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## Safeguarding Our Health: Developments in the Management of Medical Waste

Wendy Stynes\*

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## SAFEGUARDING OUR HEALTH: DEVELOPMENTS IN THE MANAGEMENT OF MEDICAL WASTE

### INTRODUCTION

In the summer of 1987, officials closed fifty miles of New Jersey beaches after a tide of used syringes, blood vials, rubber gloves, hypodermic needles, blood bags, gauze dressings and various other medical wastes washed ashore.<sup>1</sup> By the following summer the panic aroused by medical waste had spread beyond the eastern seaboard to the Great Lakes states, which also found medical waste on their shores.<sup>2</sup> Fortunately, over the last five years environmental experts have determined that most of the debris found on beaches were released by antiquated sewage systems rather than illegally dumped by individuals.<sup>3</sup> Although illegal dumping of medical waste appears to pose no serious threat to our beaches, the 1987 beach scare showed the public that without proper regulations, medical waste could be dumped in anyone's backyard.

To quell the public's fear of improper medical waste disposal, Congress hastily enacted a two-year demonstration program — The Medical Waste Tracking Act (MWTA) in 1988.<sup>4</sup> The MWTA expired in June 1991<sup>5</sup> and on November 26, 1991 Senator Dave Durenberger introduced a bill, the Medical Waste Management Act of 1991 (MWMA), to replace the demonstration program.<sup>6</sup> The following week, the Occupational Safety and Health Administration (OSHA) issued a Standard on Occupational Exposure to Bloodborne Pathogens.<sup>7</sup> Since OSHA's regulations have only recently gone into effect,<sup>8</sup> their impact on the medical industry in particular and the environment in general remains unclear.<sup>9</sup>

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1. 134 CONG. REC. S20,111 (daily ed. Aug. 3, 1988) (statement of Sen. Lautenberg).

2. In August 1988, 200 syringes and other unidentified medical objects washed up on a Cleveland, Ohio beach. In addition, two garbage bags worth of medical waste was found at a State park beach in Michigan that same summer. 134 CONG. REC. S13,202 (daily ed. Sept. 23, 1988) (statement of Sen. Glenn).

3. See Sarah Lyall, *Beach Medical Waste: Debris but No Panic*, N.Y. TIMES, Sept. 11, 1991, at B1. In July, 1992 the Natural Resources Defense Council, a private environmental group, faulted New York City's antiquated sewer system for dirtying the waters surrounding the City. Diana Jean Schemo, *Report Praises Tough Testing at Beaches*, N.Y. TIMES, July 24, 1992, at B1.

4. 42 U.S.C. §§ 6992a-6992k (1988).

5. See 56 Fed. Reg. 54,064, 3712 (1991) (ending statutory authority of the MWTA). In May of 1991, Senator Frank Lautenberg called for a two year extension of the MWTA, but the measure never gained Congressional approval. 137 CONG. REC. S5,898 (daily ed. May 15, 1991) (statement of Sen. Lautenberg).

6. S. 2108, 102d Cong., 1st Sess., 137 CONG. REC. S18,336 (1991). The bill was sent to the Committee on Environment and Public Works.

7. 56 Fed. Reg. 64,004, 64,175-82 (1991) (to be codified at 29 C.F.R. § 1910.1030).

8. The regulations went into effect 90 days after they were published, on December 3, 1991. 56 Fed. Reg. 64,004 (1991).

9. Doctors already complain that the regulations impose an unnecessary financial burden on their already escalating operating costs. See Lisa Belkin, *Frustrating Spate of New Rules for Clinics*, N.Y. TIMES, Aug. 30, 1992, at L33. *Contra infra* notes 313-15 and

This Note examines the need for a national program controlling the treatment and disposal of medical waste, constitutional obstacles to attempts at such regulation, and the success of federal efforts to date. Part I traces the events and beliefs that led to the enactment of the MWTA. Part II delineates the provisions of the MWTA. Part III explores the need for a national system regulating medical waste treatment and disposal by analyzing how the Commerce Clause and the Tenth Amendment limit the powers of both federal and state governments. Part IV explains that while OSHA's Occupational Exposure to Bloodborne Pathogens Standard addresses the handling of medical waste, Congress still must address the issue of its treatment and disposal. Part V describes the Senate proposal to control this problem with the enactment of the Medical Waste Management Act of 1991. Part VI compares the MWTA to the Medical Waste Management Act and discusses the probability of the bill's passage. Finally, this Note concludes that Congress should enact the Medical Waste Management Act to ensure proper treatment and disposal of medical waste throughout the country and to safeguard public health and the environment.

