Health Facts

Dosed Without Prescription:
Preventing Pharmaceutical Contamination of Our Nation's Drinking Water

To read our full white paper addressing the issue of pharmaceutical contamination, visit **http://docs.nrdc.org/health**.

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The presence of pharmaceuticals in our waterways and drinking water has gained national attention among lawmakers, regulators, and the public. Prescription drugs can enter water through manufacturing waste, human or animal excretion, runoff from animal feeding operations, leaching from municipal landfills, or improper disposal. With many questions still unanswered regarding the scope of the problem and its consequences for human health and the environment, NRDC conducted an extensive survey of the scientific data, legal analyses, and existing advocacy campaigns around this issue. Based on our findings, we offer several recommendations related to drug design, approval, production, use, and disposal to curb the flow of pharmaceuticals entering our water systems and lessen the impacts of the pollution they cause.

PHARMACEUTICALS ARE CONTAMINATING THE NATION'S DRINKING WATER

In March 2008 the Associated Press reported that pharmaceutical residues had been detected in the drinking water of 24 major metropolitan areas across the country serving 41 million people; detected drugs included antibiotics, anticonvulsants, and mood stabilizers.[1] Samples taken from 139 streams in 30 states in 1999-2000 by the U.S. Geological Survey identified both organic wastewater contaminants and pharmaceuticals in 80 percent of the sampled sites.[2] The range of drugs found in the water included antibiotics, hypertensive and cholesterol-lowering drugs, antidepressants, analgesics, steroids, caffeine, and reproductive hormones.

Despite these alarming findings, little or nothing has been done to evaluate the potential detrimental effects on human health caused by exposure to low levels of pharmaceuticals.

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WASTE PHARMACEUTICALS ARE HARMFUL TO THE ENVIRONMENT

The presence of pharmaceuticals in our waterways raises issues beyond concerns about their potential impacts on human health. The threats posed to wildlife ecosystems should be of equal or higher concern because of the continuous nature of the exposure.[3] Human exposure through drinking water is intermittent compared to wildlife living in contaminated waters. Environmental monitoring has identified a host of pharmaceuticals present in some ecosystems at levels likely to harm aquatic organisms at the individual and population level.[4] Low levels of exposure to certain pharmaceuticals can have serious consequences, as shown by the recent discovery that endangered vultures in Asia have been dying from eating cattle containing relatively low concentrations of the drug diclofenac.[5] Permanent developmental abnormalities have also been suspected from low-level exposures in other species, with mounting evidence that the contamination of waterways is causing intersex fish in our nation's rivers and drinking water sources.

IDENTIFYING THE MAJOR SOURCES OF CONTAMINATION

There are many paths for pharmaceuticals to reach our water systems, with some releases being intentional and others unintentional. Much of the identified waste stems from agricultural uses, human excretion, improper disposal of drugs by households and medical facilities, and drug manufacturing processes.

Pharmaceuticals Enter the Environment Through Human and Animal Excretion

A major portion of pharmaceuticals in our drinking water are excreted by animals in large concentrated animal feeding operations where antibiotics and hormones are routinely administered to prevent infection or promote growth (see box). Estimates suggest that nearly two trillion pounds of animal wastes are produced annually in the United States, and that between 25 and 75 percent of antibiotics are excreted unchanged in feces where they can persist in the environment.[6,7] Subsequently, a large amount of antibiotics (and potentially antibiotic-resistant bacteria) are entering waterways and groundwater through overflow of waste lagoons, or by over-application of manure as fertilizer in farm fields. Hormones excreted by animals can also enter the environment and alter the reproductive development of aquatic species such as fish.

Because of our "toilet to tap" system, human excretion is also a source of pharmaceuticals entering the environment, but the relative contribution from human excretion is difficult to calculate. One issue that complicates the calculation is that some of the most frequently detected drugs in the environment are not necessarily those that are most frequently prescribed, indicating that some drugs are more resistant to breakdown in the body or in the environment and may be more problematic. For example, 80 to 90 percent of the antibiotic amoxicillin is excreted in its parent form, but only 3 percent of the anti-epileptic drug carbamazepine is excreted unchanged.[10] Overprescribing of drugs, aggressive marketing by pharmaceutical manufacturers, and off-label prescribing greatly increase the unnecessary use of pharmaceuticals in this country and exacerbate the environmental contamination problem.

Most Households Practice Bad Disposal Habits

A large portion of the pharmaceuticals in our water come from the improper disposal of unused or unwanted drugs by households and medical facilities. Most people either flush them down the toilet or throw them in the trash. The best method of disposal—"take back" programs in which drugs are returned to an authority and disposed of properly—is not commonly available, leaving people with few options.

