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Leitman, Melanie

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Water R_x

The Problem of Pharmaceuticals in Our Nation's Waters

*Melanie Leitman**

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* J.D., *high honors*, Florida State University College of Law, 2011; B.A., Environmental Science and B.A., Political Science, University of Florida, 2007. Ms. Leitman is an Associate with Messer Caparello & Self in Tallahassee, Florida. The author would like to thank Professor Robin Craig for her guidance and editing and Brooks for his help and support.

I.
INTRODUCTION

In one stream in Boulder, Colorado, female white sucker fish outnumber males of the same species by a ratio of greater than five to one, and half of the males have female sex tissue.¹ Although this may seem to be a strange and possibly isolated occurrence, this situation is not restricted to Colorado, nor is it exclusive to the white sucker fish.² Streams all over the United States and the rest of the world are experiencing the feminization of male organisms or masculinization of female organisms.³ Scientists are pointing to birth control and other pharmaceuticals as the culprit, and not because the fish are concerned with family planning.⁴ Humans are the source of these compounds, and they enter the environment through many different routes.⁵

The effect of pharmaceuticals⁶ on both the water supply for human consumption and the aquatic environment is increasingly drawing the attention of regulators. Although this problem is not a new one – the general consensus is that pharmaceuticals as a class of contaminants have been present in water since their inception – new detection technologies, allowing us to detect concentrations as low as parts per trillion, have brought this contamination to the forefront of scientific concern.⁷ But even so,

1. Elizabeth Royte, *Drugging the Waters: How an Aging Population and Our Growing Addiction to Pharmaceuticals May Be Poisoning Our Rivers*, ONEARTH, Fall 2006, at 26, 30.

2. See Bethany Halford, *Side Effects*, CHEM. & ENG'G NEWS, Feb. 25, 2008, at 13; *Emerging Threats – Pharmaceuticals Polluting Lakes and Rivers*, ENV'T CAN., <http://www.ec.gc.ca/scitech/default.asp?lang=En&n=64B32D19-1> (last modified Apr. 23, 2009).

3. Halford, *supra* note 2; ENV'T CAN. *supra* note 2.

4. See, e.g., Jon P. Nash et al., *Long-Term Exposure to Environmental Concentrations of the Pharmaceutical Ethynylestradiol Causes Reproductive Failure in Fish*, 112 ENVTL. HEALTH PERSP. 1725, 1725 (2004).

5. Holly V. Campbell, *Pharmaceuticals in the Environment: Regulatory and Nonregulatory Approaches*, [2002] 32 ENVTL. L. Rep. (Envtl. Law Inst.) 11200, 11200 (Oct. 2002).

6. "Pharmaceutical drugs are chemicals used for diagnosis, treatment (cure/mitigation), alteration, or prevention of disease, health condition, or structure/function of the human body. The definition is extended to veterinary pharmaceuticals and can also be applied to illicit (recreational) drugs." Christian G. Daughton & Thomas Ternes, *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change*, 107 ENVTL. HEALTH PERSP. 907, 908 (Supp. 1999).

7. See Campbell, *supra* note 5; Royte, *supra* note 1, at 30. Some entrepreneurs have even found a way to exploit the presence of pharmaceuticals in the water for profit. See, e.g., *Pharmaceuticals*, GROUND WATER SYS., INC., <http://www.groundwatersystemsinc.com/27.html> (last visited Mar. 1, 2011) (highlighting the presence of

scientists still know very little about the effects of pharmaceuticals in low concentrations on humans and the environment.⁸

This comment addresses the growing problem of pharmaceuticals in the water. Part I discusses some of the different pathways through which pharmaceuticals enter the water. Part I also reviews what is known about the effects of these pharmaceuticals on humans and the environment. Part II presents an overview of the current state of the law. Part III examines proposed legislation addressing pharmaceuticals in the water. Part IV concludes with proposals for where to go from here.

II.

SOURCES AND IMPACTS OF PHARMACEUTICALS IN THE WATER

A. Sources

Considering the prevalence of pharmaceuticals in modern society,⁹ it is no wonder that some of these compounds find their way into our drinking water systems and the environment. As of 2007, scientists had identified more than 100 different pharmaceuticals or personal care products in the environment,¹⁰ and researchers estimate that approximately forty one million Americans face exposure to pharmaceuticals through their drinking water.¹¹ In fact, a study examining the fifty largest cities in the United States found that at least twenty four of them had pharmaceuticals in their municipal water supply.¹² Similarly, a 2002 study by the United States Geological Survey found phar-

pharmaceuticals in the water as a reason to purchase the Nature Soft system by Ground Water Systems, Inc.).

8. See Pat Hemminger, *Damming the Flow of Drugs into Drinking Water*, 113 ENVTL. HEALTH PERSP. A678, A679 (2005). See also Halford, *supra* note 2.

9. \$92 billion of medicines are sold annually in the United States, and fifty million pounds of antibiotics alone are produced per annum. Campbell, *supra* note 5, at 11201. As of 2006, Americans were filling greater than three billion prescriptions per year. Royte, *supra* note 1, at 28.

10. *Frequent Questions – Pharmaceuticals and Personal Care Products*, ENVTL. PROT. AGENCY, <http://www.epa.gov/ppcp/faq.html> (last updated Oct. 27, 2010).

11. Tanya Tillett, *Summit Focuses on Pharmaceuticals in Drinking Water*, 117 ENVTL. HEALTH PERSP. A16, A16 (2009).

12. Karyn Feiden, *Pharmaceuticals Are in the Drinking Water: What Does It Mean?*, RAPID PUB. HEALTH POL'Y RESPONSE PROJECT: GEO. WASH. SCH. OF PUB. HEALTH & HEALTH SERV., 3 (April 2008), available at <http://www.gwumc.edu/sphhs/about/rapidresponse/Pharmaceuticals.cfm>.

maceutical contamination in more than eighty percent of the streams surveyed.¹³

Pharmaceuticals enter the environment through many different avenues. This comment examines the following pathways: improper disposal; human consumption and excretion; livestock and aquaculture operations; and intentional addition. Compounding the problem of many pathways and sources of contamination, most of these pharmaceuticals are highly water soluble¹⁴ and do not “evaporate at normal temperature and pressures,”¹⁵ thereby facilitating thorough contamination.

Perhaps the most preventable conduit of contamination is improper disposal. For many years, hospitals and nursing homes disposed of their excess pharmaceuticals by flushing them down the drain.¹⁶ In fact, until as recently as 2002 this was the recommended method for disposing of unwanted pharmaceuticals¹⁷ because it ensured that the pharmaceuticals did not end up in the wrong hands (i.e. children or the illicit drug trade).¹⁸ State and local governments recently began to launch massive informational campaigns in an effort to minimize or eliminate this method of pharmaceutical disposal.¹⁹ But old habits die hard, and many people still believe that flushing is the best method of disposal for unwanted pharmaceuticals.²⁰

Pharmaceuticals also enter the water through human consumption and excretion.²¹ Humans do not fully metabolize ingested pharmaceuticals and thus excrete the unmetabolized compounds

13. Stephen E. Musson & Timothy G. Townsend, *Pharmaceutical Compound Content of Municipal Solid Waste*, 162 J. HAZARDOUS MATERIALS 730, 730 (2009).

14. Daughton & Ternes, *supra* note 6, at 912.

15. ENVTL. PROT. AGENCY, *supra* note 10.

16. See 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, 780 (2003).

17. See generally *id.* (providing examples of states promoting flushing as the preferred method of disposal as recent as 2002, including by North Carolina's Administrative Code and the California Poison Control System).

18. *Id.*

19. See *infra* notes 229–40.

20. A recent survey found that, despite advice to the contrary, approximately half of the survey participants admitted to disposing of unwanted pharmaceuticals via the sewage system. Musson & Townsend, *supra* note 13, at 730.

21. See generally, Christopher T. Nidel, *Regulating the Fate of Pharmaceutical Drugs: A New Prescription for the Environment*, 58 FOOD & DRUG L.J. 81, 83–84 (2003).

in urine or feces.²² A person's age and health can impact how much of a given drug that person metabolizes, as can timing of dose and formulation of the drug itself.²³ Federal law does not impose any monitoring requirements upon sewage treatment facilities that receive pharmaceutical-contaminated excrement.²⁴ Furthermore, municipalities do not design municipal sewage treatment plants to remove these unregulated pharmaceutical contaminants,²⁵ thus complicating any attempts to control. In fact, one study found that the treatment processes examined eliminated as little as seven percent of active drug compounds from the wastewater,²⁶ meaning that the vast majority of these excreted compounds remain in the "treated" water. This treated water is discharged and eventually reprocessed into drinking water.²⁷

Unfortunately, in most cases, the drinking water treatment processes also fail to remove these compounds.²⁸ Most drinking water treatment plants rely on absorptive and oxidative processes for removal of organic materials from the water,²⁹ but these methods are relatively ineffective at removing pharmaceuticals and other synthetic contaminants.³⁰ Ozonation is one of the more effective methods for removing pharmaceuticals, although its usefulness is limited to estrogens and a small number of other pharmaceuticals.³¹ It is not very effective at removing non-estrogen compounds or many other pharmaceuticals.³²

Another source of pharmaceutical ground and surface water pollution is the intentional disposal of unwanted drugs into mu-

22. Christian G. Daughton, *Pharmaceuticals and Personal Care Products in the Environment: Overarching Issues and Overview*, in PHARMACEUTICALS & PERSONAL CARE PRODUCTS IN THE ENVIRONMENT: SCIENTIFIC & REGULATORY ISSUES 2, 11 (Christian G. Daughton & Tammy L. Jones-Lepp, eds., 2001).

23. *Id.* at 11-12.

24. *Id.* at 6.

25. ENVTL. PROT. AGENCY, *supra* note 10. For a more thorough discussion of treatment technologies, see *infra* notes 270-80 and accompanying text.

26. Shawna Bligh, *Pharmaceuticals in Surface Waters: Use of NEPA*, NAT. RES. & ENV'T, Fall 2009, at 56, 56.

27. *Id.*

28. Paul Westerhoff et al., *Fate of Endocrine-Disruptor, Pharmaceutical, and Personal Care Product Chemicals During Simulated Drinking Water Treatment Processes*, 39 ENVTL. SCI. & TECH. 6649, 6649 (2005).

29. *Id.*

30. *Id.*

31. *Id.* at 6650.

