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Alternative Strategies *for* Managing Pharmaceutical and Personal Care Products in Water Resources



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Alternative Strategies *for* Managing Pharmaceutical and Personal Care Products in Water Resources

Prepared by: Gabriel Eckstein & George William Sherk
MAY 2011

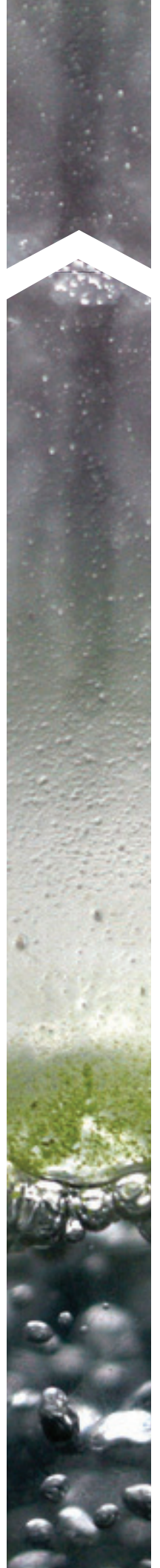


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Project funded by
U.S. Environmental Protection Agency



About the Texas Tech University Center for Water Law & Policy

The Center for Water Law & Policy at Texas Tech University was created in 2005 in response to the growing need for research into and information about global water issues. It was designed to create and nurture opportunities for interdisciplinary collaboration on legal and policy issues related to the use, allocation, management, regulation, and conservation of fresh water resources at all levels of civil society – from the purely local to the decisively global. The Center is part of the Texas Tech University interdisciplinary water initiative, which involves faculty and students representing the disciplines of law, public policy, economics, agriculture, geosciences, engineering, biological sciences, and health sciences.

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Executive Summary

In recent decades, concern has grown over the presence of pharmaceutical and personal care products (PPCPs) in water. This concern stems from the possibility that the presence of PPCPs in water supplies may pose a threat to both human and environmental health. Such threats may be both direct (e.g., exposure to endocrine disrupting compounds) and indirect (e.g., emergence of antibiotic resistant bacteria). The water treatment and wastewater treatment community has been especially concerned over PPCPs because of PPCPs ubiquitous nature and their ability to persist or only partially degrade in water and during wastewater treatment. Studies done over the past several decades have indicated that wastewater contaminants including antibiotics, other prescription drugs, non-prescription drugs, steroids, reproductive hormones, and personal care products have been found in both surface water and ground water in the United States.

Sources of PPCPs include human & animal feces and urine, hospital/medical wastes, wastes from industrial and agricultural processes, pharmaceuticals and personal care products that are disposed of inappropriately, urban runoff, and leachate from landfills. These contaminants are rarely treated or removed in the wastewater treatment process and typically remain in waters discharged from wastewater treatment plants into receiving streams and lakes, as well as in solid and liquid wastes applied to lands designated as application sites.

Various common law remedies, such as trespass, nuisance, negligence, and strict liability, may be relevant to concerns over PPCPs in water supplies. However, these remedies rely on success in litigation. Litigation is often expensive, time consuming, and very case specific. Additionally, success in litigation requires plaintiffs to prove causation – which manufacturer produced the PPCP involved in the suit, and which PPCPs resulted in the harm alleged in the suit – hurdles that may be difficult to overcome.

An alternative to common law remedies may be found under federal, state, and tribal laws and regulations where a number of agencies and statutes may be relevant. Federal agencies that have the potential to be involved in various aspects of the management of PPCPs include the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), the U.S. Geological Survey (USGS), and the Centers for Disease Control and Prevention (CDC). In addition, numerous units of state, tribal, and local governments may be involved in implementing environmental programs that are relevant to the management of PPCPs. Existing federal statutory regimes that may be relevant to PPCPs include: Clean Water Act; Safe Drinking Water Act; Resource Conservation and Recovery Act; Toxic Substance Control Act; and Endangered Species Act

(ESA). States and tribes have enacted similar legislation. While these strategies may prove to be important, their implementation can be expensive and politically unpopular.

A more effective route for responding to PPCPs in drinking water supplies may be to focus on alternative strategies that focus on removing PPCPs from the source. These alternative strategies include designing drugs and personal care products that minimize the human and animal excretion of wastes, which would then minimize the volume of PPCPs that enter the water system. Changing the delivery mechanisms may also be successful in addressing PPCPs in water systems. This strategy relies on better informing doctors and patients about the effects of PPCPs on the environment, and educating doctors and other professionals on how to individualize or tailor doses to the individual user rather than prescribing the manufacturers' recommended dose. Informing users on how to dispose of unused drugs and personal care products and producing a variety of package sizes to reduce the amount of unused drugs could also be an essential PPCP reducing mechanism.

In addition, encouraging states or manufacturers of pharmaceuticals and personal care products to develop take-back programs could also lead to the reduction of PPCPs in the water supplies. Unfortunately, institutional and financial barriers may make implementing of many of these programs difficult. For take-back programs to be successful, these institutional barriers need to be revised. Nutrition and health maintenance programs that reduce illness and the need for PPCPs, as well as the use of alternative products that do not contain PPCPs, such as probiotics, also could reduce the amount of PPCPs entering the water supply. This alternative, however, could also be costly to the patient.

The issue of PPCPs in water supplies is a complex problem that will require more than one simple solution. It will require reducing the source of PPCPs and monitoring and regulating the PPCPs that enter the water supply. New monitoring, detection, and analysis methods are needed. New drinking water treatment processes will need to be developed. Regulatory and statutory approaches need to be tailored to reducing the amount of PPCPs in water supplies. The alternative strategies discussed here will be needed to protect human and environmental health.



A. Introduction:

In the nearly forty years since the adoption of the Federal Water Pollution Control Act Amendments in 1972¹ and the Safe Drinking Water Act in 1974,² the United States has seen dramatic improvement in the quality of both surface and drinking water. Despite these improvements, serious problems and questions remain.

Chemicals occur in the environment through a wide variety of natural processes and human actions. The various federal and state programs implementing the Clean Water Act, the Safe Drinking Water Act and other environmental laws regulate only a small portion of these chemicals. Although the number of regulated chemicals is very small when compared to the universe of chemicals in the environment, an implicit assumption underlying this regulatory approach is that “these selective lists of chemicals are responsible for the most significant share of risk with respect to environmental or economic impairment or to human health.”³

In recent years, this assumption has been challenged. Chemicals from a wide variety of pharmaceutical and personal care products (PPCPs), their byproducts and endocrine disrupting

compounds (EDCs) have received growing attention from the water treatment and wastewater treatment community because of the ability of PPCPs to persist or only partially degrade in water and during wastewater treatment.⁴

Several federal agencies, including the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), the U.S. Geological Survey (USGS), and the Centers for Disease Control and Prevention (CDC), have the potential to be involved in various aspects of the management of PPCPs. In addition to these federal agencies, numerous units of state, tribal, and local governments are (or could be) involved in implementing federal, state, and tribal environmental programs that are relevant to the management of PPCPs. Industry stakeholders also play significant roles, both directly and indirectly, in the management of PPCPs.

PPCPs are an extremely diverse group of chemicals used in human health care, cosmetic care, veterinary medicine, and agriculture. They also are ubiquitous pollutants, entering the environment worldwide due to widely dispersed usage by

¹ Pub. L. No. 92-500, 86 Stat. 816 (1972) (codified as amended at 33 U.S.C. § 1251 *et seq.* (2006)) (with subsequent amendments, now known as the Clean Water Act).

² Safe Drinking Water Act, Public Law No. 93-523, 88 Statutes at Large 1661.

³ Christian G. Daughton, *Non-Regulated Contaminants Emerging Research, Existing and Future Pollutants in Water Supplies: Old Pollutants, New Concerns – New Pollutants, Unknown Issues*. Paper presented at the Presented at National Academies, Institute of Medicine: Roundtable on Environmental Health Science, Research, and Medicine (EHSRT) (Oct. 16, 2003).

⁴ For the purposes of this report, the term “PPCPs” includes a diverse group of chemicals that include pharmaceutical, such as prescription and over-the-counter human drugs, veterinary drugs, and diagnostic agents, and personal care products, including fragrances, lotions, cosmetics, and nutritional supplements. PPCPs also comprise the various byproducts of these substances as well as related endocrine disrupting compounds (EDCs). Concern regarding the presence of such compounds in water supplies was expressed by Masters:

[These] are compounds that interfere with natural production, release, transport, metabolism, binding, action, or elimination of hormones in the body. We know that the normal functions of all organ systems are regulated by endocrine factors. Small disturbances in endocrine function, especially during certain stages of the life cycle, can lead to profound and lasting effects. There is evidence that specific populations of invertebrate, fish, avian, reptilian, and mammalian species have been, or currently are being, adversely affected by exposure to environmental contaminants that effect the endocrine systems. ... The major groups of animals potentially at risk include fish, birds, reptiles, marine mammals, and invertebrates.

Robert W. Masters, *Pharmaceuticals and Endocrine Disruptors in Rivers and On Tap*, WATER RESOURCES UPDATE, no. 120, 1, 1 (2001) (citing Gerald Ankley et al., Office of Research and Development, Environmental Protection Agency, RESEARCH PLAN FOR ENDOCRINE DISRUPTORS. (1998)). See also K. Xia et al., *Occurrence, Distribution, and Fate of 4-Nonylphenol in Kansas Domestic Wastewater Treatment Plants*, 120 WATER RESOURCES UPDATE 41 (2001).

⁵ Christian G. Daughton, *Chapter 33: PPCPs in the Environment: Future Research – Beginning with the End Always in Mind*, in PHARMACEUTICALS IN THE ENVIRONMENT: SOURCES, FATE, EFFECTS AND RISKS 463 (Klaus Kümmerer ed., 2d ed. Springer 2004).

individuals and in both industry and agriculture.⁵ Recent reports in popular media regarding pharmaceuticals in drinking water have contributed to increasing public awareness of and concern about this issue.⁶

In 2006, the Center for Water Law & Policy at Texas Tech University (the “Center”) was awarded funding by the Environmental Protection Agency to conduct a study related to micropollutants (including PPCPs) in the natural environment. This study was divided into three specific projects.

Project 1 focused on the development of a PPCP database containing documents, reports, publications, and other material related to PPCPs. While information in the database was designed for use in Project 3 (discussed below), the information was also intended to be made available to those interested in understanding water law and policy issues, including researchers, decision-makers in the public and private sectors, stakeholders, interest groups, and the general public. This latter objective was achieved by the creation of the Micropollutants Clearinghouse (<http://www.micropollutants.org>).

Project 2 focused on primary research to improve the understanding of the presence and fate of mixtures of micropollutants in the environment. This research, which was based on field studies conducted on discharges from a wastewater treatment facility in West Texas, forms the basis for the case study noted below.

Project 3 focused on an analysis of alternative strategies for addressing the presence and effects of PPCPs in water supplies. Statutory and regulatory approaches that are (or could be) utilized to prevent PPCPs from entering the aquatic environment in concentrations that would exceed concentrations determined to be appropriate for protection of human health and the environment were identified and evaluated.⁷ Potential alternative strategies were also identified and evaluated. Project 3 addressed three basic questions: First, can existing statutory and regulatory authorities be utilized to collect information about and/or effectively manage PPCPs entering the environment? Second, are there other alternative strategies that should be considered? Third, what are the relative strengths and weaknesses of the existing authorities and alternative strategies? The results of Project 3 as well as answers to these three questions are contained herein.

⁶ For example, in 2008, the Associated Press released a series of investigative reports entitled AN AP INVESTIGATION: PHARMACEUTICALS FOUND IN DRINKING WATER. These reports, which were distributed by both print and electronic media worldwide, included: Jeff Donn, *PharmaWater – NYC Water: Drug Traces Turn Up in Source Waters for Nation’s Biggest City*; Jeff Donn, *PharmaWater – Philadelphia Drugs: Tests of Philadelphia’s Drinking Water Reveal 56 Drugs*; Jeff Donn, *PharmaWater – Research: Research Shows Pharmaceuticals in Water Could Impact Human Cells*; Jeff Donn, *House Panel Pressed to Consider More Tracking of Pharmaceuticals, Contaminants in US Waters*; Jeff Donn, *Medical Facilities Making Uncontrolled Releases of Controlled Drugs into Water*; Jeff Donn, *Philadelphia City Council Wants Local and Federal Action to Curb Drugs in Drinking Water*; Jeff Donn, *Philadelphia Water Officials to Address Worries over Drugs in Water and Corrected Data*; Jeff Donn, Martha Mendoza & Justin Pritchard, *Pharmawater I: Pharmaceuticals Found in Drinking Water, Affecting Wildlife and Maybe Humans*; Jeff Donn, Martha Mendoza & Justin Pritchard, *Pharmawater II: Fish, Wildlife Affected by Drug Contamination in Water*; Jeff Donn, Martha Mendoza & Justin Pritchard, *Pharmawater III: No Standards to Handle Pharmaceuticals in Water*; Jeff Donn, Martha Mendoza & Justin Pritchard, *AP Impact: Health Care Industry Sends Tons of Drugs into Nation’s Wastewater System*; Jeff Donn, Martha Mendoza & Justin Pritchard, *AP Investigation: Scant Advice on Disposal of Meds*; Tom Hester, Jr., *NJ Lawmakers Told Effects of Drugs in Water Unknown*; Steve LeBlanc, *Mass. Officials Detail Steps to Keep Pharmaceuticals from Water Supply, Call for Federal Help*; Colleen Long, *NYC Leaders Say City Must Test Drinking Water, Responding to AP Report on Drugs*; Martha Mendoza, *PharmaWater-Secrecy: Water Providers, Researchers Rarely Release Full Test Results*; Martha Mendoza, *AP Enterprise: Recent Tests Detect Pharmaceuticals in Drinking Water of 46 Million Americans*; Martha Mendoza, *Communities Prevent Pharmaceutical Contamination with Drug Takeback Programs*; Martha Mendoza, *Ill. Orders Water Testing in Reax to AP Series; Providers Elsewhere Assure Supplies are OK*; Martha Mendoza, *On Eve of Hearings, White House Documents Show Feds Failing to Take Action on Drugs in Water*; Martha Mendoza, *Scientists, Environmentalists, Utilities Agree: More Testing Needed on Drugs in Drinking Water*; Martha Mendoza, *Senators Rip EPA Over Lack of Knowledge on Drugs in Water*; Martha Mendoza, *Texas Town Releases Name of Drug Found in Water*; Mayor Cited Terrorism as Reason for Secrecy; Justin Pritchard, *PharmaWater – Bottled Water: Bottled Water Industry Faces Same Federal Standards for Pharmaceuticals as Tap Water*; Justin Pritchard, *PharmaWater – Treatments: Water Cleaning Technologies Present Challenges*; Carolyn Thompson, *EPA Urges Great Lakes Residents Not to Flush Old Meds*.

⁷ The alternatives analysis contained in Project 3 was not designed to determine whether human health and environmental hazards presented by PPCPs and their byproducts warrant specific regulatory activities. Instead, Project 3 was intended to evaluate alternative strategies that could be utilized should scientific research determine that PPCPs or their byproducts are hazardous to human health or the environment.

A.1. Methodology

Preparation of this report relied on both the outputs of Projects 1 and 2 and on the collective expertise of the authors. As noted above, the output of Project 1 (the *Micropollutants Clearinghouse*) contained an extended collection of materials relating to PPCPs in water supplies. The following section summarizes the current scientific research. Both this summary and Section IV regarding alternative strategies were prepared after the authors had reviewed a large number of articles and reports contained in the *Clearinghouse*.

To ensure comprehensiveness, and as a quality control measure, the authors also undertook an independent review of the literature. This review utilized a variety of online data retrieval systems. The results of this independent review were then compared to the contents of the *Clearinghouse*. Any items not already in the *Clearinghouse* were added following this review.⁸

Project 2 provided the information contained in the case study discussed below. This research, which focused on the presence of PPCPs in soil and groundwater in West Texas, was initiated by researchers at Texas Tech University, specifically Dr. Todd A. Anderson, Dr. Deborah L. Carr, Dr. Adcharee Karnjanapiboonwong, Dr. Jonathan D. Maul, Dr. Audra N. Morse, and Dr. John C. Zak.⁹ Meetings were held with one or more of these researchers during the course of this project. Copies of research presentations and drafts of final reports were provided to the authors. The cooperation and assistance of Dr. Anderson, Dr. Carr, Dr. Karnjanapiboonwong, Dr. Maul, Dr. Morse, and Dr. Zak are both acknowledged and very much appreciated.

The legal review contained in Section IV and the analysis of the strengths and weaknesses of a variety of statutory and regulatory alternatives contained in Section VI are based primarily on the expertise of the authors, both of whom have taught environmental, natural resources, and water law for many years. This expertise was supplemented by additional legal research regarding recent initiatives unique to the issue of PPCPs in water supplies.¹⁰

A.2. Organization of the Report

The following section provides a brief summary of current scientific research regarding sources of PPCPs in water supplies. Processes or mechanisms by which PPCPs get into water supplies are described. Both short- and long-term impacts on human and environmental health resulting from the presence of PPCPs in water supplies are reviewed.

Section III describes current legal mechanisms by which water supplies are protected, both directly and indirectly. The requirements of the Clean Water Act and the Safe Drinking Water Act are reviewed. The management of hazardous substances and wastes, as mandated by the Resource Conservation and Recovery Act, is reviewed as is the regulation of toxic substances under the Toxic Substances Control Act. Of particular relevance to the aquatic environment is the Endangered Species Act, which is also reviewed.

Potential alternative strategies leading to the minimization or elimination of PPCPs in water supplies are discussed in Section IV. This discussion, which addresses the reduction or elimination of anthropogenic sources of PPCPs, as well as the regulation and management of such sources, sets the stage for the aforementioned case study contained in Section V. As noted above, this case study is based on Project 2 results.

Strengths and weaknesses of the statutory, regulatory, and alternative strategies are discussed in Section VI. Conclusions are presented in Section VII. Section VIII contains the Project 3 bibliography.

B. Summary of the Scientific Research:

Concern over the presence of PPCPs in water supplies has increased significantly since 1965 when researchers at Harvard University first determined that effluent from wastewater treatment plants contained both natural and synthetic estrogens.¹¹ By the

⁸ The comprehensiveness of the research upon which the *Clearinghouse* was based is revealed by the fact that relatively few new references were added following the authors' independent review of the literature.

⁹ Dr. Anderson, Dr. Carr, Dr. Karnjanapiboonwong and Dr. Maul are with the Institute of Environmental and Human Health, Department of Environmental Toxicology. Dr. Morse is with the Department of Civil and Environmental Engineering. Dr. Zak is with the Department of Biological Sciences.

¹⁰ The authors would like to express their appreciation to Mr. Christopher R. Jackson, Class of 2011, Texas Tech University School of Law, and Ms. Elizabeth Miller, Class of 2011, Texas Wesleyan University School of Law, for their invaluable assistance in the preparation of this portion of the report.

¹¹ Benjamin D. Stanford et al., *Estrogenic Activity of US drinking waters: A relative exposure comparison*, 102 JOURNAL OF THE AMERICAN WATER WORKS ASSOCIATION 55, 55 (2010) (citing Elisabeth Stumm-Zollinger & Gordon M. Fair, *Biodegradation of Steroid Hormones*, 37 JOURNAL OF THE WATER POLLUTION CONTROL FEDERATION 1506 (1965)).

1970s, the subject was being studied in both the United States¹² and in Europe.¹³

However, as noted by Stanford, *et al.*, after these initial studies “only sparse attention was paid to hormones and pharmaceuticals in the environment until reproductive effects in fish were shown to be directly influenced by estrogens in wastewater outfalls.”¹⁴ By the early 1990s, researchers in Germany and Switzerland had identified multiple PPCPs in both wastewater and surface waters

into which wastewater had been discharged.¹⁵ In large measure, the growing concern over the presence of PPCPs in water supplies has been based on an increasing number of occurrence studies that have identified specific PPCPs in drinking water.¹⁶ While it is beyond the scope of the present study to review each of these studies, certain studies should be noted.

¹² *Id.* at 55 (citing A.W. Garrison et al., *GC/MS Analysis of Organic Compounds in Domestic Wastewaters*, in FIRST CHEMICAL CONGRESS OF THE NORTH AMERICAN CONTINENT 517 (1975)).

¹³ Lisa J. Schulman et al., *A Human Health Risk Assessment of Pharmaceuticals in the Aquatic Environment*, 8 HUMAN & ECOLOGICAL RISK ASSESSMENT 657, 658 (2002).

¹⁴ Stanford et al., *supra* note 11, at 55-56 (citing Shane A. Snyder et al., *Identification and Quantification of Estrogen Receptor Agonists in Wastewater Effluents*, 35 ENVIRONMENTAL SCIENCE & TECHNOLOGY 3620 (2001); C. Desbrow et al., *Identification of Estrogenic Chemicals in STW Effluent. 1. Chemical Fractionation and in Vitro Biological Screening*, 32 ENVIRONMENTAL SCIENCE & TECHNOLOGY 1549 (1998)).

¹⁵ David L. Sedlak, & Karen E. Pinkston, *Factors Affecting the Concentrations of Pharmaceuticals Released to the Aquatic Environment*, 120 WATER RESOURCES UPDATE 56 (2001) (citing H.J. Stan et al., *Occurrence of Clofibric Acid in the Aquatic System – Is the Use in Human Medical Care the Source of the Contamination of Surface, Ground, and Drinking Water?* 83 VOM WASSER 57 (1994); R. Hirsch et al., *Determination of Betablockers and β -Sympathomimetics in the Aquatic Environment*, 87 VOM WASSER 263 (1996); H. Stan & T. Heberer, *Occurrence of Polar Organic Contaminants in Berlin Drinking Water*, 86 VOM WASSER 19 (1996); Marcus Stumpf et al., *Polar Drug Residues in Sewage and Natural Waters in the State of Rio de Janeiro, Brazil*, 225 THE SCIENCE OF THE TOTAL ENVIRONMENT 135 (1999); Hans-Rudolf Buser et al., *Occurrence of the Pharmaceutical Drug Clofibric Acid and the Herbicide Mecoprop in Various Swiss Lakes and in the North Sea*, 32 ENVIRONMENTAL SCIENCE & TECHNOLOGY 188 (1998); Hans-Rudolf Buser et al., *Occurrence and Fate of the Pharmaceutical Drug Diclofenac in Surface Waters: Rapid Photodegradation in a Lake*, 32 ENVIRONMENTAL SCIENCE & TECHNOLOGY 3449 (1998); Andreas Hartmann et al., *Identification of fluoroquinolone antibiotics as the main source of umuC genotoxicity in native hospital wastewater*, 17 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 377 (1998); Thomas A. Ternes, *Occurrence of Drugs in German Sewage Treatment Plants and Rivers*, 32 WATER RESEARCH 3245 (1998); Hans-Rudolf Buser et al., *Occurrence and Environmental Behavior of the Chiral Pharmaceutical Drug Ibuprofen In Surface Waters and in Wastewater*, 33 ENVIRONMENTAL SCIENCE & TECHNOLOGY 2529 (1999); C. Hartig, *Detection and Identification of Sulphonamide Drugs in Municipal Waste Water by Liquid Chromatography Coupled with Electrospray Ionisation Tandem Mass Spectrometry*, 854 JOURNAL OF CHROMATOGRAPHY A 163 (1999); Roman Hirsch, *Occurrence of Antibiotics in the Aquatic Environment*, 225 THE SCIENCE OF THE TOTAL ENVIRONMENT 109 (1999); Thomas A. Ternes & Roman Hirsch, *Occurrence and Behavior of X-ray Contrast Media in Sewage Facilities and the Aquatic Environment*, 34 ENVIRONMENTAL SCIENCE & TECHNOLOGY 2741 (2000)). Schulman, *et al.*, have noted that these studies “identified and measured a variety of human pharmaceuticals including hormones, lipid regulators, pain killers, antibiotics, anticancer drugs, anti-epileptic drugs, and blood pressure drugs at a range of concentrations, most below 1 μ /l.” Schulman et al., *supra* note 13, at 658.

¹⁶ However, as noted by the American Water Works Association Research Foundation (AwwaRF), “[i]f water utilities choose to (or are compelled to) implement additional treatment measures for these compounds based *solely* on occurrence data, without regard to toxicological significance, there is a risk of spending tremendous amounts of public funds for very little public health benefit.” Djanette Khiari, *Endocrine Disruptors, Pharmaceuticals, and Personal Care Products in Drinking Water: An Overview of AwwaRF Research to Date*, 17 DRINKING WATER RESEARCH 1, 6 (2007) (emphasis added). The AwwaRF has also noted:

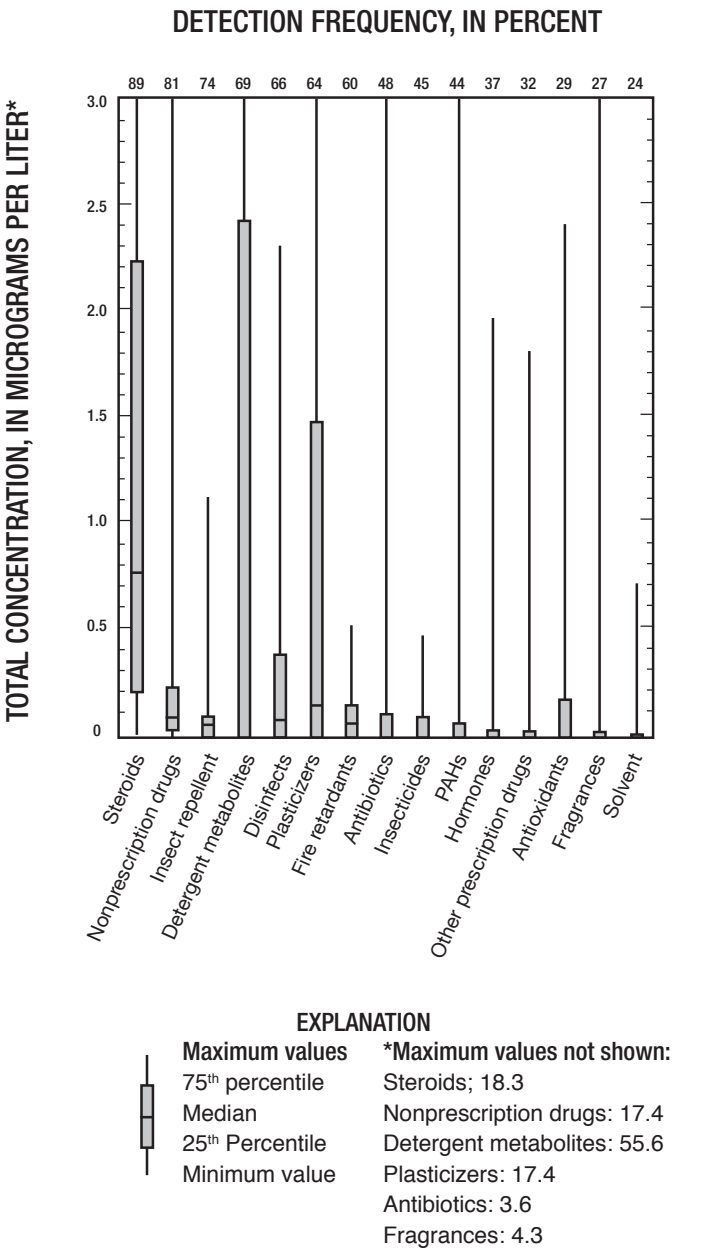
If presence/absence becomes our litmus test for risk and subsequent actions, treatment technology will be increasingly, and perhaps unnecessarily, costly and energy intensive. This is an especially important consideration due to the energy cost and greenhouse gas emissions of advanced treatment.

