

Protecting our Health and the Environment:

The Need for Sustainably Financed Drug Take-Back Programs



**Prepared by the Product Stewardship Institute
for the University of Wisconsin Extension**

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This report was developed by the Product Stewardship Institute, Inc., under contract with the University of Wisconsin Extension. This document was developed in consultation with a wide group of stakeholders including state and local government officials; environmental groups; and representatives from the pharmaceutical manufacturing, pharmacy and insurance industries.

The Product Stewardship Institute

The Product Stewardship Institute (PSI) works to ensure that all those involved in the lifecycle of a product share responsibility for reducing its health and environmental impacts. PSI's members include 47 US states; over 200 local governments; and more than 50 businesses, environmental groups, and organizations. The Product Stewardship Institute is an equal opportunity employer and provider.

For more information, visit: www.productstewardship.us.

Briefing Document

Table of Contents

The Problem in Brief	3
Why Are Drug Take-Back Programs Needed?.....	4
Leftover Medications: No Small Problem	4
Unused Medications in the Home Are a Public Health Risk	5
Preventing Prescription Drug Abuse	5
Preventing Poisonings.....	5
Improperly Discarded Medications Contaminate the Environment.....	6
Active Pharmaceutical Ingredients in our Waters	6
Pathways of Contamination.....	6
Environmental Impacts of Contamination.....	7
Why trash disposal is not the answer	7
Why Are Extended Producer Responsibility Programs Needed?	8
All Residents Should Have Access to Safe Disposal	8
Current Take-Back Programs are Limited by a Lack of Funding	8
Product Stewardship Programs Offer a Better Model for Sustainable Support.....	9
Product Stewardship Programs Already Working in Other Jurisdictions	10
Key Elements of Pharmaceutical Collection and Disposal Programs:.....	11
A Vision for the Great Lakes Region.....	11
Appendix 1: Existing Pharmaceutical Take-Back Programs in the Great Lakes Region	12
Wisconsin	12
Minnesota.....	12
Michigan.....	12
Illinois	12
Indiana	13
Ohio.....	13
Pennsylvania	13
New York.....	13
Regional Programs	14
Appendix 2: Existing Product Stewardship Programs for Pharmaceuticals.....	15
Canada	15
Europe.....	15
Appendix 3: The Controlled Substances Act.....	16

The Problem in Brief

The proper use of medicines helps to cure, treat, and prevent diseases, and prolong life. However, failure to properly store and dispose of unused medicines can contribute to the illegal possession, trafficking, and abuse of potentially addictive medicines. It can also lead to poisonings due to the unintentional consumption of medicines by children, vulnerable adults, and animals. Low levels of pharmaceuticals have been found in a high percentage of tested surface water, ground water, and drinking water supplies. Wastewater and drinking water treatment facilities do not have the technology to completely remove these chemicals and the improper disposal of unwanted medicines also unnecessarily contributes to the presence of pharmaceuticals in water. It is extremely difficult to determine the environmental and human health effects of exposure to trace amounts of many different pharmaceuticals and their biologically active metabolites. Some studies have found significant effects on wildlife linked to exposure to these chemicals.

Citizens do not currently have sufficient access to consistent, secure, and convenient disposal options for unwanted medicines, despite growing recognition of the importance of safe drug disposal. A widespread, convenient collection and disposal infrastructure is needed. This requires adequate and sustainable funding, rigorous oversight, and should not be the sole responsibility of government. More consistent public education is needed on the importance of prompt and safe disposal of unwanted medicines.

Decreasing the amount of pharmaceuticals that become waste in the first place presents an opportunity to reduce the risks to the environment and public health, and significantly reduce costs in our healthcare system. Improving prescribing and dispensing methodologies are two ways to limit the amount of pharmaceutical waste created. In addition, applying the principles of green chemistry to drug development and manufacturing will reduce environmental impacts throughout the lifecycle of pharmaceuticals.

Why Are Drug Take-Back Programs Needed?

When unused, unwanted, or expired medications are improperly stored in the home, they can inadvertently contribute to three problems. Pharmaceutical drugs are increasingly being diverted to illegal possession, trafficking, and abuse. The number of poisonings due to the unintentional consumption of medicines by children, vulnerable adults, and animals is also climbing. Medications are also polluting our waterways when they are flushed down the drain or thrown in the trash, as most wastewater treatment facilities do not have the technology to completely remove these chemicals.ⁱ While other sources also contribute to pharmaceutical compounds in surface, ground, and drinking water, improper disposal unnecessarily contributes to the problem. Establishing safe, secure collection programs is an important first step in addressing all of these issues.

