

## Key Findings

- In Washington, tests of drinking water in two major metropolitan areas have shown no traces of drugs.
- A mandatory drug take-back program would increase the cost of medicines sold in Washington, and it would be difficult to measure if the program was effective at reducing trace elements in the environment.
- The trace levels of substances such as caffeine and Ibuprofen are so low that a person would have to consume hundreds of years worth of the daily allotment of water to intake a single prescribed dose.
- Scientists have found no evidence of adverse human health effects from pharmaceuticals and personal care products as pollutants in the environment.

## Drug Take-Back Programs: What Will They Solve?

*Policymakers advocate regulation despite absence of science*

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### Introduction

What really is in our water? Increasingly, attention is being given to the water quality of area waterways, not only for our own personal health, but that of the overall environment.

For example, recent studies have shown that trace elements of pharmaceuticals, including prescription drugs and over-the-counter drugs, are showing up in many waterways around the world. This finding, along with others, is heightening the call to action to provide greater protections for our waterways.

There are many options before us that can help to improve our water quality and benefit the overall environment we live in. Drug take-back legislation, which requires pharmaceutical manufacturers to take back unused or unwanted drugs, is one policy lawmakers are considering.

Recent legislative efforts to change the policies impacting the disposal of pharmaceutical drugs all cite the same two or three studies. However, these studies do little to identify the true source of these trace elements, let alone explain what impact, if any, take-back programs will have on eliminating drugs in the environment. Additionally the proposed policies fall short of measuring the economic impacts or consequences of the legislative mandates.

The recent proposals create a patchwork of environmental solutions in an attempt to respond to the latest data or study. Unfortunately the latest reports have not yet been fully vetted in a way that would justify the proposed legislation.

As the trend toward mandating higher levels of environmental regulation continues, it will be important to weigh the cost of all proposals against the benefits in order to achieve the greatest impact.

### Measuring the Problem

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, according to a stream study program by the U.S. Geological Survey in 1999 – 2000, “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>1</sup>

The amounts 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>2</sup>

## Efforts at a Solution

Some lawmakers have proposed reducing the amount of trace elements from drugs that occur in waterways by requiring a 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, the 2000 U.S. Geological Survey notes that “The selection of sampling sites was biased toward streams susceptible to contamination (i.e. downstream of intense urbanization and livestock production).”<sup>3</sup>

The U.S. Geological Survey researchers selected streams that would most likely show the maximum amounts of trace elements from drugs present. A more representative selection of stream sites would have given a more accurate picture of the true prevalence of trace elements in the environment. A broader sample also would have made it possible to measure average amounts of trace elements, not just maximum levels.

In fact, in Washington State, tests of drinking water in two major metropolitan areas have shown no traces of drugs. The cities of Seattle and Spokane performed tests after being prompted by the findings of an AP study that revealed trace elements in other metropolitan area water sources. “We didn’t think we’d find anything because our water comes from a pristine source, but after the AP stories we wanted to make sure and reassure our customers,” said Andy Ryan, spokesman for Seattle Public Utilities.<sup>4</sup> In Spokane, after spending \$3,000 to test two city wells, results showed no traces of pharmaceuticals there as well.<sup>5</sup> Many streams and waterways may have similar results as those in Seattle and Spokane with no level of trace elements, thus affecting the overall results of an unbiased study.

As noted previously, the U.S. Geological Survey makes no effort to identify the source of trace elements from drugs. Improper disposal of unused drugs may not be the source to begin with, in which case a mandatory drug take-

<sup>1</sup> Pharmaceuticals, Hormones, and other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance; Kolpin, US Geological Survey.

<sup>2</sup> Pharmaceutical Manufacturer and Retailer Interests: Doug Finan (GlaxoSmithKline) and Leslie Wood (PhRMA) – Slide Show – April 18, 2008; <http://www.medicinereturn.com/resources/workshop/Slide1>.

<sup>3</sup> Pharmaceuticals, Hormones, and other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance; Kolpin, US Geological Survey.

