

Feds Mull Regulating Drugs in Water

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Federal regulators under President Barack Obama have sharply shifted course on long-standing policy toward pharmaceutical residues in the nation's drinking water, taking a critical first step toward regulating some of the contaminants while acknowledging they could threaten human health.

A burst of significant announcements in recent weeks reflects an expanded government effort to deal with pharmaceuticals as environmental pollutants:

- For the first time, the Environmental Protection Agency has listed some pharmaceuticals as candidates for regulation in drinking water. The agency also has launched a survey to check for scores of drugs at water treatment plants across the nation.
- The Food and Drug Administration has updated its list of waste drugs that should be flushed down the toilet, but the agency has also declared a goal of working toward the return of all unused medicines.
- The National Toxicology Program is conducting research to clarify how human health may be harmed by drugs at low environmental levels.

The Associated Press reported last year that the drinking water of at least 51 million Americans contains minute concentrations of a multitude of drugs. Water utilities, replying to an AP questionnaire, acknowledged the presence of antibiotics, sedatives, sex hormones and dozens of other drugs in their supplies.

The news reports stirred congressional hearings and legislation, more water testing and more disclosure of test results. For example, an Illinois law goes into effect Jan. 1 banning health care institutions from flushing unused medicine into wastewater systems.

The EPA's new study will look for 200 chemical and microbial contaminants at 50 plants that treat drinking water. The list includes 125 pharmaceuticals or related chemicals. This research will help federal water officials decide if regulations are needed.

In the first move toward possible drinking-water standards, the EPA has put 13 pharmaceuticals on what it calls the Contaminant Candidate List. They are mostly sex hormones, but include the antibiotic erythromycin and three chemicals used as drugs but better known for other uses.

They join a list of 104 chemical and 12 microbial contaminants that the EPA is considering as candidates for regulation under the Safe Drinking Water Act. No pharmaceutical has ever reached the list in its 12-year history, but medicines now

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make up 13 percent of the target chemicals on the latest list "based on their potential adverse health effects and potential for occurrence in public water systems," the EPA said.

They take a place beside such better-known contaminants as the metal cobalt, formaldehyde, the rocket fuel ingredient perchlorate, and the disease germ E. coli.

"I think this does signal a change in the regulatory and research approaches," said Conrad Volz, a University of Pittsburgh scientist whose research raises questions about the risk of eating fish from waters contaminated with sex hormones. "What's happening is pretty amazing."

Several scientists within and outside government tied the stronger focus on human health to the Obama administration and the president's appointment of Lisa Jackson, a highly regarded former head of the New Jersey Department of Environmental Protection, to run the EPA.

"I think we are trying to be as aggressive as we can. We understand it's a major national issue. We understand it's a major public concern," said Peter Silva, the new water administrator at the EPA.

However, making the candidate list provides no assurance that a chemical will reach full-blown regulation. In fact, no chemical on the list has ever been made subject to a national water quality standard, EPA officials acknowledge. They intend to make preliminary decisions on some of the latest contaminants by mid-2012.

"They've made a lot of good first steps, so now were waiting to see those carried through," said Nneka Leiba, a researcher at the Environmental Working Group in Washington.

Water utilities and drug makers are wary of the federal moves. Difficult scientific questions remain over the possible threat posed to humans by minuscule concentrations in drinking water, where drugs are typically found in parts per billion or trillion. That's way below medical doses.

However, some researchers fear that very small daily amounts of unwanted drugs in water could do cumulative harm to people over decades, possibly in combination with other drugs or in sensitive populations like children or pregnant women.

Alan Goldhammer, a vice president of the Pharmaceutical Research and Manufacturers of America, said such trace amounts "really do not pose a human health issue."

"We do get concerned if we think that somebody is going to require that the consumers spend money and not get any health benefit," added Tom Curtis, a lobbyist for the Denver-based American Water Works Association.

The U.S. Geological Survey first began taking notice of pharmaceutical contamination several years ago. But until now the federal government has focused

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on the presence of pharmaceuticals in rivers and streams.

A recently released EPA study found more than 40 pharmaceuticals - everything from antibiotics to heart medicine to antidepressants - at nine publicly owned wastewater treatment plants. The drugs appeared in concentrations measured in parts per billion and trillion. Many passed right through the plants.

Linda Birnbaum, who is director of the National Institute of Environmental Health Sciences and also oversees the National Toxicology Program, said some program research is focusing on how much environmental pharmaceuticals can reach animal blood and tissues and how that might compare with humans.

Waste pharmaceuticals reach the environment when people take medicine and excrete the unmetabolized portion. Millions of pounds of waste drugs also escape into waterways from hospitals, drug plants and other factories, farms and the drains of American homes, the AP has reported.

On its new list, the FDA, which regulates medicines, says only 10 active ingredients in controlled-substance drugs need to be flushed to keep them away from children, abusers and pets.

At the same time, the agency announced it is working with partners to develop programs to return unused drugs instead of flushing them down the drain. The agency wants "to encourage their development and future use for all drugs," declared Dr. Douglas Throckmorton, deputy director of the FDA's Center for Drug Evaluation and Research. Returned drugs are usually incinerated, which destroys most active ingredients. Community drug takeback programs have increased considerably since the AP's PharmaWater reports.

The recent announcements have been striking in their speed and breadth. Just last year, Ben Grumbles, Silva's predecessor at the EPA Office of Water under President George W. Bush, said only one pharmaceutical was under consideration for the list of candidates for water standards. And it was the heart medicine nitroglycerin, better known as an explosive.

Yet some environmentalists say the government should take even bolder action. "Identifying the nature and scope of the problem is not the same thing as addressing the causes of the problem," said George Mannina, an environmental lawyer in Washington.

He said the EPA should do more to keep drugs out of the nation's water supplies and not rely on expensive filtering systems at water treatment plants.

Jon Holder, a vice president at Vestara, a seller of equipment to manage waste drugs, said the EPA should be more aggressive about enforcing hazardous waste laws that already apply to some drugs used by hospitals.

"We applaud the light that's being shined on it, but we also recognize that the simple enforcement of existing law would go a long way," he said.

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For more information, visit the EPA Contaminant Candidate List via www.epa.gov/ogwdw000/ccl/ccl3.html [1] or the FDA flush list via www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm [2].

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