COMMENT

FISH ON MORPHINE: PROTECTING WISCONSIN'S NATURAL RESOURCES THROUGH A COMPREHENSIVE PLAN FOR PROPER DISPOSAL OF PHARMACEUTICALS

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Scientific research on the harmful effect of pharmaceuticals on fish and other aquatic life in Wisconsin's surface water has raised concerns over proper disposal of unused and expired pharmaceuticals. However, current regulations frustrate, rather than encourage, environmentally safe disposal methods. This Comment proposes a comprehensive regulatory scheme that will promote environmental stewardship while taking into account the concerns of all parties involved. Ultimately, these proposed changes will provide a safer environment for Wisconsin's aquatic life, protect Wisconsin's groundwater from potential pollution, reduce the cost of proper disposal for health-care facilities, and provide vital medications to those who cannot afford them.

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INTRODUCTION

Want to be happy? Just drink the water.[1]

While the preceding quotation may sound like an advertisement for the latest brand of bottled water, it is actually a joke among nurses at a long-term-care facility[2] in Colorado where nurses flush "garbage bags full" of prescription drugs down the drain annually.[3] Although it is unclear how widespread this practice is today, flushing unused or expired pharmaceuticals is nothing new.[4] In fact, since the inception of the Internet, it has been the recommended course of conduct found on pharmacy and health-care Web sites.[5] North Carolina even recommends it in its Administrative Code.[6] Many Web sites and pharmaceutical companies recommend this method of disposal to keep drugs from

1. Kevin Darst, *Pill Dump Imperils Water's Quality*, FORT COLLINS COLORADOAN, Sept. 6, 2005, at 1A.

2. "Long-term-care facility" is used in place of the more common terms "nursing home" or "assisted-living facility."

3. Darst, *supra* note 1.

4. Christian G. Daughton, *Cradle-to-Cradle Stewardship of Drug for Minimizing Their Environmental Disposition While Promoting Human Health. II. Drug Disposal, Waste Reduction, and Future Directions*, 111 ENVTL. HEALTH PERSP. 775, 780 (2003).

5. *Id.*

6. 10 A N.C. ADMIN. CODE 27G.0209 (2006).

getting into the wrong hands, namely, those of a child.[7] Furthermore, this method kept legally prescribed controlled substances from entering the illegal-drug trade.[8] However, scientific research on the effect of pharmaceuticals in the environment has caused some scientists to conclude that this method of disposal is the least desirable, despite its widespread use.[9]

Several studies conducted throughout the United States over the last twenty years demonstrate the harmful effects that pharmaceuticals can have on fish and other aquatic life in the nation's streams and rivers.[10] Scientists found fish "laden with estrogen and antidepressants"[11] with significant neurological and physiological changes.[12] For example, a Maryland researcher recently discovered male bass that produced both sperm and eggs, resulting from increased amounts of estrogen in the water.[13] The researchers suspected that the source was flushed birth-control pills.[14] A study near Las Vegas, Nevada, found a similar problem with the razorback sucker, an endangered species.[15] Other researchers are studying what effect antidepressants, which may reduce a fish's fear of predators, could have on population levels.[16]

Among the alarming research are studies by University of Wisconsin researchers that show how the problem is affecting Wisconsin's waterways.[17] Professor Stanley Dodson of the University of Wisconsin–Madison found that minute concentrations of various drugs can severely disfigure or even kill Daphnia, an invertebrate vital to the freshwater food chain.[18] Even more disturbing are the findings of Rebecca D. Klaper, a scientist at the University of Wisconsin–

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7. Daughton, *supra* note 4, at 780. *See generally* Christopher T. Nidel, *Regulating the Fate of Pharmaceutical Drugs: A New Prescription for the Environment*, 58 FOOD & DRUG L.J. 81, 101 (2003).

8. Daughton, *supra* note 4, at 780.

9. *Id.* at 775.

10. Juliet Eilperin, *Pharmaceuticals in Waterways Raise Concern: Effect on Wildlife, Humans Questioned*, WASH. POST, June 23, 2005, at A3.

11. *Id.*

12. *Id.*

13. George J. Mannina, Jr., *Medicines and the Environment: Legal and Regulatory Storms Ahead?*, LEGAL BACKGROUNDER, Mar. 24, 2006.

14. *Id.*

15. Eilperin, *supra* note 10.

16. Mannina, *supra* note 13.

17. *See* Susanne Rust, *Federal Rules Interfere with Drug Disposal Effort; Traces of Medicine in Groundwater Cause Concerns*, MILWAUKEE J. SENTINEL, Oct. 11, 2005, at A1; Eilperin, *supra* note 10.

18. Rust, *supra* note 17.

Milwaukee.[19] Klaper discontinued her experiment after twenty-four hours because the minnows she exposed to anticholesterol medication were "struggling to survive."[20] She exposed them to a level "only slightly higher" than that which can currently be found in Wisconsin streams.[21] Although the effect this problem is having on the human population is still unclear, Klaper remains "concerned."[22]

Other research raises concerns for human health. Ralph L. Cooper, chief of endocrinology in the Reproductive Toxicology Division of the Environmental Protection Agency (EPA) identified one area where "further study" may be needed.[23] A recent *New York Times* article cited several cases in which children developed signs of puberty long before the typical age.[24] In some cases, it was as early as preschool.[25] Although many of the cases were linked to personal-care products (including skin creams used for sexual performance), some scientists noted that the harmful effects of pharmaceuticals in water may be harming more than just fish and animals.[26] They contend that pharmaceutical pollutants "may also contribute to earlier or disrupted puberty in children."[27] While there is no hard evidence to date linking improper disposal of pharmaceuticals to an earlier onset of puberty, the evidence that does exist continues to worry Dr. Cooper.[28]

Pharmaceuticals find their way into Wisconsin's surface waters from a variety of sources.[29] Besides those pharmaceuticals that are intentionally flushed down the toilet, many drugs enter the sewer system after running their natural course in the human body.[30] These drugs make their way to the local wastewater-treatment facility where, equipped with current technology, removal can be "as low as seven

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19. Eilperin, *supra* note 10.

20. *Id.*

21. *Id.*

22. *Id.*

23. Darshak M. Sanghavi, *Preschool Puberty, and a Search for the Causes*, N.Y. TIMES, Oct. 17, 2006, at F1.

24. *Id.*

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.*

29. One other significant source is agricultural runoff. See WIS. STAT. § 281.16(3) (2005–06), for Wisconsin's regulation of agricultural runoff.

30. Nidel, *supra* note 7, at 83–84 (describing the course of drugs in the human body). Unfortunately, there is very little that can be done to keep drugs that run their course through the human body from entering the environment. See *infra* text accompanying notes 271–76, for a discussion of how drug design could be helpful in limiting this form of pharmaceutical pollution.

percent and never . . . complete."[31] The remaining drug compounds either bind to the plant's biosolids[32] or are discharged as plant effluent.[33] Whatever the carrier, many of these drugs find their way into Wisconsin's surface- and groundwater, where they are likely to affect aquatic life and could potentially harm humans. As an alternative to flushing, federal agencies suggest mixing drugs with an undesirable substance (such as coffee grounds) in a sealed container and disposing of the container as solid waste that will end up in landfills.[34] However, scientists note that this is "really a form of potential 'pollution postponement'" rather than a solution.[35] Pharmaceuticals in landfills will eventually enter the groundwater where their potential for harming the environment is likely the same as those drugs that reach a wastewater-treatment facility through the sewer system.[36]

The Clean Water Act (CWA) provides for the regulation of water pollution in the United States.[37] The EPA administers the provisions of the CWA at the federal level but delegates much of the enforcement to individual states.[38] This scheme makes it possible for Wisconsin to control water pollution within the state.[39] Accordingly, through the

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31. Nidel, *supra* note 7, at 84. Wastewater flushed down toilets or drains comes to the wastewater-treatment facility through a series of underground pipes. At the facility, large solid materials are first removed through a screening process. The remaining wastewater moves to a biological process where aerobic microorganisms consume and metabolize the oxygen-demanding food matter in the wastewater (much like the human digestive system functions to metabolize food). The food in the wastewater provides enough nourishment for the microorganism to grow to the point where it is heavier than water and becomes a solid. The solid material can then be separated from the water before the water is discharged to a receiving body of water. This biological process removes about 99.5 percent of all organic and solid contaminants but does not remove the majority of pharmaceutical compounds. Interview with Ron Dickrell, Superintendent, City of Marshfield Wastewater Treatment Facility, in Marshfield, Wis. (Apr. 13, 2007).

32. Biosolids are the solid materials produced from wastewater-treatment residuals. Interview with Ron Dickrell, *supra* note 31.

33. Nidel, *supra* note 7, at 84.

34. OFFICE OF NATIONAL DRUG CONTROL POLICY, PROPER DISPOSAL OF PRESCRIPTION DRUGS, http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf. Another problem with this federal guidance is that it continues to recommend flushing for certain drugs, including pain medications like morphine and oxycodone. *Id.*

35. Daughton, *supra* note 4, at 783.

36. *Id.*

37. 33 U.S.C. §§ 1251–1387 (2000).

38. PAUL G. KENT & TAMARA A. DUDIAK, WISCONSIN WATER LAW: A GUIDE TO WATER RIGHTS AND REGULATIONS 99 (2d ed. 2001).

39. *See* WIS. STAT. § 283.001(2) (2005–06) (stating that the purpose of chapter 283 is to meet the requirements of the Federal Water Pollution Control Act, also known as the Clean Water Act).

Department of Natural Resources (DNR), Wisconsin regulates the "discharge of pollutants to any waters of the state from a discernable point," including wastewater-treatment facilities, also known as publicly owned treatment works (POTWs).[40] Yet due to the limitations of current technology, POTWs cannot remove most pharmaceuticals before they discharge to state groundwater and surface water.[41] Therefore, protection of Wisconsin's waters requires removal of pharmaceuticals before they reach the POTWs.[42]

However, a complex set of federal and state regulations leave health-care facilities and the consumer with few options for environmentally safe disposal of unused and expired pharmaceuticals.[43] Incineration is the best method of disposal, but rules and regulations often keep drugs from getting to the incinerator.[44] Hospitals face complicated and outdated regulations that require time for sorting medications and expensive shipment to out-of-state facilities for disposal of several drugs as hazardous waste.[45] Due to exemptions and lack of enforcement, many health-care facilities continue to flush their unused medications.[46] Similarly, consumers with unused pharmaceuticals in their medicine cabinets must sort through complicated drug-enforcement regulations that often leave them with only two options—the toilet or the trash.[47]

This Comment proposes changes to Wisconsin's regulatory scheme that would significantly reduce the concentration of pharmaceuticals in Wisconsin's surface and drinking water. This Comment also suggests changes in the current law that could help reduce costs for health-care facilities and consumers in disposing of pharmaceuticals in an environmentally safe manner. Part I provides an overview of the current legal framework that affects water pollution, waste management, and pharmaceuticals, noting the inability of this system to provide environmentally safe and convenient methods of disposal. Part

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40. KENT & DUDIAK, *supra* note 38, at 99, 104.

