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Down the Drain: Pharmaceutical Waste Disposal in The United States

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DOWN THE DRAIN: PHARMACEUTICAL WASTE DISPOSAL IN THE UNITED STATES

*Toby K. L. Morgan**

INTRODUCTION

Annually, millions of pounds of unused pharmaceuticals are flushed down the drain.¹ As a result, mood stabilizers, antibiotics, sex hormones and various other pharmaceuticals lurk in the drinking water supplies of individuals across the nation.² Recently, interest in pharmaceutical waste disposal is gaining momentum as scientists discover mutations in aquatic life resulting from low-level exposure to pharmaceutical compounds.³ Now, legislators and citizens begin to

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1. See Jeff Donn, et al., *Health Facilities Flush Estimated 250M Pounds of Drugs a Year*, USA TODAY (Sept. 14, 2008, 12:00 PM), http://www.usatoday.com/news/health/2008-09-14-drugs-flush-water_N.htm [hereinafter *Health Facilities Flush Estimated 250M Pounds of Drugs a Year*]. See also Jeff Donn, et al., *Pharmaceuticals Lurking in U.S. Drinking Water, AP Probe Found Traces of Meds in Water Supplies of 41 Million Americans*, MSNBC.COM (Mar. 10, 2008, 11:06 AM), http://www.msnbc.msn.com/id/23503485/ns/health-health_care [hereinafter *Pharmaceuticals lurking in U.S. drinking water*]; Joseph J. Wang, *Unopened, Unused Prescription Drugs Destroyed at Taxpayer Expense*, HEALTH LAW & POL'Y INST. (Nov. 29, 2000), <https://www.law.uh.edu/healthlaw/perspectives/Food/001129Unopened.html>.

2. See *Health Facilities Flush Estimated 250M Pounds of Drugs a Year*, *supra* note 1; see also *Pharmaceuticals Lurking in U.S. Drinking Water*, *supra* note 1; see also discussion *infra* Part I, Section 5.

3. Peter P. Fong, *Zebra Mussel Spawning is Induced in Low Concentrations of Putative Serotonin Reuptake Inhibitors*, 194 BIOLOGICAL BULL. 143, 143-44 (1998) (finding that serotonin reuptake inhibitors, such as Paxil, which are used by humans for the treatment of depression, obesity, and even convulsive seizures, can effect

wonder whether long-term exposure to pharmaceuticals and personal care products (“PPCP”), in similar dosages, may pose a significant risk to human health as well.⁴

The term “PPCP” was developed quite recently.⁵ Nevertheless, each year, as more scientific research and data is collected, PPCPs become more of an important issue. Even in low concentrations, the presence of pharmaceutical waste in our waterways has resulted in environmental transformations and variations. As pharmaceutical waste continues to mount it begs the question: is it possible that what we cannot see in our waterways is equally if not more harmful than what we can?

PPCPs are engineered to interact with the environment by stimulating “a physiological response in humans, plants, and animals.”⁶ Understanding how PPCPs continue to affect plants, animals, humans, and other earth systems after disposal is perhaps one of the most difficult environmental problems science and the law face today. Significant advances in research and a change in regulation are needed if we are to reduce the presence of PPCPs in the nation’s waste, surface and drinking water.

This Note is an introduction to pharmaceutical waste disposal and regulation in the United States. The very nature of the PPCP waste issue requires synergy between legislators and the scientific community, as adequate regulation must reflect and counteract the potential implications of low-dose exposure to humans, plants and animals. Perhaps, if adequately handled, it is not too late to correct

invertebrates when they are exposed to low concentrations specifically, inducing spawning in male and female zebra mussels).

4. See *Pharmaceuticals Lurking in U.S. Drinking Water*, *supra* note 1. *But cf.* PHILLIP SCHABECOFF & ALICE SCHABECOFF, POISONED PROFITS: THE TOXIC ASSAULT ON OUR CHILDREN 99 (2008) (finding that the anti-depressant, Paxil, “is effective at 30 parts per billion, and the chemical in birth control pills” is effective “at 0.019” parts per billion (ppb)).

5. See Christian G. Daughton, *Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health. I. Rationale for and Avenues Toward a Green Pharmacy*, 111 ENVTL. HEALTH PERSP. 775, 775 (2003); see also ENVTL. PROT. AGENCY, PHARMACEUTICALS AND PERSONAL CARE PRODUCTS (PPCPs), BASIC INFORMATION (2010), <http://www.epa.gov/ppcp/basic2.html>.

6. See Dana Kolpin et al., *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance*, 36 ENVTL. SCI. & TECH. 1202, 1202 (2002).

the mistakes that a history lacking in effective PPCP research and regulation has failed to address.

Part I introduces PPCPs by discussing PPCP research developments within the past decade, while paying close attention to the current PPCP regulatory framework. Part II addresses the impact of the Environmental Protection Agency's ("EPA") Proposed Universal Waste Amendment ("UWA"), which seeks to add pharmaceutical waste to the universal waste regulatory framework. The EPA's proposals, if adopted, will allow generators of pharmaceutical waste to either continue current pharmaceutical disposal methods to conform with the Resource Conservation and Recovery Act ("RCRA") or begin regulation under the Universal Waste Rule ("UWR"). Part III discusses the burden placed on pharmaceutical waste generators, the privatization of the pharmaceutical waste disposal regime, and the regulatory quandary created by an overlap in federal, state and local legislation. Part III concludes with a review of current proposals that emphasize the important role consumers play in combating PPCP exposure.

I. PART I

A. Chemical Pollution and its Role in the Development of PPCP Specific Research

For several decades, before the EPA began conducting PPCP specific research in the 1990's, scientists were concerned that national widespread chemical use could create adverse health effects.⁷ This concern spawned further research in the area of chemical pollution and subsequently led to PPCP-specific research.⁸ Initially, the chemicals investigated included those widely used in the

7. See generally RACHEL CARSON, SILENT SPRING 15 (1962); PRISCILLA COIT MURPHY, WHAT A BOOK CAN DO: THE PUBLICATION AND RECEPTION OF SILENT SPRING 1, 159 (2005); MARK H. LYTLE, THE GENTLE SUBVERSIVE: RACHEL CARSON, SILENT SPRING, AND THE RISE OF THE ENVIRONMENTAL MOVEMENT 133 (2007); *Thirty Years After Silent Spring: Status of EPA's Review of Older Pesticides: Hearing Before the Environment, Energy, and Natural Resources Subcomm. of the Comm. on Government Operations H.R.*, 102nd Cong. 1-4 (1992) (Rachel Carson's book discussing pesticides and their effect on bird species launched much of the early chemical pollution research).

8. See SCHABECOFF & SCHABECOFF, *supra* note 4, at 207-08; Daughton, *supra* note 5, at 757; Kolpin et al., *supra* note 6, at 1202.

farming and medical industry, but eventually expanded to include the chemical compounds commonly found in pharmaceuticals and household products as well.⁹ Now, in light of this research, scientists confirm that many of these chemicals act as contaminants, traveling via a vast number of disposal pathways, slowly dispersing into and amalgamating with the environment.¹⁰

Certain chemical contaminants, such as pesticides, are deliberately disseminated into the environment, admittedly in quantifiable amounts¹¹ while other contaminants, such as industrial byproducts, often enter water resources by uncontrolled means.¹² Veterinary pharmaceuticals also inadvertently enter the environment by the “overflow or leakage” of animal waste storage vats.¹³

The nature of these chemical contaminants allows them to persist in the environment for much longer than initially anticipated.¹⁴ “Household chemicals, pharmaceuticals, and other consumables as well as biogenic hormones” still persist in the environment, even after enduring wastewater treatment, because the treatment process cannot remove these compounds from the effluent at the low concentration levels that are present in our waterways.¹⁵ Today, knowledge of these disposal pathways plays an important role in determinations made by legislators and regulators concerning pharmaceutical waste management in facilities and households across the nation.

9. See Kolpin et al., *supra* note 6, at 1202.

10. See *id.*

11. See *id.*

12. See *id.* A multitude of chemical compounds are distributed into the environment on a daily basis as a result of persistent industrial use. Trying to exhaustively list these chemicals is virtually impossible. For instance, try to imagine the amount of chemicals used to clean and maintain an industrial building and its infrastructure then multiply that use throughout a city, county, state, then nationwide. These contaminants are “industrial byproducts.” They enter our water systems by “uncontrolled means” because these contaminants can enter waterways through rainwater runoff or through the sewer system if wastewater containing cleaning products is flushed, for example. *Id.*

13. See *id.*

14. See *id.*

15. See *id.*

B. The Beginning of PPCP Specific Research

In December of 1999, a critical review of PPCPs in the environment entitled “Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?” (“PPCPs in the Environment”) was published.¹⁶ This study synthesizes the research and data available concerning PPCPs.¹⁷ PPCPs encompass “pharmaceutical, veterinary, and illicit drugs, the ingredients in cosmetics, food supplements, and other personal care products,” “together with their respective metabolites and transformation products.”¹⁸ More detailed research on PPCPS eventually developed, but this study was one of the first to address, define and legitimize the issue.¹⁹ The study aided in the development of additional PPCP specific research and would lead to more definitive determinations of the risks that PPCPs pose to the environment.²⁰

Enumerating the chemical groups that fall under the PPCP purview was one of the easier tasks, while attempting to determine and regulate the environmental impact of PPCPs is a more difficult hurdle.²¹ Just as researchers uncovered while conducting contaminant research in previous decades, PPCPs are also used and dispensed of in a variety of ways across the nation.²² Because PPCPs primarily enter the environment as the effluent of sewage treatment works (“STW”) and via terrestrial run-off, researchers discovered that a large percentage of commercially used PPCPs are ubiquitous and continuously persist in the environment.²³

At the time of “PPCPs in the Environment” publication in 1999, occurrence data was only available for fifty nonantibiotic drugs gathered using aquatic monitoring systems that could not detect

16. Christian G. Daughton & Thomas A. Ternes, *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?*, 107 ENVTL. HEALTH PERSP. 907 (1999).

17. *See id.*

18. *Id.* at 908.

