Pharmaceuticals in the Environment: Looking to Green Governance for a Remedy

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> "Water is the most important prerequisite for life on Earth. It was in water that life had its origins, and without water life cannot continue."
>
> —*Margot Wallström, former Vice President of the European Commission*[1]

Throughout the United States, researchers have discovered pharmaceuticals in surface and drinking water,[2] an occurrence that frustrates current regulations and constitutes an emerging threat to human and ecological health. A U.S. Geological Survey ("USGS") study conducted between 1999 and 2000 examined water samples from a network of 139 streams across thirty states.[3] The study concluded that eighty percent of tested samples contained at least one, a median of seven, and as many as thirty-eight of the ninety-five contaminants listed in the study.[4]

In 2008, the Associated Press reported that twenty-four major metropolitan water supplies, which provide water to over 40 million people, contained trace levels of a variety of pharmaceuticals.[5] The drinking water in Philadelphia, for example, contained fifty-six different pharmaceuticals or byproducts, ranging from heart medications to anticonvulsants.[6] Similar research conducted on Cape Cod's public water supply discovered nine pharmaceuticals, including high levels of sulfamethoxazole, an antibiotic, and Dilantin, an anti-seizure medication.[7] The actual amount of pharmaceuticals in the water, however, remains unknown because many public water utilities do not routinely test for pharmaceuticals,[8] and there is no national program to determine the presence of pharmaceuticals in other waters.[9] Yet, from antibiotics to hormones, the number of pharmaceutical compounds in the nation's water may number in the thousands.[10]

Further complicating the issue, pharmaceuticals enter the environment through a variety of pathways, ranging from intentional disposal of pharmaceuticals, to the passage of unmetabolized pharmaceuticals through bodily waste, to industrial discharge.[11] Moreover, current water-treatment

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1. Margot Wallström, *Introduction*, *in* A Healthy Future: Pharmaceuticals in a Sustainable Society 10, 11 (Bengt-Erik Bengtsson et al. eds., 2009), *available at* http://www.epa.gov/esd/bios/daughton/Pharmaceuticals-Sustainability-2009.pdf.
2. George Washington Univ. Sch. of Pub. Health & Health Servs., Pharmaceuticals are in the Drinking Water: What Does It Mean? 1 (2008), *available at* http://www.gwumc.edu/sphhs/about/rapidresponse/download/Rapid_H2O_Final.pdf.
3. Dana W. Kolpin et al., *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999–2000: A National Reconnaissance*, 36 Envtl. Sci. & Tech. 1202, 1202 (2002).
4. *Id.* The USGS survey included antibiotics, pharmaceuticals, steroids, hormones, caffeine, and various chemicals found in plastics, insecticides, fragrances, fire retardants, and solvents. *Id.*
5. Jeff Donn, Martha Mendoza & Justin Pritchard, *AP: Drugs Found in Drinking Water*, USA Today, Sept. 12, 2008, http://www.usatoday.com/news/nation/2008-03-10-drugs-tap-water_N.htm.
6. *Id.* Other studies have also found pharmaceuticals in water. *See, e.g.*, Kimberlee K. Barnes et al., U.S. Geological Survey, Open File Report 2008–1293, Water-Quality Data for Pharmaceuticals and Other Organic Wastewater Contaminants in Ground Water and in Untreated Drinking Water Sources in the United States, 2000–01, at 5 (2008), *available at* http://pubs.usgs.gov/of/2008/1293/pdf/OFR2008-1293.pdf (stating that "sixty-three of the 100 targeted compounds were detected in at least one water sample").
7. Laurel Schaider et al., Silent Spring Inst., Emerging Contaminants in Cape Cod Drinking Water 6 (2010), *available at* http://www.silentspring.org/pdf/our_research/DrinkingWaterStudyReport.pdf.
8. George Washington Univ. Sch. of Pub. Health & Health Servs., *supra* note 2, at 3.
9. *Id.* at 5.
10. *Pharmaceutical Compounds in the Environment: Hearing on Legislative Oversight Before the Mass. Water Res. Auth.*, 185th Gen. Court 1 (Mass. 2008) [hereinafter *Shine Testimony*] (statement of James Shine, Associate Professor of Aquatic Chemistry, Harvard School of Public Health), *available at* http://www.mwra.state.ma.us/04water/html/pharma/shine_hsph.pdf.
11. *See generally* Schaider et al., Silent Spring Inst., *supra* note 7, at 4; *Pharmaceuticals in Our Water Supplies*, U. Ariz. C. Agric. & Life Sci., http://ag.arizona.edu/AZWATER/awr/july00/feature1.htm (last visited Feb. 18, 2012) (noting that "[p]harmaceutical industries, hospitals and other medical facilities are obvious sources" of pharmaceuticals that enter the environment, as these entities dispose the drugs directly); Emily Sohn, *Taking Showers Could*

processes and technologies are insufficient to completely remove the pharmaceuticals prior to discharge as effluent.[12] Each pathway, therefore, eventually leads to the same location—rivers and streams—via wastewater effluent or leaching from septic systems and landfills.[13]

Because pharmaceuticals are designed to target specific biological activity, they may have effects in low doses.[14] Additionally, scientists are uncertain of the effects that bioaccumulation and pharmaceutical mixtures may have on human health, especially in more susceptible populations, such as children and pregnant women.[15] Pharmaceuticals also often contain endocrine-disrupting compounds that can alter the body's natural production of hormones and have the potential to affect proper development and reproduction.[16]

Already, there are noticeable effects on wildlife. In recent years, scientists have discovered antidepressants in fish,[17] altered fish reproduction thought to be caused by hormones from birth-control pills,[18] and the existence of transgendered fish.[19] Having discovered transgendered fish downstream from a wastewater-treatment plant, one biologist stated, "This is the first thing that I've seen as a scientist that really scared me."[20] Despite this, there is insufficient research into the risks posed by low-dose, chronic exposure to pharmaceuticals in the water.[21]

As with other emerging contaminants, pharmaceuticals in the environment pose a unique challenge to current regulations. In large part, this is because current regulations are not designed to address a low-dose, multiple-pathway, scientifically uncertain threat.[22] Regulating pharmaceuticals in the environment is further complicated because, unlike other manufacturing processes, in which the byproducts are the pollutants and regulations can seek to limit the creation and release of those pollutants, with pharmaceuticals the beneficial end product is also the pollutant, albeit in a later phase of its life cycle. Any solution, therefore, must navigate between the Scylla of hampering future pharmaceutical research, development, and use, and the Charybdis of the threat posed by pharmaceuticals in the environment.

What is needed, and what this Article suggests, is a shift from conventional regulations to a new green-governance approach, one which combines certain aspects of current regulations with various other nonregulatory "economics-based and values-based behavioral drivers."[23] Education should be the foundation of this new approach: education of the public to make them aware of the problem and to increase citizen stewardship, of patients to inform them of proper disposal methods and drug take-back programs, and of healthcare providers concerning new prescription techniques that consider environmental impacts. Building on the base of an educated public, this paper further recommends (1) crafting new federal regulations that remove barriers to creating and implementing pharmaceutical take-back programs; (2) creating economic incentives to encourage green pharmacy practices (similar to the green chemistry practices already in existence); (3) creating a prioritization scheme to focus research and monitoring, developing a searchable green-pharmacy database, and requiring more robust premarket environmental analysis from the pharmaceutical industry; (4) encouraging research and appropriate application of wastewater-treatment technologies; and (5) using a funding mechanism of shared responsibility, holding both producers and consumers financially accountable for pharmaceuticals' environmental impacts.

Part I of this Article discusses the various pathways by which pharmaceuticals enter the environment and addresses the potential risks to humans, the environment, and wildlife. Part II provides a brief review of current U.S. Environmental Protection Agency ("EPA") actions and other U.S. regulations, and their shortcomings in regulating pharmaceuticals in the environment. Part III answers the question of whether any action is necessary, and suggests, based on the precautionary principle, that action is necessary despite scientific uncertainty. Part IV provides an overview of various European regulations and programs. Drawing from both

Contaminate Drinking Water, Discovery News (Mar. 25, 2010), http://news.discovery.com/earth/showers-pollution-drinking-water.html. For a good review of animal pharmaceuticals in the environment, see Ariele Lessing, *Killing Us Softly: How Sub-Therapeutic Dosing of Livestock Causes Drug-Resistant Bacteria in Humans*, 37 B.C. Envtl. Aff. L. Rev. 463 (2010).

12. Am. Water Works Ass'n, Pharmaceutical Compounds in Drinking Water (n.d.), *available at* http://www.awwa.org/files/FlyInPhar.pdf.
13. *See generally id.*; Christian Daughton, EPA, Origins and Fate of PPCPs in the Environment (2006), *available at* http://www.epa.gov/ppcp/pdf/drawing.pdf; Schaider et al., Silent Spring Inst., *supra* note 7, at 1–4; Sohn, *supra* note 11.
14. Klaus Kümmerer, *Pharmaceuticals in the Environment*, 35 Ann. Rev. Env't & Resources 57, 59 (2010).
15. *Id.*; *see, e.g.*, Francesco Pomati et al., *Effects and Interactions in an Environmentally Relevant Mixture of Pharmaceuticals*, 102 Toxicological Sci. 129, 136 (2008).
16. Mary Tiemann, Cong. Research Serv., RL 34201, Safe Drinking Water Act (SDWA): Selected Regulatory and Legislative Issues 10 (2010), *available at* http://assets.opencrs.com/rpts/RL34201_20100727.pdf.
17. *Antidepressants in Stream Waters! Are They in the Fish Too?*, U.S. Geological Surv., http://toxics.usgs.gov/highlights/antidepressants_fish.html (last updated Oct. 28, 2011).
18. Amy L. Filby et al., *Health Impacts of Estrogens in the Environment, Considering Complex Mixture Effects*, 115 Envtl. Health Persp. 1704, 1704 (2007), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2137123/?tool=pubmed.
19. George J. Mannina, Jr., *Medicines and the Environment: Legal and Regulatory Storms Ahead?*, Legal Backgrounder (Wash. Legal Found., Washington, D.C.), Mar. 24, 2006, at 1, *available at* http://www.wlf.org/upload/032406LBmannina.pdf.
20. *Fish Near Some Colo. Plants Found with Male-Female Tissue*, USA Today, Oct. 3, 2004, http://www.usatoday.com/news/offbeat/2004-10-03-deformed-fish_x.htm?csp=34.
21. George Washington Univ. Sch. of Pub. Health & Health Servs., *supra* note 2, at 3–4; Pat Hemminger, *Damming the Flow of Drugs into Drinking Water*, 113 Envtl. Health Persp. A678, A679 (2005), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1281310/.
22. *See infra* Part II.
23. LeRoy C. Paddock, *Green Governance: Building the Competencies Necessary for Effective Environmental Management*, 38 Envtl. L. Rep. 10,609, 10,609 (2008).

the shortcomings in current U.S. regulations and Europe's response to this issue, Part V provides recommendations for limiting introduction of pharmaceuticals into the environment. Finally, Part VI concludes by considering how to pay for such programs, examining the ideas of extended producer responsibility and consumer responsibility, and finally recommending a shared responsibility framework.

I. Background

A. *Various Pathways into the Water*

Pharmaceuticals enter the water supply via multiple pathways: they are flushed down the toilet, passed unmetabolized through human excrement, rinsed off during showers, and discharged directly from manufacturers.[24] In 2009, healthcare providers dispensed more than 3.7 billion prescriptions in the United States.[25] Further, the Centers for Disease Control and Prevention estimated that forty-eight percent of citizens took a least one prescription drug per month between 2005 and 2008.[26] Certain drugs metabolize faster than others do: "Some antibiotics are metabolized up to 95%, whereas others only 5%."[27] For example, acetaminophen and the antidepressant fluoxetine are metabolized around eighty percent.[28] On the other hand, the antibiotic ciprofloxacin is not metabolized as efficiently, with approximately fifty percent passed as excrement.[29] Thus, unmetabolized medication is passed into the sewer system along with human waste. In fact, one researcher traced sixty prescribed pharmaceuticals after they were excreted from his subjects and found evidence of half of them in treated waters and rivers.[30]

In addition to unmetabolized pharmaceuticals, topical pharmaceuticals enter the wastewater system when they are rinsed off in sinks or showers, similarly making their way to wastewater-treatment systems and resulting in their eventual discharge as effluent.[31] Recent research concluded that, much like the unmetabolized pharmaceuticals, "human skin fails to absorb much of the medicine that is applied topically, such as antibiotic ointments and steroid creams."[32] Topical pharmaceuticals, unlike unmetabolized pharmaceuticals, however, remain whole as they are rinsed off, sending a concentrated load of chemicals into the sewer system.[33]

Another method of introduction occurs when people dispose of unused or expired drugs in the drain or toilet.[34] This pathway permits the pharmaceutical to pass unchanged through wastewater-treatment facilities into the environment.[35] To address this, the Food and Drug Administration ("FDA") website notes that only a "select, few medicines" should be disposed of by flushing, and that any other medications should be thrown into the trash or returned through a medicine take-back program.[36] The White House Office of National Drug Control Policy also issued a bulletin in October 2009 instructing people not to dispose of prescription drugs down the toilet or drain unless the label specifically instructs them to do so and to take advantage of community drug take-back programs or other household-hazardous-waste-collection events for proper disposal.[37] Throwing away prescription medications, however, does not completely solve the problem either; discarded pharmaceuticals often end up at dumps and landfills, and can seep into underlying groundwater.[38]

Hospitals and long-term-care facilities also introduce pharmaceuticals into wastewater systems through their patients and drug-disposal practices.[39] For years it was standard practice to flush unused or expired pharmaceuticals down the drain or toilet, and EPA believes that such practices may continue today (e.g., the emptying of intravenous bags into sinks).[40] In fact, a recent Associated Press study estimated that hospitals and long-term-care facilities flush 250 million pounds of unused drugs annually.[41]

The final pathway through which pharmaceuticals enter the environment is pharmaceutical manufacturing.[42] It had long been assumed that discharges from pharmaceutical manufacturers were minimal;[43] however, "[f]ederal scientists testing for pharmaceuticals in water have been finding significantly more medicine residues in sewage downstream from public treatment facilities that handle waste from drugmakers."[44] A USGS study from 2004 to 2009 examined effluents from two New York wastewater-treatment plants ("the target plants") that received discharges from pharmaceutical manufactur-

24. *Pharmaceuticals and Personal Care Products (PPCPs): Basic Information*, EPA, http://www.epa.gov/ppcp/basic2.html (last updated Oct. 27, 201016at 7," Japanese researchers); Sohn, *supra* note 11.
25. Henry J. Kaiser Family Found., *United States: Prescription Drugs*, StateHealthFacts.org, http://www.statehealthfacts.org/profileind.jsp?sub=66&rgn=1&cat=5 (last visited Feb. 18, 2012).
26. *Fast Stats: Therapeutic Drug Use*, Ctrs. for Disease Control & Prevention, http://www.cdc.gov/nchs/fastats/drugs.htm (last updated Feb. 18, 2011).
27. Kümmerer, *supra* note 14, at 60.
28. *PharmaWater—Metabolism: The Ins and Outs of Drug Metabolism*, Associated Press, http://hosted.ap.org/specials/interactives/pharmawater_site/day1_08.html (last visited Feb. 18, 2012).
29. *Id.*
30. *Pharmaceuticals in Our Water Supplies*, *supra* note 11.
31. Keith A. Johnston & Kristine Sendek-Smith, *Muddy Waters: Recent Developments Under the Clean Water Act*, 24 Nat. Resources & Env't 31, 38 (2010); *see also* Sohn, *supra* note 11.
32. Sohn, *supra* note 11.
33. *Id.*
34. *Id.*
35. *Pharmaceuticals in Our Water Supplies*, *supra* note 11.
36. *Disposal of Unused Medicines: What You Should Know*, FDA, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm (last updated Feb. 14, 2012).
37. Office of Nat'l Drug Control Policy, Exec. Office of the President, Proper Disposal of Prescription Drugs (2009), *available at* http://www.bethesda.med.navy.mil/Patient/health_care/clinical_support/pharmacy/Prescription%20disposal%20guideline.pdf.
38. *See e.g.*, Daughton, EPA, *supra* note 13.
39. *See* Kümmerer, *supra* note 14, at 62. Although hospital waste certainly contributes pharmaceuticals to the wastewater system, it is likely a minor contributor compared to household discharges. *See id.*
40. Office of Water, EPA, EPA-821-R-10-006, Draft Guidance Document: Best Management Practices for Unused Pharmaceuticals at Health Care Facilities 2 (2010), *available at* http://water.epa.gov/scitech/wastetech/guide/upload/unuseddraft.pdf.
41. Jeff Donn, Martha Mendoza & Justin Pritchard, *Health Facilities Flush Estimated 250M Pounds of Drugs a Year*, USA Today, Sept. 14, 2008, http://www.usatoday.com/news/health/2008-09-14-drugs-flush-water_N.htm.
42. Kümmerer, *supra* note 14, at 61.
43. *Id.*
44. *Factories Dumping Drugs into Sewage*, MSNBC.com (Apr. 19, 2009), http://www.msnbc.msn.com/id/30267705/from/ET/.

ers, and compared those effluents to one New York treatment plant that did not receive pharmaceutical manufacturer discharges and twenty-three other treatment plants across the United States ("the comparison plants").[45] The USGS scientists discovered that the effluents from the target plants had 10 to 1,000 times higher concentrations of pharmaceuticals than the effluents from the comparison plants.[46] Moreover, the presence of the pharmaceutical-laden effluents could be traced up to thirty kilometers downstream.[47]

Because water-treatment plants are neither required nor equipped to treat pharmaceuticals, the pharmaceutical compounds are not adequately removed from the wastewater prior to discharge.[48] Although wastewater-treatment plants remove some compounds, the efficacy of attempts at removal "can be substantially less than 100%."[49] Moreover, because many pharmaceuticals biodegrade slowly, they have the propensity to accumulate in measurable amounts in the environment.[50]

In areas with septic systems, pharmaceuticals enter the septic systems and can seep into the groundwater and surface water.[51] For example, in a Cape Cod study, researchers found detectable levels of pharmaceuticals in several ponds downstream of residential areas, leading to the conclusion that "[c]hemicals that are not broken down in septic systems can leach into the Cape's shallow unconfined aquifer."[52] Although the pathways are different, the result is the same: Pharmaceuticals, even when used properly, are being discharged into the nation's waters.

