DRUGS ON TAP: MANAGING PHARMACEUTICALS IN OUR NATION'S WATERS

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Pharmaceuticals in the environment and public water supplies are believed to have serious impacts on human and environmental health. Current research suggests that exposure to certain drugs and their residues may result in a variety of adverse human health effects. Other studies more conclusively show that even minute concentrations of pharmaceuticals in the environment can have detrimental effects on aquatic and terrestrial species. Unfortunately, the cost of removing these pernicious substances is out of the financial reach of most municipalities and wastewater and drinking water treatment operators.

Despite the concerns, little effort has been made to develop broad management, mitigatory, or disposal prevention strategies to address the potential threat from medications and their residues in the environment or in our drinking water. Neither the United States federal government nor the states have been able to formulate an adequate response.

The purpose of this Article is to further awareness about the lack of governmental attention to the growing problem pharmaceuticals and pharmaceutical residues pose to the environment and the nation's freshwater supplies. After describing the scope of the problem, as well as the deficiencies and loopholes in the existing statutory and regulatory regime, the Article contends that focusing regulations on pharmaceuticals once they reach the waste stream is an inadequate and ineffective approach to reducing pharmaceutical pollutants in the environment. Rather, federal and state governments should implement mechanisms that

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target the earlier lifecycle stages of pharmaceuticals so as to prevent pharmaceuticals and their residues from reaching the natural environment and, thereby, to reduce the risks to people, communities, species, and ecosystems.

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INTRODUCTION

"Doctors prescribe hydrocodone for pain. They recommend ranitidine for acid reflux, a diuretic called hydrochlorothiazide

> for congestive heart failure. But you don't need a prescription to get these drugs in tiny doses. They're found already in our nation's water supply . . . ."[1]

In recent years, serious questions have been raised about the environmental and health impacts of pharmaceuticals[2] in our nation's fresh water resources.[3] Numerous studies intimate that unintended exposure to certain drugs, such as antibiotics and endocrine disruptors, or a synergistic combination of pharmaceutical substances, may cause adverse health impacts for humans;[4] other research has more conclusively established that even minute concentrations of certain drugs can have detrimental effects on aquatic and terrestrial species.[5]

In addition, the various medications, pharmaceutical products,

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1 Dawn Fallik, *This New Study Found More Drugs in Our Drinking Water Than Anybody Knew—And No One's Doing Anything About It*, NEW REPUBLIC (Dec. 11, 2013), http://www.newrepublic.com/article/115883/drugs-drinking-water-new-epa-study-finds-more-we-knew.

2 Pharmaceuticals encompass all synthetic and natural substances, both prescription and over-the-counter, used in diagnosing, treating, altering, and preventing disease. They are also used to manage the structure and functioning of the human body as well as in veterinary activities. Christian G. Daughton & Thomas A. Ternes, *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?*, 107 ENVTL. HEALTH PERSP. 907, 908 (1999). When discussing trace environmental contamination resulting from human and animal drug use, the residual molecular entity or active pharmaceutical ingredient is the thing being measured or referenced. *See* Christian Daughton, *Pharmaceuticals in the Environment: Sources and Their Management*, *in* 62 COMPREHENSIVE ANALYTICAL CHEMISTRY: ANALYSIS, REMOVAL, EFFECTS AND RISK OF PHARMACEUTICALS IN THE WATER CYCLE OCCURRENCE AND TRANSFORMATION IN THE ENVIRONMENT 44 (Mira Petrovic et al. eds., 2013) [hereinafter Daughton, *Pharmaceuticals in the Environment*].

3 For example, in 2008, the Associated Press released a series of investigative reports. AN AP INVESTIGATION: PHARMACEUTICALS FOUND IN DRINKING WATER, http://hosted.ap.org/specials/interactives/pharmawater_site/ (last visited Mar. 23, 2014). These reports were distributed in print and electronic media worldwide. *See, e.g.*, Jeff Donn, *Drug Traces Turn up in Source Waters for Nation's Biggest City*, ASSOCIATED PRESS (Mar. 2008), http://hosted.ap.org/specials/interactives/pharmawater_site/day1_02.html; Martha Mendoza, *On Eve of Hearings, White House Documents Show Feds Failing to Take Action on Drugs in Water*, ASSOCIATED PRESS (Apr. 13, 2006), http://hosted.ap.org/specials/interactives/pharmawater_site/april13.html.

4 *See infra* notes 43–52 and accompanying text.

5 *See* Gabriel Eckstein & George William Sherk, *Alternative Strategies for Addressing the Presence and Effects of Pharmaceutical and Personal Care Products in Fresh Water Resources*, 15 DENVER WATER L. REV. 369 (2012) (surveying the growing scientific evidence on the threats that Pharmaceuticals and Personal Care Products (PPCPs) pose to people and the environment and describing the confusing regulatory regime applicable to such substances); *see also infra* notes 53–61 and accompanying text.

and their residues, metabolites, and components (collectively "pharmaceutical pollutants") that end up in the environment have received growing attention from the fresh water treatment and wastewater discharge communities because of their ability to persist, or only partially degrade, in nature as well as during freshwater and wastewater treatment.[6] Treating for these substances after they enter the sewage or wastewater system or the environment is costly and out of the financial reach of most municipalities and wastewater and drinking water treatment operators.[7] As a result, communities, health care professionals, and environmental professionals are concerned about the ability of municipalities to ensure safe freshwater for their residents and for the surrounding environment.[8]

Despite the concerns, little effort has been made to develop broad management, mitigatory, or disposal prevention strategies to address the presence of pharmaceutical waste in the environment. On the national level, Congress has not adopted legislation specifically intended to address the multitude of pharmaceutical pollutants that enter the natural environment or the threat they pose to people and the environment. While certain pharmaceuticals and pharmaceutical wastes[9] are haphazardly

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6 *See* Eckstein & Sherk, *supra* note 5 at 371–72; *see also* Kelly A. Reynolds, *Concern of Pharmaceuticals in Drinking Water*, 50 WATER CONDITIONING & PURIFICATION (2008) (noting that certain pharmaceuticals—e.g., antibiotics and estrogens—may "persist in the environment either due to their inability to biodegrade naturally or to their constant use keeping them ever-present").

7 *See infra* note 183 and accompanying text.

8 *See e.g.,* WORLD HEALTH ORG., PHARMACEUTICALS IN DRINKING WATER 15 (2012); Jeff Donn et al., *Pharmawater I: Pharmaceuticals Found in Drinking Water, Affecting Wildlife and Maybe Humans*, ASSOCIATED PRESS (Mar. 9, 2008), http://hosted.ap.org/specials/interactives/pharmawater_site/day1_01.html; Matt Harvey, *Your Tap Water Is Probably Laced with Antidepressants*, SALON (Mar. 14, 2013), http://www.salon.com/2013/03/14/your_tap_water_is_probably_laced_with_anti_depressants_partner/; David Noble, *Trouble at the Tap*, WATER QUALITY PRODUCTS (Feb. 6. 2014), http://www.wqpmag.com/trouble-tap.

9 Although there is no federal statutory or regulatory definition for pharmaceutical waste, the term refers to pharmaceutical products that have been intentionally or unintentionally discarded and have entered the waste stream. The Missouri Department of Natural Resources described pharmaceutical waste as discarded or confiscated pharmaceutical items that include pharmaceutical products, illegal drugs, and pharmaceutical precursors or ingredients. MO. DEP'T OF NATURAL RES., IS YOUR PHARMACEUTICAL WASTE ALSO HAZARDOUS WASTE?, HAZARDOUS WASTE PROGRAM FACT SHEET (2010), *available at* https://www.dnr.mo.gov/pubs/pub2128.htm. The Wisconsin Department of

subject to a few statutory and regulatory mechanisms,[10] they are, for the most part, outside the scope of the law.

The purpose of this Article is to bring attention to the lack of governmental focus on the growing problem posed by pharmaceutical pollutants in the environment and the nation's freshwater supplies. Section I describes how substances in rivers, lakes, aquifers, and soils threaten the health of various species, ecosystems, and people. Sections II and III review the existing statutory and regulatory mechanisms applicable to pharmaceutical pollutants, at both the federal and state levels, and identify the loopholes and other deficiencies that make the existing system inadequate and often irrelevant. Section IV concludes that a targeted governmental response is critically necessary to reduce existing known threats as well as minimize potential hazards. In particular, this Section argues that mechanisms that prevent pharmaceuticals from reaching the natural environment would be more effective and appropriate approaches for reducing the risks posed by pharmaceutical pollutants than the present system, which targets pharmaceuticals once they reach the waste stream.

Natural Resources identifies pharmaceutical waste as including expired drugs, patients' discarded personal medications, waste materials containing excess drugs (syringes, IV bags, tubing, vials, etc.), waste materials containing chemotherapy drug residues, open containers of drugs that cannot be used, containers that held substances regulated under the federal Resource Conservation and Recovery Act, drugs that are discarded, and contaminated garments, absorbents and spill cleanup material. WISC. DEP'T OF NAT. RES., EVALUATING & MANAGING PHARMACEUTICAL WASTE, HEALTH CARE INITIATIVE FACT SHEET (2008), *available at http://dnr.wi.gov/files/pdf/pubs/wa/wa1257.pdf*. An EPA-funded study explained that:

> Pharmaceutical waste is not one single waste stream, but many distinct waste streams that reflect the complexity and diversity of the chemicals that comprise pharmaceuticals. Pharmaceutical waste is potentially generated through a wide variety of activities in a healthcare facility, including but not limited to intravenous (IV) preparation, general compounding, spills/breakage, partially used vials, syringes, and IVs, discontinued, unused preparations, unused unit dose repacks, patients' personal medications and outdated pharmaceuticals.

CHARLOTTE SMITH, MANAGING PHARMACEUTICAL WASTE: A 10-STEP BLUEPRINT FOR HEALTHCARE FACILITIES IN THE UNITED STATES 8 (2008).

10 *See infra* notes 65–163 and accompanying text.

I. THE THREATS POSED BY PHARMACEUTICALS IN THE ENVIRONMENT

A. *Background to the Threat*

Pharmaceutical pollutants are found in nearly every corner of the globe, in rivers and lakes, ground water resources, and soils.[11] A U.S. Geological Survey study conducted in 1999–2000 sampled 139 streams throughout the United States and found at least one of ninety-five organic wastewater contaminants, such as "antibiotics, other prescription drugs, nonprescription drugs, steroids, [and] reproductive hormones," in 80 percent of stream samples.[12] In 2008, an investigation by the Associated Press revealed "[a] vast array of pharmaceuticals including antibiotics, anti-convulsants, mood stabilizers and sex hormones . . . in the drinking water supplies of at least 41 million Americans" in twenty-four major metropolitan communities.[13] More recently, a 2013 study funded by the U.S. Environmental Protection Agency (EPA) sampled fifty large wastewater treatment plants nationwide and discovered at least twenty-five different active pharmaceutical ingredients in the waste stream, including pain-relief medicines like oxycodone, blood thinners like warfarin, high blood pressure medication and beta blockers like hydrochlorothiazide, atenolol and metoprolol, and over-the-counter drugs like Tylenol and ibuprofen.[14]

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11 *See* Christian G. Daughton, *PPCPs in the Environment: Future Research—Beginning with the End Always in Mind*, *in* PHARMACEUTICALS IN THE ENVIRONMENT: SOURCES, FATE, EFFECTS AND RISKS 463, 463 (Klaus Kümmerer ed., 2d ed. 2004); Eckstein & Sherk, *supra* note 5, at 372. While pharmaceuticals have been detected in the environment since the 1970s, attention to these "emerging pollutants" became more pronounced in the 1990s when newer, more sensitive technologies for detecting and analyzing these pollutants were developed. Today, scientists have tools that allow them to identify micropollutants in all waters and soils at levels less than a nanogram (one billionth of a gram) per liter. *See* HUMAN PHARMACEUTICALS, HORMONES AND FRAGRANCES 2–3 (Thomas A. Ternes & Adriano Joss eds., 2006).

12 Dana W. Kolpin et al*., Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999–2000: A National Reconnaissance*, 35 ENVTL. SCI. & TECH. 1202, 1203 (2002).

13 Donn, *supra* note 8.

14 M.S. Kostich et al., *Concentrations of Prioritized Pharmaceuticals in Effluents from 50 Large Wastewater Treatment Plants in the U.S. and Implications for Risk Estimation*, 184 ENVTL. POLLUTION 354 (2014) (identifying in the waste stream pain relief medicines like oxycodone, blood thinners like warfarin, high blood pressure medication and beta blockers like hydrochlorothiazide, atenolol and metoprolol, and over-the-counter drugs like Tylenol and ibuprofen).

While some pharmaceutical components are naturally occurring, the most significant sources of pharmaceuticals in the environment are anthropogenic.[15] Pharmaceuticals reach the environment in many ways, including through waste from hospitals, health clinics, doctor offices, and nursing homes;[16] pharmacies;[17] discarded products and wastes from pharmaceutical manufacturers and distributors;[18] wastes from veterinary health care, aquaculture, and animal husbandry activities;[19] and the inappropriate disposal of unwanted medications (e.g., flushed down toilets).[20] Other sources of pharmaceutical pollution that are

15 *See* ED MEANS ET AL., ENDOCRINE DISRUPTORS AND PHARMACEUTICALS STRATEGIC INITIATIVE EXPERT WORKSHOP REPORT 5 (2007) (stating, with regard to endocrine disrupting chemicals, that, "[w]hile some estrogenic compounds occur naturally, most of the detected estrogenic compounds are introduced from man-made sources").

16 *See* Ternes & Joss, *supra* note 11, at 25. One of the more conspicuously wasteful practices is the disposal of excess drugs in hospitals and clinics. Manufacturers typically produce pharmaceutical products in only a few specific sizes and doses. As a result, doctors and nurses are challenged by matching these products sizes and dozes to their patients, who often require only partial dosages of specific medications. Drug use regulations require unused portions to be discarded. These portions usually end up in sinks or toilets. *See e.g.,* Erin Jordan, *Dealing with Drug Waste in the Corridor*, GAZETTE (Feb. 2, 2014), *available at* http://thegazette.com/2014/02/02/dealing-with-drug-waste-in-the-corridor/ (describing findings at a hospital in Iowa City, Iowa, where, in fiscal year 2013, hospital staff discarded 47,000 1-millimeter hydromorphone syringes that contained an average of 0.7 millimeters of the drug, and findings from an Albany, New York hospital where staff regularly discarded 90 percent of propofol, a common anesthetic, because the containers were oversized and regulations required disposal of unused portions).

17 *See*, *e.g*, Mike Lee, *CVS Agrees To Pay Big Fine in Dumping Case*, SAN DIEGO UNION TRIB. (Apr. 18, 2012, 2:49 PM), http://www.utsandiego.com/news/2012/apr/18/cvs-agrees-pay-big-fine-dumping-case/.

18 *See e.g.,* Patrick J. Phillips et al., *Pharmaceutical Formulation Facilities as Sources of Opioids and Other Pharmaceuticals to Wastewater Treatment Plant Effluents*, 44 ENVTL. SCI. & TECH. 4910 (2010); *Manufacturing Facilities Release Pharmaceuticals to the Environment*, U.S. GEOLOGICAL SURVEY (May 20, 2010), http://toxics.usgs.gov/highlights/PMFs.html; Jeff Donn, et al., *US Water Contaminated By Pharmaceutical Companies, Hospitals, Consumers*, HUFFINGTON POST (Apr. 20, 2009), http://www.huffingtonpost.com/2009/04/20/us-water-contaminated-by-_n_188852.html (asserting that "U.S. manufacturers, including major drugmakers, have legally released at least 271 million pounds of pharmaceuticals into waterways that often provide drinking water").

19 Klaus Kümmerer, *Pharmaceuticals in the Environment—Scope of the Book and Introduction*, *in* PHARMACEUTICALS IN THE ENVIRONMENT: SOURCES, FATE, EFFECTS AND RISKS 3, 5 (Klaus Kümmerer ed., 2d ed. 2004).

20 Paul D. Anderson et al., *Screening Analysis of Human Pharmaceutical Compounds in U.S. Surface Waters*, 38 ENVTL. SCI. & TECH. 838, 838 (2004); J.B. Ellis, *Pharmaceutical and Personal Care Products (PPCPs) in Urban*

less obvious include human and animal feces and urine,[21] coroner office wastes,[22] bath water,[23] leachate from landfills containing improperly discarded pharmaceutical products and items contaminated with pharmaceutical residues,[24] and irrigation water sourced from reclaimed wastewater.[25] While human excretion is thought to be the chief source of active pharmaceutical ingredients in the environment,[26] the relative contribution of each of the

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Receiving Waters, 144 ENVTL. POLLUTION 184, 185 (2006). In California, a 2007 unused medication collection program suggests that 52 percent of over-the-counter drugs and 45 percent of prescription medicines are discarded unused. TELEOSIS INST., GREEN PHARMACY PROGRAM: HELPING COMMUNITIES SAFELY DISPOSE OF UNUSED MEDICINES (2007), *available at* http://www.teleosis.org/pdf/GreenPharmacy_FullPreliminaryReport.pdf. A survey from the mid-1990s reported that only two percent of respondents fully completed their prescription medication. *See* Susan T. Glassmeyer et al., *Disposal Practices for Unwanted Residential Medications in the United States*, 35 ENV'T INT'L 566, 568 (2009) (citing to a survey reported in D.S. Kuspis & E.P. Krenzelok, *What Happens to Medications? A Survey of Community Medication Disposal*, 38 VETERINARY HUM. TOXICOLOGY 48–49 (1996)).

