



Disposal practices for unwanted residential medications in the United States[☆]

Susan T. Glassmeyer^{a,*}, Elizabeth K. Hinchey^b, Susan E. Boehme^c, Christian G. Daughton^d,
Ilene S. Ruhoy^d, Octavia Conerly^e, Rebecca L. Daniels^f, Lisa Lauer^g, Meg McCarthy^g,
Todd G. Nettesheim^h, Kathy Sykesⁱ, Virginia G. Thompson^j

^a United States Environmental Protection Agency, Office of Research and Development, Cincinnati, OH 45268, United States

^b Illinois–Indiana Sea Grant College Program, Purdue University, West Lafayette, IN 47907, United States

^c Illinois–Indiana Sea Grant College Program, University of Illinois, Urbana, IL 61801, United States

^d United States Environmental Protection Agency, Office of Research and Development, Las Vegas, NV 89119, United States

^e United States Environmental Protection Agency, Office of Water, Washington, DC, United States

^f United States Environmental Protection Agency, Office of Research and Development, Research Triangle Park, NC 27711, United States

^g United States Environmental Protection Agency, Office of Solid Waste and Emergency Response, Washington, DC, United States

^h United States Environmental Protection Agency, Great Lakes National Program Office, Chicago, IL 60604, United States

ⁱ United States Environmental Protection Agency, Office of the Administrator, Washington, DC, United States

^j United States Environmental Protection Agency, Region 3, Philadelphia, PA 19103, United States

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ABSTRACT

The occurrence of trace levels of prescription and over-the-counter pharmaceuticals in the environment began to receive concerted attention nearly two decades ago. The public's growing awareness and concern over the presence of these chemicals, especially in drinking water, has served to catalyze considerable discussion and debate regarding the best practices for disposal of unused or unwanted medications. In the United States, the first federal guidance for consumers was issued in 2007. It recommends discarding unused pharmaceuticals to household trash, after taking precautions to mix the pharmaceuticals with an inert substance and conceal the contents from view. Providing the consumer with additional options for conscientious disposal are various community, city, and state collection events, ongoing programs, and government-funded pilot projects. These strategies include the opportunity to mail or bring unused medications to various collection points, such as pharmacies, for eventual destruction. All of these approaches to medication disposal play roles in reducing the introduction of pharmaceuticals to the environment.

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1. Introduction

In the United States, the usage of both prescription and over-the-counter (OTC) medications continues to increase. The United States is currently the largest market for pharmaceuticals in the world, with combined sales of OTC and prescription pharmaceuticals exceeding \$200 U.S. billion in 2007 (IMS Health, 2008), nearly equaling the combined amount purchased in the other 12 countries where sales figures are monitored (Fig. 1).

With the increased usage of pharmaceuticals comes concern about the fate and effects of these compounds in the environment. Pharmaceuticals have been detected in surface waters (Ashton et al.,

2004; Batt et al., 2006; Glassmeyer et al., 2005), ground waters (Rodriguez-Mozaz et al., 2004; Scheytt et al., 2004; Verstraeten et al., 2005) and treated drinking water (Daughton, 2008; Snyder et al., 2007; Stackelberg et al., 2007). These low (part-per-billion) concentrations of pharmaceuticals may be responsible for environmental effects such as vitellogenin induction in male fish (Nash et al., 2004), gender and genital abnormalities in fish (Ankley et al., 2001; Woodling et al., 2006) and even population collapse (Kidd et al., 2007). Some studies suggest that these chemicals can also affect human cells exposed in laboratory settings (Pomati et al., 2006, 2008).

Pharmaceuticals can enter the environment in a number of different ways (Daughton, 2007). Fig. 2 depicts the lifecycle of pharmaceuticals through production, distribution, household acquisition and consumption. There are three main routes for household pharmaceuticals to enter the environment: (1) excretion after ingestion, injection, or infusion; (2) removal of topical medications during bathing; and (3) disposal of unwanted or leftover pharmaceuticals (Ruhoy and Daughton, 2007). Prior to excretion, pharmaceuticals may be biotransformed in the body to yield a variety of

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* Corresponding author.

E-mail address: glassmeyer.susan@epa.gov (S.T. Glassmeyer).

