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# Keeping our Drinking Water Free from Pharmaceuticals: A Joint Action Plan

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**Keeping Our Drinking Water Free from Pharmaceuticals: A Joint Action Plan**  
By Melissa Rifai

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## Keeping Our Drinking Water Free of Pharmaceuticals: A Joint Action Plan

### **Introduction**

Following a 2008 investigation, the Associated Press revealed that many different types of pharmaceuticals, including antibiotics, anti-convulsants, mood stabilizers and sex hormones are found in drinking water across the country.<sup>1</sup> The study took place over the course of five months, and tested the drinking water of twenty-four major metropolitan areas.<sup>2</sup> Though wastewater is treated before it enters the rivers and reservoirs, and is often treated a second time before it becomes drinking water, drug residues remain.<sup>3</sup> As of 2008, the federal government had not set any standards or limits for drugs in the water;<sup>4</sup> all tap water that tested positive for drugs still met federal drinking water standards.<sup>5</sup>

Recent studies have shown that the increase of pharmaceutical chemicals<sup>6</sup> in the waters has caused genetic mutations in populations of fish. Several studies conducted in the United States have found that fish experience “significant neurological and physiological changes” as a result of hormones and antidepressants being disposed of in the water.<sup>7</sup> For example, a Maryland study determined that male bass produced “both sperm and eggs” as a result of

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<sup>1</sup> Jeff Donn et al., *Drugs Found in Drinking Water*, USA TODAY (Mar. 10, 2008), available at [http://usatoday30.usatoday.com/news/nation/2008-03-10-drugs-tap-water\\_N.htm](http://usatoday30.usatoday.com/news/nation/2008-03-10-drugs-tap-water_N.htm).

<sup>2</sup> *Id.* The areas that tested positive for pharmaceuticals in the tap water included Atlanta (GA), Cincinnati (OH), Columbus (OH), Indianapolis (IN), Las Vegas (NV), Long Beach (CA), Louisville (KY), Milwaukee (WI), Minneapolis (MN), New Orleans (LA), New Jersey, Philadelphia (PA), Portland (OR), Riverside County (CA), San Diego (CA), San Francisco (CA), Southern California, Tucson (AZ), Washington D.C.

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> The increase in the amount of chemicals in the water also includes chemicals from personal care products. Toby K.L. Morgan, *Down the Drain: Pharmaceutical Waste Disposal in the United States*, 22 Fordham Env'tl. L. Rev. 393 (Spring 2011). The disposal of personal care products into the water is beyond the scope of this paper.

<sup>7</sup> Tierney Christenson, *Fish on Morphine: Protecting Wisconsin's Natural Resources Through a Comprehensive Plan for Property Disposal of Pharmaceuticals*, 2008 Wis. L. Rev. 141, 143 (citing Juliet Eilperin, *Pharmaceuticals in Waterways Raise Concerns: Effect on Wildlife, Humans Questioned*, WASH. POST, June 23, 2005, A3).

increased estrogen in the water.<sup>8</sup> The researchers believed that the source of the estrogen was birth control pills that had been flushed.<sup>9</sup> These chemicals also have the potential to cause harm to human health. Some scientists have found links between pharmaceutical pollutants and earlier puberty in children.<sup>10</sup> A study in the United Kingdom found a link between hormones in the environment, a lower sperm count and the development of breasts in men.<sup>11</sup> While the extent of the effect on human health remains unknown,<sup>12</sup> the effects will vary based on the type of drug and the concentration in which humans are exposed. In light of the results of these recent studies, the disposal of pharmaceuticals in the water is increasingly becoming a public health concern.

It was originally believed that the best way to dispose expired or unused prescription pharmaceuticals was by flushing them down the toilet, to keep them out of the hands of children and off of the black market.<sup>13</sup> Recently, as drug residue has been discovered in drinking water nationwide, a number of states have proposed legislation to regulate the disposal of pharmaceuticals and prevent their disposal in drinking water sources.<sup>14</sup> Despite these attempts to

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<sup>8</sup> *Id.* (citing George J. Mannina, Jr., *Medicines and the Environment: Legal and Regulatory Storms Ahead?*, LEGAL BACKGROUND, Mar. 24, 2006).

<sup>9</sup> *Id.* However, a 2011 study determined that flushed birth control pills account for less than one percent of the estrogen found in the water. About 90 percent of the estrogen found in the water was from hormones given to livestock. American Chemical Soc’y, *Don't blame the pill for estrogen in drinking water*, SCIENCEDAILY (Feb. 15, 2011), available at <http://www.sciencedaily.com/releases/2010/12/101208125813.htm>.

<sup>10</sup> Darshak M. Sanghavi, *Preschool Puberty, and a Search for the Causes*, N.Y. TIMES, Oct. 17, 2006.

<sup>11</sup> Elizabeth Royte, *Drugging the Waters: How an Aging Population and Our Growing Addiction to Pharmaceuticals May be Poisoning Our Rivers*, OnEarth 26, 30 (Fall 2006), available at <http://www.nrdc.org/onearth/06fal/waters1.asp>.

<sup>12</sup> World Health Org., *Information Sheet: Pharmaceuticals in Drinking Water*, available at [http://www.who.int/water\\_sanitation\\_health/emerging/info\\_sheet\\_pharmaceuticals/en/](http://www.who.int/water_sanitation_health/emerging/info_sheet_pharmaceuticals/en/) (last accessed Dec. 4, 2013).

<sup>13</sup> Louise Slaughter, *Secure Prescription Drug Take-Back Programs Protect Our Children, our Waterways, and the Public: Sign on to H.R. 293*.

<sup>14</sup> See Citizens Campaign for the Env’t., *Pharmaceutical Disposal*, (July 16, 2013) available at <http://www.citizenscampaign.org/campaigns/pharmaceutical-disposal.asp> (last accessed Dec. 4, 2014). For example, in Suffolk County New York, all hospitals, nursing home facilities, and long term care facilities must submit an annual plan for the safe disposal of unused or expired medications. Suffolk Cnty. Dep’t of Health Servs. Resolution #1402 (Mar. 22, 2011).

legislate, the “flushing method” is still the most widely used and accepted method of drug disposal,<sup>15</sup> leading to the increasing problem of drug residue in drinking water.

Further, current federal law is inadequate to regulate the disposal of pharmaceuticals because neither the Food and Drug Administration (“FDA”) nor the Environmental Protection Agency (“EPA”) has promulgated rules or regulations expressly prohibiting the disposal of pharmaceuticals in the water; the FDA regulates pharmaceuticals as a health concern, and gives the environment little consideration, while the EPA regulates without expressly prohibiting disposal of drugs in the water. Thus, neither the FDA nor the EPA is singularly regulating the disposal of pharmaceuticals in the water, leading to a fragmented and ineffective regulatory scheme, and a growing problem of pharmaceutical waste in the water. It is imprudent for the EPA and FDA to continue without regulating the disposal of pharmaceuticals in the water, because a wait-and-see approach could have harmful effects on human and environmental health.

This paper proposes a scheme in which the Environment Protection Agency and the Food and Drug Administration work together to re-conceptualize disposal of expired or unused pharmaceuticals with the goal of reducing the amount of pharmaceuticals disposed of in the water. This paper begins with a background section, which describes how pharmaceutical waste is generated, and the issues caused by pharmaceutical waste disposal in the nation’s waters. The following section provides a brief overview of the current regulatory framework and why it is inadequate to regulate the disposal of pharmaceuticals in the water. Section three describes solutions that have been proposed to curb the disposal of pharmaceuticals in the water. The final section proposes a joint action plan in which the EPA and FDA expand the scope of their respective regulatory provisions to include regulation of pharmaceutical waste disposal, and

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<sup>15</sup> The term “drugs” will be used interchangeably with the word “pharmaceuticals” throughout.

work together to require an environmental impact assessment of the impact of disposal for all new drugs before approval to market. The outcome of the impact assessment will be to determine the most environmentally friendly way to dispose of the new drug. Proposing joint federal action, rather than state action, will create a uniform system of disposal with the goal of reducing the amount of pharmaceutical waste in our nation's waters.

