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BEFORE THE
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Good afternoon Chairman Lautenberg and members of the Committee. I am Benjamin H. Grumbles, Assistant Administrator for Water at the United States Environmental Protection Agency (EPA). I appreciate the opportunity to describe EPA's actions to evaluate the potential risks to human health and aquatic life posed by trace amounts of pharmaceuticals in water, and to identify measures to minimize their occurrence in water. The Agency is committed to undertaking a scientific approach in evaluating the risks associated with contaminants in our environment so that we can take the necessary action to ensure clean and safe water.

EPA is concerned about the detection of a number of pharmaceuticals and personal care products in our water. EPA has been actively working with federal agencies and state and local government partners to better understand the implications of emerging contaminants such as pharmaceuticals, endocrine disrupting chemicals, and personal care products detected in drinking water, wastewater, surface water and ground water. We continue to evaluate their routes of exposure, levels of exposure, and potential effects on public health and aquatic life.

Over the last few years, EPA has increased its work in a number of areas to better understand pharmaceuticals and personal care products. We are focused on learning more about the occurrence of pharmaceuticals and personal care products in water. In addition, we are working to better understand what treatment technologies may remove them from wastewater and drinking water. We are developing analytical methods to improve detection capabilities. We are conducting national studies and surveys to help direct our course of action. We are also partnering with government agencies, stakeholders, and the private sector, and increasing public awareness about product stewardship and pollution prevention.

## U.S. Drinking Water is Among the Safest in the World

The U.S. has one of the safest drinking water supplies in the world. EPA is committed to keeping our water clean and healthy for the future.

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 at the extremely low levels observed in drinking water and surface water. Let me give you an example.

Although pharmaceuticals have been detected in a number of U.S. waters (as well as waters worldwide), the amounts at which they are detected -- in the parts per billion and parts per trillion range --are extremely low. For example, in looking at a number of studies, the maximum reported drinking water level for caffeine was 0.12 parts per billion. At that concentration, a person

would have to drink almost 222,000 gallons of water before coming close to ingesting the amount of caffeine that one would get from a six ounce cup of coffee.

We know that collaborating with our partners will be critical so that we can all make the best use of our existing resources and maintain consumer confidence in our drinking water. Keeping public drinking water safe and ensuring that consumers have high confidence in our nation's drinking water is an absolute tenet of EPA's approach to environmental and public health protection. It is also testimony to the daily efforts of thousands of people from the federal officials who develop standards, to the state managers that carry out programs, and the local officials who provide drinking water and treat wastewater.

## EPA's Four-Pronged Approach to Emerging Contaminants

EPA is responding to emerging contaminants, with a four-pronged approach aimed at improving science, communicating risks, identifying partnership and stewardship opportunities, and preparing to take regulatory action when appropriate.

### *Strengthening the Science*

Sound science and reliable information must be the foundation for any Agency decision. There is critical work that needs to be done in the area of research and assessment before we can make any decisions as to whether regulatory actions are needed. EPA and other federal agencies are working on projects to evaluate exposure and potential health effects on humans and aquatic life. This is a key, because while we know that pharmaceuticals have health effects at the

therapeutic dose, we are less certain about the health effects associated with long-term exposure to much lower concentrations. Effects may be more likely in aquatic life because they are continually exposed.

Several EPA offices, including my Office and the Office of Research and Development, are working together to better understand potential issues related to exposure pathways and health effects of emerging contaminants including pharmaceuticals. I will describe some of the efforts we are undertaking in my office and have provided a brief summary of efforts in the Office of Research and Development as an attachment to this testimony.

EPA's Office of Research and Development is engaged in a broad portfolio of research efforts, much of which is focused on answering key questions associated with exposure pathways and health effects. EPA is also coordinating research efforts with other federal agencies as part of the Pharmaceuticals in the Environment (PiE) workgroup, under the auspices of the White House's National Science and Technology Council Committee on Environment and Natural Resources Toxics and Risk Subcommittee. The workgroup is co-chaired by EPA, the U.S. Geological Survey, and the Food and Drug Administration.

Other key research areas are associated with assessing the sources of pharmaceuticals. Important to this effort is having analytical methods available to reliably detect these contaminants in water. It is critical to ensure sound collection and analysis of samples because there is a great potential for cross-contamination and thus false identification and incorrect concentrations 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. In December 2007, the Agency released newly developed, cutting edge methods

for the analysis of approximately 100 pharmaceuticals, personal care products, steroids, and hormones in raw sewage, treated wastewater, and biosolids which are some of the most complex samples to test. The new methods, which are continuing to be refined, use high performance liquid chromatography combined with tandem mass spectrometry. The availability of the methods responds to requests for guidance in this area and the need to support studies being conducted by the Agency. We will continue to consider and evaluate additional methods.

