Secure Medicine Return In Washington State

The PH:ARM Pilot

Pharmaceuticals from Households: A Return Mechanism

October 2006 – October 2008

PRODUCED AS A COLLABORATION OF WASHINGTON LOCAL AND STATE GOVERNMENTS, BUSINESSES AND NON-PROFIT ORGANIZATIONS

December 2009

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Contact for this report is:
Cheri Grasso
Local Hazardous Waste Management Program in King County
130 Nickerson Street, Suite 100
Seattle, WA 98109
206-263-3089
cheri.grasso@kingcounty.gov

Alternative formats available

206-263-3089 TTY Relay: 711

Layout**:** Sandra Kraus, Visual Comm. Specialist, King County DNRP
GIS, Visual Communications & Web Unit

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Suellen Mele, *Washington Citizens for Resource Conservation*.

Emma Johnson, formerly of the *Washington State Department of Ecology*.

Will Perry, *Local Hazardous Waste Management Program in King County, Public Health – Seattle & King County*.

Margaret Shield, *Local Hazardous Waste Management Program in King County*.

David Stitzhal, *Northwest Product Stewardship Council*.

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EXECUTIVE SUMMARY

Unwanted medicines pose a risk to people's safety when stored in homes and can pollute the environment when improperly disposed. A significant amount of medicine goes unused–estimates range from 10 to 33 percent of medicines sold. Currently available options for disposal of unwanted medicines are limited largely to flushing drugs down the toilet or throwing drugs in the trash. Unwanted medicines can pollute the environment when put into sewer or septic systems. Disposing of medicines in the trash increases the chance of theft and poisoning.

To address the need for a safe way to dispose of unwanted medicines, a coalition of government, nonprofit, and business partners began a pilot in 2006 called Pharmaceuticals from Households: A Return Mechanism (PH:ARM) at Group Health Cooperative, a regional healthcare organization in Washington, Bartell Drug, a Western Washington retail pharmacy chain, and two boarding homes.

The Problem with Unwanted Medicine

Residents who store unneeded medications in their homes may increase the risk of accidental poisonings and drug diversion. Medicines in the home were responsible for 85 percent of accidental poisoning deaths in Washington in 2006. Many involved young children and the elderly. The use of prescription pain relievers, stimulants, and other medicines to get 'high' is also a growing problem in our communities. Studies show nearly 11 percent of 12 to 17 year olds in Washington used prescription medicines for recreation. Most obtain prescription drugs from a friend or relative, often without their knowledge. In King County, a survey found that 39 percent of households surveyed had more than ten containers of medicine on hand, and most households did not plan to use all of these medicines within six months.

When residents dispose of medicines in the toilet or sink, these contaminants are passed on to municipal wastewater treatment systems or septic systems. Many pharmaceuticals are not effectively removed by these systems and have been measured in wastewater effluent. When medicines are disposed of in the garbage, medicines may end up in landfills that use these same wastewater treatment systems to treat their leachate. A 2002 United States Geological Survey study found organic wastewater contaminants, including pharmaceuticals, in 80 percent of sampled streams. Drinking water supplies are not routinely tested for pharmaceuticals, but limited surveys have detected medicines in drinking water of 24 U.S. cities. A growing body of research has found a relationship between environmental exposure to some medicines and developmental changes in aquatic organisms. While pharmaceuticals also enter the wastewater stream through human excretion, providing convenient and safe alternatives to the sewer or trash is a simple first step to reducing the amount of biologically-active pharmaceuticals entering the environment.

PH:ARM Pilot Overview and Results

The goal of the pilot was to demonstrate the viability, security, and convenience of a pharmacy-based collection model for unwanted household medicines, similar to programs operated by pharmaceutical manufacturers in other countries. The pilot also aimed to lay the groundwork for an ongoing statewide medicine return program provided by drug manufacturers.

Thirty-seven Washington State pharmacies and two boarding homes participated in the safe collection of unwanted medicines from household consumers, including prescription drugs, over-the-counter medicines, and nutritional supplements. The pilot was unable to accept controlled substances; however comprehensive security protocols ensured that no diversion of medicines occurred from collection through final disposal. Group Health Cooperative collected medicines at 25 clinical pharmacies, and Bartell Drugs collected medicines at 12 retail pharmacies. Two boarding homes also started collection in the last two months of the pilot. From October 2006 to October 2008, the PH:ARM pilot collected over 15,000 lbs of unwanted medicines from residents. Prescription medicines accounted for more than half of all returned medicines, and over-the-counter drugs comprised 19 to 25 percent.

Satisfaction and demand for the medicine return program was high. Surveys indicated that 74 to 96 percent of Group Health and Bartell customers were willing to participate in the program. Pharmacy staff at Group Health and Bartells reported spending relatively little time on the program (between 15 minutes to two hours per week) and that it had little impact on staff workloads. Group Health and Bartell Drug have found the program so successful that they are

continuing to offer the medicine return program on an interim basis; however, it is uncertain how long they will be able to continue funding the program.

Key Findings

- **Community demand for safe disposal of medicines is high.** With little advertising, a total of 15,798 pounds of unwanted medicines was collected from residents during the two year PH:ARM pilot at Group Health, Bartell Drugs and boarding homes. Since the conclusion of the pilot, collected medicines now total almost 35,000 pounds.
- **Pharmacy-based medicine return is convenient and effective.** The PH:ARM pilot successfully demonstrated that pharmacy-based medicine return programs are convenient and easy to use. Pharmacy staff also found the program easy to accommodate as part of their work.
- **The Controlled Substances Act should be changed to allow collection of legally prescribed controlled substances at pharmacies.** Under the federal Controlled Substances Act, the Drug Enforcement Administration (DEA) allows collection of controlled substances, such as OxyContin or Vicodin, only by law enforcement. In order to provide a convenient system for all prescription and over-the-counter medicines, the pilot team tried to obtain a DEA waiver for the project, but was unsuccessful. Federal legislation has been introduced to allow for more options to returning controlled substances. Meanwhile, a number of police and sheriff's offices in Washington are developing interim medicine return programs for controlled substances.
- **Returning medicines to a pharmacy with proper oversight and strict protocols can be safe and secure for any type of medicine, including controlled substances.** The PH:ARM pilot successfully demonstrated that pharmacy-based medicine return programs are secure. The container developed by PH:ARM and the dVault Company effectively prevents retrieving medicines after they are deposited. A tracking system was successfully used to monitor containers holding medicines from the start of collection to their final disposal. Of the 2,400 buckets and boxes of medicines collected, no signs of tampering were found and no indications of attempted diversion occurred.
- **Medicine return programs can provide environmentally sound disposal of medicines.** Medicines collected by the PH:ARM pilot were disposed via high temperature incineration, ensuring that these biologically-active pharmaceutical compounds could not contaminate our environment. Medicines collected at Bartell Drugs were disposed at a hazardous waste facility, which is currently the safest way to dispose of unwanted medicines.
- **A statewide program could collect a substantial amount of unwanted medicines.** Based on the results of a long-term, producer-funded medicine return program in British Columbia, a statewide medicine return program in Washington could collect an estimated 150,000 pounds of unwanted medicines annually (including the weight of pill containers).
- **Medicine return programs are cost-effective to operate.** Pilot operation costs for two years at 37 pharmacies, including start-up expenses, were about $134,000. Outreach costs were $35,600. Overall costs associated with implementing the PH:ARM pilot should not be extrapolated to the costs of running a permanent, statewide medicine return program. However, when compared to sales of medicines in Washington, which are about $3.6 billion annually for prescription and over-the-counter medicines, the cost for a statewide medicine return program based on the PH:ARM model is low.
- **Sustainable funding is needed for a statewide medicine return program.** The public and private grants which supported the PH:ARM pilot were short term and cannot fund an ongoing, statewide program. A sustainable funding source is needed to ensure that medicine return is available for all of Washington State residents. A producer responsibility model, similar to programs in British Columbia, Canada, and other nations, would finance a sustainable and safe medicine return program in Washington State.

1.0 INTRODUCTION

Programs known as 'Medicine Returns' or 'Take Backs' for unwanted medicines from households[1] are becoming more common in the United States due to health, safety and environmental concerns caused by leaving unwanted medicines in the home or by improperly disposing of them. Many states and locales have implemented medicine return programs ranging from one-day events to ongoing programs.

This report describes a medicine return pilot called Pharmaceuticals from Households: A Return Mechanism (PH:ARM) completed in Washington State. The study portion of the pilot operated at pharmacies, eventually totaling 37 pharmacy collection sites and two boarding homes from October 2006 through October 2008. Collection site partners continue to collect unwanted medicines at their pharmacies; however, the official pilot study ended in October 2008. Even without substantial promotion, large quantities of medicines were returned, demonstrating a significant consumer demand.

The PH:ARM medicine return pilot ultimately showed that an ongoing, statewide program would reduce the amount of medicines entering our environment, decrease the number of medicines available for children or elderly to accidentally take, and limit the number of medicines our teens have available to use illicitly.

[1] In this report, 'medicines' refer to any prescription drug, over-the-counter medicine, or nutritional supplement. It does not include biomedical waste or syringes. In addition, this report focuses on the specific issue of medicines left-over in people's homes, as opposed to businesses.

2.0 BACKGROUND

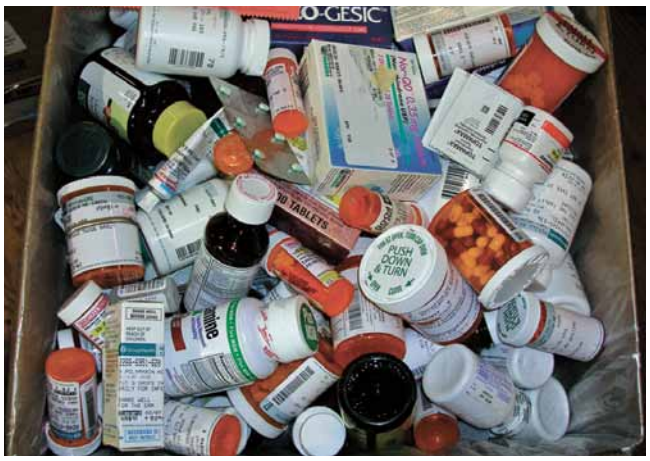
This section of the report discusses the potential risks of keeping unwanted and expired medicines in the home and the risks of unsafe disposal. It also describes past and current medicine disposal options.

2.1 Unwanted Medicines: Problems and Risks

2.1.1 Estimated Amount of Unwanted Medicines

Ideally, there would be no left-over medicines and no prescription drugs or over-the-counter medicines that could be diverted for illicit use. In reality, however, many medicines remain unused for a variety of reasons: doctors change the prescription, drugs are left behind when a person dies, medicines expire, or patients do not finish a prescription.

The percentage of medicines that go unused has not been precisely quantified, and existing studies estimate varying quantities. Our research found that the methodology heavily influences the quantity estimated. The highest estimates used in-home surveys to determine the amount of unwanted medicines. For instance, in Chapel Hill, North Carolina, interviewers discovered that 29 percent of drugs stored in the home were expired (Bush et al., 1996). In the UK, researchers conducting home waste audits found that 19 percent of medicines are thrown away. This percentage was derived by comparing the active pharmaceutical ingredient weight (API) of wasted medicines with the API in the original amount of medicines purchased (Slack et al., 2007). Swedish district nurses checking up on patients found that 33 percent of drugs at the patient's home were no longer used (Isacson & Olofsson, 1999).



Box of medicines collected at Group Health

Another methodology of estimating unwanted medicines used extrapolated data and some direct sampling of waste. A recent Florida study used a method developed in Sydney, Australia to calculate the burden of pharmaceuticals to the environment. Using a 'grab-sample' of Florida's solid waste and a conversion factor between Australia and the US, researchers estimated that 11 percent of pharmaceuticals go unused (Mussen & Townsend, 2009).

Finally, a study done in Europe and the U.S. of unwanted medicines *returned to a pharmacy* (other disposal methods were not included) estimated five percent of medicines were returned. The estimate was done by calculating the value of medicines returned to the pharmacy compared to the value of medicines sold (Castensson & Ekedahl, forthcoming).

Several studies have been done on the amount of medicines remaining in the containers of medicines that go unused. In an eight-week study in Alberta, Canada of 58 pharmacies with medicine return programs, the average amount of medicines remaining in the containers was 60 percent of the drugs in the original prescription (Cameron, 1996). Numerous studies in European countries show that 20 to 53 percent of returned medicines were unopened, with many of the remaining containers almost full (Niquille & Bugnon, 2008). A preliminary study done on medicines returned in Northern California found that the containers had an average of 52 percent of the original medicine in it (Teleosis Institute, 2008).

A 2005 study in Britain showed that whether or not people finished their medicines typically depended on the type of medicine. Twenty percent of respondents did not use all of their pain medicines, 50 percent did not finish antidepressants and beta blockers, and 82 percent did not use all of their antibiotics (Bound & Voulvoulis, 2005).

Studies also have found that a significant number of people are storing many types of medicines in their homes. In a 2006 telephone survey of King County residents, 39 percent of respondents said they had

more than ten medicine containers at home, and of these, only a third were using—or planning to use—all of their medicines within six months (Northwest Research Group, 2006).

The amount of unwanted medicines could be exacerbated by the increase in medicine sales over the past several years. Prescription drug sales in the United States have increased five-fold over a sixteen year period: from $40.3 billion in 1990 to $216.7 billion in 2006 (Lundy, 2008). Washington State residents now purchase an average of nine prescriptions a year (Kaiser Family Foundation, 2008).

The large quantity of unused medicines in homes, coupled with an increase in accidental poisonings and the intentional abuse of medicines by youth and others, have led governments and non-governmental organizations to seek safer ways to dispose of unwanted medicines.

2.1.2 Illicit Use of Medicines

Teens and young adults have been turning to the illicit use of medicines instead of illegal drugs like heroin and cocaine under the misconception that drugs from the medicine cabinet are safer (Partnership for a Drug Free America, 2009). Prescription drugs most commonly abused by teens are painkillers; depressants, such as sleeping pills or anti-anxiety drugs; and stimulants, mainly prescribed to treat attention-deficit hyperactivity disorder (ADHD). Teens are also abusing some over-the-counter (OTC) drugs, primarily cough and cold remedies that contain dextromethorphan, a cough suppressant (Office of National Drug Control Policy, 2008).

In the United States, the abuse of prescription painkillers ranks second to marijuana as the most prevalent drug problem for teens (Office of National Drug Control Policy, 2008). For the first time, new users of prescription drugs are equivalent to new users of marijuana among teens. In Washington State, 10.7 percent of 12 to 17 year olds use prescription medicines for nonmedical reasons; this is among the highest rates of all states (Sabel, 2008). Nationwide, 56 percent of those who use prescription drugs for nonmedical reasons obtain them from a friend or relative for free (Substance Abuse and Mental Health Services Administration, 2009). Results of Washington's annual Healthy Youth surveys confirm this

access to medicines in homes for pre-teens and teens; for example, in 2008, 15 percent of 10th graders in Washington who abused prescription pain relievers said they got the drugs from their own home or someone else's home without permission (RMC Research Corporation, 2009). Easy access to prescription medicines may be the most common initiation for individuals who later develop serious addictions.

The nonmedical, or illicit, use of medicines results in medical emergencies and fatal overdoses. According to a 2005 report of the Drug Abuse Warning Network (DAWN), nearly 600,000 emergency room visits in the United States were due to the illicit use of medicines (Drug Abuse Warning Network, 2009). DAWN estimates that 404 visits per a population of 100,000 are caused by non-medical use of prescription or over-the-counter medicines each year; in Washington State, this translates to almost 26,000 trips to the emergency room each year. Drug overdoses have surpassed car accidents as the leading cause of accidental deaths in Washington and several other states. The majority of overdoses involve prescription opiates (WA DOH, 2007a; Warner, Chen, & Makuc, 2009).

The prevalence of this problem prompted the White House Office of National Drug Control Policy (ONDCP), to publish a fact sheet explaining how to dispose of unwanted medicines to keep them away from potential abusers. ONDCP's recommendations encourage taking unwanted medicines to a medicine return program, if available (Office of National Drug Control Policy, 2007).

Having a convenient, safe and effective medicine return program in Washington State will reduce availability of medicines for illicit use.

2.1.3 Accidental Poisoning

Unintentional poisoning is the number one cause of injury-related deaths in Washington State (WA DOH, 2008). Of these deaths, almost 85 percent involved the use of medicines. Accidental poisoning death rates have increased significantly since 1990, up 395 percent between 1990 and 2006. Death rates are significantly higher in Washington State than other parts of the country with 14 deaths per 100,000 in Washington compared to the national average of 11 per 100,000 (WA DOH, 2008). This trend is not limited to the densely populated cities; in fact, the per capita poisoning deaths were highest in Stevens, Grays Harbor, Cowlitz and Spokane Counties (WA DOH, 2007b).

The second leading cause of injury hospitalization for Washington State children 0 – 17 years old was poisonings, and the 15 – 17 year age group had the highest poisoning rates. Thirty two percent of poisoning deaths in Washington children were caused by someone else's prescription medication and 26 percent of poisoning deaths were caused by over-the-counter medication (Sabel, 2004).

More than half of the exposure calls reported by the Washington Poison Center involved children under six, and almost half of these children were poisoned by medicines. The elderly are also at risk of accidental poisonings. In 2007, over 7,000 calls to the Poison Center were from the older adult population and 66 percent of these involved medications (WA Poison Center, 2008). Overall, more than half of the calls to the Washington Poison Center hotline in 2008 were about prescription and over-the-counter medicines (WA Poison Center, 2008).

The large and growing number of accidental poisonings likely reflects multiple factors, including the increased use and availability of prescription and over-the-counter medications. Providing a convenient, safe and effective way to dispose of unwanted medications is one practical way to reduce access to these medicines.

2.1.4 Pharmaceuticals in the Environment

Pharmaceuticals and their metabolites enter the environment after being excreted from our bodies and enter a sanitary sewer or septic system. Waste medicines are also a significant and preventable source of environmental contamination. Two community studies show that 20 percent (Northwest Research Group, 2006) and 33 percent (Kuspis & Krenzelok, 1996) of households flush unwanted medicines down the toilet. The proportionate contributions of these pathways to the total amount of pharmaceuticals in the environment is unknown; however, adopting better disposal practices for waste medicines offers the simplest approach to source reduction.

Pharmaceuticals have been detected in streams, groundwater and drinking water across the United States. A 2002 study by the U.S. Geological Survey found that more than 80 percent of the 139 streams tested in 30 states were contaminated with organic wastewater contaminants, including pharmaceuticals (Kolpin et al., 2002). Although only found at low-levels, scientists are showing that many of these contaminants can be linked to concerning ecological changes. These findings prompted state and local governments to explore this emerging category of pollutants.

A 2004 study completed by the Washington State Department of Ecology in the Sequim-Dungeness region of the Olympic Peninsula detected pharmaceuticals in effluent from tertiary wastewater treatment plants, including: acetaminophen, codeine, metformin (a diabetes medicine), sulfamethoxazole (an antibiotic), salbutamol (albuterol), carbamazepine (anticonvulsant and bipolar disorder treatment), ranitidine (Zantac), estrone (hormone), trimethoprim (antibiotic), and ketoprofen (NSAID).

Metformin was also found in groundwater and wells (Johnson, Carey, & Golding, 2004).

Levels of some pharmaceuticals in surface waters are sufficient to impact aquatic organisms. In a Boulder, Colorado study, the percentage of female fish upstream from a wastewater treatment plant was 45 percent. In stark contrast, 83 percent of fish downstream from the plant were female. Researchers speculate this disturbance could be associated with endocrine-disrupting compounds, including a synthetic estrogen drug, found in the treatment plant effluent (Woodling et al., 2006). In another study, researchers exposed western mosquito fish to fluoxetine, the active ingredient in Prozac, at doses similar to what is found in streams. They observed the fish had increased lethargy and were less responsive than the control fish (Henry & Black, 2008). Changes in reproductive behavior have been found in male bluehead wrasse exposed to fluoxetine—they were not able to compete as effectively as those not exposed (Perreault, Semsar, & Godwin, 2003). The literature is now expanding to examine additional impacts of pharmaceutical compounds on specific fish species and other aquatic organisms at environmentally relevant concentrations.