19. *See* MARC J. ZIMMERMAN, U.S. GEOLOGICAL SURV., OCCURRENCE OF ORGANIC WASTEWATER CONTAMINANTS, PHARMACEUTICALS, AND PERSONAL CARE PRODUCTS IN SELECTED WATER SUPPLIES, CAPE COD, MASSACHUSETTS, JUNE 2004 2 (2005), http://pubs.usgs.gov/of/2005/1206/pdf/ofr2005_1206.pdf.

20. *Id.*

21. *See* Daughton, *supra* note 16, at 934.

22. *See id.* at 907.

23. *See id.*

PPCPs at the low concentration levels found in the environment.²⁴ Today, not much has changed. Very few pharmaceutical contaminants have been adequately studied, leaving the thousands more that are currently approved for use without accurate occurrence data.²⁵ Equipped with limited available data, scientists eventually demonstrated that PPCPs can have a devastating effect on aquatic life, even in low concentrations.²⁶ Unfortunately, because this is such a burgeoning issue, the long-term effects that these chemicals may have on humans and the environment will remain unknown for decades to come.²⁷ Researchers are battling chemicals that are continuously infused back into the environment and are attempting to pinpoint, or even predict, the longevity and persistence of these chemical contaminants in the environment.²⁸

C. Recent Developments in PPCP Research

In March of 2002 the United States Geological Survey (“USGS”) released the results of a national reconnaissance on the occurrence of pharmaceuticals in surface waters.²⁹ The USGS reconnaissance studied various “antibiotics, prescription drugs, nonprescription drugs, steroids, [and] reproductive hormones.”³⁰ The research also addressed other contaminants such as “personal care products, products of oil use and combustion, and other extensively used chemicals.”³¹

Even after nearly five years, the USGS only had the ability to assess the environmental occurrence of ninety-five organic wastewater contaminants (“OWC”), not a far cry from the fifty pharmaceuticals that had been studied when “PPCPs in the Environment” was released in 1999.³² Astonishingly, of the 139 streams across thirty states surveyed by the USGS, one or more of the ninety-five contaminants tested for were found in 80% of the

24. *See id.* at 909.

25. *See id.*

26. *See id.* at 909-10.

27. *See* Daughton, *supra* note 16, at 908.

28. *See id.* at 908, 922-23.

29. Kolpin et al., *supra* note 6, at 1202.

30. *Id.* at 1203.

31. *Id.*

32. *See id.*

samples, with a median of seven contaminants found per stream.³³ The USGS' results proved that pharmaceutical compounds do "survive wastewater treatment and biodegradation."³⁴

However, these results only leave scientists with more questions. What impact can pharmaceutical compounds that are immersed with a variety of other chemical compounds have on the structure of the chemical?³⁵ Is it possible that "chemical combinations can exhibit additive or synergistic toxic effects?"³⁶ While technology and research take time to develop answers, legislators turn their attention toward determining how these pharmaceutical pollutants enter the environment.

D. How Pharmaceuticals Enter the Environment

As discussed above, one of the key problems scientists and regulators face when addressing pharmaceutical waste management is determining the pervasiveness of these contaminants and ascertaining how they enter the environment.³⁷ Notwithstanding the issue of various non-point sources of entry, such as run-off and atmospheric cycling, the task of identifying how these contaminants enter the environment, even from discernable point sources such as STWs and incinerators, continues to be particularly burdensome.³⁸ Consequently, in order to effectively formulate regulation, it is important to first determine how pharmaceutical waste is disposed of and managed.

Today, many pharmaceutical waste generators fail to properly distinguish between hazardous pharmaceutical waste, hazardous solid

33. Kolpin et al., *supra* note 6, at 1208-10. Interestingly, contaminants such as nonprescription drugs were detected at a much higher frequency than antibiotics and prescriptions. *See id.* at 1209.

34. *Id.* at 1210.

35. Currently, these pharmaceutical compounds are rarely found in isolation and their presence is usually documented in tandem with other contaminants. *See*, Dana W. Kolpin, Jack E. Barbash & Robert J. Gilliom, *Pesticides in Ground Water of United States, 1992-1996*, 38 *GROUND WATER* 858, 858-61 (2000); Kolpin et al., *supra* note 6, at 1210.

36. *See* Kolpin et al., *supra* note 6, at 1210.

37. *See* Despo Fatta-Kassinou et al., *Pharmaceutical Residues in Environmental Waters and Wastewater: Current State of Knowledge and Future Research*, 399 *ANALYTICAL & BIOANALYTICAL CHEMISTRY* 251, 272 (2010).

38. *Id.* at 252, 254.

waste, and other non-hazardous waste³⁹ or are simply unaware of federal reporting requirements.⁴⁰ As a result, the information that stems from what are, in many ways, quantifiable and defined pharmaceutical waste streams remains askew due to ignorance or neglect on the part of generators when implementing federal pharmaceutical waste disposal guidelines.⁴¹

Below, a brief synopsis of various pharmaceutical waste generation and disposal studies provides a rough outline of the quantity of pharmaceutical waste disposed of nationally. Although each survey is a small representation of how pharmaceutical waste enters the environment, the studies, when analyzed in tandem, reflect the amount of pharmaceutical waste released annually in the United States. This section also discusses how pharmaceutical waste disposal is currently regulated.

1. Hazardous Pharmaceutical Waste: Large Quantity Generators in the United States

The EPA conducted a cost benefit analysis for its proposal to amend the UWA relying heavily on data found in the EPA's National Biennial Report database ("BRS").⁴² This database includes data collected by the EPA from facilities defined as large-quantity generators ("LQG's") under the RCRA framework.⁴³ The EPA extrapolated the data from the BRS and used that information to estimate the quantity of pharmaceutical waste disposed of by

39. See ECON., METHODS, & RISK ANALYSIS DIV., OFF. OF SOLID WASTE, ENVTL. PROT. AGENCY, ASSESSMENT OF THE POTENTIAL COSTS, BENEFITS, AND OTHER IMPACTS OF ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, AS PROPOSED ES-1 (2008) (on file with author) [hereinafter ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE].

40. See *id.*

41. See *id.*; see also Debra Oliver & Alice Chapman, *Local Hazardous Waste Management Program in Kings County, Final Report, Pharmaceutical Waste Survey*, LOCAL HAZARDOUS WASTE MGMT. PROGRAM IN KING CNTY. 16 (2003), <http://www.govlink.org/hazwaste/publications/PharmaceuticalWasteSurvey.pdf>.

42. See ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at 7.

43. It should be noted that LQGs are only one of three classes of RCRA hazardous waste generators and that RCRA hazardous waste does not include all pharmaceuticals. As such, there are a large number of facilities and pharmaceuticals that are not considered in this analysis. See discussion *infra* Part I, F (for the definition of a LQG).

hospitals across the nation.⁴⁴ The EPA found that hospitals dispose of 9,700 tons of hazardous pharmaceutical waste annually.⁴⁵

2. Pharmaceutical Waste: Multiple Source Points

The Local Hazardous Waste Program in King County, Washington gathered data on the amount of pharmaceutical waste generated in Washington State.⁴⁶ The report analyzed ninety-nine businesses that were potential disposers of pharmaceutical waste.⁴⁷ This survey differs from the BRS because it addressed pharmaceutical waste specifically, not just RCRA hazardous waste,⁴⁸ and also included data from small quantity generators (“SQG”).⁴⁹ The survey found that approximately 1,008,395 pounds of pharmaceutical waste is disposed⁵⁰ of annually in Washington State alone.⁵¹

3. Pharmaceutical Waste: STWs

Pharmaceutical waste disposed of by coroner offices can be extrapolated to quantify the amount of pharmaceutical waste entering the environment through STWs.⁵² A study conducted with the help of

44. See ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at 10.

45. See *Id.* “This number does not include data from Michigan or Florida as they already include hazardous pharmaceutical waste in their universal waste programs.” *Id.*

46. See Oliver & Chapman, *supra* note 41, at 2.

47. *Id.* at 6. The study looked to veterinary clinics, hospitals, doctors’ offices, specialty outpatient facilities, pharmacies, nursing homes etc. *Id.*

48. See Resource Conservation and Recovery Act, 42 U.S.C. § 6903(5)(a)(b) (2006). RCRA hazardous waste is any solid waste that may “cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.” *Id.* While some pharmaceutical waste is RCRA hazardous, not all RCRA hazardous waste is a pharmaceutical.

49. See *id.*; see also discussion *infra* Part I, F (providing a definition of a SQG).

50. *Id.* at 20. Disposal methods were vast including flushing, placement in the household trash, the use of bio-hazardous containers, reverse distribution, recycling etc. See *id.* at 14.

51. See *id.* at 20.

52. It is important to note that the coroner disposal data is representative of only one of many introduction methods for pharmaceutical wastes to enter STWs.

the Clark County's Coroner Office's did just that by methodically examining how coroner offices dispose of unwanted pharmaceutical drugs.⁵³

Most coroner offices require the collection of drugs at the scene of a crime, as medication may have contributed to the cause of death or serve as evidence of a crime.⁵⁴ As a result, coroners and other investigatory staff must dispose of unwanted pharmaceutical waste once the investigation has been concluded.⁵⁵

Additional sources include, but are not limited to, excretion, bathing, and household disposal through flushing, et cetera.

53. Christian G. Daughton & Ilene S. Ruhoy, *Types and Quantities of Leftover Drugs Entering the Environment Via Disposal to Sewage - Revealed by Coroner Records*, 388 *SCI. OF THE TOTAL ENV'T* 137, 137, 143-44 (2007), available at <http://www.epa.gov/esd/bios/daughton/SOTE2007.pdf>.

54. *Id.* at 141.

