



# The United Sludge-Free Alliance Recommended Reading

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## **No standards, no mandates to test, treat or limit pharmaceuticals in water**

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### **Tainted Water**

Just a century ago, historic Philadelphia, notched by the Delaware and Schuylkill, treated these rivers as public sewers, but few cared until the waters ran black with stinking filth that spread cholera and typhoid. Today, municipal drinking water is cleansed of germs - but not drugs.

Traces of 56 human and veterinary pharmaceuticals or their byproducts - like the active ingredients in medicines for pain, infection, high cholesterol, asthma, epilepsy, mental illness and heart problems - have been detected in Philadelphia's drinking water. Starting their winding journey in medicine cabinets and feed bins, they are what's left of drugs excreted or discarded from homes and washed from farms upriver.

Is Philadelphia worried? Not so far. Tens of millions of Americans here and elsewhere drink water that has tested positive for minute concentrations of pharmaceuticals, and they don't even realize it, The Associated Press learned during a five-month investigation.

Though U.S. waterways coast to coast are contaminated with residues of prescription and over-the-counter drugs, there's no national strategy to deal with them - no effective mandates to test, treat, limit or even advise the public.

Water cleaning technologies present challenges - some work better than others Benjamin H. Grumbles, the U.S. Environmental Protection Agency's assistant administrator for water, told the AP the agency recognizes that this contamination in water supplies is a growing concern and that government has some catching up to do: "Our position is there needs to be more searching, more analysis."

He said the EPA has launched a four-pronged approach: to identify the extent of the problem, to "identify what we don't know and close the gap," to take steps using existing science and regulatory tools, and finally, to increase dialogue and awareness with water providers and state and local agencies.

But none of those goals has any regulatory firepower.

Some researchers, environmentalists, health professionals, water managers and bureaucrats say it's time for government to do more.

"The onus has been on the scientific community to provide the research, but at this point the evidence is conclusive," says U.S. Geological Survey scientist Steven Goodbred, who has studied carp in drug-tainted waters. "Now it's up to the public and policy makers to decide what they want to do about it."

Yet water regulators are barely budging:

The government has set no national standards for how much of any

pharmaceutical is too much in waterways or taps. Drugs in the environment are "not currently a priority" of the National Center for Environmental Health, says spokesman Charles L. Green, at its parent U.S. Centers for Disease Control.

Though the Food and Drug Administration can review the environmental impact of new drugs, it has never rejected one on this basis, according to Raanan Bloom, an FDA environmental officer. Most pharmaceuticals are excluded from environmental review on the basis of their presumed low concentrations in water.

Even though residues of many types of prescription and over-the-counter drugs have been discovered in scores of watersheds and drinking water systems nationwide, the EPA says it awaits more survey data before considering action. The agency has little information "that goes into whether these substances are occurring in the environment ... and at what level," says Suzanne Rudzinski, a manager at EPA's Office of Water.

But even when the EPA says it's taking action, little is accomplished. The agency analyzed 287 pharmaceuticals for inclusion on a draft list of contaminants to be considered for regulation. Only one, nitroglycerin, which can be used as a drug for heart problems, has been nominated. Asked to explain, an EPA spokesman acknowledged the primary reason for inclusion was its use in making explosives.

Though pharmaceutical sales are rising, plants that cleanse sewage or drinking water are not required to remove drugs. They aren't even required to monitor for them.

When contacted directly by the AP, many water utilities confirmed whether they had tested for the presence of pharmaceuticals in their water. But federal agencies and industry groups declined to identify the cities and treatment plants where traces of pharmaceuticals had been found during independent studies, citing confidentiality concerns.

Philadelphia has found more pharmaceuticals in its source and drinking waters than any of the other 61 big water providers surveyed by the AP. It tested for more drugs and byproducts than other utilities - a total of 72 - and it found 56, or three-quarters of those checked, in its drinking water. It found 63 - almost 90 percent of those checked - in its source waters. More study is planned.

