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# Alternative Strategies for Addressing the Presence and Effects of Pharmaceutical and Personal Care Products in Fresh Water Resources

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# ALTERNATIVE STRATEGIES FOR ADDRESSING THE PRESENCE AND EFFECTS OF PHARMACEUTICAL AND PERSONAL CARE PRODUCTS IN FRESH WATER RESOURCES*

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## I. INTRODUCTION

In the nearly forty years since adoption of the Federal Water Pollution Control Act Amendments in 1972[1] and 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, state and tribal 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, new information has arisen to challenge this assumption. 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

1. Federal Water Pollution Control Act Amendments of 1972, Pub. L. No. 92-500, 86 Stat. 816 (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 of 1974, Pub. L. No. 93-523, 88 Stat. 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 (Oct. 16, 2003) (paper presented at the National Academies, Institute of Medicine: Roundtable on Environmental Health Science, Research, and Medicine (EHSRT)) (on file with author).

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 PPCP management.

PPCPs are an extremely diverse group of chemicals used in human health care, cosmetic care, veterinary medicine, and agriculture. In 2004, it was estimated that "there may be as many as six million PPCP substances commercially available worldwide . . . ."[5] PPCPs are also ubiquitous pollutants, entering the environment worldwide due to widely dispersed usage by individuals and in both industry and agriculture.[6] Recent reports in popular media regarding pharmaceuticals in drinking water have contributed to increasing public awareness of and concern about this issue.[7]

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4. For the purposes of this report, the term "PPCPs" includes a diverse group of chemicals that include pharmaceuticals, such as: prescription and over-the-counter human drugs, veterinary drugs; 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*, 120 WATER RESOURCES UPDATE, Sept. 2001, at 1; *see also* K. Xia et al., *Occurrence, Distribution, and Fate of 4-Nonylphenol in Kansas Domestic Wastewater Treatment Plants*, 120 WATER RESOURCES UPDATE, Sept. 2001, at 41.

5. J.B. Ellis, *Pharmaceutical and Personal Care Products (PPCPs) in Urban Receiving Waters*, 144 ENVTL. POLLUTION 184, 185 (2006).

6. CHRISTIAN G. DAUGHTON, PHARMACEUTICALS IN THE ENVIRONMENT: SOURCES, FATE, EFFECTS AND RISKS 463 (Klaus Kümmerer ed., 2d ed. 2004).

7. For example, in 2008, the Associated Press released a series of investigative reports entitled AN AP INVESTIGATION: PHARMACEUTICALS FOUND IN DRINKING WATER. These reports, were distributed by both print and electronic media worldwide. *See, e.g.*, Jeff Donn, *Drug Traces Turn Up in Source Waters for Nation's Biggest City*, U.S.

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. The creation of the Micropollutants Clearinghouse ("Clearinghouse") achieved this latter objective.

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 fresh water resources. It identified and evaluated 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 appropriate for protection of human health and the environment.[8] Potential alternative strategies were also identified and evaluated. Project 3 addressed three basic questions: 1) can existing statutory and regulatory authorities be utilized to collect information about and/or effectively manage PPCPs entering the environment?; 2) are there other alternative strategies that should be considered?; 3) 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.

## A. 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 fresh water re-

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WATER NEWS, March 2008; Martha Mendoza, *On Eve of Hearings, White House Documents Show Feds Failing to Take Action on Drugs in Water*, THE ASSOCIATED PRESS (D.C.), Apr. 13.

8. 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.

sources. 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.[9]

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.[10] 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. Legal research supplemented this expertise regarding recent initiatives unique to the issue of PPCPs in fresh water resources.[11]

### B. ORGANIZATION OF THE REPORT

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

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9. 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.

10. 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.

11. 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 report.

Section III describes current legal mechanisms by which fresh water resources 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 fresh water resources 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.

## II. SUMMARY OF THE SCIENTIFIC RESEARCH

Concern over the presence of PPCPs in fresh water resources has increased significantly since 1965 when researchers at Harvard University first determined that effluent from wastewater treatment plants contained both natural and synthetic estrogens.[12] By the 1970s, the subject was being studied in both the United States[13] and Europe.[14]

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."[15] 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.[16] In large measure, the growing concern over the presence of

12. Benjamin D. Stanford et al., *Estrogenic Activity of US Drinking Waters: A Relative Exposure Comparison*, 102 J. AM. WATER WORKS ASS'N, no. 12, at 1 (2010).

13. *Id.*

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

15. Stanford et al., *supra* note 12, at 1-2.

16. Hans-Rudolf Buser et al., *Occurrence and Environmental Behavior of the Chiral Pharmaceutical Drug Ibuprofen In Surface Waters and in Wastewater*, 33 ENVTL. SCI. & TECH. 2529 (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 ENVTL. SCI. & TECH. 188 (1998); Hans-Rudolf Buser et al., *Occurrence and Fate of the Pharmaceutical Drug Diclofenac in Surface Waters: Rapid Photodegradation in a Lake*, 32 ENVTL. SCI. & TECH. 3449 (1998); 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); Andreas Hartmann et al., *Identification of Fluoro-*

PPCPs in fresh water resources resulted from an increasing number of occurrence studies that have identified specific PPCPs in drinking water.[17] While it is beyond the scope of the present study to review each of these studies, certain studies should be noted.

In 1999-2000, the USGS sampled surface and groundwater throughout the United States.[18] 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."[19] The study found at least one of

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*quinolone Antibiotics as the Main Source of umuC Genotoxicity in Native Hospital Wastewater*, 17 ENVTL. TOXICOLOGY & CHEMISTRY 377 (1998); Roman Hirsch, *Occurrence of Antibiotics in the Aquatic Environment*, 225 THE SCI. OF THE TOTAL ENV'T 109 (1999); R. Hirsch et al., *Determination of Betablockers and β-Sympathomimetrics in the Aquatic Environment*, 87 VOM WASSER 263 (1996); 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); 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 SCI. OF THE TOTAL ENV'T 135 (1999); Thomas A. Ternes, *Occurrence of Drugs in German Sewage Treatment Plants and Rivers*, 32 WATER RESEARCH 3245 (1998); Thomas A. Ternes & Roman Hirsch, *Occurrence and Behavior of X-ray Contrast Media in Sewage Facilities and the Aquatic Environment*, 34 ENVTL. SCI. & TECH. 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, anti-cancer drugs, anti-epileptic drugs, and blood pressure drugs at a range of concentrations, most below 1 μg/l." Schulman et al., *supra* note 14, at 658.

17. 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.

AM. WATER WORKS ASS'N RESEARCH FOUND., TOXICOLOGICAL RELEVANCE OF EDCS & PHARMACEUTICALS IN DRINKING WATER, at xix (2008).

18. Dana W. Kolpin et al., *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance*, 35 ENVTL. SCI. & TECH. 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/.

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

the ninety-five organic wastewater contaminants in eighty percent of stream samples and in ninety-three percent 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."[20] 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-N-diethyltoluamide (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.[21]

20. *Id.* at 1202 (citations omitted).

21. HERBERT T. BUXTON & DANA W. KOLPIN, PHARMACEUTICALS, HORMONES, & OTHER ORGANIC WASTEWATER CONTAMINANTS IN U.S. STREAMS, UNITED STATES GEOLOGICAL SURVEY, DEP'T OF THE INTERIOR, FS-027-02, at 2 (2002), *available at* http://toxics.usgs.gov/pubs/FS-027-02/.

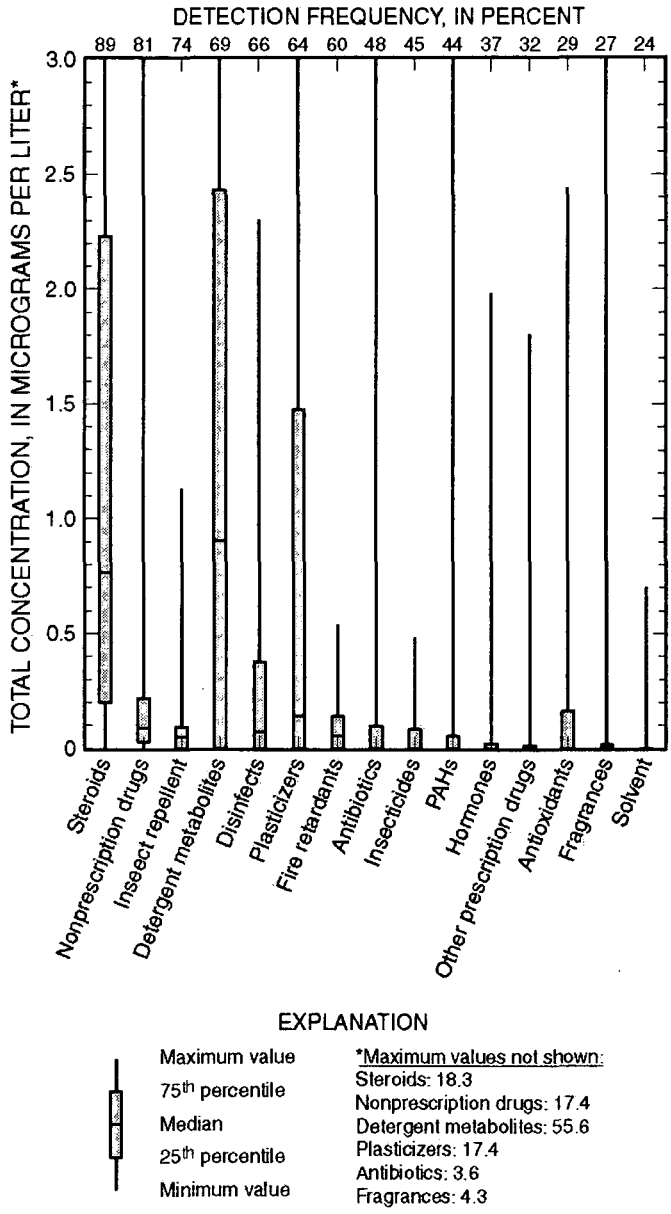


*Figure 1: Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams.*[22]

In 2001, Sedlak and Pinkston identified multiple prescription drugs in wastewater.[23] They estimated concentrations of such drugs, concluding

22. *Id.*
23. Sedlak & Pinkston, *supra* note 16.

that wastewater concentrations ranged from "less than 1 ng/L to approximately 133,000 ng/L."[24] 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., acetominophen, 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., medroxyprogresterone, equilin).[25]

Of particular concern is the presence of antibiotics in fresh water resources "because antibiotic contaminants could perturb microbial ecology, increase the proliferation of antibiotic-resistant pathogens, and could pose threats to human health."[26] 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 [sic.] 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.[27]

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24. *Id.* at 57.

25. *Id.* The identified pharmaceuticals suggest that a "larger suite of pharmaceuticals" may be present in water supplies. *Id.*

26. 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 ENVTL. HEALTH PERSP. 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 2001 GEORGIA WATER RESOURCES CONFERENCE (Kathryn J. Hatcher ed.) (2001); Kelly A. Reynolds, *Pharmaceuticals in Drinking Water Supplies*, 45 WATER CONDITIONING & PURIFICATION (2003), *available at* http://www.wcponline.com/column.cfm?T=T&ID=2199 [hereinafter Reynolds, *Pharmaceuticals in Drinking Water Supplies*].

