White Paper for National Rural Water Association on Pharmaceuticals and Personal Care Products (PPCPs) In Drinking Water

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0.0 Executive Summary

In the United States, consumers spend billions of dollars on prescription drugs and personal care products. Such pharmaceuticals and personal care products (PPCPs) are not completely degraded or removed during wastewater treatment and have been present in the environment for as long as humans have been using them. Because of their presence in wastewater discharges, PPCP compounds are likely to be detected in surface waters and groundwaters receiving treated waste water. PPCPs have also been detected in septic tank effluent and in treated drinking waters downstream of wastewater discharges.

Because of their disposal pathway, PPCPs seem to be primarily of concern in surface waters and thus have not been viewed as a particular problem in small systems that usually have groundwater sources. However, trace amounts of these substances have been detected in some instances in groundwaters. Small water systems need to exercise due diligence in assessing possible risks to small and rural system customers and promoting any necessary actions to protect public health.

Frequently detected compounds are likely to be more persistent and migrate in groundwater. Benotti et al. (2007) assessed the relative mobilities of pharmaceuticals in groundwater by regarding the distributions of compounds, on three different occasions, in the well field of an adult-assisted- living care facility with an on-site wastewater treatment plant

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discharging to groundwater. These distributions, combined with laboratory sorption experiments, suggest that caffeine, carbamazepine, nicotine, paraxanthine and sulfamethoxazole have the potential for greatest transport in the subsurface.

Focazio et al. (2008) analyzed targeted untreated sources of drinking water for 100 analytes with sub-parts per billion detection capabilities. The sites included 25 groundwater and 49 surface-water sources of drinking water serving populations ranging from one family to over 8 million people. The five most frequently detected chemicals targeted in groundwater were: tetrachloroethylene (24% of wells, solvent), carbamazepine (20% of groundwaters, pharmaceutical), bisphenol-A (20% of groundwaters, plasticizer), 1,7-dimethylxanthine (16% of groundwaters, caffeine metabolite), and tri (2-chloroethyl) phosphate (12% of groundwaters, fire retardant).

PPCPs have been detected in treated drinking water. The presence of PPCPs in treated water depends upon the amount in the untreated source water and the ability of the system's water treatment to remove the particular PPCP compounds present. Drinking water sources that are effluent dominated (are 50% or more treated wastewater) are most likely to have PPCPs in treated water.

Most PPCPs, such as pharmaceuticals, have biological effects at regular therapeutic doses. The public health risks to trace levels of PPCPs in drinking water to people, animals and aquatic organisms are uncertain, because PPCPs concentrations are very low and exposure is over a long period of time. Within the last 10 years there have been eight published studies assessing the potential human health implications of active pharmaceutical ingredients in surface and drinking water. All studies evaluated the potential human health impact for several APIs

found in surface and drinking water, and report no significant impact to human health or that human health effects are unlikely.

USEPA is assessing the potential human health effects from PPCPs in drinking water. Findings to date indicated that the small amounts of drugs in tap water are likely safe for healthy adults, even when considering mixtures of compounds. The USEPA study was intentionally conservative in estimating occurrence of compounds in water and their risk to human health (Hegstad 2008).

Snyder (2008) has noted that at the highest PPCP concentrations found, and using the most conservative safety factors to protect sensitive subpopulations such as infants and pregnant women, the report will demonstrate that one could safely consume more than 50,000 eight-ounce glasses of this water per day without any health effects.

Monitoring of PPCPs by water systems is not required by USEPA. Grumbles (2008) has indicated that USEPA will not require monitoring or treatment for trace pharmaceuticals until the health risks are better understood because other risks known to be more significant must be addressed first. Two commercial laboratories are offering analytical testing for PPCPs in drinking water and source water samples.

Drinking water treatment processes vary in their ability to remove PPCPs in general, and in removing specific compounds, therefore a water system should test their wells to determine which PPCPs are a concern and target removal of those compounds. Table 1 summarizes the effectiveness of drinking water treatment methods in removing endocrine disrupting chemicals (EDCs), PPCPs, and pharmaceutically active compounds (PhACs). Granular activated carbon (GAC) and reverse osmosis (RO) are the most effective treatment processes. Other treatment

processes may be effective in removing PPCPs depending upon the compound and the water treatment process design.

Small and rural water systems should be concerned about the possibility of customer exposure to PPCPs through drinking water and the follow recommendations are offered:

- PPCPs may be expected to occur in source waters (surface or ground) that receive treated waste water (e.g., wastewater discharges, septic tank effluent). This will be especially true for wastewater dominated source waters (e.g., where wastewater makes up more than 50% of the water source). Water systems with significant wastewater or septic tank effluent contributions to their source water should consider performing a one-time screening for PPCPs in source and treated waters using one of the two laboratories mentioned above.
- 2. If PPCPs are present in source water, conventional surface water and groundwater treatment processes can remove some, but not all, PPCPs. GAC and RO have been found to be the most effective treatment processes. USEPA has indicated that it will not require monitoring and treatment for PPCPs until it has a better assessment of the potential human health risks associated with PPCP presence in drinking water. Based on the results of the PPCP monitoring recommended above, water systems should make a determination of whether PPCPs are an issue for their source water(s).
- 3. If significant occurrence of PPCPs in treated drinking water is likely, the water system should consider actions it can take to lower customer exposure (e.g., additional treatment or other actions) to PPCPs in treated water.

4. Although potential regulation of PPCPs will be many years into the future, recent media attention will raise customer awareness regarding PPCPs in drinking water. The water system should communicate to its customers any actions taken to address PPCPs in drinking water and address any customer concerns.

1.0 Introduction

On March 9, 2008, the Associated Press reported the results of a five-month study detecting drugs in the drinking water of 24 metropolitan areas (Donn et al. 2008). Reports of detectable levels of pharmaceuticals and personal care products (PPCPs) in drinking water and the environment has caused a flurry of media coverage, elevating concerns about possible public health risks in the minds of consumers, regulators, and politicians.

Pharmaceuticals and personal care products are a large, diverse group of compounds used by people and/or given to animals for their beneficial effects. <u>Pharmaceuticals</u> are primarily prescription and over-the-counter therapeutic drugs. (Illegal drugs are included as well.) Examples include acetaminophen, benadryl, cocaine, dilantin, ibuprofen, progesterone, and veterinary drugs. Pharmaceuticals have been purposefully designed to have a biological affect at therapeutic dosages, and are therefore considered "biologically active."

<u>Personal care products</u> are compounds used for health and cosmetic reasons, and include sunscreen, insect repellent, lotions, cosmetics, vitamins, fragrances, and hygiene products.