32. *Id.*

municipal solid waste systems.³³ Disposed pharmaceuticals often end up in landfill leachate, which can percolate into the ground water.³⁴ This contamination source has the potential to eclipse sewage disposal as a source of contamination because federal and state policymakers are beginning to recommend solid waste disposal of pharmaceuticals as an alternative to sewage disposal.³⁵

Livestock and aquaculture operations also contribute to pharmaceutical contamination of ground and surface water.³⁶ Both livestock and aquaculture operations administer regular doses of antibiotics and hormones to animals in order to speed growth and to prevent the spread of disease and infection.³⁷ Like humans, animals do not fully metabolize the drugs and excrete them in manure and urine.³⁸ One major difference between veterinary and human pharmaceutical contamination is that excreted human waste generally passes through some form of treatment prior to entering surface water, whereas animals deposit their manure directly onto the ground or into the water and are thus a more direct source of pharmaceutical contamination.³⁹ Farmers often use both human and animal manure for crop fertilization, which provides additional opportunity for the pharmaceutical-contaminated excrement to leach and/or run off into ground and surface water.⁴⁰ Some studies have shown that crops

33. Musson & Townsend, *supra* note 13, at 730.

34. *Id.*

35. *Id.*

36. Livestock operations in particular are a major source of pharmaceutical contamination, with one USGS hydrologist estimating that livestock use "generates an estimated 500 million tons of waste each year." Halford, *supra* note 2, at 13; *see also* Nidel, *supra* note 21, at 84.

37. *See* Campbell, *supra* note 5, at 11201. It is widely known that overuse of antibiotics has contributed to increases in antibiotic-resistant bacteria, and it has been suggested that environmental exposure is also contributing to this increase, although one CDC researcher disagrees with this assertion. *Id.* at 11202; *See also* Jörg E. Drews & Laurence S. Shore, *Concerns About Pharmaceuticals in Water Reuse, Groundwater Recharge, and Animal Waste*, in PHARMACEUTICALS & PERSONAL CARE PRODUCTS IN THE ENVIRONMENT: SCIENTIFIC AND REGULATORY ISSUES 206, 208 (Christian G. Daughton & Tammy L. Jones-Lepp, eds., 2001).

38. *See* Nidel, *supra* note 21, at 84.

39. Thomas Ternes, *Pharmaceuticals and Metabolites as Contaminants of the Aquatic Environment*, in PHARMACEUTICALS & PERSONAL CARE PRODUCTS IN THE ENVIRONMENT: SCIENTIFIC & REGULATORY ISSUES 39, 42 (Christian G. Daughton & Tammy L. Jones-Lepp, eds., 2001).

40. Nidel, *supra* note 21, at 84.

fertilized in this manner can even uptake the pharmaceuticals.⁴¹ Thus, crop uptake followed by human consumption may be another route of exposure.⁴² Adding to the sheer quantity of contamination from farms and aquaculture operations is the fact that regulatory agencies do not usually consider these sources to be point sources, meaning that the Clean Water Act does not even govern their disposal practices.⁴³

Medication of pets represents another source of contamination. This source is not as significant as livestock operations, in part because the living conditions of domestic animals are generally not as concentrated as those of livestock.⁴⁴ Like humans and livestock, domestic animals that receive pharmaceutical medication also tend not to fully metabolize it.⁴⁵ Thus, when medicated pets relieve themselves outside, their pharmaceutical contaminated excrement has the potential to leach into the ground water or contribute to contamination of urban runoff.

Of possibly even more concern than the aforementioned pathways through which pharmaceuticals unintentionally enter the water is the fact that many municipalities and businesses are intentionally adding pharmaceuticals and other personal care products to the water. One recent news article reported that companies, including pharmaceutical manufacturers, have legally released 271 million pounds of pharmaceuticals into various water bodies, and that some of these water bodies serve as drinking water sources.⁴⁶ Furthermore, municipalities in the United States and abroad already add fluoride to the drinking water supply and have done so for over fifty years.⁴⁷ One recent article even proposed adding lithium to the drinking water after areas

41. Alistair B.A. Boxall et al., *Uptake of Veterinary Medicines from Soils into Plants*, 54 J. AGRIC. & FOOD CHEM. 2288, 2288 (2006).

42. Halford, *supra* note 2.

43. This article is not intended to be an analysis of how to deal with nonpoint source pollution. For more information on this subject, see Gloria E. Helfand & Brett W. House, *Regulating Nonpoint Source Pollution Under Heterogeneous Conditions*, 77 AM. J. AGRIC. ECON. 1024 (1995); Richard Cabe & Joseph A. Herriges, *The Regulation of Non-Point-Source Pollution Under Imperfect and Asymmetric Information*, 22 J. ENVTL. ECON. & MGMT. 134 (1992).

44. See Daughton & Ternes, *supra* note 6, at 923.

45. See *id.*

46. *271M Lbs. of Pharmaceuticals in Our Water*, CBSNEWS (Apr. 20, 2009), <http://www.cbsnews.com/stories/2009/04/20/health/main4955573.shtml>.

47. This practice began in 1945 in Grand Rapids, Michigan, and today approximately sixty countries fluoridate their water, exposing around 360 million people to its effects. For more on the effects of fluoridated water, see L.H. WEINSTEIN & A. DAVISON, *FLUORIDES IN THE ENVIRONMENT* 68-70 (2004).

with increased levels of naturally occurring lithium in the water reported lower than usual rates of suicide and violent crime.⁴⁸ In addition to ethical and human rights concerns, the intentional addition of pharmaceuticals and similar products creates further environmental and human health problems.

To make matters worse, the actual quantities of pharmaceuticals entering the environment are unknown.⁴⁹ Thus, calculating pharmaceutical pollution is difficult because pharmaceutical usage is not thoroughly documented and different living beings metabolize drugs at different rates.⁵⁰

B. Impacts

Pharmaceuticals represent only a small portion of the anthropogenically-originating (originating from humans) chemicals entering the environment. However, they pose a potentially more significant danger than do other chemicals to human health and the environment because they are specifically designed to effect biological change at relatively low concentrations.⁵¹ Generally, pharmaceuticals exist in the environment in concentrations ranging from parts per trillion to parts per billion.⁵² The concentrations at which drugs effect biological change in humans vary depending on the drug, but generally, concentrations of parts per billion (ppb) do not pose an acute risk.⁵³ In fact, one study examined concentrations of pharmaceuticals in German drinking water and found that for most of the compounds examined, the ratio between the daily therapeutic dose and intake via drinking water was 150,000 to one.⁵⁴ Moreover, the ratio was at least 1,000 to one for all of the compounds examined.⁵⁵ Thus, daily

48. Jacob Appel, *Beyond Fluoride: Pharmaceuticals, Drinking Water and the Public Health*, HUFFINGTON POST, (Dec. 21, 2009, 1:39 AM), http://www.huffingtonpost.com/jacob-m-appel/beyond-fluoride-pharmaceu_b_398874.html.

49. See Daughton & Ternes, *supra* note 6, at 912.

50. See *id.*

51. Halford, *supra* note 2. For example, estrogens can cause effects at very low levels. In one scientist's words: "If you can measure the estrogen in the water, then that's enough to cause an effect, and we can measure it at very low parts-per-trillion concentrations." *Id.*

52. Daughton & Ternes, *supra* note 6, at 912. One part per billion is approximately "one drop of water in an Olympic-sized swimming pool," and one part per trillion is one drop in 1,000 Olympic-sized pools. Feiden, *supra* note 12, at 1.

53. Daughton & Ternes, *supra* note 6, at 912.

54. Simon Webb et al., *Indirect Human Exposure to Pharmaceuticals Via Drinking Water*, 142 TOXICOLOGY LETTERS 157, 160 (2003).

55. *Id.* at 165.

intake via drinking water was significantly lower than daily therapeutic dose for the majority of compounds examined.

Table 1 presents several drugs and the concentrations at which they have been found in surface waters in environmental sampling in various locations around the world.⁵⁶

TABLE 1: DETECTED CONCENTRATIONS OF VARIOUS DRUGS IN ENVIRONMENTAL SAMPLES

Drug	Treatment purpose	Concentrations detected
Bezafibrate	Lipid regulator	3.1 ppb
Bisoprolol	Beta-blocker	2.9 ppb
Carbamazepine	Analgesic/antiepileptic	1.1 ppb
Diclofenac-Na	Analgesic/anti-inflammatory	1.2 ppb
Ibuprofen	Analgesic/anti-inflammatory	0.53 ppb
Metoprolol	Beta-blocker	2.2 ppb
Naproxen	Analgesic/anti-inflammatory	0.39 ppb

While pharmaceuticals in water may occur in concentrations far below generally prescribed doses, they may still potentially affect human health. For example, increased use of pharmaceuticals is contributing to endocrine disruption and antimicrobial resistance.⁵⁷ Endocrine disruption occurs when chemicals that have a tendency to “mimic” naturally occurring hormones interact with humans and other animals.⁵⁸ The endocrine system produces hormones, which send chemical messages to different parts of the body to regulate, among other things, growth and development, reproduction, food metabolism, sexual function, and mood.⁵⁹

The potential consequences of exposure to these chemicals are numerous. Chemicals mimicking hormones can trick the body into inappropriately responding to certain stimuli (either over-

56. Information in table pulled from Daughton & Ternes, *supra* note 6, at 913-21 tbl.2.

57. Feiden, *supra* note 12, at 4.

58. See Thomas M. Crisp et al., *Environmental Endocrine Disruption: An Effects Assessment and Analysis*, 106 ENVTL. HEALTH PERSP. 11, 11 (Supp. 1998).

59. *Id.* at 12-13. The endocrine glands are the pituitary, thyroid, adrenal, pancreas, testes, and ovaries. *Id.* at 13; see also *Hormones: MedlinePlus*, NAT'L LIBR. OF MED., U.S. NAT'L INST. OF HEALTH, <http://www.nlm.nih.gov/medlineplus/hormones.html> (last updated Mar. 1, 2011).

responding, under-responding, or responding at an inappropriate time), decrease the effectiveness of natural hormones by blocking them from reaching receptors, and even directly affect the endocrine system by causing over or underproduction of hormones themselves.⁶⁰ Although endocrine-disrupting chemicals can be of use—for example, chemical birth control⁶¹—the effects of unwanted endocrine disruption are numerous and potentially serious.⁶² Possible human health effects “include breast cancer and endometriosis in women, testicular and prostate cancers in men, abnormal sexual development, reduced male fertility, alteration in pituitary and thyroid gland functions, immune suppression and neurobehavioral effects.”⁶³

Bacterial resistance to antimicrobial agents, another potential consequence of pharmaceutical pollution, has recently become more common and poses serious public health risks.⁶⁴ Antimicrobial resistance is a naturally occurring phenomenon, but when magnified by pharmaceuticals, its consequences can be severe.⁶⁵ When microbes face exposure to an antimicrobial agent, they can respond in one of two ways: adapt or die.⁶⁶ The microbes that adapt then reproduce, passing on a resistance gene to the antimicrobial agent, thus creating a population of microbes that are genetically resistant to that antimicrobial agent.⁶⁷ Misuse and overuse of antimicrobial agents, including antibiotic pharmaceuticals, are a major cause of this problem.⁶⁸ In fact, scientists and others recognize that although antimicrobial agents have served tremendous good in improving human health and

60. *What are Endocrine Disruptors?*, ENVTL. PROT. AGENCY, <http://www.epa.gov/endo/pubs/edspoverview/whatare.htm> (last updated Aug. 11, 2011).