American Water Works Association Research Foundation, *Toxicological Relevance of EDCs and Pharmaceuticals in Drinking Water*, at xix (2008).

In 1999-2000, the U.S. Geological Survey sampled surface and groundwater throughout the United States.¹⁷ The study focused on the presence in U.S. water supplies of 95 organic wastewater contaminants including “antibiotics, other prescription drugs, nonprescription drugs, steroids, reproductive hormones, personal care products, products of oil use and combustion, and other extensively used chemicals.”¹⁸ At least one of the 95 organic wastewater contaminants was found in 80% of stream samples and in 93% of groundwater samples. As noted in the study, the environmental presence of these compounds raises concerns regarding potential consequences, including “abnormal physiological processes and reproductive impairment, increased incidences of cancer, the development of antibiotic-resistant bacteria, and the potential increased toxicity of chemical mixtures.”¹⁹ The results of the study are summarized below and depicted in Figure 1.

The most frequently detected chemicals (found in more than half of the streams) were coprostanol (fecal steroid), cholesterol (plant and animal steroid), N-Ndiethyltoluamide (insect repellent), caffeine (stimulant), triclosan (antimicrobial disinfectant), tri (2-chloroethyl) phosphate (fire retardant), and 4-nonylphenol (nonionic detergent metabolite). Steroids, nonprescription drugs, and insect repellent were the chemical groups most frequently detected. Detergent metabolites, steroids, and plasticizers generally were measured at the highest concentrations.²⁰

Figure 1: Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams²¹



¹⁷ Dana W. Kolpin et al., *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance*, 35 ENVIRONMENTAL SCIENCE & TECHNOLOGY 1202, (2002). The results of this study are summarized in Kimberlee K. Barnes et al., *Water-Quality Data for Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999- 2000*, U.S. Geological Survey, U.S. Dep’t of the Interior, No. Open-File Report 02-94 (2002), *available at* <http://toxics.usgs.gov/pubs/OFR-02-94/>.

¹⁸ Kolpin et al., *supra* note 17, at 1203.

¹⁹ *Id.* at 1202 (citations omitted).

²⁰ Herbert T. Buxton & Dana W. Kolpin, *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams*, United States Geological Society, Dep’t of the Interior, FS-027-02, at 2 (2002), *available at* <http://toxics.usgs.gov/pubs/FS-027-02/>.

²¹ *Id.*

In 2001, Sedlak and Pinkston identified multiple prescription drugs in wastewater.²² They estimated concentrations of such drugs in wastewater, concluding that the concentrations ranged from “less than 1 ng/L to approximately 133,000 ng/L.”²³ They went on to note:

The estimated concentrations are distributed over a wide range with the majority of compounds estimated to be present at concentrations between 100 and 1,000 ng/L. In general, the compounds expected to be present at the highest concentrations consisted of analgesics (e.g., acetaminophen, ibuprofen) and antibiotics (e.g., amoxicillin, cephalexin). Because some of the analgesics ... also are available as over-the-counter products, their concentrations in wastewater could be considerably higher. Compounds estimated to be present at the lowest concentrations tended to be potent drugs such as hormones (e.g., medroxyprogesterone, equilin).²⁴

Of particular concern is the presence of antibiotics in water

supplies “because antibiotic contaminants could perturb microbial ecology, increase the proliferation of antibiotic-resistant pathogens, and could pose threats to human health.”²⁵ Masters summarized this concern:

One of the dominating concerns is the creation of “Superbugs.” New strains of bacteria which are resistant to antibiotics are common near major cities and in rural areas and have been found in all 15 rivers from one study, including the Mississippi, the Ohio, and the Colorado. As bacteria is exposed to antibiotics they begin to adapt in order to survive, not unlike some of the drug resistant staph infections which have developed in hospitals. This is a concern, but like so many of today’s environmental issues, more research is needed.²⁶

Also, in 2001, Huang, *et al.*, noted the presence in water supplies of antibiotics used in both human therapy²⁷ and also in animal husbandry, specifically beef, swine, and poultry production.²⁸

²² Sedlak & Pinkston, *supra* note 15.

²³ *Id.* at 57.

²⁴ *Id.* The pharmaceuticals that were identified suggest that a “larger suite of pharmaceuticals” may be present in water supplies. *Id.*

²⁵ Ching-Hua Huang et al., *Assessment of Potential Antibiotic Contaminants in Water and Preliminary Occurrence Analysis*, 120 WATER RESOURCES UPDATE 30, 31 (2001), (citing Christian G. Daughton & Thomas A. Ternes, *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?* 107 ENVIRONMENTAL HEALTH PERSPECTIVES 1 (1999)). Accord Elizabeth A. Frick et al., *Presence of Pharmaceuticals in Wastewater Effluent and Drinking Water, Metropolitan Atlanta, Georgia*, July-September 1999, in PROCEEDINGS OF THE WAER RESOURCES CONFERENCE (Kathryn J. Hatcher ed.) (2001); Kelly A. Reynolds, *Pharmaceuticals in Drinking Water Supplies*, 45 WATER CONDITIONING AND PURIFICATION (2003), available at <http://www.wcponline.com/column.cfm?T=T&ID=2199> [hereinafter Reynolds, *Pharmaceuticals in Drinking Water Supplies*].

²⁶ Masters, *supra* note 6, at 1. Furthermore, “higher levels of antibiotic resistant bacterial strains [have been detected] downstream from a swine-feed facility, compared with upstream levels.” Rapid Public Health Policy Response Project, School of Public Health and Health Services, The George Washington University, PHARMACEUTICALS ARE IN THE DRINKING WATER: WHAT DOES IT MEAN? 4 (2008) (citing Amy R. Sapkota et al., *Antibiotic-Resistant Enterococci and Fecal Indicators in Surface Water and Groundwater Impacted by a Concentrated Swine Feeding Operation*, 115 ENVIRONMENTAL HEALTH PERSPECTIVES 1040 (2007)). “Evidence suggests that exposure to subtherapeutic doses of antibiotics has resulted in a detectable increase in antibiotic resistance in some bacteria.” Chad A. Kinney et al., *Presence and Distribution of Wastewater-Derived Pharmaceuticals in Soil Irrigated with Reclaimed Water*, 25 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 317, 323 (2006) (citing Rosamund J. Williams, & David L. Heymann, *Containment of Antibiotic Resistance*, 279 Science 1153 (1998); Wolfgang Witte, *Medical Consequences of Antibiotic Use in Agriculture*, 279 Science 996 (1998)). Accord Ken Carlson et al., *Antibiotics in the Cache la Poudre River*, AGRONOMY NEWS, Dec. 2004, at 4.

²⁷ “Antibiotics that are likely to be present in discharged municipal wastewater are primarily antibiotics used in human therapy.” Huang et al., *supra* note 25, at 32.

²⁸ As discussed in greater detail in Section VI, one of the challenges facing the use of statutory and regulatory mechanisms to address PPCPs in water supplies is the fact that both the presence of PPCPs and their concentrations vary substantially. With regard to the use of antibiotics in animal husbandry, this variability was noted by Huang, *et al.*:

[C]onsiderable differences in antibiotic usage exist among different food animal species (beef vs. swine vs. poultry). Therefore, the types of antibiotic compounds that are likely to be found in surface water will strongly depend upon the types of livestock operations within the watershed.

By 2002, it had been determined that “the amount of pharmaceuticals and personal care products (PPCPs) released into the environment each year is tantamount to the amount of

pesticides used each year.”²⁹ The principal emerging PPCPs and their uses were summarized by Ellis:³⁰

Table 1: Principal Emerging PPCP Compounds and Their Uses

Compound group/class	Compound
Pharmaceuticals	
Veterinary & human antibiotics	Trimethoprim, erythromycin, lincomycin, sulfamethoxazole, chloramphenicol, amoxycillin
Analgesics & anti-inflammatory drugs	Ibuprofen, diclofenac, fenoprofen, acetaminophen, naproxen, acetylsalicylic acid, fluoxetine, ketoprofen, indometacin, paracetamol
Psychiatric drugs	Diazepam, carbamazepine, primidone, salbutamol
Lipid regulators	Clofibrate, bezafibrate, fenofibrate acid, etofibrate, gemfibrozil
β- Blockers	Metoprolol, propranolol, timolol, sotalol, atenolol
X-ray contrasts	Iopromide, iopamidol, diatrizoate
Steroids & hormones	Estradiol, estrone, estriol, diethylstilbestrol (DES)
Personal care products	
Fragrances	Nitro, polycyclic and macrocyclic musks; phthalates
Sun-screen agents	Benzophenone, methylbenzylidene camphor
Insect repellents	<i>N,N</i> - diethyltoluamide
Antiseptics	Triclosan, chlorophene

It is quite probable that the specific PPCPs identified in these occurrence studies have been in drinking water supplies for years.³¹ PPCPs, which are manufactured in large quantities, have chemical and physical properties that make it likely for them to end up in

hydrologic systems.³² Furthermore, certain PPCPs (*e.g.*, antibiotics and estrogens) may “persist in the environment either due to their inability to biodegrade naturally or to their constant use keeping them ever present.”³³

²⁹ Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 25.

³⁰ J.B. Ellis, *Pharmaceutical and Personal Care Products (PPCPs) in Urban Receiving Waters*, 144 *Environmental Pollution* 184, 185 (2006).

³¹ “As long as humans use prescription medicines and over-the-counter drugs, we will find trace amounts in wastewater, surface water, groundwater and drinking water.” Global Water Research Coalition, GWRC SCIENCE BRIEF: OCCURRENCE AND POTENTIAL FOR HUMAN HEALTH IMPACTS OF PHARMACEUTICALS IN THE WATER SYSTEM 1 (2009). *Accord* Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 25 (“it’s reasonable to assume that as long as pharmaceuticals have been in use, they, and their metabolites, have contributed to the overall environmental contamination load”).

³² Frick et al., *supra* note 25, at 282.

³³ Kelly A. Reynolds, *Concern of Pharmaceuticals in Drinking Water*, 50 WATER CONDITIONING & PURIFICATION (2008), *available at*

The increased detection of PPCPs may be the result of dramatically improved testing equipment and procedures rather than the result of any recent introduction of PPCPs into drinking water supplies.³⁴ Such new testing equipment and procedures now allow for the detection of PPCPs at the nanogram,³⁵ or even picogram,³⁶ level. Until fairly recently, detection levels were at the microgram level.³⁷ Furthermore, as noted by Schulman, *et al.*, “detection limits are likely to decrease in the future, as more sensitive analytical detection techniques become available.”³⁸ In essence, while the detection of PPCPs has increased in frequency as testing equipment and procedures have improved, the actual presence of PPCPs may not have changed significantly.³⁹

Most of the occurrence studies that have detected PPCPs found

them to occur at very low levels, frequently at parts per trillion (picogram) or parts per billion (nanogram) levels.

B.1. Pathways

There are any number of pathways by which humans can be exposed to PPCPs contained in water supplies. The most obvious means is the consumption of water containing PPCPs. Other types of water exposures (e.g., swimming, bathing, showering) may also provide an exposure pathway.

Other exposure pathways are more indirect. Schulman, *et al.*, note that certain PPCPs bioaccumulate in fish.⁴⁰ The exposure

http://www.wcponline.com/pdf/0804On_Tap.pdf [hereinafter Reynolds, *Concern of Pharmaceuticals in Drinking Water*]. In fact, the presence of PPCPs in water supplies has been suggested as a possible indicator of human fecal contamination of those water supplies. Susan T. Glassmeyer *et al.*, *Transport of Chemical and Microbial Compounds from Known Wastewater Discharges – Potential for Use as Indicators of Human Fecal Contamination*, 39 ENVIRONMENTAL SCIENCE & TECHNOLOGY 5157 (2005). Accord Y. Carrie Guo & Stuart Krasner, *Occurrence of Primidone, Carbamazepine, Caffeine, and Precursors for N-Nitrosodimethylamine in Drinking Water Sources Impacted by Wastewater*, 45 JOURNAL OF THE AMERICAN WATER RESOURCES ASSOCIATION, 58, (2009).

³⁴ “[A]s analytical techniques grew more sensitive over the years, many more pharmaceuticals have been detected in ambient water, wastewater, and drinking water.” ToxServices LLC, APPROACHES TO SCREENING FOR RISK FROM PHARMACEUTICALS IN DRINKING WATER AND PRIORITIZATION FOR FURTHER EVALUATION 1 (2008). Accord American Water Works Association Research Foundation, *supra* note 16, at xxii (“The reality is that nearly any chemical known to man could be detected in water using the most modern and sensitive of analytical instrumentation”). See also Helen C. Poynton, & Chris D. Vulpe, *Ecotoxicogenomics: Emerging Technologies for Emerging Contaminants*, 45 JOURNAL OF THE AMERICAN WATER RESOURCES ASSOCIATION 83 (2009) (advances in analytical techniques).

³⁵ A nanogram (ng) is one billionth of a gram (1×10^{-9}). The detection level of such tests is expressed as parts per billion (ppb). One ppb is roughly equivalent to “one drop of water in an Olympic-sized swimming pool, or a single blade of grass in a football field[.]” Rapid Public Health Policy Response Project, *supra* note 26, at 1.

³⁶ A picogram (pg) is one trillionth of a gram (1×10^{-12}). The detection level of such tests is expressed as parts per trillion (ppt). One ppt is roughly equivalent to one “drop of water in one thousand pools” or one “blade of grass in one thousand football fields”. Rapid Public Health Policy Response Project, *supra* note 26, at 1.

³⁷ A microgram (μg) is one millionth of a gram (1×10^{-6}). The detection level of such tests is expressed as parts per million (ppm).

³⁸ Schulman *et al.*, *supra* note 13, at 669. Accord American Water Works Association Research Foundation, *supra* note 16, at xix (“considering the continued advancements in analytical technologies, today’s non-detectable contaminants will be tomorrow’s emerging contaminants”).

³⁹ As noted by the Global Water Research Coalition:

We hear more reports about the presence of pharmaceuticals in water mainly because of improvements of the analytical methods of detection. What was not detectable in the past has become detectable today, even at very low concentrations.

Global Water Research Coalition, *supra* note 31, at 1.

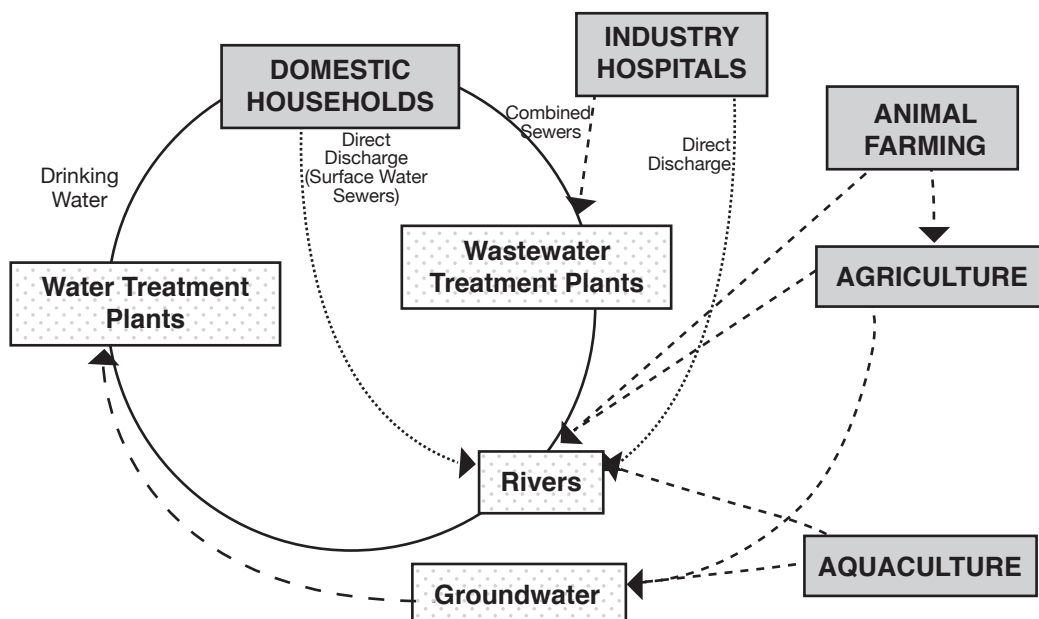
⁴⁰ Schulman *et al.*, *supra* note 13, at 659.

pathway, therefore, would be the human consumption of fish or shellfish containing PPCPs.⁴¹

In reality, there is seldom a single exposure pathway. The National Research Council recognized this, noting the existence

of both “major and minor exposure pathways” and concluding that future risk assessments for PPCPs aggregate exposure assessments across multiple pathways.⁴² This recognition was depicted graphically by Ellis:⁴³

Figure 2: Sources and Pathways of PPCPs in the Urban Water Cycle



⁴¹ Virginia L. Cunningham, Stephen P. Binks & Michael J. Olson, *Human Health Risk Assessment from the Presence of Human Pharmaceuticals in the Aquatic Environment*, 53 REGULATORY TOXICOLOGY & PHARMACOLOGY 39, 43 (2009).; Ellis, *supra* note 30, at 185 (citing Betty Bridges, *Franchise: emerging health and environmental concerns*, 17 FLAVOUR & FRAGRANCE JOURNAL 361 (2002)); Ake Wennmalm & Bo Gunnarsson, *Public Health Care Management of Water Pollution with Pharmaceuticals: Environmental Classification and Analysis of Pharmaceutical Residues in Sewage Water*, 39 DRUG INFORMATION JOURNAL 291, 296 (2005).

⁴² Committee on Toxicants and Pathogens in Biosolids Applied to Land, Board on Environmental Studies and Toxicology, Division on Earth and Life Studies, National Research Council, BIOSOLIDS APPLIED TO LAND: ADVANCING STANDARDS AND PRACTICES 13 (National Academies Press 2002). Accord Kolpin et al., *supra* note 17, at 1202 (“there are a wide variety of transport pathways for many different chemicals to energy and persist in environmental waters”).

⁴³ Ellis, *supra* note 30, at 186. It should not be assumed that these are the only pathways by which exposure to PPCPs occurs. With regard to estrogenicity, for example, the AwwaRF has noted:

[V]egetable juice had observed EEQ [estradiol equivalent] values from 1.9 to 3.3 ng/L, while coffee ranged from 11 to 17 ng/L. Various brands of beer exhibited a broad range of results with EEQ values ranging from 0.8 to 140 ng/L. The highest estrogenicity was observed in soy-based food and beverage items such as soy sauce (28 – 510 ng/L), soy baby formula (1,500 – 1,900 ng/L) and soy milk (1,900 – 4,200 ng/L). ***

Considering that food items are not labeled, or often even tested, for emerging contaminants, it is difficult to argue that the choice of exposure from food is any less involuntary than would be exposure from tap water. ... [F]or the pharmaceuticals and potential EDCs detected in water, exposure to people through water is expected to be small compared to exposures to potentially hazardous

B.2. Effects of PPCPs in Water

Though research is ongoing, it does not appear that short-term exposure to specific PPCPs at the low levels noted above results in adverse human health impacts.⁴⁴ Unfortunately, the question of adverse human or environmental health impacts resulting from PPCPs in water is not as simple as the foregoing conclusion might suggest.

B.2.1. Long-term Low-dose Exposures

As noted above, short-term exposure to low levels of specific PPCPs does not appear to result in adverse human health impacts. However, as Kolpin, *et al.*, have noted:

For many [organic wastewater contaminants], acute effects to aquatic biota appear limited because of the low concentrations generally occurring in the environment. More subtle, chronic effects from low-level environmental exposure to select [organic wastewater contaminants] appear to be of much greater concern. Such chronic effects have

been documented in the literature. In addition, because antibiotics are specifically designed to reduce bacterial populations in animals, even low-level concentrations in the environment could increase the rate at which pathogenic bacteria develop resistance to these compounds.⁴⁵

Furthermore, Reynolds has observed that “[t]rends of increased testicular cancer, reproductive abnormalities, breast cancer, early puberty and decreased sperm count have all been suggested as problems possibly related to low-level exposure to chemicals (pharmaceuticals and EDCs) in the environment.”⁴⁶ Additional research is needed regarding the effects of long-term, low-dose exposure to PPCPs.⁴⁷

B.2.2. Cumulative or Synergistic Effects

Human and environmental exposures to PPCPs are never to a specific PPCP. Such exposures are always to combinations of

compounds through prescription and nonprescription medications, food and beverages, occupational exposures, and residential activities (*e.g.*, cleaning products, personal care products, hobby chemicals, pesticides). Moreover, the concentrations of some potential EDCs (*e.g.*, plasticizers) are orders of magnitude greater in food products than in drinking waters[.]

American Water Works Association Research Foundation, *supra* note 16, at xxii-xxiii. As Stanford, *et al.* have concluded, “the exposure to natural estrogens and other suspected EDCs from drinking water pales in comparison to exposure through other dietary routes. ... [Furthermore,] compared with air exposure, water consumption by humans may represent only a small fraction of pharmaceutical, personal care products, and EDC exposure.” Stanford *et al.*, *supra* note 11, at 61, 63.

⁴⁴ See, *e.g.*, Schulman *et al.*, *supra* note 13, at 669:

The main finding of this study was that detected levels of the compounds of interest (parent compounds, acetylsalicylic acid, clofibrate, cyclophosphamide, and indomethacin, as well as the metabolites, salicylic acid and clofibric acid) in surface waters and drinking water, do not pose a risk to human health. The concentrations of each of these pharmaceuticals found in various environmental media to date, fall well below the provisional safe water quality limits derived, according to the [U.S. Environmental Protection Agency’s *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (2000)]. Thus, no adverse health effects for humans are anticipated from the levels measured.

Accord Global Water Research Coalition, *supra* note 31, at 2 (“to date no definitive link between pharmaceutical exposure in drinking water and human health risk has been reported nor established”); Rapid Public Health Policy Response Project, *supra* note 26, at 1 (“At current levels, pharmaceutical residues are unlikely to pose an immediate risk to human health, but the long-term consequences of individual chemicals, and combinations of chemicals, are unknown, especially as concentrations rise.”).

⁴⁵ Kolpin *et al.*, *supra* note 17, at 1208 (citations omitted).

⁴⁶ Reynolds, *Concern of Pharmaceuticals in Drinking Water*, *supra* note 33, at 2.

⁴⁷ “Although a wealth of toxicological information may be available for pharmaceuticals, the effects of unintended chronic exposure to subtherapeutic doses that could occur via consumption of drinking water are often not known.” Erin M. Snyder *et al.*, *Pharmaceuticals and EDCs in the US Water Industry – An Update*, 97 JOURNAL OF THE AMERICAN WATER WORKS ASSOCIATION 32, 33 (2005). *Accord* Ellis, *supra* note 30, at 186.

PPCPs, the impacts of which are relatively unknown.⁴⁸

Combinations of PPCPs may have cumulative or synergistic effects that go beyond the effects of any single PPCP. This led Kolpin, *et al.*, to conclude:

[A]dditional research on the toxicity of the target compounds should include not only the individual [organic wastewater contaminants] but also mixtures of these compounds. The prevalence of multiple compounds in water resources has been previously documented for other contaminants. In addition, research has shown that select chemical combinations can exhibit additive or synergistic toxic effects, with even compounds of different modes of action having interactive toxicological effects.⁴⁹

For example, in a study of the role of steroidal estrogens in determining sex, the researchers noted that “strong natural estrogens at low doses may synergize with low doses of weak natural and man-made estrogens.”⁵⁰ This combination of low doses of estrogen “may act synergistically to produce a strong estrogenic response.”⁵¹

Other research suggests that cumulative or synergistic effects may not be a threat to human health:

The issue of mixtures, that is the simultaneous presence of multiple pharmaceuticals, is an ever present question for trace residual compounds of all types in drinking water supplies. The guidelines for “provisionally safe” or “acceptable intake” levels are calculated separately for individual compounds. However, the “worst case scenario” approach used in screening risk assessment includes large uncertainty factors and safety factors and is considered by regulatory and health authorities (e.g., the World Health Organization in their *Drinking Water Quality Guidelines*) to be sufficient to account for possible interactions among compounds a person might be exposed to simultaneously.⁵²

Nevertheless, in addition to cumulative or synergistic effects, recent research suggests that PPCPs may become more persistent if they are combined. As Monteiro and Boxall have observed:

As pharmaceuticals will never be in the environment as single compounds, a consideration of the impacts of mixtures of different pharmaceuticals and pharmaceuticals and other compounds needs to be assessed. Our preliminary data demonstrate that degradation may be significantly slower in mixtures[.]⁵³

⁴⁸ “In field situations, organisms are exposed to not just one compound but a mélange of contaminants, which can interact within the environment and individual organisms.” Poynton & Vulpe, *supra* note 34, at 91. “[I]t is not clear what toxicological implications chronic exposure to *suites* of trace contaminants may pose.” Mark J. Benotti et al., *Pharmaceuticals and Endocrine Disrupting Compounds in U.S. Drinking Water*, 43 ENVIRONMENTAL SCIENCE & TECHNOLOGY 597 (2009) (emphasis added) (citing Oliver A. Jones et al., *Pharmaceuticals: a Threat to Drinking Water*, 23 TRENDS IN BIOTECHNOLOGY 163 (2005); Shane A. Snyder et al., *Pharmaceuticals, Personal Care Products, and Endocrine Disruptors in Water: Implications for the Water Industry*, 20 ENVIRONMENTAL ENGINEERING SCIENCE 449 (2003)). “A limited body of research ... suggests an additive effect when a mixture of pharmaceuticals is present.” Rapid Public Health Policy Response Project, *supra* note 26, at 4 (citing Francesco Pomati et al., *Effects and Interactions in an Environmentally Relevant Mixture of Pharmaceuticals*, 102 TOXICOLOGICAL SCIENCES 129 (2008)).

⁴⁹ Kolpin et al., *supra* note 17, at 1210. In a study of the effect on aquatic and terrestrial species of exposure to triclosan and triclocarban, Chalew and Halden concluded that “it appears prudent to consider the possibility of additive, antagonistic or synergistic effects from exposure to mixtures of the two.” Talia E. Chalew & Rolf U. Halden, *Environmental Exposure of Aquatic and Terrestrial Biota to Triclosan and Triclocarban*, 45 JOURNAL OF THE AMERICAN RESOURCES ASSOCIATION 4, 11 (2009). It has also been noted that “[m]ixtures of pharmaceuticals, which commonly occur in surface waters where discharges from municipal wastewater treatment plants flow, may have cumulative effects on organisms.” TDC Environmental, HOUSEHOLD PHARMACEUTICAL WASTE: REGULATORY AND MANAGEMENT ISSUES 2 (2004) (citing S.M. Richards et al., *Effects of pharmaceutical mixtures in aquatic microcosms*, 23 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 1035 (2004)). See also Jessica G. Davis, *Antibiotics in the Environment*, 24(3) AGRONOMY NEWS 1, 2 (2004) (“Degradation products and interactions among compounds have not been adequately evaluated and could result in synergistic toxic effects”).

⁵⁰ Judith M. Bergeron et al., *Developmental Synergism of Steroidal Estrogens in Sex Determination*, 107 ENVIRONMENTAL HEALTH PERSPECTIVES 93, 96 (1999).

⁵¹ *Id.*

⁵² Global Water Research Coalition, *supra* note 31, at 2.

⁵³ Sarah C. Monteiro, & Alistair A.B. Boxall, *Pharmaceuticals and Personal Care Products in the Environment: Factors Affecting the Degradation of Pharmaceuticals in Agricultural Soils*, 28 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 2546, 2553 (2009).