At least one pharmaceutical company has expressed concern about the unknown nature of pharmaceuticals in the environment. According to Mary Buzby, Director of Environmental Technology for drug maker Merck & Co. Inc., "There's no doubt about it, pharmaceuticals are being detected in the environment and there is genuine concern that these compounds, in the small concentrations that they're at, could be causing impacts to human health or to aquatic organisms" (Donn, Mendoza, & Pritchard, 2008).

Nationwide, a 2008 Associated Press study found pharmaceuticals in the drinking water of 24 major metropolitan areas serving 41 million Americans (Donn, Mendoza, & Pritchard, 2008). Although it is unknown what, if any, impact pharmaceuticals in the environment have on human health, some studies are beginning to evaluate their potential impact. One study exposed human embryonic cells to a mixture of 13 drugs at levels similar to concentrations found in the environment. The scientists observed inhibited growth of the cells—up to a 30 percent decrease in cell proliferation compared to controls. These results suggest that a mixture of drugs at nanogram per liter (ng/L) levels can inhibit cell proliferation by affecting their physiology and morphology (Pomati et al., 2006). Another study cautioned pregnant women and their fetuses to avoid drinking water containing small amounts of chemotherapy drugs (Johnson et al., 2009).

Another concern is the unknown effects of exposure to mixtures of pharmaceuticals and other chemicals in the environment. Some studies show that these multi-component mixtures can have considerable ecotoxicity, even if all components present are in concentrations that do not create significant toxic effects if acting alone on the exposed organism (Sumpter et al., 2006).

Recent research and publicity about the effect of pharmaceuticals and their metabolites in streams, groundwater, and drinking water have raised awareness that releasing medicines into the environment can pose a risk to living organisms. This, in turn, has focused attention on better ways to dispose of unwanted medicines to eliminate that source of pharmaceutical contamination in the environment.

2.2 Past and Current Medicine Disposal Practices

Medicines are designed to treat disease and improve health, but they are also chemicals which can have harmful impacts such as human addiction, poisoning, or environmental pollution when the drug is improperly used and/or disposed. Under Washington State Dangerous Waste regulations, many waste medicines designate as hazardous waste (WA Dept of

Ecology, 2008a). The designation as hazardous waste means such compounds have characteristics that make them environmentally harmful. Under federal rules set in 1976, between four and five percent of medicines designate as hazardous waste. Examples of federally-designating medicines include: nicotine patches, epinephrine, the blood thinner Coumadin, Taxol and other chemotherapy drugs, lindane-containing shampoos, and over-the-counter eye drops or nasal sprays containing thimerosal or phenylmercuric acetate. An analysis found that if federal lists were updated to include medicines developed in the past 30 years, medicines designating as hazardous waste would approach 15 percent (Smith, 2009). Under Washington's more stringent regulations many medicines designate as dangerous waste due to ignitibility, corrosivity, reactivity, toxicity or persistence (WA Dept of Ecology, 2008b). Examples of medicines that designate in Washington State include aspirin, Tylenol with codeine, digoxin, the diabetes medicine metformin, the anti-epileptic drug Dilantin, tetracycline, Zoloft, Ritalin, Fosamax Plus D and Tamoxifen. Disposal options for waste medicines are described in this section, with additional discussion in section 4.3.

2.2.1 Disposing Medicines to the Sanitary Sewer and On-Site Septic Systems

Until recently, health professionals and the Drug Enforcement Administration (DEA) recommended that patients flush unwanted medicines down the toilet. The 2002 U.S. Geological Survey study (Kolpin et al., 2002) and other studies (Johnson et al., 2004) documenting the presence of medicines in the environment have resulted in official guidance moving away from that recommendation. Local governments and state agencies are now working to educate residents against flushing unwanted medicines.

Although wastewater treatment plants are effective at removing pollutants like solids and some bacteria, they are not designed to remove organic compounds like pharmaceuticals. Some pharmaceuticals pass through the treatment process and are discharged to streams, rivers or other water bodies. Most of the pharmaceuticals that are removed in the wastewater treatment process appear to accumulate in the digested solids that are known as biosolids. A study published in 2006 looked for organic contaminants such as pharmaceuticals in biosolid samples from seven states, including Washington. The study detected pharmaceuticals in all of the samples tested and concluded that these compounds were concentrated by the wastewater treatment process (Kinney et al., 2006). Because about half of these biosolids are applied to agricultural land or forests, their use and disposal also present a potential pathway to the environment.

While new technologies are being developed to remove some of these contaminants, no one technology will remove them all. One example is Membrane Bioreactor (MBR) technology. In one laboratory scale investigation, MBR removed 80 percent or more of pharmaceuticals tested (Radjenovic, Petrovic, & Barcelo, 2007; Hubbard, 2007a). However, upgrading wastewater treatment plants in Washington State to capture some of the pharmaceutical contaminants will cost billions of dollars and will take decades. It is more cost effective to reduce medicines from entering wastewater systems. Even once improved technologies are commercially available and utilized by most municipalities, source reduction by avoiding sewering of waste medicines will still be recommended to reduce the load on wastewater treatment systems.

Nationally, about 25 percent of residents use on-site sewage systems (septic tanks) for their wastewater treatment. Disposal of medicines to these systems could result in direct release to groundwater or soil. Additionally, some pharmaceuticals (e.g. antibiotics) can kill the beneficial microbes in the septic system, greatly reducing the effectiveness of the septic system.

In summary, sewer or on-site septic systems are an ineffective method of treatment for waste pharmaceuticals.

2.2.2 Disposing of Medicines to Solid Waste Landfills

Landfill leachate

Medicines put in the garbage are primarily taken to solid waste landfills. Decomposition in the landfill may not destroy the activity of chemical compound. Such compounds can end up in the liquid byproduct of decomposition, known as leachate. In most modern landfills, the leachate is collected from within the landfill liner and sent to a wastewater treatment plant. One highly advanced landfill in the Northwest has a system to re-circulate leachate back into the landfill, but this specialized technology is not

practical in wet climates where volumes of leachate are high and would be cost-prohibitive for many municipalities.

Municipalities do not currently routinely screen landfill leachate for medicines; however, pharmaceuticals have been detected in landfill leachate in several studies (Barnes et al., 2004; Hubbard, 2007a). When the leachate arrives at the treatment plant, many of the medicines in the leachate pass through the treatment system and are discharged to surface waters. Most medicine compounds removed in the treatment process are trapped in the biosolids and applied to agricultural land or forests.

The volume of landfill leachate sent to wastewater treatment facilities is substantial. In King County, Washington for example, leachate from the Cedar Hills landfill, measuring more than 100 million gallons per year, was the single largest "industrial" flow into the South Treatment Plant in 2006 and 2007, and is the largest regulated discharge in the entire King County wastewater system (Hildebrand, 2009).

Three active municipal waste landfills in Washington State are unlined (two in Yakima County and one in Benton County). Depending on the specific conditions of an unlined landfill, its leachate could potentially move directly into the groundwater and end up in an aquifer or migrating to surface waters (Hubbard, 2007a). A U.S. Geological Survey study at an unlined landfill in Oklahoma closed in 1985 found that the leachate plume had migrated 394 feet south of the landfill to a wetland. An antibiotic and a nonprescription drug (disposed before 1985) were identified in leachate samples (Barnes et al., 2004). This study highlights, among other things, the persistence of some pharmaceuticals.

Retrieving medicines from garbage

Disposing of medicines in the garbage does not guarantee they will not be retrieved from the curb and used. Medicines can be taken from the garbage and used deliberately by drug abusers or accidentally ingested by children or pets. This is a special concern for trash disposal of controlled substances which are the most frequently sought after and abused household medicines.

Additionally, hospice caregivers in Washington State believe that current recommendations for trash disposal of controlled substances are unsafe. They are concerned that families of deceased patients may not follow through on obscuring or crushing medicines before they throw them in the trash, increasing the likelihood that someone could retrieve the medicines from the garbage. Also, terminally ill patients who request and obtain a lethal dose of medicine under Washington State's Death with Dignity law may die without taking these powerful sedatives, and surviving family members can be left without a means of safe disposal (Butler, 2008).

Pharmaceutical Industry Standards for Disposal

The pharmaceutical industry's standard for disposing of unwanted medicines from their manufacturing facilities is by high-temperature incineration. Medicines that designate as hazardous waste are required to be disposed at a hazardous waste incinerator (Finan, 2008). This standard contradicts the Pharmaceuticals Research and Manufacturers Association, or PhRMA, recommendations that unwanted medicines from households be disposed to the garbage (SMARxT Disposal, 2009).

2.2.3 Health Care Businesses' Disposal Practices

Hospitals and clinics cannot dispose of most unused medications in solid waste landfills (WA Dept of Ecology, 2008b). Instead many healthcare businesses use reverse distributors, which are companies that specialize in managing unwanted medicines from business. Most unwanted medicines from business have never been dispensed; therefore, these medicines can be more easily identified and segregated. Reverse distributors ensure medicines that designate as hazardous waste under the federal RCRA hazardous waste regulation[2] are disposed at a hazardous waste facility. The vast majority of the remaining medicines are incinerated at permitted municipal solid waste facilities (Chapman, 2003). In its guidelines, the Returns Industry Association[3] states that the role of reverse distributors is to assist "pharmacies and drug wholesalers in returning these items for credit or assuring *environmentally responsible* disposal" (emphasis added) (Returns Industry Association, 1999).

[2] Resource Conservation and Recovery Act. (40 CFR 261)
[3] The Returns Industry Association was disbanded in 2003.

Household sources are exempted from federal and state hazardous waste rules in order to streamline requirements from dispersed small sources. However, some counties and cities in Washington State have local ordinances which overrule this exemption and include households in prohibitions against disposing of hazardous or dangerous waste in the solid waste stream. Waste medicines are potentially hazardous to the environment whether they are disposed by a household or a business. Furthermore, the cumulative impact of disposal of significant amounts of medicines from residential sources is now recognized as a concern. See section 4.3.1 for additional discussion on disposal.

2.3 Emerging Solutions: Medicine Return Programs

In 2006, a panel of experts from government, academia, and the pharmaceutical and consulting industries concluded that the most effective management strategies to reduce the environmental impacts of pharmaceuticals include medicine return programs coupled with public education (Kümmerer, 2008). Many law enforcement jurisdictions and communities across the country have also identified medicine return programs as an important part of the solution to the growing problem of prescription drug abuse, and are striving to implement collection events or ongoing programs to encourage residents to get leftover medications out of their homes.

A number of countries have implemented national medicine return programs to address the public safety and environmental problems described above, including Canada, Italy, and Spain. Several of these programs are funded by pharmaceutical manufacturers. One example of this is the medications return program mandated by provincial regulation in British Columbia in 1997. Pharmaceutical manufacturers developed and fund the program, which is operated by a not-for-profit industry sponsored association funded by Canada's Research-Based Pharmaceutical Companies (Rx&D), the Canadian Generic Pharmaceutical Association (CGPA) and the NDMAC (now called Consumer Health Products Canada). Because of the BC program's focus on convenience and service, 95 percent of pharmacies in the province voluntarily participate as collection sites. This program has been very successful at collecting unwanted medicines – in 2008 over 78,000 pounds of unwanted medicines were collected and safely disposed at more than 942 British Columbia pharmacies (Vanasse, 2009b).

Resident returning medicine to law enforcement drop box.

No comparable producer-funded medicine return programs exist in the United States at this time. Rather, non-profits, government agencies, law enforcement entities, and pharmacies have begun to offer a variety of medicine return programs in some communities. A few of these are described below.

- Maine has a mail-back pilot where residents use a padded mailer to send unwanted medicines (including legally prescribed controlled substances) directly to law enforcement. This pilot started in May of 2008 with 1,800 mailers distributed from 11 drug stores to residents. In November 2008 state-wide distribution began with 100 distribution locations. As of June of 2009, with only 70 percent of the data reported, Maine had collected 74,696 pills, capsules, and tablets of prescription and over-the-counter medicines (approximately 135 lbs)[4]. Included in their top ten medicines collected is a federally classified hazardous waste (Warfarin) and one controlled substance (acetaminophen-hydrocodone, brand name Vicodin) (Perry, 2009).

[4] A Maine pharmacy (CVS) pilot program completed in 2005 inventoried 119 pounds consisting of 55,342 tablets and 18.5 lbs of fluids and inhalers. Subtracting the fluids and the inhalers, the remaining 100.5 pounds is equivalent to 55,342 tablets, or approximately 551 tablets per pound. This average can be used to convert tablet data to pounds (Northeast Recycling Council, 2005).

- Sheriffs or law enforcement agencies have set up secure drop off locations for legally prescribed controlled substances and other medicines. Examples of these include:
    - Clark County, Washington has been operating a program since 2003 and collects both controlled substances at sheriff's offices and non-controlled medicines at pharmacies. In 2008 alone, this program collected over 300 pounds of controlled substances and 700 pounds of non-controlled medicines (Mansfield, 2009).
    - The City of Sammamish, Washington State Police Department has had a take back for controlled substances for its residents since June 2009. According to Sergeant Baxter, residents have dropped off approximately 25 pounds of consumer packaged medicines.
    - San Mateo County, California began their pharmaceutical disposal program in 2006 with drop off locations at law enforcement agencies throughout the county that have grown to 16 police stations. As of June 2009, the County has disposed of 25,200 pounds of medications (controlled substances plus all other medicines) (San Mateo Court Civil Grand Jury, 2009).
    - Chicago, Illinois's medicine take-back program began in late August 2008 and is operating at five police stations where residents can take their unwanted medicines, including controlled substances, and deposit them in a drop box (Environmental News Service, 2008). In the first seven and a half months, over 1,000 pounds of unwanted medicines (including controlled substances) were collected.
- Communities across the country have organized one-day medicine return events, with or without law enforcement presence, to collect medicines.
- Some household hazardous waste (HHW) facilities, typically managed by local governments, have collected unwanted medicines from residents. In some cases, local law enforcement personnel are present to allow return of controlled substances.

One-time collection events, while providing some benefits, are typically not cost-effective or convenient. Use of municipal HHW facilities for routinely collecting waste medicines is also challenging for most municipalities due to security concerns, lack of staffing expertise related to managing medicines, inconvenient locations and the inability to accept controlled substances. The lack of adequate knowledge, oversight, and established procedures has occasionally resulted in dangerous and illegal attempts to fill the gap in service.

A sustainable, statewide medicine return program would provide a consistent and appropriately regulated program for residents to return their medicines for safe and secure disposal, protecting both public health and the environment.

3.0 ORIGIN, TEAM MEMBERS, STAKEHOLDERS AND FUNDING

3.1 Pilot Origins and Goals

Sharing a mutual concern about unwanted medicines in households, a group of state and local governments, non-profit organizations and businesses came together to discuss possible solutions to this problem in the fall of 2004. Under the umbrella of the Interagency Resource for Achieving Cooperation (IRAC), a program of the Local Hazardous Waste Management Program in King County, Washington State, they formed a team known as Pharmaceuticals from Households: a Return Mechanism (PH:ARM).

Several collection and disposal methods were explored in the planning phases of the pilot, and considerable time was spent addressing protocols, regulatory approvals, outside inquiries, stakeholder interests, and the potential need for legislation.

To determine whether consumers would use a medicine return program, Washington Citizens for Resource Conservation (WCRC), a PH:ARM pilot partner, commissioned a survey of 400 King County, Washington households in 2006 (Northwest Research Group, 2006). Survey findings include the following:

- Three-quarters of the respondents said they would be willing to return their medications to be properly disposed of if a convenient location is offered.
- Local pharmacies were identified as the most convenient location to dispose of unwanted or expired medicines by 84 percent of respondents.
- Four in five respondents said they were likely to return unwanted or expired medicines to a secure drop box set up at their pharmacy. This finding is consistent with selection of pharmacy-based return as the collection mechanism for most medicine return programs in other countries.

Based on these results and the successful medicine return program in British Columbia, Canada, PH:ARM initiated a household medicine return pilot with two key goals:

1. Reduce opportunities for illegal drug diversion, abuse and poisonings while preserving water quality and human health.
2. Demonstrate the viability of a secure, convenient and comprehensive take back approach that could operate on an ongoing basis.

3.2 PH:ARM Team

3.2.1 Team Members, Advisors and Partners

PH:ARM pilot partners included representatives of the following organizations:

- Interagency Resource for Achieving Cooperation (IRAC).
- Local Hazardous Waste Management Program in King County (LHWMP).
- Northwest Product Stewardship Council (NWPSC).
- Pacific Northwest Pollution Prevention Resource Center (PPRC).
- Public Health – Seattle & King County.
- Snohomish County Solid Waste Division.
- Washington Citizens for Resource Conservation (WCRC).
- Washington State Department of Ecology (Ecology).

Representatives of the following agencies served as advisors to the project:

- Washington State Board of Pharmacy.
- Washington State Department of Social and Health Services – Aging & Disability Services Administration.

Collection site partners included the following organizations:

- Group Health Cooperative (Group Health) a Northwest health maintenance organization. Group Health collected unwanted medicines from its members and the public at 25 clinical pharmacy locations statewide.
- Bartell Drugs (Bartell's) a family-owned statewide retail drug store chain. Bartell Drugs collected unwanted medicines from customers and the public at ultimately 12 stores around Puget Sound.

- Two boarding homes in the Seattle area collected unused medicines from their residents only.

3.2.2 Roles of Team Members

PH:ARM team members took on a variety of roles in developing, launching, and managing the pilot. While these roles changed as the project evolved, focus areas included:

- Regulatory and compliance issues and approvals.
- Funding.
- Collection and disposal protocols, including container design, signage and brochures, waste handling and transportation, coordination of collection sites, and waste disposal.
- Research on the medicines themselves, including health and environmental effects, composition and quantities.
- Assessing and monitoring public awareness and support.
- Pilot outreach and communications, including responding to the public, the press, retailers and other governments.
- Policy considerations, including alternatives to incineration and upstream waste reduction.
- Outreach to pharmaceuticals manufacturers, pharmacists, retailers, and other interested parties statewide and nationally.
- Participation in the Product Stewardship Institute's national dialogues on pharmaceuticals.

3.3 Stakeholders

Dozens of organizational and individual stakeholders were involved in researching, planning and developing the PH:ARM pilot and laying the groundwork for a permanent statewide program. Information exchange occurred via emails, phone calls, meetings, and an April 2008 stakeholder workshop. The following stakeholders participated in discussions regarding the medicine return pilot:

- Pharmacies, health care institutions, and local governments that requested "how-to" information on the PH:ARM pilot collection model were encouraged to support a permanent statewide program. While a number of parties showed interest in becoming additional PH:ARM pilot collection sites, there was no opportunity to expand the pilot due to funding and staffing constraints.
- Federal and State Agency Staff were contacted in an effort to gain a better understanding of existing regulations and to explore ways to clarify, waive, or revise regulations that impacted household medicine return. PH:ARM worked with the following agencies:
  - U.S Drug Enforcement Administration (DEA).
  - U.S. Postal Service (USPS).
  - U.S. Environmental Protection Agency (EPA).
  - U.S. Department of Transportation (DOT).
  - U.S. Food and Drug Administration (FDA).
  - White House Office of National Drug Control Policy (ONDCP).
  - Washington State Department of Ecology (Ecology).
  - Washington State Board of Pharmacy (BOP).
  - Washington Utilities and Transportation Commission (WUTC).

Discussions with agency staff and officials helped clarify how regulations from various agencies impacted household medicine return efforts. Representatives from many of these agencies are participating in national dialogues on pharmaceutical waste, described in section 7.3.5.

- **Legislators and elected officials** were initially contacted for letters of support for the DEA waiver request (see section 7.1). U.S. Senators Patty Murray and Maria Cantwell, Washington State Governor Christine Gregoire, Washington State Attorney General Rob McKenna and numerous others sent letters to the DEA in support of a waiver to allow the Washington State medicine return pilot to collect controlled substances. In later months, many of these officials continued to contact the DEA for a response to PH:ARM's waiver request (see Appendix A for a sampling of letters of support). State and local elected officials also became involved in efforts to create a statewide medicine return program via legislation described in section 7.3.

