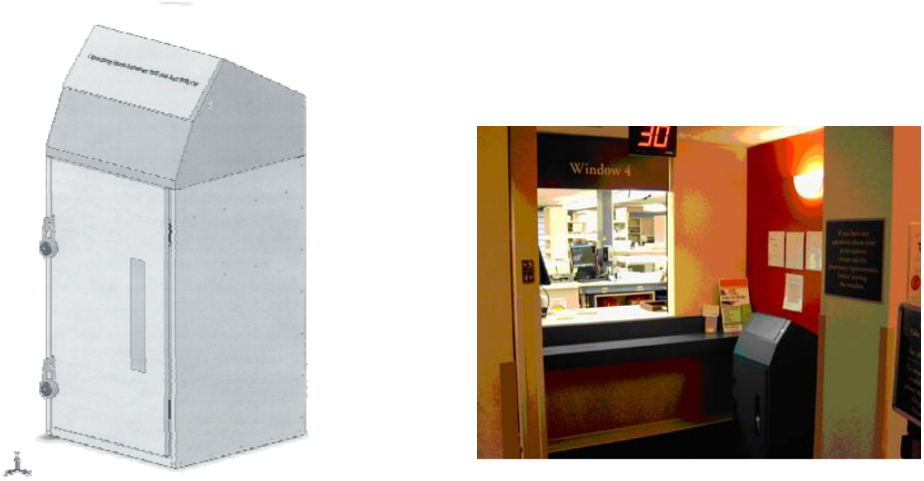


Figure 1. Group Health Collection Container (Steel Outer Drop Box)

**Once pharmaceuticals are collected, why is the supply chain the preferred consolidation service provider?**

- Distributors are already servicing pharmacies regularly.
- Distributors are permitted to handle medications.
- Oversight of wholesalers by Board of Pharmacy already exists.
- Interactions between established business systems are the most efficient.
- There are a few large wholesalers in the state that service all pharmacies, making consolidation efficient.
- It offers a secure physical location for consolidation.
- It promotes producer and supply chain responsibility.
- Other programs use a similar take-back model effectively, such as in Canada and Australia.[68]

**What kinds of problem items can enter collection programs and how can it be prevented?**

The most common problem items are <u>used</u> syringes, lancets, and IV needles. Packaged, unused syringes are not a safety concern. It is important to offer collection of used needles in a different system at a nearby location, along with visual information. The program is evaluating methods to safely remove these items if inadvertently collected. A few used syringes and lancets have been found thus far in the PH:ARM pilot program, and they have been safely removed.

Some consumers may deposit mercury thermometers into the collection

program. Mercury should not be incinerated, so it is important to inform consumers that they shouldn't put thermometers into the container. A few mercury thermometers have been found in the PH:ARM program, and we are evaluating procedures to safely remove these items if inadvertently collected. The pharmacist should also have information for the customer about where to take thermometers for proper disposal.

Several electronic glucose meters have been found in collection buckets. Electronic devices should not be incinerated due to heavy metal content. Screening procedures remove these items when inadvertently collected.

Medicated aerosol cans have flammable propellants which are classified in a different Department of Transportation class as the rest of the waste medications. DOT prohibits transport of these two material classes in the same container. Screening procedures remove aerosols, and proper signage must be in place to inform the public. The small number of *inhalers* received and the small amount of pressurized gas (typically non-flammable gas) in each inhaler allows for their acceptance into the collection system.

Pharmacists trying to dispose of their business waste properly may want to use the convenience of the household collection units. Because there is not an easy, inexpensive, or accessible pharmaceutical waste management option for small clinics, this is likely unavoidable. However, business waste is usually identifiable because it is different in appearance from individually prescribed medication. Screening procedures are needed to remove identifiable business waste and educate the business generator who is improperly using the system.

**Will patient confidentiality requirements affect collection of waste household pharmaceuticals?**

No. If patients are concerned, they can mark out patient information. However, waste containers will be disposed of in a way that destroys all patient information.

## Collecting Controlled Substances

**Can pharmaceutical collection programs currently collect waste controlled substances (CS) from consumers?**

Several states have requested permission, and the DEA has denied these requests. The denial is based on DEA regulations which:

- Permit the possession of controlled substances only by an entity that is either registered with the DEA or is specifically exempted from registration (i.e., end users in possession of a controlled substance issued via a prescription, or law enforcement).
- Do not permit a registrant to take possession of controlled substances from a non-registrant. Therefore a pharmacy,

hospital, physician or wholesaler would not be permitted to take possession of a controlled substance from a patient.