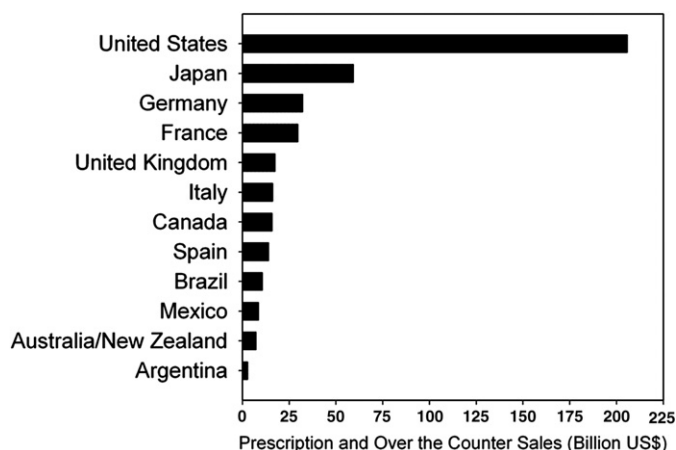


Fig. 1. Pharmaceutical sales data. Sales data for the 12 nations with the largest volume of prescription and over-the-counter sales in North America, Europe, Asia, Latin America and Oceania. Adapted from IMS Retail Drug Monitor 2008.

metabolites, some of which might have more or greater biological activity than the parent drug. The extent of metabolism and transformation spans a wide spectrum, being a function of the pharmacokinetics of a particular drug as well as the genetics and health of the patient. In addition, pharmaceuticals can be almost completely transformed to inactive metabolites or be excreted unchanged (Bound and Voulvoulis, 2005; Kümmerer, 2004). Even if a pharmaceutical is significantly biotransformed, the metabolites may revert to the parent compound during wastewater treatment, or in the environment (Daughton, 2007).

There are several avenues that the consumer can pursue for reducing the introduction of drug residues to the environment. Practicing prudent disposal of leftover medications is an obvious starting point. A more effective approach to stewardship, however, would entail cooperation between the healthcare community and the patient to prescribe, dispense, and consume medications in the optimal amounts so that leftover drugs would be minimized and the need for disposal would be consequently lessened or eliminated. There are many reasons that medications accumulate unused in the household, but a wide variety of corrective and preventative actions

are possible for reducing accumulation, and which may also yield improved healthcare outcomes and lessen healthcare costs (Daughton, 2003a,b; Ruhoy and Daughton, 2007, 2008).

The focus of this paper is on the household medication disposal practices currently used in the United States; recommendations and guidance regarding medication disposal that are supported at the federal level; and federal, state, and local programs that are exploring additional medication disposal options. This paper also places the disposal practices in the United States into context with programs in place in other countries. Note that while the focus of this paper is on human drugs, the analogous issues are faced with veterinary drugs, with the major distinction being that the formulations and doses of the pharmaceutical ingredients can differ.

2. Current pharmaceutical disposal practices

In the United States, poison control centers have long advised against discarding medications via the trash, and instead have recommended discarding to sewerage. This advice was perceived as the easiest means available for protecting humans and pets from accidental and purposeful poisonings from unwanted, leftover medications that might otherwise accumulate in the household or be recovered from the trash (Daughton, 2007).

The three most commonly used medication disposal practices have long been flushing down the toilet, washing down the sink, or discarding as household trash. All of these practices have drawbacks. The first two methods, disposal by sink or toilet, increases the load of pharmaceuticals to the wastewater system. Numerous studies have measured pharmaceuticals in treated wastewater effluents and effluent-receiving waters (Glassmeyer et al., 2008; Kolpin et al., 2002). Both on-site (septic) and municipal wastewater treatment systems are designed to primarily remove particulate matter, odor, oxygen demand, nutrients, and pathogens, not trace levels of microconstituents such as pharmaceuticals. Nevertheless, various degrees of ancillary removal of trace constituents from the liquid phase of sewage are achieved, depending on the physicochemical properties of the particular chemical. This occurs as a result of processes such as dilution, oxidation by disinfectants, biological degradation, and sorption onto solid materials (sludge) that are separated from the liquid waste stream (Ternes et al., 2004).