- **Waste transportation, disposal vendors and reverse distributors** were contacted to set up pilot services, as described in section 4. These businesses worked with PH:ARM to explore ways to accommodate a previously unaddressed waste stream under existing regulatory and business structures.
- **Medicine return programs, agencies and collection site hosts in other states and British Columbia,** have contributed in the following ways: discussing various medicine return models; exploring methods of data collection and outreach; serving on panels at conference presentations; and participating in the national pharmaceutical dialogues (see section 7.3.5).
- **Potential supporters and stakeholders,** including pharmacists, school nurses, poison centers, nursing homes, retirement communities, veterinarians, hospice workers, cruise ship operators, hotel managers, and neighborhood associations, have maintained contact with the PH:ARM pilot and participated in workshops and conferences.
- **2008 stakeholder workshop**
  An April 2008 workshop on "Medicine Return in Washington State" brought together 85 diverse stakeholders for a day of education and brainstorming about unwanted medicine return in Washington. Attendees and workshop presenters included representatives from drug manufacturers, the state legislature, the U.S. Congress, public health agencies, and from the environmental, health care, retail, solid and hazardous waste agencies and other sectors. Presentations offered diverse perspectives on medicine return programs, and stakeholder interest groups listed key needs and action steps in workshop breakout sessions.

3.4 Funding Sources

The pilot was supported by in-kind services and grants from public and private sources. See section 6.1 for more information on pilot costs. The following funding sources contributed to operational or outreach costs for the PH:ARM pilot or team members' other efforts related to unwanted medicines:

- Group Health Community Foundation.
- King County Department of Natural Resources/ Small Change & Waterworks Grant.
- Local Hazardous Waste Management. Program in King County / Voucher Incentive Program.
- Puget Sound Action Team – Public Involvement and Education Grant.
- Northwest Product Stewardship Council (using Washington State Department of Ecology Coordinated Prevention Grant (CPG) funds).
- The Russell Family Foundation.
- Seattle Public Utilities.
- Seattle Biotech Legacy Foundation (now Sustainable Path Foundation).
- Snohomish County Solid Waste Program (using CPG funds).
- Snohomish County Marine Resources Commission.
- Washington State Attorney General's Office / OxyContin Settlement Funds.
- Washington State Department of Ecology – Public Participation Grant.

Grant-funded pilot implementation and other programs related to unwanted medicines included the following:

- Collection containers and supplies.
- Waste transportation and disposal.
- Communications and outreach, including Web site content, brochures, display materials and conference presentations.
- Fact sheets and reports.
- A stakeholder workshop and follow-up.
- Surveys of collection site pharmacists and medicine return customers.
- Sampling and characterizing medicines.
- Research on funding models for medicine return programs.
- Upstream waste reduction.
- Alternative disposal methods.
- Project team management, facilitation and participation.

In-kind staff time contributions (non-grant funded) were used to support many of these same activities as follows:

- Researching, testing, and selecting secure collection containers.
- Developing collection site protocols and coordination with the Board of Pharmacy's review and approval process.
- Coordinating waste transportation and disposal approvals.
- Coordinating collection site partner contacts, agreements, and training.
- Conducting site safety checks and consolidated materials.
- Researching regulatory issues, scientific literature, industry policies and attitudes, and other issues affecting medicine return programs.

Finally, three retired pharmacists, Ken Leger, Mahmoud Abdel-Monem and Brent Olsen, volunteered their time to assist with the PH:ARM studies to characterize the collected medicines. Several pharmacy school students assisted either as volunteers or as part of their internships with Group Health.

4.0 OPERATIONS

4.1 Collection Sites and Secure Containers

4.1.1 Collection Sites

The PH:ARM pilot collected unwanted medicines at three types of businesses – clinical pharmacies (Group Health), retail pharmacies (Bartell Drugs) and two boarding homes. Collecting medicines at pharmacies was consistent with programs around the world which typically use pharmacies as collection locations.[5]

Group Health Cooperative is a consumer-governed, nonprofit health care system with headquarters in Seattle and 25 clinics in Washington State. Clinical pharmacies dispense medicines to Group Health members. More information on Group Health can be found at *www.ghc.org*.

Bartell Drugs is a family-owned, regional retail pharmacy with 57 stores in the Puget Sound area. For more information, see *www.bartelldrugs.com*. Twelve of the stores participated in the PH:ARM pilot using procedures similar to the Group Health model. Plans for Bartell collection sites were scaled back from 40 to 12 locations due to funding and timing constraints.

Two private boarding homes for seniors also participated in the pilot. Boarding homes are defined in Washington State as "…any home or other institution… providing housing, basic services, and assuming general responsibility for the safety and well-being of the residents" (Washington State Revised Code 18.20.020). The boarding home medicine return was for residents only, not for family members or the public.

4.1.2 Secure Collection Containers

The decision to run the pilot at pharmacies meant that each site needed a secure container to accept the collected medicines. Containers had to meet the following criteria:

1. Be constructed of heavy duty, tamper-resistant material.
2. Be secured to the floor or wall.
3. Be large enough to hold a removable bucket or box for collecting medicines.
4. Allow for the easy deposit of medicines while preventing removal of medicines.

After market research determined that no appropriate containers were available for purchase, the PH:ARM team pursued two options: metal containers and modified plastic containers. Our business partners preferred the metal container over the less expensive plastic model, so the metal container was used. The PH:ARM team collaborated with dVault, a company that specializes in security containers, to develop a steel container that met all the criteria (**Figure 1**). The design of containers used by Group Health and by Bartells differed slightly due to specific needs of the pharmacies; both systems are fully described below.

Figure 1. Patient using a container made by dVault at Group Health

[5] British Columbia, Canada; Alberta, Canada; Sweden; Australia; England; Spain; and Italy (plus others).

Group Health Collection Containers

The containers at Group Health are secured to the floor or cabled to the wall. Customers deposit medicines in the container via a chute that can be closed and locked when the pharmacy is closed (**Figure 2a** and **2b**).

Figure 2a.

Figure 2b.

The container uses a baffle to prevent people from retrieving medicines after they are deposited (**Figure 2c**). A viewing window on the front door allows pharmacy staff to see if the bucket inside is full. Doors feature double locks so that two pharmacy staff with separate keys have to collaborate to remove the bucket (**Figure 2d**).

Figure 2c.

Figure 2d.

Initially a five-gallon hammer-seal bucket was used but it proved difficult to seal and even more difficult to open for screening purposes. Eventually, the hammer seal buckets were replaced with reusable buckets with screw-on lids. Security is guaranteed by the use of uniquely numbered tamper-evident tags for each bucket. A plastic bucket liner is attached to hooks inside the container to direct medicines from the end of the chute into the bucket (Figure 2c). When the bucket is full, pharmacy staff close the lid and seal it with a uniquely numbered security tag (**Figure 3a**). The unique tag number is used to securely track the bucket from the pharmacy back to Group Health's central pharmacy warehouse. Any tampering with the bucket will be evident by a broken seal or altered number.

Figure 3a. Bucket with security tag.

The bucket was selected to fit into a standard grey tote used to ship materials between their central warehouse and all Group Health pharmacies. Group Health wanted to transport the collected medicines in the same type tote used to ship all other materials so as not to draw attention to the waste medicines (**Figure 3b**).

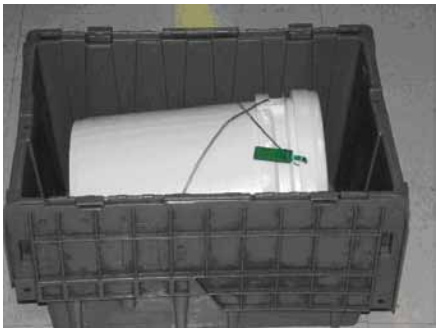


Figure 3b. Shipping tote.

Ten-gallon cardboard boxes were also tested in the Group Health system but the plastic bucket worked better because the height of the box blocked the viewing window in the door so staff could not see

when the box was full. Additionally, the larger box did not fit into the grey totes used to ship materials between the pharmacy warehouse and the individual Group Health pharmacies.

Bartell Drugs and Boarding Homes Collection Containers

The original container was used in Group Health facilities for a year. PH:ARM and dVault then developed a container for use at Bartell Drugs and the boarding homes. Instead of using a baffle to prevent people from inserting their hands into the container to retrieve medicines, the second generation container uses a moving, mailbox-type chute. Another difference is that the viewing windows are on the top of the container. Like the Group Health container, the access chute is lockable (**Figure 4**).

Figure 4. Bartell's/Boarding Home Container with Mailbox Chute

This new mailbox-type design without baffles allows the container to be small enough to be placed on the pharmacy counter while holding the same amount of medicines as the Group Health container.

The container is securely bolted or cabled to the pharmacy counter (**Figure 5**).

Figure 5. Bartell's Container Installed on Countertop

A matching stand was also developed that could be used to raise the container to the same height as the first generation containers used at Group Health (**Figure 6**). Using this configuration, the stand and container were then securely bolted to the floor.

Figure 6. Bartell's Container on Matching Stand

Bartell Drugs and the boarding homes use a 14-cubic inch cardboard box (approx. 12 gallons) as the inner container. This was less expensive than the plastic bucket used by Group Health and had twice the capacity. The outer container used at Bartell Drugs permits a larger box because the viewing window is on top and the baffle was replaced with the mailbox-type chute. At times Bartell pharmacies are able to reuse other boxes originally used to ship new pharmacy products to the pharmacy to reduce program costs (**Figure 7**).

Figure 7. 14 cubic inch Box Inside Bartell's/Boarding Homes Container

All boxes are fitted with plastic liners, sorbent pads inside the liners, and zip-tie closures. When the box is full, pharmacy staff close the lid and secure it with tamper evident tape. Sealed boxes receive a preprinted sticker with a unique number that allows secure tracking of each box back to the Bartell Drug central pharmacy warehouse and through transportation until final destruction.

The dVault company is now marketing the unit as a collection container for other drug collection programs. Details are available at *http://www.takebackexpress.com*.

4.1.3 Results of Using Secure Collection Containers

The containers worked well for function and security at all collection locations. There were no reports of people trying to get into the containers to retrieve medicines. No buckets or boxes were stolen or misplaced. All buckets and boxes put into use were filled with medicines, securely sealed, identified with tracking codes, sent to the warehouse, and properly disposed.

On rare occasions, customers brought in medicines with small leaks. At Bartells, these were easily packed into larger non-leaking containers before depositing in the chute. Occasionally, small spills, typically cough syrup, occurred inside a sealed bucket or box. In every instance, the liner and absorbent pad worked to control the spill. There were no incidents in which liquid spills escaped from their containers during transportation or storage.

4.1.4 Collection Container Design Evaluation

The secure metal containers worked well. In the future, improvements could be made to both types of containers.

The design of the secure metal container used by Group Health worked well with five-gallon plastic buckets, but the location of the viewing ports made it difficult to use larger boxes or buckets. Modifying the design to accommodate larger boxes or buckets would require fewer change-outs, saving staff time.

At Bartell Drug pharmacies, pharmacy staff had to screen medicines before they were placed in the container. This required the pharmacists to leave their normal work area and unlock the container's access chute. The process could be improved by installing the container under the pharmacy counter, with a lever that allowed the pharmacist to easily open or lock the access chute. This would provide the same security features while minimizing the pharmacists' time. The dVault company has posted preliminary drawings of this type of under-the-counter container at *http://www.takebackexpress.com/ProductDetails.asp?ProductCode=DVDC0079&Show=TechSpecs*.

4.2 Screening and Security Protocols for Collecting Medicines

Detailed protocols were developed for each collection site and approved by the Washington Board of Pharmacy prior to opening each location.

Criteria for developing protocols included the following requirements:

- Keeping medicines secure from the point of drop-off through final destruction.
- Maximizing the amount of medicine collected.
- Minimizing operational costs.
- Minimizing government oversight.
- Building on existing infrastructure business practices, authorized staff and vendor relationships, when possible.

Some medicine return programs identify, count and record each pill that is returned as part of their research study.[6] Requiring an inventory of each collected pill can provide very valuable data; however it greatly increases the cost and time involved in collecting medicine. For instance, in a pilot completed in San Francisco Bay, it took just over a half an hour of staff time to collect and inventory every pound of medicine (Bay Area Pollution Prevention Group, 2006). There is also the added potential for diversion by providing an access point to those medicines by pharmacists or other operators of medicine return programs.

[6] Examples of programs that inventory each pill, tablet and capsule, etc. include programs set up by the New England Recycling Council *http://www.nerc.org/documents/holding_unwanted_medications_collection_final_2006.pdf* and Operation Medicine Cabinet programs. *http://www.operationmedicinecabinet.org/*

Because of the anticipated large volume of returned medicines and the associated high time and labor costs and security concerns, PH:ARM decided to test a program which would not require detailed inventory. Instead, the pilot used procedures that would allow large volumes of unwanted medicines to be conveniently returned, securely stored and transported, and ultimately disposed in an environmentally protective manner. A subset of the collected material was subjected to a more detailed inventory, described in section 5.2.

4.2.1 Group Health Cooperative Program

The Group Health pilot started at seven clinics in October 2006 and expanded to all 25 clinics by January 2008. All Group Health members (close to 600,000 members) can dispose of unwanted medicines when they visit their health care providers. Though the pilot was not advertised extensively to non-members, the general public may also bring unwanted medicines to Group Health pharmacies for safe disposal.

Collection containers are located in the pharmacy waiting area, in direct view of the pharmacists. The deposit chutes are open during the pharmacies' open hours. A sign that lists acceptable and unacceptable materials is posted on each collection container. (See Appendix B for Yes/No list.) A customer with unwanted medicines simply drops their unwanted medicine in the original containers down the collection container chute. There is typically no interaction with Group Health pharmacy staff.

A viewing window on the front of the collection container allows Group Health staff to see when the bucket inside needs replacing. Bucket change-out requires two key holders to open the collection container. Full buckets are sealed with numbered, tamper evident tags. After sealing full buckets, a fax is sent to the central pharmacy warehouse notifying staff that a box of medicines will be arriving. The bucket is then sent to the warehouse using Group Health's regular pharmacy supply route drivers. The unique tag numbers allow each bucket to be individually tracked by the warehouse manager from the pharmacy to Group Health's central pharmacy warehouse.

At the warehouse, the buckets are stored in locked metal cages (**Figure 8**). Throughout this process, a complete chain of custody is maintained for the returned medicines. Completed forms are retained at the Group Health pharmacy warehouse.

Figure 8. Storage Cage at Group Health Pharmacy Warehouse

After accumulating about 100 full buckets (or about 750 pounds of unwanted medicines and consumer packaging) at the central warehouse, all buckets are opened and examined to ensure all materials are appropriate for disposal by incineration (See Appendix B for Yes/No list.) In 2008, when all 25 Group Health pharmacies were participating, this typically occurred every three weeks.

Initially, the screened material was put back into the same hammer-top plastic (affixed with a new lid) for disposal by incineration. Later, returned medicines were consolidated into lined 10- or 15-gallon cardboard boxes for reasons of economy, convenience and environmental concerns. Today, all screw-top buckets are returned to the pharmacies for reuse. A small amount of medicine that is not in its original container, i.e., loose pills, is packaged in five-gallon plastic buckets to meet the U.S. Department of Transportation regulations (see section 7.1.2 for details). The containers of returned medicines are transported by PS Industries, a local reverse distributor, to the Waste to Energy facility in Spokane, Washington, where they are incinerated (see section 4.3 for details). PS Industries documents that the material is destroyed (witnessed destruction). The destruction documentation is returned to the Group Health warehouse and filed.

4.2.2 Bartell Drugs Program

The Bartell collection containers are also located in the pharmacy waiting area in direct view of the

pharmacists. A door covering the access chute on the collection bins is typically locked. To deposit unwanted medicines, a Bartell pharmacist or pharmacist technician must visually inspect, but not handle, the medicines. After screening the medicines and rejecting unacceptable items, staff unlocks the chute and allows the customer to deposit screened medicines. A sign describing materials that can and cannot be deposited into the box is posted on the container (see Appendix B for Yes/No list). Customers are given information about how to properly dispose of their rejected items.

A window on the top of the container allows Bartell staff to determine if the box of medicines inside is full. Full boxes are removed from the container by two pharmacy staff using separate keys. After the box is taped shut, a tamper-evident seal is placed across the seams and a fax is sent to the central pharmacy warehouse notifying staff that a box of medicines will be arriving. Sealed boxes are shipped back to Bartell's central pharmacy warehouse, on the regular pharmacy route trucks. The unique numbers assigned to the boxes allow the custody and transportation to be tracked on a Shipping Notification form. At the central pharmacy warehouse, boxes are stored in a caged section of the warehouse until enough boxes accumulate for transportation to the disposal facility.

Because trained pharmacy staff pre-screen the materials deposited in the disposal container, disposal vendors can be assured that no controlled substances or other unwanted items are collected. This allows the collected medicines to be incinerated at Clean Harbors' hazardous waste incinerator in Utah without witnessed destruction, under Washington State's hazardous waste disposal contract. See section 4.3.2 for more information on disposal.

4.2.3 Boarding Home Program

The medicine return pilot was set up at two boarding homes in the Seattle area in the fall of 2008. Boarding homes are defined in Washington State as "…any home or other institution… providing housing, basic services, and assuming general responsibility for the safety and well-being of the residents (Washington State Revised Code 18.20.020). They are different from Nursing Homes in that they do not provide skilled nursing services. Collection services are for boarding home residents only.

Boxes of medicines collected at Bartell Drugs prior to shipment for final disposal.

The boarding home pilot was patterned after the Bartell model. Containers were placed in the home managers' locked offices. Returned medicines are pre-screened by each facility's nursing staff to ensure that unwanted materials are not collected. During the pilot (September 2008 – Oct 2008) not enough medicines had accumulated to complete a disposal; however, Clean Harbors did pick up the unwanted medicines from their facilities and transported them to their hazardous waste incinerator in Utah. Because of the small scale and short duration of the boarding home pilot, study data were not reported.

4.2.4 Results of Security Protocols

All collection records and shipping containers were audited for discrepancies or security problems. Of the 2,361 buckets and boxes used for collecting drugs at Group Health and the 39 boxes at Bartells, all were accounted for and no signs of tampering were found. Additionally, there were no indications of attempted diversion. Participating pharmacies did not report any attempts to pilfer collected material from the collection containers.

4.2.5 Evaluation

The different collection models used by Group Health, Bartell Drugs and the boarding homes offered the opportunity to test two approaches to the problem of screening out unacceptable materials.

In the Group Health pilot, customers did not interact with pharmacy staff before depositing materials into collection containers. Returned medicines were consolidated and screened at Group Health's main warehouse before shipment to an approved incinerator.

This "post-collection screening" approach had the advantages of impacting pharmacy staff very little and of not making customers wait for staff assistance. Opening the buckets in the warehouse allowed for a cost-saving consolidation of material. On the other hand, not screening medicines before they were deposited in the collection containers led to additional staff time to screen materials at the warehouse.

In contrast, the customers at the Bartell Drugs pilot were required to interact with pharmacy staff before depositing medicines in the collection containers. At the boarding homes the nursing staff took on this function. Once a full box was sealed in the Bartell pharmacy or at the boarding home, it required no further screening before being shipped to a disposal facility. This model could be termed the "pre-collection screening approach."

The advantage of the pre-collection screening approach is that less warehouse staff time is needed to manage collected material. A disadvantage of this approach is that customers using the service have to wait for pharmacy staff assistance, and pharmacy staff are required to spend time screening out unacceptable materials.

At boarding homes, residents retain control over their own prescription and over-the-counter medicines. This distinguishes this type of facility from nursing homes, where all medicines are controlled and dispensed by staff. Nursing homes could not be included in the pilot due to an Environmental Protection Agency regulatory interpretation maintaining that wastes from nursing homes were not "household exempt" and therefore must be managed as regulated business waste (Federal Register 54, 1989).

