# WATER RX

## THE PROBLEM OF PHARMACEUTICALS IN OUR NATION’S WATERS

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In one stream in Boulder, Colorado, female white sucker fish outnumber males of a the same species by a ratio of greater than five to one, and half of the males have female sex tissue.  

Although this may seem to be a strange and possibly isolated occurrence, this situation is not restricted to Colorado, nor is it exclusive to the white sucker fish.  

Streams all over the United States and the rest of the world are experiencing the feminizing of male organisms or

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1. Elizabeth Royte, *Drugging the Waters: how an aging population and our growing addiction to pharmaceuticals may be poisoning our rivers*, 28 OnEarth 26, 30 (Fall 2006).  
masculinizing of female organisms.³ Scientists are pointing to birth control and other pharmaceuticals as the culprit, and these compounds do not end up in fish because the fish are concerned with family planning.⁴ Humans are the source of these compounds, and they enter the environment through many different routes.⁵

The problem of pharmaceuticals in the water, both the water supply for human consumption and the aquatic environment, has begun to come to the attention of regulators. Although this problem is not a new one—the general consensus is that pharmaceuticals have been present in water since their inception—new detection technologies have brought this contamination to the forefront.⁶ Technologies allowing us to detect concentrations as low as parts-per-trillion are relatively new.⁷

Even so, scientists still know very little about the effects of pharmaceuticals in low concentrations on humans and the environment.⁸ Thus, the problem of pharmaceuticals in the water presents a specific set of regulatory challenges.⁹

This comment addresses the growing problem of pharmaceuticals in the water. Part I discusses some of the various avenues through which pharmaceuticals enter the water and reviews some of the knowns and unknowns about the effects of these pharmaceuticals on humans and the environment. Part II presents an overview of the current state of the law, while

³ Environment Canada, supra note 2; Halford, supra note 2.
⁴ See e.g., Jon P. Nash et al, Long Term Exposure to Environmental Concentrations of the Pharmaceutical Ethynylestradiol Causes Reproductive Failure in Fish, 112 ENVTL. HEALTH PERSPS. 1725, 1726 (2004).
⁶ Id. People have even found a way to exploit the presence of pharmaceuticals in the water for profit. See http://www.groundwatersystemsin.com/27.html (highlighting the presence of pharmaceuticals in the water as a reason to purchase the Nature Soft system by Ground Water Systems, Inc.)
⁷ Royte, supra note 1, at 30.
⁸ Pat Hemminger, Damming the Flow of Drugs into Drinking Water, 113 ENVTL. HEALTH PERSPS. A679, A679 (Oct. 2005). See also Halford, supra note 2.
Part III examines proposed legislation addressing pharmaceuticals in the water. Part IV concludes with proposals for where to go from here.

I. Pharmaceuticals in the Water

a. Sources

Considering the massive and widespread influence that pharmaceuticals have in our society, it is no wonder that some of these compounds find their way into the environment. In fact, as of 2007, scientists had identified more than 100 different pharmaceuticals or personal care products in the environment and drinking water, and researchers estimate that approximately forty-one million Americans face exposure to pharmaceuticals through their drinking water. In fact, a study examined the fifty largest cities in the United States and found that at least twenty-four of them have pharmaceuticals in their municipal water supply. Similarly, a 2002 study by the United States Geological Survey found pharmaceutical contamination in more than eighty percent of the streams surveyed.

Pharmaceuticals enter the environment through many different avenues, both intentional and unintentional. The paths this comment examines are: improper disposal; human consumption and excretion; livestock and aquaculture operations; and intentional addition. Compounding the problem of many avenues and sources of contamination, most of these pharmaceuticals are highly water soluble and do not “evaporate at normal temperature and pressures,” thus

10 $92 million of medicines are sold annually in the United States and fifty million pounds of antibiotics alone are produced per annum. Campbell, supra note 5, at 11200. As of 2006, Americans were filling greater than three billion prescriptions per year. Royte, supra note 1, at 28.


13 GEORGE WASHINGTON SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES, supra note 9, at 3.


15 Daughton & Ternes, supra note 9, at 912

16 EPA, Pharmaceuticals and Personal Care Products, FAQs, supra note 11.
facilitating thorough contamination.

Perhaps the most preventable conduit of contamination is improper disposal. For years hospitals and nursing homes have disposed of their excess pharmaceuticals by flushing them down the drain.\textsuperscript{17} In fact, not too long ago this was the recommended method for disposing of unwanted pharmaceuticals\textsuperscript{18} because it ensured that the pharmaceuticals did not end up in the wrong hands—children or the illicit drug trade.\textsuperscript{19} State and local governments have recently begun to launch massive informational campaigns in an effort to minimize or eliminate this method of pharmaceutical disposal.\textsuperscript{20} However, old habits die hard and many people still believe that flushing is the best method of disposal for their unwanted pharmaceuticals.\textsuperscript{21}

Pharmaceuticals also enter the water through human consumption and excretion.\textsuperscript{22} Humans do not fully metabolize ingested pharmaceuticals and thus excrete the unmetabolized compounds in urine or feces.\textsuperscript{23} A person’s age and health can impact how much of a given drug that person metabolizes, as can timing of dose and formulation of the drug itself.\textsuperscript{24} Once excreted in wastewater, the wastewater infrastructure sends the contaminated excrement to sewage treatment facilities, but federal law does not impose any monitoring requirements on these facilities regarding pharmaceuticals in the water.\textsuperscript{25} Furthermore, municipalities do not design

\begin{itemize}
\item \textsuperscript{17} Christian G. Daughton, \textit{Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health. II. Drug Disposal, Waste Reduction, and Future Directions}, 111 ENVTL. HEALTH PERSPS 775, 780 (2003).
\item \textsuperscript{18} See generally \textit{Id.} (providing examples of states promoting flushing as the preferred method of disposal as recent as 2002, including by North Carolina’s Administrative Code and the California Poison Control System).
\item \textsuperscript{19} \textit{Id.} (to be discussed in greater detail later in this article).
\item \textsuperscript{20} A recent survey found that, despite advice to the otherwise, approximately half of the survey participants admitted to disposing of unwanted pharmaceuticals via the sewage system. Musson & Townsend, supra note 14, at 730.
\item \textsuperscript{22} \textit{Pharmaceuticals & Personal Care Products in the Environment: Scientific & Regulatory Issues} 11 (Christian G. Daughton & Tammy L. Jones-Lepp, eds., 2001).
\item \textsuperscript{23} \textit{Id.} at 11-12.
\item \textsuperscript{24} \textit{Id.} at 6.
\end{itemize}
municipal sewage treatment plants to remove these unregulated pharmaceutical contaminants,\textsuperscript{26} thus complicating any attempts at control. In fact, one study found that the treatment processes that wastewater undergoes eliminate as little as seven percent of active drug compounds,\textsuperscript{27} meaning that the vast majority of these excreted compounds remain in the “treated” water, which is discharged and eventually reprocessed into drinking water.\textsuperscript{28}

Unfortunately, the drinking water treatment processes also fail to remove these compounds in most cases.\textsuperscript{29} Most drinking water treatment plants rely on absorptive and oxidative processes for removal of organic materials from the water,\textsuperscript{30} but these methods are relatively ineffective at removing pharmaceuticals and other synthetic contaminants.\textsuperscript{31} Many view ozonation as one of the more effective methods for removing pharmaceuticals, but it only works best in removing estrogens and a limited number of other pharmaceuticals.\textsuperscript{32} It is not very effective at removing non-estrogen compounds or many other pharmaceuticals.\textsuperscript{33}

Another anthropogenic method through which pharmaceuticals enter ground and surface water is the intentional disposal of these unwanted drugs into the municipal solid waste system.\textsuperscript{34} The disposed pharmaceuticals end up in the landfill leachate, which makes its way to the ground water.\textsuperscript{35} This source of contamination has the potential to eclipse flushing as a source of contamination because agencies and other interests are beginning to recommend solid waste disposal of pharmaceuticals as an alternative to sewage disposal.\textsuperscript{36} This comment further

\textsuperscript{26} EPA, Pharmaceuticals and Personal Care Products, FAQs, supra note 11.
\textsuperscript{27} Shawna Bligh, Pharmaceuticals in Surface Waters: Use of NEPA, 24 NAT. RESOURCES & ENV’T 56, 56 (2009).
\textsuperscript{28} Id.
\textsuperscript{29} Paul Westerhoff et al, Fate of Endocrine-Disruptor, Pharmaceutical, and Personal Care Product Chemicals during simulated Drinking Water Treatment Processes, 39 ENVT. SCI. & TECH. 6649, 6649 (2005).
\textsuperscript{30} Id.
\textsuperscript{31} Id.
\textsuperscript{32} Id. at 6650.
\textsuperscript{33} Id.
\textsuperscript{34} Musson & Townsend, supra note 14, at 730.
\textsuperscript{35} Id.
\textsuperscript{36} Id.
examines the landfill requirements under the Resource Conservation and Recovery Act in Part II.