### I. EVENTS PRECEDING THE ADOPTION OF THE MWTA

Since 1976, the Environmental Protection Agency (EPA) has had the authority to promulgate national regulations on medical waste under the emergency measure provisions of the Resource Conservation Recovery Act (RCRA).<sup>10</sup> By the time of the 1987 beach closings, however, the EPA had developed only a guide to the management of medical waste.<sup>11</sup> The EPA believed that regulation at state and local levels would be most effective.<sup>12</sup> In 1987, Senators Bill Bradley and Frank Lautenberg, joined by twenty-five other coastal state senators, demanded that the EPA create national regulations.<sup>13</sup> When the EPA failed to respond quickly enough<sup>14</sup> Congress enacted the Medical Waste Tracking Act (MWTA).<sup>15</sup>

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accompanying text on the economic incentives of environmental regulation and other possible reasons for the increased cost of medical care.

10. See 42 U.S.C. §§ 6903(5), 6912(a) (1988). The inaction of the EPA led one Senator to state: "It's clear that we cannot count on the EPA which has earned the name the Environmental Procrastination Agency." 134 CONG. REC. S16,685 (daily ed. Oct. 8, 1988) (statement of Sen. Lautenberg).

11. See Laurence D. Granite, Note, *The Medical Waste Tracking Act of 1988: An Analysis of its Provisions and Its Effect on New York State*, 7 *TOURO L. REV.* 259, 262 (1990). "The EPA guide only 'provide[d] guidance on the management of infectious waste[.]' and [did] not represent a body of binding rules or regulations. It [was] merely what the EPA consider[ed] 'acceptable waste management practices.'" *Id.* at 262 n.29 (citation omitted) (emphasis in the original).

12. *Id.*

13. See letter from Senator Bradley to Lee M. Thomas, Administrator of the EPA (Oct. 20, 1987) (discussing hospital waste management), reprinted in 134 CONG. REC. S15,327 (daily ed. Oct. 7, 1988) (statement of Sen. Bradley).

14. See 134 CONG. REC. S15,326 (daily ed. Oct. 7, 1988) (statement of Sen. Bradley); 134 CONG. REC. S15,327 (daily ed. Oct. 7, 1988) (statement of Sen. Baucus).

15. 42 U.S.C. § 6992 (1988).

The regulation of medical waste disposal prevents harm to the environment and protects individuals exposed to medical waste from infection. Hospital generated medical waste comprises 3.2 million tons of the 160 million tons of solid waste created annually in the United States.<sup>16</sup> Infectious medical waste constitutes ten to fifteen percent of hospital waste.<sup>17</sup> Medical and dental offices, small laboratories, medical clinics, individuals practicing home health care and illicit drug users also generate medical waste, the amount of which is difficult to assess.<sup>18</sup> A comprehensive medical waste disposal plan ensures that those exposed to infectious waste from its generation to its disposal run the most minimal risk achievable of contracting various contagious diseases.

Hospital employees and waste disposal workers, among other occupations, regularly handle infectious medical waste.<sup>19</sup> Since the infectants are living organisms capable of reproduction, even insignificant contacts with waste can cause infection.<sup>20</sup> In 1988, the federal Center for Disease Control determined that at least 18,000 people annually contract hepatitis-B through accidental exposure to medical waste.<sup>21</sup> Each year up to 200 to 300 health care workers die from hepatitis-B.<sup>22</sup> To reduce the risk of exposure to infectious material the MWTa mandated tracking the path of medical waste from "cradle to grave". However, a tracking program ensures only that medical waste reaches the correct destination. The MWTa inadequately addressed procedures for minimizing worker contact with contagions while handling medical waste and failed to address medical waste treatment. In operation, the MWTa was a permissive program which allowed Congress, through the EPA, to collect data in order to develop comprehensive legislation on the management of medical waste. Thus, the MWTa served in large part as a stalling tactic which allowed Congress to appear to have safeguarded the public from the dangers of medical waste.

## II. PROVISIONS OF THE MEDICAL WASTE TRACKING ACT

### A. *Scope of the Demonstration Program*

The MWTa was supposed to cover at least ten states, but an escape mechanism permitted all covered states to avoid participation in its pro-

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16. Michael R. Schumaker, Note, *Infectious Waste: A Guide to State Regulation and a Cry for Federal Intervention*, 66 NOTRE DAME L. REV. 555, 559 (1990).

17. *Id.* at 560.

18. David R. Mercer, Note, *A Prospectus on the Legislative Response to Medical Waste*, 55 MO. L. REV. 509, 511 (1990).

19. See 134 CONG. REC. S20,111 (daily ed. Aug. 3, 1988) (statement of Sen. Lautenberg).

20. Mercer, *supra* note 18, at 513.

21. 134 CONG. REC. H28,203 (daily ed. Oct. 4, 1988) (statement of Rep. Luken).