21 For example, a recent study reported that 90 percent of the active ingredients of the beta blocker Atenolol and 60 percent of the antibiotic Amoxycillin remain unmetabolized as they move through the human body and, thereafter, are excreted. *See* CHRIS WATTS ET AL., DESK BASED REVIEW OF CURRENT KNOWLEDGE ON PHARMACEUTICALS IN DRINKING WATER AND ESTIMATION OF POTENTIAL LEVELS 32 (2007). Excretion rates for antibiotics used in animal health care are estimated at between 25 and 75 percent. MAE WU ET AL., DOSED WITHOUT PRESCRIPTION: PREVENTING PHARMACEUTICAL CONTAMINATION OF OUR NATION'S DRINKING WATER 32 (2009).

22 Ilene S. Ruhoy & Christian G. Daughton, *Types and Quantities of Leftover Drugs Entering the Environment via Disposal to Sewage—Revealed by Coroner Records*, 388 SCI. TOTAL ENV'T 137, 144–145 (2007) (revealing that during the 13-month study period: of the pharmaceuticals collected at crime scenes and taken to coroner' offices, 92 percent were flushed and eight percent discarded in the trash; 325,000 pharmaceuticals were disposed of in the sewage system amounting to 102 kilograms of pharmaceutical wastes; extrapolating these figures nationally suggests that approximately 17.9 metric tons of pharmaceutical waste is disposed of annually by coroners in municipal sewage systems).

23 Christian G. Daughton & Ilene S. Ruhoy, *Environmental Footprints of Pharmaceuticals: The Significance of Factors Beyond Direct Excretion to Sewers*, 28 ENVTL. TOXICOLOGY & CHEMISTRY 2495, 2495 (2009); Erin M. Snyder et al., *Pharmaceuticals and EDCS in the U.S. Water Industry—An Update*, 97 J. AM. WATER WORKS ASS'N 32 (2005).

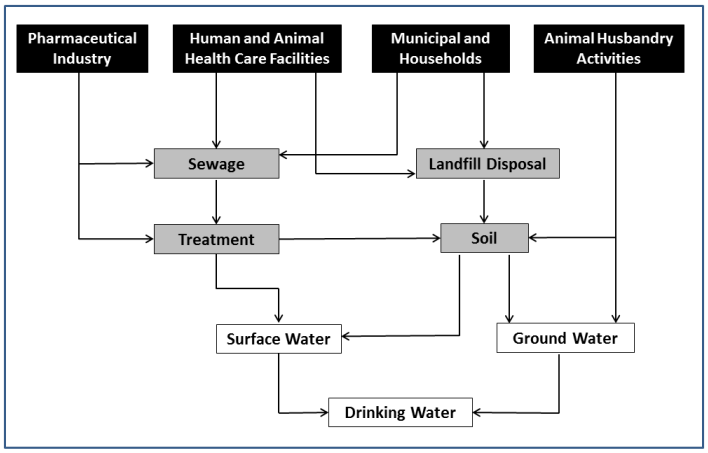
24 Mark J. Benotti et al., *Pharmaceuticals and Endocrine Disrupting Compounds in U.S. Drinking Water*, 43 ENVTL. SCI. & TECH. 597 (2009); Reynolds, *supra* note 6.

25 *See* WU ET AL., *supra* note 21, at 3.

26 *See* Klaus Kümmerer, *Strategies for Reducing the Input of Pharmaceuticals Into the Environment, in* PHARMACEUTICALS IN THE ENVIRONMENT: SOURCES, FATE, EFFECTS AND RISK 416 (Klaus Kümmerer ed.,

sources to environmental loadings is still uncertain due to a lack of precise data on the use rates, disposal practices, and disposal routes of various pharmaceutical substances.[27] Figure 1 depicts how pharmaceutical pollutants generally enter the environment and drinking water supplies.

Figure 1: Chief pathways for pharmaceuticals to enter the environment and drinking water supplies



The presence of these drugs in the environment should not come as a surprise. In 2012, Americans spent $325 billion on prescription medicines.[28] A 2008 study indicates that between 1998 and 2008, the percentage of Americans taking at least one prescribed medication monthly increased from 44 to 48 percent.[29]

2008).

27 Alexandra Titz & Petra Döll, *Actor Modelling and Its Contribution to the Development of Integrative Strategies for Management of Pharmaceuticals in Drinking Water*, 68 SOC. SCI. & MED. 672, 673 (2009).

28 Katie Thomas, *U.S. Drug Costs Dropped in 2012, but Rises Loom*, N.Y. TIMES, Mar. 18, 2013, http://www.nytimes.com/2013/03/19/business/use-of-generics-produces-an-unusual-drop-in-drug-spending.html?pagewanted=all (reporting that while 2012 saw a slight drop in prescription drug sales in the United States, the market is expected to rise by four percent in 2014 and continue to rise in the near future).

29 QIUPING GU ET AL., U.S. DEP'T OF HEALTH & HUMAN SERVS., NCHS DATA BRIEF NO. 42, PRESCRIPTION DRUG USE CONTINUES TO INCREASE: U.S. PRESCRIPTION DRUG DATA FOR 2007–2008, at 1 (2010), *available at* http://www.cdc.gov/nchs/data/databriefs/db42.pdf. The study further noted that, during the same study period, the percentage of Americans taking at least two prescribed medication monthly increased from 25 to 31 percent, and the use of five or more drugs increased from 6 to 11 percent. *Id*. The most commonly used types of drugs included: asthma medicines for children, central nervous system stimulants for adolescents, antidepressants for middle-aged adults, and cholesterol-lowering

In 2013, the average American filled 12.3 prescriptions annually at retail pharmacies,[30] amounting to nearly four billion prescriptions.[31] Moreover, most pharmaceuticals are designed to be persistent so as to reach the body part targeted for pharmacological benefit.[32] That persistence translates into a resistance to natural degradation in the environment.[33]

Despite the known prevalence and persistence of these contaminants in the environment, most wastewater and freshwater installations and processes rarely target these contaminants for treatment or removal.[34] In fact, the vast majority of treatment operations do not have the capacity, resources, or technology necessary to remove pharmaceuticals pollutants from the waste stream or freshwater supply sources.[35] Moreover, "given the vast array of mechanisms of drug action and side effects, the total number of different toxicity tests possibly required to screen the effluent from a typical [sewage treatment plant] could be

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drugs for older Americans. *Id*. at 1, 5.

30 *State Health Facts: Retail Prescription Drugs Filled at Pharmacies (Annual per Capita)*, HENRY J. KAISER FAMILY FOUND., http://kff.org/other/state-indicator/retail-rx-drugs-per-capita/#table (last visited Sept. 16, 2014).

31 *State Health Facts: Total Number of Retail Prescription Drugs Filled at Pharmacies*, HENRY J. KAISER FAMILY FOUND., http://kff.org/other/state-indicator/total-retail-rx-drugs/ (last visited Sept. 16, 2014).

32 *See* Ternes & Joss, *supra* note 11, at 386.

33 *See* Staffan Castensson, *Pharmaceutical Waste, in* PHARMACEUTICALS IN THE ENVIRONMENT: SOURCES, FATE, EFFECTS AND RISK 489, 497 (Klaus Kümmerer ed., 2008) ("Pharmaceuticals are designed to be resistant to biological degredation"); *cf.* Daughton & Ternes, *supra* note 2, at 907, 933 (noting "that many of these compounds survive biodegradation" but also explaining that "[p]ersistence is not critical if the source is constant, leading to perpetual aquatic exposure").

34 *Cf.* Castensson, *supra* note 33, at 497 (noting that treatment facilities for wastewater "are designed to remove conventional pollutants . . . but they are not designed to remove low concentrations of synthetic pollutants such as pharmaceuticals").

35 Suzanne Avena & Dayna Tann, *The Hazards of Pharmaceutical Disposal: Arising Issues of Concern*, 23 WESTLAW J. ENVTL. 1, 3 (2013) (asserting that "traditional wastewater treatment is not designed to remove pharmaceuticals" and that "while some of the upgraded facilities have more advanced treatment technologies, even these facilities are not specifically designed to remove pharmaceuticals. As a result, significant amounts of pharmaceutical waste pass through without being filtered, resulting in the waste ultimately passing into our waterways"); Shawna Bligh, *Pharmaceuticals in Surface Waters: Use of NEPA*, NAT. RES. & ENV'T, Fall 2009, at 56, 56 (indicating that "the efficiency of wastewater treatment processes to eliminate active drug compounds may be as low as 7 percent").

impractically large."[36] As a result, pharmaceutical pollutants persist in waters discharged from wastewater treatment plants into receiving streams and lakes,[37] solid and liquid wastes applied to designated land application sites,[38] and municipal water supplies.[39]

While numerous studies identifying pharmaceutical pollutants in the nation's freshwater resources emphasize that these substances are predominantly found at subtherapeutic levels[40] (typically measured in quantities of parts per billion or trillion), the vast majority acknowledge a causal relationship with abnormalities and other health impacts to various aquatic species.[41] Few negate the possibility of ill effects on people.[42]

B. *Human Exposure to Pharmaceuticals*

The most obvious pathway for unintentional human exposure to pharmaceutical substances or pollutants is ingesting contaminated water. Exposure may also occur through the consumption of fish and shellfish that have bioaccumulated pharmaceuticals or through contact with contaminated water.[43] In

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36 Daughton & Ternes, *supra* note 2, at 923.

37 Juliane B. Brown et al., *Lagrangian Sampling for Emerging Contaminants Through an Urban Stream Corridor in Colorado*, 45 J. AM. WATER RES. ASS'N 68, 69–70 (2009) (asserting that treated wastewater frequently contains "antioxidants . . . pharmaceuticals [prescription and nonprescription drugs] . . . and steroidal compounds . . . "). Such wastewater "has been shown to contain low, yet biologically active, concentrations of estrogenic compounds." Marlo K. Sellin et al., *Estrogenic Compounds Downstream from Three Small Cities in Eastern Nebraska: Occurrence and Biological Effect*, 45 J. AM. WATER RES. ASS'N 14, 15 (2009).

38 Sarah C. Monteiro & Alistair B.A. Boxall, *Pharmaceuticals and Personal Care Products in the Environment: Factors Affecting the Degradation of Pharmaceuticals in Agricultural Soils*, 28 ENVTL. TOXICOLOGY & CHEMISTRY 2546 (2009) (noting that "[i]n biosolids destined for land application, a number of pharmaceuticals . . . have been detected").

39 *See* Harvey, *supra* note 8; Jeffrey Kluger, *PHARMA in the Plumbing: Flushed Away*, TIME (Apr. 1, 2010), http://content.time.com/time/specials/packages/article/0,28804,1976909_1976907_1976871,00.html; Donn, *supra* note 8.

40 *Subtherapeutic definition*, DICTIONARY.COM, http://dictionary.reference.com/browse/subtherapeutic(last visited July 26, 2015) ("indicating a dosage, as of a drug or vitamin, less than the amount required for a therapeutic effect").

41 *See infra* notes 53–61 and accompanying text.

42 *See infra* notes 43–52 and accompanying text.

43 Virginia L. Cunningham et al., *Human Health Risk Assessment from the Presence of Human Pharmaceuticals in the Aquatic Environment*, 53 REGULATORY TOXICOLOGY & PHARMACOLOGY 39, 43 (2009); Ellis, *supra* note 20, at 185; Ake Wennmalm & Bo Gunnarsson, *Public Health Care Management*

reality, there is seldom a single exposure pathway. The National Research Council notes the existence of both "major and minor exposure pathways" and concludes that future risk assessments for pharmaceutical aggregate exposure should be evaluated across multiple pathways.[44] The Council further recommends, "where the same receptor is likely to be exposed to more than one pathway, exposures should be added across pathways."[45]

Evidence of harm from human exposure to pharmaceutical pollutants is inconclusive. Studies suggest that short-term exposure to low levels of specific pharmaceutical pollutants does not result in adverse human health impacts.[46] However, studies describing short-term exposure to high levels of specific pharmaceuticals are lacking. Moreover, studies of long-term or chronic human exposure to these substances suggest possible harmful impacts to human health.[47] For example, one researcher

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of Water Pollution with Pharmaceuticals: Environmental Classification and Analysis of Pharmaceutical Residues in Sewage Water, 39 DRUG INFO. J. 291, 296 (2005).

44 COMM. ON TOXICANTS & PATHOGENS IN BIOSOLIDS APPLIED TO LAND, NAT'L RESEARCH COUNCIL, BIOSOLIDS APPLIED TO LAND: ADVANCING STANDARDS AND PRACTICES 240–41 (2002), *available at* http://www.nap.edu/openbook.php?record_id=10426&page=240.

45 *Id*.; *see also* Kolpin et al., *supra* note 12, at 1202 (asserting that "there are a wide variety of transport pathways for many different chemicals to enter and persist in environmental waters").

46 *See e.g.,* WORLD HEALTH ORG., *supra* note 8, at 14 (asserting that "discernible risks to health arising from trace levels of pharmaceuticals in drinking-water are extremely unlikely"); GLOBAL WATER RESEARCH COALITION, OCCURRENCE AND POTENTIAL FOR HUMAN HEALTH IMPACTS OF PHARMACEUTICALS IN THE WATER SYSTEM 2 (2009), *available at* http://wvvw.weftec.org/WorkArea/DownloadAsset.aspx?id=3910 (stating that, "to date, no definitive link has been reported or established between pharmaceutical exposure in drinking water and human health risk"); GEORGE WASHINGTON SCH. OF PUB. HEALTH & HEALTH SERVS. RAPID PUB. HEALTH POLICY RESPONSE PROJECT, PHARMACEUTICALS ARE IN THE DRINKING WATER: WHAT DOES IT MEAN? 1 (2008) ("At current levels, pharmaceutical residues are unlikely to pose an immediate risk to human health, but the long-term consequences of individual chemicals, and combinations of chemicals, are unknown, especially as concentrations rise.").

47 *See e.g.,* Gerd Hamscher & Jörg Hartung, *Veterinary Antibiotics in Dust: Sources, Environmental Concentrations, and Possible Health Hazards, in* PHARMACEUTICALS IN THE ENVIRONMENT: SOURCES, FATE, EFFECTS AND RISK 95 (Klaus Kümmerer ed., 2008); Sungpyo Kima & Diana S. Aga, *Potential Ecological and Human Health Impacts of Antibiotics and Antibiotic-Resistant Bacteria from Wastewater Treatment Plants*, 10 J. TOXICOLOGY & ENVTL. HEALTH, PART B: CRITICAL REVIEWS 559 (2007); Oliver A. Jones, et al., *Pharmaceuticals: A Threat to Drinking Water?*, 23 TRENDS IN BIOTECHNOLOGY 163 (2005); Reynolds, *supra* note 6.

observed that "[t]rends of increased testicular cancer, reproductive abnormalities, breast cancer, early puberty and decreased sperm count have all been suggested as problems possibly related to low-level exposure to chemicals (pharmaceuticals and endocrine disrupting compounds (EDCs)) in the environment."[48]

Human exposure to pharmaceuticals, however, is rarely isolated to one specific drug or medicinal component. Exposure typically occurs to combinations of substances, the impacts of which are also relatively unknown.[49] Combinations of pharmaceuticals are believed to have cumulative or synergistic effects that go beyond the effects of any single pharmaceutical.[50] Moreover, studies indicate that in addition to cumulative or synergistic effects, certain pharmaceuticals may become more persistent when combined.[51] Unfortunately, "it is not clear what toxicological implications chronic exposure to suites of trace contaminants may pose."[52]

C. *Environmental Impacts from Pharmaceuticals*

In contrast to human exposure, many aquatic species are continuously subjected, over multiple generations, to pharmaceuticals in their natural habitats.[53] As a result, studies on

48 Reynolds, *supra* note 6, at 2. EDCs are chemical substances that at certain doses can interfere with human (and other mammals') endocrine or hormone systems. *See What Are Endocrine Disruptors?*, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/endo/pubs/edspoverview/whatare.htm (last updated Aug. 11, 2011).

49 Helen C. Poynton & Chris D. Vulpe, *Ecotoxicogenomics: Emerging Technologies for Emerging Contaminants*, 45 J. AM. WATER RES. ASS'N 83, 91 (2009) (stating that "[i]n field situations, organisms are exposed to not just one compound but a mélange of contaminants, which can interact within the environment and individual organisms").

50 Kolpin et al., *supra* note 12, at 1210.

51 Monteiro, *supra* note 38, at 2553 ("As pharmaceuticals will never be in the environment as single compounds, a consideration of the impacts of mixtures of different pharmaceuticals and pharmaceuticals and other compounds needs to be assessed. Our preliminary data demonstrate that degradation may be significantly slower in mixtures.").