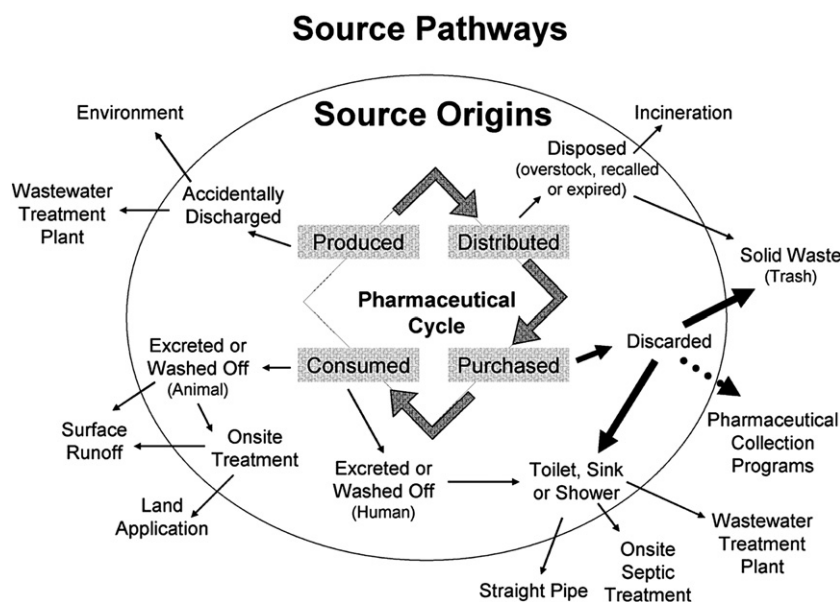


Fig. 2. Environmental entrance pathways for pharmaceuticals. Pharmaceuticals can enter the environment at many points during their lifetime, from production through use. This paper is focused on the choices a consumer can make when discarding their unwanted medications—disposing in the wastewater system, throwing away in the trash, or participating in a pharmaceutical collection event.

It is impossible to directly measure whether the pharmaceuticals present in wastewater effluents originate from disposal of unwanted medications or from excretion and bathing, but studies are emerging on ways to indirectly determine the significance of the contributions from disposal (Ruhoy and Daughton, 2007). Until now, the only method to examine the routes of medication disposal used by consumers was by questionnaire surveys. One early survey (Kuspis and Krenzelok, 1996) revealed that only 2% of respondents indicated that they consumed all of their medications before the expiration dates, indicating that unused pharmaceuticals abound. The remaining 98% of respondents used a variety of mechanisms to manage their unwanted pharmaceuticals, including slightly more than 7% of respondents who did not dispose of them at all (Fig. 3). A more recent survey conducted by Statistics Canada (2005) revealed that about a quarter of Canadian households generated leftover medications. Of the households with unused medications, the portion that continued to practice disposal via the sewer, trash, or burial (instead of returning to pharmacies via any of Canada's established programs) was significant, ranging from 20–70%.

Eliminating the wastewater system as a means of unused drug disposal is one of many ways to lessen the impact of pharmaceuticals on the aquatic environment (Daughton, 2003a,b). Disposal of pharmaceuticals in the trash holds the potential to eliminate their immediate impact on the environment, but it potentially causes other problems. Pharmaceuticals have been detected in landfill leachates (Barnes et al., 2004; Slack et al., 2005), so disposal via trash may in some cases only delay the entry of these residues to the aquatic environment. The potential exists for increased accidental exposures as a result of trash being an accessible temptation for children, pets, wildlife and those who actively seek leftover medications. Exposures to individuals for whom the medications were never intended results in significant morbidity and mortality in the United States (Ruhoy and Daughton, 2007). These inadvertent exposures can occur when drugs are stockpiled in the home before being discarded to trash, or while the trash sits in the house, awaits pickup at curbside, or even once it reaches a landfill (Daughton, 2007). Further concern regarding the disposal of medicines to trash is that personal information remaining on labels can promote identity theft, an issue especially important for the elderly and those with chronic diseases. They are the biggest consumers of prescribed medicines and may have difficulty removing labels.

In early 2007, the White House Office of National Drug Control Policy (ONDCP) issued federal guidance for consumer drug disposal (ONDCP, 2007). The ONDCP guidance was preceded the week earlier by the United States Fish and Wildlife Service's (USFWS) and the American

Pharmacists' Association's (APhA) "SMARxT Disposal™" program, an effort developed to increase consumer awareness about the hazards posed by improperly disposing medications. In March 2008, the USFWS, APhA and the Pharmaceutical Research and Manufacturers of America (PhRMA) formalized this effort (SMARxT Disposal, 2008). The three main components of both sets of guidance are:

1. Don't flush medications down the toilet.
2. Remove labeling from packaging and mix medications with unpalatable items (kitty litter, coffee grounds, etc.) and seal in a bag before placing in the trash (accessibility might be further reduced by discarding to wet garbage instead of dry trash in homes that segregate the two).
3. Utilize state and local collection programs where they are available.

The ONDCP guidance recommends flushing as a means of disposal for a distinct list of thirteen drugs with high potential for abuse or that are acutely toxic.

One precaution is worth noting. Because drug disposal can represent significant loss of healthcare dollars, an often suggested alternative to disposal is drug reuse, recycling (by dispensers), or drug sharing by consumers (Daughton, 2007). While there are highly special circumstances where reuse can be practiced in the United States, reuse and sharing should always be avoided because the identity or purity of the medication cannot be assured, and drug sharing is equivalent to self-medicating.