For example, while the degradation of individual PPCPs identified in Project 2 was relatively fast (half-lives of less than 30 days), the presence of two PPCPs in a simple mixture increased the persistence of both PPCPs.⁵⁴

B.2.3. Susceptible Groups

Specific population segments or groups may be unusually susceptible to adverse effects from exposure to PPCPs. Children, for example, are thought to be particularly susceptible as are pregnant women.⁵⁵ As Collier has noted:

[L]ong-term exposure to such chemicals, for example in children, could potentially cause long-term changes affecting organ systems and/or structural function. In addition, exposure to pharmaceuticals during the fetal period when many of the growth and development patterns for later life are laid down, may induce subtle changes that take years to manifest, but eventually have measurable physiological, morphological, or cognitive effects.⁵⁶

Other groups such as the elderly, the infirm, or the immunocompromised may also be unusually susceptible.⁵⁷ Research regarding the impacts of exposure to PPCPs on these and other population segments or groups is ongoing.

B.2.4. Environmental Health Impacts

Human beings are not exposed continuously to water supplies containing PPCPs. The same cannot be said for aquatic species, which by their very nature are continuously exposed to water supplies containing PPCPs.⁵⁸ Such species “are exposed continually, over many generations, to the higher concentrations of pharmaceuticals that linger in surface water.”⁵⁹ This exposure may result in “endocrine disruptions, reproductive effects and renal deterioration in fish, among other damage.”⁶⁰

For example, with regard to both fish and other aquatic vertebrates, the low-level presence of pharmaceutical estrogens⁶¹ leads to “a suite of adverse effects” including:

- Feminization of males⁶²

⁵⁴ These results are discussed in greater detail in Section V.

⁵⁵ Abby C. Collier, *Pharmaceutical Contaminants in Potable Water: Potential Concerns for Pregnant Women and Children*, 4 ECOHEALTH 164, 170 (2007). Collier makes reference to “the special populations of pregnant and pediatric individuals, where there is elevated risk from exposure to several drugs that are contraindicated and to which exposure should, ideally, be nil.” *Id.* See also, Cunningham, Binks, & Olson, *supra* note 41, at 40; Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 25.

⁵⁶ Collier, *supra* note 55, at 170.

⁵⁷ Cunningham, Binks, & Olson, *supra* note 41, at 40.

⁵⁸ “Exposure risks for aquatic organisms are much larger than those for humans[.]” Rapid Public Health Policy Response Project, *supra* note 26, at 4 (citing Environmental Protection Agency, PHARMACEUTICALS AND PERSONAL CARE PRODUCTS (PPCPS)).

⁵⁹ *Id.* at 4 (citing Environmental Protection Agency, PHARMACEUTICALS AND PERSONAL CARE PRODUCTS (PPCPS)).

⁶⁰ *Id.* at 4 (citing Larry B. Barber et al., *Chemical Loading into Surface Water Along a Hydrological, Biogeochemical, and Land Use Gradient: A Holistic Watershed Approach*, 40 ENVIRONMENTAL SCIENCE & TECHNOLOGY 475 (2006); S.D. Richardson, *Water Analysis: Emerging Contaminants and Current Issues*, 79 ANALYTICAL CHEMISTRY 4295 (2007); R. Triebskorn, *Toxic Effects of the Non-Steroidal Anti-Inflammatory Drug Diclofenac Part II. Cytological Effects in Liver, Kidney, Gills and Intestine of Rainbow Trout (Oncorhynchus mykiss)*, 68 JOURNAL OF AQUATIC TOXICOLOGY 151 (2004)).

⁶¹ Specifically, estrone (E1), 17 β -estradiol (E2), estriol (E3) and the synthetic estrogen, 17 α ethinylestradiol.

⁶² Marlo K. Sellin et al., *Estrogenic Compounds Downstream from Three Small Cities in Eastern Nebraska: Occurrence and Biological Effect*, 45 JOURNAL OF THE AMERICAN WATER RESOURCES ASSOCIATION 14 (2009) (citing Gordon C. Balch et al., *Feminization of Female Leukophore-Free Strain of Japanese Medaka (Oryzias latipes) Exposed to 17 β -Estradiol*, 23 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 2763 (2004); F. Brion et al., *Impacts of 17 β -Estradiol, Including Environmentally Relevant Concentrations, on Reproduction After Exposure During Embryo-Larval-, Juvenile- and Adult-Life Stages in Zebrafish (Danio rerio)*, 68 AQUATIC TOXICOLOGY 193 (2004); G.H. Panter et al., *Adverse Reproductive Effects in Male Fathead Minnows (Pimephales promelas) Exposed to Environmentally Relevant Concentrations of the Natural Oestrogens, Oestradiol and Oestrone*, 42 AQUATIC TOXICOLOGY 243 (1998)).

- Impaired reproductive capacity⁶³
- Abnormal sexual development⁶⁴

These observations led Sellin, *et al.* to conclude that “the presence of estrogens in the aquatic environment, even at low concentrations, is likely to pose a significant threat to the health of aquatic organisms.”⁶⁵

Such threats are not limited to the presence of low-levels of pharmaceutical estrogens. Antidepressants, for example, may “trigger premature spawning in shellfish while drugs designed to treat heart ailments block the ability of fish to repair damaged fins.”⁶⁶

The effects of PPCPs in water resources may be felt throughout the food web. Chalew and Halden note that “[m]any of the investigated organisms are at the bottom of the food chain; therefore, impacts to their populations, due to either die-off from acute toxic exposures or failure to reproduce successfully as a result of chronic exposures, may lead to adverse consequences throughout the ecosystem and food chain.”⁶⁷ However, they also note that “such a scenario at present is entirely speculative, since studies appropriate to probe for this outcome have not yet been conducted.”⁶⁸

⁶³ Sellin et al., *supra* note 62, at 14-15 (citing Shoko Imai et al., *Effects of 17 β -Estradiol on the Reproduction of Java-Medaka (Oryzias Javanicus), a New Test Fish Species*, 51 MARINE POLLUTION BULLETIN 708 (2005); F. Brion et al., *Impacts of 17 β -Estradiol, Including Environmentally Relevant Concentrations, on Reproduction After Exposure During Embryo-Larval-, Juvenile- and Adult-Life Stages in Zebrafish (Danio rerio)*, 68 AQUATIC TOXICOLOGY 193 (2004); Tsutomu Shioda & Meiko Wakabayashi, *Effect of Certain Chemicals on the Reproduction of Medaka (Oryzias latipes)*, 40 CHEMOSPHERE 239 (2000); V.J. Kramer et al., *Reproductive Impairment and Induction of Alkaline-Labile Phosphate, a Biomarker of Estrogen Exposure, in Fathead Minnows (Pimephales Promelas) Exposed to Waterborne 17 β -Estradiol*, 40 AQUATIC TOXICOLOGY 335 (1998)). Accord Poynton & Vulpe, *supra* note 34 (citing Karen A. Kidd et al., *Collapse of a Fish Population After Exposure to a Synthetic Estrogen*, 104 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES OF AMERICA 8897 (2007) (17 ethynylestradiol has been shown “to cause sublethal effects in fathead minnow leading to population decline at very low concentrations”)); Heiko L. Schoenfuss et al., *Effects of Exposure to Low Levels of Water-Borne 17-Estradiol on Nest Holding Ability and Sperm Quality in Fathead Minnows*, 120 WATER RESOURCES UPDATE 49 (2001). While exposure to 17 β -estradiol did not result in long-term changes in sperm quality, the authors noted that 17-estradiol “is but one of many estrogenic compounds that have been found in [sewage treatment plant] effluent, and the overall estrogenic potency of the effluent could be much greater than simulated in this experiment.” *Id.* at 52. See also Schulman et al., *supra* note 13, at 676.

⁶⁴ Sellin et al., *supra* note 62, at 15 (citing Narisato Hirai et al., *Feminization of Japanese Medaka (Oryzias latipes) Exposed to 17 β -Estradiol: Formation of Testis-Ova and Sex-Transformation During Early-Ontogeny*, 77 AQUATIC TOXICOLOGY 78 (2006); Henrik Holbech et al., *Detection of Endocrine Disruptors: Evaluation of a Fish Sexual Development Test (FSDT)*, 144C COMPARATIVE BIOCHEMISTRY AND PHYSIOLOGY 57 (2006); W.R. Hartley et al., *Gonadal Development in Japanese Medaka (Oryzias latipes) Exposed to 17 β -Estradiol*, 46 Marine Environmental Research 145 (1998)).

⁶⁵ *Id.*

⁶⁶ Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 25.

⁶⁷ Chalew & Halden, *supra* note 49, at 10.

⁶⁸ *Id.* The need for “appropriate” studies has been noted frequently. For example, Poynton & Vulpe have observed:

For many emerging contaminants, their toxicity to aquatic organisms is largely unknown. Even pharmaceuticals, which undergo extensive testing in mammalian models, may exhibit different toxicity on aquatic species. In addition, many pharmaceuticals and EDCs are not responsive to traditional toxicity assays that measure lethality or reproduction over a single generation and are requiring regulatory agencies to rethink testing requirements. This could also be true for other emerging chemicals including PBDEs [polybrominated diphenyl ethers] and nanomaterials whose mechanism of action is not known.

Poynton & Vulpe, *supra* note 34, at 84 (citing Mark C. Crane et al., *Chronic Aquatic Environmental Risks From Exposure to Human Pharmaceuticals*, 367 SCIENCE OF THE TOTAL ENVIRONMENT 23 (2006); Leon E. Gray, Jr., *Tiered Screening and Testing Strategy for Xenoestrogens and Antiandrogens*, 102-103 TOXICOLOGY LETTERS 677 (1998); John P. Sumpter, & Andrew C. Johnson, *Lessons From Endocrine Disruption and Their Application to Other Issues Concerning Trace Organics in the Aquatic Environment*, 39 ENVIRONMENTAL SCIENCE & TECHNOLOGY 4321 (2005)).

The presence of antibiotics in water supplies may also reduce the growth of aquatic plants.⁶⁹ In essence, “since pharmaceuticals is one of the few chemical classes intended to be bioactive, they are potentially harmful to the aquatic flora and fauna.”⁷⁰

B.3. Sources of PPCPs in Water

An understanding of the sources of PPCPs in water is essential for two reasons. First, as discussed in greater detail in the following section, different statutory and regulatory requirements apply to different sources of PPCPs. Second, as discussed in greater detail in Section IV, potential alternative strategies leading to the minimization or elimination of PPCPs in water may be source-specific.

There are, of course, some naturally occurring sources of PPCPs. These sources appear as background amounts, not as major PPCP sources. The major sources of PPCPs are anthropogenic.⁷¹ Assuming the use of pharmaceuticals, personal care products, dietary supplements, and other consumer products, PPCPs are contained in human and animal feces and urine. They are also commonly contained in hospital or medical wastes and in the wastes from industrial and agricultural processes. Another common source of PPCPs is unwanted pharmaceuticals and personal care products that are disposed of inappropriately (*i.e.*, by being flushed down toilets).⁷² Pharmaceuticals used in the fruit production industry are yet another source of PPCPs,⁷³ as is leachate from landfills⁷⁴ and urban runoff.⁷⁵ PPCPs may also be rinsed from a person’s body during bathing.⁷⁶

⁶⁹ TDC Environmental, *supra* note 49, at 2 (citing Richard A. Brain et al., *Effects of 25 pharmaceutical compounds to Lemna gibba using a seven-day static-renewal test*, 23 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 371 (2004)).

⁷⁰ Wennmalm & Gunnarsson, *supra* note 41, at 291. *Accord* Ellis, *supra* note 30, at 188 (“The persistent, long-term chronic exposure of aquatic organisms to low-dose PPCP concentrations although individually at or below the [Probable No-Effects Concentration] level, may well lead to cumulative stress and toxicity which could be a catalyst for subtle endpoint ecological changes.”).

⁷¹ With regard to EDCs, for example, *see* Ed Means, Amlan Ghosh & Zaid Chowdhury, ENDOCRINE DISRUPTORS AND PHARMAEUTICALS STRATEGIC INITIATIVE EXPERT WORKSHOP REPORT (Awwa Research Foundation 2007), (“while some estrogenic compounds occur naturally, most of the detected estrogenic compounds are introduced from man-made sources”). *See also* Dore Hollander, *Environmental Effects on Reproductive Health: The Endocrine Disruption Hypothesis*, 29 FAMILY PLANNING PERSPECTIVES 82, 83 (2007):

Endocrine disrupters, some of which occur naturally (phytoestrogens) and some of which are man-made, are ubiquitous: They can be found in soil, water, air and food, as well as in commonly used industrial and household products. Phytoestrogens are present in grains, legumes, grasses, herbs, nuts and a variety of fruits and vegetables; some fungi also produce compounds that may interfere with hormonal function. Phytoestrogens are weaker than endogenous estrogen (*i.e.*, they do not bind as well to hormone receptors) and are quickly excreted or broken down into other compounds; they do not accumulate in body tissue.

⁷² Paul D. Anderson et al., *Screening Analysis of Human Pharmaceutical Compounds in U.S. Surface Waters*, 38 ENVIRONMENTAL SCIENCE & TECHNOLOGY 838 (2004). *Accord* Ellis, *supra* note 30, at 185.

⁷³ Thomas Heberer et al., *Occurrence and Fate of Pharmaceuticals During Bank Filtration – Preliminary Results From Investigations in Germany and the United States*, 120 WATER RESOURCES UPDATE 4, 5 (2001) [hereinafter Heberer et al., *Pharmaceuticals During Bank Filtration*].

⁷⁴ Benotti et al., *supra* note 48. *Accord* Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 25.

⁷⁵ Juliane B. Brown, William A. Battaglin & Robert E. Zuellig, *Lagrangian Sampling for Emerging Contaminants Through an Urban Stream Corridor in Colorado*, 45 JOURNAL OF THE AMERICAN WATER RESOURCES ASSOCIATION 68 (2009); Benotti et al., *supra* note 48.

⁷⁶ Snyder et al., *supra* note 47, at 32.

B.4. Processes or Mechanisms by Which PPCPs are Introduced Into Water Supplies

There are numerous processes or mechanisms by which PPCPs are introduced into water supplies.⁷⁷ With regard to the sources of PPCPs noted above, a substantial portion of human wastes are treated at wastewater treatment plants. Following wastewater treatment plant processing, treated water may be discharged into a receiving stream or lake.

Typically, residual sludge contained in the processing tanks of the wastewater treatment plant is removed and disposed of pursuant to the regulations discussed in Section III. Both

the treated water discharged into a receiving stream or lake⁷⁸ and the residual sludge⁷⁹ will contain varying levels of PPCPs. Consequently, it is not surprising that a number of studies have noted the increased presence of PPCPs in receiving waters downstream of wastewater treatment plants.⁸⁰ As discussed in greater detail in Section V, treated wastewater used for agricultural and landscape irrigation may also contain PPCPs.⁸¹

In fact, only a portion of the wastes collected by sanitary sewers may actually be treated at wastewater treatment plants. Depending on the condition of the sewer system, a significant portion of collected wastes may be lost through cracks or breaks in sewer lines. In areas where storm drains and sanitary sewers

⁷⁷ “Pharmaceutical compounds are introduced into the environment through a number of different pathways, including excretion of the parent compound, active ingredients, water soluble conjugates, or metabolites via urine and feces after therapeutic home and hospital use, and through disposal of unused pharmaceuticals by patients or providers via landfills and sewers.” Schulman et al., *supra* note 13, at 658 (citing N.J. Ayscough et al., The Environment Agency Research and Development Dissemination Centre, REVIEW OF HUMAN PHARMAEUTICALS IN THE ENVIRONMENT 106 (2000)). *Accord* Janice M. Skadsen et al., THE OCCURRENCE AND FATE OF PHARMACEUTICALS, PERSONAL CARE PRODUCTS AND ENDOCRINE DISRUPTION COMPOUNDS IN A MUNICIPAL WATER USE CYCLE: CASE STUDY IN THE CITY OF ANN ARBOR 2 (2004), *available at* http://www.a2gov.org/government/publicservices/water_treatment/Documents/EndocrineDisruptors.pdf (“the potential exists for PPCPs to enter the environment from multiple routes, such as, wastewater treatment discharge, industrial discharge, runoff from confined animal feeding operations, and treated sludge applied to agricultural land...PPCPs may enter the treatment process in a reduced form (after passing through body) or by direct discharge of discarded PPCPs”) (citing Christian G. Daughton & Thomas A. Ternes, *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?* 107 ENVIRONMENTAL HEALTH PERSPECTIVES 1 (1999)).

⁷⁸ Treated wastewater frequently contains “antioxidants, detergents and detergent metabolites, disinfectants, fire retardants, fragrances, insect repellants, pharmaceuticals (prescription and nonprescription drugs), pesticides, plasticizers, polycyclic aromatic hydrocarbons, and steroidal compounds[.]” Brown, Battaglin, & Zuellig, *supra* note 75, at 69-70. Such wastewater “has been shown to contain low, yet biologically active, concentrations of estrogenic compounds.” Sellin et al., *supra* note 62, at 15 (citing Marta Carballa et al., *Behavior of Pharmaceuticals, Cosmetics and Hormones in a Sewage Treatment Plant*, 38 WATER RESEARCH 2918 (2004); Andrew C. Johnson & John P. Sumpter, *Removal of Endocrine-Disrupting Chemicals in Activated Sludge Treatment Works*, 35 ENVIRONMENTAL SCIENCE & TECHNOLOGY 4697 (2001); Chiara Baronti et al., *Monitoring Natural and Synthetic Estrogens at Activated Sludge Sewage Treatment Plants and in a Receiving River Water*, 34 ENVIRONMENTAL SCIENCE & TECHNOLOGY 5059 (2000)). *See also* Chalew & Halden, *supra* note 49, at 7; Kinney et al., *supra* note 26, at 317 (citing Christian G. Daughton, & Thomas A. Ternes, *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?* 107 ENVIRONMENTAL HEALTH PERSPECTIVES 907 (1999)).

⁷⁹ “In biosolids destined for land application, a number of pharmaceuticals and personal care products have been detected.” Monteiro & Boxall, *supra* note 53, at 2546 (citing Chad A. Kinney et al., *Survey of Organic Wastewater Contaminants in Biosolids Destined for Land Application*, 40 ENVIRONMENTAL SCIENCE & TECHNOLOGY 7207 (2006); Chris D. Metcalfe, *Distribution of Acidic and Neutral Drugs in Surface Waters Near Sewage Treatment Plants in the Lower Great Lakes, Canada*, 22 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 2881 (2003)). *See also* M. Silvia Diaz-Cruz et al., *Environmental Behavior and Analysis of Veterinary and Human Drugs in Soils, Sediments, and Sludge*, 22 TRENDS IN ANALYTICAL CHEMISTRY 340 (2003).

⁸⁰ Sellin et al., *supra* note 62, at 18 (greatest quantities of estrogens found in surface water downstream of wastewater treatment plants). “[P]harmaceutical and PPCP residues have been detected in fish tissues downstream of wastewater treatment facilities leading to bioaccumulation in muscles and critical organs.” Poynton & Vulpe, *supra* note 34, at 84 (citing Bryan W. Brooks et al., *Determination of Select Antidepressants in Fish From an Effluent-Dominated Stream*, 24 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 464 (2005); J. Schwaiger et al., *Toxic Effects of the Non-steroidal Anti-inflammatory Drug Diclofenac. Part 1: Histopathological Alterations and Bioaccumulation in Rainbow Trout*, 68 AQUATIC TOXICOLOGY 141 (2004)). *Accord* Brown, Battaglin, & Zuellig, *supra* note 75.

⁸¹ Kinney et al., *supra* note 26. *Accord* Benotti et al., *supra* note 48.

are combined, significant rainfall events may produce quantities of wastes that exceed the capacity of the wastewater treatment plant.⁸² These “combined sewer overflows” (CSOs) are frequently discharged into surface waters with little or no treatment, resulting in “elevated concentrations of bacteria, nutrients, and OWCs [organic wastewater compounds] in receiving waters.”⁸³ As a result, untreated sewage “derived from leaky sewers and CSOs . . . may have a disproportionately large effect on concentrations of compounds that are well removed by wastewater treatment processes (such as caffeine and ibuprofen).”⁸⁴

If the surface water is diverted subsequently for use as water supply, a portion of the PPCPs contained in the raw water supply will end up in the drinking water supply. If surface water is used to recharge groundwater, or if the surface stream is a “losing” stream that recharges groundwater, PPCPs in the surface stream may end up in the groundwater.⁸⁵ If the sludge from the processing tanks is applied to land, a common disposal method in the United States for wastewater treatment plant sludge,⁸⁶ then rain or melting snow will allow the PPCPs to be absorbed into soils⁸⁷ and to infiltrate groundwater.⁸⁸

⁸² With regard to such weather events, Wu *et al.* have noted that the release of bacteria (and presumably PPCPs) trapped in sediments may result from “sediment resuspension caused by storms, flood, tides, or strong winds[.]” Jianyong Wu *et al.*, *Fate and Transport Modeling of Potential Pathogens: The Contribution from Sediments*, 45 JOURNAL OF THE AMERICAN WATER RESOURCES ASSOCIATION 35, 36 (2009) (citing R.W. Muirhead *et al.*, *Faecal Bacteria Yields in Artificial Flood Events: Quantifying In-Stream Stores*, 38 WATER RESEARCH 1215 (2004); R.C. Jamieson *et al.*, *Resuspension of Sediment-Associated Escherichia Coli in a Natural Stream*, 34 JOURNAL OF ENVIRONMENTAL QUALITY 581 (2005)). On a related point, Guo and Krasner have noted a relationship between climatic variability and the variable presence of PPCPs in water resources. Guo & Krasner, *supra* note 33, at 64 (reduced instream flow during dry years resulting in less dilution of wastewater treatment plant outflows).

⁸³ P. Phillips, & A. Chalmers, *Wastewater Effluent, Combined Sewer Overflows, and Other Sources of Organic Compounds to Lake Champlain*, 45 JOURNAL OF THE AMERICAN WATER RESOURCES ASSOCIATION 45, 46 (2009). Accord Brown, Battaglin, & Zuellig, *supra* note 75, at 70 (storm drains as a source of PPCPs).

⁸⁴ Phillips & Chalmers, *supra* note 83, at 46 (citing Lorien J. Fono, & David L. Sedlak, *Use of the Chiral Pharmaceutical Propranol to Identify Sewage Discharges Into Surface Waters*, 39 ENVIRONMENTAL SCIENCE & TECHNOLOGY 9244 (2005)).

⁸⁵ Thomas Heberer *et al.*, *Removal of Pharmaceutical Residues and Other Persistent Organics From Municipal Sewage and Surface Waters Applying Membrane Filtration*, 120 WATER RESOURCES UPDATE 18, 19 (2001) [hereinafter Heberer *et al.*, *Removal of Pharmaceutical Residues*] (citations omitted).

⁸⁶ See Committee on Toxicants and Pathogens in Biosolids Applied to Land, *supra* note 42, at 1 (“Approximately 5.6 million dry tons of sewage sludge are used or disposed of annually in the United States; approximately 60% of that is used for land application.”). See also Xia *et al.*, *supra* note 4, at 47 (“Biosolids land application is becoming the most common means of biosolids disposal as other disposal options become cost prohibitive or heavily regulated”).

⁸⁷ Lozano, *et al.*, have observed that triclosan (TCS, “an antimicrobial compound that is added to a wide variety of household and personal care products”) “may be accumulated by earthworms after land application of biosolids.” Nuria Lozano *et al.*, *Fate of Triclosan in Agricultural Soils After Biosolid Applications*, 78 CHEMOSPHERE 760 (2010) (citing Chad A. Kinney *et al.* *Bioaccumulation of Pharmaceuticals and Other Anthropogenic Waste Indicators in Earthworms from Agricultural Soil Amended with Biosolid or Swine Manure*, 42 ENVIRONMENTAL SCIENCE & TECHNOLOGY 1863 (2008)). The potential consequences of such bioaccumulation are of note:

Since TCS is a bacteriostat, there is a real potential that concentrations in soils resulting from biosolid applications might affect bacterial ecology of these systems. Especially since the ecological balance and competitive advantages of the multiple species inhabiting any soil environment are very complex and any small advantage one microbe might achieve due to exposure to these known bacteriostat could be amplified under these conditions.

Id. at 764 (2010). The sorption and degradation of PPCPs in soil is discussed in greater detail in Section V.

⁸⁸ Concluding that several pharmaceutically active compounds “can be transported through the subsoil without any substantial attenuation[.]” Heberer *et al.* focused on clofibric acid, “the pharmacologically active metabolite of the drugs clofibrate, etofyllin clofibrate, and etofibrate, used as blood-lipid regulators in human health care.” Heberer *et al.*, *Pharmaceuticals During Bank Filtration*, *supra* note 73, at 6-7.

[B]etween 1992 and 1995, clofibric acid . . . was detected at concentrations at the µg/L level in ground water samples collected

The presence of PPCPs in groundwater has also been detected in areas where human wastes are treated using septic tank systems.⁸⁹ Human wastes containing PPCPs that flow into septic tanks will eventually flow into groundwater.

Because of the widespread use of antibiotics in animal husbandry,⁹⁰ PPCPs are also present in the feces and urine of a wide variety of domesticated animals. Manure produced by such animals will contain PPCPs. As with the sludge from wastewater treatment plants, manure is frequently applied to land as a waste disposal mechanism. Also as with wastewater treatment plant sludge, rain or melting snow will cause PPCPs contained in manure to flow into groundwater.⁹¹

Much like septic tank systems but on a larger scale, liquid wastes from domesticated animals may be collected in lagoons or ponds.⁹² These impoundments are quite effective in providing a means by which PPCPs contained in liquid wastes can find their

way into groundwater.⁹³ Of particular concern are both the land application of manure and the collection of liquid wastes in lagoons or ponds associated with Confined Animal Feeding Operations.⁹⁴

C. Current Means of Protecting Water Supplies:

C.1. Common Law Remedies Sounding in Tort

The word “tort” is derived from the Latin *tortus* meaning bent or crooked. Torts are private acts of civil wrongs in which an injured plaintiff seeks compensation from an allegedly responsible defendant. There are four tort theories, each of which is potentially applicable to injuries allegedly relating to exposure to PPCPs. It should be noted, however, that application of any of the four theories, either individually or in combination with one another, will be dependent on the facts of a specific case.

from former sewage irrigation fields near Berlin and in Berlin tap-water samples. It became evident that these residues were caused by the infiltration of sewage effluents into the soil and that clofibric acid is a very mobile compound that is not substantially adsorbed in the subsoil and is leached easily into the aquifer. ... In Germany, the first detections of clofibric acid in ground water put focus on the presence of drug residues in the aquatic system as a new emerging issue and researchers began to investigate the occurrence and fate of pharmaceutical residues in the aquatic environment, during drinking-water purification, and in drinking water samples.

Id. at 6 (citing T. Heberer & H.J. Stan, *Vorkommen von polaren organischen Kontaminanten im Berliner Trinkwasser*, 86 VOM WASSER 19 (1997); T. Heberer & H. J. Stan, *Determination of Clofibric Acid and N-(Phenylsulfonyl)-sarcosine in Sewage, River and Drinking Water*, 67 INTERNATIONAL JOURNAL OF ANALYTICAL CHEMISTRY 113 (1996); Umweltbundesamt, SACHSTANDSBERICHT ZU AUSWIRKUNGEN DER ANWENDUNG VON CLOFIBRINSÄURE UND ANDEREN ARZNEIMITTELN AUF DIE UMWELT UND DIE TRINKWASSERVERSORGUNG. (Umweltbundesamt 1996)). See also Huang et al., *supra* note 25, at 33 (“Land application of animal waste provides routes for agricultural antibiotics to enter the aquatic environments, which may eventually reach drinking water supplies”).