27. Masters, *supra* note 4, at 1. Furthermore, "higher levels of antibiotic resistant bacterial strains [have been detected] downstream from a swine-feed facility, compared with upstream levels." RAPID PUB. HEALTH POL'Y RESPONSE PROJECT, SCH. OF PUB. HEALTH & HEALTH SERVS., THE GEORGE WASHINGTON UNIV., PHARMACEUTICALS ARE IN THE DRINKING WATER: WHAT DOES IT MEAN? 4 (2008) [hereinafter RAPID PUB. HEALTH POL'Y RESPONSE PROJECT] (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 ENVTL. HEALTH PERSP. 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.,

Also, in 2001, Huang et al., noted the presence in fresh water resources of antibiotics used in both human therapy[28] and also in animal husbandry, specifically beef, swine, and poultry production.[29]

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."[30] The principal emerging PPCPs and their uses were summarized by Ellis:[31]

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*Presence and Distribution of Wastewater-Derived Pharmaceuticals in Soil Irrigated with Reclaimed Water*, 25 ENVTL. TOXICOLOGY & CHEMISTRY 317, 323 (2006) (citing Rosamund J. Williams, & David L. Heymann, *Containment of Antibiotic Resistance*, 279 SCI. 1153 (1998); Wolfgang Witte, *Medical Consequences of Antibiotic Use in Agriculture*, 279 SCI. 996 (1998)). Accord Ken Carlson et al., *Antibiotics in the Cache la Poudre River*, AGRONOMY NEWS, Dec. 2004, at 4.

28. "Antibiotics that are likely to be present in discharged municipal wastewater are primarily antibiotics used in human therapy." Huang et al., *supra* note 26, at 32.

29. 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.

*Id.* at 33.

30. Reynolds, Pharmaceuticals in Drinking Water Supplies, *supra* note 26.

31. Ellis, *supra* note 5, at 185.

| Compound group/class | Compound |
|---|---|
| Pharmaceuticals | |
| Veterinary & human antibiotics | Trimethoprim, erytromycine, lincomycin, sulfamethaxole, chloramphenicol, amoxycillin |
| Analgesics & anti-inflammatory drugs | Ibuprofen, diclofenac, fenoprofen, acetaminophen, naproxen, acetylsalicylic acid, fluoxetine, ketoprofen, indometacine, paracetamol |
| Psychiatric drugs | Diazepam, carbamazepine, primidone, salbutamol |
| Lipid regulators | Clofibric acid, bezafibrate, fenofibric 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 | *N,N*-diethyltoluamide |
| Antiseptics | Triclosan, chlorophene |

*Table 1: Principal Emerging PPCP Compounds and Their Uses*

It is quite probable that the specific PPCPs identified in these occurrence studies have been in drinking water supplies for years.[32] PPCPs have chemical and physical properties that make it likely for them to end up in hydrologic systems.[33] 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."[34]

32. "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 & POTENTIAL FOR HUMAN HEALTH IMPACTS OF PHARMACEUTICALS IN THE WATER SYSTEM 1 (2009). Accord Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 26 ("[I]t'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.").

33. Frick et al., *supra* note 26, at 282.

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

The increased detection of PPCPs may result from dramatically improved testing equipment and procedures, rather than any recent introduction of PPCPs into drinking water supplies.[35] Such new testing equipment and procedures now allow for the detection of PPCPs at the nanogram,[36] or even picogram,[37] level. Until fairly recently, detection levels were at the microgram level.[38] Furthermore, as noted by Schulman et al., "detection limits are likely to decrease in the future, as more sensitive analytical detection techniques become available."[39] 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.[40]

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.

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*from Known Wastewater Discharges—Potential for Use as Indicators of Human Fecal Contamination*, 39 ENVTL. SCI. & TECH. 5157, 5166 (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 J. AM. WATER RESOURCES ASS'N 58, 58 (2009).

35. "[A]s analytical techniques grew more sensitive over the years, many more pharmaceuticals have been detected in ambient water, wastewater, and drinking water." TOXSERVICES L.L.C., APPROACHES TO SCREENING FOR RISK FROM PHARMACEUTICALS IN DRINKING WATER AND PRIORITIZATION FOR FURTHER EVALUATION 1 (2008). Accord AM. WATER WORKS ASS'N RES. FOUND., TOXICOLOGICAL RELEVANCE OF EDCS AND PHARMACEUTICALS IN DRINKING WATER 1, 5 (2008) ("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 generally* Helen C. Poynton & Chris D. Vulpe, *Ecotoxicogenomics: Emerging Technologies for Emerging Contaminants*, 45 J. AM. WATER RES. ASS'N 83, 83 (2009) (describing advances in analytical techniques).

36. A nanogram (ng) is one billionth of a gram ($1 \times 10^{-9}$). 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 PUB. HEALTH POL'Y RESPONSE PROJECT, *supra* note 27, at 1.

37. A picogram (pg) is one trillionth of a gram ($1 \times 10^{-12}$). 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." *Id.*

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

39. Schulman et al., *supra* note 14, at 669. Accord AM. WATER WORKS ASS'N RES. FOUND., *supra* note 35, at 1 ("considering the continued advancements in analytical technologies, today's non-detectable contaminants will be tomorrow's emerging contaminants").

40. 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 32, at 1.

## A. PATHWAYS

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

Other exposure pathways are more indirect. Schulman et al., note that certain PPCPs bioaccumulate in fish.[41] The exposure pathway, therefore, would be the human consumption of fish or shellfish containing PPCPs.[42]

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.[43] Ellis graphically depicted this recognition:[44]

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41. Schulman et al., *supra* note 14, at 659.

42. 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 5, at 185 (citing Betty Bridges, *Fragrance: 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 INFO. J. 291, 296 (2005).

43. COMM. ON TOXICANTS AND PATHOGENS IN BIOSOLIDS APPLIED TO LAND, NAT'L RES. COUNCIL, BIOSOLIDS APPLIED TO LAND: ADVANCING STANDARDS AND PRACTICES 13 (2002). Accord Kolpin et al., *supra* note 18, at 1202 ("there are a wide variety of transport pathways for many different chemicals to enter and persist in environmental waters").

44. Ellis, *supra* note 5, 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 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[.]

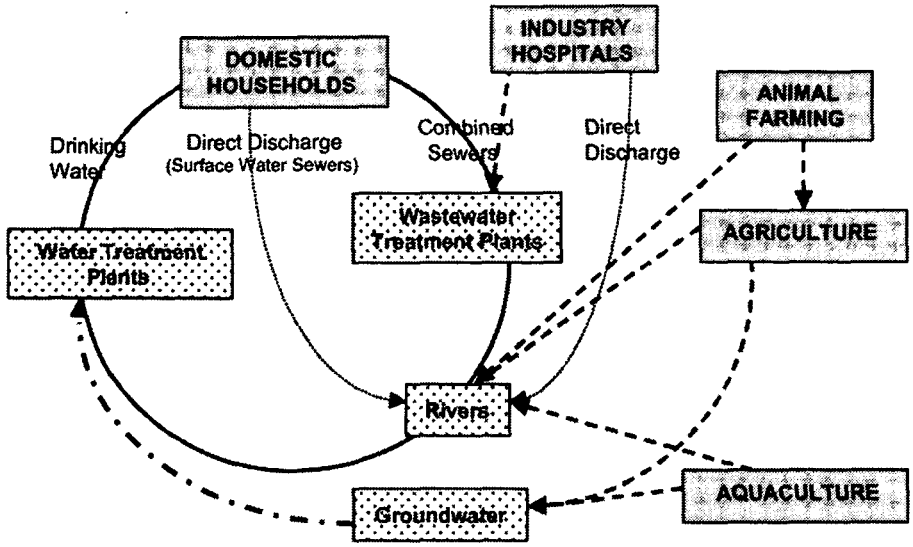


*Figure 2: Sources and Pathways of PPCPs in the Urban Water Cycle*

## B. 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.[45] 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.

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AM. WATER WORKS ASS'N RES. FOUND., supra note 35, at 4-5. 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 12, at 61, 63.

45. *See, e.g.*, Schulman et al., *supra* note 14, 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 32, at 2 ("to date, no definitive link has been reported or established between pharmaceutical exposure in drinking water and human health risk"); RAPID PUB. HEALTH POL'Y RESPONSE PROJECT, *supra* note 27, 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.").

### 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 OWCs [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.[46]

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."[47] Additional research is needed regarding the effects of long-term, low-dose exposure to PPCPs.[48]

### 2. Cumulative or Synergistic Effects

Human and environmental exposures to PPCPs are never isolated to one specific PPCP. Such exposures are always to combinations of PPCPs, the impacts of which are relatively unknown.[49] Combinations of PPCPs may have cumulative or synergistic effects that go beyond the effects of any single PPCP.[50] This led Kolpin et al., to conclude:

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46. Kolpin et al., *supra* note 18, at 1208 (citations omitted).

47. Reynolds, *Concern of Pharmaceuticals in Drinking Water*, *supra* note 34, at 2.

48. "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 J. AM. WATER WORKS ASS'N 32, 33 (2005).

49. "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 35, 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 ENVTL. SCI. & TECH. 597, 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 ENVTL. ENGINEERING SCI. 449 (2003)). "A limited body of research ... suggests an additive effect when a mixture of pharmaceuticals is present." RAPID PUB. HEALTH POL'Y RESPONSE PROJECT, *supra* note 27, at 4 (citing Francesco Pomati et al., *Effects and Interactions in an Environmentally Relevant Mixture of Pharmaceuticals*, 102 TOXICOLOGICAL SCI. 129 (2008)).

50. Koplin et al., *supra* note 18, at 1210.

> [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.[51]

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."[52] This combination of low doses of estrogen "may act synergistically to produce a strong estrogenic response."[53]

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.[54]

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:

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51. *Id.* (citations omitted). In a study of the effect of aquatic and terrestrial species exposure to tricolsan and tricolcarban, 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. A. Chalew & Rolf U. Halden, *Environmental Exposure of Aquatic and Terrestrial Biota to Triclosan and Triclocarban*, 45 J. AM. WATER RESOURCES ASS'N 4, 11 (Feb. 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 Sean M. Richards et al., *Effects of Pharmaceutical Mixtures in Aquatic Microcosms*, 23 ENVTL. TOXICOLOGY & CHEMISTRY 1035 (2004)). *See also* Jessica G. Davis, *Antibiotics in the Environment*, AGRONOMY NEWS 1, 2 (Dec. 2004) ("Degradation products and interactions among compounds have not been adequately evaluated and could result in synergistic toxic effects").

52. Judith M. Bergeron et al., *Developmental Synergism of Steroidal Estrogens in Sex Determination*, 107 ENVTL. HEALTH PERSP. 93, 96 (1999).

53. *Id.* at 93.

54. GLOBAL WATER RESEARCH COALITION, *supra* note 32, at 2.

> 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[.][55]

For example, while the degradation of individual PPCPs identified in Project 2 was relatively fast (half-lives of less than thirty days), the presence of two PPCPs in a simple mixture increased the persistence of both PPCPs.[56]

### 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.[57] 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.[58]

Other groups such as the elderly, the infirm, or the immunocompromised may also be unusually susceptible.[59] Research regarding the impacts of exposure to PPCPs on these and other population segments or groups is ongoing.

### 4. Environmental Health Impacts

Human beings are not exposed continuously to fresh water resources containing PPCPs. The same cannot be said for aquatic species, which by their very nature are continuously exposed to water supplies containing PPCPs.[60] Such species "are exposed continually, over many genera-

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

56. Discussed *infra* Part V.

57. Abby C. Collier, *Pharmaceutical Contaminants in Potable Water: Potential Concerns for Pregnant Women and Children*, 4 ECOHEALTH 164, 170 (2007) (referencing "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"). *See also* Cunningham, Binks, & Olson, *supra* note 42; Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 26.