52 Benotti, *supra* note 24, at 597; *cf.* GEORGE WASHINGTON SCH. OF PUB. HEALTH & HEALTH SERVS, *supra* note 46, at 4 (adding that "[a] limited body of research . . . suggests an additive effect when a mixture of pharmaceuticals is present").

53 GEORGE WASHINGTON SCH. OF PUB. HEALTH & HEALTH SERVS, *supra* note 46, at 4. Aquatic species, however, are not the only species detrimentally affected by the presence of pharmaceuticals in the environment. *See e.g.,* Rhys Green et al., *Collapse of Asian Vulture Populations: Risk of Mortality from Residues of the Veterinary Drug Diclofenac in Carcasses of Treated Cattle*, 43 J.

the health impacts of pharmaceutical exposure are more conclusive. For example, the low-level presence of pharmaceutical estrogens has led to "a suite of adverse effects" for certain fish and other aquatic vertebrates, including the feminization of males,[54] impaired reproductive capacity,[55] and abnormal sexual development.[56] In contrast, exposure to trebolone metabolites found in steroids used to promote muscle growth is known to cause masculinization and lower fertility rates in female fish.[57] Moreover, antidepressants are believed to "trigger premature spawning in shellfish while drugs designed to treat heart ailments block the ability of fish to repair damaged fins."[58] Focusing on endocrine disrupting compounds, one researcher concluded:

> [These] are compounds that interfere with natural production, release, transport, metabolism, binding, action, or elimination of hormones in the body. . . . Small disturbances in endocrine function, especially during certain stages of the life cycle, can lead to profound and lasting effects. There is evidence that specific populations of invertebrate, fish, avian, reptilian, and mammalian species have been, or currently are being, adversely affected by exposure to environmental contaminants that effect the endocrine systems. . . .[59]

The presence of pharmaceutical pollutants in the environment potentially affects organisms throughout the food web. However, since the majority of organisms studied for possible

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APPLIED ECOLOGY 949 (2006); Susanne Shultz, et al., *Diclofenac Poisoning is Widespread in Declining Vulture Populations Across the Indian Subcontinent*, 271 PROC. ROYAL SOC'Y LONDON S458, S458 (2004) (both studies discussing unmistaken causal relationship between use of the veterinary drug diclofenac, a non-steroidal anti-inflammatory drug used to treat farm animals, and the death of 95 percent of India's and 90 percent of Pakistan's Gyps vulture populations).

54 Sellin, *supra* note 37, at 14; Natasha Gilbert, *Drug Waste Harms Fish*, 476 NATURE 265, 265 (2011); Karen A. Kidd et al., *Collapse of a Fish Population After Exposure to a Synthetic Estrogen*, 104 PROC. NAT'L ACAD. SCI. 8897, 8897 (2007).

55 Sellin, *supra* note 37, at 14–15; *see also* Poynton & Vulpe, *supra* note 49, at 84; Heiko L. Schoenfuss et al., *Effects of Exposure to Low Levels of Water-Borne 17β-Estradiol on Nest Holding Ability and Sperm Quality in Fathead Minnows*, 120 WATER RES. UPDATE 49 (2001).

56 Sellin, *supra* note 37, at 15; Gilbert, *supra* note 54, at 265.

57 *See* E.J. Durhan et al. *Identification of Metabolites of Trenbolone Acetate in Androgenic Runoff from a Beef Feedlot*, 114 ENVTL. HEALTH PERSP. 65, 67 (2006).

58 Reynolds, *supra* note 6.

59 Robert W. Masters, *Pharmaceuticals and Endocrine Disruptors in Rivers and on Tap*, 120 WATER RESOURCES UPDATE 1 (2001).

pharmaceutical impacts are at the bottom of the food chain, the consequences that these organisms may have on species higher in the chain is generally unknown.[60] Nevertheless, the fact that chronic exposure to pharmaceuticals has been found to negatively impact the health of the base food-chain species suggests a likelihood of similar consequences for those higher in the chain.[61]

D. *Gaps in Knowledge*

Current knowledge about the impact of pharmaceuticals on people and ecosystems is inadequate to provide a clear understanding of the sources of these pollutants and all the potential implications of exposure. In particular, more information is needed about the various pathways that pharmaceutical pollutants take to reach the environment and, especially, their relative contribution to the presence of these environmental contaminants.[62] In addition, there is a dearth of information on the effects of long-term, low-dose human exposure to the multitude of pharmaceutical pollutants.[63] Similarly, research is needed on the synergistic effects and health impacts that exposure to multiple pharmaceutical substances and waste may pose to humans and other species.[64] Without this information, regulatory and management schemes will not be fully effective or protect the human and natural environments as intended.

II. THE FEDERAL APPROACH TO MANAGING PHARMACEUTICALS IN THE ENVIRONMENT

The U.S. Congress has not yet adopted legislation specifically

60 Talia E. A. Chalew & Rolf U. Halden, *Environmental Exposure of Aquatic and Terrestrial Biota to Triclosan and Triclocarban*, 45 J. AM. WATER RES. ASS'N 4, 10 (2009). One of the only pharmaceutical impact studies of a species high in the food chain was conducted on Pakistan's Gyps vultures, whose population was decimated as a result of consuming farm animals treated with the non-steroidal anti-inflammatory drug diclofenac. *See supra* note 53.

61 *See* Chalew & Halden, *supra* note 60, at 10; Poynton & Vulpe, *supra* note 49, at 84.

62 *See* Daughton, *Pharmaceuticals in the Environment*, *supra* note 2, at 54 (discussing lack of information, including source contribution and environmental loading); *see also supra* notes 15–27 and accompanying text.

63 "Although a wealth of toxicological information may be available for pharmaceuticals, the effects of unintended chronic exposure to subtherapeutic doses that could occur via consumption of drinking water are often not known." Snyder, *supra* note 23, at 33.

64 *See supra* notes 49–52 and accompanying text.

aimed at managing pharmaceutical pollutants in the environment. A number of federal agencies have interpreted three environmental statutes—the Resource Conservation and Recovery Act (RCRA),[65] the Clean Water Act (CWA),[66] and the Safe Drinking Water Act (SDWA)[67]—as applicable to certain pharmaceutical wastes in the waste stream, and another—the National Environmental Policy Act (NEPA)[68]—to the manufacturing of drug products in relation to their potential to reach the natural environment. However, none of these statutes were specifically designed with pharmaceuticals in mind, and they have proven inadequate to resolve the challenges posed by pharmaceutical pollutants in the environment.

A. *Resource Conservation and Recovery Act*

RCRA is a federal program for the "cradle-to-grave" management of hazardous substances and waste.[69] One of the statute's express goals is to protect human health and the environment from the hazards posed by waste disposal.[70] Other goals include the reduction or elimination of the amount of waste generated (including hazardous waste), and the proper management of such waste to protect human health and the environment.[71]

Under RCRA, the EPA, as well as EPA-authorized state agencies, regulates the generation, storage, transportation, treatment, and disposal of hazardous solid wastes.[72] EPA identifies

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65 Resource Conservation and Recovery Act (RCRA) of 1976, 42 U.S.C. §§ 6901–6992k (2012).

66 Clean Water Act (CWA), 33 U.S.C. §§ 1251–1387 (2012).

67 Safe Drinking Water Act (SWDA), 42 U.S.C. § 300f–300j-26 (2012).

68 National Environmental Policy Act (NEPA), 42 U.S.C. § 4321 (2012).

69 David R. Case, *Resource Conservation and Recovery Act, in* 21 ENVTL. LAW HANDBOOK 141, 142 (Thomas F.P. Sullivan ed., 21st ed. 2011).

70 42 U.S.C. § 6902(a) (providing that "[t]he objectives of this chapter are to promote the protection of health and the environment and to conserve valuable material and energy resources . . . ").

71 *Id.*

72 Under RCRA, 42 U.S.C. § 6903(5), "hazardous" waste includes:

> [A]ny 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.

RCRA, 42 U.S.C. § 6903(27), defines "solid waste" as:

> [A]ny garbage, refuse, sludge from a waste treatment plant, water

wastes as "hazardous" based on any one or a combination of four characteristics: ignitable, corrosive, toxic, or reactive.[73]

RCRA specifically excludes certain wastes from its scope, even when those wastes may otherwise exhibit one of the above characteristics or fall within one of the above classifications. In particular, RCRA excludes domestic sewage, "[a]ny mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment," and "[i]ndustrial wastewater discharges that are point source discharges subject to regulation under . . . the Clean Water Act" from its requirements.[74] In addition, RCRA applies only to those facilities that generate, store, transport, or dispose of more than one hundred kilograms of hazardous waste per month or any amount of acute hazardous waste per month.[75]

> supply treatment plant or air pollution control facility and other discarded material, including solid, liquid, semisolid, or contained gaseous materials resulting from industrial, commercial, mining and agriculture activities and from community activities but does not include solid or dissolved material in domestic sewage, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to permits under section 402 of the Federal Water Pollution Control Act, as amended, or source, special nuclear, or byproduct material as defined by the Atomic Energy Act of 1954, as amended (68 Stat. 923).

73 *See* 40 C.F.R. § 261.20–261.24 (2014); *Characteristic Wastes*, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/osw/hazard/wastetypes/characteristic.htm (last updated May 8, 2013). EPA also classifies wastes as hazardous, in two groups, in relation to their potential effect on humans or animals. The first group includes those substances that are acutely toxic and can be fatal to humans or animals above certain minimum thresholds or doses. The second group encompasses substances that either exhibit any of the four hazardous characteristics noted above or contain a toxic constituent (e.g., chemical compounds or elements that have been shown to have toxic, carcinogenic, mutagenic, or teratogenic effects on humans or other life forms) capable of posing a "substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed." 42 U.S.C. § 6903(5). While the former are listed in RCRA's so-called P-list, the latter are found in RCRA's U-list. RCRA's P-list contains 239 different "acutely toxic" substances of which 15 have been identified by the Healthcare Environmental Resources Center (HERC) as likely to be found in a healthcare facility (e.g., arsenic, cyanide salt, nitroglycerin, and Strychnine). *Hazardous Waste Determination*, HEALTHCARE ENVTL. RES. CTR., http://www.hercenter.org/hazmat/hazdeterm.cfm (last visited Mar. 23, 2014). RCRA's U-list contains 472 distinct substances of which 66 have been identified by the HERC as likely to be found in a healthcare facility (e.g., acetone, chloroform, ethyl ether, and Warfarin). *Id*.

74 40 C.F.R. § 261.4(a)(1)–(2) (2014).

75 40 C.F.R. § 261.5(a) (2014). Waste is defined as "acute hazardous waste" if it is capable of causing or significantly contributing to an increase in serious

Accordingly, while drugs and drug residues in household municipal wastes are excluded from RCRA's program, the statute applies to the thousands of health care facilities—including hospitals, clinics, and nursing homes, and pharmaceutical manufacturers and dispensers, throughout the United States—that generate, store, transport, or dispose of more than one hundred kilograms of hazardous pharmaceutical waste per month or any amount of acute hazardous pharmaceutical waste per month.[76] The statute likewise applies to doctor and veterinarian offices.[77] Yet, in 2005, only ninety-four hospitals and nineteen pharmacies became subject to any of RCRA's generation, storage, transportation, treatment, disposal, or reporting criteria.[78] Given that in that same year, there were more than 7,000 hospitals, 72,000 nursing homes and related long-term-care facilities, 27,000 veterinary care operations, 40,000 retail pharmacies, and 300,000 physician and dental offices in the United States,[79] it is inconceivable that only slightly more than one percent of hospitals, fewer than 0.05 percent of pharmacies, and no long-term care or veterinary care facilities exceeded the minimum RCRA threshold.[80]

One of RCRA's chief shortcomings is that it is difficult to implement and enforce. The regulations depend on self-reporting,[81] and EPA does not have the resources to ensure compliance throughout the community.[82] Moreover, there is a

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irreversible, or incapacitating reversible, illness. 40 C.F.R. § 261.11(a)(2) (2014).

76 RCRA applies to any entity that generates, stores, transports, or disposes of at least 100 kilograms of hazardous waste per month or any amount of acute hazardous waste per month, including certain pharmaceutical wastes. *Cf. supra* notes 72, 75 and accompanying text.

77 Doctor and veterinarian offices are exempt only if they generate no more than one hundred kilograms of hazardous waste per month. 40 C.F.R. § 261.5(a) (2014).

78 *See* Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. 73,520, 73,526 (Dec. 2, 2008).

79 *Id.* at 73,522, 73,526.

80 EPA has asserted that all of these hospitals, nursing homes, long-term-care facilities, veterinary care operations, retail pharmacies, and physician and dental offices "are likely to generate some volume of pharmaceutical wastes and many of which will generate some that are RCRA hazardous." *See id.* at 73,526.

81 *Cf. id.* at 73,527 (explaining that the process of applying RCRA begins with a generator determining whether a pharmaceutical waste is subject to RCRA's reporting requirements).

82 The issue of inadequate EPA funding is a recurring theme. *See e.g.,* U.S. GOV. ACCOUNTABILITY OFFICE, REPORT NO. GAO-07-883, ENVIRONMENTAL PROTECTION: EPA-STATE ENFORCEMENT PARTNERSHIP HAS IMPROVED, BUT EPA'S OVERSIGHT NEEDS FURTHER ENHANCEMENT (2007), *available at*

disconnect between EPA's interpretation and application of the statute, and the RCRA knowledge held by pharmaceutical and health care facilities and their staff.[83] As a result, many health care facilities and professionals are entirely unaware whether and how RCRA applies to their pharmaceutical management and disposal practices.[84]

In addition, given the growing number of pharmaceutical products and ingredients in society, it is questionable whether EPA could implement a successful program under RCRA that could adequately evaluate all of the potential hazards posed by pharmaceutical pollutants. Currently, there are over 100,000 FDA-

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http://www.gao.gov/assets/270/264845.pdf; Coral Davenport, *EPA Funding Reductions Have Kneecapped Environmental Enforcement*, NAT'L J. (May 4, 2013), http://www.nationaljournal.com/daily/epa-funding-reductions-have-kneecapped-environmental-enforcement-20130303.

83 *See* WU ET AL., *supra* note 21, at 31 (noting that "[a] significant barrier to ensuring responsible disposal of pharmaceuticals is that very few medical professionals, including doctors, nurses, pharmacists, or administrators, understand all the issues related to disposal. They are not taught the consequences of various disposal methods nor do they have any training in RCRA or other legal requirements that govern disposal of some pharmaceutical products when generated in large enough quantities"). *Cf*. Ron Seely, *Flushed Drugs Polluting Water: Complicated Rules for Disposal Result in Most Hospitals Taking Easy Way Out*, MADISON.COM (Dec. 10, 2006, 12:00 AM), http://host.madison.com/news/flushed-drugs-polluting-water-complicated-rules-for-disposal-result-in/article_acdb4a7b-6a05-5c6f-aeae-2e2431e515d7.html (observing that proper drug disposal is a confusing and expensive process for hospitals and other health-care institutions with little agency oversight or guidance).

84 As EPA asserts, "numerous health care facilities are either unaware of how the hazardous waste regulations apply to pharmaceutical wastes or, even if there is knowledge of RCRA, they have problems with training the workers that are generating these wastes on how to manage hazardous wastes properly." *See* Amendment to the Universal Waste Rule, 73 Fed. Reg. 73,520, 73,527 (Dec. 2, 2008). EPA further states that, "[w]hile the vast majority of pharmaceutical waste generators are undoubtedly [small quantity generators] . . . or [Conditionally Exempt Small Quantity Generators] . . . , information provided by generators themselves show a low level of knowledge about RCRA and its regulatory requirements, even on the part of some large facilities." *Id*. at 73,526. In a scathing rebuke of EPA's regulation of hazardous pharmaceutical wastes, the USEPA's Office of Inspector General (EPA-OIG) asserted that according to EPA itself, many "health care workers, retail pharmacy employees, and other pharmaceutical generators are often unfamiliar with or confused by RCRA hazardous waste management requirements, prompting them to improperly dispose of hazardous pharmaceuticals as municipal or bulk wastes." U.S. ENVTL. PROT. AGENCY, REPORT NO. 12-P-0508, EPA INACTION IN IDENTIFYING HAZARDOUS WASTE PHARMACEUTICALS MAY RESULT IN UNSAFE DISPOSAL 9 (2012), *available at* http://www.epa.gov/oig/reports/2012/20120525-12-P-0508.pdf [hereinafter EPA-OIG 2012 REPORT].

approved human and veterinary (prescription and over-the-counter) drug products in the United States that contain more than 2,500 structurally unique molecular entities and employ multiple mechanisms of activity.[85] Treating these substances out of the waste stream would necessitate dozens if not hundreds of disparate treatment methods and technologies.[86] Yet, the vast majority of pharmaceuticals—including antibiotics, anti-convulsants, antidepressants, beta blockers, blood thinners, diuretics, hormones, steroids, and many others—have yet to be evaluated for their possible hazardous qualities, let alone mechanisms for their removal. In fact, EPA has not updated its RCRA pharmaceuticals list since 1980 when it first listed thirty-one pharmaceutical substances.[87] Moreover, EPA has yet to establish a process for regularly identifying and reviewing new or existing pharmaceuticals that may qualify for regulation as RCRA hazardous waste products.[88]

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85 *See* Daughton, *Pharmaceuticals in the Environment*, *supra* note 2, at 45.