B. Risks to Humans

Although research shows that only trace amounts of pharmaceuticals are present in the nation's waters, many scientists remain concerned that any amount of pharmaceuticals, or mixture thereof, may have harmful effects on human health. Researchers conducting the Cape Cod study noted that pharmaceuticals are designed to be active in low doses and expressed concern there may be unknown effects from low-dose, chronic exposure.[53] This is especially troubling for fetuses and infants, who may be more susceptible to small amounts of pharmaceuticals during critical developmental stages.[54] EPA echoes this concern:

> The risks posed . . . to humans are unknown, largely because the concentrations are so low. . . . There are no known human health effects from such low-level exposures in drinking water, but special scenarios (one example being fetal exposure to low levels of medications that a mother would ordinarily be avoiding) require more investigation.[55]

Moreover, establishing a direct causal relationship is difficult.[56] Chronic exposure can cause small changes over long periods and may go unnoticed.[57]

Further complicating scientists' understanding, the effects on humans from pharmaceuticals can vary widely. For example, anticancer drugs that have been found in the water may actually cause cancer,[58] while hormones, which have also been found in the water, can impact proper development and impair reproduction.[59] In addition, most studies have traditionally focused on acute exposures as opposed to low-level, chronic effects,[60] and the studies that have been conducted have examined only about 150 of the 3,000 pharmaceutical ingredients currently used.[61]

Beyond concerns over low-dose, chronic exposure, there is also limited understanding of the effects of combinations of pharmaceuticals; that is, the cocktail effect.[62] Some initial research demonstrated that mixtures of pharmaceuticals caused effects that individual pharmaceuticals would not cause.[63] A recent Italian study discovered that by exposing developing human cells to various mixtures of thirteen pharmaceuticals—at levels similar to those found in Italian rivers—researchers could slow the growth of the cells by about a third.[64] In a separate study, a different pharmaceutical cocktail actually stimulated cell growth.[65]

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45. Patrick J. Phillips et al., *Pharmaceutical Formulation Facilities as Sources of Opioids and Other Pharmaceuticals to Wastewater Treatment Plant Effluents*, 44 Envtl. Sci. & Tech. 4910, 4910–12 (2010).
46. *Id.* at 4914.
47. *Id.* at 4911.
48. *See* Johnston & Sendek-Smith, *supra* note 31, at 31.
49. *Shine Testimony*, *supra* note 10, at 2.
50. S*ee id.*; *see also* Ana Aguera et al., *Occurrence and Removal of Emerging Pollutants in Urban Wastewater*, SciTopics (Mar. 24, 2010), http://www.scitopics.com/Occurrence_and_removal_of_emerging_pollutants_in_urban_wastewater.html.
51. George Washington Univ. Sch. of Pub. Health & Health Servs., *supra* note 2, at 1.
52. Schaider et al., Silent Spring Inst., *supra* note 7, at 1.
53. *Id.* at iv. In another study demonstrating the effects of low-dose pharmaceuticals, Japanese researchers
    > reported that communities with increased levels of lithium in their drinking water suffered a significantly lower incidence of suicide. The Japanese data confirmed a previous study of drinking water in Texas that found a decreased incidence of both suicide and violent crime in counties with higher-than-average amounts of naturally-occurring lithium in the water.

    Jacob M. Appel, *Beyond Fluoride: Pharmaceuticals, Drinking Water and the Public Health*, Huffington Post (Dec. 21, 2009), http://www.huffingtonpost.com/jacob-m-appel/beyond-fluoride-pharmaceu_b_398874.html?view=screen.
54. Schaider et al., Silent Spring Inst., *supra* note 7, at 7 (citing Pomati et al., *supra* note 15, at 136).
55. *Pharmaceutical and Personal Care Products (PPCPs): Frequent Questions*, EPA, http://www.epa.gov/ppcp/faq.html (last updated Oct. 27, 2010).
56. Kümmerer, *supra* note 14, at 64; *see also* Patricia Burkhardt-Holm, *Endocrine Disruptors and Water Quality: A State-of-the-Art Review*, 26 Int'l J. Water Resources Dev. 477, 483 (2010).
57. Kümmerer, *supra* note 14, at 64.
58. *Id.* at 63–64.
59. *Shine Testimony*, *supra* note 10, at 3.
60. George Washington Univ. Sch. of Pub. Health & Health Servs., *supra* note 2, at 3–4.
61. *Id.* at 3.
62. Schaider et al., Silent Spring Inst., *supra* note 8, at iv; Burkhardt-Holm, *supra* note 57, at 484.
63. *How Meds in Water Could Impact Human Cells*, MSNBC.com (Mar. 10, 2008), http://www.msnbc.msn.com/id/23558785//.
64. *Id.*; Francesco Pomati et al., *Effects of a Complex Mixture of Therapeutic Drugs at Environmental Levels on Human Embryonic Cells*, 40 Envtl. Sci. & Tech. 2442, 2442 (2006); *see Shine Testimony*, *supra* note 10, at 2–3 ("[*I*]*n vitro* work suggests that [pharmaceutically active compounds ("PhACs")] can induce effects at low concentrations along non-therapeutic pathways. Pomati et al[.] (2006) exposed human cell lines to a suite of PhACs at environmentally relevant concentrations and found that, among other outcomes, the drug mixture inhibited human embryonic cell growth. The effects of mixtures of pharmaceuticals and the importance of the timing of exposures are still largely uncertain.").
65. *How Meds in Water Could Impact Human Cells*, *supra* note 63.

Perhaps the most frightening risk to humans comes from pharmaceuticals that act as endocrine disruptors. The endocrine system is responsible for producing hormones that control important physical development related to growth and reproduction.[66] An endocrine disruptor is an "agent or mixture of agents that interferes [with] or alters the synthesis, secretion, transport, metabolism, binding action, or elimination of hormones that are present in the body and are responsible for homeostasis, growth, neurological signaling, reproduction and developmental processes."[67] Simply put, endocrine disruptors interfere with the body's normal operation of producing hormones and otherwise impair normal development.[68]

Some endocrine disruptors actually mimic the body's natural hormones, causing the body to overrelease that particular hormone.[69] Endocrine disruptors also can block the body's ability to react appropriately to hormones,[70] thus preventing a necessary biologic response.[71] Finally, endocrine disruptors can directly cause the endocrine system to overproduce or underproduce the body's necessary hormones.[72] For example, birth-control pills—used by approximately 10 million American women[73]—introduce hormones that prevent ovulation and cause other changes in a woman's reproductive biology that help prevent pregnancy.[74] Some of these hormones pass unmetabolized into the environment, causing scientists to worry that such endocrine disruptors will interfere with normal human production of hormones,[75] leading at least one scientist to wonder if humans "might be drowning in a sea of estrogens."[76]

Although there is currently no consensus on the risk posed to humans by endocrine disruptors, the Endocrine Society recently published the following statement: "[E]ndocrine disruptors have effects on male and female reproduction, breast development and cancer, prostate cancer, neuroendocrinology, thyroid, metabolism and obesity, and cardiovascular endocrinology. Results from animal models, human clinical observations, and epidemiological studies converge to implicate EDCs as a significant concern to public health."[77] Patricia Burkhardt-Holm echoes this concern, warning of the following potential human-health problems caused by endocrine disruption: declining semen quality, erectile dysfunction, testicular and prostate cancer, abnormal sexual development, altered pituitary- and thyroid-gland functions, immune suppression, and neurobehavioral effects.[78]

The final risk posed by pharmaceuticals, specifically antibiotics, is the potential creation of antibiotic-resistant bacteria. Among the pharmaceuticals that have been found in the nation's waters are a wide range of antibiotics.[79] Some scientists are concerned that the antibiotics in water will create antibacterial-resistant strains.[80] They fear the bacteria will develop immunity to current antibiotics, resulting in drug-resistant diseases.[81] And there is some evidence supporting this concern. In one study, researchers discovered an increased presence of antibiotic-resistant bacterial strains downstream from an animal-feeding operation that used antibiotics to treat the livestock.[82] Another study showed an increase in antibiotic-resistant strains in areas receiving effluent from wastewater-treatment plants.[83]

C. Harm to the Environment and Wildlife

Pinpointing and understanding damage to the environment and wildlife caused by pharmaceuticals is complicated by a number of factors. Pharmaceuticals are designed to cause specific biologic reactions in humans, but until recently, they have not been studied for unintended biologic reactions in wildlife.[84] The risks are also difficult to understand and pinpoint due to the variety of different organisms that make up a healthy ecosystem.[85] The impact of human pharmaceuticals is different for different species, and scientists cannot yet predict exact effects.[86] For example, serotonin, which is contained in the commonly prescribed antidepressant Prozac, affects humans and animals differently.[87] In animals, serotonin has the potential to affect egg-laying in snails and slugs, and spawning in clams and other bivalves, whereas in humans, serotonin levels affect physical activities such as "appetite, sleep, sexual arousal, and depression."[88]

66. *Endocrine Disruption Tutorial*, Tulane U., http://e.hormone.tulane.edu/learning/hormone-glands.html (last visited Feb. 18, 2012).
67. *Endocrine Disrupting Chemicals in Drinking Water: Risks to Human Health and the Environment: Hearing Before the Subcomm. on Energy and the Env't of the H. Comm. on Energy and Commerce*, 111th Cong. 2–3 (2010) [hereinafter *Solomon Testimony*] (testimony of Gina M. Solomon, Senior Scientist, Natural Resources Defense Council), *available at* http://republicans.energycommerce.house.gov/Media/file/Hearings/Energy/2010-02-25_Endocrine/Solomon.pdf.
68. *Id.* at 3; *Endocrine Primer*, EPA, http://www.epa.gov/scipoly/oscpendo/pubs/edspoverview/primer.htm (last visited Oct. 18, 2011).
69. *Endocrine Primer*, *supra* note 68.
70. *Id.*
71. Burkhardt-Holm, *supra* note 56, at 478.
72. *Endocrine Primer*, *supra* note 68.
73. Alistair B.A. Boxall, *The Environmental Side Effects of Medication*, 5 EMBO Rep. 1110 (2004), *available at* http://www.nature.com/embor/journal/v5/n12/full/7400307.html.
74. Am. Cong. of Obstetricians and Gynecologists, FAQ159, Implants, Injections, Rings, and Patches: Hormonal Birth Control Options 1 (2011), *available at* http://www.acog.org/~/media/For%20Patients/faq159.pdf?dmc=1&ts=20120211T1546420645.
75. *Pharmaceuticals in Our Water Supplies*, *supra* note 11.
76. *Food Quality Protection Act of 1995: Hearing on H.R. 1627 Before the Subcomm. on Health and the Env't of the H. Comm. on Commerce*, 104th Cong. 84 (1995) (statement of Erik Olson, Senior Attorney, Natural Resources Defense Council).
77. Evanthia Diamanti-Kandarakis et al., *Endocrine-Disrupting Chemicals: An Endocrine Society Scientific Statement*, 30 Endocrine Revs. 293, 293 (2009), *available at* http://edrv.endojournals.org/content/30/4/293.full.pdf+html.
78. Burkhardt-Holm, *supra* note 56, at 485.
79. *See* Boxall, *supra* note 73, at 1110.
80. *See id.* at 1112; *see also* George Washington Univ. Sch. of Pub. Health & Health Servs., *supra* note 2, at 4.
81. *See Pharmaceuticals in Our Water Supplies*, *supra* note 12.
82. *See* George Washington Univ. Sch. of Pub. Health & Health Servs., *supra* note 2, at 4.
83. *See* Karen L. Lachmayr et al., *Quantifying Nonspecific TEM -Lactamase (*bla$_{TEM}$*) Genes in a Wastewater Stream*, 75 Applied & Envtl. Microbiology 203, 207 (2009), *available at* http://aem.asm.org/cgi/reprint/75/1/203.pdf.
84. Boxall, *supra* note 73, at 1110.
85. *Shine Testimony*, *supra* note 10, at 3; *see also* Boxall, *supra* note 73, at 1112–13 (discussing the various impacts on a variety of organisms).
86. *Shine Testimony*, *supra* note 10, at 3.
87. *Id.*
88. *Id.*

Yet despite these complexities, a wide range of effects on the ecosystem have already been noted.[89] The effects range from impact on dung decomposition, to the structure of soil microbial communities, to stimulation of growth in cyanobacteria and aquatic plants.[90] Further, there is ample evidence of pharmaceuticals and their impact on the aquatic environment.[91] Testifying before Congress, Dr. Gina M. Solomon stated:

> I wish I could tell you these chemicals are unlikely to be a problem at the concentrations measured. Unfortunately, I can't tell you that, because my assessment of the data suggests a problem.
>
> Here's what I can tell you: wildlife populations are showing signs of harm, many of these chemicals are not eliminated by conventional drinking water treatment, and mixtures of these chemicals are present in our water supply. Although they are at low levels in water, hormones are known to have effects even in trace amounts.[92]

A USGS study recently found evidence of antidepressants in fish up to five miles downstream of a wastewater-treatment plant.[93] There was no indication of antidepressants present upstream.[94] Similarly, a Baylor University study found antidepressants in fish downstream from a wastewater-treatment plant.[95] A 2004 study compared fish upstream of a Boulder, Colorado wastewater-treatment plant to fish at the effluent site.[96] Researchers discovered the ratio of male fish at the effluent site was half that of the upstream site.[97] Most troubling, however, researchers reported that eighteen to twenty-two percent of white suckerfish sampled at the effluent site were intersex, while no intersex fish were discovered upstream.[98] "[W]herever researchers look, they are finding problems with sexual development in wildlife."[99] There are myriad examples: Researchers believe effluent from a wastewater-treatment plant caused male fathead minnows to produce vitellogenin, a female egg-yolk protein;[100] intersex fish were found in a third of USGS survey sites on nine major river basins;[101] intersex frogs have been discovered in cities and suburbs across the United States,[102] and the sexual determination of alligators in Florida is being altered, presumably by an increase in estrogenin their environment.[103]

