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**CONFLICTING PUBLIC POLICIES:
WHY IS IT SO DIFFICULT TO KEEP PHARMACEUTICALS OUT OF THE WATER?**

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For decades, Americans have been told to flush their unwanted and expired pharmaceuticals down the drain as a quick and safe method of disposal. Increasingly, water and wastewater utilities are trying to encourage the public not to use the water supply as a garbage dump for pharmaceuticals—for reasons of both water quality and water conservation. The alternatives to flushing, however, are few because the Controlled Substances Act of 1972 mandates that controlled substances, such as codeine, Oxycodone, Percocet, and Ritalin, must remain in possession of the patient for whom they were prescribed. This means they cannot be returned to a doctor or pharmacy at the end of their useful life. In addition to this hurdle, communities trying to design pharmaceutical take-back programs have also encountered challenges in the form of state and federal environmental regulations, and a lack of infrastructure designed to handle return and disposal. In Newberg, Oregon, local law enforcement, the medical community, area businesses, and City Hall have partnered to create a unique pharmaceutical take-back program that takes into account these constraints. The program relies on the leadership of local policymakers, as well as local funding sources, private firms that are willing to explore new business models, and a broad spectrum of local stakeholders.

Key terms: public policy, pharmaceuticals, take-back, controlled substances, Oregon, household hazardous waste

I. INTRODUCTION

In what has become a national wake-up call, researchers across the United States are finding pharmaceuticals and other chemicals at very low concentrations in most waterways that receive discharges from municipal wastewater treatment plants, or WWTPs (Kolpin, 2002). One researcher warns that “the continual environmental introduction of drugs...makes them ‘pseudo-persistent’ pollutants with ramifications for aquatic organisms” (Daughton, 2002).

Many of these pharmaceuticals find their way into WWTPs, having been excreted from our bodies. But others have made their way into WWTPs because for decades, Americans have been told to flush their unwanted and expired pharmaceuticals down the drain as a quick and safe method of disposal. However, most of the municipal WWTPs in the United States use biological treatment methods that were not designed to remove pharmaceuticals or other chemicals from municipal wastewater. (To clarify, this discussion focuses on wastewater treatment plants and not drinking water plants, which have more sophisticated treatment processes in place designed to remove chemical compounds and other contaminants of concern.) Increasingly, local officials are urging the public not to use the water system as a garbage dump for pharmaceuticals.

Communities across the United States have identified an alternative to flushing pharmaceuticals down the drain. They are designing “take-back” programs to collect and destroy unused pharmaceuticals in a safe and environmentally responsible manner.

These take-back programs have created an exciting coalition of organizations. The poison control centers and child advocacy groups are spearheading efforts to decrease accidental poisoning of children and pets in households. The Drug Enforcement Administration, law enforcement, and healthcare industries are leading efforts to prevent intentional drug abuse.

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The environmental and public health communities are focused on protecting water quality. All of these groups can use pharmaceutical take-back programs to further their goals.

II. PUBLIC POLICY OBSTACLES

Communities designing their own programs have been hampered by the very web of public policies, laws, and regulations that were originally designed to protect our communities and environment.

The design of pharmaceutical take-back programs must take into account the different ways in which pharmaceuticals are categorized—and subsequently regulated. In general, members of the public recognize their household pharmaceuticals as either “prescription” or “over-the-counter.” See Figure 1 below.

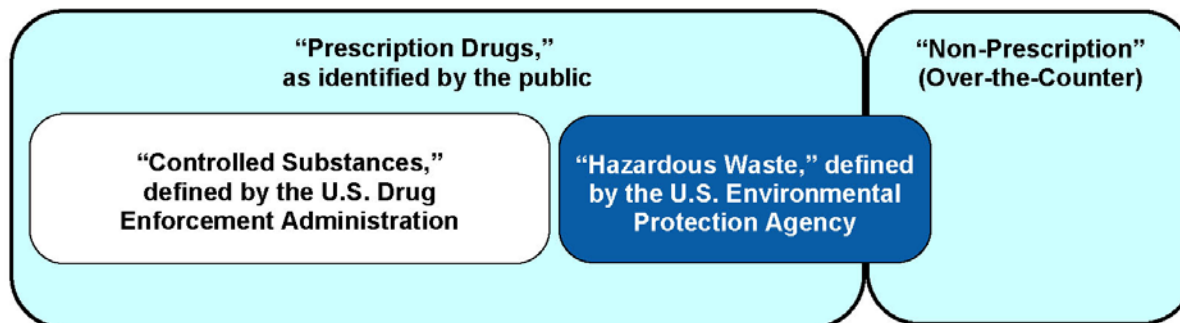


Figure 1. Pharmaceutical Categories: Three Different Perspectives

However, the U.S. Drug Enforcement Administration (DEA), an important regulatory agency in this arena, categorizes some prescription drugs as “controlled substances.” And, the U.S. Environmental Protection Agency categorizes yet a different category of pharmaceuticals as “hazardous.” Ensuring the proper collection and destruction of pharmaceuticals, therefore, requires program designers to account for all three of these perspectives. It also requires much more information than is typically available on the product label.