EPA, other federal agencies, and academic and private sector researchers are studying the occurrence of pharmaceuticals in wastewater, surface water, ground water and drinking water. We are also evaluating the occurrence of contaminants in fish and other aquatic life. In particular, EPA's Office of Water is conducting:

- a study at nine wastewater treatment facilities to better understand what is going into the plant for treatment and what is coming out in the discharge and in biosolids (sludge). We expect to complete this study by December 2009.
- a Fish Tissue Pilot Study to investigate whether pharmaceuticals and other personal care products may occur in fish from five effluent-dominated streams across the US. Results are undergoing quality assurance review and are expected later this year.
- a survey of biosolids from 74 randomly selected wastewater treatment plants to determine whether contaminants occur in biosolids, and if so at what concentration.

My office has also funded external research projects to assess occurrence. Researchers at the University of Florida are studying the fate and transport of emerging contaminants like triclocarban (an antiseptic widely used in soaps and other products) in biosolids. Researchers at Duke University are studying the presence, fate and treatability of steroid and hormone contaminants in wastewater and biosolids. They are conducting a year-long field study in four municipal wastewater treatment plants and are evaluating the overall potency of the wastewater through laboratory tests.

Additionally, EPA's Office of Research and Development's research agenda includes work to better understand pharmaceuticals in water through several important programs. A brief summary of those activities is attached to this testimony.

We will continue to work within EPA and with our federal, state, and local partners to identify and analyze available information and potential studies to assess the occurrence of pharmaceuticals in our drinking and surface water, along with any potential risks to human health and aquatic organisms.

Another important research area is treatment and removal of pharmaceuticals from wastewater and drinking water. While EPA is active in this area, research foundations representing drinking water and wastewater utilities are key players in determining the removal efficiency of different types of treatment. Research is finding that more sophisticated higher-level treatment strategies are sometimes better at removing certain types of pharmaceuticals. However, it is important to ensure that utilities continue focusing their efforts at removing those contaminants

with known risks (such as pathogens), especially when monitoring and/or treatment efforts aimed at pharmaceuticals at low levels could carry significant cost with unknown risk reduction.

*Improving Public Understanding and Risk Communication*

One of the most difficult tasks faced by public health and environmental officials is how to communicate risks in the face of uncertainty. At this time we simply do not know whether there is a human health risk of concern from the levels that have been reported in water. Some have argued that it does not make sense to monitor for pharmaceuticals in water if there is limited information about the health effects at the concentrations that could be detected. We disagree. Information about occurrence and health effects is complementary and should be developed in tandem. It would be unfortunate indeed if proactive utilities referenced in media articles made decisions to reduce their research in response to media attention. Furthermore, useful information should be shared with the public in a timely way as it is generated. It is important to communicate with the public so that they can help shape effective public policy in this area and make informed choices. We will continue to work with all of our stakeholders to do the best job possible in communicating available data on both occurrence and health effects for all emerging contaminants, including pharmaceuticals, and any associated uncertainty with that data.

*Building Partnerships for Stewardship*

One thing we know for certain is that this issue cannot be addressed by EPA alone. Other federal, state, and local agencies and industry will also need to play a role in assessing the occurrence and effects of pharmaceuticals, analyzing their risk, and in determining actions to reduce their concentration in the environment. EPA is already coordinating research efforts with seven other federal agencies as part of the PiE workgroup which is examining current efforts with regard to human and veterinary pharmaceuticals in the environment, , with the goal of avoiding duplication of effort, leveraging existing resources, and better prioritizing Federal efforts.

We also worked with the White House Office of 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. While most pharmaceuticals are entering water through natural biological functions, it is also important that the public understand that the toilet is not a trash can for unused medications.

EPA has also been working to develop and promote good stewardship efforts such as take-back programs that would allow consumers to properly dispose unwanted or unused pharmaceuticals. EPA recognizes that any such programs must be consistent with the Controlled Substances Act and regulations with respect to managing medications that are also classified as controlled substances. Toward this end, the Agency will be working with the Drug Enforcement Administration (DEA) to ensure that pilot take-back programs supported by EPA are conducted in a manner that is safe and in compliance with federal and state laws and regulations.

One such program that EPA recently funded involves the Area Resources for Community and Human Services in St. Louis. Last year, EPA's Office of Children's Health Protection and Environmental Education provided grants to this community partnership, which is working on an efficient regional model to responsibly dispose of unwanted non-controlled medications through a regional grocery store chain as the collection point. We are working on the evaluation and development of this pilot return take back programs to allow consumers to return and dispose of medications in a safe manner that complies with federal and state law and are working closely with the Drug Enforcement Administration to ensure applicability to all laws.

Additionally, EPA provided a grant to Villanova University to identify ways to better manage how prescription and non-prescription pharmaceuticals are discarded from university dormitories. The results of Villanova's work can be useful for other universities that are voluntarily taking steps to reduce pollution on their campuses as their commitment to improving the environment.