**Why should we collect controlled substances from end-users in the same system?**

- There is **no** legal or safe disposal option available for unused controlled substances from households. Even disposal to the trash is technically in violation of DEA regulations because the waste hauler is "taking possession" of the drugs contained in the household trash.
- Controlled substances are typically a small, but ubiquitous, percentage of total wasted pharmaceuticals from households (estimates of 10-15%).[69]
- Consumers cannot distinguish between prescription and controlled substances.
- A collection program offers much more security than the current routes of disposal into unlocked dumpsters or unattended home storage.
- Leftover controlled substances from home care environments present potential for abuse/suicide.

**Is there any possible way to collect controlled pharmaceuticals from households?**

Currently the only legal way to collect controlled substances is at exempt agencies (such as sheriff offices) because DEA allows them to take possession of a controlled substance (through drug arrests, etc.). If law enforcement agencies were to accept household-generated controlled substances, the agency would have to manage and dispose of the drug as they would other controlled substance seized as evidence.[70] The resources required for the handling and disposal of this waste has made law enforcement reluctant to be involved with the collection of household waste.

**Can individual states allow for disposal of controlled substances?**

DEA regulations (21 CFR 1307.21) permit the DEA to allow the Special Agent in Charge (SAC) for DEA regions (in our case, Washington, Alaska, Idaho, and Oregon) to authorize the destruction of controlled substances held in the possession of non-registrants (end-users), after the non-registrant appropriately accounts for and lists the substances to be destroyed. CFR 1307.31(d) also states that the section "*shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State*". **Thus State law may take precedence in governing the destruction of controlled substances within the State**. Further legal interpretation and guidance regarding this section may be desired.

**How can the DEA grant permission to pilot take-back of controlled substances?**

In Washington's case, the DEA was asked in March 2007 to provide a "limited waiver of enforcement" to allow for the collection and transfer of the controlled substance household waste to a permitted entity for destruction. Such licensure or waiver would then permit our pilot partners, under established procedures, to collect and consolidate waste medicines, and would allow a hauler to take the waste from the

consolidation point to the final disposal location.

**At the most recent updating of this document, DEA has responded that since their regulations are silent on the take-back of controlled substances, they are** *"studying the issue…, and the Office of Diversion Control is in the early stages of drafting regulations to address the issue in detail. The PH:ARM team can weigh in during Federal Register public comment period."*[71]

## Programs for Long Term Care Residents and Hospice

**What is the definition of a nursing home, boarding home, or assisted living facility?**

Nursing homes and boarding homes may be called assisted living facilities, managed residential care facilities, or long-term care facilities.

A *nursing home* facility provides 24 hour supervised nursing care, personal care, therapy, nutrition management, organized activities, social services, room, board, and laundry.

A *boarding home* is a facility in a community setting licensed to care for seven or more residents. The home provides housing, meal services, and assumes general responsibility for the safety and well-being of the resident. Boarding homes can range in size from 7 beds to 150 beds. Some facilities provide intermittent nursing services.

Managed residential care facilities (including skilled nursing facilities) are businesses but also temporary or permanent households. The EPA Resource Conservation and Recovery Act (RCRA) and Ecology WAC 173-303 Dangerous Waste Rules determine that pharmaceuticals that are prescribed to patients but 'wasted' in home health care settings are household waste, rather than business waste. EPA region X and the Wa State Department of Ecology are still resolving whether pharmaceutical waste from a business-residential healthcare setting is "household" waste.

Unwanted controlled substances prescribed to patients at managed care residential facilities have been commonly disposed through the sewer per Board of Pharmacy regulations, 246-865-060 Washington Administrative Code (WAC). Non-controlled 'household' waste pharmaceuticals from managed care residential facilities are sometimes disposed through a pharmaceutical waste service provider, but typically disposed via the sewer, garbage, or medical waste system. Medical waste is not equivalent to hazardous waste disposal for chemicals.