⁸⁹ Rapid Public Health Policy Response Project, *supra* note 26, at 1. Accord Kinney et al., *supra* note 26.

⁹⁰ “About 90 percent of the approximately 2.5 million kg of antibiotics sold in the United States are given as growth-promoting and prophylactic agents in sub-therapeutic doses instead of being used to treat active infections, thereby lowering the cost of animal care.” Heberer et al., *Pharmaceuticals During Bank Filtration*, *supra* note 73, at 10 (citing Dana Kolpin et al., *Pharm-Chemical Contamination – Reconnaissance for Antibiotics in Iowa Streams*, 1999, in EFFECTS OF ANIMAL FEEDING OPERATIONS ON WATER RESOURCES AND THE ENVIRONMENT. PROCEEDINGS OF THE TECHNICAL MEETING, FORT COLLINS, COLORADO, AUGUST 30-SEPTEMBER 1, 1999 (Franceska D. Wilde et al. eds., U.S. Geological Survey 2000)). Accord Reynolds, *Concern of Pharmaceuticals in Drinking Water*, *supra* note 33, at 1 (“40 percent of antibiotics manufactured are fed to livestock as growth enhancers”).

⁹¹ Heberer et al., *Pharmaceuticals During Bank Filtration*, *supra* note 73, at 6. Accord Davis, *supra* note 49.

⁹² “Researchers have shown that several classes of antibiotics (e.g., tetracyclines, sulfonamides, macrolides and ionophores) are present in hog waste lagoons at concentrations as high as 0.7 mg/L.” Carlson et al., *supra* note 26, at 4..

⁹³ Heberer et al., *Pharmaceuticals During Bank Filtration*, *supra* note 73, at 10.

⁹⁴ Benotti et al., *supra* note 48. See also, Ken Carlson et al., *Antibiotics in Animal Waste Lagoons and Manure Stockpiles*, AGRONOMY NEWS, Dec. 2004, at 7 (“a wide range of antibiotics is present in most animal waste streams, either runoff ponds, waste lagoons or manure stockpiles”); Heberer et al., *Pharmaceuticals During Bank Filtration*, *supra* note 73, at 10; Masters, *supra* note 6.

C.1.1. Trespass

There are three elements for establishing a claim under the theory of trespass. First, the plaintiff must have been harmed.⁹⁵ Second, the defendant's conduct must be shown to have been the cause of the plaintiff's harm. Third, it must be proven that the defendant intentionally (a) entered land in the possession of the plaintiff (or caused something or someone else to do so); (b) remained on the plaintiff's land; or (c) failed to remove from the plaintiff's land "a thing which he is under a duty to remove."⁹⁶ In the case of personal property (trespass to chattels), an alternative third element is applicable where it can be shown that the defendant intentionally interfered with the plaintiff's personal property by (a) damaging the personal property; (b) depriving the plaintiff of the use of the property for a substantial period of time; or (c) "dispossessing" the property from the plaintiff.⁹⁷ With regard to the requirement of intentionality, individuals are generally presumed to know the "natural consequences" of their actions.⁹⁸

C.1.2. Nuisance

As with the theory of trespass, there are three elements necessary to raise a claim under the theory of nuisance. First, the plaintiff must establish that she was harmed. Second, the evidence must show that the defendant's conduct was the cause of the plaintiff's harm. Third, it must be established that the defendant's intentional actions constituted either a public or a private nuisance.

Public nuisances result where a defendant (a) offended accepted community principles of decency or (b) interfered with the use of public highways, streams, parks, beaches or other facilities.⁹⁹ Private nuisances result where the defendant (a) substantially interfered with the plaintiff's use and enjoyment of property or (b) injured the plaintiff.¹⁰⁰

C.1.3. Negligence

There are five elements to the theory of negligence, all of which must be established to raise a claim against a defendant. First, the plaintiff must have been harmed. Second, the evidence must show that the defendant's conduct was the cause of the plaintiff's harm. Third, it must be established that the defendant owed a duty of reasonable care to the plaintiff.¹⁰¹ Fourth, the plaintiff must evidence that the defendant breached the duty of reasonable care. Fifth, the harm to the plaintiff resulting from the breach must be shown to have been foreseeable.¹⁰²

Of particular relevance is the duty of reasonable care. The standard of care is frequently expressed as the question: What would a reasonably prudent person have done? It is noteworthy that professionals, because of both education and licensing requirements, are usually held to a higher standard of care than non-professionals.¹⁰³ Corporations, because of superior knowledge regarding specific products, may also be held to a higher standard of care than the general citizenry.¹⁰⁴

⁹⁵ RESTATEMENT (SECOND) OF TORTS §§ 158, 162, 901, 907 (1979). The plaintiff does not have to show harm for the defendant to be liable for trespass. However, the plaintiff would have to show harm to receive compensatory damages, though there are other remedies, such as nominal damages, that do not require a showing of harm.

⁹⁶ *Id.* § 158. As noted in the Restatement, the protected property interest of the plaintiff is the right of "exclusive possession and physical condition of land." *Id.* § 157.

⁹⁷ *Id.* §§ 217-18.

⁹⁸ *Francis v. Franklin*, 471 U.S. 307, 311 (1985) ("A person of sound mind and discretion is presumed to intend the natural and probable consequences of his acts ...").

⁹⁹ *See State v. H. Samuels Co.*, 211 N.W.2d 417 (Wis. 1973) (holding that a violation of a noise ordinance may constitute nuisance).

¹⁰⁰ RESTATEMENT (SECOND) OF TORTS, *supra* note 96, at § 821D.

¹⁰¹ Reasonableness may be defined in permit conditions or by industry custom/practice. Violation of permit conditions or other statutory or regulatory requirements is almost always negligence *per se*. *See, e.g., Sammons v. Ridgeway*, 293 A.2d 547 (Del. 1972) (holding that the violation of a statute is negligence *per se*).

¹⁰² *See, e.g., Palsgraf v. Long Island R.R. Co.*, 162 N.E. 99 (N.Y. 1928).

¹⁰³ *See, e.g., Blair v. Eblen*, 461 S.W.2d 370 (Ky. 1970) (holding that a doctor is under a duty to use that degree of care and skill which is expected of a reasonably competent doctor in the same class to which he belongs).

¹⁰⁴ *See, e.g., Binder v. Jones & Laughlin Steel Corp.*, 520 A.2d 863 (Pa. Super. Ct. 1987) (holding that manufacturer had an affirmative duty to warn of risk due to its knowledge of the product's properties).

C.1.4. Strict Liability

There are three elements to the theory of strict liability. The first two are the same as for negligence, namely that the evidence show that the plaintiff was harmed, and the defendant's conduct was the cause of plaintiff's harm. The third element requires a showing that the defendant either engaged in an "abnormally dangerous activity" or manufactured an inherently dangerous product.¹⁰⁵

A number of factors must be considered in determining whether the defendant's activities are abnormally dangerous. These include (a) a high degree of risk or harm; (b) the gravity of the harm; (c) the possibility of eliminating the risk with reasonable care; (d) whether the activity is in common usage; (e) the appropriateness of the activity for the location where it occurred; and (f) the value of the activity to the community.¹⁰⁶ If the defendant is engaged in an abnormally dangerous activity, the defendant may be held strictly liable for injuries resulting to the plaintiff irrespective of the degree of care exercised by the defendant.¹⁰⁷

As suggested above, the defendant may also be strictly liable for injuries to the plaintiff resulting from an inherently dangerous product manufactured by the defendant. Products may be inherently dangerous due to design defects, manufacturing defects, or marketing defects.¹⁰⁸

C.2. Protection of Surface Water Quality: The Clean Water Act

The Clean Water Act (CWA) was intended to restore and maintain the chemical, physical and biological integrity of the nation's water resources.¹⁰⁹ As enacted by Congress, the CWA imposes a number of requirements intended to achieve these objectives. Initially, states are authorized to designate water quality standards or allowable uses of rivers located within the state.¹¹⁰ This designation may be in terms of water quality standards to be maintained in the river, in terms of allowable uses, or both.¹¹¹ However, these standards or designated uses, which are subject to EPA approval,¹¹² must be based on the National Recommended Water Quality Criteria.¹¹³

If a state chooses to utilize water quality standards, the standards must include total maximum daily loads (TMDLs) for those pollutants that are amenable to maximum daily load measurement.¹¹⁴ As discussed below, TMDLs are to be a part of state water quality standards applicable to the issuance of discharge permits.

Once water quality standards or designated uses have been approved, implementation is carried out through the National Pollutant Discharge Elimination System (NPDES) permit system.¹¹⁵ This system allows companies, governmental units, and other entities to obtain an NPDES permit for the discharge

¹⁰⁵ See *Caporale v. C.W. Blakeslee & Sons, Inc.*, 175 A.2d 561 (Conn. 1961) (holding that construction under the circumstances was "intrinsically dangerous").

¹⁰⁶ See RESTATEMENT (SECOND) OF TORTS, *supra* note 96, at § 402A..

¹⁰⁷ See *Rylands v. Fletcher*, UKHL 1 (United Kingdom House of Lords Decisions, 1868) (mill owner who constructed a reservoir was liable without fault when the reservoir failed and flooded an adjoining mine; mill owner was liability without fault for collecting "anything likely to do mischief if it escapes"). See also *Caporale*, 175 A.2d at 564.

¹⁰⁸ See *Saupitty v. Yazoo Mfg. Co.*, 726 F.2d 657 (10th Cir. 1984) (holding that a lawnmower as designed was inherently dangerous); *MacPherson v. Buick Motor Co.*, 111 N.E. 1050 (N.Y. 1916) (finding that defects in the manufacture of a motor vehicle rendered it inherently dangerous); *Dunham v. Vaughn & Bushnell Mfg. Co.*, 247 N.E.2d 401 (Ill. 1969) (holding that a hammer was inherently dangerous when used as advertised).

¹⁰⁹ Clean Water Act, Pub. L. No. 92-500, 86 Stat. 816 (1972) (codified as amended at 33 U.S.C. § 1251 *et seq.* (2006)).

¹¹⁰ See 40 C.F.R. § 130.0 (2010).

¹¹¹ *PUD No. 1 of Jefferson County v. Washington Dep't of Ecology*, 511 U.S. 700 (1994).

¹¹² See *WESTVACO v. EPA*, 899 F.2d 1383 (4th Cir. 1990). Such standards or designated uses may also be subject to EPA disapproval. *Id.*

¹¹³ 33 U.S.C. §§ 1313-1314.

¹¹⁴ § 130.4.

¹¹⁵ CWA § 1342. ¹¹⁶ 40 C.F.R. § 230.3(s) (2010).

of effluent from a point source into “waters of the United States.”¹¹⁶ Absent an NPDES permit, such discharges are strictly prohibited.¹¹⁷

NPDES permits contain specific provisions regarding the type of waste treatment technology required and the type and concentration of materials to be discharged.¹¹⁸ For existing facilities, the general requirement is Best Cost-Reasonable Technology (BCT).¹¹⁹ For new facilities, the requirement is Best Available Technology.¹²⁰

C.3. Protection of Groundwater and Surface Water Quality: The Safe Drinking Water Act

The primary objective of the Safe Drinking Water Act (SDWA) is to identify, monitor, and control contaminants in drinking water.¹²¹ The SDWA is also intended to provide an enforcement mechanism, provide for the collection and dissemination of water-related information, and provide funding mechanisms to upgrade water supply systems.¹²²

As with many environmental statutes, implementation of the SDWA is an example of cooperative federalism. States have primary enforcement authority once the state SDWA program has been approved by the EPA.¹²³ SDWA requirements focus primarily

on public water systems. The National Primary Drinking Water Regulations, one of the primary enforcement mechanisms of the SDWA, apply to community water systems.¹²⁴ Noncommunity or transient water systems are smaller systems that usually rely on groundwater.

C.3.1. National Primary Drinking Water Regulations

The National Primary Drinking Water Regulations are health-based standards for drinking water supplied by public water systems.¹²⁵ These regulations are without exceptions. They apply to contaminants that have been determined to pose public health risks and are expressed in terms of Maximum Contaminant Levels (MCLs).¹²⁶ In general, “Best Available Technology” is required, though cost is taken into consideration.¹²⁷ The technology should result in a discharge as close as possible to the Maximum Contaminant Level Goal (MCLG).¹²⁸

Both MCLs and MCLGs are to be based on human health effects. Risk assessments are to be used to determine these effects. In conducting such assessments, EPA is to utilize “the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices”¹²⁹ and “data collected by accepted methods or best available methods (if

¹¹⁷ *See id.*

¹¹⁸ *Id.* § 1342(p)(3).

¹¹⁹ 40 C.F.R. § 125.3.

¹²⁰ *Id.* EPA has issued New Source Performance Standards mandating the use of “best available demonstrated control technology” for a number of industrial categories.

¹²¹ Safe Drinking Water Act (SDWA), Pub. L. No. 93-523, 88 Stat. 1660 (codified as amended at 42 U.S.C. § 300f (2006)); Daniel J. Kucera, *Safe Drinking Water Act*, in ENVIRONMENTAL LAW HANDBOOK 437, 439 (Thomas F.P. Sullivan ed., Government Institutes 19th ed. 2007).

¹²² Kucera, *supra* note 121, at 439-40.

¹²³ *Id.* at 440.

¹²⁴ Community water systems are systems having at least 15 taps or providing service to at least 25 individuals. SDWA § 300f(15).

¹²⁵ 40 C.F.R. § 141.1 *et seq.* (2010). The National Primary Drinking Water Standards include 85 standards divided into six categories: disinfectants, disinfection byproducts, inorganic chemicals, microorganisms, organic chemical, and radionuclides. *Id.*

¹²⁶ SDWA § 300g-1(b)(1). MCLs may also be expressed in terms of treatment techniques if it is impossible to establish an MCL (*i.e.*, difficulty in measuring or uncertainty regarding appropriate exposure limits). *Id.* § 300g-1(b)(7).

¹²⁷ *See id.* § 300g-1(b)(4).

¹²⁸ *Id.* § 300g-1(b)(4). MCLGs are health-based goals that do not take cost into consideration. *See id.* §§ 300g-1(b)(1), (4).

¹²⁹ 42 U.S.C. § 300g-1(b)(3)(A)(i).

the reliability of the method and the nature of the decision justifies use of the data).¹³⁰

The process for establishing MCLGs is relevant vis-à-vis the PPCP control options discussed in Section VI.¹³¹ With regard to MCLGs for non-carcinogens, using the methodology noted above, a substance-specific Reference Dose (RfD) is determined.¹³² In general, depending on the availability of information about a specific substance, the RfD is calculated by dividing Lowest-Observed-Adverse-Effect Level (LOAEL)¹³³ or No-Observed-Adverse-Effect Level (NOAEL)¹³⁴ by an Uncertainty Factor (UF).¹³⁵ The MCLG is then determined by (a) multiplying the RfD by an assumed body weight of 70 kg, (b) dividing by an assumed daily water consumption of 2 liters to determine Drinking Water Equivalent Level (DWEL) and (c) multiplying DWEL by an assumed daily exposure attributed to the consumption of water.¹³⁶

The SDWA also authorizes National Secondary Drinking Water Regulations which relate to the aesthetics of water (*i.e.*,

color, taste, odor), rather than its safety.¹³⁷ The National Secondary Drinking Water Regulations are not enforceable.¹³⁸

C.3.2. The Unregulated Contaminant Monitoring Rule

The SDWA requires the EPA to both: (a) establish criteria for a monitoring program for unregulated contaminants; and (b) publish a list of contaminants to be monitored.¹³⁹ Based on information developed through the monitoring program, the EPA is to evaluate and prioritize unregulated contaminants for potential inclusion on the Contaminant Candidate List discussed below.¹⁴⁰ The Unregulated Contaminant Monitoring Rule¹⁴¹ lists contaminants that must be monitored by public water systems, describes analytical methods of assessing these contaminants, and requires the monitoring and analysis results to be submitted to the EPA for inclusion in the National Drinking Water Contaminant

¹³⁰ *Id.* § 300g-1(b)(3)(A)(ii).

¹³¹ *Infra*, note 229 and associated text.

¹³² Reference Dose is defined as “[a]n estimate of a daily oral exposure for a given duration to the human population (including susceptible subgroups) that is likely to be without an appreciable risk of adverse health effects over a lifetime. It is derived from a BMDL [Benchmark Dose Level], a NOAEL [No-Observed-Adverse-Effect Level], a LOAEL [Lowest-Observed-Adverse-Effect Level], or another suitable point of departure, with uncertainty/variability factors applied to reflect limitations of the data used.” Environmental Protection Agency, Integrated Risk Information System (IRIS), http://www.epa.gov/iris/gloss8_arch.htm (last visited Feb. 9, 2011).

¹³³ Lowest-Observed-Adverse-Effect Level is defined as “[t]he lowest exposure level at which there are statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control group.” *Id.*

¹³⁴ No-Observed-Adverse-Effect Level is defined as the “highest exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effect between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered adverse, nor precursors to adverse effects.” *Id.*

¹³⁵ “Uncertainty Factor” is defined as “[o]ne of several, generally 10-fold factors, used in operationally deriving the RfD [Reference Dose] and RfC [Reference Concentration] from experimental data. UFs are intended to account for (1) the variation in sensitivity among the members of the human population, *i.e.*, interhuman or intraspecies variability; (2) the uncertainty in extrapolating animal data to humans, *i.e.*, interspecies variability; (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure, *i.e.*, extrapolating from subchronic to chronic exposure; (4) the uncertainty in extrapolating from a LOAEL rather than from a NOAEL; and (5) the uncertainty associated with extrapolation from animal data when the database is incomplete.” *Id.*

¹³⁶ Environmental Protection Agency, Regulating Public Water Systems and Contaminants Under the Safe Drinking Water Act, <http://water.epa.gov/lawsregs/rulesregs/regulatingcontaminants/basicinformation.cfm> (last visited Feb. 9, 2011).

¹³⁷ Kucera, *supra* note 121, at 445.

¹³⁸ 40 C.F.R. § 143.1 (2010).

¹³⁹ Kucera, *supra* note 121, at 477.

¹⁴⁰ *Id.*

¹⁴¹ Unregulated Contaminant Monitoring Rule, 64 Fed. Reg. 50,556 (Sept. 17, 1999) (codified at 40 C.F.R. §§ 9, 141-42).

Occurrence Database. Public water systems are also required to notify their consumers of the results of the monitoring and analysis.¹⁴² The goal of the Unregulated Contaminant Monitoring Rule is to ensure that decisions regarding the regulation of specific contaminants are based on sound science, not political influence.¹⁴³

C.3.3. The Contaminant Candidate List

The SDWA¹⁴⁴ also requires the EPA to publish a Contaminant Candidate List every five years. This list must include contaminants that are not currently subject to National Primary Drinking Water Regulations but are known or anticipated to occur in public water systems.¹⁴⁵ The SDWA specifies three criteria to be utilized in determining whether a contaminant may be a candidate for regulation: (1) The contaminant may have an adverse effect on the health of persons; (2) The contaminant is known to occur, or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and (3) In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.¹⁴⁶

C.3.4. The Surface Water Treatment Rule

The SDWA also contains a Surface Water Treatment Rule which requires systems using surface water or groundwater under the direct influence of surface water to disinfect and filter their water so that the following contaminants are controlled at the following levels:

Cryptosporidium (99% removal), Giardia lamblia (99.9% removal or inactivation), and viruses (99.99% removal or inactivation).¹⁴⁷

C.3.5. The Wellhead Protection Program

Amendments to the SDWA in 1986 enhanced the protection of underground sources of drinking water by authorizing the wellhead protection program.¹⁴⁸ Under the SDWA as amended, states were required to develop wellhead protection programs within three years and submit them to the Administrator of the EPA for approval.¹⁴⁹ The goal of the wellhead protection program was to “protect wellhead areas . . . from contaminants which may have any adverse effect on the health of persons[.]”¹⁵⁰

To encourage the states to develop wellhead protection programs, Congress provided both an incentive and a disincentive. As an incentive, the SDWA provided that the activities of federal agencies having an effect on the wellhead protection area must be consistent with the states’ wellhead protection programs.¹⁵¹ As a disincentive, the SDWA provided that failure to develop an acceptable wellhead protection program would result in state ineligibility for certain federal funding to implement the wellhead protection program.¹⁵²

C.3.6. The Underground Injection Control Program

Protection of underground sources of drinking water also occurs through the SDWA’s Underground Injection Control

¹⁴² Kucera, *supra* note 121, at 457.

¹⁴³ See SDWA § 300g-1(b).

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ SDWA § 300g-1(b)(1)(A); see Kucera, *supra* note 121, at 447.

¹⁴⁷ Surface Water Treatment Rule, 40 C.F.R. § 141.70 (2010); see SDWA § 300g-1(b)(2)(C).

¹⁴⁸ SDWA § 300h-7.

¹⁴⁹ *Id.* § 300h-7(a).

¹⁵⁰ “Wellhead protection areas” were defined as “the surface and subsurface area surrounding a water well or wellfield, supplying a public water system, through which contaminants are reasonably likely to move toward and reach such water well or wellfield[.]” *Id.* § 300h-7(e).

¹⁵¹ *Id.* § 300h-7(h).

¹⁵² *Id.* § 300h-7(d).

Program (UICP).¹⁵³ The UICP was mandated by ongoing reliance on groundwater as a source of drinking water supplies.¹⁵⁴ Over 80% of community water systems rely on groundwater for all or part of their water supply.¹⁵⁵

With regard to well construction, the UICP both required permits and established standards based on different classes of wells:¹⁵⁶

- Class I wells are used for injection of industrial non-hazardous liquids, municipal wastewaters, or hazardous wastes beneath the lowermost underground source of drinking water.
- Class II wells are used for injection of fluids in connection with conventional oil or natural gas production, enhanced oil and gas production, and the storage of hydrocarbons which are liquid at standard temperature and pressure.
- Class III wells are used for injection of fluids associated with the extraction of minerals or energy, including the mining of sulfur and solution mining of minerals.
- Class IV wells are used for injection of hazardous or radioactive wastes into or above underground source of drinking waters.

- Class V wells include all injection wells that are not included in Classes I-IV.
- Class VI wells are used for injection of carbon dioxide.

C.3.7. The Biosolids Rule

The Clean Water Act Amendments of 1987 required EPA to promulgate regulations to protect public health and the environment from adverse impacts associated with the disposal of biosolids (i.e., the sludge from wastewater treatment plants). These regulations were published in 1993¹⁵⁷ and became Title 40, Part 503 of the Code of Federal Regulations. As a result, they are commonly known as the “Part 503 Biosolids Rule.”

Of particular relevance to the issue of PPCPs in water supplies is that portion of the Biosolids Rule relating to the application of biosolids to land.¹⁵⁸ Four general requirements are established under the Biosolids Rule. First, ceiling concentration limits were established for heavy metals.¹⁵⁹ Second, pollutant loading rate limits were formulated. Third, pathogen control requirements were

¹⁵³ *Id.* § 300h.

¹⁵⁴ Kucera, *supra* note 121, at 474.

¹⁵⁵ *See id.*

¹⁵⁶ 40 C.F.R. § 146.5 (2010). With regard to Class VI wells, *see* Federal Requirements Under the Underground Injection Control (UIC) Program for Carbon Dioxide (CO₂) Geologic Sequestration (GS) Wells, 75 *Fed. Reg.* 77,230 (December 10, 2010).

¹⁵⁷ 58 *Fed. Reg.* 9348 (February 19, 1993).

¹⁵⁸ Other portions of Part 503 apply to a variety of different uses and disposal techniques for biosolids. *See generally* Office of Wastewater Management, Environmental Protection Agency, A PLAIN ENGLISH GUIDE TO THE EPA PART 503 BIOSOLIDS RULE (1994) [hereinafter EPA GUIDE TO PART 503 BIOSOLIDS RULE].

¹⁵⁹ Ceiling concentration limits were established for arsenic, cadmium, chromium, copper, lead, mercury, molybdenum, nickel, selenium and zinc. *See* Environmental Protection Agency, *Chapter 2: Land Application of Biosolids in EPA GUIDE TO PART 503 BIOSOLIDS RULE*, *supra* note 158, at 29. To establish these limits:

EPA conducted extensive risk assessments that involved identifying the chemical constituents in biosolids judged likely to pose the greatest hazard, characterizing the most likely exposure scenarios, and using scientific information and assumptions to calculate concentration limits and loading rates (amount of chemical that can be applied to a unit area of land). [However, there] have been substantial advances in risk assessment since then, and there are new concerns about some adverse health outcomes and chemicals not originally considered. Because of the diversity of exposed populations, environmental conditions, and agricultural practices in the United States, it is important that nationwide chemical regulations be based on the full range of exposure conditions that might occur. Furthermore, there is a need to investigate whether the biosolids produced today are similar in composition to those used in the original assessments.

ascertained.¹⁶⁰ Fourth, vector-attraction reduction requirements were mandated.¹⁶¹

For land disposal to be permitted, all biosolids must comply with the ceiling concentration limits for heavy metals. There are a number of options available to fulfill the other three requirements. These options are based on the characteristics of both the biosolids and the land to which the biosolids are to be applied.¹⁶² Once biosolids have been applied to land, an ongoing monitoring program is required.¹⁶³

C.4. Protection of Groundwater and Surface Water Quality by Regulating Hazardous Substances and Wastes: The Resource Conservation and Recovery Act

One of the primary statutes dealing with hazardous substances and wastes is the Resource Conservation and Recovery Act (RCRA), which was enacted to establish a program for the “cradle-to-grave” management of hazardous substances and waste.¹⁶⁴ One of the goals of RCRA, as expressed in Subtitle A, is to protect human health and the environment from the hazards posed by waste disposal.¹⁶⁵ Other goals include the reduction or elimination of the amount of waste generated (including hazardous waste) and the proper management of such waste to protect human health and the environment.¹⁶⁶

Subtitle C of RCRA created a hazardous waste management program.¹⁶⁷ A waste is considered “hazardous” if it is a solid waste, defined as:

Committee on Toxicants and Pathogens in Biosolids Applied to Land, *supra* note 42, at 2, 12. This led the National Research Council to recommend:

[A] new national survey of chemicals in biosolids should be conducted. EPA should review available databases from state programs in designing a new survey. Other elements that should be included in the survey are an evaluation of the adequacy of detection methods and limits to support risk assessment; consideration of chemical categories, *such as odorants and pharmaceuticals*, that were not previously evaluated[.]

Id. at 12 (emphasis added).

¹⁶⁰ “In contrast to the chemical standards, the pathogen standards are not risk-based concentration limits for individual pathogens but are technologically based requirements aimed at reducing the presence of pathogens and potential exposures to them by treatment or a combination of treatment and use restrictions.” Committee on Toxicants and Pathogens in Biosolids Applied to Land, *supra* note 42, at 2. In fact, with regard to pathogens, the National Research Council has recommended use of improved risk assessment method: “Risk-assessment methods for chemicals and pathogens have advanced over the past decade to the extent that (1) new risk assessments should be conducted to update the scientific basis of the chemical limits, and (2) risk assessments should be used to supplement technological approaches to establishing regulatory criteria for pathogens in biosolids.” *Id.* at 4.

¹⁶¹ Vectors are typically flies and rodents.