61. *Id.*

62. Crisp et al., *supra* note 58, at 11.

63. *Id.* The same article lists some of the potential environmental effects of endocrine disruption as “abnormal thyroid function and development in fish and birds; decreased fertility in fish, shellfish, birds, and mammals; decreased hatching success in fish, birds, and reptiles; demasculinization and feminization of fish, birds, reptiles, and mammals; defeminization and masculinization of gastropods, fish, and birds; decreased offspring survival; and alteration of immune and behavioral function in birds and mammals.” *Id.* Keep in mind that humans are mammals.

64. Nidel, *supra* note 21, at 89-90.

65. *See Antimicrobial Resistance*, WORLD HEALTH ORG. (Feb. 2011), <http://www.who.int/mediacentre/factsheets/fs194/en/>.

66. *See id.*

67. *See id.*

68. *See id.*; Alicia Anderson et al., *Public Health Consequences of Use of Antimicrobial Agents in Food Animals in the United States*, 9 MICROBIAL DRUG RESISTANCE 373, 373 (2003).

life expectancy, antimicrobial resistance is an unavoidable consequence.⁶⁹

Antimicrobial resistance is an especially serious problem at hospitals, where large concentrations of sick patients and bacteria exist in relatively confined areas, and doctors and hospital staff use antimicrobial agents *en masse*.⁷⁰ For example, one study examining use of antimicrobial agents and bacterial resistance in hospitals found that at one Croatian hospital, between forty and seventy three percent of the *E. coli* bacteria were resistant to several popular antibiotics.⁷¹ Additionally, *Staphylococcus aureus* resisted a common antibiotic more than fifty percent of the time.⁷² If bacteria develop resistance to pharmaceuticals and these bacteria then cause infections in humans, conventional treatments for those infections are more likely to fail.⁷³ Even if hospitals implement best practices to reduce the perpetuation of antimicrobial resistance (more restricted use of antimicrobial agents, for example), antimicrobials released into the environment still pose similar threats in natural systems.

Another concern that has arisen is the possibility of allergic reactions to the residual pharmaceuticals in the water. Most authorities, however, find that current concentrations are too low to elicit allergic reactions, although allergic reactions could become a possibility if concentrations of pharmaceuticals in the drinking water increase.⁷⁴ Although there is currently very little concrete evidence linking pharmaceuticals in water to adverse human health effects, scientists know very little about the impacts of pharmaceutical-contaminated water on humans.⁷⁵ In fact, of the 3,000 pharmaceutical compounds that are currently in use, only 150 have undergone environmental studies.⁷⁶ Predictions of effects on human health range from no impacts to apocalypse. One scientist has argued that it is not necessary to expend capital to update sewage treatment mechanisms in order to filter out pharmaceuticals because the low concentrations of pharmaceuti-

69. See, e.g., Vera Vlahovic-Palcevski et al., *Antimicrobial Utilization and Bacterial Resistance at Three Different Hospitals*, 17 EUR. J. EPIDEMIOLOGY 375, 375 (2001) (Neth.).

70. See *id.* In fact, this article found that more than one half of hospital patients receive some sort of antimicrobial agent. *Id.* at 376.

71. *Id.* at 379.

72. *Id.* at 375.

73. Anderson et al., *supra* note 68, at 374.

74. *Id.*

75. Hemminger, *supra* note 8, at A679; see also, Halford, *supra* note 2.

76. Feiden, *supra* note 12, at 3.

cals do not pose a significant enough risk to warrant such a drastic action.⁷⁷ On the other hand, many scientists emphasize that a lack of concrete evidence concerning the effect of pharmaceuticals is more indicative of a deficiency of knowledge than the safety of long-term consumption of pharmaceutical-tainted water.⁷⁸

Although scientists have not yet established concrete links between trace pharmaceutical consumption via drinking water and adverse human health effects, there are many examples of the impacts of pharmaceutical-contaminated water on isolated cells. In one study, breast cancer cells exposed to estrogens taken from fish that were caught near untreated sewage areas grew twice as quickly as did cells not exposed to these estrogens.⁷⁹ An MSNBC article provided information from a study in which scientists exposed normal cells to a very low dose of a thirteen-drug mix similar to that found in Italian rivers.⁸⁰ The result: Cell growth slowed by one third.⁸¹ Other drugs, when introduced separately to cells, stimulated growth, but when combined resulted in slower growth than usual.⁸² This exhibits the danger of synergistic effects—a drug's anticipated effect may vary to an unknown degree when combined with other drugs.⁸³

The presence of pharmaceuticals in the water is of particular concern with regards to the more sensitive human subpopulations, such as pregnant women, children, people with compromised immune systems, and the elderly.⁸⁴ Developing fetuses are particularly vulnerable to external chemical and hormonal changes, and scientists are examining links between endocrine disruption and developmental problems in fetuses and young children.⁸⁵ Hormones from the mother's thyroid are particularly

77. Halford, *supra* note 2.

78. Feiden, *supra* note 12, at 3.

79. *How Meds in Water Could Impact Human Cells*, MSNBC (Feb. 16, 2010), <http://www.msnbc.msn.com/id/23558785>.

80. *Id.*

81. *Id.*

82. *Id.*

83. Francisco Pomati et al., *Effects and Interactions in an Environmentally Relevant Mixture of Pharmaceuticals*, 102 TOXICOLOGY SCI. 129, 129 (2008).

84. *Emerging Contaminants in U.S. Waters: Hearing Before the Subcomm. on Water Res. and the Env't of the H. Comm. on Transp. and Infrastructure*, 110th Cong. (2008) [hereinafter *Hearings*] (statement of Matthew C. Larsen, Associate Director for Water, U.S. Geological Survey), available at http://www.usgs.gov/congressional/hearings/docs/larsen_18sept08.doc.

85. See, e.g., Theo Colborn, *Neurodevelopment and Endocrine Disruption*, 112 ENVTL. HEALTH PERSP. 944, 945 (2004).

essential to fetal brain development, and even a minor adjustment in fetal concentration of that hormone can result in “significant changes in intelligence in children.”⁸⁶ Furthermore, scientists in the United Kingdom have linked the presence of hormones in the environment with “lowered sperm counts and gynecomastia—the development of breasts in men.”⁸⁷

Some scientists and policymakers take the view that the lack of direct evidence linking pharmaceutical-contaminated water to effects on humans is proof that we need not worry, but this is a shortsighted view that ignores the possibility of currently unknown direct or indirect impacts on humans.⁸⁸ Even ignoring the potential for direct human impacts, environmental impacts, discussed below, stand to indirectly impact humans.⁸⁹

In addition to impacting humans directly, endocrine disruption and antimicrobial resistance are causing adverse environmental impacts. Endocrine disruption is of particular concern because it can happen after exposure to very low concentrations of the relevant chemicals.⁹⁰ Endocrine disruption causes, for example, feminization of fish, which can result in:

- (1) a higher percentage of females in some fish populations than commonly expected, (2) changes in behavioral characteristics, such as nesting behavior, or (3) the presence of male fish with female characteristics, such as the presence of female egg cells in testes or of a female egg protein in their blood.⁹¹

Scientists originally discovered feminized fish in the U.K. but are now finding them in surface water across Europe and the United States.⁹² In one study, scientists seeded a Canadian lake with a specific concentration of estrogen comparable to a concentration found in municipal water bodies.⁹³ Scientists observed the fathead minnow present in the lake and found that feminization of male minnow resulted in a dramatically decreased popu-

86. *Id.* The author is not exaggerating when he says “minor.” One study collected blood from women during pregnancy and tested the child’s IQ test seven years later. The study found that children with thyroid hormone concentrations which were 1.5 parts per trillion lower scored four points lower on IQ tests than did the children with the higher concentration. *Id.* at 945-46.

87. Royte, *supra* note 1, at 30.

88. Nidel, *supra* note 21, at 88.

89. *See id.* at 84.

90. *Hearings, supra* note 84.

91. *Id.*

92. Halford, *supra* note 2.

93. *Id.*

lation of the species.⁹⁴ At the end of a four-year period, according to the study, "the fish had all but disappeared from the lake."⁹⁵ Interestingly, three years after the scientists ceased adding the estrogen, the targeted species population rebounded.⁹⁶ Even if the pharmaceuticals themselves do not persist in the tissues of organisms, continual discharge of these compounds into the environment results in continuous and unremitting exposure.⁹⁷ The fish studied were relatively close to the bottom of the food chain, so it is important to note that decreases in the population of these fish can reverberate all the way up to higher-order predators.⁹⁸

A different study also examined the effect of chemical birth control on fathead minnows.⁹⁹ This study found that when fathead minnows spend their entire lifecycle exposed to chemical birth control, they become completely feminized.¹⁰⁰ Fish that are genetically male express female characteristics and are unable to mate or fertilize eggs.¹⁰¹ Scientists observed these effects in water with synthetic estrogen concentrations as low as three parts per billion, a concentration achieved by placing one birth control pill into 2,641 gallons of water.¹⁰² According to the study, "[a] human female using the birth control pill will excrete this amount in her urine over the course of a single day."¹⁰³ Thus, the concentration studied is not an unrealistic concentration to find in water bodies with pharmaceutical contamination.

Another study found that presence of antidepressants in the water had myriad effects on aquatic flora and fauna.¹⁰⁴ These effects included the triggering of spawning in bivalves and crustaceans, decrease in prey capture ability, and reduced predator avoidance.¹⁰⁵ Activities such as spawning and prey capture di-

94. *Id.*

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.*

99. ENV'T CAN., *supra* note 2.

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.* Ten million women in the United States take birth control pills; a similar number are on hormone-replacement therapy. Royte, *supra* note 1, at 28.

104. Melissa M. Schultz et al., *Antidepressant Pharmaceuticals in Two U.S. Effluent-Impacted Streams: Occurrence and Fate in Water and Sediment, and Selective Uptake in Fish Neural Tissue*, 44 ENVTL. SCI. & TECH. 1918 (2010).

105. *Id.* at 1918.

rectly affect the survival of both the animal and the entire species, and if these activities are adversely affected, the individual animal or species as a whole can suffer.¹⁰⁶

Antimicrobial resistance is not a phenomenon restricted to hospitals; it also exists in the environment.¹⁰⁷ In fact, one study found increased levels of antibacterial-resistant *Enterococci* in surface and ground water downstream from a swine feeding operation.¹⁰⁸ Thus, it is clear that pharmaceuticals in the water pose a very significant risk to both humans and the environment.

III.

CURRENT STATE OF THE LAW

Currently, from an environmental perspective, federal law does not effectively regulate the disposal of pharmaceuticals. In fact, our current legal and regulatory regime recognizes pharmaceuticals as either a health concern or an environmental concern, but never both. Thus, current statutes at best address the problem in a piecemeal manner.

Nevertheless, as discussed below there are several federal statutes that may be used to regulate the disposal of pharmaceuticals and their subsequent contamination of ground and surface water:

- Federal Food, Drug, and Cosmetic Act¹⁰⁹
- National Environmental Policy Act¹¹⁰
- Clean Water Act¹¹¹
- Safe Drinking Water Act¹¹²
- Resource Conservation and Recovery Act¹¹³
- Toxic Substances Control Act¹¹⁴

106. *Id.*

107. 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, 1040 (2007).

108. *Id.*

109. 21 U.S.C. §§ 301–399 (2006).