Leftover Medications: No Small Problem

The exact quantity of unused and expired pharmaceuticals in American homes is currently unknown; however, evidence from a broad range of sources indicates that between 10 to 43% of the almost 4 billion prescriptions dispensed in the U.S. every year go unused and become waste.ⁱⁱ Over just three one-day collection events, the Drug Enforcement Administration (DEA) collected more than 995,185 pounds of medication during its National Prescription Drug Take Back Days in 2010 and 2011.ⁱⁱⁱ The amount of prescription drug waste will likely increase as the number of prescriptions written in the United States continues to increase with the aging population.



Preventing Pharmaceutical Waste

Reducing the amount of medications that become waste should be a high priority. Implemented correctly, pharmaceutical waste reduction can simultaneously improve patient care and reduce costs in the healthcare system;

however, it will take time and extensive coordination across a range of industries to implement scalable policies that reduce the quantity of dispensed drugs that go unused. It is unlikely that pharmaceutical waste will ever be completely eliminated due to the myriad reasons for medicinal waste, such as early recovery from an illness, or intolerance of a medication's side effects. Due to the inevitability of some amount of medical waste, there is an immediate need to create a system for people to safely dispose of the material that is left over every year.



Unused Medications in the Home Are a Public Health Risk

Preventing Prescription Drug Abuse

Deaths due to unintentional drug overdoses have surpassed car accidents as the leading cause of accidental death in 2009.^{iv} Nationwide, unintentional prescription opioid overdoses now kill more Americans than cocaine and heroin combined.^v Over the past several years the incidences of death due to prescription drugs has increased dramatically. In Ohio, for example, the death rate due to unintentional drug poisoning increased more than 350 percent from 1999 to 2008, and is now the leading cause of injury death in the state.^{vi} The rising incidence of prescription drug addiction also contributes to an increase in drug-related crimes including violent home break-ins and even murders of elderly citizens to gain access to their medicine cabinets.^{vii} Unlike illicit drugs, most users of prescription opioid drugs reported obtaining them from a friend or relative.^{viii} Teen drug users in particular cited the ease of access to prescription drugs as a reason for preferred use.^{ix} As a first step, parents can reduce easy access to these drugs by promptly disposing of all unused drugs.



Preventing Poisonings

Keeping unused and expired medications in the home also presents acute risks to children, seniors, and pets. Every 15 minutes, a child under age 4 will overdose on drugs found at home.^x Incidents of child poisoning in particular have been on the rise, with accidental drug poisoning among children up 22 percent from 2001 to 2008, according to a report published in *The Journal of Pediatrics* in September 2011.^{xi} This study found that among the nearly 454,000 children age 5 years or younger, only 5 percent of these poisonings were attributable to dosing errors, whereas approximately 95 percent of the cases involved "self-discovery" and "self-ingestion" of prescription medications (55%) or over-the-counter drugs (40%). According to the study, 43 percent of the children rushed to the hospital emergency room after an accidental ingestion of prescription drugs incident were sent to intensive care.

How Will Drug Take Back Programs Help?

Ready access to pharmaceuticals is a significant contributor to both prescription drug abuse and accidental poisonings. Providing a safe, secure means for residents to clear their medicine cabinets of unused and expired medications is a critical step to reducing that supply. Creating a take back program is not enough. It must include an education program that not only lets the public know how to safely dispose of medications but also explains the important reasons to promptly and safely dispose of their unused and expired medications.