## I. Pharmaceutical Waste

The use of pharmaceuticals has been advantageous to modern society.<sup>16</sup> For example, in 1995, the life expectancy of a person who was HIV positive was 10 years.<sup>17</sup> Due to the introduction of antiretroviral pharmaceuticals, the life expectancy had risen to 22.5 years by 2008.<sup>18</sup> Also, antibiotic use on livestock has been critical to preventing, controlling and treating disease in livestock, which subsequently reduces animal to human transmission of bacteria.<sup>19</sup> However, for as long as pharmaceuticals have been prevalent, society has been faced with the problem of proper disposal practices. Disposal of pharmaceuticals in the water has long been a widespread practice; a 1970 study found heart medication, pain relief medication and birth control pills in wastewater.<sup>20</sup> As the volume and quantity of pharmaceutical consumption increases,<sup>21</sup> the concentration of pharmaceutical residue in the water also increases.

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<sup>16</sup> World Health Org. Work Group Report, *Pharmaceuticals in Drinking Water* (2012).

<sup>17</sup> Linda Dahlstrom, *Aging with AIDS: Living Longer, Living with Loss* (2011), available at [http://www.nbcnews.com/id/43230322/#.Up1kN421\\_4g](http://www.nbcnews.com/id/43230322/#.Up1kN421_4g) (last accessed Dec. 4, 2013).

<sup>18</sup> *Id.*

<sup>19</sup> Animal Health Institute, *Animal Antibiotics* (2013), available at <http://www.ahi.org/issues-advocacy/animal-antibiotics/> (last accessed Dec. 4, 2013).

<sup>20</sup> World Health Org. Work Group Report, *supra* n. 16.

<sup>21</sup> Health at a Glance 2011: OECD Indicators, available at [http://www.oecd-ilibrary.org/sites/health\\_glance-2011-en/04/11/index.html;jsessionid=3dln9sdrovedm.delta?contentType&itemId=/content/chapter/health\\_glance-2011-39-en&containerItemId=/content/serial/19991312&accessItemIds=/content/book/health\\_glance-2011-en&mimeType=text/html](http://www.oecd-ilibrary.org/sites/health_glance-2011-en/04/11/index.html;jsessionid=3dln9sdrovedm.delta?contentType&itemId=/content/chapter/health_glance-2011-39-en&containerItemId=/content/serial/19991312&accessItemIds=/content/book/health_glance-2011-en&mimeType=text/html) (last accessed Dec. 4, 2013).

### A. Pharmaceutical Waste Defined

How the federal government defines waste determines whether federal law regulates the disposal a particular compound. “Waste” generally refers to “any discarded material” that is not otherwise excluded.<sup>22</sup> Discarded material is defined as any material, which is “abandoned,” “recycled,” or “considered inherently waste-like.”<sup>23</sup> Though expired or unused pharmaceuticals seemingly fall within this scope, most pharmaceutical compounds are not included in federal definitions of waste, resulting in unclear and non-uniform regulation of disposal of unused pharmaceuticals. Further, certain pharmaceutical compounds, such as hormones from the disposal or excretion of oral contraceptives, are not even included in the federal definitions of pharmaceutical waste. So long as disposed pharmaceuticals are not regulated under the federal definition of waste, it is unlikely that there will be a uniform implementation of disposal requirements nationwide. Therefore, a first step in the process of regulating pharmaceutical waste is defining it.

The EPA regulates the disposal of a number of different types of waste, including solid waste, medical waste, and hazardous waste. The definition of medical waste does not expressly include pharmaceuticals.<sup>24</sup> Hazardous waste can be categorized as either listed waste or characteristic waste. Listed waste is listed in four categories (P, F, K, U) and pharmaceuticals can be found on both the P and U lists,<sup>25</sup> but only a few pharmaceuticals are included on these lists. The P-list contains “commercial chemicals that are acutely toxic” meaning that they can

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<sup>22</sup> 40 C.F.R. 261.2

<sup>23</sup> *Id.*

<sup>24</sup> Medical Waste Tracking Act, H.R. 3515 (1988) (amendment to the Solid Waste Disposal Act).

<sup>25</sup> Healthcare Envtl. Res. Ctr., *Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States* 14 (August 2008), available at <http://www.hercenter.org/hazmat/tenstepblueprint.pdf>

cause death or irreversible illness at low doses.<sup>26</sup> The U-list has less stringent toxicity requirements.<sup>27</sup> Chemical compounds found on the P or U list are regulated by the Resource Conservation and Recovery Act (“RCRA”) Subtitle C Generator requirements.<sup>28</sup> A pharmaceutical is only covered under this list if the sole active ingredient of the drug is listed.<sup>29</sup>

Characteristic wastes are regulated because they exhibit certain hazardous properties – ignitability,<sup>30</sup> corrosivity,<sup>31</sup> reactivity,<sup>32</sup> and toxicity.<sup>33</sup> Generators of hazardous waste intended for disposal must determine whether the waste has any of these characteristics.<sup>34</sup> Waste that neither is listed nor exhibits one of the mentioned characteristics is considered solid waste and should be discarded according to state and local regulations.<sup>35</sup> Only in some states will these regulations include medical waste.<sup>36</sup> The number of P-listed and U-listed pharmaceuticals is small, and the majority of pharmaceuticals do not exhibit one or more of the mentioned characteristics, leaving the majority of disposed pharmaceuticals exempt from federal regulation as hazardous waste. Thus, oftentimes, a state or local government regulates the disposal of pharmaceutical waste. Differences in definitions of pharmaceutical waste, such as defining it as hazardous waste or medical waste, leaves unclear regulations that differ between states.

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<sup>26</sup> See generally Health Env’t. Res. Ctr., *Hazardous Waste Determination*, available at <http://www.hercenter.org/hazmat/hazdeterm.cfm#listed> for discussion of RCRA listed hazardous waste and its application to healthcare facilities.

<sup>27</sup> *Id.*

<sup>28</sup> Env’tl. Prot. Agency, *Hazardous Waste Generators*, available at <http://www.epa.gov/waste/hazard/generation/index.htm> (last accessed Dec. 4, 2013).

<sup>29</sup> *Id.*

<sup>30</sup> Ignitability refers to whether the waste presents a fire hazard under normal storage, disposal or transportation. *10 Step Blueprint*, *supra* n. 25 at 20.

<sup>31</sup> Corrosivity refers to waste which is highly acidic, with a pH less than or equal to two, or highly basic, with a pH of greater than or equal to 12.5. *Id.* at 22.

<sup>32</sup> Reactivity refers to wastes, which are unstable under normal conditions. *Id.* at 24.

<sup>33</sup> Toxicity refers to the point at which chemicals and heavy metals exceed the stated limits. *Id.* at 24; A waste need only have one of these characteristics to be considered hazardous. *Id.* at 20.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> *Id.* Regulated medical waste is defined by the state or locality. *Id.* at 26.

However, pharmaceutical residue in the water does not respect jurisdictional boundaries, leaving even the states with stringent disposal requirements vulnerable to pharmaceutical waste pollution. In order for a uniform federal regulation to be effective, a discrete definition of pharmaceutical waste must be promulgated.

The FDA has promulgated federal guidelines for consumer disposal of pharmaceuticals.<sup>37</sup> These guidelines are not binding, and are intended only to direct domestic consumers to proper disposal of small quantities of unused medications.<sup>38</sup> However, as discussed in further detail below, humans and animals create the majority of pharmaceutical waste through industrial disposal, hospital disposal, and excretion.<sup>39</sup> Thus, non-binding guidelines for the disposal of small quantities of domestic pharmaceutical waste is not sufficient to curb the growing problem of pharmaceutical waste in the water as it does not stop pollution from the biggest sources. Without the express inclusion of pharmaceutical waste in a federally regulated waste disposal statute, the current definitions of solid waste, medical waste, and hazardous waste are inadequate to properly regulate the disposal of pharmaceuticals.