22. 134 CONG. REC. H28,208 (daily ed. Oct 4, 1988) (statement of Rep. Wyden). See also *infra* notes 165-68 and accompanying text on OSHA's findings on the threat of hepatitis-B and HIV to workers three years later.

gram.<sup>23</sup> Congress wanted the MWTa to cover the states of Connecticut, Illinois, Indiana, Michigan, Minnesota, Ohio, New Jersey, New York, Pennsylvania, and Wisconsin.<sup>24</sup> However, the escape mechanism allowed those states not contiguous to the Atlantic Ocean, or whose regulations were at least as strict as the EPA regulations, to withdraw from the program if their governors notified the Administrator.<sup>25</sup> Congress' motives for including the Great Lakes states and then allowing all of them to opt out of the program, regardless of whether they had a viable medical waste tracking program, remain unclear.<sup>26</sup> Congressional records indicate that Congress had to preserve the option to secure the votes of the Great Lakes senators, whose states had had little opportunity to fully explore the matter.<sup>27</sup> Furthermore, there was a perception that the medical waste problem was "primarily an 'East Coast problem'"<sup>28</sup>

States could also petition in to the program.<sup>29</sup> Only Puerto Rico and Rhode Island did so,<sup>30</sup> although the District of Columbia and Louisiana also had demonstrated an interest in the program.<sup>31</sup> Ultimately, the MWTa covered only Connecticut, New Jersey, New York, Puerto Rico and Rhode Island.<sup>32</sup>

### B. *The Definition of Medical Waste*

Lack of a standardized definition of medical waste proved one of the greatest obstacles to regulation.<sup>33</sup> Congress developed its own broad definition of medical waste in the MWTa and required the Administrator of the EPA to issue a regulated medical waste definition.<sup>34</sup> The MWTa defined medical waste as cultures and stocks of infectious agents,<sup>35</sup> path-

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23. 42 U.S.C. § 6992(a), (b) (1988).

24. Mercer, *supra* note 18, at 519.

25. 42 U.S.C. § 6992(b). New Jersey and New York did have regulations as strict as those promulgated by the EPA, and therefore could have opted out of the program if they had desired. Mercer, *supra* note 18, at 520. Thus, Connecticut was the only state which was required to participate in the MWTa.

26. See Mercer, *supra* note 18, at 519-20.

27. See 134 CONG. REC. S15,326-27 (daily ed. Oct. 7, 1988) (statement of Sen. Chafee).

28. See Mercer, *supra* note 18, at 520.

29. 42 U.S.C. § 6992(c) (1988).

30. See 40 C.F.R. § 259.20(b) (1989).

31. The District of Columbia and Louisiana originally opted into the MWTa, but then utilized the escape mechanism allowing them to opt out because they had regulations as strict as the MWTa. See Mercer, *supra* note 18, at 520.

32. 40 C.F.R. § 259.20(b) (1989).

33. Mercer, *supra* note 18, at 521.

34. 42 U.S.C. § 6992a (1988).

35. *Id.* § 6992a(a)(1). The section states: "Cultures and stocks of infectious agents and associated biologicals, including cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures." *Id.*

ological wastes,<sup>36</sup> waste human blood and products of blood,<sup>37</sup> used sharps,<sup>38</sup> contaminated animal carcasses, body parts and bedding of animals that were exposed to infectious agents,<sup>39</sup> wastes from surgery or autopsy that were in contact with infectious agents,<sup>40</sup> laboratory wastes that were in contact with infectious agents,<sup>41</sup> dialysis wastes,<sup>42</sup> discarded medical equipment previously in contact with infectious agents,<sup>43</sup> biological waste and discarded materials contaminated by humans or animals isolated to protect others from communicable diseases,<sup>44</sup> and any other waste that the Administrator believed posed a threat to human health or the environment.<sup>45</sup>

The regulated medical waste definition did not have to contain five of the categories included in Congress' definition of medical waste if the Administrator did not believe that the waste posed a threat to human health or the environment when improperly treated.<sup>46</sup> Thus, the Administrator included the five mandatory categories and two additional types of medical waste in his regulations.<sup>47</sup> The non-mandatory categories included in the regulated medical waste definition were isolation wastes<sup>48</sup>

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36. *Id.* § 6992a(a)(2). The section states: "Pathological wastes, including tissues, organs, and body parts that are removed during surgery or autopsy." *Id.*