Livestock and aquaculture operations also contribute to pharmaceutical-contaminated water. Both livestock and aquaculture operations administer regular doses of antibiotics and hormones to animals to speed growth and prevent the spread of disease and infection. 

Like humans, animals do not fully metabolize the drugs and hence excrete them in manure and urine. One major difference between veterinary and human pharmaceutical contamination is that excreted human pharmaceuticals generally pass through some sort of treatment facility prior to entering surface water, while animals deposit their manure containing veterinary pharmaceuticals directly onto the ground or into the water and are thus a more direct source of contamination. In addition, farmers often use both human and animal manure for crop fertilization, which provides additional opportunity for the pharmaceutical-contaminated excrement to leach and/or run off into ground and surface waters. Some studies have shown that crops fertilized in this manner can even uptake the pharmaceuticals. As a result, if humans then consume these crops, crop uptake becomes another route of exposure.

Adding to the sheer quantity of contamination from farms and aquaculture operations is the fact that regulatory agencies do not usually consider these sources to be point sources, meaning that the Clean Water Act does not even govern their disposal practices.

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37 Livestock operations in particular are a major source of pharmaceutical contamination, with one USGS hydrologist guessing that livestock use “generates an estimated 500 million tons of waste each year.” Halford, supra note 2; see also Nidel, supra note 22, at 84.
38 Campbell, supra note 5, at 11201. It is widely known that overuse of antibiotics has contributed to increases in antibiotic-resistant bacteria and has been suggested that environmental exposure is also contributing to this, although one CDC researcher disagrees with this assertion. Id. at 11202. See also PHARMACEUTICALS & PERSONAL CARE PRODUCTS IN THE ENVIRONMENT, supra note 23, at 208.
39 Nidel, supra note 22, at 84.
40 PHARMACEUTICALS & PERSONAL CARE PRODUCTS IN THE ENVIRONMENT, supra note 23, at 42.
41 Nidel, supra note 22, at 84.
43 Halford, supra note 2.
44 This article is not intended to be an analysis of how to deal with non point source pollution, for more information
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Medication of pets represents another source of contamination, although not as significant as livestock operations, partially because the living conditions are not as concentrated.\(^{45}\) When people medicate their pets, the medications are similarly not fully metabolized by the pet.\(^{46}\) Thus, when medicated pets relieve themselves outside, the pharmaceutical-contaminated excrement has the potential to leach into the groundwater or contribute to contamination of urban runoff.

Possibly even more frightening than the numerous methods through which pharmaceuticals unintentionally enter the water is the fact that municipalities and businesses are actually intentionally adding pharmaceuticals and other personal care products to the water. A 2009 article reported that companies have legally released 271 million pounds of pharmaceuticals into water bodies—and some of these bodies serve as drinking water sources.\(^{47}\) Furthermore, municipalities already add fluoride to the drinking water supply and have done so for over fifty years.\(^{48}\) One recent article even proposed adding lithium to the drinking water after areas with increased levels of naturally-occurring lithium in the water reported lower than usual rates of suicide and violent crime.\(^{49}\) In addition to ethical and human rights concerns, the intentional addition of pharmaceuticals and like products creates further environmental and human health concerns.

To make matters worse, actual quantities of pharmaceuticals entering the environment are

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\(^{45}\) Daughton & Ternes, *supra* note 9, at 923.

\(^{46}\) Id.


\(^{48}\) This practice began in 1945 in Grand Rapids, Michigan, and today approximately sixty countries fluoridate their water, exposing around 360 million people to its effects. For more on the effects of fluoridated water, see L.H. WEINSTEIN & A. DAVIDSON, *FLUORIDES IN THE ENVIRONMENT* 68-70 (2004).

unknown. Thus, calculating pharmaceutical pollution is difficult because usage is not thoroughly documented and different living beings metabolize drugs at different rates.

b. Impacts

Although pharmaceuticals represent only a small portion of the anthropogenically-originating chemicals entering the environment, they pose a potentially more significant danger because these compounds are specifically designed to effect biological change at relatively low concentrations. Technology has improved over the years, and currently we are able to detect compounds in the water down to parts per trillion by using a detection technique known as gas chromatography-mass spectrometry. Generally, pharmaceuticals exist in the environment in concentrations ranging from parts per trillion to parts per billion. The concentrations at which drugs effect change in humans vary depending on the drug, but generally concentrations of parts per billion (ppb) do not pose an acute risk. In fact, one study examined concentrations of pharmaceuticals in German drinking water and found that for most of the compounds examined, the margin between the daily therapeutic dose and intake via drinking water was 150,000. Moreover, the margin was at least 1,000 for all of the compounds examined. Thus, daily intake via drinking water was significantly lower than daily therapeutic dose for the majority of compounds examined.

Table 1 presents several drugs and the concentrations at which they have been found in

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50 Daughton & Ternes, supra note 9, at 912.
51 Id.
52 Halford, supra note 2. For example, estrogens can cause effects as very low levels – in one scientist’s words: “[i]f you can measure the estrogen in the water, then that’s enough to cause an effect, and we can measure it at very low parts-per-trillion concentrations.” Id.
53 This technology has a detection limit of 0.1 parts per trillion. Nash et al, supra note 4, at 1726.
54 Daughton & Ternes, supra note 9, at 912. One part per billion is approximately “one drop of water in an Olympic-sized swimming pool,” and one part per trillion is one drop in 1,000 Olympic-sized pools. GEORGE WASHINGTON SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES, supra note 9, at 1.
55 Daughton & Ternes, supra note 9, at 912.
56 Simon Webb et al., Indirect human exposure to pharmaceuticals via drinking water, 142 TOXICOLOGY LETTERS 157, 160 (2003).
57 Id. at 165.
surface waters in environmental sampling in various locations. This is by no means an exhaustive list.

Table 1: Detected Concentrations of Various Drugs in Environmental Samples

<table>
<thead>
<tr>
<th>Drug</th>
<th>Treatment purpose</th>
<th>Concentrations detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bezafibrate</td>
<td>Lipid regulator</td>
<td>3.1 ppb</td>
</tr>
<tr>
<td>Bisoprolol</td>
<td>Beta-blocker</td>
<td>2.9 ppb</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>Analgesic/antiepileptic</td>
<td>1.1 ppb</td>
</tr>
<tr>
<td>Diclofenac-Na</td>
<td>Analgesic/anti-inflammatory</td>
<td>1.2 ppb</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>Analgesic/anti-inflammatory</td>
<td>0.53 ppb</td>
</tr>
<tr>
<td>Metoprolol</td>
<td>Beta-blocker</td>
<td>2.2 ppb</td>
</tr>
<tr>
<td>Naproxen</td>
<td>Analgesic/anti-inflammatory</td>
<td>0.39 ppb</td>
</tr>
</tbody>
</table>

While pharmaceuticals in water may occur in concentrations far below medical doses, they do still have biological effects. For example, increased use of pharmaceuticals is contributing to endocrine disruption and antimicrobial resistance. Endocrine disruption occurs when chemicals that have a tendency to mimic naturally-occurring hormones interact with organisms. The endocrine system produces hormones, which serve to send chemical messages to different parts of the body to regulate such things as growth and development, reproduction, food metabolism, sexual function, and mood. The consequences of the exposure to the mimicking chemical are numerous: the chemical can trick the body into inappropriately responding to certain stimuli (either over-responding, under-responding, or responding at an inappropriate time), it can decrease the effectiveness of natural hormones by blocking them from reaching the receptors, and it can even directly affect the endocrine system by causing over or

58 Information in table pulled from Daughton & Ternes, supra note 9, at 913-21.
59 GEORGE WASHINGTON SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES, supra note 9, at 4.
underproduction of hormones themselves. We use some drugs for their endocrine-disrupting properties—for example, chemical birth control. However, the effects of unwanted endocrine disruption are numerous and potentially serious. One article lists several possible human health effects of endocrine disruption, including “breast cancer and endometriosis in women, testicular and prostate cancers in men, abnormal sexual development, reduced male fertility, alteration in pituitary and thyroid gland functions, immune suppression and neurobehavioral effects.”