86 *See* Eckstein & Sherk, *supra* note 5 at 432–33 (noting that removal of pharmaceutical wastes from the waste stream requires multiple techniques and technologies); *see also infra* note 183 and accompanying text (discussing various treatment options).

87 *See* EPA-OIG 2012 REPORT, *supra* note 84, at 7. According to the Healthcare Environmental Resources Center, seven of the thirty-one pharmaceutical substances identified by EPA are found under EPA's P-list (Arsenic trioxide, Epinephrine, Nicotine, Nitroglycerin, Physostigmine, Physostigmine salicylate, and Warfarin >0.3 percent), and twenty-four are included in the Agency's U-list (Chloral Hydrate, Chlorambucil, Chloroform, Cyclophosphamide, Daunomycin, Dichlorodifluromethane, Diethylstilbestrol, Formaldehyde, Hexachlorophene, Lindane, Melphalan, Mercury, Mitomycin C, Paraldehyde, Phenacetin, Phenol, Reserpine, Resorcinol, Saccharin, Selenium sulfide, Streptozotocin, Trichloromonofluromethane, Uracil mustard, Warfarin <0.3 percent). *Listed Wastes*, HEALTHCARE ENVTL. RESOURCE CENTER, http://www.hercenter.org/hazmat/pharma.cfm#listed (last visited Mar. 23, 2014). The challenge of evaluating potential harmful qualities of pharmaceutical substances has been addressed, albeit to a more limited extent, by other federal agencies. For example, the National Institute for Occupational Safety and Health (NIOSH) has identified approximately 160 drugs that it states should be handled as hazardous materials, and the Occupational Safety and Health Administration (OSHA) lists sixty-one pharmaceuticals on its hazardous drug list. *See* U.S. DEP'T OF HEALTH & HUMAN SERV., PUB. NO. 2012-150, NIOSH LIST OF ANTINEOPLASTIC AND OTHER HAZARDOUS DRUGS IN HEALTHCARE SETTINGS (2012), *available at* http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf; U.S. DEP'T OF LABOR, OSHA TECHNICAL MANUAL (OTM), SOME COMMON DRUGS CONSIDERED HAZARDOUS § VI: ch. 2, app. VI: 2-1 (1999), *available at* https://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html#app_VI:2_1.

88 *Cf.* EPA-OIG 2012 REPORT, *supra* note 84, at 7.

In a 2012 report, EPA's Office of Inspector General (EPA-OIG) asserted that:

> RCRA hazardous waste regulations are not keeping up with drug development and the potential hazards they may pose if mismanaged and disposed without the necessary protections to human health and the environment. Without an established process to review pharmaceuticals, EPA cannot ensure that it has identified pharmaceutical contaminants that may pose a hazardous risk to human health and the environment.[89]

In response to the EPA-OIG report, EPA indicated that it would "consider the appropriate next steps to take given significant resource constraints and competing priorities."[90] The Agency anticipated issuing a proposed rule in spring of 2013 responding to some of the deficiencies identified by the EPA-OIG.[91] As of January 2015, the proposed rule had not been issued and, according to EPA's website, the proposed rule will focus solely on "hazardous waste pharmaceuticals that are generated by healthcare-related facilities."[92]

RCRA was never intended to apply to pharmaceutical hazardous wastes. While EPA has attempted to interpret and implement the statute with regard to pharmaceutical pollutants, those efforts will likely prove fruitless.

B. *Clean Water Act*

The CWA was intended "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters."[93] Functionally, CWA requires each state to designate water quality standards or allowable uses (e.g., domestic water supply, recreation, propagation of fish and aquatic life, etc.) for all rivers, streams, and lakes within its jurisdiction.[94] These standards

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89 *See id.* Among other factual findings, EPA-OIG identified three pharmaceuticals currently regulated by EPA under RCRA's "toxic" criteria (U-list), but that actually met RCRA's "acutely" toxic standards (P-list). OIG also distinguished twenty-one other pharmaceuticals that currently are not regulated by EPA, but which may qualify as "toxic" under EPA's RCRA criteria. *Id*. at 7–8.

90 *Id*. at 17.

91 *Id*. at 18.

92 *Management of Hazardous Waste Pharmaceuticals*, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/osw/hazard/generation/pharmaceuticals.htm (last updated Jan. 1, 2015).

93 33 U.S.C. § 1251(a) (2012).

94 *See* 40 C.F.R. § 130.10 (2014).

and uses must be based on the National Recommended Water Quality Criteria[95] and are subject to EPA approval.[96] Once EPA approves water quality standards or designated uses, "impaired" bodies of water—those that do not meet the designated water quality or use standards—are monitored and pollution discharges strictly regulated by EPA or an authorized state agency.[97] These actions are implemented in relation to each impaired water body's ability to absorb specific pollutants—total maximum daily load (TMDL)—without exceeding the designated water quality or use standards.[98] Pollution discharges are managed through the National Pollutant Discharge Elimination System (NPDES),[99] a permit system that allows private, governmental, and other dischargers to release certain pollutants into designated surface water bodies.[100] Those discharges are subject to strict discharge quantity and concentration limitations and waste treatment technology requirements.[101] Absent an NPDES permit, discharges are strictly prohibited.[102]

Despite its potential relevance, the CWA's applicability to

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95 33 U.S.C. §§ 1313–1314 (2012). National Recommended Water Quality Criteria are standards developed by EPA, per 33 U.S.C. §§ 1313–1314 (2012), that provide guidance for states in their development of state-specific water quality standards. *See National Recommended Water Quality Criteria*, U.S. ENVTL. PROT. AGENCY, http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm (last updated Dec. 3, 2014).

96 40 C.F.R. § 131.5, 131.21 (2014).

97 33 U.S.C. § 1314(l)(1) (2012).

98 33 U.S.C. § 1313(d)(1)(C) (2012) provides that the TMDL "shall be established at a level necessary to implement the applicable water quality standards with seasonal variations and a margin of safety which takes into account any lack of knowledge concerning the relationship between effluent limitations and water quality."

99 33 U.S.C. § 1342 (2012). Implementation and oversight of the NPDES permit program has been delegated to authorized state agencies in forty-six states. *National Pollutant Discharge Elimination System (NPDES): State Program Status*, U.S. ENVTL. PROT. AGENCY, http://water.epa.gov/polwaste/npdes/basics/NPDES-State-Program-Status.cfm (last updated Sept. 9, 2014). In those states, the NPDES permit is issued directly by the authorized state agency. For example, in Texas, the permit is designated as the Texas Pollutant Discharge Elimination System permit. *What Is the "Texas Pollutant Discharge Elimination System (TPDES)?"*, TEXAS COMM'N ON ENVTL. QUALITY, http://www.tceq.state.tx.us/permitting/wastewater/pretreatment/tpdes_definition.html (last updated Nov. 6, 2014).

100 40 C.F.R. § 230.12 (2014) (describing the NPDES permitting system); 40 C.F.R. § 230.3(s) (2014) (defining "waters of the United States").

101 *See* 33 U.S.C. § 1342(p)(3) (2012) (referring to 33 U.S.C. § 1311 (2012) for the specific discharge limitations).

102 *Id.*; 40 C.F.R. § 230.12 (2014).

pharmaceutical substances in the environment is limited at best. With two minor exceptions,[103] EPA has never developed water quality criteria or standards under the CWA for pharmaceuticals, pharmaceutical wastes, or pharmaceutical residues, and NPDES permits do not currently include any limitations on the discharge of pharmaceutically active pollutants.[104] Nevertheless, like RCRA, the CWA was not designed to address pharmaceutical pollutants. Given the challenge of assessing tens of thousands of pharmaceutical products and components, and then implementing hundreds (if not thousands) of different technology and management standards, the task will likely be an exercise in futility. In addition, the Act's key regulatory provisions exclude nonpoint sources of waste,[105] which may be significant sources of the pharmaceuticals found in the environment.[106]

C. *Safe Drinking Water Act*

The SDWA is designed to protect the quality of the nation's drinking water and authorizes the EPA to set national standards for drinking water quality and contaminant regulation in public water systems and their sources.[107] Known as National Primary Drinking

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103 EPA's current national criteria provide both human health and aquatic life criteria for lindane, an organochlorine, and malathion, an organophosphate insecticide; both are used to treat lice, as well as in agriculture as an insecticide. *National Recommended Water Quality Criteria*, U.S. ENVTL. PROT. AGENCY, http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm (last visited Mar. 2, 2015) (listing human health criteria for lindane and malathion); *National Recommended Water Quality Criteria*, U.S. ENVTL. PROT. AGENCY, http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm (last visited Mar. 23, 2014) (listing aquatic life criteria for lindane and malathion).

104 *See* U.S. GOV'T. ACCOUNTABILITY OFFICE, GAO-11-346, ACTION NEEDED TO SUSTAIN AGENCIES' COLLABORATION ON PHARMACEUTICALS IN DRINKING WATER 11 (2011) [hereinafter USGAO-ACTION NEEDED], *available at* http://www.gao.gov/new.items/d11346.pdf, (bolstering Eckstein and Sherk's assessment).

105 *See* Michael C. Blumm & William Warnock, *Roads Not Taken: EPA vs. Clean Water*, 33 LEWIS & CLARK ENVTL. L. 79, 82 (2003).

106 *Cf.* Daughton & Ternes, *supra* note 2, at 909, 923 (noting that pharmaceuticals in the environment originate, in part, from terrestrial run-off from animal husbandry, aquaculture, and excrement of domesticated animals); *See* Blumm & Warnock, *supra* note 105, at 82 (asserting that "today nonpoint sources contribute more pollution to the nation's waters than point sources, and in the rural West, nonpoint source pollution is the overwhelming source of water pollution").

107 40 C.F.R. § 141.1 (2014). NPDWRs include eighty-five standards divided into six categories: disinfectants, disinfection byproducts, inorganic chemicals, microorganisms, organic chemical, and radionuclides. *Id*. §§ 141.50−55.

Water Regulations (NPDWRs), these health-based standards are legally enforceable maximum levels for specific contaminants in public water systems.[108] If maximum contaminant levels cannot be determined, NPDWRs can mandate water treatment procedures and techniques designed to remove contaminants.[109] Under the SDWA, EPA must develop a Contaminant Candidate List (CCL) identifying contaminants not presently subject to an NPDWR, but that "are known or anticipated to occur in public water systems" and that may require a national drinking water regulation in the future.[110]

While EPA has established NPDWRs for more than ninety contaminants,[111] it has never done so for a pharmaceutical. Moreover, until quite recently, it had never placed a pharmaceutical on the CCL. In August 2008, EPA issued its third CCL listing 104 chemicals or chemical groups and twelve microbiological contaminants.[112] During the preparation stage, EPA identified 287 pharmaceuticals for possible inclusion in the CCL; however, all but one were removed prior to list finalization.[113] The sole pharmaceutical substance listed as an unregulated contaminant was nitroglycerin, a volatile substance known better for its use in the production of explosives and rocket propellants, but also used medically to treat heart conditions.[114]

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108 42 U.S.C. § 300g-1(b)(1) (2012).

109 42 U.S.C. § 300g-1(b)(7).

110 42 U.S.C. § 300g-1(b)(1)(B)(i). Unregulated contaminants are placed on the CCL where:

> i) the contaminant may have an adverse effect on the health of persons; ii) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

42 U.S.C. § 300g-1(b)(1)(A).

111 *Drinking Water Contaminants*, ENVT'L PROT. AGENCY, http://water.epa.gov/drink/contaminants/#List (last updated Oct. 29, 2014).

112 Drinking Water Contaminant Candidate List 3, 74 Fed. Reg. 51,850 (Oct. 8, 2009).

113 *See Pharmaceuticals in the Nation's Water: Assessing Potential Risks and Actions to Address the Issue Before the Transp. Safety, Infrastructure Sec. and Water Subcomm. of the Comm. on Env't and Public Works U.S. Senate,* 110th Cong. 10 (2008) (statement of Benjamin H. Grumbles, Assistant Administrator for Water, Environmental Protection Agency), *available at* http://epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=7f39d92b-3089-4703-9063-e5d6c1381332.

114 *MedlinePlus, Nitroglycerin*, U.S. NAT'L LIBR. MED. & NAT'L INST.

Not surprisingly, EPA included it in the CCL primarily because of environmental and water quality concerns arising from its use as an explosive.[115]

In 2009, the Science Advisory Board Drinking Water Committee of the EPA Office of Ground Water and Drinking Water recommended changes to the CCL selection process:

> There are also some clear categories of contaminants that need special attention in selecting the CCL including pharmaceuticals, personal care products, endocrine disruptors, antibiotics, and algal toxins. Such contaminants may warrant changes in the CCL selection processes. General exposure to even low levels of antibiotics in drinking water, for example, may lead to antibiotic-resistant pathogens either in a person drinking the water or the general environment. The current CCL process for chemicals would not identify this as an adverse effect.[116]

In addition, in August 2011, Government Accountability Office (GAO) recommended that EPA establish a formal mechanism for federal agencies to collaborate and coordinate research on pharmaceuticals in the nation's drinking water.[117] In 2012, EPA responded by organizing an inter-agency working group composed of EPA (Office of Water), U.S. Department of Agriculture (Agricultural Research Service), U.S. Department of Health and Human Services (Food and Drug Administration), and U.S. Department of Interior (U.S. Geological Survey).[118] The purpose of this collaboration is, partly, to aid EPA evaluate which,

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HEALTH, http://www.nlm.nih.gov/medlineplus/druginfo/meds/a601086.html (last updated Aug. 1, 2010); *Nitroglycerin*, NEW WORLD ENCYCLOPEDIA, http://www.newworldencyclopedia.org/p/index.php?title=Nitroglycerin&oldid=681895 (last updated Apr. 2, 2008).

115 Jeff Donn et al., *No Standards to Test for Drugs in Water*, ASSOCIATED PRESS (Mar. 11, 2008), http://www.foxnews.com/printer_friendly_wires/2008Mar11/0,4675,PharmaWaterIII,00.html.

116 EPA SCI. ADVISORY BD. DRINKING WATER COMM., SAB ADVISORY ON EPA'S DRAFT THIRD DRINKING WATER CONTAMINATION CANDIDATE LIST (CCL 3) 7 (2009).

117 USGAO-ACTION NEEDED, *supra* note 104, at 41.

118 Memorandum of Understanding on Sustainability of Federal Collaboration on Pharmaceuticals in Drinking Water between the U.S. Environmental Protection Agency (EPA) Office of Water (OW); U.S. Department of Agriculture (USDA) Agricultural Research Service (ARS); U.S. Department of Health and Human Services (HHS) Food and Drug Administration (FDA); and U.S. Department of Interior (DOI) U.S. Geological Survey (USGS) (Nov. 29, 2012), *available at* http://water.epa.gov/scitech/swguidance/ppcp/upload/mou_pharm_drinking_water12182012.pdf.

if any, pharmaceutical contaminants should be regulated under SDWA.[119]

While certainly a logical effort, the SDWA suffers from the same ailment afflicting the RCRA and CWA. The statute was never intended to respond to the tens of thousands of pharmaceutical pollutants that plague the environment, and it is questionable whether it could ever do so successfully. In addition, the SDWA exclusively targets the protection of drinking water sources for human consumption. Accordingly, its scope excludes broader environment concerns including known hazards that pharmaceutical pollutants pose to many aquatic and terrestrial species.

D. *National Environmental Policy Act*

In contrast to the above three federal statutes, which focus on pollutants in the waste stream, NEPA imposes procedural requirements on federal actions and decision making. NEPA mandates that all federal agencies consider the significant environmental impacts of their proposed major actions and publically disclose the results of their assessments prior to carrying out those actions.[120] If a preliminary environmental assessment (EA) indicates that the action could significantly affect the quality of the human environment, a more rigorous environmental impact statement (EIS) is required.[121] NEPA does not dictate whether or not a project should be pursued; rather, its chief objective is to require the federal government to take a "hard look," in a public process, at the possible environmental consequences of proposed

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119 *Id*. at 2.

120 *See* Balt. Gas & Elec. Co. v. Natural Res. Def. Council, Inc., 462 U.S. 87, 97 (1983). Under 40 C.F.R. § 1508.18 (2014), "major federal actions" can include:

> new and continuing activities, including projects and programs entirely or partly financed, assisted, conducted, regulated, or approved by federal agencies; new or revised agency rules, regulations, plans, policies, or procedures; and legislative proposals . . . [but not] funding assistance solely in the form of general revenue sharing funds, distributed under the State and Local Fiscal Assistance Act of 1972 . . . with no Federal agency control over the subsequent use of such funds . . . [or] bringing judicial or administrative civil or criminal enforcement actions.

121 *See* COUNCIL ON ENVTL. QUALITY, A CITIZEN'S GUIDE TO THE NEPA: HAVING YOUR VOICE HEARD 12 (2007), *available at* http://www.blm.gov/pgdata/etc/medialib/blm/nm/programs/planning/planning_docs.Par.53208.File.dat/A_Citizens_Guide_to_NEPA.pdf.

actions.[122]

As a federal agency, the U.S. Food and Drug Administration (FDA) is tasked with ensuring "the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines, and other biological products, and medical devices" in the United States.[123] This includes regulating, reviewing, and approving or denying new drugs and related pharmaceutical products.[124] Accordingly, NEPA should cover the FDA's actions and decision making as they relate to pharmaceutical products.