3. United states regulations that govern or impact pharmaceutical disposal

In the United States, several federal agencies have jurisdiction over different aspects of pharmaceutical regulation. The Food and Drug Administration (FDA) protects public health by assuring the safety, efficacy, and security of human and veterinary drugs, such as through the federal Food, Drug and Cosmetic Act and the Prescription Drug Marketing Act (both as amended). The Drug Enforcement Administration (DEA) enforces the controlled substances laws and regulations of the United States (e.g., the Controlled Substances Act [CSA]) to ensure medications are not diverted for improper uses. The U.S. Environmental Protection Agency (USEPA) protects the environment and human health from chemical exposure via a series of acts, such as the Resource Conservation and Recovery Act (RCRA), the Clean Water Act, and the Safe Drinking Water Act. In some cases, the DEA and the USEPA also delegate their authorities to their state counterparts; as a result, some states may be subject to more stringent requirements.

The Controlled Substances Act (CSA) regulates the importation, manufacture, distribution, possession and improper use of any chemical that can be abused for intoxication (21 USC 811). The CSA establishes five schedules (21 USC 812) to classify drugs of abuse, ranging from Schedule I, which are not allowed to be prescribed, to Schedule V, which have a low potential for abuse. The CSA schedules regulate how prescriptions for these drugs may be written and filled (21 USC 829). The CSA also mandates that any person who manufactures, distributes or dispenses a scheduled pharmaceutical must be registered (21 USC 823). Possession of a scheduled pharmaceutical without registration or prescription is punishable by monetary fines and/or imprisonment (21 USC 844). The CSA can impact how pharmaceutical collection events are designed and held (see further discussion by Daughton, 2007). For example, a scheduled pharmaceutical carried by a consumer to a collection event for disposal must be collected and inventoried by law enforcement to avoid violating the CSA. The CSA is a major factor that has led the United States away from the use of pharmacies or other depots to serve as a nationwide collection system.

Under the USEPA's purview, RCRA is the framework for the proper management of hazardous and nonhazardous solid waste in the United States. RCRA established three distinct, yet interrelated,

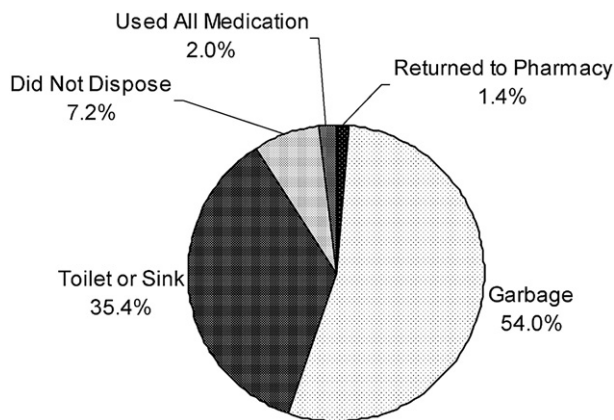


Fig. 3. Survey of unused medication disposal practices. Most of the households contacted in a survey of pharmaceutical disposal practices either threw the materials in the garbage or rinsed them down the toilet or sink. Over 7% of respondents did not dispose of their unused medications, creating a household stockpile that may lead to accidental or deliberate wrongful ingestions. Adapted from Kuspis and Krenzelok (1996).

programs, two of which are relevant to the disposal of pharmaceutical wastes. First, the solid waste program in RCRA Subtitle D encourages states to develop comprehensive plans to manage nonhazardous industrial and municipal solid waste, sets criteria for municipal solid waste landfills and other disposal facilities, and prohibits the open dumping of solid waste. Second, the hazardous waste program in RCRA Subtitle C establishes a system for controlling hazardous waste from the time it is generated until its ultimate disposal – in effect, from “cradle to grave.” Hazardous wastes are those wastes that are dangerous or potentially harmful to human health or the environment. Specifically, hazardous wastes are defined under RCRA as those wastes appearing on one of the four hazardous wastes lists in 40 CFR 261.31–261.33, or exhibiting at least one of four characteristics—ignitability, corrosivity, reactivity, or toxicity—as defined in 40 CFR 261.21–261.24. It is important to note that, relative to the large number of prescription or OTC drugs currently on the market in the United States, only a small number are categorized under RCRA as hazardous waste when discarded.

Currently, hazardous wastes from households, including hazardous pharmaceuticals, are not subject to the federal RCRA hazardous waste regulations, as household hazardous wastes are exempt from RCRA subtitle C regulations under 40 CFR 261.4(b)(1). This is known as the “household hazardous waste exclusion.” While this exclusion from federal law allows for disposal of household hazardous waste, including pharmaceuticals, in the trash, USEPA encourages households to participate in local household hazardous waste collection programs, some of which may accept pharmaceutical wastes. Many States have regulations that are more stringent than the federal program regarding hazardous waste, including household hazardous wastes.

