SENATE ENVIRONMENTAL QUALITY COMMITTEE
INFORMATIONAL HEARING

Home-Generated Pharmaceutical Waste Disposal: Take-Back Programs in California

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Pharmaceutical Use

Pharmaceutical drug use in the United States is ubiquitous. Forty-eight percent of Americans reported using at least one prescription drug in 2008; for adults over the age of 60, almost 90% used at least one prescription drug during the same year, and over 35% used five or more drugs in the same study.

Based on a 2010 report, the average U.S. household has four or more prescription drugs and five or more over-the-counter medications at any given time. However, in a 2004 survey of patients, as few as 2% of individuals with medications used all of the pills prior to their expiration.

There is currently no clear pathway for proper and safe disposal of medications as they expire or are no longer needed.

Storage of unused medications can lead to risks of diversion through theft and illegal consumption, accidental ingestion of expired or incorrect medications, or inappropriate disposal; all of these avenues are risks for human health.

Disposal of medications in the trash, sink, or toilet can result in downstream ecological and environmental health effects. For medications that have expired or that were unused, as many as 90% are disposed.

Pharmaceutical Contamination in the Environment

A study conducted by the United States Geological Survey from 1999-2000 sampled 139 streams across 30 states and found that 80% had measurable concentrations of prescription and nonprescription drugs, steroids, and reproductive hormones. Since the USGS released its report in 2002, a number of studies have demonstrated the low-level presence of pharmaceutical agents throughout the environment and water supply.

Quantity and Type of Contamination

Environmental levels of pharmaceuticals are typically at parts per million (ppm) or parts per billion (ppb). However, pharmaceutical compounds, such as synthetic hormones and antibiotics, are often active at low levels and by design affect the health of a target organism. Due to their continual use, pharmaceuticals are constantly being reintroduced to the water supply, which results in consistent levels of contamination.

Additionally, studies have found that contaminated waterways typically contain a variety of different compounds. In the original USGS study, 75% of streams had at least two contaminants, and 13% contained 20 or more pharmaceutical agents.

Sources of Contamination

There are two general sources of pharmaceutical contamination in the environment: human excretion and disposal.

After an individual takes a drug, some of the active pharmaceutical agent will eventually leave the body via urine or feces, either in its original or slightly modified form. This is a natural consequence of the proper use of a pharmaceutical agent, and reports vary as to the extent of contribution of this source. There is no way to currently regulate or stop this contamination pathway before it enters the environment.

The disposal of unused pharmaceutical agents in the trash, down the sink, or flushed down the toilet is a second form of pharmaceutical environmental contamination.

A 2004 patient survey revealed that only 2% used all medication prior to expiration, and that 90% disposed of their medications in the trash, toilet, or sink. Although this number is at the high end of estimates for the amount of discarded

pharmaceuticals, most estimates suggest that 3 to 50% of prescriptions become waste; United States hospitals and long-term care facilities annually flush approximately 250 million pounds of unused pharmaceuticals down the drain.

Following a campaign to discourage flushing medications down the toilet, the American Pharmacists Association and the U.S. Fish and Wildlife Service jointly recommended that patients instead mix expired medications with an undesirable substance (such as coffee grounds) and throw them in the trash. The intention for this initiative was that lined landfills would prevent pharmaceutical compounds from entering the environment. However, several studies in the U.S. have shown that the leachate from landfills contains pharmaceutical drugs in low levels, and this leachate eventually contaminates ground water and surface supplies. While many of these landfills are older and unlined, the Augusta double-lined landfill was identified by the Maine Department of Environmental Protection as a source for pharmaceutical-contaminated leachate.

Ecological and Human Health

The environmental and health consequences of pharmaceutical contamination can be broken down into two sets: human or aquatic, and short-term or long-term.

To date, the short-term human health effect of trace levels of pharmaceuticals in the water has been found to be minimal. Most scientific studies conclude that the level of active compounds in the water is too low to cause negative effects, particularly over short periods of time. However, the effects of long-term exposure have not been established.

Only 150 of the estimated 3,000 pharmaceutical contaminants have been tested for their environmental impact. In addition, the interplay between multiple pharmaceutical drugs and their effects on human health are unknown, particularly with respect to chronic toxicity.