In a 2006 survey of pharmacy customers in Tacoma, Washington, more than half of respondents reported storing prescriptions in their homes (54 percent) and flushing them down the toilet or sink (35 percent).[11] In a survey of Southern California residents a similar trend was found, with 45 percent disposing of their pharmaceuticals in the trash and 28 percent disposing of them down the toilet or sink. A random survey in King County, Washington showed that 52 percent of respondents disposed of pharmaceuticals in the trash, 20 percent flushed them down the toilet or sink, and only 1 percent returned them to a pharmacy or doctor.[12]

The "Ticking Time Bomb" of Antibiotic Resistance

There is a significant amount of activity and advocacy taking place to address the eroding efficacy of antibiotics, a public health crisis that some have referred to as a ticking time bomb. Tens of millions of pounds of antibiotics are used in agriculture to treat infections, to compensate for conditions that contribute to infection, and to promote growth (as feed additives). Many of these antibiotics are in the same classes of drugs that are used in humans.[8]

This overuse of antibiotics is resulting in needless infiltration of groundwater and surface waters. The U.S. Institute of Medicine and the World Health Organization (WHO) have both stated that the widespread use of antibiotics in agriculture is contributing to antibiotic resistance in pathogens that are harmful or even deadly to humans.[9]

Medical Facilities are Bigger Polluters Than Households

Hospitals deal with many unused pharmaceuticals, but not all dispose of the unused ones properly. A significant barrier to ensuring responsible disposal is that few medical professionals, including doctors, nurses, pharmacists, or administrators are educated about the issue. There is little, if any, teaching of proper disposal of pharmaceuticals or legal requirements in medical, dental, nursing, pharmacy, or veterinary schools. In addition to hospitals, long-term care facilities and other institutions also deal with large quantities of unused pharmaceuticals.[13] For example, nursing home residents are often transient, and to avoid liability issues, most facilities will not transfer medications with the residents. The protocol for most of these types of facilities is to flush even large quantities of unused medication.[14] There is little information about the extent to which these facilities and groups contribute to the problem of pharmaceuticals in the human waste stream, but some experts estimate that they could be the cause of 20 to 30 percent of the pharmaceuticals disposed intentionally into the waste system.[15] One survey in Washington State found that over 65 percent of pharmaceutical waste was coming from "specialty outpatient" facilities, more than 20 percent from hospitals, and about 5 percent coming from nursing homes, boarding homes, and retail pharmacies.[16]

REGULATION OF PHARMACEUTICALS IS INSUFFICIENT

Adding to the complexity of the problem is that the manufacture, collection, discharge, and disposal of pharmaceuticals are regulated by a number of different federal laws and three different federal agencies—the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Drug Enforcement Agency (DEA). The U.S. Department of Agriculture provides guidance for animal waste management (quantity and storage), but regulating the environmental impacts of waste is deferred to the EPA. Although EPA has made progress in regulating the manufacture of pharmaceuticals and protecting water resources, there remain loopholes in the system that allow pharmaceutical companies to evade certain restrictions. For example, while the FDA requires an environmental assessment discussing the potential environmental impacts of a drug as part of all new drug applications and some supplementary submissions, historically these assessments have consisted of little more than a statement that a compound had no potential environmental impact.

Furthermore, the FDA has a number of categorical exclusions to the environmental assessment requirement, most notably exempting from review the production of drugs predicted to occur at less than 1 ppb in the aquatic environment or 100 ppb in soil, which likely excludes many drugs.[17]

RECOMMENDATIONS FOR REDUCING PHARMACEUTICAL CONTAMINATION OF WATERWAYS AND DRINKING WATER

Stemming the tide of pharmaceutical contamination will require stronger regulations to reduce both intentional and unintentional disposal. Further research is needed to determine the impacts of the most frequently identified and persistent pharmaceuticals in the environment. Until the major knowledge gaps surrounding the problem are addressed and filled, regulators and policymakers will be ill-equipped to make important decisions to reduce future contamination and mitigate the damage that has already been done. NRDC has identified the highest priorities for policymakers, researchers, and the general public. We also provide recommendations for the additional funding, advocacy, and research needed to address each problem.

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Immediate action in the five target areas outlined below could result in significant progress toward protecting people and the environment:

1. Improve Drug Design: Drugs should be designed so that the active parent compound or its metabolites, if they are biologically active, do not persist in the environment after excretion. Factors like extent of metabolism and environmental persistence should be more rigorously evaluated during the drug design phase.

2. Tighten FDA Approval Processes: The FDA must properly consider environmental impacts by requiring thorough environmental assessments prior to granting approvals. The FDA should also help curb antibiotic resistance by restricting the use in animals of antibiotics that are critical for protecting human health. The FDA can help preserve the effectiveness of these antibiotics in humans by limiting approvals for both new uses and off-label uses of these antibiotics for animals and by revisiting approvals already granted to determine whether they should be withdrawn.

3. Improve Pharmaceutical Production Processes: Pharmaceutical production processes should be modified to generate less waste. Adoption of green chemistry principles would help reduce the generation of biologically active waste products.

4. Reduce Unnecessary Pharmaceutical Use: Overprescribing and overuse of pharmaceuticals in both humans and animals are major contributors to the contamination problem. Extensive advocacy and public education campaigns on this issue should continue, including efforts to reduce the overuse of antibiotics in livestock and education for healthcare providers on reducing unnecessary prescriptions.

5. Dispose of Pharmaceuticals More Safely: Many opportunities are available to prevent the discharge of pharmaceuticals into aquatic ecosystems. In response to the gap in responsible disposal options for households, many groups and local governments have begun creating "take back" programs as one alternative to flushing. The programs can involve permanent collection boxes set up in a pharmacy, one-day events sponsored by the local government, or special envelopes distributed to consumers to mail their leftover drugs to the appropriate agency. These opportunities should be made widely available to the public, and pharmacies should educate patients about disposal practices when prescriptions are made. For now, people who want to dispose of their unwanted pharmaceuticals responsibly should contact their local health officials or household hazardous waste facility to find out what options exist in their region.

For a more detailed set of recommendations please see the full NRDC white paper on the issue of pharmaceutical contamination in our water systems at http://docs.nrdc.org/health.

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[17] 21 CFR § 25.31(b).