MYTH vs. REALITY
Extended Producer Responsibility for Pharmaceuticals

MYTH #1

Industry-funded drug take-back programs will drive up costs of pharmaceuticals for consumers.

REALITY

Drug companies are required to fund medicine take-back programs in parts of Europe and Canada, and these programs have not resulted in increases in drug costs. In British Columbia, for example, the province-wide Medications Return Program cost just $516,800 (USD) in 2010 to collect more than 151,000 pounds of medication from a population of 4.53 million. Most pharmaceutical manufacturers in British Columbia pay less than $2,000 a year to comply with the program. Industry-wide take-back programs provide an opportunity for pharmaceutical manufacturers to demonstrate leadership in reducing the risks of improper medicine disposal.

MYTH #2

Drug Take-Back programs are unnecessary and will be underused.

REALITY

Consumers have expressed continued appreciation for drug take-back programs in the communities where they are offered. Since 2010, the U.S. Drug Enforcement Administration’s (DEA) bi-annual National Prescription Drug Take-Back events have collected over 4.1 million pounds of medicine, and the amount collected has increased each year. Although ongoing drop-off programs available in a number of communities across the U.S. also collect large amounts of medicine, the vast majority of medicine is improperly disposed of or stored indefinitely in the home. Furthermore, 75 percent of residents in British Columbia who are aware of the Medications Return Program use it. Without convenient and secure access to drug take-back programs, consumers have no choice but to dispose of medicine in the trash, or worse, to flush it or store it in the home. Federal and state agencies, including the White House Office of National Drug Control Policy (ONDCP), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the DEA encourage consumers to use drug take-back programs in their communities as the safest and most secure option to get rid of unwanted medicine.

MYTH #3

Producer responsibility legislation for pharmaceuticals requires cumbersome bureaucratic oversight and is too prescriptive.

REALITY

Legislation allows drug manufacturers to join a collective stewardship organization or choose to run their own take-back program to meet stewardship obligations. Manufacturers participating in producer responsibility programs for other products, such as paint and mercury thermostats, have formed stewardship organizations to fund and manage collection programs. While government oversight is necessary to ensure a level-playing field, producer responsibility legislation is designed to minimize government’s role and to provide flexibility to industry. Greater flexibility allows drug manufacturers to develop efficient and effective take-back and proper disposal programs.
Drug Take-Back programs do not address environmental or public health concerns.

Drug take-back programs play a critical role in protecting public health and safety by providing consumers with a safe and convenient method to dispose of unused and unwanted medicine free of charge. These programs can save lives by keeping leftover medicines out of the hands of potential abusers, as well as children and pets, which are particularly vulnerable to accidental poisonings. Every 14 minutes, someone in the U.S. dies from an unintentional drug overdose, with prescription medicines killing more Americans today than cocaine and heroin combined.\(^6\)\(^7\) In addition, among children, emergency room visits for accidental drug poisonings are twice as common as poisonings from other household products, such as cleaning solutions.\(^8\) The fact that seven out of 10 people who abuse prescription drugs get them from friends and family provides strong evidence that cleaning out the medicine cabinet and properly disposing of unwanted and unused pharmaceuticals is critical to preventing abuse.\(^7\) The rising rate of prescription drug addiction also contributes to an increase in drug-related crimes, including violent home break-ins to gain access to medicine cabinets. In addition to safety concerns, medicine that’s flushed or thrown in the trash ends up contaminating our waterways, since most wastewater treatment plants are not designed to remove pharmaceutical compounds. Studies have found trace amounts of a wide array of drugs, including antibiotics, anti-seizure medicines, mood stabilizers, and sex hormones, in drinking water across the U.S. Although the long-term human health effects of repeated exposure to low levels of these chemicals are not yet known, the effects on marine life are well documented and include serious harm to fish populations. While medicine enters the environment through multiple sources, including excretion, pharmaceutical take-back programs are a way to reduce one known source of contamination.

Pharmaceutical contaminants enter waterways primarily through human excretion and agricultural runoff and, therefore, collecting drugs through take-back programs will not make a difference.

Pharmaceutical contaminants enter the environment through multiple sources, including human excretion, agricultural runoff from farm animal antibiotics and other medicines, and the improper disposal of unwanted medicine (e.g., flushing and discarding in the trash). While the exact amount of contamination that each source contributes is relatively unknown, a recent USGS study has identified landfills as a significant contributor to water contamination. The presence of pharmaceutical chemicals in landfill runoff is widespread, and water contamination is especially high in areas of high precipitation.\(^9\) By preventing two of the known pathways—flushing and trash disposal—drug take-back programs apply a practical approach to preventing waste medicine from entering and polluting the environment. This is consistent with the EPA’s recommendation that household pharmaceuticals be disposed of in a hazardous waste or municipal waste combustor.\(^10\) Drug take-back programs are a “low-hanging fruit” solution that address known sources of pollution.

It doesn’t make sense to require industry-wide take-back programs for pharmaceuticals because federal law prohibits drug manufacturers from collecting controlled substances.

In September 2014, the DEA released rules authorizing retail pharmacies, law enforcement, manufacturers, drug distributors, reverse distributors, narcotic treatment programs, hospitals, and clinics with an on-site pharmacy to voluntarily collect controlled substances.\(^11\) In light of this new rule, the previous regulatory system is undergoing significant change. Industry-wide take-back programs may soon become commonplace. Regardless, drug manufacturers can provide financial support to take-back initiatives operated by law enforcement, pharmacies, narcotics treatment centers, long-term care facilities, and hospitals and clinics.
Medicine take-back programs increase risks of diversion, particularly through collection at retail pharmacies.

Drug take-back collection programs are designed to reduce the risk of drug diversion that is happening every day in people’s homes. Program operators establish protocols to ensure the safe and secure collection, handling, transportation, and proper disposal of collected medicine. Serving as a drug take-back collection site should not increase the risk of diversion in a pharmacy, especially since medicines are comingled and deposited in locked containers that are securely fastened. Furthermore, pharmacies already have procedures in place to minimize theft and reduce the diversion of medicine being prescribed—even among their own employees.

State and local laws that require drug manufacturers to establish medicine take-back programs violate the Commerce Clause in the US Constitution.

On August 28, 2013, a federal court judge in California ruled against the pharmaceutical industry and in favor of Alameda County, California, allowing the county’s Safe Drug Disposal law to continue in effect, requiring drug manufacturers to pay disposal costs for medications obtained within the County. The industry appealed the ruling with backing from the U.S. Chamber of Commerce, but in September 2014 a federal appeals court rejected the pharmaceutical industry’s challenge of the ordinance once again, ruling that the measure would not substantially burden interstate commerce. As Judge N. Randy Smith noted, “the Ordinance neither discriminates against nor directly regulates interstate commerce...because it applies to all manufacturers that make their drugs available in Alameda County—without respect for the geographic location of the manufacturer,” and the pharmaceutical industry, in its appeal, “provided no evidence that the Ordinance will affect the interstate flow of goods.”

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2 Personal communication between the local Hazardous Waste Management Program in King County and Gigette Vanasse, Executive Director of the British Columbia Medications Return Program.
12 Pharmaceutical Research and Manufacturers of America, et. al., vs. County of Alameda, et. al. No. C 12-6203 RS (August 29, 2013)
13 Pharmaceutical Research and Manufacturers of America, et. al., vs. County of Alameda, et. al. No. 13-16833, U.S. Court of Appeals 9 Cir., (September 30, 2014)
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