HHS COMMITTEE #1
October 20, 2011

Discussion

MEMORANDUM

October 18, 2011

TO: Health and Human Services Committee

FROM: Keith Levchenko, Senior Legislative Analyst

SUBJECT: **Discussion:** Household Pharmaceutical Disposal Issues

The following officials and staff are expected to participate in this discussion

- Dr. Ulder Tillman, County Health Officer
- Dan Locke – Chief, Division of Solid Waste Services (DSWS), Department of Environmental Protection (DEP)
- Eileen Kao – Chief, Waste Reduction and Recycling Section, DSWS, DEP
- Dr. Mohammad Habibian, Environmental Group Leader, Washington Suburban Sanitary Commission (WSSC)
- Christopher Brous, Chief of Police, WSSC
- Sheila Brous, Office of Intergovernmental Relations, WSSC
- Lieutenant Marcus Jones, Montgomery County Police Department
- Steven Bieber, Metropolitan Washington Council of Governments
- Howard Schiff, Executive Director, Maryland Pharmacists Association
- Peggy Funk, Assistant Executive Director, Maryland Pharmacists Association
- Marc Isaacson, President, Village Green Apothecary

Background

In March 2008, the Associated Press released several reports (see ©1-14) after a 5 month inquiry that noted that tests had detected trace concentrations (parts per billion or parts per trillion) of pharmaceuticals in the drinking water supplies of at least 46 million people in two dozen metropolitan areas in the United States, including the Washington, DC metropolitan area.

Pharmaceuticals are assumed to be getting into the water supply via local wastewater systems. The human body does not absorb all of a medicine ingested, and a portion is passed through the body and flushed down the toilet. Unused medicines are also finding their way into local waterways after people pour them down a drain or flush them down a toilet.

While research to date does not demonstrate a short-term/immediate human health risk from trace concentrations of pharmaceuticals that may be present in drinking water, potential long-term effects are unknown.

There are also concerns regarding the effects of pharmaceuticals in waterways on aquatic populations.

WSSC's perspective on this issue is attached (see ©15-23). WSSC staff will be available to describe the water testing results to date and efforts WSSC is pursuing regarding this issue.

Recommended Disposal Practices

As a result of the concerns noted above, household disposal recommendations have evolved in recent years.

An Environmental Protection Agency (EPA) information sheet on proper disposal of medicines is attached on ©24-25 and suggests utilizing a drug "take-back" program, if possible. The second choice is to dispose of the medicines in the trash (mixing and diluting the medicine in other trash first) to prevent scavenging. Flushing medicines or pouring medicine down a sink are specifically not recommended, unless the label or accompanying patient information guidance instructs one to do so.

Information on the United States Food and Drug Administration (FDA) website (attached on ©26-30) also recommends utilizing "take-back" programs and otherwise disposing of medicines in household trash. The FDA identifies a list of particularly powerful medicines which are recommended for flushing down the toilet, to reduce the danger of unprescribed use (see ©29).

The SMARxT Disposal Public Awareness Campaign (http://www.smarxtdisposal.net/index.html), a public-private partnership between the U.S. Fish and Wildlife Service, the American Pharmacists Association, and the Pharmaceutical Research and Manufacturers of America, encourages people to dispose of unused medication in their household trash rather than flushing it down the toilet or pouring it down a sink or drain. The campaign does note that some medications are recommended by the FDA to be flushed.

The Montgomery County DEP website (excerpt attached on ©31-32) echoes the FDA instructions. The DEP site also provides links to organizations that promote the donation of unused medicines to needy populations.

"Take Back" and Drop-Off Programs

The Drug Enforcement Administration (DEA) organizes a semi-annual National "Take Back" program throughout the country, in coordination with local law enforcement authorities.[1] Lt. Marcus Jones of the Montgomery County Police Department will be available at the Committee meeting to discuss how the DEA Take Back program works in Montgomery County.

[1] According to a press release from the Montgomery County Police from the last "Take Back" day (April 30, 2011), the pharmaceuticals collected are incinerated by the DEA, according to State and Federal guidelines.

The next "Take Back" day is on October 29. There are five "Take Back" locations in Montgomery County (including the Bethesda, Germantown, and Rockville District police stations) and numerous others in the DC area. More details regarding this program (as well as "Take Back" locations) are available at: http://www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html.

Take Back programs are particularly well-suited for controlled substance pharmaceuticals, since there are significant federal handling requirements for these types of pharmaceuticals (see ©33).

Some pharmacies provide for customer drop-off of some drugs. Because of the issues noted above regarding controlled substances, these drop-off locations only accept non-controlled substances. The website (www.disposemymeds.org) notes two independent pharmacies in Montgomery County that provide drop-offs: Village Green Apothecary in Bethesda and Village Pharmacists in Montgomery Village.

A representative of Village Green Apothecary will be available at the Committee meeting to discuss his pharmacy's drug drop-off program. A representative from the Maryland Pharmacists Association will also be available to discuss pharmacy drug drop-off efforts statewide.

Legislation

HHS has provided some background information on State and Federal laws regarding the disposal and potential donation of unused pharmaceuticals (see ©34-39), as well as information on currently approved drop-off sites and repositories. A summary of recent legislation is provided below:

- The State of Maryland passed SB1059 in 2006 that established the Prescription Drug Repository program, by which individuals that have unopened medication and unused medical supplies can donate them at a designated pharmacy. However, the program has had a difficult startup, due to the costs and liabilities to become a repository and/or drop-off site.

- In the 2011 legislative session, HB460 was enacted that expands the purpose of the Prescription Drug Repository Program to include acceptance of prescription drugs and medical supplies returned to a pharmacy for proper disposal. Each pharmacy for which a pharmacy permit has been issued must dispose of prescription drugs or medical supplies in accordance with program policies. A number of independent pharmacies have joined this program, although none are in Montgomery County, according to the current list on the Maryland Pharmacy Board website: (http://dhmh.maryland.gov/pharmacyboard/verifications/DrugRepository.htm)

- HB3 "Pharmacies - Taking Back and Disposing of Unused Drugs" was also considered during the 2011 Maryland Legislative Session. This bill would have required specified pharmacies to take back and dispose of unused prescription and nonprescription drugs in accordance with guidelines established by the FDA. The bill failed to pass the House and was not considered in the Senate.

- At the Federal level, in October 2010, the President signed into law S3397 "Secure and Responsible Drug Disposal Act of 2010", which provides states and localities the authority to collect expired, unused, or unneeded prescription drugs. Federal regulations will need to be put in place to implement this law. When in place, this program is expected to supersede the DEA "Take Back"

days noted earlier.

- Most recently, H.R. 2939 – "Pharmaceutical Stewardship Act of 2011" – was introduced on September 15, 2011 by Congresswoman Louis Slaughter (D-NY). This bill would create a National Pharmaceutical Stewardship Organization that, once established, would have 2 years to implement a national pharmaceutical stewardship program. The stewardship program would provide for the safe disposal of drugs. H.R. 2939 would be funded by drug manufacturers and brand owners.

Questions

1. Given the fact that pharmaceuticals are ending up in regional waterways and that proper disposal in the trash of unused medicines reduces this volume and also effectively prevents future illicit use of medicines, why are some medicines still recommended to be flushed down the toilet by the FDA? In addition to resulting in some of the most potent drugs being put in WSSC's wastewater system, does this approach send a mixed message to the public and likely lead to other drugs not on the flush list also being disposed of in this manner?

2. Does household pharmaceutical disposal in the trash (with an ultimate destination of the County's Resource Recovery Facility (RRF) for incineration) create any operational or environmental issues for Montgomery County?

3. For jurisdictions that landfill their trash, are there operational or environmental issues associated with disposing of pharmaceuticals in the trash?

4. For the pharmacies that provide a customer drop-off for some pharmaceuticals, what are the costs and other challenges of these programs? What is the ultimate destination of the collected pharmaceuticals? Are the pharmaceuticals incinerated or landfilled? What is the potential to expand drop-off programs at more pharmacies in the County?

5. Council Staff finds the concept of donating pharmaceuticals fraught with problems. While it is laudable to get unused medicines to needy populations, there appear to be many difficult issues, such as quality control and operational cost and complexity, for pharmacies. Also, none of the federal guidelines reference donation as an option.

6. Given the current recommendations for pharmaceutical disposal, is the current education and outreach effort sufficient, or are greater efforts needed? Should these efforts be coordinated regionally? Or, because of different disposal circumstances in various jurisdictions (i.e., landfilling versus incineration), does the message necessarily have to be tailored to each jurisdiction?

Attachments

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AN AP INVESTIGATION : Pharmaceuticals Found in Drinking W

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PHARMAWATER I

Pharmaceuticals found in drinking water, affecting wildlife and maybe humans

By JEFF DONN, MARTHA MENDOZA and JUSTIN PRITCHARD
Associated Press Writers

A vast array of pharmaceuticals including antibiotics, anti-convulsants, mood stabilizers and sex hormones have been found in the drinking water supplies of at least 41 million Americans, an Associated Press investigation shows.

To be sure, the concentrations of these pharmaceuticals are tiny, measured in quantities of parts per billion or trillion, far below the levels of a medical dose. Also, utilities insist their water is safe.

But the presence of so many prescription drugs and over-the-counter medicines like acetaminophen and ibuprofen in so much of our drinking water is heightening worries among scientists of long-term consequences to human health.