41. Nidel, *supra* note 7, at 84.

42. *Id.*

43. Ron Seely, *Flushed Drugs Polluting Water; Complicated Rules for Disposal Result in Most Hospitals Taking Easy Way Out*, WIS. ST. J., Dec. 10, 2006, at A1.

44. *Id.* Although some toxins are released into the air after incineration, they are generally in very small proportions because incinerators have filters in their chimneys. FEDERAL MINISTRY FOR THE ENVIRONMENT, NATURE CONSERVATION AND NUCLEAR SAFETY, WASTE INCINERATION—A POTENTIAL DANGER? 4 (2005), *available at* http://www.seas.columbia.edu/earth/wtert/sofos/Waste_Incineration_A_Potential_Danger.pdf.

45. Seely, *supra* note 43, at A1.

46. *Id.*

47. *Id.*

II discusses several proposed methods for dealing with the problem and the shortcomings of such methods. Finally, Part III proposes changes to the law that will reduce the concentration of pharmaceuticals in Wisconsin's water and make proper disposal of pharmaceuticals more convenient and less expensive. Ultimately, these proposed changes will provide a safer environment for Wisconsin's aquatic life, protect Wisconsin's groundwater from potential pollution, and provide vital medications to those who cannot afford them.

I. OVERVIEW OF THE CURRENT LAWS AFFECTING PHARMACEUTICALS AND WATER POLLUTION

A. Keeping Wisconsin's Water Clean

In keeping with Wisconsin's tradition as a leader in environmental protection,[48] Wisconsin's legislature statutorily recognized that "[u]nabated pollution of the waters of this state continues to arouse widespread public concern" by passing section 147.01 of the Wisconsin Statutes in 1973.[49] Among its concerns were public health and the health of fish and other aquatic life.[50] Wisconsin legislators established a goal that "wherever attainable . . . water quality which provides for the protection and propagation of fish, shellfish, and wildlife . . . be achieved."[51] The state also established a policy that "the discharge of toxic pollutants in toxic amounts be prohibited."[52]

While the EPA regulates water pollution at the national level under the CWA, individual states can regulate water pollution if the state's regulation either meets or surpasses that of the federal government.[53] Wisconsin codified its version of the CWA in chapter 283 of the Wisconsin Statutes and granted authority to enforce those standards to the DNR.[54] Nevertheless, the EPA may revoke a state's authority to implement and enforce the standards of the CWA if the EPA finds the state's program does not fully comply.[55]

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48. Wisconsin Historical Society, The Modern Environmental Movement, http://www.wisconsinhistory.org/turningpoints/tp-048/?action=more_essay (last visited Feb. 8, 2008).

49. WIS. STAT. § 283.001(1) (2005–06). The statute was moved to chapter 283 in 1995.

50. *Id.*

51. *Id.* § 283.001(1)(b).

52. *Id.* § 283.001(1)(c).

53. KENT & DUDIAK, *supra* note 38, at 99.

54. WIS. STAT. § 283.001(2).

55. Clean Water Act, 33 U.S.C.S. § 1342(c) (LexisNexis 2003).

Wisconsin's program regulates discharge to surface waters from both discernible points ("point sources"), such as factories, and indiscernible sources ("nonpoint sources"), such as runoff from farms or construction sites.[56] Although discharge from nonpoint sources is a significant source of the pharmaceuticals found in surface water, regulation of these sources is difficult.[57] Furthermore, small farms and businesses often cannot incur the substantial costs associated with nonpoint-pollution reduction.[58] For these reasons, this Comment focuses primarily on point-source regulation.[59]

The DNR regulates the introduction of pollutants to surface water from point sources through Wisconsin Pollution Discharge Elimination System (WPDES) discharge permits.[60] Any point source that discharges any pollutant into any "waters of the state"[61] must obtain a permit before discharging.[62] The permit limits the amount of discharge for specific pollutants on the basis of levels that will keep the water safe for fish and other aquatic life.[63]

Still, pharmaceutical waste poses several problems. The first problem is determining whether a given drug is, in fact, a pollutant and at what level it becomes toxic. Wisconsin gives the DNR the duty of creating a list of those substances that are toxic pollutants.[64] After the DNR lists a substance as a pollutant, it must also determine at what level these compounds become toxic and include this limitation in the WPDES discharge permit.[65] Although industries other than health care use many of the compounds on the list, several pharmaceuticals contain regulated hazardous chemicals.[66] However, the DNR does not list many of the active ingredients in pharmaceuticals, including the hormones in birth-control pills.[67]

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56. KENT & DUDIAK, *supra* note 38, at 99.

57. *Id.* at 107. See *id.* at 107–15, for an overview of the current legal framework regulating such sources.

58. *Id.* at 107.

59. For a discussion of nonpoint-source water pollution and the difficulties associated with controlling them, see Daniel R. Mandelker, *Controlling Nonpoint Source Water Pollution: Can It Be Done?*, 65 CHI.-KENT L. REV. 479 (1989).

60. KENT & DUDIAK, *supra* note 38, at 100.

61. WIS. STAT. § 283.01(20) (2005–06).

62. KENT & DUDIAK, *supra* note 38, at 100.

63. *Id.* at 101.

64. WIS. STAT. § 283.21(1)(a). The list may be found at WIS. ADMIN. CODE NR § 215.03 (2000).

65. KENT & DUDIAK, *supra* note 38, at 102.

66. For a list of pharmaceuticals that contain hazardous chemicals, see the Pharmaceutical Waste Guidelines issued by the University of California, Irvine, *avaliable at* http://www.ehs.uci.edu/programs/enviro/Pharmaceutical%20Waste.pdf.

67. *See* WIS. ADMIN. CODE NR § 215.03.

Nevertheless, adding further compounds to the list of toxic pollutants and monitoring the levels of these compounds when discharged from point sources is not the best solution to this problem because POTWs are generally unable to remove pharmaceutical compounds before discharging.[68] Reducing the level of pharmaceutical compounds could have a small effect, but even with the most current scientific methods, POTWs could not remove most compounds.[69] "While the idea of building idealized treatment plants with universally high removal rates is attractive, it may not be scientifically workable."[70] Equally as important, the government would likely bear the cost for designing and implementing a system that could remove most pharmaceutical compounds (assuming modern science could design such a system).[71] Sending the bill for removal of drugs from Wisconsin's waters to the taxpayer fails to place responsibility on the parties that created the problem in the first place.[72]

In addition to the CWA, the Resource Conservation and Recovery Act (RCRA) protects the nation's waters by promoting proper disposal of hazardous and solid waste.[73] The RCRA, enacted in 1976, regulates not only the disposal of hazardous waste but also its transportation, storage, and processing.[74] Under the RCRA, a solid waste is hazardous if it is ignitable, corrosive, reactive, or toxic.[75] The EPA separated the lists of hazardous wastes into four categories, called the F-list, the K-list, the P-list, and the U-list.[76] Industries, including health care, rely heavily on the lists promulgated by the EPA to determine whether a particular compound is hazardous.[77] Since most hazardous pharmaceuticals are on the P-list or U-list, health-care facilities focus primarily on these lists.[78] P-list RCRA chemicals are considered

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68. *See generally* Nidel, *supra* note 7, at 85 ("[F]ield research confirms that current treatment methods are inadequate.").

69. *Id.* at 92.

70. *Id.*

71. *Id.*

72. *Id.*

73. Resource Conservation and Recovery Act, 42 U.S.C. §§ 6901–92 (2000). Much like the CWA, states often enforce the RCRA locally. Wisconsin's rules either meet or exceed the federal RCRA rules. *See* WIS. STAT. § 291.001(9) (2005–06).

74. David H. Getches, *Groundwater Quality Protection: Setting a National Goal for State and Federal Programs*, 65 CHI.-KENT L. REV. 387, 399 (1989).

75. Margaret M. Menicucci & Cheryl L. Coon, *Environmental Regulation of Health Care Facilities: A Prescription for Compliance*, 47 SMU L. REV. 537, 549 (1994).

76. *See* 40 C.F.R. pt. 261 (2007).

77. Menicucci & Coon, *supra* note 75, at 549.

78. Daughton, *supra* note 4, at 782.

hazardous no matter the concentration while U-list chemicals are only deemed hazardous at higher concentrations.[79]

While the RCRA exempts households from pharmaceutical regulations,[80] hospitals must bear the expense of additional staff training to ensure compliance.[81] Additional training is necessary because the waste generator must determine whether waste is hazardous.[82] This means that health-care facilities must train their personnel not only on how to dispose (or not dispose) of different types of waste but also how to identify wastes that are hazardous and categorize them appropriately.[83] P-list waste creates an additional expense for health-care facilities in Wisconsin, which must pay to ship P-list waste to an out-of-state, EPA-approved facility for incineration.[84]

The RCRA lists further discourage health-care facilities because the list of hazardous drugs "has not been substantially updated since the rules went into effect in 1976."[85] For example, only eight out of 100 different chemotherapy drugs are currently on the list of hazardous wastes.[86] In fact, health-care facilities have an extremely difficult time dealing with the RCRA because the regulations were not designed for the health-care industry.[87] Thus, when there are regulations, they are complicated and expensive to follow, and when there are not regulations, hospitals are left in the unenviable position of developing their own disposal programs or flushing drugs down the toilet.[88]

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79. *Id.*

80. 40 C.F.R. § 261.4(a)(1).

81. Seely, *supra* note 43.

82. Daughton, *supra* note 4, at 782; *see also* 40 C.F.R. § 262.11 (2007).

83. Interview with P. Wayne Pattengill, Director of Environmental Services, St. Joseph's Hospital–Marshfield, in Marshfield, Wis. (Dec. 27, 2006); *see also* Seely, *supra* note 43.

84. Interview with P. Wayne Pattengill, *supra* note 83. There are no EPA-approved facilities in Wisconsin. *Id.* EPA-approved facilities must follow the extensive regulations that make them expensive to own and operate. *See* 40 C.F.R. §§ 263.10–.11, 264.340–.345 (2007).