Controlled Versus Non-Controlled Substances

Within the family of prescription medicines, some are considered “controlled” substances, so defined by their potential for abuse and addiction. Well known examples include tranquilizers like Valium, stimulants like Ritalin, and painkillers like Codeine, Oxycodone, and Percocet. This category of medications is significant, as controlled substances typically comprise between 5 and 15 percent of the items collected in a take-back program.

The Controlled Substances Act of 1972 not only defines controlled substances, but also represents the most formidable obstacle to the design of pharmaceutical take-back programs in the United States. The Controlled Substances Act prohibits the transfer of dispensed, controlled substances, except between DEA registrants—entities registered with the DEA to handle or manage controlled substances (21 CFR §1301.11(a), § 802.11, and § 841(a)). This means that once controlled substances are prescribed and dispensed, the patient cannot legally give them to friends, family, a doctor, the pharmacist, or anyone else.

The sole exception to this rule allows law enforcement personnel to accept controlled substances from the public (21 CFR §1301.24). Law enforcement officials are then supposed to ensure that these controlled substances are destroyed beyond recovery. Usually, this means taking the collected items to a local incinerator and staying on site long enough to witness “the burn.” However, this method of destruction is not formally required by Federal law, and some law enforcement departments have hired contractors to haul controlled substances to far away incinerators on their behalf. Regardless of the ultimate destruction destination, any successful, comprehensive take-back program must rely on the participation of local law enforcement officials to accept controlled substances from the public.

Hazardous Versus Non-Hazardous Pharmaceuticals

Another important perspective for categorizing pharmaceuticals comes from the U.S. Environmental Protection Agency, whose most relevant regulation in this case is the 1976 Resource Conservation and Recovery Act (RCRA). RCRA defines a

substance as “hazardous” if its chemical properties are ignitable, toxic, corrosive, or reactive (40 CFR §261(c)), and categorizes six, non-controlled pharmaceuticals as hazardous. They are: Arsenic Trioxide (a chemotherapeutic agent), Epinephrine (adrenaline), Nicotine and Nicotine patches, Nitroglycerin (controls chest pain), Physostigmine (a glaucoma treatment), and Warfarin / Coumadin (blood thinners). These half-dozen pharmaceuticals may constitute up to 10 percent of the items found among the unwanted or expired medications in residential medicine cabinets.

Individual households are exempt from RCRA regulations and are legally allowed to throw these items into household trash. But households that are trying to be environmentally responsible and community programs that are collecting and consolidating medications will need to transport these items to a household hazardous waste facility that ensures destruction by incineration.

Lack of Local Incinerators

EPA-approved incinerators, with all their appropriate environmental controls, are the backbone of any good medication disposal program. Unfortunately, they are few and far between, making it somewhat difficult and expensive to design good medication disposal programs for the public.

Complicating the issue are the customary law enforcement protocols requiring law enforcement officials to be physically present to witness the destruction / incineration of controlled substances. Some communities that are designing medication disposal programs have found themselves in a situation where the local incinerator will accept controlled substances from law enforcement agencies, but refuses to accept non-controlled substances that are defined as “hazardous” under RCRA. And while other incinerators do accept these “hazardous” substances, the trip may be too far away for law enforcement officials to personally deliver controlled substances and witness their destruction. Therefore, program coordinators are obliged to expend time and labor sorting collected medications into two waste streams going to two separate incinerators.

III. HOW ARE COMMUNITIES COPING?

There is a growing community of professionals working on the design of pharmaceutical take-back programs. These professionals represent a wealth of experience in law enforcement, public health, community education, coalition building, advertising, and best practices in take-back programs. One of the best resources for the design of community programs is a “pharmwaste” list-serve administered by Florida’s Department of Environmental Protection.

Asking the Public “Not to Flush”

The most immediate priority is to keep the public from flushing unwanted and expired medications down the drain. The easiest alternative, employed by most poison control centers and state environmental agencies, is to advise residents to destroy any patient identifiers printed on the medication, mix the contents with kitty litter or something equally unpalatable, and then encase the bottle or package in a water-tight plastic bag before dropping it into the garbage. While this method prevents the medication from entering the water system right away, it does pose health and safety problems for children, pets, or animals that may have access to garbage cans or landfills.