Understanding the impact on wildlife is important not only to protect the environment and the animals for their own sake, but also because harm to animals can serve as a harbinger of potential threats to human health.[104] Although it would take a lot of estrogen to cause acute effects in fish, the aforementioned studies suggest there is an impact from low-dose, long-term exposure.[105]

II. Current U.S. Federal Actions

A. EPA's Actions

EPA has devoted some attention to the problem of pharmaceuticals in the environment. Currently, EPA lists approximately fifty studies it is either conducting or supporting concerning the occurrence of pharmaceuticals and endocrine disruptors in the environment.[106] Additionally, EPA drafted guidance for healthcare facilities, which describes the best practices for "Reducing or Avoiding Unused Pharmaceuticals," provides recommendations for "Identifying & Managing Types of Unused Pharmaceuticals," and discusses applicable disposal regulations.[107] Although EPA anticipates these best practices will help reduce the amount of pharmaceuticals discharged to water bodies,[108] the guidance only addresses the intentional disposal of unused pharmaceuticals by healthcare facilities.[109] It does not address metabolized, excreted pharmaceuticals or those rinsed off of patients.[110]

Additionally, in September 2009, EPA released its third drinking-water-contaminant-candidate list ("CCL3"), as required by the Safe Drinking Water Act ("SDWA").[111] Starting with a universe of 7,500 potential chemical and microbial contaminants, EPA selected 116 contaminants for the final CCL3: 104 chemicals and 12 microbiological contaminants.[112] Of the 104 chemicals listed, 14 were either pharma-

89. *See* Boxall, *supra* note 73, at 1110.
90. *Id.* at 1114 tbl.2.
91. Kümmerer, *supra* note 14, at 62. There is evidence of the occurrence of some 160 different active pharmaceutical ingredients in the aquatic environment. *Id.*
92. *Solomon Testimony*, *supra* note 67, at 3.
93. *Antidepressants in Stream Waters! Are They in the Fish Too?*, *supra* note 17.
94. *Id.*
95. Noreen Parks, *Fish on Prozac*, Science (Nov. 4, 2003), http://news.sciencemag.org/sciencenow/2003/11/04-01.html.
96. Alan M. Vajda et al., *Reproductive Disruption in Fish Downstream from an Estrogenic Wastewater Effluent*, 42 Envtl. Sci. & Tech. 3407, 3408 (2008).
97. *Id.* at 3409.
98. *Id.* at 3410.
99. *Solomon Testimony*, *supra* note 67, at 2.
100. Larry B. Barber et al., *Reproductive Responses of Male Fathead Minnows Exposed to Wastewater Treatment Plant Effluent, Effluent Treated with XAD8 Resin, and an Environmentally Relevant Mixture of Alkylphenol Compounds*, 82 Aquatic Toxicology 36, 39, 44 (2007).
101. Jo Ellen Hinck et al., *Widespread Occurrence of Intersex in Black Basses (*Micropterus *spp.) from U.S. Rivers, 1995–2004*, 95 Aquatic Toxicology 60, 61–62, 65 tbl.2 (2009) (reporting occurrences in the Apalachicola, Colorado, Columbia, Mobile, Mississippi, Pee Dee, Rio Grande, and Savannah river basins).
102. Felicity Barringer, *Hermaphrodite Frogs Found in Suburban Ponds*, N.Y. Times, Apr. 8, 2008, at F2; David K. Skelly et al., *Intersex Frogs Concentrated in Suburban and Urban Landscapes*, 7 EcoHealth 374, 376–77 (2010).
103. Louis J. Guillette, Jr. & Mark P. Gunderson, *Alterations in Development of Reproductive and Endocrine Systems of Wildlife Populations Exposed to Endocrine-Disrupting Contaminants*, 122 Reproduction 857, 858–59 (2001).
104. *Hearing on the Testing by the Department of Environmental Protection for the Presence of Pharmaceuticals and Personal Care Products in the NYC Drinking Water Supply Before the Comm. on Envtl. Prot.*, 2009 Sess. (N.Y. City Council 2009) [hereinafter *Naidenko Testimony*] (statement of Olga V. Naidenko, Senior Scientist, Environmental Working Group), *available at* http://www.ewg.org/testimony/pharmaceuticals-personal-care-products-in-NYC-drinking-water.
105. *Id.*
106. *Pharmaceutical and Personal Care Products (PPCPs): EPA PPCP Research*, EPA, http://www.epa.gov/ppcp/work.html (last updated Oct. 27, 2010).
107. Office of Water, EPA, *supra* note 40, at i.
108. *See id.*
109. *Id.* at 2.
110. *Id.*
111. Safe Drinking Water Act § 1412(b)(1), 42 U.S.C. § 300g-1(b)(1) (2006); *see* Johnston & Sendek-Smith, *supra* note 31, at 38.
112. *Contaminant Candidate List 3—CCL*, EPA, http://water.epa.gov/scitech/drinkingwater/dws/ccl/ccl3.cfm (last updated Oct. 19, 2011).

ceuticals or used in process or delivery of medicine.[113] Recall, there are thousands of pharmaceutical compounds in use today.[114]

EPA has also taken steps to address the specific problem of endocrine disruptors.[115] In 1996, Congress passed the Food Quality Protection Act ("FQPA") and amended SDWA.[116] Specifically, the amendments required EPA to "develop a screening program . . . to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate."[117] Section 136 of the SDWA Amendments of 1996 further allowed EPA to test for "any other substance that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance."[118] Accordingly, EPA created the Endocrine Disruptor Screening and Testing Advisory Committee ("EDSTAC").[119]

The EDSTAC, which was made up of representatives from industry, environmental groups, government agencies, academia, and public health groups,[120] was charged with recommending a screening program that would advise EPA on regulatory decisions about the listed endocrine-disrupting compounds.[121] The EDSTAC provided their report to EPA in August of 1998.[122] Importantly, the EDSTAC recommended, and EPA concurred, that endocrine-disruption risks extend beyond estrogen and expanded the screening to include any chemical interference with male hormones and the thyroid system.[123] The FQPA and SDWA required EPA to develop the Endocrine Disruptor Screening Program ("EDSP") by August 1998, to implement it by August 1999, and report on its progress by August 2000.[124]

The purpose of the EDSP was to find validated methods for screening, identifying, and testing potential endocrine-disrupting chemicals in order to assess and manage the risks under current laws.[125] This was a large task considering that EPA initially started with approximately 87,000 potential endocrine-disrupting chemicals.[126] To accomplish this, EPA planned a three-step approach: (1) priority-setting to determine how to narrow the list; (2) tier 1 analysis designed to identify which chemicals have the potential to interact with the estrogen, androgen, and thyroid hormone systems; and (3) tier 2 analysis designed to determine whether a chemical may have endocrine-related effects in humans similar to those of naturally occurring hormones and to ascertain at what dose level effects occur.[127]

On April 15, 2009, EPA announced the initial list of chemicals to be screened under the EDSP,[128] and on October 29, 2009, the first test orders were issued.[129] Of the original 87,000 potential endocrine-disrupting chemicals, 67 chemicals were listed for the first round of screening, none of which were pharmaceuticals.[130] On November 17, 2010, EPA published a second list of chemicals it intends to include for tier 1 screening.[131] Of the 134 chemicals published in the second list, three were pharmaceuticals (erythromycin, nitroglycerin, and quinoline).[132] Thus, more than fourteen years after EPA was required to start researching and screening potential endocrine-disrupting chemicals, only three pharmaceuticals have been included in the screening program. This is not to fault EPA or the EDSP; the purpose of the EDSP was to address the problem of endocrine-disrupting chemicals, which come from various nonpharmaceutical sources as well. These figures do, however, highlight the need to establish programs and regulations designed to specifically address the presence of pharmaceuticals in the water.

B. Current U.S. Regulations

There is little federal regulation of emerging contaminants,[133] including pharmaceuticals.[134] Much of the current regulatory framework, at least to some extent, requires EPA to first identify pollutants, study the pollutants, and then to set appropriate levels. In addition to the time and expense, such regulation still fails to address the concerns of low-dose, chronic exposure—the risks posed by pharmaceutical cocktails—and does not address the various pathways through

113. *Id.* For example, erythromycin is used in pharmaceutical formulations as an antibiotic; estradiol (17-beta estradiol) is an estrogenic hormone and is used in pharmaceuticals; and estriol is an estrogenic hormone and is used in veterinary pharmaceuticals. *Id.*
114. *Shine Testimony*, *supra* note 10, at 1.
115. *See generally* Johnston & Sendek-Smith, *supra* note 31, at 37–38.
116. *Endocrine Primer*, *supra* note 68.
117. Food Quality Protection Act of 1996 § 405, 21 U.S.C. § 346a(p)(1) (2006).
118. Safe Drinking Water Amendments of 1996 § 136, 42 U.S.C. § 300j-17 (2006).
119. *Endocrine Primer*, *supra* note 68.
120. *Solomon Testimony*, *supra* note 67, at 4.
121. The Keystone Ctr., *Keystone Convening Report*, EPA (Oct. 1996), http://www.epa.gov/endo/pubs/edsparchive/keystone.htm.
122. *Endocrine Primer*, *supra* note 68.
123. *See id.* Among other recommendations were: (1) the use of new technology to rapidly prescreen numerous chemicals to see if they interact with hormone receptors *in vitro* (in the "test tube"); (2) use of a computer-based tracking system allowing information about health effects and exposure to be collected in one place to facilitate prioritization; and (3) acceptance by EPA of nominations from the public of chemicals or chemical mixtures for expedited testing. *See Solomon Testimony*, *supra* note 67, at 4–5.
124. Food Quality Protection Act of 1996 § 405, 21 U.S.C. § 346a(p)(1)–(2), (7) (2006); Safe Drinking Water Amendments of 1996 § 136, 42 U.S.C. § 300j-17 (2006).
125. *Endocrine Primer*, *supra* note 68.
126. Endocrine Disruptor Screening Program; Proposed Statement of Policy, 63 Fed. Reg. 71,542, 71,545 (Dec. 28, 1998).
127. *EDSP Background*, EPA, http://www.epa.gov/scipoly/oscpendo/pubs/edspoverview/background.htm (last updated Aug. 11, 2011); *see also* Endocrine Disruptor Screening Program, 63 Fed. Reg. 42,852, 42,854 (Aug. 11, 1998).
128. *See* Final List of Initial Pesticide Active Ingredients and Pesticide Inert Ingredients to be Screened Under the Federal Food, Drug, and Cosmetic Act, 74 Fed. Reg. 17,579, 17,580 (Apr. 15, 2009).
129. *Endocrine Disruptor Screening Program (EDSP)*, EPA, http://www.epa.gov/endo/ (last updated Dec. 13, 2011).
130. Final List of Initial Pesticide Active Ingredients and Pesticide Inert Ingredients to be Screened Under the Federal Food, Drug, and Cosmetic Act, 74 Fed. Reg. at 17,583.
131. *Endocrine Disruptor Screening Program (EDSP)*, *supra* note 129.
132. Endocrine Disruptor Screening Program; Second List of Chemicals for Tier 1 Screening, 75 Fed. Reg. 70,248, 70,248–54 (Nov. 17, 2010).
133. "An emerging contaminant (EC) is a chemical or material characterized by a perceived, potential, or real threat to human health or the environment or by a lack of published health standards. A contaminant also may be 'emerging' because of the discovery of a new source or pathway to humans." *Perchlorate and Other Emerging Contaminants*, EPA, www.epa.gov/fedfac/documents/emerging_contaminants.htm (last updated June 9, 2011).
134. *See generally* Johnston & Sendek-Smith, *supra* note 31.

which pharmaceuticals enter the environment. Simply put, the current regulatory framework was designed to handle conventional pollutants; it was not designed to handle multiple-pathway, low-dose, long-term exposure to a cocktail of pharmaceuticals. Thus, the current regulations can only provide part of the solution and leave gaps, which need to be filled in by nonregulatory measures.

1. The Federal Food, Drug and Cosmetic Act, FDA, and the National Environmental Policy Act

Per the FDA-specific National Environmental Policy Act ("NEPA") regulations, FDA requires any pharmaceutical manufacturer to submit a NEPA-compliant environmental assessment ("EA") or claim of categorical exclusion with any application for drug approval.[135] FDA then evaluates the EA "to determine . . . whether the proposed action may significantly affect the quality of the human environment, and whether an [environmental-impact statement ("EIS")] will be prepared."[136] Under this framework, the pharmaceutical company could complete some form of mitigation when an EIS is required or when there is a finding of no significant impact through mitigation.[137] Getting to that level of environmental review, however, is unlikely for a number of reasons.

One initial weakness in the NEPA framework regarding pharmaceuticals is the broad categorical exclusions allowed for human pharmaceuticals.[138] Categorical exclusions are permitted when the estimated concentration at the point of entry into the environment will be below one part per billion and for substances that occur naturally in the environment.[139] Thus, pharmaceuticals that have low-dose, chronic effects would likely be subject to a categorical exclusion.[140] There is an override mechanism to these broad categorical exclusions: when extraordinary circumstances exist.[141] The basis for this override mechanism, however, is predicated upon available data and requires FDA to demonstrate that "at the expected level of exposure, there is the potential for serious harm to the environment."[142] If there are no available data—and accordingly, no evidence of potentially serious harm—the override mechanism would not be triggered, a categorical exclusion would apply, and an EA would not be required.[143]

FDA also must require an EA for any action that adversely affects a species or the critical habitat protected by the Endangered Species Act, the Convention on International Trade in Endangered Species of Wild Fauna and Flora, or any other federal law.[144] Even if an EA and subsequent EIS were required under 21 C.F.R. § 25.21(a) or (b), the requisite studies generally consist of ecotoxicity tests, which fail to consider low-dose, long-term exposure.[145] Moreover, these studies focus on mortality as the endpoint, leaving scientists uncertain about lesser effects, such as reproduction and fertility.[146]

Finally, even if pharmaceutical manufacturers were required to file an EA or EIS for every new drug, two weaknesses lie within NEPA itself. First, NEPA does not indicate the weight that should be given to such environmental concerns. "Rather, it require[s] only that the agency take a 'hard look' at the environmental consequences before taking a major action."[147] Second, although NEPA does not specifically provide for remedies, courts have found that the appropriate remedy is an injunction to prohibit the agency from proceeding with the project in question.[148] In this context, the project in question would be the market authorization of a new pharmaceutical. One must question whether a greater harm is caused by blocking the marketing of a new drug in such a scenario—a difficult judgment to make.

2. The Clean Water Act

The Clean Water Act ("CWA") could provide some regulation of pharmaceuticals as toxic pollutants;[149] however, it too has many shortcomings. First, the National Pollutant Discharge Elimination System ("NPDES") permit program applies only to "point sources" that discharge into the nation's waters.[150] In the present case, the NPDES program could regulate direct discharges from pharmaceutical manufacturers and publicly owned treatment works;[151] however, the CWA would not be able to regulate the up-the-pipe cause of the discharge of pharmaceuticals into the environment: household discharges.[152] As the amount of prescription medicines used increases, the solution must also address the underlying problem of entry into the environment rather than focusing solely on regulating the back end of the problem.[153]

Second, "there is little regulation of emerging contaminants, in large part because many of them have not yet been identified."[154] Thus, prior to applying either technology-based or water-quality standards, EPA would have to determine cri-

135. 21 C.F.R. § 25.15(a) (2011); *see* Christopher T. Nidel, *Regulating the Fate of Pharmaceutical Drugs: A New Prescription for the Environment*, 58 Food & Drug L.J. 81, 93 (2003).
136. *Id.* § 25.15(b).
137. *Id.*
138. *Id.*
139. *Id.* § 25.31(b)–(c).
140. Nidel, *supra* note 135, at 93–94.
141. § 25.21(a).
142. *Id.*
143. *Id.* § 25.15(c)–(d).
144. *Id.* § 25.21(b) (citing Endangered Species Act, 16 U.S.C. §§ 1531–44 (2006 & Supp. II 2008); Convention on International Trade in Endangered Species of Wild Fauna and Flora, *opened for signature* Mar. 3, 1973, 27 U.S.T. 1087 (entered into force July 1, 1975)).
145. Boxall, *supra* note 73, at 1112.
146. *Id.*
147. Balt. Gas & Electric Co. v. Natural Res. Def. Council, 462 U.S. 87, 97 (1983).
148. Sierra Club v. Morton, 405 U.S. 727, 730 (1972).
149. Jacki Lopez, *Endocrine-Disrupting Chemical Pollution: Why the EPA Should Regulate These Chemicals Under the Clean Water Act*, 10 Sustainable Dev. L. & Pol'y 19, 19 (2010).
150. 33 U.S.C. § 1342 (2006 & Supp. II 2008); *see also id.* § 1311.
151. *Id.* § 1342.
152. *Id.*
153. *See generally* William Wombacher, *There's Cologne in the Water: The Inadequacy of U.S. Environmental Statutes to Address Emerging Environmental Contaminants*, 21 Colo. J. Int'l Envtl. L. & Pol'y 521, 552 (2010) (calling for substantial research before new chemicals are released into the marketplace).
154. Johnston & Sendek-Smith, *supra* note 31, at 38.

teria to prioritize which pharmaceuticals should even be considered for being listed as toxic. While this process is certainly worth pursuing, it does not represent a near-term solution. EPA currently regulates only approximately sixty-five toxic pollutants and has been criticized for "its less than robust control of toxic pollutants."[155] Add to this the complexity of bioaccumulation and the cocktail effect and it is unlikely that adding hundreds of pharmaceutical compounds to the list would result in the desired amount of control.[156]

Third, there is a question of whether low-dose pharmaceuticals would even cause the water to fail to meet water-quality standards; such listings are usually reserved "for only the most dangerous chemicals such as DDT, TCE, and Benzene."[157] Because this is an emerging problem, there are issues of scientific uncertainty and causation, which further frustrate regulation under the CWA.[158]

Finally, even if EPA decided to regulate pharmaceutical discharges—an option further discussed below—wastewater-treatment technologies remove some pharmaceuticals better than others, cannot be relied on to remove all the pharmaceuticals, and are expensive.[159] Accordingly, at best, the CWA only represents a partial solution to the problem posed by pharmaceuticals in the water.