Improperly Discarded Medications Contaminate the Environment

Active Pharmaceutical Ingredients in our Waters

Pharmaceuticals are pervasive in our environment and some researchers have determined that “the amount of pharmaceuticals and personal care products (PPCPs) released into the environment each year is tantamount to the amount of pesticides used each year.”^{xii} A study conducted by The United States Geological Survey found that 80 percent of streams tested were contaminated with at least one pharmaceutical, personal care product or other organic wastewater contaminant.^{xiii} Studies specific to the Great Lakes have also found pharmaceuticals in source drinking water; studies included those by the Illinois EPA in 2008^{xiv}; Lake County, Illinois in 2008^{xv}; Erie, Pennsylvania in 2008^{xvi}; and a Michigan study which found pharmaceuticals in the source waters for the municipal water supplies for Ann Arbor (Huron River), Grand Rapids (Lake Michigan), and Monroe (Lake Erie).^{xvii}



While levels of contamination are generally low, the concentration varies significantly — ranging over roughly 9 orders of magnitude.^{xviii} The impacts of this contamination (explained in greater detail below) remain largely unknown; however, application of the precautionary principle requires examining ways to minimize this risk to public health and the environment.

Pathways of Contamination



Pharmaceutical compounds enter the environment a number of different sources, including: runoff from agricultural fields fertilized with biosolids,^{xix} or contaminated from livestock wastes containing hormones and antibiotics, and discharges from pharmaceutical manufacturing facilities. Human excrement and washed away sweat can also contain pharmaceutical compounds that go to wastewater plants.^{xx} In addition, rainwater trickling through landfills becomes contaminated leachate, which is commonly sent to wastewater treatment plants. In general, wastewater treatment facilities are not able to remove all of this contamination; as a result these facilities become another potential source of pharmaceuticals in the environment.^{xxi} While there are many sources of pharmaceuticals in our environment, drugs that are improperly disposed of down drains (“flushed”) or in the trash are one preventable source of such pollution.^{xxii}

No strong scientific evidence currently exists to determine the relative contribution of different pathways to the level of pharmaceuticals in our environment. According to a study published by the U.S. EPA in the fall of 2010:

“The question as to what fraction of collective or individual APIs [active pharmaceutical ingredients] residues in the aquatic environment emanates from direct disposal versus excretion and bathing is currently not answerable.”^{xxiii}

This question has not been answered in any peer-review study to date because it is currently impossible to easily distinguish pharmaceutical compounds that were improperly disposed of from those that originated from excretion.^{xxiv} Historical practice (including recommendations from many public safety agencies) has been to flush such left-over drugs down the drain. This practice is now strongly discouraged by many state and local agencies, although the U.S. Food and Drug Administration suggests flushing a small number of medicines.^{xxv} A safe, convenient alternative is needed.

Environmental Impacts of Contamination

Pharmaceutical compounds are specifically designed to affect biological organisms. Their presence in the environment should therefore be minimized. Despite the low levels of contamination, pharmaceutical pollution still presents a significant risk to aquatic ecosystems due to the continuous nature of exposure.^{xxvi} Studies have already found pharmaceuticals present in some ecosystems at levels likely to harm aquatic



Why trash disposal is not the answer

Throwing medicines in the trash is not recommended because rain water passing through the trash in landfills picks up some of the pharmaceutical compounds present. This leachate is pumped out of the landfill and sent to wastewater treatment plants. These treatment plants are not able to completely remove the pharmaceutical compounds and they are released into streams, rivers, lakes, and oceans. Additionally, the risk of diversion still exists if the drugs are not rendered inedible prior to throwing them into the trash.

organisms at the population level.^{xxvii} Certain pharmaceutical classes are particularly toxic to aquatic organisms, including analgesics/anti-inflammatories, antibiotics, antiepileptics, and steroid hormones.^{xxviii} Fish are particularly susceptible to the endocrine disrupting chemicals^{xxix} and studies have found widespread sexual disruption in fish species across the country.^{xxx} The potential impacts of antibiotic pollution, which are contributing to the development of antibiotic resistant bacteria, are also of serious concern to public health.^{xxxi} The presence of antibiotics in the natural environment could also induce significant ecological impacts through disruption of the biosphere.^{xxxii} The potential long-term impacts of this pollution on ecosystems remain almost entirely unstudied.

How Will Drug Take Back Programs Help?



While there are many sources of pharmaceuticals in our environment, drugs that are improperly disposed of down drains or in the trash are one easily preventable source of this pollution.^{xxxiii} Since current wastewater treatment and landfill technologies cannot completely prevent these pharmaceutical compounds from eventually reaching our waterways, it is important to provide the public with an environmentally sound means to dispose of the 10 to 43% of the 3.7 billion prescriptions that become waste every year.^{xxxiv}

Why Are Extended Producer Responsibility Programs Needed?