**What quantity of pharmaceuticals do managed residential care facilities generate?**

According to a National Health Policy Newsbrief from 2002, routine medication orders in nursing homes increased by 14 percent from 1997 to 2000. The percentage of nursing home residents using nine or more prescription medications per day also rose from 18 percent in 1997 to 27 percent in 2000.[72]

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**What is the total quantity of waste pharmaceuticals from Long Term Care Facilities?**

A 2005 pharmaceuticals workshop for the EPA stated that long term care facilities account for a third of unused medications, with households accounting for the remaining two-thirds (non-hospital/non-pharmacy).[73] Two state specific studies cite the following[74];

- A Massachusetts study referenced in the table below determined 6.7% of total medications prescribed ended up wasted.
- The value of unused drugs in *long term care facilities* may be as high as $378 million, or between 4 and 10 percent of the total dispensed costs.[75]
- More than 90 percent of the wasted medication is due to change in prescription, death, or transfer of the resident.[76] These discontinued drugs are often disposed of into the toilet.[77]

**% Medication Destroyed by Reason**
**(Long Term Care Facility Study from Massachusetts) [78]**

| |
|---|
| Medication changed 6.3% |
| Medication discontinued 34.2% |
| Medication decreased 3.4% |
| Medication increased 2.0% |
| Medication expired 1.9% |
| Patient died 35.5% |
| Patient hospitalized 6.8% |
| Patient transferred 7.3% |
| Other 2.6% |

A 2003 King County survey estimated that managed residential care facilities in Washington generate 7,200 lbs annually statewide, or 8 lbs/facility/year.[79]

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**How would medications be collected from nursing homes?**

- The system would allow for safe management of all types of waste pharmaceutical products, including controlled substances.
- Nursing home staff would have a secure return container located in the "med room" for depositing waste household medications on behalf of patients in their care. In assisted living situations, a container could be located in the clinic area for patients to deposit their own medications.
- This return container would be able to accommodate both bingo cards (blister packaging) and individual vials of medication.
- The nursing home staff would not have to inventory most of the material deposited into the container.
- The nursing home staff would still account for controlled substances disposed (as they currently do) according to current State and Federal regulations.
- Depositing medications into the container would be considered irretrievable destruction.
- Nursing home staff would not have access to the contents once material was deposited.
- The waste medications would be collected on a schedule by a licensed pharmaceutical waste hauler for final, environmentally-responsible disposal.

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**How does hospice care take responsibility for household medication disposal?**

Hospice agencies provide symptom and pain management to terminally ill individuals and emotional, spiritual, and bereavement support to the individual and family, in the home or places of permanent or temporary residence.

Hospice agencies are licensed by the state to provide care within the minimum health and safety standards established by statute and rule. Hospice services may also include the provision of home health and home care services. The Department of Health enforces the standards by periodically conducting unannounced surveys of these agencies. The rules state that:

A pharmacist must provide sufficient on-site consultation to ensure that medications are ordered, prepared, disposed, secured, stored, accounted for and administered in accordance with the policies of the center and chapter 246-865 WAC;

Schedule II - IV controlled substances must be:

(a) Kept in a separate keyed storage unit; and
(b) When heat sensitive, be kept in a locked refrigeration unit;

Schedule II - IV controlled substances no longer needed by the patient must be disposed in compliance with chapter 246-865 WAC.

The Washington state pilot hopes DEA will allow hospice care providers to use secure collection containers or a mail-back program.

## Financing a Collection System

**What are the costs of a pharmacy take-back collection program?**

The current B.C. program estimates the total aggregated costs associated with management of waste consumer medications at $5.27 per lb (US Dollar).

A full scale program at 1,300 pharmacies could collect over 470 lbs[80] annually per participating pharmacy. Using the Canadian $5.27/lb rate, the program would cost approximately $2,500/yr per location. If 1,300 pharmacies in Washington participated in the program, collection and disposal costs could total $1 million to $3 million.

PH:ARM is currently spending $5.00 per lb to collect, manage, and dispose of collected waste pharmaceuticals. This does not include purchase of reusable supplies, such as secure drop box ($600 each) or the wheeled tote ($100 each).

Mail-back programs have an additional postal cost. It would take 940 mailers to mail 470 lbs of material collected at each pharmacy annually (assuming each mailer is 0.5 lbs). Oregon estimates the purchase and shipment of the mailer at $3.40 per piece[81], thus 470 lbs of drug waste shipped through the mail will cost $3,200. Thus, full participation of 1,300 Washington pharmacies would require $4 million in single-use mailer costs alone. Disposal costs are additional.

