TESTIMONY OF
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ON BEHALF OF:
NATURAL RESOURCES DEFENSE COUNCIL

BEFORE THE US SENATE
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
SUBCOMMITTEE ON TRANSPORTATION SAFETY, INFRASTRUCTURE SECURITY, AND WATER QUALITY

AT HEARING ENTITLED:
PHARMACEUTICALS IN THE NATION'S WATER: ASSESSING POTENTIAL RISKS AND ACTIONS TO ADDRESS THE ISSUE

APRIL 15, 2008

Good morning and thank you for this opportunity to testify on the health concerns and policy proposals addressing pharmaceuticals and personal care products in the nation's waterways and drinking water sources. I am Jennifer Sass, PhD., a Senior Scientist in the Health Program at the Natural Resources Defense Council (NRDC). I have a Ph.D. in molecular and developmental biology, and a post-doctoral certificate in environmental toxicology. I have worked at NRDC on environmental health issues for over 7 years. NRDC is a not-for-profit environmental advocacy organization with over 1 million members and activists whose mission is to safeguard the Earth: its people, its plants and animals and the natural systems on which all life depends.

NRDC's Health program focuses on toxic chemical pollutants in air, water, food, and shelter. Over the years, we have focused our particular attention on the "biggest pollutants" in these media, the ones disproportionately responsible for the biggest threats to human health. This has led to successful efforts to substantially reduce diesel air emissions from trucks and buses, for example, and to take a number of dangerous and outdated pesticides off the market. There are more than 70,000 chemicals in commerce, but some are much more toxic than others, and we can make great progress in environmental health protection if we focus on the chemicals pollutants that pose the greatest threat to human and ecological health.

We are very pleased to testify today on the health risks posed to humans and wildlife by pharmaceuticals and personal care products that contaminate our waterways.

Summary of Testimony

Compounds such as nicotine, caffeine, and aspirin that are designed to influence our body's normal chemistry have been identified as environmental contaminants since the 1980s, moving from sewage and human waste into waterways. As our use of pharmaceuticals increases, it is logical to expect them to turn up in our environment. Although the levels reported to contaminate our waterways are much lower than therapeutic doses, it would be naïve to think of this as 'safe', knowing that the agents are chemically reactive in our bodies, and that we are exposed daily over a life-time to multiple compounds in unknown combinations.

When a medical professional prescribes a drug, they are considering the patient's health status, age, gender, nutritional status, and any other drugs that may cross-react. For example, a woman who was at risk for breast cancer would not want to be exposed to high levels of estrogenic compounds. A pregnant woman would never knowingly expose her fetus to chemicals that cause birth defects such as antiepileptic drugs. A doctor would never knowingly prescribe toxic chemotherapy agents to a healthy person. Yet, all these things and more are in our Nation's drinking water. The Associated Press reported that pharmaceutical residues were detected in the drinking water of 24 major metropolitan areas across the country serving 41 million people. Detected drugs included antibiotics, anti-convulsants, and mood stabilizer drugs. These results were supported by findings of the U.S. Geological Survey that found organic wastewater contaminants and pharmaceuticals in 80% of sampled streams- including antibiotics, hypertensive and cholesterol-lowering drugs, antidepressants, analgesics, steroids, caffeine, and reproductive hormones.

Pharmaceuticals and personal care products (PPCPs) may end up in the environment through waste from human or animal excretion, improper disposal such as flushing down a toilet, runoff from animal feeding operations, or leaching from municipal landfills. However they get there, they are contaminating our waterways and tap water systems.

Large animal feeding operations generate a large amount of antibiotic-contaminated waste that contaminates waterways and contributes to antibiotic resistant pathogens. Because many of the same antibiotics are used in both human and veterinary medicine, almost every bacteria that can cause infections in humans has developed resistance to at least one antibiotic, and some are resistant to multiple antibiotics.

Pharmaceuticals that mimic estrogen are excreted as waste by-products from the use of birth-control pills, menopause treatments, and cancer therapy. In addition to human uses, endocrine disrupting steroids used in livestock operations contribute to widespread environmental contamination. Research by the US Geological Survey reported a high incidence of intersex fish in the Potomac watershed associated with sites of intense farming and high human population density; 75% of male smallmouth bass in the most densely populated heavily farmed Potomac basin had eggs in their testicles.