85. Seely, *supra* note 43.

86. *Id.*

87. *Id.*

88. *Id.* For an example of a complicated hazardous-waste regulation, 40 C.F.R. § 261.24(a) reads as follows:

> A solid waste (except manufactured gas plant waste) exhibits the characteristic of toxicity if, using the Toxicity Characteristic Leaching Procedure, test Method 1311 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW–846, as incorporated by reference in § 260.11 of this chapter, the extract from a representative sample of the waste contains any of the contaminants listed in table 1 at the concentration equal to or greater than the respective value given in that table. Where the waste contains less than 0.5 percent filterable solids, the

Enforcement of these regulations is also a challenge.[89] While many hospitals in Wisconsin do comply with the regulations, hospital management often enforces compliance internally.[90] The EPA recently handed out fines on the East Coast for noncompliance, including fining prominent organizations like Memorial Sloan-Kettering Cancer Center.[91] So far, the Midwest has been largely immune from EPA enforcement, leaving Charlotte Smith, the owner of the health-care consulting company PharmEcology, to estimate that 80 percent of Wisconsin hospitals do not have appropriate pharmaceutical-disposal programs in place.[92]

B. Drug Regulation and Control

Through the Food and Drug Administration (FDA), Drug Enforcement Agency (DEA), and state agencies, drug regulations also affect the proper disposal of pharmaceuticals. Both federal and state regulations apply different standards to controlled substances and drugs that are not controlled.[93] The government classifies a drug as a controlled substance partly on the basis of a determination that the drug has a potential for abuse.[94] For this reason, the government regulates the disposal of controlled substances more tightly than noncontrolled substances.[95]

For the health-care industry and consumers, "DEA laws are one of the biggest stumbling blocks" on the road toward proper disposal.[96] This is largely due to the DEA's strict control of controlled substances, under which disposal becomes quite complicated.[97] When an individual is unsure how to dispose of a controlled substance, that individual may contact an authorized DEA agent, who will then instruct the individual to dispose of the controlled substance in one of the following manners: (1) by transfer to a person authorized to possess controlled substances

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waste itself, after filtering using the methodology outlined in Method 1311, is considered to be the extract for the purpose of this Section.

89. Seely, *supra* note 43.

90. *Id.*

91. *Id.*

92. *Id.* PharmEcology is "a Milwaukee company that provides consultation on drug and medical waste disposal to hospitals and other health care institutions." *Id.*

93. *See* Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801–971 (2000); Uniform Controlled Substances Act, WIS. STAT. ch. 961 (2005–06).

94. 21 U.S.C. § 812(b).

95. *See* 21 C.F.R. § 1307.21 (2007).

96. Seely, *supra* note 43.

97. *See* 21 C.F.R. § 1307.21

(likely a law-enforcement officer), (2) by delivery to a DEA agent, (3) by destruction in the presence of a DEA agent, or (4) by some other means determined by a DEA agent.[98] In other words, the only persons who can possess a controlled substance that is prescribed to an individual are that individual, a law-enforcement officer, or a DEA agent.

Under this scheme, the same pharmacist who is authorized to distribute medications to an individual is not authorized to take the medication back without prior approval by a DEA agent.[99] The reason for this approach is simple: the current scheme for drug regulation in the United States is not based on environmental concerns.[100] Rather, the current regulatory scheme ensures that controlled substances do not fall into the hands of children or drug abusers.[101] These concerns are noble and should not be taken lightly, but the issue that needs to be addressed is whether there is an environmentally safe manner of disposal that will still keep drugs from getting into the wrong hands.

C. The Bureaucratic Quagmire[102]

Current regulations and guidance lead to significant confusion.[103] The average consumer will often search for an environmentally safe way to dispose of their unused or expired drugs to no avail.[104] Many will follow the advice of local pharmacies and health-care professionals and end up flushing.[105] Others may follow current federal guidance, resulting in "pollution postponement" but ultimately failing to protect Wisconsin's water.[106] When faced with the alternative of contacting the DEA, many consumers will understandably take the easier way out.

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98. *Id.* § 1307.21(b).

99. *Id.*

100. Daughton, *supra* note 4, at 780.

101. *Id.*

102. Seely, *supra* note 43 ("The problem is that the regulatory environment isn't set up in the right way to allow people to do the right thing environmentally. It's an infuriating bureaucratic quagmire." (quoting Mark Borchardt, a Marshfield Clinic water researcher)).

103. Daughton, *supra* note 4, at 780 (calling the current regulatory framework "a fragmented patchwork of often-contradictory regulations, guidance, and formal/informal advice").

104. Seely, *supra* note 43.

105. *See id.* (noting that in December of 2006, Walgreens.com still recommended flushing).

106. *See supra* text accompanying notes 34–35.

For health-care facilities that are willing to sift through the complicated regulations, the options become daunting.[107] Developing a system for proper disposal involves considerable training for staff and increased shipping expenses for hazardous waste.[108] On the other hand, flushing the drugs down the toilet is the fast, easy, and inexpensive alternative.[109] It becomes a matter of convenience, especially for rural hospitals and nursing homes.[110] Therefore, health-care facilities need a new solution that will promote proper disposal without requiring substantial training for staff.

II. PREVIOUSLY PROPOSED SOLUTIONS

In fashioning a solution to this problem, scholars have asked who is legally responsible for creating the problem.[111] Suggested parties include pharmaceutical manufacturers, health-care facilities (including hospitals, nursing homes, and hospice-care centers), doctors, patients, and POTWs.[112] Each of these parties provides a valuable service to the public.[113] Nonetheless, under the current legal framework, the parties could follow the letter of the law and still contribute to environmentally unsound disposal of pharmaceuticals.[114] Therefore, the question becomes: how can the law change to ensure proper disposal of pharmaceuticals while also making certain that each of these entities will continue to provide its needed services? At the moment, little consensus exists as to the proper solution to this problem.[115] This Part examines several proposals, including (1) establishing mail-back programs, (2) strengthening premarket environmental analysis of drugs, (3) creating take-back programs, (4) improving POTW technology, (5) changing drug-delivery norms, (6) increasing regulation of health-care facilities, (7) reusing pharmaceuticals, and (8) promoting reverse distribution.

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107. Seely, *supra* note 43 (quoting Dr. David Musa of University of Wisconsin Hospitals).

108. *Id.*

109. *Id.*

110. *Id.*

111. Mannina, *supra* note 13.

112. *Id.* Mannina also adds animal feeding operations to the list, which may be a significant contributor to the problem but are not the subject of this Comment. *Id.*

113. *Id.*

114. *Id.*

115. *Id.*

A. Mailing Drugs Back to the Manufacturer

A group of Maine legislators suggested that pharmaceutical manufacturers should be held accountable for proper disposal.[116] "Product stewardship is a concept that recognizes the responsibility of the manufacturer of a product from the manufacturing process through final disposal in an environmentally sound manner."[117] In keeping with this philosophy, Maine's legislature designed a mail-back program.[118] Under the program, pharmacies and health-care facilities make proper packaging for drug shipment available to consumers.[119] Consumers mail unused or expired drugs in these packages to a single collection location run by the Maine Drug Enforcement Agency (MDEA).[120] The MDEA then disposes of all returned drugs in an environmentally sound manner.[121] A fund established and maintained by the MDEA and funded by private contributions pays the costs of the program.[122]

Currently, two problems plague the mail-back program proposal. First, although manufacturers regularly package and ship prescription drugs for consumption, it is much more difficult to have them shipped for disposal.[123] In Wisconsin, for example, accumulated drugs that qualify as hazardous waste must be shipped out of the state for incineration, and the DEA will not approve the transport of hazardous waste across state lines without proper agents accompanying it.[124]

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116. Maine's legislators saw this as a solution when establishing a mail-back program. MAINE DRUG RETURN IMPLEMENTATION GROUP, FINAL REPORT TO ST. OF ME. 122nd Leg., 1st Sess., at 7 (2005), *available at* http://www.maine.gov/legis/opla/drugrpt.pdf.

117. *Id.*

118. ME. REV. STAT. ANN. tit. 22, § 2700 (2004 & Supp. 2007). Wisconsin is considering a pilot program to look into the feasibility of such a program. Steve Brachman of the UW-Extension Solid and Hazardous Waste Education Center is submitting a grant proposal entitled "Wisconsin Old Medicine Mail Back Pilot" to the Great Lakes Protection Fund to secure funding for the project. The pilot program was planned to begin around the publication of this Comment. *Open Session on Solid Waste: Hearing Before the Winnebago County Board of Supervisors: Solid Waste Management Board* (2007), *available at* http://www.co.winnebago.wi.us/countyclerk/docs/swm070801.pdf.

119. ME. REV. STAT. ANN. tit. 22, § 2700(3). The Maine Drug Enforcement Agency and United States Postal Service determine what packaging is proper. ME. DRUG RETURN IMPLEMENTATION GROUP, *supra* note 116, at 6.

120. ME. REV. STAT. ANN. tit. 22, § 2700(3).

121. *Id.* § 2700(4).

122. *Id.* § 2700(5).

123. *Id.* § 2700(4).

124. *See* Ron Dickrell, *Pharmaceutical Take-Back A Community's Success Story*, THE CLARIFIER, Sept. 2006, at 48–49, *available at* http://www.wwoa.org/clerifier/archive/wwoa_1183473921Sept06.pdf (noting that the DEA would not approve of the transport of hazardous waste across state lines without law-enforcement officers).

Second, due to the potentially high costs involved, it is unlikely that pharmaceutical companies would provide the necessary funds to run the entire program.[125] In fact, Maine's statute provides that the program may not begin operation until the MDEA's fund is "sufficient to operate the program for 2 years."[126] At this point, it is unclear when the program will take effect.[127] Maine's government could consider legislation that would require pharmaceutical companies to significantly contribute to the fund. However, given that the pharmaceutical industry is one of the leading lobbyists in the United States, any proposed legislation that would force manufacturers to significantly contribute to the fund would likely meet significant opposition.[128] Furthermore, drug companies may pass the cost to the consumer in the price of pharmaceuticals.[129] If the scheme places the financial burden on consumers, it fails to follow the product-stewardship model that underlies this solution.[130]

B. Strengthening Premarket Environmental Analysis of Drugs

Another recommendation for increasing environmental stewardship of pharmaceutical manufacturers involves strengthening FDA regulations to require a careful look at the environmental effects of drugs before they go to market.[131] The FDA already has an extensive process for drug approval in place.[132] In spite of this, the environmental assessment required by the FDA has several exceptions and loopholes for pharmaceutical manufacturers who want to get their drugs to market

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This problem may not exist if a state has a federally permitted hazardous-waste incinerator.

125. Eilperin, *supra* note 10.

126. ME. REV. STAT. ANN. tit. 22, § 2700(7).

127. MAINE DRUG RETURN IMPLEMENTATION GROUP, *supra* note 116, at 7. The recommended start date for the product stewardship model was July 1, 2007. *Id.*

128. *See* Jim Drinkard, *Drugmakers Go Furthest to Sway Congress,* USA TODAY, Apr. 26, 2005, at B1 (stating that drug companies spent more on lobbying than any other industry from 1998 to 2004). Furthermore, in order to affect all pharmaceutical manufacturers, such legislation would likely need to be passed at the federal level.