**How does the cost of a medicine return program compare to the value of medicines sold in Washington State?**

$3.1 billion was spent in Washington to purchase 53.6 million prescriptions in 2006.[82] $15.4 billion was spent on over-the-counter medication and/or personal care products nationwide, excluding Wal-Mart.[83] Thus, approximately $51 per capita is spent on OTC drugs, totaling $327 million in Washington State. Washingtonians spend $3.4 billion annually on the retail purchase of prescription and OTC medications.

In comparison, the cost of a hypothetical Washington take-back program collecting 1.5 lbs per day[84] per pharmacy could range from $1 million to $3 million. That is 0.03 to 0.09 percent of the purchase price of prescriptions and OTCs sold in Washington, or $0.02 to $0.05 per prescription (not including the number of OTC sales).

**Why should manufacturers operate and finance a pharmaceutical disposal program?**

Increasingly, products with potential negative impacts on society and the environment are being collected at their end-of-life through programs managed and/or funded by the manufacturers of those products. This approach is being used for rechargeable batteries and cell phones in the US, and for electronics and mercury-containing devices in several states, Europe and Asia. There are many successful and cost-effective examples of manufacturer stewardship for pharmaceuticals, including British Columbia, Australia (partially manufacturer-funded), Prince Edward Island, France, Italy, and several other European countries.

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

By managing their products at end-of-life, manufactures get significant information with which to inform product redesign. In the case of pharmaceuticals, such data can help inform prescribing practices, patient compliance practices, and possibly drug formulation. Efforts in Sweden are already underway to inform prescribing practices with data about a medicine's potential Persistant, Bioaccumulative, or Toxic qualities.

## Transportation Requirements

**Who can transport household generated pharmaceutical waste?**

Any company that is managing pharmaceutical waste needs to possess a wholesaler/ manufacturer license from a Board of Pharmacy where their facility is located.[85]

A company that is managing controlled substances must have a DEA registration number for each designated location at which controlled substances 're-packaged' or handled. DEA registration numbers are federally issued and allow for the transfer of controlled substances from one DEA registrant to another. A DEA registration number does not currently allow for patient returns.

Any firm that is handling household-exempt hazardous waste must either have a solid waste G permit (issued by the Washington State Utilities and Transportation Commission, or UTC)[86], EPA Identification number for a transporter (issued by the Washington State Department of Ecology)[87], or be classified as a product take-back center (defined in the 173-350-360 WAC ; exempt from solid waste handling permitting). These transporters must also have common carrier permit from the UTC.[88]

**What are the shipping requirements enforced by the Federal Department**

The U.S. Department of Transportation has the responsibility to enforce rules related to the transport of hazardous materials for commerce that may pose unreasonable risks to health and safety, and to promulgate regulations for the safe transportation of these hazardous materials.

**of Transportation?**

Household hazardous waste that is pharmaceutical waste may be shipped as medicine, solid/ liquid, toxic, n.o.s. (not otherwise specified), division of 6.1[89] or ORM-D Consumer Commodity (if in the original consumer package) defined in 49 CFR 171.8. ORM-D includes medications. The quantity limit for ORM-D is 66 lbs, or less than 55 gallons. Inner packaging units should not exceed 250 ml (8 ounces) net capacity for liquids or 250 g (8.8 ounces) net capacity for solids. *Unpackaged* medicine, solid/liquid, toxic, n.o.s. has a quantity limit for shipping of 11 lbs (solid) or 5 Liters (liquid).

Two material types that are not compatible for shipping are flammable aerosols and solutions with greater than 24% alcohol.

1) Aerosols with flammable propellants cannot be combined in the same container as poisons. Inhalers are not included in this flammable category because the product is shipped as DOT class 2.2 aerosol non-flammable gas.[90]
2) Typical over-the-counter cough syrup concentrations of alcohol are less than 24% alcohol. However, even if the medicine has a content of >24% alcohol, they are not subject to DOT if inner packages are less than 0.5 liter (0.1 gallon).[91]

DOT regulations state that packaging and containers marked or labeled for biomedical waste may contain no other wastes. [92] This is a potential barrier to proper management of residential pharmaceutical waste because it requires waste screening to remove used sharps or lancets.

Labels

Shipping labels are not required for ORM-D (if 49 CFR 173.156 is met) but are required for medicine, solid/liquid, toxic, n.o.s. However, ORM-D packages must be marked as such.