*Using Regulatory Tools*

We recognize stewardship activities alone are not always sufficient to manage issues associated with emerging contaminants in water. We are also gathering information that will help us assess whether direct regulatory action is warranted. For example, under the Clean Water Act, EPA establishes technology-based national regulations, termed "effluent guidelines," to reduce pollutant discharges from categories of industrial facilities to waters of the United States. As part of the effluent guidelines planning process, the Agency is reviewing the pharmaceutical disposal

practices of hospitals and long-term health care facilities. We expect to issue a report on our findings in 2009. We view this as an important opportunity to increase product stewardship and proper waste disposal.

Under the Safe Drinking Water Act, the Agency carries out a program to assess contaminants for potential drinking water regulation. On February 21, 2008, the Agency released the draft Contaminant Candidate List (CCL 3) for public review and comment. As part of the process to develop the list, the Agency evaluated pharmaceuticals and personal care products to identify those that have the potential to occur in drinking water provided by public water systems. EPA considered 287 chemicals identified as pharmaceuticals and personal care products; however, only one was included on the Draft CCL 3 because most occurred at levels far below those currently associated with any adverse health effects, based on the best available human health effects data. 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 their presence. We are also interested in receiving feedback on how we considered pharmaceuticals within the CCL 3 process.

The CCL 3 process evaluated many types of contaminants that can occur in drinking water – including microbial pathogens, pesticides, and chemicals used in industrial practices and consumer products. The 104 contaminants on the Draft CCL 3 include 93 chemicals and 11 microbiological contaminants. In the absence of reliable data indicating potential risks associated with pharmaceuticals in water at the very low levels at which they have been detected, it would be inappropriate to require monitoring and/or treatment that could carry significant cost, with no evidence of significant risk reduction based on currently available data. The Agency needs to

instead focus its regulatory resources on contaminants with known significant risks in order to maximize public health protection.

## Looking to the Future

EPA will continue to work on the important issue of pharmaceuticals in water. We regard this as an issue that warrants additional, on-going scrutiny.

I have sent letters to the directors of state environmental and health agencies to inform them about some of our efforts and to request their assistance. In conjunction with the CCL 3 comment period, I have asked them whether they are currently implementing, or planning to implement, a program to monitor for pharmaceuticals and personal care products in wastewater, surface water, ground water, or tap water. This type of information can be very useful to EPA as we carry out our contaminant candidate listing process to identify potential contaminants for unregulated contaminant monitoring and/or drinking water regulation, revise effluent guidelines, and determine which contaminants are the highest priorities for development of new or revised water quality criteria.

As part of EPA's broader strategy to strengthen and expand technical partnerships and information sharing at all levels, I have also asked the states to share information with us with respect to stewardship activities they may be undertaking to manage the presence of pharmaceuticals and personal care products in water within their state. We will compile the information we receive with the goal of sharing best practices and encouraging broad adoption of effective programs across the country.

Some of the additional activities we are considering include:

- expanding our current fish tissue pilot study to ensure a statistically and nationally representative picture of the presence of pharmaceuticals and personal care products in aquatic life;
- improving our public access web site to provide information on the work that we are doing and to communicate our understanding of risks to human and aquatic health;
- working within EPA and across federal agencies to better understand stewardship efforts they are undertaking to both improve coordination and share information; and,
- working to obtain toxicology data from available sources (including other federal agencies) and exploring ways to improve understanding of health effects posed by exposure to low levels of pharmaceuticals in water.

I will also be meeting with a number of key stakeholder groups over the next several weeks – including those representing state programs, the water and wastewater industry, research associations, and the environmental community. It is essential for us to share information and understand specific concerns so that we can work together as effectively as possible in communicating with the public.

Finally, while I have primarily discussed Office of Water activities here today, other offices within EPA and across the EPA Regions have also been carrying out efforts associated with

pharmaceuticals and other emerging contaminants. They are reviewing their efforts to date and assessing what additional activities they may undertake in the future.

## Conclusion

The U.S. continues to have one of the safest drinking water supplies in the world due to our collective long-standing commitment to keep our water clean and healthy. We know that good science and information must continue to drive our decisions. We will continue to evaluate health effects, occurrence, and risk reduction strategies so that we can make sound decisions to protect public health and aquatic life. We recognize the public must be a full partner in our efforts to collect and evaluate data so they can help shape effective public policy in this area and make informed choices. By engaging the full range of public and private partners and by using appropriate regulatory tools, we will continue to ensure the safety of the nation's water.

Thank you Chairman Lautenberg and members of the Committee for this opportunity to describe EPA's important work on pharmaceuticals and other emerging contaminants. I would be happy to answer any questions you may have.