58. Collier, *supra* note 57, at 170.

59. Cunningham, Binks, & Olson, *supra* note 42, at 40, 44.

60. RAPID PUB. HEALTH POL'Y RESPONSE PROJECT, *supra* note 27, at 4.

tions, to the higher concentrations of pharmaceuticals that linger in surface water."[61] This exposure may result in "endocrine disruptions, reproductive effects and renal deterioration in fish, among other damage."[62]

For example, with regard to both fish and other aquatic vertebrates, the low-level presence of pharmaceutical estrogens[63] leads to "a suite of adverse effects" including: feminization of males;[64] impaired reproductive capacity;[65] and abnormal sexual development.[66]

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61. *Id.* at 4 (citing Environmental Protection Agency, PHARMACEUTICALS AND PERSONAL CARE PRODUCTS, http://www.epa.gov/ppcp/faq.html#whatarethemajorissues).

62. *Id.* at 4.

63. Specifically, estrone ($E_1$), 17β-estradiol ($E_2$), estriol ($E_3$) and the synthetic estrogen, 17α-ethinylestradiol.

64. Marlo K. Sellin et al., *Estrogenic Compounds Downstream from Three Small Cities in Eastern Nebraska: Occurrence and Biological Effect*, 45 J. OF THE AM. WATER RESOURCES ASS'N 14 (2009) (citing Gordon C. Balch et al., *Feminization of Female Leukophore-Free Strain of Japanese Medaka (Oryzias latipes) Exposed to 17β-Estradiol*, 23 ENVTL. TOXICOLOGY AND CHEMISTRY 2763 (2004); F. Brion et al., *Impacts of 17β-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)).

65. *Id.* at 14-15 (citing Shoko Imai et al. *Effects of 17β-Estradiol on the Reproduction of Java-Medaka (Oryzias Javanicus), a New Test Fish Species*, 51 MARINE POLLUTION BULL. 708 (2005); F. Brion et al., *Impacts of 17β-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 17β-Estradiol*, 40 AQUATIC TOXICOLOGY 335 (1998)). *See also* Poynton & Vulpe, *supra* note 35, at 84 (citing Karen A. Kidd et al., *Collapse of a Fish Population After Exposure to a Synthetic Estrogen*, 104 PROC. OF THE NAT'L ACAD. OF SCI. OF THE UNITED STATES OF AMERICA. 8897 (2007) (17α 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 17β-Estradiol on Nest Holding Ability and Sperm Quality in Fathead Minnows*, 120 WATER RESOURCES UPDATE 49 (2001). While exposure to 17β-estradiol did not result in long-term changes in sperm quality, the authors noted that 17β-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 14, at 676.

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

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."[67]

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."[68]

The presence of PPCPs in water resources affect organisms 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."[69] 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."[70]

The presence of antibiotics in fresh water resources may also reduce the growth of aquatic plants.[71] 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."[72]

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67. *Id.*

68. Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 26.

69. Chalew & Halden, *supra* note 51, at 10.

70. *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 35, at 84 (citing Mark C. Crane et al., *Chronic Aquatic Environmental Risks From Exposure to Human Pharmaceuticals*, 367 SCI. OF THE TOTAL ENV'T 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 ENVTL. SCI. & TECH. 4321 (2005)).

71. TDC ENVIRONMENTAL, *supra* note 51, at 2 (citing Richard A. Brain et al., *Effects of 25 Pharmaceutical Compounds to Lemna Gibba Using a Seven-Day Static-Renewal Test*, 23 ENVTL. TOXICOLOGY AND CHEMISTRY 371 (2004)).

72. Wennmalm & Gunnarsson, *supra* note 42, at 291. Accord Ellis, *supra* note 5, 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.").

## C. 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.[73] 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).[74] Pharmaceuticals used in the fruit production industry are yet another source of PPCPs,[75] as are leachate from landfills[76]

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73. *See* Ed Means, Amlan Ghosh, & Zaid Chowdhury, *Endocrine Disruptors and Pharmaceuticals Strategic Initiative Expert Workshop Report*, AM. WATER WORKS ASS'N RES. FOUND. 5 (2007) *available at* http://www.waterrf.org/Research/ResearchPrograms/StrategicResearchInitiatives/Documents/EDCWorkshopReport.pdf (regarding EDCs, "[w]hile 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 PERSP. 82, 83 (1997):

> 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.

*Id.*

74. Paul D. Anderson et al., *Screening Analysis of Human Pharmaceutical Compounds in U.S. Surface Waters*, 38 ENVTL. SCI. & TECH. 838, 838 (2004). Accord Ellis, *supra* note 5, at 185.

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

76. Benotti et al., *supra* note 49, at 597. Accord Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 26.

and urban runoff.[77] PPCPs may also be rinsed from a person's body during bathing.[78]

## D. PROCESSES OR MECHANISMS BY WHICH PPCPS ARE INTRODUCED INTO FRESH WATER RESOURCES

There are numerous processes or mechanisms that can introduce PPCPs into fresh water resources.[79] With regard to the sources of PPCPs noted above, wastewater treatment plants treat a substantial portion of human wastes. Following wastewater treatment plant processing, treated water may be discharged into a receiving stream or lake.

Typically, wastewater treatment plants remove and dispose of the residual sludge contained in the processing tanks pursuant to the regulations discussed in Section III. Both the treated water discharged into a receiving stream or lake[80] and the residual sludge[81] will contain varying

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77. Juliane B. Brown, William A. Battaglin, & Robert E. Zuellig, *Lagrangian Sampling for Emerging Contaminants Through an Urban Stream Corridor in Colorado*, 45 J. AM. WATER RES. ASS'N 68, 70 (2009); Benotti et al., *supra* note 49, at 597.

78. Snyder et al., *supra* note 48, at 32.

79. "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 14, at 658 (citing N.J. Ayscough et al., *The Environment Agency Research and Development Dissemination Centre*, REVIEW OF HUMAN PHARMACEUTICALS IN THE ENVIRONMENT 106 (2000)). Accord Janice M. Skadsen et al., THE OCCURRENCE AND FATE OF PHARMACEUTICALS, PERSONAL CARE PRODUCTS AND ENDOCRINE DISRUPTING COMPOUNDS IN A MUNICIPAL WATER USE CYCLE: A CASE STUDY IN THE CITY OF ANN ARBOR 2 (2004), *available at* http://www.a2gov.org/government/publicservices/water_treatment/Documents/Endocrine Disruptors.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 ENVTL. HEALTH PERSP. 1 (1999)).

80. 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 77, at 69-70. Such wastewater "has been shown to contain low, yet biologically active, concentrations of estrogenic compounds." Sellin et al., *supra* note 64, at 15 (citing Marta Carballa et al., *Behavior of Pharmaceuticals, Cosmetics and Hormones in a Sewage Treatment Plant*, 38 WATER RES. 2918 (2004); Andrew C. Johnson & John P. Sumpter, *Removal of Endocrine-Disrupting Chemicals in Activated Sludge Treatment Works*, 35 ENVTL. SCI. & TECH. 4697 (2001); Chiara Baronti et al., *Monitoring Natural and Synthetic Estrogens at Activated Sludge Sewage Treatment Plants and in a Receiving River Water*, 34 ENVTL. SCI. & TECH. 5059 (2000)). *See also* Chalew & Halden, *supra* note 51, at 7; Kinney et al., *supra* note 27, at 317 (citing Christian G. Daughton, & Thomas A. Ternes, *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?* 107 ENVTL. HEALTH PERSP. 907 (1999)).

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.[82] As discussed in greater detail in Section V, treated wastewater used for agricultural and landscape irrigation may also contain PPCPs.[83]

In fact, only a portion of the wastes which sanitary sewers collect 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 are combined, significant rainfall events may produce quantities of wastes that exceed the capacity of the wastewater treatment plant.[84] 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."[85] As a result, untreated sewage "derived from leaky sewers and CSOs . . . may have a disproportion-

81. "In biosolids destined for land application, a number of pharmaceuticals and personal care products have been detected." Monteiro & Boxall, *supra* note 55, at 2546 (citing Chad A. Kinney et al., *Survey of Organic Wastewater Contaminants in Biosolids Destined for Land Application*, 40 ENVTL. SCI. & TECH. 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 ENVTL. TOXICOLOGY AND CHEMISTRY 2881 (2003)).

82. Sellin et al., *supra* note 64, at 19 (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 35, at 84 (citing Bryan W. Brooks et al., *Determination of Select Antidepressants in Fish From an Effluent-Dominated Stream*, 24 ENVTL. 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 77, at 68.

83. Kinney et al., *supra* note 27, at 317. Accord Benotti et al., *supra* note 49, at 597.

84. With regard to such weather events, 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 J. AM. WATER RESOURCES ASS'N 35, 36 (2009) (citing R.W. Muirhead et al., *Faecal Bacteria Yields in Artificial Flood Events: Quantifying In-Stream Stores*, 38 WATER RES. 1215 (2004); R.C. Jamieson et al., *Resuspension of Sediment-Associated Escherichia Coli in a Natural Stream*, 34 J. ENVTL. QUALITY 581 (2005)). On a related point, there is a relationship between climatic variability and the variable presence of PPCPs in water resources. Guo & Krasner, *supra* note 34, at 64 (reduced instream flow during dry years resulting in less dilution of wastewater treatment plant outflows).

85. P. Phillips, & A. Chalmers, *Wastewater Effluent, Combined Sewer Overflows, and Other Sources of Organic Compounds to Lake Champlain*, 45 J. AM. WATER RESOURCES ASS'N 45, 46 (2009). Accord Brown, Battaglin, & Zuellig, *supra* note 77, at 70 (storm drains as a source of PPCPs).

ately large effect on concentrations of compounds that are well removed by wastewater treatment processes (such as caffeine and ibuprofen)."[86]

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.[87] If water treatment plants apply the sludge from the processing tanks to land, a common disposal method in the United States for wastewater treatment plant sludge,[88] then rain or melting snow will allow the PPCPs to be absorbed into soils[89] and to infiltrate groundwater.[90]

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86. Phillips & Chalmers, *supra* note 85, at 46 (citing Lorien J. Fono, & David L. Sedlak, *Use of the Chiral Pharmaceutical Propranol to Identify Sewage Discharges Into Surface Waters*, 39 ENVTL. SCI. & TECH. 9244 (2005)).

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

88. *See* COMM. ON TOXICANTS AND PATHOGENS IN BIOSOLIDS APPLIED TO LAND, *supra* note 43, 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.").

89. Triclosan ("TCS") is "an antimicrobial compound that is added to a wide variety of household and personal care products" that "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, 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 ENVTL. SCI. & TECH. 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. The sorption and degradation of PPCPs in soil is discussed in greater detail in Section V.

90. 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 75, at 6-7.

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

The presence of PPCPs in groundwater has also been detected in areas where human wastes are treated using septic tank systems.[91] Human wastes containing PPCPs that flow into septic tanks will eventually flow into groundwater.

Because of the widespread use of antibiotics in animal husbandry,[92] 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. As with wastewater treatment plant sludge, rain or melting snow will cause PPCPs contained in manure to flow into groundwater.[93]

Much like septic tank systems, but on a larger scale, liquid wastes from domesticated animals may be collected in lagoons or ponds.[94] These impoundments are quite effective in providing a means by which PPCPs contained in liquid wastes can find their way into groundwater.[95] 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.[96]

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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. *See also* Huang et al., *supra* note 26, at 33 ("Land application of animal waste provides routes for agricultural antibiotics to enter the aquatic environments, which may eventually reach drinking water supplies").

91. RAPID PUB. HEALTH POL'Y RESPONSE PROJECT, *supra* note 27, at 1; Kinney et al., *supra* note 27.

92. "About ninety percent of the approximately 2.5 million kg of antibiotics sold in the United States are given as growth-promoting and prophylactic agents in subtherapeutic 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 75, at 10. Accord Reynolds, *Concern of Pharmaceuticals in Drinking Water, supra* note 34, at 1 ("forty percent of antibiotics manufactured are fed to livestock as growth enhancers").