¹⁶² See Office of Wastewater Management, Environmental Protection Agency, A GUIDE TO THE BIOSOLIDS RISK ASSESSMENTS FOR THE EPA PART 503 RULE (1995). The options include the Exceptional Quality option, the Pollutant Concentration option, the Cumulative Pollutant Loading Rule option and the Annual Pollutant Loading Rate option. The requirements applicable to each option are discussed in *Chapter 2: Land Application of Biosolids*, in EPA GUIDE TO PART 503 BIOSOLIDS RULE, *supra* note 158, at 30-40. These requirements were based on a comprehensive risk assessment.

¹⁶³ Monitoring must include pollutants, pathogen densities (fecal coliform, *salmonella*, viable helminth ova and enteric virus) and vector attraction reduction. See *Chapter 2: Land Application of Biosolids*, in EPA GUIDE TO PART 503 BIOSOLIDS RULE, *supra* note 158, at 47-49; *Chapter 6: Sampling and Analysis*, in EPA GUIDE TO PART 503 BIOSOLIDS RULE, *supra* note 158, at 129-51.

¹⁶⁴ Resource Conservation and Recovery Act of 1976 (RCRA; Solid Waste Disposal Act), Pub. L. No. 94- 580, 90 Stat. 2795 (codified as amended at 42 U.S.C. §§ 6901-6992k (2006)); David R. Case, *Resource Conservation and Recovery Act*, in ENVIRONMENTAL LAW HANDBOOK 133, 134 (Thomas F.P. Sullivan ed., Government Institutes 19th ed. 2007).

¹⁶⁵ RCRA § 6902(a).

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

[A]ny garbage, refuse, sludge from a waste treatment plant, water supply treatment plant or air pollution control facility and other discarded material, including solid, liquid, semisolid, or contained gaseous materials resulting from industrial, commercial, mining and agriculture activities and from community activities but does not include solid or dissolved material in domestic sewage, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to permits under section 402 of the Federal Water Pollution Control Act, as amended, or source, special nuclear, or byproduct material as defined by the Atomic Energy Act of 1954, as amended (68 Stat. 923).¹⁶⁸

Certain wastes are specifically excluded from the definition of solid waste, including “(a) any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly owned treatment works and (b) industrial wastewater discharges that are point source discharges under the Clean Water Act.”¹⁶⁹

Waste is considered hazardous if it is:
any solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may (A) Cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible illness; or (B) Pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.¹⁷⁰

This statutory language gives the EPA broad authority to define hazardous wastes through regulation. Applicable regulations establish several lists of hazardous wastes:¹⁷¹

- The “F” list – hazardous wastes from nonspecific sources (*e.g.*, spent nonhalogenated solvents, such as toluene or methyl ethyl ketone).
- The “K” list – hazardous wastes from specific sources (*e.g.*, petroleum refining wastes or bottom sediment sludge from the treatment of wastewaters by the wood preserving industry).
- The “P” list – chemicals considered “acutely” hazardous irrespective of concentration (*e.g.*, nitric oxide).
- The “U” list – chemicals considered hazardous at higher concentrations (*e.g.*, acetone) Christenson notes that, “[s]ince most hazardous pharmaceuticals are on the P-list or Ulist, health-care facilities focus primarily on these lists.”¹⁷²

C.4.1. The Mixture Rule

In addition, the “mixture rule” provides that a mixture of a listed hazardous waste and a solid waste must also be considered a hazardous waste.¹⁷³ This rule may not apply if (a) the mixture does not exhibit the characteristics for which the waste was considered hazardous (ignitability, corrosivity, reactivity or toxicity), (b) the mixture is regulated under the Clean Water Act, or (c) the mixture contains only *de minimis* quantities of hazardous wastes.¹⁷⁴

C.4.2. Categories of Generators

Hazardous waste generators are regulated depending on the amount of waste they generate each month.¹⁷⁵ There are three categories:

- Large quantity generators (LQG, generators of more the 1,000 kilograms of hazardous waste per month)

¹⁶⁸ *Id.* § 6903(27).

¹⁶⁹ Case, *supra* note 164, at 138.

¹⁷⁰ RCRA § 6903(5).

¹⁷¹ 40 C.F.R. § 261.31, 261.32, Part 273 (2010); Case, *supra* note 164, at 141-42.

¹⁷² Teirney Christenson, Comment, *Fish on Morphine: Protecting Wisconsin’s Natural Resources Through a Comprehensive Plan for Proper Disposal of Pharmaceuticals*, 2008 WISCONSIN LAW REVIEW 141, 149 (2008) (citing Christian G. Daughton, *Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health. II. Drug Disposal, Waste Reduction, and Future Directions*, 111 ENVIRONMENTAL HEALTH PERSPECTIVES 775, 782 (2003))

¹⁷³ § 261.3(a)(2); Case, *supra* note 164, at 145.

¹⁷⁴ 40 C.F.R. § 261.3 (2010).

¹⁷⁵ 40 C.F.R. Part 260 (2010); *see* Case, *supra* note 164, at 152-53.

- Small quantity generators (SQG, generators of between 100 and 1,000 kilograms of hazardous waste per month)
- Conditionally exempt small quantity generators (CESQGs, generators of less than 100 kilograms of hazardous waste per month)

Under RCRA, hazardous waste generators must comply with regulations concerning record keeping and reporting, must observe waste accumulation time limits, and must comply with storage requirements.¹⁷⁶

C.4.3. The Uniform Hazardous Waste Manifest System

Generators of hazardous wastes; transporters of such wastes; and operators of treatment, storage, and disposal facilities (TSDFs) must also comply with the Uniform Hazardous Waste Manifest System.¹⁷⁷ This System requires the use of a manifest process to track hazardous waste from its point of origin to its ultimate point of treatment or disposal (i.e., “cradle to grave”).¹⁷⁸ Transporters of hazardous waste must also meet requirements established by the Department of Transportation.¹⁷⁹ For example, regulations implementing the Hazardous Materials Transportation Act require (a) labeling, (b) placarding, (c) proper containers for hazardous materials, and (d) the development of emergency (spill) response procedures.¹⁸⁰

C.4.4. Treatment, Storage and Disposal Facilities

Requirements for TSDFs are also established under RCRA. A permit is required to construct and operate a TSDF.¹⁸¹ The permit contains specific operating standards and requirements applicable to the TSDF.¹⁸² The operator of a TSDF must demonstrate financial responsibility (in case of accidents) as well as the capability to close the TSDF in accordance with EPA regulations.¹⁸³ In terms of remediation and corrective actions that might be required at a TSDF, the owner or operator is responsible for investigating and, when necessary, remediating releases from their facilities.¹⁸⁴

A number of specific limitations and prohibitions are contained in RCRA. Bulk (noncontainerized) hazardous liquid waste is prohibited from disposal in any landfill.¹⁸⁵ There are also severe restrictions on the disposal of containerized hazardous liquid waste.¹⁸⁶ Land disposal of specific highly hazardous waste was phased out between 1986 and 1990.¹⁸⁷

RCRA also establishes minimum technological standards for new landfills and surface impoundments. Requirements include: (a) double liners, (b) a leachate collection and treatment system, (c) groundwater monitoring, and (d) in general, the use of “Best Demonstrated Available Technology.”¹⁸⁸

C.4.5. The Universal Waste Rule

In 1995, EPA promulgated regulations to streamline the management of certain types of commonly occurring hazardous

¹⁷⁶ Case, *supra* note 164, at 150.

¹⁷⁷ § 262.20; Case, *supra* note 164, at 150.

¹⁷⁸ Case, *supra* note 164, at 150.

¹⁷⁹ *Id.* at 134.

¹⁸⁰ *Id.*

¹⁸¹ 40 C.F.R. § 264.1 (2010).

¹⁸² *Id.*

¹⁸³ See § 264.145; see also Case, *supra* note 164, at 161.

¹⁸⁴ Case, *supra* note 164, at 170.

¹⁸⁵ § 264.314.

¹⁸⁶ *Id.*

¹⁸⁷ Case, *supra* note 164, at 164-65.

¹⁸⁸ § 264.301; Case, *supra* note 164, at 164-65.

wastes.¹⁸⁹ These wastes (known as “universal wastes”) included batteries, certain types of lamps (*e.g.*, containing mercury), mercury-containing equipment (*e.g.*, thermostats) and certain types of pesticides. Concluding that the “current RCRA regulations have been a major impediment to national collection and recycling campaigns for these wastes,”¹⁹⁰ the Universal Waste Rule (UWR)¹⁹¹ was promulgated to “facilitate [their] environmentally sound collection and increase the proper recycling or treatment” of such wastes.¹⁹²

To achieve these goals, the UWR allowed for longer storage of covered wastes, reduced record keeping requirements and simplified the procedure for recycling such wastes. Transportation was facilitated by exempting the transport of wastes included within the UWR from the manifest requirements discussed above.

C.4.6. State Implementation

The EPA encouraged states to assume responsibility for RCRA’s hazardous waste program in part by providing financial assistance.¹⁹³ At the present time, all but two of the states have been granted authority to implement the RCRA program.¹⁹⁴

C.5. Protection of Groundwater and Surface Water Quality by Regulating Toxic Substances: The Toxic Substance Control Act

In 1971, the Council on Environmental Quality (CEQ) recommended comprehensive legislation to identify and control chemicals whose manufacture, processing, distribution, use, and/or disposal was potentially dangerous and not adequately regulated under other environmental statutes.¹⁹⁵

The result, the Toxic Substances Control Act (TSCA), was signed into law by President Ford on October 11, 1976.¹⁹⁶

Title I of TSCA focuses on the control of toxic substances. Manufacturers and processors are required to conduct tests of existing chemicals if (a) the manufacture, distribution, processing, use or disposal of the chemicals may present an unreasonable risk of injury to health or the environment; (b) the chemicals are or will be produced in substantial quantities and the potential for environmental release or human exposure is substantial or significant; and (c) existing data are inadequate to predict the effects of human exposure and environmental releases.¹⁹⁷ The required testing may be based on risk triggers (chemical toxicity, etc.), exposure triggers (long-term, low-level exposure) or both.¹⁹⁸ Chemicals known or suspected to be carcinogenic, mutagenic or teratogenic are to be assigned a higher priority for testing.¹⁹⁹

¹⁸⁹ Universal Waste Rule (Hazardous Waste Management System; Modification of the Hazardous Waste Recycling Regulatory Program); 60 Fed. Reg. 25492 (May 11, 1995).

¹⁹⁰ *Id.* at 25492.

¹⁹¹ 40 C.F.R. Part 273.

¹⁹² 60 Fed. Reg. at 25492.

¹⁹³ RCRA § 6947.

¹⁹⁴ It appears that Alaska and Iowa have not been granted authority to implement the RCRA program. *See* Environmental Protection Agency, Wastes-Laws & Regulations-RCRA State Authorization: State Authorization Federal Register Notices and Authorization Activity, http://www.epa.gov/osw/lawsregs/state/stats/stats_safrn.htm (last visited Sept. 10, 2010).

¹⁹⁵ This recommendation was contained in the CEQ report *Toxic Substances* (1971). Linda Schierow, CONGRESSIONAL RESEARCH SERVICES, SUMMARY OF ENVIRONMENTAL LAWS ADMINISTERED BY THE EPA, *available at* <http://ncseonline.org/nle/crsreports/briefingbooks/laws/k.cfm> (last visited July 18, 2010).

¹⁹⁶ Toxic Substance Control Act (TSCA), Pub. L. No. 94-469, 90 Stat. 2003 (codified as amended at 15 U.S.C. §§ 2601-1692(2006)); Stanley W. Landfair, *Toxic Substance Control Act*, in ENVIRONMENTAL LAW HANDBOOK 607, 607 (Thomas F.P. Sullivan ed., Government Institutes 19th ed. 2007).

¹⁹⁷ TSCA § 2603; Landfair, *supra* note 196, at 644.

¹⁹⁸ Landfair, *supra* note 196, at 644.

¹⁹⁹ *See id.* at 643.

C.5.1. The Inventory

The EPA is required to develop and maintain an inventory of all chemicals, or categories of chemicals, manufactured or processed in the United States.²⁰⁰ All chemicals not on the Inventory are, by definition, “new” and are subject to the Pre-Manufacture Notification requirements.²⁰¹

In 2008, the EPA initiated a phased, multi-year program to obtain health and safety information from manufacturers and processors of inorganic, high-production volume (HPV) chemicals.²⁰² Such information on 2,200 organic chemical HPV chemicals has already been obtained by the EPA.²⁰³

C.5.2. Pre-Manufacture Notification

With limited exceptions, manufacturers, importers, and processors of chemicals not listed in the inventory are required to notify the EPA at least 90 days prior to producing a new chemical product into the United States.²⁰⁴ The EPA then has 45 days to evaluate the potential risk posed by the new chemical product.²⁰⁵ If the EPA determines that the new chemical product presents or will present an unreasonable risk of injury to human health or the environment, then requirements to protect against such risks must be promulgated. If data are inadequate to make an informed judgment, the EPA may prohibit or limit the use of the new chemical product until sufficient information has been submitted.²⁰⁶

C.5.3. Regulatory Controls

The TSCA requires the EPA to regulate the manufacturing, processing, distribution, use, and disposal of a chemical if it will present an unreasonable risk of injury to health or the environment.²⁰⁷ This authority allows EPA to: (a) prohibit or limit the amount of production or distribution of a chemical; (b) prohibit or limit the production or distribution of a chemical for a particular use; (c) limit the volume or concentration of the chemical produced; (d) prohibit or regulate the manner or method of commercial use; (e) require warning labels and/or instructions on containers or products; (f) require notification of the risk of injury to distributors and (to the extent possible) consumers; (g) require record-keeping by producers; (h) specify disposal methods; and (i) require replacement or repurchase of products already distributed.²⁰⁸ However, the EPA is to exercise this authority only “to the extent necessary to protect adequately” against a risk. Furthermore, the EPA is to use the “least burdensome” regulatory approach, even when unreasonable risks are being controlled.²⁰⁹

C.5.4. Imminent Hazards

The TSCA also authorizes the EPA to take emergency action through federal courts to control a chemical substance or mixture which presents an imminent and unreasonable risk of serious, widespread injury to human health or the environment²¹⁰

²⁰⁰ TSCA § 2607(b)(1).

²⁰¹ See *id.* §2607(b); see also Landfair, *supra* note 196, at 611.

²⁰² High Production Volume (HPV) Challenge Program, <http://www.epa.gov/hpv> (last visited Sept. 9, 2010).

²⁰³ *Id.*

²⁰⁴ TSCA § 2604(a)(1)(B).

²⁰⁵ *Id.* §2604(e)(1)(B).

²⁰⁶ *Id.* §2604(e)(1)(A).

²⁰⁷ *Id.* §2605(a).

²⁰⁸ *Id.*

²⁰⁹ *Id.*

²¹⁰ *Id.* § 2606(b)(1).

C.6. *Protection of Species: The Endangered Species Act*

Perhaps the best known of the federal species protection statutes, the Endangered Species Act (ESA) ²¹¹ essentially prohibits any federal agency from taking any action (including destruction of “critical habitat”) that would jeopardize the continued existence of a threatened or endangered plant or animal species. As more fully discussed below, the ESA also prohibits all parties (both public and private) from undertaking actions that would result in the “taking” of a threatened or endangered species. ²¹²

The purposes of the ESA are “to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, [and] to provide a program for the conservation of such endangered species and threatened species[.]”

²¹³ In order to achieve these goals, Congress established the policy that “all Federal departments and agencies shall seek to conserve

endangered species and threatened species and shall utilize their authorities in furtherance of the purposes of this chapter.” ²¹⁴ In essence, the ESA was intended to protect threatened and endangered species virtually irrespective of the cost of the protection. ²¹⁵

C.6.1. *“Taking” Endangered Species*

With only limited exceptions, Congress prohibited the “taking” of an “endangered” ²¹⁶ plant or animal species. ²¹⁷ Fish and Wildlife Service regulations extending these provisions to “threatened” ²¹⁸ species were sustained when challenged as a reasonable and permissible interpretation of the ESA. ²¹⁹

Concurrent with the determination that a species is endangered or threatened, the Secretary of the Interior must designate critical habitat. ²²⁰

²¹¹ See generally Endangered Species Act (ESA), Pub. L. No. 93-205, 87 Stat. 884 (codified as amended at 16 U.S.C. §§ 1531-1544 (2006)).

²¹² ESA § 1538(a)(1).

²¹³ *Id.* § 1531(b).

²¹⁴ *Id.* § 1531(c)(1).

²¹⁵ See *Tennessee Valley Authority v. Hill*, 437 U.S. 153 (1978) (holding that the protection of the endangered snail darter under the ESA could preclude completion of a water project). ²¹⁶ Endangered species are defined as “any species which is in danger of extinction throughout all or a significant portion of its range other than a species of the Class Insecta determined by the Secretary to constitute a pest whose protection under the provisions of this chapter would present an overwhelming and overriding risk to man.” ESA §1532(6).

²¹⁷ In relevant part, the ESA provides that “with respect to any endangered species of fish or wildlife listed pursuant to ... this title it is unlawful for any person subject to the jurisdiction of the United States to ... (B) take any such species within the United States or the territorial sea of the United States ... or (G) violate any regulation pertaining to such species or to any threatened species of fish or wildlife listed pursuant to ... this title.” ESA § 1538(a)(1). Furthermore, “with respect to any endangered species of plants listed pursuant to ... this title, it is unlawful for any person subject to the jurisdiction of the United States to ... (B) remove and reduce to possession any such species from areas under Federal jurisdiction; maliciously damage or destroy any such species on any such area; or remove, cut, dig up, or damage or destroy any such species on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law ... or (E) violate any regulation pertaining to such species or to any threatened species of plants listed pursuant to ... this title....” *Id.* § 1538(a)(2).

²¹⁸ Threatened species are defined as “any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.” *Id.* § 1532(20).

²¹⁹ *Sweet Home Chapter of Communities for a Great Oregon v. Lujan*, 806 F. Supp. 279 (D.D.C. 1992), *aff’d sub nom Sweet Home Chapter of Communities for a Great Oregon v. Babbitt*, 1 F.3d 1 (D.C. Cir. 1993), *modified*, 17 F.3d 1463 (D.C. Cir. 1994), *rev’d*, 515 U.S. 687 (1995).

²²⁰ In making a determination regarding the designation of critical habitat, the Secretary

shall designate critical habitat ... on the basis of the best scientific data available and after taking into consideration the economic impact, and any other relevant impact, of specifying any particular area as critical habitat. The Secretary may exclude any area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific and commercial data available, that the failure to designate such

With regard to the “taking” of an endangered or threatened species, the definition of “take” is noteworthy: “The term ‘take’ means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct.”²²¹ To conclude that the definition of “take” is quite broad would be an understatement. Registration of a pesticide by the EPA, for example, was considered a “taking” since endangered species were poisoned by the pesticide.²²² Forest management practices of the Forest Service, which resulted in harm to an endangered species, constituted a “taking” in *Sierra Club v. Lyng*.²²³

C.6.2. Interagency Coordination

Federal agencies are required to insure that agency actions are not likely to jeopardize the continued existence of a threatened or endangered species.²²⁴ Such agencies are also required to insure that agency actions do not result in the destruction or adverse modification of critical habitat.²²⁵ In this context, “agency action”

includes: (a) actions authorized by a federal agency (*e.g.*, through the issuance of permits or licenses); (b) actions funded by federal agencies; and (c) actions undertaken by the agency itself.²²⁶

In order to fulfill this requirement, agencies are required to “use the best scientific and commercial data available.”²²⁷ Agencies are also required to act “in consultation with and with the assistance of” the Secretary of the Interior.²²⁸

D. Alternative Strategies:

As an alternative to a regulatory approach, there are a number of possibilities that could be utilized to address the presence of PPCPs in water supplies through source control.²²⁹ These possibilities fall generally into six categories: drug design, drug delivery, drug marketing, drug dispensing, drug disposal/recycling, and drug alternatives.²³⁰ While these categories focus primarily on pharmaceuticals, they apply equally to personal care products and

area as critical habitat will result in the extinction of the species concerned.

ESA § 1533(b)(2).

²²¹ *Id.* §1532(19).

²²² *Defenders of Wildlife v. Administrator, EPA*, 882 F.2d 1294 (8th Cir. 1989).

²²³ *Sierra Club v. Lyng*, 694 F. Supp. 1260 (E.D. Tex. 1988), *aff’d in part, vacated in part*, 926 F.2d 429 (5th Cir. 1991).

²²⁴ ESA § 1536(a)(2).

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ *Id.*

²²⁸ *Id.*

²²⁹ The need for source control has been stressed in a number of studies. *See, e.g.*, the recommendations of a 2008 study by the School of Public Health and Health Services at The George Washington University included:

An emphasis on controlling the discharge of contaminated water at the *source*, rather than treatment at the point of use. This would be safer for the environment, while reducing the burden on downstream drinking water treatment plants.

Rapid Public Health Policy Response Project, *supra* note 26, at 6 (citing U.S. Environmental Protection Agency, SOURCE WATER PROTECTION). *See also* Keith J. Jones, *Endocrine Disruptors and Risk Assessment: Potential for a Big Mistake*, 17 VILLANOVA ENVIRONMENTAL LAW JOURNAL 357, 386 (2006) (“It might be more feasible to ban the use of an endocrine disruptor or otherwise prevent it from reaching source water (*e.g.*, source water protection programs) rather than try to remove it from drinking water.”).

²³⁰ The structure of this section and the concepts described herein are based on Christian G. Daughton, *Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health. II. Drug Disposal, Waste Reduction, and Future Directions*, 111 ENVIRONMENTAL HEALTH PERSPECTIVES 775 (2003) [hereinafter Daughton, *Drug Disposal, Waste Reduction, and Future Directions*]. *See also* the section on “source water protection” in Snyder et al., *supra* note 47, at 34.

the full array of PPCPs previously identified in footnote 6.²³¹

D.1. Drug Design

The environmental impacts of drug use, such as the excretion of PPCPs in both human and animal wastes, should be considered as new drugs are being designed or formulated. While maintaining or improving therapeutic efficacy, the chemical structure, properties, and formulation (combinations of active and inactive ingredients) of new drugs could focus on “maximizing their susceptibility to biodegradation, photolysis, or other physicochemical alterations to yield innocuous end products.”²³² The need for such an approach was described by Wennmalm and Gunnarsson:

[I]t appears urgent that future drugs not be persistent. Presently, several frequently used drugs have half-lives in surface water exceeding one year or more. Residues of such drugs may reach concentrations in surface or ground water near urban areas of 100 nanograms/litre or more before a kinetic balance between supply of new drug residues from sewage treatment plant effluents and biodegradation in the aquatic medium has been reached. Such high concentrations are not readily eliminated in processes aimed at purifying the water to be drinkable. Thus, significant concentrations of bioactive drug residues may appear in drinking water.²³³

In this context, it should be noted that the U.S. Food and Drug Administration mandates environmental risk assessments for new pharmaceuticals having a predicted environmental concentration of more than 1 µg/L.²³⁴

It would be possible to design drugs to improve the physiologic sorption characteristics of the drug. This would result in a reduction in the amount of the drug ultimately excreted. This possibility is “being pursued on many fronts[.]”²³⁵

Daughton notes that the “advancing ‘omnics’ revolution”²³⁶ could lead to the design of drugs that specifically target certain groups of patients. This could have the effect of reducing the use of drugs having similar therapeutic effects by the general population.²³⁷ If use of drugs resulting in the excretion of PPCPs by the general population was reduced, then the quantity of PPCPs entering water supplies would also be reduced.

Other drug design possibilities could include the development of drugs that maintain their therapeutic effectiveness despite substantially reduced dosage levels²³⁸ as well as the development of “smart” drugs that “better emulate the nonanthropocentric, native chemistries of natural products.”²³⁹

²³¹ See *supra* note 6.

²³² Daughton, *Rationale for and Avenues toward a Green Pharmacy*, *supra* note 230, at 765.

²³³ Wennmalm & Gunnarsson, *supra* note 41, at 295-296 (citing Ettore Zuccato et al., *Environmental loads and detection of pharmaceuticals in Italy*, in *PHARMACEUTICALS IN THE ENVIRONMENT* 23-24 (K. Kümmerer ed., Springer Verlag 2001)).

²³⁴ Snyder et al., *supra* note 47, at 34.

²³⁵ Daughton, *Rationale for and Avenues toward a Green Pharmacy*, *supra* note 230, at 765 (citing Joe Alper, *Breaching membranes*, 296 *SCIENCE* 838 (2002)) (regarding the creation of *in situ* synthetic transporters as well as work by XenoPort, Inc. of Santa Clara, California regarding “better drug design to accommodate existing membrane transporters[.]”).

²³⁶ This would include genomics (the study of genes and their functions), proteomics (the study of proteins and their functions), glycomics (study of the structure and function of sugars and saccharides) and metabolomics (the study of metabolites and their functions). See generally Cambridge Healthtech Institute, -Omes and -omics Glossary & Taxonomy: Evolving Terminology for Emerging Technologies, <http://www.genomicglossaries.com/content/omes.asp> (last visited Mar. 1, 2011).

²³⁷ Daughton, *Rationale for and Avenues toward a Green Pharmacy*, *supra* note 230, at 765.

²³⁸ *Id.* at 766.

²³⁹ *Id.*

D.2. Drug Delivery

The first step in the drug delivery system identified by Daughton as playing a role vis-à-vis PPCPs in water supplies is the prescribing of drugs. Both physicians and patients need to be better informed of the consequences of using specific drugs,²⁴⁰ particularly both the “medical and environmental consequences of overprescribing medications.”²⁴¹

Numerous studies have shown that “the therapeutically effective dose for many drugs can be significantly lower than that initially recommended by the manufacturer.”²⁴² In fact, Cunningham, et al., have noted, “[t]he preferred safety profile for human pharmaceuticals is that the desired therapeutic response is the lowest effect observed (i.e., at the lowest dose).”²⁴³ With regard to drugs whose use results in the excretion of PPCPs, lowering the dosage to the therapeutically effective level, rather than the level recommended by the manufacturer, could have the result of reducing the quantity of PPCPs entering water supplies.²⁴⁴

The same result could be achieved through more precise formulation and dosing of drugs.²⁴⁵ Related to this would be “individualization of therapy,” which would require drug manufacturers to “provide the medical community with more easily implementable information (and requisite unit doses) to tailor drug dosages for the individual.”²⁴⁶

The development of alternative drug delivery mechanisms is another suggested means of improving the efficiency of drug use. This could include “better targeted delivery routes (*e.g.*, expanding the utility of pulmonary and transdermal/mucosal delivery), mechanisms of release (*e.g.*, rapid-dissolving formulations, controlled release), and mechanisms for delivery of drugs to the target (*e.g.*, antibody-linked drugs; *in situ* implants).”²⁴⁷

With regard to the delivery of drugs, the role of patient education cannot be overstated. As noted by Daughton, it is quite common for patients to “fail to finish their courses of medication[.]”²⁴⁸ As a result, unused (and perhaps outdated) drugs accumulate and eventually require disposal. If patients completed

²⁴⁰ Wennmalm and Gunnarsson describe such an approach in Sweden as well as actions taken by the Stockholm County Council to implement it:

Despite the fact that pharmaceuticals may have adverse environmental effects, no information on such effects is easily available to prescribing doctors. We have developed a model for easy but accurate evaluation of the environmental effects of drugs, aimed at helping doctors to make an environmentally-conscious selection between medically equivalent drugs with different environmental impacts. Health care professionals have expressed much interest in the classification system and the Stockholm County Council has decided that the environmental score of each pharmaceutical obtained in the classification shall be one variable for consideration when its list of recommended pharmaceuticals is revised.

Wennmalm, & Gunnarsson, *supra* note 41, at 294-295.

²⁴¹ Daughton, *Rationale for and Avenues toward a Green Pharmacy*, *supra* note 232, at 766.