Bacterial resistance, another potential consequence of pharmaceutical pollution, has become more widespread as well, posing serious public health risks. Antimicrobial resistance is a naturally occurring phenomenon; however, when you magnify its effects, the consequences can be severe. When microbes face exposure to an antimicrobial agent, they have two options: die or adapt. The microbes that adapt then reproduce, passing on a gene for resistance to the antimicrobial agent, thus creating a population of microbes that are genetically resistant to that antimicrobial agent. One major factor exacerbates this naturally-occurring process: misuse/overuse of antimicrobial agents. In fact, scientists and others recognize that although antimicrobial agents have served tremendous good in improving human health and life

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63 Id.
64 Crisp et al, supra note 60, at 11.
65 Id. The same article lists some of the potential environmental effects of endocrine disruption as “abnormal thyroid function and development in fish and birds; decreased fertility in fish, shellfish, birds, and mammals; decreased hatching success in fish, birds, and reptiles; demasculinization and feminization of fish, birds, reptiles, and mammals; defeminization and masculinization of gastropods, fish, and birds; decreased offspring survival; and alteration of immune and behavioral function in birds and mammals.” Id. Keep in mind that humans are mammals.
66 Nidel, supra note 22, at 89-90.
68 Id.
69 Id.
expectancy, antimicrobial resistance is an unavoidable consequence.\textsuperscript{71}

Antimicrobial resistance is an especially serious problem at hospitals, where large concentrations of sick people (and bacteria) exist in a small area and doctors and hospital staff use antimicrobial agents \textit{en masse}.\textsuperscript{72} For example, one study examined bacterial resistance at three Croatian hospitals and found that at one, between forty and seventy-three percent of the \textit{E. coli} bacteria were resistant to several popular antibiotics.\textsuperscript{73} Additionally, \textit{Staphylococcus aureus} resisted a common antibiotic more than fifty percent of the time.\textsuperscript{74} Drug resistance represents a potentially serious public health problem.\textsuperscript{75} If bacteria develop resistance to pharmaceuticals and these bacteria cause infections in humans, then the potential for fatality rises because conventional treatments are more likely to fail.\textsuperscript{76} Even if hospitals implement best practices to reduce the perpetuation of antimicrobial resistance (more restricted use of antimicrobial agents, for example), antimicrobials released into the environment still pose similar threats in natural systems.

Another concern that has arisen is the possibility of allergic reactions to the residual pharmaceuticals in the water. Most authorities, however, find that current concentrations are too low to elicit allergic reactions, although allergic reactions could become a possibility if concentrations of pharmaceuticals in the drinking water increase.\textsuperscript{77}

Although there is currently very little concrete evidence linking pharmaceuticals in water

\textsuperscript{71} Vera Vlahovic-Palevski et al, \textit{Antimicrobial Utilization and Bacterial Resistance at Three Different Hospitals}, 17 EUR. J. EPIDEMIOLOGY 375, 375 (2001).
\textsuperscript{72} \textit{Id.} In fact, this article found that greater than one-half of hospital patients receive some sort of antimicrobial agent. \textit{Id.} at 376.
\textsuperscript{73} \textit{Id.} at 379.
\textsuperscript{74} \textit{Id.} at 375.
\textsuperscript{75} \textit{Id.} at 381.
\textsuperscript{76} Anderson et al, \textit{ supra} note 70, at 374.
\textsuperscript{77} GEORGE WASHINGTON SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES, \textit{ supra} note 9, at 4; Webb et al., \textit{ supra} note 56, at 158; KLAUS KUMMERER, \textit{PHARMACEUTICALS IN THE ENVIRONMENT: SOURCES, FATE, EFFECTS AND RISK} 83 (2004).
to adverse human health effects, scientists know very little about the impacts of pharmaceutical-contaminated water on humans.\textsuperscript{78} In fact, of the 3,000 pharmaceutical components that are currently in use, only 150 have undergone environmental studies.\textsuperscript{79} Predictions of effects on human health range from no impacts to apocalypse. One scientist’s view was that it was not necessary to expend the capital to update sewage treatment mechanisms to filter out pharmaceuticals.\textsuperscript{80} On the flip side, many scientists are emphasizing that lack of concrete results is more indicative of a deficiency of knowledge than the safety of long-term consumption of pharmaceutical-tainted water.\textsuperscript{81} In one study, breast cancer cells exposed to estrogens taken from fish caught near untreated sewage areas grew twice as fast as cells not exposed to these estrogens.\textsuperscript{82} An MSNBC article provided information from a study in which scientists exposed normal cells to a very low dose of a thirteen-drug mix similar to that found in Italian rivers.\textsuperscript{83} The result: cell growth slowed by one third.\textsuperscript{84} Other drugs, when introduced separately to cells, stimulated growth, but when combined resulted in slower growth than usual.\textsuperscript{85} This exhibits the danger of synergistic effects—a drug’s expected effect may be changed to an unknown degree when combined with other drugs.\textsuperscript{86}

The presence of pharmaceuticals in the water is especially a concern with regards to the more sensitive subpopulations, such as pregnant women, children, people with compromised immune systems, and the elderly.\textsuperscript{87} Developing fetuses are particularly vulnerable to external

\textsuperscript{78} Hemminger, supra note 8, at A679. See also, Halford, supra note 2.
\textsuperscript{79} GEORGE WASHINGTON SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES, supra note 9, at 3.
\textsuperscript{80} Halford, supra note 2.
\textsuperscript{81} GEORGE WASHINGTON SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES, supra note 9, at 3.
\textsuperscript{82} Francisco Pomati et al, Effects and Interactions in an Environmentally Relevant Mixture of Pharmaceuticals, 102 ENVTL TOXICOLOGY 129, 129 (2008).
\textsuperscript{83} How Meds in water could impact human cells, supra note 83.
\textsuperscript{85} Id.
\textsuperscript{86} Id.
\textsuperscript{87} Statement of Dr Matthews C Larsen, USGS, to the Committee on transportation and infrastructure 5 (Sept. 18, 2008), www.usgs.gov/congressional/hearings/docs/larsen_27oct09.doc.
chemical and hormonal changes, and scientists are examining links between endocrine disruption and developmental problems in fetuses and young children.\textsuperscript{88} Hormones from the mother’s thyroid are particularly essential to fetal brain development, and even a minor adjustment during fetal development in concentration of that hormone can result in “significant changes in intelligence in children.”\textsuperscript{89} Furthermore, scientists in the United Kingdom have linked the presence of hormones in the environment with “lowered sperm counts and gynecomastia—the development of breasts in men.”\textsuperscript{90}

Some people take the view that the lack of direct evidence linking pharmaceutical contaminated water and human impacts is proof that we need not worry, but this is a shortsighted view that ignores the possibility of currently unknown direct or indirect impacts on humans.\textsuperscript{91} Environmental impacts, discussed below, have the potential to enormously impact human lives.\textsuperscript{92}

In the environment, endocrine disruption and antimicrobial resistance are also two of the broader problems pharmaceutical contamination could cause. Endocrine disruption is of particular concern because it can happen with exposure to very low concentrations of the relevant chemicals.\textsuperscript{93} Endocrine disruption causes, for example, feminization of fish, which can cause such impacts as:

1. a higher percentage of females in some fish populations than commonly expected,
2. changes in behavioral characteristics, such as nesting behavior, or
3. the presence of male fish with female characteristics, such as the presence of female egg cells in testes or of a female egg protein in their blood.\textsuperscript{94}

\textsuperscript{88} See, e.g., Theo Colborn, \textit{Neurodevelopment and Endocrine Disruption}, 112 ENVTL. HEALTH PERSPS. 944, 945 (2004).

\textsuperscript{89} \textit{Id.} The author is not exaggerating when he says “minor” – one study collected blood from women during pregnancy and tested the child’s IQ test seven years later. The study found that children with thyroid hormone concentrations which were 1.5 parts per trillion lower scored four points lower on IQ tests than the children with the higher concentration. \textit{Id.} at 945-46.

\textsuperscript{90} Royte, \textit{supra} note 1, at 30.

\textsuperscript{91} Nidel, \textit{supra} note 22, at 88.

\textsuperscript{92} \textit{Id.} at 84.

\textsuperscript{93} Statement of Dr Matthews C Larsen, \textit{supra} note 87, at 4.

\textsuperscript{94} \textit{Id.}
Water $R_x$

Scientists originally discovered feminized fish in the U.K. but are now finding them in surface water across Europe and the United States. What impacts do feminized fish have upon the general population? Scientist seeded one lake in Canada with a specific concentration of estrogen that mimicked a concentration found in municipal water bodies. Scientists observed the fathead minnow and found that feminization of males resulted in a dramatically decreased population of the species of fish studied. At the end of a four-year period “the fish had all but disappeared from the lake.” Even if the pharmaceuticals themselves do not persist in the tissues of organisms, continual discharge of these compounds into the environment results in a continuous and unremitting exposure. The fish studied were relatively close to the bottom of the food chain, so it is important to note that decreases in the population of these fish can reverberate all the way up to higher-order predators.