In the course of a five-month inquiry, the AP discovered that drugs have been detected in the drinking water supplies of 24 major metropolitan areas from Southern California to Northern New Jersey, from Detroit to Louisville, Ky.

Water providers rarely disclose results of pharmaceutical screenings, unless pressed, the AP found. For example, the head of a group representing major California suppliers said the public "doesn't know how to interpret the information" and might be unduly alarmed.

How do the drugs get into the water?

People take pills. Their bodies absorb some of the medication, but the rest of it passes through and is flushed down the toilet. The wastewater is treated before it is discharged into reservoirs, rivers or lakes. Then, some of the water is cleansed again at drinking water treatment plants and piped to consumers. But most treatments do not remove all drug residue.

And while researchers do not yet understand the exact risks from decades of persistent exposure to random combinations of low levels of pharmaceuticals, recent studies which have gone virtually unnoticed by the general public have found alarming effects on human cells and wildlife.

"We recognize it is a growing concern and we're taking it very seriously," said Benjamin H. Grumbles, assistant administrator for water at the U.S. Environmental Protection Agency.

Members of the AP National Investigative Team reviewed hundreds of scientific reports, analyzed federal drinking water databases, visited environmental study sites and treatment plants and interviewed more than 230 officials, academics and scientists. They also surveyed the nation's 50 largest cities and a dozen other major water providers, as well as smaller community water providers in all 50 states.

Here are some of the key test results obtained by the AP:

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drinking water, including medicines for pain, infection, high cholesterol, asthma, epilepsy, mental illness and heart problems. Sixty-three pharmaceuticals or byproducts were found in the city's watersheds.

_Anti-epileptic and anti-anxiety medications were detected in a portion of the treated drinking water for 18.5 million people in Southern California.

_Researchers at the U.S. Geological Survey analyzed a Passaic Valley Water Commission drinking water treatment plant, which serves 850,000 people in Northern New Jersey, and found a metabolized angina medicine and the mood-stabilizing carbamazepine in drinking water.

_A sex hormone was detected in San Francisco's drinking water.

_The drinking water for Washington, D.C., and surrounding areas tested positive for six pharmaceuticals.

_Three medications, including an antibiotic, were found in drinking water supplied to Tucson, Ariz.

The situation is undoubtedly worse than suggested by the positive test results in the major population centers documented by the AP.

The federal government doesn't require any testing and hasn't set safety limits for drugs in water. Of the 62 major water providers contacted, the drinking water for only 28 was tested. Among the 34 that haven't: Houston, Chicago, Miami, Baltimore, Phoenix, Boston and New York City's Department of Environmental Protection, which delivers water to 9 million people.

Some providers screen only for one or two pharmaceuticals, leaving open the possibility that others are present.

The AP's investigation also indicates that watersheds, the natural sources of most of the nation's water supply, also are contaminated. Tests were conducted in the watersheds of 35 of the 62 major providers surveyed by the AP, and pharmaceuticals were detected in 28.

Yet officials in six of those 28 metropolitan areas said they did not go on to test their drinking water Fairfax, Va.; Montgomery County in Maryland; Omaha, Neb.; Oklahoma City; Santa Clara, Calif., and New York City.

The New York state health department and the USGS tested the source of the city's water, upstate. They found trace concentrations of heart medicine, infection fighters, estrogen, anti-convulsants, a mood stabilizer and a tranquilizer.

City water officials declined repeated requests for an interview. In a statement, they insisted that "New York City's drinking water continues to meet all federal and state regulations regarding drinking water quality in the watershed and the distribution system" regulations that do not address trace pharmaceuticals.

In several cases, officials at municipal or regional water providers told the AP that pharmaceuticals had not been detected, but the AP obtained the results of tests conducted by independent researchers that showed otherwise. For example, water department officials in New Orleans said their water had not been tested for pharmaceuticals, but a Tulane University researcher and his students have published a study that found the pain reliever naproxen, the sex hormone estrone and the anti-cholesterol drug byproduct clofibric acid in treated drinking water.

Of the 28 major metropolitan areas where tests were performed on drinking water supplies, only Albuquerque; Austin, Texas; and Virginia Beach, Va.; said tests were negative. The drinking water in Dallas has been tested, but officials are awaiting results. Arlington, Texas, acknowledged that traces of a pharmaceutical were detected in its drinking water but cited post-9/11 security concerns in refusing to identify the drug.

The AP also contacted 52 small water providers one in each state, and two each in Missouri and Texas that serve communities with populations around 25,000. All but one said their drinking water

questions, also citing post-9/11 issues.

Rural consumers who draw water from their own wells aren't in the clear either, experts say.

The Stroud Water Research Center, in Avondale, Pa., has measured water samples from New York City's upstate watershed for caffeine, a common contaminant that scientists often look for as a possible signal for the presence of other pharmaceuticals. Though more caffeine was detected at suburban sites, researcher Anthony Aufdenkampe was struck by the relatively high levels even in less populated areas.

He suspects it escapes from failed septic tanks, maybe with other drugs. "Septic systems are essentially small treatment plants that are essentially unmanaged and therefore tend to fail," Aufdenkampe said.

Even users of bottled water and home filtration systems don't necessarily avoid exposure. Bottlers, some of which simply repackage tap water, do not typically treat or test for pharmaceuticals, according to the industry's main trade group. The same goes for the makers of home filtration systems.

Contamination is not confined to the United States. More than 100 different pharmaceuticals have been detected in lakes, rivers, reservoirs and streams throughout the world. Studies have detected pharmaceuticals in waters throughout Asia, Australia, Canada and Europe even in Swiss lakes and the North Sea.

For example, in Canada, a study of 20 Ontario drinking water treatment plants by a national research institute found nine different drugs in water samples. Japanese health officials in December called for human health impact studies after detecting prescription drugs in drinking water at seven different sites.

In the United States, the problem isn't confined to surface waters. Pharmaceuticals also permeate aquifers deep underground, source of 40 percent of the nation's water supply. Federal scientists who drew water in 24 states from aquifers near contaminant sources such as landfills and animal feed lots found minuscule levels of hormones, antibiotics and other drugs.

Perhaps it's because Americans have been taking drugs and flushing them unmetabolized or unused in growing amounts. Over the past five years, the number of U.S. prescriptions rose 12 percent to a record 3.7 billion, while nonprescription drug purchases held steady around 3.3 billion, according to IMS Health and The Nielsen Co.

"People think that if they take a medication, their body absorbs it and it disappears, but of course that's not the case," said EPA scientist Christian Daughton, one of the first to draw attention to the issue of pharmaceuticals in water in the United States.

Some drugs, including widely used cholesterol fighters, tranquilizers and anti-epileptic medications, resist modern drinking water and wastewater treatment processes. Plus, the EPA says there are no sewage treatment systems specifically engineered to remove pharmaceuticals.

One technology, reverse osmosis, removes virtually all pharmaceutical contaminants but is very expensive for large-scale use and leaves several gallons of polluted water for every one that is made drinkable.

Another issue: There's evidence that adding chlorine, a common process in conventional drinking water treatment plants, makes some pharmaceuticals more toxic.

Human waste isn't the only source of contamination. Cattle, for example, are given ear implants that provide a slow release of trenbolone, an anabolic steroid used by some bodybuilders, which causes cattle to bulk up. But not all the trenbolone circulating in a steer is metabolized. A German study showed 10 percent of the steroid passed right through the animals.

Water sampled downstream of a Nebraska feedlot had steroid levels four times as high as the water taken upstream. Male fathead minnows living in that downstream area had low testosterone levels

Other veterinary drugs also play a role. Pets are now treated for arthritis, cancer, heart disease, diabetes, allergies, dementia, and even obesity sometimes with the same drugs as humans. The inflation-adjusted value of veterinary drugs rose by 8 percent, to $5.2 billion, over the past five years, according to an analysis of data from the Animal Health Institute.

Ask the pharmaceutical industry whether the contamination of water supplies is a problem, and officials will tell you no. "Based on what we now know, I would say we find there's little or no risk from pharmaceuticals in the environment to human health," said microbiologist Thomas White, a consultant for the Pharmaceutical Research and Manufacturers of America.

But at a conference last summer, Mary Buzby director of environmental technology for drug maker Merck & Co. Inc. said: "There's no doubt about it, pharmaceuticals are being detected in the environment and there is genuine concern that these compounds, in the small concentrations that they're at, could be causing impacts to human health or to aquatic organisms."

Recent laboratory research has found that small amounts of medication have affected human embryonic kidney cells, human blood cells and human breast cancer cells. The cancer cells proliferated too quickly; the kidney cells grew too slowly; and the blood cells showed biological activity associated with inflammation.

Also, pharmaceuticals in waterways are damaging wildlife across the nation and around the globe, research shows. Notably, male fish are being feminized, creating egg yolk proteins, a process usually restricted to females. Pharmaceuticals also are affecting sentinel species at the foundation of the pyramid of life such as earth worms in the wild and zooplankton in the laboratory, studies show.

Some scientists stress that the research is extremely limited, and there are too many unknowns. They say, though, that the documented health problems in wildlife are disconcerting.

"It brings a question to people's minds that if the fish were affected ... might there be a potential problem for humans?" EPA research biologist Vickie Wilson told the AP. "It could be that the fish are just exquisitely sensitive because of their physiology or something. We haven't gotten far enough along."

With limited research funds, said Shane Snyder, research and development project manager at the Southern Nevada Water Authority, a greater emphasis should be put on studying the effects of drugs in water.