4.3 Transportation and Disposal

Medicines collected in the PH:ARM pilot were securely transported to facilities that ultimately destroyed the medicines by high temperature incineration. Documentation to track the location and custody of the material was necessary to ensure security and accountability.

4.3.1 Safest Disposal Method for Medicines

After careful review, the PH:ARM team chose hazardous waste (HW) incineration as the preferred disposal method because it is currently the most protective technology available for disposal of medicines. This decision was based on the following reasons:

- Hazardous waste disposal is designed for materials and chemicals which require special handling and disposal to protect people and the environment. It is the best way to dispose of unused and unwanted medications because so many drugs are chemicals that, while designed to treat disease and improve health, also have dangerous properties when disposed.
    - Approximately four to five percent of pharmaceutical products designate under the federal Resource Conservation and Recovery Act (RCRA) regulations as hazardous waste. If RCRA Discarded Chemical Products lists (developed 30+ years ago) were updated to include products developed in the last three decades, the number of products designating as hazardous waste would approach 15 percent (Smith, 2009).
    - Many more medicines meet the criteria of dangerous waste, under Washington State's Dangerous Waste regulations, due to their toxicity or persistence.
    - Business generators of drug waste are required to manage drugs that classify as hazardous waste under RCRA at hazardous waste facilities.
- The U.S. Drug Enforcement Administration (DEA) requires destruction beyond reclamation for controlled substances and accepts incineration as a technology that ensures destruction beyond reclamation. Although the PH:ARM pilot did not accept controlled substances, the objective was to demonstrate that they could be safely collected and disposed in the same system used for other unwanted medicines. Therefore, our protocols were written with high security standards that are appropriate for controlled substances.
- Hazardous waste incineration is conducted under more environmentally-protective standards than municipal solid waste incineration, including:
    - stringently maintained high burn temperatures to minimize combustion by-products;
    - improved emission monitoring and controls to capture air-borne pollutants; and

  - more frequent testing of residual ash that is stabilized prior to disposal in a hazardous waste landfill or other special landfill.
- Washington State's Office of State Procurement has a blanket contract price for hazardous waste disposal, and it is available to local governments and non-profits. The current contract offers cost effective rates for disposal of non-controlled substances by Clean Harbors (a cost of $0.91 per pound) at a hazardous waste incinerator.

4.3.2 Bartell Drugs and Group Health Disposal Protocols

Group Health and Bartell Drugs used different systems for transporting and disposing medicines collected in the pilot due to differences in their screening protocols.

Bartell Drugs and Boarding Homes

The "pre-collection screening" of all medicines by pharmacists at Bartell Drugs and by staff at the boarding home sites ensured that controlled substances and other unacceptable materials were identified and rejected. This pre-collection screening made it possible for medicines from Bartell and the boarding homes to be transported to and disposed at a hazardous waste incinerator by Clean Harbors, Washington State's hazardous waste vendor. Under the state contract, the cost to dispose of medicines with Clean Harbors was $0.91 per pound.

Medicines collected at the Bartell pilot were transported on the vendor's trucks to its Utah facility, with individual container numbers recorded using the standard non-hazardous waste manifest. Trucks were locked, and manifests documented that facilities and staff had custody of the material.

Each container barcode number was recorded on the non-hazardous waste manifest (used for exempt household hazardous waste) and managed by Clean Harbors, similar to other household hazardous waste. Documentation of disposal was returned to Bartell Drugs and retained as a record that each collection container was destroyed. This security, tracking and documentation protocol was similar to protocols required by the DEA for the transport and destruction of controlled substances.

Group Health

Medicines collected in the Group Health pilot were not screened by pharmacy staff before being deposited in the collection containers. All collected material received a safety check at the pharmacy warehouse prior to consolidation for disposal, but the pharmacists did not do a pill-by-pill screening of the medicines in the buckets. The hazardous waste vendor available under the state contract was unable accept materials that had not undergone a thorough screening for items such as controlled substances. (For information on how controlled substances can be collected by law enforcement and disposed as hazardous waste see section 7.1.1). The PH:ARM team developed an interim solution with a reverse distributor who transported the medicines to the Spokane Waste to Energy (WTE) facility using witness destruction protocols. This interim solution was possible due to short-term agreements with the Spokane facility and regulatory agencies, and using product take-back regulations in Washington State (Chapter 173-350-100 WAC) as well as household hazardous waste exemptions (see section 2.2.3). At the Spokane WTE, the reverse distributor recorded each container as it was placed into the incinerator, documenting its destruction. The cost to dispose of medicines at the Spokane WTE was $3 per pound.

The Spokane WTE facility, the Spokane Regional Air Board, and the PH:ARM team developed protocols to ensure that unacceptable materials (e.g. mercury, iodine, and sharps) would not be sent to the incinerator. The Spokane WTE is allowing incineration of limited quantities of household medicines. The PH:ARM team members consider incineration at the Spokane WTE facility to be an interim solution.

4.3.3 Results

The Group Health pilot disposed 15,134 pounds of unwanted medicines in their original containers during the period October 2006 through October 2008 at 25 clinical pharmacies in Washington State. The number of participating pharmacies was phased in over the first 15 months of the pilot.

The Bartell Drugs pilot ultimately grew to 12 retail pharmacy sites around Puget Sound from April 2008 through November 2008; however, because several of these locations opened as the pilot was ending, these locations had not collected enough medicines

to dispose of them prior to the pilot's conclusion. There was one disposal shipment of 664 pounds of unwanted medicine between April 2008 and November 11, 2008.

The two boarding homes collected nine pounds of unwanted medicines between September 2008 and November 2008. No disposal occurred during the pilot; however, waste pick-up for hazardous waste disposal occurred at both homes several months after the pilot's conclusion.

4.3.4 Discussion: Disposing of Controlled Substances as Hazardous Waste

The federal Controlled Substances Act and DEA regulations pertaining to controlled substances were written long before the need for medicine return programs was recognized. DEA regulations currently allow only law enforcement officials to accept controlled substances from the public. Therefore, organizations or businesses operating a medicine return program currently must either involve law enforcement to handle controlled substances, or adopt methods to screen out and refuse controlled substances. Legislation has been introduced in Congress to amend the Controlled Substances Act to allow for more options to collect controlled substances from residents, see section 7.1.1 for more information.

Several hazardous waste disposal companies dispose of controlled substances as hazardous waste, including Clean Harbors, Heritage Environmental and Veolia. The DEA allows transfer of controlled substances from law enforcement to law enforcement (21 C.F.R. § 1301.24). This allowance means that local law enforcement could transfer controlled substances to another law enforcement entity located near a hazardous waste incinerator (Carter, 2009; Hubbard, 2007b) who would then provide witnessed destruction of the medicines. This process constitutes a transfer of the material from one law enforcement entity to another, thus maintaining tight security. Security features at hazardous waste facilities may include cameras, limited access, fencing, and a secured vault. Specific details of secure transfer would need to be arranged according to jurisdictional law enforcement's procedures and the final hazardous waste destination.

4.4 Outreach and Communications

Because of limited funding and the limited number of collection sites, the pilot was not advertised extensively to the general public. The pilot did benefit from more widespread promotion to Group Health members via the cooperative's member newsletter, as noted below.

Methods Used to Promote the Pilot

- Advertising at collection sites. Collection site partners used minimal advertising when the pilot began. Signs (Appendix C) and brochures were placed at the pharmacy counter on or near the collection container. Group Health promoted the program in its member newsletter. Bartell Drugs displayed small posters at participating stores.
- Brochures and displays. Three brochures were developed with different purposes (Appendix D). Group Health and Bartell Drugs created separate brochures promoting their programs. A more general brochure advertised the program as a whole.

  A tabletop display, developed before the pilot began, was used to generate support for starting the pilot. A second display, developed at the start of the pilot, educated the general public about the issue, the pilot, and long-term options (Appendix E).
- Project Web site. As the pilot began, the PH:ARM team created the *www.medicinereturn.com* Web site providing information about why, how and where to return medicine and listing items accepted and not accepted for return.

  The Web site is still active, providing information about the risks of poisoning, abuse and environmental contamination due to improperly disposed household medicines and giving operational information about the pilot—how it worked, who was involved, and what were the long-term goals of the pilot. Web pages include links to reports, contacts, and other resources.
- Presentations. PH:ARM team members gave presentations on the medicine return pilot at more than two dozen conferences, workshops and events during 2007 and 2008. Audiences included health care providers, public health staff, environment and waste management

professionals, pharmacists, state and local government staff, law enforcement, researchers, scientists, and pharmaceutical manufacturers/distributors.

- Newsletters. Articles about the pilot appeared in a number of announcements or newsletters produced by local governments or non-profits.
- Tours. Tours of pilot collection sites were given to federal government staff, elected officials, and staff from other medicine return programs.
- Response to outside inquiries. The PH:ARM team fielded hundreds of inquiries for information on the pilot. Inquiries often came through the project Web site and general email address (*info@medicinereturn.com*).
- Correspondence, press releases, op-ed pieces initiated by PH:ARM. The pilot team responded to many media inquiries, and the pilot received significant media coverage. In addition, a small number of press releases, op-ed pieces, and e-mails were issued by the PH:ARM team during the pilot. A list of news items is posted at *http://www.medicinereturn.com/resources/resources/press/press-room*.
- Fact sheets and reports. Pilot reports and fact sheets were made available at *www.medicinereturn.com*. Some of these include detailed information and resources designed to help others developing medicine return programs.

5.0 RESULTS

5.1 Amount of Medicines Collected and Disposed

Group Health, Bartell Drugs and the boarding homes have been successful in providing convenient collection services for the unwanted medicines of their customers and clients.

Group Health

During its two year pilot, Group Health safely disposed of 15,134 pounds of unwanted consumer-packaged medicines at its 25 clinics in six counties. All material was transported and tracked from clinic to warehouse to incinerator with no sign of tampering or attempted diversion. All material was screened for safety purposes, using staff provided by Group Health, the PH:ARM team and volunteers.

Customer use of the pilot and amounts of collected medicines grew rapidly at the start of the pilot, and then leveled off once all 25 locations were in operation by 2008. The Group Health pilot collected a median value of 1.2 pounds (about 0.75 gallons) per pharmacy per business day, although amounts varied significantly from pharmacy to pharmacy. The lowest amount (S Regal/S Hill pharmacy in Spokane) was 0.2 pounds per business day and the highest amount (Olympia pharmacy) was 4.2 pounds (about two and a half gallons) per business day.

Indicators of business volume at Group Health Cooperative pharmacies in 2008 (patient enrollment and prescriptions dispensed) were highly correlated with the amounts of unwanted medicines collected (see **Figure 9**[7] on page 26).Group Health pharmacies had different operating schedules; for example, pharmacies were open five, six or seven days per week. Even when calculated per business day, patient enrollment at a clinical pharmacy was more highly correlated to the amount of unwanted medicines dropped off than to prescriptions dispensed. Pharmacies starting a medicine return program can use these indicators of business volume to anticipate the amounts that may be returned.

Waste collected at the Group Health warehouse is transported to a disposal facility about every three weeks, with shipments averaging about 700 - 800 pounds (including consumer packaging, but not the shipping box weight).

In the clinics, pharmacy staff monitor collection containers to determine when the bucket is full. Sites with high collection volumes change out the buckets sometimes up to three times a day, while other sites replace their buckets only once a week.

Group Health discovered during the pilot that customers with sharps, insulin injectors, and/or blood glucose testing materials used in treating diabetes need help disposing of these properly. After observing clients bringing used lancets in brown paper bags and candy tins, Group Health staff developed new educational materials for their diabetic patients.

A very small percentage of customers using the service were from clinics and other businesses attempting to bring their pharmaceutical waste for disposal. They were redirected to dispose of it elsewhere as business waste. These incidents highlight the need for education, outreach and better access to disposal services for small medical clinics and other health care businesses.

All collection records and shipping containers were audited for discrepancies or security problems. All were accounted for, and no signs of tampering were found. There were no signs of attempted diversion. Participating clinics did not report any attempts to pilfer collected material from the collection containers.

[7] Spearman correlations were calculated for the average pounds returned each month to the pharmacy compared to the average number of patients enrolled and the average number of prescriptions dispensed per month. With a 99 percent confidence level, the correlation coefficient was 0.74 for enrollment and 0.67 for prescriptions dispensed. Spearman correlations were calculated for the pounds of unwanted drugs returned per business day compared to the indicators of business volume. With a 99 percent confidence level, the correlation coefficient was 0.76 for enrollment and 0.61 for prescriptions dispensed; quite close to the coefficients for monthly averages.

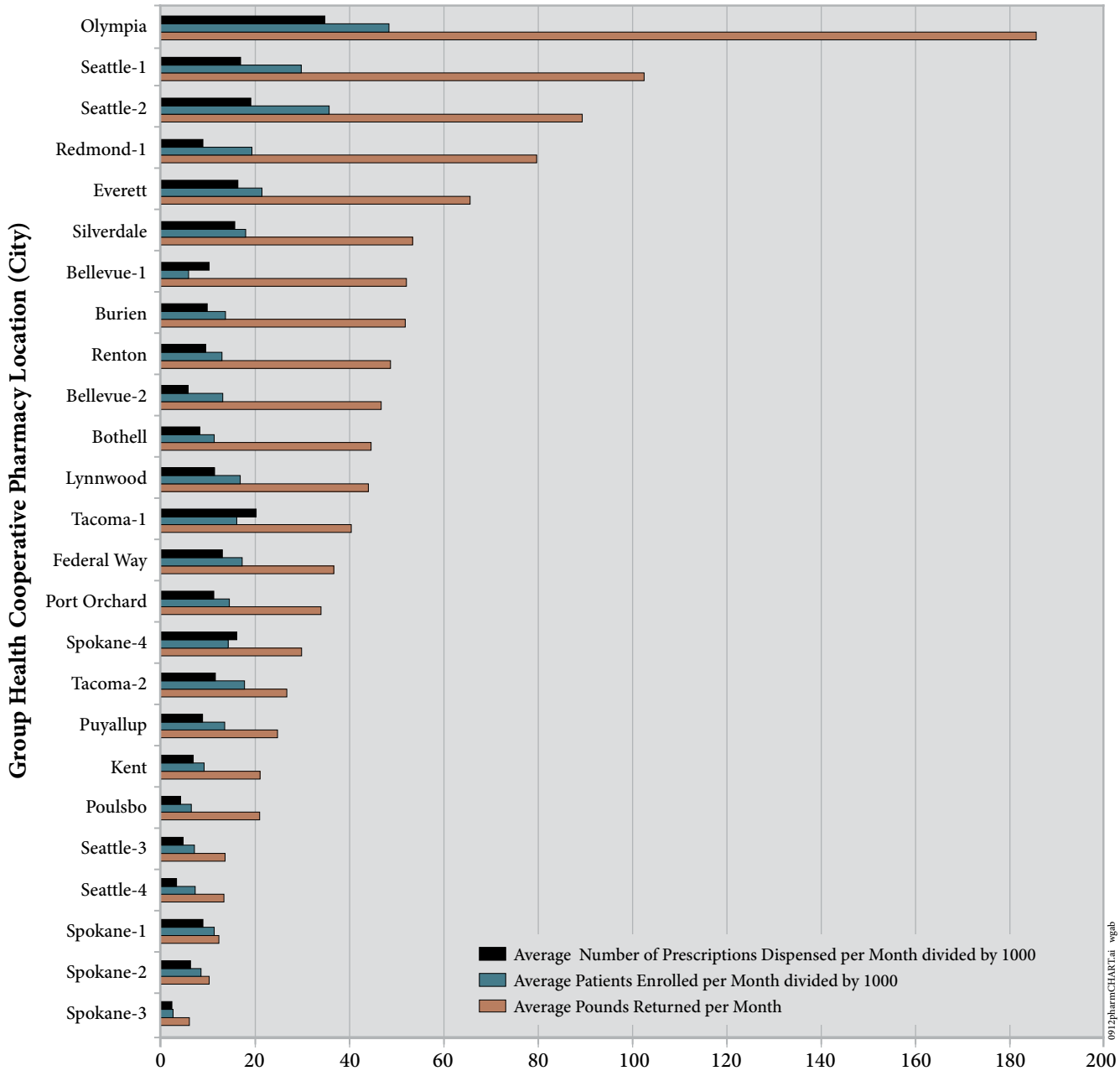


Figure 9. Unwanted Drugs Collected Compared to Group Health Business Volumes in 2008 [8]

[8] Group Health had 25 pharmacies participating during the pilot, but for unrelated business reasons, some locations moved, closed or opened. Data from 26 pharmacies were recorded. Data from the Eastside Hospital (now closed) were excluded from the chart because hospital pharmacy operations were not comparable to clinical pharmacies. While operating, Eastside Hospital returned 69 pounds per month with 6,800 prescriptions (inpatient and outpatient) dispensed per month. Patients "enroll" in Group Health clinics, but not in hospitals.

Bartell Drugs

Bartell Drugs started its collection service at one location in March 2008 and gradually increased to nine locations by October 2008. By the end of the PH:ARM pilot in October 2008, Bartell Drugs had collected 664 pounds of unwanted medicines from these nine sites. The remaining three Bartell sites opened in November 2008.

The pilot ended when Bartell Drugs' sites had been operating just a few months; therefore, only a relatively small amount of information is available about the medicines received at Bartells compared to Group Health. The Bartell Drugs pilot collected a median value of 0.6 pounds (less than half a gallon) per pharmacy per business day, and again the amounts varied significantly from pharmacy to pharmacy. The lowest amount (Burien pharmacy) was 0.12 pounds per business day and the highest amount (Queen Anne pharmacy) was 1.2 pounds (about 0.7 gallons) per business day.

Boarding Homes

One of the boarding homes, which had been operating the pilot for two months, had collected nine pounds of medicines. The second boarding home, where the pilot had just commenced, had not collected any medicines. The data from this part of the pilot is not sufficient to evaluate. The boarding homes will continue to collect and safely dispose of unwanted medicines from their facilities at least through 2009.

5.2 Description of Medicines Collected and Disposed

5.2.1 Study Scope and Methods

This section provides an overview of key findings of the study. Additional findings and study details are in preparation and may provide additional resources for those planning medicine return programs.

The PH:ARM pilot study focused on the practical aspects of operating a take-back program including acceptance criteria (unwanted medicines and nutritional supplements), segregation requirements, packaging, transportation, disposal and personnel safety. The study had two separate parts:

1. Through cursory safety checks, unwanted medicines (prescription, over-the-counter and nutritional supplements) were separated from "other materials". Because of limited resources, only the total amounts of unwanted medicines and nutritional supplements were measured. The "other materials", because they were such a small amount, were looked at in more depth.
2. Collected wastes were sampled and sorted into selected medicine categories, as resources allowed.

We were unable to record detailed information about all returned medicines because the volumes of waste were too large, especially from Group Health; however, some random samples of collected medicines were examined. Information on customers was not collected because most dropped off unwanted medicines without interacting with pharmacy staff, making it difficult to collect this information. The boarding homes were not included in our analysis because the amounts collected were too small (less than ten pounds). Medicines were not removed from their packaging during the study; loose pills were not characterized.

5.2.2 Categorization of Collected Medicines: Sample Size and Results

Cursory safety checks were conducted at both Bartell Drugs and Group Health to remove materials unsuitable for incineration and solid wastes like empty pill bottles. Of the 16,776 pounds of total waste collected, 15,798 pounds of medicines and nutritional supplements were sent for disposal and 978 pounds of "other materials" were removed. "Other materials" were primarily medical-related wastes that can be safely disposed or recycled as solid waste, such as empty pill bottles. The program received a small percentage of "other materials" that were not acceptable due to Department of Transportation regulations, biomedical waste regulations, or incinerator restrictions.

On the next page is a summary table of medicines (**Table 1**) collected and disposed at Group Health and Bartells.