There are thousands of PPCPs and some are more of a concern than others. PPCPs differ with regard to chemical structure, chemistry, chemical structure, amount manufactured annually, potency, and potential to be found in source water and treated drinking water.

PPCPs have at least two characteristics that set them aside from other water contaminants. Pharmaceuticals at therapeutic dosages in particular are known to have biological effects, which is what makes them useful. In addition, PPCPs and/or their degradation products are introduced into the environment through wastewater plant discharges, either as a result of biological elimination from people or intentional disposal into the sewer by individuals and the medical community.

PPCPs are "emerging contaminants," which are broadly defined as any synthetic or naturally occurring chemical or microbiological contaminant that is not commonly monitored in the environment but has the potential to enter the environment and cause known or suspected adverse ecological and (or) human health effects.

In some cases, PPCP release to the environment has likely occurred for a long time, but it was not recognized until new detection methods were developed. In other cases, synthesis of new chemicals or changes in use and disposal of existing chemicals can create new sources of emerging contaminants.

Because of their disposal pathway, PPCPs seem to be primarily of concern in surface waters and thus have not been viewed as a particular problem in small systems that usually have groundwater sources. However, trace amounts of these substances have been detected in some instances in groundwaters. Small water systems need to exercise due diligence in assessing possible risks to small and rural system customers and promoting any necessary actions to protect public health.

The purpose of this white paper is to evaluate PPCPs with respect to their potential health risk to small water system customers and any actions that should be taken by rural water systems to minimize any such risks.

The literature and currently available information was reviewed in order to assess the current status of PPCPs with respect to:

- 1) The degree and magnitude of occurrence of these compounds in groundwaters.
- Current estimates by the U.S. Environmental Protection Agency (USEPA) and other recognized authorities of the public health risks of these products in drinking water.
- 3) Major research efforts underway to better define any such risks.
- 4) The practicality and cost of monitoring for these compounds.
- 5) Possible treatment and or control methods to minimize exposure to these products.

Results of this evaluation are provided in this white paper. In addition, a separate Question and Answer document is attached that may be used by small water systems in answering questions that arise because of the current and planned publicity by the media about PPCPs.

2.0 Occurrence of PPCPs

2.1 How PPCPs Enter the Environment

In the United States, consumers spend billions of dollars on prescription drugs and personal care products. Spending in 2005 for prescription drugs alone was \$240 billion. Prescription drug use is rising among all ages. More than half of all Americans take at least one prescription drug. One in six takes three or more drugs. Medication that is not absorbed passes through the body and is passed into wastewater and surface water. Other personal care products (e.g., soap, shampoo) also find their way down the drain. PPCPs are not completely degraded or removed during wastewater treatment and have been present in the environment for as long as humans have been using them. Other avenues of PPCPs introduction into wastewater include showering, swimming, disposal of medicines in toilets or sinks, use and manufacture of illicit drugs, veterinary use, and disposal from medical facilities. The pathways by which PPCPs enter the environment is summarized in the attached diagram prepared by the USEPA.

2.2 Research on Occurrence of PPCPs

In 1998, the U.S. Geological Survey (USGS) initiated research on pharmaceuticals and other human- and animal-waste related chemicals. European researchers looking for a pesticide, detected a heart medication in the North Sea (Buser et al. 1998). Detectable concentrations of a drug in such a large water body drew attention to the need for further research. By 2002, a nationwide USGS study (Kolpin et al. 2002, Barnes et al. 2002, and Buxton and Kolpin 2002) documented the presence of pharmaceuticals and other waste-associated chemicals in U.S. streams.

Since 2002, the USGS has published more than 160 reports on PPCPs.² USEPA and others have also conducted studies on PPCP occurrence (e.g., Boyd et al. 2003) and removal.³ The occurrence, concentration, and mixtures of PPCPs have been documented in various environmental media, including stream water, well water, stream sediment, and soil amended with manure and biosolids (e.g., Nakada et al. 2007, Lapen et al. 2008, Yu et al. 2006). The comparative contributions from various sources have been documented, including wastewater treatment plants, livestock production and animal feedlot wastes, aquaculture, onsite septic systems, combined sewer overflows, and other industrial discharges. Assimilation of some of

² A bibliography of USGS reports supporting the findings on pharmaceuticals and other emerging contaminants in the environment is available on the Internet at: *http://toxics.usgs.gov/bib/bib-Emerging.html*. ³ USEPA PPCP research studies are listed at: *http://www.epa.gov/ppcp/work2.html*

these chemicals by organisms has also been documented (Kinney et al. 2008), as well as adverse ecological health effects (Vajda et al. 2008).

To summarize, PPCP compounds are likely to be detected in surface waters and groundwaters receiving treated waste water. PPCPs have also been detected in septic tank effluent and in treated drinking waters downstream of wastewater discharges. Acidic drugs, beta-blockers, and antibiotics are often present in the effluent of conventional municipal wastewater treatment plants at concentrations between 10 and 10,000 ng/L (Sedlak et al. 2005). Selected key studies are summarized below.

2.3 Groundwater Occurrence

Most USGS studies of PPCP occurrence have focused on surface waters. A few studies have detected PPCPs in groundwater. Benotti et al. (2007) compared data from two studies, conducted by Stony Brook University and the USGS regarding pharmaceutical occurrence in susceptible groundwater wells of Suffolk County, NY. Both studies targeted wells which were near permitted wastewater treatment facilities discharging to groundwater. The Stony Brook wells were generally shallower (68 +/- 31 ft) and closer (0.25 +/- 0.23 mi) than the USGS wells (250 +/- 132 ft and 0.73 +/- 0.83 mi) to the point source. Both methods employed solid phase extraction (SPE) followed by liquid chromatography-mass spectrometry (LC-MS) and targeted similar suites of compounds. Pharmaceuticals were detected in both studies. The range of detected concentrations was generally 1 to 200 ng/L.

Acetaminophen, caffeine, carbamazepine, nicotine, paraxanthine and sulfamethoxazole were detected in >50% of samples in the shallower wells, whereas only carbamazepine and sulfamethoxazole were detected in >5% of samples from the deeper wells. These results are

consistent with other published frequencies of detection for pharmaceuticals in susceptible waters. Frequently detected compounds are likely to be more persistent in groundwater.

The relative mobilities of pharmaceuticals in groundwater were assessed by regarding the distributions of compounds, on three different occasions, in the well field of an adult-assistedliving care facility with an on-site wastewater treatment plant discharging to groundwater. These distributions, combined with laboratory sorption experiments, suggest that **caffeine**, **carbamazepine**, **nicotine**, **paraxanthine and sulfamethoxazole have the potential for greatest transport in the subsurface**. Other removal processes like microbial degradation were not investigated.