"I think it's a shame that so much money is going into monitoring to figure out if these things are out there, and so little is being spent on human health," said Snyder. "They need to just accept that these things are everywhere every chemical and pharmaceutical could be there. It's time for the EPA to step up to the plate and make a statement about the need to study effects, both human and environmental."

To the degree that the EPA is focused on the issue, it appears to be looking at detection. Grumbles acknowledged that just late last year the agency developed three new methods to "detect and quantify pharmaceuticals" in wastewater. "We realize that we have a limited amount of data on the concentrations," he said. "We're going to be able to learn a lot more."

While Grumbles said the EPA had analyzed 287 pharmaceuticals for possible inclusion on a draft list of candidates for regulation under the Safe Drinking Water Act, he said only one, nitroglycerin, was on the list. Nitroglycerin can be used as a drug for heart problems, but the key reason it's being considered is its widespread use in making explosives.

So much is unknown. Many independent scientists are skeptical that trace concentrations will ultimately prove to be harmful to humans. Confidence about human safety is based largely on studies that poison lab animals with much higher amounts.

There's growing concern in the scientific community, meanwhile, that certain drugs or combinations of drugs may harm humans over decades because water, unlike most specific foods, is consumed in sizable amounts every day.

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continuously over a half century, perhaps subtly stirring allergies or nerve damage. Pregnant women, the elderly and the very ill might be more sensitive.

Many concerns about chronic low-level exposure focus on certain drug classes: chemotherapy that can act as a powerful poison; hormones that can hamper reproduction or development; medicines for depression and epilepsy that can damage the brain or change behavior; antibiotics that can allow human germs to mutate into more dangerous forms; pain relievers and blood-pressure diuretics.

For several decades, federal environmental officials and nonprofit watchdog environmental groups have focused on regulated contaminants pesticides, lead, PCBs which are present in higher concentrations and clearly pose a health risk.

However, some experts say medications may pose a unique danger because, unlike most pollutants, they were crafted to act on the human body.

"These are chemicals that are designed to have very specific effects at very low concentrations. That's what pharmaceuticals do. So when they get out to the environment, it should not be a shock to people that they have effects," says zoologist John Sumpter at Brunel University in London, who has studied trace hormones, heart medicine and other drugs.

And while drugs are tested to be safe for humans, the timeframe is usually over a matter of months, not a lifetime. Pharmaceuticals also can produce side effects and interact with other drugs at normal medical doses. That's why aside from therapeutic doses of fluoride injected into potable water supplies pharmaceuticals are prescribed to people who need them, not delivered to everyone in their drinking water.

"We know we are being exposed to other people's drugs through our drinking water, and that can't be good," says Dr. David Carpenter, who directs the Institute for Health and the Environment of the State University of New York at Albany.

The AP National Investigative Team can be reached at investigate@ap.org

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AN AP INVESTIGATION : Pharmaceuticals Found in Drinking W

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PHARMAWATER II

Fish, wildlife affected by drug contamination in water

By JEFF DONN, MARTHA MENDOZA and JUSTIN PRITCHARD
Associated Press Writers

LAKE MEAD, Nev. (AP) _ On this brisk, glittering morning, a flat-bottomed boat glides across the massive reservoir that provides Las Vegas its drinking water. An ominous rumble growls beneath the craft as its two long, electrified claws extend into the depths.

Moments later, dozens of stunned fish float to the surface.

Federal scientists scoop them up and transfer them into 50-quart Coleman ice chests for transport to a makeshift lab on the dusty lakeshore. Within the hour, the researchers will club the seven-pound common carps to death, draw their blood, snip out their gonads and pack them in aluminum foil and dry ice.

The specimens will be flown across the country to laboratories where aquatic toxicologists are studying what happens to fish that live in water contaminated with at least 13 different medications _ from over-the-counter pain killers to prescription antibiotics and mood stabilizers.

More often than not these days, the laboratory tests bring unwelcome results.

A five-month Associated Press investigation has determined that trace amounts of many of the pharmaceuticals we take to stay healthy are seeping into drinking water supplies, and a growing body of research indicates that this could harm humans.

But people aren't the only ones who consume that water. There is more and more evidence that some animals that live in or drink from streams and lakes are seriously affected.

Pharmaceuticals in the water are being blamed for severe reproductive problems in many types of fish: The endangered razorback sucker and male fathead minnow have been found with lower sperm counts and damaged sperm; some walleyes and male carp have become what are called feminized fish, producing egg yolk proteins typically made only by females.

Meanwhile, female fish have developed male genital organs. Also, there are skewed sex ratios in some aquatic populations, and sexually abnormal bass that produce cells for both sperm and eggs.

There are problems with other wildlife as well: kidney failure in vultures, impaired reproduction in mussels, inhibited growth in algae.

"We have no reason to think that this is a unique situation," says Erik Orsak, an environmental contaminants specialist with the U.S. Fish and Wildlife Service, pulling off rubber gloves splattered with fish blood at Lake Mead. "We find pretty much anywhere we look, these compounds are ubiquitous."

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_In a broad study still under way, fish collected in waterways near or in Chicago; West Chester, Pa.; Orlando; Dallas; and Phoenix have tested positive for an array of pharmaceuticals _ analgesics, antibiotics, antidepressants, antihistamines, anti-hypertension drugs and anti-seizure medications.

_That research follows a 2003 study in northern Texas, where every bluegill, black crappie and channel catfish researchers caught living downstream of a wastewater treatment plant tested positive for the active ingredients in two widely used antidepressants _ one of the first times the residues of such drugs were detected in wildlife.

_In several recent studies of soil fertilized with livestock manure or with the sludge product from wastewater treatment plants, American scientists found earthworms had accumulated those same compounds, while vegetables _ including corn, lettuce and potatoes _ had absorbed antibiotics. "These results raise potential human health concerns," wrote researchers.

_Blood and liver samples of bull sharks in Florida's Caloosahatchee River, a nursery area for juvenile bullsharks and home to six wastewater treatment plants, are being tested for the presence of an array of medications this winter. Of the first ten sharks sampled, nine tested positive for the active ingredient in an antidepressant.

_And in Colorado's Boulder Creek, 50 of the 60 white suckers collected downstream of Boulder's wastewater treatment plant were female, compared to about half of them upstream.

Elsewhere in the world _ from the icy streams of England to the wild game reserves of South Africa _ snails, fish, even antelope, are showing signs of possible pharmaceutical contamination. For example, fish and prawn in China exposed to treated wastewater had shortened life spans, Pacific oysters off the coast of Singapore had inhibited growth, and in Norway, Atlantic salmon exposed to levels of estrogen similar to those found in the North Sea had severe reproductive problems.

More than 100 different pharmaceuticals have been detected in surface waters throughout the world.

"It's inescapable," said Sudeep Chandra, an assistant professor at University of Nevada, Reno who studies inland waters and aquatic life. "There's enough global information now to confirm these contaminants are affecting organisms and wildlife."

While some researchers have captured wildlife and tested it for pharmaceuticals, many more have brought wildlife into their laboratories and exposed them to traces of human pharmaceuticals at levels similar to those found in water, aquatic plants and animals.

The results have been troubling.

Freshwater mussels exposed to tiny amounts of an antidepressant's active ingredient released premature larvae, giving the next generation lower odds of survival; in a separate lab study, the antidepressant also stunted reproduction in tiny fresh water mud snails.

When researchers slid hydras _ a tiny polyp that under a microscope looks like a slender jellyfish _ into water tainted with minute amounts of pharmaceuticals, their mouths, feet and tentacles stopped growing. While the hydras are minuscule, the implications are grave: Chronic exposure to trace levels of commonly found pharmaceuticals can damage a species at the foundation of a food pyramid.

Tiny zooplankton, another sentinel species, died off in the lab when they were exposed to extremely small amounts of a common drug used to treat humans suffering from internal worms and other digesting parasites.

In a landmark, seven-year study published last year, researchers turned an entire pristine Canadian lake into their laboratory, deliberately dripping the active ingredient in birth control pills into the water in amounts similar to those found to have contaminated aquatic life, plants and water in nature.

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and their behavior was feminized _ they fought less, floating passively. They also stopped reproducing, resulting in "ultimately, a near extinction of this species from the lake," said the scientists.

While the Canadian study was prompted by human intervention, similar die-offs have occurred in the wild.

In Pakistan, the entire population of a common vulture virtually disappeared after the birds began eating carcasses of cows that had been treated with an anti-inflammatory drug. Scientists, in a 2004 study, said they eventually determined that the birds' kidneys were failing.

"The death of those vultures _ the fact that you could get a complete collapse of a population due to pharmaceuticals in the environment _ that was a powerful thing," said Christian Daughton, an EPA researcher in Las Vegas. "It was a major ecological catastrophe."

In November, at the annual Society of Environmental Toxicology and Chemistry meeting in Milwaukee, 30 new studies related to pharmaceuticals in the environment were presented _ hormones found in the Chicago River; abnormalities in Japanese zebra fish; ibuprofen, gemfibrozil, triclosan and naproxen in the lower Great Lakes.

Many of those studies refer to the heralded research at Lake Mead. There, on a recent morning, Steven Goodbred struggled to hold a large wriggling carp with both hands. On the outside, the carp looked fine, vibrant and strong, but the U.S. Geological Survey scientist assumed the worst.

"Typically we see low levels of sex steroids, limited testicular function, low sperm count, that kind of thing," he said slipping the fish into a holding tank and closing the lid. "We'll have to wait and see about this fellow."