²⁴² *Id.* at 767.

²⁴³ Cunningham, Binks, & Olson, *supra* note 41, at 43.

²⁴⁴ *Id.*:

For a given use rate by the population, only low production volumes are needed for potent pharmaceuticals. For the same population use rate, a high therapeutic dose requires more production. So, the total amount of an API [active pharmaceutical ingredient] entering the environment is generally inversely correlated to its potency.

Id. at 44.

²⁴⁵ Daughton, *Rationale for and Avenues toward a Green Pharmacy*, *supra* note 230, at 767.

²⁴⁶ Daughton notes that “individualization of therapy” is particularly relevant with regard to long-term maintenance drugs. *Id.*

²⁴⁷ *Id.* (citing Mona Mort, *Multiple Modes of Drug Delivery*, 3 MODERN DRUG DISCOVERY 30 (2000)).

²⁴⁸ *Id.* at 768 (citing Daughton, *Drug Disposal, Waste Reduction, and Future Directions*, *supra* note 230).

courses of medication as prescribed, the quantity of drugs inappropriately disposed of would be reduced. This could reduce the quantity of PPCPs entering water supplies.

Of equal importance is education of the medical community regarding both appropriate dosages of specific drugs and appropriate disposal mechanisms. Daughton advocates the use of continuing education programs involving both the medicine and environmental science to teach the importance of “cradle-to-cradle stewardship” of medications.²⁴⁹

D.3. Drug Marketing

As noted above, patient education is a critical factor. The importance of the role of drug marketing in educating both the patient and the public cannot be overstated. For example, Daughton notes that the packaging of both over-the-counter (nonprescription) and prescription drugs in the United States does not provide guidance for the disposal of any unused portion of the medication.²⁵⁰ Guidance may also be missing regarding the ingestion of different drugs having the same mechanism of action or the same drug from different sources, both of which may result in a cumulative dose in excess of therapeutic requirements.²⁵¹ This problem may be exacerbated by different drugs having a similar name or appearance.²⁵²

With regard to the disposal of drugs, both the size and integrity of drug packaging may play a role. Daughton notes, for example, that a broader selection of package sizes could result in a reduction in the quantity of drugs that are ultimately discarded.

²⁵³ This quantity could also be reduced if improved packaging extended the shelf-life of drugs.²⁵⁴

Finally, the role of drug advertising must be considered. Such advertising substantially influences consumer decisions regarding the use of both over-the-counter (nonprescription) and prescription drugs. Different types of advertising may also influence the medical community. Because of this, Daughton argues that such advertising should “include information for the public regarding the proper disposition of unused products and the imperative for environmental stewardship.”²⁵⁵

D.4. Drug Dispensing

There are any number of means by which both legal and illegal drugs are dispensed. Sale of drugs via the Internet, for example, will “undoubtedly [lead] to overdispensing and dispensing without a prescription[,]” which could have the effect of contributing to the overall environmental exposure burden caused by such drug use.²⁵⁶

This is particularly true with regard to the distribution of black-market and counterfeit drugs, some 25% of which are sold via the Internet.²⁵⁷ In addition to potential health benefits, reducing the quantity of such drugs sold online would also reduce the quantity of such drugs entering the environment either through excretion or disposal.

With regard to the disposal of drugs, a number of issues relate to expiration dates, after which drugs are no longer considered effective. Daughton notes that expiration dates should be based on actual, empirical data regarding stability duration rather than on

²⁴⁹ Daughton, *Rationale for and Avenues toward a Green Pharmacy*, *supra* note 230, at 768.

²⁵⁰ *Id.*

²⁵¹ “This multiple-exposure pathway scenario is especially problematic when patients are prescribed medications by multiple physicians; for patients with multiple health care providers, poor communication can also lead to represcribing of medication that has already been shown for the patient to be nonefficacious.” *Id.*

²⁵² *Id.* at 768-769 (citing Committee on Quality of Health Care in America, Institute of Medicine, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn, Janet M. Corrigan, & Molla S. Donaldson eds., National Academy Press 2000)). “Although these problems can jeopardize patient safety, they also lead to unnecessary (and inappropriate) use of drugs and their eventual discharge to the environment, as well as to the purchase of medications that might not have been made by a betterinformed consumer.” *Id.* at 769.

²⁵³ *Id.* at 769.

²⁵⁴ *Id.*

²⁵⁵ *Id.*

²⁵⁶ *Id.* (citing U.S. Food and Drug Administration, *BUYING MEDICINES AND MEDICAL PRODUCTS ONLINE* (2002)).

²⁵⁷ Daughton, *Rationale for and Avenues toward a Green Pharmacy*, *supra* note 230, at 769 (citing Cyveillance, *Cyveillance Partners with Biocode to Serve Pharmaceutical Industry* [press release] (2001)).

the recommendations of specific drug manufacturers.²⁵⁸

The need to dispose of unwanted drugs could also be reduced if more disciplined dispensing and inventory control protocols were developed. Both pharmacies and consumers could be encouraged to minimize their drug inventories in order to minimize the quantity of unwanted or unneeded drugs needing disposal.²⁵⁹ For example, the need to dispose of specific drugs would be reduced if the quantity either purchased or prescribed could be utilized completely prior to the expiration date of the drug. The disposal need could also be reduced if “[r]easonable, minimal quantities of medication could be purchased or prescribed until the effects of the medication and its therapeutic effectiveness are understood by both the physician and patient.”²⁶⁰

Daughton makes two additional points regarding drug dispensing vis-à-vis PPCPs in water supplies. First, the use of drugs for purposes not originally intended requires both vigilance and ongoing review, particularly if such use results in the introduction of PPCPs into water supplies.²⁶¹ Second, a nationwide database of drug sales is needed. This database, which should be publically accessible, would compile and track

the sale and use of both over-the-counter (nonprescription) and prescription drugs. Daughton concludes that such a database “would be extremely useful for predicting the actual quantities of drugs that could be entering the environment (by using pharmacokinetic models based on ADME/Tox – adsorption, distribution, metabolism, excretion, and toxicity).”²⁶²

D.5. Drug Disposal/Recycling

The need for appropriate disposal or recycling of pharmaceuticals has been noted repeatedly.²⁶³ A number of suggestions have been offered to encourage such disposal or recycling programs. Daughton, for example, has suggested that an appropriate incentive for drug companies to implement drug disposal/recycling programs “would be to offer patent extensions to companies that formulate vibrant, comprehensive stewardship programs tailored for each particular drug.”²⁶⁴ Daughton has also suggested that the role of “reverse distributors” currently being used by pharmacies in the United States for the return of unsold or expired drugs be expanded “into a larger, comprehensive disposal/recycling program, one that accommodates the consumer sector.”²⁶⁵ Such an expansion might also include drug

²⁵⁸ “Scientifically sound protocols need to be implemented for the public sector to define, determine, predict, and/or monitor actual expiration periods for both factory-sealed and unsealed drugs.” Daughton, *Rationale for and Avenues toward a Green Pharmacy*, *supra* note 230 at 770.

²⁵⁹ *Id.*

²⁶⁰ *Id.*

²⁶¹ For example, “[t]he long-running debates regarding the use of subtherapeutic antibiotics and of anabolic steroids in animal feed have resulted in a number of actions in certain countries to reduce or abolish their use.” *Id.* at 771.

²⁶² *Id.* (citing Christian G. Daughton, U.S. Environmental Protection Agency, *Factors Complicating Prediction of Drug Elimination from the Body* (2002)).

²⁶³ See, e.g., TDC Environmental, *supra* note 49, at 2; Christenson, *supra* note 172, at 164-166 (reviewing programs in Arizona, Arkansas and Wisconsin).

²⁶⁴ Daughton, *Drug Disposal, Waste Reduction, and Future Directions*, *supra* note 230, at 776.

²⁶⁵ *Id.* See also TDC Environmental, *supra* note 49:

U.S. EPA has authorized reverse distribution of pharmaceuticals without hazardous waste management permits. The U.S. EPA authorization specifically requires the returns industry not to be used as a “waste management system” (U.S. EPA, 1981; U.S. EPA, 1991). Any items that are inherently “waste-like” (like a broken container or contaminated prescription) cannot be shipped as products to a reverse distributor.

TDC Environmental, *supra* note 49, at 4-5 (citing Letter from Alan S. Corson, Chief, Waste Characterization Branch, Hazardous and Industrial Waste Division, U.S. EPA, to Steven Wittmer, Merck, Sharp & Dohme (May 13, 1981), *available at* <http://yosemite.epa.gov/OSW/rcra.nsf/Documents/F3001B817EF4265885256611005156D2>; Letter from Sylvia K. Lowrance, Director, Office of Solid Waste, U.S. EPA, to Mark J. Schulz, Browning-Ferris Industries (May 16, 1991) *available at* <http://yosemite.epa.gov/OSW/rcra.nsf/Documents/354FE6A290ED95E1852565DA006F04A1>). Accord Christenson, *supra* note 172, at 165-166. However, it should be noted that any consumer “reverse distribution” program would have to comply with the privacy requirements of the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. §201, *et seq.* TDC Environmental, *supra* note 49, at 6.

samples given to physicians because the “distributors of physician samples often instruct physicians to dispose of outdated samples to the sewage system.”²⁶⁶

Minimization of waste flows into the environment should have the effect of reducing the presence of PPCPs in water supplies. One approach could be re-engineered toilets to separate liquid and solid wastes. This could have the effect of both minimizing waste flows and reducing water supply requirements.²⁶⁷

Another approach could be “drug mining” (i.e., recovery of highly toxic drugs from excreta and other hospital wastes).²⁶⁸ However, with only limited exceptions, any subsequent use of reclaimed or recycled drugs is prohibited:

Once prescribed and given to patients, pharmaceuticals cannot be reused. State [California] and Federal law require pharmacists and pharmaceutical manufacturers to

ensure that pharmaceuticals provided to patients are pure and safe. Once a drug has left the control of a pharmacy, its storage, handling, and condition are uncertain – and therefore it cannot be assured to be pure and safe. Because there is no viable reuse for unwanted residential pharmaceuticals, they are – by definition – waste.²⁶⁹

Development of water recycling systems that allow wastewater to be upgraded for both potable and non-potable uses provides another approach to minimization of waste flows.²⁷⁰ As Daughton notes: “By use of advanced water treatment technology such as reverse osmosis, nearly complete removal of all PPCPs can be achieved.”²⁷¹ This is an issue of particular concern in arid regions, particularly the southwestern United States, where limited water supplies and growing populations virtually mandate the reuse of water.²⁷²

Improvements to wastewater collection²⁷³ and treatment²⁷⁴ systems are closely associated with the development of water

²⁶⁶ Daughton, *Drug Disposal, Waste Reduction, and Future Directions*, *supra* note 230, at 776.

²⁶⁷ *Id.* (citing Tove A. Larsen et al., *Re-engineering the Toilet for Sustainable Wastewater Management*, 35 ENVIRONMENTAL SCIENCE & TECHNOLOGY 192A (2001); Novaquatis, EAWAG (Swiss Federal Institute for Environmental Science and Technology), INNOVATIVE MANAGEMENT OF ANTHROPOGENIC NUTRIENTS IN URBAN WATER MANAGEMENT AND AGRICULTURE (2002); R. Otterpohl, Options for *Alternative Types of Sewerage and Treatment Systems Directed to Improvement of the Overall Performance*, 45 WATER SCIENCE & TECHNOLOGY 149 (2002))

²⁶⁸ *Id.* at 776 (referring to a prototype of such a system developed by Pharmaceuticals.org). See Pharmaceuticals.org, Pharmaceuticals from Human System to Human System, <http://www.toilets.com/pharmaceuticals.htm> (last visited March 1, 2011).

²⁶⁹ TDC Environmental, *supra* note 49, at 8.

²⁷⁰ Daughton, *Drug Disposal, Waste Reduction, and Future Directions*, *supra* note 232, at 776 (citing Jorge E. Drewes & Laurence S. Shore, *Concerns About Pharmaceuticals in Water Reuse, Groundwater Recharge, and Animal Waste*, in PHARMACEUTICALS AND PERSONAL CARE PRODUCTS IN THE ENVIRONMENT: SCIENTIFIC AND REGULATORY ISSUES 206 (Christian G. Daughton & Tammy L. Jones-Lepp eds., American Chemical Society 2002); Lindsey A. Greene, *Controversy Swirls Around Toilet-to-Tap Project*, 108 Environmental Health Perspectives A447 (2000)).

²⁷¹ *Id.* It should be noted, however, that “all the solutes removed by reverse osmosis are concentrated in the rejected “brine” – a waste stream that must be disposed itself.” *Id.*

²⁷² Snyder et al., *supra* note 47, at 34.

²⁷³ Collection system improvements need to address both combined sewer overflows and urban streamstormflows as these are “significant contributors of OWCs [organic water compounds] to receiving waters[.]” Phillips & Chalmers, *supra* note 86, at 56.

This in turn indicates that efforts to decrease the amounts of OWCs entering large receiving waters need to identify and treat waters that bypass normal wastewater treatment processes. Future evaluations of the annual contributions from these sources will require sampling of WWTP effluents, CSO effluents, and urban streams under differing seasons and flow conditions.

Id.

²⁷⁴ With regard to the control of PPCPs in water supplies, development of advanced wastewater treatment systems “could have the greatest potential benefit, as it would remove not only intentionally flushed drugs but also drugs that pass through the body naturally.” Christenson, *supra* note 172, at 159 (citing George J. Mannina, Jr., *Medicines and the Environment: Legal and Regulatory Storms Ahead?*, 21 LEGAL BACKGROUNDER, no. 11, 2 (March 26, 2006)).

recycling systems. Advanced wastewater treatment systems using reverse osmosis have the capability to remove PPCPs through a physical separation process.²⁷⁵ Utilization of granular activated charcoal systems, as well as ozonation, has been effective in removing antibiotics from wastewater.²⁷⁶ Engineered wetlands and groundwater infiltration basins have been suggested as mechanisms to attenuate PPCPs²⁷⁷ as has phytoremediation.²⁷⁸ At a more basic level, Daughton recommends both that “[s]traight-piping of sewage to surface waters ... continue to be identified and eliminated”²⁷⁹ and that “[p]rivies and septic systems ... be converted to municipal systems when feasible.”²⁸⁰

With regard to reducing the environmental burden caused by both the legal and illegal disposal of drugs, Daughton notes the need to revise state laws that either (a) restrict the donation of prescription drugs to charity (e.g., Oklahoma)²⁸¹ or (b) restrict or limit the authority of pharmacies to accept returns of unused drugs.²⁸²

The complexity of issues relating to PPCPs in water supplies is illustrated by Daughton’s observation that funeral practices need to be environmentally sound. Not only can burial practices

“pose problems with respect to groundwater pollution if they have not been properly engineered and sited with local hydrogeologic processes in mind,”²⁸³ but the presence of PPCPs in the bodies of the deceased “could be expected to be extensive as a result of long-term medication and heroic treatment measures.”²⁸⁴

Once again, the role of public education needs to be stressed, this time in the context of drug disposal/recycling. Daughton emphasizes the importance of public outreach programs:

A well-designed, concerted public outreach program for communicating the issues associated with PPCPs as environmental pollutants could accomplish dual aims: (a) enhance the public’s appreciation and understanding of a wide range of principles associated with environmental science, and (b) increase the public’s sense of environmental responsibility by showing how their actions as individuals collectively contribute to the burden of PPCPs in the environment, how PPCPs can possibly affect environmental processes (e.g., aquatic biota), and the collateral advantages (human health and economic) accrued by conscientious/responsible disposal and use of PPCPs.²⁸⁵

²⁷⁵ Sedlak and Pinkston, *supra* note 15, at 56. *Accord* Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 25; Heberer et al., *Removal of Pharmaceutical Residues*, *supra* note 85, at 28.

²⁷⁶ Huang et al., *supra* note 25, at 37. *Accord* Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 25, (citing Marc M. Huber et al., *Oxidation of pharmaceuticals during ozonation and advanced oxidation processes*, 36 ENVIRONMENTAL SCIENCE & TECHNOLOGY 1202 (2003)).

²⁷⁷ Sedlak and Pinkston, *supra* note 15, at 65.

²⁷⁸ N. Gujarathi & J. Linden, *Potential for Phytoremediation of Antibiotic-Contaminated Water*, 24 *Agronomy News* 9 (2004).

²⁷⁹ Daughton, *Drug Disposal, Waste Reduction, and Future Directions*, *supra* note 230, at 776 (citing Sue Anne Pressley, *North Carolina Effort Seeks to Wipe Out Outhouses*, WASHINGTON POST, Apr. 25, 1999, at A3).

²⁸⁰ *Id.*

²⁸¹ *Id.* at 776-77 (citing College of Osteopathic Medicine, Oklahoma State University, PRESCRIPTION MEDICINES AND NURSING HOME: A PROBLEM ... A SOLUTION, HEALTH AND MEDICINE ISSUE PAPER (2000); and College of Osteopathic Medicine, Oklahoma State University, PRESCRIPTION MEDICINES AND NURSING HOMES: LAWS - LETTERS - REPORTS - POLICIES. AN ISSUE PAPER RESOURCE SUPPLEMENT (2000)).

²⁸² *Id.* at 777.

²⁸³ *Id.* (citing Croukamp, Environmental-, Engineering- and Marine-Geoscience Division, Council for Geoscience, CEMETERY SITE INVESTIGATIONS (1999)).

²⁸⁴ *Id.*

²⁸⁵ *Id.*

D.6. Drug Alternatives

A condition precedent to the release of PPCPs into water supplies is the use of PPCPs. It is both obvious and frequently overlooked that a reduction in the use of PPCPs would also reduce the quantity of PPCPs released into water supplies. Daughton notes, for example, that nutrition and health maintenance programs, by reducing the incidence of diseases requiring treatment, also reduce the release of PPCPs associated with such treatment.²⁸⁶

When treatment is required, use of alternative drugs (*i.e.*, drugs not containing PPCPs) should be considered. As an example, Daughton notes that there is a “wide range of medical uses of probiotics” (beneficial, endogenous microflora).²⁸⁷ Such “bacteriotherapy” may achieve the same results as the use of drugs containing PPCPs but without the attendant excretion or disposal problems.²⁸⁸

²⁸⁶ *Id.* In terms of reducing the use of PPCPs, Daughton suggest that “more research could be directed at reducing (or eliminating) drug dosages via the use of placebos.” *Id.* (citing Damaris Christensen, *Medicinal Mimicry: Sometimes, Placebos Work – But How?* 159 SCIENCE NEWS 74 (2001); Andrew F. Leuchter et al., *Changes in Brain Function of Depressed Subjects During Treatment with Placebo*, 159 AMERICAN JOURNAL OF PSYCHIATRY 122 (2002)).

²⁸⁷ *Id.* (citing Bob Beale, *Probiotics: Their Tiny Worlds are Under Scrutiny*, 16 SCIENTIST 20 (2002)).

²⁸⁸ As an example, Daughton notes that probiotics “have long been used and studied for the protection of the gut” because of the capability of probiotics to block pathogen adhesion. *Id.* (citing Indu Pal Kaur et al., *Probiotics: Potential Pharmaceutical Applications*, 15 EUROPEAN JOURNAL OF PHARMACEUTICAL SCIENCES 1 (2002)).

²⁸⁹ All of the sites involved in this research had been subjected to disposal of treated waste water effluent through land application by the City of Lubbock’s municipal waste water treatment facility, in some cases, for the past 70 years. These sites were ideal for this type of study, in part, because there are very few discharges of treated waste water effluent “upstream” of the City of Lubbock’s chief sources of municipal fresh water, which include Lake Meredith on the Canadian River and the Ogallala Aquifer. The effects of being located downstream of a waste water treatment are discussed *supra* note 80, and accompanying text.

²⁹⁰ Monteiro & Boxall express concern “over the potential impacts of biosolid-associated pharmaceuticals on terrestrial systems and associated groundwaters and surface waters[,]” Monteiro & Boxall, *supra* note 53, at 2546, noting:

- “In biosolids destined for land application, a number of pharmaceuticals and personal care products have been detected.” *Id.* (citing Chad A. Kinney et al., *Survey of Organic Wastewater Contaminants in Biosolids Destined for Land Application*, 40 ENVIRONMENTAL SCIENCE & TECHNOLOGY 7207 (2006); Chris D. Metcalfe et al., *Distribution of Acidic and Neutral Drugs in Surface Waters Near Sewage Treatment Plants in the Lower Great Lakes, Canada*, 22 ENVIRONMENTAL TOXICOLOGY & CHEMISTRY 2881 (2003)).
- “Other studies have detected pharmaceuticals in biosolid-amended soils.” *Id.* (citing Chad A. Kinney et al., *Bioaccumulation of Pharmaceuticals and Other Anthropogenic Waste Indicators in Earthworms from Agricultural Soil Amended with Biosolid or Swine Manure*, 42 ENVIRONMENTAL SCIENCE & TECHNOLOGY 1863 (2008); Eva M. Golet et al., *Determination of Fluoroquinolone Antibacterial Agents in Sewage Sludge and Sludge-treated Soil Using Accelerated Solvent Extraction Followed by Solid-phase Extraction*, 64 ANALYTICAL CHEMISTRY (2002)).

²⁹¹ As noted previously, this is an increasing concern in areas of the world where reclaimed wastewater is being used for irrigation. Kinney et al. addressed this issue:

As the range of uses and number of demands for potable water has increased, alternatives to using drinking water for agricultural and landscape irrigation have been of increasing interest. Reclaimed water is gaining use for irrigation; however, little is known

E. Case Study Based on Project 2 Results:

The Project 2 research focused on the presence of PPCPs in soil and groundwater in West Texas.²⁸⁹ As more thoroughly discussed below, this research focused on four inter-related research topics: (a) the sorption of PPCPs in different types of soils; (b) the degradation of PPCPs in soil under aerobic and anaerobic conditions; (c) the degradation of PPCPs in soil with high water content; and (d) the presence of PPCPs in a wastewater treatment plant and in both soil and groundwater at sites to which treated wastewater had been applied.²⁹⁰

As noted in Section II, the research is relevant to the issue of PPCPs in water supplies because of disposal methods used by wastewater treatment plants for both solid and liquid wastes.²⁹¹ Solid wastes (sludge or biosolids) and liquid wastes are applied to

lands that have been designated as application sites. The waste products then are degraded by natural processes.

An emerging concern is the sufficiency of natural processes to degrade PPCPs before they migrate through the soils into groundwater or bioaccumulate in species inhabiting the soil environment.²⁹² With regard to the effects of bioaccumulation of PPCPs, specifically triclosan (TCS), Lozano *et al.* concluded:

Since TCS is a bacteriostat, there is a real potential that concentrations in soils resulting from biosolid applications might affect bacterial ecology of these systems. Especially since the ecological balance and competitive advantages of the multiple species inhabiting any soil environment are very complex and any small advantage one microbe might achieve due to exposure to these known bacteriostat could be amplified under these conditions.²⁹³

*E.1. Sorption of Estrogens, Triclosan, and Caffeine in a Sandy Loam and a Silt Loam Soil*²⁹⁴

Simply stated, sorption is the process by which one substance attaches to or holds another substance. Karnjanapiboonwong *et al.*'s research focused on the sorption of sample PPCPs in different types of soil.

The sample PPCPs were estrogens (estrone, 17-estradiol, estriol and 17-ethynylestradiol)²⁹⁵ triclosan,²⁹⁶ and caffeine.²⁹⁷ The PPCPs were contained in biosolids produced from a municipal wastewater treatment plant. The soil types were a sandy loam

collected in Terry County, Texas and a silt loam collected in Harlan County, Nebraska. As a control, laboratory sand was used.

The results of the study indicated that sorption capacity was a function of the organic carbon content of the soils. The silt loam, having the highest organic carbon content, also had the greatest sorption capacity. The laboratory sand, having the lowest organic carbon content, also had the least sorption capacity.

In terms of the sample PPCPs, estrone, 17-estradiol, 17-ethynylestradiol, and triclosan had a strong tendency to sorb to the test soils. Once sorbed, the tendency of these substances to desorb and migrate into groundwater was minimal. The same could not be said for estriol and caffeine, both of which had the potential to migrate into groundwater if soil leaching occurred.

*E.2. Microbially Mediated Degradation of Common Pharmaceuticals and Personal Care Products in Soil Under Aerobic and Anaerobic Conditions*²⁹⁸

The City of Lubbock, Texas, disposes of treated effluent from its municipal wastewater treatment plant by applying it to lands designated a land application site. This site received an average of 13 million gallons per day of effluent, which was applied to the land using 31 center pivot sprinklers. Soil samples were collected from areas irrigated by the sprinklers (exposed soils) and from adjacent areas that had not been exposed to the treated effluent (unexposed soils).

about the potential for contamination of surface water and groundwater by use of this source.

Kinney *et al.*, *supra* note 26 (citing H. Bouwer *et al.*, *Integrating Water Management and Re-use: Causes for Concern?* 1-2 *Water Quality International* 19 (1999)).

²⁹² *Id.* (organic wastewater contaminants “might accumulate in soil if introduced through irrigation water”).

²⁹³ Lozano *et al.*, *supra* note 87, at 764.

²⁹⁴ Adcharee Karnjanapiboonwong *et al.*, *Sorption of Estrogens, Triclosan, and Caffeine in a Sandy Loam and a Silt Loam Soil*, 10 *JOURNAL OF SOILS AND SEDIMENTS* 1300 (2010).

²⁹⁵ Estrone, 17 β -estradiol and estriol are naturally-occurring estrogens while 17 α -ethynylestradiol is a synthetic estrogen commonly used in birth control pills. Research has indicated that 17 α -ethynylestradiol may disrupt the reproductive capabilities of a number of different species. *Id.*

²⁹⁶ Triclosan is an antibacterial agent found in a number of consumer products such as soaps and cleaning supplies. Concern has been expressed that the presence of triclosan in water supplies may be causing bacteria to develop immunities to antibiotics. It has also been suggested that triclosan in combination with chlorine may form chloroform, a known carcinogen. *Id.*

²⁹⁷ The presence of caffeine usually indicates the presence of human waste products as no other animal consumes or excretes caffeine. *Id.*

²⁹⁸ Deborah L. Carr, Audra N. Morse, John C. Zak & Todd A. Anderson, *Biological Degradation of Common Pharmaceuticals and Personal Care Products in Soils with High Water Content*, *WATER, AIR & SOIL POLLUTION* (forthcoming).

The researchers identified numerous PPCPs in the treated effluent, including estrogens (estrone, 17-estradiol, estriol and 17-ethynylestradiol), triclosan, ibuprofen,²⁹⁹ and ciprofloxacin.³⁰⁰ The rate of degradation of these PPCPs was calculated under aerobic and anaerobic conditions for PPCPs introduced into both exposed and unexposed soils.

The degradation rates for specific substances varied with soil type and with aerobic/anaerobic condition. The most notable finding was that, under anaerobic conditions, the degradation rate increased in exposed soils.

E.3. Biological Degradation of Common Pharmaceuticals and Personal Care Products in Soils with High Water Content³⁰¹

This element of this case study addressed the movement of water through soils. As noted by the researchers, soil texture affects the movement of water, with more finely textured soils holding water in pore space. The researchers also noted that oxygen availability is limited in submerged soils and that this slows the process of biological decay.

Soil samples were collected from the aforementioned site used by the City of Lubbock, Texas for land disposal of treated effluent. This effluent contained multiple PPCPs, including estrogens (estrone, 17 α -estradiol, estriol and 17 α -ethynylestradiol), triclosan, and ibuprofen. The research focused on the extent to which biological decay of these PPCPs was affected by the moisture content of the soils at the land application site.