Shipping Papers

DOT laws state that a carrier may not transport a hazardous material unless it is accompanied by a shipping paper prepared in accordance with 49CFR172.200, 172.201, 172.202, and 172.203.[93]

- Shipping documentation is not required for ORM-D except when the material is offered or intended for transportation by air.[94]
- Hazardous waste manifests are only required for hazardous waste, which is defined by 40 CFR 261. A manifest is not required for household-exempt hazardous materials.

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**What are the responsibilities of transporters?**

EPA hazardous waste transporters are responsible for receiving the proper paperwork from the generator, ensuring delivery to the specified receiving facility (or specified alternate facility), and retaining records. Hazardous waste transporters cannot store the material for more than 10 days at a registered transfer station.

Solid waste transporters who are offering a service for hire must obtain a G-permit from the Utilities and Transportation Commission and ensure delivery to a facility that meets the performance standards of 173-350-040 WAC (Washington Administrative Code). Issuance of a G-permit depends on proof of public convenience and necessity. Typically the UTC only grants one G-permit per 'territory.'

Product take-back centers,[95] defined in 173-350-100 WAC, must prevent releases to the environment, exposure of the public, and ensure delivery to a facility that meets the performance standards of 173-350-040 WAC. They must notify the health department of any failure to comply with 173-350-360 (3) (b, e, f) WAC. Product take-back centers must ensure that they are taking household hazardous waste back which is comparable to the type sold or distributed at that location.

Companies that transport non-household goods for compensation within the state of Washington must also have a common carrier permit from the Washington UTC.

## Disposal Options

**What is the best available final disposal treatment for collected waste medications?**

Most other countries with medicine take-back programs use incineration for final disposal. The World Health Organization recommends high temperature incineration for cytotoxic medications (toxic to cells, or chemotherapy drugs) and recommends that no more than 5% of the fuel fed into the incinerator be pharmaceuticals.[96] Without direct evidence of harmful air emissions from incineration of medications, it is best to act with precaution and dispose of hazardous medicines in the most protective way possible.

**Reasons for concern about landfill disposal:**

- Groundwater or to surface water contamination from landfill leachate containing pharmaceuticals.
- Vinyl chloride leaching from Polyvinyl Chloride (PVC) medicine containers (PVC is present in some blister packaging and IV bags).
- Security and ultimate destruction at the disposal location.
- Scavenging from trash receptacles or at the disposal location.

**Reasons for concern about incineration:**

- The quantity and severity of air pollution from medicines burned in solid, medical, or hazardous waste incinerators is unknown.
- Emissions monitoring for solid waste and medical waste facilities does not occur on a daily basis.
- Ash residue from solid and/or hazardous waste incinerators may contain pollutants from medicine if they are non-organic chemicals.
- The variations in temperature and burn time at which pharmaceuticals are destroyed are not consistent at solid waste

and medical waste incinerators, because the feed stock (garbage in) determines the temperature.
- Carcinogenic dioxin can form when containers containing Polyvinyl Chloride are burned.
- Transportation costs, handling efficiency, and environmental impacts of shipping to and from disposal site must be considered. No commercial hazardous waste incinerators are located west of Utah.

**General concerns about the final disposal location include:**

- Community impacts and compliance issues at the disposal location.
- Regulatory oversight at in-state and out-of-state facilities may vary. (Occasionally, out-of-country facilities may be used for disposal.)

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**What are the waste acceptance policies of hazardous waste (RCRA) and municipal solid waste (MSW) incinerators?**

RCRA incinerators must comply with their permit conditions issued by the delegated authority. Usually, this is the state where the facility is located. All hazardous waste facilities are required to confirm knowledge about a dangerous waste before storing, treating, or disposing of it. This information is provided on a document called a **profile** (supplied by the generator) or is developed through detailed chemical analysis at the facility. The owner or operator of a hazardous waste facility must develop and follow a written waste analysis plan that describes the procedures that will be used to comply.

The profile is a form supplied by the final disposal company which contains information about the waste. The information is derived from material safety data sheets (MSDS), chemical analysis, or other types of research. The profile is approved by the final disposal company before shipment of the waste commences.

In Washington, county health departments have permit authority over solid waste incinerators. Regulations adopted locally can be found in 173-350-240 WAC. These facilities must ensure that dangerous waste is not disposed at the solid waste incinerator (business-generated hazardous waste) and that only fuels approved in writing by the agency with jurisdiction over the facility for air quality regulation are combusted.