The issue of pharmaceuticals and personal care products in drinking water is not news to EPA, and yet despite the various safeguards and processes that EPA could have taken to develop a robust picture of the scope of the problem, the Agency has taken advantage of none of them. First, the Safe Drinking Water Act requires EPA every five years to publish a list of currently unregulated contaminants that should be considered for potential regulation. For these lists EPA has identified 130 potential chemicals for regulation – none of which are pharmaceuticals or personal care products. Second, in 1999 EPA promulgated an unregulated contaminant monitoring rule that imposed various monitoring requirements on community water systems for a list of unregulated contaminants; there are no pharmaceuticals or personal care products identified as unregulated contaminants for which water systems must monitor. Third, to our knowledge, EPA has never asked water systems to provide voluntarily testing and monitoring data for pharmaceuticals and personal care products. Fourth, the Safe Drinking Water Act requires community water systems to mail to each of their customers an annual report on the level of contaminants in the drinking water that they supply; there are no mandates to inform customers when pharmaceutical or personal care products are identified. Fifth, Congress mandated that EPA must address endocrine disrupting chemicals in drinking water; it has now been 12 years since this mandate and the Endocrine Disruptor Screening Program has failed to even start testing chemical contaminants.

The FY08 funding for the Toxics Program is $13.5 M; for FY09 the request is $10.7 M, reflecting a nearly $3 M cut from the USGS budget. The proposed cuts to the Toxics Program will significantly reduce research capacity on new and understudied environmental contaminants, including pharmaceuticals and personal care products.

Pharmaceuticals and personal care products are contaminating our waterways and sources of drinking water

An investigation by the Associated Press reported that pharmaceutical residues were detected in the drinking water of 24 major metropolitan areas across the country serving 41 million people.[1] Detected drugs included antibiotics, anti-convulsants, and mood stabilizer drugs. These results were supported by findings of the U.S. Geological Survey that sampled 139 streams in 30 states, and found organic wastewater contaminants and pharmaceuticals in 80% of sampled sites- including antibiotics, hypertensive and cholesterol-lowering drugs, antidepressants, analgesics,steroids, caffeine, and reproductive hormones.[2]

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[1] Jeff Donn, Martha Mendoza, Justin Pritchard. Associated Press. March, 2008. http://www.msnbc.msn.com/id/23503485/

[2] Barber, L.B., Murphy, S.F., Verplanck, P.L., Sandstrom, M.W., Taylor, H.E., and Furlong, E.T., 2006, Chemical loading into surface water along a hydrological, biogeochemical, and land use gradient—A holistic watershed approach: Environmental Science and Technology, v. 40, no. 2, p. 475-486, doi: 10.1021/es051270q. (Supporting Information) http://toxics.usgs.gov/highlights/pharm_watershed/

Pharmaceuticals and personal care products (PPCPs) include human and veterinary drugs, both prescription and over-the-counter, medical agents such as chemotherapeutic drugs and x-ray contrast media, antibiotics, anti-inflammatories, blood pressure and cholesterol lowering medications, psychotropic drugs, oral contraceptives, anti-seizure medications, fragrances, sunscreens, 'antibacterial' soaps, lotions, shampoos, and creams. They may end up in the environment through waste from human or animal excretion, improper disposal such as flushing down a toilet, runoff from animal feeding operations, or leaching from municipal landfills.

The problem of unintended movement of toxic and hormone disrupting compounds from pharmaceuticals and personal care products to wastewater effluents and drinking water sources is an international problem that has been documented and publicly reported by government experts and academic researchers for nearly two decades.[3] However, until recently, the public has been in the dark about the presence of these chemicals in our drinking water. As discussed more fully below, pharmaceuticals and personal care products have been excluded from the regulatory safeguards put in place by Congress – and the public's right to know has suffered as a result of that exclusion.

The contaminants come from many sources (medical waste, consumer waste, agriculture and industrial uses, etc.), have diverse toxicology profiles and biological activity, and are likely to have complex and poorly understood toxic interactions (antagonistic, synergistic, additive, etc.). However, among others, these contaminants share one very disturbing characteristic: in general, they are not effectively controlled under U.S. environmental statutes.

Widespread antibiotic contamination poses a serious health threat

Although the human health impacts of these exposures to pharmaceuticals and personal care products are poorly understood, what we do know is troubling. For example, we know that widespread exposure to antibiotics is contributing to the growth of bacterial resistance, and this problem is of grave concern. In the past several decades

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3 Aherne GW, Briggs R. The relevance of the presence of certain synthetic steroids in the aquatic environment. J Pharm Pharmacol 41:735-736 (1989).

Ankley GT, Brooks BW, Huggett DB, Sumpter JP. Repeating history: pharmaceuticals in the environment. Environ Sci Technol. 2007 Dec 15;41(24):8211-7

Kolpin, D. W.; Furlong, E. T.; Meyer, M. T.; Thurman, E. M.; Zaugg, S. D.; Barber, L. B.; Buxton, H. T. Pharmaceuticals, hormones, and other organic wastewater contaminants in U.S. streams, 1999-2000: A national reconnaissance. Environ. Sci. Technol. 2002, 36, 1202-1211.