However, water managers detected scant concentrations similar to other places, suggesting they found so much largely because they tested for a larger list of pharmaceuticals - not necessarily because their watersheds are more contaminated. David A. Katz, a deputy water commissioner for the city, said the water was tested so heavily out of vigilance: "We choose to know; we choose to look."

Under no obligation to tell, Philadelphia keeps it quiet when tests show that drugs have reached its drinking water, the AP found. Philadelphia Water Department spokeswoman Laura Copeland provided the findings for an AP survey but added: "We don't want to create any perception where people would be alarmed."

John Muldowney, who oversees the city's three drinking water treatment plants, said no immediate upgrades are planned to filter out pharmaceuticals. "Based just on the data that's available now ... we would be risking spending a lot of money, a lot of public funds, for very little health benefit," he explained.

Government leaders seem largely to share that attitude. "We're not really doing anything on this right now," says a spokesman for U.S. Sen. Harry Reid, D-Nev., though he has earmarked funds in the past to study environmental drugs in his state.

Congress held hearings in 2006 on endocrine-disrupting compounds after researchers discovered that the Potomac River, dotted with sewage treatment plants, contains feminized male bass which create egg yolk proteins, a process usually restricted to females. But the hearings produced no new proposals.

In Boston, drug makers, state representatives and water managers have been grinding through their third year trying to craft a compromise approach to dealing with the problem on a national scale. Scott Cassel, director of the Product Stewardship Institute, which is hosting the dialogue, says controlling waterborne pharmaceuticals will make the disposal of old computers "seem simple by comparison."

"There's definitely a growing movement and a growing concern, but at this point there isn't a lot of direction from the federal government," adds Susan Frechette, a policy expert at the institute.

Grumbles, the EPA's top water pollution official, said the agency has embarked on four studies specific to the presence of pharmaceuticals and personal care products in wastewater and fish tissue. One "national study," expected to be completed next year, will look at the inflow and outflow at nine sewage plants; another will study sludge from 74 randomly selected sewage treatment plants.

The fish tissue study will focus on five streams where the flow primarily originates at a sewage treatment plant.

Just two months ago the agency developed three new methods to detect and quantify about 160 different pharmaceuticals and personal care products, including steroids and hormones, in wastewater and sewage sludge, Grumbles said.

A year ago, the federal government put out its first consumer guidelines for discarding leftover or expired medicines. The goal was to slow the flow of drugs flushed down the toilet. Though Grumbles acknowledged that human excretions are the major factor in spreading pharmaceuticals through the waste stream, he said it is important for all Americans to realize "the toilet is not a trash can."

But the guidelines immediately drew criticism from some environmentalists, water treatment experts and pharmaceutical researchers who say they are contradictory, confusing, and don't solve the problem.

The guidelines say that about a dozen specific drugs should still be flushed down the toilet to keep others from finding and abusing them. The rest should be mixed with something unsavory like coffee grounds and tossed into the trash. That just moves the problem, though: The drugs end up at landfills, where they can slowly seep into the groundwater.

The EPA is also engaged in a national study - expected to be completed by the end of the summer - to examine how long-term health care facilities and nursing homes dispose of pharmaceuticals.

"We don't really know what to do with waste pharmaceuticals," acknowledges Laura Brannen, executive director of the professional group Hospitals for a Healthy Environment.

The government barely oversees drugs spilled or tossed by hospitals and drug makers. Discharge limits for drug makers concentrate on chemicals used in manufacturing, not the drugs themselves; Virginia Cunningham, an environmental executive at drug maker GlaxoSmithKline PLC, says the industry spills very little of the drugs that turn up in waterways.

At hospitals, the EPA flags about three dozen specific drugs as hazardous waste. Though their dangers are acknowledged, the rules for special disposal have been casually observed, according to environmental specialists in the industry. They say many hospitals still dump some of those hazardous pharmaceuticals into their other garbage.