37. *Id.* § 6992a(a)(3). The section states: "Waste human blood and products of blood, including serum, plasma, and other blood components." *Id.*

38. *Id.* § 6992a(a)(4). The section states: "Sharps that have been used in patient care or in medical, research, or industrial laboratories, including hypodermic needles, syringes, pasteur pipettes, broken glass, and scalpel blades." *Id.*

39. *Id.* § 6992a(a)(5). The section states: "Contaminated animal carcasses, body parts, and bedding of animals that were exposed to infectious agents during research, production of biologicals, or testing of pharmaceuticals." *Id.*

40. *Id.* § 6992a(a)(6). The section states: "Wastes from surgery or autopsy that were in contact with infectious agents, including soiled dressings, sponges, drapes, lavage tubes, drainage sets, underpads, and surgical gloves." *Id.*

41. *Id.* § 6992a(a)(7). The section states: "Laboratory wastes from medical, pathological, pharmaceutical, or other research, commercial, or industrial laboratories that were in contact with infectious agents, including slides and cover slips, disposable gloves, laboratory coats, and aprons." *Id.*

42. *Id.* § 6992a(a)(8). The section states: "Dialysis wastes that were in contact with the blood of patients undergoing hemodialysis, including contaminated disposable equipment and supplies such as tubing, filters, disposable sheets, towels, gloves, aprons, and laboratory coats." *Id.*

43. *Id.* § 6992a(a)(9). The section states: "Discarded medical equipment and parts that were in contact with infectious agents." *Id.*

44. *Id.* § 6992a(a)(10). The section states: "Biological waste and discarded materials contaminated with blood, excretion, exudates or secretion from human beings or animals who are isolated to protect others from communicable diseases." *Id.*

45. *Id.* § 6992a(a)(11). The section states: "Such other waste material that results from the administration of medical care to a patient by a health care provider and is found by the Administrator to pose a threat to human health or the environment." *Id.*

46. *Id.* § 6992a(b).

47. 40 C.F.R. § 259.30(a) (1989). *See supra* notes 35-39 for definitions of categories which Congress required the Administrator to include as regulated medical waste; *see supra* notes 40-44 for definitions of categories which Congress did not require the Administrator to include as regulated medical waste.

48. *Id.* § 259.30(a)(6). This section is almost identical to 42 U.S.C. § 6992a(a)(10).

and unused sharps.<sup>49</sup> The definition of sharps was expanded to include blood vials, needles with attached tubing, and culture dishes, regardless of any presence of infectious agents.<sup>50</sup> Also included were other types of broken or unbroken glassware that were in contact with infectious agents, such as slides and cover slips.<sup>51</sup>

The health care industry challenged Congress' list as over-inclusive and imprecise. The industry complained about the extra cost of medical waste disposal, and the time and energy waste handlers must expend to segregate it from the normal waste stream.<sup>52</sup> In contrast, the list's defenders suggested that "[i]mprecision [would] allow a broad analysis of the problems and [would] produce a body of reliable data during the demonstration program."<sup>53</sup> Conversely, lawmakers and environmental groups criticized the EPA list for failing to include many categories of infectious waste.<sup>54</sup> Because the Administrator was required to ascertain that the waste was not toxic to human health or the environment before excluding the waste from regulation, such criticisms were unfounded.<sup>55</sup> Including less waste also helped lower disposal costs. Finally, since the MWTA was an experimental program, the possibility for inclusion of excluded wastes in a future program minimized any potential safety risks posed by their omission.

### C. From "Cradle to Grave"

The MWTA required that medical waste be tracked from "cradle to grave."<sup>56</sup> Generators, transporters, destruction facilities, intermediate handlers and destination facilities were required to fill out forms which allowed the EPA to monitor medical waste.<sup>57</sup> Congress exempted generators of small quantities from the tracking regulations,<sup>58</sup> probably be-

49. *Id.* § 259.30(a)(7). The section states: "Unused, discarded sharps [include] hypodermic needles, suture needles, syringes and scalpel blades."

50. *Id.* § 259.30(a)(4).

51. *Id.*

52. Tokarski, *Hospitals Brace for Waste-Tracking Costs*, MOD. HEALTHCARE, Apr. 14, 1989, at 58. Generally waste handlers charge ten to fifteen times more to handle medical waste than they do for other waste. Furthermore, additional staff is necessary to ensure that the hospital and the waste handler's are following EPA's tracking requirements. *Id.*

53. Granite, *supra* note 11, at 268.

54. Tokarski, *EPA Sets Waste Tracking Plan*, MOD. HEALTHCARE, Mar. 17, 1989, at 4. It is interesting to note that the word "infectious" is not used in the U.S.C. or C.F.R. definitions. Not differentiating between waste types forces generators to treat all waste as infectious, which increases the cost of disposal greatly. Suzan Onel, Note, *The Medical Waste Tracking Act of 1988: Will It Protect Our Beaches?*, 9 VA. ENVTL. L.J. 225, 234-35 (1990).