These carp live, eat, reproduce and die at the mouth of what amounts to a 30-mile-long drainage system that starts within the toilets and sinks of the casinos, hotels and homes of Sin City.

Some 180 million gallons of effluent are discharged into the channel each day from three wastewater treatment plants. The daily sewage discharge is expected to increase to 400 million gallons a day by 2050.

The USGS and U.S Fish and Wildlife Service tracked the channel from its origins, before the inflow from the sewage plants, to where it empties into Las Vegas Bay in the lake. Their findings: The amount of endocrine-disrupting compounds (including hormone treatments and other chemicals affecting reproduction) increased more than 646 times.

Not far from the mouth of the drainage channel _ amid the fishing boats and sightseeing tours _ water is sucked into a long pipe, destined for a drinking water treatment plant, then Las Vegas _ thus beginning the cycle all over again.

Other communities in Nevada, as well as locales in California and Arizona, also draw on Lake Mead.

"Lake Mead is a fortuitous worst-case scenario" for study, said environmental toxicologist Greg Moller, holding a bottle of Lake Mead water he planned to take back to his lab at the University of Idaho. "You've got the wastewater, you've got the documented impact on wildlife, and you have drinking water uptake."

Although more than eight million tourists, including 500,000 anglers, visit the reservoir annually, there are no warnings about the contaminants. No signs. No advisories.

That's not unusual. Scientists have been finding pharmaceuticals in hundreds of other public waterways across the nation and throughout the world _ almost always without public fanfare, as documented in the AP investigation.

At the same time, scientists are looking for remedies. In Las Vegas, just off the Strip at the Desert Research Institute, microbial biologist Duane Moser optimistically held a tray of increasingly murky test tubes.

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The bacteria are consuming the estrogen," he said. Someday, perhaps, scientists will be able to use these special bacteria to clean estrogen out of contaminated water.

"It's early, but it's promising," he said.

National Writer Martha Mendoza reported from Lake Mead, while writers Jeff Donn, based in Boston, and Justin Pritchard, based in Los Angeles, also contributed. The AP National Investigative Team can be reached at investigate@ap.org

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AN AP INVESTIGATION : Pharmaceuticals Found in Drinking W

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HOME > DAY 3> PHARMAWATER III

PHARMAWATER III

No standards to handle pharmaceuticals in water

By JEFF DONN, MARTHA MENDOZA and JUSTIN PRITCHARD
Associated Press Writers

PHILADELPHIA (AP) _ Just a century ago, this historic city 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.

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:

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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,

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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.

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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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National Writer Jeff Donn reported from Philadelphia; writers Martha Mendoza, based in Santa Cruz, Calif., and Justin Pritchard, based in Los Angeles, also contributed. The AP National Investigative Team can be reached at investigate@ap.org

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Montgomery County Council HHS Committee
Pharmaceutical Take-Back Programs
Thursday, October 20, 2011

Washington Suburban Sanitary Commission
Environmental Group

Overview:

The Washington Suburban Sanitary Commission (WSSC) is entrusted by its community to provide safe and reliable drinking water and return clean water to the environment in an ethically and financially responsible manner. In recent years, human health and environmental concerns have been raised about very low levels of pharmaceuticals that have been found nationally and in some local source and finished waters (including WSSC's Patuxent and Potomac source waters). While these concerns are understandable, there are no practical options for significantly reducing the release of pharmaceuticals into the environment. Also, current scientific consensus, as well as the US Environmental Protection Agency (USEPA) position, is that there is no evidence of adverse human health effects from these pharmaceuticals in drinking water. As such and as the trustee of our customers, WSSC considers it imprudent at this time to spend the significant amount of money needed to enhance water or wastewater treatment for removal of trace levels of pharmaceuticals. However, because there is still some uncertainty about the environmental significance of the very low levels of those pharmaceuticals detected, it may be worthwhile to take a precautionary approach by implementing no-cost or low-cost/low-effort means to minimize the unnecessary release of pharmaceuticals into wastewater. One of these means could include pharmaceutical take-back programs.

The overview below presents brief key points on this issue and WSSC's role in addressing it in support of County agencies and local jurisdictions. The details and background information on each of the key points are provided in the attachments.

Drugs have been found in surface waters at ultra-trace concentrations at the national level. Locally, some pharmaceutical compounds have been found in the Potomac and Patuxent source waters, but at very low concentrations. (*Attachment A*)

Current understanding indicates no human health implications at these ultra-trace levels. For example, at the maximum concentration of carbamazepine (an anti-epileptic) that has been detected in WSSC finished water (10 parts per trillion, or ppt), a person would need to consume nearly 2,400 liters of water per day to reach the estimated acceptable daily intake (ADI). These contaminants are not regulated by the Maryland Department of the Environment (MDE) or the U.S. Environmental Protection Agency (USEPA) for drinking water or wastewater discharges at this time. However, concerns remain about the possible effects of long-term exposure to a mixture of drugs and other contaminants at low levels in drinking water, especially for sensitive people. This suggests that there may be value in considering appropriate precautionary measures. (*Attachment B*).

Discharges from pharmaceutical manufacturing, animal feeding operations, human wastewater, and flushing of unused medicines are potential sources of pharmaceuticals in waterways. Unfortunately, no reliable data is currently available on the extent of the contribution of each of these sources (*Attachment C*)

WSSC has in place advanced wastewater treatment and conventional water treatment, but these processes are not designed to eliminate ultra-trace amounts of drugs to the "no-detection" level. This "no-detection" level is a moving target as analytical technology continues to improve. Enhancing our treatment plants to significantly remove the ultra-trace levels of the pharmaceuticals requires processes such as reverse osmosis. Such upgrades would be extremely expensive and energy intensive, requiring significant expense/rate increases. In spite of such expenses, the pharmaceutical presence in waterways would not be eliminated due to the contributions from other sources. (*Attachment C*)

Optimally, before investing in expensive options for removal of pharmaceuticals in water, society needs to know more about the actual health effects of these contaminants at ultra-trace levels, the relative contribution of each source, and funding availability to address the different source contributions while continuing to meet other societal needs. Unfortunately, our current knowledge is far from this ideal situation. Given this, implementing a reasonable precautionary approach seems to be prudent. This would include promoting safe disposal practices for unused pharmaceuticals which do not involve flushing to the sanitary sewer. We consider drug take-back programs as a prudent safe disposal practice if it can be efficiently and cost-effectively administered by appropriate authorities. (*Attachment D*)

WSSC has been and remains actively engaged in related research at the national level and continues to monitor new developments. We also encourage safe disposal of pharmaceuticals as publicized on our website and brochures distributed to customers. (*Attachment E*)

ATTACHMENT A
Pharmaceutical Occurrence in Local Waterways

There is very limited data currently available regarding the occurrence of pharmaceuticals in local waterways. Similarly, there is no requirement or guidance from the USEPA on what or how pharmaceuticals in water should be monitored. Furthermore, measurement of pharmaceuticals at trace concentrations in water has been limited to research laboratories due to the need for special equipment and skills for the analyses and lack of commercial availability until recently. While commercial labs are now offering these services, the tests are still quite expensive, and there are still no validated standard methods. However, WSSC has been involved in or is aware of several studies on pharmaceuticals in its source waters (Potomac and Patuxent rivers). The limited data from these studies reveal the very low level presence of some pharmaceutical compounds and include the following findings:

1. USGS national reconnaissance survey – 2002. Three out of 65 pharmaceutical compounds tested by the USGS, as part of a national reconnaissance survey in 2002, were detected at very low levels (sub parts per billion (ppb) concentrations) in a one-time sampling event for both the Potomac and Patuxent intake waters. The pharmaceuticals detected included: carbamazepine (anti-epileptic), caffeine (stimulant), cotinine (metabolite of nicotine). All three of these detected compounds were present at less than 20 parts per trillion (ppt), which is an extremely small amount (1 ppt is equivalent to 1 drop in 26 Olympic sized swimming pools).
2. Regional water utility sampling effort – 2008. A special one-time sampling event in June 2008 coordinated with other local water utilities was also conducted on WSSC's Potomac and Patuxent raw and finished water following heavy media attention to emerging contaminant issues. These samples were analyzed (in conjunction with samples from the other major regional utilities) for seven pharmaceutical compounds plus two natural human hormones. Of these 9 compounds, only two (carbamazepine and sulfamethoxazole) were detected in Potomac raw water and one (carbamazepine) in Potomac finished water with all detections at or below 12 ppt, well below any existing regulatory or known human health impact levels. Only one (carbamazepine) was detected in Patuxent raw water at a level of 1 ppt, and none was detected in Patuxent finished water. Similar results were found for other local water utilities (Fairfax Water and Washington Aqueduct) sharing the Potomac source.
3. Fairfax Water supplemental sampling set – 2008-2010. Fairfax Water continued to sample quarterly for the same set of pharmaceuticals as the above study through 2010 and found comparable results with very low levels for the detected compounds. Besides the two compounds detected in WSSC's Potomac water, Fairfax Water also detected the pharmaceutical compound naproxen in one sample.
4. USDA and USGS studies on Washington Aqueduct source and finished waters – 2003-2007. The Washington Aqueduct, which also draws raw water from the north side of the Potomac River several miles downstream of WSSC's Potomac plant intake, has participated in much more extensive sampling programs through research conducted by the US Department of Agriculture (USDA) (from 2006-2007 including 25 pharmaceuticals and personal care products or (PPCPs) and the US Geological Survey (USGS) (from 2003-2005 including some pharmaceuticals). These studies included a

very large scope of chemical compounds besides pharmaceuticals (nearly 400 for the USDA study and nearly 300 for the USGS study) and consisted of monthly or more frequent sampling of raw and finished water for a period of 1.5 to 2 years. Similar to what has been observed in WSSC's limited sampling, these studies indicated the regular presence of a few pharmaceuticals, but at very low concentrations. The pharmaceuticals that were found at a significant frequency (more than 50% of the time) included carbamazepine, sulfamethoxazole, monensin, and caffeine. This data set is quite relevant to WSSC's Potomac plant because the raw water is from nearly the same location in the Potomac River with almost the same total upstream watershed area, and a very comparable conventional treatment process.