It is important to note that the household hazardous waste exclusion not only applies to wastes generated by individuals in temporary residences, such as hotels, but also to extended residences, such as nursing homes and other long-term care facilities (LTCFs). Most LTCFs generate two types of hazardous pharmaceutical waste. First, the facility itself generates hazardous wastes as a result of its central management of pharmaceuticals in its pharmacy or pharmacy-like area. These hazardous pharmaceutical wastes are subject to RCRA hazardous waste generator regulations since the pharmaceuticals are under the control of the facility, and thus, are generated by that facility. The LTCFs are then responsible for managing any RCRA hazardous pharmaceutical wastes in accordance with RCRA Subtitle C. Second, patients and residents in LTCFs generate hazardous waste. Those pharmaceuticals under the control of the patient or resident of the LTCF, when discarded, would be subject to RCRA's household hazardous waste exemption in 40 CFR 261.4(b)(1), as these hazardous pharmaceutical wastes generated by the patient or resident are similar to the hazardous wastes typically generated by a household.

A wide spectrum of state laws governs the handling and disposition of unused drugs, especially controlled substances (Daughton, 2007). These are compiled in the database “Current Substance Abuse Legislation” (CESAR, 2005) and, combined with federal regulations, compose a complex but comprehensive system of controls.

4. Federally sponsored pilot collection programs in the United States

Given that the ONDCP guidance is only an interim solution for guiding the release of unwanted medications away from waterways and sewage sludge, there is considerable interest in developing a consistent, sustainable approach for handling drug waste that can be implemented on the national scale. In 2007, the USEPA announced the recipients of two \$150,000 grants from a competitive solicitation on the prudent disposal of unwanted medications. One of the grantees, the University of Maine's Center on Aging, is piloting a statewide effort to “mail back” unused or unwanted medications. The second pilot,

undertaken by the Area Resources Community and Human Resources (ARCHS), is evaluating the conventional approach for returning medications at “take-backs” located on the premises of a grocery store chain's pharmacies in the St. Louis, Missouri area.

Maine's pilot project builds on its 2004 state legislation, which enacted the nation's first statewide program for take-back of unused drugs: “An Act to Encourage the Proper Disposal of Unused Pharmaceuticals” (State of Maine, 2005).

The purpose of the Maine pilot project is fivefold:

- Devise, implement, and evaluate a mail-back plan to remove unused and unwanted prescription and OTC medications from residences, and dispose of them in compliance with state and federal laws and sound environmental practices.
- Quantify unused medications collected during the pilot by weight, type, and hazardous characteristics.
- Identify all costs and cost-related variables to determine funding needed for larger-scale roll-out.
- Test the effectiveness of an educational campaign to create awareness of risks associated with the retention and accumulation of medications, focusing on population over 65 years old.
- Assess the reasons that medications remain unused, requiring eventual disposal.

Maine plans this to be a two-phase project with an initial limited roll-out in mid-2008, and a second phase beginning in the fall of 2008. With the help of older adults and participating pharmacies, 9000 return mailers will be disseminated throughout the state of Maine. The mailers will contain a survey to determine why medications were unused and to understand what motivated people to return the medications. Because the United States Postal Service (USPS) is responsible for the delivery of mail, and will be in possession of the pharmaceuticals during the mail-back transport, they were included in the project planning. Results are expected in early 2009. The program in the state of Maine is unique due to the cooperation of the state legislature, Maine DEA and USPS. This program will not likely be readily applied to other localities without significant interagency cooperation and local legislation.

The ARCHS pilot began to take back medications in January 2008. Twice a month during the pilot, Schnucks, a chain of grocery stores, will accept unwanted non-scheduled medications at their pharmacies. They are also interviewing persons returning the medications to assess what was returned and why the medications were not fully used. Senior pharmacy students will identify the medications and enter the data about the medications into a database. Final results are expected by the end of 2008.

The data collected from both pilot projects should inform healthcare practitioners about patient compliance/adherence regarding particular classes of medications, which might promote actions that could lead to fewer unused or unwanted medications (Ruhoy and Daughton, 2007).

5. State and local collection programs

Many state and local governments have established pharmaceutical collection programs. Collection programs are aimed at reducing the quantity of unused and unwanted medicines entering the environment and reducing the amount of drugs available for diversion, theft, or accidental poisoning. These initiatives provide the legal framework and the logistical resources required to allow the general public to turn in unwanted medicines for safe disposal. Typically, collectors of household medicines accept unwanted or expired medicines, including both prescription and OTC medicines. These collections are beneficial because:

- Unwanted medicines accumulating in the household present a public safety hazard.

- Diverting medicines from the toilet or trash can decrease the environmental pollution from wastewater treatment discharge and landfill leachate.
- Collections help educate the general public about the environmental impact of improper medicine disposal.