3. The Endangered Species Act

The Endangered Species Act ("ESA")[160] also could play a role in regulating pharmaceuticals in the environment. The ESA prohibits any action that causes a "taking" of any listed species of endangered fish or wildlife.[161] The ESA also requires each federal agency to consult with the National Marine Fisheries Service or the U.S. Fish and Wildlife Service to "insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species."[162]

The ESA, therefore, would be triggered when the occurrence of pharmaceuticals in the water has the potential to harm a listed species. For example, a USGS survey detected elevated levels of pharmaceuticals and endocrine-disruptors in Lake Mead, which have the potential to affect the reproductive capabilities of the razorback sucker, an endangered species.[163] Discussing "how little proof of impact is required before the ESA's 'insure' no harm standard triggers regulatory controls," one commentator posits that in the context of pharmaceuticals in the environment, "it is not a very long leap before the ESA can be brought to bear on protected species such as the razorback sucker and other listed species of fish, including virtually all the salmon and steelhead species in the Pacific northwest."[164]

The ESA also requires that federal agencies carry out programs for the conservation of endangered species.[165] This could include scientific research. Thus, the ESA could provide the authority and funding for additional research into the impact pharmaceuticals have on wildlife. However, "the affirmative conservation mandates of section 7(a)(1) have historically exerted little influence over the actions of federal agencies."[166]

The primary problem of regulating pharmaceuticals under the ESA, however, is that the statute is only triggered when an endangered species is at risk, thus limiting the ESA's application to nonlisted species.[167] Additionally, in determining whether section 7(a)(2) is triggered, an agency is required to "use the best scientific and commercial data available."[168] Again, scientific uncertainty and lack of information frustrate the use of current regulations to effectively control the occurrence of pharmaceuticals in the environment.

4. The Resource Conservation and Recovery Act

The Resource Conservation and Recovery Act ("RCRA") also casts a limited regulatory shadow over the issue of pharmaceuticals in the water. RCRA would apply to some pharmaceuticals disposed of by pharmaceutical-manufacturers and the healthcare industry. Under RCRA, a waste is regulated as a hazardous waste if EPA specifically lists it (P- or U-listed wastes)[169] or if the waste exhibits one or more of the following characteristics: ignitability, corrosivity, reactivity, or toxicity.[170] If the pharmaceutical or its sole active ingredient is a P- or U-listed waste, the facility must manage that pharmaceutical as a hazardous waste in accordance with all applicable federal, state, and local environmental regulations.[171] Currently, there are thirty-one listed chemicals with pharmaceutical or medicinal uses.[172]

In December 2008, EPA proposed adding hazardous pharmaceutical wastes to the Universal Waste Rule.[173] According to EPA, "The proposed addition is intended to make it easier for generators to collect and properly dispose of these items as hazardous wastes, resulting in a simpler and more streamlined waste management system."[174] The Universal Waste Rule would allow longer accumulation times and thresholds than the current hazardous-waste regulations allow, does not require waste to be manifested when transported, and

155. Mark A. Latham, *(Un)Restoring the Chemical, Physical, and Biological Integrity Of Our Nation's Waters: The Emerging Clean Water Act Jurisprudence of the Roberts Court*, 28 Va. Envtl. L.J. 411, 421–22 (2010).
156. *Id.* at 422.
157. Wombacher, *supra* note 153, at 543.
158. *Id.* at 529.
159. Johnston & Sendek-Smith, *supra* note 31, at 38.
160. Endangered Species Act, 16 U.S.C. §§ 1531–1544 (2006 & Supp. II 2008).
161. *Id.* § 1538(a)(1)(A).
162. *Id.* § 1536(a)(2).
163. Michael Rosen, *Endocrine Disruption in Lake Mead*, U.S. Geological Surv., http://nevada.usgs.gov/water/projects/mead_endocrine.htm (last updated Mar. 15, 2010).
164. Mannina, *supra* note 19, at 2.
165. § 1536(a)(1).
166. Daniel Rohlf, *Jeopardy Under the Endangered Species Act: Playing a Game Protected Species Can't Win*, 41 Washburn L.J. 114, 117 (2001).
167. *See* § 1531(b).
168. *Id.* § 1536(a)(2).
169. *See* 40 C.F.R. § 261.33 (2011).
170. *See id.* §§ 261.20–.24.
171. *See* Office of Water, EPA, *supra* note 40, at 2.
172. *Proposed Universal Waste Rule for Pharmaceuticals*, EPA, http://www.epa.gov/epawaste/hazard/wastetypes/universal/pharm-rule.htm (last updated Feb. 12, 2012).
173. Office of Water, EPA, *supra* note 40, at 19.
174. *Id.*

eliminates training requirements.[175] EPA also expects that, in order to avoid having to sort pharmaceutical wastes, facilities will apply the proposed rule to all pharmaceutical wastes, including those not currently regulated under RCRA.[176] The import of this hope is that, as opposed to disposing of pharmaceuticals in traditional wastewater systems, facilities would send all pharmaceutical wastes to a licensed incinerator.[177] Finally, EPA asserts that the new rule would facilitate pharmaceutical take-back programs by removing the regulatory complexity of current RCRA regulations.[178]

However, like the other regulations, RCRA has the ability to regulate only a small part of the problem. First, as noted above, only thirty-one chemicals with pharmaceutical or medicinal uses are P- or U-listed wastes.[179] Second, RCRA's definition of solid waste specifically excludes domestic wastewater and discharges permitted under section 402 of the CWA.[180] RCRA, therefore, leaves a major pathway—household discharges—unregulated. Finally, although the proposed addition of pharmaceuticals to the Universal Waste Rule has the potential to limit the introduction of pharmaceuticals from hospitals, it would only effectively do so if hospitals voluntarily chose to treat *all* pharmaceutical wastes under the rule.

5. The Safe Drinking Water Act

Under SDWA, EPA identifies contaminants with potential adverse effects on public health and then determines maximum contaminant levels or treatment techniques.[181] According to some experts, "The national standard setting process established by Congress through the SDWA and administered by [EPA] and state primacy agencies is the appropriate forum to develop monitoring and treatment requirements for [pharmaceutical and personal-care products]."[182] Although SDWA has the potential to provide some regulation of pharmaceuticals in drinking water, the effectiveness of this limited application of SDWA is questionable.

EPA currently regulates 90 chemicals in drinking water and has proposed an additional 104 chemicals in CCL3.[183] As mentioned above, of the 104 chemicals listed, only 14 are pharmaceuticals or medicinal compounds.[184] In fact, "[d]rinking water standards do not exist for 81 of the 95 chemicals detected in the USGS study of 139 waterways in 30 states."[185] Additionally, before a chemical can be regulated under SDWA, EPA must have extensive background data on the effects of the chemical.[186] Regulators, however, lack much of the requisite data on pharmaceutical compounds found in the environment.[187] Even if EPA had adequate information on every pharmaceutical present in the water, it is unlikely that EPA or states would be equipped to handle the additional burden of regulating and enforcing standards for potentially thousands of chemicals. It is also unlikely that water systems, especially small systems, would be able to comply with increasingly complex and costly standards.[188] Indeed, compliance data indicate that under current standards, EPA and state authorities handle tens of thousands of SDWA violations a year.[189]

III. Application of the Precautionary Principle—In Just the Right Amount

An important initial consideration is whether action to protect the country's waters from pharmaceuticals is necessary in the first place. One study determined that a person could drink over 50,000 glasses of water per day without any negative effects from the trace amounts of pharmaceuticals in the study.[190] The American Water Works Association noted that, as of 2009, research has not demonstrated a link between low levels of pharmaceuticals in the water and actual harm to humans.[191]

Such arguments, however, are flawed because they fail to account for (1) long-term ingestion versus therapeutic dose, (2) more susceptible populations such as children and fetuses, and (3) the unknown risks posed by mixtures of pharmaceuticals.[192] While it is true that there is no evidence of actual human harm from pharmaceuticals in the water,[193] it is appropriate to take a precautionary approach. Testifying before Congress, Dr. Jennifer Sass explained, "Although the levels reported to contaminate our waterways are much lower than therapeutic doses, it would be naïve to think of this as

175. *See* Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. 73,520, 73,522, 73,528–29, 73,536 (proposed Dec. 2, 2008) (to be codifed at 40 C.F.R. pts. 260–61, 264–265, 268, 270, 273).
176. *Id.* at 73,528.
177. Gregg Blesch, *Putting Hospitals on Notice: Regulators Taking More Interest in Healthcare Drug-Dumping*, Modern Healthcare, May 24, 2010, at 6, 6.
178. Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. at 73,520. *But see* Greg Lavine, *Federal Rule Change Could Streamline Pharmaceutical Waste Management*, Am. Soc'y Health-System Pharmacists (Feb. 15, 2009), http://www.ashp.org/menu/News/PharmacyNews/NewsArticle.aspx?id=3013 (noting that under the proposed rule a facility would not be required to manifest its pharmaceutical waste, which raises concerns regarding drug diversion, and led to comments suggesting some sort of drug-tracking requirements be included in the final rule).
179. *Proposed Universal Waste Rule for Pharmaceuticals*, *supra* note 172.
180. 42 U.S.C. § 6903(27) (2006) (excluding domestic waste and discharges under CWA section 402 from RCRA's definition of solid waste).
181. *Id.* § 300f(1).
182. Paul G. Foran, Vice President, Regulatory Programs, Am. Water, Presentation at National Association of Regulatory Utility Commissioners Summer Committee Meetings: Pharmaceuticals in Drinking Water 18 (July 20–23, 2008), http://www.narucmeetings.org/Presentations/Pharmaceuticals%20Summer%20NARUC.ppt.
183. *Contaminant Candidate List 3—CCL*, *supra* note 112; *see Drinking Water Contaminants*, EPA, http://water.epa.gov/drink/contaminants/index.cfm (last updated Jan. 30, 2012).
184. *Contaminant Candidate List 3—CCL*, *supra* note 112.
185. Mannina, *supra* note 19, at 3.
186. Silent Spring Inst., Emerging Contaminants in Cape Cod Drinking Water: Frequently Asked Questions 1 (n.d.), *available at* http://www.commwater.com/Silent%20Springs/faq2silent.pdf.
187. *Id.*
188. Tiemann, Cong. Research Serv., *supra* note 16, at 1.
189. *Id.*
190. *Pharmaceuticals in the Nation's Water: Assessing Potential Risks and Actions to Address the Issue: Hearing Before the Subcomm. on Transp. Safety, Infrastructure Sec., and Water Quality of the S. Comm. on Env't and Pub. Works*, 110th Cong. (2008) [hereinafter *Potential Risks Hearing*] (statement of Dr. Shane Snyder, Research and Development Project Manager, Southern Nevada Water Authority, at 2), *available at* http://epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=f6376de2-be60-4bcf-89b3-80a51ae1750e.
191. Am. Water Works Ass'n, *Pharmaceuticals and Personal Care Products (PPCPs) in Drinking Water*, DrinkTap.org, http://www.drinktap.org/consumerdnn/Home/WaterInformation/WaterQuality/PharmaceuticalsPPCPs/tabid/73/Default.aspx (last visited Feb. 19, 2012).
192. Kümmerer, *supra* note 14, at 64.
193. Am. Water Works Ass'n, *supra* note 191.

'safe', knowing that the agents are chemically reactive in our bodies, and that we are exposed daily over a life-time to multiple compounds in unknown combinations."[194]

The precautionary principle instructs that harm to humans and the environment should be avoided through regulations designed to anticipate and prevent potential harm.[195] In such situations, the precautionary principle can serve to address the potential hazards even in the absence of clear evidence of such hazards.[196] The emerging threat of pharmaceuticals in the environment creates such a novel, scientifically uncertain problem.

In Europe, the precautionary principle plays a key role in environmental regulations.[197] As the United States looks to develop solutions to this problem, the precautionary principle should play a role in informing decisions regarding regulations and programs.[198] However, because pharmaceuticals directly benefit society—as does their corollary, pharmaceutical research and development—any solution should avoid reliance on regulations that hamper or discourage pharmaceutical research and development and the use of medicines. Thus, as will be discussed in the next section, in requiring environmental-risk assessments for new pharmaceuticals, European regulators are careful to ensure that precautionary measures will "neither hamper innovations in drug development nor impair the quality of medical care."[199]

IV. Looking Across the Ocean: Examples of Europe's Response to Pharmaceuticals in Water

A. *European Environmental-Risk Assessment*

Europe requires pharmaceutical manufacturers to conduct and submit an environmental-risk assessment ("ERA") prior to new-drug market authorization.[200] The ERA process is divided into two phases. In phase I, researchers screen for persistence, bioaccumulation, and toxicity, and estimate the exposure of the pharmaceutical to the environment.[201] The analysis during phase I results in a predicted environmental concentration ("PEC") score.[202] Based on the PEC value during phase I, a phase II environmental analysis may be required.[203]

Phase II of the ERA analysis collects information about the fate and effect of the pharmaceutical on the environment, and is divided in two parts: tier A and tier B.[204] Tier A consists of "a standard long-term toxicity test set on fish, daphnia and algae" to determine the predicted-no-effect concentration ("PNEC").[205] The purpose of this analysis is to predict the concentration of the substance for which adverse effects are not expected to occur.[206] If the PEC/PNEC ratio indicates a potential environmental impact, additional testing is conducted under tier B.[207] Table 1 explains the ERA process:

Table 1. The Phased Approach in the Environmental-Risk Assessment[a]

Stage in Regulatory Evaluation	Stage in Risk Assessment	Objective	Method	Test/Data Requirement
Phase I	Prescreening	Estimation of exposure	Action limit	Consumption data, logKow.
Phase II, tier A	Screening	Initial prediction of risk	Risk assessment	Base-set aquatic toxicology and fate
Phase II, tier B	Extended	Substance and compartment-specific refinement and risk assessment	Risk assessment	Extended data set on emission, fate, and effects

a. Comm. for Med. Prods. for Human Use, European Meds. Agency, Doc. Ref. EMEA/CHMP/SWP/4447/00 corr 1, Guideline on the Environmental Risk Assessment of Medical Products for Human Use §3 tbl.1 (2006), *available at* http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500003978.pdf.