55. *Id.* Under the Controlled Substances Act ("CSA"), once an individual has been prescribed a drug, he is prohibited from allowing anyone else to take possession of the drug on his behalf, save a law enforcement official. As a result, all pharmaceuticals identified by investigating officials at a crime scene must be taken into possession by law enforcement officers. *See id.* Currently, the CSA allows individuals to dispose of unwanted drugs as they see fit. *See Disposal of Controlled Substances*, 21 C.F.R. § 1307.21(b)(4) (2009). The FDA advises that individuals "follow any specific disposal instructions on the drug label. . ." CONSUMER HEALTH INFO., U.S. FOOD & DRUG ADMIN., HOW TO DISPOSE OF UNUSED MEDICINES, 1 (2011) available at <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm107163.pdf>. The following drugs recommend flushing as the preferred method of disposal: "Actiq, oral transmucosal lozenge, Fentanyl Citrate, Avinza capsules (extended release), Morphine Sulfate, Daytrana, transdermal patch system, Methylphenidate, Demerol, tablets, Meperidine Hydrochloride, Demerol oral solution, Meperidine Hydrochloride, Diastat/Diastat AcuDial rectal gel, Diazepam, Dilaudid tablets, Hydromorphone Hydrochloride, Dilaudid oral liquid, Hydromorphone Hydrochloride, Dolophine Hydrochloride tablets, Methadone Hydrochloride, Duragesic patch (extended release), Fentanyl, Embeda capsules (extended release), Morphine Sulfate; Naltrexone Hydrochloride, Exalgo tablets (extended release), Hydromorphone Hydrochloride, Fentora tablets (buccal), Fentanyl Citrate, Kadian capsules (extended release), Morphine Sulfate, Methadone, Hydrochloride oral solution, Methadone Hydrochloride, Methadose tablets, Methadone Hydrochloride, Morphine Sulfate tablets (immediate release), Morphine Sulfate, Morphine Sulfate oral solution, Morphine Sulfate, MS Contin tablets (extended release), Morphine Sulfate, Onsolis soluble film (buccal), Fentanyl Citrate, Opana tablets (immediate release), Oxymorphone Hydrochloride, Opana ER tablets (extended release), Oxymorphone Hydrochlorid." U.S. FOOD & DRUG ADMIN., DISPOSAL OF UNUSED MEDICINES: WHAT YOU SHOULD KNOW

The study uncovered that of the pharmaceuticals collected at crime scenes over 92% were flushed⁵⁶ while approximately 7% of other medications were disposed of in the trash.⁵⁷ In all, less than 1% of the pharmaceutical waste collected was incinerated and usually only incinerated when the drugs were unidentifiable.⁵⁸

The researchers also found that 325,000 pharmaceuticals were discarded into the STWs of Clark County, Nevada,⁵⁹ amounting to over 224 pounds of pharmaceutical waste.⁶⁰ Due to the similarities between the death rates in Nevada and the rest of the country, researchers conducting the study extrapolated the data to estimate that 17.9 tons of pharmaceutical waste enters STWs annually across the nation.⁶¹

4. Pharmaceutical Waste: Drinking Water

In March 2008, the Associated Press (“AP”) investigated the presence of pharmaceuticals in drinking water across the nation.⁶² The investigation relied on scientific reports, federal drinking water databases, and interviews with more than 230 officials, academics and scientists.⁶³ The AP surveyed major water providers in the nation’s fifty largest cities and also surveyed smaller water providers in all states.⁶⁴ Over the course of five months, the AP detected

(2011) (list revised Mar., 2010) *available at* <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm#MEDICINES>.

56. Daughton & Ruhoy, *supra* note 53, at 144.

57. *Id.* at 144-45.

58. *Id.* at 145.

59. *See Id.* at 145. It is important to note that other medical waste, such as powders, liquids, “inhalers, patches, and syringes” were not quantified in the study even though powders and liquids were flushed (the other items were thrown away in the household trash). *Id.*

60. *Id.*

61. *Id.*

62. *US Water* (AP Television broadcast Mar. 10, 2008) (transcript on file with the Associated Press Archive), *available at* <http://www.aparchive.com/Search.aspx?remem=x&st=k&kw=drinking+water#mainActionMenu>.

63. *See Pharmaceuticals Lurking in U.S. Drinking Water*, *supra* note 1.

64. *See id.*; *see also US Water*, *supra* note, 62. The television broadcast notes that several water providers were reluctant to disclose the results of the

pharmaceuticals, including “antibiotics, anti-convulsants, mood stabilizers and sex hormones,” in the drinking water of forty-one million residents.⁶⁵

E. PPCP Effects

The environmental and physical effects of PPCP contaminants have long remained a mystery.⁶⁶ However, in recent decades, studies have uncovered some of PPCPs’ adverse effects on biological and aquatic life.⁶⁷ As discussed above, the USGS reconnaissance⁶⁸ uncovered that pharmaceutical waste contaminants could create “abnormal physiological processes and reproductive impairment, increased incidences of cancer, the development of antibiotic-resistant bacteria, and the potential increased toxicity of chemical mixtures.”⁶⁹

Today we find that this hypothesis might be accurate. In certain countries, the human male sperm count has dropped by fifty

pharmaceutical probe because the “public might be unduly alarmed if informed.”
Id.

65. *US Water*, *supra* note 62. Key test results obtained by the AP: (1) Fish exposed to contaminants found in wastewater have “reduced testicular growth, reduced sperm quality and altered hormone ratios.” (2) “Steroids, narcotics and birth control” medications were found in Lake Mead, one of the largest reservoirs in the world, which provides drinking water to residents in Arizona, California, and Nevada. (3) Small amounts of medication can cause “human embryonic kidney cells” to grow too slowly, human blood cells to become inflamed and can allow breast cancer cells to “proliferate too quickly.” (4) In New York, trace amounts of more than fifteen drugs were found in drinking water. (5) Fish exposed to pharmaceuticals in wastewater show marked reduction in “testicular growth,” “sperm quality” and an alteration in “hormone ratios.” (6) More than 100 different pharmaceuticals have been detected in the waters on every continent including the Swiss lakes and the North Sea. (7) Hormones, antibiotics and other drugs were found in samples drawn from aquifers in twenty-four states. This information is particularly alarming as forty percent of the national water supply is sourced from aquifers. *Id.*

66. *See* Daughton & Ternes, *supra* note 16, at 908.

67. *See* CAROLYN J. OBLINGER ET AL., U.S. GEOLOGICAL SURV., OCCURRENCE OF PHARMACEUTICALS, PERSONAL-CARE PRODUCTS, OWCs, AND PESTICIDES IN THE LOWER TALLAPOOSA RIVER ’ 2 (2007), <http://pubs.usgs.gov/sir/2007/5266/pdf/sir2007-5266.pdf>.

68. *See* Kolpin et al., *supra* note 6, at 1202.

69. *Id.*

percent.⁷⁰ There have also been increases in hormone-related cancers and endometriosis.⁷¹ Additionally, the impact on aquatic life is remarkable. Scientists “have found fish laden with estrogen and antidepressants” facing significant neurological and physiological changes.⁷² A study in Maryland found that certain sea bass produced both sperm and eggs as a result of the heightened levels of estrogen in the water.⁷³ Similarly, in Wisconsin scientists discontinued an experiment after only twenty-four hours when they discovered that the minnows they were exposing to anti-cholesterol medication, at levels only slightly above what was present in their normal environment, were struggling to survive.⁷⁴ There is also the certainty of unforeseen future effects as antibiotic resistance rises and as research is conducted into the effect of antidepressants on predatory marine relationships.⁷⁵

F. PPCP Regulation: Why Compliance is Difficult

Attempts to regulate PPCPs are not new. In 1976, the Resource Conservation and Recovery Act (“RCRA”), enforced by the EPA, was enacted to regulate the disposal of solid waste and hazardous waste.⁷⁶ Under RCRA, hazardous waste is defined as,

a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may—
cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or pose a substantial present or potential hazard to human health or the environment when

70. See generally, THEO COLBORN ET AL., OUR STOLEN FUTURE: ARE WE THREATENING OUR FERTILITY, INTELLIGENCE, AND SURVIVAL?—A SCIENTIFIC DETECTIVE STORY 172-75 (1997).

71. See *id.* See also, SCHABECOFF & SCHABECOFF, *supra* note 4, at 38-67.

72. See Teirney Christenson, *Comment, Fish on Morphine: Protecting Wisconsin’s Natural Resources Through A Comprehensive Plan for Proper Disposal of Pharmaceuticals*, 2008 WIS. L. REV. 141, 143 (2008).

73. See *id.* Cf. Fong, *supra* note 3, at 143-49.

74. See Christenson, *supra* note 73, at 144-45.

75. See *id.* at 143.

76. Resource Conservation and Recovery Act, 42 U.S.C. §§ 6901-6992(k) (2006).

improperly treated, stored, transported, or disposed of, or otherwise managed.⁷⁷

To prevent these wastes from posing a substantial risk to human health, RCRA is responsible for tracking hazardous waste from the point of creation to its eventual disposal.⁷⁸ As a result, RCRA has been termed the “cradle to grave” system.⁷⁹ To ensure that these hazardous wastes are safely disposed, RCRA places stringent requirements on the generators and handlers of hazardous waste post-production to ensure that transportation, storage, treatment, and, finally, the disposal of the waste is safely managed.⁸⁰

Currently, RCRA’s Subtitle D regulates hazardous waste by placing solid waste on one of four hazardous waste lists; the F-list⁸¹, K-list⁸², P-list⁸³, or U-list.⁸⁴ Within the last decade, waste products appearing on RCRA’s P-list⁸⁵ and U-list⁸⁶ have acquired legal interest and importance as discussion of the appearance of PPCPs in solid waste and ground water has become more prevalent.

The P and U-lists contain commercial chemical products that either have been, or intend to be, discarded by generators.⁸⁷ Chemicals on the P-list are identified as acute hazardous waste⁸⁸ and those on the

77. 42 U.S.C. § 6903(5)(a)(b).

78. *See RCRA Statute, Regulations & Enforcement*, ENVTL. PROT. AGENCY, <http://www.epa.gov/oecaerth/civil/rcra/rcraenfstatreq.html> (last updated Mar. 30, 2011).

79. *See id.* *See also* Daughton, *supra* note 5, at 775.

80. *See* Hazardous Waste Management System, General, 40 C.F.R. §§ 206.1-206.43 (2010); *RCRA Statute, Regulations & Enforcement*, *supra* note 78.

81. *See* Lists of Hazardous Waste, 40 C.F.R. § 261.31 (2010).

82. *See id.* § 261.32.

83. *See id.* § 261.33.

84. *See id.*

85. *See id.* P-listed pharmaceutical wastes include, among others, Warfarin, & salts, when present at concentrations greater than 0.3% (P001), Aldrin (P004), arsenic trioxide (P012), epinephrine (P042), nicotine (P075), Potassium cyanide (P098), Mercury, (acetato-O)phenyl- (P092), nitroglycerin (P081), physostigmine salicylate (P188). *Id.*

86. *See id.* U-listed pharmaceutical wastes include, among others, Acetone (U002), benzene (U019), chloral hydrate (CIV)(U034), chlorambucil (U035), Methyl chloride (I,T) (U045), Melphalan (U150), mercury (U151), and warfarin, & salts, when present at concentrations of 0.3% or less (U248). *Id.*

87. *See* 42 U.S.C. § 6903(5)(a)(b) (2006); 40 C.F.R. §§ 261.33(e)-(f).

