UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 4 2008

OFFICE OF
WATER

The Honorable James M. Inhofe
United States Senate
Washington, DC 20510

Dear Senator Inhofe:

Thank you for your letter of March 10, 2008 to Stephen Johnson, Administrator of the Environmental Protection Agency (EPA), in which you expressed your concern about recent media reports related to the detection of pharmaceuticals in drinking water. The Agency shares your concern and is actively working on this issue.

Although the Associated Press series brought broad attention to this issue, EPA has been working with other agencies and stakeholders over the past several years to better understand the implications of emerging contaminants such as pharmaceuticals and other personal care products that are detected in our waters. As analytical techniques have improved, so has our awareness of their presence in water. However, as reported by the media and other studies, indications are that these contaminants occur at very low trace levels in water, including drinking water.

EPA, other federal agencies, and stakeholders have increased efforts to better understand the effects of pharmaceuticals, analyze their occurrence in water and fish, and how to best remove them from wastewater and drinking water. We are conducting national studies and surveys to inform our course of action. We are reviewing emerging contaminants for their potential to be regulated, partnering with government agencies and the private sector, and increasing public awareness about product stewardship and pollution prevention. An enclosure to this letter describes our efforts in these areas.

We understand the concerns of Congress and the public with respect to this issue, but we also know that science must drive our actions. While there is much information about the health effects of pharmaceutical products at the therapeutic doses provided in medication, there is still uncertainty about their potential effects on public health and aquatic life from long-term exposure to the low levels observed in water. In the absence of fully understanding the risks associated with low levels, it is difficult to move forward to require monitoring and/or treatment that carry significant cost, particularly when the Agency also needs to carry out activities to address contaminants with known risks.

We also know that this issue cannot be addressed by EPA alone. Other federal agencies and industry will also need to play a role. We will take your recommendation to establish an advisory committee or working group under consideration. EPA has been working with other agencies as part of the Pharmaceuticals in the Environment working group convened by the Office of Science and Technology Policy to review the range of research that has been conducted and which is underway so that the agencies understand what is still needed. We also worked with the White House Office on National Drug Control Policy to develop joint guidelines that recommend appropriate disposal methods for unused medication. EPA, other agencies, and the pharmaceutical industry are involved in a number of stewardship activities across the country to communicate the guidelines to the public.

The U.S. has one of the safest drinking water supplies in the world and the Agency is committed to keeping our water clean and healthy for the future. Over the coming weeks, we will be reviewing our current efforts to determine if they are sufficient to address concerns that have been raised. We know that collaboration with our internal and external partners will be critical so that we can all make the best use of our existing resources and restore consumer confidence in drinking water.

Again, thank you for your letter. If you have further questions, please contact me or your staff may call Greg Spraul in EPA's Office of Congressional and Intergovernmental Relations, at 564-0255.

Sincerely,

Benjamin H. Grumbles
Assistant Administrator

Enclosure

EPA Activities to Address Pharmaceuticals and Personal Care Products in Water

The following represents efforts that EPA had underway prior to release of the March 2008 Associated Press series on pharmaceuticals in water. Over the coming months, the Agency will review current efforts to determine if additional activities are appropriate.

Cross Government Coordination

EPA, the Food and Drug Administration, and the U.S. Geological Survey co-chair a working group on Pharmaceuticals in the Environment (PIE) under the auspices of the National Science and Technology Council Committee on Environment and Natural Resources Toxics and Risk Subcommittee. Seven agencies are represented on the working group, which is examining current federal efforts with regard to human and veterinary pharmaceuticals in the environment, including antibiotics, with the goal of better prioritizing federal efforts. The group anticipates releasing a final report by the end of 2008.

Research

EPA's Office of Research and Development has been carrying out a significant amount of research related to pharmaceuticals and other personal care products for several years. An inventory of projects developed for the period from 1996 through 2014 is available on the EPA web site at http://www.epa.gov/ppcp/work2.html. Research has included projects to develop techniques to support monitoring and detection of pharmaceuticals, projects to investigate potential sources of pharmaceuticals, and their fate and transport in the environment. Projects have also evaluated human and ecological exposure pathways and associated health effects. The Agency has also supported and cooperated with research efforts carried out by industry organizations, such as the American Water Works Association Research Foundation (AwwaRF) and Water Environment Research Foundation (WERF).

Methods Development

In December 2007, the Agency released methods for the analysis of approximately 160 pharmaceuticals, personal care products, steroids, and hormones in water, soil, sediment, and biosolids by high performance liquid chromatography combined with tandem mass spectrometry. The availability of the methods responds to requests for guidance in this area; however we will continue to refine them and consider additional methods. It is important to note that it is critical to ensure sound collection and analysis of samples because there is a great potential for cross-contamination at the low levels detected in most samples. It is also important to note that the equipment needed to test for pharmaceuticals is highly technical and that analyses are very expensive relative to other contaminants.

Occurrence

The Agency has a number of projects underway to evaluate the occurrence of pharmaceuticals in wastewater effluent, biosolids and fish tissue, including:

- A survey of nine Publicly-Owned Treatment Works (POTW) that will help the Agency to better understand what is going into the POTW for treatment and what is coming out both in the discharge and in the biosolids. The expected completion date is December 2009.
- A Pilot Fish Tissue Study to investigate whether pharmaceuticals and other personal care products may occur in fish from five effluent-dominated streams across the US. Results are expected this year.
- A Targeted National Sewage Sludge Survey to determine whether approximately 100 pharmaceuticals and other personal care products may occur in biosolids. EPA is sampling sludge from 74 randomly selected POTWs across the country and expects to complete the project later this year.

Regulatory-Related Activities

As part of the effluent guidelines planning process, the Agency is examining the pharmaceutical disposal practices of long term care facilities. With respect to drinking water, EPA recently released a draft of the third Contaminant Candidate List (CCL3) for public review and comment. The CCL3 identifies 104 contaminants that the Agency will evaluate to determine if national drinking water regulations are needed to protect public health. The CCL3 process, which is based on recommendations from the National Academy of Science and the National Drinking Water Advisory Council, considered the full range of contaminants that can occur in drinking water – including microbial pathogens, pesticides, pharmaceuticals and personal care products, and chemicals used in industrial practices and consumer products. EPA included 287 chemicals identified as pharmaceuticals and personal care products within the 7,500 chemicals that were evaluated to develop the CCL3. None were included on the Draft CCL 3 because they occurred at very low levels compared to the best available health effects data. As part of the public comment process, the Agency is seeking additional data and information on the concentrations of pharmaceuticals in treated or ambient water and adverse health effects that may be posed by pharmaceuticals in drinking water.

Reducing Inappropriate Disposal

In conjunction with the White House Office on National Drug Control Policy (ONDCP), EPA issued drug disposal guidelines early last year to help reduce the quantities of pharmaceuticals entering our nation's waterways. EPA has also been working to develop, support, and promote good stewardship efforts such as voluntary take-back programs for unwanted or unused pharmaceuticals.