194. *Potential Risks Hearing*, *supra* note 190, (statement of Dr. Jennifer Sass, Senior Scientist, Natural Resources Defense Council, at 2), *available at* http://epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=a5ef042e-26fc-41f1-9af1-a2aa1d16f88b.
195. John S. Applegate, *The Taming of the Precautionary Principle*, 27 Wm. & Mary Envtl. L. & Pol'y Rev. 13, 13 (2002) ("[The precautionary principle] reflects the implicit judgment that, in the absence of some degree of *ex ante* regulatory review, new technologies will create novel, severe, and irreversible—but avoidable—harms to human health and the environment.").
196. START, Pharmaceuticals for Human Use: Options of Action for Reducing the Contamination of Water Bodies 15 (Florian Keil ed., 2008) *available at* http://www.start-project.de/downloads/start_Practical_Guide.pdf.
197. *Id.*
198. Diamanti-Kandarakis et al., *supra* note 77, at 293.
199. START, *supra* note 196, at 15.
200. Comm. for Med. Prods. for Human Use, European Meds. Agency, Doc. Ref. EMEA/CHMP/SWP/4447/00 corr 1, Guideline on the Environmental Risk Assessment of Medical Products for Human Use § 2 (2006), *available at* http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500003978.pdf. Subsequent directives have extended the ERA requirement to generics as well. *See* Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, pmbl., ¶¶ 9, 14–15, art. 1(8), 2004 O.J. (L 136) 34, 35, 39; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, 2001 O.J. (L 311) 67.
201. Comm. for Med. Prods. for Human Use, European Meds. Agency, *supra* note 200, § 4.
202. *Id.* § 4.2.
203. *Id.* § 4.3.
204. *Id.* § 5. This document notes, however, that regardless of the quantity released into the environment, "[c]ertain substances, such as highly lipophilic compounds and potential endocrine disruptors, may need to be addressed." *Id.* § 3.
205. *Id.* § 5.1.2.
206. *Id.*
207. *Id.* § 5.2.

The European Medicines Agency evaluates the ERA and determines whether to limit the potential environmental impact of the pharmaceutical.[208] When the Agency determines a pharmaceutical has potential environmental risk, it may require only precautionary measures to mitigate the risk.[209] These measures are largely limited to providing informational materials to physicians and patients.[210] Further, such risk "should not constitute a criterion for refusal of a marketing authorization" of a pharmaceutical.[211]

It should also be noted that the amendments in Directive 2004/27/EC required that member states "ensure that appropriate collection systems are in place for medicinal products that are unused or have expired."[212] This collection system was required to be in place by October 2005.[213] Germany, for example, has had a pharmaceutical-return system in the majority of its pharmacies since 1995.[214]

B. The Swedish Model

In 2003, the Stockholm County Council initiated an environmental-hazard-assessment program.[215] The Council recognized there was insufficient data on the low-dose, long-term, continuous effects of pharmaceuticals on human health and welfare.[216] Applying a precautionary rationale, the Stockholm County Council explained, "[E]ven if we do not have scientific proof that chemicals in nature can cause health problems we should reduce our unintentional exposure to them as much as possible."[217] The Swedish Association of Pharmaceutical Industry was coincidentally developing an environmental risk assessment and, in 2005, its environmental risk assessment was added to the Stockholm classification system.[218]

As a result, by 2010 almost all the pharmaceuticals marketed in Sweden had undergone environmental risk assessment and had been classified.[219] Thus, the new combined Swedish system of environmental assessment is based on two criteria: environmental risk and environmental hazard.[220]

Environmental risk examines the acute risks to the acquatic environment and, like the European ERA, produces a ratio between the predicted environmental concentration of the pharmaceutical (PEC) and the highest concentration of the substance that does not have a harmful effect in the environment (PNEC).[221] Environmental hazard grades a pharmaceutical on three criteria: persistence, bioaccumulation, and toxicity ("PBT").[222] Each value is given a score of zero to three, and the final combined PBT score (zero to nine) is refered to as the PBT index.[223] In another example of the precautionary principle, if there are insufficient data to determine any of the PBT factors, the researcher is expected to assume that the substance is not readily biodegradable and is potentially bioaccumulating and highly toxic.[224]

The classification sytem is then used to create an online searchable database of pharmaceuticals, which provides the environmental risk and hazard of each drug.[225] Thus, a patient or healthcare provider can compare the environmental impacts of drugs that may be equally suitable for treatment purposes and make an environmentally informed decision. The website also provides educational tools on limiting the introduction of pharamceuticals into the environment.[226] For example, the website recommends that providers (1) prescribe starter packs of medication and then prescribe refill packs as necessary; (2) inform patients to return used estrogen patches because most of the estrogen remains in the patch after use; and (3) encourage patients to return unused medicine.[227]

The Swedish classification system, however, is not without its critics, and any system implemented in the United States should consider these shortcomings. One study of the system noted that the guidance document provided no clear definition of a "long-term" versus "short-term" study,[228] thus potentially failing to address the concerns of long-term, chronic exposure. Additionally, when the system was supplemented with additional, current scientific information, the environmental-impact results varied.[229] Thus, critics argue the system's scoring does not provide a completely accurate picture of the pharmaceutical's true environmental impact.[230] All in all, however, the Swedish classification provides a good model for a U.S. classification system and is novel in that it includes environmental impacts of pharmaceuticals as well as other drug information in a searchable database.

208. *Id.* § 2 (citing Directive 2001/83/EC, *supra* note 200, art. 8(3)).
209. *Id.* § 6.
210. *Id.*
211. *Id.* § 2.
212. Directive 2004/27/EC, *supra* note 200, art. 1(87).
213. START, *supra* note 196, at 13.
214. *Id.*
215. Siv Martini, Stockholm Cnty. Council, *About the Environment and Pharmaceuticals*, Janusinfo, http://www.janusinfo.se/v/About-the-environment-and-pharmaceuticals/?id=9930 (last updated July 23, 2008).
216. Stockholm Cnty. Council, *Impact of Pharmaceuticals on the Environment*, Janusinfo, http://www.janusinfo.se/v/About-the-environment-and-pharmaceuticals/Impact-of-pharmaceuticals-on-the-environment//?id=9931 (last updated July 3, 2009).
217. *Id.*
218. Martini, Stockholm Cnty. Council, *supra* note 215.
219. *Id.*
220. Bo Gunnarsson & Ake Wennmalm, *Environmental Risk Assessment and Environmental Classification of Drugs*, *in* Environment and Pharmaceuticals 117, 123–25 (Bengt-Erik Bengtsson et al. eds., 2005), *available at* http://www.janusinfo.se/Global/Miljo_och_lakemedel/lakemed_miljo_eng2007.pdf.
221. Stockholm Cnty. Council, *About Classification*, Janusinfo, http://www.janusinfo.se/v/About-the-environment-and-pharmaceuticals/About-classification//?id=9933 (last updated Mar. 7, 2011).
222. *Id.*
223. *Id.*
224. *Id.*
225. Stockholm Cnty. Council, *Environmentally Classified Pharmaceuticals*, Janusinfo, http://www.janusinfo.se/v/About-the-environment-and-pharmaceuticals/Environmentially-classified-pharmaceuticals//?id=9932 (last visited Feb. 19, 2012).
226. Stockholm Cnty. Council, *What You Can Do*, Janusinfo, http://www.janusinfo.se/v/About-the-environment-and-pharmaceuticals/What-You-Can-Do//?id=9934 (last visited Apr. 2, 2007).
227. *Id.*
228. Marlene Ågerstrand & Christina Rudén, *Evaluation of the Accuracy and Consistency of the Swedish Environmental Classification and Information System for Pharmaceuticals*, 408 Sci. Total Env't 2327, 2327 (2010).
229. *Id.*
230. *Id.*

V. A Green-Governance Approach to Limiting Pharmaceuticals in the Environment

The emerging threat of pharmaceuticals in the environment raises many novel issues not posed by conventional pollutants.[231] Thus, it should be no surprise that conventional regulations do not provide an overall solution to the problem.[232] As discussed in part II.B, a "traditional regulatory approach cannot, by itself, achieve the kind of environmental outcomes needed to solve many of the nation's most critical environmental problems."[233] In large part, this is because many emerging environmental problems occur outside of the current regulatory regimes.[234]

Similarly, the solution to the problem of pharmaceuticals in the water lies beyond the current regulatory regime.[235] The current statutory framework has difficulties regulating low-dose, long-term exposures, with scientifically uncertain effects.[236] Moreover, current regulations are not able to regulate the multiple pathways through which pharmaceuticals enter the water, nor are they able to sufficiently look "up the pipe" to prevent pharmaceuticals from entering the system in the first place.[237] That is not to say that current regulations should play no role in the solution; for example, as discussed in Part II.B, current regulations can provide the authority and funding for additional research.[238] However, rather than relying solely on government interventions and regulation, the solution "should encourage businesses, nonprofit organizations, government agencies, and individual citizens to reach higher levels of responsibility, accountability, commitment, and stewardship."[239]

In order to address the variety of problems posed by pharmaceuticals and the variety of pathways through which they reach the environment, the solution should be holistic in nature, including a mix of regulatory and nonregulatory programs that employ financial incentives and value-based drivers.[240] The solution should consist of the following elements: (1) education of the public and providers, (2) drug take-back programs, (3) a green-pharmacy initiative, (4) additional research and monitoring and an associated pharmaceutical database, and (5) a focus of treatment technologies. Finally, although the public bears some responsibility for introducing pharmaceuticals into the environment,[241] and therefore should bear some financial responsibility for addressing this phenomenon, pharmaceutical manufacturers should also fund part of the solution under the concept of shared responsibility.

A. Public Education and Information

The first and most critical step to addressing the problem of pharmaceuticals in the environment is establishing an education and awareness program. An educated public is necessary for citizen engagement; it forms the backbone for any future public, market-based programs and can give politicians the political climate necessary to push for new regulations. Furthermore, the public is primed for such an education. "The public desires to be more fully engaged in decisions about environmental issues in their community and more generally."[242] Additionally, at some point, it is likely that members of the public are going be asked to pay for this problem,[243] and they should understand the problem to justify any increase in taxes, or in costs for services or products. Until the public acknowledges and, to some extent, understands the potential risk of pharmaceuticals in the water, change is unlikely to occur.[244]

EPA's website provides a good overview of the problem and the potential risks posed by pharmaceuticals in the water;[245] however, in order to access that information one must first choose to visit the website. Therefore, an information and education campaign would facilitate education of the public. This can be accomplished via print media, online sources, or public-service announcements.

For example, No Dirty Gold was a consumer-based campaign launched in 2004 by Earthworks/Mineral Policy Center and Oxfam, intended to educate the public and change mining and business practices in the gold industry.[246] During Valentine's Day, No Dirty Gold campaign workers stood outside major retail stores and passed out Valentine's cards with the message, "Don't tarnish your love with dirty gold."[247] Coincident to this campaign, "Earthworks and Oxfam released the report 'Dirty Metals: Mining, Communities and the Environment' . . . which detail[ed] the massive pollution, huge open pits, devastating community health effects, worker dangers and, in many cases, human rights abuses that have become hallmarks of gold and metals mining in several countries."[248] As a result, more than seventy-five retailers and merchants, from JC Penney to Alberto Parada to Tiffany & Co., supported the "golden rules" and were listed on the No

231. *See supra* text accompanying notes 2–22.
232. *See supra* Part II.
233. Paddock, *supra* note 23, at 10,611.
234. *See supra* Part II.
235. *See supra* Part II.B.2.
236. *See supra* Part II.B.
237. *See supra* Part II.B.2.
238. *See supra* Part II.
239. Paddock, *supra* note 23, at 10,613.
240. *Id.*
241. Most people use pharmaceuticals at some point and intentionally (flushing unused medicines) or unintentionally (nonmetabolized pharmaceuticals in human excrement) introduce them into the environment.
242. Paddock, *supra* note 23, at 10,610.
243. *Id.*
244. *See, e.g.*, Wayne Pacelle, *Law and Public Policy: Future Directions for the Animal Protection Movement*, 11 Animal L. 1, 3 (2005) (arguing that until the public decides animal-rights laws and regulations need to change, the old perspective will remain).
245. *See Pharmaceuticals and Personal Care Products (PPCPs): Basic Information*, *supra* note 24.
246. *See Africa: "The More You Know, the Less Gold Glows,"* WRM Bull. (World Rainforest Movement, Montevideo, Uru.), Mar. 2004, *available at* http://www.wrm.org.uy/bulletin/80/Africa.html; Earthworks, *About Us*, No Dirty Gold (2004), http://www.nodirtygold.org/about_us.cfm.
247. *Africa: "The More You Know, the Less Gold Glows," supra* note 246.
248. *Id.*

Dirty Gold website as taking the pledge to use more environmentally friendly practices.[249]

When the public supports a cause, even absent government involvement, change can occur. For example, in 2007, a report linked bisphenol A ("BPA") to developmental changes, cancer, urogenital abnormalities in male babies, decrease in sperm production, early-onset puberty in girls, type 2 diabetes, obesity, and neurobehavioral problems.[250] Various news sources and blogs picked up this story,[251] and, even though FDA initially maintained that BPA was within safe levels,[252] manufacturers such as Nalgene and Playtex, and retailers such as Toys-R-Us and Wal-Mart, removed BPA from their products and stores.[253] By 2009, more than twenty states and Canada had taken steps to limit exposure to BPA.[254]

Additionally, the public has a right to know about potential threats to its health; that is, Americans should have the information necessary to make informed decisions. The Association of Metropolitan Water Agencies recommended, "*Water utilities should take steps to keep their consumers informed of their efforts to monitor and remove pharmaceuticals from water sources. Just as water utilities need data to make informed decisions, we believe that consumers should have the information they need to make personal health decisions.*"[255]

The public also must be educated about proper disposal techniques: when to flush a drug down the toilet versus when to throw it in the trash. Although both methods ultimately result in introducing pharmaceuticals into the environment,[256] flushing is a more direct route to the aquatic ecosystem and, therefore, is more harmful to the environment.[257] Senate Special Committee on Aging Chairman Herb Kohl stated:

> Odds are that many of us have half empty bottles of medicine lying around our houses. Some of us may have thought we were doing the right thing by flushing them down the toilet, or throwing them away with our trash. But these disposal methods can have a damaging effect on our environment.[258]

To address this issue, the U.S. Fish and Wildlife Service, the American Pharmacists Association, and the Pharmaceutical Research and Manufacturers of America ("PhRMA") have recently partnered to educate the public on proper disposal methods for pharmaceuticals.[259]

As researchers begin to better understand which drugs pose the most significant threats to the environment, such information should be passed on to patients. Proper disposal techniques for unused pharmaceuticals are not always intuitive. Medicinal patches provide one example. "[N]ew dermal patches containing methylphenidate can contribute the equivalent amount of [pharmaceuticals] as from excretion resulting from 3,280 oral doses; patches containing ethynylestradiol can contribute the equivalent of 214 doses."[260] Based on this information, it seems clear that medicinal patches should be not be flushed down the toilet, but this assumption is not exactly true. Consider that a fentanyl patch retains enough of a dose after three days to kill a child,[261] so it is likely more dangerous to throw it away in the trash instead of flushing it down the toilet. A better solution, discussed in the next section, is establishing and educating the public on pharmaceutical take-back programs. Until such programs are established and used, however, education about proper disposal techniques remains important.

Additionally, if healthcare professionals know which medicines should be flushed, as opposed to thrown away in the trash, they can provide education to individual patients on proper disposal methods at the time the drug is prescribed.[262] Thus, it is vital that education programs also focus on healthcare professionals. "[T]he environmental effects of medicinal drugs should be included in the medical education and advanced training by instructors

249. Earthworks, *Retailers Who Support the Golden Rules*, No Dirty Gold, http://www.nodirtygold.org/supporting_retailers.cfm (last updated May 2009).

250. Frederick S. vom Saal et al., *Chapel Hill Bisphenol A Expert Panel Consensus Statement: Integration of Mechanisms, Effects in Animals and Potential to Impact Human Health at Current Levels of Exposure*, 24 Reprod. Toxicology 131 (2007), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2967230/pdf/nihms206975.pdf.

