Testimony for May 13, 2008 Oversight Hearing on
Reports of Pharmaceutical Contamination in Public Water Supplies
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Introduction. Public Employees for Environmental Responsibility (PEER) is a Washington D.C.-based non-profit, non-partisan public interest organization concerned with honest and open government. Specifically, PEER serves and protects public employees working on environmental issues. PEER represents thousands of local, state and federal government employees nationwide; our New England chapter is located outside of Boston, Massachusetts.

PEER is extremely concerned about the pharmaceuticals and personal care products (PPCPs) found in our water supplies. We appreciate that you are holding this Oversight Hearing, and soliciting comments from the public. PEER's specific comments are set forth below.

Background. Regulatory agencies at all levels of government are realizing that pharmaceutical and personal care products (PPCPs) and endocrine disrupting chemicals (EDCs) in surface and drinking water are of concern. PPCPs and EDCs are being found in rivers, lakes, and groundwater, all which serve as sources of drinking water, and even in treated drinking water.

PPCPs include over-the-counter (OTC) medications, prescription medications, dietary supplements, hormones, cleaning agents (especially antibacterial cleaners), and the inert ingredients that are associated with these products (which can be just as harmful, if not more so, than the active ingredients themselves). Many of the PPCPs are actually designed to impact the human hormone system. Some PPCPs are also Endocrine Disrupting Chemicals (EDCs). The endocrine system is a complex network of hormones and glands which release hormones into the body and regulate growth, development and maturation. Endocrine disruptors are synthetic chemicals which either block or mimic natural hormones, which in turn disrupt normal functioning of organs. PPCPs and EDCs are often present in wastewater as complex mixtures, which can lead to unknown synergistic effects (http://www.neiwpcc.org/ppcpconference/ppcp-docs/EdwardFurlong.pdf).

How do PPCPs get into our drinking water? Many of the components of OTC drugs, supplements, and prescription medications are not completely metabolized by the human body. Therefore, the unmetabolized portions of these compounds are excreted when people defecate or urinate. For example, when amoxicillin, a common antibiotic, is ingested, 60% of the drug comes out unchanged in the urine (See "Survey of the New York City Watershed for the Presence of Pharmaceuticals," NYS Department of Health, Troy, NY and Wadsworth Center for Laboratories and Research, NYS Department of Health, Albany, NY; (http://www.neiwpcc.org/ppcpconference/ppcp-docs/Barbara%20Hartley%20Grimes/BarbaraHartleyGrimes.pdf). Similarly, 40% to

50% of atenolol is excreted unchanged; and 90% of cephalexin (also known as the antibiotic Keflex).

Even if these compounds are then treated to the highest standards prescribed by state and federal law, the compounds make it into the waste stream and are discharged into the environment. Waste water treatment plants are neither designed nor intended to remove these compounds from the waste stream. In fact, scientists researched the reaction of the common painkiller acetaminophen to wastewater disinfection, and found that it formed 11 discernable "daughter compounds," two of which were known toxic compounds (Bedner, M. and W. A. MacCrehan, Transformation of Acetaminophen by Chlorination Produces the Toxicants 1,4-Benzoquinone and *N*-Acetyl-*p*benzoquinone Imine, *Environ. Sci. Technol.*, 2005).

What are the effects of PPCPs in our wastewater? From 1999 to 2002, the United States Geological Survey (USGS) studied surface and groundwater samples from around the country to determine whether PPCPs were present. They found at least one compound in 80% of streams and 93% of groundwater. The most commonly found compounds were: steroids, OTC medications (like ibuprofen), and insect repellants.

Different PPCPs have different toxilogical effects. For example:

> The PPCPs **triclosan and tricloscarban**[1] have been found to disrupt development in frogs (Veldhoen, N. et al, Aquatic Toxicology 80, *The bactericidal agent triclosan modulates thyroid hormone-associated gene expression and disrupts postembryonic anuran development*, (2006) 217-227); causes endocrine disruption in mussels (Canesi, L. et al., *Effects of Triclosan on Mytilus galloprovincialis hemocyte function and digestive gland enzyme activities: Possible modes of action on non target organisms*, Comparative Biochemistry and Physiology Part C 145, (2007) 464- 472); disrupts thyroid hormones in rats after only short-term exposure (Crofton, et al., *Short term in Vivo exposure to the water contaminant triclosan: Evidence for disruption of thyroxine*, (2007), (www.ealing.gov.uk). Triclosan and triclocarban are toxic to aquatic biota, bioaccumulate in algae and earthworms, are endocrine disruptors, can contain dioxin and other carcinogens, degrade to form other carcinogens, and are persistent in the environment (http://www.neiwpcc.org/ppcpconference/ppcp-docs/RolfHalden.pdf).
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> Antibiotics such as **sulfamethoxazole**, **trimethoprim**, **erythromycin**, and **Keflex** can get into the water and create antibiotic resistance. Antibiotics are turning up in surface and ground waters, and are of concern due to the fact that antibiotics in the environment selects for drug-resistant strains of bacteria. When bacteria are exposed to low doses of antibiotics, they develop a tolerance for those same drugs. When humans are subsequently infected with these drug-resistant bacteria,

