



## 2016 Shareholder Proposal to Merck & Co. Report on Pharmaceutical Drug Disposal Policy

### Executive Summary

- Drug overdose now is the leading [cause](#) of accidental death in the U.S., surpassing auto accidents, with 47,055 lethal drug overdoses in 2014. Opioid addiction is [driving](#) the epidemic, with **18,893 overdose deaths related to prescription pain relievers**, and 10,574 overdose deaths related to heroin.
- Many consumers hold onto unneeded drugs because they lack convenient collection and disposal options, which can have tragic consequences. President Barack Obama has [stated](#) that most young people who begin misusing prescription drugs get them from the family medicine cabinet.
- Only 1% of U.S. pharmacies offer a drug take back kiosk or program. Lack of free, convenient programs for safe disposal of unneeded or expired consumer prescription drugs and accessories contributes to water pollution, illicit drug use, drug addiction, and threats to sanitation workers.
- As You Sow has filed shareholder resolutions in 2016 with [AbbVie](#), [Johnson & Johnson](#) and [Merck & Co.](#), asking the companies to develop policy options for working with industry peers to take primary responsibility for developing community-based prescription drug disposal programs.
- While drug disposal programs are not a common practice in the pharmaceutical industry, some government officials and companies say they need to become common as soon as possible. The Drug Enforcement Administration chief has stated “we look forward to the day when safe drug disposal options are commonplace.”
- Companies like Merck are stalling by saying they can’t act alone. Industry peers have acted. Eli Lilly & Co. has awarded grants to drug stores in Indiana to develop take back systems. Walgreens has agreed to fund 500 kiosks in 39 states, stating “when the stakes are this high, the solutions must be comprehensive.”
- ***There is no evidence Merck & Co. has a comprehensive policy on responsibility for safe disposal of prescription drugs or has taken any substantive action on its own or with peers to increase availability of community-based drug disposal options.***



## Resolution Summary

The proposal asks the company to issue a report reviewing the company's existing policies for safe disposition by users of prescription drugs to prevent water pollution, and setting forth policy options for a proactive response, including determining whether the company should endorse partial or full industry responsibility for take back programs by providing funding or resources for such programs. **[Note: The proposal does not seek a legislative solution]**

## Company Liability

The company lacks a policy on the extent to which, individually as a company, or collectively with industry peers, it should be responsible for collection and financing of a national system of safe, convenient drug disposal options. Drug industry liability for disposal is increasing. Seven West Coast counties and one state have passed laws requiring pharmaceutical companies to pay for drug disposal (details below).

## Issue Background

**Drug abuse:** In September 2015, addressing the drug abuse crisis, President Obama stated that “most young people who begin misusing prescription drugs don’t buy them in some dark alley – they get them from the medicine cabinet.” Many of these are drugs no longer used or needed by the person they were prescribed for. Thousands of annual pain killer related deaths and excessive prescription of opioids by doctors led the Centers for Disease Control in March 2016 to [issue](#) guidelines asking physicians to limit opioid treatment for short-term pain to three days, and rarely longer than seven days.

Most U.S. communities lack free, convenient, on-going collection programs that could help alleviate these critical problems. Only 1% of U.S. pharmacies offer a drug take back kiosk or program. The Drug Enforcement Administration has partnered with state and local law enforcement agencies to hold periodic National Take-Back Days for medicines, collecting and disposing of more than 5.5 million pounds of medications in just 10 events. But far more convenient and ongoing collection services are [needed](#).

Two Obama Administration drug abuse plans have cited the need for better drug disposal options:

- The Administration’s Prescription Drug Abuse Prevention Plan [cites](#) “providing proper disposal methods, like take back programs, to remove unused medications from the home,” as one of four key focus areas. It states that once DEA regulations have been revised making it simpler for pharmacies and distributors to take back licensed drugs, federal agencies will engage the pharmaceutical industry to support community-based medication disposal programs.
- Drug disposal programs are also one of four pillars of the President’s [National Drug Control Strategy](#), which states “Medication disposal programs allow individuals to dispose of unneeded or expired medications in a safe, timely, and environmentally responsible manner and can help prevent potential diversion and abuse.”



Medical accessories like syringes and needles also need safe disposal options. Three billion needles are used in U.S. homes annually to deliver medication; improper disposal puts sanitation workers at risk.

**Water quality:** Lack of disposal programs also impacts water quality. Many residents flush drugs down the toilet to water treatment plants not equipped to process medicines. The U.S. Environmental Protection Agency [advises](#) not to flush prescription drugs, but return them to a disposal location. A 2008 Associated Press [investigation](#) found antibiotics, anti-convulsants, mood stabilizers and sex hormones in the drinking water supplies serving 41 million Americans. Synthetic estrogens in oral contraceptives flushed into waterways have been linked to impaired reproduction and [sex changes](#) in aquatic species. In February 2016, researchers disclosed [evidence](#) of 81 drugs and personal-care products in the water and tissue of chinook in Puget Sound “with levels detected among the highest in the nation.”

Last year, EPA [proposed](#) new rules to protect waterways by barring the flushing of pharmaceuticals deemed as hazardous waste under federal law, which would prevent the flushing of more than 6,400 tons of hazardous waste pharmaceuticals annually.

**Producer Responsibility:** The pharmaceutical industry, which puts these drugs on the market, has no established policy of taking responsibility for disposal of unused or expired drugs. The concept of producer responsibility delegates end-of-life accountability to companies that have placed them on the market. Electronics and paint manufacturers, for instance, are required to pay for collection and recycling of their products at end-of-life under numerous U.S. state producer responsibility [laws](#). Under paint EPR laws, [PaintCare](#), an industry-run non-profit organization, is responsible for the major costs of managing leftover paint, including transportation, recycling, and processing.