251. *E.g.*, Lyndsey Layton, *FDA Will Continue to Study BPA; Has No Plans to Amend Position that Plastics Chemical Is Safe*, Wash. Post (Dec. 16, 2008), http://www.washingtonpost.com/wp-dyn/content/article/2008/12/15/AR2008121502920.html (stating that FDA will continue to study BPA after learning of associated health risks); Robert Bazell, *Plastic Bottles—Are They Safe?*, MSNBC.com (Apr. 17, 2008), http://dailynightly.msnbc.msn.com/_news/2008/04/17/4373665-plastic-bottles-are-they-safe ("For the past few days we have been covering an issue that is generating a lot of concern. Certain types of plastic containers can leech a chemical called bisphenol A (BPA). The chemical can mimic the female hormone estrogen. Given to animals at high doses it can cause all sorts of health problems ranging from infertility and obesity to several types of cancer."); *The BPA Debate Continues—Is BPA Safe or Not?*, Greener, Healthier Living (Feb. 11, 2008), http://amomsblog.wordpress.com/2008/02/11/the-bpa-debate-continues-is-bpa-safe-or-not/ (citing sources describing health risks of BPA); Heather Corley, *FDA Says BPA Is Safe*, About.com (May 3, 2008), http://babyproducts.about.com/b/2008/05/03/fda-says-bpa-is-safe.htm (citing FDA statement that products containing BPA are safe for children).

252. *See Bisphenol A (BPA) Information for Parents*, U.S. Dep't Health & Hum. Servs., http://www.hhs.gov/safety/bpa/ (last visited Feb. 21, 2012) ("In 2008, the Food and Drug Administration conducted a review of toxicology research and information on BPA, and, at that time, judged food-related materials containing BPA on the market to be safe.").

253. *See* Jane Houlihan, Sonya Lunder & Anila Jacob, *Timeline: BPA from Invention to Phase-Out*, Envtl. Working Group, http://www.ewg.org/reports/bpatimeline (last updated Mar. 2011).

254. *See id.*

255. Press Release, Ass'n of Metro. Water Agencies, AMWA Discusses Pharmaceuticals in Water Supplies (Mar. 11, 2008), http://www.amwa.net/cs/news_releases/March11, *quoted in Naidenko Testimony*, *supra* note 104.

256. Daughton, EPA, *supra* note 13.

257. *See generally* 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 (2008), *available at* http://www.deq.virginia.gov/export/sites/default/vpdes/pdf/USGSRecon-PharmsUntreatedDW.pdf ("More frequent detections in surface-water sources than ground-water sources likely reflect the more direct pathways for transport of [organic wastewater contaminants] into surface waters (e.g., direct discharge of wastewater effluent) . . . .").

258. *Drug Waste and Disposal: When Prescriptions Become Poison: Hearing Before the S. Spec. Comm. on Aging*, 111th Cong. 1 (2010) (statement of Sen. Herb Kohl).

259. George Washington Univ. Sch. of Pub. Health & Health Servs., *supra* note 2, at 6.

260. Christian G. Daughton, EPA, NERL-LV-ESD 10/081, EPA/600/R-10/106, Drugs and the Environment: Stewardship & Sustainability 20 (2010) (citation omitted), *available at* http://www.epa.gov/nerlesd1/bios/daughton/APM200-2010.pdf.

261. *Id.*

262. *See* Kümmerer, *supra* note 14, at 66.

of health education and health policy."[263] Healthcare professionals should also be more conscious of the amount of drugs they prescribe; for example, for short-term prescriptions, physicians should provide the minimum amount, and the patient can obtain a refill if necessary.[264] Moreover, if the United States ever implements a classification system like that in Sweden, providers should compare the environmental effects of certain drugs and include that information in their treatment decisions and informed-consent conversations.[265]

An educated public could also create a new market for green pharmaceuticals, encouraging pharmaceutical manufacturers to make the investment in green pharmaceutical research and design.[266] This will be discussed in detail in Part V.C, but it is worth noting in this context that a Yale University study found that most Americans were willing to pay more for environmentally friendly products.[267]

Finally, while it is necessary to educate the public, it is important not to overstate the problem and to make sure that the information coming from the government is uniform.[268] Returning to the BPA example, at one point, in the span of just over six months, the National Toxicology Program issued a report noting concern over BPA's effect on human health; FDA determined that BPA did not pose a threat to humans; the American Medical Association published a study linking BPA to heart disease, diabetes, and liver problems; and a number of states introduced legislation to limit BPA.[269] Such confusion in messages can lead to rushed regulation and other unintended consequences.[270] For example, if the message the public hears is "Don't drink tap water," many people may decide to drink only bottled water. That is not a desirable outcome either, because there is no standardized testing for emerging contaminants in bottled water, the water may be subject to plasticizers, and bottled water is resource-intensive.[271]

B. Pharmaceutical Take-Back Programs

Another important facet of any solution should be pharmaceutical take-back programs. Before the implementation of these programs on a local level, however, the federal government needs to clarify and simplify the regulations concerning return of controlled substances.[272] Current regulations require an individual wishing to dispose of a controlled substance to write a letter to the Drug Enforcement Agency's ("DEA") regional special agent in charge providing the following information: the applicant's name and address; the name and quantity of the substance; how the applicant obtained the controlled substance; and the name, address, and registration number, if known, of the person who possessed the controlled substance prior to the individual.[273] DEA then instructs the individual to either transfer the controlled substance to someone authorized to possess the substance, to deliver the controlled substance to a DEA agent or office, to destroy the controlled substance in the presence of a DEA agent or other authorized person, or in some other manner as the special agent may instruct.[274] These regulations do not provide a simple or convenient way for individuals to legally return controlled substances.

Additionally, facilities and organizations attempting to run take-back programs face confusing RCRA obligations.[275] Although household hazardous wastes are exempt from RCRA,[276] according to EPA most communities manage the waste in compliance with RCRA regulations.[277] EPA's proposed pharmaceutical Universal Waste Rule, however, would "facilitate the implementation of pharmaceutical take-back programs by removing RCRA barriers in the collection of pharmaceutical wastes from health care and other such regulated facilities,"[278] and remove much of the confusion over the household-waste exemption. For this reason, EPA should implement the proposed rule.

Due to such strict and sometimes confusing federal regulations, take-back events have varied widely.[279] In most locales, the task is handled by local governments or pharmacies, an approach that can be time-consuming and expensive.[280] Some are one-time events, while others occur regularly. Some accept controlled substances, but others do not. For example, Medication Cleanout is a Texas-based community project started by the Amarillo Independent School District and

263. *Id.* at 67; *see generally* Paddock, *supra* note 23, at 10,611.
264. Daughton, EPA, *supra* note 260, at 66.
265. *See id.* at 129.
266. *See* Kümmerer, *supra* note 14, at 67.
267. GfK Roper Pub. Affairs & Media & Yale Sch. of Forestry & Envtl. Studies, The GfK Roper Yale Survey on Environmental Issues: Consumer Attitudes Toward Environmentally-Friendly Products and Eco-labeling 4 (2008), *available at* http://environment.research.yale.edu/documents/downloads/a-g/GfK-Roper-Yale-Survey.pdf, (finding that a majority of Americans say that it is important that the products they purchase be environmentally friendly, such as automobiles (66% say it is important or essential to them), clothes detergent (62%), and computer printer paper (51%)); *see also* Press Release, Mintel, Are Americans Willing to Pay More Green to Get More Green? (Mar. 2010), http://www.mintel.com/press-centre/press-releases/514/are-americans-willing-to-pay-more-green-to-get-more-green.
268. *See* Daughton, EPA, *supra* note 260, at 48.
269. Iain A. Lang et al., *Association of Urinary Bisphenol A Concentration with Medical Disorders and Laboratory Abnormalities in Adults*, 300 JAMA 1303, 1303 (2008); Meredith Cohn, *Md. Among States Seeking to Limit BPA*, Balt. Sun, Feb. 23, 2010, http://articles.baltimoresun.com/2010-02-23/health/bal-md.hs.bpa23feb23_1_baby-bottles-bottles-and-sippy-cups-maryland-pirg; *Bisphenol A (BPA) Information for Parents*, *supra* note 252.
270. *See* Daughton, EPA, *supra* note 260, at 51.
271. Schaider et al., Silent Spring Inst., *supra* note 7, at 8; *see also Naidenko Testimony*, *supra* note 104.
272. Teirney Christenson, Comment, *Fish on Morphine: Protecting Wisconsin's Natural Resources Through a Comprehensive Plan for Proper Disposal of Pharmaceuticals*, 2008 Wis. L. Rev. 141, 151–52 (2008).
273. 21 C.F.R. § 1307.21(a) (2011).
274. *Id.* § 1307.21(b). It is possible to apply to DEA for an exception to these regulations. *Id.* § 1307.03.
275. Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. 73,520, 73,522 (proposed Dec. 2, 2008) (to codified at 40 C.F.R. pts. 260–61, 264–65, 268, 270, 273).
276. *See supra* notes 179–180 and accompanying text.
277. Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. at 73,526.
278. *Id.* at 73,520.
279. *See* Emily Main, *Get Rid of Unused Prescription Drugs Without Contaminating Your Drinking Water*, Rodale News (Aug. 12, 2009), http://www.rodale.com/safe-prescription-drug-disposal?page=0,0.
280. *See id.*

the Texas Tech University Health Sciences Center.[281] Medication Cleanout has organized regular take-back events in various locations since September 2009 and generally accepts controlled substances.[282] Conversely, Southwest General Hospital in Olmstead, Ohio runs a regular take-back program at the hospital; however, it does not accept controlled substances.[283]

An example of a government-run take-back program is Maine's Safe Medicine Disposal for ME ("SMDME") program. SMDME, established through state legislation, employs a mail-return system.[284] Maine residents request special envelopes, place their unused pharmaceuticals in the provided envelopes, and then send their unused controlled and uncontrolled pharmaceuticals to the Maine Drug Enforcement Agency, where they are immediately incinerated.[285] SMDME disposes of more than 2,300 pounds of pharmaceuticals and boasts a forty-two percent utilization rate based on envelope distribution and return.[286] Moreover, the SMDME program also includes a telephone hotline to assist consumers with questions or concerns.[287]

Pharmaceutical take-back programs can also play a role in diversion; they can remove such pharmaceuticals from medicine cabinets and thereby take them out of teenage hands. Prescription drugs are currently the second-most abused category of drugs in the United States.[288] Many teens can access controlled substances simply by perusing their parents' medicine cabinets.[289] A recent survey completed by the National Center on Addiction and Substance Abuse at Columbia University found the most common sources for prescription drugs were teens' homes, family members, and friends.[290] Additionally, teens reported that purchasing prescription drugs to get high was easier than purchasing beer.[291]

However, one point of criticism regarding take-back programs has been their effectiveness. PhRMA asserts that such programs fail to educate about prescription-drug abuse, and it claims that the easiest way to dispose of unused medicines is simply to throw them away.[292] Some researchers have echoed this concern:

> Even if nationwide approaches were available for collecting leftover medications . . . a major unaddressed question is what portion of the public would routinely make use of them; limitations or concerns that have been expressed by consumers include inconvenience, insufficient time, privacy concerns, preferences for alternative routes of disposal (such as flushing), and skepticism as to the seriousness of the disposal problem.[293]

This concern is resolved by step one of this Article's proposed solution, education. Education informs the public of the legitimacy and potential risk of the problem and makes people more likely to participate in such take-back programs. Education removes some of the confusion regarding the necessity and details of the take-back program and can address any privacy concerns. Education makes it more likely that people will not take the easy way out and just flush their drugs, having come to understand the consequences of their actions. The take-back programs themselves also can serve to further educate the public. The Maine program, for example, sent out an informational mailer to educate the public about the take-back program and the broader issue of pharmaceuticals in the environment.[294] The same pamphlet that informed the public of the program informed the public of the solution.[295] "It involves citizens in an easy, 'DIY' (do it yourself) problem-solving program that prevents environmental harm, prevents drug diversion, and prevents poisoning. . . . It is for this reason that consumer involvement should be a key component in any drug return program model."[296] Such programs engage and empower the community, making the public part of the solution.[297]

In fact, almost half of the participants surveyed in Maine's mail-in program said that without the take-back program they would have flushed their drugs down the toilet, and a third would have thrown them away in the trash.[298] A mail-in program removes much of the burden of looking for a local event and collecting and transporting the unused medicine, and also removes concerns about privacy. Furthermore, according to EPA's final project conclusion, Maine's program demonstrated that a mail-in take-back program is feasible and effective.[299]

Another point of criticism has been that take-back programs can vary widely and lack consistency. The major source of confusion with the variety of take-back programs, as demonstrated by the Texas and Ohio take-back events, is whether controlled substances are included, a question that is depen-

281. *About Us*, MedicalCleanout.com, http://medicationcleanout.com/aboutus.aspx (last visited Feb. 21, 2012).
282. *See id.*
283. Prod. Stewardship Inst., *Ohio*, Drug Take-Back Network, http://www.takebacknetwork.com/ohio.html (last visited Feb. 21, 2012).
284. Lenard Kaye, Jennifer Crittenden & Stevan Gressitt, *Executive Summary: Reducing Prescription Drug Misuse Through the Use of a Citizen Mail-Back Program in Maine*, EPA (Apr. 2010), http://www.epa.gov/aging/RX-report-Exe-Sum/ ("This program partnership with the Maine Drug Enforcement Agency facilitated review and subsequent approval of the program by the federal Drug Enforcement Agency.").
285. *See id.*
286. . *See id.* Approximately seventeen percent of the drugs were schedules II, III, and IV—"controlled drugs." . *See id.* These included narcotic pain relievers, tranquilizers, sedatives, and stimulants. *See id.*
287. The helpline answered 2,777 telephone calls. *See id.*
288. Office of Nat'l Drug Control Policy, Exec. Office of the President, Teens and Prescription Drugs: An Analysis of Recent Trends on the Emerging Drug Threat 2 (2007), *available at* http://www.theantidrug.com/pdfs/TEENS_AND_PRESCRIPTION_DRUGS.pdf.
289. *Teen Prescription Drug Abuse Prompts Calls for Medicine Cabinet Locks, Drug Disposal*, Addiction Intervention, http://www.addiction-intervention.com/current-events/teen-prescription-drug-abuse-prompts-calls-for-medicine-cabinet-locks-drug-disposal/ (last visited Feb. 21, 2012).
290. Press Release, Nat'l Ctr. on Addiction & Substance Abuse at Columbia Univ., National Survey of American Attitudes on Substance Abuse XIV: Teens and Parents (Aug. 26, 2009), http://www.casacolumbia.org/templates/PressReleases.aspx?articleid=566&zoneid=66.
291. *Id.*
292. *Id.*
293. Daughton, EPA, *supra* note 260, at 24.
294. Kaye, Crittenden & Gressitt, *supra* note 284.
295. *Id.*
296. *Id.*
297. *See generally* Paddock, *supra* note 23, at 10,610 (arguing that solutions to future environmental issues should engage the public and involve the public in the process).
298. Kaye, Crittenden & Gressitt, *supra* note 284.
299. *Id.*

dent on whether DEA or other law-enforcement agencies are involved.[300] Having a national standard, implemented by localities, would remove some of the confusion. This concern was addressed in the Secure and Responsible Drug Disposal Act of 2010 ("SRDDA").[301] Congress recognized that many states and localities have established take-back programs;[302] however, it noted that these programs were limited because federal law did not permit disposal of "the most dangerous pharmaceutical drugs—controlled substances," absent approval from DEA.[303] Congress determined that the public had few disposal options and that take-back programs represented a "convenient and effective means" for individuals to dispose of pharmaceuticals.[304] Accordingly, Congress authorized the Attorney General to promulgate new regulations that would permit "public and private entities to develop a variety of methods of collection and disposal of controlled substances, including some pharmaceuticals, in a secure, convenient, and responsible manner."[305] In accordance with the SRDDA, DEA recently announced public meetings to discuss drafting regulations to implement the SRDDA.[306]

Thus, once the Attorney General removes the regulatory barriers and confusion surrounding pharmaceutical take-back programs, states and local organizations can establish take-back programs that make sense for their communities. While the Maine model may not work in every community, some sort of take-back program should be implemented in localities across the country.