Despite NEPA's applicability to FDA's oversight of pharmaceuticals, NEPA allows federal agencies to categorically exclude certain classes of actions from the Act's procedural requirements on grounds that "as a class, these actions, individually or cumulatively, do not significantly affect the quality of the human environment."[125] Currently, FDA's activities are ordinarily excluded from NEPA's EA requirements if they fall within any one of ten categories listed in 21 C.F.R. § 25.31(a)–(j). These exclusions include new drugs whose residual aquatic presence does not exceed one part per billion, investigational new drugs, and substances that occur naturally in the environment. [126]

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122 *See* Kleppe v. Sierra Club, 427 U.S. 390, 410 n. 21 (1976).

123 *FDA Fundamentals*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/aboutfda/transparency/basics/ucm192695.htm (last updated June 12, 2014).

124 *What Does FDA Regulate?*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm (last updated Nov.18, 2014).

125 21 C.F.R. § 25.10(c) (2014); 40 C.F.R. § 1508.4 (2014); U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: ENVIRONMENTAL ASSESSMENT OF HUMAN DRUG AND BIOLOGICS APPLICATIONS 2 (1998) [hereinafter HHS GUIDANCE FOR INDUSTRY].

126 *See* HHS GUIDANCE FOR INDUSTRY, *supra* note 125, at 2. The complete list of exclusions is:

> (a) Action on [a new drug application] . . . abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications . . . if the action does not increase the use of the active moiety.
>
> (b) Action on [a new drug application] . . . abbreviated application, or a supplement to such applications . . . if the action increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion.
>
> (c) Action on [a new drug application] . . . abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications . . . for substances that occur naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or

While potentially innocuous, these categorical exclusions, as applied to pharmaceutical-related actions and decisions, have allowed an untold number of drugs and related products to circumvent the NEPA process. If the NEPA procedures had not been bypassed, information about the drugs and related products might have filled many of the knowledge gaps that currently exist, including on potential hazards from human and environmental exposure to those substances.

Moreover, some of the categories subject to exclusion from NEPA may be inappropriate given the state of the science. For example, the exclusion in 21 C.F.R. § 25.31(b) for drugs whose projected residue concentration reaching the environment is below one part per billion is woefully inadequate given that certain contaminants, such as estrogen and trebolone metabolites, have a detrimental impact on aquatic species at detection levels of parts per trillion.[127] While the direct impact here is on aquatic species,

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> degradation products in the environment.
> (d) Withdrawal of approval of [a new drug application] or an abbreviated application.
> (e) Action on [investigational new drug applications].
> (f) Testing and release by the Food and Drug Administration of lots or batches of a licensed biologic product.
> (g) Establishment of bioequivalence requirements for a human drug or a comparability determination for a biologic product subject to licensing.
> (h) Issuance, revocation, or amendment of a standard for a biologic product.
> (i) Revocation of a license for a biologic product.
> (j) Action on an application for marketing approval for marketing of a biologic product for transfusable human blood or blood components and plasma.

21 C.F.R. §§ 25.31 (a)–(j) (2014).

127 *See* WU ET AL., *supra* note 21, at 5 (noting that laboratory studies conducted on the synthetic estrogen, ethinylestradiol, predict that a concentration of 0.1 ng/L [0.1 part per trillion] in surface water could induce male rainbow trout to produce the female egg protein vitellogenin); Durhan, *supra* note 57, at 67 (citing research by Ankely and Jensen K finding that exposure to trenbolone metabolites in nanogram per liter [equivalent of one part per trillion] concentration can result in masculinization of fish); Bethany Halford, *Side Effects*, 86 CHEMICAL & ENGINEERING NEWS 13, 13 (2008), *available at* http://cen.acs.org/articles/86/i8/Side-Effects.html (reporting on research indicating that the feminization of male fish can occur due to estrogen exposure at concentrations of parts-per-trillion); *see also* Shawna Bligh, *Pharmaceuticals in Surface Waters: Use of NEPA*, 24 NAT. RES. & ENV'T 56, 56–57 (2009) (noting that "certain pharmaceuticals, such as hormone-regulating drugs, can take effect at concentrations as low as a few nanograms per liter" and that "[t]hese compounds alter sex characteristics of certain fish at concentrations as low as 20 parts per trillion"); Kidd, *supra* note 54 (reporting that chronic

the mutation and potential loss of certain species could have significant consequences for the quality of the human environment.[128] The exclusion for substances that occur naturally in the environment is also questionable because it ignores the consequence of cumulative and chronic exposure to such substances by aquatic and other species, including humans, as well as the possible synergistic outcomes of these substance's interaction with other chemicals.[129]

Not all FDA actions are subject to NEPA categorical exclusions. For example, "[a]pproval of [new drug applications], abbreviated applications, applications for marketing approval of a biologic product, supplements to such applications, and actions on [investigational new drug]" are not excluded unless they specifically fall under §25.31(a), (b), (c), (e), or (l).[130] In addition, 21 C.F.R. § 25.20 specifies certain proposed actions that "ordinarily require[] at least the preparation" of an EA.[131] More generally, FDA must file an EIS when the agency determines, through the preparation of an EA, that "a proposed action may

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exposure over seven years of fathead minnows to low concentrations (5–6 part per trillion) of the estrogen 17α-ethynylestradiol led to the feminization of males, and nearly caused the extinction of the fathead minnows population studied).

128 *See* Toby K. L. Morgan, *Down the Drain: Pharmaceutical Waste Disposal in the United States*, 22 FORDHAM ENVTL. L. REV. 393, 430 (2011) ("This then begs the question of whether mutations and spawning abnormalities in aquatic life significantly affect the quality of the human environment under NEPA therefore necessitating an amendment of the one ppb categorical exclusion currently in place."). It is noteworthy that the European Agency for the Evaluation of Medicinal Products proposed a trigger value of ten parts per trillion. Christian G. Daughton, *Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health. I. Rationale for and Avenue Toward a Green Pharmacy*, 111 ENVTL. HEALTH PERSP. 757, 760 (2003).

129 *See supra* notes 48–52, 61 and accompanying text.

130 21 C.F.R. § 25.20(l) (2014).

131 § 25.20. Unless otherwise categorically excluded, proposed actions that ordinarily require at least the preparation of an EA include, *inter alia*: major legislative recommendations or reports prepared for Congress related to pharmaceuticals; regulations for labeling requirements or for standards related to pharmaceuticals; exemptions and variances from FDA regulations; establishment of a tolerance for unavoidable poisonous or deleterious substances in food or in packaging materials to be used for food; approval of new drug applications, abbreviated applications, applications for marketing approval of a biologic product, supplements to such applications, and actions on investigational new drugs; approval of new animal drug applications, abbreviated applications, supplements, actions on investigational new animal drugs. §§ 25.20(a), (f), (g), (j), (l), & (m).

significantly affect the quality of the human environment."[132]

Nevertheless, FDA's regulatory interpretation and implementation of NEPA have substantially neutered the Act's procedural requirements as they apply to the agency and its activities. For example, FDA regulations provide that "[t]here are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."[133] Moreover, since a significant proportion of the agency's activities are excluded from the EA requirement, few of FDA's activities are subjected to the scrutiny of either an EA or an EIS.[134] In fact, since NEPA's enactment in 1970, the FDA has only performed one EIS related to human medicines. That EIS addressed chlorofluorocarbons used as propellants in self-pressurized or aerosolized containers in products subject to the Federal Food, Drug, and Cosmetic Act.[135]

Even if a particular FDA action was subjected to EIS scrutiny, FDA regulations thwart the very NEPA process mandated for nearly every other federal regulatory action across the U.S. government. Under FDA regulations implementing NEPA, an EIS "will become available only at the time of the approval of the product[,]"[136] and public comments are accepted only after an EIS is released.[137] Moreover, where public comments are submitted to the agency, they can be used solely "as a basis" for the agency to consider withdrawal of approval.[138] In other words, FDA rules effectively remove EIS consideration from the agency's decision-making process since the decision to act would have been made in advance of and absent public participation. While courts will

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132 § 25.22(b).

133 § 25.22(a).

134 The only exception to the categorical exclusions is a finding that "extraordinary circumstances" suggesting a significant effect on the human environment. § 25.21.

135 *See* Ternes & Joss, *supra* note 11, at 112. In 1978, FDA prepared a programmatic EIS regarding a proposed ban on the use of chlorofluorocarbons as propellants in self-pressurized containers of various food and pharmaceutical products. In that EIS, FDA concluded that such use "poses an unreasonable risk of long-term biological and climatic impacts" because of the impact chlorofluorocarbons had on the ozone layer. U.S. FOOD & DRUG ADMIN., FLUOROCARBONS: ENVIRONMENTAL AND HEALTH IMPLICATIONS: FINAL ENVIRONMENTAL IMPACT STATEMENT PREPARED IN ACCORDANCE WITH SECTION 102(2)(C) OF P.L. 91-190, at iii (1978).

136 § 25.52(a).

137 § 25.52(b).

138 *Id*.

likely defer to agency interpretation under *Chevron U.S.A. v. Natural Resources Defense Council*,[139] it is difficult to have faith in a process that appears to employ NEPA merely as a perfunctory procedural step. By delaying publication of the EIS, FDA is effectively undermining NEPA's fundamental and critically important purpose of informed decision making and public participation.[140]

In addition, FDA's justification for its unconventional interpretation and implementation of the NEPA requirements may no longer pass muster. In the FDA's final rule introducing the categorical exclusions, the agency explained that those exclusions were based on a presumption that the excluded classes of actions will "not individually or cumulatively have a significant effect on the human environment."[141] Essentially, the agency contended that few if any pharmaceutical-related activities and decisions—including new drug approvals and changes to existing authorized drug uses—would detrimentally affect the environment. Given the state of science and what is now known about the effect of many pharmaceuticals on the natural environment, and possibly on the human environment,[142] that presumption is no longer convincing or legally defensible.

E. *Secure and Responsible Drug Disposal Act*

In 2010, Congress enacted the Secure and Responsible Drug Disposal Act (SRDDA),[143] primarily as a means to respond to the

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139 Chevron U.S.A. v. Natural Res. Def. Council, 467 U.S. 837 (1984). Under *Chevron*, courts should defer to agency statutory interpretation unless Congress has expressed unambiguous intent regarding the precise question at issue or the agency's answer is not based on a permissible construction of the statute. *Id*. at 842–43.

140 Generally, NEPA requires federal agencies to complete and publish an EIS and consider public comments prior to taking a final agency action. *See* COUNCIL ON ENVTL. QUALITY, *supra* note 121, at 13–18. On the value of public participation in NEPA decision making, see William Murray Tabb, *The Role of Controversy in NEPA: Reconciling Public Veto with Public Participation in Environmental Decisionmaking*, 21 WM. & MARY ENVTL. L. & POL'Y REV. 175 (1997) and Nancy Perkins Spyke, *Public Participation in Environmental Decisionmaking at the New Millennium: Structuring New Spheres of Public Influence*, 26 B.C. ENVTL. AFF. L. REV. 263 (1999).

141 National Environmental Policy Act; Revision of Policies and Procedures, 62 Fed. Reg. 40,570, 40,591 (July 29, 1997).

142 *See supra* note 43–61 and accompanying text.

143 Secure and Responsible Drug Disposal Act of 2010, Pub. L. No. 111-273, 124 Stat. 2858 (2010).

misuse of pharmaceuticals "particularly among teenagers."[144] Legislators also recognized the value of proper drug disposal for protecting the environment from pharmaceutical pollutants.[145] Accordingly, the SRDDA authorized the U.S. Drug Enforcement Administration (DEA) to promulgate regulations that would expand the options available for the collection and proper disposal of unused controlled substances[146] to designated entities for proper disposal.[147]

In response, on September 9, 2014, DEA issued new rules allowing consumers to deliver illegal and prescription medication to drug manufacturers, distributors, and reverse distributors, narcotic treatment programs, hospitals and clinics with on-site pharmacies, and retail pharmacies.[148] Authorized delivery and collection methods include take-back and mail-back programs and designated collection receptacles.[149]

While the new rule is certainly welcome, it is still early to assess whether it will succeed in diminishing the volume of pharmaceuticals that reach the environment, let alone those that are illicitly distributed. The opportunities created under the new rules are entirely voluntary and all costs and liabilities are to be borne directly by authorized collectors.[150] Whether the

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144 *Id*. § 2(1).

145 In its perambulatory findings, Congress acknowledged that:

> Individuals seeking to reduce the amount of unwanted controlled substances in their household consequently have few disposal options beyond discarding or flushing the substances, which may not be appropriate means of disposing of the substances. Drug take-back programs are also a convenient and effective means for individuals in various communities to reduce the introduction of some potentially harmful substances into the environment, particularly into water.

Id. § 2(4)(C).

146 Controlled substances, generally, are drugs subject to government regulations and include illegal drugs and prescription medication, such as Ambien, oxycodone, and codeine. *See* 21 U.S.C. § 802(6) (2012) (defining "controlled substance" as "a drug or other substance, or immediate precursor" that is subject to the Controlled Substances Act); U.S. DRUG ENFORCEMENT ADMIN., LISTS OF: SCHEDULING ACTIONS, CONTROLLED SUBSTANCES, REGULATED CHEMICALS (2014). Under DEA regulations, controlled substances are drugs that have some potential for abuse or dependence. *See Controlled Substance Schedules*, U.S. DRUG ENFORCEMENT ADMIN., http://www.deadiversion.usdoj.gov/schedules/index.html (last visited Mar. 23, 2014).

147 Pub. L. No. 111-273 § 3(a).

148 Disposal of Controlled Substances, 79 Fed. Reg. 53,520 (Sept. 9, 2014).

149 79 Fed. Reg. at 53,521.

150 *See infra* notes 218–221 and accompanying text.

pharmaceutical industry willingly accepts this responsibility remains to be seen.

In addition, the new rules may have cancelled DEA's relatively successful national drug "take-back" event aimed at reducing the number of unwanted, expired, or unused medications in the home.[151] On September 23, 2014, the agency held its ninth, and possibly last, national event, which netted 617,150 pounds of expired and unwanted medications at 5,495 take-back sites nationwide.[152] Between September 2010 and September 2014, the program removed over 4.8 million pounds of pharmaceuticals from circulation.[153] Accordingly to the DEA, it has "no plans to sponsor more nationwide Take-Back Days in order to give authorized collectors the opportunity to provide this valuable service to their communities."[154]

III. THE STATE APPROACH TO MANAGING PHARMACEUTICALS IN THE ENVIRONMENT

A. *Managing Pharmaceutical Wastes*

Under RCRA, the EPA permits states to develop and implement their own hazardous waste management programs so long as the programs are no less stringent than the federal program.[155] The adoption of state-specific programs has resulted in

151 *See News Releases*, U.S. DRUG ENFORCEMENT ADMIN., http://www.deadiversion.usdoj.gov/drug_disposal/takeback/newsrelease.htm (last visited Jan. 07, 2015) (providing news releases discussing eight take back events between October 2010 and November 2014).

152 *See DEA and Partners Collect 309 Tons of Pills on Ninth Prescription Drug Take-Back Day*, U.S. DRUG ENFORCEMENT ADMIN., (Nov. 5, 2014), http://www.dea.gov/divisions/hq/2014/hq110514.shtml [hereinafter *Ninth Prescription Take-Back Day*] (referencing the ninth take-back program); *DEA's Ninth and Final Prescription Drug Take Back Day Being Held Saturday September 27*, U.S. DRUG ENFORCEMENT ADMIN., (Sept. 23, 2014), http://www.dea.gov/divisions/hq/2014/hq092314.shtml [hereinafter *Final Prescription Drug Take-Back Day*] (suggesting that this ninth event may be the "final" DEA national take back event).

153 *See Ninth Prescription Take-Back Day*, *supra* note 152.

154 *Final Prescription Drug Take Back Day*, *supra* note 152.

155 *See* 42 U.S.C. § 6926(b) (2012); John Johnson et al., *Challenges in Pharmaceutical Waste Management: "First, Do No Harm"*, 26 NAT. RESOURCES & ENV'T 1, 5 (2012). With the exception of Alaska and Iowa, every state has developed and implemented its own hazardous waste management program. *See* U.S. ENVTL. PROT. AGENCY, AUTHORIZATION STATUS BY RULE: STATS DATA AS OF JUNE 30, 2014 (2014), *available at* http://www.epa.gov/epawaste/laws-regs/state/stats/authall.pdf.

a myriad of different standards, compliance criteria, and other regulatory variations among the states and between the states and EPA.