129. *See, e.g.*, Nidel, *supra* note 7, at 92 (explaining that where fees are assessed to the drug manufacturer, the consumer will likely pay the bill).

130. *See supra* text accompanying note 117.

131. Nidel, *supra* note 7, at 92–95. For information on how better drug design could reduce harmful environmental effects, 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. 757, 765–66 (2003).

132. Nidel, *supra* note 7, at 92–93.

quickly.[133] The FDA, rather than providing loopholes, "could strengthen the environmental review within the current framework to more effectively address these new [environmental] concerns."[134] By examining the toxicity of drugs on the environment before the drug goes to market, these changes would address the root of the problem rather than dealing with the aftereffects.[135] Furthermore, under such a model, the FDA could follow through by monitoring the environmental effects of the drug after approval.[136]

This proposal would be a much-needed step in the right direction, and Wisconsin and other states should encourage the change.[137] However, there are several reasons why Wisconsin should not rely on the federal government to remedy this problem. First, federal legislation that would add additional requirements for drug approval is unlikely, due to the pharmaceutical lobby mentioned previously.[138] Second, it would be imprudent for Wisconsin to wait for the federal government to act during an era when the federal government has been slow to act on environmental-protection measures.[139] Third, Wisconsin's abundance of lakes and rivers and reliance on groundwater should cause increased concern about water quality in the state.[140] Finally, regulation at the state level would allow Wisconsin to focus on state-specific needs.[141]

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133. *Id.* at 93.

134. *Id.* at 94.

135. *Id.* at 92, 101. One great example of how this system could work is found in Sweden, where pharmaceuticals are classified on the basis of environmental risk and prescribing physicians have access to those classifications. Ake Wennmalm & Bo Gunnarsson, *Public Health Care Management of Water Pollution with Pharmaceuticals: Environmental Classification and Analysis of Pharmaceutical Residues in Sewage Water*, 39 DRUG INFORMATION J. 291 (2005).

136. Nidel, *supra* note 7, at 94.

137. One potential problem could be a longer drug-approval time. *See* Mary T. Griffin, *AIDS Drugs and the Pharmaceutical Industry: A Need for Reform*, 17 AM. J.L. & MED. 363, 386 n.145 (1991) (noting that Sweden's system for classifying drugs according to environmental risk results in a longer drug-approval time).

138. *See supra* text accompanying note 128.

139. *See* Getches, *supra* note 74, at 388 (noting that the 1960s and 1970s were ripe for environmental legislation). However, more recently, "[e]nvironmental legislation is notoriously slow to win consensus." Manimoli Dinesh, *United States: Warming to Global Warming*, ENERGY COMPASS, Dec. 1, 2006. It is unclear whether this trend will continue.

140. *See* Thomas S. Hanrahan, Comment, *Water Quality Controls: Wisconsin Inland Lakes*, 77 MARQ. L. REV. 585, 585 (1994) (noting that Wisconsin has over fifteen thousand lakes); Getches, *supra* note 74, at 403.

141. *See* Getches, *supra* note 74, at 402. State-specific needs could include protecting Wisconsin's two adjacent Great Lakes from pollution or addressing concerns raised by Wisconsin's fishing community.

C. Creating Take-Back Events and Programs

To date, take-back events offer the best solution for consumers who are searching for an ecologically responsible way to dispose of unused pharmaceuticals.[142] Take-back events, typically organized by hospitals, pharmacies, or environmental groups, create a place for consumers to bring their unused pharmaceuticals.[143] With proper personnel available to sort pharmaceuticals and law enforcement available to handle controlled substances, these events are often extremely successful, resulting in hundreds of gallons of pharmaceuticals collected in single-day events.[144]

Despite the success of these events, organizing them within the confines of the law is quite a challenge.[145] For example, a take-back event in Marshfield, Wisconsin, took over a year to organize, due in part to regulations governing the transfer of controlled substances and hazardous waste.[146] In order to hold the event, an environmental organization in the city had to locate an approved hazardous-waste incinerator and secure the help of law-enforcement officers to oversee the collection and transport of controlled substances.[147] Furthermore, the organization needed properly trained personnel to sort through the pharmaceuticals.[148] Along with making the event more difficult to organize, these regulations also added to the cost of the event.[149]

Even when organized successfully, these take-back events are only available to a small portion of the population at very limited times. In contrast, take-back programs in Canada, Australia, and parts of Europe offer services full-time and nationwide.[150] For example, Canada's Medications Return Program, originally established in 1996 by British Columbia's pharmaceutical industry and later adopted nationwide, provides several benefits in addition to its favorable environmental

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142. Seely, *supra* note 43. For guidance on take-back events in Wisconsin, see WIS. DEP'T NATURAL RES., COLLECTING UNWANTED HOUSEHOLD PHARMACEUTICALS (2006), *available at* http://dnr.wi.gov/org/aw/wm/publications/anewpub/WA1024.pdf.

143. Seely, *supra* note 43. In 2007, over thirty such events were held across the state of Wisconsin, and many more are planned for 2008. Steven Brachman, *Wisconsin Collects . . . Pharmaceutical Waste*, UW-EXTENSION NEWS (Solid and Hazardous Waste Education Center), Nov. 2007, *available at* http://www4.uwm.edu/shwec/publications/newsletters/pdf/November2007.pdf.

144. Seely, *supra* note 43; Dickrell, *supra* note 124, at 48.

145. Seely, *supra* note 43; Dickrell, *supra* note 124.

146. Seely, *supra* note 43.

147. Dickrell, *supra* note 124, at 48.

148. *Id.* at 49.

149. *Id.* at 48–49. Donations from private organizations, including health-care facilities, funded this event. *Id.*

150. Daughton, *supra* note 4, at 780.

impact.[151] Among the additional benefits are child safety,[152] reduced costs,[153] and the ability to perform studies on the actual use of drugs.[154] One such study charted returned drugs and allowed physicians to examine which patients are less likely to use all of their medication.[155] Physicians adjusted initial prescription levels on the basis of the study's findings.[156]

Wisconsin created a similar program in 1993, although on a limited basis.[157] Run by the Wisconsin Department of Health and Family Services (DHFS), the program creates a repository for unused cancer and chronic-disease drugs.[158] Through the program, consumers can return unused drugs to participating pharmacies or health-care facilities if they are not controlled substances, are still in their original, unopened container, and will not expire for more than six months.[159] Once again, however, the program is limited in scope. First, there are very few pharmacies involved in the program.[160] Second, federal regulations only allow for the return of uncontrolled substances.[161] Third, pharmacies can only accept cancer and chronic-disease drugs that remain unopened.[162] Finally, the program requires the consumer to determine whether the drug at issue is a controlled or uncontrolled substance.[163]

Take-back programs and events, despite providing the best method for consumer disposal to date, could be strengthened by revisiting current federal regulations that restrict take back of controlled

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151. *Id.*

152. Drugs that sit in medicine cabinets are more likely to be used by someone for whom they are not prescribed. *Id.*

153. The program encourages consumers to buy only what they will use. *Id.*

154. *Id.*

155. *Id.*

156. *Id.* For example, a study showed that geriatric patients often return their medication unused. Doctors have been prescribing smaller amounts initially to determine whether the drug will work before prescribing larger quantities that will not be used. *Id.*

157. WIS. STAT. § 255.056 (2005–06); *see also* Ron Seely, *To Reduce Disposal, Watch What You Buy*, WIS. ST. J., Dec. 10, 2006, at A11.

158. Seely, *supra* note 157.

159. *Id.* More information on the program is available at http://dhfs.wisconsin.gov/bqaconsumer/cancerdrugreposy.htm (last visited Feb. 8, 2008).

160. *See* Seely, *supra* note 157. For example, the closest pharmacies to Madison are in Milwaukee and Boscobel (both over seventy miles away). A list of participating pharmacies is available on the DHFS Web site at http://dhfs.wisconsin.gov/bqaconsumer/CDRparticips.pdf (last visited Feb. 8, 2008).

161. 21 C.F.R. § 1307.21 (2007).

162. WIS. STAT. § 255.056(3)(a).

163. Seely, *supra* note 157.

substances.[164] Because the regulations require the presence of law-enforcement officers for handling controlled substances, organizers must ensure law-enforcement presence at all events.[165] Given concern over the improper redistribution of controlled substances, event oversight remains important. Nonetheless, the presence of pharmacists or health-care professionals that are qualified and trained to sort drugs is sufficient.[166] While law-enforcement presence would create a greater sense of safety, requiring their presence may result in fewer take-back events due to added cost and time constraints on law-enforcement officials. Ultimately, eliminating the need for law-enforcement presence is justified by the potential environmental advantages. However, changing the regulation of controlled substances would require federal action.[167] For reasons already discussed, Wisconsin should not wait for the federal government to act but should encourage the federal government to take a second look at the regulation of controlled substances.[168]

D. Improving POTW Technology

Some environmental groups have suggested an end-of-the-line approach to solving this problem: requiring the development of improved methods for the removal of drugs at POTWs.[169] This approach could have the greatest potential benefit, as it would remove not only intentionally flushed drugs but also drugs that pass through the body naturally.[170] It may also be the easiest area for the government to regulate because there would be no extensive lobbying effort from pharmaceutical manufacturers to block the proposal and no change in disposal methods for health-care facilities or consumers.[171]

In spite of all the positives, this proposal has several shortcomings.[172] The first is scientific. The technology currently available at POTWs removes a small percentage of the drugs that reach

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164. Daughton, *supra* note 4, at 783; *see* 21 C.F.R. § 1307.21.

165. *See* Dickrell, *supra* note 124.

166. These professionals are required to keep detailed records. *See, e.g.*, WIS. STAT. § 961.235 (relating to records for pseudo ephedrine products); WIS. ADMIN. CODE Phar § 7.055(3) (2006) (showing the specific requirements for record keeping involved in transfer of controlled substances).

167. *See* Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801–971 (2000).

168. *See supra* text accompanying notes 138–41.

169. Mannina, *supra* note 13, at 4.

170. *Id.* at 2.

171. *See supra* text accompanying note 128 (noting that pharmaceutical companies are one of the leading lobbyists in the United States).