110. 42 U.S.C. §§ 4321–4370f (2006).

111. 33 U.S.C. §§ 1251–1387 (2006).

112. 42 U.S.C. §§ 300f–300j-26 (2006).

113. 42 U.S.C. §§ 6901–6992k (2006).

114. 15 U.S.C. §§ 2601–2692 (2006).

A. *The FDA's Regulatory Approach to Pharmaceuticals in the Environment*

The federal agency responsible for the regulation of pharmaceuticals is the Food and Drug Administration (FDA).¹¹⁵ The primary goal of the FDA is to ensure the safety and quality of food, drugs, and other health care products, animal food and drugs, and cosmetics.¹¹⁶ The FDA is statutorily obligated to prioritize protection of public health,¹¹⁷ not protection of environmental health. The result is that the FDA's approach to regulation of drugs slights the environment. The Federal Food, Drug, and Cosmetic Act¹¹⁸ and the National Environmental Policy Act¹¹⁹ are two statutes relevant to the FDA's regulation of pharmaceuticals in the environment.

1. Federal Food, Drug, and Cosmetic Act

The FDA requires that pharmaceuticals undergo a risk evaluation prior to entering the marketplace.¹²⁰ However, the FDA's risk evaluation criteria do not include any environmental considerations such as breeding or behavior, which pharmaceuticals can adversely impact.¹²¹ Thus, many scientists and policymakers consider these risk assessments to be generally ineffective because they take a short-sighted view of adverse impacts.¹²² Additionally, drugs can often present latent harms, meaning that adverse effects can take decades or longer to realize.¹²³ Sometimes impacts do not even manifest until the second generation of organisms.¹²⁴

Additionally, organisms do not usually face exposure to one drug in isolation. Some drugs may break down into their components and/or combine with other drugs already present in the water supply, causing a synergistic effect that may result in impacts not predicted by either drug alone.¹²⁵ Thus, the FDA has,

115. 21 U.S.C. § 393b (2006).

116. *Id.*

117. *Id.*

118. 21 U.S.C. §§ 301-399 (2006).

119. 42 U.S.C. §§ 4321-4370f (2006).

120. 21 U.S.C.A § 355-1 (2007).

121. *Id.* § 355-1(a)(1)(A)-(F); Daughton & Ternes, *supra* note 6, at 935.

122. *Id.*

123. Campbell, *supra* note 5, at 11203.

124. One noted possible consequence of exposure to endocrine-disrupting compounds is decreased offspring survival. Crisp et al., *supra* note 58, at 11.

125. Halford, *supra* note 2.

for the most part, allowed pharmaceutical contamination to fall through the cracks of FDCA regulation.

2. National Environmental Policy Act

The National Environmental Policy Act (NEPA)¹²⁶ is also relevant to FDA's oversight of pharmaceutical drugs. All federal agency actions must comply with NEPA, which requires that the agency "prepare a detailed statement . . . on (i) the environmental impact of the proposed action, (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented, [and] (iii) alternatives to the proposed action" for every "major federal action[] significantly affecting the quality of the human environment[.]"¹²⁷ Generally, agencies first prepare an environmental assessment, and, depending on whether the assessment reveals a significant environmental impact, either proceed with the action or prepare an environmental impact statement (EIS).¹²⁸ Thus, the FDA could be required to more strictly regulate pharmaceuticals under NEPA than it does under its current approach. For example, the FDA could be required to conduct an environmental assessment for all new drug approvals, which would serve a valuable information-gathering function.

NEPA allows federal agencies to categorically exclude some classes of actions from the environmental impact statement requirement because "these actions individually or cumulatively do not significantly affect the environment."¹²⁹ The categorical exclusion regulations have limited the potential effect of the environmental impact analysis requirement as applied to FDA's regulation of pharmaceuticals. This is in part because the FDA has allowed a blanket categorical exclusion for drugs so long as concentrations at the point of entry into the environment are below one part per billion.¹³⁰ It is important to note that adverse

126. 42 U.S.C. §§ 4321-4370f (2006).

127. *Id.* § 4332(C).

128. *Frequently Asked Questions—National Environmental Policy Act*, ENVTL. PROT. AGENCY, <http://www.epa.gov/compliance/resources/faqs/nepa/index.html> (last updated Jan. 2, 2009). An environmental impact statement need not be prepared if there is a "finding of no significant impact" as a result of the environmental assessment. *Id.*

129. Ranga Velagleti & Michael Gill, *Regulatory Oversight for the Environmental Assessment of Human and Animal Health Drugs: Environmental Assessment Regulations for Drugs*, in *PHARMACEUTICALS & PERSONAL CARE PRODUCTS IN THE ENVIRONMENT: SCIENTIFIC & REGULATORY ISSUES*, 320, 321 (Christian G. Daughton & Tammy L. Jones-Lepp, eds., 2001).

130. 21 C.F.R. § 25.31(b) (2009).

impacts from some contaminants, namely estrogens, can occur at the threshold of detection, which is in the low parts per trillion.¹³¹ Another exception to the NEPA requirement applies to “substances that occur naturally in the environment”¹³² and to applications for new drugs intended for use on nonfood animals.¹³³ Thus, many drugs are actually, categorically excluded from NEPA’s environmental impact assessment requirement.

The FDA requires completion of an environmental assessment for every action that is not categorically excluded.¹³⁴ The FDA regulations do not categorically exclude some new drug applications or all investigational new drug applications.¹³⁵ However, there are no regulations that automatically require preparation of an environmental impact statement.¹³⁶ Instead, as with NEPA regulations, an EIS is required only if, upon preparation of the environmental assessment, the evaluating authority (i.e. the FDA) determines that significant environmental harm is likely to result.¹³⁷

The FDA’s approach to the EIS requirement is somewhat troubling. The agency’s regulations state that “if FDA determines that an EIS is necessary for an action . . . an EIS will be prepared but will become available only at the time of approval of the product[,]”¹³⁸ and the only opportunity for comment is after the EIS is released (after approval of the substance).¹³⁹ Thus, the only opportunity for the public to learn of the potential environmental impacts and to contribute comments is after the drug has already been approved and released into the market. This approach runs counter to NEPA’s function in other regulatory situations. Generally, an agency must complete an EIS and ad-

131. Halford, *supra* note 2; Bligh, *supra* note 26, at 56.

132. 21 C.F.R. § 25.31(c).

133. 21 C.F.R. § 25.33(d). There is an exception to the exceptions discussed here if “extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment[.]” even if the concentrations will be below one part per billion. *Id.* § 25.21.

134. 21 C.F.R. § 25.15(a). Also, 21 C.F.R. § 25.20 lists several situations that ordinarily require preparation of an environmental assessment.

135. 21 C.F.R. § 25.20(l).

136. 21 C.F.R. § 25.22 (2009).

137. *Id.*

138. 21 C.F.R. § 25.52(a).

139. 21 C.F.R. § 25.52(b).

dress related challenges before it may carry out the action at issue.¹⁴⁰

An agency's duty under NEPA is not very strong, meaning that the FDA is not required to ban a drug or deny a new drug application merely because of an indication of adverse environmental impacts.¹⁴¹ Furthermore, environmental impact statements do not seem to carry much weight with the FDA, considering that the FDA has never cited an environmental assessment as a basis for rejecting a new drug application.¹⁴² Regardless whether or not the environmental assessment or environmental impact statement spurs action by the FDA, preparation of these documents nonetheless provides the agency and possibly the public with information about the potential impacts of these drugs that would not be available if the drug were categorically excluded. So, while NEPA is probably the least relevant statute for the purposes of eliminating pharmaceutical contamination from the water, it could at least be used to gather more information about the potential environmental impacts of drugs.

B. *The EPA's Regulatory Approach to Pharmaceuticals in the Environment*

The primary federal agency that regulates environmental contamination is the Environmental Protection Agency (EPA).¹⁴³ Although the EPA does not have any rules or regulations that directly prohibit disposal of unwanted medications or require removal of pharmaceutical compounds as part of the water treatment process,¹⁴⁴ it does have several statutes at its disposal that have the potential to address pharmaceutical contamination.¹⁴⁵

140. See COUNCIL ON ENVTL. QUALITY, A CITIZEN'S GUIDE TO THE NEPA: HAVING YOUR VOICE HEARD 13-18 (2007), available at http://ceq.hss.doc.gov/nepa/Citizens_Guide_Dec07.pdf.

141. *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989) (indicating that NEPA's mandate is procedural in nature and does not require a specific outcome). See also *Strycker's Bay Neighborhood Council, Inc v. Karlen*, 444 U.S. 223, 227-28 (1980); *Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council*, 435 U.S. 519, 558 (1978).

142. Nidel, *supra* note 21, at 94.

143. *Our Mission and What We Do*, ENVTL. PROT. AGENCY, <http://www.epa.gov/epahome/whatwedo.htm> (last visited Feb. 27, 2011).

144. VIRGINIA THOMPSON, PHARMACEUTICALS, HEALTHCARE, AND THE ENVIRONMENT PRESENTATION, <http://www.triumvirate.com/developing-an-epa-compliant-pharmaceutical-program/> (last visited Feb. 25, 2011).

145. See the statutes outlined in the remainder of this section.

1. Clean Water Act

The national law governing water pollution is the Clean Water Act (CWA).¹⁴⁶ This statute provides a permitting scheme for the discharge of pollutants from a point source into navigable waters and makes it illegal for point sources to discharge pollutants if not in compliance with this permitting scheme.¹⁴⁷ Thus, this statute regulates such activities as industrial discharges, sewage treatment, concentrated animal feeding operations (CAFOs), aquaculture, and other point source discharges.¹⁴⁸ These are all potentially significant sources of pharmaceutical contamination.

Nevertheless, the CWA does not yet address discharges of pharmaceuticals, so none of these sources are regulated with respect to discharge or release of pharmaceutical compounds.¹⁴⁹ Several reasons exist for the EPA's failure to regulate pharmaceuticals under the CWA. For one, the statute was designed before scientists and policymakers were aware of the danger of many emerging contaminants, pharmaceuticals included. Thus, the statute could not propose regulation of something which was not yet a known problem.¹⁵⁰

Municipal water treatment plants are considered to be point sources¹⁵¹ under the CWA, meaning that the EPA has the authority to regulate their effluent discharges. Unfortunately,

146. 33 U.S.C. §§ 1251–1387 (2006). The congressional declaration of goals in this statute states that its purpose is the “restoration and maintenance of chemical, physical, and biological integrity of [the] Nation’s waters[.]” 33 U.S.C. §1251.

147. 33 U.S.C. § 1311(a) (2006). The permitting scheme is known as the National Pollutant Discharge Elimination System and is found in 33 U.S.C. § 1342.

148. *Clean Water Act (CWA)*, ENVTL. PROT. AGENCY, <http://www.epa.gov/agriculture/lcwa.html#Nonpoint> Source Pollution and Agriculture (last visited Apr. 5, 2010). Point source is defined as “any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged.” 33 U.S.C. § 1362(14) (2006).