## **B. Generation of Pharmaceutical Waste**

Identifying the largest generators of pharmaceutical waste is necessary for determining which industries should be included within the scope of the reformed regulation. Pharmaceutical waste is generated by a variety of activities ranging from patient care in the hospital setting to outpatients' disposal of personal medications that are unused or expired.<sup>40</sup> Hospitals are a significant contributor to the amount of pharmaceutical waste generated annually. In fact, in an

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<sup>37</sup> Food and Drug Admin., *How to Dispose of Unused Medicines*, available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm> (last accessed Dec. 4, 2013).

<sup>38</sup> *Id.*

<sup>39</sup> *10-Step Blueprint*, *supra* n. 25.

<sup>40</sup> *Id.*

EPA analysis of nationwide hospital pharmaceutical disposal, the EPA found that hospitals dispose of 9,700 tons of pharmaceutical waste per year.<sup>41</sup> For a long time, hospitals disposed of their unused or expired pharmaceuticals by flushing them down the toilet.<sup>42</sup> Other contributors to pharmaceutical waste may include illicit drug laboratories, which frequently dispose of “raw products and intermediaries” by flushing them down the toilet.<sup>43</sup>

Pharmaceutical waste also enters the environment through sewage treatment facilities,<sup>44</sup> and via burial in landfills.<sup>45</sup> Human consumption and excretion contributes to this because humans do not fully metabolize pharmaceuticals.<sup>46</sup> Similarly, excretion of medications and other pharmaceuticals given to pets and livestock contribute, though less significantly, to the amount of pharmaceutical waste.<sup>47</sup> One study found that as little as seven percent of “active drug compounds” found in sewage water was removed in the sewage treatment process.<sup>48</sup> Thus, the majority of “active drug compounds” remain in the water. While the disposal of pharmaceuticals into the water through the human excretory process is unintentional, the intentional disposal of pharmaceuticals or other over-the-counter medications into the waste systems also occurs.<sup>49</sup>

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<sup>41</sup> *Down the Drain*, 22 Fordham Envtl. L. Rev. at 401-402 (citing Econ., Methods, & Risk Analysis Div., Off. Of Solid Waste, Envtl. Prot. Agency, Assessment of the Potential Costs, Benefits and Other Impacts of Adding Pharmaceuticals to the Universal Waste Rule as Proposed by ES-1 (2008) (on file with author)).

<sup>42</sup> Christian G. Daughton, *Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health. II. Drug Disposal, Waste Reduction, and Future Directions*, 111 Envtl. Health Persp. 775, 780 (May 2003).

<sup>43</sup> Christian G. Daughton & Thomas A. Ternes, *Pharmaceuticals and Personal Care products in the Environment: Agents of Subtle Change?*, 107 Envtl. Health Persp. 907, 908 (Dec. 1999).

<sup>44</sup> *Id.* at 912.

<sup>45</sup> *Id.*

<sup>46</sup> Christian G. Daughton, *Pharmaceuticals and Personal Care Products in the Environment: Overarching Issues and Overview*, in *Pharmaceuticals and Personal Care Products in the Environment: Scientific and Regulatory Issues* 2, 11 (Christian G. Daughton & Tammy L. Jones-Lepp, eds., 2001).

<sup>47</sup> Melanie Leitman (Student Comment), *Water Rx the Problem of Pharmaceuticals in our Nation's Waters*, 29 UCLA J. Envtl. L. & Pol'y 395. (citing Bethany Halford, Side Effects, Chem & Eng'g News, Feb. 25, 2008).

<sup>48</sup> *Id.* at 399 (citing Envtl. Prot. Agency, *Frequent Questions – Pharmaceuticals and Personal Care Products*, available at <http://www.epa.gov/ppcp/faq.html>).

<sup>49</sup> Stephen E. Musson & Timothy G. Townsend, *Pharmaceutical Compound Content of Municipal Solid Waste*, 162 Hazardous Materials 730 (2009).

### C. Problems with disposing of pharmaceuticals in the water

The effects of pharmaceutical residue on human health, animal health, and environmental health have been the subject of a number of scientific studies. These studies have returned sobering results that highlight the problems posed by pharmaceutical waste in the water. These effects will be exacerbated if the practice of disposing of pharmaceuticals in the water remains unchecked.

#### (i) Public Health

Pharmaceuticals, by nature, elicit physiological change in humans.<sup>50</sup> While the exact effect on humans of pharmaceuticals in the waters remains largely unknown,<sup>51</sup> a number of studies have found a link between drugs in the water and physiological change in humans. For example, a United Kingdom study found a link between the presence of hormones in the water with lower sperm counts and the development of breasts in men.<sup>52</sup>

Pharmaceuticals in the water are of particular concern to vulnerable populations, such as pregnant women, young children, and people with compromised immune systems. One study cited cases in which children were exhibiting premature signs of puberty and linked this change to pharmaceuticals in the water.<sup>53</sup> People with certain drug allergies may also be vulnerable.

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<sup>50</sup> *Water Rx*, *supra* n. 47 at 204.

<sup>51</sup> Darshak M. Sanghavi, *Preschool Puberty & A Search for the Causes*, N.Y. Times (Oct. 17, 2006) n.1. *available at* [http://www.nytimes.com/2006/10/17/science/17puberty.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2006/10/17/science/17puberty.html?pagewanted=all&_r=0).

<sup>52</sup> Christopher T. Nidel, *Regulating the Fate of Pharmaceutical Drugs: A New Prescription for the Environment*, 50 Food & Drug L. J. 81, 84 (2003).

<sup>53</sup> Darshak M. Sanghavi, *Preschool Puberty & a Search for the Causes*, N.Y. Times (Oct. 17, 2006) n.1. *available at* [http://www.nytimes.com/2006/10/17/science/17puberty.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2006/10/17/science/17puberty.html?pagewanted=all&_r=0).

While current concentrations of pharmaceutical residue in drinking water are too low to elicit allergic reactions,<sup>54</sup> allergic reactions may manifest if the residue concentration increases.<sup>55</sup>

Finally, scientists have expressed concerns about antimicrobial bacterial resistance.<sup>56</sup> A number of disease-causing bacteria can be found in the water.<sup>57</sup> Scientists are concerned that if antibiotics are being disposed of in the water, the bacteria will become resistant to these antibiotics.<sup>58</sup> If these drug-resistant bacteria cause disease in humans, conventional drug treatment will be ineffective.<sup>59</sup> Drug resistance is not a problem that is unique to water pollution,<sup>60</sup> but the consequences of drug-resistant waterborne pathogens could be severe.

(ii) Environmental & Animal Health

The significant amount of pharmaceutical waste found in the water has distinct effects on environmental and animal health. A number of studies have been conducted that document the considerable changes to the physiological health of fish in contaminated waters. As a result of the amount of estrogen found in the water, male fish are being feminized and producing egg yolk proteins, which is normally produced by female fish.<sup>61</sup> Scientists have found that the increased feminization of the male fish “dramatically decreased” the population of certain species.<sup>62</sup>

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<sup>54</sup> Alicia Anderson et al., *Public Health Consequences of Use of Antimicrobial Agents in Food Animals in the United States*, 9 *Microbial Drug Resistance* 373 (2003).

<sup>55</sup> *Water Rx*, *supra* n. 47 at 405.

<sup>56</sup> *Id.*

<sup>57</sup> World Health Org. Water Sanitation Health, *Waterborne Pathogens*, available at [http://www.who.int/water\\_sanitation\\_health/gdwqrevision/watpathogens.pdf](http://www.who.int/water_sanitation_health/gdwqrevision/watpathogens.pdf)

<sup>58</sup> *Water Rx*, *supra* n. 47 at 405.