Proponents believe drug manufacturers who place drugs on the market should be responsible for financing systems that provides for free and convenient take back nationwide. The province of Ontario, Canada enacted a regulation in 2012 assigning responsibility for end-of-life management of pharmaceutical waste to manufacturers. Many European countries have industry-funded drug take back programs.

## Recent Activity

After Alameda County, California, passed an ordinance in 2012 requiring pharmaceutical companies to fund and operate take-back programs for unused prescription drugs, the Pharmaceutical Research and Manufacturers Association (PhRMA) sued. The group argued that the law violated the commerce clause of the U.S. Constitution, but the county prevailed in district and appeals courts and the Supreme Court [declined](#) to review the case. As a result, company liability for prescription drug disposal has been firmly established in law.

So far, seven West Coast counties have passed ordinances requiring pharmaceutical companies to pay for drug disposal programs, and on March 14, 2016, Massachusetts became the first state to [mandate](#) a system requiring drug companies to safely dispose of unwanted medications.



The drug industry has complained that a national take back program would be excessively expensive. However, it could be far more cost efficient for the drug industry to develop its own national disposal plan than to be forced to pay for possibly less efficient systems mandated by local ordinances enacted out of frustration that the industry failed to act to develop its own system.

Instead, the drug industry is using its trade association to [fight](#) ordinances requiring takeback systems that Walgreens, the DEA and the Obama Administration say are badly needed, without proposing a constructive alternative to them.

Industry peers have has taken individual actions. Eli Lilly & Co. recently provided a [grant](#) to a program that will provide 100 disposal boxes at pharmacies in Indiana. In February 2016, Walgreens, the largest U.S. pharmacy chain, [announced](#) it will install drug disposal kiosks in 500 drugstores in 39 states and Washington, D.C. as part of a broader effort to counter drug abuse. Walgreen emphasized that **“prescription drug abuse continues to be a public health and safety risk”** and said kiosks would address a key contributor to the drug abuse crisis. Richard Ashworth, Walgreens president of pharmacy and retail operations, further stated: “We understand the challenges our communities face, and we stand ready to help our patients and customers lead healthier lives. **When the stakes are this high, the solutions must be comprehensive.**” [bold emphasis added] This statement rebuts assertions by the drug manufacturers that simply encouraging consumers to place unused drugs in the trash are adequate.

The Drug Enforcement Administration agrees. “We look forward to the day when safe drug disposal options are commonplace and hope this action inspires others to create similar programs,” added DEA Acting Administrator Chuck Rosenberg.

This voluntary action by Walgreens gives additional credence to our view that more local drug disposal options are urgently needed. It’s a welcome start, but 500 locations comprise less than 1% of U.S. pharmacies. Drug makers like Merck need to work both individually and with peers to develop policies that will result in far more substantive local disposal options.

## **Response to Merck & Co. Statement in Opposition**

The company’s statement in opposition says it discusses its position in detail on responsible disposal of drugs in two public policy statements: one on disposal of medicines in the household, and a second on pharmaceuticals in the environment.

The company says in the household statement that it works with government agencies and stakeholder groups to “understand” disposal options that can provide sound disposal at minimal cost, but cites no specific actions, collaborations or pilot projects with stakeholders that it is involved with. It further states it supports efforts to offer disposal programs to local communities, but again offers no evidence of anything other than verbal, theoretical support. Thus the company’s current policy statement fails to meet the request of proponents for a “proactive response, including determining whether the company should endorse partial or full industry responsibility for take back programs...”



The company further states that the public interest will be best served by disposal options that have a proven ability to reduce drug abuse and misuse. However, it offers no perspective on how such proven ability is to be established without its focused involvement in supporting development of programs that can test the value of disposal options.

The company says disposal of unwanted medicine is a “shared responsibility” and that it cannot unilaterally institute solutions without the commitment and participation of all stakeholders. Its peers have already demonstrated that companies *can* act unilaterally. As noted above, companies can take incremental action that will have real impact, such as a grant made recently by Ely Lilly & Co. to support drug disposal collection boxes at Indiana pharmacies, and Walgreens agreement in February to site 500 take back kiosks in 39 states. These examples demonstrate ways companies can act while a broader national strategy is developed.

In the absence of company and industry leadership, companies and the industry are losing their ability to shape a cost effective national approach as regional and state governments impose mandated solutions. As noted above, it could be more cost efficient for the industry to develop its own national disposal plan than to be forced to pay for possibly less efficient systems mandated by hundreds of local ordinances.

The report requested by proponents can demonstrate to shareholders that the company has thoroughly studied the reputational and financial risks posed by inadequate drug disposal options, and has developed policies, programs and actions on both an individual level and in collaboration with peers to resolve it.

### **Conclusion**

Shareholders and the company would benefit from the report requested by the proposal.

- Companies can both act on their own and with peers to devise a solution for the lack of drug disposal options. We cite above two recent individual actions by Eli Lilly and Walgreens. Such actions can be taken to help seed fund local programs, while the pharma industry simultaneously works to develop a national take back strategy.
- Shareholders deserve evidence—lacking to date—that thoughtful consideration has been given to this issue, through development of a policy explaining the extent to which the company, and the drug industry, should be actively participating in financing safe collection of unused drugs.
- In the absence of company and industry leadership, both entities are losing their ability to shape a cost effective national approach as regional and state governments impose mandated solutions (noted above).