MYTH *vs* REALITY

Extended Producer Responsibility for Pharmaceuticals

MYTH #1

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

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 $516,800 (USD) in 2010 to collect more than 151,000 pounds of medication from 4.53 million people.[1] Most pharmaceutical manufacturers in British Columbia pay less than $2,000 a year to comply with the program.[2] In the U.S., such programs will cost manufacturers an estimated one penny for every $10 in revenue earned.[3] Industry-wide take-back programs provide an opportunity for manufacturers to demonstrate leadership in reducing the risks of improper medicine disposal.

MYTH #2

Drug take-back programs are unnecessary and will be underused.

Consumers express continued appreciation for drug take-back programs in 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 7 million pounds of medicine, and the amount collected has increased each year.[4] While the limited number of ongoing drop-off programs nationwide collect large quantities of medicine, the vast majority of Americans do not have convenient access to secure drug take-back programs and therefore have no choice but to dispose of medicine in the trash, or worse, to flush it or store it in the home.[5] In a 2011 study on consumer perceptions about a community pharmacy-based medication take-back programs, all users viewed the medication take-back program as a valuable service, while 90% non-users viewed the program as a potentially valuable service.[6] Today, the White House Office of National Drug Control Policy (ONDCP), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the DEA, and the vast majority of state agencies encourage consumers to use community drug take-back programs to get rid of unwanted medicine.

MYTH #3

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

While government oversight is necessary to ensure a level-playing field, producer responsibility legislation is designed to minimize government's role and provide flexibility to industry in developing effective take-back programs. Legislation allows drug manufacturers to choose to join a collective stewardship organization or to run their own take-back program that meets the law's obligations. Manufacturers participating in drug take-back programs or programs for other products, such as paint and mercury thermostats, have formed stewardship organizations to fund and manage them.

MYTH #4

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 unwanted and expired 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.[7,8] Among children, emergency room visits for accidental drug poisonings are twice as common as poisonings from other household products, such as cleaning solutions.[9] Seven out of 10 people who abuse prescription drugs get them from friends and family, often from medicine cabinets.[8] Medicine that's flushed or thrown in the trash ends up contaminating our waterways, since wastewater treatment plants are not designed to remove pharmaceutical compounds. Studies have found trace amounts of pharmaceutical compounds, including antibiotics, mood stabilizers, and sex hormones, in waterways across the U.S. Although the long-term human health effects of repeated exposure to low levels of these chemical mixtures are not yet known, the effects on marine life are well documented and include serious harm to fish and other aquatic populations.

MYTH #5

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 the improper disposal of unwanted medicine (e.g., flushing and discarding in the trash). While the precise contribution to contamination from each source is unknown, a recent U.S. Geological Survey study identified landfills as a significant contributor to water contamination.[10] Pharmaceutical chemicals are often present in landfill runoff because drugs disposed of in the trash make their way to landfills where they can leach into soil or water. The U.S. Environmental Protection Agency therefore recommends disposing of household pharmaceuticals in a hazardous waste or municipal waste combustor.[11] By preventing flushing and trash disposal of pharmaceuticals, drug take-back programs represent a practical approach to pollution prevention.

MYTH #6

Federal law prohibits drug manufacturers from collecting controlled substances; it doesn't make sense to require industry-wide take-back programs for pharmaceuticals.

In September 2014, the DEA authorized 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.[12] Drug manufacturers can finance and manage collection programs at authorized locations that are convenient for residents.

MYTH #7

Drug take-back programs increase diversion risk, particularly through collection at retail pharmacies.

Pharmacies have strict procedures in place to minimize theft and reduce the diversion of medicine being prescribed—even among their own employees. Serving as a drug take-back collection site will not increase the risk of diversion in a pharmacy, since program operators must follow detailed protocols to ensure the safe and secure collection, handling, transportation, and proper disposal of collected medicine. Collection receptacles have receiving slots that can be locked when the container's inner liner fills up. Two employees, each with their own set of keys, must work together to change a full inner liner. This increases accountability and helps reduce the possibility of drug diversion.

MYTH #8

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

In 2015, the U.S. Supreme Court let stand a lower court ruling that allows medicine take-back programs. It all started in 2012, when Alameda County unanimously approved a landmark Safe Drug Disposal Ordinance requiring pharmaceutical companies that sell, offer for sale, or distribute their drugs in the county to fund and manage a drug take-back program. The Pharmaceutical Research and Manufacturers of America (PhRMA) and two other industry trade groups filed suit, claiming that the ordinance violated a legal doctrine called the dormant Commerce Clause. A federal district court ruled in favor of the County in August 2013. PhRMA and the two groups appealed, and in September 2014, the U.S. Court of Appeals for the Ninth Circuit also ruled in favor of Alameda.[13] The industry then filed a petition for certiorari with the Supreme Court. In May 2015, the U.S. Supreme Court denied certiorari, which left standing the Ninth Circuit court ruling in favor of Alameda County's law.[14]

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