While the human effects of pharmaceutical agents in the environment are not fully understood, harm to aquatic organisms and ecosystems due to low levels of pharmaceutical agents are clearly established. Life-long exposure to ppb levels of an estrogen-based synthetic hormone resulted in complete population failure in fish due to the males failing to develop properly. Mood altering drugs, such as Prozac, lead to changes in the behavior of fish, making them easier prey. The presence of persistent antibiotics, particularly downstream from hospitals, has been partially credited for the rise in resistant bacterial strains, which may also have an indirect human impact.

Legal Framework for Pharmaceutical Waste Management

Laws regulating the collection and disposal of pharmaceuticals are present at the federal, state, and local levels. As reported by the Department of Resources Recycling and Recovery (CalRecycle), there is no single federal or state agency that has sole or ultimate authority for home-generated pharmaceutical waste collection, consolidation, management, and disposal. Instead, the federal Drug Enforcement Administration (DEA) and several California state agencies (Department of Public Health (DPH), Board of Pharmacy, and Department of Toxic Substances Control (DTSC)) all have responsibility, sometimes overlapping, making it challenging for local jurisdictions to develop and maintain effective collection and management programs they know conform to legal requirements.

Federal Regulations

Two federal laws currently control the regulation of pharmaceuticals and their waste.

Under the United States Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration (FDA) is authorized to oversee the safety of food, *drugs*, and cosmetics.

Additionally, under the Resource Conservation and Recovery Act (RCRA) of 1976, the management of solid and hazardous wastes is regulated. This results in strict protocols for the collection of controlled substances to prevent their illegal diversion and abuse such that only law enforcement officials can handle certain pharmaceutical wastes; there is no equivalent law in any other country.

The Secure and Responsible Drug Act of 2010 should make this process easier by allowing take-back disposal options for pharmaceutical waste. Regulations are currently in development by the DEA. The draft regulations allowed pharmacies to accept controlled substances for disposal, and final regulations are expected to be published in March 2014.

State Regulations

Under the California Integrated Waste Management Act (SB 966, Simitian, 2007), CalRecycle created a model collection program for household hazardous substances, such as pharmaceuticals, and evaluated how local programs implemented take-back programs. CalRecycle identified 297 take-back programs and assessed the programs based on their accessibility to consumers, safety, cost, and amount of pharmaceutical waste collected.

The Medical Waste Management Act (MWMA) requires DPH to regulate the management and handling of medical waste, and defines pharmaceuticals as

prescription or over-the-counter human or veterinary drugs, excluding those regulated by RCRA or the Radiation Control Law. SB 1966 (Wright, 1996) defined general pharmaceutical waste as medical waste under the MWMA.

AB 1442 (Wieckowski) in 2012 defined pharmaceutical waste as any pharmaceutical that may no longer be sold or dispensed; this definition excludes pharmaceuticals that could be returned to a reverse distributor for possible manufacturer credit.

While not explicitly in statute or regulations, DPH has interpreted consolidated home-generated pharmaceutical waste as medical waste.

Local Ordinances

In July 2012, Alameda County passed a first in the nation Safe Drug Disposal Ordinance that requires producers of covered drugs (including both brand name and generic drugs) to operate take-back programs after submitting a plan to the county's Department of Environmental Health. Such operation includes the creation, administration, promotion, and payment of the program (including the payment of Alameda County's costs to administer and enforce the Ordinance). The ordinance was challenged by several pharmaceutical organizations on the basis that the ordinance violates the dormant Commerce Clause for interstate commerce and discriminates against out-of-county producers. In August 2013, the U.S. District Court upheld the ordinance, although litigation is ongoing. Several other California counties are considering similar ordinances.

Federal Bills to Expand Regulations

In December 2013, Representative Matt Cartwright (D-PA) introduced H.R. 3714, the Servicemembers and Veterans Prescription Drug Safety Act of 2013. That bill would provide for a federally managed prescription drug take-back program for members of the Armed Forces and veterans. A similar bill (S. 1089) was introduced in June 2013 by Senator Susan Collins (R-ME).

In July 2013, Representative Frank Pallone Jr. (D-NJ) reintroduced the Medical Waste Management Act (H.R. 2891) that would revise the federal definition of medical waste. However, this bill does not specifically address pharmaceutical waste.

Representative Candice Miller (R-MI) introduced the Drug Free Water Act of 2011 (H.R. 1677). This bill required the US EPA to convene a task force to develop recommendations on the proper disposal of unused pharmaceuticals. This bill was not enacted.