<sup>59</sup> *Id.*

<sup>60</sup> *See generally*, Nat'l. Instit. of Allergy and Infectious Disease, *Antimicrobial Drug Resistance*, available at <http://www.niaid.nih.gov/TOPICS/ANTIMICROBIALRESISTANCE/Pages/default.aspx> (last accessed Dec. 4, 2013).

<sup>61</sup> Jeff Donn et al., *Drugs Found in Drinking Water*, *supra* n. 1.

<sup>62</sup> *Water Rx*, *supra* n. 47 at 407-08. “Scientists observed the fathead minnow present in the lake and found that the feminization of male minnow resulted in a dramatically decreased population of the species. At the end of a four-year period, according to the study, ‘the fish had all but disappeared from the lake.’ Interestingly, three years after the scientists ceased adding the estrogen, the targeted species population rebounded.” (citing Bethany Halford, *Side Effects*, *Chem & Eng'g News*, Feb. 25, 2008).

One study from the University of Wisconsin introduced anti-cholesterol medication into the water of a school of fathead minnows.<sup>63</sup> The medication was introduced at a level “only slightly higher” than what was currently found in Wisconsin’s streams.<sup>64</sup> “[The minnows] were sitting at the bottom of the tank, barely moving and barely breathing.”<sup>65</sup> The study, intended to run for a week, was discontinued after only 24 hours, because the minnows were “struggling to survive.”<sup>66</sup> The researchers expressed concern that the pharmaceuticals “are not only having an effect on aquatic organisms, but on human populations as well.”<sup>67</sup>

(iii) Pharmaceuticals in our drinking water

In the United States, the water contamination is not just at the surface.<sup>68</sup> “Pharmaceuticals also permeate aquifers<sup>69</sup> deep underground.”<sup>70</sup> Water tested from aquifers drawn from sites near landfills and animal feedlots also had trace amounts of pharmaceuticals in it.<sup>71</sup> These aquifers source 40% of the nation’s water supply.<sup>72</sup> Though water in the United States goes through both disinfection and filtration processes before it becomes drinking water,<sup>73</sup> pharmaceutical residue is still found in finished drinking water. Researchers have estimated that about 41 million people have been exposed to pharmaceutical residue in their drinking water.<sup>74</sup> This problem will not

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<sup>63</sup> *Fish on Morphine*, *supra* n. 7, at 144. Study conducted by Rebecca D. Klaper, University of Wisconsin.

<sup>64</sup> *Id.*

<sup>65</sup> Juliet Eilperin, *Pharmaceuticals in Waterways Raise Concern: Effect on Wildlife, Humans Questioned*, *supra* n. 7.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*

<sup>69</sup> “An aquifer is a body of saturated rock through which water can easily move.” *See* <http://imnh.isu.edu/digitalatlas/hydr/concepts/gwater/aquifer.htm> (last accessed Dec. 4, 2013)

<sup>70</sup> Jeff Donn et al., *Drugs Found in Drinking Water*, *supra* n. 1.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> Sewage and Water Board, *The Water Purification Process at the Carrollton Plant*, available at [http://www.swbno.org/history\\_water\\_purification.asp](http://www.swbno.org/history_water_purification.asp); *see also* Eurotherm, *The Water Purification Process*, available at <http://www.eurotherm.com/industries/life-sciences/applications/water-purification/>.

<sup>74</sup> *Water Rx*, *supra* n. 47 at 397.

resolve itself; federal or state action is necessary to reduce the amount of pharmaceutical residue in drinking water.

## **II. Current Regulatory Framework**

As explained above, current EPA and FDA regulations are inadequate to ensure safe disposal of pharmaceutical waste. However, if the EPA and FDA are empowered to work together to address this issue, they may be able to develop new regulations that lessen the concentration of pharmaceutical waste in the water. To determine what changes are required, it is important to understand the current regulatory framework. The following is an overview of the existing regulations and the ways in which current statutes have the potential to address pharmaceutical waste.

### **A. EPA**

The Environmental Protection Agency is charged with enforcing statutes that direct cleanliness standards for the nation's water. The relevant provisions are: the Clean Water Act which operates to reduce pollutants and contamination in the water,<sup>75</sup> the Safe Drinking Water Act<sup>76</sup> and the Resource Conservation and Recovery Act<sup>77</sup> which work to regulate the hazardous waste in the water. Through these regulations, the EPA regulates hazardous waste in the water, which could add more regulations to extend to the disposal of pharmaceutical waste in the water if the scope of the regulations is expanded.

#### **(i) Clean Water Act**

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<sup>75</sup> 33 U.S.C. § 1251.

<sup>76</sup> 42 U.S.C. § 300g-1.

<sup>77</sup> 42 U.S.C. § 6901.

The Clean Water Act<sup>78</sup> does not expressly prohibit the disposal of pharmaceutical waste in the water, but does have the potential to address pharmaceutical contamination.<sup>79</sup> “The Clean Water Act establishes the basic structure for regulating discharges of pollutants into the waters of the United States and regulating quality standards for surface waters.”<sup>80</sup> The statute provides a regulatory scheme for the discharge of pollutants into the water,<sup>81</sup> regulating activities such as industrial discharges, sewage treatment, concentrated animal feeding operations,<sup>82</sup> aquaculture<sup>83</sup> and other point source discharges.<sup>84</sup> However, none of these sources are regulated for the disposal of pharmaceuticals.

The Clean Water Act also includes a best available technology provision.<sup>85</sup> This provision requires the use of the best available technology economically achievable to further the goal of eliminating discharge of all pollutants.<sup>86</sup> This acts as a floor for the types of treatment that must be used by dischargers of pollutants.<sup>87</sup> The assessment of best available technology includes a number of factors over which the EPA has the discretion to weigh.<sup>88</sup> These factors are:

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<sup>78</sup> 33 U.S.C. § 1251.

<sup>79</sup> *Water Rx*, *supra* n. 47.

<sup>80</sup> Env'tl. Prot. Agency, Summary of the Clean Water Act, *available at* <http://www2.epa.gov/laws-regulations/summary-clean-water-act> (last accessed Dec. 4, 2013).

<sup>81</sup> 33 U.S.C. § 1311(a)(2006).

<sup>82</sup> Animal Feeding Operations (“AFO”) are agricultural operations where animals are kept and raised in confined situations. Concentrated Animal Feeding Operations (“CAFO”) are Animal Feeding Operations that (i) meet the definition of AFO; and (ii) meets the regulatory definition of either (a) large CAFO, (b) medium CAFO, or (c) small CAFO. *See* <http://www.epa.gov>.

<sup>83</sup> Aquaculture is the farming of aquatic organisms such as fish, crustaceans, mollusks and aquatic plants. Nat'l Oceanic and Atmospheric Admin., “What is Aquaculture?” *available at* [http://www.nmfs.noaa.gov/aquaculture/what\\_is\\_aquaculture.html](http://www.nmfs.noaa.gov/aquaculture/what_is_aquaculture.html) (last accessed Dec. 4, 2013).

<sup>84</sup> Clean Water Act, Env'tl. Prot. Agency, <http://www.epa.gov/agriculture/lcwa.html>; Nonpoint Source Pollution and Agriculture. Point source is defined as “any discernable confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged.” 33 U.S.C. § 1362(14)(2006).

<sup>85</sup> 33 U.S.C. §§ 1311(b)(2)(A), 1311(b)(2)(C).

<sup>86</sup> *Id.*

<sup>87</sup> *Water Rx*, *supra* n. 47 at 416.

<sup>88</sup> Env'tl. Prot. Agency, Water: Industry Effluent Guidelines FAQ, *available at* [http://water.epa.gov/scitech/wastetech/guide/questions\\_index.cfm](http://water.epa.gov/scitech/wastetech/guide/questions_index.cfm) (last accessed Dec. 4, 2013).

(i) the cost of achieving the reductions; (ii) the age of equipment and facilities involved; (iii) the process employed; (iv) potential process changes; and (v) non-water quality environmental impacts, including energy requirements.<sup>89</sup> The EPA's significant enforcement discretion may serve as a way for the EPA to regulate the disposal of pharmaceuticals.