A collection program provides the opportunity to inventory unused drugs and can yield data on the types and amounts of pharmaceuticals that are wasted, as well as to survey the reasons that the medicines were not used, which could prove valuable to the healthcare community in optimizing its prescribing and dispensing practices to reduce the generation of leftover drugs.

Unwanted medicine collections are a relatively new phenomenon in the United States. Most are often driven by city, county, or community organizations and are initiated as a result of a wide range of factors (see Table 1 for a description of some example programs). The types of collections that have been developed range from small-scale, one-day events to sustained collection programs involving either drop-off sites, mail-back (pilot basis only), or regularly scheduled collection days and events. Programs that have been initiated by law enforcement most commonly result from concerns about teenage drug abuse, such as “pharming” (e.g., Milwaukee, Wisconsin and Indiana TRIAD), or older adult issues such as accidental poisonings due to confusion over too many medications stored in the

home, identity theft, and drug theft (e.g. Chicago, Illinois). As more products, such as paint, pesticides, and electronic wastes are banned or discouraged from disposal in landfills, household hazardous waste (HHW) collections have been developed to help the public dispose of unwanted materials. Some HHW collections have begun to add pharmaceuticals to their programs. Concern for the environment has also become a driving factor for collection of unwanted medications. For example, the city of Palo Alto, California (2005), developed a large public awareness campaign and developed take-back programs focusing on protecting the San Francisco Bay. The theme of impacts on fish as a way to visually connect the collection of pharmaceuticals to the environment has been used on numerous collection advertisements.

In many cases, collection programs have been initiated at the county level, especially in rural communities, to address unwanted medicine issues (e.g., Monroe County, Indiana). The proliferation of local programs is prompting state Environmental Departments to begin aligning policies, regulations, and guidance to ensure statewide consistency in the safe and legal collection and disposal of medications (e.g., the state of Wisconsin). This has proven to be a challenge, as states must operate within the bounds of federal regulations (previously discussed in Section 3), as well as state-specific regulations that determine whether the material collected is considered a hazardous waste under RCRA, a controlled substance under the CSA, a

Table 1
Compilation of selected pharmaceutical take-back events

Program sponsor	Program type	Collection details	Stated goals of collection programs
Los Angeles and Orange County California Sanitation Districts	Ongoing education	The “No Drugs Down the Drain” campaign is an ongoing public awareness effort to direct residents to take medicines to household hazardous waste centers.	Raise concern about an emerging national environmental issue.
San Francisco Bay area Pollution Prevention Group (wastewater treatment plants) California	One week event	“Safe Medicine Disposal Week” collection events at 39 locations. 1500 residents participated and 3,634 lb of waste were collected and incinerated at a cost of ~\$90,000.	Raising awareness about potential public health and environmental risks posed by improper disposal of unwanted medicines.
Alachua County Environmental Protection Department Florida (pop. 220,000)	Ongoing	500 participants brought 305 lbs of medicines to 12 locations over the course of 5 months. The cost of the program was ~\$16,000.	Prevent secondhand use of medicines, reduce identity theft, and prevent water supply contamination.
City of Chicago Police Department (city and suburbs) Illinois	Single day annual	Annual collection events have been held for the last 3 years at 25+ locations around Chicago. From 2004–2006, nearly 6000 lb of unwanted medicines was collected.	The police department has spearheaded this effort targeting older citizens due to concerns about identity and drug theft.
Kendall County Health Department and TRIAD Illinois	Ongoing	Medicine drop offs are accepted at the Yorkville Police Department M–F (began July 2007). As needed, pharmacists go to Station to separate controlled (destroyed by police) and non-controlled (destroyed by IL-EPA) medicines.	Assist senior citizens with disposal of unwanted medicines and protect the environment.
Monroe County Solid Waste Management District Indiana (pop. 121,407)	Annual week-long events and ongoing drop off	In 2006, the weekly event collected 280 lb (solid), 76 lb (liquid), and 272 containers of controlled substances. Disposal costs (\$285/55 gal drum) covered by the County. AARP provides publicity and volunteers.	TRIAD, a partnership between senior citizens and law enforcement, pushed for collections to reduce crime and increase consumer education and safety. Reduced harm to children and animals are also noted as goals.
Earth Keeper Initiative, Upper Peninsula Michigan	Single day	Earth Keepers are a coalition of nine faith communities. 19 sites were established during earth week 2007 and 2,000 people participated turning in over one ton of medicines. Costs were \$20,000. The street value of the controlled substances was estimated to be \$500,000.	Care for the environment and concern about abuse with their community.
Philadelphia, PA	Three month pilot	Three month public education of senior citizens with three 1-day collection events; education of nursing home staff and changed disposal practices for non-controlled substances; all medications mailed to reverse distributor for incineration.	Educate senior citizens and healthcare sector; provide alternative methods for disposal at nursing homes.
Clark County Washington (pop. 380,000)	Ongoing	Began in 2003; ~50 locations (pharmacies, sheriff’s offices) were involved.	Motivated by environmental concerns.
The State of Washington	Ongoing pilot	Statewide pilot program (Pharmaceuticals from Households: A Return Mechanism PH:ARM). ~1000 lb was collected from 7 locations year 1. Costs are predicted to be \$3.3 M/yr statewide.	Public health and environmental concerns; accidental poisoning prevention, reduce water pollution and foster producer responsibility.
LaCross County Wisconsin Solid Waste Department	Ongoing	Hazardous waste facility staff have been conditionally deputized for the purpose of safe disposal of medicines. LaCrosse residents can bring medications to the facility during business hours. The program costs ~\$15,000 per yr.	The goals are security, and to be low-cost, effective, ongoing and user friendly.
Milwaukee Metropolitan Sewerage District Wisconsin	Single day annual	Two annual events have resulted in ~640 people disposing of 3200 lb of non-controlled and over 35,000 controlled substances (individual pills, patches, bottles).	Raise environmental concerns about trace amounts of pharmaceuticals in waterways, concern for aquatic health, and water quality.