For example, Connecticut, Michigan, Oregon, Rhode Island, and Vermont have adopted regulations designating certain non-RCRA wastes as hazardous wastes.[156] Similarly, California created a new category of non-RCRA wastes called "biohazardous waste," a subset of "medical waste," that is regulated as California-only hazardous wastes and which applies to all licensed health-care facilities, regardless of amount of waste produced, as well as anyone else who produces more than one hundred kilograms of infectious waste per month.[157] In contrast, Minnesota expanded its hazardous waste definition by adding *lethality* to the four RCRA hazardous waste characteristics,[158] while Florida and Michigan extended RCRA's universal waste program—a streamlined RCRA disposal program designed to facilitate the proper collection and recycling or treatment of certain common, widely generated, hazardous wastes[159]—to pharmaceutical hazardous waste.[160]

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156 For Connecticut regulations, see CONN. GEN. STAT. § 22a-454 (2014) and Non-RCRA Hazardous Waste (Connecticut Regulated Waste), CONN. DEP'T OF ENERGY & ENVTL. PROT., http://www.ct.gov/DEep/cwp/view.asp?a=2718&q=325428&deepNav_GID=1967 (last updated Feb. 20, 2013). For Michigan regulations, see MICH. ADMIN. CODE r. 299.9228 (2013). *See also infra* note 160 and accompanying text. For Oregon regulations, see OR. DEP'T OF ENVTL. QUALITY, OREGON "STATE-ONLY" HAZARDOUS WASTE CODES (2008), *available at* http://www.deq.state.or.us/lq/pubs/docs/hw/Reporting/OregonWasteCodes.pdf. For Rhode Island regulations, see 2014 R.I. Gov't Reg. 5502 (LexisNexis January 2014), *available at* http://www.dem.ri.gov/pubs/regs/regs/waste/hwregs07.pdf. For Vermont regulations, see 7-1-9 VT. CODE R. (2013), *available at* http://www.anr.state.vt.us/dec/wastediv/rcra/regs.htm. *See also State-Specific Universal Waste Regulations*, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/osw/hazard/wastetypes/universal/statespf.htm (last updated June 13, 2014).

157 Medical Waste Management Act, CAL. HEALTH & SAFETY CODE §§ 117600–118360 (describing a standard that is quite different from the federal program described in Section III.a).

158 *See* MINN. R. 7045.0131(6) (2013); *see also* MINN. POLLUTION CONTROL AGENCY, THE LETHALITY CHARACTERISTIC: A MINNESOTA-SPECIFIC HAZARDOUS-WASTE CHARACTERISTIC (2009), *available at* http://www.pca.state.mn.us/index.php/view-document.html?gid=4002.

159 The RCRA Universal Waste Rule applies to certain common, widely generated hazardous waste that can be managed under a streamlined disposal program designed to facilitate the proper collection and recycling or treatment of those wastes. *See* U.S. ENVTL. PROT. AGENCY, EPA530-K-05-019, TRAINING MODULE: INTRODUCTION TO UNITED STATES ENVIRONMENTAL PROTECTION AGENCY UNIVERSAL WASTE (2005), *available at* http://epa.gov/waste/inforesources/pubs/training/uwast05.pdf. Under current EPA regulations, the

In addition, many states have adopted inconsistent implementation strategies of RCRA regulations and EPA interpretations. For example, EPA excludes certain pharmaceutical waste from RCRA disposal regulation.[161] These interpretative exclusions are not binding on states that have implemented their own hazardous waste management programs.[162] Accordingly, while many states have adopted EPA's exclusions in their entirety, others have adopted them selectively or not at all. Connecticut and Michigan, for example, have refused to adopt the epinephrine or nitroglycerine federal exclusions, while Washington has declined to adopt the exclusion for P-listed waste in used syringes.[163]

While many of these state-specific approaches and criteria are more stringent than the federal RCRA program, the differences in compliance regimes effectively create substantial challenges for regulated entities with facilities in multiple states to implement consistent pharmaceutical waste compliance programs. Rather than raising the bar, the disparate standards, compliance criteria, and other regulatory variations have resulted in inconsistent and inadequate monitoring and enforcement.[164]

B. *Drug Collection and Disposal Programs*

In addition to DEA-run drug "take-back" events, several states have implemented their own collection and disposal programs.[165] The vast majority of these schemes focus more on

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federal program applies only to certain batteries, pesticides, mercury-containing equipment, and light bulbs. 40 C.F.R. § 273 (2005).

160 FLA. ADMIN. CODE ANN. r. 62-730.186 (2013); MICH. ADMIN. CODE. r. 299.9228 (2013).

161 *See* SMITH, *supra* note 9, at 17–18.

162 Johnson, *supra* note 155, at 3.

163 *Id.*

164 *E.g.*, Jason M. Levy, *Conflicting Enforcement Mechanisms Under RCRA: The Abstention Battleground Between State Agencies and Citizen Suits*, 39 ECOLOGY L.Q. 373 (2012) (discussing enforcement conflicts in RCRA and other statutes that authorize multiple enforcement mechanisms, including implementation and enforcement by states); U.S. ENVTL. PROT. AGENCY, OFFICE OF INSPECTOR GEN., REPORT NO. 12-P-0113, EPA MUST IMPROVE OVERSIGHT OF STATE ENFORCEMENT 6 (2011), *available at* http://www.epa.gov/oig/reports/2012/20111209-12-P-0113.pdf (discussing EPA's failure to administer consistent enforcement across the nation of state implementation of the RCRA, CWA, and Clear Air Act).

165 For a summary of take-back programs in the Great Lakes region, see PRODUCT STEWARDSHIP INST., PROTECTING OUR HEALTH AND THE ENVIRONMENT: THE NEED FOR SUSTAINABLY FINANCED DRUG TAKE-BACK PROGRAMS 8, 12–15 (2012), *available at* http://www.productstewardship.us/

halting the illegal circulation and use of drugs rather than on preventing their introduction into the environment.[166] To the extent that there is a reduction in the use of unwanted, unused, improperly discarded, and stolen drugs, which are then directed toward proper disposal, it is logical to assume fewer pharmaceutical pollutants reach the environment.

Utah operates a drug take-back program, the goal of which is to "prevent and reduce the misuse and abuse of prescription pain medications."[167] The program, however, also recognizes that "drugs that are disposed by flushing can enter the environment because sewage treatment plants and septic systems are not designed to remove them" and that "scientific research suggests that certain drugs may cause harm to fish and other aquatic life."[168]

Maine, which is credited with implementing the first statewide drug take-back program in 2007, experimented with an anonymous and no-cost drug mail-back pilot program funded partly by an EPA grant.[169] The eighteen-month program, which ran

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associations/6596/files/Pharmaceuticals%20White%20Paper%20on%20EPR_Final.pdf. For summaries of several early drug take-back programs, see MONICA HUBBARD, OREGON PHARMACEUTICAL TAKE BACK STAKEHOLDER GROUP: FINAL REPORT 1 (2007), *available at* http://www.oracwa.org/pdf/oregon-drug-takeback-report.pdf and Glassmeyer, *supra* note 20.

166 *Cf.* Christian G. Daughton, *Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health. II. Drug Disposal, Waste Reduction, and Future Directions*, 111 ENVTL. HEALTH PERSP. 775, 780 (2003) (explaining that "[m]ost existing laws directed at drug disposal are written around two concerns: a) the disposition of 'controlled' substances, or b) the imperative to keep expired/unwanted medication away from children (this is perhaps the major imperative for disposing of drugs to sewage that has been instilled in the public over the years)").

167 *Preventing Prescription Drug Overdoses*, UTAH DEP'T OF HEALTH, http://www.health.utah.gov/vipp/topics/prescription-drug-overdoses/prevention.html (last visited Mar. 2, 2015). Utah's program authorizes a number of permanent collection sites and continues to organize periodic community take-back events. *Safe Disposal: Learn the Facts*, USE ONLY AS DIRECTED, http://www.useonlyasdirected.org/safe-disposal (last visited July 11, 2014).

168 *See Safe Disposal: Learn the Facts*, *supra* note 164. The "Use Only as Directed" program is "a media and education campaign funded by the Utah Commission on Criminal and Juvenile Justice and a federal grant awarded to the Utah Division of Substance Abuse and Mental Health." *The Campaign*, USE ONLY AS DIRECTED, http://www.useonlyasdirected.org/campaign (last visited Mar. 23, 2014).

169 *See* LENARD KAYE et al., EXECUTIVE SUMMARY: REDUCING PRESCRIPTION DRUG MISUSE THROUGH THE USE OF A CITIZEN MAIL-BACK PROGRAM IN MAINE (2010); Brett Walton, *Unprescribed: Legislation to Keep Drugs out of Water Thwarted by U.S. Pharmaceutical Lobbying*, CIRCLE OF BLUE (Nov. 10,

between May 2008 and October 2009, generated 2,373 pounds of drugs.[170] Due to budgetary concerns and a change in state government administration, the program was not funded by the Maine legislature following its expiration.[171] Maine, however, continues to offer drug drop-off and disposal services.[172]

Other states also have initiated various drug take-back and drop-off program with varying degrees of success. Between 2009 and 2011, Colorado collected twelve thousand pounds of drugs in a pilot project utilizing only eleven drop-off locations statewide. During the same time period, the Iowa program generated nearly 21,545 pounds of unwanted, expired, and unused pharmaceutical products.[173] In 2011, Wisconsin's statewide, take-back program generated nearly 93,500 pounds of household pharmaceuticals, although, a subsequent study suggests that this volume was a mere two percent of the estimated 4.4 million pounds of unwanted pharmaceuticals in the state that year.[174]

Funding is one of the primary challenges facing all of these programs.[175] While a number of states have proposed initiatives mandating industry-funded drug collection and disposal programs, none have passed largely due to industry opposition.[176] Mandated industry-funded programs in the United States have been implemented at the local level only in Alameda County, California and King County, Washington State.[177] The City of San Francisco

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2011), http://www.circleofblue.org/waternews/2011/world/unprescribed-u-s-pharmaceutical-industry-fights-to-avoid-paying-for-drug-disposal-programs/.

170 KAYE, *supra* note 169; *see* Walton, *supra* note 169.

171 *See* Walton, *supra* note 169.

172 *Safe Medicine Disposal for ME Program*, U ME., http://umaine.edu/safemeddisposal (last visited Nov. 16, 2014).

173 *See* Walton, *supra* note 169.

174 U. OF WISC. COOP. EXTENSION & PROD. STEWARDSHIP INST., WISCONSIN HOUSEHOLD PHARMACEUTICAL WASTE COLLECTION—CHALLENGES AND OPPORTUNITIES, at v, 5–6, & 39 (2012), *available at* http://dnr.wi.gov/topic/HealthWaste/documents/2012HouseholdPharmStudy.pdf. The other ninety-eight percent "were discarded in the trash, flushed down the drain, abused, or stored indefinitely in the medicine cabinet." *Id*. at v.

175 *See, e.g.*, KAYE, *supra* note 169; Walton, *supra* note 169 (raising the funding issue with Maine's program); UNIVERSITY OF WISCONSIN COOPERATIVE EXTENSION & PRODUCT STEWARDSHIP INSTITUTE, *supra* note 174, at v (noting "high costs [and] lack of sustainable funding" as some of the chief barriers for developing an effective state-wide drug collection program).

176 *See* Walton, *supra* note 169.

177 *See* Brett Walton, *Who Will Pay for Disposal? Drug Companies Lose Against Local Governments in California and Washington*, CIRCLE OF BLUE (Sept. 11, 2013), http://www.circleofblue.org/waternews/2013/world/who-will-

implemented a similar program, albeit with voluntary collaboration of the pharmaceutical industry.[178] Both the Alameda County and King County programs have been challenged in court by the pharmaceutical industry.[179]

IV. MANAGING PHARMACEUTICALS IN THE ENVIRONMENT: A LIFECYCLE APPROACH

Given the potential threats pharmaceuticals in the environment pose to human and environmental health, as well as the haphazard and inadequate state of the regulatory regime for managing those threats, it is prudent to question whether pharmaceuticals and their residues should be regarded as safe until proven unsafe, or unsafe until proven safe. The answer to this query, though, is not straightforward. Pharmaceuticals benefit humans and other species by addressing health problems, improving quality of life, and even extending life. Yet, they have the potential to cause great harm to the health of people and countless other species when improperly released into the environment.[180] Should society continue to produce pharmaceuticals, even at the possible expense of human and environmental health? Should we place limitations on pharmaceuticals to prevent them from reaching the environment, even if such restrictions raise costs and stifle innovation?

While these two positions—regulating pharmaceuticals will increase costs and stifle innovation; failing to regulate pharmaceuticals will harm people and the environment—may

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pay-for-drug-disposal/.

178 Press Release, S.F. Dep't of the Env't, San Francisco's Pharmaceutical Industry Sponsored Unused Medicine Take-Back Program Is Funded for an Additional Year (Aug. 14, 2013), *available at* http://www.sfenvironment.org/news/press-release/san-franciscos-pharmaceutical-industry-sponsored-unused-medicine-takeback-program-is-funded-for-an-additional-year. San Francisco, however, is moving to make the program mandatory for drug makers. *See* Ed Silverman, *That Flushing Sound: San Francisco Moves Closer to a Take-Back Program*, WALL ST. J. (Feb. 27, 2015, 9:00 AM), http://blogs.wsj.com/pharmalot/2015/02/27/that-flushing-sound-san-francisco-moves-closer-to-a-take-back-program/.

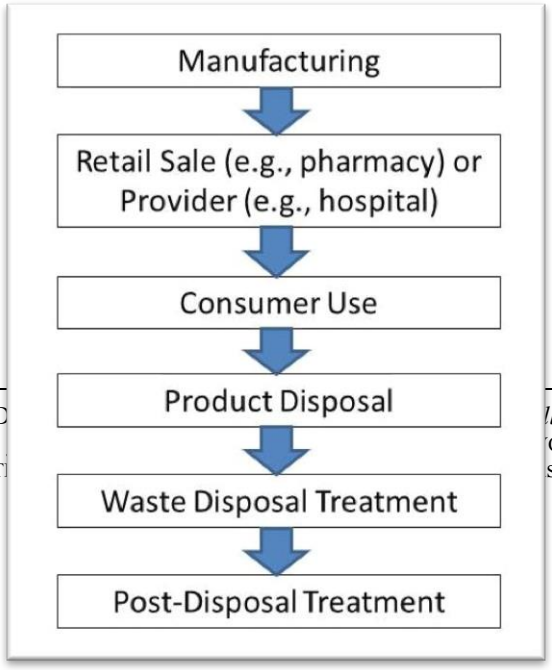
179 *See* Kurt R. Karst, *Royal Flush? Trade Groups Challenge a Second Drug Stewardship Program; This Time the Target is King County, Washington*, FDA L. BLOG (Dec. 17, 2013), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2013/12/trade-groups-challenge-a-second-drug-stewardship-program-this-time-the-target-is-king-county-washing.html; *see also infra* notes 227–229 and accompanying text (discussing status of these cases).

180 *See supra* notes 43–61 and accompanying text.

appear mutually exclusive, they need not be entirely incompatible. The challenge is to find a middle ground that acknowledges and balances the potential risks associated with pharmaceuticals in the environment with the likely impacts that policy and legislative restrictions could have on the pharmaceutical industry. The challenge is also to find an approach that diminishes the likelihood that pharmaceutical pollutants will reach the nation's rivers, lakes, aquifers, and soils, while minimizing additional costs for pharmaceutical research, production, and distribution to an acceptable and predictable level. That middle ground may be found by targeting the earlier lifecycle stages of pharmaceuticals products for regulatory action.

As a policy matter, there are many points in the lifecycle of a pharmaceutical at which standards and regulations might be implemented. C.G. Daughton's chart of the Environmental Lifecycle of Pharmaceuticals is particularly instructive, albeit somewhat overwhelming, in that it illustrates the dozens of interfaces that exist among manufacturing and distribution companies, medical facilities, individuals, and disposal and treatment activities.[181] For purposes of relative simplicity, Daughton's chart can be condensed to the six chief stages in the lifecycle of a pharmaceutical at which regulatory intervention may be warranted and applied (see Figure 2). These include design and manufacturing, retail sale and distribution by health care professionals, consumer use, product disposal, waste disposal treatment, and post-disposal treatment.

Figure 2. The six chief stages in the lifecycle of a pharmaceutical at which regulatory intervention may be warranted and applied



181 C.G. D *llutants: The Ramifications* CLOPEDIA OF PUBLIC HEALT s., 2008).

As indicated above, the current regulatory structure targeting pharmaceutical pollutants in the environment focuses primarily on the final two lifecycle stages: waste disposal treatment and post-disposal treatment.[182] Such a narrow approach is both flawed and inadequate largely because it is doubtful that regulatory-imposed techniques or processes can be devised to effectively treat or remove all of the thousands of different pharmaceutical substances and their varying active ingredients and components at the disposal and post-disposal stages.[183] Accordingly, targeting the terminal point of the pharmaceutical lifecycle is unlikely to achieve much success in terms of eliminating or reducing pharmaceutical pollutants in the environment.[184] Instead, it may be

182 *See supra* notes 69–119, 155–162 and accompanying text.