[1] Triclosan and triclocarban are antibacterial agents found in some toothpaste, mouthwash, cleaning products, soaps and cleaners. It is also prescribed for patients with resistant *staph* infections as a shower gel.

certain antibiotics are ineffective at treatment (see, e.g., http://www.ijc.org/rel/pdf/09_Pharma-fall2002.pdf). This is of concern to people because there are 14,000 deaths annually due to antibiotic resistance. (Reckhow, D. and Anastas, N. UMass, "Investigating Treatment Effects on Targeted Endocrine Disrupting Compounds and Pharmaceuticals in Drinking Water, 2007).

In 2006, the USGS found intersex fish in the Potomac River that were likely created by **EDCs.** EDCs are also responsible for other abnormal sexual function in non-human animals, such as decreased fertility. During a March, 2007 congressional briefing on compounds of emerging concern, Dana Kolpin, Chief of the U.S. Geological Survey's toxic substances hydrology program, stated that the USGS has "definitive" evidence from laboratory experiments that chemical compounds found in household detergents, drugs, and other compounds that pass through wastewater treatment plants are responsible for "feminizing" male fish downstream of such plants (http://www.mgsglaw.com/ehsarchive.html). Potential human health impacts include: cancer, Type II diabetes, behavioral changes such as increased aggressiveness and decreased attention span, compromised immunity, and neurological effects (Spano, T., "Contaminants of Emerging Concern: Endocrine Disruptors," Presentation to COG Chief Administrative Officers Committee, August 1, 2007). It has also been suggested that EDCs may cause lowered sperm counts in humans, and abnormalities in male sex organs. There is clear evidence that exposure to EDCs result in adverse health impacts on non-humans and many scientists therefore caution that we must invoke the precautionary principal when considering the potential impacts on humans. In fact, the World health Organization states:

> "…the biological plausibility of possible damage to human reproduction from exposure to EDCs seems strong when viewed against 1) the background of known influences of endogenous and exogenous hormones on many of the processes involved, and 2) the evidence of adverse reproductive outcomes in from wildlife and laboratory animals exposed to EDCs. The biological plausibility and the striking changes in human reproductive health trends in some areas, for some outcomes, are sufficient to warrant concern and make this area a research priority….there is biological plausibility and some experimental evidence that EDCs may contribute to hormonally influenced human cancer…" (Damstra, T., Barlow, S., Bergman, A., Kavlock, R., and Van der Kraak, G. (2002). "Global Assessment of the State-of-the-Science of Endocrine Disruptors," WHO publication No. WHO/PCS/EDC/02.2, pages 69 and 86).

Other PPCPs found in water include:

- Sulfamethoxazole – antibiotic
- Codeine – painkiller
- Cotinine – metabolite of nicotine

- Trimethoprim – antibiotic
- Dehydronifedipine – metabolite of hypertension and angina med
- Diltiazem – high blood pressure and angina
- Acetaminophen – OTC pain killer
- Ranitidine – peptic ulcer and reflux
- Caffeine – found in some painkillers
- Diphenhydramine – benadryl – antihistamine
- Carbamazepine - anticonvulsant and mood stabilizing drug, used primarily in the treatment of epilepsy and bipolar disorder
- Cimetidine – ulcer medication
- Metformin – anti –diabetic drug
- Erythromycin – antibiotic
- Thiabendazole – fungicide and parasiticide (used primarily for roundworm treatment)
- Atenolol – a beta-blocker used to treat cardiovascular disease