Ternes, T. A. Occurrence of drugs in German sewage treatment plants and rivers. Water Res. 1998, 32, 3245-3260.

Snyder, S. A.; Westerhoff, P.; Yoon, Y.; Sedlak, D. L. Pharmaceuticals, personal care products, and endocrine disruptors in water: Implications for water treatment. Environ. Eng. Sci. 2003, 20, 449-469.

Daughton, C. H.; Ternes, T. A. Special Report: Pharmaceuticals and personal care products in the environment: Agents of subtle change? (Vol. 107, p 907, 1999), Environ. Health Perspect. 2000, 108, 598-598.

almost every bacteria that can cause infections in humans has developed resistance to at least one antibiotic, and some are resistant to multiple antibiotics. The Center for Disease Control has identified antibiotic resistance as one of the most pressing public health problems to face our nation.[4] Infections caused by bacteria with resistance to at least one antibiotic have been estimated to kill over 60,000 hospitalized patients each year.[5] However, antibiotic resistant bacteria are not limited to our healthcare settings. Methicillin-resistant *Staphylococcus aureus* (MRSA), a skin bacteria resistant to several antibiotics, was once found only in hospitals and nursing homes. MRSA is now commonly found in the community.[6] Infection with MRSA can cause skin and soft tissue infections and pneumonia. Some MRSA infections are now only treatable with one antibiotic, vancomycin; it is extremely worrisome that microbial resistance to even this powerful antibiotic now has been reported.

Antibiotic resistance is caused by a number of factors including repeated and improper use of antibiotics in both humans and animals. Scientists also agree that exposure to low levels of antibiotics actually promotes bacterial resistance by exerting selective pressure for genes that promote resistance. Antibiotics end up in waste water because the body does not completely breakdown all drugs, so both the metabolized and unmetabolized drug are excreted by humans into wastewater. For example, when amoxicillin is ingested, 60-75% of the antibiotic is excreted unchanged into the urine. This antibiotic, now in the environment, may encounter other bacteria and promote resistance. It is unknown how much of an impact current low levels of antibiotics in drinking water are having on the problem of bacterial resistance. However, the potential has been recognized for many years.[7]

Massive quantities of antibiotics are used in agriculture both to treat infections and as food additives to promote growth and to compensate for conditions that contribute to infection. Animals raised in Concentrated Animal Feeding Operations (CAFOs) are at increased risk for infection due to close confinement and stress. In fact, it has been estimated that 70% of the antibiotics used in the US are for animal husbandry.[8] Improper and overuse of antibiotics in livestock and poultry can cause resistance in strains of bacteria that can infect humans. Furthermore, half of the antibiotics used in livestock are in the same classes of drugs that are used in humans. As a result the US Institute of Medicine (IOM) and the World Health Organization (WHO) both stated that the

[4] http://www.cdc.gov/drugresistance/healthcare/problem.htm

[5] Citation from Health Care Without Harm fact sheet, Antibiotic Resistance and Agricultural Overuse of Antibiotics.. Available at http://www.noharm.org/details.cfm?ID=938&type=document

[6] Centers for Disease Control, Overview of CA-MRSA. http://www.cdc.gov/ncidod/dhqp/ar_mrsa_ca.html

[7] USA Today, in an 11/8/00 news article stated, "Experts fear that even low levels of antibiotics fouling the nations water supply may help create super-bugs: micro organisms that have evolved to survive an antibiotic's lethal assault."

[8] Mellon et al. *Hogging It: Estimates of Antimicrobial Abuse in Livestock.* Union of Concerned Scientists: Cambridge MA. 2000.

widespread use of antibiotics in agriculture is contributing to antibiotic resistance in humans.[9]

Large animal feeding operations generate a large amount of waste that can potentially contaminate groundwater and waterways contributing to antibiotic resistance and contamination of waterways with steroid hormones.[10] As occurs in humans, some portion of the antibiotics administered to livestock will pass unchanged through their bodies and will be excreted in their waste. It has been estimated that between 25-75% of antibiotics are excreted unchanged in feces and can persist in the soil after land application.[11] Manure is applied in large quantities as fertilizer in farm fields. In addition to potentially contaminating the food supply with antibiotic resistant bacteria, antibiotics in manure can persist in soil promoting the development of more antibiotic resistant bacteria. Animal waste and its associated contaminants can enter waterways through groundwater contamination, overflow of waste lagoons into surface water or by over-application of manure as fertilizer in farm fields. A recently published study found evidence of fecal contamination and increased levels of antibiotic resistant bacteria downstream of a swine concentrated feeding operation.[12] Other studies have found antibiotic resistance in groundwater underlying a swine waste lagoon.[13]

Widespread contamination of waterways with steroid hormones and endocrine disrupting chemicals may pose a serious health threat

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[9] Quotes from the Healthcare Without Harm factsheet. Antibiotic Resistance and Agricultural Overuse of Antibiotics. Novermber 8, 2005. Available at http://www.noharm.org/us/food/issue

U.S. Institute of Medicine/National Academy of Science: "Clearly, a decrease in antimicrobial use in human medicine alone will have little effect on the current [antibiotic-resistant] situation. Substantial efforts must be made to decrease inappropriate overuse in animals and agriculture as well."