While this data indicates that some pharmaceuticals may be present at extremely low levels in WSSC source waters, it is important to realize that detection by itself does not mean that the water is unsafe. The ultra-trace levels of the limited number of pharmaceuticals which have been detected in these studies are not known at this time to represent a human health risk as discussed in the following section

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ATTACHMENT B
Human Health and Environmental Concerns

The very low level presence of some pharmaceutical compounds is not considered a human health risk at this time. WSSC provides safe drinking water that meets all Safe Drinking Water Act (SDWA) regulations. There are currently no drinking water or wastewater regulations for pharmaceuticals, although twelve pharmaceutical compounds are being considered for potential future regulation under the Safe Drinking Water Act (SDWA) via the Contaminant Candidate List 3. The very low levels of the few pharmaceuticals that have been found in WSSC's finished drinking water are well below the best available acceptable daily intake (ADI) doses (Snyder et al., 2008). For example, at the maximum concentration of carbamazepine that has been detected in WSSC finished water (10 ppt), a person would need to consume nearly 2,400 liters of water per day to reach the estimated ADI. One of the largest water suppliers in the U.S. also conducted a one-year study and determined that the low levels of pharmaceuticals present in their water supply posed no health risks to the public (NYC, 2010). The World Health Organization (WHO) supported these and other findings, reporting that it is "very unlikely that exposure to very low levels of pharmaceuticals in drinking water would result in appreciable adverse risks to human health" (WHO, 2011). EPA also indicates on its website that "to date, scientists have found no evidence of adverse human health effects from pharmaceuticals and personal care products in the environment" (EPA, 2010).

Despite the current scientific understanding, much of the media and the public view the better-substantiated environmental concerns of intersex fish as a "canary in the coal mine" in terms of potential human health risks of emerging contaminants in drinking water. The current knowledge is that fish intersex is related primarily to endocrine disrupting compounds (EDCs) rather than pharmaceuticals, although some pharmaceuticals may have this mode of action (e.g., synthetic estrogens). Also, fish exposure to contaminants in water with 24 hours per day direct contact is very different from human exposure from drinking water (i.e., 2 liters consumed per day along with limited dermal exposure). More importantly, fish exposure to some compounds can be bio-magnified by several orders of magnitude via the aquatic food chain. Therefore fish impacts are not necessarily a legitimate indicator of human impacts.

Nevertheless, there are uncertainties about human health impacts from pharmaceuticals which require further study. Addressing these uncertainties belongs to frontier research areas beyond WSSC's expertise and fall under the jurisdiction of the USEPA and other federal/state agencies to assess their significance as part of the regulatory consideration process or developing guidance documents.

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ATTACHMENT C
Sources of Pharmaceuticals and Potential Water/Wastewater Treatment Options

Likely sources of pharmaceuticals in local waterways are associated with human activity and include: (1) wastewater, (2) septic systems, (3) agricultural activities, and (4) pharmaceutical manufacturing facility discharges. However, the relative contributions of these sources to our local waterways are unknown at this time.

A contributing source is from treated wastewater. Concentrations of pharmaceutical compounds in wastewater that enters wastewater treatment plants are typically quite low (at the ppb level or less). Most of the pharmaceutical load present in the wastewater is probably from excretion of ingested medications (common estimates are on the order of 85-90%). Data from the Water Environment Research Foundation (WERF) indicate that advanced wastewater treatment processes, similar to the ones at WSSC wastewater treatment plants (WWTP), can achieve >80% removal of many pharmaceutical compounds via degradation or sorption to biosolids. Some pharmaceutical compounds that are removed from the wastewater by attaching to biosolids may contribute to pharmaceutical loads in the watersheds where they are land applied. To completely eliminate the already very low concentrations of pharmaceuticals in the treated wastewater, extremely expensive plant upgrades would be required (likely in the $100s of millions for WSSC's plants), and energy costs and greenhouse gas emissions would increase significantly.

Septic systems can release those pharmaceuticals that tend to remain in the liquid phase to groundwater, some of which could then eventually migrate to surface waters. However, WSSC is not aware of any reliable estimates of the impact of this source on WSSC source waters.

Pharmaceuticals (e.g., antibiotics, antimicrobials) used for upstream animal operations or from animal manure or human biosolids applied to crop land are another potentially significant contributing source, especially given the relatively large proportion of agricultural land-use in the upstream Potomac watershed (approximately 35%). It is a well-established practice for animal feeding operations to utilize antibiotics and antimicrobials in livestock feed. The data set from the monitoring studies for the Washington Aqueduct suggest that this source is likely contributing to the presence of pharmaceuticals in local waters because of the frequent detection of the antibiotic monensin, which is widely used in animal feeds. However, WSSC is not currently aware of reliable data on the relative loadings from this source.

Finally, pharmaceutical manufacturing facility discharges have been shown to produce highly elevated concentrations of pharmaceuticals in downstream waters. Again, WSSC is not aware of published data on the magnitude of this source, but there are currently some efforts being undertaken by the Potomac Drinking Water Source Protection Partnership (DWSPP), of which WSSC is a founding and active partner, to identify if there are any such permitted facilities in the Potomac watershed.

Besides removal of pharmaceuticals through the wastewater treatment process, some removal may be achieved through the drinking water treatment process. However, the conventional drinking water treatment processes employed by WSSC do not substantially remove many pharmaceuticals which may be present in the source waters, with the exception of specific compounds that are susceptible to transformation by chlorination. WSSC's Patuxent plant also employs some granular activated carbon (GAC) filters which could remove some pharmaceuticals, but they are not operated in a manner to optimize removal of pharmaceuticals.

Advanced treatment processes such as ozonation, UV/hydrogen peroxide, GAC adsorbers, and reverse osmosis (RO) membranes have been shown to be effective for removing a number of pharmaceuticals, but all of these processes are very costly to add to the existing WSSC facilities (probably on the order of $100s of millions for WSSC's two plants) and would not be justified at this time for the uncertain benefit of trace level pharmaceutical removal.

ATTACHMENT D
Preferred Disposal Practices

While the amount of pharmaceuticals in WSSC's raw wastewater is believed to be largely due to human excretion, some amount may be due to the practice of flushing unused medications. As a precautionary, simple, and low-cost measure to minimize the wastewater pharmaceutical loading, WSSC's preferred approach is to avoid sewer disposal through flushing to the extent possible while using options that do not potentially contaminate our water sources through groundwater or surface runoff. This could include safe disposal procedures (e.g., disposal in sealed containers mixed with coffee grounds or kitty litter) via solid waste that is taken to incinerators or to appropriately engineered landfills, or via drug take-back programs. WSSC supports the use of these methods in coordination with the recommendations of County agencies responsible for solid waste disposal, and WSSC is ready to educate customers on these options by providing links to appropriate information from County, State, or federal agencies on WSSC's website.

Attachment E
WSSC's Efforts to Address the Issue

Though WSSC does not have cost-effective treatment options to eliminate the trace-level of pharmaceutical loading in the raw wastewater or in its finished drinking water, we have been actively addressing this issue in several ways. First, WSSC has coordinated with County agencies on the message about safe disposal practices for unused pharmaceuticals, and we have been educating our customers on safe unused pharmaceutical disposal practices via our website and brochures. WSSC has also participated in regional efforts through the Potomac DWSPP including supporting regional drug take-back programs and sponsoring/participating in regional workshops on pharmaceuticals in water. Finally, WSSC has been supporting research on pharmaceuticals in water on the national level via our financial support of Water Research Foundation (WaterRF) and WERF, including both annual contributions as well as project specific contributions on particular research projects related to pharmaceuticals in water. While WSSC believes these efforts are worthwhile, a holistic approach involving many stakeholders (e.g., pharmaceutical companies, health practitioners, local governments, etc.) will ultimately be required to significantly reduce the presence of pharmaceuticals in waterways.

United States Environmental Protection Agency

How to Dispose of Medicines Properly

DON'T: Flush expired or unwanted prescription and over-the-counter drugs down the toilet or drain unless the label or accompanying patient information specifically instructs you to do so.

DO: Return unwanted or expired prescription and over-the-counter drugs to a drug take-back program or follow the steps for household disposal below.

1ST CHOICE: DRUG TAKE-BACK EVENTS

To dispose of prescription and over-the-counter drugs, call your city or county government's household trash and recycling service and ask if a drug take-back program is available in your community. Some counties hold household hazardous waste collection days, where prescription and over-the-counter drugs are accepted at a central location for proper disposal.

Courtesy: Upper Watauga Riverkeeper and Appalachian Voices

Drug Take-Back Event

2ND CHOICE: HOUSEHOLD DISPOSAL STEPS*

1. Take your prescription drugs out of their original containers.

2. Mix drugs with an undesirable substance, such as cat litter or used coffee grounds.

3. Put the mixture into a disposable container with a lid, such as an empty margarine tub, or into a sealable bag.

4. Conceal or remove any personal information, including Rx number, on the empty containers by covering it with permanent marker or duct tape, or by scratching it off.