Barnes et al. (2008) collected water samples from a network of 47 groundwater sites across 18 states in 2000. All samples collected were analyzed for 65 organic wastewater contaminants (OWCs) representing a wide variety of uses and origins. Site selection focused on areas suspected to be susceptible to contamination from either animal or human wastewaters (i.e. down gradient of a landfill, unsewered residential development, or animal feedlot). Thus, sites sampled were not necessarily used as a source of drinking water but provide a variety of geohydrologic environments with potential sources of OWCs. OWCs were detected in 81% of the sites sampled, with 35 of the 65 OWCs being found at least once.

The most frequently detected compounds include *N*,*N*-diethyltoluamide (35%, insect repellant), bisphenol A (30%, plasticizer), tri(2-chloroethyl) phosphate (30%, fire retardant), sulfamethoxazole (23%, veterinary and human antibiotic), and 4-octylphenol monoethoxylate (19%, detergent metabolite). Sampling procedures were intended to ensure that all groundwater samples analyzed were indicative of aquifer conditions. However, it is possible that detections

of some OWCs resulted from leaching of well construction materials and/or other site-specific conditions related to well construction and materials.

2.4 Source Water Occurrence

Focazio et al. (2008) analyzed targeted untreated sources of drinking water for 100 analytes with sub-parts per billion detection capabilities. The sites included 25 groundwater and 49 surface-water sources of drinking water serving populations ranging from one family to over 8 million people.

Sixty-three of the 100 targeted chemicals were detected in at least one water sample. In spite of a low analytical detection limit, 60% of the 36 pharmaceuticals (including prescription drugs and antibiotics) analyzed were not detected in any water sample. The five most frequently detected chemicals targeted in surface water were: cholesterol (59%, natural sterol), metolachlor (53%, herbicide), cotinine (51%, nicotine metabolite), β -sitosterol (37%, natural plant sterol), and 1,7-dimethylxanthine (27%, caffeine metabolite).

The five most frequently detected chemicals targeted in groundwater were: tetrachloroethylene (24% of groundwaters, solvent), carbamazepine (20% of groundwaters, pharmaceutical), bisphenol-A (20% of groundwaters, plasticizer), 1,7dimethylxanthine (16% of groundwaters, caffeine metabolite), and tri (2-chloroethyl) phosphate (12% of groundwaters, fire retardant). A median of 4 compounds were detected per site indicating that the targeted chemicals generally occur in mixtures (commonly near detection levels) in the environment and likely originate from a variety of animal and human uses and waste sources.

2.5 Septic Tanks and Groundwater Migration

Septic systems serve approximately 25% of U.S. households. Swartz et al. (2006) monitored several estrogenic organic wastewater contaminants in a residential septic system and in downgradient groundwater on Cape Cod, MA. OWCs monitored included nonylphenol (NP), nonylphenol mono- and diethoxycarboxylates (NP1EC and NP2EC), the steroid hormones 17- estradiol (E2), estrone (E1) and their glucuronide and sulfate conjugates, and other OWCs such as methylene blue active substances (MBAS), caffeine and its degradation product paraxanthine, and two fluorescent whitening agents.

E1 and E2 were present predominantly as free estrogens in groundwater. Near-source groundwater concentrations of all OWCs were highest in the suboxic to anoxic portion of the wastewater plume, where concentrations of most OWCs were similar to those observed in the septic tank on the same day. NP and NP2EC were up to 6- to 30-fold higher, and caffeine and paraxanthine were each 60-fold lower than septic tank concentrations, suggesting net production and removal, respectively, of these constituents.

At the most shallow, oxic depth, concentrations of all OWCs except for NP2EC were substantially lower than in the tank and in deeper wells. Boron, specific conductance, and the sum of nitrate-and ammonia-nitrogen were highest at this shallow depth, suggesting preferential losses of OWCs along the more oxic flow lines. As far as 6.0 m downgradient, concentrations of many OWCs were within a factor of 2 of near-source concentrations. **These results indicate that migration of these OWCs is possible in groundwater.**

2.6 Wastewater Discharge Impacts on Downstream Drinking Water Treatment

Weinberg et al. (2006) developed analytical methods for analyses of 25 antibiotics, including tetracyclines, sulfonamides, macrolides, quinolones, fluoroquinolones, trimethoprim, and lincomycin in surface waters impacted by upstream wastewater treatment plant (WWTP) discharges, sediments in the water basins, and finished drinking waters using SPE-LC-MS/MS. The method detection limits of the target analytes are generally below 10 ng/L in source water and below 5 ng/L in finished water.

A variety of residual antibiotics were detected at concentrations up to 95 ng/L in source waters of selected drinking water treatment plants mostly located downstream of wastewater effluent discharges. Most of the antibiotics detected in source waters were either below the practical quantitation level or were found at greatly reduced levels in finished water, indicating their partial removal in full-scale water treatment. Sulfamethoxazole was the most often detected antibiotic in source waters in this study probably because of its high usage and stability in aqueous systems. Tetracyclines were the least detected antibiotics in this study probably because they are more likely to partition out of the water column and into sediments and, therefore, not be transported to drinking water supplies.

2.7 Likelihood of PPCP Occurrence in Treated Drinking Water

PPCPs have been detected in treated drinking water. The presence of PPCPs in treated water depends upon the amount in the untreated source water and the ability of the system's water treatment to remove the particular PPCP compounds present. Drinking water sources that are effluent dominated (are 50% or more treated wastewater) are most likely to have PPCPs in treated water.

3.0 Public Health Risks of PPCPs

Most PPCPs, such as pharmaceuticals, have biological effects at regular therapeutic doses. The public health risks to trace levels of PPCPs in drinking water to people, animals and aquatic organisms are uncertain, because PPCPs concentrations are very low and exposure is over a long period of time. Major concerns include resistance to antibiotics and disruption of the endocrine system (the system of glands that produce hormones that help control the body's metabolic activity) by natural and synthetic sex steroids. There are no known human health effects from such low-level exposures in drinking water, but special scenarios require more investigation (one example being fetal exposure to low levels of medications that a mother would ordinarily be avoiding).

The highest concentrations of PPCPs detected in U.S. drinking waters are approximately 5,000,000 times lower than the therapeutic dose. So far, the research on this topic is showing that the human health effects are not significant for people who drink water containing the very low levels of PPCPs that are typically found.