In 2008, the US EPA proposed an amendment to its 1995 Universal Waste Rule (UWR) to provide a system for disposing of hazardous pharmaceutical waste that protects public health and the environment. The US EPA has not reviewed any pharmaceuticals for regulation as hazardous waste since the promulgation of RCRA regulations in 1980. However, the 2008 proposal raised too many public concerns; as a result, the US EPA is currently working to "develop another proposal for health care facility-specific regulations for the management of hazardous pharmaceutical wastes in order to provide a regulatory scheme that addresses the unique issues that hospitals, pharmacies and other health care-related facilities face. It is anticipated that the proposal will be available for public comment in Spring 2013." (Office of Inspector General, Report Number 12-P-0508) As of February 4, 2014, the US EPA had not yet released its 2014 proposal to address the management of hazardous waste pharmaceuticals from healthcare facilities. (http://www.epa.gov/waste/hazard/generation/pharmaceuticals.htm)

Implementation of Take-Back Programs

Under current statutes, pharmaceuticals in their original packaging can be returned to manufacturers by pharmacists and hospitals, or individual pharmaceutical users can throw away unused or expired medications in the trash.

In order to reduce improper disposal and long-term storage of pharmaceuticals, the most common approach by local governments has been to offer programs that encourage and make it easier for the public to return excess medications. These are typically referred to as "take-back programs," and take on a variety of forms.

One-Time Take-Back Programs

The most common method of pharmaceutical waste control is "Drug Take-Back Days," which is typically administered by law enforcement, often in conjunction with county health offices or other local government agencies. These one-time events allow for individuals to dispose of prescription or non-prescription medications; following the collection, the pharmaceuticals are taken to a safe disposal site.

The DEA's seventh National Take-Back Day in October 2013 collected 324 tons of expired and unwanted medications across all 50 states.

Since the inception of the National Take-Back Day in 2010, the DEA has collected over 3.4 million pounds of medicine from circulation. The next national collection event is scheduled for April 26, 2014.

Local take-back events have occurred throughout California. The statewide "No Drugs Down the Drain" campaign consisted of more than 200 local one-day or ongoing pharmaceutical collection options during the week of October 4-11, 2008. CalRecycle reported 53 events between 2009 and 2010, resulting in a total of 5,000 pounds of disposed pharmaceuticals.

These one-day events have raised concerns about accessibility to the event or stockpiling of pharmaceuticals in anticipation of such events.

Continuous Take-Back Programs in California

In contrast to the one-day take-back events, continuous programs operate year-round, and typically provide a permanent receptacle for pharmaceutical disposal.

These programs offer an advantage over the one-day events in that they provide greater accessibility for individuals to return expired or unwanted medications.

Between 2009 and 2010, CalRecycle identified 177 continuous collection programs at pharmacies and law enforcement offices in California. In that time, these programs collected more than 200,000 pounds of pharmaceuticals.

San Francisco:

In April 2012, San Francisco launched its Safe Medicine Disposal Pilot Program. Residents can return non-controlled pharmaceuticals to 13 pharmacies via secured collection bins or any pharmaceuticals to San Francisco police stations during business hours. This program is funded partially through a grant from PhRMA and Genentech, although the city of San Francisco heavily subsidizes the program as well. PhRMA recently agreed to extend their funding for another year.

As of October 2013, over 25,800 pounds of pharmaceuticals had been collected, 93% of which was at the pharmacy locations. During this same period, the National DEA take-back days collected only 2,400 pounds of pharmaceuticals within San Francisco.

After a formal bid process, San Francisco entered into a formal contract with Sharps Solutions, a medical waste hauler, to charge a $75 fee per container pickup. This includes replacement packaging, shipping paper, and disposal via incineration. In contrast, the largest medical waste hauler, Stericycle, charges closer to $250 per pickup. For small quantity medical waste generators (<200 pounds per month, 12/14 facilities), there is a one-time $188 fee for registering. The two most popular sites that generate more than 200 pounds per month classify as large quantity medical waste generators, have an annual fee of $639, and require annual inspections by the local health department.

Los Angeles County:
The Los Angeles County Sheriff's Department launched their Safe Drug Drop-Off program in September 2009 where drug disposal boxes are available 24 hours a day, 365 days a year outside of sheriff's stations. A total of 21 drop-off locations have collected over 53,000 pounds of prescription medication as of September 2013.