World Health Organization: "There is clear evidence of the human health consequences due to resistant organisms resulting from non-human usage of antimicrobials. These consequences include infections that would not have otherwise occurred, increased frequency of treatment failures (in some cases death) and increased severity of infections."

[10] Gilchrist MJ, Greko C, Wallinga DB, Beran GW, Riley DG, Thorne PS. The potential role of concentrated animal feeding operations in infectious disease epidemics and antibiotic resistance. Environ Health Perspect. 2007 Feb;115(2):313-6. Epub 2006 Nov 14.

Wallinga D, Mellon M, Roach S. Antibiotic use in swine farms in Alberta. Can Vet J. 2006 Dec;47(12):1153; author reply 1153-4.

Wallinga D. Public health advocate. Prev Vet Med. 2006 Feb 24;73(2-3):221-8. Epub 2005 Oct 28.

[11] Chee-Sanford, J.C., et al. Occurrence and Diversity of Tetracycline Resistance Genes in Lagoons and Groundwater Underlying Two Swine Production Facilities. *Applied and Environmental Microbiology*, April 2001. Vol. 6 no. 4, pp. 1494-1502.

[12] Sapkota AR, et al. Antibiotic-resistant enterococci and fecal indicators in surface water and groundwater impacted by a concentrated Swine feeding operation. Environ Health Perspect. 2007 Jul;115(7):1040-5.

[13] Chee-Sanford, J.C., et al. Occurrence and Diversity of Tetracycline Resistance Genes in Lagoons and Groundwater Underlying Two Swine Production Facilities. *Applied and Environmental Microbiology*, April 2001. Vol. 6 no. 4, pp. 1494-1502.

Congress and the EPA have recognized that some environmental contaminants are able to interfere with the actions of normal hormones.[14] These contaminants are called endocrine disrupting chemicals and have been demonstrated to interfere not just with sex hormones but other hormonal systems including the thyroid gland. Pharmaceuticals that mimic estrogen are excreted as waste by-products from the use of birth-control pills, menopause treatments, and cancer therapy. In addition to human uses, endocrine disrupting steroids used in livestock operations contribute to widespread environmental contamination.

Beef cattle raised in large feedlots are also treated with anabolic steroids to promote the growth of muscle. One of the most common steroids used is the androgen mimic, trebolone acetate. The breakdown products of this steroid are stable in water and bind with high affinity to the androgen receptor in fish. [15] Exposure to trebolone metabolites causes masculinization of female fish and cause reduced fertility at concentrations in the parts per trillion range. [16] Although we are much larger than fish, our bodies do not require larger doses of hormones to have effects. Sex hormones in all vertebrate species work in the parts per billion to parts per trillion range.

A recent study was done at an Ohio-based CAFO with a capacity for 9,800 cattle.[17] This study found detectable concentrations of trebolone in the discharge from the facility at levels that were sufficient to induce gene expression associated with exposure to androgens.

Recognition of the effects of endocrine disrupting chemicals in laboratory animal models has resulted in questions about whether problems in wildlife could be caused by environmental contaminants that are endocrine disrupting chemicals. For example, there is increasing public scrutiny and mounting evidence of the environmental effects of chemical contamination of waterways resulting in intersex fish in our nation's rivers and drinking water sources. Research by the US Geological Survey (USGS) reported a high incidence of intersex fish in the Potomac watershed at sites of intense farming and high human population density.[18] The USGS found 75% of male smallmouth bass in the most densely populated heavily farmed Potomac basin had eggs in their testicles. Other research has found environmental androgens associated with masculinization in female

[14] http://www.epa.gov/endo/

[15] Durhan EJ, et al. Identification of metabolites of trenbolone acetate in androgenic runoff from a beef feedlot. Environ Health Perspect. 2006 Apr;114 Suppl 1:65-8.

[16] Durhan EJ, et al. Identification of metabolites of trenbolone acetate in androgenic runoff from a beef feedlot. Environ Health Perspect. 2006 Apr;114 Suppl 1:65-8.