Description	Group Health (Oct. 2006 – Oct. 2008)	Bartell Drugs (Mar. – Oct. 2008)	Pilot Total
Unwanted medicine and nutritional supplements properly disposed	15,134 pounds	664 pounds	15,798 pounds
Other materials properly disposed	932 pounds	46 pounds	978 pounds
Total waste collected	16,066 pounds	710 pounds	16,776 pounds

Table 1. Waste Collected and Disposed at Group Health and Bartells

All of the 710 pounds of waste received by Bartell Drugs were sorted into the medicine categories. Due to larger volumes at Group Health, 1,951 pounds, or 12 percent of the 16,066 pounds of total waste, were sorted into medicine categories as a sample of the total volume collected. The buckets/boxes selected for this evaluation were randomly sampled and not statistically representative of the waste. Unless otherwise noted, percents reported were on a percent by weight basis.

5.2.3 Objectives and Findings

Objective 1: Determine general categories of medicines collected

Medicines were sorted into prescription drugs, over-the-counter drugs, and nutritional supplements, with additional categories for unknowns and "other materials". Nutritional supplements included vitamins, minerals, herbs, etc. Examples of unknowns were drugs with foreign language labels, loose pills with no container, and drugs in containers with the label removed and the contents not otherwise identifiable. The "other materials" category included items not accepted by the take-back pilot to comply with U.S. Department of Transportation regulations, biomedical waste regulations, incinerator requirements or because the items were not medicines. These wastes were primarily medical-related wastes that can be safely disposed or recycled as solid waste, such as empty pill bottles, or other wastes such as sharps, aerosol cans, or mercury thermometers. Few personal care products were received.

The pilot intended to collect prescription drugs, over-the-counter drugs and nutritional supplements. More than ninety percent of the collected waste was prescription drugs, over-the-counter drugs, nutritional supplements and unknown drugs. The percentages by individual category for Group Health and Bartell Drugs are noted in **Table 2**:

Description	Group Health Percent by Weight*	Bartell Drugs Percent by Weight*
Prescription (Legend)	53	55
Over-the-Counter	19	26
Nutritional Supplements	14	11
Drugs (category unknown)	5	1
Other Materials	9	7
Total	100	100

Table 2. General Categories of Medicines Collected

*At Group Health, a 12 percent random sample of the waste collected was sorted into these categories. At Bartell Drugs, all waste collected was sorted. See also the "Sample Size" discussion above.

The percentage of "other materials" collected at Bartell Drugs (seven percent) and Group Health (nine percent) appear to be comparable. However, the seven percent collected at Bartell Drugs included expired pharmacy stock (about 34 pounds) that Bartell staff mistakenly placed into two medicine return boxes. Once discovered, this situation was immediately corrected by returning the pharmacy stock to a reverse distributor, and the responsible staff were alerted to the correct procedure. The pharmacy stock was categorized as "other materials" because they were not household pharmaceuticals. Once this weight is adjusted for, Bartell's "other material"

percent drops from 7 percent to 2 percent. This lower percentage of "other material" collected at Bartell's demonstrates that a pre-collection screening model is effective in minimizing the collection of non-acceptable materials.

The Group Health collection pilot received a relatively low amount of "other materials" even without the pre-collection screening of medicines, prior to placing in the container. "Other materials" from Group Health were measured at 9 percent from the random sample of 12 percent of the total waste. "Other material" from Group Health was more accurately measured at six percent in the cursory safety check of all waste received.

Objective 2: Determine the amount of specific categories of unwanted medicine

Another objective was to determine the amounts of antibiotics and hormones removed from the community, the sewer, solid waste landfills or otherwise prevented from entering the environment.

The PH:ARM pilot properly disposed of antibiotics, preventing their release to the environment. Antibiotics released to the environment contribute to bacteria developing resistance to the antibiotic, thereby reducing antibiotic effectiveness for treating infections (Kümmerer, 2004). Antibiotics were also prevented from being flushed into onsite septic systems. Because antibiotics kill beneficial bacteria, onsite septic systems can be disrupted if antibiotics are flushed in a home connected to a septic system. Antibiotics comprised eight percent of categorized material from Group Health and four percent at Bartell Drugs, or about 1,310 pounds of consumer-packaged antibiotics.

Cages holding buckets of medicines collected in three weeks at Group Health clinics.

The PH:ARM pilot studied returned hormone products defined as medicines that were clearly human or animal hormones such as birth control pills, Premarin, testosterone or thyroid replacement prescriptions. Improper disposal of hormones contributes to the overall presence of endocrine disrupting chemicals (EDCs) in the environment. EDCs are natural or synthetic chemicals that interfere with or mimic the hormones responsible for growth and development of an organism (King County, 2009). There are many other medicines with endocrine disrupting properties that were excluded from the study category because they were not human or animal hormones. At both Group Health and Bartell Drugs, human and animal hormones comprised about one percent of the categorized material, or about 170 pounds. A characteristic of hormones is their potency in small doses, so an individual hormone pill is quite small and weighs less when compared to other medicines.

Objective 3: Characterize waste for incinerator approval

Unwanted medicines and nutritional supplements collected in the pilot were incinerated at either the Spokane Waste to Energy Facility or the Clean Harbors hazardous waste incinerator in Aragonite, Utah. Each incinerator has individual acceptance criteria based on facility design, facility operations and state or local permits. About 99 percent of the waste met both incinerators' acceptance criteria. See Section 4.3 for more information about incineration.

Medicines containing mercury or iodine were not accepted in the pilot to prevent incinerator emissions problems. Extremely small amounts of materials containing mercury were received: 0.05 percent at Group Health (merthiolate, mercurochrome, fever thermometers, contact lens solution with thimerosol, compounding kit chemicals, a few other medicines and batteries) and 0.06 percent (merthiolate, mercurochrome, fever thermometer and homeopathic remedy) at Bartell Drugs. Products containing iodine comprised only about 0.1 percent at both Group Health and Bartell Drugs. At Bartells, customers that had unacceptable materials were told to call the Department of Ecology's 1-800-732-9253

(1-800-RECYCLE) number for information on how to properly dispose of these items. If they had controlled substances, they were given an instruction sheet for disposal per the Office of National Drug Control Policy's recommendations (see Appendix F).

Medicines from non-residential sources (hospitals, nursing homes, medical clinics, etc.) were not accepted because the PH:ARM pilot was focused on unwanted medicines from households, and because wastes from businesses must be handled according to other regulations. Almost all unwanted medicines collected came from residential sources; however, a significant amount of professional samples or pharmacy stock containers were occasionally observed in a bucket or box of medicines. In three cases, the disposer's identity was confirmed and the material was returned to the business source. A small percentage of customers who represented non-residential sources did attempt to inappropriately use the residential take-back program; therefore, business education efforts on proper disposal options, especially for small clinics, should be part of a residential collection program.

The amounts and nature of chemotherapy drugs were evaluated for handling or incineration risks. Chemotherapy drugs were received at both Group Health (0.2 percent) and Bartell Drugs (0.1 percent). These products were received in sealed vials or other safe prescription containers as packaged for use at home. In this sealed packaging, chemotherapy drugs were of no greater concern for safe handling or disposal than other medicines received and should continue to be accepted.

Sharps were also a concern for some incinerators (see Objective 4 on U.S. Department of Transportation classification).

Objective 4: Characterize waste according to U.S. Department of Transportation (DOT) classification

Two DOT "proper shipping names" were selected for unwanted medicines, "Consumer Commodity" and "Medicine, solid, toxic, n.o.s. (not otherwise specified)". Section 4.3 describes transportation regulations further. Based on these shipping names the following items were not accepted: aerosol cans, sharps, biomedical waste and hydrogen peroxide. During safety checks, medicines and nutritional supplements with acids, bases, potentially oxidizing or reactive ingredients were also removed, as were lice treatment shampoos, disinfectants and other products of concern. These were properly disposed at the household hazardous waste facility in South Seattle.

At both Group Health and Bartell Drugs, more than 99 percent of the material collected fit the two selected DOT proper shipping names. Data from this study could be used to apply for a DOT special permit to include unwanted medicines with some materials currently screened out, or to use a single DOT proper shipping name instead of two.

To assure DOT compliance, it is necessary to continue checking materials brought in by customers. Both Group Health and Bartell Drugs received aerosol cans (less than 0.15 percent) and wastes regulated by DOT under other shipping names (0.67 percent). The in-store pre-screening method at Bartell Drugs was effective at keeping out sharps and biomedical waste. Small amounts of these were received at Group Health (0.2 percent sharps and 0.04 percent other biomedical waste).

Unwanted medicines were primarily solid, but liquids, semi-solids and aerosol inhalers were also received. One important benefit of the Consumer Commodity shipping name was that unwanted medicines did not require segregation and packaging based on the physical state of the medicine (solid, liquid, gas, etc.). Inhalers were accepted in the pilot and made up less than two percent of categorized material at both Group Health and Bartell Drugs. These low percentages confirmed that inhalers were not a transportation concern. Inhalers in this category contained compressed gas at low volume and low pressure and were confirmed by local hazardous waste professionals to fit the Consumer Commodity shipping name.

Objective 5: Determine amounts of solid, liquid, semi-solid or compressed gas

Basic physical state information is used for waste management, transportation and disposal. Physical state information was collected for most, but not all categorized unwanted medicines and nutritional supplements. Semi-solids refer to ointments and other paste-like materials.

The unwanted medicines and nutritional supplements from Group Health and Bartell Drugs were categorized as:

Physical State	Group Health Percent by Weight*	Bartell Drugs Percent by Weight*
Solid	68	56
Liquid	19	29
Semi-solid	3	5
Aerosol inhalers	2	2
State not categorized	8	8
Total	**100**	**100**

Table 3. Physical State of Collected Medicines (packaging excluded)

*At Group Health, a 12 percent random sample of the waste collected was sorted into these categories. At Bartell Drugs, all waste collected was sorted. See also the "Sample Size" discussion above.

5.2.4 General Observations

The following observations were not part of the study objectives nor were they quantified, but they do provide qualitative insights into what was received.

The composition of returned medicines was highly variable when examined one collection bucket or box at a time. Whether the medicines were prescription, over-the-counter or nutritional supplements varied greatly, as did the physical state of the medicines, depending on the particular medicines dropped off by the customer. For example, one container had large quantities of albuterol inhalation solution while another container was filled with individual dose blister packs for long-term care residents. Another container was mostly allergy and anti-itch treatments.

By observing clues in a container such as the types of medicine or literature disposed with the medicine, it was reasonable to deduce that some drugs came from hospice patients, long-term care residences and schools. The age of drugs ranged from a few drugs that were nearly 100 years old to many drugs not yet past the expiration date. Labeling on the medicines revealed products manufactured and purchased in countries around the world. Some individuals brought in enough unwanted medicines to fill one or more containers.

The amount of drug samples was not significant at either Group Health or Bartell Drugs (about two percent each). Drug samples typically have more packaging and associated marketing materials; however, since the frequency of drug samples was very low it did not use excessive volume.

5.2.5 Conclusion

The studies confirmed the effectiveness of the pilot design to safely collect, transport and dispose of unwanted medicines from households. Even with minimal oversight, customers used the service primarily for drugs from residential sources. The PH:ARM team recommends that materials brought in by customers be checked—either at the pharmacy (Bartells) or at the warehouse (Group Health)—to assure that program acceptance criteria are met. However, these study results may be used to reduce the complexity of screening.

Collection of a small percentage of sharps and "other materials" suggests the need for better disposal options and education for small clinics with drug wastes, diabetics and others with sharps at home, and residents with empty pill bottles or mercury fever thermometers.

5.3 Pharmacist Satisfaction and Patient Perceptions Surveys

Over the course of the pilot program, multiple surveys were performed to evaluate pharmacy satisfaction and patient perceptions at Group Health and Bartell Drugs. Summary survey reports are available at *www.medicinereturn.com.*

At Group Health, surveys were done to gauge the perceptions of patients/customers and pharmacy staff involved in the return program at the start and conclusion of the pilot. A similar survey was conducted at Bartell Drug collection locations, allowing comparisons to be made between the two programs.

The surveys were as follows:

- An initial survey was done at Group Health

pharmacies in April 2007, about six months into the pilot to evaluate pharmacy staff satisfaction with the program and patient response to the program. Completed survey responses were received from 68 Group Health pharmacy staff and 162 Group Health patients.

- Group Health members were mailed a survey in June 2008; 379 returned completed surveys, a 25.5 percent response rate.
- A survey of Bartell Drugs pharmacy managers or pharmacists at 12 collection sites was conducted between November 2008 and January 2009. At this time the Bartell Drugs collection sites had three to eight months' experience with the collection site program; most sites had 5 months' experience or less with the program.
- In December 2008 and January 2009 surveys were performed for Bartell Drugs customers (125 respondents) and pharmacy staff (12 respondents) as well as Group Health pharmacy staff (91 respondents). At the time of these surveys, all Group Health and Bartell Drug pilot program collection sites had been open for anywhere from two to 15 months.

The following are some highlights of the results for all of the surveys:

Customer/patient willingness to use program

Patients indicated that they were "somewhat likely" or "very likely" to participate in a pharmacy-based medication disposal program:

Group Health first survey = 74 percent

Group Health second survey = 90 percent

Bartell Drugs = 96 percent

Bartells customer disposing medicines.

Patient perception of program benefits

When asked about benefits of the program, all respondents indicated they believed there were benefits to the medicine return program. Ninety two percent of Bartell Drug customer respondents indicated "Protecting the environment" as a benefit of the program. When asked for additional comments or questions, 83 percent of Group Health first survey respondents indicated that the program was a good idea, and there were no negative comments.

Customer feedback to pharmacy staff

Pharmacy staff mostly report receiving positive feedback from patients/customers regarding the program. When asked about comments on the whole from patients, 88 percent of surveyed pharmacists indicated they have been "very positive" or "somewhat positive." For Bartell Drug surveys (first and second surveys), 100 percent of pharmacy staff reported customer comments have been excellent, very positive, or positive. Two respondents also noted that customers do have some confusion about handling [disposing of] controlled substances properly.

Pharmacy staff time

Pharmacy staff at both collection programs reported spending relatively little time on maintaining the program– 89 percent at Group Health (second survey) report spending 30 minutes or less per week on program maintenance. Bartell Drug staff (first and second surveys) report spending two hours or less per week on the pilot program, with most responses falling in the one to two-hour range. This is consistent with the additional staff time required for pre-collection screening of returned medicines prior to accepting them at Bartell Drug collection sites versus Group Health collection sites where screening occurs after the medicines are collected.

Benefits to pharmacy

All Bartell Drugs pharmacy staff (100 percent, first survey) commented favorably on the benefits the collection program brings to their pharmacy. The top three responses were:

- Customer & community service.
- Customer satisfaction and customer appreciation.
- Increases the number of people coming into the store.

Pharmacist satisfaction with program

Over 80 percent of the Bartell pharmacy staff (first survey) made specific comments about their approval and support for the collection program. These comments fell into two main categories:

- Good idea. E.g., great program; great thing to be doing; it's been a good experience.
- Easy. E.g., easy to implement; not time-consuming; hasn't disrupted our flow.

Pharmacists' suggestions for changes

The three most common changes suggested by surveyed pharmacy staff were the need for:

- Accepting controlled substances.
- Larger internal collection bins to allow for less frequent maintenance.
- More signage and more advertising.

Other suggested improvements included

- Making the collection program even simpler.
- Seeing that everyone can be part of the collection program.
- Offering the program as a public service.
- Making the program available nationwide.

For more information, view the survey summaries at *www.medicinereturn.com*.

6. PH:ARM PILOT AND INTERIM PROGRAM COSTS

6.1 PH:ARM Pilot Costs

The PH:ARM pilot was funded by in-kind donations and staff time as well as public and private grants (see section 4.d for a listing of grantors). Trained volunteers also assisted with screening operations at Group Health. Pilot expenses should not be used to determine the costs of a permanent, statewide program due to the added costs in the pilot associated with initial planning, start-up, and research and analysis. Additionally, a larger, permanent program could take advantage of economies of scale and could negotiate better prices.

Pilot operational expenses for the two-year period of the pilot are summarized in **Table 4** below.

Task	One-time costs	Recurring Costs	Total
Protocol development, review, and request for DEA waiver.	$10,100		$10,100
One-time container purchases for 25 Group Health,12 Bartell pharmacies, and two boarding homes (39 secure metal containers at an average cost of $673 each)	$26,200		$26,200
Supplies (boxes, tape, security seals and tags, liners, absorbent pads, buckets)	$5,260 (reusable buckets)	$15,800	$21,100*
Transportation & disposal at Group Health (15,134 pounds of medicines plus weight of shipping boxes x $3.00/lb at Spokane WTE facility)		$52,100	$52,100
Transportation & disposal at Bartell Drugs (664 pounds of medicines plus weight of shipping boxes x $0.91/lb at Clean Harbors Hazardous Waste incinerator) + $400 for the state contract membership.	$400	$725	$1,130
Project management and facilitation.		$23,100	$23,100
TOTALS	**$42,000**	**$91,700**	**$134,000**

Table 4. Grant-Funded Pilot Operational Costs for Group Health and Bartell Drugs, Oct. 2006 – Oct. 2008
Costs do not include in-kind time from collection site partners & public agency staff

*Supply costs decreased over time with protocol improvements. Initially medicines were disposed in the plastic bucket that collected them. Later, medicines were transferred out of buckets into less expensive boxes for disposal and the buckets were reused.

Note: Costs are rounded to three significant figures to account for estimates.

Pilot outreach costs included designing and maintaining a website, design and printing of brochures and miscellaneous outreach tools. Total outreach costs are summarized below in **Table 5**.

Task	Cost
Website design, build & maintenance	$15,400
Group Health brochures (70,000) and Bartell (5,000) brochures (produced in-house and with their own funds.	$9,700
Public Outreach materials (displays, general pilot brochure, pill box handouts)	$4,500
Outreach coordination and management (est.)	$6,000
Total	**$ 35,600**

Table 5. Pilot Outreach Costs, Oct. 2006 – Oct. 2008
Costs do not include in-kind time from collection site partners & public agency staff

Note: Costs are rounded to three significant figures to account for estimates.

Grant funds beyond the amount outlined here were used for a variety of activities above and beyond the pilot, including researching issues and communicating with stakeholders. The project led to the formation of two work groups to research future alternative disposal options and upstream waste reduction opportunities, and a stakeholders' workshop in April 2008 to discuss the problem of disposing of waste medicines. Organizations contributing to the PH:ARM pilot gave presentations, developed technical summaries and reports, and responded to inquires about the pilot program from communities in Washington and across the country.

6.2 Post-Pilot: "Interim" Medicine Return Programs and Costs

6.2.1 Interim Medicine Return Programs

With the completion of the PH:ARM pilot in October 2008, the medicine collection program entered an 'interim' phase— that is, the period between the end of the pilot and the start of a future statewide program. At the publication of this report, Group Health and Bartell Drugs were still accepting unwanted medicines from households and have been internalizing program costs at least since September 2009 when all grant funds were exhausted. Group Health Cooperative and Bartell Drugs wanted to continue providing medicine return services to their customers. The clinical and retail pharmacies consider the medicine return program a valuable public service and feel it contributes to client/customer satisfaction. However, it is uncertain how long these partners will be able to continue funding this program.

PH:ARM team members and advisors also recognize the need to continue medicine return services at the pilot sites and to remain engaged in state and national efforts aimed at establishing permanent medicine return programs. Because grant and in-kind staff funding obtained for the PH:ARM pilot are not available long-term, the primary challenge is to obtain permanent funding.

A key principle underlying the shift from pilot to interim phases is the conviction that government funds and grant resources, whether public or private, are not the most appropriate or sustainable means of support for a permanent medicine return program. During the interim phase, efforts will focus on transitioning the medicine return program away from government or pharmacy funding models to a sustainable producer-funded permanent program.

Key aspects of the interim phase medicine return program include:

- Collection site partners (Group Health and Bartell Drug) will continue to pay for waste transportation and disposal costs as long as they are able. This is a significant cost and a challenging commitment for pharmacies.
- PH:ARM team members will continue to coordinate with collection site partners to maintain the smooth implementation of the interim medicine return program and some members will continue to work on regulatory issues, legislative efforts, outreach and assistance, and national dialogues. The focus continues to be on creating a permanent, producer-financed, secure, convenient and comprehensive medicine return program in the state.
- Interim phase plans will be assessed and updated periodically to reflect changing conditions throughout 2009 and beyond.