149. Regulations exist which apply to pharmaceutical manufacturing facilities, but these regulations only address things such as volatile organic compounds, biological oxygen demand, and suspended solids; furthermore, they do not directly address or limit discharge of pharmaceuticals themselves. Pharmaceutical Manufacturing Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards, 63 Fed. Reg. 50,388, 50,389 (Sept. 21, 1998).

150. Amy Pickle, *Conference Report: Considering the Clean Water Act*, NICHOLAS INST. FOR ENVTL. POLICY SOLUTIONS & THE JOHNSON FOUND. AT WINGSPREAD, RACINE, WISCONSIN (October 26–28, 2009), 11, <http://nicholasinstitute.duke.edu/water/considering-the-clean-water-act>. The same source also cited lack of funding and limited jurisdiction as other shortcomings of the CWA. *Id.* at 11–13.

151. 33 U.S.C. § 1362(14) (2006).

pharmaceuticals are unregulated contaminants, so treatment plants are not designed to remove them from the water¹⁵² or monitor for their presence.¹⁵³ However, the fact that the EPA does not regulate pharmaceutical contaminants released from point sources under the CWA does not change the fact that the agency *could* do it, and the viability of this option will be examined in Part IV.

Unfortunately, the CWA does not provide jurisdictional authority to regulate non-point sources, which exclude some potential sources of pharmaceutical contamination. Livestock operations not considered to be CAFOs¹⁵⁴ are one example. Animals in these facilities still receive antibiotics and hormones but the operations are not regulated point sources because they do not meet the CAFO criteria.¹⁵⁵

The CWA serves as a technology-forcing mechanism through its technology-based standards.¹⁵⁶ Under Section 301(b)(2)(A), the EPA has the authority to require dischargers of toxic pollutants (those which are not biodegradable and create a risk of substantial human health impairment)¹⁵⁷ to use the best available technology economically achievable to minimize toxic pollution.¹⁵⁸ Thus, the CWA establishes a floor for the treatment technology that dischargers must use. The CWA regulates publicly owned treatment works (POTWs), but they are subject to different technology-based effluent limitations.¹⁵⁹ These regula-

152. *Pharmaceuticals and Personal Care Products, FAQs*, ENVTL. PROT. AGENCY, <http://www.epa.gov/ppcp/faq.html> (last visited Feb. 25, 2011).

153. Michael J. Focazio et al., *A National Reconnaissance for Pharmaceuticals and Other Organic Wastewater Contaminants in the United States – II) Untreated Drinking Water Sources*, 402 SCI. TOTAL ENV'T 201, 202 (2008). The EPA's Unregulated Contaminant Monitoring Rule does require that facilities which provide public water monitor several specific unregulated contaminants; however, pharmaceuticals are not included in this requirement. *Id.*

154. CAFO is defined in 40 C.F.R. § 122.23(b) (2010) as operations where animals are held and fed for forty five days or more in a twelve-month period and where no vegetation is sustained.

155. *Clean Water Act*, ENVTL. PROT. AGENCY, [http://www.epa.gov/agriculture/lcwa.html#Nonpoint Source Pollution and Agriculture](http://www.epa.gov/agriculture/lcwa.html#Nonpoint%20Source%20Pollution%20and%20Agriculture) (last visited Feb. 27, 2011).

156. See e.g., Sara Gersen, *In Brief: Riverkeeper, Inc. v. United States Environmental Protection Agency: Applying the Clean Water Act's Best Available Technology Available Standard to Existing Cooling Systems*, 35 ECOLOGY L.Q. 269, 273; CONG. RESEARCH SERV., RL30030, CLEAN WATER ACT: A SUMMARY OF THE LAW 2 (2008), <http://www.nationalaglawcenter.org/assets/crs/RL30030.pdf>.

157. 33 U.S.C. § 1362(13) (2006).

158. 33 U.S.C. §§ 1311(b)(2)(A), 1311(b)(2)(C) (2006).

159. 33 U.S.C. § 1311(b)(1)(A) (2006); see also 40 C.F.R. § 403 (2010) (containing the regulations for POTWs).

tions prohibit certain discharges from POTWs and establish pretreatment standards for water to be discharged into POTWs in order to ensure the most effective functioning of these facilities.¹⁶⁰ These regulations also prohibit “pass through,” which means that inputs into the POTWs may not result in discharge out of the POTW in violation of the POTW’s CWA permit.¹⁶¹ If pharmaceuticals were included in the CWA permits of POTWs, and if the water delivered to a POTW contained concentrations above the limits allowed by the permit, these inputs might be considered pass through because current treatment processes do not remove pharmaceutical compounds. This means that the pharmaceutical concentrations in the output of a POTW would be the same as the pharmaceutical concentrations in the input, and if the CWA permit placed limits on concentration of pharmaceuticals, the output could potentially be a violation of the concentrations listed in the permit. Thus, the user inputting the pharmaceutical-contaminated water would be in violation of the national pretreatment standards.¹⁶² This is a tool that the EPA could use to regulate the discharge of pharmaceuticals.

2. Safe Drinking Water Act

Under the Safe Drinking Water Act (SDWA),¹⁶³ the EPA regulates drinking water. The SDWA requires the EPA to establish drinking water quality standards that states and localities must implement.¹⁶⁴ The standards regulate both naturally occurring and manmade contaminants and are health-based in nature.¹⁶⁵ More specifically, under the SDWA, the EPA must promulgate standards for listing contaminants,¹⁶⁶ which the EPA then regulates as “listed.”¹⁶⁷

160. 40 C.F.R. §§ 403.2, 403.5, 403.6 (2010).

161. 40 C.F.R. §§ 403.5(a)(1), 403.3(p) (2010).

162. 40 C.F.R. § 403.5(a)(1) (2010).

163. 42 U.S.C. § 300f (2006).

164. 42 U.S.C. § 300g-1(b)(1)(A) (2006).

165. 42 U.S.C. § 300f(6) (2006) (defining contaminant as “any physical, chemical, biological, or radiological substance or matter in water”).

166. The standards are “that (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) . . . regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.” 42 U.S.C. §300g-1(b)(1)(A) (2009).

167. 42 U.S.C. §300g-1(b)(1)(A) (2006).

Although treatment was originally the focus of the SDWA, some of the focus has shifted to protection of source waters.¹⁶⁸ Thus, the SDWA has the potential to become an extremely useful tool in the regulation of pharmaceutical contaminants, but the EPA has yet to realize its potential.

The EPA has been slow to develop standards for listed substances.¹⁶⁹ Also, the SDWA excludes many pharmaceuticals from the list of regulated contaminants because they exist in the environment in such low concentrations.¹⁷⁰ The presence of pharmaceuticals in such low concentrations presents a difficult situation for regulators because, although most of the pharmaceuticals that the SDWA could regulate as contaminants occur in concentrations below those known to cause adverse health effects,¹⁷¹ scientists know very little about the impacts of exposure to low concentrations of pharmaceuticals over a long period of time.¹⁷² Thus, it is difficult to use a health-based rationale to regulate contaminants when so little is known about health impacts of exposure to residual pharmaceuticals in the water and there is no concrete data linking the two.¹⁷³ Nevertheless, the SDWA represents another potential tool that the EPA has at its disposal to regulate pharmaceuticals in the water.

3. Resource Conservation and Recovery Act

Another environmental statute that regulates pharmaceutical disposal is the Resource Conservation and Recovery Act (RCRA),¹⁷⁴ which regulates the land disposal of hazardous and

168. *Safe Drinking Water Act*, ENVTL. PROT. AGENCY, <http://water.epa.gov/lawsregs/rulesregs/sdwa/index.cfm> (last visited Feb. 27, 2011).

169. EPA was supposed to have developed standards for eighty three contaminants by 1995, although in 2002 standards were in place for only sixty seven. Campbell, *supra* note 5, at 11207.

170. See *Pharmaceuticals in the Nation's Water: Assessing Potential Risks and Actions to Address the Issue Before the S. Comm. on Env't and Public Works* (Apr. 15, 2008) (statement of Benjamin H. Grumbles), available at http://epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=7f39d92b-3089-4703-9063-e5d6c1381332 (explaining that in a recent draft contaminant list, 287 pharmaceutical and personal care products were considered, but only one was added); see also Feiden, *supra* note 12, at 5 (pointing out that the one pharmaceutical nominated for regulation, nitroglycerin, was nominated because of its possible use in explosives, not because of its environmental consequences or concentrations).

171. Statement of Benjamin H. Grumbles, *supra* note 170, at 10.

172. *Id.* at 4.

173. Hemminger, *supra* note 8, at A679. See also, Halford, *supra* note 2.

174. 42 U.S.C. § 6901 (2006).

solid waste.¹⁷⁵ RCRA's purpose is to prevent the improper disposal of hazardous waste by regulating the entities that manufacture, transport, treat, store, and dispose of the waste.¹⁷⁶ RCRA allows the EPA to designate certain wastes as hazardous, but exclusion from the list does not mean that the waste is not hazardous.¹⁷⁷ Thus, RCRA also contains criteria for determining whether the EPA would consider the non-listed waste to be hazardous, based on its characteristics.¹⁷⁸ RCRA exempts from its regulation domestic sewage or any other substance from a domestic source that passes to a publicly owned treatment facility.¹⁷⁹ This means that RCRA does not provide the EPA with jurisdiction over pharmaceuticals that people flush, directly or indirectly. This exemption is likely in place because the CWA potentially covers those discharges.

Nevertheless, hospitals and nursing homes are subject to RCRA's provisions.¹⁸⁰ Because they could be considered both generators¹⁸¹ of hazardous waste and treatment, storage, and disposal facilities,¹⁸² they are potentially subject to the regulations for both kinds of entities.¹⁸³ Thus, hospitals and nursing homes must determine whether or not the wastes that they have are hazardous,¹⁸⁴ they must maintain a manifest for the wastes that are considered hazardous,¹⁸⁵ and, because they often store the potentially hazardous pharmaceuticals, the facility must comply with the RCRA storage requirements as well.¹⁸⁶ A waste is considered to be hazardous under RCRA if it exhibits any of the statutorily defined characteristics: ignitability, corrosivity, reac-

175. 42 U.S.C. § 6903(5), 6903(27) (2006).

176. 42 U.S.C. § 6902 (2006).

177. 42 U.S.C. § 6921 (2006).

178. *Id.*

179. 40 C.F.R. § 261.4(a)(1) (2010).

180. Teirney Christenson, *Fish on Morphine*, 2008 Wisc. L. Rev. 141, 150–51 (2008).

181. "Generator means any person, by site, whose act or process produces hazardous waste identified in . . . this chapter or whose act first causes a hazardous waste to become subject to regulation." 40 C.F.R. § 260.10 (2010).

182. Treatment, storage, and disposal facilities are defined as "[a]ll contiguous land, and structures, other appurtenances, and improvements on the land, used for treating, storing, or disposing of hazardous waste, or for managing hazardous secondary materials prior to reclamation." 40 C.F.R. § 260.10 (2009).

183. These regulations are found in 42 U.S.C. §§ 6922, 6924 (2006).

184. 42 U.S.C. § 6922 (2006).