[17] Durhan EJ, et al. Identification of metabolites of trenbolone acetate in androgenic runoff from a beef feedlot. Environ Health Perspect. 2006 Apr;114 Suppl 1:65-8.

[18] US Geological Survey (2008, February 11). Intersex Fish Linked To Population And Agriculture In Potomac River Watershed. *ScienceDaily*. Retrieved March 24, 2008, from http://www.sciencedaily.com /releases/2008/02/080208115302.htm

fish living downstream of pulp mills and concentrated animal feeding operations.[19] These organisms serve as sentinels for environmental contamination by endocrine disrupting chemicals and also raise concerns about potential impacts on human health, since humans share many of the same metabolic systems as fish.

There is concern that exposure to endocrine disrupting chemical contaminants could promote the growth of estrogen dependent cancers in some exposed people.[20] We must achieve greater understanding of which chemicals are causing these effects and conduct further laboratory testing to understand the potential human health effects.

Low dose exposures to endocrine disrupting chemicals pose health risks

The traditional toxicology dogma has been "the dose makes the poison" but when considering the toxicity from exposures to endocrine disrupting chemicals, the timing of exposure maybe more important than the dose. Exposures to endocrine disrupting chemicals during critical windows of development have been shown to have permanent effects.[21] Some of these effects, such as infertility or cancer, are not manifest until adulthood even though the exposure occurred during fetal or neonatal life. In animal studies, prenatal exposures to low levels (1 part per billion) of the synthetic estrogen, DES, has been shown to cause infertility, cancers of the reproductive tract and obesity.[22] Other laboratory studies have demonstrated that exposures to endocrine disrupting chemicals found in the environment, sometimes at low doses, are associated with reproductive harm or the development of reproductive tract cancers.[23] In humans, there is a noted decrease in the age at puberty, increases in infertility, increases in birth defects of male genitalia, increases in testicular cancer and continued high rates of breast cancer.

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[19] Hotchkiss AK, et al. 2008 Fifteen years after "Wingspread" – Environmental Endocrine Disruptors and human and wildlife health: Where are we today and where we need to go. Toxicological Science Advance Access published Feb 16, 2008.

Durhan EJ, et al. Identification of metabolites of trenbolone acetate in androgenic runoff from a beef feedlot. Environ Health Perspect. 2006 Apr;114 Suppl 1:65-8.

[20] *State of the Evidence 2008*: The Connection Between Breast Cancer and the Environment Edited by Janet Gray, Ph.D., published by the Breast Cancer Fund and available at: http://www.breastcancerfund.org/site/pp.asp?c=kwKXLdPaE&b=206137

[21] Grandjean P, et al., The Faroes Statement: Human Health Effects Of Developmental Exposure To Chemicals In Our Environment. Basic Clin Pharmacol Toxicol. 2008 Feb;102(2):73-5.

[22] Newbold RR.Lessons learned from perinatal exposure to diethylstilbestrol. Toxicol Appl Pharmacol. 2004 Sep 1;199(2):142-50.

Newbold RR, et al. Perinatal exposure to environmental estrogens and the development of obesity. Mol Nutr Food Res. 2007 Jul;51(7):912-7.

[23] Vandenbergh JG. Animal models and studies of in utero endocrine disruptor effects. ILAR J. 2004;45(4):438-42.

Gray LE Jr, et al. Adverse effects of environmental antiandrogens and androgens on reproductive development in mammals. Int J Androl. 2006 Feb;29(1):96-108.

Each of these conditions has been shown in laboratory experiments to occur associated with exposures to endocrine disrupting chemicals during critical periods of development. We do not yet know whether similar exposures to endocrine disrupting chemicals in our environment could be causing the increased incidence of disease.

Despite the fact that low level contamination by pharmaceuticals and personal care products has been documented in the technical literature for some time, we have but an extremely rudimentary understanding of the hazards that these chemicals might pose to human health and the environment, or even the patterns of their occurrence in our nation's drinking water. We do know that many of these chemicals are designed to interact with our body's normal functioning, even at low doses, and that at therapeutic doses, drug interactions occur that can be harmful or even fatal. For example, we have no idea how low level exposure to psychotropic drugs might affect behavior of people and/or wildlife when occurring as a water contaminant. Therapeutic-level exposure to the anti-seizure medication valproic acid has been associated with increased birth defect risk,[24] but we do not know if exposures at lower levels will confer a similar risk. The long-term potential harm from the interactions of all these compounds, even at low exposures, is unknown, particularly for vulnerable populations such as infants, the elderly, and people with health ailments.