183 *See* WU ET AL., *supra* note 21, at 42. It is unlikely that any "single water treatment process will be capable of reducing all trace organic contaminants to below increasingly sensitive analytical detection limits." Benjamin D. Stanford et al., *Estrogenic Activity of U.S. Drinking Waters: A Relative Exposure Comparison*, 102 J. AM. WATER WORKS ASS'N 56 (2010). Likewise, Jones states that "[t]he total costs of removing every possible endocrine disrupting compound could quickly become astronomical. Although the public may want pure water, people are not prepared to pay what it would actually cost even if sufficient technology did exist." Keith J. Jones, *Endocrine Disruptors and Risk Assessment: Potential for a Big Mistake*, 17 VILL. ENVTL. L.J. 357, 385–86 (2006); *see also* Eckstein & Sherk, *supra* note 5, at 44 (maintaining that "[i]mposing such costs on the operators of publically-owned treatment works may be both financially and politically impossible").

184 Pharmaceutical pollutants are often found in very low concentrations, e.g., at the nanogram to low microgram per liter range. *See* WORLD HEALTH ORG., *supra* note 8, at 5, 15. Some conventional wastewater treatment processes, such as the use of activated sludge and biofiltration, can remove certain pharmaceuticals from the waste stream. Results, however, vary and depend on a variety of factors, including the kind of methodology used and pharmaceutical pollutant targeted. Advanced wastewater treatment methods, including ozonation, membrane treatment, and advanced oxidation, have been considerably more effective at removing certain pharmaceutical pollutants from the waste

more prudent to abide by Benjamin Franklin's adage that an ounce of prevention is worth a pound of cure and focus on the first four stages of the pharmaceutical lifecycle where mechanisms could be implemented for minimizing the probability that pharmaceutical pollutants actually reach the environment.

A. *Drug Design and Manufacturing*

Pharmaceutical companies tend to focus on efficiency and economics when manufacturing new drugs and reformulating existing drugs.[185] Drug manufacturers, however, should also be incentivized or required to consider the environmental impacts of drug use resulting from the accumulation of pharmaceuticals in soils and fresh water resources.[186] In particular, manufacturers should target the manufacturing-related causes of these

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stream. Nevertheless, neither conventional nor advanced technology can remove all pharmaceuticals from the waste stream. *Id*. at 17, 20–21; NAT'L ASS'N OF CLEAN WATER AGENCIES & ASS'N OF METRO. WATER AGENCIES, PHARMACEUTICALS IN THE WATER ENVIRONMENT 19 (2010), *available at* https://www.dcwater.com/waterquality/PharmaceuticalsNACWA.pdf; *see also* Kummerer, *supra* note 26, at 412–14 (discussing some of the merits and shortcomings of various advanced effluent treatment processes). While removal of some pharmaceutical wastes at the drinking water treatment stage is possible, such as with methodologies that include chlorination and ozonation, most existing processes are not designed to remove such pollutants. *See* WORLD HEALTH ORG., *supra* note 8, at 18.

185 *See* Jeremy Laurance, *Drugs Companies Putting Profit Ahead of Medical Discoveries, Warn Scientists*, INDEPENDENT (Aug. 8, 2012), http://www.independent.co.uk/life-style/health-and-families/health-news/drugs-companies-putting-profit-ahead-of-medical-discoveries-warn-scientists-8015784.html (asserting that drug companies prioritize profits above new discoveries); John LaMattina, *Do Drug Companies Make Drugs, Or Money?*, FORBES (July 29, 2014, 9:03 AM), http://www.forbes.com/sites/johnlamattina/2014/07/29/do-drug-companies-make-drugs-or-money/ (opining that while "[a] pharma company's business is making drugs . . . in doing so it had better make profits"); *Big Pharma Spends More on Advertising than Research and Development, Study Finds*, SCIENCEDAILY (Jan. 7, 2008), http://www.sciencedaily.com/releases/2008/01/080105140107.htm (discussing findings of a study supporting the proposition that pharmaceutical companies are predominantly marketing-driven).

186 Incentives for pharmaceutical manufacturers could include drug patent extensions, tax benefits, and reduced environmental testing obligations for "green" products. *See e.g.*, EUROPEAN ENVTL. AGENCY, PHARMACEUTICALS IN THE ENVIRONMENT: RESULTS OF AN EEA WORKSHOP, EAA TECHNICAL REPORT NO. 1/2010, at 10 (2010) (discussing patent incentives and different testing requirements); Daughton, *supra* note 166, at 776 (discussing patent incentives); Marvin E. Herring et al., *Current Regulations and Modest Proposals Regarding Disposal of Unused Opioids and Other Controlled Substances*, 108 J. AM. OSTEOPATHIC ASS'N 338, 341 (2008) (proposing providing economic incentives to pharmaceutical manufacturers).

accumulations.

To reduce the amount of pharmaceutical pollutants that reach the environment, manufacturers could seek to enhance the physiological sorption rates of drugs,[187] as well as formulate drugs that maintain their therapeutic effectiveness at substantially reduced dosage levels.[188] They also could develop "smart" drugs that "better emulate the non-anthropocentric, native chemistries of natural products"[189] and design drugs that are specifically tailored to groups of patients based on physiological traits, such as weight or genetic predisposition.[190] In addition, manufacturers should produce certain drugs in multiple formulations and doses so as to accommodate patients of different ages, sizes, weight, and medical needs.[191] Lastly, they should formulate drugs to be more susceptible to biodegradation, photolysis, and other physicochemical alterations that yield less harmful end products.[192]

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187 *See e.g.*, WU ET AL., *supra* note 21, at 16; Daughton, *supra* note 128, at 765.

188 *Id*. at 766.

189 *Id*.

190 *Id*. at 767. Such tailoring increasingly is becoming a reality given advances in genomics (the study of genes and their functions), proteomics (the study of proteins and their functions), glycomics (study of the structure and function of sugars and saccharides), and metabolomics (the study of metabolites and their functions). *Id*. at 765; *see -Omes and -omics Glossary & Taxonomy: Evolving Terminology for Emerging Technologies*, CAMBRIDGE HEALTHTECH INST., http://www.genomicglossaries.com/content/omes.asp (last updated Jan. 12, 2015).

191 *See* L.J. Lesko & S. Schmidt, *Individualization of Drug Therapy: History, Present State, and Opportunities for the Future*, 92 CLINICAL PHARMACOLOGY & THERAPEUTICS 458 (2012) (discussing the evolution and current status of individualized drug therapy); Su Yasuda et al., *The Role of Ethnicity in Variability in Response to Drugs: Focus on Clinical Pharmacology & Therapeutics*, 84 CLINICAL PHARMACOLOGY & THERAPEUTICS 417, 418, 422 (2008) (noting that while "scientific data demonstrate genetic differences in the expression of drug-metabolizing enzymes, transporters, and targets," most recently approved pharmaceuticals were not evaluated for the effect of race or ethnicity on efficacy or safety); Anne Zajicek et al., *A Report from the Pediatric Formulations Task Force: Perspectives on the State of Child-Friendly Oral Dosage Forms*, 15 AAPS J. 1072 (2013) (noting that "[m]ost medications are produced for adults as capsules and tablets," that these are "often not suitable for children," and the "dearth of oral pediatric formulations"); *see also supra* note 16; *cf.* Christian G. Daughton & Ilene S. Ruhoy, *Lower-Dose Prescribing: Minimizing "Side Effects" of Pharmaceuticals on Society and the Environment*, 443 SCI. TOTAL ENV'T 324 (2013) (discussing dose reduction as a means for reducing environmental API loadings).

192 *See* WU ET AL., *supra* note 20, at 16; Daughton, *supra* note 128, at 765; Wennmalm & Gunnarsson, *supra* note 43, at 296.

Without imposing regulatory obligations on the pharmaceutical industry, it is quite unlikely that drug manufacturers will pursue these objectives on their own. Absent a clear business objective or a regulatory mandate, most for-profit companies are more likely to prioritize their own economic interests over broader societal concerns. While the pharmaceutical industry probably might oppose it, an effective mechanism for integrating the environmental impacts of drug use into the drug design and manufacturing process would be a re-empowered NEPA process applied to FDA's drug approval process.

As a preliminary matter, FDA should reevaluate its categorical NEPA exclusions in light of the current state of science and the tremendous advances made in assessing the consequences of pharmaceuticals in the environment. These exclusions date back to 1997[193] and are based on outdated scientific information.[194] In particular, the Agency should acknowledge that pharmaceutical products, wastes, and residues are a source of potentially harmful environmental pollutants. This recognition should encompass the individual, cumulative, and synergistic effects that pharmaceutical substances may have on both people and the environment and should result in the elimination of the presumptive safe threshold of 1 part per billion. The presumption that agency action routinely will not affect the environment[195] should also be withdrawn. The burden to prove no significant harm should be placed on applicants for new drugs as well as those submitting modifications to the use or formulation of currently authorized pharmaceutical products. Moreover, the FDA should eliminate the exclusion for substances that occur naturally in the environment[196] on grounds that the cumulative and chronic exposure to heightened levels of these substances, as well as exposure to these substances in combination with other exposures, has the potential to affect human and environmental health.

Finally, FDA's NEPA process must be amended to more closely follow the statute's original procedures designed to obligate the federal government to incorporate environmental concerns into the decision-making process prior to undertaking

193 National Environmental Policy Act; Revision of Policies and Procedures, 62 Fed. Reg. 40,570 (July 29, 1997).

194 *See supra* note 127–129 and accompanying text.

195 *See supra* note 125 and accompanying text.

196 *See* 21 C.F.R. § 25.31(c).

any action.[197] FDA should revise its regulations (21 C.F.R. § 25.52(a)-(b)) to ensure that EISs are subjected to public dissemination and notice-and-comment, prior to the agency taking decisive action.[198] "The hope is that with an adequately informed FDA sitting as gatekeeper to this highly profitable market, drug design will evolve. This will lead drug companies to internalize the external impacts of their products and, where feasible, design drugs of the future that are noted for their minimal impact on the environment as well as for their therapeutic effectiveness."[199]

B. *Drug Sale and Dispensing by Health Care Professionals*

Doctors, nurses, pharmacists, veterinarians, and other health care professionals have a tremendous impact on the use and disposal of pharmaceutical products. Prescription drugs, for example, cannot reach the final user without going through a healthcare provider.

Accordingly, all health care professionals involved in dispensing and administering drugs should be educated and specially trained to instruct their patients and customers on the safe use and disposal of pharmaceutical products. This includes information on proper dosing, whether to take with or without food or water, and dose spacing to maximize efficacy and sorption. Training should incorporate information on the proper disposal of unspent and expired medication that includes proper disposal techniques and location of approved collection sites.[200] Additionally, it should encompass information on possible alternatives to the use of pharmaceuticals, including natural and non-pharmaceutical products and those with less harmful residues, as well as preventative health care options that would reduce the need for medication.[201] Training and education of health care

197 *See supra* note 120–123 and accompanying text.

198 *See supra* note 136–138 and accompanying text.

199 Christopher T. Nidel, *Regulating the Fate of Pharmaceutical Drugs: A New Prescription for the Environment*, 58 FOOD & DRUG L.J. 81, 100 (2003).

200 *See* Kummerer, *supra* note 26, at 415 ("Proper information for doctors, pharmacists and patients can contribute to the reduction of the input of APIs into the aquatic environment . . . . Proper information on how to handle leftover drugs will result in the reduction of the environmental burden of drugs.").

201 For example, Daughton suggests that nutrition and health maintenance programs can reduce the incidence of diseases and, thereby, reduce the release of PPCPs associated with the treatment of those diseases. *See* Daughton, *supra* note 166, at 777. Daughton further suggests consideration of drug alternatives, such as probiotics that can block pathogen adhesion, and that may achieve the same

professionals could be achieved through continuing education licensing requirements for individual doctors, nurses, pharmacists, and veterinarians, as well as licensing and certification criteria for health care institutions. It also could be integrated into the degree granting criteria for these professions. Ultimately, though, ensuring minimum standards and consistency in health care provider knowledge and patient education may require regulatory intervention.

C. *Consumer Use*

Consumers and end users should also be educated on the safe use and disposal of pharmaceutical products, as well as on alternatives and preventative health care options. In particular, consumers need to be educated on the potential impact of pharmaceutical pollutants reaching the environment through improper disposal and excretion.

Drug education may be especially prudent for certain dangerous drugs, such as those listed in Schedule II of the Controlled Substances Act (CSA),[202] as part of an effort to ensure safe use and disposal. While such a program may be difficult to impose on the general public, it could be implemented through FDA regulations as a requirement for the use of these powerful pharmaceuticals. Nevertheless, requiring the public to undertake training for all prescription medication clearly would be a tremendous challenge and a likely barrier to the provision of appropriate health care. Accordingly, consumer education should be pursued as a government-led public service initiative and undertaken collaboratively with the pharmaceutical industry, health care professionals, public health and safety institutions, professional associations and non-governmental organizations specializing in human or environmental health issues, and other relevant entities. Educational efforts can include: brochures and other written material supplied by manufacturers and health care professionals in conjunction with the distribution of pharmaceutical products and health care services; direct conversations between health care professionals and consumers;

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therapeutic results without the attendant drug execration or disposal problems. *Id*.

202 Drugs listed in Schedule II of the CSA include drugs with a high potential for abuse that may lead to severe psychological or physical dependence, but which also have a currently accepted medical use in treatment in the United States. 21 U.S.C. § 812(b)(2).

public service announcements transmitted by radio, television, movie theaters, and other media; and public education advertising campaigns.

D. *Product Disposal*

Drug disposal in the United States is, at best, haphazardly managed and regulated. For example, while the FDA recommends disposal of dozens of pharmaceuticals by flushing them down the toilet, EPA urges the public never to flush expired or unwanted prescription and over-the-counter drugs unless the product label specifically advises such disposal.[203] While the two approaches are not mutually exclusive, the FDA flushing recommendation is based primarily on potential misuse and overuse concerns rather than post-disposal human and environmental hazards.[204] Moreover, FDA sanctioning of flushing for some pharmaceuticals could easily be misconstrued as applicable to all household medicines.[205]

Furthermore, while RCRA applies to any facility that generates more than one hundred kilograms of hazardous pharmaceutical waste per month,[206] the statute appears to be only minimally enforced against health care providers and facilities.[207] Moreover, while the assortment of take-back projects implemented by DEA, states, and various local governments are laudable, the lack of funding and consistency among the programs constrains their efficacy. Yet, given the astonishing quantities of

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203 *Compare Disposal of Unused Medicines: What You Should Know*, U.S. FOOD & DRUG ADMIN. (advocating disposal of numerous pharmaceuticals by flushing them down the toilet), http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm (last updated Feb. 10, 2015), *with* ENVT'L PROT. AGENCY, EPA 816-F-11-003, HOW TO DISPOSE OF MEDICINES PROPERLY (2011) (admonishing against the disposal of expired or unwanted prescription and over-the-counter drugs down the toilet or drain unless the product label or accompanying patient information specifically directs such disposal), *available at* http://water.epa.gov/scitech/swguidance/ppcp/upload/ppcpflyer.pdf.

204 *See How to Dispose of Unused Medicines*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/forconsumers/consumerupdates/ucm101653.html (last updated Aug. 19, 2014).

205 *Cf.* Marvin E. Herring et al., *Current Regulations and Modest Proposals Regarding Disposal of Unused Opioids and Other Controlled Substances*, 108 J. AM. OSTEOPATHIC ASS'N 338, 341 (2008) (discussing the "disposal dilemma" facing patients and health care providers as a result of ambiguous and often inconsistent drug disposal recommendations at the state and federal levels).

206 *See* 40 C.F.R. § 261.5(a); *see also supra* text accompanying note 74.

207 *See supra* notes 77–78 and accompanying text.

pharmaceutical products collected through the various DEA and state and local programs,[208] the demand and need for such programs is undeniable.

1. *Reverse Distribution*

Hospitals, clinics, pharmacies, doctor offices, and other health care facilities are often left with significant quantities of unsold, expired, damaged, recalled, or discontinued pharmaceutical products.[209] These products are usually disposed through the waste stream[210] and occasionally through authorized donation programs.[211] Many of these entities also have the option of returning these drugs through a reverse distribution system.

Reverse distribution refers to a process by which authorized companies recycle or dispose of unused and unsold expired, damaged, recalled, or discontinued pharmaceutical products obtained from wholesaler, distributor, pharmacies, and hospitals.[212] This subset of the pharmaceutical industry emerged to

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208 *See supra* notes 151–152, 169, 172–74 and accompanying text.

209 While few health care facilities keep track of the quantities of pharmaceutical waste generated, a 2008 sampling by the Associated Press suggested that the volume of pharmaceuticals and contaminated packaging generated in the United States annually exceeded 250 million pounds. *See* Jeff Donn et al., *AP IMPACT: Health Care Industry Sends Tons of Drugs into Nation's Wastewater System*, ASSOCIATED PRESS (Apr. 14, 2008), http://hosted.ap.org/specials/interactives/pharmawater_site/sept14a.html. A 2003 survey of sixty primary doctor's offices, health care and veterinary centers, and hospitals in King County, Washington showed that these facilities disposed of nearly four thousand pounds of medical waste annually through hazardous waste vendors, reverse distributors, and municipal trash disposal, and dumped down drains or toilets an additional 10,610,644 milliliters of liquid medication (e.g., narcotics, cough syrup, injectable liquids, and IV liquids) and 6,188 pills and tablets. *See* D. OLIVER & A. CHAPMAN, LOCAL HAZARDOUS WASTE MANAGEMENT PROGRAM, PHARMACEUTICAL WASTE SURVEY 11 tbl.9 (2003), *available at* http://www.lhwmp.org/home/publications/publications_detail.aspx?DocID=zI8Wbqv9QSk%3d.