A different study examined the effect of birth control on fathead minnows. This study found that when fathead minnows spend their entire lifecycle in the presence of birth control, they become completely feminized. Fish that are males, genetically, express female characteristics and are unable to mate or fertilize eggs. Scientists observed these effects in water with synthetic estrogen concentrations as low as three parts per billion, a concentration

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95 Halford, supra note 2.
96 Id.
97 Id.
98 Id. Interestingly, three years after the scientists ceased adding the estrogen, the targeted species population rebounded. Id.
99 Campbell, supra note 5, at 11202.
100 The targeted species of fish was not the only species to suffer population declines—another species which fed on the species studied also suffered a 30% population decline. Halford, supra note 2. One group of scientists traced the cause of a mass vulture die-off to an anti-inflammatory, which they suspected the birds had ingested from their primary food source: dead domestic livestock. J. Lindsay Oaks et al, *Diclofenac residues as the cause of vulture population decline in Pakistan*, 427 NATURE 630, 630-31 (2004).
101 Environment Canada, supra note 2; see also Nash et al, supra note 4, at 1726.
102 Environment Canada, supra note 2
103 Id.
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achieved by placing one birth control pill into 2,641 gallons of water.\(^{104}\) Interestingly, “[a] human female using the birth control pill will excrete this amount in her urine over the course of a single day.”\(^{105}\)

Another study found that presence of antidepressants in the water had a myriad of effects on the aquatic flora and fauna.\(^{106}\) These effects include triggering of spawning in bivalves and crustaceans, decrease in prey capture ability, and reduced predator avoidance.\(^{107}\) Activities such as spawning and prey capture directly affect the survival of the animal and the species, and if these activities are adversely affected, the individual animal or species as a whole can suffer.\(^{108}\)

Antimicrobial resistance is not a phenomenon restricted to hospitals; it also exists in the environment.\(^{109}\) In fact, one study found increased levels of antibacterial-resistant *Enterococci* in surface and ground water downstream from a swine feeding operation.\(^{110}\) Thus, it is clear that pharmaceuticals in the water pose a very significant risk to both humans and the environment.

II. Current State of the Law

Currently, from an environmental perspective, the law does not effectively regulate the disposal of pharmaceuticals. In fact, under our current legal and regulatory regime, the law recognizes pharmaceuticals as only a health concern or only an environmental concern, but never both. Thus, current statutes address the problem in one context or the other, but no current law connects the two, addressing pharmaceuticals as a problem in both spheres.

\(^{104}\) Id.
\(^{105}\) Id. Ten million women in the United States take birth control pills, a similar number are on hormone-replacement therapy. Royte, *supra* note 1, at 28.
\(^{107}\) Id.
\(^{108}\) Id.
\(^{110}\) Id.
Nevertheless, there are several potentially relevant statutes that might regulate the
disposal of pharmaceuticals and their contamination of water:

- Federal Food, Drug, and Cosmetic Act\textsuperscript{111}
- National Environmental Policy Act\textsuperscript{112}
- Clean Water Act\textsuperscript{113}
- Safe Drinking Water Act\textsuperscript{114}
- Resource Conservation and Recovery Act\textsuperscript{115}
- Toxic Substances Control Act\textsuperscript{116}

This part will discuss each in turn.

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

The federal agency responsible for the regulation of pharmaceuticals is the Food and
Drug Administration (FDA).\textsuperscript{117} The primary goal of the FDA is to ensure the safety and quality
of food, drugs, and other health care products, animal food and drugs, and cosmetics.\textsuperscript{118} The
agency’s primary goal is not the promotion of environmental stewardship, and intuitively it
seems that these goals can be at odds because the agency is statutorily obligated to prioritize
protection of public health,\textsuperscript{119} not protection of environmental health. Thus, it seems that the
FDA’s approach to regulation of drugs slights the environment. The Federal Food, Drug, and
Cosmetic Act\textsuperscript{120} and the National Environmental Policy Act\textsuperscript{121} are two statutes relevant to the
FDA’s regulation of pharmaceuticals in the environment.

1. Federal Food, Drug, and Cosmetic Act

The FDA requires that pharmaceuticals undergo a risk evaluation prior to entering the

\begin{tab}
\textsuperscript{117} 21 U.S.C. §393(b).
\textsuperscript{118} Id.
\textsuperscript{119} Id.
\textsuperscript{120} 21 U.S.C. §301.
\textsuperscript{121} 42 U.S.C. §§ 4321-4370f.
\end{tab}
However, the risk evaluation criteria do not include any environmental considerations. Many people consider these risk assessments to be generally ineffective because they take a short-sighted view of adverse impacts. These assessments do not consider impacts on other aspects of environmental health, such as breeding or behavior, which pharmaceuticals can adversely impact. Additionally, drugs can often present latent harms, meaning that adverse effects can take decades or longer to realize. Sometimes impacts do not even manifest until the second generation of organisms.

Additionally, organisms do not usually face exposure to one drug in isolation—some drugs may break down into their components and/or combine with other drugs already present in the water supply, causing a synergistic effect that may result in impacts not predicted by either drug alone. Thus, the FDA has, for the most part, allowed pharmaceutical contamination to fall through the cracks of FDCA regulation.

2. National Environmental Policy Act

The National Environmental Policy Act (NEPA) is also relevant to the approval of drugs because this Act requires all federal agencies to consider the environmental impacts of each major action that they take. All federal agency actions must comply with NEPA, which requires that the agency “prepare a detailed statement...on (i) the environmental impact of the proposed action, (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented, (iii) alternatives to the proposed action” for every “major federal

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122 Id. at §355-1.
123 Id. at § 355-1(a)(1)(A)-(F).
124 Halford, supra note 2.
125 Daughton & Ternes, supra note 9, at 935.
126 Campbell, supra note 5, at 11203
127 One noted possible consequence of exposure to endocrine disrupting compounds is decreased offspring survival. Crisp et al, supra note 60, at 12.
128 Halford, supra note 2.
action[] significantly affecting the quality of the human environment[].”\textsuperscript{131} Generally, agencies will first prepare an environmental assessment, and, based on whether the assessment reveals a significant environmental impact, either proceed with the action or prepare an environmental impact statement.\textsuperscript{132} Thus, it seems that pharmaceuticals that are potentially dangerous for the environment could be more strictly regulated at this phase. The FDA could be required to conduct at least an environmental assessment for all new drug approvals, which would serve an information-gathering function.

NEPA allows federal agencies to categorically exclude some classes of actions from the environmental impact statement requirement because “these actions individually or cumulatively do not significantly affect the environment.”\textsuperscript{133} The categorical exclusion regulations have resulted in the environmental impact analysis requirement not being as effective in preventing environmental contamination as it potentially could be, partly because the FDA has allowed a blanket categorical exclusion for drugs so long as concentrations at the point of entry into the environment are below one part per billion.\textsuperscript{134} It is important to note that adverse impacts from some contaminants, namely estrogens, can occur at the threshold of detection, which is in the low parts-per-trillion.\textsuperscript{135} Another exception to the NEPA requirement applies to “substances that occur naturally in the environment”\textsuperscript{136} and to applications for new drugs intended for use on nonfood animals.\textsuperscript{137} Thus, many drugs are actually categorically excluded from NEPA’s

\textsuperscript{131} Id.
\textsuperscript{132} Environmental Protection Agency, Frequently Asked Questions, National Environmental Policy Act, http://www.epa.gov/compliance/resources/faqs/nepa/index.html (last visited Apr. 20, 2010). An environmental impact statement need not be prepared if there is a “finding of no significant impact” as a result of the environmental assessment. Id.
\textsuperscript{133} PHARMACEUTICALS & PERSONAL CARE PRODUCTS IN THE ENVIRONMENT, supra note 23, at 321.
\textsuperscript{134} 21 C.F.R. §25.31(b) (2009).
\textsuperscript{135} Halford, supra note 2 and Bligh, supra note 27, at 56.
\textsuperscript{136} 21 C.F.R. §25.31(c) (2009).
\textsuperscript{137} 21 C.F.R. §§ 25.31(c), 25.33 (2009). There is an exception to the exceptions discussed here if “extraordinary circumstances indicated that the specific proposed action may affect the quality of the human environment[,]” even if the concentrations will be below one part per billion. 21 CFR § 25.21 (2009).
environmental impact assessment requirement.

The FDA requires completion of an environmental assessment for every action that is not categorically excluded.\footnote{21 C.F.R. §25.15 (2009). Also, 21 CFR §25.20 (2009) lists several situations which ordinarily require preparation of an environmental assessment.} The FDA regulations do not categorically exclude some new drug applications or all investigational new drug applications.\footnote{21 C.F.R. §25.20(l) (2009).} However, there are no regulations that automatically require preparation of an environmental impact statement.\footnote{21 C.F.R. §25.22 (2009).} Instead, as with NEPA regulations, an EIS is only required if, upon preparation of the environmental assessment, the evaluating authority (the FDA) determines that significant environmental harm is likely.\footnote{\textit{Id.}}

The approach that the FDA takes to the completion of an EIS, if required, is somewhat troubling. The agency’s regulations state that “if FDA determines that an EIS is necessary for an action...an EIS will be prepared but will become available only at the time of approval of the product[,]”\footnote{21C.F.R. §25.52(a) (2009).} and the only opportunity for comment is after the EIS is released (after approval of the substance).\footnote{21 C.F.R. §25.52(b) (2009).} Thus, the only opportunity for the public to learn of the potential environmental impacts and contribute comments is after the drug’s approval and release into the market. This approach seems to run counter to the way that NEPA functions in other regulatory situations–generally, the agency must complete the EIS and clear up challenges relating to the EIS prior to the agency taking action.\footnote{COUNCIL ON ENVIRONMENTAL QUALITY, A CITIZEN’S GUIDE TO THE NEPA: HAVING YOUR VOICE HEARD 5 (2007), http://ceq.hss.doe.gov/nepa/Citizens_Guide_Dec07.pdf.}

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

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

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

1. Clean Water Act

The national law governing water pollution is the Clean Water Act (CWA). This

146 Nidel, supra note 22, at 94.
147 Environmental Protection Agency, Our Mission and What We Do, http://www.epa.gov/epahome/whatwedo.htm (last visited April 21, 2010).
149 See the statutes outlined in the remainder of this section
150 33 U.S.C. §§ 1251-1387. The congressional declaration of goals in this statute states that its purpose is the
statute provides a permitting scheme for the discharge of pollutants from a point source into navigable waters and makes it illegal for point sources to discharge pollutants if not in compliance with this permitting scheme.\textsuperscript{151} Thus, this statute is relevant for such things as industrial discharges, sewage treatment, concentrated animal feeding operations (CAFOs), aquaculture, and other point sources.\textsuperscript{152} These are all potentially significant sources of pharmaceutical contamination.