88. *See* 40 C.F.R. § 261.33(e).

U-list are identified as toxic waste.⁸⁹ There are also characteristic pharmaceutical waste products not contained in the P or U-lists that are considered hazardous waste and are nonetheless regulated by RCRA.⁹⁰ Characteristic pharmaceutical waste are those that exhibit one or more of four characteristics: ignitability,⁹¹ reactivity,⁹² corrosivity,⁹³ or toxicity.⁹⁴ There are, however, exceptions to the characteristic pharmaceutical waste group. If a listed hazardous waste is listed solely because it exhibits the characteristics of ignitability, toxicity, corrosivity and/or reactivity, and the waste no longer exhibits this characteristic, then it is no longer considered hazardous waste under RCRA.⁹⁵ Additionally, local and state regulations may be broader or more stringent than RCRA standards.⁹⁶ Therefore, hazardous pharmaceutical waste generators must look to local regulations when determining the applicable exemptions to ensure they are interpreting the laws correctly and to maintain compliance with these standards.⁹⁷

There are approximately 600,000 health care facilities in the United States, 40,000 retail pharmacies, and over 7,000 hospitals.⁹⁸

89. See 40 C.F.R. § 261.33(f).

90. See *id.* §§ 261.20 - 261.24 (Characteristic hazardous wastes are unlisted wastes that exhibit one or more of the four characteristics identified by the C.F.R.: ignitability, reactivity, corrosivity, and toxicity).

91. See *id.* § 261.21(a)(1).

92. See *id.* § 261.23. The term reactive generally applies to wastes that are unstable and that undergo violent changes in the presence of water, for example, by generating toxic vapors or fumes when mixed with water. See *id.*

93. See *id.* § 261.22. The term corrosive is generally limited to strong acids and bases or liquids that are capable of corroding steel above a certain rate per year. See *id.*; Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. 73,520, 73,524 (Dec. 2, 2008) (to be codified at 40 C.F.R. pt. 260, 261, 264, 265, 268, 270 and 273) [hereinafter Amendment to the Universal Waste Rule].

94. See 40 C.F.R. § 261.24. Solid waste becomes toxic when the contaminants listed in 40 C.F.R. § 261.24, such as arsenic (D004), barium (D005), benzene (D018), cadmium (D006) etc. cetera, exceed their permissible regulatory level. *Id.*

95. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,524; Hazardous Waste Identification Rule (HWIR): Revisions to the Mixture and Derived-From Rules, 66 Fed. Reg. 27,266, 27,283 (May 16, 2001) (to be codified at 40 C.F.R. pt. 261, and 268).

96. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,520, 73,524.

97. See *id.*

98. Amendment to the Universal Waste Rule, *supra* note 93, at 73,526. '

In addition, there are more than 300,000 physicians,⁹⁹ over 2.9 million registered nurses¹⁰⁰, and an indefinite number of other hospital staff and personnel.¹⁰¹ These figures do not include dental offices and veterinary clinics, and their support staff, which may also be considered hazardous waste generators.¹⁰² With such a large number of facilities that can potentially be generators of RCRA hazardous pharmaceutical waste, and therefore subject to generator regulations, it can be difficult to ensure that regulatory standards are being met.¹⁰³

A facility's generator status, as defined and regulated under RCRA, depends on the amount of hazardous waste generated at the location on a monthly basis.¹⁰⁴ SQG's and Conditionally Exempt Small Quantity Generators ("CESQG's") are subject to fewer requirements than LQG's.¹⁰⁵ For example, SQGs do not need to complete a biennial report, and have fewer personnel training and contingency planning requirements than LQGs.¹⁰⁶ In addition, CESQGs are not subject to RCRA's Subtitle C hazardous waste regulations, if they comply with certain requirements set forth within RCRA.¹⁰⁷

99. *Id.* at 73,522.

100. *The Registered Nurse Population: Findings from the 2004 National Sample Survey of Registered Nurses*, HEALTH RES. & SERV. ADMIN., U.S. DEPT. OF HEALTH AND HUMAN SERVICES, <http://bhpr.hrsa.gov/healthworkforce/rnsurvey04/> (last visited April 2, 2011).

101. This could include more or less of the following: hospital administrators, nurses, physical and occupational therapists, lab techs, nursing assistants, catering and cleaning services employees, environmental services personnel, pharmacists, medical students, interns, psychologists, etc.

102. *See* Definitions, 40 C.F.R. § 260.10 (2010).

103. *See id.*; *see also* Standards Applicable to Generators of Hazardous Waste, 40 C.F.R. § 262 (2010).

104. *See* tbl. 1, *infra* p. 17.

105. *E.g.*, Special requirements for hazardous waste generated by conditionally exempt small quantity generators, 40 C.F.R. § 261.5.

106. *See* 40 C.F.R. § 262.44.

107. *See id.* § 261.5. CESQGs must comply with requirements set forth in 40 C.F.R. §§ 261.5(f)(3), 261.5(g)(3). *Id.*

The following table displays the differences between LQGs, SQGs and CESQGs.

Table 1:¹⁰⁸

RCRA Hazardous Waste Generator Class	LQG (large quantity generator)	SQG (small quantity generator)	CESQG (conditionally exempt small quantity generator)
Hazardous Waste Accumulation Limit per Month	>/ = 1000 kg	> 100kg and< 1000kg	</ = 100kg
Acutely Hazardous Waste Accumulation Limit per Month	> 1 kg	</ = 1kg	</ = 1kg

108. See Definitions, 40 C.F.R. § 260.10; see also 40 C.F.R. §§ 261.5(e)(1), 262.

However, because the determination of a generator's status, as large, small or conditionally exempt, is made on a monthly basis, the status can fluctuate from one month to the next.¹⁰⁹ If a generator's status changes, the generator must comply with RCRA requirements imposed on the new generator class for the quantity of hazardous waste generated in that month.¹¹⁰

Regulating such a wide array of potentially hazardous waste material has become problematic for health care professionals.¹¹¹ Hospitals classified as LQGs can typically generate "10,600 tons of RCRA hazardous pharmaceutical waste annually."¹¹² In contrast, some retail pharmacies "may only generate [five] pounds of hazardous pharmaceutical wastes in a year."¹¹³

Many facilities have multiple generation points for pharmaceutical hazardous waste, such as hospital pharmacies, emergency rooms, operating rooms, and nurses' stations, with several employees contributing to waste generation.¹¹⁴ For many health care professionals, the difficulty of appropriately discarding pharmaceutical waste only increases as RCRA hazardous pharmaceutical wastes are identified by their chemical name, rather than by commercial name, making it difficult for professionals to determine whether pharmaceutical waste contains potentially hazardous or relatively insignificant components.¹¹⁵

II. PART II

A. The Need for Regulatory Action

The Universal Waste Rule of 1995 was established to streamline the collection and management of various hazardous wastes.¹¹⁶ This

109. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,522.

110. See *e.g.*, 40 C.F.R. § 261.5(e)(1); see also ENVTL. PROT. AGENCY, RCRA ORIENTATION MANUAL 2008: RESOURCE CONSERVATION AND RECOVERY ACT III-43 (2008), available at <http://www.epa.gov/osw/inforesources/pubs/orientat/?.>

111. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,526.

112. *Id.* at 73,522; see also ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at 7.

113. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,522.

114. See ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-61.

115. See 40 C.F.R. § 261.33.

116. See Standards for Universal Waste Management, 40 C.F.R. pt. 273.

was done in an effort to “greatly facilitate the environmentally-sound collection and increase the proper recycling or treatment of hazardous waste.”¹¹⁷ Many of the wastes that currently appear on the Universal Waste List are generated in a variety of settings, and are “managed in significant volumes in the non-hazardous waste management system.”¹¹⁸ Examples include batteries, pesticides, thermostats, lamps and mercury containing equipment.¹¹⁹ Similarly, pharmaceutical waste products are generated by several types of facilities and are often managed through a non-hazardous waste management system.¹²⁰

In November 2008, the EPA proposed an amendment of the UWR to include the addition of pharmaceuticals.¹²¹ The proposal stems from the EPA’s recognition that many pharmaceutical hazardous waste generators have difficulty complying with the requirements of RCRA subtitle C.¹²² Legislators hope that the addition of pharmaceutical waste to the UWR will simplify the hazardous waste management process for generators, further encouraging proper disposal of pharmaceutical hazardous waste and potentially reducing the prevalence of these chemical compounds in water.¹²³ This hope is reflected in the EPA’s stated objective for the amendment to the UWR proposal which states that the amendment will “simplify hazardous waste management for the healthcare industry, thereby encouraging proper disposal of these wastes.”¹²⁴

Under RCRA Subtitle C regulations, hazardous waste generators must comply with requirements regarding the handling, storing, reporting, transporting, and disposal of hazardous waste.¹²⁵

117. Universal Waste Rule (Hazardous Waste Management System; Modification of the Hazardous Waste Recycling Regulatory Program), 60 Fed. Reg. 25,492, 25,492 (May 11, 1995) (to be codified at 40 C.F.R. pt. 9 §§ 260, 261, 262, 264, 265, 266, 268, 270 & 273).

118. Amendment to the Universal Waste Rule, *supra* note 93, at 73,528.

119. *See* 40 C.F.R. §§ 273.2 - 273.5.

120. *See* ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-1. *See also* discussion, *supra* Part I, D (discussing the types of facilities that generate pharmaceutical waste and their various disposal methods).

121. Amendment to the Universal Waste Rule, *supra* note 93, at 73,520.

122. *See id.* at 73,522.

123. *See id.*

124. ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-1.