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**Where can household pharmaceutical waste legally be disposed?**

Regulations in Washington state legally allow for the disposal of household-generated hazardous material as solid waste. Whether this is appropriate depends on the facility, quantity and quality of waste, evidence of safety, and the control technology. Local county or city regulations may prohibit certain types of material, such as electronics or all hazardous waste (regardless of the household origin), into their solid waste systems.

Disposal facilities can accept household pharmaceuticals, <u>if they OR the</u>

transporter possesses a license from the state Board of Pharmacy.

If a DEA witness is required, the facility or transporter must hold a DEA reverse distributor license.

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**What are the alternatives to incineration?**

Environmentally-preferred alternatives to incineration that need additional research include:

- Waste prevention efforts
- Transformation and stabilization of pharmaceutical waste for disposal to a hazardous waste landfill.
- Alkaline hydrolysis (not commercially available at this time).
- Pyrolysis-type chemical reactions or plasma arc (not commercially available at this time).

If controlled substances are included in the collection of pharmaceutical waste, the Drug Enforcement Administration requires destruction beyond reclamation of this material.

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**Can collected waste pharmaceutical material be reused?**

Collected waste pharmaceuticals from households are not yet able to be reused or redirected from a final disposal program per FDA regulations.

Donations to other countries must be initiated by the receiving organizations. Waste or expired medications should NEVER be given to charitable organizations as a method of disposal.

Reprocessing of collected waste pharmaceuticals could be a potential solution in the future, but needs major technical and regulatory change to become a realistic option.

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**Can pharmaceutical products become more environmentally friendly?**

Research is just beginning in this area. One notable effort is the Stockholm County Council which developed a scoring system for different medications, taking into account environmental persistence (P), bio-accumulation (B) and toxicity (T). They have published this information in a brochure called "Environmentally Classified Pharmaceuticals." [97] The information is meant to provide doctors tools to prescribe similarly effective drugs that have fewer environmental impacts.

Other ways to 'green' pharmaceuticals is to reassess appropriate expiration dates, design more targeted drug interactions, and create metabolites that quickly break down under conventional wastewater treatment.

# Support for the PH:ARM Approach

## Organizations that Support a DEA Waiver

**U.S. Senators** Murray and Cantwell
**Washington State Governor**, Christine Gregoire
**Washington State Attorney General**, Rob McKenna
**King County Executive**, Ron Sims
**Washington State Department of Health Secretary**, Mary Selecky
**Environmental Protection Agency, Region X Director, Office of Air, Waste & Toxics,** Rick Albright and **Region X Regional Administrator,** Elin Miller
**City of Renton Mayor**, Kathy Keolker
**Washington Association of Sheriffs and Police Chiefs Executive Director**, Donald Pierce
**Seattle Office of Sustainability and Environment Director**, Steve Nicholas
**Group Health Cooperative Pharmacy Clinical Services Associate Director**, Shirley Reitz
**Bartell Drug Company Assistant Vice President**, Dan Connelly
**Washington Board of Pharmacy Executive Director**, Steven Saxe
**Washington State Pharmacy Association CEO**, Rod Shafer
**Washington State Board of Health Chair**, Treuman Katz
**King County Wastewater Treatment Division Director**, Don Theiler
**Seattle-King County Public Health Director and Health Officer**, David Fleming
**People for Puget Sound Executive Director,** Kathy Fletcher
**Washington Poison Control Medical Director,** William O. Robertson
**Washington State Department of Ecology Program Managers**, Cullen Stephenson and Darin Rice
**University of Washington Industrial Hygienist,** William Rowe and **Research Scientist**, Caleb Banta-Green
**Ritchie Law Firm Attorney and Pharmacist**, Craig Ritchie
**Pacific Northwest Pollution Prevention Resource Center Executive Director**, Chris Wiley
**Snohomish County Corrections Nurse Practitioner,** Sandra Needham
**Puget Sound Action Team Director,** Brad Ack

## Team Members of PH:ARM

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**Local Hazardous Waste Management Program in King County**, Cheri Grasso and Alice Chapman
**Washington Citizens for Resource Conservation**, Eva Dale and Suellen Mele
**Washington State Board of Pharmacy**, Stan Jeppesen
**Northwest Product Stewardship Council**, David Stitzhal
**Snohomish County Solid Waste Management Division**, Sego Jackson
**Public Health – Seattle & King County**, Will Perry
**Bartell Drug Company**, Dan Connelly
**Group Health Cooperative**, Shirley Reitz, Bob Willott, and Walter Sidles
**Pacific NW Pollution Prevention Resource Center (PPRC)**, Cathy Buller
**DSHS, Aging and Disability Services**, Todd Henry