Nevertheless, the CWA does not (yet) address discharges of pharmaceuticals, so none of these sources are regulated with respect to discharge or release of pharmaceutical compounds.\textsuperscript{153} Several reasons exist for the EPA’s failure to regulate pharmaceuticals under the CWA: the statute was designed before people were aware of the danger of many emerging contaminants (pharmaceuticals included), and thus the statute could not propose regulation of something which was not yet a known problem.\textsuperscript{154}

Municipal water treatment plants are considered to be point sources\textsuperscript{155} under the statute, meaning that the EPA has the authority to regulate their effluent discharges under the CWA. Unfortunately, pharmaceuticals are unregulated contaminants and thus treatment plants are not

\begin{itemize}
\item \textsuperscript{151} 33 U.S.C. § 1311(a). The permitting scheme is known as the National Pollutant Discharge Elimination System and is found in 33 U.S.C 1342.
\item \textsuperscript{152} Environmental Protection Agency, Clean Water Act, http://www.epa.gov/agriculture/lcwa.html#Nonpoint Source Pollution and Agriculture (last visited Apr. 5, 2010). Point source is defined in 33 U.S.C. §1362(14)as “any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged.”
\item \textsuperscript{153} Regulations exist which apply to pharmaceutical manufacturing facilities, but these regulations only address things such as volatile organic compounds, biological oxygen demand, and suspended solids and do not directly address or limit discharge of pharmaceuticals themselves. Pharmaceutical Manufacturing Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards, 63 Fed. Reg. 50,388, 50,389 (Sept. 21, 1998) (to be codified at 40 C.F.R. pt. 136 & 439).
\item \textsuperscript{154} THE JOHNSON FOUNDATION AT WINGSPREAD, CONSIDERING THE CLEAN WATER ACT 11 (2009), http://nicholas.duke.edu/institute/clean.water.2010.pdf. The same source also cited lack of funding and limited jurisdiction as other shortcomings of the CWA. \textit{Id.} at 11-13.
\item \textsuperscript{155} 33 U.S.C. § 1362(14).
\end{itemize}
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designed to remove them from the water\textsuperscript{156} or monitor for their presence.\textsuperscript{157} However, the fact
that the EPA does not regulate pharmaceutical contaminants released from point sources under
the CWA does not change the fact that the agency \textit{could} do it, and the viability of this option will
be examined in Part IV.

Unfortunately, the CWA does not provide jurisdictional authority to regulate non-point
sources, which excludes some potential sources of pharmaceutical contamination. Livestock
operations not considered to be CAFOs\textsuperscript{158} are one example–these animals still receive antibiotics
and hormones but the operations are not regulated point sources because they do not meet the
CAFO criteria.\textsuperscript{159}

The CWA serves as a technology-forcing mechanism in some respects through its
technology-based standards.\textsuperscript{160} Under section 301(b)(2)(A), the EPA has the authority to require
dischargers of toxic pollutants (those which are not biodegradable and create a risk of substantial
human health impairment)\textsuperscript{161} to use the best available technology economically achievable to
minimize toxic pollution.\textsuperscript{162} Thus, this statute establishes a floor for the treatment technology
that dischargers must use. The CWA regulates publicly owned treatment works (POTWs), but

\textsuperscript{156} EPA, Pharmaceuticals and Personal Care Products, FAQs, http://www.epa.gov/ppcp/faq.html (last visited Feb. 2, 2010).
\textsuperscript{157} Michael J. Focazio et al, \textit{A National reconnaissance for pharmaceuticals and other organic wastewater contaminants in the United States – II) Untreated drinking water sources}, 402 SCI. TOTAL.ENV’T 201, 202 (2008). The EPAs Unregulated Contaminant Monitoring Rule does require that facilities which provide public water monitor several specific unregulated contaminants however pharmaceuticals are not included in this requirement. \textit{Id.}
\textsuperscript{158} CAFO is defined in 40 C.F.R. § 122.23(b) as operations where animals are held and fed for forty-five days or more in a twelve month period and where no vegetation is sustained.
\textsuperscript{159} Environmental Protection Agency, Clean Water Act, http://www.epa.gov/agriculture/lcwa.html#Nonpoint Source Pollution and Agriculture, (last visited Apr. 5, 2010).
they are subject to different technology-based effluent limitations. These regulations prohibit certain discharges from the POTW and establish pretreatment standards for water to be discharged into POTWs to help ensure the most effective functioning of these facilities. One thing that these regulations prohibit is pass through, which means that inputs into the POTWs may not result in discharge out of the POTW in violation of the POTW’s CWA permit. If pharmaceuticals were included in the POTW’s CWA permit, and the water delivered to the POTW contained concentrations above the limits in the permit, it seems like these inputs might be considered pass through because current treatment processes do not remove pharmaceutical compounds. This means that the pharmaceutical concentrations in the output would be the same as the pharmaceutical concentrations in the input, and if the CWA permit placed limits on concentration of pharmaceuticals, the output could potentially be a violation of the concentrations listed in the permit. Thus, the user inputting the pharmaceutical-contaminated water would be in violation of the national pretreatment standards. This is a tool that the EPA could use to regulate the discharge of pharmaceuticals.

2. Safe Drinking Water Act

Under the Safe Drinking Water Act, the EPA regulates drinking water. This Act requires the agency to establish drinking water quality standards that states and localities must implement. The standards regulate both naturally-occurring and manmade contaminants and are health-based in nature. More specifically, under the Act, the EPA must promulgate

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164. 40 C.F.R. §403.5, §403.6, §403.2
169. Id.
standards for listing contaminants,\textsuperscript{170} which the EPA then regulates as “listed.”\textsuperscript{171}

Although treatment was originally the focus of this act, some of the focus has shifted to protection of source waters.\textsuperscript{172} Thus, this Act has the potential to become an extremely useful tool in the regulation of pharmaceutical contaminants, but it has yet to realize that potential.

The EPA has been slow to develop standards for listed substances\textsuperscript{173} and the statute excludes many pharmaceuticals from the list of regulated contaminants because they exist in the environment in such low concentrations.\textsuperscript{174} The presence of pharmaceuticals in such low concentrations presents a difficult situation for regulators because, although most of the pharmaceuticals that they could regulate as contaminants under the SDWA occur in concentrations below those known to cause adverse health effects,\textsuperscript{175} scientists and researchers know very little about the impacts of exposure to low concentrations of pharmaceuticals over a long period of time.\textsuperscript{176} Thus, it is difficult to use a health-based rationale to regulate contaminants when so little is known about health impacts of exposure to residual pharmaceuticals in the water and there is no concrete data linking the two.\textsuperscript{177} Nevertheless, the SDWA represents another potential tool that the EPA has at its disposal to regulate.

\begin{itemize}
\item The standards are “that(i)the contaminant may have an adverse effect on the health of persons; (ii)the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and (iii)...regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.” 42 C.F.R. §300g-1(b)(1)(A) (2009)
\item 42 C.F.R. §300g-1(b)(1)(A) (2009).
\item EPA was supposed to have developed standards for eighty-three contaminants by 1995, although in 2002 standards were in place for only sixty-seven. Campbell, \textit{supra} note 5, at 11207.
\item See \textit{Testimony of Benjamin H. Grumbles, Environmental Protection Agency, to the Environment and Public Works Committee of the US Senate} 10 (Apr. 15, 2008), http://www.epa.gov/ow/speeches/final_testimony_bg_pharms_in_water_4.14.08.pdf. (explaining that in a recent draft contaminant list, 287 pharmaceutical and personal care products were considered but only one was added). See also \textit{George Washington School of Public Health and Health Services, \textit{supra} note 9, at 5} (pointing out that the one pharmaceutical nominated for regulation, nitroglycerin, was nominated because of its possible use in explosives, not because of its environmental consequences or concentrations).
\item \textit{Testimony of Benjamin H. Grumbles, \textit{supra} note 174, at 10.}
\item \textit{Id.} at 4.
\item Hemminger, \textit{supra} note 8, at A679. \textit{See also}, Halford, \textit{supra} note 2.
\end{itemize}
pharmaceuticals in the water.