172. Nidel, *supra* note 7, at 91.

it, but most of the drug compounds still have the potential to reach Wisconsin's waters.[173] Therefore, while the DNR could easily write regulations that require POTWs to decrease the measure of drug compounds that pass through their facilities untreated, POTWs would require new technology.[174] Despite that, it is unclear at the moment whether such technology is even scientifically workable.[175] It would be "remarkable, if not impossible" to design a system that would remove all of the toxic compounds found in the wide and increasing variety of drugs available.[176] Even if such a system is feasible, it is likely a product of the distant future.[177]

The second shortcoming is economic. Assuming that a scientifically workable system is feasible, the potential cost of designing and implementing such a system would likely be significant.[178] Although POTWs could draw resources from several sources, including pharmaceutical manufacturers, the government would likely bear much of the burden.[179] The government could create a tax on the sale of drugs to offset the cost of keeping the environment free of the drugs.[180] On the other hand, many consumers already struggle with the high cost of needed medications.[181] Adding a tax to those medications would not only be extremely unpopular but also fundamentally unfair.[182]

Wisconsin faced a similar problem in fashioning regulations for mercury removal at POTWs.[183] Amidst concern over the amount of mercury found in Wisconsin lakes,[184] the DNR examined possible methods for controlling the level of mercury in point-source discharge.[185] Like pharmaceuticals, the technology for removal of mercury by POTWs generally leads to "a sludge or other resultant

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173. *Id.* at 84; *see also* text accompanying notes 29–33.

174. *See* Dickrell, *supra* note 124, at 48 (noting that conventional wastewater-treatment operations would be incapable of removing all pharmaceutical waste).

175. Nidel, *supra* note 7, at 92. It would also be incredibly difficult to keep the technology up-to-date as scientists create new drug compounds.

176. *Id.*

177. *See id.*

178. *Id.*

179. *Id.*

180. *Id.*

181. Daughton, *supra* note 4, at 776.

182. Nidel, *supra* note 7, at 92.

183. Wisconsin confronted this challenge in 2002 by creating WIS. ADMIN. CODE NR § 106.145 (2005).

184. *See* Carol Garland, *Acid Rain Over the United States and Canada: The D.C. Circuit Fails to Provide Shelter under Section 115 of the Clean Air Act while State Action Provides a Temporary Umbrella*, 16 B.C. ENVTL. AFF. L. REV. 1, 11 (1988) (citing a Wisconsin study that found mercury at harmful levels in fish).

185. WIS. ADMIN. CODE NR § 106.05 (2005).

wastewater stream that can be as much or more of an environmental liability than the untreated effluent."[186] Therefore, rather than lowering the discharge limits to a point that no POTW could meet, the DNR recommended "mercury source reduction activities" that would lower the amount of mercury getting to the POTW.[187] A similar scheme for pharmaceutical removal is preferable to spending significant sums on developing a system for removal that may or may not be scientifically feasible.[188]

E. Lowering the Number of Drugs That Need to Be Disposed

Expired and unused drugs are found in nearly every medicine cabinet.[189] One proposal for solving the problem of pharmaceutical disposal involves lowering the amount of pharmaceuticals that require disposal.[190] For over-the-counter medications, this responsibility rests with the consumer.[191] The DNR recommends not "buy[ing] the 500-pill container of aspirin when you only need 25 a year."[192] For prescribed medications, however, the responsibility may lie in several different hands.[193] For one, prescribing physicians should stay up-to-date on proper-dosage schemes and alternative-medicine options, including placebos.[194] At the dispensing level, pharmacies could limit the number of drugs that expire on the shelves by lowering inventory.[195] Nevertheless, much of the responsibility still lies with the consumer.

Patient compliance may be the most practical way to lower the quantity of drugs that sit in medicine cabinets.[196] Prescribing physicians and pharmacists often instruct patients to finish a bottle of medication even if they start feeling better.[197] Patients often ignore the doctor's or pharmacist's advice or simply forget to continue taking their

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186. *Id.* § 106.145(1)(c).

187. *Id.*

188. *See* Nidel, *supra* note 7, at 92; *infra* Part III.B.2.c.

189. Seely, *supra* note 43.

190. Daughton, *supra* note 131, at 766 (calling for an examination of "prescribing, dispensing, patient compliance, and medication delivery mechanisms").

191. Seely, *supra* note 157.

192. *Id.* (quoting Barbara Bickford, medical-waste coordinator with the DNR). One could argue that drug companies should not offer such large amounts of medicine over the counter, but larger amounts are often discounted, providing an inexpensive alternative for individuals with significant needs and large families.

193. Daughton, *supra* note 131, at 766–67.

194. *See id.* at 767; Daughton, *supra* note 4, at 777. Placebos do not pose the same environmental risks as drugs.

195. Daughton, *supra* note 131, at 770.

196. *Id.* at 768.

197. *Id.*

medications once they feel better.[198] This leads to the need to dispose of medication that the patient normally would have used.[199] One scholar suggests that direct-to-consumer drug marketing exacerbates this problem, causing consumers to demand unnecessary drugs from physicians.[200]

Consumers, physicians, and pharmacies should change their habits where possible to prevent unnecessary disposal of drugs.[201] This is especially true given the dramatic increase in the number of prescribed drugs.[202] In spite of positive potential impacts, this solution fails to address the larger problem. Even when physicians prescribe drugs in proper dosages and instruct patients to finish their medications, patients will sometimes have adverse reactions to drugs or simply refuse to comply.[203] Consumers will need to discard these drugs, and proper disposal methods should be available.

F. Increasing Regulation of Disposal Methods at Health-Care Facilities

"Properly disposing of billions of unused pharmaceutical products is a growing problem for the nation's medical facilities . . . ."[204] Nevertheless, despite the regulations that are in place, health-care facilities can still legally flush many pharmaceuticals that have adverse environmental effects.[205] State and federal agencies could add those pharmaceuticals to lists of hazardous waste and pollutants. Industries

198. *Id.*

199. *Id.* This can also lead to increased health-care costs and further health risks. *Id.* On the other hand, taking more drugs than the body can use will also allow significant levels of pharmaceuticals to reach water sources, as the unused portions of the drugs will run their natural course out of the body and into the sewer system. *Id.*

200. *Id* at 769. Supporters of direct-to-consumer advertising note that it empowers the consumer to make more informed decisions. *Id.*

201. Other important changes in the health-care field, such as training physicians in proper drug dosage and alternative medicines, could be an important part of the solution to this problem. However, they are not the topic of this Comment. See Daughton, *supra* note 131, for a comprehensive look at changes that can be made in the health-care field.

202. KAISER FAMILY FOUNDATION, PRESCRIPTION DRUG TRENDS (2007), *available at* http://www.kff.org/rxdrugs/upload/3057_06.pdf. The number of prescriptions purchased increased 71 percent from 1994 to 2005. *Id.*

203. More specifically, this fails to address the problem encountered by long-term-care facilities when patients die with cabinets full of prescription drugs.

204. Press Release, Vestara, Emerging Medical Company Targets $1B Market in Pharmaceutical Waste Management with New Technology: Vestara's Automated Drug Disposal System Solves Hospitals' Regulatory Compliance, Reduces Water Safety, Environmental Concerns (June 22, 2005), *available at* http://www.vestara.com/images/Vestara_PR_62205.pdf.

205. Seely, *supra* note 43.

that discharge pollutants to the sewer system must give notice to the DNR and the applicable POTW of the "types of pollutants to be discharged"[206] and must meet pretreatment standards.[207] The DNR could limit the introduction of pharmaceuticals to our sewer system statewide by lowering pretreatment standards for industry, including the health-care industry.[208] Generally, industry must comply by preventing "the introduction of pollutants that will interfere with POTW operations . . . [or] pass through POTW treatment operation untreated."[209] Clearly, pharmaceuticals would fit in this category.[210]

Due to the inability of POTWs to fully treat pharmaceutically polluted water, regulating the source of the pollutant offers several advantages. First, this change would simply require health-care facilities to do what they are already doing.[211] Health-care facilities already spend significant time and energy sorting pharmaceuticals to determine their waste classification.[212] They already bear the cost of shipping some drugs for incineration.[213] Adding further drugs to the list may not pose a significant burden. Second, modifying the law would not be a significant challenge, because the legislative and administrative scheme is already in place. The DNR could simply modify applicable water-pollution laws.[214]

However, this proposal also has several drawbacks, the most important being implementation. Hospitals and other health-care facilities already face significant hurdles in disposal of hazardous waste.[215] Given the lack of enforcement for these regulations,[216] hospitals may simply choose to ignore the law rather than employing time-consuming and expensive methods for sorting and properly disposing of unused medications.[217] Furthermore, it is unclear how much of an impact this would have, as health-care facilities are not the largest source of the problem.[218]

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206. KENT & DUDIAK, *supra* note 38, at 104.

207. *Id.*

208. *See id.*

209. *Id.*

210. *See supra* text accompanying notes 66–67.

211. *See supra* text accompanying notes 83–84.

212. *See supra* text accompanying notes 83–84.

213. *See supra* text accompanying note 84.

214. *See* WIS. STAT. §§ 283.21, 291.05(2) (2005–06) (authorizing the DNR to promulgate a list of pollutants and hazardous waste).

215. Seely, *supra* note 43.

216. *Id.*

217. *Id.*

218. *Id.* The largest source is the consumer. *Id.*; *see also* Mannina, *supra* note 13. However, hospitals may be the largest source of highly toxic drugs. Daughton, *supra* note 4, at 778.

G. Pharmaceutical Reuse through Drug-Repository Programs

Despite concerns over quality assurance,[219] many states have developed pharmaceutical-reuse programs.[220] Under these programs, health-care facilities and individuals return unopened and unused pharmaceuticals to pharmacies or charitable clinics for distribution to indigent persons.[221] These programs provide a much-needed alternative to flushing pharmaceuticals or throwing them away. Wisconsin developed a cancer-drug repository in 2003 in which individuals could return unused cancer drugs to pharmacies or medical facilities for redistribution to uninsured or indigent individuals.[222] Recently Wisconsin passed legislation to expand the cancer-drug repository to include prescription drugs used for chronic diseases.[223] Other states, however, have gone much further in creating drug repositories for all prescription drugs that are not controlled substances.[224]

For example, Arkansas's Prescription Drug Redispensing Program provides for transfer of uncontrolled prescription drugs from nursing homes to charitable clinics.[225] The charitable clinic's pharmacy determines which drugs are accepted, provided they meet specified requirements that ensure the safety of the charitable clinic's patients.[226] The requirements specify that the drugs must be in their original container,[227] be transferred by an authorized person,[228] and be examined by a pharmacist to determine that the drug has not been "adulterated or misbranded."[229] Nevertheless, the statute limits the program by only allowing transfers only from nursing facilities, not individual consumers.[230]

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219. This includes drug shelf history, tampering, and counterfeiting. Daughton, *supra* note 4, at 777.

220. *See, e.g.*, ARIZ. REV. STAT. ANN. § 32-1909 (2002 & Supp. 2007); ARK. CODE ANN. §§ 17-92-1101 to -1107 (1987 & Supp. 2007); GA. CODE ANN. §§ 26-4-190 to -195 (2003 & Supp. 2007); TENN. CODE ANN. §§ 63-10-501 to -508 (2004 & Supp. 2006); text accompanying notes 150–51.

221. *See supra* note 220.