<sup>4</sup> “Drugs found in more drinking water,” by Martha Mendoza, *Seattle PI*, September 9, 2008.

<sup>5</sup> “No drug in Spokane water,” by Mike Prager, *Spokesman Review*, August 21, 2008.

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back program would have no effect in reducing the presence of trace elements in streams and waterways.

It is even unclear how much of prescribed medications are not used by patients and are discarded. Some studies report only about three percent of prescribed medications go unused, but other reports say unused drugs may represent as much as fifty percent or more of all pharmaceuticals.<sup>6</sup>

## Proposed Legislation

Despite the lack of evidence pinpointing the source of pharmaceuticals in the environment, policymakers have elected to move forward in adopting programs that are aimed at solving a problem that has yet to be fully identified.

One example of a proposed mandatory drug take-back program is HB 3064, introduced in the 2008 Legislative Session.<sup>7</sup> The bill would require the collection of unused drugs from people's homes, and would not cover hospitals, clinics, nursing homes and other medical care facilities. The safe disposal of unused drugs at medical facilities is already covered by a directive issued by the Department of Ecology, the Interim Enforcement Policy.<sup>8</sup>

HB 3064 would have created a Product Stewardship Program to collect unused, unwanted or outdated drugs from private homes. Drug manufacturers would be required to pay for and operate the program, contributing to the already-rising cost of prescription drugs.

After a three-year phase-in period, all companies providing medicines in the state would be required to pay all collection, administrative, disposal and recycling costs of unused drugs. The program would be managed by the state Board of Pharmacy. Any company that failed to meet the costs and requirements of the program could be barred from selling medicines to Washington residents. As a result of this requirement residents of Washington could lose access to some pharmaceuticals.

A provision of the bill would make it illegal for a drug company to include the added cost of a mandatory take-back program in the price of its product. This provision is a price control and would certainly fail for several reasons. First, it would be impossible for the state to administer. The price of all consumer products increases for many reasons; state enforcers could never identify accurately why the price of a drug went up.

Second, drug company executives would have to account for the added cost of the program in other ways, through cut-backs in service or quality, restricting supply, or by increasing the cost of other products. Third, Washington's effort at price controls would create even further incentive for drug companies to withdraw from the Washington market, thus reducing the number of medicines available to Washington residents.

While the goals of HB 3064 may at first seem sensible, its practical

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<sup>6</sup> Household Pharmaceutical Disposed Issue Overview: Dave Galvin; Local Hazardous Waste Manager, King County, WA, April 18, 2008; [www.medicinereturn.com/reserouces/workshop](http://www.medicinereturn.com/reserouces/workshop).

<sup>7</sup> Substitute House Bill 3064 – Washington Legislature 2008; [www.washingtonvotes.org](http://www.washingtonvotes.org).

<sup>8</sup> Department of Ecology – Interim Enforcement Policy, Pharmaceutical Waste in Healthcare.

implementation would be costly and problematic. A mandatory drug take-back program would increase the cost of medicines sold in Washington, and it would still be difficult to measure whether the program was effective at reducing the presence of trace elements in the environment. This is especially true since it is not known whether unused drugs from private homes are the source of these elements in first place.

### **The PH:ARM Drug Collection Program**

In 2006, Washington began a program for drug disposal called PH:ARM, in cooperation with Group Health Cooperative. The program is voluntary and operates at over twenty pharmaceutical return locations in six counties across the state, mostly at Group Health clinics and independent pharmacies. To date, about 6,000 pounds of unused or unwanted drugs have been returned and properly disposed of through the program.<sup>9</sup> Due to the narrow scope of the PH:ARM program it is not clear if their collection efforts have resulted in a lower level of drugs showing up in Washington's waterways.

### **Programs in Other States and Countries**

The idea of a drug take back program is not new. Lawmakers in Maine, California and Iowa have passed legislation to develop similar programs. Additional programs exist in Canada, Australia, and throughout parts of Europe. Despite the similarities in the take back programs, there are significant differences compared with the producer program introduced as legislation in Washington.