3. Resource Conservation and Recovery Act

Another environmental statute that regulates pharmaceutical disposal is the Resource Conservation and Recovery Act (RCRA),\textsuperscript{178} which regulates the land disposal of hazardous and solid waste.\textsuperscript{179} RCRA’s purpose is to prevent the improper disposal of hazardous waste by regulating the entities that manufacture, transport, store, and dispose of the waste.\textsuperscript{180} RCRA allows the EPA to designate certain wastes as hazardous, but exclusion from the list does not mean that the waste is not hazardous.\textsuperscript{181} Thus, RCRA also contains criteria for determining whether the EPA would consider the non-listed waste to be hazardous, based on its characteristics.\textsuperscript{182} RCRA exempts from its regulation domestic sewage and anything else from a domestic source that passes to a publicly owned treatment facility,\textsuperscript{183} meaning that RCRA does not provide the EPA with jurisdiction over pharmaceuticals that people flush, directly or indirectly. This exemption is likely in place because the CWA potentially covers those discharges.

Nevertheless, hospitals and nursing homes are subject to RCRA’s provisions.\textsuperscript{184} Because they could be considered both generators\textsuperscript{185} of hazardous waste and treatment, storage, and disposal facilities,\textsuperscript{186} they are potentially subject to the regulations for both kinds of entities.\textsuperscript{187}

\textsuperscript{182} Id.
\textsuperscript{183} 40 C.F.R. § 261.4(a)(1) (2009).
\textsuperscript{184} Teirney Christenson, Fish on Morphine, 2008 WISC. L. REV. 141, 150-51 (2008).
\textsuperscript{185} “Generator means any person, by site, whose act or process produces hazardous waste identified in...this chapter or whose act first causes a hazardous waste to become subject to regulation.” 40 C.F.R. § 260.10 (2009).
\textsuperscript{186} Treatment, storage, and disposal facilities are defined as “[a]ll contiguous land, and structures, other appurtenances, and improvements on the land, used for treating, storing, or disposing of hazardous waste, or for managing hazardous secondary materials prior to reclamation.” 40 C.F.R. § 260.10 (2009).
Thus, they must determine whether or not the wastes that they have are hazardous, they must maintain a manifest for the wastes that are considered hazardous, and, because they often store the potentially hazardous pharmaceuticals, the facility must comply with the RCRA storage requirements as well. A waste is considered to be a hazardous under RCRA if it exhibits the following characteristics: ignitability, corrosivity, reactivity, or toxicity. Some pharmaceuticals do meet these characteristics; for example, nitroglycerine may exhibit reactivity and pharmaceuticals containing such chemicals as arsenic, chromium, or mercury may exhibit toxicity.

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

A noted in Part I, another source of pharmaceutical contamination is landfill leachate, and thus the landfill provisions of RCRA are also relevant for the disposal of pharmaceuticals.

These regulations require that landfills use liners to prevent waste migration and groundwater

191 40 C.F.R. §§ 261.21 – 261.24 contains the definitions of these different characteristics.
193 Several pharmaceuticals are contained on RCRAs P-list, found at 40 CFR 261.33, such as epinephrine, nicotine, and nitroglycerine.
194 Christenson, supra note 184, at 150-51.
195 Environmental News Stand, EPA urged to up RCRA Pharmaceuticals Enforcement at Hospitals, July 1, 2009, http://environmentalnewsstand.com/insider_special.asp?issue=POLICYALERT-26-13-5. According to the same coordinator, the problems with the listing of pharmaceuticals as hazardous wastes is serious: “a large number of prescription drugs are considered non-hazardous by RCRA regulations, despite evidence that they contain cancerous agents.” Id.
196 These provisions are found in subpart N of 40 C.F.R. § 264.
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contamination. Additionally, the RCRA landfill regulations require landfills to install several leachate collection and removal mechanisms throughout the facility and to have systems designed to prevent stormwater from running into the active parts of the landfill.

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

Additionally, this amendment proposes removing RCRA barriers that pharmaceutical collection and take-back facilities face to encourage proper disposal. When RCRA regulations

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197 40 CFR § 264.301(a)
198 40 CFR § 264.301(a)(2). This section of the regulations does not mandate that anything specific be done with the leachate collected from the collection system. This has a potential to be another source of pharmaceutical contamination because if the leachate is subjected to the customary wastewater treatment mechanism, the pharmaceutical compounds will likely remain in the water because normal treatment does not remove these compounds. Environmental Protection Agency, Pharmaceuticals and Personal Care Products, Frequently Asked Questions, http://www.epa.gov/ppcp/faq.html (last visited Feb. 2, 2010).
199 40 C.F.R. §264.301(g) (2009).
203 Id. at 73,530.
204 Id. at 73,522.
apply to pharmaceutical collection programs, they make the programs more difficult and expensive to run because the programs must observe RCRA’s requirements for treatment, storage, and disposal facilities. The EPA’s proposed rule would remove some of the RCRA requirements (such as hazardous waste determination and storage time limits) for facilities that accumulate pharmaceutical waste. For example, the rule would allow common carriers to transport pharmaceutical wastes, instead of certified hazardous waste transporters. Additionally, facilities would not have to separate out different kinds of wastes, as they do under RCRA in general. One of the justifications for these dispensations is that these wastes present a relatively low environmental risk during accumulation and transport compared to other, more volatile, wastes. This proposed amendment has the potential to result in proper disposal of greater quantities of pharmaceuticals. If hospitals and nursing homes are subject to less stringent regulations, they are more likely to comply, thus properly disposing of more pharmaceuticals.

4. Toxic Substances Control Act

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

205 Id. at 73,528.
206 Id. at 73,522.
207 Id. at 73,530.
208 Id.
209 Id. at 73,529.
212 See, e.g., Lautenberg says TSCA reform bill coming; manufacturers must prove chemicals safe, Daily Env’t Rep. (BNA), 23 DEN A-4 (Feb 5, 2010).
III. A Look into the Future

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

a. Interagency Workgroup

Federal agencies are making efforts to tackle the problem of pharmaceuticals in the water. Several agencies came together in 2006 to establish a federal interagency work group co-chaired by the USGS, EPA, and FDA to address pharmaceuticals in the environment.\textsuperscript{213} The goal of this group is to increase coordination between the agencies and to facilitate additional research on the issue.\textsuperscript{214} Subsequent evaluation of this group, however, has been riddled with criticism. As reported in the Associated Press, this work group “missed its deadline and failed to produce mandated reports and recommendations[.]”\textsuperscript{215} Much of the documentation relating to this task force is classified and is thus not available for public consumption, making it nearly impossible to track the progress and effectiveness of the group.\textsuperscript{216}

b. Pharmaceutical Take-Back Programs

The 2009 Congress was a busy time for the issue of pharmaceuticals, with several bills addressing their proper disposal and contamination of water.\textsuperscript{217} Although none of these bills made it all the way to the President, they suggest a growing congressional concern about pharmaceutical contamination of the water and an increased desire to address it.

Several of the bills proposed creation of a pharmaceutical take-back program, which is an


\textsuperscript{214} Id.

\textsuperscript{215} Martha Mendoza, Water task force misses target, Seattle PI, Apr. 14, 2008.

\textsuperscript{216} Id.

idea that has been growing in popularity in recent years. A variety of take-back programs currently exist; for example, Michigan, Maine, and Minnesota all have programs up and running. Federal legislation governing these programs generally would have involved local or state government agencies providing some sort of mechanism for people to properly dispose of their unwanted pharmaceuticals. Some of these programs proposed a mail-back program, where people would mail their unused and unwanted drugs to a processing and disposal venue. Other programs would have established a location where people take their unwanted pharmaceuticals, similar in idea to hazardous waste disposal facilities that many local landfills provide. Yet a third option for take-back programs would have been holding pharmaceutical drives, in which state or local officials establish a temporary pharmaceutical disposal site for one or two days, usually in a busy location, where people can bring their unwanted pharmaceuticals for proper disposal. This approach is similar in nature to electronics drives, where old and broken electronics equipments are collected at a temporary location to ensure recycling and proper disposal. Some municipalities could utilize one or all of these collections mechanisms. In fact, one website is dedicated to promoting pharmaceutical take-back and provides a central

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218 According to The Drug Take Back Network, twenty-one states have some sort of pharmaceutical take back program. The Drug Take-Back Network, Local Efforts, http://www.takebacknetwork.com/local_efforts.html (last viewed Apr. 3, 2010).
220 See Michigan’s program, supra note 219.
221 See Maine’s program, supra note 219.
222 See Minnesota’s program, supra note 219.
223 For example, a recent pharmaceutical collection drive in Ithaca collected nearly one ton of unwanted medication, including some medication that was nearly 100 years old. Stacey Shackford, Pharmaceutical collection event draws hundreds, ITHACA JOURNAL, Mar. 9, 2010, http://www.theithacajournal.com/article/20100308/NEWS01/3080361/Pharmaceutical-collection-event-draws-hundreds.
224 See e.g., Mike Leonard, IU plans electronic waste collection drive April 8-10, HERALD-TIMES, Mar. 23, 2010.
resource for people to learn about the take-back programs in their home state.\textsuperscript{225}

Not all reviews of the take-back programs are positive, however. One article highlights a Minnesota take-back program, in which the sheriff’s office collects unwanted pharmaceuticals at a drop site and then sends the drugs to an incinerator.\textsuperscript{226} Although incineration effectively prevents the drugs from contaminating the water supply, it raises questions about air contamination, seemingly shifting the pollution from one medium to another. Furthermore, these programs are not free,\textsuperscript{227} raising issues of funding sources.