All Residents Should Have Access to Safe Disposal

Pharmaceutical take-back programs are a common sense approach to simultaneously reduce the risks of prescription drug abuse, accidental poisoning, and pharmaceutical pollution. There is broad consensus to support expanding pharmaceutical take-back programs among major government and public health agencies, including the World Health Organization, The Drug Enforcement Agency (DEA), Food and Drug Administration (FDA), the White House Office of National Drug Control Policy, the Environmental Protection Agency (EPA), and the National Association of Drug Diversion Investigators (NADDI).

A number of successful take-back programs have been created over the last decade. These programs, mostly local or regional, have significantly raised public awareness of the need for proper disposal. (More information on these programs in the Great Lakes Region is provided in Appendix 1.) The exact nature of these take-back programs varies significantly by jurisdiction, ranging from one day collection events hosted sporadically by local governments, to permanent drop-off collection boxes hosted by pharmacies and law enforcement agencies. These programs offer varying levels of convenience as some are available just a few hours a year, or accept only a subset of the medications residents have in their homes, while some progressive communities have been able to provide a number of reasonably convenient on-going collection opportunities. Despite significant progress, the majority of Americans currently do not have sufficient access to consistent, secure, and convenient disposal options for unwanted medicines. There is a critical need to expand opportunities for residents to safely dispose of unused medications in order to protect public health and the environment.

Current Take-Back Programs are Limited by a Lack of Funding

While there have been increasing numbers of pharmaceutical collection programs, these programs have been constrained by a lack of funding and are not able to adequately meet the need for such ongoing, convenient, safe collection programs in the Great Lakes region. The burden for funding these programs also falls almost entirely on government (including law enforcement) and taxpayers. These programs primarily rely on government grants, private donations, and in-kind contributions. Many take-back programs have adequate funding to offer only sporadic collection events or have established a very limited number of collection sites, neither of which adequately addresses the scale of the problem.

One contributing factor to the costs of existing drug take-back programs are requirements under the Controlled Substances Act, passed by Congress in 1972, which restricts the handling of certain "controlled substances." Controlled substances are drugs which have been deemed particularly addictive or otherwise dangerous. Under the original Act, law enforcement was the only entity authorized to take possession of a controlled substance from the patient to whom it was prescribed. As of 2010, the Act was changed to allow a wider range of entities to take possession of such drugs for

the purpose of safe disposal. As of January 2012, the Drug Enforcement Administration, which administers the Controlled Substances Act, is developing regulations that will specify which entities, in addition to law enforcement, will be allowed to accept this subset of prescription drugs for disposal. For more information, please see Appendix 3.

These programs rarely offer the most convenient opportunities for the public to dispose of unused medications. As a result, most people end up flushing their medications, throwing them in the trash, or storing them in cabinets.^{xxxv} By shifting the costs of management from taxpayer-funded government programs to manufacturers, a product stewardship solution creates the funding base needed to expand and sustain pharmaceutical collection programs without depleting scarce government resources.

Product Stewardship Programs Offer a Better Model for Sustainable Support

To ensure continued service and outreach, programs should be based on a sustainable and adequate funding system. A fair and effective product stewardship approach would distribute the costs of recovery among all who benefit from the manufacture, sale, and use of these products. Companies manufacturing pharmaceuticals should take the lead by supporting existing programs and developing and implementing new or expanded collection and disposal programs.

Product stewardship means that manufacturers, retailers, governments, and consumers share responsibility for reducing a product's health and environmental impacts. Those stakeholders with the greatest ability to reduce those impacts shoulder the greatest responsibility. Product stewardship programs can take many forms, but all systems assign responsibilities in essentially the same manner. Manufacturers are responsible for collecting, recycling, or appropriately disposing of unwanted consumer products.

In the case of pharmaceuticals, other stakeholders, including state and local governments, pharmacies, prescribers and non-profit organizations would partner with these manufacturers to educate the public, and provide collection services and other activities consistent with their capabilities. Consumers play a critical role by bringing products they no longer need or want to appropriate collection points or by using mail-back programs. Governments oversee product stewardship systems to ensure fairness, effectiveness, and consumer protection. Waste management companies must ensure materials are handled in a manner that does not harm workers or the environment.