185. *Id.* The requirements for the manifest system are found in 42 U.S.C. § 6922(a)(5) (2006).

186. *See* 42 U.S.C. § 6924 (2006).

tivity, or toxicity.¹⁸⁷ Some pharmaceuticals do meet these characteristics; for example, nitroglycerine may exhibit reactivity and pharmaceuticals containing such chemicals as arsenic, chromium, or mercury may exhibit toxicity.¹⁸⁸

RCRA does list some pharmaceuticals as wastes,¹⁸⁹ but out-of-date regulations and shortcomings in enforcement have rendered RCRA somewhat ineffective in this area.¹⁹⁰ In fact, as of June 2009, one hospital pharmacy operations coordinator testified “that there is ‘virtually no EPA enforcement’ against hospitals to ensure they follow . . . RCRA requirements for disposal of pharmaceuticals.”¹⁹¹

As noted in Part I, another source of pharmaceutical contamination is landfill leachate, and thus the landfill provisions of RCRA are also relevant for the disposal of pharmaceuticals.¹⁹² These regulations require that landfills use liners to prevent waste migration and groundwater contamination.¹⁹³ In addition, the RCRA landfill regulations require landfills to install several leachate collection and removal mechanisms throughout the facility¹⁹⁴ and to have systems designed to prevent stormwater from running into the active parts of the landfill.¹⁹⁵

The EPA’s ineffectiveness in regulating discharge of pharmaceuticals under RCRA may change in the near future be-

187. 40 C.F.R. §§ 261.21–261.24 (2010) (defining ignitability, corrosivity, reactivity, and toxicity).

188. *Pharmaceuticals*, ENVTL. PROT. AGENCY, <http://www.epa.gov/osw/hazard/wastetypes/universal/pharm.htm> (last visited Feb. 15, 2010).

189. Several pharmaceuticals are contained on RCRA’s P-list, such as epinephrine, nicotine, and nitroglycerine. 40 C.F.R. § 261.33 (2010).

190. Christenson, *supra* note 180, at 150-51.

191. Env’tl. Prot. Agency, *EPA Urged to Up RCRA Pharmaceuticals Enforcement at Hospitals*, ENVTL. NEWS STAND, July 7, 2009, http://environmentalnewsstand.com/insider_special.asp?issue=POLICYALERT-26-13-5 (quoting Fred Massoomi, Pharmacy Operations Coordinator, Nebraska Methodist Hospital). The problems with the listing of pharmaceuticals as hazardous wastes are serious: “[A] large number of prescription drugs are considered non-hazardous by RCRA regulations, despite evidence that they contain cancerous agents.” *Id.*

192. These provisions are found in subpart N of 40 C.F.R. § 264 (2010).

193. 40 C.F.R. § 264.301(a) (2010).

194. 40 C.F.R. § 264.301(a)(2) (2010). This section of the regulations does not mandate that anything specific be done with the leachate collected from the collection system. This has a potential to be another source of pharmaceutical contamination because if the leachate is subjected to the customary wastewater treatment mechanism, the pharmaceutical compounds will likely remain in the water since normal treatment does not remove these compounds. *Pharmaceuticals and Personal Care Products, Frequent Questions*, ENVTL. PROT. AGENCY, <http://www.epa.gov/ppcp/faq.html> (last visited Feb. 27, 2011).

195. 40 C.F.R. § 264.301(g) (2010).

cause the EPA is currently in the process of developing and promulgating amended restrictions on the storage and disposal of pharmaceuticals and pharmaceutical-related waste, with the goal of streamlining and facilitating proper disposal.¹⁹⁶ The EPA is proposing to add pharmaceutical waste that is already considered to be hazardous under RCRA to RCRA's Universal Waste Rule.¹⁹⁷ This move would regulate an estimated 600,000 individual facilities that may generate hazardous pharmaceutical waste.¹⁹⁸ The purpose of the Universal Waste Rule is to "reduce the complexity of the RCRA hazardous waste generator regulations for universal wastes . . . [by] streamlin[ing] the collection and handling requirements for . . . hazardous wastes and facilitates their inclusion in the hazardous waste management system."¹⁹⁹

Additionally, this amendment proposes removing RCRA barriers that pharmaceutical collection and take-back facilities face in order to encourage proper disposal.²⁰⁰ When RCRA regulations apply to pharmaceutical collection programs, they make the programs more difficult and expensive to run because the programs must observe RCRA's requirements for treatment, storage, and disposal facilities.²⁰¹ The EPA's proposed rule would remove some of the RCRA requirements (such as hazardous waste determination and storage time limits) for facilities that accumulate pharmaceutical waste.²⁰² For example, the rule would allow common carriers to transport pharmaceutical wastes, instead of certified hazardous waste transporters.²⁰³ Additionally, facilities would not have to separate out different kinds of wastes, as they do under RCRA in general.²⁰⁴ One of the justifications for the Universal Waste Rule exceptions is that these wastes present a relatively low environmental risk during accumulation and transport compared to other, more volatile,

196. ENVTL. PROT. AGENCY, EPA530-F-08-028, EPA PROPOSES STREAMLINED DISPOSAL OF HAZARDOUS PHARMACEUTICAL WASTES (2008), <http://www.epa.gov/osw/hazard/wastetypes/universal/pharm-fs.pdf>.

197. RCRA's universal waste rule already includes "hazardous waste batteries, mercury-containing equipment, pesticides, and lamps." 40 C.F.R. §273.1(a) (2010).

198. Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. 73520, 73522 (Dec. 2, 2008).

199. *Id.* at 73530.

200. *Id.* at 73522.

201. *Id.* at 73528.

202. *Id.* at 73522.

203. *Id.* at 73530.

204. *Id.*

wastes.²⁰⁵ This proposed amendment has the potential to result in proper disposal of greater quantities of pharmaceuticals. If hospitals and nursing homes are subject to less stringent regulations, they are more likely to comply, thus properly disposing of more pharmaceuticals.

4. Toxic Substances Control Act

The Toxic Substances Control Act (TSCA) is another potentially useful federal statute because it regulates toxic substances and provides authority to the EPA to compel reporting and testing requirements as well as to restrict commercial sales of toxic substances.²⁰⁶ However, TSCA explicitly excludes drugs from its coverage because the FDCA regulates them.²⁰⁷ Notably, the current Presidential administration has pledged to reform TSCA, meaning that drugs could at some point in the future fall under the purview of this statute.²⁰⁸

IV.

A LOOK INTO THE FUTURE

Regulators are beginning to take action regarding the problem of pharmaceuticals in the water.

A. *Interagency Workgroup*

One of the ways in which federal agencies are making efforts to tackle the problem of pharmaceuticals in the water is by establishing an interagency workgroup. Several agencies came together in 2006 to establish a federal interagency work group co-chaired by the USGS, EPA, and FDA to address pharmaceuticals in the environment.²⁰⁹ The goal of this group is to increase coordination between the agencies and to facilitate additional research on the issue.²¹⁰ But subsequent evaluations of this group have been critical. One news report stated that the work group “missed its deadline and failed to produce mandated reports and

205. *Id.* at 73529.

206. 15 U.S.C. §§ 2603-2605, 2607 (2006).

207. 15 U.S.C. § 2602(2)(B)(vi) (2006).

208. *See, e.g., Lautenberg Says TSCA Reform Bill Coming; Manufacturers Must Prove Chemicals Safe*, DAILY ENV'T REP. (BNA), 23 DEN A-4 (Feb 5, 2010).

209. *Pharmaceuticals in the Nation's Water: Assessing Potential Risks and Actions to Address the Issue Before the S. Comm. on Env't and Public Works* (Apr. 15, 2008) (statement of Dr. Robert M. Hirsch), available at http://usgs.gov/congressional/hearings/docs/hirsch_15april08.doc (last visited Apr. 20, 2010).

210. *Id.*

recommendations[.]”²¹¹ Much of the documentation relating to this work group is classified and is thus not available for public consumption, making it nearly impossible to track the progress and effectiveness of the group.²¹²

B. *Pharmaceutical Take-Back Programs*

Many bills proposed in the 111th Congressional session addressed the issue of pharmaceutical disposal and contamination.²¹³ Although Congress did not pass any of these bills, they suggest a growing federal concern about pharmaceutical contamination of the water and an increased desire to address it.

Several of the bills proposed creation of a pharmaceutical take-back program, which is an idea that has been gaining popularity in recent years.²¹⁴ Many state-level take-back programs already exist, for example, in Michigan, Maine, and Minnesota.²¹⁵ Proposed federal legislation governing these programs requires local or state government agencies to provide some sort of mechanism through which individuals can properly dispose of their unwanted pharmaceuticals.²¹⁶ Some of this legislation proposes “mail-back” programs, through which individuals can mail their unused and unwanted drugs to processing and disposal facilities.²¹⁷ Other proposed federal programs would have established

211. Martha Mendoza, *Water Task Force Misses Target*, SEATTLE POST-INTELLIGENCER, Apr. 14, 2008.

212. *Id.*

213. To list a few: Safe Drug Disposal Act of 2009, H.R. 1191, 111th Cong. (2009); Drug Free Water Act of 2009, H.R. 276, 111th Cong. (2009); Water Quality Investment Act of 2009, H.R. 1262, 111th Cong. (2009).

214. According to The Drug Take-Back Network, twenty-one states have some sort of pharmaceutical take-back program. *Local Efforts*, THE DRUG TAKE-BACK NETWORK, http://www.takebacknetwork.com/local_efforts.html (last visited Apr. 3, 2010).

215. Michigan has several designated sites for collection of unwanted pharmaceuticals, although these sites do not accept any controlled substances. *Michigan*, THE DRUG TAKE-BACK NETWORK, <http://www.takebacknetwork.com/michigan.html> (last visited Apr. 3, 2010) [hereinafter Michigan’s program]. Maine has a mail-back program. *Maine*, THE DRUG TAKE-BACK NETWORK, <http://www.takebacknetwork.com/maine.html> (last visited Apr. 3, 2010) [hereinafter Maine’s program]; Tom Meersman, *A County Lockup for Unwanted Pills*, MINNEAPOLIS-ST. PAUL STAR TRIB., Mar. 2, 2010, at 1A [hereinafter Minnesota’s program] (describing the Chisago County’s pharmaceutical drop location – a steel mailbox located in the wall of the county sheriff’s office).