93. Heberer et al., *Pharmaceuticals During Bank Filtration, supra* note 75, at 6. Accord Davis, *supra* note 51, at 1-3.

94. "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 27, at 4.

95. Heberer et al., *Pharmaceuticals During Bank Filtration, supra* note 75, at 10.

96. Benotti et al., *supra* note 49 at 597. *See also,* Carlson et al., *supra* note 27, 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 75, at 10; Masters, *supra* note 4, at 1.

## III. CURRENT MEANS OF PROTECTING FRESH WATER RESOURCES

### A. COMMON LAW REMEDIES SOUNDING IN TORT

The word "tort" is derived from the Latin *tortus*, meaning bent or crooked. Torts are private acts or 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.

#### 1. Trespass

There are three elements for establishing a claim under the theory of trespass. First, the plaintiff must have been harmed.[97] Second, the defendant's conduct must have caused the plaintiff's harm.[98] Third, the defendant must have 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."[99] In the case of personal property (trespass to chattels), an alternative third element is applicable when 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.[100] With regard to the requirement of intentionality, individuals are generally presumed to know the "natural and probable consequences" of their actions.[101]

#### 2. Nuisance

As with the theory of trespass, a nuisance claim contains three elements. First, the plaintiff's interest must be harmed.[102] Second, the defendant's conduct must have caused the plaintiff's harm.[103] Third, the defen-

97. RESTATEMENT (SECOND) OF TORTS §§ 158, 162 (1965). 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. RESTATEMENT (SECOND) OF TORTS §§ 901, 907 (1979).

98. RESTATEMENT (SECOND) OF TORTS §158 (1965).

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

100. *Id.* §§ 217-18.

101. 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 act . . .").

102. RESTATEMENT (SECOND) OF TORTS § 821D cmt. d (1979).

103. RESTATEMENT (SECOND) OF TORTS § 822 (1979).

dant's intentional actions must be either a public or a private nuisance. Public nuisances result where a defendant unreasonably interferes "with a right common to the general public" including a significant interference with public health, safety, peace, comfort, or convenience; additionally, a defendant's actions may be a public nuisance when the conduct is proscribed by statute or ordinance.[104] Private nuisances result where the defendant (a) substantially interfered with the plaintiff's use and enjoyment of property or (b) caused the plaintiff harm.[105]

### 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.[105] Second, the evidence must show that the defendant's conduct caused the plaintiff's harm.[106] Third, the defendant must have owed a duty of reasonable care to the plaintiff.[107] Fourth, the plaintiff must evidence that the defendant breached the duty of reasonable care.[108] Fifth, the harm to the plaintiff resulting from the breach must have been foreseeable.[109]

The duty of reasonable care is particularly relevant. The standard of care is frequently expressed as the question: What would a reasonably prudent person have done? Professionals are usually held to a higher standard of care than non-professionals because of both education and licensing requirements.[110] Corporations, because of superior knowledge regarding specific products, may also be held to a higher standard of care than the general citizenry.[111]

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104. State v. H. Samuels Co., 211 N.W.2d 417, 421 (Wis. 1973) (holding that a violation of a noise ordinance may constitute nuisance); RESTATEMENT (SECOND) OF TORTS § 821B (1979).

105. RESTATEMENT (SECOND) OF TORTS § 821D (1979); *Id.* § 821D cmt. d.

105. RESTATEMENT (SECOND) OF TORTS § 281 (1965).

106. *Id.*

107. Palsgraf v. Long Island R.R. Co., 162 N.E. 99, 102 (N.Y. 1928). Reasonableness may be defined by permit conditions, by industry custom/practice, or by statute. RESTATEMENT (SECOND) OF TORTS § 286 (1965). Violation of permit conditions or other statutory or regulatory requirements is almost always negligence per se. Sammons v. Ridgeway, 293 A.2d 547, 549 (Del. 1972) (holding that the violation of a statute is negligence per se).

108. Palsgraf, 162 N.E. at 102.

109. *Id.* at 100.

110. *E.g.*, Blair v. Eblen, 461 S.W.2d 370, 373 (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).

111. See, e.g., Binder v. Jones & Laughlin Steel Corp., 520 A.2d 863, 866-67 (Pa. Super. Ct. 1987) (holding that manufacturer had an affirmative duty to warn of risk due to its knowledge of the product's properties).

### 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 must show that the product harmed the plaintiff, and the defendant's conduct caused the plaintiff's harm.[112] The third element requires a showing that the defendant either engaged in an "abnormally dangerous activity" or manufactured an inherently dangerous product.[113]

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.[114] 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.[115]

As suggested above, the defendant may also be strictly liable for injuries to the plaintiff resulting from manufacturing an inherently dangerous product. Products may be inherently dangerous due to design defects, manufacturing defects, or marketing defects.[116]

## B. 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.[117] As Congress enacted it, 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

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112. *See* RESTATEMENT (SECOND) OF TORTS § 430 (1965); RESTATEMENT (SECOND) OF TORTS § 519 (1977).

113. *See* Caporale v. C.W. Blakeslee & Sons, Inc., 175 A.2d 561, 564 (Conn. 1961) (holding that construction under the circumstances was "intrinsically dangerous"); RESTATEMENT (SECOND) OF TORTS § 402A (1965); RESTATEMENT (SECOND) OF TORTS § 519 (1977).

114. *See* RESTATEMENT (SECOND) OF TORTS § 520 (1977).

115. *See* Rylands v. Fletcher [1868] UKHL 1, [1861-1873] Eng. Rep. 1 (appeal taken from Eng.) (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.

116. *See* Saupitty v. Yazoo Mfg. Co., 726 F.2d 657 (10th Cir. 1984) (holding that a lawnmower as designed was 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); 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).

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

located within the state.[118] This designation may be in terms of maintaining river water quality standards, in terms of allowable uses, or both.[119] But these standards or designated uses, which are subject to EPA approval,[120] must be based on the National Recommended Water Quality Criteria.[121]

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.[122] As discussed below, TMDLs are an element 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.[123] This system allows companies, governmental units, and other entities to obtain an NPDES permit for the discharge of effluent from a point source into "waters of the United States."[124] Absent an NPDES permit, such discharges are strictly prohibited.[125]

NPDES permits contain specific provisions regarding the type of waste treatment technology required and the type and concentration of materials to be discharged.[126] For existing facilities, the general requirement is Best Conventional Pollutant Control Technology ("BCT").[127] For new facilities, the requirement is Best Available Technology.[128]

### C. 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.[129] Congress also intended the SDWA to provide an enforcement mechanism,

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118. *See* 40 C.F.R. § 130.0 (2012).

119. Jefferson Cnty v. Wash. Dep't of Ecology, 511 U.S. 700 (1994).

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

121. 33 U.S.C.A. §§ 1313-14 (West 2012).

122. 40 C.F.R. § 130.4 (2012).

123. 33 U.S.C.A § 1342.

124. 40 C.F.R. §§ 230.3(s), 230.12.

125. *Id.* § 230.12.

126. 33 U.S.C. § 1342(p)(3).

127. 40 C.F.R. § 125.3.

128. *Id.* The Environmental Protection Agency has issued New Source Performance Standards mandating the use of "best available demonstrated control technology" for a number of industrial categories. *Id.*

129. 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).

the collection and dissemination of water-related information, and funding mechanisms to upgrade water supply systems.[130]

As with many environmental statutes, implementation of the SDWA is an example of cooperative federalism. States have primary enforcement authority once the EPA approves their state SDWA program.[131] 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.[132] Noncommunity or transient water systems are smaller systems that usually rely on groundwater.

### 1. National Primary Drinking Water Regulations

The National Primary Drinking Water Regulations are health-based standards for drinking water supplied by public water systems.[133] 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").[134] In general, "Best Available Technology" is required, though cost is taken into consideration.[135] The technology should result in a discharge as close as possible to the Maximum Contaminant Level Goal ("MCLG").[136]

Both MCLs and MCLGs must be based on human health effects, as determined through risk assessments. In conducting such assessments, the EPA is to utilize "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices"[137] and "data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)."[138]

The process for establishing MCLGs is relevant vis-à-vis the PPCP control options discussed in Section VI.[139] With regard to MCLGs for non-carcinogens, using the methodology noted above, a substance-

130. Kucera, *supra* note 129, at 439-40.

131. *Id.* at 440.

132. Community water systems are systems having at least 15 taps or providing service to at least 25 individuals. 42 U.S.C.A. § 300f(15).

133. 40 C.F.R. § 141.1 (2012). The National Primary Drinking Water Standards include 85 standards divided into six categories: disinfectants, disinfection byproducts, inorganic chemicals, microorganisms, organic chemical, and radionuclides. *Id.* §§ 141.50-.55.

134. 42 U.S.C.A § 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).

135. *See id.* § 300g-1(b)(4)(D).

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

137. *See id.* § 300g-1(b)(3)(A)(i).

138. *Id.* § 300g-1(b)(3)(A)(ii).

139. *See* RAPID PUB. HEALTH POL'Y RESPONSE PROJECT, *supra* note 27 (*See also infra*, note 243 with accompanying text.)

specific Reference Dose ("RfD") is determined.[140] In general, depending on the availability of information about a specific substance, the RfD is calculated by dividing Lowest-Observed-Adverse-Effect Level ("LOAEL")[141] or No-Observed-Adverse-Effect Level ("NOAEL")[142] by an Uncertainty Factor ("UF").[143] 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.[144]

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.[145] The National Secondary Drinking Water Regulations are not enforceable.[146]

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140. 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." *Integrated Risk Information System (IRIS) Glossary*, ENVTL. PROT. AGENCY, http://www.epa.gov/iris/gloss8_arch.htm (last visited Feb. 9, 2011).

141. *Id.* 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.*

142. *Id.* 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.*

143. *Id.* "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.*

144. *Regulating Public Water Systems and Contaminants Under the Safe Drinking Water Act*, ENVTL. PROT. AGENCY, http://water.epa.gov/lawsregs/rulesregs/regulatingcontaminants/basicinformation.cfm (last visited Feb. 9, 2011).

145. Kucera, *supra* note 129, at 445.

146. 40 C.F.R. § 143.1 (2012).