Product stewardship does not simply shift costs from the public sector to the private sector. It reduces overall system costs by requiring all stakeholders to work together and assume clearly defined roles. Under a product stewardship system, manufacturer-run programs can be more efficient than government programs. A recent analysis by CalRecycle staff found, for example, that California's government-run paint collection programs cost about 20 percent more per gallon than British Columbia's manufacturer-run program. In addition to higher costs, California collected less than half as much paint. To achieve British Columbia's collection rate of 77 percent, California would need to spend an additional \$28 million (assuming it continued to rely on a government-run system).^{xxxvi}

On July 24, 2012, Alameda County, California, passed the nation's first local ordinance to require pharmaceutical companies whose products are sold in the County to pay for collection programs for unwanted prescription drugs. Responding to the lack of leadership at the federal and state level on the issue, Alameda County has demonstrated its commitment to protecting public health and the environment by supporting a producer financed solution to safely disposing of unwanted pharmaceuticals.

Product Stewardship Programs Already Working in Other Jurisdictions

Pharmaceutical manufacturers are already providing pharmaceutical take-back programs to their customers in other jurisdictions. These product stewardship programs for pharmaceuticals have been operating successfully for several years without increasing the costs of medicine. More information on these programs is provided in Appendix 2. These same pharmaceutical companies could choose to provide a similar service for their customers in the United States to protect public health and the environment.

Key Elements of Pharmaceutical Collection and Disposal Programs:

A Vision for the Great Lakes Region

Significant progress has been made to establish safe and secure medicine collection and disposal programs in the Great Lakes Region. These programs include collections through retail pharmacies, clinics, law enforcement agencies, and municipal facilities, as well as through mail-back programs. Due primarily to funding constraints, programs are unable to fully meet the needs of residents throughout the region. The following key elements of a model program were developed by local and state agencies, organizations, and other stakeholders, with the goal to expand effective pharmaceutical collection and disposal programs throughout the region.

- **Programs should protect public health and the environment** by maximizing prompt collection and proper disposal of unused pharmaceuticals, including controlled substances. To this end, programs should be:
 - **On-going.** Residents should have year-round access to safe disposal opportunities for pharmaceutical drugs, reducing the need for home storage.
 - **Convenient throughout the Great Lakes region.** Programs should be available to all residents throughout the Great Lakes region. Eventually, there should be ongoing collection sites in every county, and every town or city of a population of 5,000 or greater. Mail-in services can help to fill gaps.
 - **Set up to collect all types of pharmaceutical drugs.** To the extent feasible under state and federal regulations, programs should accept all types of pharmaceuticals from households.
 - **Secure.** All programs must be operated in a secure manner, and in compliance with all state and federal regulations. Security is critical to minimizing the risk of illegal diversion.
 - **Free at the point of delivery for disposal.** There should be no charge to the public when they deliver unwanted pharmaceutical drugs via a collection location or mail-in service.
 - **Widely promoted.** A high level of public awareness must be created about the importance of safely storing and promptly disposing unused medications through the program. Public education should be a shared responsibility of all key stakeholders including those who prescribe, dispense, and manufacture pharmaceuticals.
- **Programs should minimize the impact on the environment** by ensuring that collected medicines are destroyed in compliance with federal, state, and local regulations. When possible, all material collected should be destroyed through high temperature incineration, or with the best available technology, to minimize the risk of environmental contamination. To the extent possible, transportation of wastes should be minimized.
- **Programs should be sustainably and adequately funded** to ensure continued service and widespread public outreach. Those who benefit from the manufacture, sale, and use of pharmaceutical drugs have the greatest responsibility for ensuring program success. Pharmaceutical companies should fund the expansion of existing programs and/or the development of new ones. Other stakeholders, including state and local governments, pharmacies, and prescribers, should partner with pharmaceutical companies to educate the public, provide collection services, and/or implement other activities consistent with their capabilities and mission.
- **Programs should also identify and address the underlying drivers that contribute to pharmaceutical waste.** Reducing the quantity of drugs that become waste not only reduces environmental and public health risks, it also has the potential to improve medical care and reduce medical costs for individuals and taxpayers through Medicare and Medicaid programs. It may also reduce costs for manufacturers, distributors, and retail establishments.