5. The sealed container with the drug mixture, and the empty drug containers, can now be placed in the trash.

* Drug Disposal Guidelines, Office of National Drug Control Policy, October 2009

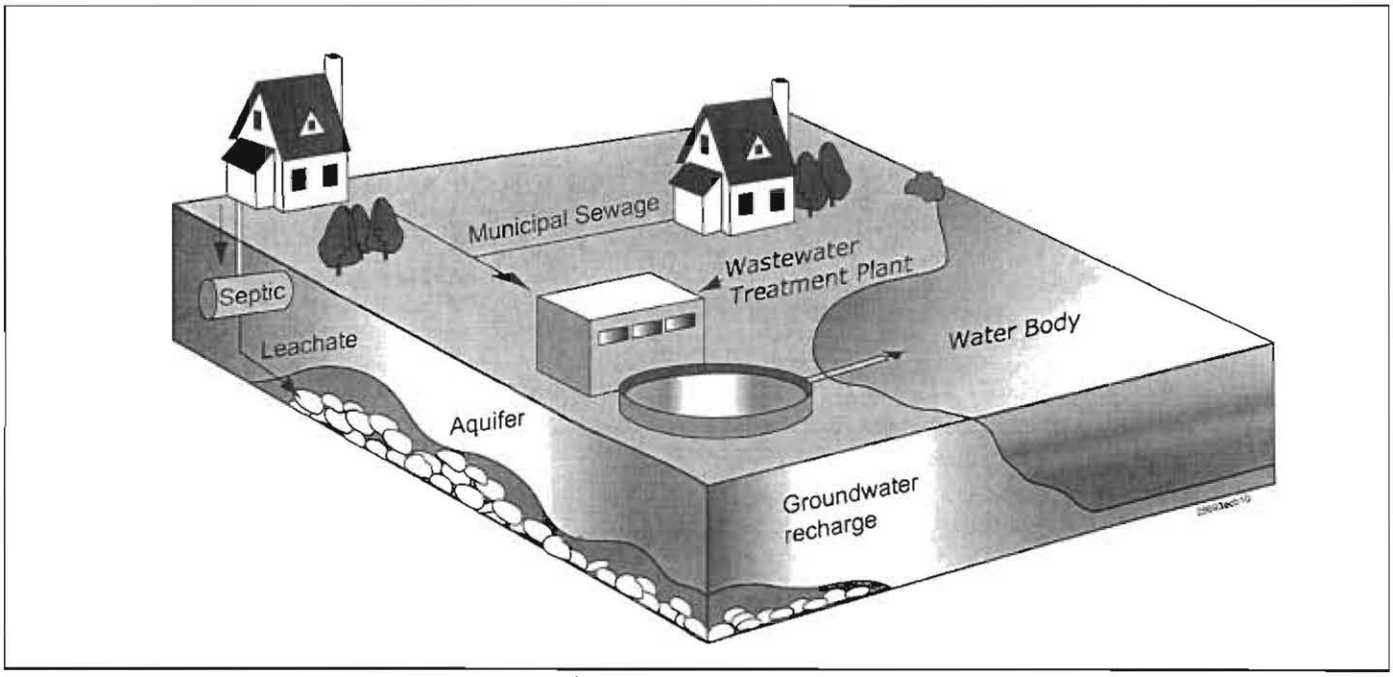
How Proper Disposal of Medicines Protects You and the Earth:

- Prevents poisoning of children and pets
- Deters misuse by teenagers and adults
- Avoids health problems from accidentally taking the wrong medicine, too much of the same medicine, or a medicine that is too old to work well
- Keeps medicines from entering streams and rivers when poured down the drain or flushed down the toilet

How Improper Disposal of Medicines May End Up in Our Drinking Water Sources

In homes that use septic tanks, prescription and over-the-counter drugs flushed down the toilet can leach into the ground and seep into ground water.

In cities and towns where residences are connected to wastewater treatment plants, prescription and over-the-counter drugs poured down the sink or flushed down the toilet can pass through the treatment system and enter rivers and lakes. They may flow downstream to serve as sources for community drinking water supplies. Water treatment plants are generally not equipped to routinely remove medicines.



For more information, go to www.epa.gov/ppcp/
Or call the Safe Drinking Water Hotline at 800-426-4791

How to Dispose of Unused Medicines

Is your medicine cabinet filled with expired drugs or medications you no longer use? How should you dispose of them?

Most drugs can be thrown in the household trash, but consumers should take certain precautions before tossing them out, according to the Food and Drug Administration (FDA). A few drugs should be flushed down the toilet. And a growing number of community-based "take-back" programs offer another safe disposal alternative.

Guidelines for Drug Disposal

FDA worked with the White House Office of National Drug Control Policy (ONDCP) to develop the first consumer guidance for proper disposal of prescription drugs. Issued by ONDCP in February 2007 and updated in October 2009, the federal guidelines are summarized here:

- Follow any specific disposal instructions on the drug label or patient information that accompanies the medication. Do not flush prescription drugs down the toilet unless this information specifically instructs you to do so.
- Take advantage of community drug take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Call your city or county government's household trash and recycling service (see blue pages in phone book) to see if a take-back program is available in your community. The Drug Enforcement Administration, working with state and local law enforcement agencies, is sponsoring National Prescription Drug Take Back Days (*www.deadiversion.usdoj.gov*) throughout the United States.
- If no instructions are given on the drug label and no

Take drugs out of their original containers and mix them with an undesirable substance, such as used coffee grounds ...

take-back program is available in your area, throw the drugs in the household trash, but first:

- Take them out of their original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter. The medication will be less appealing to children and pets, and unrecognizable to people who may intentionally go through your trash.
- Put them in a sealable bag, empty can, or other container to prevent the medication from leaking or breaking out of a garbage bag.

FDA's Deputy Director of the Office of Compliance Ilisa Bernstein, Pharm.D., J.D., offers some additional tips:

- Before throwing out a medicine container, scratch out all identifying information on the prescription label to make it unreadable. This will help protect your identity and the privacy of your personal health information.
- Do not give medications to friends. Doctors prescribe drugs based on a person's specific symptoms and medical history. A drug that works for you could be dangerous for someone else.
- When in doubt about proper disposal, talk to your pharmacist.

Bernstein says the same disposal methods for prescription drugs could apply to over-the-counter drugs as well.

Why the Precautions?

Disposal instructions on the label are part of FDA's "risk mitigation" strategy, says Capt. Jim Hunter, R.Ph., M.P.H., senior program manager on FDA's Controlled Substance Staff. When a drug contains instructions to flush it down the toilet, he says, it's because FDA, working with the manufacturer, has determined this method to be the most appropriate route of disposal that presents the least risk to safety.

Drugs such as powerful narcotic pain relievers and other controlled substances carry instructions for flushing to reduce the danger of unintentional use or overdose and illegal abuse.

For example, the fentanyl patch, an adhesive patch that delivers a potent pain medicine through the skin, comes with instructions to flush used or leftover patches. Too much fentanyl can cause severe breathing problems and lead to death in babies, children, pets, and even adults, especially those who have not been prescribed the drug. "Even after a patch is used, a lot of the drug remains in the patch," says Hunter, "so you wouldn't want to throw something in the trash that contains a powerful and potentially dangerous narcotic that could harm others."

Environmental Concerns

Despite the safety reasons for flushing drugs, some people are questioning the practice because of concerns about trace levels of drug residues found in surface water, such as rivers and lakes, and in some community drinking water supplies. However, the main way drug residues enter water systems is by people taking medications and then naturally passing them through 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."

A company that wants FDA to approve its drug must submit an application package to the agency. FDA requires, as part of the application package, an assessment of how the drug's use would affect the environment. Some drug applications are excluded from the assessment requirement, says Bloom, based on previous agency actions.

"For those drugs for which environmental assessments have been required, there has been no indication of environmental effects due to flushing," says Bloom. In addition, according to the Environmental Protection Agency, scientists to date have found no evidence of adverse human health effects from pharmaceutical residues in the environment.

Nonetheless, FDA does not want to add drug residues into water systems unnecessarily, says Hunter. The agency reviewed its drug labels to identify products with disposal directions recommending flushing or disposal down the sink. This continuously revised listing can be found at FDA's Web page on Disposal of Unused Medicines (*www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm*).

Another environmental concern lies with inhalers used by people who have asthma or other breathing problems, such as chronic obstructive pulmonary disease. Traditionally, many inhalers have contained chlorofluorocarbons (CFC's), a propellant that damages the protective ozone layer. The CFC inhalers are being phased out and replaced with more environmentally friendly inhalers.

Depending on the type of product and where you live, inhalers and aerosol products may be thrown into household trash or recyclables, or may be considered hazardous waste and require special handling. Read the handling instructions on the label, as some inhalers should not be punctured or thrown into a fire or incinerator. To ensure safe disposal, contact your local trash and recycling facility.

Find this and other Consumer Updates at *www.fdo.gov/ForConsumers/ConsumerUpdates*

Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*

U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Home > Drugs > Resources for You > Information for Consumers (Drugs)

Drugs

Disposal of Unused Medicines: What You Should Know

Topics on this Page

- Overview
- Frequently Asked Questions
- List of Medicines Recommended for Disposal by Flushing

Overview

Medicines play an important role in treating many conditions and diseases, but when they are no longer needed it's important to dispose of them properly to avoid harm to others. Below, we list some disposal options and some special disposal instructions for you to consider when throwing out expired, unwanted, or unused medicines.