222. WIS. STAT. § 255.056(2) (2005–06).

223. A.B. 197, 2005–06 Leg., Reg. Sess. (Wis. 2005). The bill was codified as WIS. STAT. § 255.056.

224. *See, e.g.*, ARIZ. REV. STAT. ANN. § 32-1909.

225. ARK. CODE ANN. § 17-92-1103(b).

226. *Id.* § 17-91-1104(c).

227. *Id.* § 17-91-1104(c)(1)(A).

228. *Id.* § 17-91-1104(c)(4).

229. *Id.* § 17-91-1104(c)(2).

230. *Id.* § 17-91-1104(a)(1).

Arizona's law provides for redispensing but under a more comprehensive scheme.[231] Under Arizona law, "[a] person, manufacturer or health-care institution may donate prescription medication to a physician's office, pharmacy, hospital or health-care institution that volunteers to participate in the program and that meets the requirements prescribed by the board."[232] Thus, the Arizona law allows for transfer from both health-care facilities and individuals.[233] By casting its net wider, the Arizona program has greater potential for keeping unused pharmaceuticals from harming the environment.

In addition to their environmental benefits, these programs have further policy goals that make them even more appealing.[234] First and foremost, the programs provide needed medications for individuals in the community who otherwise could not afford them.[235] Without the reuse program, these medications would be paid for with public funds through programs like Medicaid.[236] Therefore, in addition to providing a much-needed service, reuse programs could also potentially lower the cost of programs like Medicaid and allow the government to spend money on other needed services for indigent peoples.[237] Some government agents have expressed concerns over liability and safety, but these concerns are offset by the potential benefits and the safeguards placed in the statutes.[238]

H. Promoting Reverse-Distribution Companies and Programs

The reverse-distribution industry offers needed assistance to hospitals, pharmacies, and clinics trying to manage unused pharmaceuticals.[239] Reverse distributors pick up unused pharmaceuticals for return to manufacturers or off-site disposal.[240] Pharmacies and

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231. ARIZ. REV. STAT. ANN. § 32-1909 (2002 & Supp. 2007).

232. *Id.* § 32-1909(B). The Arizona Board of Pharmacy has not yet promulgated the requirements but discussion has begun. *See* Arizona State Board of Pharmacy, Board Meeting Minutes (Nov. 8 & 9, 2006), *available at* http://www.azpharmacy.gov/pdfs/1106AGENDA.pdf.

233. ARIZ. REV. STAT. ANN. § 32-1909.

234. *See, e.g.*, ARK. CODE ANN. § 17-92-1101(1) (1987 & Supp. 2007).

235. The Arkansas program requires that the person's income be "below two hundred percent (200%) of the federal poverty level." *Id.* § 17-92-1102(4).

236. Daughton, *supra* note 4, at 776–77.

237. *Id.*

238. Andy Miller, *Drug Recycling Gets Fresh Debate*, ATLANTA J. CONST., Dec. 15, 2005, at A1.

239. TDC ENVIRONMENTAL, HOUSEHOLD PHARMACEUTICAL WASTE: REGULATORY AND MANAGEMENT ISSUES 8 (2004), *available at* http://www.tdcenvironmental.com/HouseholdPharmWasteMgtIssuesFinal.pdf.

240. *Id.*

health-care facilities are generally willing to employ the services of reverse distributors for two reasons.[241] First, the reverse distributor will often sort the drugs, saving pharmacies and health-care facilities the time and money associated with sorting.[242] Second, many manufacturers offer credit to pharmacies for returned pharmaceuticals, which the manufacturer can sometimes process for reuse.[243] In spite of the benefits, these programs are not without cost for the pharmacy or health-care facility.[244]

Like Arkansas's reuse program, reverse distributors do not receive medications that have been prescribed to individual consumers.[245] The government licenses reverse distributors to generate waste but not to transfer waste.[246] Because the drugs they transport from pharmacies may still have financial value, the regulations label the drugs "products in commerce" and not waste.[247] However, once a pharmacist dispenses a prescription drug to a patient, the drug is either used by a patient or considered waste.[248] Because reverse distributors cannot transfer waste, the reverse distributor cannot handle any drugs that were prescribed to a patient but can only handle unused drugs from medical facilities or pharmacies.[249] Consequently, reverse distribution does not offer a solution for consumers who are searching for an environmentally sound way to dispose of their unused medications. Furthermore, this solution relies on the willingness of manufacturers to take back drugs.

III. FINDING A COMPREHENSIVE SOLUTION

The largest drawback of the proposed solutions is that they fail to address the concerns of every party involved in pharmaceutical distribution, consumption, and disposal.[250] Furthermore, many of the proposed solutions only address a narrow set of pharmaceuticals, such as over-the-counter medication, without addressing either prescribed drugs or controlled substances.[251] This Part proposes a wide-reaching solution that will confront the challenge of disposing of a broader number of pharmaceuticals and address the concerns of all parties

241. *Id.*
242. *Id.*
243. *Id.*
244. *Id.*
245. *See id.*
246. The drug becomes waste when it no longer has financial value. *Id.*
247. *Id.*
248. *Id.*
249. *Id.*
250. *See supra* text accompanying notes 160–63, 179–80, 203, 215, 230.
251. *See supra* Part II.E.

involved. This Part proposes changes to federal and state law that would help consumers and health-care facilities dispose of pharmaceuticals in an environmentally safe manner. Specifically, the Part identifies how Wisconsin's legislature and administrative agencies can act to prevent environmental contamination from pharmaceuticals.

A. The Need for Federal Change

Many scholars have suggested that the United States needs a nationally consistent program for proper disposal of pharmaceuticals.[252] Christian G. Daughton cites recent troubles with mercury disposal as proof that "a large disjointed patchwork of often conflicting [state] guidance and regulations" will not suffice.[253] When the American Academy of Pediatrics issued a policy statement instructing parents to remove mercury thermometers from their homes, many parents sought to comply.[254] However, state and local health officials often gave conflicting advice.[255] In fact, only 24 percent of health officials surveyed gave the correct advice (to turn them in as hazardous waste).[256] Many officials gave unsafe and environmentally unsound advice, instructing the parents to throw the mercury in the trash.[257]

In many aspects, this Comment agrees with Daughton and others that federal change is necessary. This is primarily true because some changes can only be made at the federal level.[258] For example, federal agencies create and enforce drug-approval standards, RCRA hazardous-waste lists, and controlled-substance regulations.[259] In spite of this, Daughton's concern about "a large disjointed patchwork of . . . regulations"[260] may be overstated. The federal government has granted significant authority to the states in the area of environmental regulation, and, for the most part, states have accepted the responsibility.[261] Forty-four states now enforce CWA provisions at the

252. *See, e.g.*, Daughton, *supra* note 4, at 780, 782; Mannina, *supra* note 13; Nidel, *supra* note 7.

253. Daughton, *supra* note 4, at 782.

254. *Id.*

255. *Id.*

256. *Id.*

257. *Id.*

258. *See infra* Part III.B.1.

259. *See infra* Part III.B.1.

260. Daughton, *supra* note 4, at 782.

261. *See supra* text accompanying notes 53–55; EPA OFFICE OF INSPECTOR GENERAL, WATER ENFORCEMENT: STATE ENFORCEMENT OF CLEAN WATER ACT DISCHARGERS CAN BE MORE EFFECTIVE 2 (2001), *available at* http://www.house.gov/georgemiller/cwaenforce.pdf.

state level.[262] Furthermore, the EPA Office of Inspector General recently opined that states could be more effective if given greater latitude by the federal government.[263] In fact, allowing each state a certain level of control over its regulations may have some advantages.[264] In Wisconsin specifically, where lakes and rivers are a significant source of enjoyment for both residents and nonresidents,[265] stricter regulations may be desirable.[266] However, this does not eliminate the need for federal financial and research assistance.[267]

B. Finding a State Solution

As already discussed, some needed changes can only be made at the federal level.[268] Where this is the case, Wisconsin should pass resolutions encouraging both Congress and federal agencies to change laws and regulations that make environmentally sound disposal of pharmaceuticals difficult and expensive.[269] Absent federal action, Wisconsin can and should make changes that will significantly reduce the flow of pharmaceuticals in Wisconsin's waters. Where possible, Wisconsin should act to protect its wildlife and drinking water from pollution before additional adverse effects are discovered.[270] This Section begins by proposing that Wisconsin pass resolutions urging the federal government to (1) require stricter environmental review of drugs, (2) update the RCRA to address health-care-industry concerns, (3) change the regulation of controlled substances to facilitate take-back programs, and (4) require pharmaceutical companies to contribute to consumer education. This Section continues by proposing that Wisconsin (1) amend the Cancer and Chronic Disease Drug Repository Statute to include all uncontrolled prescription drugs, (2) change effluent standards for discharge from health-care facilities, (3)

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262. *Id.*

263. *Id.* at iv.

264. Hanrahan, *supra* note 140, at 609.

265. *Id.* at 585

266. *Id.*

267. *Id.* at 609.

268. *See supra* Part III.A.

269. These resolutions would be largely symbolic but are one way state governments can express their wishes for changes to federal law or practice. For a recent example, see S.J. Res. 21, 2007–08 Leg., Reg. Sess. (Wis. 2007) (asking the federal government to cease and desist mandates beyond the scope of its constitutionally delegated power). Other states have passed resolutions requesting that the federal government take specific actions. *See, e.g.*, A.J. Res. 49, 2006 Leg., Reg. Sess. (Cal. 2006).

270. If scientists discover a link between improper pharmaceutical disposal and human-health risks, the potential for lawsuits exists. *See* Mannina, *supra* note 13.

reclassify pharmaceuticals as universal waste, (4) require pharmacies to clearly mark controlled substances, and (5) encourage voluntary take-back events.

1. RESOLUTIONS FOR FEDERAL ACTION

Unfortunately, there is nothing the Wisconsin government can do to rid the sewer system of drugs that run their natural course through the human body.[271] However, changes in drug design do have potential to significantly limit the amount of drugs not used by the body.[272] Increased environmental review of drugs before the FDA approves them could significantly decrease pharmaceutical levels in the nation's waters.[273] Assuming that drug manufacturers would oppose such changes, an incentive-based approach could encourage greater environmental stewardship by drug manufacturers.[274] The FDA used six-month patent extensions in the past as incentives for pharmaceutical manufacturers who researched safe-dosage levels for children.[275] Wisconsin should consider a resolution that urges the FDA to increase environmental review of the design of new drugs or offer intellectual-property or tax-based incentives to those manufacturers who voluntarily test for environmental effects.[276]

Wisconsin should also consider recommending an update of the RCRA at the federal level. The RCRA laws are "not only confusing but outdated."[277] The complicated regulations may be leading hospitals and other health-care facilities to flush unused pharmaceuticals rather than encouraging them to dispose of them properly.[278] A uniform federal law governing medical waste more specifically and an exemption for health-care facilities from current RCRA regulations could provide a solution.[279] This would provide disposal guidance to health-care

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271. Nidel, *supra* note 7, at 83–84 (describing the course of drugs in the human body).