The Endocrine Disruptor Screening Program has failed to even start testing after 12 years

It is unknown how many of the pharmaceuticals and personal care products which contaminate our nation's drinking water are endocrine disrupting chemicals. We do know that some of the pharmaceuticals found in waterways are intentionally made to mimic our body's hormones. These include medications such as thyroid hormone replacement, estrogen replacement therapy, or birth control pills. Other pharmaceuticals are synthesized to block the action of our body's hormones, for example breast or prostate cancer therapies. We also know that certain chemicals found in personal care products are endocrine disrupting chemicals. For example, some chemicals used to carry fragrance, called phthalates, are known to inhibit the production of the male sex hormone, testosterone. However, for the vast majority of chemicals found as contaminants in the environment, there is no information to tell us whether or not they are endocrine disrupting chemicals.

In 1996, the Food Quality Protection Act (FQPA) required EPA to develop a screening program that would ascertain whether certain substances may have estrogenic (or other endocrine) effects on humans. The Safe Drinking Water Act extended this mandate to include substances that may be found in sources of drinking water. The Endocrine Disruptor Screening Program (EDSP) was intended to help define which

[24] Duncan S. Teratogenesis of sodium valproate. Curr Opin Neurol. 2007 Apr;20(2):175-80. Review.

James L, Barnes TR, Lelliott P, Taylor D, Paton C. Informing patients of the teratogenic potential of mood stabilizing drugs: a case note review of the practice of psychiatrists. J Psychopharmacol. 2007 Nov;21(8):815-9. Epub 2007 Sep 19.

chemicals could be capable of causing these effects and ultimately, provide information to be used to protect the public's health.

The Food Quality Protection Act mandated that EPA develop a screening program by 1998 and implement it by 1999. According to the original EPA timeline for implementation, the priority setting database was to be complete by June 2000 and was to be used for priority setting in November 2000. Despite the established deadlines, EPA failed to adhere to the original timeline for priority setting, which was the subject of prior litigation between NRDC and EPA. The Agency settled that lawsuit by agreeing to publish a proposed initial list of chemicals for screening by December 31, 2002 and to validate and begin requiring chemicals to be tested by December 2003. EPA missed these deadlines as well. In fact, it has been twelve years since Congress mandated EPA to create this screening program, but the Agency has yet to begin actual testing of any chemicals under this program.

EPA has failed to protect the public's health not only by delaying implementation of the testing program but also by refusing to regulate any chemicals that have been shown to be endocrine disruptors by other research studies. In addition to failing to reduce exposures to known endocrine disrupting chemicals, EPA has failed to begin testing the tens of thousands of other chemicals where we have no information about their potential endocrine disrupting effects.

A decade ago, the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) devised clear recommendations for a prioritization process for selecting chemicals for screening. These recommendations were adopted by EPA in 1998. For the first round of screening, EPA has proposed to test 73 chemicals that are in pesticides or are considered High Production Volume (HPV) pesticide inerts. EPA is under a mandate from Congress to begin testing by August 2008.

Although EPA finally appears to be making progress on this program, we are concerned that EPA has diverged from the EDSTAC's recommendations about how to select the chemicals for this initial list. In particular, and in light of concerns regarding pharmaceuticals and personal care products and other endocrine disrupting chemicals in water, EPA should include drinking water contaminants and not just pesticides in future testing protocols. Although EDSTAC recommended that EPA should test drinking water contaminants and mixtures of chemicals found in drinking water, EPA has not indicated that it intends to screen drinking water contaminants in the EDSP. In fact, EPA has the authority to do this under the Safe Drinking Water Act Amendments of 1996. These amendments authorized EPA to screen drinking water contaminants for endocrine disrupting effects. Specifically, Section 136 of the SDWA Amendments states, "In addition to the substances referred to in [the Food Quality Protection Act], the Administrator may provide for testing under the screening program authorized by [the FQPA] for any other substance that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance."

EPA's failure to regulate pharmaceuticals and personal care products as drinking water contaminants

The issue of pharmaceuticals and personal care products in drinking water is not news to EPA. The Agency has been aware that these chemicals were contaminating our drinking water; studies on these chemicals ending up in our drinking water date back well over a decade. Yet despite this, EPA has failed to take the steps that would provide a fully, informed snapshot of the scope of the problem.

The Safe Drinking Water Act (SDWA) governs the regulation of contaminants in our drinking water supplies. Pursuant to the SDWA, EPA sets health-based standards for certain contaminants that may appear in drinking water. In addition to these regulated contaminants, the SDWA also created a system that would push EPA to determine whether other contaminants should also be regulated. Despite the various safeguards and processes that EPA could have taken to develop a robust picture of the scope of the problem of pharmaceuticals and personal care products in drinking water, the Agency has taken advantage of none of them.