Collection receptacles are also available for sharps (over 31,000 pounds) and illicit drugs (79 pounds). The boxes are emptied weekly and stored at a sheriff's department facility; up to five times a year, sheriff's department personnel accompany the drugs to an incinerator in Long Beach, where sworn personnel witness the destruction of all drugs.

Santa Clara County:
Santa Clara County currently has two county agencies that collect and safely dispose of pharmaceuticals. The first is the county Household Hazardous Waste (HHW) Program, which spends roughly $21,600 annually on the collection and disposal of 7.2 tons of medication a year (1,200 pounds a month).

The second program is run by the county sheriff's office at 10 locations. Through this program, deputies pick up, sort, and deliver pharmaceuticals to the sheriff's headquarters, where the drugs are weighed, packaged, and stored. Twelve times a year, the collected pharmaceuticals are transported to a disposal site in the San Joaquin Valley by two technicians and two sheriff's deputies. Annually, this amounts to a cost of $41,600 for 10.8 tons of collected and disposed medication.

Alameda County:
Prior to Alameda County's Ordinance (see above), voluntary hosts (including independent pharmacies, public hospitals, fire stations, and police stations) were responsible for collection and disposal.

Continuous Take-Back Programs outside of California
Several types of take-back and drug disposal programs are used throughout North America.

Canada:
In 1999, British Columbia established the "Post-Consumer Pharmaceutical Stewardship Association" (PCPSA) to establish a pharmaceutical drug take-back program funded by manufacturers. Manufacturers are required to pay for the cost of collecting and managing the program; they are not required to pay for cost of agency oversight. Currently, over 100 companies participate in the PCPSA.

Within British Columbia, 95% of pharmacies choose to participate in the program, accounting for over 1,000 collection sites. The pharmacies collect medicines and store them until the container is full, then contact the program for pick-up within seven days. In 2009, the program diverted 112,000 pounds of medication from improper disposal or abuse for an estimated cost of $400,000. An extensive education and outreach campaign led to a 250% increase in collected pharmaceuticals between 2007 and 2010.

Other provinces in Canada, such as Ontario, have also initiated pharmaceutical stewardship organizations that are responsible for coordinating and paying for drug take-back programs.

Washington:

The first pharmaceutical take-back program in Washington began in King County at the 25 Group Health pharmacies in 2006. The program collected over 28,000 pounds of medication between 2010 and 2012. However, the program is entirely financed by Group Health and is only available for Group Health clients.

In 2008, Bartell Drugs began to offer drop boxes at its stores in Western Washington. The program is financed by Bartell Drugs, and the Local Hazardous Waste Management Program (LHWMP) covers disposal costs. From 2010 through 2012, Bartell Drugs collected and disposed of over 20,000 pounds of medications in King County alone.

The LHWMP has also paid for secure steel drop boxes at police departments in King County for the collection of prescription and non-prescription drugs, including controlled substances. Most programs ultimately dispose of the collected medicines with their evidentiary drugs or through the semi-annual DEA National Prescription Drug Take-Back Events.

Statewide, pharmaceutical take-back programs and drop sites have collected and destroyed more than 160,000 pounds of pharmaceuticals through 2011. Most of these programs were funded by local governments or programs.

In 2013, King County established an industry-funded product stewardship model to collect and safely dispose of unwanted household medicines from residents of the county. King County estimated that their program would cost $2.5 million (compared to the $4 billion in sales from pharmaceutical products). This drug take-back program is currently under litigation.

Great Lakes Region (WI, MN, MI, IL, IN, OH, PA, NY):

All states in this region have some form of pharmaceutical drug collection event, although Minnesota is the only state without any permanent collection facilities.

The seven states with permanent collection sites all utilize police stations for their collection efforts. However, these programs are primarily funded by pharmacies and local governments. In the case of Wisconsin's "Get the Meds Out" initiative, loss of funding led to the program suspension after four months.

On March 4, 2014, Michigan passed Public Act 24 (HB 5005) which allows businesses and local governments to create waste collection centers for used pharmaceuticals and other household hazardous wastes.

Pennsylvania:
Fifteen Pennsylvania state legislators introduced HR 611 in January 2014, which urges congress to "pass legislation authorizing pharmacies to serve as collection sites for unused or expired controlled prescription drugs." The release of the DEA regulations regarding controlled substances is listed on the Federal Register for March 2014 and should address this issue.