(ii) Safe Drinking Water Act

The Safe Drinking Water Act could also be used to regulate the concentration of pharmaceuticals in the water, but in its current form does not do enough to keep pharmaceuticals out of the water. The Safe Drinking Water Act empowers the EPA to regulate both naturally occurring and manmade substances that “may have an adverse effect on the health of persons”<sup>90</sup> through implementation of drinking water quality standards.<sup>91</sup> The Act requires the EPA to promulgate standards for listing contaminants, which the EPA then regulates as “listed.”<sup>92</sup> Unfortunately, the EPA's listed contaminants exclude many pharmaceuticals because of the low concentrations in which they are found in the water.<sup>93</sup> However, with increasing concern about adverse human health effects as a result of pharmaceuticals in the water, the EPA could use the Safe Drinking Water Act to promulgate standards for keeping pharmaceuticals out of the water by listing pharmaceutical compounds as drinking water contaminants.

(iii) Resource Conservation and Recovery Act (“RCRA”)

The Resource Conservation and Recovery Act (“RCRA”)<sup>94</sup> could also be used to regulate the disposal of pharmaceuticals, but in its current form is not robust enough to do so. The

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<sup>89</sup> *Id.*

<sup>90</sup> *Id.* at § 300g-1(b)(1)(A)(i); *Water Rx*, *supra* n. 47 at 416 (citing 42 U.S.C. § 300f(6)).

<sup>91</sup> 42 U.S.C. § 300g-1(b)(1)(A) (2006).

<sup>92</sup> Melanie Leitman, *supra* n. 47 at 416.

<sup>93</sup> *Id.* at 417 (citing *Pharmaceuticals in the Nations Water: Assessing Potential Risks and Actions to Address the Issue Before the S. Comm. on Env't. and Public Works*, (Apr. 15, 2008) (statement of Benjamin H. Grumbles), available at [http://epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore\\_id=7f39d92b-3089-4703-9063-e5d6c1381332](http://epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=7f39d92b-3089-4703-9063-e5d6c1381332) (last accessed Dec. 4, 2013)).

<sup>94</sup> 42 U.S.C. § 6901 et seq.

disposal of solid waste is regulated through RCRA, the purpose of which is to “promote the protection of health and the environment and to conserve valuable material and energy resources.”<sup>95</sup> However, despite the express inclusion of a number of types of medical waste, unused or expired pharmaceuticals fit only within the catchall provision of RCRA.<sup>96</sup> RCRA exempts domestic sewage or any other substance from a domestic source from the regulation,<sup>97</sup> and therefore exempts pharmaceutical waste from domestic sources.<sup>98</sup>

The statute also includes provisions for the management of hazardous waste<sup>99</sup> and a program for tracking medical waste.<sup>100</sup> In the chapter, Congress declares it to be national policy of the United States that “wherever feasible, the generation of hazardous waste is to be reduced or eliminated as expeditiously as possible...to minimize the present and future threat to human health and the environment.”<sup>101</sup> This chapter is to be integrated with the Clean Water Act<sup>102</sup> to the extent that it can be done in a “manner consistent with the goals and policies” of both the Solid Waste Disposal Act and the Clean Water Act.<sup>103</sup> Within this chapter, “hazardous waste” is defined as:

A solid waste, or combination of solid wastes which because of its quantity, concentration, or physical, chemical or infectious characteristics may –

- (a) Cause, or significantly contribute to an increase in mortality or an increase in serious, irreversible, or incapacitating reversible, illness; or
- (b) Pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.<sup>104</sup>

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<sup>95</sup> 42 U.S.C. § 6902(a).

<sup>96</sup> The catchall exception reads, “Such other waste material that results from the administration of medical care to a patient by a health care provider and is found by the Administrator to pose a threat to human health or the environment.” § 6902a(a)(11).

<sup>97</sup> 40 C.F.R. § 261.4(a)(1).

<sup>98</sup> *Id.* Domestic sewage is “waste that passes through a sewer system to a publicly-owned treatment works for treatment.”

<sup>99</sup> 42 U.S.C. §§ 6921-6939g.

<sup>100</sup> 42 U.S.C. §§ 6992-6992k.

<sup>101</sup> § 6902(b).

<sup>102</sup> The chapter is also to be integrated with other federal acts to the extent possible.

<sup>103</sup> 42 U.S.C. § 6905(b)(1).

<sup>104</sup> 21 U.S.C. § 6903(5).

This definition is broad and could potentially include within its scope a number of different types of waste; the definition of “medical waste” narrows its scope. Medical waste is defined as, “any solid waste, which is generated in the diagnosis, treatment or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals.”<sup>105</sup> In Subchapter X, the definition of medical waste is further narrowed.<sup>106</sup>

RCRA categorizes hazardous waste into four lists, the P-list, the F-list, the K-list and the U-list.<sup>107</sup> RCRA does list some pharmaceutical compounds on its P-list and U-list as wastes,<sup>108</sup> and therefore hospitals and skilled nursing facilities are subject to its provisions.<sup>109</sup> However, the RCRA hazardous waste lists have not been substantially updated, and the enforcement of the regulations against hospitals and skilled nursing facilities is challenging, as the lists were not originally intended for regulation of the health-care industry.<sup>110</sup>

As they currently stand, the Clean Water Act, the Safe Drinking Water Act, and RCRA are inadequate to address the growing problem of pharmaceutical waste in the water.

## **B. FDA**

The FDA has its own approach to the regulation of pharmaceuticals in the environment. While the FDA’s role is to protect public health rather than the environment,<sup>111</sup> the analysis of

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<sup>105</sup> § 6903(40).

<sup>106</sup> 42 U.S.C. § 6992a(a).

<sup>107</sup> 40 C.F.R. 261

<sup>108</sup> 40 C.F.R. § 261.33

<sup>109</sup> *Fish on Morphine*, *supra* n. 7 at 150-51.

<sup>110</sup> *Id.* at 150 (citing Ron Seely, *Flushed Drugs Polluting Water; Complicated Rules for Disposal Result in Most Hospitals Taking Easy Way Out*, Wis. St. J., Dec. 10, 2006).

<sup>111</sup> Food and Drug Administration, *About FDA*, available at <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm> (last accessed Dec. 4, 2013) (“FDA is responsible for protecting public health by assuring that foods are safe, wholesome, sanitary and properly labeled; ensuring that human and veterinary drugs, and vaccines, and other biological products and medical devices intended for human use are safe and effective”).

the Food, Drug and Cosmetic Act<sup>112</sup> is useful in understanding the FDA's approach to pharmaceutical waste entering the environment.

(i) Federal Food, Drug & Cosmetic Act ("FDCA")

In its current form, the FDCA is inadequate to regulate the disposal of drugs into water sources, because it requires that the FDA prioritize human health over environmental concerns.<sup>113</sup> The goals of the FDCA are to assure that foods are safe for human consumption; that drugs and medical devices are safe and effective for human use; and that cosmetics are safe.<sup>114</sup> New drugs seeking market approval must undergo a rigorous evaluation process prior to entry into interstate commerce.<sup>115</sup> The approval criteria do not include environmental considerations.<sup>116</sup> However, drug residue in drinking water may pose a risk to human health, as humans are exposed to these drugs by drinking the water. Thus, within the scope of the FDCA, the FDA may be able to find the authority to investigate the impact that pharmaceuticals in the water will have on human health.

The EPA has a small stake in the FDCA, as they are given the authority to set maximum residue limits for pesticide residue on food.<sup>117</sup> While this is not related to the disposal of pharmaceutical waste into the water, the provision could be expanded to set residue limits for pharmaceutical residue in the water. The inclusion of the EPA's regulatory authority in the

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<sup>112</sup> 21 U.S.C. § 301 et seq.

<sup>113</sup> *Water Rx*, *supra* n. 47 at 410.