Although we do not yet know all of the effects of PPCPs and EDCs on humans, we do know that chronic exposure (low levels of compounds over a long period of time) is of great concern. This is particularly true for children in utero, young children, elderly, and people with compromised immune systems. Numerous sources state that there is a potential risk from PPCPs in our drinking water. For example, a study done at the University of Barcelona states, "PPCPs can pose a huge risk… because long exposure to trace levels leads to unpredicted and unknown subtle effects. The enormous diversity of chemical composition of pollutants in waters excludes the possibility of using an universal treatment method and suggests the requirement of special treatment technologies for water decontamination." (http://www. tesisenxarxa.net/TDX-0126107-111807). The Harvard School of Public Health's web site states, "The effects of PPCPs once released into the natural environment and drinking water sources are largely unknown. Because many were designed to counteract chemical interactions or to target specific metabolic and biological pathways in humans, there is concern that some PPCPs may disrupt key processes in sensitive non-target organisms, including certain human populations." Even Dr. Christian Daughton, EPA's expert on pharmaceuticals, states that some of the detected PPCPs in the environment exhibit negative hormonal and toxic effects on various organisms at concentrations as low as $\mu g\ kg^{-1}$ (Daughton, C.G., and T.A. Ternes. 1999. Pharmaceuticals and personal care products in the environment: Agents of subtle changes? Environ. Health Perspect. 107:907–938, 1999).

Some people argue that PPCPs and EDCs are found in our drinking water in such tiny amounts (parts per trillion, or ppt) that they cannot possibly cause human harm. However, EPA regulates land disposal of dioxin at 300 ppt. Moreover, insulin, estrogen, and other hormones are exceptionally potent chemicals that operate at concentrations of ppt, and fetuses are sensitive to chemicals in the parts per *quadrillion* range.

Therefore, concern is based in part on the fact that most PPCPs: (1) are *designed* to have biological effects on humans, (2) are continually added to waters through

wastewater effluent, (3) have demonstrated negative environmental effects on aquatic life, even at extremely low levels, and (4) likely have cumulative and synergistic effects when combined together.

How far will the contaminants travel? It is impossible to predict how far the PPCPs and EDCs discharged from wastewater treatment plants will travel. However, a study in Massachusetts found that acetaminophen, carbamazepine, and sulfamethoxazole detected in a wastewater plume one mile away from the source (see Zimmerman, M.J., 2005, Occurrence of Organic Wastewater Contaminants, Pharmaceuticals, and Personal Care Products in Selected Water Supplies, Cape Cod, Massachusetts, June 2004, U.S. Geological Survey Open-File Report 2005-1206, (http://pubs.usgs.gov/of/2005/1206). Obviously, factors that affect the distance these substances travel include soil type, groundwater and surface water flow, geology of the landscape, and pumping characteristics of nearby wells.

Certain types of developments are more likely to result in effluent containing high levels of PPCPs. It makes sense that people who take more medication, and facilities that use many medications on a daily basis would result in effluent with much higher concentrations of PPCPs than residential developments or retail developments. The types of developments that will likely discharge high concentrations of PPCPs include hospitals, nursing homes, medical facilities, assisted living facilities, elderly housing, and veterinary hospitals and facilities, and medical laboratories. There are data supporting the contention that housing that have many elderly, such as elderly housing, assisted living, and nursing homes, would indeed discharge more PPCPs. According to the National Institute on Aging, people ages 65 and older consume more prescription and OTC medicines than any other age group. Moreover, seniors tend to have more long-term, chronic illnesses that require pharmaceuticals, including arthritis, diabetes, high blood pressure and heart disease than younger people. In fact, people over age 65 buy 30% of all prescription drugs and 40% of all OTC drugs (http://www.fda.gov/fdac/features/1997/697_old.html). Specifically:

> **Bacterial infections**: The elderly have increased susceptibility to bacterial infections, and therefore are on antibiotics more often than younger counterparts (http://www.biochemsoctrans.org/bst/031/0449/0310449.pdf).
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> **Heart disease**: Several of the PPCPs commonly found in water are used to treat heart disease, such as dehydronifedipine, diltiazem, and atenolol. Heart disease is a leading cause of death in the United States, and 84% of persons 65 years or older succumb to heart disease. Prescription drugs are a standard method of treating heart disease in the elderly (http://www.aafp.org/afp/20050615/2289.html). To complicate matters further, the elderly often have multiple cardiovascular risk factors (e.g., high blood pressure, diabetes, and/or abnormal cholesterol), and therefore need multiple drugs to treat them.

Pain medications: Pain is also far more common among the elderly than among younger people. Scientists found that pain prevalence in the elderly ranged from 36% to 88%, with pain more prevalent among nursing home residents. In the US, about 1/5 of elderly people take analgesics at least several times per week, and 2/3 of these people take prescription analgesics for longer than 6 months (http://www.merck.com/mkgr/mmg/sec6/ch43/ch43a.jsp).

EDCs: Hormones are frequently given to the elderly to treat and prevent various diseases. Osteoporosis, an age-related disorder, is treated in postmenopausal women by estrogen replacement (Am J Obstet Gynecol. 1987 Jun;156(6):1516-23). Oral estrogen is given to elderly men to improve serum lipids, homocysteine and fibrinolysis **(**Atherosclerosis. 1998 Apr;137(2):359-66). Hormone replacement therapy (HRT) is used in women over than 60 to prevent coronary artery disease (J R Soc Med. 1998 September; 91(9): 475–478).