And when the packaging decomposes, the medications will ultimately reach the water. In older, unlined landfills, the leachate (liquid produced from the decomposition of waste) leaks into local groundwater supplies (Slack, 2005). In modern landfills, the leachate is collected and sent to municipal wastewater treatment plants, which, as previously mentioned, typically are not designed to handle these wastes.

Don’t Ask, Don’t Tell

Time and again, household hazardous waste (HHW) facilities are receiving calls or visits from residents who want to dispose of unwanted medications in an environmentally responsible manner. The current web of regulatory and infrastructure limitations has spawned HHW programs that are trying to be responsive to the public, while operating in a legal gray area.

Under today’s regulatory atmosphere, many HHW facilities accept “all medications” from households without inquiring whether they include controlled substances or not. The facilities then package everything together in steel drums and ship them off for incineration. Residential customers have no idea whether their bag of unwanted medications includes “controlled” substances or not, and local HHW programs accept these bags knowing that controlled substances may well be included. This “don’t ask, don’t tell” approach is getting unwanted medications out of medicine cabinets, while keeping them off the streets, out of landfills, and out of the nation’s water supplies. Strictly speaking, however, this transfer is outside the law if facilities knowingly accept controlled substances.

Without a change in the Controlled Substances Act, communities that want to design formal programs to collect and consolidate unwanted medications from their residents cannot plan to use local HHW facilities to dispose of controlled substances. The formal protocols necessitated by such a program will require HHW facilities to identify and reject any controlled substances. Communities must come up with a better plan.

Pharmaceutical Take-Back Programs

Some communities across the United States have been conducting pharmaceutical take-back programs for years, but most have not hit upon the right combination of infrastructure, staffing, and resources to create sustainable programs. See Figure 2 below for a sampling of programs currently underway in the United States.

Location	Accepts Both Controlled & Non-Controlled Substances?	Year-Round Program?	How the Program Works
California (Palo Alto) Illinois (Cook County) Indiana (Monroe County) Maine (Mid Coast Region) Wisconsin (several counties)	✓		Events: Every year, week-long or day-long collection events accept both controlled and non-controlled substances.
California (Marin County, Palo Alto, San Francisco) Florida (Alachua County) Michigan (Macomb County) Oklahoma (Tulsa) Washington State Pilot (Puget Sound Area)		✓	Partial program: Residents can bring only non-controlled substances to participating drop-off sites during business hours.
Indiana (Monroe County) Washington (Clark County)	✓	✓	Two, year-round, simultaneous programs: Residents can bring: (1) <u>controlled substances</u> to law enforcement facilities, and (2) <u>non-controlled substances</u> elsewhere. The Indiana drop-off site is a HHW facility; Washington sites are participating pharmacies.
California (San Mateo County & City of Vacaville) Iowa (Statewide)	✓	✓	One, year-round, consolidated program: Program accepts <u>all</u> pharmaceuticals from residents. In California, drop-sites are law enforcement offices; the Iowa site is the state's household hazardous waste (HHW) facility.
Oregon (City of Newberg)	✓	✓	Adult care facilities only: Law enforcement holds the only key to disposal containers and collects controlled substances on a quarterly basis; garbage collection service takes non-controlled substances to HHW facilities.

Figure 2. Sampling of Pharmaceutical Take-Back Programs in the United States

Most programs involve day-long or week-long take-back “events” that are expensive to advertise and staff, because of the need for pharmacists to identify controlled versus non-controlled substances, law enforcement officers to take possession of controlled substances, and garbage haulers to take the non-controlled substances. Typically, these events also have staff to control traffic, “greet” participants, collect data, take surveys, and serve as support staff. Such events accept both controlled and non-controlled substances. Perhaps one of the most extensive events took place during May 2006 in the San Francisco Bay area. With participation from 17 agencies, the program partners collected 3,634 pounds of pharmaceuticals from 1,500 residents or about two pounds per person (Jackson, 2006).

Other programs run year-round and their successes hinge on the use of a locked collection container. These containers have the same basic design as a curbside mailbox, in that items go into a depository door at the top, and are inaccessible thereafter—except through a locked door at the bottom of the container. Some programs have placed these drop-boxes in law enforcement facilities so that they can accept controlled substances under supervised conditions. Other programs have placed the drop-boxes in retail settings (pharmacies and health clinics), and can only accept non-controlled substances because no law enforcement officers are stationed on-site. This approach poses some logistical problems, because unless someone stands there to supervise and sort the waste stream, the public has no idea whether the pharmaceuticals are “controlled” substances or not.

Still other programs have focused on residential situations, such as nursing homes or assisted living centers, where pharmaceuticals are found in more concentrated numbers.

