WHAT TO DO ABOUT THE ANTIDEPRESSANTS, ANTIBIOTICS AND OTHER DRUGS IN OUR WATER

As pharmaceuticals taint rivers and lakes, scientists search for solutions.

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August 11, 2015 — There's no way around it, the headlines are disturbing. And they come, not from tabloids or click-bait blogs, but from papers published in scientific journals. They describe fish and birds responding with altered behavior and reproductive systems to antidepressants, diabetes medication, and other

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psychoactive or hormonally active drugs at concentrations found in the environment. They report on opiods, amphetamines and other pharmaceuticals found in treated drinking water; antibiotics in groundwater capable of altering naturally occurring bacterial communities; and over-the-counter and prescription drugs found in water leaching from municipal landfills. And these are just some of many recent studies examining the countless pharmaceuticals that are now being found just about everywhere scientists have looked for them in the environment.

Exactly how many drugs are in use and how many may be detectable in the environment is difficult to pinpoint. But according to the U.S. Centers for Disease Control and Prevention, U.S. healthcare providers order or provide millions of drugs each year. In 2002, the U.S. General Accountability Office estimated that more than 13 million pounds of active pharmaceutical ingredients were sold for animal use alone. And according to one analysis, the U.S. Food and Drug Administration has approved about 1,500 drugs since it was established in 1938. Recent studies by the U.S. Geological Survey have found dozens of different pharmaceuticals in surface water sampling, and the USGS is now testing water from 38 streams in 24 states plus Puerto Rico for the presence of about 200 different pharmaceuticals or their metabolites (compounds drugs morph into as they pass through the body).

Regulatory and health authorities, including the U.S. Environmental Protection Agency, the FDA and the World Health Organization, note that levels of individual pharmaceutical compounds being measured environmentally — typically in water — have not been shown to harm human health. But many individual scientists, as well as the European Commission and other groups, have expressed concern about potential effects of the mixture of pharmaceutical chemicals present in the environment. Others, including researchers at the USGS who have been studying pharmaceuticals since the 1990s, also express concern about the consequences — for plants, animals and naturally occurring bacteria as well as human health — of long-term, low-level exposure to the various types of compounds being detected.

Where are these compounds coming from? How do we know if they pose hazards to people or the natural systems on which we depend? And what's being done to address concerns about the ubiquitous presence of so many drugs in the environment?

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Prescribing Trouble

About 90 percent of pharmaceuticals found in the environment arrive there after being excreted. Of these, antibiotics are a particular source of growing concern given the rise of antibiotic resistance, says Anna Zorzet, coordinator for ReAct Europe, an antibiotic resistance awareness and advocacy group hosted by Uppsala University in Sweden. The recent rapid increase in antibiotic use in humans and on livestock has reduced these drugs' effectiveness as bacteria evolve to tolerate frequently used antibiotics, a problem that can be compounded by their presence in the environment.

The rest of the pharmaceuticals in the environment come from discarded medicine and effluent releases at pharmaceutical manufacturing sites, explains Dan Caldwell, toxicology fellow with Johnson & Johnson Environment, Health, Safety, and Sustainability. Many of those discards and much of that effluent also ends up in water — either as runoff from landfill or discharge from factories.

That treatment plants don't target drugs is actually not surprising in the United States, where there are no drinking water quality standards for pharmaceuticals.

While most of the world's urban wastewater goes to treatment plants, typical waste- and drinking-water treatment methods are not designed to remove pharmaceuticals. In a 2011 report, WHO estimated that depending on the method, conventional water treatment plants might remove anywhere from less than 20 to

more than 90 percent of the pharmaceuticals compounds present.

That treatment plants don't target drugs is actually not surprising in the United States, where there are no drinking water quality standards for pharmaceuticals. About 10 drugs are now included on the EPA's "contaminant candidate" list of pollutants being considered for possible regulation. But none is yet regulated, meaning there are no set limits on what's considered a safe level in drinking water. This makes it very hard when local water utilities report on pharmaceuticals they find in their systems — as many do — to know what the reporting actually means or what (if anything) to do about it.

Sophisticated Testing

With use of pharmaceuticals growing worldwide, it's no surprise that we're finding more and more of them in the environment. But increased usage is not the only reason detection is on the rise. As increasingly sophisticated environmental testing methods have become available in recent years, what have come to be called micro-pollutants and emerging contaminants — a category that includes pharmaceuticals — have started to be detected with greater precision.

"Analytical chemistry has progressed from being able to detect parts per million to parts per billion to parts per quadrillion," says Caldwell. USGS research hydrologist Dana Kolpin, who's been studying pharmaceuticals in the environment for more than 15 years, explains that early on, scientists could only measure about 19 pharmaceuticals in a one liter water sample. Today, he says, "we use a 15-milliliter vial in which we can now measure 110 pharmaceuticals at much more sensitive levels."