125. *See id.*

However, many pharmaceutical waste generators are either unaware of these regulations, or if they are aware of the regulations, the hazardous waste generator may have difficulty training personnel in the proper waste management.¹²⁶

Several factors can contribute to a generator's inability to secure employee compliance with RCRA Subtitle C standards. First, many healthcare workers generally receive no training on hazardous waste management and are thus unfamiliar with federal standards.¹²⁷ In addition, safety and environmental management personnel are sometimes not aware of the "active ingredients and formulations of pharmaceutical" hazardous waste "and cannot make the hazardous waste determination for all the waste generated in patient rooms" or nurses' stations.¹²⁸ Compounding the issue is the difficulty involved with establishing separate collection systems for non-hazardous pharmaceutical waste and hazardous pharmaceutical waste, especially as this waste can stem from multiple sources within a given facility.¹²⁹ The plethora of pharmaceutical waste and the differentiation between hazardous and non-hazardous waste groups have rendered many facilities non-compliant with RCRA hazardous waste regulations or have rendered them incapable of properly managing their waste streams.¹³⁰

B. Defining the Issue

Under the proposed amendment, a pharmaceutical is defined as:

...any chemical product, vaccine or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or allergenic), not containing a radioactive component, that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or injury in man or other animals; or any chemical

126. *See id.*; *see also* Amendment to the Universal Waste Rule, *supra* note 93, at 73,526; Oliver & Chapman, *supra* note 41, at ES-1.

127. *See* ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-1. *See also* Amendment to the Universal Waste Rule, *supra* note 93, at 73,526.

128. ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-1.

129. *See id.*

130. *See id.*

product, vaccine or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or allergenic), not containing a radioactive component, that is intended to affect the structure or function of the body in man or other animals.¹³¹

Several over-the-counter pharmaceuticals and commonly used medical supplies are included in this definition.¹³²

However, not included in the proposed definition are “sharps,”¹³³ “infectious or biohazardous ‘red-bag’ waste,”¹³⁴ “waste chemicals from laboratories, medical devices,”¹³⁵ “dental amalgams, personal protective equipment contaminated with hazardous pharmaceuticals,”¹³⁶ “or any material used to clean up hazardous

131. Amendment to the Universal Waste Rule, *supra* note 93, at 73,522. “This definition includes products, such as transdermal patches, and oral delivery devices, such as gums or lozenges.” *Id.* at 73,523. This definition does not include “sharps or other infectious or biohazardous waste, medical devices, not used for delivery or dispensing purposes, equipment, contaminated personal protective equipment” (scrubs, gowns, gloves, etc.) “or contaminated cleaning materials.” *Id.* The amendment adapted its definition of “pharmaceutical” from the Federal Food, Drug and Cosmetic Act’s definition of “drug.” *Id.* See also 21 U.S.C. § 321(g)(1)(B) (2006).

132. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,522. “[P]ills or tablets, medicinal gums and lozenges, medicinal liquids, ointments and lotions, intravenous (IV) or other compounded solutions, chemotherapy drugs, vaccines, allergenics, medicinal shampoos, antiseptics and medicinal dermal patches, and delivery devices with the primary purpose to deliver or dispense a chemical product, vaccine or allergenic.” *Id.* at 73,523.

133. Amendment to the Universal Waste Rule, *supra* note 93, at 73,523. Sharps, “needles or syringes with needles,” and are not included under the proposed amendment because they are considered “medical wastes”, which are currently regulated by states and localities. *Id.*

134. *Id.* at nn. 4-5. “Infectious or biohazardous “red-bag” wastes[,]” like sharps, are also not included under the proposed amendment as they are regulated by states and localities. *Id.*

135. *Id.* at n.6. Medical devices such as “blood pressure cuffs, mercury thermometers, and x-ray films” are not regulated under the proposed amendment because they do not fall within the definition of a “pharmaceutical” as defined by the proposal. *Id.* However, these products may have agents that display hazardous waste characteristics, for example mercury (D009), and thus still may be subject to RCRA requirements. *Id.* See also 40 C.F.R. § 261.24 (2010).

136. Amendment to the Universal Waste Rule, *supra* note 93, at 73,523. Contaminated “personal protective equipment” and “clean-up materials” are not

pharmaceutical waste” spills.¹³⁷ Additionally, under the proposed amendment, “residues” that result from the “manufacture, production, or distribution of . . . pharmaceuticals,” are not deemed to be pharmaceutical wastes and, therefore, will not be regulated under the proposed amendment.¹³⁸

C. Summary of the Proposal

As the proposal stands, hazardous pharmaceutical waste generators may choose to continue management under RCRA Subtitle C guidelines or they may choose to manage their waste under the UWA.¹³⁹ The key differences between the two requirements include the following:

1. Accumulation Time Limits and Generation Thresholds

Under RCRA regulations, LGQs may store hazardous waste onsite for up to ninety days, while SGQs may store hazardous waste onsite for 180 to 270 days.¹⁴⁰ Under the UWA, hazardous pharmaceutical waste may be stored onsite for up to one year.¹⁴¹ Generation thresholds¹⁴² will be eliminated and “accumulation limits” will be bifurcated into two broad categories that allow for greater accumulation amounts.¹⁴³ As CESQGs will be eliminated, SQGs will

included in the proposed amendment because they may be “different in form and composition from the universal waste they come from.” *Id.* at n.7.

137. *Id.* at 73,523.

138. *Id.* The EPA has chosen not to regulate wastes generated in the “industrial setting” because are not well suited for regulation under the universal waste management system. *See id.*; Universal Waste Rule (Hazardous Waste Management System; Modification of the Hazardous Waste Recycling Regulatory Program), 60 Fed. Reg. at 25,514.

139. *See* Amendment to the Universal Waste Rule, *supra* note 93, at 73,520.

140. *See* ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-2.

141. *See id.* at ES-1.

142. *Id.* Generators of RCRA hazardous wastes are identified as CESQG, SQG, or LQG based on the amount of waste generated (generation threshold) in a certain amount of time (accumulation time limit). *Id.* Generation thresholds and accumulation time limits will also determine whether a generator must comply with additional requirements under RCRA. *Id.*

143. *See* Amendment to the Universal Waste Rule, *supra* note 93, at 73,535, 73,536 (Generators will now have the option to accumulate waste for one year or more than one year).

simply be required to stay within an accumulation limit of 5,000kg per year and LGQs will be permitted to accumulate anything above 5,000kg per year;¹⁴⁴ therefore, generators will no longer be concerned with an episodically changing generator status, as acutely hazardous waste accumulation amounts increase and decrease from month to month.

2. Inspecting Waste in Storage

Under RCRA Subtitle C, SQGs and LQGs must conduct weekly inspections of any hazardous waste kept in storage.¹⁴⁵ Under the Universal Waste Rule, universal waste handlers are not required to conduct regular inspections of their stored universal waste.¹⁴⁶ Interestingly, the proposed amendment does not discuss inspection requirements and generators are left in the dark as to whether these inspections will be required if they opt to comply with the proposed amendment.¹⁴⁷

3. Transportation of Waste and the Preparation of a Manifest

RCRA allows the transportation of hazardous waste by registered hazardous waste transporters only.¹⁴⁸ In contrast, the Universal Waste Rule allows waste to be transported by common carriers, meaning a generator may chose to transport its own universal waste;¹⁴⁹ the proposed amendment will allow generators to dispose of pharmaceutical waste generated at their facility themselves. In addition, unlike subtitle C requirements for LQGs and SQGs, the Universal Waste Rule does not require the preparation of a manifest¹⁵⁰ for the shipment of waste offsite, unless the waste is transported through a state that does not recognize the waste as

144. See ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-2.

145. See *id.* at ES-5.

146. See *id.* at ES-2.

147. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,520.

148. See ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-5.

149. See *id.*

150. See 40 C.F.R. § 262.20(a)(1) (2010) (“A generator who transports, or offers for transport a hazardous waste for offsite treatment, storage, or disposal, or a treatment, storage, and disposal facility who offers for transport a rejected hazardous waste load, must prepare a Manifest. . . .”) *Id.*

universal waste.¹⁵¹ If pharmaceutical waste products are included in the universal waste stream, the manifest requirement will also be eliminated.¹⁵²

4. Emergency Preparedness

Under RCRA Subtitle C, generators must develop contingency plans for accidental spills of hazardous waste and procedures to appoint an emergency coordinator for the facility.¹⁵³ The UWA will still include emergency preparedness standards and employee training requirements, though they will differ from those of RCRA.¹⁵⁴

III. PART III

A. Necessary Changes to Federal Regulatory Standards

Several factors make compliance with federal hazardous waste standards difficult. The foremost difficulty is the issue of defining “hazardous” waste. Several federal statutes regulate hazardous pharmaceutical waste disposal.¹⁵⁵ Additionally, an agency’s jurisdiction over hazardous waste depends on factors such as the waste’s source, method of disposal, or end user.¹⁵⁶ Even when a generator attempts to properly comply with RCRA, the chemical ingredients that appear on the P-list and U-list can be found in at least 100 pharmaceutical products, significantly hindering the identification process for the generator’s employees, as many are unaware of the appearance of these chemical ingredients in each drug.¹⁵⁷ Also, a number of drugs and pharmaceuticals meet RCRA’s

151. See Amendment to the Universal Waste Rule, *supra* note 93, at 73, 543-44.

152. See ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-5.

153. See *id.*

154. See *id.* at 4-5.

155. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,527.

156. See *infra* pp. 25-31.

157. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,526. Of the wastes included on RCRA’s P and U-lists, roughly thirty-one contain chemical ingredients used in pharmaceutical drugs. When this information is extrapolated, one can estimate that these thirty-one chemical ingredients may result in the appearance of RCRA hazardous waste in 100 or more pharmaceuticals. For example, “warfarin and salts (P001) are used in at least [six] commercial pharmaceutical products, and Melphalan (U150) is used in [five] products.” *Id.*

definition of characteristic hazardous wastes and are therefore not listed on the P-list or U-list.¹⁵⁸ The issues that make compliance difficult, as well as other miscellaneous problems not solved by current regulation, are discussed in this section.