<sup>114</sup> *Overview of Federal Food Drug and Cosmetic Act*, Gerald I. Gillock & Associates (Lexis 2012) available at <http://www.gillockandassociates.com/newsletters/products-liability/overview-of-federal-food-drug-and-cosmetic-act/>.

<sup>115</sup> 21 U.S.C. § 355

<sup>116</sup> *Id.* See also *Water Rx*, *supra* n. 47 at 410.

<sup>117</sup> Env'tl. Prot. Agency, *Summary of the Federal Food, Drug, and Cosmetic Act*, available at <http://www2.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act> (last accessed Dec. 4, 2013).

FDCA is indicative of the fact that Congress has previously contemplated joint action between the FDA and the EPA. Within the scope of the FCDA, the EPA and the FDA may be able to create a regulatory framework that addresses the disposal of pharmaceuticals in the water.

(ii) National Environmental Policy Act (“NEPA”)

The National Environmental Policy Act (“NEPA”) provides a useful framework for the design of a new environmental assessment program for the disposal of pharmaceutical wastes. However, as it currently stands, NEPA is inadequate because the FDA has determined pharmaceuticals to be exempt from NEPA’s requirements. NEPA was enacted to require federal agencies to investigate the environmental impact of their activities before undertaking a certain action.<sup>118</sup> NEPA requires all federal agencies to “use all practicable means to create and maintain conditions under which man and nature can exist in productive harmony.”<sup>119</sup> Government agencies satisfy this requirement by undertaking to prepare detailed statements (“environmental impact statements”) that assess the environmental impact of their actions.<sup>120</sup> Environmental impact statements are required only after an environmental assessment determines that significant environmental harm is likely to result from the action.<sup>121</sup>

The preparation of environmental impact statements requirement is waived for certain actions, which the respective agency has determined do not significantly affect the

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<sup>118</sup> Env’tl. Prot. Agency, *Summary of the National Environmental Policy Act*, available at <http://www2.epa.gov/laws-regulations/summary-national-environmental-policy-act> (last accessed Dec. 4, 2013).

<sup>119</sup> Env’tl. Prot. Agency, *National Environmental Policy Act: Basic Information*, available at <http://www.epa.gov/compliance/basics/nepa.html> (last accessed Dec. 4, 2013).

<sup>120</sup> *Id.*

<sup>121</sup> 21 C.F.R. § 25.22

environment.<sup>122</sup> To be excluded means that the action does not require the preparation of either an environmental assessment or an environmental impact statement prior to taking the action.<sup>123</sup> One such exclusion made by the FDA is the categorical exclusion of pharmaceuticals with a concentration of less than one part per billion at the point of entry into the environment.<sup>124</sup> Substances that “occur naturally in the environment” are also excluded.<sup>125</sup> This exclusion is not broad enough to cover all pharmaceuticals; some new drug applications are required to conduct an environmental assessment and determine whether an environmental impact statement is necessary.<sup>126</sup> Conversely, certain chemicals enter the environment in very low concentrations – parts per trillion – but even at such low concentrations have a significant impact on the environment and on animal health.<sup>127</sup> The FDA has the discretion to amend or rewrite the exclusion to require an environmental assessment for all new drug applications. To do so would be a significant step in understanding the impact that the disposal of pharmaceuticals has on the environment.

### III. Proposed Solutions

The problem of pharmaceutical waste in the water is not a new one, and for many years scientists and agencies have worked to develop ways to solve this problem. Regulators have proposed a number of solutions, but none quite accomplish the goal of reducing the amount of pharmaceutical waste in the waters. The best practices fliers put out by the EPA and the FDA are

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<sup>122</sup> *Water Rx*, *supra* n. 47 at 411 (citing Ranga Velagleti & Michael Gill, Regulatory Oversight for the Environmental Assessment of Human and Animal Health Drugs, Environmental Assessment Regulations for Drugs, in *Pharmaceuticals & Personal Care Products in the Environment: Scientific and Regulatory Issues*, 320, 321 (Christian G. Daughton & Tammy L. Jones-Lepp, eds., 2001)).

<sup>123</sup> 21 C.F.R. § 25.31.

<sup>124</sup> § 25.31(b).

<sup>125</sup> § 25.31(c).

<sup>126</sup> Env'tl. Prot. Agency, *Frequently Asked Questions – National Environmental Policy Act*, available at <http://www.epa.gov/compliance/resources/faqs/nepa/index.html> (last accessed Dec. 4, 2013).

<sup>127</sup> *Water Rx*, *supra* n. 47 at 411.

inadequate because they do not impose binding requirements on consumers, and are not properly publicized to ensure consumer awareness. The pharmaceutical take-back programs have yielded great results, but are not held often enough to be effective. Finally, Congresswoman Slaughter's pharmaceutical stewardship program, which had great potential, was not enacted.

Best Practices Fliers. Pharmacies and practitioners that are registered with the Drug Enforcement Agency ("DEA") must follow certain guidelines for disposal of unused controlled substances.<sup>128</sup> However, for the general public, the regulations are less clear. The FDA and the EPA have separately determined the best practices for disposal of unused pharmaceuticals. In 2009, EPA issued a flier, which ranked and explained the best practices for disposing of pharmaceuticals.<sup>129</sup> This flier explicitly rejects flushing pharmaceuticals in the toilet, and ranks returning unused drugs to the pharmacy over other domestic disposal practices.<sup>130</sup> The FDA, on the other hand, suggests that consumers with unused drugs dispose of them in the trash.<sup>131</sup> Further, for certain drugs, the recommended disposal practice is flushing the unused pharmaceuticals down the toilet.<sup>132</sup> This disparity in accepted disposal practices is pervasive, and leads to consumer confusion, which is why a joint action plan would be useful.

Returning Unused Drugs/Pharmaceutical Take-Back Programs. In the 111th Congressional session,<sup>133</sup> a number of bills addressed the issue of pharmaceutical disposal and

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<sup>128</sup> 21 C.F.R. § 1307.21; For more information, see [http://www.deadiversion.usdoj.gov/drug\\_disposal/index.html](http://www.deadiversion.usdoj.gov/drug_disposal/index.html)

<sup>129</sup> Env'tl. Prot. Agency, *How to Dispose of Medicines Properly* (Oct. 2009) available at, <http://water.epa.gov/scitech/swguidance/ppcp/upload/ppcpflyer.pdf>

<sup>130</sup> *Id.*

<sup>131</sup> Food & Drug Admin., *How to Dispose of Unused Medicine* (Apr. 2011), available at <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm107163.pdf> (last accessed Dec. 4, 2013).

<sup>132</sup> Food & Drug Admin., *Disposal of Unused Medicines: What You Should Know*, (Updated Oct. 28, 2013) available at

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm#MEDICINES> (last accessed Dec. 4, 2013).

<sup>133</sup> The 111th Congressional Session took place from 2009 to 2010. U.S. Senate, *Cloture Motions*, available at, [http://www.senate.gov/pagelayout/reference/cloture\\_motions/111.htm](http://www.senate.gov/pagelayout/reference/cloture_motions/111.htm)

contamination, though none of the bills passed.<sup>134</sup> One such bill proposed a pharmaceutical take-back program, which would require state or local government agencies to provide a mechanism through which consumers can return unwanted medicines.<sup>135</sup> A number of states have created programs in which consumers can mail back<sup>136</sup> or drop off<sup>137</sup> their unused or unwanted pharmaceuticals and over-the-counter medications.

Despite a failure to pass these bills, the DEA implemented a national drug take-back program in 2010.<sup>138</sup> The most recent program was held in October 2013 and yielded almost 700 thousand pounds of unused and expired pharmaceuticals.<sup>139</sup> During the latest take-back program, there were over 5,000 take-back locations across all 50 states and the District of Columbia.<sup>140</sup> These take-back days are vitally important, as the DEA heavily regulates the people and entities authorized to handle controlled substances.<sup>141</sup>

However, despite the vastness of the DEA's drug take-back program, and the fact that there have been seven take-back days in the last three years,<sup>142</sup> the sheer volume of drugs returned in the most recent take-back day indicates that more needs to be done. Considering the extremely high number of prescriptions written per year,<sup>143</sup> it is likely that a significant number

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<sup>134</sup> *Water Rx*, *supra* n. 47 at 422.

