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Mr. Chairman and members of the subcommittee, thank you for the opportunity to provide testimony on the source, occurrence, and effects of pharmaceuticals in the nation's drinking water and surface water, as well as on effective disposal and destruction practices to help prevent pharmaceuticals from entering the water supply.

THE SOURCE OF PHARMACEUTICALS IN THE ENVIRONMENT

The known major sources of pharmaceuticals entering our water supply include human activities (e.g. bathing, shaving, swimming), residues from pharmaceutical manufacturing, residues from hospitals, illicit drugs, veterinary drug use, especially antibiotics and steroids, and agribusiness.[1] During the last decade, due to advances in detection techniques, pharmaceuticals and other contaminants of emerging concern are increasingly being detected at low levels in the Nation's wastewater, surface water, ground water and drinking water. This issue has received national and international attention and media coverage. Although reports have been published documenting low level concentrations of contaminants such as prescription and over-the-counter drugs and other unregulated chemical contaminants in the environment, the ability to detect these contaminants does not necessarily translate to harmful effects to aquatic life or human health.

However, EPA is concerned about these contaminants in our nation's water. As a result, over the last few years, EPA has conducted a number of studies to better understand the implications of these contaminants. Several studies were conducted to characterize the occurrence of pharmaceuticals in sewage sludge, wastewater and fish tissue. Results from these

[1] http://www.epa.gov/ppcp/

studies confirm that very low traces of these contaminants are present in the environment.[2] EPA continues to support other monitoring efforts that will further increase our scientific knowledge regarding pharmaceuticals in the environment and in water supplies. For example, EPA's Office of Research and Development is conducting a survey for a wide array of pharmaceuticals and other unregulated contaminants, in partnership with the United States Geological Survey, of drinking water treatment plants across the United States to determine which contaminants are not being removed by drinking water treatment processes. This survey will further contribute to our characterization of the issue.

THE EFFECTS OF PHARMACEUTICALS ON HUMAN HEALTH AND AQUATIC LIFE

We know that pharmaceuticals have health effects at the therapeutic dose, but we do not know if there are effects associated with long-term exposure at much lower concentrations of the same chemicals. There are no known human health effects in the general population from such low-level exposures in drinking water, but sensitive populations (one example being fetal exposure to low levels of medications that a mother would ordinarily be avoiding) require more investigation.

Some effects to aquatic life have been seen in laboratory settings.[3] Laboratory studies have demonstrated effects to fish and other aquatic life from pharmaceuticals and estrogenic chemicals,[4] however, it is not known whether these low-level, chronic exposures adversely impact fish populations in natural settings. An experimental whole lake study[5] conducted by Canadian scientists (with EPA collaboration) assessed the impact of an endocrine disruptor on

[2] http://www.epa.gov/waterscience/ppcp/studies/9potwstudy.pdf
http://www.epa.gov/waterscience/fish/library/residuevol1.pdf
http://www.epa.gov/waterscience/biosolids/tnsss-overview.pdf
[3] Ellis, RJ et al., 2003, Knorr, S. and Braunbeck, T., 2002, Parks, L.G., et al., 2001
[4] http://www.jmst.org.tw/marine/15-2_1/29-36.pdf
[5] Kidd, K.A., 2007, et al.

the sustainability of a wild fish population. The seven year study involved the addition of a synthetic estrogen (17α ethinyl estradiol) that is used in birth control pills to a natural lake located in the Experimental Lakes Area of northwestern Ontario, Canada.

The study showed that chronic exposure of a common species of minnow to low concentrations (5-6 parts per trillion) of the hormone led to feminization of male fish and altered reproductive fitness in female fish using molecular, protein, tissue, and individual whole body tests and measurements. Ultimately, these impacts led to a near extinction of this species from the lake. These observations show that the concentrations of an estrogen observed in freshwaters can impact the sustainability of wild fish populations. Based on these research findings, EPA is currently examining whether synthetic estrogen and chemicals like it occur in the natural environment at levels that could produce these effects.

TREATMENT AND DISPOSAL PRACTICES

EPA has been investigating whether certain treatment technologies would be effective in eliminating or reducing pharmaceuticals in our nation's drinking water, particularly those that are naturally excreted. Certain drinking water treatment technologies, such as filtration, reverse osmosis, and ozonation, may be effective for removing pharmaceuticals. However, some removal technologies will be more effective than others (e.g. reverse osmosis) depending on water quality characteristics, the chemical's physical/chemical properties, and the fact that pharmaceuticals that occur at low concentrations may be out-competed by other contaminants removed by the same treatment processes (e.g., activated carbon).