216. See Michigan’s program, *supra* note 215.

217. See Maine’s program, *supra* note 215.

drop-off locations for the same purpose, similar to hazardous waste disposal facilities that many local landfills provide.²¹⁸

A third option for take-back programs is to hold pharmaceutical drives, in which state or local officials establish a temporary pharmaceutical disposal site for one or two days, usually in a busy location, where individuals can bring their unwanted pharmaceuticals for proper disposal.²¹⁹ This approach is similar in nature to electronics drives, where old and broken electronics equipment is collected at a temporary location to ensure recycling and proper disposal.²²⁰

Another proposed bill in the 111th Congress prohibited drug labels containing recommendations to flush unwanted medications.²²¹ Yet another bill proposed creation of a task force to provide environmentally sound recommendations for the proper disposal of unwanted pharmaceuticals by consumers and health care providers and to develop a strategy for a widespread public education campaign on the recommendations.²²² A third bill proposed a study "on the presence of pharmaceuticals and personal care products . . . in the waters of the United States."²²³ Additionally, many states are trying to force pharmaceutical companies to pay for the various take-back programs, although pharmaceutical corporations are not willing to support this idea.²²⁴

In addition to these federal proposals, states are taking initiative as well. Many states have recently proposed their own legislation to establish drug take-back programs.²²⁵ Oregon's

218. See Minnesota's program, *supra* note 215.

219. For example, a recent pharmaceutical collection drive in Ithaca collected nearly one ton of unwanted medication, including some medication that was nearly 100 years old. Stacey Shackford, *Pharmaceutical Collection Event Draws Hundreds*, ITHACA J., Mar. 9, 2010.

220. See e.g., Mike Leonard, *IU Plans Electronic Waste Collection Drive April 8-10*, HERALD-TIMES, Mar. 23, 2010.

221. Safe Drug Disposal Act of 2009, H.R. 1191, 111th Cong. (2009).

222. Drug Free Water Act of 2009, H.R. 276, 111th Cong. (2009).

223. Water Quality Investment Act of 2009, H.R. 1262, 111th Cong. (2009).

224. See e.g., *Maine House Oks Prescription Drug Take-Back Plan*, DRUGS.COM, <http://www.drugs.com/news/maine-house-oks-back-plan-23273.html> (last visited Apr. 3, 2010).

225. According to The Drug Take-Back Network, "a central information source for all parties interested in learning about drug take-back and disposal issues[,] five states introduced legislation in 2009 which "would require drug manufacturers to operate and pay for stateside systems to collect, transport, and dispose of leftover pharmaceuticals from the public and certain facilities." *Monthly Feature, Legislative Update*, THE DRUG TAKE-BACK NETWORK, http://www.takebacknetwork.com/monthly_feature_04_09.html (last visited Apr. 3, 2010). These states are Florida,

program, which has not yet been passed by the Oregon state legislature, would require drug manufacturers to establish a convenient and environmentally friendly system for collecting and disposing of unwanted pharmaceuticals.²²⁶ Minnesota's Safe Drug Disposal Act of 2009 was passed²²⁷ but in a seriously denuded form when compared to the originally proposed language.²²⁸

Despite these legislative stalemates, some states do have effective programs up and running.²²⁹ Under these programs, consumers with unwanted pharmaceuticals either mail these drugs in to a central repository or bring their drugs to a collection site.²³⁰ Nonprofits have even begun to produce guidance documents for states and localities seeking to establish their own take-back programs.²³¹

While take-back programs are potentially effective, they also present several problems. Most important, the Drug Enforcement Agency (DEA) "prohibits the transfer of dispensed controlled substances from an individual to a doctor, pharmacist, reverse distributor, or any other entity registered with the US-DEA to handle or manage controlled substances[.]" the only exception being in the circumstance of a recall.²³² As a result, the DEA highly regulates who is authorized to legally take back pharmaceuticals that are controlled substances, although law enforcement officials are included in this restricted exception.²³³

Maine, Minnesota, Oregon, and Washington. Legislation was also introduced in California that encouraged all stakeholders to work together to establish a sustainable program to manage the disposal of pharmaceuticals.

226. S.B. 598, 75th Leg. Assemb., Reg. Sess. (Ore. 2009).

227. H.F. No. 1217 (Minn. 2009) (codified in Minn. Stat. §§ 151.37, 151.44 (2009)).

228. This bill originally proposed that pharmaceutical companies could not sell their products in the state unless they participated in a collection and disposal program. H.F. No. 1217, 86th Leg. Sess. (Minn. 2009), available at <http://wdoc.house.leg.state.mn.us/leg/LS86/HF1217.0.pdf>. What actually passed was essentially a series of minor adjustments to the statutory language governing who is legally allowed to possess pharmaceuticals for the purpose of disposal. H.F. No. 1217 (Minn. 2009) (codified in Minn. Stat. §§ 151.37, 151.44 (2009)).

229. In fact, I received a flier in my local paper published by the Florida Department of Environmental Protection that advertised a free medicine collection event. Flier on file with author.

230. See *Local Efforts*, *supra* note 214.

231. See LYNN RUBINSTEIN, OPERATING UNWANTED MEDICATION COLLECTIONS – A LEGAL & SAFE APPROACH, (2006), http://nerc.org/documents/operating_unwanted_medication_collections_final_2006.pdf. The preparers of this document even launched pilot locations to analyze the response and amounts collected.

232. *Id.* at 5. See also Christenson, *supra* note 180.

233. 21 C.F.R. § 1307.21 (2009).

Thus, when operating a collection facility, law enforcement officers or DEA agents must be the parties responsible for accepting, taking possession of, and disposing of any controlled substances.²³⁴

Recent reviews of take-back programs have highlighted additional problems. One news article highlighted a Minnesota take-back program, in which the sheriff's office collects unwanted pharmaceuticals at a drop site and then sends the drugs to an incinerator.²³⁵ Although incineration effectively prevents the drugs from contaminating the water supply, it raises questions about air contamination, seemingly shifting the pollution from one medium to another. Furthermore, these programs are not free,²³⁶ raising issues of funding sources.

C. Potential Litigation

One author has examined the viability of judicial action by interested parties to force changes in the FDA's approach to pharmaceutical regulation to incorporate environmental impacts.²³⁷ The author proposed that interested parties could use the courts to compel FDA action under the FDCA's drug approval process or NEPA's impact analysis requirement.²³⁸ Along the same vein, parties could also potentially sue the EPA to compel changes in its regulation of contaminants under the CWA. Several barriers exist to this option, two of the most notable being the Administrative Procedure Act and the constitutional standing requirement.²³⁹

Another possibility is to sue drinking water providers or pharmaceutical companies for toxic torts for exposure to the pharmaceuticals in the water.²⁴⁰ A case search did not find any such case, which is unsurprising considering the complicated nature of these types of cases and the limited state of the science to establish causation. There are many barriers to suit, legal and

234. *Id.*

235. Tom Meersman, *A County Lockup for Unwanted Pills*, MINNEAPOLIS-ST PAUL STAR TRIB., Mar. 1, 2010, at 1A.

236. By one estimate, a statewide pharmaceutical drop disposal program in Minnesota would cost over \$700,000. *Id.*

237. See Nidel, *supra* note 21, at 95-100.

238. *Id.*

239. The purpose of this comment is not to delve into the APA or standing. For more information on how these two barriers operate with respect to suing the aforementioned agencies see *id.*

240. A brief search in Lexis did not reveal any cases of this nature, likely because of the legal barriers discussed. See discussion *infra* pp.34-35 and notes 245-46.

other. For example, any group bringing legal action would have to establish standing to sue.²⁴¹ With a potential toxic tort claim, plaintiffs would have to establish all of the elements of a torts claim, including causation resulting in the plaintiff's realized injury. Moreover, many pharmaceuticals are generally fungible, presenting yet another difficulty in establishing causation against a particular defendant pharmaceutical company.²⁴² Establishing the elements of the claim would prove to be particularly difficult for several reasons. First, people rarely live in the same place (and drink the same water) for their entire lives. Second, if the plaintiff had taken pharmaceuticals during his or her life, it may be nearly impossible to prove that the injury resulted from the unwanted rather than the wanted exposure.

Furthermore, there are other non-legal barriers to promoting stricter regulations on drug approval. The development of new and improved pharmaceuticals is generally considered to be a valuable public health tool, and the public may have an unfavorable view of any group seen as seeking to impede this progress. In addition, litigation can be costly and time-consuming, and there are no guarantees that improvements will be realized. Thus, litigation is probably not the most effective tool available because the state of science and the law seem to present insurmountable barriers to this option.

D. *Other Countries' Approaches*

Other countries are also beginning to deal with the pharmaceutical contamination problem. The European Union, through the European Medicines Agency (EMA), began responding to this issue in 1999 when it developed environmental risk assessment procedures that would apply to applications for new pharmaceuticals.²⁴³ These risk assessments are required for new veterinary drugs and must include information about the possibility for environmental exposure as well as a specific battery of

241. Plaintiff must establish (1) injury in fact, (2) traceability (i.e., some sort of causal connection between the defendant's action and the harm realized), and (3) redressability (i.e., the court must be capable of remedying the injury). *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992).

242. See, e.g., *Hymowitz v. Eli Lilly & Co.*, 73 N.Y.2d 487, 503 (N.Y. 1989).

243. Stephen E. Musson et al., *A Continuous Collection System for Household Pharmaceutical Wastes: A Pilot Project*, *ENTREPRENEUR* (July 2007), <http://www.entrepreneur.com/tradejournals/article/print/166778956.html>.

effects testing.²⁴⁴ Unlike the FDA, the EMEA has even proposed a long-term ecotoxicity analysis.²⁴⁵

V.

PROPOSALS FOR IMPROVEMENT IN THE U.S.

As regulation currently stands, the FDA is responsible for regulating pharmaceuticals as they enter the market, and the EPA is responsible for regulating pharmaceuticals, as contaminants, as they leave the market. It is not possible to rectify or remediate the problem of pharmaceutical contamination while only addressing one side of the equation. Collaboration between these two agencies is essential, and both agencies must ramp up their regulations.

The major difficulty with placing more restrictions on the FDA's drug approval process is the tension and competition that often exist between environmental protection and pharmaceutical innovation. Developing pharmaceuticals is enormously important to society and public health,²⁴⁶ but at the same time it is important to prevent unwanted exposure and environmental degradation.

Addressing pharmaceutical contamination requires a multi-pronged approach. Both the FDA's and the EPA's regulations and statutory authorities must be more stringent. It is useful to categorize these proposals into two groups: source-based protections and treatment-based protections.

A. *Source-based Protections*

We should place a greater focus on source-based protections because they reduce the need for treatment-based protections. Treatment-based protections necessitate more physical change and investment because infrastructure actually has to be constructed or updated. Furthermore, even the most advanced treatment processes are not 100 percent effective in removing pharmaceuticals from the water.²⁴⁷

244. The "[e]ffects testing includes algal growth inhibition, fish acute/chronic/bioaccumulation exposure, avian dietary and reproductive, earthworm toxicity, terrestrial plant growth, and activated sludge respiration inhibition." Daughton & Ternes, *supra* note 6, at 935.

245. Musson et al., *supra* note 243.

246. See e.g., Vlahovic-Palcevski et al., *supra* note 69.

247. Westerhoff et al., *supra* note 28, at 6659.

First, the FDA should remove its broad categorical exclusion from NEPA for drugs. Many drugs slip through the cracks with regard to environmental impact, partly because of this provision.²⁴⁸ NEPA does not mandate a specific action; however, allowing a categorical exclusion for drugs means that there are information deficits regarding these drugs and their environmental effects. While eliminating the broad categorical exclusions would not alone solve this problem, the EIS or even EA process would require much more information-gathering than what currently occurs, and this could help responsible parties to make informed decisions about whether or not the pharmaceuticals should be in the market. Notably, many of the drugs that are categorically excluded cause proven environmental harm at concentrations much lower than the concentration established for the categorical exclusion (ten ppb).²⁴⁹

Second, Congress should amend the FDA's governing legislation to mandate a more stringent risk assessment process. The FDA should be required to integrate an environmental risk analysis component into its regulatorily-mandated obligation. Similar to the process used in the EU, it should include a more long-term analysis. Certain compounds, such as endocrine disruptors, can cause environmental impacts at very low concentrations,²⁵⁰ which is why it is important to conduct more rigorous risk analysis.