Also, the list hasn't been updated for years and ignores scores of troublesome newer drugs, including toxic chemotherapy agents.

"It has not been practical or economical to keep pace with the large number of pharmaceuticals developed, approved ... and marketed each year," explains EPA spokeswoman Roxanne Smith.

And what of the drug waste generated by millions of U.S. households? It's exempt from these rules. The EPA again says it would be impractical to act.

In fairness, even those pressing for action realize that regulators must strike a hard balance between potential benefits and costs. Several recent studies indicate that even very dilute pharmaceuticals can harm human cells, but scientists are still unsure if there's a significant health risk from drinking water with trace drugs.

Environmental standards focus on better-understood contaminants from disease-causing germs to manmade dioxins. The government also is pondering a raft of newly identified water contaminants in many products from cosmetics to vitamins - not just in pharmaceuticals.

The government has tried to narrow the focus of much of its drugs-in-water research to powerful hormones that orchestrate reproduction and development and omnipresent antibiotics that strengthen the very germs in the environment that they're meant to kill in the body.

"This is a complex issue because each and every one of us is a part of this problem. But there's no doubt we need a new standard of wastewater treatment. If the limits were there, believe me when I say it could be done," argues environmental toxicologist Greg Moller, at the University of Idaho. As with global warming, some cities and states have tried to forge ahead, even without strong federal direction. Small pilot programs and one-day pickups of unused drugs have popped up in the Northeast, California, Washington state, Florida, and elsewhere.

Maine is preparing to accept unwanted pharmaceuticals on a grander scale. The federal and state governments have split the \$300,000 cost to launch a four-county trial in coming months. Pharmaceutical buyers will take home prepaid mailers to send drug leftovers to a way station, where most will be picked up for transport to incinerators. Organizers intend eventually to roll out the program statewide.

Drug pollution stirs more anxiety in Europe, Canada and Australia, and officials in those places have acted more aggressively to reclaim unused drugs. A French program recaptured about 6,500 tons at drug stores in 2005, managers estimate. Two-thirds of the French say they participate, according to one poll.

That program is run by Jacques Aumonier, an environmental officer for Cephalon, Inc., a Pennsylvania-based biopharmaceuticals firm. He said pharmaceutical levels in water may be modest now, "but with more and more drug use, it can become more important."

Some researchers and activists want to catch and stop drugs from entering waterways at both types of water treatment plants - those for sewage and for drinking water. Standard techniques allow many to slip through, research shows. It seems possible to remove virtually all detectable pharmaceutical traces with an advanced treatment known as reverse osmosis, and hotter incinerators also could burn more drugs.

But all that is viewed as too expensive and maybe unnecessary, at least until the threat is better understood.

"When there's no regulation or limit, and no evidence of human health impacts, it's very hard to justify putting in energy and money to test for it," said Shane Snyder, research and development project manager at the Southern Nevada Water Authority in Las Vegas. Never mind spending much more to remove it.

Some critics want drug companies to design medicines that break down more easily into safer byproducts. "In the long run ... we can at least make some of the compounds greener," says chemist Klaus Kuemmerer, at the University of Freiburg Medical Center in Germany.

However, that would come "a distant third" after designing drugs for effectiveness and safety, says Cunningham of GlaxoSmithKline.

In coming years, public pressure is likely to grow, as more pharmaceuticals find their way into less water. Drug use is expanding in many countries, and more communities will need to recycle treated wastewater for drinking to cope with increased demand, drought, and global warming.

At the same time, today's chemical tests that reveal pollutants in parts per trillion will no doubt be able to detect even finer levels in the future. The added knowledge may not equal bliss, though.

"There isn't such a thing as 100 percent pure water," said EPA scientist Christian Daughton, one of the first to sound warnings over pharmaceutical pollution. "Yet people have a tough time with the idea that water contains all kinds of chemicals."

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