To date, local governments have led the way in the design and funding of pharmaceutical take-back programs. However, several efforts are also underway to develop state-wide solutions. Maine passed legislation in 2004 allowing residents to mail unwanted controlled substances to the state's Drug Enforcement Agency, although the state has not yet funded or implemented a program. California, Iowa and Massachusetts have introduced legislation about pharmaceutical take-back in their 2007 Legislatures. Oregon has a state-wide stakeholder committee evaluating designs for a take-back program as well.

IV. CITY OF NEWBERG PILOT PROGRAM: SERVING ADULT CARE FACILITIES

In the City of Newberg, located southwest of Portland, Oregon, City Hall has partnered with local law enforcement, the department of public works, the garbage collection franchise, medical community, and area businesses to create Oregon's first pharmaceutical take-back program. A 15-member team, comprised of city leaders and citizens, has designed a program that takes into account the public policy challenges described above. On March 5, 2007, City Council approved a take-back program specifically for the town's adult care facilities.

With permission from Oregon's State Board of Pharmacy, adult care facilities in Oregon already send some non-controlled substances back to consultant pharmacies for re-sale if the pharmaceuticals meet certain criteria. See Figure 3. This results in a higher percentage of controlled substances in these collections than in the general public, because many non-controlled substances have returned to the pharmacy for re-dispensing. The take-back program disposes of any pharmaceuticals remaining in the facility after qualifying drugs are returned to the pharmacy.

<p>Under Oregon Administrative Revised Statutes Pharmacies Can Re-Dispense Non-Controlled Pharmaceuticals if the Drugs...</p>
<ol style="list-style-type: none"> 1. Are in an unopened, tamper-evident unit (i.e., bubble packs); 2. Remained under the control of a person trained in the storage and administration of drugs in long-term care facilities using the services of a consultant pharmacist; 3. Have not been adulterated or misbranded; 4. Have been stored under conditions meeting U.S. Pharmacopeia standards. <p style="text-align: right;">—ORS 800 OAR 855, Division 41, § 0080</p>

Figure 3. Conditions Allowing Oregon Facilities to Re-dispense Pharmaceuticals

Until the creation of this take-back program, nursing staff at the adult care facilities discarded pharmaceuticals down the drain. The take-back program allows adult care facilities to dispose of medications in a more environmentally responsible manner, depositing them into "mailbox"-type collection containers in each facility's locked medicine room. Having staff participate in community take-back events and transport controlled substances to law enforcement facilities would be a problem, because prescriptions are in the patients'—not the staff members'—names. Local law enforcement officials have agreed to come into the adult care facilities to remove controlled substances. The container for controlled substances is locked so that only local law enforcement officials have access. Law enforcement officials pick-up the controlled drugs for witnessed incineration during their regularly scheduled trips to destroy unnecessary / unwanted evidence.

A second locked box collects non-controlled substances. The local garbage collection franchise, as part of a new business practice, takes the non-controlled substances to a household hazardous waste facility, using a manifest and chain-of-custody system. Household hazardous waste is generated at the residential level and is exempt from RCRA regulations. In October 2006, the Oregon Department of Environmental Quality (DEQ) categorized adult care facilities as "households" for



the purposes of pharmaceutical take-back programs (Volpel, 2006).

At the time of disposal, the nursing staff documents the name of each medication, dosage strength, whether it is in liquid or solid form, and the amount remaining. Oregon's DEQ has approved a complete set of handling and disposal protocols written for the Newberg Program. A new logo, seen in Figure 4, was trademarked in the state of Oregon and created in time to launch the Newberg program. Oregon communities that want to use the logo to brand and publicize their pharmaceutical take-back programs can customize the tag-line to identify their community.

Figure 4. Oregon Pharmaceutical Take-Back Logo

The City's department of public works administers and funds the overall project, while local law enforcement pays for the collection and disposal of the controlled substances. Adult care facilities paid one-time purchase costs for the secure metal containers.

IV. CONCLUSION

In the current regulatory environment, law enforcement must physically accompany controlled substances to incinerators for "witnessed destruction," HHW facilities are not allowed to knowingly accept controlled substances from the public, and many incinerators will accept controlled substances or hazardous pharmaceuticals, but not both. Communities that are trying to protect their streams and rivers from discarded pharmaceuticals are spending an inordinate amount of time and resources sorting, handling, and documenting these unwanted medicines. This creates pharmaceutical take-back programs that are expensive for participants, and cumbersome for program coordinators.

The policies originally designed to protect our environment and communities are unintentionally damaging our nation's water resources. Program designers who want to launch take-back services right now—under the current rules—must limit what they accept, the hours of operation, participating locations, or the demographics of whom they can serve. Unless the rules are modernized, the public will continue to find it more convenient, affordable—and legal—to continue flushing expired and unwanted medications down the drain. However, protection of our nation's water resources need not conflict with prudent drug disposal policy. We must develop integrated public policies that facilitate the design and proliferation of pharmaceutical take-back programs.

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