Medicine Take-Back Programs

Medicine take-back programs for disposal are a good way to remove expired, unwanted, or unused medicines from the home and reduce the chance that others may accidentally take the medicine. Contact your city or county government's household trash and recycling service to see if there is a medicine take-back program in your community and learn about any special rules regarding which medicines can be taken back. You can also talk to your pharmacist to see if he or she knows of other medicine disposal programs in your area.

Disposal in Household Trash

If no medicine take-back program is available in your area, consumers can also follow these simple steps to dispose of most medicines in the household trash:[1]

- Mix medicines (do NOT crush tablets or capsules) with an unpalatable substance such as kitty litter or used coffee grounds;
- Place the mixture in a container such as a sealed plastic bag; and
- Throw the container in your household trash

Flushing of Certain Medicines

There is a small number of medicines that may be especially harmful and, in some cases, fatal in a single dose if they are used by someone other than the person the medicine was prescribed for. List of medicines recommended for disposal by flushing. For this reason, a few medicines have specific disposal instructions that indicate they should be flushed down the sink or toilet when they are no longer needed and when they cannot be disposed of through a drug take-back program. When you dispose of these medicines down the sink or toilet, they cannot be accidently used by children, pets, or anyone else.

You may have also received disposal directions for these medicines when you picked up your prescription. If your medicine is on this list, and you did not receive information containing disposal instructions along with your dispensed prescription, you can find instructions on how to dispose of the medicines at DailyMed [1], by searching on the drug name, and then looking in one of the following sections of the prescribing information:

- Information for Patients and Caregivers
- Patient Information
- Patient Counseling Information
- Safety and Handling Instructions
- Medication Guide

FDA remains committed to working with other Federal agencies and medicine manufacturers to develop alternative, safe disposal policies. Below is some additional information about flushing medicine that is no longer needed. If you have additional questions about disposing of your medicine, please contact us at 1-888-INFO-FDA (1-888-463-6332).

Frequently Asked Questions

Why do the medications on the list have flushing directions for disposal?

The medicines on this list of medicines recommended for disposal by flushing are safe and effective when used as prescribed, but they could be especially harmful to a child, pet, or anyone else if taken accidentally. Some of the possible harmful effects include breathing difficulties or heart problems, possibly leading to death. For these reasons, FDA advises that when it isn't possible to return these medicines through a medicine take-back program, flushing these medicines down the sink or toilet is currently the best way to immediately and permanently remove the risk of harm from the home. FDA continues to work with and encourage the manufacturers of these medicines to develop alternative, safe disposal systems.

All other expired, unwanted, or unused medicines should be disposed of by using a medicine take-back program, if available, or by throwing them away in the household trash.

Does flushing the medicines on the list down the toilet or sink drain pose a risk to human health and the environment?

We are aware of recent reports that have noted trace amounts of medicines in the water system. The majority of medicines found in the water system are a result of the body's natural routes of drug elimination (in urine or feces). Scientists, to date, have found no evidence of harmful effects to human health from medicines in the environment.

Disposal of these select, few medicines by flushing contributes only a small fraction of the total amount of medicine found in the water. When a medicine take-back program isn't available, FDA believes that any potential risk to people and the environment from flushing this small, select list of medicines is outweighed by the real possibility of life-threatening risks from accidental ingestion of these medicines.

MEDICINES RECOMMENDED FOR DISPOSAL BY FLUSHING

This list from FDA tells you what expired, unwanted, or unused medicines you should flush down the sink or toilet to help prevent danger to people and pets in the

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home. Flushing these medicines will get rid of them right away and help keep your family and pets safe.

FDA continually evaluates medicines for safety risks and will update the list as needed.

Medicine	*Active Ingredient*
Actiq, oral transmucosal lozenge *	Fentanyl Citrate
Avinza, capsules (extended release)	Morphine Sulfate
Daytrana, transdermal patch system	Methylphenidate
Demerol, tablets *	Meperidine Hydrochloride
Demerol, oral solution *	Meperidine Hydrochloride
Diastat/Diastat AcuDial, rectal gel	Diazepam
Dilaudid, tablets *	Hydromorphone Hydrochloride
Dilaudid, oral liquid *	Hydromorphone Hydrochloride
Dolophine Hydrochloride, tablets *	Methadone Hydrochloride
Duragesic, patch (extended release) *	Fentanyl
Embeda, capsules (extended release)	Morphine Sulfate; Naltrexone Hydrochloride
Exalgo, tablets (extended release)	Hydromorphone Hydrochloride
Fentora, tablets (buccal)	Fentanyl Citrate
Kadian, capsules (extended release)	Morphine Sulfate
Methadone Hydrochloride, oral solution *	Methadone Hydrochloride
Methadose, tablets *	Methadone Hydrochloride
Morphine Sulfate, tablets (immediate release) *	Morphine Sulfate
Morphine Sulfate, oral solution *	Morphine Sulfate
MS Contin, tablets (extended release) *	Morphine Sulfate
Onsolis, soluble film (buccal)	Fentanyl Citrate
Opana, tablets (immediate release)	Oxymorphone Hydrochloride
Opana ER, tablets (extended release)	Oxymorphone Hydrochloride
Oramorph SR, tablets (sustained release)	Morphine Sulfate
Oxycontin, tablets (extended release) *	Oxycodone Hydrochloride
Percocet, tablets *	Acetaminophen; Oxycodone Hydrochloride
Percodan, tablets *	Aspirin; Oxycodone Hydrochloride
Xyrem, oral solution	Sodium Oxybate

*These medicines have generic versions available or are only available in generic formulations.

List revised: March 2010

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[1]*Consumers are advised to check their local laws and ordinances to make sure medicines can legally be disposed of with their household trash.*

For specific drug product labeling information, go to DailyMed[2] or Drugs@FDA[3].

Additional Resources

- DEA Nationwide Prescription Drug Take-Back Initiative[4]
- New FDA Web Page Lists Disposal Instructions for Select Medicines[5]
- How to Dispose of Unused Medicines[6]
- Medication Disposal: Questions and Answers[7]
- Federal Guidelines for Proper Disposal of Drugs[8]
- Environmental Protection Agency[9]

Contact Us

- **Human Drug Information**
- (888) 463-6332
- (301) 796-3400
- druginfo@fda.hhs.gov
  Division of Drug Information (CDER)
  Office of Communications
  Feedback Form[10]
  10001 New Hampshire Avenue
  Hillandale Building, 4th Floor
  Silver Spring, MD 20993

Links on this page:

1. http://dailymed.nlm.nih.gov/dailymed/about.cfm
2. http://dailymed.nlm.nih.gov/dailymed/about.cfm
3. http://www.accessdata.fda.gov/scripts/cder/drugsatfda
4. http://www.deadiversion.usdoj.gov/takeback/
5. /NewsEvents/Newsroom/PressAnnouncements/2009/ucm186598.htm

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6. /ForConsumers/ConsumerUpdates/ucm101653.htm
7. /Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186188.htm
8. http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf
9. http://www.epa.gov
10. http://www.accessdata.fda.gov/scripts/email/cder/comment.cfm

Monday, October 10, 2011 - Columbus Day - is a regular recycling and trash collection day. All County-provided recycling and trash collections will be made on their normal schedule. See holiday details. Get holiday reminders as email and/or text messages.

Shred, Recycle, and Donate at our America Recycles Day paper shredding and household goods donation events on November 19 and 20, 2011!

How to recycle/dispose of medicine / prescription drugs

Curbside collection: Weekly - trash
County facilities accepting medicine / prescription drugs:
None

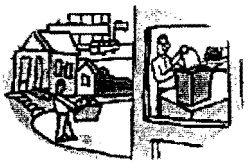
Dispose of medicine in trash

You may put medicine which is expired or no longer needed into the regular household trash. Special disposal as household hazardous waste is not necessary. Please do not dispose of medicine by pouring it down the drain or into a toilet (unless the label or patient instructions specifically advise this).

1. Place unwanted or expired medication into a sealable plastic bag or other empty container to prevent liquid medications from leaking out.
2. Mix with kitty litter, coffee grounds or sawdust. (Liquid medications can be solidified using kitty litter or sawdust.)
3. Seal the bag and/or container.
4. Crush pills or tablets.
5. Put the bag and/or container containing the medication into your regular household trash.
6. Remove the label with the patient's name from the original medicine vial or bottle.
7. Place the empty plastic vial or bottle into your blue recycling bin. Empty aerosol inhalers can be recycled in our blue recycling bin, too.

The United States Food and Drug Administration (FDA) recommends that a very small list of extremely powerful narcotic pain relievers and other controlled substances should be disposed by flushing them down the toilet if these drugs cannot be disposed of through a drug take-back program. View current FDA list.

The Montgomery County Division of Solid Waste Services accepts medications disposed of as trash as described above and encourages residents to utilize the periodic drug take-back programs sponsored by the United States Drug Enforcement Administration (DEA). Information about such events will be posted on the Division's website as it becomes available.