Appendix 1: Existing Pharmaceutical Take-Back Programs in the Great Lakes Region

Wisconsin

There are over 80 permanent drug drop-boxes in police stations throughout the state of Wisconsin. Many counties also host one-day collection events, typically funded through grants from the Department of Agriculture, Trade and Consumer Protection. In 2010, these events collected over 50,000 pounds of medicines. La Crosse County also hosts a collection program for non-controlled substances at the county's Household Hazardous Materials (HHM) facility. In August 2011, the University of Wisconsin introduced "Get the Meds Out," a free pharmaceutical waste mail-back program available in 36 counties, funded by a grant from the US EPA's Great Lakes Restoration Initiative. The program had approximately 350 locations and collected over 2,900 pounds of pharmaceuticals before it was suspended in December 2011.

Minnesota

The Western Lake Superior Sanitation Department in Minnesota has hosted a series of medication collection events called "[Medicine Cabinet Clean-Out Days](#)" since October 2008. The first event collected approximately 250 pounds of medication. [Hennepin County](#) also offers one-day collection events. Chisago County has hosted an ongoing program for several years and Ramsey, Cass, and Dakota Counties have recently launched new collection programs. About 50 law enforcement agencies in Minnesota participated in the Drug Enforcement Agency's national Take-Back Day in April 2011.

Michigan

[The Yellow Jugs Old Drugs program](#), operated by [Great Lakes Clean Water Organization](#), is a pharmacy-based pharmaceutical collection program available throughout Michigan. In 2012 the program will be available in Wisconsin and Illinois. Since its inception in May 2009, this program has collected over 30,000 pounds of unwanted medications and now includes 216 participating pharmacies. This program is primarily funded by the participating pharmacies, with additional grant funding to partially defray cost. In addition, pharmacies in Washtenaw County participate in the Pharmaceutical Take-Back Program. A third program, the [West Michigan Take Back Meds](#), has successfully collected over 11,000 pounds of pharmaceuticals. Michigan also offers permanent drug collections in some police departments. [Livingston County's Big Red Barrels](#) prescription drug collection program collects all types of medication, including controlled substances, in police stations throughout the county

Illinois

[The Prescription Pill Drug Disposal Program](#) (P2D2) has established many permanent drug drop boxes throughout the United States. This program, available in 17 States including 54 counties in Illinois, has collected over 150,000 pounds of pharmaceuticals to date. The Illinois EPA also runs a statewide collection program. The full list of collection locations is available on the IL EPA [website](#). The [Solid Waste Agency of Northern Cook County](#) (SWANCC) has 21 collection locations within Cook County and has collected over 11,000 pounds of medications. The [Solid Waste Agency of Lake County](#) (SWALCO) owns and operates a permanent household hazardous waste facility and its program includes collection of non-controlled pharmaceuticals at the 30 free collection events it holds each year. SWALCO typically collects about 6,000 pounds of pharmaceuticals each year and those drugs are then managed by the IEPA's hazardous waste contractor. In addition to SWALCO's program, the Deerfield, Fox Lake, Highland Park, Lake Bluff and Mundelein police departments collect both controlled and non-controlled pharmaceuticals at drop-off sites located at the police

departments on a year round basis. The Fox Metro Water Reclamation District also accepts non-controlled medications from their residents. DuPage County also has the [Rx Drop Box program](#), with 14 locations that have collected over 5 tons since its launch in 2009. In addition to DuPage County's Program, the Regional Hazardous Waste Facility, operating in Naperville, also accepts unwanted medicines. The IL EPA provides a list of medication disposal locations at: <http://www.epa.state.il.us/medication-disposal/locations/index.html>.

Indiana

The state of Indiana has over 85 permanent collection programs, which provide a mix of controlled and non-controlled substance collections. For example Monroe, Allen, Howard, Warren, Kosciusko, Randolph, and Porter Counties all host prescription drug collection and disposal programs. The Indiana Department of Environmental Management provides a list of medicine collection programs at: <http://www.in.gov/recycle/6141.htm>.

Ohio

Lake County started a permanent collection at multiple police stations around the county in 2011 and collected 1,482 pounds during the first seven months of operation. Ohio EPA has been involved with providing guidance to communities and organizations around the state since 2009. The City of Olmsted Falls, in partnership with Southwest General Health Center, developed a Drug Disposal Program for residents, which accepts non-controlled substances. A non-profit organization, Help Out Ohio, in collaboration with local police departments and pharmacies also regularly hosts collection events. During the April 30, 2011 DEA-sponsored Take Back Day, Ohioans turned in 21,098 pounds of pharmaceuticals.