C. Green-Pharmacy Initiatives

Another important aspect of the solution is looking "up the pipe" in an attempt to limit pharmaceuticals' entry into the environment through green chemistry. Already, EPA has been authorized to pursue green technology as part of the Green Chemistry Program,[307] and the President's Council on Sustainable Development recommended that future environmental governance should include "a voluntary system that ensures responsibility throughout a product's life cycle by all of those involved in the life cycle."[308] The Green Chemistry Program encourages reducing or eliminating "the use or generation of hazardous substances during the design, manufacture, and use of chemical products and processes."[309] The principles of green chemistry should be applied in the context of pharmaceutical manufacturing.

Green chemistry, as applied to pharmaceuticals, would include designing and manufacturing drugs in a way that either reduces their toxicity or increases their biodegradability.[310] Because pharmaceutical compounds do not always degrade quickly,[311] engineering the base chemicals to be more biodegradable and shortening their occurrence in the ecosystem limits their impact on the environment.[312] "Taking into account the full life cycle of pharmaceuticals . . . . means that easy degradability after use or application is taken into account even before a pharmaceutical's synthesis ('benign by design')."[313] For example, 5-fluorouracil ("5-FU"), a chemotherapy agent, does not biodegrade easily or quickly; however, uracil, one of the biological components of 5-FU, is easily degradable.[314] Researchers discovered that the fluorine atom in 5-FU hampered degradability and that a structurally similar drug, without the fluorine atom, was biodegradable.[315] Most importantly, in addition to the "green" drug being more biodegradable and environmentally friendly, it had improved treatment application.[316] Until recently, however, biological degradability has not played a role in pharmaceutical design.[317]

Looking at the entire life cycle of a pharmaceutical, the green principle also considers delivery mechanisms and use.[318] Christian Daughton suggests that applying any of the following seven green pharmacy principles would reduce the amount of pharmaceuticals in the environment:

(1) Using ethnobiology to streamlining drug discovery;

(2) Relying less on hazardous reactants, producing less hazardous waste, and using less energy;

(3) Eliminating non-therapeutic chemicals, reducing the overall dose of the drug;

(4) Designing pharmaceuticals to be more biodegradable;

(5) Designing delivery mechanisms that enable the pharmaceutical to reach the desired target and thus reducing dosage;

(6) Designing packaging with longer shelf life in order to reduce the waste of pharmaceuticals; and

(7) Destruction/disposal methods that can be adopted by water treatment facilities, or even healthcare facilities and consumers.[319]

300. Daughton, EPA, *supra* note 260, at 27.
301. Secure and Responsible Drug Disposal Act of 2010, Pub. L. No. 111-273, 124 Stat. 2858 (codified in scattered sections of 21 U.S.C.). The SRDDA passed via unanimous vote in the Senate, and was signed into law on Oct. 12, 2010. *Bill Summary & Status, S. 3397*, Library of Congress, http://thomas.loc.gov/cgi-bin/bdquery/z?d111:SN03397:@@@L&summ2=m& (last visited Feb. 21, 2012).
302. Secure and Responsible Drug Disposal Act of 2010 § 2(4)(A), 124 Stat. at 2859.
303. *Id.* § 2(4)(B), 124 Stat. at 2859.
304. *Id.* § 2(4)(C), 124 Stat. at 2859.
305. *Id.* § 2(6), 124 Stat. at 2859.
306. *See* Procedures for the Surrender of Unwanted Controlled Substances by Ultimate Users; Notice of Meeting, 75 Fed. Reg. 80,536 (Dec. 22, 2010).
307. *See generally Green Chemistry Program at EPA*, EPA, http://www.epa.gov/gcc/pubs/epa_gc.html (last updated Oct. 3, 2011).
308. President's Council on Sustainable Dev., Sustainable America: A New Consensus for the Prosperity, Opportunity and a Healthy Environment for the Future 40 (1996), *quoted in* Paddock, *supra* note 23, at 10,612.
309. *Green Chemistry Program at EPA*, *supra* note 307.
310. *See generally* Kümmerer, *supra* note 14, at 67; *Green Chemistry Program at EPA*, *supra* note 307.
311. *See* Kümmerer, *supra* note 14, at 67.
312. *See id.*
313. *Id.*
314. START, *supra* note 196, at 19.
315. *Id.*
316. *Id.*
317. *Id.* at 18.
318. *See generally Green Chemistry Program at EPA*, *supra* note 307.
319. Christian G. Daughton & Ilene Sue Ruhoy, *Pharmaceuticals and Sustainability: Concerns and Opportunities Regarding Human Health and the Environment*,

The issue remains how to encourage pharmaceutical manufacturers to implement green practices. The German START study listed a number of ways to promote the development of green pharmacy, such as funding research programs, publishing a list of green active ingredients to show successes, extending patents for green pharmaceuticals, and promoting public-relations campaigns.[320] The United States should consider such measures as well.

Creating market-based incentives would encourage pharmaceutical companies to focus more resources on green technology. The pharmaceutical companies could justify this economically as well, by brand reputation, consumer loyalty, product-differentiation, and new market growth.[321]

> [A] number of studies have highlighted that final consumption and affluence . . . are the main drivers for the level and growth of environmental pressure. Even though these studies provide a clear incentive for complementing producer-focused environmental policy with some consideration for consumption-related aspects, demand-side measures to environmental problems are rarely exploited.[322]

As discussed above, educating the public about the occurrence of pharmaceuticals in the environment could encourage such demand-side measures.[323] Moreover, pharmaceutical manufacturers, with their direct-to-consumer advertising experience, already possess the marketing prowess to bolster such a market.[324]

FDA could also create incentives to promote green-pharmacy practices through its regulations. It could offer a fast-track approval method for green pharmaceuticals through its market-authorization process, or, with congressional authorization, could extend the time period covering patents for green pharmaceuticals.[325] Either action would further encourage pharmaceutical companies to focus on green principles. Engaging in environmentally responsible practices also could have the added benefit of preventing the need for new, stricter regulations, which would likely translate to increased business costs.[326]

The United States also should implement an online searchable database, or "wise list," like that used in Sweden.[327] This would enable the public to make environmentally informed decisions regarding which pharmaceuticals to purchase, and would enable healthcare providers and hospitals to make environmentally informed prescribing, purchasing, and stocking decisions.[328] This further would build a market for green pharmacy and make pharmaceutical companies more likely to dedicate more resources to following green principles.

D. Research and Monitoring

Recall, a major shortcoming of the current statutory regime is the lack of scientific data concerning the presence, amount, and effect of pharmaceuticals in the environment.[329] As such, the solution must also include more testing and monitoring. Because there are thousands of pharmaceuticals in existence, it is necessary to prioritize which ones to test first.[330] "Unless [pharmaceutically active compounds] are prioritized based on their relative potential to exert adverse outcomes, potentially important [compounds] will go understudied because research will be biased toward compounds with well-established analytical methods or high name recognition."[331] A study recently prioritized the top 200 generic pharmaceuticals in the United States based on the pharmaceuticals' toxic load ("TL")—a concept that scores each pharmaceutical based on its load in the environment and potential toxicity.[332] The results indicated that many of the pharmaceuticals with high TL scores had not been adequately studied.[333]

EPA recently employed a prioritization scheme to narrow down a list of approximately 87,000 potentially endocrine-disrupting chemicals.[334] Similarly, EPA narrowed down a universe of 7,500 chemicals when finalizing CCL3.[335] EPA could employ a comparable prioritization scheme focusing on pharmaceuticals. Prioritization allows regulators to focus their limited resources on those pharmaceuticals that are most likely to pose risks to humans and the environment. For example, regulators in England used a prioritization scheme, combining data on veterinary medicines' ecotoxicity, metabolism, annual usage, and administration routes,

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in A Healthy Future Pharmaceuticals in a Sustainable Society 14, 17 (Bengt-Erik Bengtsson et al. eds., 2009), *available at* http://www.epa.gov/esd/bios/daughton/Pharmaceuticals-Sustainability-2009.pdf.

320. START, *supra* note 196, at 20.

321. Paddock, *supra* note 24, at 10,611 ("[C]ompanies will establish their own environmental standards driven by economic factors including cost savings and the opportunity to differentiate their products, but also by reputation, customer demand, insurance availability, investor decisions, and other factors like corporate values.").

322. Manfred Lenzen et al., *Shared Producer and Consumer Responsibility—Theory and Practice*, 61 Ecological Econ. 27, 28 (2007) (citation omitted) (footnote omitted).

323. *See supra* notes 207–230 and accompanying text.

324. *See* Amanda L. Connors, Comment, *Big Bad Pharma: An Ethical Analysis of Physician-Directed and Consumer-Directed Marketing Tactics*, 73 Alba ny L. Rev. 243, 246–47 (2009) (citing Families USA, Profiting from Pain: Where Prescription Drug Dollars Go 1, 3–5 (2002)). By 2001, the top nine pharmaceutical companies spent more money on advertising and marketing than on research and development of new drugs. *Id.* at 246. Eight of those nine top pharmaceutical companies spent twice as much on advertisements as they did on research and development. *Id.* at 246–47. By 2005, direct-to-consumer advertising had grown to $4.2 billion. *Id.* at 271. By 2009, spending on direct-to-consumer advertising reached just under $5 billion. Gary Humphreys, *Direct-to-Consumer Advertising Under Fire*, 87 Bull. World Health Org. 576, 576 (2009), *available at* http://www.who.int/bulletin/volumes/87/8/09-040809.pdf.

325. START, *supra* note 196, at 20, 22–23; Kümmerer, *supra* note 14, at 68.

326. Eric Assadourian, *The State of Corporate Responsibility and the Environment*, 18 Geo. Int'l Envtl. L. Rev. 571, 574 (2006).

327. *See supra* note 225 and accompanying text.

328. *See generally* Kümmerer, *supra* note 14, at 67 ("If an internal commission of a hospital provides a list of recommended pharmaceuticals that is the basis for hospital purchasing activities, the variety of products is reduced, resulting in savings. Limiting the drug storage space in wards reduced the share of outdated medicaments and thereby the environmental burden.").

329. *See generally supra* Part II.B.

330. *Shine Testimony*, *supra* note 10, at 3–4.

331. *Id.* at 4.

332. *Id.*

333. *Id.* at 5.

334. Endocrine Disruptor Screening Program; Proposed Statement of Policy, 63 Fed. Reg. 71,542, 71,545 (Dec. 28, 1998).

335. Drinking Water Contaminant Candidate List 3—Final, 74 Fed. Reg. 51,850, 51,852 (Oct. 8, 2009).

to determine which drugs should be included in a national monitoring program.[336]

In addition to increased testing and monitoring of pharmaceuticals that enter the water, research is necessary to understand the potential threats to humans. Studies need to be focused on long-term, low-dose exposure. Because pharmaceuticals are designed to have physiological effects in low amounts, the current testing, ecotoxicity, should be replaced by the examination of effects such as behavior, physiology, and biochemical changes in response to low-dose, chronic exposure.[337]

Monitoring and research can result in better treatment technologies and methods, which will be discussed in a later section. In a research-and-monitoring context, in order to make the water-treatment process as cost-effective as possible, it is necessary to understand the pharmaceuticals that are most commonly found in certain water sources and which ones pose the largest risks to humans and the environment.[338] Armed with such knowledge, researchers can focus water-treatment techniques and treatment research on specific pharmaceuticals.[339]

In the 111th Congress, there were a number of bills introduced to specifically authorize research. Most, however, did not fare well:

- H.R. 1145 would have created a national research and development initiative to conduct research into the prevention and removal of emerging contaminants, including pharmaceuticals, from the nation's waters.[340] It passed the House but failed to make it out of the Senate Committee on Environment and Public Works.[341]
- H.R. 1262 would have amended the Clean Water Act by directing EPA to conduct a study on pharmaceuticals and other personal-care products in the nation's waters.[342] It also passed the House but did not make it out of the Senate Committee on Environment and Public Works.[343]
- H.R. 5320, the Assistance, Quality, and Affordability Act of 2010, would have revised the EDSP and directed EPA to list at least 100 potentially endocrine-disrupting chemicals for screening and to issue testing orders for the 100 new substances within ten years.[344] Further, it would have directed EPA to conduct testing on emerging pharmaceuticals and other personal-care products in drinking water and their potential health effects on humans.[345] It also passed the House but remained in the Senate Committee on Environment and Public Works.[346]
- The Water Infrastructure Financing Act of 2009 would have required the National Academy of Sciences to study the sources of pharmaceuticals in the environment and evaluate potential water-treatment methods.[347] It was referred out of committee, but never reached a vote in the Senate.[348]

Any potential solution to the issue of pharmaceuticals in the water must contain a research-and-monitoring component. This is where the current regulatory framework can play a key role. Statutes such as the CWA and SDWA already contain requirements and mechanisms that can be used to address the lack of research concerning pharmaceuticals in the environment.[349] And while this is a matter that is appropriate for government regulators to address, pharmaceutical manufacturers can and should play a role as well. Pharmaceutical manufacturers should be required to perform and provide the FDA with additional premarket research that is specifically designed to address the unique issues of low-dose, long term effects and bioaccumulation.[350]

As discussed earlier, FDA does not require a pharmaceutical company to conduct an EA when the estimated concentration at the point of entry into the environment is below one part per billion or for substances that occur naturally in the environment.[351] FDA should close this loophole and affirmatively require pharmaceutical manufacturers to research potential risks to humans and the environment, similar to the ERA requirement in Europe. The only exception to this rule should be when extraordinary circumstances exist, such as where the new drug has the potential to save lives. Moreover, like in Europe,[352] FDA should be able to include mitigation measures when there may be environmental impacts. Unlike Europe's mitigation measures, however, FDA should be able to require measures that go beyond providing informational pamphlets to healthcare providers and patients.

Another facet of any proposed solution is what to do with the research once it is collected. Taking note of Sweden's classification system, the United States should also create a

336. Boxall, *supra* note 73, at 1111.
337. *Id.* at 1112.
338. *Naidenko Testimony*, *supra* note 104.
339. *See id.* (proposing an amendment to New York City's administrative code that would require testing by the Department of Environmental Protection for the presence of pharmaceuticals and personal-care products in the drinking water supply).
340. National Water Research and Development Initiative Act of 2009, H.R. 1145, 111th Cong. (2009); *see Bill Summary and Status, H.R. 1145*, Library of Congress, http://thomas.loc.gov/cgi-bin/bdquery/z?d111:HR01145:@@@L&summ2=m&http://thomas.loc.gov/cgi-bin/bdquery/D?d111:1:./temp/~bdY25R:@@@L&summ2=m&|/home/LegislativeData.php?n=BSS;c=111 (last visited Feb. 21, 2012).
341. *Bill Summary and Status, H.R. 1145*, *supra* note 340.
342. Water Quality Investment Act of 2009, H.R. 1262, 111th Cong. (2009); *see Bill Summary and Status, H.R. 1262*, Library of Congress, http://thomas.loc.gov/cgi-bin/bdquery/z?d111:HR01262:@@@L&summ2=m& (last visited Feb. 21, 2012).
343. *Bill Summary and Status, H.R. 1262*, *supra* note 342.
344. Assistance, Quality, and Affordability Act of 2010, H.R. 5320, 111th Cong. (2009); *see Bill Summary and Status, H.R. 5320*, Library of Congress, http://thomas.loc.gov/cgi-bin/bdquery/z?d111:HR05320:@@@L&summ2=m& (last visited Feb. 21, 2012).
345. H.R. 5320.
346. *Bill Summary and Status, H.R. 5320*, *supra* note 344.
347. Water Infrastructure Financing Act, S. 1005, 111th Cong. § 302(f)(2) (2009).
348. *Bill Summary & Status, S. 1005*, Library of Congress, http://thomas.loc.gov/cgi-bin/bdquery/z?d111:SN01005:@@@L&summ2=m& (last visited Feb. 21, 2012).
349. 33 U.S.C. §§ 1254–1254a (2006); 42 U.S.C. § 300j-18 (2006).
350. *See* George Washington Univ. Sch. of Pub. Health & Health Servs., *supra* note 2, at 4–5; *see also* Christenson, *supra* note 272, 156–57.
351. 21 C.F.R. § 25.31(b)–(c) (2011).
352. *See supra* notes 208–211 and accompanying text.