3.1 Research on Human Health Risks

Research on PPCPs is currently being funded by USEPA, the AWWA Research Foundation, the USGS, and the Water Environment Federation (WEF). USEPA is working to understand health effects, occurrence, and removal treatment for PPCPs, including national studies and surveys. Current USEPA research on PPCPs is listed at

www.epa.gov/ppcp/work2.html.

There have been several studies to assess the human health risks of pharmaceuticals in U.S. surface waters. Data to support environmental risk assessments are also generated to

support registration of products in the U.S., Europe, and other countries, as required by existing regulations. In the U.S., formal environmental assessments are submitted to the U.S. Food and Drug Administration (FDA) for any new drug with a projected use that could result in a surface water concentration above 1 ug/L (FDA 1998).

Through the Pharmaceutical Research and Manufacturers of America (PhRMA), the pharmaceutical industry has developed an environmental fate and effects model (PhATE) to predict concentrations of active pharmaceutical ingredients (APIs) in surface and drinking water to support risk assessments (Anderson et al. 2004). Using this model, calculated concentrations in surface waters can be estimated for PPCPs using the methods recommended by FDA (1998).

Within the last 10 years there have been eight published studies assessing the potential human health implications of active pharmaceutical ingredients in surface and drinking water. Christensen (1998), Schulman et al. (2002), Reddersen et al. (2002), Mons et al. (2003), Webb et al. (2003), the Global Water Research Coalition (2004), Schwab et al. (2005), and Bercu et al. (2008), have **all evaluated the potential human health impact for several APIs found in surface and drinking water, and report no significant impact to human health or that human health effects are unlikely.**

Recently, Kostich et al. (2008) reported on the status of USEPA's multi-year research project to assess the potential human health effects from PPCPs in drinking water. Trace amounts of pharmaceuticals detected are so low that an adult would have to drink a half a gallon of water a day for almost a year to ingest the equivalent of a single minimal dose of the drugs. **Findings to date indicated that the small amounts of drugs in tap water are likely safe for healthy adults, even when considering mixtures of compounds. The USEPA study was**

intentionally conservative in estimating occurrence of compounds in water and their risk to human health (Hegstad 2008).

Pharmaceuticals pose a complicated problem for risk assessment, involving multiple dissimilar compounds, multiple routes of potential exposure, and a range of potentially affected organisms that span the tree of life. Key uncertainties include not knowing which of the thousands of available APIs to study, uncertainties about the most significant routes of human or ecological exposure, and (for ecotoxicology) identifying susceptible species.

An inventory of projects developed for the period of 1996 through 2014 has been compiled by USEPA.⁴ USEPA research to date has focused on a broad class of human prescription pharmaceuticals introduced into the environment via municipal wastewater effluents. Published marketing data and wastewater production rates have been used to predict the maximum likely wastewater concentration of each of 400 top-selling APIs potentially entering the environment each year. APIs were prioritized for monitoring based on projected potential to affect human biology, inhibit microbial growth, or affect other organisms. Chemical monitoring studies, which are currently underway, will be used to refine model-based risk estimates, and select APIs for toxicological investigation under environmentally relevant conditions.

The AWWA Research Foundation funded a four-year study of the health relevance of trace pharmaceuticals which is currently expected to be completed later in 2008. Snyder (2008) has noted that at the highest PPCP concentrations found, and using the most conservative safety factors to protect sensitive subpopulations such as infants and pregnant women, the

⁴ USEPA PPCP research studies are listed at: <u>http://www.epa.gov/ppcp/work2.html</u>

report will demonstrate that one could safely consume more than 50,000 eight-ounce glasses of this water per day without any health effects.

4.0 Monitoring of PPCPs

4.1 Monitoring of PPCPs Is Not Currently Regulated

Monitoring of PPCPs by water systems is not required by USEPA. **Grumbles (2008) has** indicated that USEPA will not require monitoring or treatment for trace pharmaceuticals until the health risks are better understood because other risks known to be more significant must be addressed first.

Recently, USEPA released the third Contaminant Candidate List (CCL) for public comment. The CCL lists contaminants that the Agency is considering for future regulation. No PPCPs where included in this latest list, although 287 PPCPs were considered. USEPA did not include PPCPs because these compounds have been found at such low levels. When compared to the best available health effects data, the public health risks are not significant in the studies done so far.

USEPA will be reviewing what is known about PPCPs to determine if the compounds should be regulated in the future, including determining which compounds should be included in future Unregulated Contaminant Monitoring Regulation (UCMR) sampling plans.

4.2 Laboratory Analysis for PPCPs

A water system can sample and test water from their wells, surface water source, and/or treated drinking water to detect PPCPs. Testing for most PPCPs at very low levels requires sophisticated equipment, and different PPCPs require different methods of analysis.

Analysis of PPCPs in aqueous samples requires instrumental methods using Gas

Chromotography/Mass Spectrometry (GC/MS) and Liquid Chromotography/Mass Spectrometry (LC/MS) analytical techniques. Until recently, this analytical capability resided only in research laboratories (e.g., USGS, USEPA, limited university laboratories, etc.).

Currently (2008), only two commercial laboratories are offering analytical services for PPCPs in drinking water:

MWH Laboratories 750 Royal Oaks Drive #100 Monrovia, CA 91016 Phone: (800) 566-LABS Fax: (626) 386-1101 <u>mwhlabs@mwhglobal.com</u> <u>www.mwhlabs.com</u>

Underwriters Laboratories 110 S. Hill Street South Bend, IN 46617 Phone: (800) 332-4345 www.ul.com

Water systems interested in testing their water for PPCPs can contact these laboratories. The laboratory will send the appropriate sample bottles to a water system for the analyses to be performed. The sampling and shipping procedures for PPCP testing are similar to other organic contaminant sampling.

Because analysis for PPCPs detects such low levels of compounds, extra care should be taken to not contaminate the samples. Also, the laboratories have limited capacity; testing for PPCPs should be scheduled in advance, particularly for MWH laboratories. Standardized analytical methods do not exist for PPCPs. Therefore, results from these and other laboratories and from different analytical methods may vary. Careful quality control measures must be followed. The two laboratories (MWH Laboratories and Underwriters Laboratories) each offer different analytical testing packages and pricing. Contact the laboratory for the most current services and prices.