### 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.[147] 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.[148] The Unregulated Contaminant Monitoring Rule lists contaminants that public water systems must monitor, describes analytical methods of assessing these contaminants, and requires submission of monitoring and analysis results to the EPA for inclusion in the National Drinking Water Contaminant Occurrence Database.[149] The rule also requires public water systems to notify their consumers of the results of the monitoring and analysis.[150] The goal of the Unregulated Contaminant Monitoring Rule is to ensure that sound science, not political influence, forms the basis for decisions regarding the regulation of specific contaminants.[151]

### 3. The Contaminant Candidate List

The SDWA also requires the EPA to publish a Contaminant Candidate List every five years.[152] 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.[153] The SDWA specifies three criteria for determining whether a contaminant may be a candidate for regulation:

(i) The contaminant may have an adverse effect on the health of persons;

(ii) 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

(iii) 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.[154]

### 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 in-

147. Kucera, *supra* note 129, at 477.
148. *Id.*
149. Unregulated Contaminant Monitoring Rule, 64 Fed. Reg. 50,556 (Sept. 17, 1999) (codified at 40 C.F.R. pt. 9, 141-42).
150. Kucera, *supra* note 129, at 457.
151. *See* Safe Drinking Water Act, 42 U.S.C. § 300g-1(b) (2006).
152. *Id.* § 300g-1(b)(1)(B)(i).
153. *Id.*
154. *Id.* § 300g-1(b)(1)(A); *see* Kucera, *supra* note 129, at 447.

fluence of surface water to disinfect and filter their water so that the following contaminants are controlled at these levels: Cryptosporidium (99% removal), Giardia lamblia (99.9% removal or inactivation), and viruses (99.99% removal or inactivation).[155]

### 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.[156] 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.[157] 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 . . . ."[158]

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 comply with all requirements of the states' wellhead protection programs.[159] 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.[160]

### 6. The Underground Injection Control Program

Protection of underground sources of drinking water also occurs through the SDWA's Underground Injection Control Program ("UICP").[161] Ongoing reliance on groundwater as a source of drinking water supplies necessitated the creation of the UICP.[162] Over eighty percent of community water systems rely on groundwater for all or part of their water supply.[163]

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

- Class I wells are used for injection of industrial nonhazardous liquids, municipal wastewaters, or hazardous

155. Surface Water Treatment Rule, 40 C.F.R. § 141.70 (2011); *see also* Safe Drinking Water Act § 300g-1(b)(2)(C).
156. Safe Drinking Water Act § 300h-7.
157. *Id.* § 300h-7(a).
158. "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).
159. *Id.* § 300h-7(h).
160. *Id.* § 300h-7(d).
161. *Id.* § 300h.
162. Kucera, *supra* note 129, at 474.
163. *See id.*

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.[164]

### 7. The Biosolids Rule

The Clean Water Act Amendments of 1987 required the 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). In 1993, the EPA published these regulations, which became Title 40, Part 503 of the Code of Federal Regulations. As a result, the regulatory community commonly refers to these as the "Part 503 Biosolids Rule."[165]

Of particular relevance to the issue of PPCPs in fresh water resources is a portion of the Biosolids Rule relating to the application of biosolids to land.[166] Four general requirements are established under the Biosolids Rule: (1) ceiling concentration limits for heavy metals;[167] (2) pollutant

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164. 40 C.F.R. § 146.5 (2011). With regard to Class VI wells, see Federal Requirements Under the Underground Injection Control (UIC) Program for Carbon Dioxide ($CO_2$) Geologic Sequestration (GS) Wells, 75 Fed. Reg. 77, 230 (Dec. 10, 2010) (to be codified at 40 C.F.R. pt. 124, 144-47).

165. 58 Fed. Reg. 9248 (Feb. 19, 1993) (as codified at CFR pt. 257, 403, 503).

166. Other portions of Part 503 apply to a variety of different uses and disposal techniques for biosolids. See generally OFFICE OF WASTEWATER MANAGEMENT, ENVTL. PROT. AGENCY, A PLAIN ENGLISH GUIDE TO THE EPA PART 503 BIOSOLIDS RULE (1994) [hereinafter EPA GUIDE TO PART 503 BIOSOLIDS RULE].

167. Ceiling concentration limits were established for arsenic, cadmium, chromium, copper, lead, mercury, molybdenum, nickel, selenium and zinc. See EPA GUIDE TO PART 503 BIOSOLIDS RULE, *supra* note 166, ch. 2 at 29-30. 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 con-

loading rate limits; (3) pathogen control requirements;[168] and (4) vector-attraction reduction requirements.[169]

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.[170] Once biosolids have been applied to land, an ongoing monitoring program is required.[171]

## D. 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 established a program for the "cradle-to-grave" management of hazardous

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> ditions, 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.

COMM. ON TOXICANTS AND PATHOGENS IN BIOSOLIDS APPLIED TO LAND, *supra* note 43, 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).

168. "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." COMM. ON TOXICANTS AND PATHOGENS IN BIOSOLIDS APPLIED TO LAND, *supra* note 43, 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.

169. Vectors are typically flies and rodents. *Id.* at 2.

170. The options include the Exceptional Quality option, the Pollutant Concentration option, the Cumulative Pollutant Loading Rule option and the Annual Pollutant Loading Rate option. These requirements were based on a comprehensive risk assessment. EPA GUIDE TO PART 503 BIOSOLIDS RULE, *supra* note 166, at 30-40.

171. Monitoring must include pollutants, pathogen densities (fecal coliform, salmonella, viable helminth ova and enteric virus) and vector attraction reduction. *See* EPA GUIDE TO PART 503 BIOSOLIDS RULE, *supra* note 166, at 47-49.

substances and waste.[172] One of RCRA's goals, as expressed in Subtitle A, is to protect human health and the environment from the hazards posed by waste disposal.[173] 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.[174]

Subtitle C of RCRA created a hazardous waste management program.[175] A waste is considered "hazardous" if it is a solid waste, defined as:

> [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).[176]

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."[177]

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.[178]

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172. 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 ENVTL. LAW HANDBOOK 133, 134 (Thomas F.P. Sullivan ed., Government Institutes 19th ed. 2007).

173. 42 U.S.C. § 6902(a).

174. *Id.*

175. *Id.* §§ 6921-6931.

176. *Id.* § 6903(27).

177. Case, *supra* note 172, at 138.

178. 42 U.S.C. § 6903(5).

This statutory language gives the EPA broad authority to define hazardous wastes through regulation. Applicable regulations establish several lists of hazardous wastes: [179]

- 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 U-list, health-care facilities focus primarily on these lists."[180]

### 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.[181] 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.[182]

### 2. Categories of Generators

Hazardous waste generators are regulated depending on the amount of waste they generate each month.[183] There are three categories:

- Large quantity generators (LQG, generators of more the 1,000 kilograms of hazardous waste per month)
- Small quantity generators (SQG, generators of between 100 and 1,000 kilograms of hazardous waste per month)

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179. 40 C.F.R. § 261.31, 261.32 (2012); *id.* pt. 273; Case, *supra* note 172, at 141-42.

180. Teirney Christenson, Comment, *Fish on Morphine: Protecting Wisconsin's Natural Resources Through a Comprehensive Plan for Proper Disposal of Pharmaceuticals*, 2008 WIS. L. REV. 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 ENVTL. HEALTH PERSP. 775, 782 (2003)).

181. 40 C.F.R. § 261.3(a)(2); Case, *supra* note 172, at 145.

182. 40 C.F.R. § 261.3.

183. *Id.* pt. 260 (1987); *see* Case, *supra* note 172, at 152-53.

- 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, observe waste accumulation time limits, and comply with storage requirements.[184]

### 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.[185] 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").[186] Transporters of hazardous waste must also meet requirements established by the Department of Transportation.[187] 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.[188]

### 4. Treatment, Storage and Disposal Facilities

Requirements for TSDFs are also established under RCRA. A permit is required to construct and operate a TSDF.[189] The permit contains specific operating standards and requirements applicable to the TSDF.[190] 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.[191] 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.[192]

RCRA contains a number of specific limitations and prohibitions. Bulk (non-containerized) hazardous liquid waste is prohibited from disposal in any landfill.[193] There are also severe restrictions on the disposal

184. Case, *supra* note 172, at 150.
185. 40 C.F.R. § 262.20; Case, *supra* note 172, at 150.
186. Case, *supra* note 172, at 150.
187. *Id.* at 134.
188. *Id.*
189. 40 C.F.R. § 264.1.
190. *Id.*
191. *See Id.* §§ 264.144-.145, 264.147; *see also* Case, *supra* note 172, at 161.
192. Case, *supra* note 172, at 170.
193. 40 C.F.R. § 264.314(a).

of containerized hazardous liquid waste.[194] Land disposal of specific highly hazardous waste was phased out between 1986 and 1990.[195]

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."[196]

### 5. The Universal Waste Rule

In 1995, the EPA promulgated regulations to streamline the management of certain types of commonly occurring hazardous wastes.[197] 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.[198] Concluding that the "current RCRA regulations have been a major impediment to national collection and recycling campaigns for these wastes,"[199] the Universal Waste Rule ("UWR")[200] was promulgated to "facilitate [their] environmentally-sound collection and increase the proper recycling or treatment" of such wastes.[201]

To achieve these goals, the UWR allowed for longer storage of covered wastes, reduced recordkeeping requirements, and simplified the procedure for recycling such wastes.[202] Transportation was facilitated by exempting the transport of wastes included within the UWR from the manifest requirements discussed above.[203]

### 6. State Implementation

The EPA encouraged states to assume responsibility for RCRA's hazardous waste program in part by providing financial assistance.[204] At the present time, all but two of the states have been granted authority to implement the RCRA program.[205]

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194. *Id.* § 264.314(b)-(c).
195. Case, *supra* note 172, at 164-65.
196. 40 C.F.R. § 264.301; Case, *supra* note 172, at 164-65.
197. Universal Waste Rule (Hazardous Waste Management System; Modification of the Hazardous Waste Recycling Regulatory Program), 60 Fed. Reg. 25492 (May 11, 1995) (codified at 40 C.F.R. §§ 9, 260-66, 268, 270, 273).
198. *See* 40 C.F.R. § 273.1 (2005).
199. Universal Waste Rule, 60 Fed. Reg. at 25492.
200. 40 C.F.R. § 273.
201. Universal Waste Rule, 60 Fed. Reg. at 25492.
202. *Id.* at 25495, 25498, 25502.
203. *Id.* at 25501.
204. Resource Conservation and Recovery Act (RCRA) § 6947.
205. 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, Alaska State Report (2011), http://www.epa.gov/osw/laws-regs/state/stats/ak.pdf (showing rule package not submitted by Alaska as of December

## E. 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.[206] The resulting legislation, the Toxic Substances Control Act ("TSCA"), was signed into law by President Ford on October 11, 1976.[207]

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 is inadequate to predict the effects of human exposure and environmental releases.[208] The required testing may be based on risk triggers (chemical toxicity, etc.), exposure triggers (long-term, low-level exposure), or both.[209] Chemicals known or suspected to be carcinogenic, mutagenic, or teratogenic are to be assigned a higher priority for testing.[210]

### 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.[211] All chemicals not on the Inventory are, by definition, "new" and are subject to the Pre-Manufacture Notification requirements, as discussed below.[212]

In 2008, the EPA initiated a phased, multi-year program to obtain health and safety information from manufacturers and processors of in-

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31, 2011), Iowa State Report (2011), http://www.epa.gov/osw/ laws-regs/state/stats/ia.pdf (showing rule package not submitted by Iowa as of December 31, 2011).

206. This recommendation was contained in the CEQ report Toxic Substances (1971). Linda Schierow, *Toxic Control Substances Act, in* ENVIRONMENTAL LAWS: SUMMARY OF ENVIRONMENTAL LAWS ADMINISTERED BY THE EPA 87, 88 (2010), http://www.fas.org/sgp/crs/misc/RL30798.pdf.

207. 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).

208. Toxic Substance Control Act § 2603; Landfair, *supra* note 207, at 644.

209. Landfair, *supra* note 208, at 644.

210. *See id.* at 643.