6.2.2 Interim Medicine Return Cost Estimates

Boarding Homes

The boarding homes continue to collect medicines and they anticipate filling two to three 12-gallon boxes a year. Because of the small volume collected, costs have not been projected for these sites.

Group Health

The *projected* annual cost of the medicine collection program at 25 Group Health locations, based on their 2009 budget, was approximately $109,600. This cost included the following:

Group Health Projected Costs – 2009

Supplies	**$4,000** Tape, boxes, security seals, security tags, tracking logs, etc.
Transportation & Disposal	**$39,600** Witnessed destruction for security - $3/lb x 13,200 lbs/year of collected medicines.
Staff time	**$66,000** 0.5 FTE (full time employee) technician in warehouse and 0.2 FTE pharmacist to manage screening and compliance audits
Total	**$109,600**

Group Health's *actual* costs for 2009 were much less than their projected budget. The actual cost of their medicine return program in 2009 was $66,698. This averages to $4.70 per pound of medicine disposed (including containers).

Group Health Actual Costs – 2009

Supplies	**$500** (this cost may be less due to remaining supplies from 2008)
Transportation & Disposal	**$35,515** ($2.50/lb to waste-to-energy facility)
Staff time	**$30,683**
Total	**$66,698**

In addition to these costs, each location incurred a one-time cost (paid for by grants during the pilot) to purchase secure collection containers at an average of $673 each. With 25 clinics, that initial purchase cost was $16,825. Additionally, a one-time cost for 300 reusable screw-lid buckets was approximately $5,259 – also paid for with grant monies during the pilot.

Envisioning a statewide program, the costs of supplies, including containers, and possibly disposal costs would be less expensive because better prices could be negotiated with larger purchases.

Bartell Drugs

The Bartell Drugs pilot started much later than Group Health – the first collection site opened in March of 2009 and the last three sites did not open until November, 2008. Based on the first four months in which all 12 sites were operating (November 2008 through March, 2009), the *projected* annual costs for 12 Bartell Drugs locations for one year was approximately $9,000.

Bartell Drugs Projected Costs – 2009

Supplies	**$1,265** Reuse of appropriate shipping cartons keeps supply costs low.
Transportation & Disposal	**$7,735** Estimated 8,000 pounds/year x $0.91/lb with disposal at a hazardous waste incinerator under the Washington State contract.
Staff time	**In kind** Time to operate the program is incorporated into the regular pharmacy workload schedule, so no extra costs are calculated.
Total	**$9,000**

Costs for Bartell Drugs to run their medicine return program in 2009 were also much less than their projected budget. Total costs for Bartell's to collect and dispose of 3,871 pounds of medicines (including containers) were $3,914 or $1.01 per pound.

Bartell Drugs Actual Costs – 2009

Supplies	**$239** Bartells reused boxes from their warehouse
Transportation & Disposal	**$3,675** ($0.95/pound for hazardous waste disposal)
Staff time	**In kind**
Total	**$3,914**

Additional costs of setup included the purchase of secure steel containers at approximately $673 per container. Container costs for 12 Bartell sites totaled $8,076, which was paid with grant monies.

6.2.3 Discussion

Actual costs for the Group Health interim program were significantly higher than costs for the Bartell interim program for several reasons

- Group Health collected more medicines than Bartells.
- Group Health's disposal costs are two and a half times higher than Bartell's. Group Health disposes of medicines at the Waste to Energy in Spokane for $2.50/lb and Bartell's is using the state contract to dispose of their medicines at a hazardous waste incinerator for $0.95/lb.
- Group Health costs include staff hired to screen the medicines after collection and prior to disposal. Bartells has their pharmacy staff screen the medicines prior to a customer putting it in the collection container, so no additional staff are needed.
- Bartell Drugs is recycling boxes to use in the collection container, thus saving on supplies costs.

7.0 KEY ISSUES AND POLICY RECOMMENDATIONS

7.1 Regulatory Issues

The PH:ARM pilot demonstrated that pharmacy-based medicine return programs can be convenient, effective and secure; however, regulatory restrictions on the return of consumer medicines to a pharmacy are a significant consideration. This section summarizes how federal and state regulations relate to medicine return programs and describes how they impacted the PH:ARM pilot. The regulations addressed are administered by the U.S. Drug Enforcement Administration (DEA), the U.S. Department of Transportation (DOT), and the U.S. Environmental Protection Agency (EPA), and the Washington State Department of Ecology.

7.1.1 U.S. Drug Enforcement Administration (DEA)

The DEA, under the authority of the Controlled Substances Act (21 U.S.C. 821 et seq.) regulates the distribution and possession of controlled substances. Legally prescribed controlled substances which comprise about eleven percent of all prescription medicines (Smith, 2009) have the potential for abuse or addiction. Examples include Ritalin, Vicodin, morphine, oxycodone, Darvon, Xanax, Valium and some cough medicines.

Under the 1970 regulation, individuals who hold the prescription, referred to as "end users", are not allowed to return leftover or expired controlled substances to someone who is licensed to dispense or handle controlled substances (e.g., pharmacist, doctor, reverse distributor). The regulation assumed that consumers would not have waste medicines, and/or when they did, individuals could dispose of their unwanted controlled substances by flushing them down the toilet. At the time of this report, law enforcement is the only entity that can legally accept controlled substances from "end users."

In 2006, PH:ARM met with DEA representatives to present the PH:ARM pilot concept with the intent of eventually soliciting a waiver that would allow the pilot to accept controlled substances. The DEA agreed to work with PH:ARM and requested detailed protocols for the safe collection of unwanted medicines at pharmacies (Cavendish, 2006). PH:ARM developed protocols and determined it was necessary to test them at a few locations. PH:ARM notified the DEA that a test phase of the pilot would begin in October 2006, without collecting controlled substances.

In March 2007, PH:ARM sent protocols to the DEA and requested a waiver to collect controlled substances. The request included over twenty letters of support from local, state and federal officials (Various authors, 2007) (see Appendix A). When the DEA did not reply, U.S. Senators Patty Murray and Maria Cantwell followed up with the DEA asking for a response. The DEA's reply dated October 25, 2007, acknowledged that the lack of a safe and secure disposal method for unwanted household medicines was a serious problem, but their legal counsel had determined that federal regulations did not allow for DEA to grant a waiver. However, they were beginning to draft revised regulations to address unwanted household medicines. The Washington State Attorney General responded to this letter in December of 2007, expressing strong disagreement with the DEA's interpretation of the Controlled Substances Act, arguing that the Controlled Substances Act "authorizes the Attorney General to waive the requirement for registration 'if he finds it consistent with the public health and safety" (Appendix G).

In January of 2009, the DEA published an advance notice of proposed rule-making titled "Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration" (Federal Register 74, 2009). The publication provided numerous questions to various stakeholders regarding the return of unwanted household medications. At the time of this report, no official response has been published by the DEA.

In February of 2009, U.S. Congressman Jay Inslee introduced legislation to amend the Controlled Substances Act to allow medicine return programs more options for accepting controlled substances, without law enforcement presence. A companion bill was also introduced in the U.S. Senate by Senator Patty Murray. For more information on the bill go to

http://thomas.loc.gov/cgi-bin/query/z?c111:H.R.1191.IH:. Another bill to amend the Controlled Substances Act was also introduced by Congressman Stupak (HR 1359) with a companion bill in the Senate introduced by Senator Klobuchar. For more information on this bill go to *http://thomas.loc.gov/cgi-bin/bdquery/z?d111:SN01292:*.

Although the PH:ARM pilot was unable to accept controlled substances, the pilot protocols followed the spirit and intent of the DEA's controlled substance regulations by managing the material through chain of custody tracking and other security measures listed below. Signage at the collection sites, pilot brochures, the medicine return Web site and collection site staff training stated clearly that controlled substances were not accepted. At Bartell Drug locations, individuals seeking to get rid of controlled substances were given Office of National Drug Control Policy instructions for disposal of controlled substances as solid waste. Operating the pilot as if controlled substances were being accepted was part of PH:ARM's goal of demonstrating that household medicine return, including controlled substances, could be securely implemented at pharmacies.

The PH:ARM pilot's security measures relevant to controlled substances included the following (see also section 4):

- Collection containers of steel construction, designed to prevent retrieval of materials through the access slot.
- Collection containers bolted to the ground or cabled to the wall, with buckets or boxes holding returned medicines behind locked doors.
- Container design with two separately keyed padlocks, requiring a witness be present when changing buckets or boxes.
- Tracked and documented custody for each container of collected medicines from the point of collection, to secure storage and transport, to final destruction.

Controlled substances are now being collected at a number of sheriff's offices and police stations in Washington State. The amendment of the Controlled Substances Act that is currently under consideration in Congress will hopefully allow more options to exist for the safe collection and disposal of controlled substances.

7.1.2 U.S. Department of Transportation (DOT)

Many pharmaceuticals are classified under federal Department of Transportation (DOT) regulations as hazardous materials, therefore unwanted medicines collected by drug take-back programs must be safely packaged, categorized and labeled for transportation on public roads. Before shipping hazardous material, DOT requires selection of a "proper shipping name" from the choices in the hazardous materials table (see hazardous materials table 49 CFR 172.101). Because there was not one "proper shipping name" that matched the variety of collected household medicines (medicines in their original containers and the occasional plastic bag with loose pills in it), the medicine return program at Group Health and Bartell Drugs selected two "proper shipping names" that most closely matched. The material was sorted into two categories before shipment to the incinerator.

The two shipping names used by Group Health and Bartell Drugs are described below.

- ***Consumer Commodity, Other Regulated Materials (ORM-D).*** This is a common shipping name used to transport consumer products to and from the retail sector. Medications returned in their original consumer packaging (e.g., pill bottle) to a medicine return program can be shipped under this category. A consolidated container of Consumer Commodities can weigh up to 66 pounds.
- ***Medicine, Solid, Toxic, n.o.s.*** (not otherwise specified). This category best fits solid medicines returned to the PH:ARM pilot that were not in their original containers. The PH:ARM pilot used this shipping name for some medicines because people occasionally returned a bag of loose pills. During the pilot (October 2006 – October 2008), containers shipped under this category had an 11-pound weight limit (equivalent to about 2.5 gallons for returned medicines). This weight restriction doubled the handling and paperwork required to process these materials. After the pilot's conclusion, and for unrelated reasons, the DOT removed the 11-pound maximum weight limit of the Medicine, Solid, Toxic, n.o.s. category.

Sorting the materials after collection into separate shipping categories is time consuming. In addition, the excess packaging increases the weight and volume of the shipment, thus increasing the cost of disposal and how frequently the collection container needs to be changed out. The easiest and most cost-effective disposal approach would be to have residents return their pills, capsules and tablets without the containers and keep the liquids, powders, ointments, pastes, etc. in their containers. The hazardous materials table in the DOT regulations does not have a "proper shipping name" that fits this description of a mixture of loose pills and other medicines in containers. Based on consultation with DOT on this issue (Edmonson, 2009), we recommend that an ongoing medicine return program apply for a special permit to allow for this mix of materials to be shipped.

British Columbia's medications return program allows pharmacists to remove pills from their packaging before putting into the collection container while powders, liquids, gels and creams are kept in their containers. This allows vials and other packaging to be recycled or disposed as solid waste. No chemical reactions or other adverse impacts have been reported in the program's thirteen-year history. With this model, there are significant benefits:

- Reduced transportation costs (based on weight transported).
- Reduced disposal costs (based on weight disposed).
- Reduced amount of material sent for hazardous waste disposal.
- Reduced amount of plastic incinerated.
- Reduced pharmacy staff time changing buckets or boxes without the volume of containers.

7.1.3 The U.S. Environmental Protection Agency (EPA) and the Washington State Department of Ecology

The transportation, storage and disposal of hazardous wastes were established in 1976 under the federal Resource Conservation and Recovery Act (RCRA) (42 U.S.C. §6901 et seq. (1976)).

Under RCRA, states can be delegated the authority to implement the hazardous waste regulation provided implementation is equivalent to, or stricter than the federal law. Washington State received this delegation of authority and developed the Dangerous Waste regulations (Chapter 173-303 WAC[9]). Washington State regulations are much more stringent than the federal law, and are enforced by the Washington State Department of Ecology.

Under RCRA rules, between four and five percent of medicines designate as hazardous waste. According to Charlotte Smith, founder of PharmEcology, if RCRA lists were updated to include comparable products developed in the last 30 years, the number of products designating as hazardous waste would approach 15 percent (Smith, 2009).

Under Washington's more stringent regulation many medicines designate as dangerous waste due to ignitibility, corrosivity, reactivity, toxicity or persistence. Also, if a waste is on either of the state's "P" or "U" lists, it designates as dangerous waste. Examples include certain cough syrups (alcohol-based, and therefore ignitable) and Warfarin (on the "U" list).

Under both the federal and state regulations, hazardous/dangerous wastes generated from households are exempt from regulation and the paperwork associated with it. However, because most medicines designate as dangerous waste in Washington State, the PH:ARM pilot planned to dispose of all collected medicines at a hazardous waste disposal facility.

The EPA regulations impacted the PH:ARM pilot in the following ways:

- The EPA does not allow reverse distributors (companies that take back medicines that have not been dispensed for manufacturer credit) to accept waste medicines (US EPA, 1991). This limited the pilot's options for the transportation and disposal of collected material.
- In a 1989 Federal Register notice (Federal Register 54, 1989), EPA interpreted unwanted medicines from nursing homes as business waste instead of exempt household waste. Therefore, nursing homes could not participate in the pilot.

The EPA has proposed adding business and household medicines to its Universal Waste Rule (Federal Register 73, 2008). If approved and Ecology adopts

[9] Washington Administrative Code

these rules in Washington State, reverse distributors could act as handlers of pharmaceutical waste and could accept medicines from consumers, including medicine return programs. This rule change would also allow medicine return programs to accept medicines as universal waste from nursing homes (Lauer, 2008); however, it would not resolve current restrictions on handling of controlled substances by the DEA.

PH:ARM team members participated in state and national discussions to clarify and create guidance on how best to handle household medicines. PH:ARM is also a regular contributor to national discussions regarding regulation changes particularly through the national dialogues and workgroups facilitated by the Product Stewardship Institute (see section 7.3.5).

7.2 Waste Reduction

Methods for reducing the toxicity and the amounts of pharmaceutical waste and for mitigating the environmental impacts of medicines are being addressed by partnering PH:ARM team members, including the Washington Citizens for Resource Conservation (WCRC).

WCRC coordinated a local Pharmaceutical Waste Reduction Think Tank comprised of individuals and organizations involved with healthcare and environmental protection. The group strategized about how to prevent the generation of household pharmaceutical waste in the first place. Examples include changing prescribing practices, exploring fewer doses for some new treatments, and using an ecological impact rating system for equivalent medications. These approaches will require long-term efforts and do not alter the immediate need for medicine return programs. Initial efforts are focused on the education of healthcare professionals on the issue. For additional information on this subject, go to *www.medicinereturn.com/resources/resources/links* and *www.wastenotwashington.org/*.

7.3 Establishing an Ongoing Statewide Medicine Return Program

7.3.1 Producer Responsibility Funding Model

The PH:ARM pilot was supported by grants and in-kind staff support from pilot partners and operated in limited locations to demonstrate protocols for secure collection and safe disposal of unwanted medicines. An ongoing medicine return program serving all communities in the state would require a sustainable funding system. Permanent funding for a statewide program could be achieved through an approach known as producer responsibility in which manufacturers take responsibility for financing and operating a take back program for their products at end-of-life. A producer responsibility model has proven to be much more sustainable than grants or funds from limited state or local budgets.

Producer responsibility programs for drug take back are operating in British Columbia and Alberta, Canada, and in Spain, Portugal and France. In most cases, program costs are shared by producers of prescription drugs (brand name and generic) and over-the-counter drugs, and the program is administered by third-party non-profit organizations established by the manufacturers. In British Columbia, for example, more than 900 retail pharmacies voluntarily participate as collection sites. They collected over 78,000 pounds of material in 2008 at a cost of about $326,000 (U.S.) (including disposal). About one hundred drug producers fund the program through the Post Consumer Pharmaceutical Stewardship Association. The amount producers pay for the program varies depending on the number prescriptions dispensed and/or the percentage of sales of over-the-counter medicines. In 2008, the range of fees paid by producers was $200 to $15,000. Fifteen companies that sell less than $1 million into the province pay the minimum of $200. Most companies paid from $5,000 to $7,000 per year. Only a few companies paid $15,000 per year (Vanasse, 2009a).

7.3.2 Benefits of Manufacturers Taking Responsibility for End-of-Life Product Management

Unwanted products with potential negative impacts on society and the environment are increasingly being recycled or properly disposed at end-of-life through programs managed and funded by the manufacturers of those products. Successful, cost-effective examples of producer responsibility can be found for a number of products, including electronics, rechargeable batteries, paint and mercury lighting and thermostats in numerous Canadian provinces, most member nations of the European Union, Japan and Australia. In the U.S., many states are implementing "E-Waste" recycling laws where producers

of computers, monitors and TVs provide a no-charge recycling program for households and certain small businesses. The E-Cycle program in Washington State, launched in January 2009, has collected over 29 million pounds of electronics from residents in the first nine months of the program, showing that convenient programs are very popular and effective (*www.ecyclewashington.org*).

Recycling and disposal programs are effective when they are convenient and accessible for consumers. Local governments lack the funding, infrastructure and staffing to provide the most convenient recycling or disposal of all unwanted, hazardous or hard-to-handle products. Household hazardous waste (HHW) facilities, for example, are expensive, have limited operating hours, and are limited in number. These factors contribute to an inconvenient, low-volume household hazardous waste collection infrastructure. In addition, HHW collection events may be staffed by corrections workers and therefore not be appropriate sites for the collection of some products, such as unwanted medicines.

In contrast, pharmaceutical manufacturers are well-positioned to finance a medicine return program and to establish cost-effective organizations to collect and safely destroy unwanted medicines. They have the expertise, knowledge, commercial relationships, and resources to establish safe, convenient and effective programs. Manufacturers are the most equitable provider of product take back programs since they gain the most financially from sales of the product. Manufacturers can incorporate the cost of the recycling or disposal of a product directly into the cost of doing business to create a sustainable funding model.

A key benefit of producer responsibility for end-of-life product management is that it connects the people responsible for recycling the product with the people who design and manufacture the product. This linkage creates an incentive for designing and marketing products in ways that improve recyclability and reduce toxicity. For medicines, where changes to the product formulation are more challenging, operating medicine return programs encourages manufacturers and others to try to decrease the quantities of unwanted medicines. For example, drug take-back programs can obtain detailed data on unwanted and unused medicines, which can inform prescribing practices, patient compliance, and drug formulation. Improvements in these areas will decrease the amount of unwanted medicines that must be disposed. In Sweden, efforts are being made to influence prescribing practices with data about a medicine's potential effects on the environment (Martini, 2008). Better prescribing practices could reduce health care delivery costs by reducing expenses for medicines, thereby off-setting costs for implementing a take-back program.

7.3.3 Cost Considerations for an Ongoing, Statewide Medicine Return Program

Expanding secure collection and safe disposal of unwanted medicines to communities across the state will require a sustainable funding source, but a comprehensive statewide approach also offers potential for economies of scale and efficiencies that were not available to the PH:ARM pilot. We do not attempt in this report to estimate the total overall costs of a statewide medicine return program as many of the PH:ARM pilot costs were specific to research and start-up of the pilot. Additionally, the PH:ARM pilot did not include the costs of collection of legally prescribed controlled substances through drop-off or mail-back to law enforcement. Variables determining the overall costs of a statewide program include: (1) the method of medicine collection (pharmacy take back, mail back, collection by law enforcement, or other method), (2) the amount of medicine collected, (3) the cost of disposal, and (4) the scale of the program.