1. Difficulties with Compliance

a. Determining Whether a Pharmaceutical Waste is Subject to Hazardous Waste Regulations

Solid waste generators are required to determine whether their solid waste is “hazardous waste” under RCRA.¹⁵⁹ If waste is not properly classified at the commencement of the generator’s compliance procedure, the objective of the “cradle to grave” system is undermined. The following are the steps a solid waste generator must take to determine whether it is generating RCRA hazardous waste:

Step 1: Is the substance a solid waste as defined in 40 C.F.R. 261.2?¹⁶⁰

Step 2: Is the substance excluded from the definition of a solid waste under 40 C.F.R. 261.4?¹⁶¹

Step 3: Is the substance a hazardous waste listed in Part 261.30-261.35?¹⁶²

Step 4: If not, does the substance exhibit any of the characteristics defined in Part 261.20 - 261.24?¹⁶³

The process is tedious, potentially confusing, time consuming, and impractical. To make matters worse, at the conclusion of this process, generators may be forced to determine whether their waste is

Pharmaceuticals may also contain chemicals that appear on the toxicity list, “such as arsenic or chromium.” *Id.* at n. 26.

158. *See Id.* at 73,524.

159. *See* 40 C.F.R. § 262.11 (2010).

160. *See id.*

161. *See id.*

162. *See id.*

163. *See id.*; *see also* Amendment to the Universal Waste Rule, *supra* note 93, at 73,523, 73,527.

hazardous under other federal and/or state regulations and then comply with those corresponding regulatory measures.¹⁶⁴

The difficulty involved with this process is reflected in an EPA Assessment conducted before the introduction of the amendment.¹⁶⁵ According to the Assessment, “there are over 7,000 hospitals, and approximately 72,000 long-term-care facilities, 27,000 veterinary care facilities, 40,000 retail pharmacies, and several hundred thousand offices of doctors, dentists and other health care service providers in the United States.”¹⁶⁶ All of these entities are potential pharmaceutical waste generators and many generate wastes that are deemed hazardous under RCRA.¹⁶⁷ However, of these figures, only ninety-four hospitals and nineteen pharmacies identified themselves as LQGs of hazardous waste.¹⁶⁸ For hospitals, this is a little over ten percent, and for pharmacies a small fraction of a percent.¹⁶⁹ Even if the vast majority of pharmaceutical waste generators classify themselves as SQGs or CESQGs, this still reflects the fact that large and small facilities know very little about RCRA and its regulatory requirements.¹⁷⁰

The FDA approves thousands of pharmaceutical drugs for use.¹⁷¹ Each year a generator disposes of hundreds, or even hundreds of thousands, of different types of pharmaceutical waste.¹⁷² Attempting to determine RCRA regulated hazardous pharmaceutical waste, Drug

164. See discussion *supra* notes 132-33. Mixed waste, for example, can contain both RCRA hazardous characteristics or special nuclear, or byproduct material, making it subject to Atomic Energy Act of 1954 (AEA) requirements. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,523, 73,532; See also Radioactive Waste; Byproduct Material, 52 Fed. Reg. 539 (May 1, 1987).

165. See generally ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39.

166. Amendment to the Universal Waste Rule, *supra* note 93, at 73,526; ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at 8.

167. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,526; ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at 8.

168. Amendment to the Universal Waste Rule, *supra* note 93, at 73,526.

169. ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at 8.

170. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,526.

171. See *Drugs@FDA: FDA Approved Drug Products*, FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm> (last visited Mar. 29, 2011) (Each drug is indexed by name. Click on the name of the drug to receive FDA labeling information).

172. See discussion *supra* Part I, D.

Enforcement Agency (“DEA”) regulated waste,¹⁷³ Atomic Energy Act (“AEA”) regulated wastes¹⁷⁴ or the Health Insurance Portability and Accountability Act (“HIPAA”) regulated waste¹⁷⁵ and separating them from potentially non-hazardous pharmaceutical waste, at multiple points of origin within facilities (such as nursing stations, emergency rooms, intensive care units, operating rooms et cetera), can be difficult and realistically impossible.

Furthermore, under the proposed amendment, the daily collection of small volumes of hazardous waste, from multiple source points within a facility, will accumulate in waste storage bins for up to a year (whether the bins will be covered or uncovered is still up for debate).¹⁷⁶ Will the determination of the correct waste stream as hazardous or non-hazardous be made before the pharmaceuticals enter storage bins or after? Will facilities be able to accurately waste through a year’s worth of pharmaceutical waste and separate waste streams efficiently? Even more troubling is the question of whether all pharmaceutical waste will be considered “non-hazardous” for the purpose of easing generator’s burdens. The implications for pharmaceuticals regulated under the Controlled Substances Act (“CSA”) will be impacted as facilities must effectively regulate waste shortages and prevent employees from misappropriating addictive drug substances. These are difficult questions and the proposed amendment seems content to ignore them in favor of easing the financial burden on generators.¹⁷⁷

The UWA allows generators to choose between continued regulation under RCRA Subtitle C or regulation under the UWA.¹⁷⁸ Under the UWA, the hazardous waste identification process will be simplified most notably by the removal of RCRA distinction between P-listed wastes and other hazardous wastes to ease the accumulation

173. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,527; ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at n.8.

174. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,527.

175. See *id.*

176. *Id.* at 73,535-36.

177. *Id.* at 73,527, 73,528, 73,531.

178. See *id.* at 73,520.

and volume generation limits on generators.¹⁷⁹ The framers of the amendment hoped to streamline the disposal process and allow generators to place non-hazardous pharmaceutical waste in the same or in similar, waste management streams as RCRA hazardous pharmaceutical waste.¹⁸⁰ The issues of identification and sorting¹⁸¹ would be considerably reduced if not completely nullified, as generators could simply dump all pharmaceutical drugs in one universal waste bin.

While this proposal makes compliance with federal standards easier for generators, it impairs the “cradle to grave” system, one of the more noble aspects of RCRA. The streamlining of waste combined with relaxed recordkeeping and recording requirements will leave the EPA without valuable information about disposal rates and may tempt generators to relax disposal standards.¹⁸² The EPA should still require that hospitals inspect hazardous waste containers over the course of the year and ensure that containers remain closed when not in use. Manifests should be required for off-site shipment of hazardous waste when the amount of waste shipped exceeds a certain quantity, and the waste should be in the hands of registered hazardous waste disposers.¹⁸³

While the UWA’s relaxed standards encourage generators to dispose of all pharmaceutical waste in the same stream,¹⁸⁴ thereby easing the hazardous waste identification process, issues of

179. *See id.* at 73,530. This is also a positive addition because generators no longer have to worry about a change in generator status due to the accumulation of acute hazardous waste. *See* discussion *supra* Part II, C.

180. *See* Amendment to the Universal Waste Rule, *supra* note 93, at 73,527; ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at 1.

181. *See* discussion *supra* Part II, C.

182. *See* ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-2-4. Under the proposed rule, SQGs have no recordkeeping requirements, hazardous manifests are not required for off-site shipment for either SQGs or LGQs, generators are no longer required to ship hazardous pharmaceutical wastes to registered hazardous waste disposers, there are no notification requirements for SQGs, there are no container inspection requirements and there is no requirement that containers remain sealed during storage. *See id.*

183. ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-3. As the UWA will encourage generators to ship larger quantities of potentially hazardous waste, the EPA should stay abreast of these shipments. The EPA could seek comment from generators as to what quantity would be a reasonable to trigger manifest requirements.

184. *See* Amendment to the Universal Waste Rule, *supra* note 93, at 73,530.

identification will inevitably arise. The UWA does not supersede or amend other federal regulations and will only affect the states that choose to codify the amendment.¹⁸⁵ For instance, if radioactively contaminated waste¹⁸⁶ is inadvertently dumped in a UWA-regulated pharmaceutical waste bin, the waste will still become mixed, low-level hazardous waste (“LLW”) and will then be subject to regulation under the AEA.¹⁸⁷ Similarly, if generators are no longer forced to differentiate between hazardous and non-hazardous pharmaceutical waste, drums will be filled with a mélange of pharmaceutical waste substances, any of which may individually, or when combined, exhibit RCRA hazardous waste characteristics outlined under 40 C.F.R. § 261.21 - § 261.24. At some point it will become inevitable for a generator to make a determination as to the status of a pharmaceutical waste, whether it be that the drug, or combination of drugs, is “hazardous,” a controlled substance, or a mixed waste.¹⁸⁸ Eliminating the issue of differentiating between wastes on the P or U-list does not eliminate the issue of identification.

Instead of trying to eliminate the identification issue altogether, the EPA should consider developing a list that identifies all pharmaceuticals by both their commercial and chemical names in an easily accessible format.¹⁸⁹ Access to this list would simplify the identification process for generators who choose to continue

185. *See id.* at 73,520.

186. *See* ENVTL. PROT. AGENCY, GUIDANCE ON THE DEFINITION AND IDENTIFICATION OF COMMERCIAL MIXED LOW-LEVEL RADIOACTIVE AND HAZARDOUS WASTE, <http://www.epa.gov/radiation/mixed-waste/guidance-identification-llmw.html>.

187. *See id.*; *see also* Amendment to the Universal Waste Rule, *supra* note 93.

188. *See* ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-3. UWA will no longer require a mandatory waste handling training program for employees of LGQs. *Id.* With the addition of a new regulatory scheme individuals may still experience issues correctly identifying hazardous wastes and determining the proper method of disposal. *Id.*

189. Charlotte Smith and James McCauley have patented a pharmaceutical hazardous waste identification and management system. *See* Pharmaceutical Hazardous Waste Identification and Management System, U.S. Patent No. 7,096,161, figs. 6 & 7 (filed Dec. 12, 2002) (issued Aug. 22, 2006). The system can be used by generators to provide personnel with the information necessary to determine which pharmaceuticals are hazardous wastes as defined by state, national, and international regulations. *Id.* This program is particularly impressive as it also provides information on hazardous pharmaceuticals as defined by Occupational Safety and Health Administration (“OSHA”) regulations. *Id.*

operating under RCRA.¹⁹⁰ The EPA should also encourage manufacturers to actively participate in the disposal and recycling process.¹⁹¹ Drugs that still have economic value to the generator, because they are being returned to a reverse distributor¹⁹² for example, are not considered hazardous waste and therefore are not subject to RCRA.¹⁹³ Perhaps if manufacturers (and reverse distributors) were encouraged to collect drugs that are damaged, no longer packaged, or impaired in some way, these drugs could be recycled or disposed of efficiently.¹⁹⁴

b. Overlap in Regulation

Pharmaceuticals are subject to various other regulations administered by other federal agencies¹⁹⁵ and their regulatory regimes, as well as by state and local regulations.¹⁹⁶ The overlap in regulatory requirements can make the management of pharmaceutical waste a complex endeavor for generators as federal statutes use the

190. See ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-1; see also Amendment to the Universal Waste Rule, *supra* note 93, at 73,523.