## Funding Organizations of PH:ARM Project

**Russell Family Foundation**
**King County Waterworks**
**Group Health Community Foundation**
**Puget Sound Action Team**
**Washington State Department of Ecology**
**Snohomish County Solid Waste Division**
**King County Department of Natural Resources Solid Waste Division**
**Seattle Biotech Legacy Foundation**
**Seattle Public Utilities**

## Sample Media Covering PH:ARM Project

- 2/1/2007, Curing the problem of discarding pills, *Seattle Post-Intelligencer* Feature. http://seattlepi.nwsource.com/health/301869_hcenter01.html
- 3/2/2007, New way to dump old meds, *The Herald* (Everett) Lead story. http://www.heraldnet.com/article/20070302/NEWS01/703020764&SearchID=73291847693648
- 3/2/2007, Drug take-back program protects streams and fish, KING-TV (NBC) http://www.king5.com/topstories/stories/NW_030207HEBgrouphealthEL.1240fe18.html
- 3/5/2007, Group Health creates pilot program for disposing old medication, KUOW radio Feature. http://www.kuow.org/defaultProgram.asp?ID=12367
- 3/18/2007, Don't flush drugs down the toilet, *The News Tribune* (Tacoma) Feature. http://www.thenewstribune.com/soundlife/story/6420862p-5723303c.html
- 4/19/07 –Good for us; bad for fish? *Wenatchee World*
- 4/22/2007, Pharmacy disposal sites established, *The Spokesman-Review* Feature. http://www.spokesmanreview.com/local/story.asp?ID=185907
- 4/22/2007, Close the lid on old medicine, *USA Today* http://www.usatoday.com/news/health/painter/2007-04-22-old-medicine_N.htm?csp=34
- 5/5/07 The Environmental Side Effects of Old Medicines, Eco-Consumer Article, *The Seattle Times.* http://archives.seattletimes.nwsource.com/cgi-bin/texis.cgi/web/vortex/display?slug=ecoconsumer05&date=20070505&query=medications
- 5/19/07 American Society of Health-System Pharmacists Saving the Environment One Prescription at a Time *Members Devise a Unique, Safe Disposal System for Consumers*
- 5/28/07 Program Accepts Old Medicines, *The Olympian.* http://www.theolympian.com/environment/story/117172.html

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[43] June 2005, DNR Behavior Survey, available through King County Local Hazardous Waste Management Program.

[44]SoundStats Survey of King County households (2006, WCRC) www.wastenotwashington.org/Pharmsurvey.pdf

[45] 40 CFR Section 261.4(b) (1) and WAC 173-303-071(3)(c) state that waste generated at a household is excluded from regulation as a hazardous waste.

[46] Seattle-King County Public Health Title 13.04.058 prohibits disposal of hazardous waste to septic tanks. Seattle Municipal Code 21.36.025 prohibits HHW and SQG hazardous wastes from being disposed in any commercial or residential garbage container. Snohomish Health District Solid Waste Code Chapter 3.1 XXI G 1 prohibits disposal of hazardous waste to sewer, septic, or solid waste routes. Kitsap County Code 2004-2 (6)(d)(i) states that household hazardous waste shall not be deposited in the general municipal solid waste collection system, a public sewer system, a storm drain, an on-site sewage system, in surface or ground water, or onto or under the surface of the ground.

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[48] Hazardous waste recycling facilities may operate under more streamlined regulations or certain exemptions. Permits are issued by the state where the TSDF is located or by the EPA if the State doesn't have federally delegated permitting authority. A manifest is used to track the waste generated by businesses from the point of generation to the final disposal.

[49] SoundStats Survey of King County households (2006, WCRC) www.wastenotwashington.org/Pharmsurvey.pdf

[50] RCRA online, document 11606. www.epa.gov/rcraonline/

[51] See WAC 173-350-360 (3)

[52] Small Quantity Generators may transport their own hazardous waste to a hazardous waste disposal facility or vendor without a manifest. The land disposal restriction (disposal to permitted landfills) for hazardous waste does not apply to Small Quantity Generators. Small Quantity Generator requirements focus on determining which wastes are hazardous and ensuring disposal at a safe location.