<sup>135</sup> *Id.*

<sup>136</sup> Maine has a mail-back program in which individuals can "mail their unused or unwanted drugs to processing and disposal facilities." *Id.*, *see also* n. 217.

<sup>137</sup> "Michigan has several designated sites for collection of unwanted pharmaceuticals, although these sites do not accept any controlled substances." *Id.* at n. 215.

<sup>138</sup> Drug Enforcement Admin., *Americans Turn Out in Drove for DEA's Seventh Annual Prescription Drug Take Back Day*, Press Release (Nov. 6, 2013) available at <http://www.justice.gov/dea/divisions/hq/2013/hq110613.shtml>

<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* Controlled substances are distinct from other pharmaceuticals, and are the types of drugs that are often abused.; *See also*, Controlled Substances Act, 21 U.S.C. § 801 et seq., Amended by Secure and Responsible Drug Disposal Act of 2010, S-3397 (January 5, 2010) (To amend the scope of the Controlled Substances Act to allow take-back programs to accept controlled substances).

<sup>142</sup> *Id.*

<sup>143</sup> An estimated 4.02 billion prescriptions in 2011. American Chemical Society, *Record 4.02 billion prescriptions in United States in 2011*, SCIENCE DAILY, (Sept. 2012) available at <http://www.sciencedaily.com/releases/2012/09/120912125529.htm>

of prescription drugs were not returned.<sup>144</sup> Further, for consumers worried about their children or other members of their household abusing leftover prescription drugs, bi-annual take-back programs are too infrequent, requiring these consumers to choose a different disposal method. Take-back programs are valuable and likely contribute significantly to the goal of decreasing the amount of pharmaceutical waste in the water, but are inadequate as currently implemented.

Pharmaceutical Stewardship Program – H.R. 2939. In 2011, Congresswoman Louise Slaughter proposed the Pharmaceutical Stewardship Program, which introduces a way to safely dispose of pharmaceuticals and “ensure that they are kept out of drinking water and out of the hands of unsuspecting children or criminals.”<sup>145</sup> The bill proposed the creation of a private, not-for-profit corporation, financed by pharmaceutical companies, which would be responsible for creating drug take-back programs in every state.<sup>146</sup> The bill also proposed the creation of a commission tasked with developing a “strategy to prevent pharmaceutical contaminants from polluting our waterways and environments from production to disposal.”<sup>147</sup> The bill was not passed in the 112th Congressional session,<sup>148</sup> though had it been passed, it would have been integral in reducing the amount of domestically used pharmaceuticals disposed of in the water.

#### **IV. Proposed Joint Action Plan between EPA and FDA**

Previous actions attempting to curb the amount of pharmaceuticals in our waters have been inadequate; a lack of uniformity in approaches and a lack of widespread knowledge contribute to the inability to properly regulate. This section proposes a joint action plan in which the EPA and the FDA work together to develop a single regulatory approach to the disposal of

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<sup>144</sup> Future pharmaceutical take-back days should be publicized more to increase the amount of pharmaceuticals recovered.

<sup>145</sup> Louise Slaughter, *supra* n. 13.

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> To see full text of the proposed bill, see <https://www.govtrack.us/congress/bills/112/hr2939> (last accessed Dec. 4, 2013).

pharmaceuticals. Creating an entirely new regulatory structure to address a singular problem would be cumbersome and likely unnecessary, so, regulatory agencies should operate under framework of existing regulations. The joint action plan involves reworking and strengthening current regulatory structures to include the disposal of pharmaceutical compounds within their scope. Once the current regulations are expanded to include the disposal of pharmaceuticals, the creation of a required NEPA-like environmental assessment will be implemented. This will shift the burden of investigating disposal practices and evaluating their environmental impact to the pharmaceutical companies. This burden shift is important because it places the financial burden of investigation on the pharmaceutical companies rather than the federal government, and would eliminate ex post facto examinations of toxicity. The EPA would no longer have to deal with the pharmaceutical waste's effects on the environment and aquatic wildlife after the waters were already polluted. This joint action plan will allow the FDA and the EPA to monitor the environmental effects of a drug long before the drug pollutes our waters.

#### **A. Creation of a More Robust Regulatory Framework**

The Clean Water Act already regulates the discharge of pollutants by point sources into the water. The EPA should write a new regulation that includes as point sources all major contributors to the discharge of pharmaceutical waste water sources. The Clean Water Act includes pharmaceutical manufacturing plants<sup>149</sup> as regulated point sources.<sup>150</sup> Under the new regulation, hospitals, long term care facilities and other acute care facilities should be considered point sources of pharmaceutical waste discharge. This will subject other major polluters<sup>151</sup> to

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<sup>149</sup> Env'tl. Prot. Agency Office of Compliance, Profile of the Pharmaceutical Manufacturing Industry, 109 (Sept. 1997).

<sup>150</sup> *Id.* (citing 40 C.F.R. Part 439 (Subpart A-E)).

<sup>151</sup> Kevin Darst, *Pill Dump Imperils Water's Quality*, FORT COLLINS COLORADOAN (Sept. 6, 2005) available at <http://lists.dep.state.fl.us/pipermail/pharmwaste/2005-September/000232.html> (Discussion of prevalence of dumping pharmaceuticals in the water at hospitals and long term care facilities).

EPA regulation and investigation.<sup>152</sup> RCRA already regulates hospitals and skilled nursing facilities' discharge of P-list and U-list wastes,<sup>153</sup> and requires integration with the Clean Water Act. Thus, the EPA can use the hazardous waste disposal requirements under RCRA as a framework, but include more pharmaceuticals on these lists. Alternatively, a new list can be created that lists pharmaceutical compounds that are commonly discharged by hospitals and skilled nursing facilities.

Once these polluters are included under the Clean Water Act umbrella, the EPA has the ability to enforce best available technology standards. The EPA and the FDA should jointly create a task force that includes members of both environmental protection groups and public health groups to determine the best available technology for the discharge of pharmaceutical pollutants. Since technology is always evolving and changing, the task force should reevaluate annually.

The enforcement of the best available technology standard is important as a way to regulate the disposal of pharmaceuticals that are already on the market by changing disposal practices to reflect current knowledge about best practices, and creating a regulatory floor that operates to reduce the amount of pharmaceutical discharge disposed of into the water. Further, a strong enforcement scheme will be technology forcing, creating incentives for regulated industry to develop new cost-effective technology to comply with the Clean Water Act requirements. It is important for the FDA and the EPA to have equal investigatory and enforcement powers to ensure compliance with the best available technology requirements.

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<sup>152</sup> See generally *Profile of the Pharmaceutical Manufacturing Industry*, *supra* n. 149 at 124 for the proposition that the EPA inspects and enforces violations of the Clean Water Act.

<sup>153</sup> 40 C.F.R. § 261.33.

In revising their regulatory framework, the EPA should also include pharmaceutical contaminants in its water quality standards under the Safe Drinking Water Act. Under the Safe Drinking Water Act, the EPA interacts with states to implement water quality standards.<sup>154</sup> The EPA should use this relationship with state agencies to have the states conduct independent investigations of the pharmaceutical contaminants with the highest concentrations in the state's drinking water supply. Including pharmaceuticals as a listed contaminant would force state agencies to test for pharmaceutical contaminants as a part of the tests currently required under the Safe Drinking Water Act. The EPA should work with the FDA to determine the concentration threshold of pharmaceutical contaminants, based on state reports of drinking water concentrations, necessary to protect public health. Compliance with the Safe Drinking Water Act is mandatory and subject to legal enforcement,<sup>155</sup> thus including pharmaceuticals as listed contaminants will force states to create mechanisms for reducing the pharmaceutical contaminants in their drinking water.