191. See Stephen Musson & Timothy Townsend, *Management of Discarded Pharmaceuticals*, 3 PRAC. PERIODICAL OF HAZARDOUS, TOXIC, & RADIOACTIVE WASTE MGMT. 89 (1998). Manufacturers currently accept pharmaceuticals and in some instances provide rebates for the drugs when returned. *Id.* at 91. The EPA should support the return of pharmaceuticals to the manufacturer, as this will encourage recycling alternatives and charitable donations. *Id.*

192. Reverse distributors are companies that recycle or dispose of controlled substances. See 21 C.F.R. §§ 1300.01(b)(41), 1307.11(a)(2) (2010).

193. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,532.

194. *Cf. id.* at 73,533 (under the proposed amendment, reverse distributors may become handlers of pharmaceutical waste enabling them to receive both universal pharmaceutical waste and unused waste). While reverse distributors may not receive pharmaceutical waste directly from consumers because of Drug Enforcement Agency (DEA) restrictions, pharmaceutical take-back programs may choose to ship the wastes received from households and consumers to these reverse distributors for disposal. *Id.* If this is the case, why not allow reverse distributors to receive drugs from the general public directly?

195. See *id.* at 73,537. For example, pharmaceuticals can be subject to the CSA and DEA regulations; Health Insurance Portability and Accountability Act ("HIPAA") patient privacy requirements; and the AEA. See *id.*

196. See *id.* Some states and localities may regulate "infectious pharmaceutical wastes" as hazardous, infectious, or both. *Id.*

same language to define very different concepts within the purview of each individual piece of legislation and vice versa.¹⁹⁷

For example, the Federal Food, Drug, and Cosmetic Act (“FFDCA”) and the CSA both regulate certain aspects of pharmaceuticals with their own respective definitions.¹⁹⁸ So too does the DEA, which often regulates the disposal of pharmaceutical drugs.¹⁹⁹ For example, what the FFDCA considers a “device,” the proposed amendment considers a “container.”²⁰⁰ How the FFDCA defines a “drug,” is how the amendment defines a “pharmaceutical.”²⁰¹ Thus, in order to determine whether a particular waste is managed under the AEA, or FFDCA, or RCRA, or even the DEA, the generator must first look to the definitions housed in each regulation, as the definitions contained in other regulatory programs may differ.²⁰²

The UWA only adds to the plethora of other federal pharmaceutical regulations.²⁰³ As generators still have the option to continue regulation under RCRA,²⁰⁴ the UWA only forces generators to consider whether they dare venture deeper into this regulatory labyrinth.²⁰⁵ The intentions of the EPA, as expressed within the proposal, indicate that the UWA will simply encourage generators to employ other methods of disposal, such as using a reverse distributor²⁰⁶ or a pharmaceutical take-back program.²⁰⁷ However,

197. *See id.*

198. *See id.* at 73,523.

199. *See* discussion *supra* Part I, D (discussing the flushing methods used by coroners offices in order to comply with DEA regulations).

200. Amendment to the Universal Waste Rule, *supra* note 93, at 73,523.

201. *Id.*

202. *Id.*

203. *See supra* note 196 and accompanying text.

204. Amendment to the Universal Waste Rule, *supra* note 93, at 73,520.

205. *See supra* Part II, C.

206. *See* Definition and Registration of Reverse Distributors, 68 Fed. Reg. at 41222, 41228 (July, 11 2003) (to be codified at C.F.R. pts. 1300, 1301, 1304, 1305, and 1307). Reverse distributors are defined as “a registrant who receives controlled substances acquired from another DEA registrant for the purpose of (i) returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer’s agent; or (ii) [w]here necessary, processing such substances or arranging for processing such substances for disposal.” *Id.* “When reverse distributors return unwanted, unusable, or outdated controlled substances acquired from legitimate medical, scientific, research or other industrial channels to a manufacturer or a manufacturer’s agent, they must follow the same DEA

reverse distribution is governed by the DEA and does not apply to all hazardous pharmaceutical waste,²⁰⁸ therefore, a generator that uses reverse distribution will have to comply with DEA requirements in addition to other pharmaceutical waste requirements.

c. Accumulation Time Limits and Generation Thresholds

Many health care facilities, and other pharmaceutical waste generators, have expressed concern with the monthly accumulation time limits set for hazardous waste generators.²⁰⁹ Pharmaceutical waste typically accumulates in small volumes over a long period of time.²¹⁰ As a result, generators that choose to outsource their hazardous waste disposal to off-site sources are burdened by generation thresholds that prevent them from accumulating more P or U-listed waste than legally permissible for their generator status. For many facilities, the conflict between generation thresholds and accumulation time limits can make the cost of off-site shipment inefficient.²¹¹

Many hospitals and health care facilities have episodically shifting RCRA hazardous waste generator status, due to their generation of P-listed pharmaceutical waste.²¹² Hazardous container requirements can also contribute to a change in a generator's status.²¹³ If facilities do not clean containers holding P-listed wastes, the weight of the container alone, not the chemical residue within the container, can

requirements as distributors follow." *Id.* See also Disposal of Controlled Substances, 21 C.F.R. § 1307.21(b)(4) (2009).

207. See *infra* Part III, B.

208. See *supra* text accompanying note 195 and accompanying text.

209. Amendment to the Universal Waste Rule, *supra* note 93, at 73,522, 73,527.

210. See *id.* at 73,527.

211. See *id.*

212. See *id.* P-listed wastes, or acutely hazardous wastes, have a low generation threshold. If a CESQGs generates more than one kilogram (kg) a month they exceed their threshold and become a LQG. *Id.*

213. See Identification and Listing of Hazardous Waste, 40 C.F.R. § 261.33(c) (2009) (requiring containers once holding P-listed hazardous wastes be considered P-listed hazardous wastes, unless considered "RCRA empty"). See also 40 C.F.R. § 261.7(b)(13)(iii)(B)(3)(i) (Containers are considered RCRA empty once they are triple-rinsed with an appropriate solvent. The solvents and liquid components used during the triple-rinsing of containers are also RCRA hazardous wastes because of the "mixture and derived-from rule"). 40 C.F.R. § 261.3(a)(2)(iv).

push the facility from CESQG status into LQG status leaving the facility subject to more rigorous requirements.²¹⁴

Requirements that fluctuate monthly only add to the difficulty of managing pharmaceutical waste appropriately under RCRA hazardous waste regulations. Additionally, given the relatively small number of low volume pharmaceutical wastes generated daily,²¹⁵ the benefit of the additional P-list requirements can be burdensome.

To combat this issue, the UWA proposes different accumulation time limits for LQGs and SQGs alike.²¹⁶ The increase in limits will address the issue of fluctuating generator statuses and, if implemented, will be a positive amendment to RCRA standards. However, the inclusion of accumulation limits carries with it the implicit assumption that universal wastes are collected and stored in a marked container separate from other hazardous wastes that may be subject to other state and federal regulations;²¹⁷ therefore, the issue of waste determination and overlap in regulation will still exist. Without fully addressing issues of waste determination and overlap in regulation, an increase in storage accumulation time limits and quantities will simply encourage generators not to make accurate hazardous waste determinations and may result in inadvertent non-compliance by waste generating facilities.

B. Proposed Solutions

Many of the issues discussed above only scratch the surface of the difficulties associated with pharmaceutical waste management. While the proposed amendment to the Universal Waste Rule is laudable, as it will address many of the issues broached in the previous section, there are still many issues that abound in regard to pharmaceutical waste disposal in the United States. This section discusses some of the proposals posed by scientists in the federal regime and will look to the role consumers play in the disposal

214. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,527.

215. See *id.* at 73,532.

216. See *id.* at 73,536.

217. Under the proposed amendment, all containers holding UWA waste must be marked with the words "Universal Waste – Pharmaceuticals" or "Waste Pharmaceuticals." See ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE, *supra* note 39, at ES-2; Amendment to the Universal Waste Rule, *supra* note 93, at 73,536.

process.²¹⁸ These proposals could reduce the concentration of pharmaceuticals in wastewater, make proper disposal of pharmaceuticals more viable and convenient, and potentially result in actual compliance with current regulations.

1. Expanded Use of Reverse Distribution and Pharmaceutical Take-Back Programs

Many generators currently use reverse distribution to dispose of or return unused or expired pharmaceuticals.²¹⁹ This activity could be expanded, creating a more comprehensive reverse distribution model inclusive of consumer pharmaceuticals.²²⁰ If reverse distributors keep collection records, the information could be used to better understand the needs of consumers. Many drugs are returned unused each year, costing the pharmaceutical industry billions of dollars

218. See generally Christian G. Daughton & Thomas A. Ternes, *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?*, 107 ENV'T. HEALTH PERSP. 907 (Supp. 6 1999); Christian G. Daughton & Tammy L. Jones-Lepp, *Pharmaceuticals and Personal Care Products in the Environment: Scientific and Regulatory Issues*, in *Pharmaceuticals and Care Products in the Environment* (2001); Susan T. Glassmeyer et al., *Disposal Practices for Unwanted Residential Medications in the United States*, 35(3) ENV'T. INT'L. 566 (2009) (Daughton is the PPCP pioneer and has spent over a decade publishing articles in books and publications dedicated to the subject. His proposals and suggestions for the management of PPCPs significantly influenced the regulation of PPCPs today. For an exhaustive list of Daughton's publications please look to his biography on the EPA website available at <http://www.epa.gov/esd/bios/daughton.htm>). The UWA will not address disposal methods used by consumers. See Amendment to the Universal Waste Rule, *supra* note 93, at 73,532. However, consumers also contribute to the disposal of these wastes. Pharmaceutical sales reached \$286.5 billion in the United States last year. See Press Release, IMS Health Inc., Lance Longwell, *IMS Health Reports U.S. Prescription Sales Grew 3.8 Percent in 2007, to \$286.5 Billion*, IMS HEALTH INC. (Mar. 12, 2008), available at <http://www.imshealth.com/portal/site/imshealth/menuitem> (follow "Press Room" hyperlink; then follow "Press Releases" hyperlink; then follow "2008" drop down to "IMS Health Reports U.S. Prescription Sales Grew 3.8 Percent in 2007, to \$286.5 Billion" hyperlink).