Currently (2008),⁵ one of the PPCP tests offered by MWH Laboratories screens for the following 18 compounds: acetaminophen, bisphenol A (BPA), caffeine, carbamazepine, diazepam, estradiol, estrone, ethinyl estradiol – 17 alpha, fluoxetine, gemfibrozil, ibuprofen, iopromide (iodinated contrast media), progesterone, sodium perfluoro-1-octanesulfonate (PFOS), sulfamethoxazole, testosterone, triclosan, and trimethoprim. Currently, this screening for one sample of surface water costs approximately \$800 plus shipping costs. The same screening for one sample of groundwater or treated drinking water costs approximately \$500 plus shipping costs.

Currently (2008), two tests for PPCPs offered by Underwriters Laboratories are:

- Method L221 Negative screens for 28 compounds: bezafibrate, chloramphenicol, chlorotetracycline, clofibric acid, diclofenac, dilantin, doxycycline, gemfibrozil, ibuprofen, levothyroxine (synthroid), naproxen, oxytetracycline, penicillin G, penicillin V, prednisone, salinomycin, sulfachloropyridazine, sulfadiazine, sulfadimethoxine, sulfamerazine, sulfamethazine, sulfamethizole, sulfamethoxazole, sulfathiazole, theophylline, triclosan, tylosin, and virginiamycin. Method L221 Negative currently costs approximately \$400 plus shipping for one sample.
- Method L220 Positive screens for the following 40 compounds: acetaminophen, antipyrine, azithromycin, bacitracin, caffeine, carbadox, carbamazepine, ciprofloxacin, cotinine, DEET, dilantin, diltiazem, enrofloxacin, erythromycin, fluoxetine (prozac), lasalocid, levothyroxine (synthroid), lincomycin, monensin, narasin, nicotine, norfloxacin, oleandomycin, paraxanthine, prednisone, roxithromycin, salinomycin, simvastatin, sulfachloropyridazine, sulfadiazine, sulfadimethoxine, sulfamerazine, sulfamethazine, sulfadiazine, sulfathiazole, theobromine, trimethoprim, tylosin, and virginiamycin M1. Method L220 Positive costs approximately \$400 plus shipping for one sample.

⁵ MWH flyer and phone interview with MWH Laboratories, June 16, 2008.

For Underwriters Laboratories, the same prices apply to samples of untreated groundwater, surface water, or treated drinking water.⁶

These laboratories do not offer reduced prices for testing for individual compounds, because the same testing effort is required to obtain results for one compound as for multiple compounds.

5.0 Treatment and Control of PPCPs

A number of treatment studies have examined the removal of PPCPs. Weinberg et al. (2006) and Snyder et al. (2007) have performed the most extensive studies of treatment technology for PPCPs to date. Other studies include a general evaluation of removal by water treatment (Sedlak et al. 2005), water treatment pilot studies (Vieno et al. 2007), bench scale water treatment studies (Westerhoff et al. 2005), filtration removal (Zuehlke et al. 2007), bank filtration (Massmann et al. 2008), ozonation and granular activated carbon (GAC) (Ternes et al. 2002), and coagulation (Vieno et al. 2006).

Drinking water treatment processes vary in their ability to remove PPCPs in general, and in removing specific compounds, therefore a water system should test their wells to determine which PPCPs are a concern and target removal of those compounds.

Table 1 summarizes the effectiveness of drinking water treatment methods in removing endocrine disrupting chemicals (EDCs), PPCPs, and pharmaceutically active compounds (PhACs). Granular activated carbon (GAC) and reverse osmosis (RO) are the most effective treatment processes. Other treatment processes may be effective in removing PPCPs depending upon the compound and the water treatment process design.

⁶ Emailed analysis quote and phone interview with Underwriters Laboratories, June 16, 2008.

Snyder et al. (2007) found the following drinking water technologies to be the most effective in removing PPCPs:

- Chlorine disinfection can remove many target compounds depending on the chemical structure of the contaminant. Chloramines are much less effective than chlorine.
- Ozone is much more effective than chlorine and is able to significantly remove the majority of target compounds.
- Ultraviolet (UV) at high energy doses can be very effective, but UV at disinfection doses is mostly ineffective.
- Advanced oxidation processes (such as ozone and peroxide; and UV and peroxide) are very effective.
- Activated carbon is very effective, but only when the carbon medium is not exhausted.
- Reverse osmosis and nanofiltration (high pressure membranes) are very effective.
- Riverbank filtration, biological filtration, and soil aquifer treatment can reduce concentration of many compounds. Soil aquifer treatment has been found to remove most pharmaceutically active compounds.

One study analyzed 12 pharmaceuticals in river water and their removal by a pilot-scale drinking water system. Ozone was very effective for 11 compounds; and granular activated carbon was effective for nine compounds. Little removal was accomplished by coagulation, sedimentation, and rapid sand filtration.

Free chlorine disinfection can remove many target compounds, particularly those with certain chemical structures, such as phenolic groups. Chlorine was found to be very effective in removing the following: acetaminophen, benzo(a)pyrene, diclofenac, erythromycin-H₂O,

estradiol, estriol, estrone, ethynyl estradiol, hydrocodone, musk ketone, naproxen, oxybenzone, sulfamethoxazole, triclosan, and trimethoprim. Chlorine was somewhat effective in removing the following: gemfibrozil, diazepam, galaxolide, and pentoxifylline. Some of the compounds that resulted from PPCP reaction with chlorine may cause taste and odor problems, and may have unknown health risks. Also, chlorine's removal ability is affected by pH, other constituents in the water, and contact time.

The following drinking water technologies have been found to be mostly <u>ineffective</u> in removing most PPCPs:

- UV at disinfection doses
- Magnetic ion-exchange
- Ultrafiltration and microfiltration (low pressure membranes)
- Conventional coagulation, flocculation, and sedimentation

6.0 Recommendations

 PPCPs may be expected to occur in source waters (surface or ground) that receive treated waste water (e.g., wastewater discharges, septic tank effluent). This will be especially true for wastewater dominated source waters (e.g., where wastewater makes up more than 50% of the water source). Water systems with significant wastewater or septic tank effluent contributions to their source water should consider performing a one-time screening for PPCPs in source and treated waters using one of the two laboratories mentioned above.

- 2. If PPCPs are present in source water, conventional surface water and groundwater treatment processes can remove some, but not all, PPCPs. GAC and RO have been found to be the most effective treatment processes. USEPA has indicated that it will not require monitoring and treatment for PPCPs until it has a better assessment of the potential human health risks associated with PPCP presence in drinking water. Based on the results of the PPCP monitoring recommended above, water systems should make a determination of whether PPCPs are an issue for their source water(s).
- 3. If significant occurrence of PPCPs in treated drinking water is likely, the water system should consider actions it can take to lower customer exposure (e.g., additional treatment or other actions) to PPCPs in treated water.
- 4. Although potential regulation of PPCPs will be many years into the future, recent media attention will raise customer awareness regarding PPCPs in drinking water. The water system should communicate to its customers any actions taken to address PPCPs in drinking water and address any customer concerns.