Table 2. Most Prescribed Sex-Hormone Medications

ID	Active Ingredient	CAS Number	Test	Toxicity	Species	Species (Sci.)
30[a]	Estradiol	50-28-2	6-7d EC50	>10 mg/l	Copepod	Acartia tonsa
146[b]	Ethinyl estradiol	57-63-6	LD50	0.0000014–0.00000203 mg/l	Sheepshead minnow	Cyprinodon variegatus
150[c]	Methylestosterone	58-18-4	LD50	0.0000804 mg/l	Alaskan sickleback	Gasterosteus aculeatus
30[d]	Estradiol	50-28-2	96h LD50	0.0187 mg/l	Mimmichog	Fundulus heteroclitus
146[e]	Ethinyl estradiol	57-63-6	LD50	0.51 mg/l	Harpacticoid copepod	Nitocra spinipes

a. *Active Ingredient Summary: Estradiol*, Nat'l Oceanic & Atmospheric Admin., http://www.chbr.noaa.gov/peiar/detail.aspx?substanceid=30 (last updated Aug. 25, 2009).
b. *Active Ingredient Summary: Ethinyl Estradiol*, Nat'l Oceanic & Atmospheric Admin., http://www.chbr.noaa.gov/peiar/detail.aspx?substanceid=146 (last updated Aug. 25, 2009).
c. *Active Ingredient Summary: Methyltestosterone*, Nat'l Oceanic & Atmospheric Admin., http://www.chbr.noaa.gov/peiar/detail.aspx?substanceid=150 (last updated Aug. 25, 2009).
d. *Active Ingredient Summary: Estradiol*, *supra* note 370.
e. *Active Ingredient Summary: Ethinyl Estradiol*, *supra* note 371.

"wise list" of pharmaceuticals. Currently, there are a number of U.S. databases concerning pharmaceuticals in the environment;[353] however, all have shortcomings.

One such database, ECOTOX, is maintained by EPA and provides links to research on the effects of chemicals on different species.[354] ECOTOX requires the user to know at least one of the following search parameters: chemicals, taxonomic species, major effect group, or publication year(s).[355] If one queries aquatic impact data for chromium, for example, the ECOTOX database returns a report containing almost 1,500 different studies concerning chromium and its effects on a variety of aquatic species, test methods, and results in a large amount of data not easily understood by a layperson.[356] ECOTOX provides academic sources for researchers and scientists, who are likely the desired audience, but it is not helpful or understandable for a patient wanting to know the environmental impacts of her antibiotic or birth control.

Additionally, the Center for Coastal Environmental Health and Biomolecular Research maintains the Pharmaceuticals in the Environment ("PEIAR") database, which "provide[s] searchable information on potential environmental effects of pharmaceuticals entering waterways from both point and nonpoint sources."[357] The PEIAR database contains data on 349 pharmaceuticals, including the "top 200 prescribed [pharmaceuticals] in the US during either 2003 or 2004."[358] The website allows users to run a query on a general category of pharmaceuticals;[359] for example, a general query on "hormones," subcategory "sex hormones," sorted by most prescribed medications, yields the results in Table 2.[360]

The database can also be searched by specific pharmaceuticals. For example, running a search on ibuprofen produces the following:

> **Formula:** $C_{13}H_{18}O_2$
> **Molecular Weight:** 206.28
> **Melting Point (°C):** 75–77
> **Notes:** Non-Steroidal Anti-Inflammatory (NSAID)
> . . . .
> **Rank of prescriptions dispensed in 2004**: 23
> **Biological Half-Life**:
> **$t_{1/2}$:** 2 hour(s)
> **Notes:** Half-life in plasma after oral admin
> **Environmental Half-Life**:
> **$t_{1/2}$:** 20 day(s)
> **Sphere:** "water samples from lake Greifensee, Switzerland that were incubated at room temperature for 37 days with 200 ng/l racemic ibuprofen"
> **Notes:** Ibuprofen has shown to be inherently biodegradable by sewage treatment. However, analysis of activated sludge from the wastewater treatment plant at Gossau, Switzerland indicates that a residence time in excess of 6 hours is required for complete removal of ibuprofen. Influent concentration of 0.3 ug/l in Brazilian treatment plants showed a removal efficiency of ranging from 22–75%
> **$t_{1/2}$:** < 1 day(s)[361]

Although the PEIAR database provides information concerning environmental impacts of pharmaceuticals, the scientifically complex results make it unwieldy for a layperson who is simply looking to compare pharmaceuticals and make an environmentally informed decision. Further, the database is limited to information from a literature review completed in 2005,[362] and, as discussed earlier, most research to date on pharmaceuticals has not focused on low-dose, long-term effects.[363]

353. *E.g.*, *ECOTOX Database*, EPA, http://cfpub.epa.gov/ecotox/quick_query.htm (last updated Feb. 21, 2012); *Pharmaceuticals in the Environment (PEIAR)*, Nat'l Oceanic & Atmospheric Admin., http://www.chbr.noaa.gov/peiar/ (last updated Aug. 19, 2009).
354. *ECOTOX Database*, *supra* note 353.
355. *Id.*
356. *Id.*
357. *Pharmaceuticals in the Environment (PEIAR)*, *supra* note 353.
358. *PEIAR—About the Project*, Nat'l Oceanic & Atmospheric Admin., http://www.chbr.noaa.gov/peiar/about.aspx (last updated Aug. 19, 2009).
359. *PEIAR—Search*, Nat'l Oceanic & Atmospheric Admin., http://www.chbr.noaa.gov/peiar/search.aspx (last updated Aug. 25, 2009).
360. *Id.*
361. *Active Ingredient Summary: Ibuprofen*, Nat'l Oceanic & Atmospheric Admin., http://www.chbr.noaa.gov/peiar/detail.aspx?substanceid=15 (last updated Aug. 25, 2009) (footnotes omitted).
362. *PEIAR—About the Project*, *supra* note 358.
363. *See* Boxall, *supra* note 73, at 1112 (discussing questions remaining to be addressed in research on the environmental impact of low-dose, long-term pharmaceutical exposure).

The United States should set a goal of creating a searchable, online list of pharmaceuticals and their environmental impacts. Although this list is largely dependent on more research being conducted and data gathered, the framework should be created and filled in with current data as such data is compiled. The purpose of the database, however, should be clear from the outset: It should focus on providing laypersons with simple, understandable information concerning the potential environmental risks of particular pharmaceuticals to allow them to make environmentally informed decisions.

E. Focus on Treatment Technologies and Methods

Finally, while the primary focus of any solution should be on preventing pharmaceuticals from entering wastewater in the first place, research into water-treatment technologies should also be part of the solution.[364] Currently, wastewater-treatment systems concentrate on removing microorganisms, not pharmaceuticals.[365] Research, therefore, is needed into treatment technologies specifically designed to remove pharmaceuticals. Also needed is monitoring of wastewater for the presence of pharmaceuticals and cost-effective, tailored implementation of technologies specifically designed to remove pharmaceuticals.[366]

The advanced treatment of effluents, thus far, has shown mixed results.[367] "Advanced treatments such as ozonation, granulated activated carbon, [ultraviolet] treatment and advance oxidation process can remove significant amounts of pharmaceuticals but are expensive."[368] Moreover, even among effective technologies, some are better at removing certain pharmaceuticals than others.[369] For example; coagulation, flocculation, ultrafiltration, and microfiltration are largely ineffective at removing pharmaceutical compounds from wastewater.[370] Some treatments, while effective at removing the desired pharmaceuticals, create more persistent and mobile byproducts.[371] Although ozonation may remove pharmaceutical compounds, it can also produce a toxic byproduct,[372] and "mutagenic and toxic properties have been found for the reaction products of (photo)oxidation processes."[373]

Moreover, such treatment is very expensive. One group warned, "If water utilities choose to (or are compelled to) implement additional treatment measures for these compounds based solely on occurrence data, without regard to toxicological significance, there is a risk of spending tremendous amounts of public funds for very little public health benefit."[374] Thus, in order to make the treatment as effective as possible, research is needed to determine which pharmaceuticals are most commonly found in the water, their routes of delivery into water sources, and which pharmaceuticals pose the biggest threats to humans and the environment.[375] By monitoring the amount and type of pharmaceuticals in wastewater, each treatment plant could then apply tailored, cost-effective wastewater-treatment technology that would remove the most prevalent pharmaceuticals that pose the greatest risks to humans and the environment.[376]

VI. Financing the Change: Moving Toward a Shared Responsibility

A major challenge for implementing any aspect of this solution is determining who will pay: government (federal, state, or local), consumers, or pharmaceutical companies. The concept of extended producer responsibility ("EPR") as applied to pharmaceuticals would make manufacturers responsible for the environmental impacts of a pharmaceutical throughout its life cycle, from production, to use, to discharge in the environment.[377] EPR "assigns long-term environmental responsibility for products to producers in an attempt to internalize costs and convert the linear 'cradle-to-grave' production and distribution chain into a 'cradle-to-cradle' system that encourages recycling, reuse, and improved product design."[378] Thus, under an EPR framework, pharmaceutical manufacturers could be held responsible for funding take-back programs, implementing more environmentally friendly research and design, and the costs associated with treating pharmaceutical-contaminated wastewater before it is discharged into the environment. The National Association of Counties recently stated that it supports creating a pharmaceutical take-back program (including collection, transportation, and disposal) financed exclusively by the pharmaceutical industry.[379]

364. *Naidenko Testimony*, *supra* note 104; *see also* George Washington Univ. Sch. of Pub. Health & Health Servs., *supra* note 2, at 6 ("Greater public investment in drinking and wastewater infrastructure. Rather than taking a contaminant-by-contaminant approach, upgrading technology offers an opportunity to address water quality issues, and ecological stressors, systematically."); Tiemann, Cong. Research Serv., *supra* note 16, at 11 ("Recognizing that people and animals will continue to take and use pharmaceutical products, water suppliers and other stakeholders consider changes at wastewater treatment plants to be a key part of the solution."); Mannina, *supra* note 19, at 2 ("Concerned environmental groups, however, assert that waste treatment facilities need to do a better job of removing pharmaceuticals and that the release of hormones and pharmaceuticals from animal feedlots needs to be better controlled.").
365. *Naidenko Testimony*, *supra* note 104.
366. *Potential Risks Hearing*, *supra* note 190, at 14–15 (statement of Dr. Jennifer Sass, Senior Scientist, Natural Resources Defense Council, at 14–15), *available at* http://epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=a5ef042e-26fc-41f1-9af1-a2aa1d16f88b.
367. Djanette Khiari, Am. Water Works Ass'n Research Found., Endocrine Disruptors, Pharmaceuticals, and Personal Care Products in Drinking Water: An Overview of AwwaRF Research to Date 2–5 (2007), *available at* http://www.cwwa.ca/pdf_files/AwwaRF_EDC%20article1.pdf.
368. *Naidenko Testimony*, *supra* note 105 (citation omitted); *see also* Focazio et al., *supra* note 257.
369. *See* Khiari, Am. Water Works Ass'n Research Found., *supra* note 367, at 2–5.
370. *See id.*
371. Boxall, *supra* note 73, at 1114.
372. *Naidenko Testimony*, *supra* note 105.
373. Kümmerer, *supra* note 14, at 66 (citation omitted).
374. *See* Khiari, Am. Water Works Ass'n Research Found., *supra* note 367, at 6.
375. *Naidenko Testimony*, *supra* note 105.
376. *Naidenko Testimony*, *supra* note 104; Kümmerer, *supra* note 14, at 66.
377. *See generally* Bette K. Fishbein, *EPR: What Does it Mean? Where is it Headed?*, 8 P2: Pollution Prevention Rev. 43 (1998).
378. Noah Sachs, *Planning the Funeral at the Birth: Extended Producer Responsibility in the European Union and the United States*, 30 Harv. Envtl. L. Rev. 51, 53 (2006).
379. Nat'l Ass'n of Cntys., Resolution in Support of a Safe, Convenient Medicine Return Program 1 (2009), *available at* http://www.productpolicy.org/ppi/NACo-2009_Pharma-takeback-resolution.pdf; Main, *supra* note

One of the principle goals of an EDR regime is to encourage manufacturers to implement more ecologically friendly designs; however, the experience of EDR in Europe has shown this to be ineffective.[380] Additionally, consumers should not be permitted to ignore their role in contributing to the occurrence of pharmaceuticals in the environment. As one economist questioned: In a scenario where a pollution-emitting manufacturer produces material solely to satisfy the needs of a separate, nonpolluting sector, which party is ultimately responsible for creating the pollution: the manufacturer or the user who creates the demand?[381] In the pharmaceutical context, consumers not only create the market—and should therefore bear some responsibility on that account—they also directly introduce pharmaceuticals into the environment intentionally (by flushing unused medication) and unintentionally (through unmetabolized pharmaceuticals). In fact, some theories suggest that the consumer should be solely responsible.[382] "[L]ife-cycle thinking chooses the full consumer responsibility paradigm: it chooses to heap all impact onto final consumers, and to exclude intermediate producers from responsibility."[383] However, because Americans spent $287 billion on prescriptions in 2007, a figure expected to double by 2017,[384] this approach is not likely to garner much public support. Thus, the solution should not be financed exclusively by either manufacturers or consumers.

Rather, the appropriate solution should account for the interconnectedness of the parties that contribute to the problem and apply a concept of shared responsibility.[385] The concept of shared responsibility notes there are always at least two groups in every transaction—the producers and the consumers—and divides the responsibility for the product between those groups.[386]

> [T]he concept of product stewardship "suggests that *all* parties with a role in designing, producing, selling or using a product are responsible for minimising the environmental impact of the product over its life. In practice, this 'shared responsibility' extends beyond the producers and users of a product to include local governments and general taxpayers who incur the expense of managing products at their end-of-life as part of the residential waste stream."[387]

The costs, therefore, should be allocated between all parties. Because manufacturers and consumers operate in different spheres of political, social, and economic influence, allocating the responsibility between parties should generally be based on each party's financial ability, innovation potential, ability to control production, and area of expertise.[388] For example, it would not necessarily make sense for the pharmaceutical industry to run a nationwide pharmaceutical take-back program, because the industry lacks the ability to change federal regulations and may not be aware of local community characteristics that make one type of program more or less successful than another. Similarly, because pharmaceutical manufacturers have the expertise in drug design and manufacturing, they should be responsible for conducting more robust premarket analysis and implementing green chemistry practices.

VII. Conclusion

As noted at the outset, "[w]ater is the most important prerequisite for life on Earth,"[389] and if our current practices continue unabated, the nation's waters may turn into pharmaceutical soup. The impacts have already been felt by aquatic and animal life: There are transgendered fish, frogs with deformed limbs, and alligators with shrinking penises.[390]

Waiting until evidence of human harm is established is not a viable option. However, overregulation would be an equally unattractive decision because of potential unintended consequences. Further, because pharmaceuticals enter the environment through various pathways, pose risks from mixtures, low-doses, and chronic exposure, and—unlike conventional pollutants—are primarily beneficial in and of themselves, limiting the occurrence of pharmaceuticals in the environment largely defies conventional regulations.[391]

A different approach, therefore, is required to address the occurrence of pharmaceuticals in the environment. Current federal law and regulations should play a role—at this point primarily in the form of funding, driving additional research and monitoring requirements, and removing regulatory barriers to drug take-back programs—but a green governance approach is needed to address the unique nature of the problem. As recommended above, economic and values-based behavioral drivers should be employed and new policy tools implemented to remedy the occurrence of pharmaceuticals in the environment.[392]

279 (citing Bill Sheehan, director of the Product Policy Institute, which helped the National Association of Counties draft its proposal).

380. Sachs, *supra* note 378, at 75.
381. Lenzen et al., *supra* note 322, at 36.
382. *Id.* at 31.
383. *Id.* at 38.
384. Elizabeth Cohen, *Ten Ways to Save on Prescription Drugs*, CNN.com (Mar. 19, 2009), http://articles.cnn.com/2009-03-19/health/ep.prescription.drug.costs_1_prescription-drugs-elderly-patients-coumadin?_s=PM:HEALTH.
385. Lenzen et al., *supra* note 322, at 28.
386. *See id.* at 31–32.
387. *Id.* at 28 (quoting Kate McKerlie et al., *Advancing Extended Producer Responsibility in Canada*, 14 J. Cleaner Production 616, 620 (2006)).
388. *See id.* at 36.
389. Wallström, *supra* note 1.
390. *See supra* notes 17, 20, 102.
391. *See supra* Part I.A–B.
392. *See supra* note 23 and accompanying text.