211. Toxic Substance Control Act § 2607(b)(1).

212. *See id.* §2607(b).

organic, high-production volume ("HPV") chemicals.[213] Such information on 2,200 organic chemical HPV chemicals has been obtained by the EPA.[214]

### 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 ninety days prior to producing a new chemical product into the United States.[215] The EPA then has forty-five days to evaluate the potential risk posed by the new chemical product.[216] 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.[217] 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.[218]

### 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."[219] This authority allows the 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.[220] However, the EPA is to exercise this authority only "to the extent necessary to protect adequately" against a risk.[221] Furthermore, the EPA is to use the "least burdensome" regulatory approach, even when unreasonable risks are being controlled.[222]

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213. *High Production Volume (HPV) Challenge Program*, ENVTL. PROT. AGENCY, http://www.epa.gov/hpv (last updated Jan. 26, 2012).
214. *Id.*
215. Toxic Substance Control Act § 2604(a)(1)(B).
216. *Id.* §2604(e)(1)(B).
217. *Id.* §2604(e)(1)(A).
218. *Id.*
219. *Id.* §2605(a).
220. *Id.*
221. *Id.*
222. *Id.*

### 4. Imminent Hazards

The TSCA also authorizes the EPA to take emergency action through federal courts to control a chemical substance or mixture that presents an imminent and unreasonable risk of serious, widespread injury to human health or the environment.[223]

## F. PROTECTION OF SPECIES: THE ENDANGERED SPECIES ACT

Perhaps the best known of the federal species protection statutes, the Endangered Species Act ("ESA")[224] 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.[225]

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[.]"[226] 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."[227] In essence, the ESA was intended to protect threatened and endangered species virtually irrespective of the cost of the protection.[228]

### 1. "Taking" Endangered Species

With limited exceptions, Congress prohibited the "taking" of an "endangered"[229] plant or animal species.[230] Fish and Wildlife Service regula-

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223. *Id.* § 2606(b)(1).

224. *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)).

225. Endangered Species Act § 1538(a)(1).

226. *Id.* § 1531(b).

227. *Id.* § 1531(c)(1).

228. *See* Tennessee Valley Auth. 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).

229. 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." Endangered Species Act § 1532(6).

230. 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 pertain-

tions extending these provisions to "threatened"[231] species were sustained when challenged as a reasonable and permissible interpretation of the ESA.[232]

The Secretary of the Interior must designate critical habitat concurrent with the determination that a species is endangered or threatened.[233]

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."[234] To conclude that the definition of "take" is quite broad would be an understatement. For example, registration of a pesticide by the EPA was considered a "taking" when endangered species were poisoned by the pesticide.[235] Forest management practices of the Forest Service, which resulted in harm to an endangered species, constituted a "taking" in *Sierra Club v. Lyng*.[236]

### 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.[237] Such agencies are also required to insure that agency actions do not result in the destruction or adverse modification of critical

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ing to such species or to any threatened species of fish or wildlife listed pursuant to ... this title." *Id.* § 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 Act...." *Id.* § 1538(a)(2).

231. 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).

232. Sweet Home Chapter of Comts. for a Great Oregon v. Lujan, 806 F. Supp. 279 (D.D.C. 1992), *aff'd sub nom* Sweet Home Chapter of Comts. 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).

233. 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 area as critical habitat will result in the extinction of the species concerned. Endangered Species Act § 1533(b)(2).

234. *Id.* § 1532(19).

235. Defenders of Wildlife v. Adm'r EPA, 882 F.2d 1294, 1303 (8th Cir. 1989).

236. Sierra Club v. Lyng, 694 F. Supp. 1260, 1263 (E.D. Tex. 1988), *aff'd in part, vacated in part sub nom*, Sierra Club v. Yeutter, 926 F.2d 429, 439 (5th Cir. 1991).

237. Endangered Species Act § 1536(a)(2).

habitat.[238] 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.[239]

In order to fulfill this requirement, agencies are required to "use the best scientific and commercial data available."[240] Agencies are also required to act "in consultation with and with the assistance of" the Secretary of the Interior.[241]

## IV. ALTERNATIVE STRATEGIES

As an alternative to a regulatory approach, there are a number of source control possibilities that could be utilized to address the presence of PPCPs in fresh water resources.[242] These possibilities fall generally into six categories: (1) drug design; (2) drug delivery; (3) drug marketing; (4) drug dispensing; (5) drug disposal/recycling; and (6) drug alternatives.[243] While these categories focus primarily on pharmaceuticals, they apply equally to personal care products and the full array of PPCPs previously identified.[244]

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238. *Id.*
239. *Id.*
240. *Id.*
241. *Id.*
242. 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 PUB. HEALTH POL'Y RESPONSE PROJECT, *supra* note 27, at 6 (citing U.S. ENVTL. PROT. AGENCY, SOURCE WATER PROTECTION, http://cfpub.epa.gov/safewater/sourcewater/index.cfm, emphasis added). *See also* Keith J. Jones, Endocrine Disruptors and Risk Assessment: Potential for a Big Mistake, 17 VILL. ENVTL. L.J. 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.").

243. 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. I. Rationale for and Avenue Toward a Green Pharmacy, 111 ENVIRONMENTAL HEALTH PERSPECTIVES 757 (2003) [hereinafter Daughton, *Rationale for and Avenues toward a Green Pharmacy*] and 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 48.

244. *See* Masters, *supra* note 4.

### A. 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."[245] Wennmalm and Gunnarsson described the need for such an approach:

> [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.[246]

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 one micrograms per liter.[247]

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. . . ."[248]

Daughton notes that the "advancing 'omnics' revolution"[249] 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

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245. Daughton, Rationale for and Avenues toward a Green Pharmacy, *supra* note 243, at 765.

246. Wennmalm & Gunnarsson, *supra* note 42, at 295-96 (citing Ettore Zuccato et al., Environmental Loads and Detection of Pharmaceuticals in Italy, PHARMACEUTICALS IN THE ENVT. 23-24 (K. Kümmerer ed., Springer Verlag 2001)).

247. Snyder et al., *supra* note 48, at 34.

248. Daughton, *Rationale for and Avenues Toward a Green Pharmacy*, *supra* note 244, 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. . . .").

249. 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 -Omes and -omics Glossary & Taxonomy: Evolving Terminology for Emerging Technologies*, CAMBRIDGE HEALTHTECH INST., http://www.genomicglossaries.com/content/omes.asp (last updated Sept. 12, 2011).

therapeutic effects by the general population.[250] If use of drugs resulting in the excretion of PPCPs by the general population were reduced, then the quantity of PPCPs entering fresh water resources would also be reduced.

Other drug design possibilities could include the development of drugs that maintain their therapeutic effectiveness despite substantially reduced dosage levels[251] as well as the development of "smart" drugs that "better emulate the nonanthropocentric, native chemistries of natural products."[252]

## B. DRUG DELIVERY

The first step in the drug delivery system identified by Daughton as playing a role vis-à-vis PPCPs in fresh water resources is the prescribing of drugs.[253] Both physicians and patients need to be better informed of the consequences of using specific drugs,[254] particularly both the "medical and environmental consequences of overprescribing medications."[255]

Numerous studies have shown that "the therapeutically effective dose for many drugs can be significantly lower than that initially recommended by the manufacturer."[256] 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)." [257] 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 fresh water resources.[258]

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250. Daughton, Rationale for and Avenues Toward a Green Pharmacy, *supra* note 243, at 765.

251. *Id.* at 766.

252. *Id.*

253. *Id.* at 766-67.

254. 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 42, at 294-95.

255. Daughton, Rationale for and Avenues Toward a Green Pharmacy, *supra* note 243, at 766.

256. *Id.* at 767.

257. Cunningham et al., *supra* note 42, at 43.

258. Cunningham et al. state:

The same result could be achieved through more precise formulation and dosing of drugs.[259] 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 . . ."[260]

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)."[261]

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. . . ."[262] As a result, unused—and perhaps outdated—drugs accumulate and eventually require disposal. If patients completed courses of medication as prescribed, the quantity of drugs inappropriately disposed of would be reduced. This could reduce the quantity of PPCPs entering fresh water resources.

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.[263]

## C. 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

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> 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

259. Daughton, *Rationale for and Avenues Toward a Green Pharmacy*, *supra* note 243, at 767.

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

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

262. *Id.* at 768 (citing Daughton, *Drug Disposal, Waste Reduction, and Future Directions*, *supra* note 243).

263. Daughton, *Rationale for and Avenues Toward a Green Pharmacy*, *supra* note 243, at 768.

portion of the medication.[264] 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.[265] This problem may be exacerbated by different drugs having a similar name or appearance.[266]

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.[267] This quantity could also be reduced if improved packaging extended the shelf-life of drugs.[268]

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."[269]

## D. 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.[270]

This is particularly true with regard to the distribution of black-market and counterfeit drugs, some twenty-five percent of which are sold via the Internet.[271] 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.

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264. *Id.*

265. "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.*

266. *Id.* at 768-769 (citing Comm. on Quality of Health Care in America, Inst. 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 better-informed consumer." *Id.* at 769.

267. *Id.* at 769.

268. *Id.*

269. *Id.*

270. *Id.* (citing U.S. FOOD & DRUG ADMINISTRATION, BUYING MEDICINES AND MEDICAL PRODUCTS ONLINE (2002)).

271. Daughton, *Rationale for and Avenues toward a Green Pharmacy*, *supra* note 243, at 769 (citing Press Release, Cyveillance Inc., Cyveillance Partners with Biocode to Serve Pharmaceutical Indus. (June 5, 2001)).

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 the recommendations of specific drug manufacturers.[272]

The need to dispose of unwanted drugs could also be reduced by developing more disciplined dispensing and inventory control protocols. 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.[273] 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."[274]

Daughton makes two additional points regarding drug dispensing vis-à-vis PPCPs in fresh water resources. 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.[275] 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)."[276]

## E. DRUG DISPOSAL/RECYCLING

The need for appropriate disposal or recycling of pharmaceuticals has been noted repeatedly.[277] 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

272. "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 243, at 770.

273. *Id.*

274. *Id.*

275. 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.

276. *Id.* at 769 (citing Christian G. Daughton, U.S. Envt'l Prot. Agency, Factors Complicating Prediction of Drug Elimination from the Body (2002)).

277. *See, e.g.*, TDC ENVIRONMENTAL, *supra* note 51, at 2; Christenson, *supra* note 180, at 164-166 (reviewing programs in Arizona, Arkansas and Wisconsin).

implement drug disposal/recycling programs "would be to offer patent extensions to companies that formulate vibrant, comprehensive stewardship programs tailored for each particular drug."[278] 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."[279] Such an expansion might also include drug samples given to physicians because the "distributors of physician samples often instruct physicians to dispose of outdated samples to the sewage system."[280]

Minimization of waste flows into the environment should have the effect of reducing the presence of PPCPs in fresh water resources. 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.[281]

Another approach could be "drug mining" (i.e., recovery of highly toxic drugs from excreta and other hospital wastes).[282] However, with only

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278. Daughton, Drug Disposal, Waste Reduction, and Future Directions, *supra* note 243, at 776.

279. *Id. See also* TDC ENVIRONMENTAL, *supra* note 51:

> 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 51, 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/F3001B817EF426588525661100515 6D2; 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/354FE6A290ED95E1852565DA006 F04A1). Accord Christenson, *supra* note 181, 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 51, at 6.

280. Daughton, Drug Disposal, Waste Reduction, and Future Directions, *supra* note 243, at 776.

281. *Id.* (citing Tove A. Larsen et al., Re-engineering the Toilet for Sustainable Wastewater Management, 35 ENVTL. SCI. & TECH. 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 SCI. & TECH. 149 (2002)).

282. Daughton, Drug Disposal, Waste Reduction, and Future Directions, *supra* note 243, 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).

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.[283]

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.[284] As Daughton notes, "by use of advanced water treatment technology such as reverse osmosis, nearly complete removal of all PPCPs can be achieved."[285] This is an issue of special concern in arid regions, particularly the southwestern United States, where limited fresh water resources and growing populations virtually mandate the reuse of water.[286]

Improvements to wastewater collection[287] and treatment[288] systems are closely associated with the development of water recycling systems. Advanced wastewater treatment systems using reverse osmosis have the ca-

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283. TDC ENVIRONMENTAL, *supra* note 51, at 8.

284. Daughton, *Drug Disposal, Waste Reduction, and Future Directions*, *supra* note 243, at 776; Lindsey A. Greene, *Controversy Swirls Around Toilet-to-Tap Project*, 108 ENVTL. HEALTH PERSPECTIVES A447 (2000).