The Clean Water Act's Pretreatment program[6] regulates certain discharges to municipal wastewater treatment plants through a regulatory program implemented through a combination

[6] epa.gov/npdes/pretreatment

of national, state and local authorities. While wastes from commercial facilities such as hospitals and pharmacies could be addressed through the national pretreatment program in some instances, the program does not regulate household wastes from private residences.

Municipalities that have been approved to administer a pretreatment program are required to develop local limits to control certain pollutants that would cause the municipality to violate its Clean Water Act permit. Some municipalities are implementing take back programs to reduce the amount of pharmaceuticals that are flushed down the toilet or disposed of in landfills. Municipalities, however, cannot be required to develop such programs unless there is evidence that the pharmaceuticals are interfering with its wastewater treatment plant or passing through the treatment plant and causing it to violate its Clean Water Act discharge permit.

FEDERAL GUIDELINES AND DRUG DISPOAL STEWARDSHIP PROGRAMS

EPA is also concerned about the disposal of unused pharmaceuticals by the general public and the health care industry. In February 2007, ONDCP in conjunction with the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA) published consumer guidelines for the disposal of unused medications, including dispensed controlled substances.[7] The guidelines advise the public to flush medications only if the prescription label or accompanying patient information specifically states to do so. Instead of flushing, the federal guidelines recommended that, after performing a minimal procedure to make the drugs unpalatable and sealed to prevent leaching, the medications be disposed of in common household trash or at community pharmaceutical "take-back" programs.

[7] Office of National Drug Control Policy, Executive Office of the President. Proper Disposal of Prescription Drugs. February 2007. http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf

Due to concerns about public safety, there currently ten controlled substances identified by the U.S. Food and Drug Administration (FDA) that retain a recommendation of disposal by flushing. Primarily narcotics, these preparations have life-threatening capabilities if improperly handled or improperly ingested.[8] Since 2007, EPA, HHS, and ONDCP have updated these federal guidelines, most recently in October 2009, to further refine the recommended steps and ensure the most accurate and current list of drugs that must be flushed in accordance with FDA policy as a tool to prevent substance misuse of prescription drugs which is a growing problem.

EPA has also been working to develop and promote good stewardship efforts such as take-back programs that would allow consumers to properly dispose of unwanted or unused pharmaceuticals. Take-back programs and events are collection methods that reduce the quantity of unused pharmaceuticals entering the environment and reduce the amount of drugs available for diversion, theft, or accidental poisoning. EPA recognizes that these programs must be consistent with the Controlled Substances Act and regulations for managing medications that are also classified as controlled substances. The Agency will work with DEA to ensure that pilot take-back programs supported by EPA are conducted safely and in compliance with federal and state laws and regulations.

Along these lines, in 2007, EPA funded a grant to the Area Resources for Community and Human Services in St. Louis. EPA's Aging Initiative in the Office of Children's Health Protection and Environmental Education provided a grant to this community partnership, which is piloting an efficient regional model to responsibly dispose of unwanted, non-controlled medications using a regional grocery store chain as the collection point. The grantee is evaluating this pilot take-back program for its potential broader applicability.

[8] Testimony by Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice on June 30, 2010

Similarly, EPA also funded a grant to the University of Maine's Center on Aging that resulted in completion of the first statewide mail-back pilot to manage pharmaceutical waste from consumers. The pilot collected more than 2,300 pounds of drugs and catalogued 380,000 pills of which 17 percent, or 250 pounds, were of controlled substances. Older adults were actively involved in the design and implementation of the Safe Medicine Disposal for Maine pilot. This grant was part of EPA's larger efforts to protect the health of older adults, a population susceptible to environmental hazards, and encourage older adults to engage in environmental stewardship in their communities.

In addition, EPA's regional offices have sponsored or provided grants to local communities to support several activities related to the prudent disposal of unused medications, including the successful April 2008 "Great Lakes Earth Day Challenge," which collected nearly 4.5 million pills for safe disposal.

In 2006, EPA identified the pharmaceutical disposal practices of the health care industry for study as part of its Effluent Guidelines Planning Process. This study has focused on the disposal of unused medications from health care facilities such as hospitals and long term care facilities. In the course of this study EPA staff met with over 700 stakeholders and visited 14 facilities to understand existing practices associated with unused medication disposal and to identify best disposal practices to prevent disposal of medications to water. EPA has drafted a guidance document and coordinated with other relevant federal agencies on the best practices for disposal of unused pharmaceuticals and plans to issue it for stakeholder comment in the fall.