In Maine, Iowa and Australia, the take-back programs are government sponsored and funded as pilot programs.

California's legislation passed in 2007 and requires the Pharmacy Board to develop a model program in conjunction with other state and local governments, as well as producers and suppliers of drugs. Funding for the California program was initially provided by the state, but as part of the model program the Pharmacy Board is to recommend long-term funding strategies.

The British Columbia Canada Medications Return Program operated by the Post Consumer Pharmaceutical Stewardship Association (PCPSA) is perhaps the most expansive drug take back program that exists. This program provides the pharmaceutical industry with a voluntary collective means of adhering to the requirements of the British Columbia Recycling Regulation and is funded by the pharmaceutical and self-care health product industries. The fees are collected by the association from brand-owners selling pharmaceuticals in British Columbia.<sup>10</sup>

According to the PCPSA, participants of the program do not pass along the cost of the program to consumers, but current law does not prohibit them from recouping cost if they choose. Costs are kept low in the British Columbia program, in part the PCPSA says, because of voluntary nature of their program.

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<sup>9</sup> Progress Report for Pharmaceuticals from Households: A Return Mechanism - [http://www.medicinereturn.com/resources/ed\\_materials/resources/ed\\_materials/PHARMProgressReport2Apr2008.pdf](http://www.medicinereturn.com/resources/ed_materials/resources/ed_materials/PHARMProgressReport2Apr2008.pdf).

<sup>10</sup> Post Consumer Pharmaceutical Stewardship Association – Medications Return Program: Annual Report 2006.

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For example, there are no legislative mandates that require the program to set goals for collections of drugs. Instead success in the B.C. Program is measured in two ways; first, on knowledge and awareness of the consumer about the program and second, by consumer behavior.

A common theme among all these programs is that these programs are voluntary and do not carry the burden of legislative mandates. Washington appears to be the only drug take-back program that would measure success based on the weight or size of recovery of drugs by the program. In fact, participation by consumers returning their drugs through take-back programs around the globe varies widely with the UK at 20%, Austria at 1%, and in France at 80%.<sup>11</sup>

Despite the various methods employed by each of the aforementioned programs, not one of them has provided data or research to show that they are reducing the amount of drugs in the environment. Perhaps a logical reason for the inability of these programs to measure their impact is the lack of understanding and research to identify where these drugs actually enter the environment.

## **Better Solutions**

As previously discussed in this paper, there is little doubt that manufactured pharmaceuticals are appearing in our waterways. The same studies showing caffeine at 25 ppt reveal additional data for trace elements of many other drugs including Ibuprofen. At the trace levels this drug is present in streams and waterways, a person would have to drink 180 years worth of the recommended daily allotment of water to ingest a single prescribed dose of Ibuprofen.<sup>12</sup>

However, given that we know that these trace elements of pharmaceuticals exist, there are solutions other than elaborate mandates targeted at the producers of drugs to plausibly reduce the level of trace elements or better the environment.

## **Approved Disposal Methods**

In February 2007 the White House Office of National Drug Control Policy along with the Department of Health and Human Services and the Environmental Protection Agency (EPA) issued a joint press release with new guidelines for the safe disposal of unused or unwanted drugs. The release stated that “the new guidelines ... are designed to reduce the diversion of prescription drugs, while also protecting the environment.”<sup>13</sup> 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 them sealing them in an impermeable container before throwing the unused drugs in the trash.

Along with supporting the new standards for proper drug disposal, the EPA acknowledges research that shows pharmaceutical drugs are showing up in the environment. However the EPA also points out that, “More research is needed

<sup>11</sup> Pharmaceutical Manufacturer and Retailer Interests: Doug Finan (GlaxoSmithKline) and Leslie Wood (PhRMA) - Slide Show April 18, 2008 found at <http://www.medicinereturn.com/resources/workshop> Slide 3.

<sup>12</sup> Ibid.; Slide 1.

<sup>13</sup> Office of National Drug Control Policy – Press Release, February 20, 2007.