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 Table 1: Effectiveness of Drinking Water Treatment Methods in Removing Endocrine Disrupting Chemicals (EDCs), Pharmaceutically Active Compounds (PhACs), and Personal Care Products (PCPs).
 See key and definitions of acronyms used in table below.

Com- pounds	Classification	Act. Carbon	Bio. Act. Carbon	Ozone/ Advanced Oxidation Processes	UV*	Chlorine/ Chlorine Dioxide	Coagulation/ Flocculation	Softening/ Metal Oxides	Nano- Filtration	Reverse Osmosis	Degradation** Biodegradation/ Solar-photo- degradation/ Act. Sludge
EDCs	Pesticides	Excel.	Excel.	Variable	Excel.	Variable	Poor	Good	Good	Excel.	Solar: Excel.
	Industrial Chemicals	Excel.	Excel.	Variable	Excel.	Poor	Variable	Variable	Excel.	Excel.	Bio.: Variable
	Steroids	Excel.	Excel.	Excel.	Excel.	Excel.	Poor	Variable	Good	Excel.	Bio.: Variable
	Metals	Good	Good	Poor	Poor	Poor	Variable	Variable	Good	Excel.	Bio.: Poor Sludge: Excel.
	Inorganics	Variable	Fair	Poor	Poor	Poor	Poor	Good	Good	Excel.	Variable
	Organometallics	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Excel.	Variable
PhACs	Antibiotics	Variable	Excel.	Variable	Variable	Variable	Variable	Variable	Excel.	Excel.	Bio.: Excel. Solar.: Variable
	Antidepressants	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Excel.	Variable
	Anti- inflammatory	Excel.	Variable	Excel.	Excel.	Variable	Poor	Variable	Variable	Excel.	Bio.: Excel.
	Lipid regulators	Excel.	Excel.	Excel.	Variable	Variable	Poor	Variable	Variable	Excel.	Bio.: Poor
	X-ray contrast media	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Excel.	Bio.: Excellent Solar: Excellent
	Psychiatric control	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Excel.	Variable
PCPs	Synthetic musks	Variable	Variable	Variable	Excel.	Variable	Variable	Variable	Variable	Excel.	Bio.: Excel.
	Sunscreens	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Excel.	Variable
	Antimicrobials	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Excel.	Solar: Poor
	Detergents/ surfactants	Excel.	Excel.	Variable	Variable	Poor	Variable	Variable	Excel.	Excel.	Bio.: Variable

* A recent AWWARF study (Snyder et al. 2007) noted that UV at high energy doses can be very effective for removing EDCs and pharmaceuticals, but UV at disinfection doses is mostly ineffective.

**Degradation includes biodegradation (Bio.), solar-photo degradation (Solar), and activated sludge (Sludge) wastewater treatment.

Excellent removal = more than 90% Good removal = 70 to 90% Fair removal = 40 to 70% Poor removal = less than 20% Variable removal depends on specific compounds.

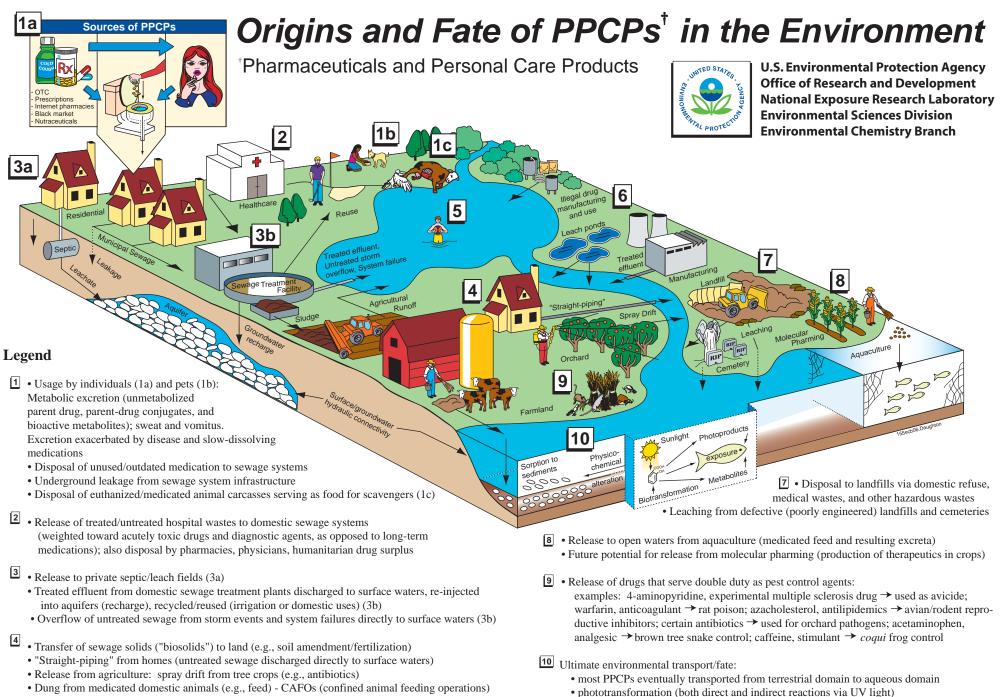
Acronyms and Abbreviations

Act. Carbon - Activated Carbon Bio. - Biodegradation Bio. Act. Carbon - Biologically Activated Carbon EDCs - Endocrine Disrupting Chemicals Excel. - Excellent PPCPs - Pharmaceuticals and Personal Care Products PhACs - Pharmaceutically Active Compounds Sludge - Activated Sludge Solar - Solar-Photo Degradation

Table Source

Pharmaceuticals in Drinking Water: Issues and Answers. MWH Laboratories brochure. 2008.

Adapted from: Snyder, S.A., Westerhoff, P., Yoon, Y. and Sedlack, D. 2003. Pharmaceuticals, Personal Care Products, and Endocrine Disrupters in Water: Implications for the Water Industry. *Environmental Engineering Science* 20, 449-469.



- Dung from medicated domestic animals (e.g., feed) CAFOs (confined animal feeding operations)
- 5
 - Direct release to open waters via washing/bathing/swimming
- 6 • Discharge of regulated/controlled industrial manufacturing waste streams
 - Disposal/release from clandestine drug labs and illicit drug usage Christian G. Daughton, U.S. EPA-Las Vegas

• some uptake by plants • respirable particulates containing sorbed drugs (e.g., medicated-feed dusts)

• physicochemical alteration, degradation, and ultimate mineralization

• volatilization (mainly certain anesthetics, fragrances)

March 2006 (original February 2001)

Questions and Answers Pharmaceuticals and Personal Care Products (PPCPs)

What are pharmaceuticals and personal care products (PPCPs)?