## **B. Environmental Assessment**

The final portion of the joint action plan borrows its scheme from the National Environmental Policy Act. The FDA already has rigorous requirements in order for a drug to be approved to market.<sup>156</sup> However, an assessment of the environmental impact of drugs pre-approval is not always conducted or required.<sup>157</sup> To remedy this, the FDA and the EPA should create a joint regulatory scheme which requires an environmental assessment of all new drugs

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<sup>154</sup> Env't Prot. Agency, *Understanding the Safe Drinking Water Act* (June 2004) available at [http://water.epa.gov/lawsregs/guidance/sdwa/upload/2009\\_08\\_28\\_sdwa\\_fs\\_30ann\\_sdwa\\_web.pdf](http://water.epa.gov/lawsregs/guidance/sdwa/upload/2009_08_28_sdwa_fs_30ann_sdwa_web.pdf) (last accessed Dec. 4, 2013).

<sup>155</sup> *Id.*

<sup>156</sup> Food and Drug Admin., *What is the Approval Process for New Prescription Drugs?*, available at <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194949.htm>.

<sup>157</sup> Food and Drug Admin. Consumer Update, *How to Dispose of Unused Medicines*, (Nov. 25, 2013), available at <http://www.fda.gov/forconsumers/consumerupdates/ucm101653.htm>.

seeking market approval, similar to NEPA. The EPA should begin by determining the pharmaceutical compounds most commonly found in drinking water. The EPA should also conduct an investigation into each of the disposal methods that they, and the FDA, have proposed. Investigating the environmental impact of incineration, household solid waste disposal, and flushing,<sup>158</sup> the agencies should jointly set thresholds of environmental impact at which an environmental impact statement would be required. This list should be given to the FDA to promulgate a list of newly regulated pharmaceutical compounds. The regulation should require pharmaceutical companies seeking market approval for new drugs containing these compounds to conduct an environmental assessment. The environmental assessment should focus on the impact that disposal of the drug would have on the environment. If the disposal of the approval-seeking drug surpasses the set threshold, the pharmaceutical company should be required to conduct an environmental impact statement. The environmental impact statement should require then pharmaceutical company to conduct an investigation of each of the disposal methods, and recommend the best practice for disposal. The best disposal practice may be incineration, solid waste disposal, flushing, return to the pharmacy, or any other method that pharmaceutical company determines to have the least environmental impact. Conducting an environmental assessment should be required of all pharmaceutical companies before the drug is approved to market. The subsequent environmental impact statement and recommendation of disposal practice should also be required when an environmental assessment reveals the impact of disposal to be greater than the EPA-determined threshold.

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<sup>158</sup> See Food and Drug Admin. Consumer Health Information, *How to Dispose of Unused Medicines* (April 2011), available at <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm107163.pdf>; & <http://water.epa.gov/scitech/swguidance/ppcp/upload/ppcpflyer.pdf> (last accessed Dec. 4, 2013).

Based on the pharmaceutical company's disposal recommendation, the FDA should change the labeling requirements of pharmaceuticals to require the packaging of pharmaceuticals to include specific instructions for disposal. In some cases, disposal methods are already required to be included on drug packaging. However, this is neither an inclusive nor universal requirement. The FDA should expand the labeling requirement to include all pharmaceuticals. This should be relatively easy to implement prospectively because the environmental assessment will already have been conducted.

Lastly, the EPA and the FDA have to act to make it easier for people to return unused or unwanted pharmaceuticals to pharmacies or hospitals. Rather than having two take-back days a year, there should be hazardous waste bins in each pharmacy where consumers can return unused pharmaceuticals at any time. This will require the FDA to further expand the scope of the Controlled Substances Act to allow all pharmacies to accept the return of controlled substances. Further, the EPA would be required to determine a way to sort the returned pharmaceuticals in order to dispose of them in the most environmentally friendly way, and keep these returned pharmaceuticals out of the water. Lastly, the EPA and FDA would still face the hurdle of actually getting people to return their unused pharmaceuticals, because for the consumer, flushing them is more convenient than returning them. This may include the implementation of a rebate or other sort of benefit plan in which the consumer gains a reward or a rebate for returning unused pharmaceuticals.<sup>159</sup> Through joint action, the EPA and the FDA can create a regulatory scheme that prospectively limits the amount of pharmaceuticals in the water.

## **V. Remaining open questions/problems**

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<sup>159</sup> This, of course, may have the unintended consequence of persuading people not to take all of their prescription.

While the implementation of a joint action plan is a step in the direction of reducing the pharmaceutical waste in the water, a number of problems remain unsolved. One remaining problem is the feasibility of creating an environmental impact statement for disposal of each newly introduced pharmaceutical. There are a significant number of variables that may impact the ability for the pharmaceutical company to engage in a comprehensive study of the impact of disposal in the water. While it would be feasible for the company to engage in a short-term study of the immediate, or near immediate effects of a concentration of the drug in the water, it will be difficult to study the long-term effects. This raises the question of the length of time the environmental impact study should span. A month may be insufficient, but a year may recklessly or unnecessarily delay the introduction of a drug into the market. This delay of introduction may adversely affect public health, by restricting people from receiving a potentially beneficial or therapeutic drug. Finding this balance will be a hurdle that the FDA and the EPA will have to clear.

A second remaining problem is the dissemination of the information about the proper disposal technique of a particular pharmaceutical. The results of the environmental impact statements will vary depending on the pharmaceutical. Thus, the best, and most environmentally friendly disposal method may also vary depending on the pharmaceutical. This creates the problem of dissemination of disposal information. Each pharmaceutical bottle should include information about the proper disposal method, and information about disposal should also be included in the package insert,<sup>160</sup> preferably in the “Highlights” portion.<sup>161</sup> The information

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<sup>160</sup> The package insert is a form of labeling that is included with pharmaceutical drugs. The FDA regulates the type of information that is included in the package insert. *See generally*, 21 C.F.R § 201.57.

<sup>161</sup> 21 C.F.R § 201.56(d)(1) requires specific information to be included in all pharmaceutical labeling. This includes a Highlights section to appear at the beginning of all pharmaceutical labeling. While the Highlights section need not be exhaustive, but must include information about the U.S. approval. *See* § 201.57(a)(4). Since a disposal best practices assessment is required under this regime prior to approval, the information should be included in this section.

about disposal can be included on the bottle, underneath the dosage information. It is most likely to be seen by patients if the information is put on the bottle. As an alternative, the package insert can, and should, include information about proper practice for disposing of the drug. However, it is unlikely that a majority of patients look at the information. Further, it is unlikely that a majority of patients consider proper disposal of their pharmaceuticals germane enough to check the package insert for information about proper disposal. Thus, there would need to be notices placed in ways that they would reach a significant number of people. These notices would need to inform patients that proper disposal information is included in the package insert. Including disposal information in the package insert would also require prescribing physicians to inform patients to check the proper disposal method in the package insert. The dissemination of information remains a problem because despite the FDA's and the EPA's efforts to reduce the amount of pharmaceuticals in the water by requiring an environmental impact statement regarding the disposal of the pharmaceutical, if patients do not cooperate with the disposal requirements, the pharmaceuticals may still end up in the water.

Finally, this solution does not address the problem of pharmaceutical waste that is already in the water. While it may curb the disposal of future pharmaceuticals being disposed of in our nation's waters, there are still billions of prescriptions being written each year for pharmaceuticals that are already approved. In order for this to make a significant change, the FDA and the EPA must retroactively apply the environmental impact statement and labeling requirements to pharmaceuticals that are already market-approved. This would come at extreme cost to pharmaceuticals companies and would likely be difficult to enforce.

## **Conclusion**

It is unlikely that worldwide dependence of pharmaceuticals is on the decline. It is, therefore, necessary to take regulatory action to stop the disposal of pharmaceuticals in the water. The FDA and the EPA should work together to develop a regulatory scheme that focuses both on protecting human health and preserving the environment while requiring pharmaceutical companies seeking approval for new drugs to bear the burden of developing the proper disposal practices.