Pennsylvania

Under a pilot project started in January 2011, there are 25 pharmacies in the state that have been approved by the Pennsylvania DEP to collect unwanted, non-controlled medicines. Pharmaceutical collections are also included in the state's Household Hazardous Waste Collection category and therefore County Recycling Coordinators can choose to dedicate a portion of their funds to collecting pharmaceuticals at their discretion. The PA DEP will reimburse 50% of the costs of these collections as funding allows. Over 400 sites in PA have partnered with the DEA on their National Take Back Days. Indiana County hosts "Drug Take-Back" days, which are co-sponsored by Indiana County District Attorney's Office, Indiana County Drug Task Force, local state legislators, and Pennsylvania Department of Health.

New York

In 2008, the New York State Department of Environmental Conservation (DEC) launched a "[Don't Flush Your Drugs](#)" campaign. This campaign discourages flushing of household pharmaceuticals by raising public awareness, providing information on how to properly dispose of the waste pharmaceuticals with the recommendation that residents use pharmaceutical collection programs where available. The DEC and New York State's Department of Health (DOH) have developed a collaborative approval process for community-sponsored collection events. A full list of those collection sites and events is available on the DEC's [website](#). In 2010, over 30,000 pounds of household pharmaceuticals were collected at local community collection events. Many of the Great Lakes coastal counties including Chautauqua, Erie, Niagara, and Monroe have held and continue to offer collection events on their own throughout the year and all have taken part in the DEA sponsored collection events. Several local police departments in Suffolk County have taken the initiative to install permanent drug drop boxes to collect household pharmaceuticals as well. In Tompkins County, a local coalition called The Coalition for Safe Medication Disposal (CSMD) includes representatives from the Tompkins County Health Department, Tompkins County Solid Waste Management Division, Tompkins County Sheriff, Tompkins County Administration, Lifelong (a seniors group), the Community Coalition for Healthy Youth, Tompkins County Area Transit (TCAT), and the Ithaca Area Wastewater Treatment Facility. The CSMD is supported by many area pharmacies

and Police Departments and has, to date, collected more than 4,100 pounds of pharmaceuticals at four one day collection events. The CSMD will soon install permanent drop-boxes in many county law enforcement buildings. Also, Kinney Pharmacies, which has locations in some of the coastal counties, collects non-controlled prescription drugs and over-the-counter medications on the last Saturday of every month. Palmer, a local pharmacy chain, also has ongoing collection of non-controlled medications.

Regional Programs

Walgreens, a national pharmacy chain, recently partnered with Novo Nordisk, a national health care company, to sell mailers (with full rebates available) to return non-controlled medications for safe destruction.

CVS, a national pharmacy chain, has also started selling postage-paid envelopes for the return of unused medications. This program cannot legally accept controlled substances.

The Yellow Jugs Old Drugs program, operated by [Great Lakes Clean Water Organization](#), is a pharmacy-based pharmaceutical collection program available throughout Michigan. In 2012 the program will be available in Wisconsin and Illinois. This program cannot legally accept controlled substances.

[The Prescription Pill Drug Disposal Program](#) (P2D2) has established many permanent drug drop boxes throughout the United States. This program, available in 17 States including 54 counties in Illinois, has collected over 150,000 pounds of pharmaceuticals to date.

Appendix 2: Existing Product Stewardship Programs for Pharmaceuticals

Canada

The Post-Consumer Pharmaceutical Stewardship Association (PCPSA) is a non-profit organization that directly administers the Medications Return Program through funding from pharmaceutical and consumer health products members. The industry established the PCPSA to comply with British Columbia's Waste Management Act, a law intended to reduce the environmental and public health risks associated with consumer goods, including leftover medications. The act requires producers to establish a system to safely collect and dispose of the public's unused medications. PCPSA has been successfully administering the program since 2000 and now represents over 140 pharmaceutical and consumer health products brand owners. The program is regulated in B.C. and Manitoba, and similar voluntary programs exist in other provinces and territories.