<u>Pharmaceuticals</u> are primarily prescription and over-the-counter therapeutic drugs used by people and animals. (Illegal drugs are included as well.) Examples include acetaminophen, benadryl, cocaine, dilantin, ibuprofen, progesterone, and veterinary drugs. Pharmaceuticals have been purposefully designed to have a biological affect, and are therefore considered "biologically active."

<u>Personal care products</u> are compounds used by people and animals for health and cosmetic reasons, and include sunscreen, insect repellent, lotions, cosmetics, vitamins, fragrances, and hygiene products.

There are thousands of PPCPs and some are more of a concern than others. PPCPs differ with regard to chemical structure, chemistry, chemical structure, amount manufactured annually, potency, and potential to be found in source water and treated drinking water.

PPCPs are "emerging contaminants, which are broadly defined as any synthetic or naturally occurring chemical or microbiological contaminant that is not commonly monitored in the environment but has the potential to enter the environment and cause known or suspected adverse ecological and (or) human health effects.

In some cases, PPCP release to the environment has likely occurred for a long time, but it has not been recognized until new detection methods were developed. In other cases, synthesis of new chemicals or changes in use and disposal of existing chemicals can create new sources of emerging contaminants.

How do PPCPs enter the environment?

In the United States, consumers spend billions of dollars on prescription drugs and personal care products. Spending in 2005 for prescription drugs alone was \$240 billion. Prescription drug use is rising among all ages. More than half of all Americans take at least one prescription drug. One in six take three or more drugs. Medication that is not absorbed passes through the body and is passed into wastewater and surface water. Other personal care products (e.g., soap, shampoo) also find their way down the drain. PPCPs are not completely degraded or removed during wastewater treatment and have been present in the environment for as long as humans have been using them.

Other avenues of PPCPs introduction into wastewater include showering, swimming, disposal of medicines in toilets or sinks, use and manufacture of illicit drugs, veterinary use, and disposal from medical facilities.

How PPCPs enter the environment is summarized in the attached diagram prepared by the US Environmental Protection Agency (USEPA).

Are PPCPs in surface waters?

Since 2002, the US Geological Survey (USGS) has published more than 160 reports on PPCPs. USEPA and others have also conducted studies on PPCP occurrence. The occurrence, concentration, and mixtures of PPCPs have been documented in various environmental media, including stream water, well water, stream sediment, and soil amended with manure and biosolids. The comparative contributions from various sources have been documented, including wastewater treatment plants, livestock production and animal feedlot wastes, aquaculture, onsite septic systems, combined sewer overflows, and other industrial discharges. Assimilation of some of these chemicals by organisms has also been documented, as well as adverse ecological health effects.

In sum, PPCP compounds are likely to be detected in surface waters and ground waters receiving treated waste water. They have also been detected in septic tank effluent and in treated drinking waters downstream of wastewater discharges. Acidic drugs, beta-blockers, and antibiotics are often present in the effluent of conventional municipal wastewater treatment plants at concentrations between 10 and 10,000 ng/L.

Can PPCPs be found in ground water wells?

PPCPs have been detected in ground water wells that receive wastewater or septic tank effluent. One study of 25 ground water sources of drinking water found the following five most frequently detected chemicals targeted in ground water: tetrachloroethylene (24%, solvent), carbamazepine (20%, pharmaceutical), bisphenol-A (20%, plasticizer), 1,7-dimethylxanthine (16%, caffeine metabolite), and tri (2-chloroethyl) phosphate (12%, fire retardant).

Are PPCPs in treated drinking water?

Some PPCPs have been detected in treated drinking water. The key factor is the amount of PPCPs that are in each system's untreated source water, and, secondarily, the ability of the system's water treatment to remove the PPCPs. Drinking water sources that are effluent dominated (are 50% or more treated wastewater) are most likely to have PPCPs in treated water.

What health concerns are associated with PPCPs in drinking water?

Most PPCPs, such as pharmaceuticals, have biological effects at regular therapeutic doses. The health risks to people, animals and aquatic organisms are uncertain, because PPCPs concentrations are very low and exposure is over a long period of time. The major concerns include resistance to antibiotics and disruption of the endocrine system (the system of glands that produce hormones that help control the body's metabolic activity) by natural and synthetic sex steroids, and many other PPCPs have unknown consequences. There are no known human health effects from such low-level exposures in drinking water, but special scenarios (one example being fetal exposure to low levels of medications that a mother would ordinarily be avoiding) require more investigation.

The highest concentrations of PPCPs detected in US Drinking Waters is approximately 5,000,000 times lower than the therapeutic dose. So far, the research on this topic is showing that the human health effects are not significant for people who drinking water containing the very low levels of PPCPs that are typically found.

Within the last 10 years there have been eight published studies assessing the potential human health implications of active pharmaceutical ingredients in surface and drinking water. One study was just published in 2008. All of these studies report no significant impact to human health or that human health effects are unlikely.

Recently, USEPA reported on the initial results of a multi-year research project to assess the potential human health effects from PPCPs in drinking water. Trace amounts of pharmaceuticals are so low that an adult would have to drink a half a gallon of water a day for almost a year to ingest the equivalent of a single minimal dose of the drugs. Findings to date indicated that the small amounts of drugs in tap water are likely safe for healthy adults, even when considering mixtures of compounds. The USEPA study was intentionally conservative in estimating occurrence of compounds in water and their risk to human health

A study by the AWWA Research Foundation to be completed in 2008 has found that, at the highest PPCP concentrations found, and using the most conservative safety factors to protect sensitive subpopulations such as infants and pregnant women, one could safely consume more than 50,000 eight-ounce glasses of this water per day without any health effects.

What research is being done to investigate the potential health risks of these compounds?

Research on PPCPs is currently being funded by USEPA, the AWWA Research Foundation, the USGS, and the Water Environment Federation (WEF). USEPA is working to understand health effects, occurrence, and removal treatment for PPCPs, including national studies and surveys. Current USEPA research on PPCPs is listed at www.epa.gov/ppcp/work2.html.

Does USEPA have any regulations now or coming soon that we have to meet for these compounds? Is testing for PPCPs required now or will it be required soon?

