

## Proposals to Impose Drug Take-back Mandate Would Increase Health Care Costs and Do Little for the Environment

by Paul Guppy Vice President for Research

February 2012

LEGISLATIVE MEMO

## Introduction

Proposals to force collection of unused pharmaceuticals claim such mandates are needed to protect ground water quality, stating: "Disposing of medicines by flushing them down the toilet or placing them in the garbage can lead to the contamination of groundwater and other bodies of water, contributing to long-term harm to the environment and to animal life."<sup>1</sup> There is no firm evidence, however, that this is an accurate description of how pharmaceutical elements end up in groundwater.

## Background

There is little doubt that very small trace amounts of natural and synthetic drugs are showing up in waterways in some parts of the country. For instance, a stream study by the U.S. Geological Survey states: "Results show that a broad range of chemicals found in residential, industrial, and agricultural wastewaters commonly occurs in mixtures at low concentrations in streams in the United States."<sup>2</sup>

The amounts Geological Survey scientists detected are exceedingly small. The trace amounts are expressed in parts per trillion; one unit of a trace element present in one trillion units of water. For example, caffeine is one of the more common elements found in the U.S. Geological Survey study. On average, researchers detected levels of caffeine in natural streams at up to 25 parts per trillion. At this level, a person would have to drink over 2,000 years worth of stream water at a daily intake of two to three liters per day to ingest the same amount of caffeine present in one cup of coffee.<sup>3</sup>

Some lawmakers have proposed trying to reduce even the tiny amount of trace elements that occur in waterways by requiring a mandatory drug take-back program. The primary flaw in this approach is that scientists do not know whether unused or discarded drugs are actually the source of the trace elements in the first place. So far, reliable studies have only measured the presence of trace elements, with no attempt at determining their source.

In addition, there is no evidence the presence of part-per-trillion levels of trace elements poses a threat to human health and safety or to wildlife. Federal research has found no effect on

<sup>&</sup>lt;sup>1</sup> SB 5234, "Creating a statewide program for the disposal of unwanted medicines," introduced by Senator Adam Kline (D-Seattle), January 18, 2011, at www.washingtonvotes.org/Legislation.aspx?ID=123843. The House companion bill is HB 1370.

<sup>&</sup>lt;sup>2</sup> "Pharmaceuticals, Hormones, and other Organic Wastewater Contaminants in U.S. Streams, 1999–2000: A National Reconnaissance," Kolpin, U.S. Geological Survey, June 2002, at www.toxics.usgs.gov/pubs/FS-027-02/.

<sup>&</sup>lt;sup>3</sup> "Pharmaceutical Manufacturer and Retailer Interests," presentation by Doug Finan (GlaxoSmithKline) and Leslie Wood (PhRMA), slide 1, April 18, 2008, at www.medicinereturn.com/resources/workshop.

human health from trace elements in the environment. The EPA points out: "More research is needed to determine the extent of ecological harm and any role it [the presence of drug elements] may have in potential human health effects. To date, scientists have found no evidence of adverse human health effects from Pharmaceuticals and Personal Care Products as Pollutants in the environment."<sup>4</sup> These findings show that imposing a new mandate would increase costs for citizens, without any indication it would actually help the environment.

Independent research clearly documents that drug take-back laws increase the cost of medicines for businesses and medical patients, while providing no benefit to the environment. Before lawmakers force producers to implement a drug take-back program, they should consider the following key findings:

- 1. Mandatory take-back programs are not shown to reduce the presence of drugs in the environment.
- 2. Municipal wastewater treatment is more effective at removing trace elements from the environment.
- 3. Sending unwanted drugs to protected landfills keeps them out of groundwater and the environment.