272. Daughton, *supra* note 131, at 765.

273. Christopher G. Nidel was the first to propose this solution. Nidel, *supra* note 7.

274. Daughton, *supra* note 4, at 776.

275. *Id.* "[I]ronically, the rationale for this need is that it is not possible to predict the differing responses of children (compared with adults)—the same as what might very well be true for potential effects on nontarget organisms." *Id.*

276. The FDA already has the necessary authority to do so. Nidel, *supra* note 7, at 94.

277. Seely, *supra* note 43.

278. Mannina, *supra* note 13.

279. Menicucci & Coon, *supra* note 75, at 541–47. Many of the provisions in the RCRA that are applicable to health-care facilities could be incorporated into a law governing medical waste.

facilities that focuses specifically on waste generated in the care of patients. Wisconsin should pass a resolution encouraging the EPA to update the RCRA or create new regulations that specifically address the concerns of health-care facilities.

Wisconsin should also pass a resolution encouraging Congress to reexamine regulation of controlled substances.[280] Concern over the improper transfer of controlled substances is clearly justified.[281] In spite of this, a law that allows a pharmacist to dispense such a dangerous substance yet not take it back is illogical. Pharmacists are fully trained to handle drugs like these, and the government trusts them to treat controlled substances with care.[282] Naturally, pharmacists should not redispense returned controlled substances and should ensure they are disposed of properly.[283] Nonetheless, if pharmacists could accept controlled substances, a comprehensive pharmacy take-back program, like those in Canada and Europe, would be feasible.[284]

Finally, Wisconsin should urge Congress to increase consumer education about the adverse effects of pharmaceuticals on the environment. Consumer education is often the most important part of achieving environmental change.[285] Although recent news articles may have heightened public awareness about the harmful effects of pharmaceuticals on the environment,[286] the federal government could create a public-awareness campaign using a variety of sources. First, information about proper disposal could be included with drug purchases at pharmacies. Second, the government could design a media campaign that includes information on the adverse effects of pharmaceutical pollution on the environment and potential effects of such pollution on human health.[287] To fund such an endeavor, the government could consider requiring pharmaceutical companies to contribute.[288] One writer suggested that with improved knowledge of

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280. Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801–971 (2000).

281. *See supra* Part I.B.

282. *See* WIS. ADMIN. CODE Phar §§ 4.01–.05 (2002).

283. These drugs could then become part of the redistribution chain. *See supra* Part II.H.

284. *See* Daughton, *supra* note 4, at 780.

285. *See* PAUL WAPNER, ENVIRONMENTAL ACTIVISM AND WORLD CIVIC POLITICS 41–71 (1996).

286. *See, e.g.*, Rust, *supra* note 17; Seely, *supra* note 43.

287. Daughton, *supra* note 4, at 777.

288. While this may lead to increased prices for consumers, it would require pharmaceutical companies to consider the product-stewardship philosophy discussed earlier. *See supra* text accompanying note 117. Furthermore, placing greater cost on the consumer is more logical than using public funds that are partially from taxpayers who may or may not use many drugs.

the connection between individual behavior and broad environmental harm, this issue could become self-regulating.[289] While this may be unrealistic, consumers who are not aware that flushing their medications causes environmental harm will likely continue to flush them.

2. TAKING ACTION IN WISCONSIN

Wisconsin has long been a leader in the area of environmental protection.[290] In keeping with that tradition, Wisconsin should take action to protect its natural resources from pharmaceutical pollutants.[291] A comprehensive scheme for reducing the introduction of pharmaceuticals into the environment will involve action by legislators and several different agencies. However, the following changes to Wisconsin's laws and regulations could reduce the environmental harm caused by improper disposal of pharmaceuticals. Furthermore, these changes could provide needed drugs for the uninsured and indigent and research opportunities for health-care professionals.[292] This Section explores changes to the (1) Cancer and Chronic Disease Repository statute, (2) effluent standards on discharge from health-care facilities; (3) classification of pharmaceutical waste, (4) identification of controlled substances, and (5) support of take-back events.

a. Increasing the scope of the drug-repository scheme

Wisconsin should consider amending the Cancer and Chronic Disease Drug Repository statute to allow for repository of all prescription drugs that are not controlled substances.[293] This legislation would be relatively simple to draft, as the statute for the drug repository is already in place. The current statute already includes all necessary safeguards, including a ban on reusing drugs that are not in "their original, unopened, sealed and tamper-evident unit dose packaging"; are less than six months from expiry; or have been tampered with, as determined by a pharmacist.[294] Furthermore, the

289. Daughton, *supra* note 4, at 777.

290. *See* Wisconsin Historical Society, *supra* note 48.

291. *See supra* text accompanying notes 48–52.

292. Daughton, *supra* note 4, at 780.

293. *See* WIS. STAT. § 255.056 (2005–06). Alternatively, Wisconsin could create a new chapter in order to avoid confusion. The statute is currently under the chapter heading "Chronic Disease and Injuries," but if broadened to include all prescription medication that is not controlled, this chapter heading may not be appropriate.

294. *Id.* § 255.056(3).

statute already requires the DHFS to promulgate requirements for pharmacies and health-care facilities that receive medication and eligibility standards for those who receive the medication.[295] The eligibility standards must "prioritize dispensation to individuals who are uninsured or indigent."[296] This gives the statute a humanitarian purpose, along with creating an avenue to avoid improper disposal of unopened pharmaceuticals.[297]

One problem with the current program in Wisconsin is that pharmacies participating in the repository are few and far between.[298] The DHFS would need to take an active role in encouraging more pharmacies to participate in the program. Consumers will not likely drive one hour to dispose of their pharmaceuticals when they could just throw them in the trash.[299] Furthermore, long-term-care facilities, which have a national monetary value of unused drugs estimated at $73–378 million,[300] may lack the necessary personnel and resources to drive seventy miles to the nearest participating pharmacy.[301] However, it "[s]houldn't be any harder to dispose of medications than it is to get them."[302] By actively recruiting pharmacies, the DHFS could increase the humanitarian aid provided by this statute.

While this legislation would provide an alternative to flushing for unopened medications that are not controlled substances, Wisconsin must also address other unused pharmaceuticals. Due to the inability of POTWs to remove pharmaceuticals before discharge, flushing unused medication cannot be an option.[303] Recently, the Wisconsin Department of Agriculture, Trade, and Consumer Protection (DATCP) applied for federal funding to pilot a permanent pharmaceutical-disposal program.[304] The DATCP hopes to include seventy to one hundred

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295. *Id.* § 255.056(7).

296. *Id.* § 255.056(7)(b).

297. It may also have the added benefit of lowering health-care costs. *See supra* text accompanying note 237.

298. *See supra* note 160 and accompanying text.

299. TDC ENVIRONMENTAL, *supra* note 239, at 11.

300. Daughton, *supra* note 4, at 777.

301. *See supra* note 160.

302. SEGO JACKSON & SNOHOMISH COUNTY WA & NORTHWEST PRODUCT STEWARDSHIP COUNCIL, OVERVIEW OF DRUG RETURN PROGRAMS 9 (2006), http://www.productstewardship.us/supportingdocs/PharmaceuticalCallNWPresentation5-18-06revised.ptt.

303. Daughton, *supra* note 4, at 783 (noting that flushing is the "least desirable" method of disposal).

304. WIS. DEP'T OF AGRICULTURE, TRADE & CONSUMER PROTECTION, COMMUNITY-BASED COLLECTION OF UNUSED PHARMACEUTICALS APPLICATIONS REQUEST FORM (2007) (on file with author).

public collection points in five to ten communities in the state.[305] The program hopes to provide for disposal of controlled substances as well as uncontrolled substances by petitioning for a "waiver of enforcement" from the DEA's controlled-substance laws.[306] Should Congress grant the request for federal funding and the DEA waive enforcement of controlled-substance laws, such a program may be a long-term solution for pharmaceutical disposal in Wisconsin. Furthermore, the DATCP notes in the grant-request form that the program could be replicated by other states to solve the problem nationally.[307]

In the meantime, disposal in household trash may be the most environmentally sound solution but this cannot be a long-term solution.[308] To protect the environment to the fullest extent possible, Wisconsin must seek a regulatory scheme that will (1) keep unused pharmaceuticals from being placed in the trash or flushed down the toilet, and (2) provide a convenient and inexpensive way for proper disposal of those same pharmaceuticals. Wisconsin must address these problems for health-care facilities, including long-term-care facilities, and the consumer.

b. Changing effluent standards for health-care facilities

In order to ensure compliance from health-care facilities, the DNR should amend Wisconsin Administrative Code NR chapter 250 to create additional effluent limitations for discharge to POTWs.[309] Because many of the pharmaceuticals flushed at health-care facilities will be from natural human emission, limitations may need to be set high.[310] Where pharmaceutical levels in discharge are extremely high, POTWs could be certain that pharmaceuticals are being flushed down the toilet.[311] In such cases, POTWs could take actions to encourage compliance under their legally authorized authority.[312] The DNR could also create a new chapter to monitor discharge from long-term-care facilities.

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305. *Id.*

306. *Id.*; *see also supra* Part I.B.

307. WIS. DEP'T OF AGRICULTURE, TRADE & CONSUMER PROTECTION, *supra* note 304.

308. Daughton, *supra* note 4, at 783.

309. WIS. ADMIN. CODE NR § 250.10 (1997).

310. Nidel, *supra* note 7, at 83–84.

311. POTW investigation of potential noncompliance is authorized under WIS. ADMIN. CODE NR § 211.23(1)(h) (2002).

312. *Id.* § 211.22.

As noted above, there are problems with this solution.[313] First, enforcement may be a challenge. POTWs cannot spend all of their time testing health-care facilities for compliance.[314] In spite of this, creating the restrictions may be enough to ensure compliance or at least encourage it. Second, health-care facilities are not the largest source of pharmaceutical pollutants.[315] While this may be true, this should not create a bar to regulation. The greatest problem with this solution is that it adds insult to injury. Health-care facilities must already comply with several waste-management regulations.[316] Adding yet another regulation will only complicate matters. However, the next Section explores a potential solution to that problem.

c. Reclassifying pharmaceuticals as universal waste

Wisconsin DNR could amend its Universal Waste Management Standards to reclassify pharmaceuticals as universal waste.[317] Universal wastes are wastes that contain materials that are environmentally unfriendly but do not require full treatment as hazardous waste.[318] The universal-waste rule "provides an alternate set of standards under which universal wastes may be managed instead of full regulation as hazardous waste under these rules."[319] Among the universal wastes listed in Wisconsin's current regulations are batteries, pesticides, mercury thermostats, and lamps.[320] The regulations list specific instructions for each individual universal waste.[321] Therefore, this scheme would allow Wisconsin to specify exactly how pharmaceutical waste should be handled.[322]

Wisconsin Administrative Code Section NR 673 should be amended as follows: "Pharmaceuticals as described in s. NR 673.06" should be added to the list of universal wastes in NR 673.01 and NR

313. *See supra* text accompanying notes 215–18.