Recently, USEPA released the third Contaminant Candidate List (CCL) for public comment. The CCL lists contaminants that the Agency is considering for future regulation. No PPCPs where included in this latest list, although 287 PPCPs were considered. USEPA did not include PPCPs because these compounds have been found at such low levels. When compared to the best available health effects data, the public health risks are not significant in the studies done so far.

USEPA will be reviewing what is known about PPCPs to determine if the compounds should be regulated in the future, including determining which compounds should be included in future Unregulated Contaminant Monitoring Regulation (UCMR) sampling plans.

How can we determine if these compounds are in our drinking water?

A water system can sample and test water from their wells, surface water source, and/or treated drinking water to detect PPCPs. Testing for most PPCPs at very low levels requires sophisticated equipment, and different PPCPs require different methods of analysis. Currently (2008), only two commercial U.S. laboratories offer testing:

MWH Laboratories 750 Royal Oaks Drive #100 Monrovia, CA 91016 Phone: (800) 566-LABS Fax: (626) 386-1101 <u>mwhlabs@mwhglobal.com</u> <u>www.mwhlabs.com</u>

Underwriters Laboratories 110 S. Hill Street South Bend, IN 46617 Phone: (800) 332-4345 www.ul.com

Sampling and shipping procedures for PPCP testing are similar to other drinking water samples, however, because the analysis detects such low levels of compounds, extra care should be taken to not contaminate the samples. Also, note that because these laboratories have limited capacity, testing for PPCPs should be scheduled in advance.

Because testing methods for these analysis are not standardized, the results from different laboratories and different methods could vary.

What does testing for PPCPs cost?

MWH Laboratories and Underwriters Laboratories each offer different analytical testing services for PPCPs. Contact the laboratory for the most recent tests offered and current pricing.

Currently (2008), one of the PPCP tests offered by MWH Laboratories screens for the following 18 compounds: acetaminophen, bisphenol A (BPA), caffeine, carbamazepine, diazepam, estradiol, estrone, ethinyl estradiol – 17 alpha, fluoxetine, gemfibrozil, ibuprofen, iopromide (iodinated contrast media), progesterone, sodium perfluoro-1-octanesulfonate (PFOS), sulfamethoxazole, testosterone, triclosan, and trimethoprim. Currently, this screening for one sample of surface water costs approximately \$800 plus shipping costs. The same screening for one sample of ground water or treated drinking water costs approximately \$500 plus shipping costs.

Two tests for PPCPs offered by Underwriters Laboratories are:

- Method -- L221 Negative screens for 28 compounds: bezafibrate, chloramphenicol, chlorotetracycline, clofibric acid, diclofenac, dilantin, doxycycline, gemfibrozil, ibuprofen, levothyroxine (synthroid), naproxen, oxytetracycline, penicillin G, penicillin V, prednisone, salinomycin, sulfachloropyridazine, sulfadiazine, sulfadimethoxine, sulfamerazine, sulfamethazine, sulfamethizole, sulfamethoxazole, sulfathiazole, theophylline, triclosan, tylosin, and virginiamycin. Method -- L221 Negative currently costs approximately \$400 plus shipping for one sample.
- Method -- L220 Positive screens for the following 40 compounds: acetaminophen, antipyrine, azithromycin, bacitracin, caffeine, carbadox, carbamazepine, ciprofloxacin, cotinine, DEET, dilantin, diltiazem, enrofloxacin, erythromycin, fluoxetine (prozac), lasalocid, levothyroxine (synthroid), lincomycin, monensin, narasin, nicotine, norfloxacin, oleandomycin, paraxanthine, prednisone, roxithromycin, salinomycin, simvastatin, sulfachloropyridazine, sulfadiazine, sulfadimethoxine, sulfamerazine, sulfamethazine, sulfamethizole, sulfamethoxazole, sulfathiazole, theobromine, trimethoprim, tylosin, and virginiamycin M1. Method -- L220 Positive costs approximately \$400 plus shipping for one sample.

For Underwriters Laboratories, the same prices apply to samples of untreated groundwater, surface water or treated drinking water.

These labs do not offer reduced prices for testing for individual compounds, because the same testing effort is required to obtain results for one compound as for multiple compounds.

How can PPCPs be removed from drinking water?

Drinking water treatment processes vary in their ability to remove PPCPs in general, and in removing specific compounds, therefore a water system should test their wells to determine which PPCPs are a concern and target removal of those compounds.

The attached table summarizes the effectiveness of drinking water treatment methods in removing endocrine disrupting chemicals (EDCs), PPCPs, and pharmaceutically active compounds (PhACs).

A recent AWWA Research Foundation study found the following drinking water technologies to be the most effective in removing PPCPs:

- Chlorine disinfection can remove many target compounds depending on the chemical structure of the contaminant. Chloramines are much less effective than chlorine.
- Ozone is much more effective than chlorine and is able to significantly remove the majority of target compounds.

- Ultraviolet (UV) at high energy doses can be very effective, but UV at disinfection doses is mostly ineffective.
- Advanced oxidation processes (such as ozone and peroxide; and UV and peroxide) are very effective.
- Activated carbon is very effective, but only when the carbon medium is not exhausted.
- Reverse osmosis and nanofiltration (high pressure membranes) are very effective.
- Riverbank filtration, biological filtration, and soil aquifer treatment can reduce concentration of many compounds. Soil aquifer treatment has been found to remove most pharmaceutically active compounds.

One study analyzed 12 pharmaceuticals in river water and their removal by a pilot-scale drinking water system. Ozone was very effective for 11 compounds; and granular activated carbon was effective for 9 compounds. Little removal was accomplished by coagulation, sedimentation, and rapid sand filtration.

Free chlorine disinfection can remove many target compounds, particularly those with certain chemical structures, such as phenolic groups. Chlorine was found to be very effective in removing the following: acetaminophen, benzo(a)pyrene, diclofenac, erythromycin-H₂O, estradiol, estriol, estrone, ethynyl estradiol, hydrocodone, musk ketone, naproxen, oxybenzone, sulfamethoxazole, triclosan, and trimethoprim. Chlorine was somewhat effective in removing the following: gemfibrozil, diazepam, galaxolide, and pentoxifylline. Some of the compounds that resulted from PPCP reaction with chlorine may cause taste and odor problems, and may have unknown health risks. Also, chlorine's removal abilities is effected by pH, other constituents in the water, and contact time .

The following drinking water technologies have been found to be mostly ineffective in removing most PPCPs:

- UV at disinfection doses
- Magnetic ion-exchange
- Ultrafiltration and microfiltration (low pressure membranes)
- Conventional coagulation, flocculation, and sedimentation