Third, regulations that apply hospitals and nursing homes must also be stricter and must be better enforced. RCRA is an extremely valuable statute for this goal, and the proposed amendment to the Universal Waste Rule is a significant start in ensuring proper disposal of pharmaceuticals. The amendment will remove some of the regulatory burden (and thus expense) from hospitals and nursing homes wishing to properly dispose of pharmaceuticals.²⁵¹ However, the EPA must put a greater focus on enforcement. These entities should have a limited range of choices for disposal of unwanted pharmaceuticals, and the EPA should implement a more stringent penalty scheme and actually enforce it to help ensure compliance.

248. *Supra* Part II.(a)(2).

249. Halford, *supra* note 2.

250. This is in contrast to FDA protocol, which exempts drugs found in concentrations less than one part per billion from the assessment process. Musson et al., *supra* note 243.

251. *Supra* Part II.(B)(3).

Fourth, both the federal government and the states should pair massive public education plans with widespread collection programs in which regulatory agencies, pharmaceutical manufacturers, and the health care industry all cooperate. Many states are launching their own pharmaceutical collection programs, and several have proposed making the pharmaceutical companies pay for it.²⁵² These programs are currently becoming more and more popular, with state agencies and local jurisdictions sponsoring drug collection drives.²⁵³ In addition to educating people about pharmaceutical collection programs, the government should also engage in educating doctors and patients about the consequences of pharmaceuticals and the non-medicinal options available as an alternative.²⁵⁴

Fifth, we need to reconsider our current view on prescription practices. In many cases, doctors prescribe pharmaceuticals to patients in higher amounts and dosages than necessary,²⁵⁵ leaving a greater potential for leftover pharmaceutical to be disposed of improperly. Instead, doctors could prescribe in smaller quantities and allow for more refills, ultimately prescribing the same number of dosages but reducing the possibility for leftover pharmaceuticals. In the same vein, one article recommends that doctors and pharmaceutical companies take a more individualized approach to prescribing medication, providing fluctuating doses in response to an individual patient's age, sex, health, weight, etc.²⁵⁶ Additionally, entities such as the World Health Organization suggest that doctors should place a greater focus on non-medicinal therapy, thereby reducing the stream of pharmaceuticals entering the environment.²⁵⁷ A shift in prescription practices could help reduce the amounts of wasted pharmaceuticals, especially in long-term care facilities and nurs-

252. See proposed legislation, *supra* note 213.

253. See *supra* Part II, however, for a summary of the problems presented by these drives.

254. Christian G. Daughton, *Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health. I. Rationale for and Avenues Toward a Green Pharmacy*, 111 ENVTL. HEALTH PERSP. 757, 768 (2003).

255. *Id.* at 767 (describing a study where patients prescribed antibiotics three days at a time nearly halved the use of the antibiotics and explaining other studies stating that dosages prescribed are usually significantly higher than the necessary therapeutic dose).

256. *Id.*

257. Florian Keil et al., *Systemic Risk Governance for Pharmaceutical Residues in Drinking Water*, 17 GAIA 355, 358 (2008); Daughton, *supra* note 255, at 766.

ing homes where patients are often prescribed many different medications at a time.²⁵⁸ One recent news article outlined a study that estimated that a Minnesota nursing home with only 125 beds wasted approximately 35,000 tablets annually.²⁵⁹ One group of scientists also presented proposals for reducing use of antimicrobial agents for food animals.²⁶⁰

Sixth, we should reexamine our current desire to take pharmaceuticals for every problem, small or large.²⁶¹ Not only does this arguably excessive use of pharmaceuticals for humans and animals create the potential for more pharmaceutical contamination of water, but it also contributes to antimicrobial resistance and greater concentrations of endocrine disrupting compounds in the environment.²⁶² This is not something that the government could reasonably attempt to regulate, but it could provide information and education to help everyone make this personal decision on his or her own.

Finally, we must also explore creative alternatives. One alternative that balances the competing interests of pharmaceutical development and environmental protection is the combination of green pharmaceuticals and green chemistry. Green pharmaceuticals involve designing drugs that biodegrade rapidly so their impact on the environment is minimal.²⁶³ Another goal explored by this movement is increasing the therapeutic efficacy of drugs so that less of the unmetabolized drug is excreted in waste.²⁶⁴ Green chemistry involves using new and innovative processes (and even chemicals) "to reduce waste which is formed during the synthesis of chemicals."²⁶⁵ Although this idea has much potential, if implemented it would probably not result in immediate change. Indeed, one study found that "new knowledge gained from clinical trials takes an average of 17 years to become incor-

258. Meersman, *supra* note 215.

259. *Id.*

260. Anderson et al., *supra* note 68.

261. Americans over 65 years of age fill twice as many prescriptions as their younger counterparts. Royte, *supra* note 1, at 28.

262. Problems associated with these consequences are discussed *supra* Part I(b).

263. Keil et al., *supra* note 257, at 358.

264. Daughton, *supra* note 254, at 765.

265. Klaus Kümmerer, *Sustainable from the Very Beginning: Rational Design of Molecules by Life Cycle Engineering as an Important Approach for Green Pharmacy and Green Chemistry*, 9 GREEN CHEMISTRY 899, 899 (2007). Some of the chemicals used in green chemistry may not, themselves, be biodegradable or non-persistent or toxic, but are used because they present the opportunity for an overall reduction of toxic chemicals in the environment. *Id.*

porated into routine practice.”²⁶⁶ Nonetheless, the government should encourage and incentivize research and development in the area of green pharmaceuticals.

B. *Treatment-based Protections*

Once the FDA allows manufacturers to market drugs, too many drugs escape regulation by other agencies, especially the EPA, because of their low ambient concentrations. Now that scientists are able to detect these compounds below concentrations of parts per trillion,²⁶⁷ the EPA should list and regulate them under the SDWA and RCRA and should more stringently regulate treatment plants as point sources for these contaminants under the CWA. Furthermore, the EPA should, pursuant to the CWA, require that municipal treatment plants at least monitor for these contaminants. This monitoring would help to increase information regarding concentrations of pharmaceuticals in the water and would provide the agencies and public with a better idea of the quantities and types of pharmaceuticals being discharged into the environment.

Also under the CWA, the EPA could amend the POTW pretreatment regulations²⁶⁸ to include pharmaceuticals among the prohibited pollutants or included pharmaceuticals in the POTW's National Pollutant Discharge Elimination System permit,²⁶⁹ shifting some of the regulatory burden off of treatment plants because dischargers into the treatment plants (indirect dischargers) would be responsible for their share of pharmaceutical contamination. Spreading regulatory and financial responsibility for treatment among different actors, rather than placing it solely with the POTW, could ease some of the burdens on POTWs and lower the costs to these facilities.

Second, municipalities must upgrade their wastewater treatment plants. One article considers two different possible options for reducing pharmaceuticals in the drinking water.²⁷⁰ One is urine separation, which would prevent the pharmaceuticals from reaching the wastewater in the first place.²⁷¹ Through this pro-

266. Daughton, *supra* note 255, at 765.

267. Royte, *supra* note 1, at 30.

268. See 40 C.F.R. § 403.5(b) (2009).

269. This permit is issued pursuant to the CWA. This comment is not intended to be a review of the CWA permitting scheme.

270. Webb et al., *supra* note 54, at 164.

271. *Id.*

cess, wastewater with the heaviest pharmaceutical contamination would be taken out of the drinking water treatment stream. Urine separation does not completely solve the problem, however, because treatment plants would still have to treat and dispose of this heavily pharmaceutically contaminated wastewater somehow. Additionally, this approach would require infrastructure development to allow for the separation of the source waters.

In the short term, the article recommends taking advantage of more effective available treatment technologies.²⁷² Several studies have examined different treatment methods and their effectiveness in removing pharmaceuticals from water. One study found that the more advanced treatment options, such as “ozonation, activated carbon, and reverse osmosis and nanofiltration membranes” were the most effective in removing pharmaceuticals.²⁷³ Another study also found ozonation to be a very effective tool.²⁷⁴ Yet another study found that a combination of treatments brought concentrations of many organic contaminants (of which pharmaceuticals is a sub-category) to levels lower than analytical detection.²⁷⁵ Combining the more advanced treatment processes with the urine separation technique could allow for a better use of resources because the more expensive treatment process would be used only on the water truly needing it.

Finally, if the EPA promulgates regulations making allowable concentrations of pharmaceutical contaminants more stringent, it will force more technological innovation, thus resulting in higher-tech and more capable treatment facilities. Regulators and policymakers should design these regulations to provide standards for new facilities as well as help retrofit existing facilities, and the government should support treatment upgrades with a grant program. Additionally, the EPA should elevate the “best available technology” floor under the CWA²⁷⁶ to include treat-

272. *Id.*

273. Halford, *supra* note 2.

274. PHARMACEUTICALS & PERSONAL CARE PRODUCTS IN THE ENVIRONMENT, *supra* note 22, at 51; Webb et al., *supra* note 54, at 164.

275. In this study, the original water contained thirty two contaminants. At the end of a three-phase treatment process, sixteen were undetected and seven decreased in concentration by 75% or more. Several of the compounds were fairly persistent and were reduced in concentration by smaller amounts. Paul E. Stackelberg et al., *Efficiency of Conventional Drinking-Water-Treatment Processes in Removal of Pharmaceuticals and Other Organic Compounds*, 377 *SCI. TOTAL ENV'T* 255, 269 (2007).

276. 33 U.S.C. §§ 1251-1387 (2006).

ment processes that drastically reduce or eliminate pharmaceutical compounds.

VI. CONCLUSION

Pharmaceutical contamination of the water is becoming a pervasive problem, with many potential deleterious effects on humans and the environment. While there is a substantial regulatory structure available to address this problem, agencies and regulators are under-utilizing these tools because of numerous regulatory exceptions and/or simple lack of enforcement. Addressing the problem of pharmaceuticals in the environment does not require a whole new regulatory structure; it simply requires strengthening the existing regulations to cover pharmaceutical contaminants. Additionally, it requires implementation of newer technologies at water treatment facilities. However, we should place a greater focus on source protection—preventing pharmaceuticals from entering the environment in the first place—because source protection obviates the need for mass expenditures to update water treatment infrastructure.

The growing problem of pharmaceuticals in the water needs to be addressed before concentrations reach the point at which definite and distinct links exist between the pharmaceutical-contaminated water and adverse effects on human health. It is essential that both the FDA and the EPA collaboratively lead in our efforts to eliminate Water Rx.