McGill University associate professor of chemical engineering Viviane Yargeau and colleagues have found "illicit drugs" — including amphetamines, methamphetamine, cocaine and prescription opiods — in Canadian drinking water sources at nanograms per liter (parts per trillion) levels. These concentrations are "really small," says Yargeau, and the impacts of these particular compounds on wildlife and other biota have yet to be determined.

Pharmaceuticals being measured in the environment in small concentrations can produce biological effects when those levels are tested in controlled experiments.

"The fact they are there, shouldn't be cause for alarm," says Caldwell of pharmaceuticals being found in various water sources at this range of levels.

Yet impacts at infinitesimal levels are increasingly what studies are finding. Pharmaceuticals being measured in the environment in small concentrations can produce biological effects when those levels are tested in controlled experiments. For example, University of Wisconsin researchers recently discovered that levels of the antidiabetic drug metformin comparable to those found environmentally caused male fathead minnows to develop intersex gonads. Scientists in the U.K. have found that concentrations of the antidepressant fluoxetine (sold under various names, including Prozac) found in environmental samples altered behavior of starlings in an experimental study. Others in Sweden found similar results when fish were exposed to levels of another psychoactive drug, oxazepam, at levels found in wastewater samples.

While regulators stress the lack of evidence that such levels are harming human health on an acute basis — a point J&J's Caldwell also made — some scientists, including Kolpin and Yargeau, note that monitoring drugs at low levels is important for understanding possible long-term effects.

"We want to go as low as we can go in measurement as this is important in understanding long-term trends of exposure," says Kolpin. Even though organisms may look healthy, he explains, when you start to examine their tissues and behavior, "more subtle effects" of chemical exposure may become apparent. Having as much detailed data as possible will help scientists figure out what might be happening at a population level, rather than only to isolated individuals.

This type of detailed information about individual drugs will also help pinpoint which pharmaceuticals to target for removal, says

Yargeau. Additional studies are needed to guide regulators toward improving monitoring and treatment, she explains. “If we don’t do something, it might get worse,” she says.

How Big of a Problem?

Part of what’s needed is a more comprehensive grasp of exactly what’s out there and how big of a problem various pharmaceuticals pose in terms of human and environmental health impacts. As the Natural Resources Defense Council noted in a 2009 white paper, there are large data gaps in this domain — exact volumes of drugs used, relative contributions from humans and livestock, and a full accounting of what drugs are in the environment. Many studies document the presence of drugs, but thus far in the U.S. no data yet yield an overall picture. New studies forthcoming from USGS and the EPA may start to fill in those blanks.

When it comes to assessing a drug’s environmental impacts, things can get very complicated.

When it comes to assessing a drug’s environmental impacts, things can get very complicated. To understand what the environmental and health ramifications of a particular pharmaceutical may be, regulatory agencies in both the U.S. and Europe rely on information that comes from manufacturers. In the U.S., pharmaceutical manufacturers must submit this information to the FDA as part of the drug registration process, explains Raanan Bloom, senior toxicologist with the FDA’s Center for Drug Evaluation and Research.

This environmental assessment — in Europe called an environmental risk assessment — includes information about the drug’s ecotoxicity at various concentrations and about its effects on various aquatic organisms. The information is then correlated with manufacturers’ projections of production, sales and use volume to estimate what potential environmental impacts will be.

Drug categories now receiving particular attention from the

FDA are hormonally active compounds, antibiotics and what the FDA calls “high volume” drugs — those used frequently.

A study by a group of Swedish and U.K. researchers found 83 percent of ERAs produced in 2011 and 2012 to be either lacking in data or incomplete. And a report just released by the Swedish Foundation for Strategic Environmental Research is extremely critical of the environmental risk assessments pharmaceutical manufacturers submit to European Union authorities. The report also criticizes claims in these assessments of a need to keep certain information confidential — something that is also a feature of the environmental assessments drug manufacturers submit to the FDA — and calls for making the assessments available to the public. To improve efficiency in understanding and heading off potential problems, the study also suggests grouping risk assessment for similar compounds rather than relying on the current compound-by-compound approach. Among its other recommendations is the inclusion of information about a drug’s potential contribution to antibiotic resistance.

Drug categories now receiving particular attention from the FDA are hormonally active compounds, antibiotics and what the FDA calls “high volume” drugs — those used frequently. In April the FDA proposed guidelines about whether manufacturers will have to submit environmental assessments with applications for new drugs with hormonal effects. This, said Bloom, “points out our concern with hormonally active drugs.” But what’s being proposed wouldn’t necessarily prevent such compounds or their breakdown products from ending up in local water sources.