As a part of Governor Corbett's "Healthy Pennsylvania" pledge, Pennsylvania will continue its partnership with local law enforcement officials to support the statewide drug take-back program. This program utilizes secure and permanent drop boxes that are distributed throughout the state. The Pennsylvania Commission on Crime and Delinquency awards grants to district attorneys in 29 counties for these boxes.

West Virginia:
In 2013, the West Virginia Legislature considered HB 2113 that would establish a pilot program using pre-paid mailing envelopes to dispose of unwanted pharmaceutical drugs. These envelopes would be made available to consumers at pharmacies, physicians' offices, and other locations. However, this legislation stalled following its introduction.

According to officials in West Virginia, the majority of crimes committed in the state are attributed to people looking for prescription drugs. Although DEA Prescription Drug Take-Back events collected over 9,000 pounds of medications in 2013 across the state, the Putnam County Sheriff's Department runs the only permanent drug collection box in West Virginia.

Colorado:
On January 1, 2014, Colorado legalized recreational marijuana use. However, under federal law, marijuana cannot be taken onto planes. As a result, airports in Colorado are taking steps to prevent marijuana from being taken through the terminal. In Denver, individuals are asked to leave their marijuana in their cars and not bring it onto airport property. At the Colorado Springs airport, however, two

marijuana amnesty bins were installed, providing a location for travelers to safely and legally dispose of their marijuana.

The bins were installed at the request of the police department and paid for by the Colorado Springs airport. The bins are repurposed MedReturn boxes, which are more commonly used to collect unwanted pharmaceutical drugs. There are currently two bins – one at the main entrance, and another at the screening checkpoint. The police department is responsible for emptying the bins and disposing of the collected marijuana; however, one week after their installation, no marijuana had been deposited in the amnesty bins.

Mail-Back Programs

Some pharmacies provide envelopes for sale which individuals can use to mail their pharmaceuticals directly to a hazardous waste facility for disposal. These types of programs are uncommon in California; CalRecycle reported only three in operation between 2009 and 2010. Both Kaiser Permanente and Walgreens offer mailers for purchase by individual patients.

During the CalRecycle reporting period, these programs collected almost 900 pounds of pharmaceuticals.

Maine:

Chapter 679 of Maine's Public Law 2003 established the state requirement for an Unused Pharmaceutical Disposal Program. Launched in 2007, Maine's drug take-back program allows residents to safely dispose of unwanted pharmaceuticals by providing envelopes to "mail-back" the unused drugs to the state Drug Enforcement Administration.

Since its implementation, the program has reported the collection of over 380,000 pills and safely destroyed 250 pounds of controlled pharmaceuticals. When surveyed, 46% of program participants stated that had the mail-back program not been in place, they would have flushed the drugs down the toilet. Many respondents noted that they participated in the program not only to prevent drug diversion and ensure safe disposal, but also because they felt this solution was best for the environment.

TakeAway Environmental Return System:

The TakeAway Environmental Return System is a postage-prepaid return envelope for non-controlled pharmaceuticals. It was created in February 2009 by Sharps Compliance. Envelopes are sold at independent pharmacies and cities, and can be used by pharmacies, veterinarians, or individual users to dispose of unwanted medications. Once the envelope is put in the mail, it is delivered to a DEA-certified incineration facility where a police officer receives and scans the packages. All

shipments are tracked and documented to provide proof of destruction within 30-45 days.

Since 2009, the program has destroyed 325 tons of returned pharmaceuticals. (2009, 4 tons; 2010, 35 tons; 2011, 79 tons; 2012, 98 tons; 2013, 108 tons)

Pharmaceutical Redistribution Programs

One alternate method for managing unopened, but still usable, drugs is a pharmaceutical redistribution program.

Dispensary of Hope and Supporting Initiatives to Redistribute Unused Medicines (SIRUM) both work to collect samples from physician offices and surpluses from the manufacturing process and dispensaries. However, individuals cannot participate in these types of programs. Some pharmaceutical companies have partnered with Dispensary of Hope to fund their operations, but non-disclosure agreements prevent the release of information regarding specific contributions.

Take-Back Program Implementation Cost

CalRecycle reports that the average cost of current take-back programs in California vary from $3-$7 a pound. Although a statewide program would lower the per-pound cost, estimates vary for the ultimate price. Costs associated with storage, training, processing, and disposal are all factors.