Data collected from unwanted medication take backs includes the drug packaging in the measurement of mass or volume. This makes it very difficult to draw accurate conclusions used to make meaningful intercomparisons as to overall effectiveness of the take backs. For more information on all collections, and more examples of events, please see the Illinois-Indiana Sea Grant webpage on Disposal of Unwanted Medicines [http://www.iisgcp.org/unwantedmeds/\(IISG, 2007\)](http://www.iisgcp.org/unwantedmeds/(IISG, 2007)).

medical or infectious waste, or some combination of some or all of these. Depending on the drug's status, the state regulations may prescribe how long the collected material can be stored, how it can be transported, and how must it be destroyed (typically incineration, but autoclaving and landfilling are also used in some cases).

As more collection programs are developed and implemented, efforts are being made to target participation by older adults, who are most likely to practice the highest rate of polypharmacy (taking multiple medications for any number of reasons). These programs reach out not only to individuals in private residences, but also to facilities such as hospices, nursing homes, older-adult communities, long-term care facilities, and other non-hospital healthcare facilities. These facilities fall into a grey area where individuals may consider these facilities their home (and therefore the drugs being disposed of could be considered household), while the facilities themselves are regulated and managed as businesses. The regulations applicable to these facilities are numerous and complicated. Federal and state regulators are attempting to alert these facilities to the applicability of regulations to their facilities, while also aiding these facilities to obtain compliance with the regulations. In keeping with this trend, the state of Wisconsin's Department of Natural Resources (DNR) has developed guidance documents for some of these facilities. For example, "Pharmaceutical waste at non-hospital healthcare facilities" (Wisconsin DNR, 2008) provides guidance on how various facilities are defined by the state and the requirements for collection and disposal of HHW.

6. Challenges for collection programs

The number of collection events across the United States will continue to grow as both the public's awareness of pharmaceuticals in the environment and the number of medications being used continue to increase. Organizing and staging successful and legal collection programs requires a significant commitment of time, money, and human resources. The most significant complications result from the regulations surrounding controlled substances. For disposal, the CSA requires scheduled pharmaceuticals to be placed under the control of law enforcement. A pharmacist should also be present to identify controlled substances, and document their name, strength, and total quantity. The law enforcement officers are then responsible for ensuring proper collection, handling, inventory, and final destruction. Other barriers include the cost of destruction of all of the collected pharmaceuticals, as well as the costs associated with staging an event or hosting a program including advertising, equipment rental, and personnel salaries. Finally, individual consumers may be frustrated by the lack of consistently available collection programs, resulting in low participation rates, and potentially the build-up of unwanted and expired medications at home. Ideally, a collection program would be free or inexpensive for the residents of a community to use, continuous, conveniently located, and simple to use for everyone; mail-back programs and returns to pharmacies are the prime models.

7. Unwanted pharmaceutical disposal in other nations

The United States is not the first country to begin to examine different options to dispose of unwanted medications. Article 127b of the *European Union Directive 2004/27/EC (2004)* requires that "Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired." In 2007, the European Federation of Pharmaceutical Industry Association (EFPIA) conducted a survey of the 27 EU Member States and Norway to determine how these collection programs were being implemented (Taylor and Poulmaire, 2008). Twenty of the 28 nations surveyed have established a pharmaceutical waste collection scheme, the majority of which (11) are pharmacy-based collection systems. The interpretation of the scope of Article 127b varies greatly from country to country.