One bill from the 2009 Congress proposes facilitating state pharmaceutical take-back programs as well as prohibiting drug labels containing recommendations to flush unwanted medications.\textsuperscript{228} Another bill proposes creation of a task force to provide environmentally-sound recommendations for the proper disposal of unwanted pharmaceuticals by consumers and health care providers and to develop a strategy for a widespread public education campaign on the recommendations.\textsuperscript{229} Yet another bill proposes a study “on the presence of pharmaceuticals and personal care products...in the waters of the United States.”\textsuperscript{230} Additionally, many states are trying to force pharmaceutical companies to pay for the various take-back programs, although pharmaceutical corporations are not willingly supporting this idea.\textsuperscript{231}

In addition to these federal proposals, states are beginning to take initiative as well. Many states have recently proposed legislation to establish drug take-back programs;\textsuperscript{232} unfortunately,
many of these bills failed to become law. Oregon’s program would have required drug
manufacturers to establish a convenient and environmentally friendly system for collecting and
disposing of unwanted pharmaceuticals.\(^{233}\) Minnesota’s Safe Drug Disposal Act of 2009 did
become law,\(^{234}\) but in a seriously denuded form when compared to the originally proposed
language.\(^{235}\)

Despite these legislative stalemates, some states do have programs up and running.\(^{236}\)
Under these programs, consumers with unwanted pharmaceuticals either mail these drugs in to a
central repository or bring their drugs to a collection site.\(^{237}\) Nonprofits have even begun to
produce guidance documents for states and localities seeking to establish their own take-back
programs.\(^{238}\)

While the take-back programs seem like a good idea, there are several problems that
these programs present. Most importantly, the Drug Enforcement Agency (DEA) “prohibits the
transfer of dispensed controlled substances from an individual to a doctor, pharmacist, reverse
distributor, or any other entity registered with the USDEA to handle or manage controlled
substances[,]” the only exception being in the circumstance of a recall.\(^{239}\) As a result, DEA
regulations authorize only a limited number of people to legally take back pharmaceuticals that

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\(^{233}\) Oregon HB 598 (2009).


\(^{235}\) This bill originally proposed that pharmaceutical companies could not sell their products in the state unless they
participated in a collection and disposal program. Minnesota H.F. 1217, 86th session, http://wdoc.house.leg.state.mn.us/leg/LS86/HF1217.0.pdf. What actually passed was essentially a series of minor adjustments to the statutory
language governing who is legally allowed to possess pharmaceuticals for the purpose of disposal. Minnesota H.F.

\(^{236}\) In fact, I received a flier in my local paper published by the Florida Department of Environmental Protection
which advertised a free medicine collection event. Flier on file with author.

\(^{237}\) See supra note 219.

\(^{238}\) See LYNN RUBINSTEIN, OPERATING UNWANTED MEDICATION COLLECTIONS – A LEGAL & SAFE APPROACH,
this document even launched pilot locations to analyze the response and amounts collected.

\(^{239}\) Id. at 5. See also Christenson, supra note 184.
are controlled substances, although law enforcement officials are included in this restricted exception.\textsuperscript{240} Thus, when operating a collection facility, law enforcement officers or DEA agents must be the parties responsible for accepting, taking possession of, and disposing of any controlled substances.\textsuperscript{241}

C. Potential Litigation

One author has examined the viability of judicial action by interested parties to force changes in the FDA’s approach to pharmaceutical regulation to incorporate environmental impacts.\textsuperscript{242} The author proposed that interested parties could use the courts to compel FDA action under the FDCA’s drug approval process or NEPA’s impact analysis requirement.\textsuperscript{243} Along the same vein, parties could also potentially sue the EPA to compel changes in its regulation of contaminants under the CWA. Several barriers exist to this option; the Administrative Procedure Act and the constitutional requirement of standing are two of the most notable.\textsuperscript{244}

Another possibility is suing drinking water providers or pharmaceutical companies for toxic torts for exposure to the pharmaceuticals in the water.\textsuperscript{245} A case search did not find any such cases, which is unsurprising considering the complicated nature of these types of cases and the limited state of the science to establish causation. There are many barriers to suit, legal and other. For example, any group bringing legal action would have to establish standing to sue.\textsuperscript{246} With the toxic tort possibility, plaintiffs must establish all of the elements of a torts claim, and

\begin{verbatim}
\textsuperscript{240} 21 C.F.R §1307.21 (2009).
\textsuperscript{241} Id.
\textsuperscript{242} See Nidel, supra note 22, at 95-100.
\textsuperscript{243} Id.
\textsuperscript{244} The purpose of this comment is not to delve into the APA or standing. For more information on how these two barriers operate with respect to suing the aforementioned agencies, see id.
\textsuperscript{245} A brief search in Lexis did not reveal any cases of this nature, likely because of the legal barriers discussed infra.
\textsuperscript{246} Plaintiff must establish (1) injury in fact, (2) traceability (ie some sort of causal connection between the defendant’s action and the harm realized), and (3) redressability (ie the court must be capable of remedying the injury). Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992).
\end{verbatim}
thus there must be some realized injury for which a plaintiff can demonstrate causation. Moreover, many pharmaceuticals are generally fungible, which presents another difficulty in establishing causation against a particular defendant pharmaceutical company.\textsuperscript{247} Establishing the elements of the claim would prove to be a particularly difficult problem to surmount for several reasons. First, people rarely live in the same place (and drink the same water) for their entire lives. Second, if the plaintiff had taken pharmaceuticals during his or her life, it may be nearly impossible to prove that the injury resulted from the unwanted rather than the wanted exposure.

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

\textbf{D. Other Countries’ Approaches}

Other countries are also beginning to deal with the pharmaceutical contamination problem. The European Union, through the European Medicines Agency (EMEA), began responding to this issue in 1999 when it began to develop environmental risk assessment procedures that would apply to applications for new pharmaceuticals.\textsuperscript{248} These risk assessments are required for new veterinary drugs and must include information about the possibility for

\begin{footnotesize}
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\item \textsuperscript{247} See, e.g., \textit{Hymowitz v. Eli Lilly & Co.}, 73 N.Y.2d 487, 503 (1989).
\end{itemize}
\end{footnotesize}
environmental exposure as well as a specific battery of effects testing.\textsuperscript{249} Unlike the FDA, the EMEA has even proposed a long-term ecotoxicity analysis.\textsuperscript{250}

E. Proposals for Improvement in the U.S.

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

The major difficulty with placing more restrictions upon the FDA’s drug approval process is the tension and competition that often exists between environmental protection and pharmaceutical innovation. Developing pharmaceuticals is enormously important to society and public health,\textsuperscript{251} but at the same time it is important to prevent unwanted exposure and environmental degradation.

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

A. Source-based protections

We should place a greater focus on source-based protections because they reduce the need for treatment-based protections. Treatment-based protections necessitate more physical change and investment because infrastructure actually has to be constructed or updated.

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\item \textsuperscript{249} The “[e]ffects testing includes algal growth inhibition, fish acute/chronic/bioaccumulation exposure, avian dietary and reproductive, earthworm toxicity, terrestrial plant growth, and activated sludge respiration inhibition.” Daughton & Ternes, supra note 9, at 935.
\item \textsuperscript{250} Musson et al, supra note 248.
\item \textsuperscript{251} See e.g., Vlahovic-Palcevski et al, supra note 71.
\end{itemize}
\end{footnotesize}
Furthermore, even the most advanced treatment processes are not 100 percent effective in removing pharmaceuticals from the water.\textsuperscript{252}

First, the FDA should remove its broad categorical exclusion from NEPA for drugs. Many drugs slip through the cracks with regard to environmental impact, partially because of this provision.\textsuperscript{253} NEPA does not mandate a specific action; however, allowing a categorical exclusion for drugs means that there are information deficits regarding these drugs and their environmental effects. While eliminating the broad categorical exclusions would not alone solve this problem, the EIS or even EA process would require much more information-gathering than currently occurs, which could help responsible parties to make informed decisions about whether or not the pharmaceuticals should be in the market. Notably, many of the drugs that are categorically excluded cause proven environmental harm at concentrations much lower than the concentration established for the categorical exclusion (ten ppb).\textsuperscript{254}

Second, Congress should amend the FDA’s governing legislation to mandate a more stringent risk assessment process. The FDA should be required to integrate an environmental risk analysis component into its regulatorily-mandated obligation. Similar to the process used in the EU, it should include a more long-term analysis. Certain compounds, such as endocrine disruptors, can cause environmental impacts at very low concentrations,\textsuperscript{255} which is why it is important to conduct more rigorous risk analysis.