In general, the research demonstrated that the time needed for biological decay to occur increased in soils with high water content.³⁰² The extent of this increase varied with both the specific substance and the duration of the high water content. Another variable was the extent to which the soils had been exposed to the

substance previously (as was the case at the land application site) as compared to soils that had not been previously exposed.

E.4. Occurrence of PPCPs at a Wastewater Treatment Plant and in Soil and Groundwater at a Land Application Site³⁰³

The aforementioned Lubbock, Texas wastewater treatment plant and land application site were also involved in this component of the research. Water and sludge samples were obtained from the wastewater treatment plant with soil and groundwater samples being obtained from the land application site. As noted above, the treated effluent was distributed through the use of 31 center pivot irrigation sprinklers. Samples were also obtained from adjacent areas that were not irrigated with this effluent.

The target PPCPs, all of which were present in the wastewater effluent,³⁰⁴ were estrogens (estrone, 17 β -estradiol, estriol and 17 α -ethynylestradiol), triclosan, caffeine, ibuprofen and ciprofloxacin. The research question was whether these PPCPs biodegraded, accumulated in the soils, or migrated into groundwater.

The research results are illustrative of the difficulties inherent in the management of PPCPs. The presence of PPCPs in both the sludge and effluent from the wastewater treatment plant varied over time. PPCPs may sorb to the wastewater treatment plant sludge, which could complicate land disposal of such sludge.

With regard to the land application site, PPCPs were detected within the areas receiving effluent from the center pivot sprinklers as well as from adjacent areas that had not been irrigated but apparently were receiving runoff from the areas that had been irrigated. The presence of PPCPs in both areas varied over time. This variability was most likely a function of the variable presence of PPCPs in the effluent from the wastewater treatment plant.

²⁹⁹ Ibuprofen is a non-steroidal anti-inflammatory drug that is marketed for pain relief under a variety of different names (e.g., Motrin, Advil, etc.).

³⁰⁰ Ciprofloxacin is a common antibiotic that is sold worldwide for both human and veterinary use.

³⁰¹ Deborah L. Carr et al., *Microbially Mediated Degradation of Common Pharmaceuticals and Personal Care Products in Soil Under Aerobic and Anaerobic Conditions*, 216 WATER, AIR & SOIL POLLUTION 633 (2011).

³⁰² The only exception was ibuprofen which appeared to demonstrate increased degradation in soils with high water content.

³⁰³ Adcharee Karnjanapiboonwong et al., *Occurrence of PPCPs at a Wastewater Treatment Plant and in Soil and Groundwater at a Land Application Site*, 216 Water, Air, & Soil Pollution 257 (2010) [hereinafter Karnjanapiboonwong, *Occurrence of PPCPs*].

³⁰⁴ Interestingly, 17 α -ethynylestradiol was not detected in the sludge from the wastewater treatment plant. All the other target PPCPs were detected. *Id.*

The presence of PPCPs also varied with the depth of the soil from which samples were taken. This led the researchers to conclude: “Any trend in target PPCP concentrations with soil depth was difficult to discern and is likely due to the various biodegradation rates of PPCPs with soil depth; degradation of PPCPs can be affected by environmental conditions such as temperature, pH, moisture content, organic carbon, presence of specific microorganisms, and presence/absence of oxygen.”³⁰⁵

Of all of the PPCPs included in the study, only ibuprofen was not detected in the groundwater samples. This was true irrespective of whether the groundwater samples were drawn from the areas irrigated with the wastewater effluent or from adjacent areas that had not been irrigated. The research concluded:

PPCPs in the effluent from a wastewater treatment plant can eventually move to groundwater via land application of the effluent. However, PPCPs detected in groundwater at the study site were at low concentrations which are not likely to represent a concern and indicate that the land application process is reasonably effective at PPCP removal[.] ... Our findings may be important for

evaluating the potential long-term effects of PPCPs from contamination of soil and eventually groundwater if that water is to be used for drinking-water purposes.³⁰⁶

E.5. Conclusions from the Case Study

The research results summarized above relate to a series of studies involving the presence of a fairly limited number of PPCPs at a relatively small number of sites. With one exception (soil samples from Harlan County, Nebraska), all of the sampling was done at the Lubbock, Texas wastewater treatment plant, the land application site for effluent from the plant, or lands adjacent to the land application site.

Nonetheless, a significant amount of variability was noted. Degradation of PPCPs was seen to be affected by: (a) soil type and organic content; (b) soil moisture content (including variation in rainfall); (c) soil oxygen content; and (d) prior exposure to PPCPs. As noted above with regard to the presence of PPCPs in soils, additional variables could include temperature, acidity/alkalinity and the presence of specific microorganisms.³⁰⁷

³⁰⁵ *Id.* (citing Monteiro, *supra* note 56; Alistair B.A. Boxall, *Fate and Transport of Veterinary Medicines in the Soil Environment*, in *FATE OF PHARMACEUTICALS IN THE ENVIRONMENT AND IN WATER TREATMENT SYSTEMS* (Diana S. Aga ed., CRC Press 2008); Michael S. Colucci, Henry Bork, & Edward Topp, *Persistence of Estrogenic Hormones in Agricultural Soils: I. 17 β -Estradiol and Estrone*, 30 *JOURNAL OF ENVIRONMENTAL QUALITY* 2070 (2001)).

³⁰⁶ *Id.*

³⁰⁷ With regard to temperature, Kinney *et al.*, have noted seasonal variability:

Down-core migration of pharmaceuticals may occur from either the reclaimed-water irrigation or from pharmaceutical-free precipitation. This result also could be explained by variations in the concentration of these compounds in the reclaimed water or a change in removal/degradation rate. The latter could be accounted for by differences in soil microbial population dynamics. Higher soil temperatures, consistent soil moisture, and perhaps, a steady supply of substrate and nutrients in the reclaimed water could result in greater degradation of the compounds by soil microbes *during the summer irrigation period compared to that during the winter months*.

Kinney *et al.* *supra* note 26, at 322 (emphasis added). Lozano, *et al.*, noting that soil concentrations of triclosan (TCS) were quite variable, concluded: “Our data suggests that the two most important parameters controlling TCS top soil concentrations are the biosolids application rate and the time between application and sampling.” Lozano *et al.*, *supra* note 90, at 762. This variability was also addressed in Monteiro & Boxall, *supra* note 53, at 2546:

- “Laboratory studies show that degradation rates of pharmaceutical compounds in soils vary widely, with half-lives ranging from days to years.” *Id.* (citing Alistair B.A. Boxall, *Fate and Transport of Veterinary Medicines in the Soil Environment*, in *FATE OF PHARMACEUTICALS IN THE ENVIRONMENT AND IN WATER TREATMENT SYSTEMS* 123 (Diana S. Aga ed., CRC Press 2008)).
- “Within the same therapeutic class, half-lives can still be significantly different [20].” *Id.* (citing Michael P. Schlüsener & Kai Bester, *Persistence of Antibiotics Such as Macrolides, Tiamulin and Salinomycin in Soil*, 143 *ENVIRONMENTAL POLLUTION* 565 (2006)).
- “These differences are probably explained by differences in soil properties such as moisture content, organic carbon, pH, and soil bioactivity; climate (temperature); and physicochemical properties of the compound such as degree of dissociation and

This variability, especially when considered over a national scale, points to the difficulty of controlling or managing PPCPs once they have been introduced into the environment.³⁰⁸ Different PPCPs degrade at different rates and under different conditions at different locations. Given the complexity of the problem, it is highly likely that post-release solutions will be inadequate.

Consequently, as discussed in greater detail below, eliminating or reducing PPCPs in the waste stream is much more likely to reduce both human and environmental risks than any postrelease alternatives. In essence, it is much easier to keep PPCPs out of waste stream than to safely dispose of waste containing PPCPs.

F. Strengths and Weaknesses of the Statutory, Regulatory and Alternative Strategies:

F.1. Statutory and Regulatory

Statutory and regulatory approaches to the control of PPCPs may have both substantial benefits and significant costs. Though

statute-specific strengths and weaknesses are discussed below, many of the benefits and costs of a statutory or regulatory approach are not statute specific.

Any regulatory program must be authorized by statute. Such enabling legislation defines the scope of an agency's regulatory authority. Existing environmental statutes have vested substantial authority in the Environmental Protection Agency (EPA). Similar legislation at the state, territorial and tribal levels has vested authority in entities whose functions mirror those of the EPA.³⁰⁹

The result has been the development of substantial agency expertise regarding specific issues. This is one of the major strengths of the existing statutory/regulatory approach to environmental regulation.

Agency expertise has developed as environmental law in the United States has matured. At this point in the history of environmental law, the requirements of the statutes are fairly well known and understood, and the scope of EPA authority has been established. The result is a fairly complete understanding of the requirements of different statutes and regulations. As with the

lipophilicity." *Id.* (citing Edward Topp et al., *Fate of the Nonsteroidal Anti-inflammatory Drug Naproxen in Agricultural Soil Receiving Liquid Municipal Biosolids*, 27 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 2005 (2008); Melanie Kah et al., *Factors Influencing Degradation of Pesticides in Soils*, 55 JOURNAL OF AGRICULTURE AND FOOD CHEMISTRY 4487 (2007); Edward Topp et al., *Biodegradation of Caffeine in Agricultural Soils*, 86 CANADIAN JOURNAL OF SOIL SCIENCE 533 (2006); and M.S. Collucci et al., *Persistence of Estrogenic Hormones in Agricultural Soils (I. 17-beta Estradiol and Estrone)*, 30 JOURNAL OF ENVIRONMENTAL QUALITY 2070 (2001)).

³⁰⁸ Such variability is not confined to the case study. A study of PPCPs in the Ann Arbor, Michigan water use cycle identified a number of antibiotics, analgesics, antiepileptics, steroids and hormones in raw wastewater influent over a number of months. Variability in the presence of these substances can be seen by comparing the mean concentrations with the standard deviation (a measure of variance):

Analyte	Mean concentration (µg/l)	Standard deviation (µg/l)
Coprostanol (steroid/hormone)	682.500	568.880
Cholesterol (steroid/hormone)	560.000	451.368
Sitosterol (steroid/hormone)	241.500	173.077
Dihydrocholesterol (steroid/hormone)	67.500	46.458
Stigmasterol (steroid/hormone)	37.125	27.497
Acetaminophen (analgesic)	53.000	37.151
Ibuprofen (analgesic)	11.000	7.685

Skadsen et al., *supra* note 77 at 4, Table 4.

³⁰⁹ The Food and Drug Administration also has substantial authority under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* This authority, which includes the responsibility to ensure the safety and efficacy of both human and animal drugs (21 U.S.C. § 355), was expanded with enactment of the Food Quality Protection Act of 1996. The 1996 amendments authorized the Environmental Protection Agency "to screen substances that may be found in sources of drinking water for endocrine disruption potential." Keith A.

development of agency expertise, this is also one of the strengths of the current statutory/regulatory system.

However, a weakness associated with this system is the limited ability of the system to respond to site-specific issues. If PPCPs are determined to be a threat to human health and the environment, for example, a national regulatory program could be implemented based on one of the statutes discussed herein. Unfortunately, the problem of PPCPs may be localized as the number of variables identified in the Section V case study would appear to indicate. The response could be the proverbial use of a sledgehammer to kill a gnat.

F.1.1. Common Law Remedies Sounding in Tort

Entitlement to relief under the common law remedies is based on success in litigation. Since the common law tort theories apply to disputes between individuals (civil wrongs as opposed to criminal or societal wrongs), application of the theories arises in the context of litigation between such individuals.

Consequently, all of the weaknesses of litigation as a means of environmental regulation would be applicable to litigation involving potential PPCP liability. Litigation is expensive and time-consuming. Assuming that the party bringing the action has the requisite legal standing, the scope of issues before the court is limited to the issues raised by the parties which are almost always unique to a specific case.

Likewise, any remedy provided by the court is limited to the parties before the court. The outcome of litigation is influenced frequently by the resources available to the parties. Any potential outcome may change dramatically if the parties, for whatever reason, choose to settle the litigation.

In general, litigation has not proven to be an effective means of protecting public health and the environment. That said, litigation will certainly continue based both on common law tort theories and the statutes discussed in Section III.

It is at least theoretically possible that a trespass action could be brought involving PPCPs. In the Section V case study, for example, treated effluent containing PPCPs was applied to lands using center pivot irrigation systems. The researchers noted that PPCPs were also found in soil samples taken from lands adjacent to the areas where the treated effluent had been sprayed. It was speculated that PPCPs were found on adjacent lands because of run-off from the irrigated areas. On these facts, a trespass action might be feasible. However, in order to recover more than merely nominal damages, the plaintiff would have to prove that the conduct of the defendant resulted in damage to the plaintiff. Given the low levels of PPCPs noted in the case study, fulfilling the burden of proof regarding damages may be difficult.

A public nuisance action might be possible if it could be shown that the use of public “streams, parks, beaches and other

Johnston & Kristine Sendek-Smith, *Muddy Waters: Recent Developments Under the Clean Water Act*, 24-WINTER NATURAL RESOURCES AND ENVIRONMENT 31, 37 (2010):

Through what has been a long and contentious process, the EPA's Endocrine Disruptor Screening Program is finally making progress in helping identify endocrine disruptors from the tens of thousands of chemicals currently in use, and it will eventually study the effects of those chemicals and compounds on humans and wildlife. EPA is near publication of the results of its sampling performed in 2007 to determine the prevalence of certain chemicals in drinking water and is also set to expand sampling this year to obtain water samples from up to fifty drinking water treatment plants to help analyze the prevalence of about 200 emerging contaminants in drinking water.

Id. at 37-38 (citing Alan Kovski, *Drinking Water: EPA Details Emerging Contaminants Survey, Responds to Questions about Its Usefulness*, 40 ENVIRONMENT REPORTER 2361 (Oct. 9, 2009)). Johnston and Sendek-Smith also note that the U.S. Geological Survey is in the process of developing a national reconnaissance program for emerging contaminants. This program is to focus “on four groups of compounds: veterinary and human antibiotics, human drugs, industrial and household products (such as insecticides, detergents, fire retardants, and fuels), and sex and steroidal hormones.” *Id.* at 38 (citation omitted). Authority for such a program, they note, is provided by the Safe Drinking Water Act (42 U.S.C. § 300j-17), the Toxic Substances Control Act (15 U.S.C. § 2603), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 346(a)(p), 408(p)) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. § 136(c)(2)(B)). *Id.* In addition, Nidel has noted that the authority of the Food and Drug Administration “was expanded into the environmental realm by enactment of the National Environmental Policy Act (NEPA), which not only provides FDA with the authority to bring environmental considerations into its decisionmaking, but also requires that it take these considerations into account.” Christopher T. Nidel, *Regulating the Fate of Pharmaceutical Drugs: A New Prescription for the Environment*, 58 FOOD & DRUG LAW JOURNAL 81, 92 (2003) (citing 42 U.S.C.S. §§ 4321 *et seq.*). Accord Christenson, *supra* note 172, at 156; George J. Mannina, Jr., *Medicines and the Environment: Legal and Regulatory Storms Ahead?*, 21 LEGAL BACKGROUNDER, no. 11, 1, 3 (March 26, 2006).

facilities”³¹⁰ was adversely affected by water supplies contained PPCPs. Again, it would be the plaintiff’s burden to show harm. As noted above, given the low levels of PPCPs noted in the case study, fulfilling this burden of proof requirement may be difficult.

Application of the theory of negligence might be appropriate when it could be documented that a specific plaintiff was injured by PPCPs released into the environment by a specific defendant. However, this assumes that the appropriate chain of causation could be established. This is not a safe assumption given the ubiquitous nature of PPCPs. There is no question that the manufacturers of PPCPs owe a duty of due care to prevent adverse public and environmental health impacts. The weakness in trying to apply the theory of negligence to such manufacturers is the great degree of difficulty in determining the manufacturer of any specific PPCP alleged to have caused harm.

Applying the theory of strict liability would be predicated on the averment that PPCPs are inherently dangerous products for which the manufacturers should be strictly liable. Given the “value of the activity to the community”³¹¹ (*i.e.*, the prevention or treatment of disease), it would be exceptionally difficult, if not impossible, for a plaintiff to demonstrate that PPCPs are inherently dangerous.³¹²

However, as noted above, litigation is always fact-specific. Given an appropriate set of circumstances, application of one of the common law tort theories might be an appropriate response to human and environmental health injuries resulting from the release of PPCPs.³¹³

F.1.2. The Clean Water Act

As noted in Section III, states are authorized to promulgate water quality standards based on the National Recommended Water Quality Criteria (“Criteria”). The state standards are then subject to EPA approval. Lopez has argued that the Environmental Protection Agency has a mandatory duty to revise the Criteria “to establish limitations for EDCs [and other PPCPs] to protect against endocrine disruption.”³¹⁴ Should this occur, National Pollutant Discharge Elimination System (NPDES) permits ultimately would have to include appropriate measures to eliminate or control PPCPs. Absent such an NPDES permit, discharges of PPCPs from point sources into “waters of the United States” would be prohibited.

The wastewater treatment industry is familiar with both the Clean Water Act and the use of NPDES permits. While this may be one of the strengths of this approach to the control of PPCPs in

³¹⁰ Restatement (Second) of Torts, *supra* note 96, at § 821D and related text.

³¹¹ *Id.* at § 402A.

³¹² For example, acetylsalicylic acid is used for both human therapy and in animal husbandry. It is “a nonsteroidal anti-inflammatory” that is “also used for its analgesic, antipyretic and anti-coagulating properties.” Acetylsalicylic acid “is known to cause skin, eye and upper respiratory tract irritation upon direct contact and gastrointestinal bleeding following chronic ingestion.” It is “a known systemic allergen and can produce anaphylaxis at doses in the lowest end of the therapeutic range (10 mg/kg).” However, there is “strong epidemiological evidence” that acetylsalicylic acid may also afford protection from some cancers. When used for both human therapy and in animal husbandry, salicylic acid and other metabolites are excreted in urine and may end up in water supplies. On these facts, it would be difficult to argue that acetylsalicylic acid is an inherently dangerous product, especially since its commonly used name is aspirin. Schulman et al., *supra* note 13, at 660 (citation omitted).

³¹³ In fact, Mannina provides an example of such circumstances:

[A]n Illinois municipal water district which owns and operates a plant providing water to municipal residents and businesses has sued the manufacturers of certain herbicides demanding that the manufacturers clean up all residue from a substance which has found its way into the source of the drinking water and also pay for the costs of installing and operating additional water treatment systems to guarantee the removal of any residue from this herbicide. What makes this case significant is that the plaintiff does not allege the herbicide is being used unlawfully or contrary to the manufacturer’s instructions. Nor are there any allegations of a violation of the safe drinking water standards established by EPA or the State of Illinois. Rather, the plaintiff, citing various studies allegedly demonstrating adverse human health impacts of herbicide residue at concentrations less than the existing safe drinking water standards, asserts that the federal and state standards are not protective of human health. The plaintiff then asserts that the herbicide manufacturers are guilty under state law of *trespass*, *nuisance*, *negligence*, and releasing “contaminants” into the environment solely because residue from the herbicide has come to be located in water owned and used by the plaintiff. While this case does not involve pharmaceuticals or personal care products, one can imagine creative attorneys using similar and related theories.

Mannina, *supra* note 309, at 3 (emphasis added).

water supplies, it is also one of the weaknesses. If PPCPs are to be controlled through the use of NPDES permits, which PPCPs should the regulation target and using what technology? The plethora of PPCPs would appear to require a plethora of control technologies.

A directly related question, assuming that control of PPCPs is mandated at wastewater treatment plants, focuses on treatment techniques and systems. As noted in Section IV, new water treatment systems have been (and are being) developed.³¹⁵ A number of authors have noted the need for these technological developments to continue. Nidel, for example, notes the need to develop new wastewater treatment systems that “more effectively break down these compounds leaving only environmentally inert effluents.”³¹⁶ The related question, therefore, is whether the development and use of new wastewater treatment technology should be a condition precedent to the issuance of NPDES permits.

Requiring pretreatment of wastes containing PPCPs has been suggested.³¹⁷ Such requirements would be applicable to a variety of entities (i.e., manufacturing facilities, health care facilities) that discharge wastes containing PPCPs.³¹⁸ The goal of such requirements would be to mandate the pretreatment of wastes that would either interfere with the operation of a wastewater treatment plant or that would pass through a wastewater treatment plant untreated.³¹⁹

Assuming that wastewater treatment techniques and systems can be developed to control the plethora of PPCPs, the cost could be staggering.³²⁰ Imposing such costs on the operators of

publically-owned treatment works may be both financially and politically impossible. As Jones has noted: “Although the public may want pure water, people are not prepared to pay what it would actually cost even if sufficient technology did exist.”³²¹

Finally, perhaps the most significant limitation regarding use of the Clean Water Act as a means of preventing the introduction of PPCPs into water supplies is the fact that the statutory requirements do not apply to nonpoint sources of wastes. Such nonpoint sources (e.g., runoff from farms) are “a significant sources of the pharmaceuticals found in surface water[.]”³²²

F.1.3. The Safe Drinking Water Act

Inclusion of PPCPs in the National Primary Drinking Water Regulations would be one means of limiting human exposure to PPCPs. Maximum Contaminant Level Goals (MCLGs) and Maximum Contaminant Levels (MCLs) could be established for PPCPs.

In fact, such an approach is being considered by EPA. As indicated in Section III, the Contaminant Candidate List (CCL) includes contaminants not presently subject to the National Primary Drinking Water Regulations but which may have an adverse impact on human health and is known to occur in water supply systems. If so, the EPA Administrator may subject the contaminant to the National Primary Drinking Water Regulations. The current CCL, which was published on 21 August 2008, lists 104 contaminants.³²³ Unfortunately, virtually all of the PPCPs that

³¹⁴ Jacki Lopez, *Endocrine-Disrupting Chemical Pollution: Why the EPA Should Regulate These Chemicals Under the Clean Water Act, Spring Sustainable Development Law and Policy* 19, 22 (2010).

³¹⁵ *Supra*, notes 268 to 280 and associated text.

³¹⁶ Nidel, *supra* note 309, at 82. However, “this solution is under-inclusive [in that it] does not address the large amounts of animal drugs that make their way directly into the environment.” *Id.* at 91.

³¹⁷ Christenson, *supra* note 172, at 163 (citing P.G. Kent & T.A. Dudiak, *WISCONSIN WATER LAW: A GUIDE TO WATER RIGHTS AND REGULATIONS* 104 (2d ed. 2001)).

³¹⁸ *Id.*

³¹⁹ *Id.*

³²⁰ “The total costs of removing every possible endocrine disrupting compound could quickly become astronomical.” Jones, *supra* note 229, at 385-386.

³²¹ *Id.* at 386.

³²² Christenson, *supra* note 172, at 148 (citing P.G. Kent & T.A. Dudiak, *WISCONSIN WATER LAW: A GUIDE TO WATER RIGHTS AND REGULATIONS* 107 (2d ed. 2001)).

³²³ Notice, Drinking Water Contaminant Candidate List 3, 73 Fed. Reg. 9628 (2008).

were proposed for inclusion on the CCL were not included.³²⁴

Perhaps because of this outcome, the Science Advisory Board Drinking Water Committee of the EPA Office of Ground Water and Drinking Water recommended changes to the CCL selection process:

The Committee recommends consideration of emerging issues and on-going research when selecting chemicals. There are also some clear categories of contaminants that need special attention in selecting the CCL including pharmaceuticals, personal care products, endocrine disruptors, antibiotics, and algal toxins. Such contaminants may warrant changes in the CCL selection processes. General exposure to even low levels of antibiotics in drinking water, for example, may lead to antibiotic-resistant pathogens either in a person drinking the water

or the general environment. The current CCL process for chemicals would not identify this as an adverse effect.³²⁵

A final decision regarding “whether to regulate five or more of the contaminants from this list” is expected by 2013.³²⁶ If PPCPs are included within the regulatory scope of the Safe Drinking Water Act, it has been suggested that a “No Observed Transcriptional Effect Level” (NOTEL, defined as “the dose of chemical which results in no significant changes to gene expression”) should be the regulatory limit.³²⁷

The weakness of this approach has been noted already: the ubiquitous nature of PPCPs. As with alternatives under the Clean Water Act, requiring public water supply systems to address all PPCPs could impose financial burdens that are neither financially nor politically feasible.

³²⁴ The process that preceded the current Contaminant List was described by ToxServices LLC:

EPA identified 287 pharmaceuticals in its initial listing of a broad range of potential drinking water contaminants in the draft CCL3 [Drinking Water Contaminant Candidate List 3] that had data to indicate a potential to occur in drinking water and health effects. The health data used was primarily from the FDA’s Database on Maximum Recommended Daily Doses and the occurrence data was from the U.S. Geological Survey’s Toxic Substances Hydrology Program’s National Reconnaissance of Emerging Contaminants, and TRI [Toxic Release Inventory] and high production volume chemical data. Further screening moved approximately 10 percent of the pharmaceuticals to the preliminary CCL. Only one of the pharmaceuticals, nitroglycerin, was included in the draft CCL3.

ToxServices LLC, *supra* note 34, at 12.

³²⁵ EPA Science Advisory Board Drinking Water Committee, Environmental Protection Agency, SAB ADVISORY ON EPA’S DRAFT THIRD DRINKING WATER CONTAMINATION CANDIDATE LIST (CCL 3) 7 (2009). The Committee also addressed PPCPs in the context of contaminants that were not included on the draft CLL. With regard to concentrations of contaminants in wastewater and the potential reuse of such water supplies, the Committee concluded:

The Committee concludes that it will be important to consider information regarding wastewater concentrations when evaluating potential exposure in the CCL process. In some areas of the country, wastewater discharges are increasingly a greater percentage of water supplies, and they are being processed into potable water. Wastewater contains a wide variety of contaminants including pharmaceuticals, personal care products, enteric pathogens, and other emerging contaminants. In the case of pharmaceuticals, perfluorinated surfactants, and other contaminants that are prevalent in wastewater effluent, EPA may want to consider using data obtained in specialized wastewater effluent monitoring programs for the CCL screening process.

Id. at 14. In terms of chemical contaminants, the Committee noted the absence of data:

The absence of data on the occurrence of pharmaceuticals in surface waters was also noted. The Committee recommends use of the data from the USGS, or any of the numerous studies in the peer-reviewed literature, to include these chemicals.

Id.

³²⁶ Johnston & Sendek-Smith, *supra* note 309, at 38 (citing Alan Kovski, *Drinking Water: EPA Completes List of Water Contaminants to Consider as Candidates for Regulation*, 40 ENVIRONMENT REPORTER 2246 (Sept. 25, 2009)). EPA has also considered inclusion of PPCPs within the Unregulated Contaminant Monitoring Rule.

The Surface Water Treatment Rule could be amended to require removal of PPCPs in addition to the contaminants already subject to the Rule. Again, the cost of such an approach may not make it financially or politically opportune.

An alternative that may not face the twin roadblocks of financial and political feasibility would be to amend the Wellhead Protection Program to preclude the discharge of wastes containing PPCPs in wellhead protection areas. For example, prohibiting either (a) the installation or use of septic tanks in wellhead protection areas or (b) the land application of wastewater treatment plant residues (biosolids) in such areas could protect groundwater from wastes containing PPCPs.

A similar amendment could be implemented regarding the Underground Injection Control Program. Injection of wastes containing PPCPs could be restricted to Class I injection wells. As with the possible amendment to the Wellhead Protection Program, the goal would be to prevent the migration of PPCPs into groundwater resources.