285. Daughton, *Drug Disposal, Waste Reduction, and Future Directions*, *supra* note 243, at 776. 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.

286. Snyder et al., *supra* note 48, at 34.

287. Collection system improvements need to address both combined sewer overflows and urban stream-stormflows as these are "significant contributors of OWCs [organic water compounds] to receiving waters[.]" Phillips & Chalmers, *supra* note 85, 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.*

288. 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 180, at 159 (citing George J. Mannina, Jr., *Medicines and the Environment: Legal and Regulatory Storms Ahead?*, 21 LEGAL BACKGROUNDER (2006)).

pability to remove PPCPs through a physical separation process.[289] Utilization of granular activated charcoal systems, as well as ozonation, has been effective in removing antibiotics from wastewater.[290] Research also suggests using engineered wetlands and groundwater infiltration basins,[291] as well as phytoremediation,[292] as mechanisms to attenuate PPCPs. At a more basic level, Daughton recommends both that "[s]traight-piping of sewage to surface waters . . . continue to be identified and eliminated"[293] and that "[p]rivies and septic systems. . . be converted to municipal systems when feasible."[294]

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 restrict the donation of prescription drugs to charity (*e.g.*, Oklahoma)[295] or restrict or limit the authority of pharmacies to accept returns of unused drugs.[296]

Daughton's observation that funeral practices need to be environmentally sound illustrates the complexity of issues relating to PPCPs in fresh water resources. 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,"[297] 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."[298]

The role of public education is also important 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

289. Sedlak and Pinkston, *supra* note 16, at 56; Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 26; Heberer et al., *Removal of Pharmaceutical Residues*, *supra* note 87, at 28.

290. Huang et al., *supra* note 26, at 37; Reynolds, *Pharmaceuticals in Drinking Water Supplies*, *supra* note 26, (citing Marc M. Huber et al., *Oxidation of Pharmaceuticals during Ozonation and Advanced Oxidation Processes*, 36 ENVTL. SCI. & TECH. 1202 (2003)).

291. Sedlak & Pinkston, *supra* note 16, at 62.

292. Ninad Gujarathi & James Linden, *Potential for Phytoremediation of Antibiotic-Contaminated Water*, 24 AGRONOMY NEWS 9 (2004).

293. Daughton, *Drug Disposal, Waste Reduction, and Future Directions*, *supra* note 243, at 776.

294. *Id.*

295. *Id.* at 776-77.

296. *Id.* at 777.

297. *Id.*

298. *Id.*

advantages (human health and economic) accrued by conscientious/responsible disposal and use of PPCPs.[299]

## IV. DRUG ALTERNATIVES

A condition precedent to the release of PPCPs into fresh water resources is the use of PPCPs. Experts frequently overlook the obvious fact 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.[300]

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).[301] Such "bacteriotherapy" may achieve the same results as the use of drugs containing PPCPs but without the attendant execration or disposal problems.[302]

## V. CASE STUDY BASED ON PROJECT 2 RESULTS

The Project 2 research focused on the presence of PPCPs in soil and groundwater in West Texas.[303] 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.[304]

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299. *Id.*

300. *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.*

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

302. 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 PHARM. SCI. 1 (2002)).

303. 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 wastewater treatment are discussed *supra* note 82, and accompanying text.

304. 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 55, at 2546, noting:

As noted in Section II, the research is relevant to the issue of PPCPs in fresh water resources because of disposal methods used by wastewater treatment plants for both solid and liquid wastes.[305] Solid wastes (sludge or biosolids) and liquid wastes are applied to lands that have been designated as application sites, and the waste products are then 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.[306] 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.[307]

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"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 ENVTL. SCI. & TECH. 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 ENVTL. 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 ENVTL. SCI. & TECH. 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)).

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

Kinney et al., *supra* note 27, at 317 (citing H. Bouwer et al., *Integrating Water Management and Re-use: Causes for Concern?* 1-2 WATER QUALITY INT'L. 19 (1999)).

306. *Id.*, at 318 (organic wastewater contaminants "might accumulate in soil if introduced through irrigation water").

307. Lozano et al., *supra* note 89, at 764.

### A. SORPTION OF ESTROGENS, TRICLOSAN, AND CAFFEINE IN A SANDY LOAM AND A SILT LOAM SOIL[308]

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

The sample PPCPs were estrogens (estrone, 17β-estradiol, estriol and 17α-ethynylestradiol),[309] triclosan,[310] and caffeine. 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. Laboratory sand served as a control.[311]

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, 17β-estradiol, 17α-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.

### B. MICROBIALLY MEDIATED DEGRADATION OF COMMON PHARMACEUTICALS AND PERSONAL CARE PRODUCTS IN SOIL UNDER AEROBIC AND ANAEROBIC CONDITIONS[312]

The City of Lubbock, Texas, disposes of treated effluent from its municipal wastewater treatment plant by applying it to lands designated as

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308. 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).

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

310. 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. *See* Lyndsey Layton, *FDA Says Studies on Triclosan, Used in Sanitizers and Soaps, Raise Concerns*, WASH. POST, April 8, 2010, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2010/04/07/AR2010040704621.html.

311. Karnjanapiboonwong et al., *supra* note 308.

312. 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).

a land application site. This site received an average of thirteen million gallons per day of effluent, which was applied to the land using thirty-one 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).

The researchers identified numerous PPCPs in the treated effluent, including estrogens (estrone, 17β-estradiol, estriol and 17α-ethynylestradiol), triclosan, ibuprofen,[313] and ciprofloxacin.[314] 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.

### C. BIOLOGICAL DEGRADATION OF COMMON PHARMACEUTICALS AND PERSONAL CARE PRODUCTS IN SOILS WITH HIGH WATER CONTENT[315]

This element of this case study addressed the movement of water through soils. As the researchers noted, 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, 17β-estradiol, estriol and 17α-ethynylestradiol), triclosan, and ibprofen. 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.[316] 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.

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

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

315. 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*, 217 WATER, AIR & SOIL POLLUTION 127 (2011).

316. The only exception was ibuprofen, which appeared to demonstrate increased degradation in soils with high water content. *Id.*

## D. OCCURRENCE OF PPCPS AT A WASTEWATER TREATMENT PLANT AND IN SOIL AND GROUNDWATER AT A LAND APPLICATION SITE[317]

The 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 thirty-one 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,[318] were estrogens (estrone, 17β-estradiol, estriol and 17α-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.

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."[319]

Of all of the PPCPs included in the study, only ibuprofen was not detected in the groundwater samples. This was true irrespective of whether

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317. 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*].

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

319. *Id.* at 18 (citing Michael S. Colucci, Henry Bork, & Edward Topp, *Persistence of Estrogenic Hormones in Agricultural Soils: I. 17β-Estradiol and Estrone*, 30 J. ENVTL. QUALITY 2070 (2001); 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, 127 (Diana S. Aga ed., CRC Press 2007); Monteiro & Boxall, *supra* note 55, at 2546).

the groundwater samples were drawn from the areas irrigated with the wastewater effluent or from adjacent areas that had not been irrigated. The researchers 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.[320]

## E. 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.[321]

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320. *Id.* at 22.

321. 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 27, 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 89, at 762. This variability was also addressed in Monteiro & Boxall, *supra* note 55, 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 Envi-

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.[322] 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 post-release alternatives. In

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ronment, in FATE OF PHARMACEUTICALS IN THE ENVIRONMENT AND IN WATER TREATMENT SYSTEMS 123 (Diana S. Aga ed., CRC Press 2007)).

"Within the same therapeutic class, half-lives can still be significantly different." Id. (citing Michael P. Schlüsener & Kai Bester, *Persistence of Antibiotics Such as Macrolides, Tiamulin and Salinomycin in Soil*, 143 ENVTL. 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 lipophilicity." *Id.* (citing Edward Topp et al., *Fate of the Nonsteroidal Anti-inflammatory Drug Naproxen in Agricultural Soil Receiving Liquid Municipal Biosolids*, 27 ENVTL. TOXICOLOGY & CHEMISTRY 2005, 2008 (2008); Melanie Kah et al., *Factors Influencing Degradation of Pesticides in Soil*, 55 J. AGRIC. & FOOD CHEMISTRY 4487, 4491-4492 (2007); Edward Topp et al., *Biodegradation of Caffeine in Agricultural Soils*, 86 CAN. J. SOIL SCI. 533, 543 (2006); M.S. Collucci et al., *Persistence of Estrogenic Hormones in Agricultural Soils (I. 17-beta Estradiol and Estrone)*, 30 J. ENVTL. QUALITY 2070, 2075 (2001)).

322. 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 79, at 4, Table 4.

essence, it is much easier to keep PPCPs out of waste stream than to safely dispose of waste containing PPCPs.

## VI. STRENGTHS AND WEAKNESSES OF THE STATUTORY, REGULATORY AND ALTERNATIVE STRATEGIES

### A. 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 EPA. Similar legislation at the state, territorial, and tribal levels has vested authority in entities whose functions mirror those of the EPA.[323]

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323. 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. Johnston & Kristine Sendek-Smith, *Muddy Waters: Recent Developments Under the Clean Water Act*, 24-Winter NATURAL RES. AND ENV'T 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 ENV'T REP. 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)). *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 decision-making, but also requires that it take these considerations into account." Christopher T. Nidel, *Regulating the Fate of Pharmaceutical Drugs: A New Prescription*

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 the EPA's authority has been established. The result is a fairly complete understanding of the requirements of different statutes and regulations. As with the 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.

### 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. Notably, litigation is expensive and time-consuming. Furthermore, 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

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*for the Environment*, 58 FOOD & DRUG LAW JOURNAL 81, 92 (2003) (citing 42 U.S.C.S. §§ 4321 et seq.). *See* Mannina, *supra* note 289, at 1, 3; *see also* Christenson, *supra* note 180, at 156.

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 facilities"[321] was adversely affected by water supplies containing 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 could prove 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"[325] (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.[326]

However, as noted above, litigation is always fact-specific. Given an appropriate set of circumstances, application of one of the common law

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324. RESTATEMENT (SECOND) OF TORTS, *supra* note 96, at § 821B.

325. *Id.* at § 402A.

326. For example, acetylsalicylic acid is used for both human therapy and in animal husbandry. It is "a non-steroidal 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 14, at 660 (citation omitted).

tort theories might be an appropriate response to human and environmental health injuries resulting from the release of PPCPs.[327]

### 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 EPA has a mandatory duty to revise the Criteria "to establish limitations for EDCs [and other PPCPs] to protect against endocrine disruption."[328] Should this occur, 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 fresh water resources, 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

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327. 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 288, at 3 (emphasis added).

328. Jacki Lopez, *Endocrine-Disrupting Chemical Pollution: Why the EPA Should Regulate These Chemicals Under the Clean Water Act*, Spring SUSTAINABLE DEV. L. & POL'Y 19, 22 (2010).

been (and are being) developed.[329] A number of authors have noted the need for these technological developments to continue. Nidel, for example, notes the need to development new wastewater treatment systems that "more effectively break down these compounds leaving only environmentally inert effluents."[330] 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.[331] Such requirements would be applicable to a variety of entities (i.e., manufacturing facilities, health care facilities) that discharge wastes containing PPCPs.[332] 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.[333]

Assuming that wastewater treatment techniques and systems can be developed to control the plethora of PPCPs, the cost could be staggering.[334] 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."[335]

Finally, perhaps the most significant limitation regarding use of the Clean Water Act as a means of preventing the introduction of PPCPs into fresh water resources 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[.]"[336]

### 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.

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329. *Supra*, notes 278 to 300 and associated text.