[53] A Small Quantity Generator, or Conditionally Exempt Small Quantity Generator, generates less than 220 lbs per month of designating hazardous waste, or less than 2.2 lbs per month of extremely hazardous waste.

[54] Some RD's (Kellcor, Inc. and Strong Environmental, www.strongenvironmental.com) and some hazardous waste vendors (Philips) are willing to "take back" household medication waste (non-controlled medications) for a fee. The fee is usually based on weight. This is partially not allowed

under Federal and State law (Board of Pharmacy licensing rules and EPA), but has been overlooked by enforcement regulators.

[55] DEA-1: DEA Interim final rule: FR Doc 03-17578, Fed. Register July 11,2003(vol 68,No. 133), [docket No. DEA0108] Rin 1117-AA19, Definition and Registration of Reverse Distributors. 21 CFR parts 1300, 1301,1304,1305, 1307.

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[59] Conversations with BC Residuals Management Group, Paul Iverson, July 7, 2005

[60] Prescription Drug Expenditures in 2001. National Institute for Health Care Management, Revised May 6, 2002 http://www.nihcm.org/~nihcmor/pdf/spending2001.pdf

[61] Data was analyzed by Alice Chapman, King County, who gathered information from the Northeast Recycling Council pilot project and California.

[62] SoundStats Survey of King County households (2006, WCRC) www.wastenotwashington.org/Pharmsurvey.pdf

[63] Evidenced in Washington State Household Hazardous Waste collection events, which have costs several times that of a permanent facility per pound collected. Washington electronic waste take-back events have been often overwhelmed by the amount of material collected due to the appearance of scarcity of service.

[64] Oregon Drug Take Back Group, Final Draft Report, July 1, 2007

[65] U.S. Postal Code 48. http://pe.usps.gov/text/pub52/pub52c4_008.html#NL508_52

[66]SoundStats Survey of King County households (2006, WCRC) www.wastenotwashington.org/Pharmsurvey.pdf

[67] Includes Costco, Group Health Cooperative, and Bartell Drug Company.

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[69] Alan Jones, hospital waste consultant and Stan Jeppesen, Washington Board of Pharmacy, estimates

[70] Reference: DEA,2: DEA letter to Mr. Phil Bobel, Manager, Environmental Compliance, City of Palo Alto, California

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[84] July and September 2007 screening results are 2 lbs per day to 1.5 lbs per day at Group Health Cooperative. This is per open day, not per calendar day.
[85] Washington State Department of Health, Board of Pharmacy, https://fortress.wa.gov/doh/hpqa1/HPS4/Pharmacy/forms.htm#firms
[86] Washington State Utilities and Transportation Commission. www.wutc.wa.gov
[87] How to obtain a RCRA Site ID number. Washington State Department of Ecology, www.ecy.wa.gov/pubs/9112j.pdf
[88] Washington Utilities and Transportation Commission http://www.wutc.wa.gov/commoncarriers
[89] US Department of Transportation. http://www.myregs.com/dotrspa/
[90] 49CFR 173.306 Limited quantities of compressed gases.(i) Aerosols with a capacity of less than 50 mL. Aerosols, as defined in §171.8 of this subchapter, with a capacity not exceeding 50 mL and with a pressure not exceeding 970 kPa (141 psig) at 55 °C (131 °F), containing no hazardous materials other than a Division 2.2 gas, are not subject to the requirements of this subchapter.
[91] 49CFR 173.150 Limited quantities of flammable liquids and combustible liquids are excepted from labeling requirements, unless offered for transportation or transported by aircraft, with strong inner packaging not over 0.5 L.net capacity each, packed in strong outer packaging.
[92] WAC 480-70-451. (5) Packaging and containers marked or labeled as containing biomedical waste may not be used to ship or transport waste that does not meet the definition of biomedical waste.
[93] 49CFR 177.817(a)
[94] 49CFR 172.200(b)(3)
[95] "Product Take-Back Center" means a retail outlet or distributor that accepts household hazardous waste of comparable types as the products offered for sale or distributed at that outlet. This definition could be extended to reverse distributors accepting household hazardous waste.
[96] World Health Organization "Guidelines for Safe Disposal of Pharmaceuticals in and after Emergencies" 1999 WHO/EDM/PAR/99.2 p.23
[97] Janus Info website, http://www.janusinfo.org/imcms/servlet/GetDoc?meta_id=7236