First, the SDWA requires EPA every five years to publish a list of currently unregulated contaminants that should be considered for potential regulation. EPA is then required to make a final determination about whether or not to regulate at least five of the contaminants identified on the Candidate Contaminant List (CCL).

To date, the Candidate Contaminant List listing process has gone through 3 iterations, beginning in 1998 with the publication of CCL1 and then CCL2 in 2005. CCL1 contained 50 chemical contaminants, including industrial organic chemicals, pesticides, and inorganic chemicals; in July 2003, EPA decided not to regulate any of the nine chemicals it evaluated on the CCL1. CCL2 consisted of a subset of the chemical contaminants listed on CCL1; and in May 2007, EPA again decided not to regulate any of the 11 chemicals it considered from the CCL2. In February 2008, EPA published the draft CCL3. According to EPA, the 104 candidates for the draft CCL3 emerged from their evaluation of approximately 6,000 chemicals, 287 of which were pharmaceuticals.[25] EPA narrowed down the universe of 6,000 chemicals to a preliminary CCL3, which consisted of over 500 chemicals. In our review of the preliminary CCL3, aspirin was the only PPCP identified for further evaluation. According to the Associated Press, only one chemical on the draft CCL3 – nitroglycerine – is considered a pharmaceutical; however EPA indicated that it chose to include it on the draft CCL3 because of its use in explosives, not because of its pharmaceutical uses. All told, between the three CCLs, EPA has identified 130 potential chemicals for regulation – none of which are pharmaceuticals or personal care products.

Second, the Safe Drinking Water Act includes a process to inform both the determination about whether to regulate a contaminant on the Candidate Contaminant

[25] http://www.epa.gov/OGWDW/ccl/ccl3.html, last visited 11 April 2008; 73 Fed. Reg. 9627, 9652 (February 21, 2008).

List and whether even to list a contaminant on the Candidate Contaminant List. Specifically, public water systems are tasked with collecting monitoring data on unregulated contaminants, and that data help EPA to decide whether or not to regulate a given contaminant. In 1999 EPA promulgated an unregulated contaminant monitoring rule (UCMR) that imposed various monitoring requirements on community water systems for a list of unregulated contaminants. The first round of the UCMR consisted of 26 unregulated contaminants that required some amount of monitoring data. The second UCMR identified an additional 24 unregulated contaminants not identified by the first UCMR. Just as with the three rounds of CCLs – there are no pharmaceuticals or personal care products identified as unregulated contaminants for which water systems must monitor.

Third, to our knowledge, EPA has never asked water systems to provide voluntarily testing and monitoring data for pharmaceuticals and personal care products.

Fourth, in recognition of the public's right to know the Safe Drinking Water Act requires community water systems to mail to each of their customers an annual report on the level of contaminants in the drinking water that they supply. These consumer confidence reports (CCRs) must contain, among other things, information on the source of the water, detections of regulated contaminants in the water, and levels of unregulated contaminants found in the water (those unregulated contaminants identified by the UCMR). Because none of these chemicals appear on any of the Candidate Contaminant List or Unregulated Contaminant Monitoring Rule lists, there are no mandates requiring water systems to inform their customers of the presence of these chemicals. As a result, the public's right to know about contaminants in their drinking water has been harmed by EPA's inaction.

Fifth, Congress mandated that EPA must address endocrine disrupting chemicals in drinking water. As discussed earlier, EPA has dragged its feet in implementing the endocrine disruptor screening program. Since so many pharmaceuticals and personal care products are potential endocrine disruptors, the Agency's failure to begin timely testing of chemicals continues to put all Americans at potential risk, simply from drinking water. Despite the recommendations of its advisory committee (EDSTAC) to include drinking water contaminants on its list of chemicals intended to be screened in the endocrine disruptor screening program as required by the SDWA, EPA's list of 73 chemicals does not include any pharmaceuticals or personal care products.

Sixth, EPA has yet to conduct a risk assessment of pharmaceuticals and personal care products in drinking water or assessed the health effects of the presence of these chemicals in our drinking water. EPA has failed in this respect, despite the fact that it claims it "established a leadership role [on the issue of pharmaceuticals and personal care products in drinking water] beginning in 1999 with publication of a critical review article that attempted to bring together the many different aspects of this complex issue."[26] Despite almost 20 years of evidence that these categories of chemicals were appearing in

[26] http://www.epa.gov/ppcp/faq.html#Whatwasepa, last visited April 11, 2008.

drinking water, EPA still has yet to conduct a risk assessment for pharmaceuticals and personal care products in drinking water.

Finally, as identified by the Associated Press report on pharmaceuticals in drinking water, not all water providers will test for these chemicals in their water. Those that do, rarely disclose this information to their customers. Until EPA chooses to include these chemicals on the UCMR – action EPA has so far refused to take – no disclosure is required under the SDWA and the public remains unaware of the presence of these chemicals in our drinking water.