330. Nidel, *supra* note 323, 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.

331. Christenson, *supra* note 180, at 163 (citing P.G. KENT & T.A. DUDIAK, WISCONSIN WATER LAW: A GUIDE TO WATER RIGHTS AND REGULATIONS 104 (2d ed. 2001)).

332. *Id.*

333. *See Id.*

334. "The total costs of removing every possible endocrine disrupting compound could quickly become astronomical." Jones, *supra* note 243, at 385-386.

335. *Id.* at 386.

336. Christenson, *supra* note 181, at 148 (citing P.G. Kent & T.A. Dudiak, WISCONSIN WATER LAW: A GUIDE TO WATER RIGHTS AND REGULATIONS 99, 107 (2d ed. 2001)).

In fact, the EPA is considering such an approach. 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 are 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.[337] Unfortunately, virtually all of the PPCPs that were proposed for inclusion on the CCL were not included.[338]

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 ongoing 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.[339]

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337. Drinking Water Contaminant Candidate List 3, 73 Fed. Reg. 194, 51850 (2008).

338. The process that preceded the current Contaminant List was described by TOXServices L.L.C.:

> 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 L.L.C., *supra* note 35, at 12.

339. EPA SCIENCE ADVISORY BOARD DRINKING WATER COMMITTEE, ENVTL. PROT. 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

A final decision regarding "whether to regulate five or more of the contaminants from this list" is expected by 2013.[340] 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.[341]

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.

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.

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> pharmaceuticals, personal care products, enteric pathogens, and other emerging contaminants. In the case of pharmaceuticals, perflourinated 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, "[t]he 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.*

340. Johnston & Sendek-Smith, *supra* note 323, at 38 (citing Alan Kovski, *Drinking Water: EPA Completes List of Water Contaminants to Consider as Candidates for Regulation*, 40 ENV'T REPORTER 2246 (Sept. 25, 2009)). EPA has also considered inclusion of PPCPs within the Unregulated Contaminant Monitoring Rule.

341. Poynton & Vulpe, *supra* note 35, 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)). 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.* *See also* Gerald T. Ankley et al., *Toxicogenomics in Regulatory Ecotoxicology*, 40 ENVTL. SCI. & TECH. 4055, 4060 (2006).

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.

### 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.[342] 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 RCRA requirements.[343] 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.

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342. 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 180, at 150 (citing R. Seely, *Flushed Drugs Polluting Water; Complicated Rules for Disposal Result in Most Hospitals Taking Easy Way Out*, WIS. STATE JOURNAL, Dec. 10, 2006, at A1.). *See also* Mannina, *supra* note 288, 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.").

343. As noted by Mannina, "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, *supra* note 288, 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.*

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.

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.[344] 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.[345] 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.[346] The amendments would allow producers of hazardous pharmaceutical wastes to choose whether to (a) continue to have their wastes regulated under the current RCRA regulations or (b) manage their hazardous wastes under the Universal Waste Rule.[347]

The proposed revision is also intended to facilitate the collection of pharmaceutical wastes from households, including non-hazardous pharmaceutical wastes.[348] Of relevance to the source control options discussed below, the 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."[349]

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."[350]

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344. Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. 232, 73520 (Dec. 2, 2008) (to be codified at 40 C.F.R. pt. 260, 261, 264, 265, 268, 270 and 273).

345. ENVTL. PROT. AGENCY, EPA PROPOSES STREAMLINED DISPOSAL OF HAZARDOUS PHARMACEUTICAL WASTE (Nov. 2008), *available at* http://www.epa.gov/osw/hazard/wastetypes/universal/pharm-fs.pdf.

346. Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. 232, 73520 (Dec. 2, 2008) (to be codified at 40 C.F.R. pt. 260, 261, 264, 265, 268, 270 and 273).

347. *Id.*

348. *Id.*

349. *Id.* at 73526.

350. Johnston & Sendek-Smith, *supra* note 324, at 38 (citing Environmental News Stand, EPA Urged to Up RCRA Pharmaceuticals Enforcement at Hospitals, INSIDE EPA (July 1, 2009)).

### 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."[351]

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.[352] 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.

### 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 fresh water resources 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.[353]

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."[354] 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*).[355]

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351. Toxic Substance Control Act (TSCA), 15 U.S.C. § 2603 (2006).

352. *Id.* at § 2605(a).

353. 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 (2006); the Marine Mammal Protection Act, 16 U.S.C. §§ 1361-1421h (2006); the Migratory Bird Treaty Act, 16 U.S.C. §§703-712 (2006). Similar species protection legislation enacted by state, local and Tribal governments might provide additional causes of action.

354. Lopez, *supra* note 328, 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)).

355. *Id.* at 21; *see also* Mannina, *supra* note 288, 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

Mannina notes an alternative cause of action, 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."[356] 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.*[357]

Implementing a recovery plan under the ESA can be both socially disruptive and expensive. The preferred alternative is to take the necessary steps 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 discharge of such wastes is the cause of the "taking." While such an approach may not be politically popular, the alternatives (listing a species and implementing a recovery plan) are substantially less popular.

## B. ALTERNATIVE STRATEGIES

The source control alternative strategies discussed in Section IV may be more effective in reducing or eliminating PPCPs in fresh water resources than the imposition of a statutory or regulatory approach. The approaches advocated by Daughton and others focus on minimizing or eliminating sources of PPCPs.[358]

### 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 fresh water resources. Commentators argue that the Food and Drug Administration ("FDA") needs to assess the PPCP dis-

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in sperm production in three species of fish, including the endangered razorback sucker.").

356. Mannina, *supra* note 289, at 2.

357. *Id.* (emphasis added).

358. 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. *See supra* note 4.

charge potential as a component of the FDA's drug approval process.[359] The Environmental Assessment process mandated by the National Environmental Policy Act could undertake such an assessment.[360] "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."[361]

As noted below, Daughton has suggested that extending patents would encourage drug companies to implement alternative source control strategies.[362] Others have suggested the need for financial incentives or other types of financial support, particularly with regard to drug design.[363]

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 fresh water resources is an open question.

### 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.[364]

### 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 fresh water resources. 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

359. 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 323, at 82.

360. *Id.* at 92-93.

361. *Id.* at 100.

362. *Infra* note 365 and associated text.

363. Christenson, *supra* note 180, at 169, 169 n.276 (citing Nidel, *supra* note 323, 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.").

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

prices, those alternatives with the least costs are more than likely the most feasible.

### 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."[365] 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.

### 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 Christenson:

> 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.[366]

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 take-back 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."[367]

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365. 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.

366. Christenson, *supra* note 180, at 157 (citing R. Seely, *Flushed Drugs Polluting Water; Complicated Rules for Disposal Result in Most Hospitals Taking Easy Way Out*, WIS. STATE JOURNAL, Dec. 10, 2006, at A1; R. Dickrell, *Pharmaceutical Take-Back A Community's Success Story*, 167 THE CLARIFIER 48 (2006)).

367. *Id.* at 152 (citing Juliet Eilperin, *Pharmaceuticals in Waterways Raise Concern: Effect on Wildlife, Humans Questioned*, WASHINGTON POST, June 23, 2005, at A3).

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.[368] Christenson summarized the program:

> 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.[369]

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."[370] "Second, due to the potentially high costs involved, it is unlikely that pharmaceutical companies would provide the necessary funds to run the entire program."[371]

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> 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 151-52 (citing 21 C.F.R. § 1307.21 (Drug Enforcement Administration, Office of Diversion Control, Procedure for disposing of controlled substances); R. Seely, *Flushed Drugs Polluting Water; Complicated Rules for Disposal Result in Most Hospitals Taking Easy Way Out*, WIS. STATE JOURNAL, Dec. 10, 2006, at A1).

368. 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/.

369. Christenson, *supra* note 180, at 154 (citing ME. REV. STAT. ANN. tit. 22, §§ 2700(3)-(5)).

370. *Id.* (citing ME. REV. STAT. ANN. tit. 22, § 2700(4)).

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

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.[372] Alternative programs include the Canadian Medications Return Program.[373] Daughton's suggestion to extend the patents of drug companies implementing "vibrant, comprehensive stewardship programs tailored for each particular drug"[374] 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.[375]

### 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 fresh water resources justify the cost?

## VII. 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 fresh water resources.

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

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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 (explaining drug companies spent more on lobbying than any other industry from 1998 to 2004)).

372. McGrath, *supra* note 365.

373. Christenson, *supra* note 180, at 157-158 (citing Daughton, *Drug Disposal, Waste Reduction, and Future Directions*, *supra* note 244, at 780).

374. Daughton, *Drug Disposal, Waste Reduction, and Future Directions*, *supra* note 243, 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 180, at 154).

375. As Christenson noted, "[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 180, at 155.

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 Wennmalm and Gunnarsson note "[t]he consumption of pharmaceuticals is increasing worldwide, due both to continued population growth and increased consumption of pharmaceuticals per capita."[376] The ever-increasing number of PPCPs,[377] combined with the concentration variability discussed in Section V, precludes any single approach to their regulation or management.[378] New monitoring,[379] detection,[380] and analysis[381] methods are needed. New management alternatives need to be developed. New statutory or regulatory approaches embodying the Precautionary Principle[382] need to be tailored to the goal of reducing PPCPs in fresh water resources.[383]

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376. Wennmalm & Gunnarsson, *supra* note 42, 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 5, at 185 (citing Christian G. Daughton, *Non-regulated Water Contaminants: Emerging Research*, 24 ENVTL. IMPACT ASSESSMENT REVIEW 711 (2004)); Accord Reynolds, *Concern of Pharmaceuticals in Drinking Water*, *supra* note 34, at 2.

377. As of 2004 there were "as many as 6 million PPCP substances commercially available worldwide." Ellis, *supra* note 5, at 185 (citing Christian G. Daughton, *Non-regulated Water Contaminants: Emerging Research*, 24 ENVIRONMENTAL IMPACT ASSESSMENT REVIEW 711 (2004)).

378. "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 32, at 2. Accord Reynolds, Pharmaceuticals in Drinking Water Supplies, *supra* note 26 ("With 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").

379. G. Tracy Mehan, III, *Water Data and Monitoring as Indispensable Tools to Manage Water Quality*, DAILY ENV'T REPORT, August 4, 2010, at 4.

380. "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 32, at 1.

381. Poynton & Vulpe, *supra* note 35, 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 PUB. HEALTH POL'Y RESPONSE PROJECT. *supra* note 27, at 3-4 (discussing need for human health assessments of low-level, chronic exposure to PPCPs); Jones, *supra* note 242, at 385 (discussing need for new risk assessment models that account for synergistic effects).

382. "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 & BIOANALYTICAL CHEMISTRY 1159 (2007) (quoted in RAPID PUB. HEALTH POL'Y RESPONSE PROJECT, *supra* note 27, 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

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."[384] 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."[385]

As noted in the Introduction, this report is predicated on the assumption that the ongoing scientific inquiry regarding the effects of PPCPs in fresh water resources 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 to protect both human and environmental health.

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cause and effect relationships are not fully established scientifically." *Wingspread conference on the Precautionary Principle*, SCI. & ENVTL. HEALTH NETWORK, http://www.sehn.org/wing.html (last visited Feb. 29, 2012). The conferees went on to explain that "[t[he 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." *Id.*

383. *See, e.g.*, Heberer et al., Removal of Pharmaceutical Residues, *supra* note 87, 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 42, at 296 ("[I]n 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]").

384. Snyder et al., *supra* note 48, at 34.

385. Stanford et al., *supra* note 12, at 2 (citing Benotti et al., *supra* note 49; Shane A. Snyder et al., AM. WATER WORKS ASS'N, 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 ENVTL. SCI. & TECH. 7312 (2006)).