Depression: Depression affects more than 6.5 million of the 35 million Americans 65 years or older. Depression in older persons is closely associated with dependency and disability, and is often treated with prescription drugs (http://www.nami.org/Template.cfm?Section=By_Illness&template=/ContentManagement/ContentDisplay.cfm&ContentID=7515).

It is clear, then, that the elderly tend to take more pharmaceuticals than their younger counterparts. Moreover, according to Silent Spring, a not-for-profit organization that looks at environmental contaminants, residential density is a factor in the number of PPCPs and EDCs, and the concentrations of those contaminants ("Contamination of Ponds on Cape Cod, MA by Steroidal Hormones and Pharmaceuticals from Septic-Contaminated Groundwater," Standley, L. et al., (www.silentspring.org, 2007). Nursing homes and long-term care facilities are known to produce significant quantities of PPCPs (http://www.nesc.wvu.edu/nsfc/pdf/pipline/PL_wi07.pdf).

Solutions. The Massachusetts Department of Environmental Protection (DEP) is currently doing a study with UMass Amherst, EarthTech and the American Water Works Association Research Foundation on the effects of different treatment technologies on removing PPCPs and EDCs from water. However, the results of this study are likely years away.

There are basically two ways to tackle the problems of PPCPs in our water. The Commonwealth can: 1) decrease the amount of PPCPs released into our drinking water supplies, or 2) develop more efficient removal at wastewater treatment plants. Given that we do not even know which PPCPs pose the greatest potential human and ecological health risks, together with the fact that there are tens of thousands of pharmaceuticals on the market, and thousands of new products being introduced into the environment annually, treatment of wastewater does not seem to be the most efficient short-term solution. In other words, it is not practical to approach the issue by conducting research on all compounds, because PPCPs are too numerous, each one reacts differently in the

environment, the number of possible synergistic effects are enormous and therefore unquantifiable, and the measurement of PPCPs and their daughter compounds is extremely expensive.

Regulatory agencies such as DEP and the U.S. Environmental Protection Agency (EPA) are likely hesitant to regulate these chemicals for three reasons: 1) they are ubiquitous; 2) they are extremely expensive to test for; and 3) there is no known technology for removing them from the water. We do not believe that these hurdles should result in ignoring the situation. It is crucial that the Commonwealth at the very least work to prevent additional PPCPs and EDCs from entering our water supply. Simple steps, such as prohibiting the construction of hospitals, nursing homes, elderly housing, assisted living facilities and veterinary hospitals in our aquifer protection districts, Zone IIs, and near private drinking water wells, would prevent the problem from being exacerbated.

However, DEP appears to be giving lip service only to the problem of PPCP contamination. It is of great concern to note that DEP's new proposed groundwater discharge regulations reclassify nursing homes and hospitals as "residences," therefore making it ***easier*** for these facilities to discharge into Zone IIs of municipal wells. Specifically, the proposed groundwater discharge regulations at 314 CMR 5.02 defines "Residential Uses or Residential Developments" as "apartment buildings, townhouses, condominiums, cooperatives, single family homes, two and three family homes, ***hospitals, nursing homes, assisted living facilities, rehabilitation facilities***, dormitories, and homeless shelters" (emphasis added; see http://www.mass.gov/dep/service/regulations/proposed/3145cln.pdf).

Currently, effluent from hospitals is considered industrial wastewater, and discharges from these facilities are more restricted (http://www.mass.gov/dep/water/wastewater/aboutiww.htm).

Finally, DEP's website states that 47.8% of groundwater discharge permits were in significant non-compliance in FY 2007 (see http://www.mass.gov/dep/water/priorities/sggwhome.htm#gwcom). Given this poor compliance rate of wastewater treatment plants discharging to groundwater, together with the proposed regulations making it easier for PPCP effluent to enter our water supplies, it appears that DEP is actually moving towards increasing the contamination of our water supplies. We urge the Oversight Committee to ask DEP to delete the reclassification of nursing homes and hospitals as residences from the proposed regulatory changes, and also add a regulation that prohibits the construction of wastewater treatment plants for these types of facilities in our Zone IIs and near private drinking water wells.

Conclusion. Thank you for allowing us the opportunity to comment, and for taking this important step of holding the hearing on pharmaceuticals in our water. The Commonwealth can be a national leader on this issue by taking a very simple preventative measure, and I hope that you will give it due considerations.