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to determine the extent of ecological harm and any role it (drugs) 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>14</sup>

Certainly these new standards put much of the burden on the consumer to understand and follow through with these guidelines. But this is no different than the Canadian program that measures success through consumer awareness and behavior. To assist with these standards many pharmaceutical manufactures participate in programs, such as PhRMA’s SMARxT Disposal program, to provide consumers with information on proper disposal methods.

## Opportunity Cost

Any new mandate comes with opportunity costs: consuming resources that cannot be used elsewhere. Putting limited public effort into creating and enforcing a mandatory drug take-back program would pull energy and resources away from initiatives that would do much more to improve water quality at much less cost. For example, nearly 2,500 miles of high-quality salmon habitat are blocked by state highways and roads. Over 1,670 drainage culverts obstruct the free flow of water and prevent migrating salmon from reaching clean, protected spawning grounds.<sup>15</sup>

Putting state resources into enlarging drainage culverts would achieve more for water quality and salmon populations, and achieve it faster, than the questionable benefit that might come from implementing a mandatory drug take-back program.

The problem of opportunity cost is discussed by Denmark professor Bjørn Lomborg in his book *Cool It*. He suggests that applying scarce time and resources in a way that gains the most benefit can be applied to all areas of protecting the environment. He writes “We need to get our perspective back. There are many more pressing problems in the world ... by addressing them we can help more people, at lower cost, with much higher chance of success.”<sup>16</sup>

## Conclusion

There is no argument that trace elements of pharmaceuticals are showing up in the environment. Unfortunately there is no consensus or data that helps to pinpoint the source. Despite the lack of data that clearly identifies improper disposal of unused or unwanted drugs as the contaminant to our waterways, policymakers have been quick to act by proposing take-back programs that may or may not have any effect at resolving a perceived problem.

This paper has shown that proposals in Washington State to place the burden on drug manufacturers are premature and a result of limited studies. Before any further legislation attempts to mandate producer led take-back programs, policymakers should try and answer the following questions that to date

<sup>14</sup> United States, Environmental Protection Agency – Frequent Questions; <http://www.epa.gov/ppcp/faq.html>, Aug. 1. 2008.

<sup>15</sup> Policy Guide for Washington State, Washington Policy Center, Guppy; p. 82.

<sup>16</sup> *Cool It*, Knopf, Bjorn Lomborg, 2007, p. 8.

remain unknown.

- What is the cause and source of these trace elements?
- What amounts of drugs go unused or unwanted?
- What are the costs and benefits of diverting resources to these programs versus providing appropriate attention to identified solutions?

Existing take back programs, unlike Washington's proposed program, do not have goals that are based on knowing the answers to the previous questions. In fact, although these programs have producers and manufactures as part of the process, much of the burden is on the consumer much like the federal guidelines for proper disposal. Even the PH:ARM pilot project's announcement of over 6,000 pounds collected of unused drugs is largely irrelevant without being able to quantify the need for collections.

A more sensible approach to dealing with this issue would be for policymakers to encourage more research to pinpoint the cause of the pharmaceuticals appearing in the environment. By not overreaching on this issue policymakers will be able to fulfill other obligations that have greater and a more immediate impact on the environment.

Again, the idea of the state following through with rebuilding state-owned culverts provides a prime example of the improvements that can be made if we properly prioritize based on cost and benefits for the environment. For example speeding the pace of WSDOT's culvert rebuilding projects would set the stage for even greater expansion of salmon habitat. Private landowners whose roads block salmon streams are not required to make any improvements as long as there is a downstream impediment. Rapidly making repairs on WSDOT roads would force the removal of barriers on private land farther upstream.<sup>17</sup>

Although the Puget Sound Partnership has made drug take-back a prominent piece of its recently released Action Agenda it does not remove the need to answer the basic questions that science has yet to yield, especially before we mandate time and resources to unproven methods.

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<sup>17</sup> Policy Guide for Washington State, Washington Policy Center, Guppy; p. 84.