314. For example, POTWs only test an industrial user's need for a slug-control plan every two years. WIS. ADMIN. CODE NR § 211.235 (2002).

315. Mannina, *supra* note 13.

316. Seely, *supra* note 43.

317. WIS. ADMIN. CODE NR § 673 (2006). Precedent for this can be found in Michigan, where the Michigan Department of Environmental Quality recently reclassified pharmaceutical waste as universal waste. *See* MICH. ADMIN. CODE r. 299.9228 (2006). The EPA has proposed amending the RCRA to add hazardous pharmaceuticals to the universal-waste list. 72 Fed. Reg. 23,281, 23,282 (Apr. 30, 2007).

318. WIS. ADMIN. CODE NR § 673.09(11).

319. MICH. ADMIN. CODE r. 299.9228(1).

320. WIS. ADMIN. CODE NR § 673.01.

321. *Id.* § 673.13.

322. *Id.*

673.09(11). NR 673.06 should define those pharmaceuticals that are governed as universal waste as "drugs intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans."[323] Unlike Michigan's scheme, which exempts pharmaceuticals that are not hazardous wastes, Wisconsin's scheme should not exempt such wastes.[324] This will allow regulation of drugs like birth-control pills that are not listed as hazardous substances but have toxic environmental potential.[325] The DNR should create a subsection for pharmaceuticals under section 673.13 that specifies disposal methods. The primary concern in drafting the disposal methods should be assurance that the pharmaceuticals do not enter the environment.[326] For example, regulations often require universal waste to be completely sealed and brought to a community hazardous-waste-destination facility.[327]

Wisconsin regulations divide universal-waste handlers into large- and small-quantity waste handlers.[328] The regulations would categorize many health-care facilities, particularly long-term-care facilities, as small-quantity–universal-waste handlers, while some larger hospitals would be categorized as large-quantity–universal-waste handlers.[329] Small-quantity–universal-waste handlers do not have to register with the DNR or receive an EPA identification number.[330] This may encourage compliance at long-term-care facilities, as there would be little paperwork involved.[331] However, absent an exception, no handler can dispose of universal waste itself unless it is a registered universal-waste-destination facility.[332]

While it seems counterintuitive to lower the classification of pharmaceutical waste from hazardous to universal when studies have shown how toxic pharmaceuticals can be, this reclassification can provide several benefits. First, disposal at health-care facilities would be less expensive and more convenient. Health-care workers would no longer need to sort through medications to determine their waste

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323. This is similar to Michigan's definition. MICH. ADMIN. CODE r. 299.9106(n).

324. *See id.* 299.9228(2)(m).

325. *See* WIS. ADMIN. CODE NR § 215.03 (2000); Mannina, *supra* note 13.

326. See MICH. ADMIN. CODE r. 299.9228(4)(e)(i) (2006), for an example.

327. *See* WIS. ADMIN. CODE NR § 673.18 (2006).

328. *Id.* § 673.09(6), (9).

329. *Id.* Households would still be exempt. *Id.* § 673.08.

330. *Id.* § 673.12; *see also id.* § 673.32.

331. *Id.* § 673.12.

332. *Id.* § 673.60; 40 C.F.R. § 273.60 (2007). There are exceptions for very small-quantity handlers and households. WIS. ADMIN. CODE NR § 673.08. Many waste-management companies around Wisconsin are registered to handle universal wastes. The list at http://www.dnr.state.wi.us/markets/matcompany.asp?sortby=city is helpful.

categorization.[333] Rather, the amended regulation would allow for disposal of all pharmaceuticals through universal-waste mechanisms, which are less stringent than hazardous-waste mechanisms.[334]

For example, universal-waste-handler regulations can be used in place of hazardous-waste-handler regulations.[335] This would allow health-care facilities the option of using incinerators that are not EPA-approved for P-list waste, lowering the cost of disposal.[336] If the hospital manages its own incinerator, it could seek authorization as a universal-waste-destination facility and dispose of pharmaceuticals without shipment.[337] Thus, the reclassification of pharmaceuticals as universal waste would encourage health-care-facility compliance by making compliance less complicated and more cost-effective. Moreover, for medications that have toxic environmental effects and are not on the hazardous-waste lists, this change would ensure that these medications cannot be flushed down the toilet.[338]

Second, reclassification would also encourage take-back programs and reverse distribution. One problem encountered by take-back-event organizers is the need for hazardous-waste disposal.[339] This adds expense to the program in two ways.[340] First, it requires the help of individuals trained to sort hazardous waste from nonhazardous waste and P-list waste from U-list waste.[341] Second, it requires transport by law-enforcement officers or EPA agents.[342] If the DNR classified every pharmaceutical as universal waste, take-back events would no longer require significant personnel for sorting. When consumers return controlled substances, law-enforcement officers would still be needed for supervision and for transport.[343] When consumers do not return

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333. *See* MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY, WASTE MANAGEMENT GUIDANCE: UNIVERSAL WASTE 12 (2006), *available at* http://www.deq.state.mi.us/documents/deq-ead-tas-univwaste.pdf.

334. *Id.* at 2.

335. *See* 40 C.F.R. §§ 273.50–273.56.

336. *See supra* note 84 and accompanying text (noting the high standards imposed on EPA-approved incinerators).

337. *See* 40 C.F.R. § 273.60.

338. Seely, *supra* note 43 (noting that the RCRA is out of date, leaving some toxic chemotherapy drugs off the list of hazardous waste).

339. Dickrell, *supra* note 124, at 48.

340. *Id.* at 48–49.

341. *Id.* at 48. These individuals may be willing to donate their time but sorting drugs is an arduous task.

342. *Id.*

343. *Id.*

controlled substances, the take-back event organizers could employ universal-waste handlers.[344]

d. Clearly identifying controlled substances on packaging

The primary difficulty with controlled substances is that consumers are often unaware whether a substance is controlled.[345] The Wisconsin Pharmacy Board could consider requiring clear identification of controlled substances on the box or bottle that accompanies the prescription. The Board could modify Wisconsin Administrative Code section Phar 8.05(1), which governs the dispensing of controlled substances, to require clear identification on every bottle or box containing controlled substances. While this would create more administrative work for pharmacists, the work would be minimal. Pharmacies could design bright-colored stickers that identify a substance that is controlled. This would also further the education scheme described earlier.[346] Clearly identifying controlled substances will allow consumers to quickly identify proper disposal methods.

e. Encouraging voluntary take-back events

Finally, Wisconsin must begin to encourage and support take-back events. One reasonably economical option would involve a program similar to the current Adopt-a-Highway program.[347] Under such a program, concerned citizens and organizations could turn to a government department, such as DHFS, for information on how to set up a take-back event. The information would detail the need for law-enforcement officers and proper waste management, as well as providing information on how to advertise and raise funds for the event.[348] Where groups in the past have been discouraged from organizing a take-back event due to the bureaucratic quagmire, such a system could encourage more groups to be stewards of their environment.[349] Furthermore, it would avoid significant government

344. Potentially, separate take-back programs could be created for controlled and uncontrolled substances.

345. TDC ENVIRONMENTAL, *supra* note 239, at 12.

346. *See supra* Part III.B.1.

347. Under the Adopt-a-Highway program, qualified groups volunteer to remove litter around Wisconsin highways three times a year. Information on the Adopt-a-Highway program is available on the Department of Transportation Web site at http://www.dot.state.wi.us/localgov/aid/adopt-a-highway.htm.

348. The government could also encourage law-enforcement officials to get involved.

349. Seely, *supra* note 43 (quoting Dr. Mark Borchardt, a Marshfield Clinic water researcher).

spending, as the only government involvement would be oversight by the department.[350]

CONCLUSION

Only a comprehensive regulatory scheme that takes into account the concerns of all parties involved will provide a wide-ranging solution for disposal of pharmaceuticals in Wisconsin. Nevertheless, the current legal scheme frustrates proper disposal efforts rather than promoting them.[351] These proposed changes will allow each involved party to promote environmentally sound disposal while also making disposal more convenient and less expensive.

Where Wisconsin requires the assistance of the federal government, Wisconsin should consider resolutions that will (1) require strict environmental review of drugs, (2) update the RCRA to address health-care industry concerns, (3) change the regulation of controlled substances, and (4) require pharmaceutical companies to contribute to consumer education. At the state level, Wisconsin should (1) add all prescription medications to the Cancer and Chronic Disease Drug Repository program to provide medications for the uninsured and indigent, including all uncontrolled prescription drugs;[352] (2) change effluent standards for discharge from health-care facilities to prevent pharmaceutical compounds from reaching POTWs;[353] (3) reclassify pharmaceuticals as universal waste to promote compliance from health-care facilities[354] and facilitate take-back events;[355] (4) require pharmacies to clearly mark controlled substances so consumers can easily identify them;[356] and (5) encourage voluntary take-back events by providing information to community groups.[357]

As the baby-boomer population reaches retirement, the number of dispensed pharmaceuticals will continue to increase.[358] At the same time, science continually produces new drugs that will promote longer

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350. The group could raise funds to pay for the costs of the event or search for volunteers to oversee the program and transportation of the drugs for disposal.

351. *Id.*

352. *See supra* Part III.B.2.a.

353. *See supra* Part III.B.2.b; Nidel, *supra* note 7, at 92.

354. *See supra* text accompanying notes 333–37.

355. *See supra* text accompanying notes 339–44.

356. *See supra* Part III.B.2.d.

357. *See supra* Part III.B.2.e.

358. Regina Sharlow Johnson, *PBMs: Ripe for Regulation*, 57 FOOD & DRUG L.J. 323, 323 (2002).

life.[359] Scientific evidence demonstrates the harmful effects that pharmaceuticals already have on our environment.[360] Scientists may soon discover adverse effects for human health.[361] Although changes in the federal law are needed in the future to address these concerns, Wisconsin should not wait for federal action.[362] Wisconsin's legislature and administrative agencies must simplify regulations that promote environmentally unsound disposal of pharmaceuticals and design laws that will keep pharmaceuticals out of Wisconsin's environment.

359. John T. Dunlop, *To Form a More Perfect Union*, 9 LAB. LAW. 1, 2 (1993) (listing pharmaceuticals among those things which lead to increased life expectancy).

360. Eilperin, *supra* note 10.

361. *Id.*

362. *See supra* text accompanying notes 138–41.