Third, regulations that apply hospitals and nursing homes must also be stricter and must be better enforced. RCRA is an extremely valuable statute for this goal, and the proposed amendment to the Universal Waste Rule is a significant start in ensuring proper disposal of

\textsuperscript{252} Westerhoff et al, supra note 29, at 6659.
\textsuperscript{253} Supra Part II(a)(2).
\textsuperscript{254} Halford, supra note 2.
\textsuperscript{255} This is contrasted with the FDA’s protocol, which exempts drugs found in concentrations less than 1 part per billion from the assessment process. Musson et al, supra note 248.
pharmaceuticals. The amendment will remove some of the regulatory burden (and thus expense) from hospitals and nursing homes wishing to properly dispose of pharmaceuticals. However, the EPA must put a greater focus on enforcement. These entities should have a limited range of choices for disposal of unwanted pharmaceuticals, and the EPA should implement a more stringent penalty scheme and actually enforce it to help ensure compliance.

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

Fifth, we need to reconsider our current view on prescription practices. In many cases, doctors prescribe pharmaceuticals to patients in greater supplies and higher dosages than necessary, leaving a greater potential for leftover pharmaceutical to be disposed of improperly. Instead, doctors could prescribe in smaller quantities and allow for more refills, ultimately prescribing the same number of dosages but reducing the possibility for leftover

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256 Supra part II(B)(3).
257 See proposed legislation, supra notes 217.
258 Although see part II for a summary of the problems presented by these drives.
259 Christian G. Daughton, Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health. I. Rationale for and Avenues toward a Green Pharmacy, 111 ENVTL. HEALTH. PERSPS. 757, 768 (2003).
260 Id. at 767 (describing a study where patients prescribed antibiotics three days at a time nearly halved the use of the antibiotics and explaining other studies stating that dosages prescribed are usually significantly higher than the necessary therapeutic dose).
pharmaceuticals. Along the same vein, one article recommends that doctors and pharmaceutical
companies take a more individualized approach to prescribing medication, providing fluctuating
doses in response to an individual patient’s age, sex, health, weight, etc. Additionally, entities
such as the World Health Organization suggest that doctors should place a greater focus on non-
medicinal therapy, thereby reducing the stream of pharmaceuticals entering the environment.
A shift in prescription practices could help reduce the amounts of wasted pharmaceuticals,
especially in long-term care facilities and nursing homes where patients are often prescribed
many different medications at a time. One recent news article outlined a study that estimated
that a Minnesota nursing home with only 125 beds wasted approximately 35,000 tablets
annually. One group of scientists also presented proposals for reducing use of antimicrobial
agents for food animals.

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

Finally, we must also explore creative alternatives. One alternative that balances the

261 Id.
262 Florian Keil et al., Systemic Risk Governance for Pharmaceutical Residues in Drinking Water, 17 GAIA 355,
358 (2008); Daughton, Cradle-to-Cradle Stewardship I, supra note 260, at 766.
263 Meersman, supra note 219.
264 Id.
265 Anderson et al, supra note 70.
266 Americans over 65 years of age fill twice as many prescriptions as their younger counterparts. Royte, supra note
1, at 28.
267 Problems associated with these consequences are discussed supra part I(b).
competing interests of pharmaceutical development and environmental protection is the combination of green pharmaceuticals and green chemistry. Green pharmaceuticals involve designing drugs that biodegrade rapidly so their impact on the environment is minimal.\textsuperscript{268} Another goal explored by this movement is increasing the therapeutic efficacy of drugs so that less of the unmetabolized drug is excreted in waste.\textsuperscript{269} Green chemistry involves using new and innovative processes (and even chemicals) “to reduce waste which is formed during the synthesis of chemicals.”\textsuperscript{270} This idea has a lot of potential; however, the system is slow to change, so it probably would not result in immediate change. Indeed, one study found that “new knowledge gained from clinical trials takes an average of 17 years to become incorporated into routine practice.”\textsuperscript{271} Nonetheless, the government should encourage and incentivize research and development in the area of green pharmaceuticals.

B. Treatment-Based Protections

Once the FDA allows manufacturers to market drugs, too many drugs escape regulation by other agencies, especially the EPA, because of their low ambient concentrations. First, the EPA has unused regulatory authority at its disposal with respect to regulating pharmaceuticals in the environment. Now that we are able to detect these compounds below concentrations of parts per trillion,\textsuperscript{272} the EPA should list and regulate them under the SDWA and RCRA and should more stringently regulate treatment plants as point sources for these contaminants under the CWA. Furthermore, the EPA should, pursuant to the CWA, require that municipal treatment plants at least monitor for these contaminants. This monitoring would help to increase

\begin{itemize}
\item \textsuperscript{268} Florian Keil et al., supra note 262, at 358.
\item \textsuperscript{269} Daughton, Cradle-to-Cradle Stewardship I, supra note 259, at 765.
\item \textsuperscript{270} Klaus Kümmerer, Sustainable from the very beginning: rational design of molecules by life cycle engineering as an important approach for green pharmacy and green chemistry, 9 GREEN CHEMISTRY 899, 899 (2007). Some of the chemicals used in green chemistry may not, themselves, be biodegradable or non-persistent or toxic, but are used because they present the opportunity for an overall reduction of toxic chemicals in the environment. \textit{Id.}
\item \textsuperscript{271} Daughton, Cradle-to-Cradle Stewardship I, supra note 260, at 765.
\item \textsuperscript{272} Royte, supra note 1, at 30.
\end{itemize}
information regarding concentrations of pharmaceuticals in the water and would provide the agencies and public with a better idea of the quantities and types of pharmaceuticals being discharged into the environment.

Also under the CWA, the EPA could amend the POTW pretreatment regulations\textsuperscript{273} to include pharmaceuticals among the prohibited pollutants or included pharmaceuticals in the POTW’s National Pollutant Discharge Elimination System permit,\textsuperscript{274} shifting some of the regulatory burden off of treatment plants because dischargers into the treatment plants (indirect dischargers) would be responsible for their share of pharmaceutical contamination. Spreading regulatory and financial responsibility for treatment among different actors, rather than placing it solely with the POTW, could ease some of the burdens on POTWs and lower the costs to these facilities.

Second, municipalities must upgrade their wastewater treatment plants. One article considers two different possible options for reducing pharmaceuticals in the drinking water.\textsuperscript{275} One is urine separation, which would prevent the pharmaceuticals from reaching the wastewater in the first place.\textsuperscript{276} Through this process, wastewater that has the heaviest pharmaceutical contamination would be taken out of the drinking water treatment stream. Urine separation does not completely solve the problem, however, because treatment plants would still have to treat and dispose of this heavily pharmaceutically contaminated wastewater somehow. Additionally, this approach would require infrastructure development to allow for the separation of the source waters.

In the short term, the article recommends taking advantage of more effective available

\footnotesize\textsuperscript{273} Found in 40 C.F.R. § 403.5(b) (2009).  
\footnotesize\textsuperscript{274} This permit is issued pursuant to the CWA. This comment is not intended to be a review of the CWA permitting scheme.  
\footnotesize\textsuperscript{275} Webb et al., \textit{supra} note 56, at 164.  
\footnotesize\textsuperscript{276} \textit{Id.}
Water treatment technologies. Several studies have examined different treatment methods and their effectiveness in removing pharmaceuticals from water. One study found that the more advanced treatment options, such as “ozonation, activated carbon, and reverse osmosis and nanofiltration membranes” were the most effective in removing pharmaceuticals. Another study also found ozonation to be a very effective tool. Yet another study found that a combination of treatments brought concentrations of many organic contaminants (of which pharmaceuticals is a sub-category) to levels lower than analytical detection. Combining the more advanced treatment processes with the urine separation technique could allow for a better use of resources because the more expensive treatment process would be used only on the water truly needing it.

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

Conclusion

Pharmaceutical contamination of the water is becoming a pervasive problem, with many potential deleterious effects on humans and the environment. While there is a substantial

277 Id.
278 Halford, supra note 2.
279 PHARMACEUTICALS & PERSONAL CARE PRODUCTS IN THE ENVIRONMENT, supra note 23, at 51; Webb et al., supra note 56, at 164.
280 In this study, the original water contained thirty two contaminants. At the end of a three-phase treatment process, sixteen were undetected and seven decreased in concentration by 75% or more. Several of the compounds were fairly persistent and were reduced in concentration by smaller amounts. Paul E. Stackelberg et al, Efficiency of conventional drinking-water-treatment processes in removal of pharmaceuticals and other organic compounds, 377 SCI. TOTAL ENV’T 255, 269 (2007).
regulatory structure available to address this problem, agencies and regulators are under-utilizing these tools because of numerous regulatory exceptions and/or simple lack of enforcement. Addressing the problem of pharmaceuticals in the environment does not require a whole new regulatory structure; it simply requires strengthening the existing regulations to cover pharmaceutical contaminants. Additionally, it requires implementation of newer technologies at water treatment facilities. However, we should place a greater focus on source protection—preventing pharmaceuticals from entering the environment in the first place—because source protection obviates the need for mass expenditures to update water treatment infrastructure.

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