210 Donn et al., *supra* note 209 (reporting on the finding of an Associated Press investigation that revealed that "U.S. hospitals and long-term care facilities annually flush millions of pounds of unused pharmaceuticals down the drain, pumping contaminants into America's drinking water . . . ").

211 Kevin B. O'Reilly, *Charity Helps Medical Practices Donate Unused Drug Samples*, AM. MED. NEWS (Aug. 22, 2012), http://www.amednews.com/article/20120822/profession/308229996/8/.

212 Reverse distributor is defined in 21 C.F.R. § 1300.01(b) as:

> a registrant who receives controlled substances acquired from another DEA registrant for the purpose of—
>
> (1) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or

facilitate manufacturers' return policies for potential credit for unsold pharmaceutical products.[213] As a secondary objective, reverse distribution is now accepted as a mechanism for minimizing the likelihood that these products would be diverted for illicit use.[214]

With the recent adoption of DEA's new rules, reverse distributors are now authorized to administer consumer mail-back programs and maintain collection receptacles for consumers' unused, unwanted, and expired pharmaceutical products.[215] Although the justifications for the rule change might still emphasize law enforcement objectives, to the extent that the efforts reduce the volume of drugs that are improperly circulated, used, or discarded, the outcome could also have a beneficial impact on human and environmental health.

2. *Pharmaceutical Take-Back Programs*

Federal and state governments should make greater efforts to organize, promote, and fund drug disposal and collection programs. Whether structured through designated drop-off locations or through a mail-in process, these programs should be developed to maximize the collection and proper disposal of unused, unwanted, and expired pharmaceutical products. Two challenges, however, must be overcome to facilitate the development and expansion of such programs.

The first challenge relates to the CSA and DEA regulations that, until recently, effectively prohibited consumers and health care institutions that were not registered with the DEA (e.g., many nursing homes and other long term health care facilities) from transferring possession of dispensed controlled substances to anyone other than a law enforcement official.[216] While

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(2) Where necessary, processing such substances or arranging for processing such substances for disposal.

Reverse distributors currently are not permitted to accept controlled substances from consumers, doctors, and others not authorized by the DEA. *See* Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. 73,520, 73,533 n. 45 (Dec. 2, 2008).

213 *See* Johnson, *supra* note 155, at 3; Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. at 73,525.

214 *See* Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. at 73,525.

215 *See supra* note 148–150 and accompanying text.

216 Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. at 75,785, 75,787. It is noteworthy that the CSA and DEA

maintaining control over these dangerous drugs is an important law enforcement objective,[217] creating more opportunities for proper disposal in a secure manner could serve both law enforcement and human and environmental health objectives.

As noted above, in September 2014, DEA issued new regulations expanding the options available for collecting controlled substances from ultimate users, including reverse distribution, through take-back events, mail-back programs, and collection box locations.[218] While the new rule does purport to expand opportunities for the disposal of unused prescription medication, the rule's impact is unlikely to be significant in terms of removing unused pharmaceuticals from circulation and, thereby, decreasing their introduction into the environment. The rule's chief shortcoming is that rather than mandating specific mechanisms for the proper disposal and collection of these pharmaceuticals, it merely authorizes the pharmaceutical industry to voluntarily undertake such programs.[219] Moreover, it imposes both the costs associated with program implementation,[220] as well as liability for theft, improper diversion, and other illegal conduct by third parties, on the volunteers.[221] Accordingly, absent a clear business advantage, it is unlikely that a significant segment of the

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regulation do not explicitly prohibit such transfers. Nevertheless, the Act and the regulations have no provisions that explicitly authorize a DEA registrant (such as a pharmacy) to receive and accept a controlled substance from a non-registrant or individual end-user. BRIAN T. YEH, CONG. RESEARCH SERV., R40548, LEGAL ISSUES RELATING TO THE DISPOSAL OF DISPENSED CONTROLLED SUBSTANCES 10 (2010). Moreover, the CSA expressly prohibits consumers from engaging in the "distribution" of controlled substances, which includes transferring such drugs to anyone for disposal or other purpose. 21 U.S.C. § 841(a)(1); Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration, 74 Fed. Reg. 3481 (Jan. 21, 2009). Accordingly, "if the CSA does not explicitly permit an action pertaining to a controlled substance, then by its lack of explicit permissibility the act is prohibited." Electronic Prescriptions for Controlled Substances, 73 Fed. Reg. 36,724 (proposed June 27, 2008).

217 The CSA's Introductory Provisions contains Congressional findings and declarations concluding that "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people" and that "Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic." 21 U.S.C. § 801(2), (6).

218 *See* Disposal of Controlled Substances, 79 Fed. Reg. 53,520 (Sept. 9, 2014); *see supra* text accompanying note 149.

219 *See* Disposal of Controlled Substances, 79 Fed. Reg. at 53,520–21.

220 *Id*. at 53,521, 53,551–53.

221 *Id*. at 53,534, 53,543–44.

industry will willingly assume such responsibility.

The second challenge relates to the costs associated with take-back programs. Take-back programs generally are funded from a variety of sporadic sources, including grants, local government budgets, facilities generating unused, unwanted, and expired drugs, and in-kind contributions.[222] Program costs often include collection receptacles, the presence of law enforcement, transportation and destruction of collected drugs, as well as public education and promotion.[223] The lack of adequate and consistent funding to cover these expenses is a significant barrier to developing effective pharmaceutical collection on a scale responsive to the need. For example, a review of Wisconsin's take-back program concluded that only a fraction of unused pharmaceuticals were collected via take-back programs, in part, because of "high costs [and] lack of sustainable funding."[224] The rest "were discarded in the trash, flushed down the drain, abused, or stored indefinitely in the medicine cabinet."[225]

The most obvious source of funding for such programs is the pharmaceutical manufacturing, distribution, and dispensing industry. Until recently, drug manufacturers have been able to thwart efforts to require their financial involvement.[226] On September 30, 2014, the Ninth Circuit Court of Appeals upheld an Alameda County, California, law requiring drug manufacturers to pay for a prescription drug collection and disposal program.[227] In that case, the Ninth Circuit rejected the pharmaceutical industry's claim that the law violated the "dormant Commerce Clause" as an

222 *See generally* PRODUCT STEWARDSHIP INSTITUTE, *supra* note 165 at 8–10 (discussing the challenge of funding take-back programs, and refers to funding mechanisms for programs in other U.S. jurisdictions as well as Canada and Europe); MONICA HUBBARD, OREGON PHARMACEUTICAL TAKE BACK STAKEHOLDER GROUP, FINAL REPORT 23–27 (2007), *available at* http://www.oracwa.org/pdf/oregon-drug-takeback-report.pdf (surveying various take-back programs and referring to their funding mechanisms).

223 *See* UNIVERSITY OF WISCONSIN COOPERATIVE EXTENSION & PRODUCT STEWARDSHIP INSTITUTE, *supra* note 174, at 53.

224 *See generally id*. at vi.

225 *See generally id.* at v.

226 *See* Walton, *supra* note 169.

227 *See* Pharm. Research & Mfrs. of Am. v. Cnty. of Alameda, 768 F.3d 1037 (9th Cir. 2014), *cert denied,* 83 USLW 3865 (U.S. May 26, 2015) (No. 14-751); *see also* Ed Silverman, *That Flushing Sound: Pharma Must Pay for a Drug Take-Back Program*, WALL ST. J. (Oct. 1, 2014, 9:00 AM), http://blogs.wsj.com/pharmalot/2014/10/01/that-flushing-sound-pharma-must-pay-for-a-drug-take-back-program/.

unconstitutional discrimination against or burden on interstate commerce.[228] The industry has also challenged a similar law adopted in King County, Washington, which is broader in scope in that it applies to all over-the-counter medications in addition to prescription drugs.[229] Following the Ninth Circuit's decision in the Alameda County case, King County began implementing its new regulations.[230]

Industry-financed drug collections and disposal programs, though, are not a novel concept. The pharmaceutical industry funds take-back programs in Canada, France, Spain, Sweden and Australia.[231] For example, in Sweden, pharmacies are tasked by the government with fully funding and managing the country's take-back program for unused, unwanted, and expired household-generated pharmaceuticals, including the safe storage and handling of collected drugs, and promotion of the program.[232] In the Canadian province of British Columbia, drug manufacturers are financially responsible for the "collection, transportation, storage, promotional activities and disposal" of their unused or expired pharmaceutical products.[233] Given the local efforts in California and Washington, as well as growing interest in state-level initiatives,[234] it remains to be seen whether the industry's opposition to funding collection and disposal programs in the United States can be maintained. As an incentive, some have recommended providing drug manufacturers patent extensions and other inducements for implementing effective drug collection, disposal, recycling, or other stewardship programs.[235]

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228 *See Alameda,* 768 F.3d at 1042–43, 1045–46.

229 Complaint for Declaratory and Injunctive Relief, Pharm. Research & Mfrs. Of Am. v. King Cnty., No. 2:13-cv-2151 (W.D. Wash. Dec. 27, 2013), *available at* http://www.alston.com/files/docs/King-County-Suit.pdf.

230 KING COUNTY, WA., BOARD OF HEALTH ch. 11.50 (2010).

231 *See* UNIVERSITY OF WISCONSIN COOPERATIVE EXTENSION & PRODUCT STEWARDSHIP INSTITUTE, *supra* note 174, at 19.

232 *See id*. at 54.

233 *See* POST-CONSUMER PHARMACEUTICAL STEWARDSHIP ASS'N, MEDICATIONS RETURN PROGRAM: PROVINCIAL PROGRAM TO ASSIST IN THE COLLECTION, TRANSPORTATION AND DISPOSAL OF UNUSED AND EXPIRED MEDICATIONS FROM THE PUBLIC 9 (2006), *available at* http://www2.gov.bc.ca/gov/DownloadAsset?assetId=AEABE2EBA4DA41CDA0C70F8822B4D586; *see also* UNIVERSITY OF WISCONSIN COOPERATIVE EXTENSION & PRODUCT STEWARDSHIP INSTITUTE, *supra* note 174, at 54.

234 *See* Walton, *supra* note 169.

235 *See e.g.*, Daughton, *supra* note 166, at 776; Herring et al., *supra* note 186, at 341.

CONCLUSION

In May 2014, British headlines scandalized readers with a United Kingdom governmental finding that cocaine use in Britain had become so pervasive that its metabolite, Benzoylecgonine, was now found in that nation's drinking water supplies.[236] While most journalists focused on the sensationalist aspects of the story, the presence of the drug in the drinking water supply of a highly developed Western nation should raise more poignant questions, including: how did the pernicious substance get into the public drinking water supply; why did the wastewater and drinking water treatment systems not eliminate it; what other pharmaceutical pollutants might be lurking in the water; and, more importantly, what might be the human and environmental consequence of the presence of such substances in the environment?

The reality today is that pharmaceuticals, both licit and illicit, and their components and residues are ubiquitous in soils, rivers,

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236 *See e.g.*, Ben Spencer, *Cocaine Use in Britain So Widespread It Can Be Found in our DRINKING WATER*, DAILY MAIL, May 12, 2014, http://www.dailymail.co.uk/news/article-2625659/Cocaine-use-Britain-widespread-DRINKING-WATER.html; Adam Withnall, *Cocaine Use in Britain So High It Has Contaminated Drinking Water, Report Shows*, INDEPENDENT, May 12, 2014, http://www.independent.co.uk/news/uk/home-news/cocaine-use-in-britain-so-high-it-has-contaminated-our-drinking-water-report-shows-9350477.html. The British scenario is not an outlier. Illicit drugs have also been found in municipal wastewater discharges in the United States, as well as various continental European nations. For studies in the United States, see e.g., Caleb J. Banta-Green et al., *The Spatial Epidemiology of Cocaine, Methamphetamine and 3,4-methylenedioxymethamphetamine (MDMA) Use: A Demonstration Using a Population Measure of Community Drug Load Derived from Municipal Wastewater*, 104 ADDICTION RES. REP. 1874, 1875 (2009) (describing a study in Oregon where researchers were able to conclude that cocaine use was much higher in cities while methamphetamine was popular in all areas based on testing of wastewater from 96 Oregon municipalities); Shannon L. Bartelt-Hunt et al., *The Occurrence of Illicit and Therapeutic Pharmaceuticals in Wastewater Effluent and Surface Waters in Nebraska*, 157 ENVTL. POLLUTION 786, 786 (2009) (discussing the "occurrence and estimated concentration of twenty illicit and therapeutic pharmaceuticals and metabolites in surface waters influenced by wastewater treatment plant . . . discharge and in wastewater effluents in Nebraska . . . "). For studies in Europe, see e.g., Maria Huerta-Fontela et al., *Occurrence of Psychoactive Stimulatory Drugs in Wastewaters in North-Eastern Spain*, 397 SCI. TOTAL ENV'T 31 (2008); Sara Karolak et al., *Estimation of Illicit Drugs Consumption by Wastewater Analysis in Paris Area (France)*, 200 FORENSIC SCI. INT'L. 153 (2010); Carla Repice et al., *Licit and Illicit Drugs in a Wastewater Treatment Plant in Verona, Italy*, 463 SCI. TOTAL ENV'T 27 (2013); Senka Terzic et al., *Illicit Drugs in Wastewater of the City of Zagreb (Croatia)—Estimation of Drug Abuse in a Transition Country*, 158 ENVTL. POLLUTION 2686 (2010).

lakes, and aquifers across the globe. Moreover, the evidence is quite good that these substances are having an adverse impact on aquatic and other species and may similarly be affecting human health.

Despite the growing concerns, there is presently a dearth of political and regulatory attention focused on this situation. In the United States, neither the federal nor the various state governments have adopted any policy, legislation, or comprehensive programs designed to respond to the growing threats posed by this situation, and the existing environmental and drug-related regulations and programs have been, at best, disorganized and ineffective. While the federal and a handful of state governments have issued a number of significant citations for violation of existing law,[237] that effort should not be confused with an effective regime for managing or preventing the presence and fate of pharmaceuticals in the environment.

The recommendations proposed here all focus on the early stages in the pharmaceutical lifecycle, which would reduce the likelihood that pharmaceutical pollutants actually reach the nation's soils, rivers, lakes, and aquifers. These options are not meant to prioritize environmental considerations over the health benefits derived from modern medicine. Rather, they are offered

237 For example, in 2003 and 2004, EPA Region 2 issued fines under RCRA ranging from $40,000 to $280,000 after identifying violations at a number of health care facilities. EPA-OIG 2012 REPORT, *supra* note 84, at 10. In 2009, EPA Region 7 issued a hospital a $51,501 RCRA fine and required the facility to implement programs to manage pharmaceutical and other waste at a cost of nearly $500,000. *See* Johnson, supra note 155, at 1; *Large EPA Settlement Points to Common Problems with Hazardous Waste*, HOSPITAL SAFETY INSIDER (Nov. 18, 2009), http://www.hcpro.com/SAF-242333-874/Large-EPA-settlement-points-to-common-problems-with-hazardous-waste.html. At the state level, in 2010, the New York Attorney General settled with five health care facilities after investigations showed they violated the federal SDWA by released releasing pharmaceutical waste into the New York City watershed. *See Product Stewardship for Drug Manufacturers*, N.Y. STATE SOLID WASTE EXAM'R (Legislative Comm. on Solid Waste), Fall 2011, at 9. In April 2012, California settled with retail drugstore giant, CVS Pharmacy, for $13.75 million on claims that the national chain illegally disposed of pharmaceutical and other hazardous waste in violation of California's hazardous waste laws. Sarah Rohrs, *CVS Retail Giant Must Pay $13.75 Million in Fines Over Waste Disposal Violations*, VALLEJO TIMES HERALD, Apr. 19, 2012,, http://www.timesherald online.com/ci_20431774/cvs-retail-giant-must-pay-13-75-million. Two months later, California settled with Costco for $3.6 million on similar allegations of state law violations. *Costco to Pay $3.6M Settlement*, RECORDNET.COM (June 5, 2012), http://www.recordnet.com/apps/pbcs.dll/article?AID=/20120605/a_biz/206050307.

as strategies for improving the design, approval, manufacturing, distribution, use, and disposal of pharmaceuticals in ways that both ensure their continued safe use and prevent them from causing unintended harm to people and the environment. While pursuing such strategies could increase the costs of pharmaceutical products, consumers and the general public are already paying a price in the form of environmental harm and possible health effects. Eventually, the public might also have to pay for enhanced wastewater and drinking water treatment operations.

There is no single culprit responsible for pharmaceutical pollutants reaching our nation's waters and environment. Manufacturers produce the products; consumers readily ingest or absorb them and then excrete them into the environment. In between, drug distributors, pharmacies, and health care providers route and dispense these substances, while miscreants divert them for illicit purposes. In order to not only reduce existing known threats but also minimize potential hazards, an approach for addressing pharmaceutical pollutants requires the involvement of all stakeholders, such as local communities, health care providers, environmental organizations, the pharmaceutical industry, law enforcement officials, and state and federal regulatory agencies and legislators.