Nine countries have broadened the definition of "medicinal products" to include not only prescription and OTC pharmaceuticals, but also illicit "recreational" drugs; seven have also included the collection of syringes. Eight of the programs targeted only residential waste, but some nations also included the collection of unused pharmaceuticals from nursing homes (seven programs), hospitals (four programs), and/or pharmacies (eight programs). The financial support for these programs is just as varied. Some countries rely solely on government funding, while others are supported through the pharmaceutical industry or the pharmacies themselves.

Outside of the EU, there are only a few established national pharmaceutical collection schemes. Australia's Return Unwanted Medicines (RUM) Project, initiated in July 1998, is a permanent, national, government-financed program that provides for the collection of unwanted and expired medicines by community pharmacies. Commonwealth funds currently cover these costs with significant support from the pharmaceutical industry. The RUM Program has achieved high levels of success due to the clarity and simplicity of the program. Consumers are simply asked to bring expired or unwanted medicines to any pharmacy, where the pharmacist collects them in a special bin for correct disposal. Pharmaceutical wholesalers have agreed to a dramatic discount in charges for delivery and collection of bins from pharmacies.

The Canadian ENVIRx disposal program was launched in October 1996 (sponsored by the pharmacy and pharmaceutical industries) and allows the return of all unused medications to pharmacies throughout Alberta and British Columbia; collected medications are then transported for incineration. ENVIRx accepts all prescription drugs, nonprescription medicine, herbal products, vitamin and mineral supplements, and throat lozenges, but not other personal care products. The user-friendliness of the program is the key to its success with an easy and on-demand pick-up schedule.

Information on household pharmaceutical disposal in other areas of the world is limited. Consumers in Japan, who are second only to the United States in terms of amount of pharmaceuticals sold (Fig. 1), are advised to dispose of all non-sharp medical waste, presumably including pharmaceuticals, in their household garbage (JPMA, 2007). In addition, the Federation of Pharmaceutical Manufacturers Association of Japan (FPMAJ) was created in October 2007 to address the environmental issues that affect the pharmaceutical industry, including medication waste (JPMA, 2007).

The success of pharmaceutical collection programs may be a function of the local culture. In Kuwait, a pilot collection program was attempted in 200 households (Abahussain and Ball, 2007). In this program, the residents were given special bags to place unwanted pharmaceuticals, which were then to be collected by the municipality. While a plurality of participants thought this was an acceptable way of collection and disposal, none of the homes involved in the program actually utilized it. The authors of the study believe that the participants may accumulate medications to hedge against scarcity. In a subsequent study, investigators went to residences and spoke to citizens about the dangers unwanted medications posed to humans and the environment. Only after this direct intervention were any unused pharmaceuticals collected.

8. Summary and conclusions

Despite an insufficient understanding of the significance of drug disposal as a contributing source to the environmental loading of drug residues, disposal of unwanted medications is the easiest target for source control. Roughly 30 countries have implemented some form of drug collection system, on national, state, or local levels. The approaches used for collection vary among countries, but in general, pharmacies play a central role in one capacity or another. In the United States, various environmental acts – and regulations governing controlled substances – pose some challenges mostly unique to the

United States. The limited questionnaire surveys of public beliefs and practices show a broad range of approaches used for disposing drugs, but the most common are discarding to sewerage and trash or returning via drug collection systems or hazardous waste facilities.

While disposal is generally purported to play a small and perhaps even insignificant role in environmental contamination, research is just beginning to determine the magnitude, characteristics, and extent of the contributions originating from disposal. Disposal is a complex function of patient compliance/adherence, excretion pharmacokinetics, and packaging, all of which can vary dramatically for each medication (Ruhoy and Daughton, 2007), and leaving the possibility that disposal plays a significant role for certain drugs.

The disposal of drugs poses a quandary with regard to optimizing the dual protection of ecological health and human safety (Ruhoy and Daughton, 2007). Flushing to sewerage increases environmental exposure, but disposal to trash increases the possibility of human or pet exposure – both unintentionally and via diversion. While prudent practices for drug disposal need to be widely promulgated, a more optimal and sustainable solution would be various alterations to the healthcare system to minimize the incidence of leftover drugs to begin with by optimizing the amounts prescribed and dispensed (Daughton, 2007).

Pharmacovigilance has long focused on the occurrence of adverse outcomes from the intended use of pharmaceuticals in both humans and domestic animals, however an additional responsibility is emerging – the need to also protect the environment from unintentional contact with trace residues of pharmaceuticals. To expand the role of pharmacovigilance to capture environmental protection, “pharmEcovigilance” (Daughton and Ruhoy, 2008) could employ a broad spectrum of means to minimize the ecological footprint of medications as well as reduce the possibility of their causing harm to humans and domestic animals.

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