Expected efficiencies in a permanent statewide program

It would be expected that operational efficiencies could be achieved in a permanent statewide program that were not available to a first-time pilot due to economies of scale. A larger program could buy supplies in bulk and negotiate lower waste transportation and disposal fees for larger bulk volumes. Material screening methods (trialed at Group Health) could also be streamlined and simplified from those used in our PH:ARM pilot for research purposes. Additionally, a permanent program could reduce costs by obtaining an exemption from the Department of Transportation that allows the collection and shipping of medicines without their containers. Packaging containers, estimated at 28 percent of the total weight of medicines collected, could then be recycled

rather than disposed. The DOT has indicated to members of the PH:ARM team that this is a viable option (Edmonson, 2009).

Potential Collection Amounts

Washington State is likely to collect a similar number of unwanted medicines as the medications return program in British Columbia if a pharmacy model is used. Funded by pharmaceutical manufacturers, this program has collected unwanted medicines at pharmacies for over twelve years. Collection amounts have been steadily increasing as awareness of the program expands. Extrapolating results from the B.C. program (population of 4.4 million), which collected 78,000 pounds of unwanted medicines in 2008 (without consumer packaging), we can expect to collect in Washington State (population of 6.5 million) about 150,000 pounds through a medicine return program. This potential weight includes an additional 28 percent to account for the weight of consumer packaging. Pharmaceutical manufacturers could apply for a permit from the Department of Transportation to allow for the collection of unwanted medicines without their original containers, thus reducing the weight and disposal costs for the medicines.

Costs examples from British Columbia's Medications Return Program

The annual costs of the pharmacy-based medications return program operating in British Columbia, Canada for the past twelve years are informative. A British Columbia Recycling Regulation requires all brand-owners of pharmaceutical products to be responsible for the management of their products, including collection of left-over products. The Post Consumer Pharmaceutical Stewardship Association (PCPSA) provides the medications return program. PCPSA is a not-for-profit industry sponsored association founded by Canada's Research-Based Pharmaceutical Companies (Rx&D), the Canadian Generic Pharmaceutical Association (CGPA) and the NDMAC, Advancing Canadian self-care. Program costs such as management, communications, collection, transportation, storage, disposal, and promotional activities are covered by approximately 100 brand-owners through annual payments to the PCPSA. In 2008 the British Columbia program collected and disposed of 78,000 pounds of unwanted medicines (without containers) from 942 voluntary pharmacy collection sites throughout the province at a cost of $326,000 (USD). Unfortunately, the costs of the medicine return program in British Columbia cannot be fully extrapolated to potential costs in Washington because our regulatory requirements are different, likely adding to some program costs in Washington State. There are no long-standing medicine return programs in the U.S. for comparison.

Market Snapshot: Medicine Return Costs Relative to Medicine Sales

A look at the amount of money spent on medicines by Washington residents is instructive. In 2007, Washington residents spent an estimated $3.6 billion on the retail purchase of prescription and over-the-counter medicines in a year. This included $3.3 billion (Kaiser Family Foundation, 2007b) to purchase 59 million prescriptions (Kaiser Family Foundation, 2007a) and $322 million to buy over-the-counter medicines (The Consumer Healthcare Products Association, 2009). Costs to establish and maintain a medicine return program in Washington State would be a small fraction of the costs of that spent on medicines in Washington State.

7.3.4 Efforts to Engage Manufacturers in Producer Responsibility

PH:ARM has sought to work with drug manufacturers throughout the pilot's planning and implementation. Specifically, PH:ARM solicited input from manufacturers:

- to discuss the companies' policies and existing involvement in medicine return programs.
- to solicit input from the Pharmaceuticals Research and Manufacturers' Association (PhRMA), the industry trade association.
- to provide input on and support draft legislation during the 2008 and 2009 legislative sessions in Washington State.

In addition, PH:ARM organized three meetings to inform manufacturers about the medicine return pilot, to request input from manufacturers, and to initiate discussions about financial and other support. The first meeting was the April 2008 Stakeholder Workshop described in section 3.3. In September 2008, a few PH:ARM team members and two state legislators (Representative Dawn Morrell and Representative Zack Hudgins) convened a meeting with drug industry lobbyists to discuss the 2009 Safe

Medicine Return Bill. And finally, national drug manufacturers were invited to an October 2009 meeting to discuss whether manufacturers would individually—or collaboratively—fund an interim medicine take back program after the pilot ended in late 2008. This latter meeting, however, was cancelled when insufficient responses were received to warrant a group meeting.

To date, no drug manufacturer has contacted PH:ARM to offer funding for medicine return programs in Washington State. It would be very useful for the manufacturers to join forces in the effort to address regulatory constraints. Ideally, the manufacturers, in partnership with PH:ARM, could approach the DEA to request a waiver or other solution to the existing prohibition against collecting controlled substances in medicine return programs (see section 7.1.1).

7.3.5 National Dialogue on Pharmaceuticals

PH:ARM members have actively participated in the National Multi-Stakeholder Dialogue on Pharmaceuticals sponsored by the Product Stewardship Institute (PSI). Participants in the dialogue are evaluating the need for a national system to manage unwanted medicines. A second goal of the dialogue is to address issues of safety, legality and environmental protection in the collection of unwanted medicines through the development of best management practices.

The dialogue serves as a national forum in which PH:ARM members can meet and work with others in the manufacturing and regulatory sectors, as well as with governmental agencies and non-profits. The PH:ARM pilot was profiled during the initial national meeting in June 2008.

7.3.6 Washington State Legislation

State Representative Dawn Morrell (Dist. 25, Puyallup) introduced legislation in the 2008 and 2009 legislative sessions that would require drug manufacturers to develop, manage and fund a statewide return program for unwanted medicines from households. In 2009 Senator Adam Kline (Dist. 37, Seattle) introduced a companion bill in the Senate. The 2009 bills were supported by a diverse coalition of more than 54 organizations, including health & medical organizations, substance abuse organizations, children's and senior's advocates, law enforcement,

Photo: Walt Bowen

environmental organizations, local governments, and others. In 2009, the bill passed out of the House Environmental Health Committee, the General Government Appropriations Committee and the Rules Committee. However, it did not get a House floor vote. For further information on the bill, go to *www.leg.wa.gov*, go to Bill Search and type in 1165. For bill language, scroll down to the link under bill documents for the Second Substitute (APPG 09).

Under the Secure Medicine Return bill, medicines will be collected and disposed using the safest current technology with the goal of reducing poisonings, misuse, and environmental contamination.

The Washington State bill's producer responsibility approach includes the following features:

- Manufacturers would provide the medicine return program. The bill requires drug manufacturers to take back unwanted medicines, but does not spell out specific collection methods or types of programs. Drug manufacturers are allowed the flexibility to create programs that work best, with regulatory oversight by the Board of Pharmacy. Manufacturers may work together, as they do in other countries, or can create separate programs. Manufacturers must cover the costs of collection,

transportation and disposal, with no charge to consumers returning medicines.

- State government provides oversight. The Washington State Board of Pharmacy will review, approve, and monitor the medicine return program (or programs) in consultation with the Department of Ecology. Agency staffing will be minimal but will provide oversight and ensure that performance standards are met. Costs to the Board of Pharmacy for overseeing the program(s) will be recovered from the manufacturers.
- Retailers can voluntarily participate. If drug manufacturers want to offer collection services in pharmacies, retailers can choose to participate or not. Results of the PH:ARM pilot and similar programs in British Columbia and Europe suggest that many retail pharmacies will want to voluntarily provide this customer service.

8.0 NEXT STEPS FOR MEDICINE RETURN IN WASHINGTON STATE

- Continue to provide technical support for Group Health and Bartell Drugs medicine return programs. Because of the positive response that our business partners received from their customers, Group Health, Bartell Drugs and the two boarding homes have decided to continue their medicine return programs to serve their customers and their communities. The PH:ARM team will continue to provide technical support and guidance for these programs as needed.

- Support improvements in federal regulations and laws impacting medicine return programs. Our work will continue with the DEA, the EPA, the DOT and other stakeholders seeking to streamline regulations or change laws that unnecessarily restrict setting up and operating medicine return programs.

- Continue building stakeholder partnerships. The PH:ARM team will work with our numerous stakeholder organizations, including law enforcement, health organizations, children's advocates, senior groups, environmental organizations, and local governments, to continue building partnerships with stakeholders interested in promoting medicine return programs to protect public safety and our environment.

- Dialogue with pharmaceutical manufacturers. Members of the PH:ARM team will continue discussions with pharmaceutical manufacturers with the goal of partnering with one or more manufacturer to pass producer responsibility legislation establishing secure medicine return program in Washington State.

- Support passage of producer responsibility legislation for medicine return in Washington State. Many members of the PH:ARM team and other stakeholders have joined forces to pass legislation that would require pharmaceutical manufacturers to provide and pay for a secure medicine return program throughout Washington State. When passed, this bill will provide a safe and secure method for all residents of Washington State to dispose of their unwanted medicines. This service will reduce access to unwanted medicines that could lead to misuse by our youth and accidental poisonings by our youth and elderly.

9.0 CONCLUSION

The Washington State PH:ARM Pilot demonstrated a convenient, effective, and secure method of collecting and safely disposing of unwanted medicines from households. The two-year pilot was a success and safely collected over 15,000 pounds of medicines. It now continues to operate on an interim basis using short-term funding. Demand for a medicine return program is high. Between the pilot's end in October 2008 and December 2009, an additional 20,000 pounds of medicines have been collected at the 37 pharmacies.

What is needed now is a sustainable source of funding to continue and expand the medicine return program. In addition, regulatory changes are recommended to the Controlled Substance Act to allow more options for potentially addictive drugs to be safely collected in our communities.

British Columbia, Washington's northern neighbor, has a successful and cost-efficient medicine return model which is funded by drug manufacturers and available at pharmacies throughout the province. If a similar program were implemented here in Washington State, we estimate that 150,000 lbs of consumer-packaged medicines could be safely disposed of annually. Such a stewardship service provided by the manufacturers would significantly benefit the safety of our families and reduce pharmaceutical pollution in our waterways.

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Secure Medicine Return In Washington State

The PH:ARM Pilot

Pharmaceuticals from Households: A Return Mechanism

APPENDICES

October 2006 – October 2008

PRODUCED AS A COLLABORATION OF WASHINGTON LOCAL AND STATE GOVERNMENTS, BUSINESSES AND NON-PROFIT ORGANIZATIONS

December 2009

APPENDIX A

United States Senate
WASHINGTON, DC 20510

Karen Tandy, Administrator
U.S. Drug Enforcement Administration
Mailstop AES
2410 Jefferson Davis Highway
Alexandria, WA 22301

Dear Administrator Tandy:

We are writing to request that you offer a practical solution to Washington State's Pharmaceuticals from Households: A Return Mechanism (PH:ARM) project in their efforts to collect controlled substances along with other unwanted medications from consumers. If you or your staff have issues regarding the project, we recommend that representatives of the PH:ARM team meet with you in Washington, D.C. and work through these details.

On March 22, 2007 the Washington State Board of Pharmacy submitted to John Cavendish of your offices a request for a limited waiver to pilot a take-back of unwanted medicines. This proposed project is already in the pilot phase for non-controlled drugs and is functioning extremely well.

The US DEA is considering a limited agreement with the partners who are offering collection and disposal of household pharmaceuticals. We commend this decision; however we strongly urge that this agreement allow for the partners to develop cost efficient, secure, and environmentally sound protocols through this pilot. Severe restrictions that do not consider the cost and overhead impacts on participating organizations, the public safety, transportation regulations, and environmental compliance will jeopardize the sustainability of this important program.

Collecting medications from households is a new frontier, and we are pleased the DEA is considering waiving their regulations for this pilot. However, because a pilot of this magnitude has never been done, we believe it is important to test different systems for their security, cost-effectiveness and ease of use for the consumer. Allowing PH:ARM to go forward with their pilot will significantly enhance the status quo of medicine disposal and benefit the health and welfare of the citizens of Washington State. The project is anticipated to reduce the dangers of child poisoning, drug abuse, illegal diversion, and "teen pharming" in our homes and communities which result from unsecured storage of unwanted medications and improper disposal to the garbage. Continued flushing and trash disposal of this material will only continue to put our water ways and our health at risk.

We must all work together to address the significant issues posed by the absence of a practical and comprehensive program to properly dispose of unwanted medications. Please contact us at our Seattle Offices with an update regarding the granting of this request.

Sincerely,

Patty Murray
United States Senator
2988 Jackson Federal Building
915 Second Avenue
Seattle, WA 98174

Maria Cantwell
United States Senator
3206 Jackson Federal Building
915 Second Avenue
Seattle, WA 98174

CC:

Representative, Department of Justice
The Honorable Rob McKenna, Attorney General of Washington
The Honorable Christine Gregoire, Governor

CHRISTINE O. GREGOIRE
Governor

STATE OF WASHINGTON
OFFICE OF THE GOVERNOR
P.O. Box 40002 • Olympia, Washington 98504-0002 • (360) 753-6780 • www.governor.wa.gov

March 9, 2007

Karen Tandy, Administrator
U.S. Drug Enforcement Administration
Mailstop: AES
2401 Jefferson Davis Highway
Alexandria, VA 22301

Dear Administrator Tandy:

I am writing to request that the U.S. Drug Enforcement Administration (DEA) grant a limited waiver to permit a Washington State "take back" pilot program to collect unwanted controlled substances from end users.

Without a legitimate and effective collection program, unwanted pharmaceuticals accumulate in households or are tossed in the garbage, increasing present and real dangers that include child poisoning, drug abuse, and "teen pharming" in our homes and communities. When flushed through the sewer system, these substances end up in our surface waters. Washington State testing shows the presence of elevated levels of many pharmaceuticals in our wastewater treatment effluents. These, in turn, are discharged directly into Puget Sound, an estuary of key, national significance.

A Washington coalition of government and private partners (PH:ARM – Pharmaceuticals from Households: A Return Mechanism) designed a secure "take back" pilot making unwanted pharmaceuticals easy to dispose of. The pilot provides 80 secure take-back locations in Washington, is approved by the Washington State Board of Pharmacy, and meets important state health and environmental standards.

Current DEA rules do not allow the program to collect and dispose of narcotics and other controlled substances, which could be accomplished with this waiver. Without the requested waiver, this program will be partially successful, at best. I believe this program serves your Administration's mission to reduce the availability of illicit, abuse-type drugs in the U.S. market, and supports our goal of better-protecting Washington's communities and environment.

For additional information, please contact my Executive Policy Advisor Keith Phillips at (360) 902-0630. Thank you for your consideration of this important request.

Sincerely,

Christine Gregoire

Christine O. Gregoire
Governor

Copy Furnished: Rebecca Hille, Washington State Board of Pharmacy

Rob McKenna
ATTORNEY GENERAL OF WASHINGTON
1125 Washington Street SE • PO Box 40100 • Olympia WA 98504-0100

March 28, 2007

Mark Caverly
Chief, Office of Diversion Control
Liaison and Policy Section
600 Army Navy Drive
Arlington, VA 22202

RE: PH:ARM DEA Request

Dear Mr. Caverly:

As your office knows all too well, the widespread availability of pharmaceuticals in our communities increases the present dangers of drug abuse, child poisoning, and "teen pharming." This is all the more true when legitimate disposal mechanisms are not available for consumers to utilize in the disposal of their legitimately obtained medicinal products. I am writing to encourage the Federal Drug Enforcement Administration (DEA) to grant a limited waiver to permit the collection of unwanted controlled substances from end-users in a tightly-monitored Washington State pilot program.

A coalition of government and private partners (PH:ARM - Pharmaceuticals from Households: A Return Mechanism) is currently collaborating to design a tightly-managed, secure pilot "take-back" program that will make unwanted pharmaceuticals as easy to return as they are to purchase. This pilot will provide approximately 80 locations in the state of Washington that are operating under guidelines approved by the Washington State Board of Pharmacy. The PH:ARM team also intends to pilot pharmaceutical collection in 20 nursing home settings in a later phase.

DEA rules do not permit this program to collect and dispose of narcotics and other controlled substances. The Washington State Board of Pharmacy will be requesting a limited waiver of the Federal DEA regulations to allow the Washington State-sponsored PH:ARM program to securely collect controlled substances along with other pharmaceuticals from consumers and provide for their ultimate destruction. This waiver would apply only to the pilot program and protocols as approved by the Washington State Board of Pharmacy.

If launched statewide, PH:ARM estimates that close to 100,000 pounds of waste medications per year will be collected, equivalent to approximately 80 million pills. Currently it is estimated that this amount of medication is wasted in sewers and landfills, or diverted for misuse. The DEA now estimates that

ATTORNEY GENERAL OF WASHINGTON

illicit drug usage accounts for the majority of drug abuse in this country, and prescription drug availability in households contributes to this problem.

In addition to the Board of Pharmacy, PH:ARM is supported by the Washington State Department of Health, the Washington State Department of Ecology and the Washington State Department of Social and Health Services, as well as local solid and hazardous waste management agencies and public health agencies in King and Snohomish Counties.

We believe that this program will serve both the mission of the DEA to reduce the availability of illicit abuse-type drugs in the United States and the mission of the Washington State Attorney General's Office to protect the citizens of Washington State. My office joins the Washington Association of Sheriffs and Police Chiefs in strongly encouraging the DEA to support this waiver.

If you have any questions, please do not hesitate to contact me at (360) 664-9083.

Sincerely,

ROB MCKENNA
Attorney General

RMM/jlg

cc: Mary Selecky, Secretary, Washington State Department of Health
Rebecca Hille, Chair, Washington State Board of Pharmacy
Don Pierce, Executive Director, Washington Association of Sheriffs and Police Chiefs

WASHINGTON ASSOCIATION OF SHERIFFS & POLICE CHIEFS
3060 Willamette Dr NE Lacey, WA 98516 PHONE (360) 486-2380 FAX (360) 486-2381 WEBSITE – www.waspc.org
Serving the Law Enforcement Community & the Citizens of Washington

April 24, 2006

To Whom It May Concern,

Please accept this letter in support of efforts by the PH:ARM Project (Pharmaceuticals from Households: A Return Mechanism). As you likely know, this group represents a broad coalition of government agencies and other stakeholders who have spent considerable time designing a pioneering safe and secure yet practical pilot program to capture unwanted medications from households and residents of nursing homes.

While the environmental and public health impacts of disposed pharmaceuticals are still coming into sharper focus as an emerging environmental pollutant, local jurisdictions responsible for public health and environmental protection are under increasing pressure to prevent potentially harmful disposal, illegal diversion and accidental poisonings. Currently there is no legal or practical method to meet all three of these concerns. The members of WASPC share these concerns, particularly in the context of our stated mission to enhance public safety.

The Washington Association of Sheriffs and Police Chiefs (WASPC) already faces considerable challenges in the management of evidentiary drugs. Nationally, the DEA has allowed collection of controlled pharmaceuticals ONLY with the presence of law enforcement. Law enforcement's burden of being required to play an active role in the management of waste medications from households and residents in nursing homes is not manageable or cost effective.

While the DEA interpretation of the Controlled Substances Act requires the presence of law enforcement officials at pharmaceutical take-back programs, (as currently implemented in a number of east coast pilots), we firmly believe that this is not a long term, broadly applicable solution for capturing significant volumes of unwanted medications. PH:ARM's proposed pilot model is safe, practical, realistic and feasible. We are willing to participate in its implementation to assure necessary measures are taken to prevent diversion and to preserve public safety. We encourage you to grant any necessary waivers or other policy instruments necessary to allow the proposed pilot to begin. We will all gain valuable lessons from its implementation.

Please do not hesitate to contact me should you have any questions 360.486.2380 or dpierce@waspc.org.

Sincerely,

Donald G. Pierce
Executive Director

PH: ARMsupportletter04.24.06

APPENDIX B

What items can you return for safe disposal?

Return YES

- Medication: prescription and over-the-counter
- Medication samples
- Veterinary medications
- Vitamins
- Medicated ointments/lotions
- Inhalers
- Liquid medication in glass or leak-proof containers

Do not return NO

- Needles
- Thermometers
- IV bags
- Bloody or infectious waste
- Personal care products
- Controlled substances
- Hydrogen peroxide
- Empty containers
- Business waste

Take it BACK Network Medicines

Safely dispose of unwanted medications at your Group Health pharmacy

Protect your family

Fact: Medication mistakes at home are the most common cause of accidental poisoning.