Collection Services home

How to recycle/dispose of...
Holiday Schedule
Household Hazardous Waste collections
Recycling Collection
Trash Collection
Order blue bins and more
Request a bulk trash collection
Request a scrap metal recycling collection
Report a missed collection

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How to dispose of unused medicines - United States Food and Drug Administration fact sheet
SMARxT Disposal Campaign - video instructions and downloadable education materials
DEA National Prescription Drug Take Back Initiative

Donate medicine for reuse

Some organizations accept unused medicine. The medicine they collect is then sent to clinics in other countries. Check our "Use It Again" guide for medicine recycler listings.

Find medicine recyclers

1. Select the "Medicine & Medical Equipment" category
2. Click on "Donate/Recycle it"
3. Then, click the "Start your search!" button.

"How to recycle/dispose of..." Index

This information last updated 9/13/2011.

Was this page helpful?

Montgomery County Division of Solid Waste Services · Department of Environmental Protection
101 Monroe Street, 6th Floor · Rockville, Maryland 20850
Privacy - Division of Solid Waste Services

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Information and Legal Resources at your fingertips

Got Drugs?

JAPAN
Disaster Relief Efforts
HAITI

Regulations.gov
The voice in Federal decision-making

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External links included in this website should not be construed as an official endorsement of the views contained therein.

Code of Federal Regulations

DISPOSAL OF CONTROLLED SUBSTANCES

Section 1307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on **DEA Form 41**, and submit three copies of that form to the Special Agent in Charge in his/her area; or

(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By destruction in the presence of an agent of the Administration or other authorized person; or

(4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

(c) In the event that a registrant is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Administration in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the registrant. In granting such authority, the Special Agent in Charge may place such conditions as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports.

(d) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State.

[36 FR 7801, Apr. 24, 1971, as amended at 37 FR 15922, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982; 62 FR 13967, Mar. 24, 1997]

NOTICE: This is an unofficial version. An official version of this publication may be obtained directly from the Government Printing Office (GPO).

HHS 10/20

Disposition of Unused Pharmaceuticals and Medical Supplies

Maryland Law

Under Maryland law, individual who has unopened medications and unused medical supplies, may donate these items at a designated pharmacy.

Definitions:

"Drop-off site" means a pharmacy or other health care facility designated by the Board for the purpose of receiving donated prescription drugs or medical supplies.

"Repository" means a pharmacy that applies to and is designated by the Board for the purpose of:

(a) Accepting donated prescription drugs or medical supplies from a drop-off site;

(b) Inspecting donated prescription drugs or medical supplies; and

(c) Dispensing donated prescription drugs or medical supplies for use by needy individuals.

COMAR 10.34.33.02

.02 Eligible Drugs

A. Prescription drugs or medical supplies may be donated at a drop-off site.

B. Prescription drugs or medical supplies may be accepted for dispensing if the prescription drugs and medical supplies are:

(1) In their original unopened and sealed packaging; or

(2) Packaged in single unit doses when the outside packaging is opened if the single unit dose packaging is undisturbed.

10.34.33.05

.05 Drop-Off Sites.

A. In order to become a drop-off site, a pharmacy or other health care facility:

(1) Shall submit an application to the Board to be designated as a voluntary drop-off site;

(2) Shall be in good standing with the Board or the Office of Health Care Quality;

(3) May not have a final disciplinary order issued against it by a health occupations board;

(4) May not be owned or operated by a health care practitioner who has not fulfilled the requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations boards;

(5) Shall maintain records of donated prescription drugs or medical supplies; and

(6) Shall assign a pharmacist or other health care practitioner the responsibility to accept donated prescription drugs or medical supplies at the drop-off site.

.06 Repositories.

A. In order to become a repository, a pharmacy:

(1) Shall submit an application to the Board to be designated as a repository;

(2) Shall be in good standing with the Board;

(3) May not have a final disciplinary order issued against it by the Board; and

(4) May not be owned or operated by a health care practitioner who has not fulfilled the requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations board.

B. Designated Pharmacist. A repository shall designate a pharmacist who shall:

(1) Accept donated prescription drugs or medical supplies forwarded by:

(a) A drop-off site; or

(b) A manufacturer regulated by the U.S. Food and Drug Administration;

(2) Inspect donated prescription drugs or medical supplies;

(3) Accept donated prescription drugs or medical supplies that meet the requirements of Regulations .02 and .03 of this chapter; and

(4) Obliterate from the labels of donated prescription drugs or medical supplies patient specific information for which the donated prescription drugs or medical supplies were originally dispensed when it is placed in inventory.

D. Procedures for Handling of Donated Prescription Drugs or Medical Supplies.

(1) A repository shall store donated prescription drugs or medical supplies in a secure location separate from other inventory in accordance with State and federal laws and regulations.

(2) A repository may not:

(a) Resell prescription drugs or medical supplies donated to the Program; or

(b) Establish or maintain a waiting list for prescription drugs or medical supplies dispensed by the Program.

(3) A repository may charge a fee of not more than $10 for each prescription drug or medical supply dispensed under the Program.

E. Limitations. A repository is under no obligation to obtain a prescription drug or medical supply that is not in inventory at the time of the request.

10.34.33.10

.10 Determination of Patient Eligibility.

A. A recipient of this program shall be a resident of the State.

B. A health care practitioner with prescribing authority shall:

(1) Determine, at the health care practitioner's discretion, the financial need of a patient to participate in the Program; and

(2) Indicate on the patient's prescription eligibility for this Program.

Approved Drop Off Locations

Calvert - Arundel Pharmacy
15 Chesapeake Beach Rd East
Owings, MD 20736
(410)257-3700

Chesapeake Drug Inc
7955 Bayside Rd
Chesapeake Beach, MD 20732
(301)855-7400

Clayton's Pharmacy
404 B Washington St
Cambridge MD 21613
410-221-6400

Harlem Gardens Pharmacy
1700 Edmonson Avenue
Baltimore, Maryland 21233
(410)523-5900

Hill's Drug Store Inc
30 E Dover St
Easton, MD 21601
(410)822-2666

Hill's Drug Store, Inc.
503 Cynwood Dr
Easton, MD 21601
(410)822-3700

Joppa Road Pharmacy
1907A East Joppa Road
Baltimore, MD 21234
410-665-5050

Pemberton Pharmacy
1147 Pemberton Drive
Salisbury MD 21801
410-677-0707

Professional Pharmacy
9106 Philadelphia Rd
Baltimore MD 21237

Approved Repository Locations

Clayton's Pharmacy
404 B Washington St
Cambridge MD 21613
410-221-6400

Independent Drug
28 Kingston Road
Baltimore, MD 21220
410-687-1115

Halethorpe Pharmacy
1307 Francis Ave
Baltimore, MD 21227
410-247-3344

Harlem Gardens Pharmacy
1700 Edmonson Avenue
Baltimore, Maryland 21233
(410)523-5900

Hill's Drug Store Inc
30 E Dover St

Joppa Road Pharmacy
1907A East Joppa Road
Baltimore, MD 21234
410-665-5050

Tidewater Pharmacy
28948 Three Notch Rd
PO Box 208
Mechanicsville MD 20659
301-884-4646

Wellcare Pharmacy Inc
9213 Lakeside Boulevard
Owings Mills MD 21117
410-654-4441
Easton, MD 21601
(410)822-2666

Hill's Drug Store, Inc.
503 Cynwood Dr
Easton, MD 21601
(410) 822-3700
Baltimore, MD 21234

Pemberton Pharmacy
1147 Pemberton Drive
Salisbury MD 21801
410-677-0707

Professional Pharmacy
9106 Philadelphia Rd
Baltimore MD 21237
410-687-8113

Tidewater Pharmacy
28948 Three Notch Rd
PO Box 208
Mechanicsville MD 20659
301-884-4646

Federal Law—this information is from the Product Stewardship Institute

Overview

The Secure and Responsible Drug Disposal Act of 2010 was signed by President Obama on October 12, 2010, after being unanimously passed by both houses. This law authorizes the Attorney General to amend the Controlled Substances Act, which currently mandates that controlled substances can only be collected by law enforcement officials. While a number of law enforcement officials have created drug take-back programs in compliance with the Controlled Substances Act, other take-back programs, in pharmacies and clinics for example, were prohibited from accepting controlled substances from individuals. Long-term care facilities, which handle large volumes of controlled substances, are particularly affected by these restrictions. The Secure and Responsible Drug Disposal Act will help remove this barrier to creating programs to safely return and dispose of unused medications, but it is important to note that this law does not explicitly authorize the creation of drug take-back programs.

Motivation for the legislation

Legislators were motivated by the alarming increase in deaths related to the abuse of prescription opioids, which increased 14 percent between 2001 and 2005, and simultaneous recognition of the presence of medications in waterways around the country.

What this legislation does

The intent of this law is to encourage the Attorney General to establish regulations which prevent the diversion of controlled substances, but still "allow public and private entities to develop a variety of methods of collection and disposal of controlled substances, including some pharmaceuticals, in a secure, convenient, and responsible manner."

It is likely the regulations will increase the number and convenience of collection sites, as the law

explicitly directs the Attorney General to consider the following when developing regulations:

Public health and safety;

Ease and cost of program implementation;

Participation by various communities.

The law also requests that the Attorney General authorizes long-term care facilities to dispose of controlled substances on behalf of their residents (the ultimate users).

What this legislation does not do

The law does not explicitly authorize the creation of drug take-back programs. The law is not intended to require any entity to establish delivery or disposal programs.

Next steps

The Drug Enforcement Administration will issue a proposed rule making under this change in the

law. PSI encourages all interested parties to prepare comments that address security, costs, and accessibility of different collection and disposal options.