USGS budget cuts will severely impair critical water monitoring programs

We look to the federal government to protect the public's health. The public has reasonable and serious concerns that exposures to medications and other synthetic chemicals found in drinking water could be impacting human health. However, with limited data, it is impossible to gauge whether or not pharmaceuticals and personal care products in drinking water could be contributing to the development or progression of human health ailments. A commitment to rigorous long-term monitoring of our nation's waterways is absolutely essential for identifying contaminants, assessing risk, characterizing and localizing contamination patterns, identifying sources of contamination where possible, and measuring the effectiveness of mitigation measures. Resources to undertake this task are inadequate and falling, which will severely undermine our nation's ability to address this issue. Congress should allocate resources to undertake this task as a top priority.

The US Geological Survey (USGS) is responsible for the two main water-quality monitoring programs for the Nation's waterways: the National Water Quality Assessment Program (NAWQA) and the Toxic Substances Hydrology Program. Both water quality programs will suffer devastating blows if the proposed FY09 budget cuts are enacted. Adequate funding for these two programs is necessary to understanding many crucial aspects of water quality, including the impacts of new and under-studied contaminants such as pharmaceuticals and personal care products, and the efficacy of water quality policy-decisions. In short, the proposed deep cuts to these programs will strip the regulatory agencies of their ability to make wise decisions about how to allocate their limited resources to protect the Nation's waterways effectively.

The NAWQA is the larger of the two USGS water-quality monitoring programs; it monitors for environmental contaminants using established measurement methodologies for measuring (pesticides, volatile organic compounds, metals, etc.). Budget constraints over the last eight years has forced NAWQA to cut back from 496 surface-water fixed station water-quality monitoring sites in 2000, to only 113 sites in 2008. The FY09 proposed President's budget would reduce current funding by $9.8M, or 15% from the FY08 enacted funding. To adjust to this severe reduction, the USGS will

be forced to cut monitoring at half of the existing ground water-quality sites so that it can continue to conduct research and analysis of existing data.[27]

The Toxic Substances Hydrology (aka Toxics Program) is the smaller of the two programs. It is a water quality research and methods development program that examines new and understudied environmental contaminants, such as the hormones, pharmaceuticals, and personal care products at issue in this hearing. The Toxics Program develops new capabilities, new methodologies, and new information that enable state water quality programs and NAWQA to address new issues effectively. FY08 funding for the Toxics Program is $13.5 M; for FY09 the request is $10.7 M, reflecting a nearly $3 M cut from the USGS budget. The proposed cuts to the Toxics Program will significantly reduce research capacity on new and understudied environmental contaminants, including pharmaceuticals and personal care products, as well as methyl mercury, arsenic, and nanomaterials.

EPA and Congress should act to address the problem of pharmaceuticals and personal care products contaminating the public's drinking water

Under the Safe Drinking Water Act and the Food Quality Protection Act, EPA has the authority and obligation to ensure the safety of our drinking water. As discussed elsewhere in this testimony, EPA should:

- Include pharmaceuticals and personal care products in the unregulated contaminant monitoring rule to require public water systems to monitor for their presence in our drinking water and to identify in the consumer confidence reports the levels found in the drinking water; in the meantime, water systems should test for pharmaceuticals and personal care products and report the results to their customers;
- Add pharmaceuticals and personal care products to the candidate contaminant list 3 (CCL3) and evaluate the need to regulate the presence of these chemicals in drinking water;
- Immediately finalize and implement testing under the endocrine disruptor screening program and add drinking water contaminants, including mixtures of pharmaceuticals and personal care products to the list of chemicals that must be screened under that program;
- Evaluate and identify wastewater and drinking water treatment practices for removing pharmaceuticals and personal care products;
- In consultation with FDA and other federal research bodies, conduct studies to understand the health effects of discarded pharmaceuticals and personal care products on the nation's waterways and drinking water supplies; and
- Work with other federal agencies and states to prevent or limit the overuse of antibiotics in agriculture, particularly those that are critical for human use.

Congress needs to take additional steps to help address this issue, including:

[27] USGS briefing sheet: Impacts of proposed FY09 budget cuts on National Water-Quality Assessment (NAWQA) program. February, 2008

- Establish take back programs for pharmaceuticals;
- Increase funding for wastewater and drinking water infrastructure; and
- Reform the Toxic Substances Control Act to reduce the number and amount of persistent, bioaccumulative and toxic chemicals that are released into the environment.

Thank you for inviting me to testify before you today. NRDC looks forward to working with the Subcommittee and Full Committee to address these important issues. I would be happy to answer any questions from the Committee.