While brand owners are required to cover the full cost of the program, pharmacies serve as collection sites on a voluntary basis without compensation. The program has been extremely successful in gaining the support of community pharmacies throughout British Columbia; more than 97.5% of all pharmacies are participating in the program. This high pharmacy participation rate facilitates patient access to over 1,080 convenient disposal locations for unused medication. Consumers can return their leftover, unused, and expired medication to any participating pharmacy free of charge. Pharmacies place these medications in a special container and, once the container is full, the pharmacist contacts the program administrator who will pick up the container and leave a replacement within a week. The program administrator tracks collection and stores the product before it is sent to a licensed incinerator. The collection rates achieved in British Columbia have increased significantly since the beginning of the program. In 2009, 4,145 containers were collected in British Columbia, or 51,205 kilograms of waste. If the U.S. were to collect an equivalent quantity, it would amount to over 12 million pounds of re-directed waste annually.

Europe

Spain. SIGRE (Spain Integrated Waste Management System) is a non-profit organization established by the National Corporate Association of the Pharmaceutical Industry, The General Board of Official Pharmacists' Association, and the National Federation of Associations of Wholesale Distributors of Pharmaceutical Specialties. This program collects unused medications from customers at pharmacies and then sorts collected materials. Non-hazardous drugs are sent to waste-to-energy facilities and the packaging materials that can be recovered are recycled. The service is free to customers and available at pharmacies across the country. To help educate their customers about the types of materials that are accepted, a "SIGRE" logo is included on all packaging of medications which can be returned through the program. The amount of material collected through the program continues to increase annually (at a rate of 3.5% a year in 2010). The program was collecting approximately 0.164 pounds per resident each year in 2010. The pharmaceutical industry funds the take-back program (on the basis of their market share) and also promotes 'prevention measures' aimed at reducing the amount of waste generated in the first place.

France. Cyclamed, is a French non-profit organization that was established by stakeholders involved in the pharmaceutical supply chain, including the pharmaceutical manufacturers, distributors, and pharmacists. The organization was established in 1995 and accepts unused medications from patients at pharmacies. The materials collected are destroyed at waste-to-energy facilities. The voluntary program became a law under a federal decree passed in 2009. The program operates throughout the country and collected approximately 29.3 million pounds in 2009, or approximately 0.45 pounds per resident. Program costs are paid for by the pharmaceutical manufacturers through fees based on prior year's sales.

Appendix 3: The Controlled Substances Act

The Controlled Substances Act, passed by Congress in 1972, restricts the handling of certain "controlled substances." Controlled substances are drugs which have been deemed particularly addictive or otherwise dangerous. Under the original Act, law enforcement was the only entity authorized to take possession of a controlled substance from the patient to whom it was prescribed. While a number of law enforcement officials have created drug take-back programs in compliance with the Controlled Substances Act, other take-back programs, in pharmacies and clinics for example, were prohibited from accepting controlled substances from individuals. Long-term care facilities, which handle large volumes of controlled substances, are particularly affected by these restrictions.

In October 2010, the Act was changed to allow a wider range of entities to take possession of such drugs for the purpose of safe disposal. The Secure and Responsible Drug Disposal Act of 2010 was signed by President Obama after being unanimously passed by both houses. This law authorizes the Attorney General to amend the Controlled Substances Act in order to help remove barriers to creating programs for safe return and disposal of unused medications, but it is important to note that this law does not explicitly authorize the creation of drug take-back programs.

The intent of this law is to encourage the Attorney General to establish regulations which prevent the diversion of controlled substances, but still "allow public and private entities to develop a variety of methods of collection and disposal of controlled substances, including some pharmaceuticals, in a secure, convenient, and responsible manner." It is likely the regulations will increase the number and convenience of collection sites, as the law explicitly directs the Attorney General to consider the following when developing regulations: public health and safety; ease and cost of program implementation; and participation by various communities. The law also requests that the Attorney General authorizes long-term care facilities to dispose of controlled substances on behalf of their residents (the ultimate users). It is important to note that the law does not explicitly authorize the creation of drug take-back programs and is not intended to require any entity to establish delivery or disposal programs.

The Drug Enforcement Administration will issue a proposed rule making under this change in the law. PSI encourages all interested parties to prepare comments that address security, costs, and accessibility of different collection and disposal options. As of July 2012 the DEA had not issued proposed regulations.

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