219. See *supra* note 195.

220. See Daughton, *supra* note 5, at 776; see also *supra* note 195 and accompanying text.

annually and unnecessarily contributing to pharmaceutical waste streams.²²¹

In addition, many PPCPs with RCRA hazardous characteristics are *de facto* exempt from federal standards because the laws do not apply to consumers.²²² Many pharmaceutical take-back programs, accepting the free return of prescription medications, exist across the country.²²³ Pharmaceutical take-back programs ensure that the consumer's medication is disposed of in compliance with state and federal regulations.²²⁴

However, expanded use of reverse distributors and pharmaceutical take-back programs will only be effective if federal regulations adopt environmentally sound pharmaceutical disposal practices. Permissible flushing and the discretionary disposal of pharmaceuticals cannot be the solution to proper waste management.²²⁵

221. Physicians sometimes receive free pharmaceutical samples from the manufacturer. These samples may also contribute to the number of returned unused pharmaceuticals each year. *See* Daughton, *supra* note 5, at 776.

222. *See* 40 C.F.R. § 261.4(b)(1) (2009). For instance, household hazardous wastes are excluded from RCRA and are not subject to its regulations. *Id.* *See also* Amendment to the Universal Waste Rule, *supra* note 93, at 73,522, 73,525, 73,526, 73,532, 73,533.

223. *The Drug Take Back Network, Local Efforts*, TAKEBACKNETWORK.COM, http://www.takebacknetwork.com/local_efforts.html (last visited April 11, 2011) (providing links to a list of states with information on permanent and regularly recurring take-back events).

224. Amendment to the Universal Waste Rule, *supra* note 93, at 73,526.

225. *See* Disposal of Controlled Substances, 21 C.F.R. § 1307.21(b)(4) (2009) (“The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance . . . (4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.”) In October 2009, the Office of National Drug Control Policy changed their pharmaceutical waste disposal statement to no longer reflect the promotion of drug flushing (unless required to do so by FDA label). *Proper Disposal of Prescription Drugs*, OFF. OF NAT’L DRUG CONTROL POL’Y, (October 2009), available at http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf. In the guidelines, the FDA suggests that consumers mix unwanted drugs with “cat litter or used coffee grounds” before sealing the drugs in a plastic bag or container and throwing them away. *Id.* Ironically, hazardous household waste is regulated by states and should be treated differently than non-hazardous household waste. *See* ENVTL. PROT. AGENCY, HOUSEHOLD HAZARDOUS WASTE, <http://www.epa.gov/epawaste/conserva/materials/hhw.htm> (last visited

2. No More Flushing

Flushing remains a permissible means of disposal under RCRA and the CSA.²²⁶ The FDA also endorses flushing certain drugs.²²⁷ If facilities choose to operate under the UWA, use reverse distribution or pharmaceutical take-back programs as viable methods of disposal, or even if they choose to continue to comply with RCRA hazardous waste requirements, pharmaceuticals can still enter the environment through permissible flushing.

Flushing medication or disposing of medications down the drain is unconscionable in the face of developing research.²²⁸ The EPA, FDA and DEA need to synthesize their approach and amend the conflicts present in the current regulatory system. These agencies need to implement a national standard for the proper disposal of pharmaceutical waste to promote the incineration of damaged or adulterated medication.²²⁹ Medications that remain unused should be returned to the manufacturer for recycling.²³⁰ This should be a blanket policy that is applicable to both to consumers and generators. Consumers and generators who do not have access to RCRA certified

April 11, 2011). States and localities may or may not provide for year round collection and proper disposal of these wastes. *See id.*

226. RCRA has a domestic sewage exception that allows for the disposal of “Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment.” 40 C.F.R. § 261.4(a)(1)(ii) (2009). *See* Disposal of Controlled Substances, 21 C.F.R. § 1307.21(b)(4)(2009). *But cf.* H.R. 1191, 111th Cong. (2009).

227. The FDA suggests, and sometimes requires, that certain drugs be flushed. Examples include, but are not limited to, Actiq (fentanyl citrate), Daytrana transdermal patch (methylphenidate), Duragesic transdermal system (fentanyl), Tequin tablets (gatifloxacin), and Fentora (fentanyl buccal tablet). *Index to Drug-Specific Information, supra* note 55. *But cf.* H.R. 1191.

228. *See* discussion *supra* Part I, E. *See also* Kolpin et al., *supra* note 6, at 1210 (discussing evidence that select chemical combinations can exhibit additive or synergistic toxic effects and OWCs that “exhibit weak hormonal activity with the potential to disrupt normal endocrine function”). *See also* H.R. 1191.

229. *See* H.R. 1191. *See also* Incinerators, 40 C.F.R. §§ 264.340 - 264.351 (2009). The problem of pharmaceutical waste disposal is massive, and there are currently no viable methods that will result in the true “disposal” of these substances. *See* Despo Fatta-Kassinou et al., *supra* note 37, at 271-72. Even those pharmaceuticals that have been disposed of will have a continued presence in water and soil for decades and perhaps even centuries to come. *See id.* at 264-69, 272.

230. The EPA should encourage pharmaceutical manufacturers to play a more active role in the recycling of the pharmaceuticals they dispense.

incinerators could then employ the services of pharmaceutical take-back programs and reverse distributors to handle proper disposal. To further aid consumers, pharmacies can also serve as free drop-off points where unused and unwanted pharmaceuticals may be returned for recycling or proper disposal.²³¹

3. Drinking Water Standards

Many pharmaceuticals enter SWTs and end up in the drinking water supplies of residents.²³² Although more research must be conducted on the effects of pharmaceutical disposal on human and aquatic life, if we pay specific attention to the potential interactive effects that may occur from complex mixtures of these compounds in the environment, proactive steps can be taken in the interim.

Data has been collected on a select number of contaminants. However, the potential for, and existence of, adverse effects outweigh the need for continued research without concrete action. Non-hazardous or RCRA hazardous pharmaceuticals that appear in the drinking and surface water on a national scale should be added to the Drinking Water Contaminant List.²³³ While technology to detect pharmaceuticals at the low concentration levels present in the environment is still developing, this should not hinder the implementation of minimum requirements that can be coupled with the use of existing technology. As the technology advances, the minimum allowable levels can be amended.

231. Iowa has a statewide pharmaceutical take back program termed "TakeAway" that encourages pharmacies to receive unused and unwanted products from consumers. See *Take Away Environmental Return System*, IOWA PHARMACY ASS'N, <http://www.iarx.org/takeaway/> (last visited April 11, 2011).

232. See discussion *supra* Part I, Section 1.

233. The EPA conducts research into the contaminants that appear on this list in order to determine whether regulation is needed. While, they are currently unregulated by existing national primary drinking water regulations, the EPA usually chooses from this list when adding contaminants to the National Primary and Secondary Drinking Water standards. See ENVTL. PROT. AGENCY, DRINKING WATER CONTAMINANT LIST AND REGULATORY DETERMINATIONS, <http://www.epa.gov/safewater/ccl/basicinformation.html> (last visited Mar. 17, 2009).

4. Ecotoxicity

The FDA considers the environmental impact of all human and veterinary drug applications unless a categorical exemption applies.²³⁴ Indeed, most federal agencies are required to assess the environmental impact of their proposals under the National Environmental Policy Act (“NEPA”).²³⁵ Currently, many drug applications can be granted a categorical exclusion to NEPA and Center for Drug Evaluation and Research requirements if the concentration of the substance will be below one part per billion (“ppb”) at the time of entry into the environment.²³⁶ A categorical exclusion cannot be granted if it is established that the substance will have a significant effect on the quality of the human environment.²³⁷ 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. NEPA’s interpretation of the “human environment” is broad and includes both “the natural and physical environment and the relationship of people with that environment”.²³⁸ In addition, NEPA also interprets “effects” comprehensively considering ecological effects that impact natural resources and the functioning of ecosystems.²³⁹ It is arguable that the categorical exclusion granted to

234. 21 C.F.R. §§ 21.250 (l), (m) (2010).

235. 42 U.S.C. §§ 4321-4347 (2009).

236. See GARY M. RAND, *FUNDAMENTALS OF AQUATIC TOXICOLOGY* 736, 741-42 (Gary M. Rand ed., 2d ed. 1995); U.S. DEP’T OF HEALTH & HUM. SERVICES, FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RES., CTR FOR BIOLOGICS EVALUATION & RES., *Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications*, 2 -5 (1998), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070561.pdf>;

237. See Cooperation of agencies; reports; availability of information; recommendations; international and national coordination of efforts, 42 U.S.C. § 4332(2)(c) (2009); 21 C.F.R. § 25.22(b) (2010).

238. See 40 C.F.R. § 1508.14 (2010) (“Human environment shall be interpreted comprehensively to include the natural and physical environment and the relationship of people with that environment.”); See also 40 C.F.R. §§ 1508.27(b)(4), (5) (2010) (discussing the “quality” of the human environment and “effects” to the human environment).

239. 40 C.F.R. § 1508.8(b) (2010) (“Effects includes ecological (such as the effects on natural resources and on the components, structures, and functioning of

pharmaceuticals does significantly affect the quality of the human environment and that the one ppb standard should be amended.

CONCLUSION

The presence of pharmaceuticals in our waterways can be addressed with targeted efforts. As many of the ramifications of our current actions may not be seen for several decades, it is imperative that we act now to reduce or maintain current levels before we begin to see serious and significant environmental problems in our ecosystem.

It is important that states address hospital and veterinary waste management inefficiencies and ensure that, at a minimum, they understand and are in compliance with federally mandated standards. It is also essential that individuals are made aware of the environmental impact that PPCP use and disposal have on our nation's water. A system for the collection and proper disposal of unused pharmaceuticals, an increase in scientific research on these chemical contaminants, paired with improvements to wastewater treatment systems, can greatly reduce the prevalence of these contaminants in our waterways.

Finally, as it is difficult to pinpoint which sources are contributing the most to this burgeoning PPCP problem, it is necessary that federal initiatives not only target large facilities, such as hospitals and pharmacies, but also the general population. Federal Agencies, States and private organizations alike should launch initiatives that will raise citizen awareness about the issue.

affected ecosystems), aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, or cumulative.”).