What Can We Do?

Given the demonstrated and potential impacts, what can we do about drugs in the environment?

Unused and unneeded drugs can go into take-back programs. In the EU, take-back and collection programs are required by law. Most collections there are handled by pharmacies, and much of what’s collected is incinerated. In the U.S., the Drug Enforcement Administration has, in many states, offered twice-

yearly collections that since 2010 have collected more than 4.8 million pounds of prescription drugs. Some U.S. states and other local governments have drug take-back programs as well. But there are logistical challenges for both recipients and contributors: Collectors of unwanted drugs — typically healthcare facilities, pharmacies and law enforcement offices — must be authorized by the DEA and arrange for proper handling of the unwanted drugs, and such facilities may not be conveniently located for drop-off.

Drug manufacturing offers another opportunity for reducing release of pharmaceuticals to the environment. Although manufacturing's contribution to pharmaceutical pollution is comparatively small, it can create "hot spots" of pollution. For example, near Hyderabad, India, which has been a major production site for generic drugs, researchers testing wastewater treatment plant effluent found levels of several antibiotics that Zorzet describes as being comparable to those that would be prescribed for treatment.

Pharmaceutical companies are also working to improve their manufacturing processes' environmental footprint, not just at the end of the pipe but also by moving to "green chemistry solutions.

To reduce such emissions, the industry is working to develop and implement what are being called "Ecopharmacostewardship" guidelines. The goal, Caldwell explains, is to work with facilities and suppliers around the world to, as he and colleagues wrote in a recent paper, "achieve the general standard of 'no discharge of APIs [active pharmaceutical ingredients] in toxic amounts.'"

Both Caldwell and the FDA note that pharmaceutical companies are also working to improve their manufacturing processes' environmental footprint, not just at the end of the pipe but also by moving to "green chemistry" solutions. Those include both more efficient drug production and designing drugs that will biodegrade more efficiently or that are effective as intended but minimize by-products that will be excreted and end up in the environment.

There is also concerted and substantial work underway in the pharmaceutical industry — including in India — to make manufacturing processes more efficient given that, historically, the industry was known for inputs — raw materials and energy — at volumes that dwarfed the volume of the finished product. Several pharmaceutical manufacturers, including Bristol-Myers Squibb, Eli Lilly, Merck & Co. and Pfizer, have won U.S. Presidential Green Chemistry Challenge awards for these efforts.

Wastewater treatment plants, meanwhile, are exploring possibilities for boosting their ability to remove pharmaceuticals from sewage.

Wastewater treatment plants, meanwhile, are exploring possibilities for boosting their ability to remove pharmaceuticals from sewage. Options range from treating water with ozone to enlisting the assistance of microbes. But, as the 2011 WHO report cautions, "Advanced and costly water treatment technology will not be able to completely remove all pharmaceuticals to concentrations less than the detection limits of the most sensitive analytical procedures at all times."

Just Beginning

All indications are that we're just at the beginning when it comes to understanding the presence and importance of pharmaceuticals in the environment, let alone what to do about them. Even as scientists investigate what's actually out there, pharmaceutical companies work to make drugs and drug production more environmentally benign, wastewater treatment professionals develop better ways to remove pharmaceuticals, and environmental and public health advocates work on campaigns to change practices, studies finding pharmaceuticals in the environment keep coming.

In fact, Kolpin says, hundreds are published each year. And although the amounts of pharmaceuticals being measured are exceptionally small, he says this information is important because it provides a base line for future comparison.

"What we think today is safe, we may find 10 years from now

there is some effect, that we didn't realize at the time was important," he says. "We're not trying to say the sky is falling. We're trying to put out the science saying there are some things that are of concern."

Add Your Comments

bcritskelly
Aug. 12th, 2015

Thank you for your informative article called "What to do about the antidepressants, antibiotics and other drugs in our water".

I appreciated the info HOWEVER, YOU OMITTED SOMETHING VERY IMPORTANT:

What can WE DO to help reduce this in our personal drinking water??

If you're going to write a doomsday article, you need to balance it with helpful information for us. Otherwise, your article is incomplete.

Can you add this most helpful, but missing information to this article?

Dan Gerrity
Aug. 12th, 2015

This is a great summary of the issue and covers the problem from many different angles…great job!

bcritskelly: Although these contaminants are detected in many surface waters, the concentrations of these compounds in many finished drinking waters are below the detection limits of those incredibly sensitive analytical instruments mentioned in the article. At the part-per-trillion (ng/L) level, these compounds have not been shown to have adverse health impacts on humans. So that means there are even greater margins of safety when they can't even be reliably detected because the concentrations are so low. However, it's understandable to be concerned about this. The carbon filters in some refrigerators or pitchers might remove some of these compounds as long as you