To date, none of the scientific research shows that mandatory take-back programs reduce the small amount of drugs in the environment. This, in part, is because the drugs being found in the environment come from human and animal excretion after the use of drugs, not from disposal of unwanted medicines. The FDA reports:

"The main way drug residues enter water systems is by people taking medications and then naturally passing them though their bodies," says Raanan Bloom, Ph.D., an environmental assessment expert in FDA's Center for Drug Evaluation and Research. "Most drugs are not completely absorbed or metabolized by the body, and enter the environment after passing through waste water treatment plants."<sup>5</sup>

A study by the Department of Ecology and the U.S. Environmental Protection Agency reports on the benefits of advanced wastewater treatment technologies in removing the trace elements of pharmaceuticals and personal care products from the environment. The study found that:

Results of this screening indicate that the combination of enhanced biological nutrient removal and filtration processes provides the greatest PPCP [Pharmaceuticals and Personal Care Products] removal.<sup>6</sup>

Compared to effective wastewater treatment, mandatory take-back programs do almost nothing for the environment, but they do increase the cost of medicine for patients.

The U.S. Environmental Protection Agency and the Office of National Drug Control Policy have issued clear directives for the effective disposal of unused or unwanted drugs. The federal rules "are designed to reduce the diversion of prescription drugs, while also protecting the environment."<sup>7</sup> These standards call for the disposal of unused or unwanted drugs by placing them in protected landfills, not flushing them into the sewer system.

<sup>&</sup>lt;sup>4</sup> "What is the overall scientific concern," Frequent Questions, U.S. Environmental Protection Agency, accessed November 31, 2011, at www.epa.gov/ppcp/faq.html.

<sup>&</sup>lt;sup>5</sup> "How to Dispose of Unused Medicines, Environmental Concerns," U.S. Food and Drug Administration, accessed December 2, 2011, at www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm.

<sup>&</sup>lt;sup>6</sup> "Pharmaceutical and Personal Care Products in Municipal Wastewater and their Removal," Control of Toxics in Puget Sound, U.S. Environmental Protection Agency, Washington state Department of Ecology, and Puget Sound Partnership, Publication Number 10-03-004, January 2010, at www.ecy.wa.gov/pubs/1003004.pdf.

<sup>&</sup>lt;sup>7</sup> U.S. Environmental Protection Agency and the Office of National Drug Control Policy, press release, February 20, 2007.

The focus of these new guidelines is educating the consumer on proper and safe methods of disposal. These include removing drugs from original containers and mixing them with undesirable substances, like coffee grounds and sealing them in an impermeable container before throwing the unused drugs in the trash.

Rather than imposing ineffective mandates, lawmakers should encourage more research so scientists can pinpoint the cause of the pharmaceuticals appearing in the environment. This research should be directed at answering the following questions:

- What is the cause and source of these trace elements?
- What impact, if any, do these trace elements have?
- What amounts of drugs go unused or unwanted?
- What are the costs and benefits of diverting resources to mandatory drug take-back programs compared to providing appropriate funding to proven solutions?

By not overreaching, policymakers will be able to fulfill other obligations that have greater and more immediate impacts on the environment. Thinking passage of mandatory drug take-back legislation will help the environment ignores the scientific findings related to the disposal of drugs in the environment. Even with maximum enforcement, a state drug take-back mandate would do little to protect the environment if the true source of trace elements in groundwater lies somewhere else. In addition, trying to reduce the very minimal impact unused drugs have on the environment shows a failure by lawmakers to prioritize more serious threats to the environment.

## **Policy Recommendations**

1. Lawmakers in Olympia should avoid imposing a costly mandatory drug take-back program on Washington citizens and businesses.

There is little evidence drug take-back mandates reduce the presence of trace elements in the environment, because current research has not identified the source of these elements, but mandates do increase the cost of medicines for Washington citizens.

2. Policymakers should encourage the disposal of unwanted medicines in a way that is simple and effective.

Managed landfills are designed to protect groundwater from all forms of pollution that could come from municipal waste. Disposal of expired or unwanted medicines in the managed trash stream, rather than into the sewer system, would insure that traces of drug elements do not find their way into the groundwater.

3. Policymakers should seek additional research to determine the source of trace drug elements in the environment.

Before imposing new laws, lawmakers need more information about how very small levels of drug elements get into groundwater in the first place. Once the source has been identified, new regulations can be developed as needed to reduce or eliminate it.

Paul Guppy is Vice President for Research at Washington Policy Center, a non-partisan independent policy research organization in Washington state. Nothing here should be construed as an attempt to aid or hinder the passage of any legislation before any legislative body. For more information, visit washingtonpolicy.org.