Sludge or biosolids containing PPCPs from water treatment plants could be subject to the Part 503 Biosolids Rule. The Rule would have to be amended to establish both ceiling and loading rate limits for PPCPs. As noted in the case study, liquid wastes containing PPCPs were used to irrigate a waste disposal site. It may be necessary to expand the Biosolids Rule to apply to such situations.

F.1.4. The Resource Conservation and Recovery Act

The definition of a “hazardous” waste contained in the Resource Conservation and Recovery Act (RCRA) could be expanded to include additional wastes containing PPCPs.³²⁸ At the present time, for example, wastes discharged pursuant to a National Pollutant Discharge Elimination System Permit are not subject to the requirements of RCRA.

Inclusion of wastes containing PPCPs within the definition of a “hazardous” waste would subject the waste stream to the requirements of RCRA.³²⁹ Generators and transporters of wastes containing PPCPs, as well as operators of treatment, storage and disposal facilities (TSDF) for such wastes, would have to comply with the requirements of RCRA, including use of the Uniform Hazardous Waste Manifest System and permit requirements to construct and operate a TSDF.

However, because of the limited number of TSDFs and the difficulty of establishing new TSDFs, imposing such requirements could be both costly and burdensome to the waste management community. The volume of waste subject to RCRA requirements would increase dramatically. The cost of disposing such waste could increase in proportion to the quantity of wastes generated.

One result seen repeatedly when disposal costs are excessive is an increase in illegal dumping of hazardous wastes. If costs increase because of an imposition of RCRA requirements on wastes containing PPCPs, the resultant illegal dumping would most likely include a wide variety of hazardous wastes that previously would have gone to an approved TSDF.

³²⁷ Poynton & Vulpe, *supra* note 34, at 91 (citing E.K. Lobenhofer et al., *Exploration of Low-Dose Estrogen Effects: Identification of No Observed Transcriptional MAQC Effect Level* (NOTEL), 32 TOXICOLOGIC PATHOLOGY 482 (2004); Gerald T. Ankley et al., *Toxicogenomics in Regulatory Ecotoxicology*, 40 ENVIRONMENTAL SCIENCE & TECHNOLOGY 4055 (2006)). As Poynton and Vulpe concluded, “[a]ny significant cellular perturbation should cause some change in gene expression; therefore, the NOTEL represents a true No Observed Effect Concentration.” *Id.* at 91.

³²⁸ Christenson addressed this approach in the context of health-care facilities, concluding:

[T]he list of hazardous drugs “has not been substantially updated since the rules went into effect in 1976.” For example, only eight out of 100 different chemotherapy drugs are currently on the list of hazardous wastes. In fact, health-care facilities have an extremely difficult time dealing with the RCRA because the regulations were not designed for the health-care industry. Thus, when there are regulations, they are complicated and expensive to follow, and when there are not regulations, hospitals are left in the unenviable position of developing their own disposal programs or flushing drugs down the toilet.

Christenson, *supra* note 172, at 150 (citing R. Seely, *Flushed Drugs Polluting Water; Complicated Rules for Disposal Result in Most Hospitals Taking Easy Way Out*, WISCONSIN STATE JOURNAL, Dec. 10, 2006, at A1.). *See also*, Mannina, *supra* note 309, at 4 (“Provisions in RCRA and in Drug Enforcement Administration regulations which are designed to protect the public from the improper discharge or disposal of medical waste and controlled substances may, in reality, be encouraging medical professionals and the public to flush unused pharmaceuticals in toilets or drains.”).

³²⁹ As noted by Mannina:

An alternative could be to revise the Universal Waste Rule to include PPCPs. In fact, on December 2, 2008, the EPA proposed adding PPCPs to the Universal Waste list.³³⁰ The proposed revisions would add hazardous pharmaceuticals to the list. The rule, as amended, would apply to pharmacies, hospitals, physicians' offices, dentists' offices, outpatient care centers, ambulatory health care services, residential care facilities and veterinary clinics as well as other facilities that produce hazardous pharmaceutical wastes.³³¹ EPA has estimated that the proposed revision would affect up to 634,552 entities, of which approximately 181 are large quantity generators of hazardous waste.³³² The amendments would allow producers of hazardous pharmaceutical wastes to choose whether (a) to continue to have their wastes regulated under the current RCRA regulations or (b) to manage their hazardous wastes under the Universal Waste Rule.³³³

The proposed revision is also intended to facilitate the collection of pharmaceutical wastes from households, including non-hazardous pharmaceutical wastes.³³⁴ Of relevance to the source control options discussed below, EPA believes that the amendments will simplify pharmaceutical take-back programs by "streamlining the requirements for handling hazardous pharmaceutical wastes received as part of a take-back program."³³⁵

However, concerns have been expressed regarding the inclusion of PPCPs on the Universal Waste list. These concerns focus on the contention that the regulation of PPCPs under the Universal Waste Rule "may be less stringent than the rules for hazardous wastes under RCRA."³³⁶

F.1.5. The Toxic Substance Control Act

Solid and liquid wastes containing PPCPs could also be subject to the requirements of the Toxic Substances Control Act (TSCA). If so, Title I of TSCA would require manufacturers and processors of such wastes to conduct a testing program "to predict the effects of human exposure and environmental releases."³³⁷

Regulatory controls are available under TSCA regarding the processing, distribution, use or disposal of a chemical presenting an unreasonable risk of injury to health or the environment.³³⁸ If wastes containing PPCPs fall within the purview of TSCA, then this provision, as well as all of the regulatory controls authorized by TSCA, could be applicable. If so, given the wide variety of PPCPs, the potential scope and cost of complying with these requirements could make compliance problematic.

EPA has listed several common medications and nine chemotherapy agents as hazardous waste if discarded. But there are more than 100 toxic chemotherapy agents which are not yet RCRA regulated.

Mannina, *surpa* note 309, at 2. Regulation of these wastes could have unintended consequences:

If regulated substances are released into the environment, as those terms are understood under Superfund [the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. § 9601 *et seq.*] and the Clean Water Act, can we look forward to cleanup orders and claims for natural resource damages under those laws? The answer is probably yes.

Id.

³³⁰ Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. 73520 (Dec. 2, 2008) (to be codified at 40 C.F.R. pt. 260, 261, 264, 265, 268, 270 and 273).

³³¹ Environmental Protection Agency, EPA PROPOSES STREAMLINED DISPOSAL OF HAZARDOUS PHARMACEUTICAL WASTE (Nov. 2008), available at <http://www.epa.gov/osw/hazard/wastetypes/universal/pharm-fs.pdf>.

³³² Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. at 73520.

³³³ *Id.*

³³⁴ *Id.*

³³⁵ *Id.* at 73526.

³³⁶ Johnston & Sendek-Smith, *surpa* note 309, at 38 (citing Environmental News Stand, *EPA Urged to Up RCRA Pharmaceuticals Enforcement at Hospitals*, INSIDE EPA (July 1, 2009)).

³³⁷ TSCA, § 2603, *surpa* note 196 and associated text.

³³⁸ *Id.* at § 2605(a).

F.1.6. The Endangered Species Act

The financial and political burdens confronting use of the aforementioned statutes would cease to be a threshold issue if wastes containing PPCPs led to the “taking” of a threatened or endangered species. As discussed in Section II, the impacts of PPCPs in water supplies have been observed in a wide variety of aquatic species. At some point, a cause of action will arise when PPCPs in water supplies result in the “taking” of a species protected by the ESA or similar legislation enacted by state, local or Tribal governments.³³⁹

In fact, these causes of action may already have ripened. Lopez notes that “[t]here is evidence that EDCs are significantly degrading habitat, including federally designated critical habitat, and are likely injuring fish and wildlife by disrupting behavior patterns such as breeding ability.”³⁴⁰ This could give rise to a “taking” cause of action regarding a number of threatened or endangered species including the Razorback Sucker (*Xyrauchen texanus*), the Desert Pupfish (*Cyprinodon macularius*) and the Santa Ana Sucker (*Catostomus santaanae*).³⁴¹

An alternative cause of action noted by Mannina is based on the ESA requirement that “federal agencies (including agencies approving the use of pharmaceuticals and hormones) ‘insure’ that any action they take or authorize is not likely to adversely affect species protected by the ESA.”³⁴² Based on this requirement, Mannina concluded:

Experienced ESA attorneys are all too well aware of how little proof of impact is required before the ESA’s “insure” no harm standard triggers regulatory controls. In one ESA

case, a federal judge upheld a finding that fishing was adversely affecting an ESA-protected species even though there was no evidence that fishing was causing any impact. The logic, using the ESA’s insure no harm standard, was that fishermen catch fish, the listed species eat fish, and, therefore, there must be an adverse impact from fishing. *Apply that reasoning to pharmaceuticals in the environment and it is not a very long leap before the ESA can be brought to bear on protected species such as the razorback sucker and other listed species of fish, including virtually all the salmon and steelhead species in the Pacific northwest.*³⁴³

Implementing a recovery plan under the ESA can be both socially disruptive and expensive. The preferred alternative is to take whatever steps might be needed to preclude the need to list a species as threatened or endangered. This could include regulating or prohibiting the discharge of wastes containing PPCPs, especially if the cause of the “taking” is related to the discharge of such wastes. While such an approach may not be politically popular, the alternatives (listing a species and implementing a recovery plan) are substantially less popular.

F.2. Alternative Strategies

The source control alternative strategies discussed in Section IV may be more effective in reducing or eliminating PPCPs in water supplies than the imposition of a statutory or regulatory approach. The approaches advocated by Daughton and others focus on minimizing or eliminating sources of PPCPs.³⁴⁴

³³⁹ The Endangered Species Act is not the only federal species protection statute that might provide a cause of action should protected species be affected adversely by PPCPs. *See, e.g.*, the Bald and Golden Eagle Protection Act, 16 U.S.C. §§ 668-668d; the Marine Mammal Protection Act, 16 U.S.C. §§ 1361- 1421h; the Migratory Bird Treaty Act, 16 U.S.C. §§703-712. Similar species protection legislation enacted by state, local and Tribal governments might provide additional causes of action.

³⁴⁰ Lopez, *supra* note 314, at 20 (citing Susan Jobling et al., *Wild Intersex Roach (Rutilus rutilus) Have Reduced Fertility*, 67 BIOLOGY OF REPRODUCTION 515 (2002) (finding that EDC-caused altering of sex characteristics leads to reduced reproductive ability)).

³⁴¹ *Id.* at 21. *See also*, Mannina, *supra* note 309, at 2 (“ESA issues may already be present in Nevada where a USGS toxicologist detected elevated levels of pharmaceuticals and hormones in waterways downstream from Las Vegas and a very large decrease in sperm production in three species of fish, including the endangered razorback sucker.”).

³⁴² Mannina, *supra* note 309, at 2.

³⁴³ *Id.* (emphasis added).

³⁴⁴ As in Section IV, the discussion in this Section focuses primarily on pharmaceuticals. Nevertheless, the analysis is equally applicable to personal care products and the full array of PPCPs previously identified in footnote 6. *See supra* note 4.

F.2.1. Drug Design

Designing drugs to minimize the human and animal excretion of wastes containing PPCPs would have the effect of reducing the volume of PPCPs entering water supplies. Any number of commentators have argued that the Food and Drug Administration (FDA) needs to assess the PPCP discharge potential as a component of the FDA's drug approval process.³⁴⁵ Such an assessment could be undertaken in the context of the Environmental Assessment process mandated by the National Environmental Policy Act.³⁴⁶ "The hope," observed Nidel, "is that with an adequately informed FDA sitting as gatekeeper to this highly profitable market, drug design will evolve. This will lead drug companies to internalize the external impacts of their products and, where feasible, design drugs of the future that are noted for their minimal impact on the environment as well as for their therapeutic effectiveness."³⁴⁷

As noted below,³⁴⁸ Daughton has suggested that patent extension be used as an incentive to encourage drug companies to implement alternative source control strategies. Others have suggested the need for financial incentives or other types of financial support, particularly with regard to drug design.³⁴⁹

Despite the provision of such financial support, a restraint on the feasibility of this alternative could be the need for drug manufacturers to pass the cost of drug development to the general public. Absent a definitive showing of adverse human or environmental health impacts resulting from exposure to PPCPs, the political feasibility of increasing the cost of drugs in order to limit PPCPs in water supplies is an open question.

F.2.2. Drug Delivery

The drug delivery alternatives suggested by Daughton are predicated in part on voluntary participation by physicians, patients, pharmacies and drug manufacturers. Despite Daughton's faith in public education programs, such appeals to conscience have not been an effective means of addressing environmental health problems.³⁵⁰

F.2.3. Drug Marketing

The cost of informing consumers of appropriate means of discarding unused drugs should be minimal vis-à-vis the benefit of reducing PPCPs in water supplies. However, the cost of producing a variety of package sizes in order to minimize the quantity of unused drugs needing disposal could be substantial. Given the sensitivity of consumers to drug prices, those alternatives with the least costs are more than likely the most feasible.

F.2.4. Drug Dispensing

McGrath notes that the State of Maine has limited the quantity of drugs that physicians may "prescribe for first-time users of certain medications."³⁵¹ The political feasibility of such an approach raises issues regarding both the social responsibility of physicians and the role of the state in the doctor-patient relationship.

Dispensing the correct quantity of a drug with an appropriate expiration date (*i.e.*, the drugs will not expire before the course of treatment has been completed) could be a win-win situation, at least for the patient and the environment. Whether such an approach would be considered a "win" for drug manufacturers is an open question.

³⁴⁵ As Nidel has noted, "[r]equiring a more rigorous assessment when applying for new drug approval would shift the focus of the root-cause of the problem." Nidel, *supra* note 309, at 82.

³⁴⁶ *Id.* at 92-93.

³⁴⁷ *Id.* at 100.

³⁴⁸ *Infra*, note 360 and associated text.

³⁴⁹ Christenson, *supra* note 172, at 169 (citing Nidel, *supra* note 309, at 94 for the proposition that the Food and Drug Administration "already has the necessary authority" to "increase environmental review of the design of new drugs or offer intellectual-property or tax-based incentives to those manufacturers who voluntarily test for environmental effects.").

³⁵⁰ See, e.g., Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243, 1246-1247 (the "tragedy of the commons" cannot be remedied by appeals to conscience).

³⁵¹ Neal McGrath, *Water Pollution: Pharma's Next Big Headache?*, GREENBIZ.COM BLOGS (August 31, 2009), <http://www.greenbiz.com/blog/2009/08/28/water-pollution-pharmas-next-big-headache>.

F.2.5. Drug Disposal/Recycling

Existing institutional barriers to drug disposal and recycling need to be revised. While there may be good reasons for some of these barriers to continue (*e.g.*, prevention of theft of discarded pharmaceuticals), blanket prohibitions encourage the inappropriate disposal of unused or unwanted drugs.

One approach to a drug disposal and recycling program would be a “take-back” program such as the one described by Christensen:

Take-back events, typically organized by hospitals, pharmacies, or environmental groups, create a place for consumers to bring their unused pharmaceuticals. With proper personnel available to sort pharmaceuticals and law enforcement available to handle controlled substances, these events are often extremely successful, resulting in hundreds of gallons of pharmaceuticals collected in single-day events.³⁵²

The successful implementation of drug take-back programs has been challenging. As noted above, having “law enforcement available to handle controlled substances” may be a condition precedent to a successful program. This statement masks a serious

impediment to takeback programs, that “the same pharmacist who is authorized to distribute medications ... is not authorized to take the medication back without prior approval by a DEA [Drug Enforcement Administration] agent.”³⁵³

Despite such impediments, a number of states have sought to develop drug take-back programs. For example, legislation enacted in Maine authorized a drug mail-back program.³⁵⁴ The program was summarized by Christensen:

Consumers mail unused or expired drugs in these packages to a single collection location run by the Maine Drug Enforcement Agency (MDEA). The MDEA then disposes of all returned drugs in an environmentally sound manner. A fund established and maintained by the MDEA and funded by private contributions pays the costs of the program.³⁵⁵

Implementation of the Maine program encountered two problems. First, “although manufacturers regularly package and ship prescription drugs for consumption, it is much more difficult to have them shipped for disposal.”³⁵⁶ Second, “due to the potentially high costs involved, it is unlikely that pharmaceutical companies would provide the necessary funds to run the entire program.”³⁵⁷

³⁵² Christenson, *supra* note 172 at 157 (citing R. Seely, *Flushed Drugs Polluting Water; Complicated Rules for Disposal Result in Most Hospitals Taking Easy Way Out*, WISCONSIN STATE JOURNAL, Dec. 10, 2006, at A1; R. Dickrell, *Pharmaceutical Take-Back A Community's Success Story*, 167 THE CLARIFIER 48 (2006)).

³⁵³ *Id.* at 151 (citing Juliet Eilperin, *Pharmaceuticals in Waterways Raise Concern: Effect on Wildlife, Humans Questioned*, WASHINGTON POST, June 23, 2005, at A3).

For the health-care industry and consumers, “DEA laws are one of the biggest stumbling blocks” on the road toward proper disposal. This is largely due to the DEA’s strict control of controlled substances, under which disposal becomes quite complicated. When an individual is unsure how to dispose of a controlled substance, that individual may contact an authorized DEA agent, who will then instruct the individual to dispose of the controlled substance in one of the following manners: (1) by transfer to a person authorized to possess controlled substances (likely a law-enforcement officer), (2) by delivery to a DEA agent, (3) by destruction in the presence of a DEA agent, or (4) by some other means determined by a DEA agent. In other words, the only persons who can possess a controlled substance that is prescribed to an individual are that individual, a law-enforcement officer, or a DEA agent.

Id. at 151-152 (citing R. Seely, *Flushed Drugs Polluting Water; Complicated Rules for Disposal Result in Most Hospitals Taking Easy Way Out*, WISCONSIN STATE JOURNAL, Dec. 10, 2006, at A1; 21 C.F.R. § 1307.21 (Drug Enforcement Administration, Office of Diversion Control, Procedure for disposing of controlled substances)).

³⁵⁴ As opposed to a take-back event as described above, a “statewide mail-back model offers a centralized coordination component, adds an element of confidentiality and anonymity not found with in-person take back programs and is the least burdensome of all models in terms of consumer access and utilization.” Lenard Kaye, Jennifer Crittenden, & Stevan Gressitt, EXECUTIVE SUMMARY: REDUCING PRESCRIPTION DRUG MISUSE THROUGH THE USE OF A CITIZEN MAIL-BACK PROGRAM IN MAINE (2010), *available at* <http://www.epa.gov/aging/RX-report-Exe-Sum/>.

³⁵⁵ Christenson, *supra* note 172, at 154 (citing Me. Rev. Stat. Ann. tit. 22 §§ 2700(3)-(5)).

³⁵⁶ *Id.* (citing Me. Rev. Stat. Ann. tit. 22 § 2700(4)).

³⁵⁷ *Id.* at 155 (citing Juliet Eilperin, *Pharmaceuticals in Waterways Raise Concern: Effect on Wildlife, Humans Questioned*, WASHINGTON

McGrath notes that seven states have considered legislation to “mandate take-back programs” and that a mandatory system, funded by the drug companies, has been implemented in France.³⁵⁸ Alternative programs would include the Canadian Medications Return Program³⁵ Daughton’s suggestion to extend the patents of drug companies implementing “vibrant, comprehensive stewardship programs tailored for each particular drug”³⁶⁰ has merit, but it also could mean that consumers could pay higher drug prices over time because the introduction of alternative generic drugs could be delayed by the patent extensions.³⁶¹

F.2.6. Drug Alternatives

The benefit of drug alternatives is a reduction in the discharge of PPCPs associated with the use of such products. The burden has been stated already: potential cost to the patient. The use of “bacteriotherapy” may be as effective as the use of a drug resulting in the discharge of PPCPs, but at what cost? Perhaps more importantly, does the reduction in PPCPs discharged into water supplies justify the cost?

G. Conclusions:

The words of H.L. Mencken ring true: “For every complex problem, there is a solution that is simple, neat, and wrong.” Mencken’s conclusion appears to be particularly appropriate regarding PPCPs in water supplies.

The general conclusions are deceptively simple: The anthropogenic sources of PPCPs identified in Section II need to be reduced or eliminated. As discussed in Section III, such sources of PPCPs may be subject to regulation. As discussed in Section IV, source control alternatives exist that could have the effect of reducing or eliminating some sources of PPCPs without the costs associated with statutory or regulatory programs.

The devil, however, is in the details. As noted by Wennmalm and Gunnarsson, “The consumption of pharmaceuticals is increasing worldwide, due both to continued population growth and increased consumption of pharmaceuticals per capita.”³⁶² The ever-increasing number of PPCPs³⁶³ combined with the concentration variability discussed in Section V precludes any single approach to

Post, June 23, 2005, at A3). Christenson notes the issue of political feasibility:

Maine’s government could consider legislation that would require pharmaceutical companies to significantly contribute to the fund. However, given that the pharmaceutical industry is one of the leading lobbyists in the United States, any proposed legislation that would force manufacturers to significantly contribute to the fund would likely meet significant opposition.

Id. (citing Jim Drinkard, *Drugmakers Go Furthest to Sway Congress*, USA TODAY, Apr. 26, 2005, at B1 (drug companies spent more on lobbying than any other industry from 1998 to 2004)).

³⁵⁸ McGrath, *supra* note 350.

³⁵⁹ Christenson, *supra* note 172, at 157-158 (citing Daughton, “Drug Disposal, Waste Reduction, and Future Directions,” *supra* note 232 at 780).

³⁶⁰ Daughton, *Drug Disposal, Waste Reduction, and Future Directions*, *supra* note 230, at 776. The concept of stewardship underlay the Maine mail-back program. “Product stewardship is a concept that recognizes the responsibility of the manufacturer of a product from the manufacturing process through final disposal in an environmentally sound manner.” State of Maine Final Report of the Maine Drug Return Implementation Group, 122nd Legis., 1st Reg. Sess. at 7 (2005), available at <http://www.maine.gov/legis/opla/drugrpt.pdf>, (quoted in Christenson, *supra* note 172, at 154).

³⁶¹ As noted by Christenson, “[i]f the scheme places the financial burden on consumers, it fails to follow the product-stewardship model that underlies this solution.” Christenson, *supra* note 172, at 155.

³⁶² Wennmalm & Gunnarsson, *supra* note 41, at 291 (citing European Federation of Pharmaceutical Industries and Associations. THE PHARMACEUTICAL INDUSTRY IN FIGURES (2002)). Consumption of pharmaceuticals is increasing 3-4% by weight per year. Ellis, *supra* note 30, at 185 (citing Christian G. Daughton, *Non-regulated Water Contaminants: Emerging Research*, 24 ENVIRONMENTAL IMPACT ASSESSMENT REVIEW 711 (2004)). Accord Reynolds, *Concern of Pharmaceuticals in Drinking Water*, *supra* note 33, at 2.

³⁶³ “[T]here may be as many as 6 million PPCP substances commercially available worldwide[.]” Ellis, *supra* note 30, at 185 (citing Christian G. Daughton, *Non-regulated Water Contaminants: Emerging Research*, 24 ENVIRONMENTAL IMPACT ASSESSMENT REVIEW 711 (2004)).

their regulation or management.³⁶⁴ New monitoring,³⁶⁵ detection³⁶⁶ and analysis³⁶⁷ methods are needed. New management alternatives need to be developed. New statutory or regulatory approaches embodying the Precautionary Principle³⁶⁸ need to be tailored to the goal of reducing PPCPs in water supplies.³⁶⁹

It is quite possible that new drinking water treatment processes will need to be developed. However, while such processes might protect human health, they would “provide no protection for aquatic life.”³⁷⁰ Furthermore, it is unlikely that any “single water treatment

process will be capable of reducing all trace organic contaminants to below increasingly sensitive analytical detection limits.”³⁷¹

As noted in the Introduction, this report is predicated on the assumption that the ongoing scientific inquiry regarding the effects of PPCPs in water supplies produces evidence of risks to human and environmental health. If so, then all of the alternatives discussed herein, as well as any number of additional alternatives that have yet to emerge, will be needed if both human and environmental health are to be protected.

³⁶⁴ “The aging population and more pharmaceutical development are two driving factors behind an expectation that increased pharmaceutical use will result in higher levels of trace residues in water.” Global Water Research Coalition, *supra* note 31, at 2. *Accord* Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 25 (“a growing and aging population as well as increased reliance on drug treatments, and development of new drugs, the problem with pharmaceutical contamination promises to also increase”).

³⁶⁵ G. Tracy Mehan, III, *Water Data and Monitoring as Indispensable Tools to Manage Water Quality*, DAILY ENVIRONMENT REPORT, August 4, 2010, at 4.

³⁶⁶ “Methods of detection are not available for all pharmaceuticals, and new pharmaceuticals are developed every year, which may require new methodologies to enable their detection in water.” Global Water Research Coalition, *supra* note 31, at 1.

³⁶⁷ Poynton & Vulpe, *supra* note 34, at 92:

New chemicals and drugs are continuously developed and released in the environment. New approaches are needed for environmental risk assessment to catch up with the backlog of contaminants and keep pace with the increasing surge of new potential risks.

Accord Rapid Public Health Policy Response Project, *supra* note 26, at 3-4 (need for human health assessments of low-level, chronic exposure to PPCPs); Jones, *supra* note 231, at 385 (need for new risk assessment models that account for synergistic effects).

³⁶⁸ “Irrespective of any risks, the precautionary principle should apply and micropollutants from wastewater should not be present in drinking water.” C. Zwiener, *Occurrence and Analysis of Pharmaceuticals and their Transformation Products in Drinking Water Treatment*, 387 ANALYTICAL AND BIOANALYTICAL CHEMISTRY 1159 (2007) (quoted in Rapid Public Health Policy Response Project, *supra* note 26, at 6. Among the various definitions of the Precautionary Principle, perhaps the one most applicable to PPCPs is the definition resulting from the Wingspread Conference on the Precautionary Principle (26 January 1998): “When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.” The conferees went on to explain that the “precautionary principle shifts the burden of proof, insisting that those responsible for an activity must vouch for its harmlessness and be held responsible if damage occurs.” Science and Environmental Health Network, <http://www.sehn.org/wing.html> (last visited Jan. 30, 2011).

³⁶⁹ See, e.g., Heberer et al., *Removal of Pharmaceutical Residues*, *supra* note 85, at 19 (citing T. Heberer & H.-J. Stan, *Arzneimittelrückstände im Aquatischen System*, 50 WASSER UND BODEN 20 (1998); Umweltbundesamt, ANNUAL REPORT 1999 (2000)):

[L]ow concentrations [of pharmaceutically active compounds] may, from a toxicological point of view, not be harmful to humans but their occurrence in ground or drinking water is also not desirable from a hygienic point of view or with regard to the precautionary principle. Thus, there is a need to develop and study new drinking water treatment technologies to remove such organic contaminants from drinking water.

Accord Wennmalm & Gunnarsson, *supra* note 41, at 296 (“in line with the precautionary principle, measures should be taken by public health authorities to avoid contamination of drinking water with ... low concentrations of bioactive chemicals such as pharmaceuticals”).

³⁷⁰ Snyder et al., *supra* note 47, at 34.

³⁷¹ Stanford et al., *supra* note 11, at 56 (citing Benotti et al., *supra* note 48; Shane A. Snyder et al., American Water Works Association, *Removal of EDCs and Pharmaceuticals in Drinking and Reuse Treatment Processes* (2007) ; Brett J. Vanderford & Shane A. Snyder, *Analysis of Pharmaceuticals in Water by Isotope Dilution Liquid Chromatography/Tandem Mass Spectrometry*, 40 ENVIRONMENTAL SCIENCE & TECHNOLOGY 7312 (2006)).



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