Protect the environment

Fact: Flushing or throwing away medications puts our waterways and marine life at risk.

Look for the medication disposal unit at this location's pharmacy.

GroupHealth

Medication Disposal Unit

What to do:

1. Gather your unwanted medications and other approved items (see list). Leave items in the original containers. Mark out any personal information if you wish.
2. Bring items to this pharmacy. Deposit into this medication disposal unit.

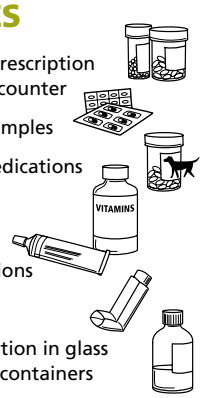
Take it BACK Network Medicines

GroupHealth

What items can you return for safe disposal?

Return YES

- Medication: prescription and over-the-counter
- Medication samples
- Veterinary medications
- Vitamins
- Medicated ointments/lotions
- Inhalers
- Liquid medication in glass or leak-proof containers



Do not return NO

- Needles
- Thermometers
- IV bags
- Bloody or infectious waste
- Personal care products
- Controlled substances
- Hydrogen peroxide
- Empty containers
- Business waste

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)

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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!

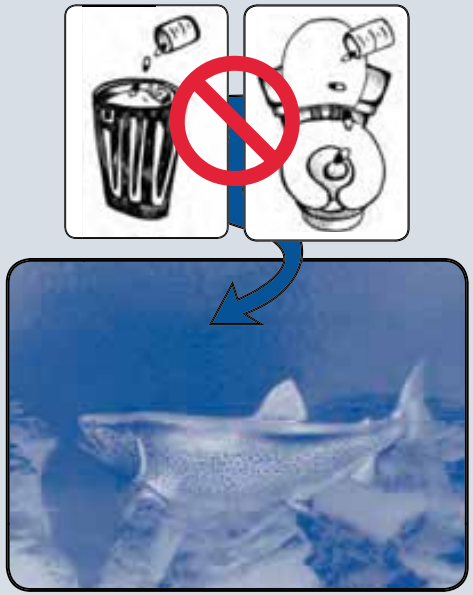
- ☑ Prescription medications
- ☑ Over-the-counter medications
- ☑ Medication samples
- ☑ Medications for pets
- ☑ Vitamins
- ☑ Medicated ointments/lotions
- ☑ Inhalers
- ☑ Liquid medication in glass or leak-proof containers

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.

Why Return Unwanted Medications?

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.

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

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

It's dangerous to use medicine prescribed for someone else or to give your unwanted prescriptions to someone else to use.

The Medication Take-Back Program is available at participating Bartell pharmacies.

To locate a participating pharmacy, ask your Bartell Pharmacist or visit bartelldrugs.com

For more information on the Medication Take-Back Program, please visit **www.medicinereturn.com** or call **1-800-732-9253**

This program is made possible by:

- Interagency Resource for Achieving Cooperation (IRAC)
- King Co. Dept. of Natural Resources & Parks, Waterworks Grant Program
- Local Hazardous Waste Management Program in King County
- Northwest Product Stewardship Council
- Pacific NW Pollution Prevention Resource Center
- Public Health – Seattle & King County
- 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)

BARTELL DRUGS
Washington's Own Drugstores®

Illustrations: Shannon Leahy
Printed on 100% post-consumer recycled paper

Safely Dispose of Unwanted Medications at Bartell Drugs

Protect your family

Protect our community

Protect our environment

This is a free service brought to you by...

Take it BACK Network

BARTELL DRUGS
Washington's Own Drugstores®

How to Return Your Unwanted Medications

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 Bartell's pharmacy. To locate a participating pharmacy ask your Bartell's pharmacist or visit bartelldrugs.com

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

Cleaning out your medicine cabinet will help avoid mistakes.

Take it BACK Network

What can you return for safe disposal?

Return: YES!

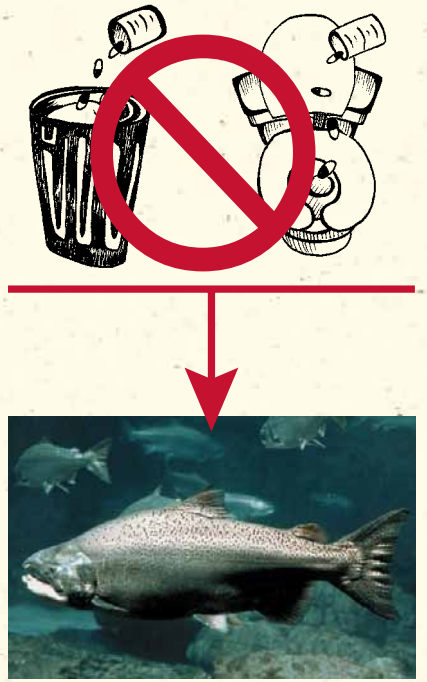
- ☑ Prescription medications
- ☑ Over-the-counter medications
- ☑ Medication samples
- ☑ Medications for pets
- ☑ Vitamins
- ☑ Medicated ointments/lotions
- ☑ Inhalers
- ☑ Liquid medication in glass or leak-proof containers

Return: NO!

- ⊘ Needles/Sharps containers
- ⊘ Thermometers
- ⊘ Narcotics (controlled substances)
- ⊘ IV bags
- ⊘ Bloody or infectious waste
- ⊘ Personal care products
- ⊘ Business waste
- ⊘ Empty containers
- ⊘ Hydrogen peroxide
- ⊘ Aerosol cans
- ⊘ Medical samples from Doctor's offices and clinics

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.

What to do: 3 steps to safety

1. Gather your unwanted medications and other approved items (see list). Leave items in the original containers. Mark out any personal information if you wish.
2. Bring items to a participating Group Health pharmacy.
3. Deposit items into the medication disposal unit.

Cleaning out your medicine cabinet will help avoid mistakes.

What items can you return for safe disposal?

Return YES

- Medication: prescription and over-the-counter
- Medication samples

- Veterinary medications

- Vitamins
- Medicated ointments/lotions

- Inhalers
- Liquid medication in glass or leak-proof containers

Do not return NO

- Needles

- Thermometers
- IV bags

- Bloody or infectious waste
- Personal care products
- Controlled substances (narcotics)

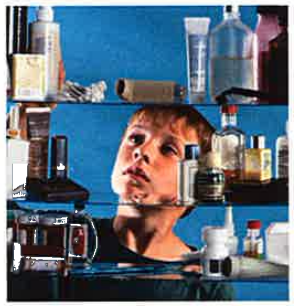
- Hydrogen peroxide
- Empty containers

- Business waste
- Aerosol cans

For questions, please contact your pharmacist.

Why dispose of unwanted medications this way: 3 great reasons

1. Your home is safer.



Protect children and the elderly from the most common cause of accidental poisoning.*

Storing unwanted medications puts everyone in your home at risk.

2. When you return your medications for disposal, you are protecting local waters and marine life.

3. Medications will be disposed of in the most environmentally safe manner. No medications will be re-sold or re-used.

*Unintentional Injury Data, CDC, 2004

Medications and the environment: what you should know

Are medications present in the environment?

Yes. They have been found in waterways and wastewater throughout the United States. Trace amounts of medications have also been found in fish.

How do medications get into the waterways and water supply?

Through direct disposal, by landfill garbage or by flushing down sinks or toilets, and through human and animal excretion of drugs.

Do wastewater treatment plants remove all medications?

No. These plants remove biodegradable pollutants, but they cannot remove all synthetic pollutants or medications.

How is returned medication disposed of?

The waste is properly disposed of at regulated facilities in the U.S.

For the locations of participating pharmacies, call Group Health's pharmacy customer service, weekdays between 8:30 a.m. to 5 p.m., at 1-800-245-7979 (toll-free). You can also view participating sites on our Web site, www.ghc.org.

For more information on household recycling and medication return, call the Washington State Department of Ecology's Recycle Hotline at 1-800-RECYCLE (1-800-732-9253).

This program is made possible by:

Group Health Cooperative
Group Health Community Foundation
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
Pacific NW Pollution Prevention Resource Center
Puget Sound Action Team
Washington State Department of Social and Health Services–Aging and Disability Services Administration
Washington State Department of Ecology
Washington Board of Pharmacy (Project Advisor)

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GroupHealth

911701 (7-07)

Take it BACK Network Medicines

Safely dispose of unwanted medications at your Group Health pharmacy

Protect your family

Fact: Medication mistakes at home are the most common cause of accidental poisoning.

Protect the environment

Fact: Flushing or throwing away medications puts our waterways and marine life at risk.

GroupHealth

Pharmaceuticals from Households: A Return Mechanism (PH:ARM)

A Washington State Pilot Program to Return Pharmaceuticals for Proper Disposal

Prevent Child Poisoning

More than 6,000 children under the age of six were poisoned by medications in their homes.

Washington Poison Center (WPC) Data - FY 2004-05 as reported on WPC's Web page.

Reduce the Potential for Substance Abuse

The number of Americans who abuse controlled prescription drugs has nearly doubled from 7.8 to 15.1 million from 1992 to 2003. Abuse among teens has more than tripled during that time.

National Center on Addiction and Substance Abuse at Columbia University, July 7, 2005

Protect Aquatic Organisms

Two tadpoles after 57 days of development in the lab. The one on the right, which has yet to sprout limbs, was exposed to fluoxetine, the active ingredient in Prozac, at 50 parts per billion.

Credit: Marsha Black, PhD, University of Georgia in Athens

Reduce Pollution from Improper Disposal

In King County

- 36.5 % disposed of pharmaceuticals to the trash
- 29.4% disposed of pharmaceuticals to the sink or toilet

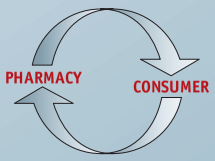
June 2005, Behavior Survey, King County

Two out of three (66%) residents report they will not use all of the medicines in their household in the next six months.

Soundstats Survey, January 2006

PH:ARM Mission

To create a simple, low-cost and secure take-back system to collect unwanted medications from household sources. The system will operate year round at local pharmacies and nursing homes and will be funded by pharmaceutical manufacturers. The local system is designed to be expanded state and nationwide. Our goal is to prevent pharmaceutical pollution and improve public safety.

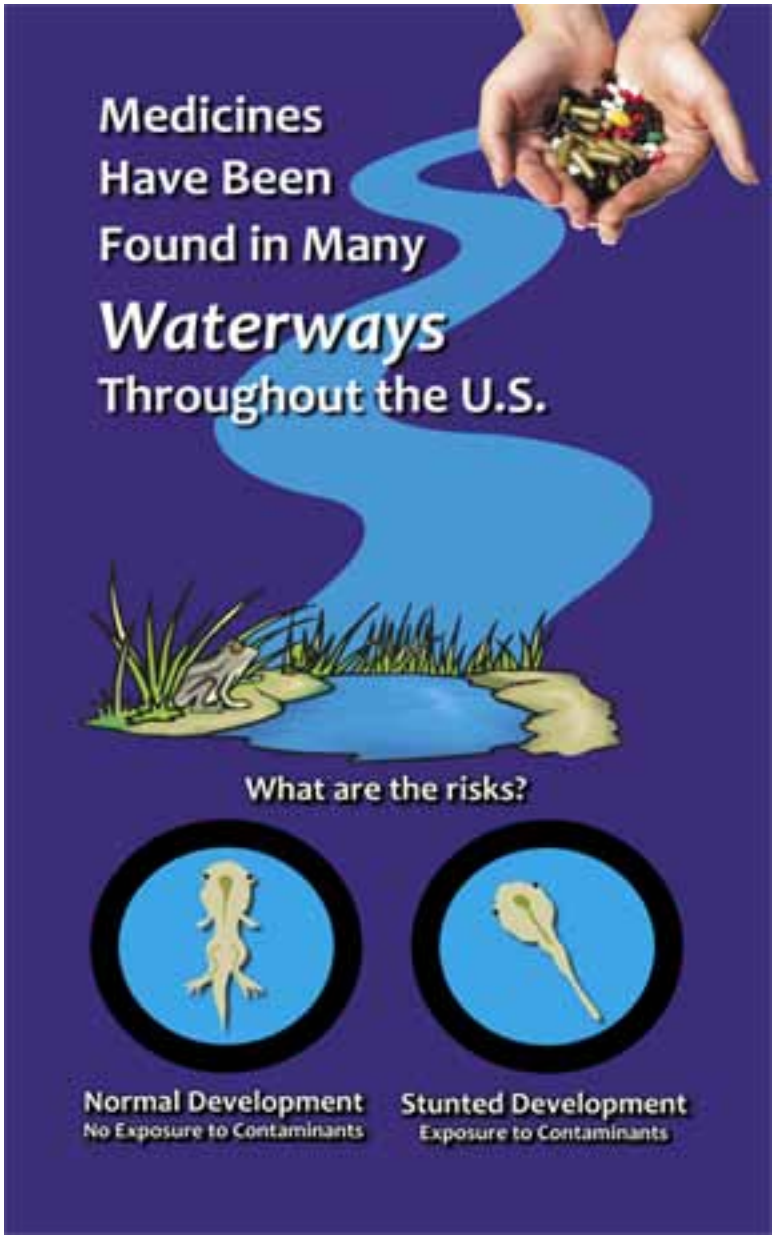


A statewide program could collect **83,000 lbs per year for proper disposal**

(based on data from a similar British Columbia program)

Partners: Interagency Resource for Achieving Cooperation (IRAC), Local Hazardous Waste Management Program in King County, Snohomish County Solid Waste Management Division, Seattle-King County Public Health, Northwest Product Stewardship Council, Washington Citizens for Resource Conservation, Pollution Prevention Resource Center, Washington State Department of Ecology, Group Health Cooperative, Bartell Drug Company and advised by the Washington State Board of Pharmacy.


Return Unwanted Medications
to participating pharmacies
Protect your home,
your community,
and the environment.
DON'T TRASH!
DON'T FLUSH!


Medicines
Have Been
Found in Many
Waterways
Throughout the U.S.
What are the risks?
Normal Development
No Exposure to Contaminants
Stunted Development
Exposure to Contaminants


Manufacturers
should provide
safe, free,
and easy
return for
their
products...
MEDICINE
RETURN
...and design more
environmentally
friendly products

APPENDIX F

HOW TO DISPOSE OF YOUR CONTROLLED SUBSTANCES

This take back program cannot accept controlled substances. Controlled substances are drugs with potential for addiction or abuse. They are regulated by the Drug Enforcement Administration (DEA), and current DEA regulations do not allow for the collection of controlled substances from consumers. Many government agencies and non-governmental organizations are working to change these regulations.

Until that time, we recommend you follow the recommendations of the White House's Office of National Drug Control Policy.

- Take your controlled substances out of their container
- Mix them with used coffee grounds or kitty litter or some other undesirable substance.
- Put them in an impermeable, container, (.e.g., empty cans or sealable bags,) This will hopefully ensure that the drugs are not stolen or accidentally taken by children or pets
- Throw into the trash.

More detail is available at:
http://www.whitehousedrugpolicy.gov/drugfact/factsht/proper_disposal.html

Rob McKenna
ATTORNEY GENERAL OF WASHINGTON
1125 Washington Street SE • PO Box 40100 • Olympia WA 98504-0100

November 29, 2007

Mark Caverly
Chief, Office of Diversion Control
Liaison and Policy Section
600 Army Navy Drive
Arlington, VA 22202

RE: PH:ARM DEA WAIVER REQUEST

Dear Mr. Caverly:

By letter dated March 28, 2007, I notified you of my support for a DEA waiver to allow the coalition of government and private partners (PH:ARM – Pharmaceuticals from Households: A Return Mechanism) to collect unwanted controlled substances for destruction. A copy of my March 28, 2007 letter is enclosed.

I am writing again to express my strong support for the granting of a waiver under 21 U.S.C. § 822(d), which authorizes the Attorney General to waive the requirement for registration "if he finds it consistent with the public health and safety." 21 U.S.C. § 802(39)(A)(iii) also authorizes the Attorney General to exclude from the definition of "regulated transaction" any category of transaction as unnecessary for enforcement of 21 U.S.C. Subchapters I and II.

Presently, patients and their family members are disposing of prescriptions, including controlled substances, by either flushing them down drains, which contributes to water contamination, or by tossing these substances into their trash bins. These household trash bins are not as secure a method of disposal as the containers proposed for use by the PH:ARM program. In many instances, due to concerns about contamination and the risk of unsecured disposal, patients are not disposing of unwanted prescriptions. Instead, these patients are "stockpiling" the unwanted prescriptions, unsure how to safety and securely dispose of the controlled substances. This accumulation of unwanted prescriptions, particularly controlled substances, creates a public safety risk for children, including both poisonings and "teen pharming," and drug abuse or illegal sales by others with access to these stores of unwanted controlled substances. For these reasons, a waiver for the PH:ARM program under 21 U.S.C. § 822(d) is certainly "consistent with the public health and safety."

The PH:ARM program could serve as a demonstration project. Ideally, the demonstration project should authorize one hundred sites for one year to evaluate its success in providing a secure disposal of pharmaceuticals, including controlled substances. For the demonstration project to serve as a practical, affordable and workable solution for the secure collection of returned medications, there should be no requirement to inventory each item or the presence of law enforcement at the time of collection of the secure bins.

Presently, the PH:ARM project has negotiated an arrangement for incineration of collected medications at the incinerator in Spokane, Washington. The PH:ARM project would like authority to negotiate with out-

of-state hazardous waste incineration companies. Under 21 U.S.C. § 802(3), a common or contract carrier and their employees, are not "agents" when acting in the usual and lawful course of their business. 21 U.S.C. § 822(c)(2) exempts these common or contract carriers and their employees from the requirement to register and allows them to possess controlled substances.[1]

We invite careful monitoring of the demonstration project to evaluate its value in enhancing public safety by the secure collection of unwanted medications, including controlled substances. It would be ideal if DEA representatives would come to Washington to evaluate the program and negotiate with members of the PH:ARM coalition the final design elements for the collection units, the handling and transportation of the unwanted pharmaceuticals. Once the final design elements are negotiated, the local Seattle DEA office and the Washington Board of Pharmacy could provide oversight under your delegation, and, if within your delegation, authorize any expansion of the program if the one year demonstration project is found to enhance public safety.

I would be delighted to meet with you either here or when I am next in Washington D.C. to discuss this worthwhile endeavor to better control the availability, abuse and illegal distribution of controlled substances. Your agency has wide latitude in regulating the distribution chain from the manufacture to the distribution to the ultimate user of the controlled substances. The PH:ARM project is designed to address an area which has received little regulatory attention; the ultimate users' disposal of unwanted controlled substances. While criminal laws are designed to address the illegal distribution and use of these controlled substances, those laws are only triggered after the distribution or attempted distribution has occurred. The PH:ARM project presents an earlier opportunity to prevent the illegal distribution, as well as the tragedy of accidental poisonings.

I look forward to the opportunity to discuss the PH:ARM project with you and your representatives.

Sincerely,

ROB MCKENNA
Washington State Attorney General

cc: Mary Selecky, Secretary, Washington State Department of Health
Rebecca Hille, Chair, Washington Board of Pharmacy
Don Pierce, Executive Director, Washington Association of Sheriffs and Police Chiefs
Al Cheeseman, Diversion Program Manager, Seattle District DEA Office
David Stitzhal, Coordinator, NW Product Stewardship Council

[1] If the restriction in 21 U.S.C. § 822(39)(A)(ii), which indicates that the "regulated transaction" exemption does not apply if the common or contract carrier or their employees will be distributing the controlled substance to a third person, is interpreted to apply to the delivery from the common carrier to the company performing the hazardous waste incineration, then questions arise about the current practice of patient's disposing of controlled substances in their household garbage. Most, if not all, of Washington's household and commercial garbage collection is transported to waste incinerators operated by different companies than the common or contract carriers which operate as garbage collectors. This is likely true in many jurisdictions, so this interpretation would lead to absurd results.