55. See *supra* notes 45-50 and accompanying text.

56. Granite, *supra* note 11, at 268.

57. 40 C.F.R. § 259.1(c) (1989). An example of a tracking form is found in Appendix I to 40 C.F.R. pt. 259. In addition to allowing the EPA to monitor the waste, the forms also assured the generators that the waste had been received by the disposal facility. 42 U.S.C. § 6992b(a)(2) (1988).

58. 42 U.S.C. § 6992b(b) (1988). The EPA did not require generators which pro-

cause keeping track of such small amounts would have been too costly and administratively impractical. However, the MWTAs did require small generators to meet the same pre-transport requirements as large generators unless exempted by 40 C.F.R. § 259.51.<sup>59</sup>

All generators were required to segregate medical waste into sharps, fluids, and other waste.<sup>60</sup> In addition, all generators were required to follow special packaging requirements.<sup>61</sup> Medical waste had to be placed in containers that were rigid, leak-resistant, impervious to moisture, strong enough to prevent tearing or bursting under normal conditions of use and handling, and sealed to prevent leakage.<sup>62</sup> Any stored medical waste had to be protected from water, rain and wind and if it was stored outdoors the waste had to be locked to prevent unauthorized access by humans or animals.<sup>63</sup>

Finally, generators had to label untreated regulated medical waste as either "medical waste" or "infectious" or display the universal biohazard symbol before transport.<sup>64</sup> In addition, the generator had to mark the packages with its name,<sup>65</sup> its state permit or identification number,<sup>66</sup> the transporter's name,<sup>67</sup> the transporter's state permit or identification number,<sup>68</sup> the date of shipment,<sup>69</sup> and identify the contents as medical waste.<sup>70</sup> Furthermore, inner containers had to display the generator's name<sup>71</sup> and state permit or identification number.<sup>72</sup>

#### D. Enforcement

Congress modeled the enforcement scheme of the MWTAs on the Solid Waste Disposal Act (SWDA).<sup>73</sup> It authorized EPA employees to enter a generator, storage or treatment facility, transportation or disposal site at

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duced less than fifty pounds of medical waste monthly to participate in the program. 40 C.F.R. § 259.50(e)(2)(i) (1989).

59. 40 C.F.R. § 259.50(e)(2)(i) (1989).

60. *Id.* § 259.40(a)(2). If other waste was mixed with the medical waste the generator still had to label its entire contents. *Id.* § 259.40(b).

61. *Id.* § 259.40(a)(2).

62. *Id.* § 259.41(a). Furthermore, sharps had to be packaged in puncture-resistant containers, *id.* § 259.41(b)(1), and fluids of quantities of greater than twenty cubic centimeters had to be packaged in break-resistant and tightly-lidded containers. *Id.* § 259.41(b)(2).

63. *Id.* § 259.42.

64. *Id.* § 259.44(a).

65. *Id.* § 259.45(a)(1).

66. *Id.* § 259.45(a)(2).

67. *Id.* § 259.45(a)(3).

68. *Id.* § 259.45(a)(4).

69. *Id.* § 259.45(a)(5).

70. *Id.* § 259.45(a)(6).

71. *Id.* § 259.45(b)(1).

72. *Id.* § 259.45(b)(2).

73. Mercer, *supra* note 18, at 543. The inspection and enforcement provisions are almost identical to the hazardous waste provisions. See *infra* notes 257-77 and accompanying text.

reasonable times to inspect the premises and obtain samples of medical waste.<sup>74</sup> As one commentator suggested, Congress may have structured a random inspection program to ensure that those subjected to the MWTAs would comply in order to avoid severe fines, thereby making compliance routine and cost effective.<sup>75</sup> Without the threat of detection many facilities might not have complied.<sup>76</sup> In addition, if the Administrator discovered a violation he could have imposed a civil penalty or brought a civil suit in the United States district court in the district where the violation occurred.<sup>77</sup> Civil penalties for each violation could not have exceeded \$25,000 per day of noncompliance.<sup>78</sup> The potential for such high fines communicated that it was more expensive to pollute than to legally dispose of the medical waste.<sup>79</sup>

Criminal penalties could have been brought against anyone who knowingly violated the requirements of the MWTAs,<sup>80</sup> or those who knowingly omitted material information or made false statements or representations to comply with the MWTAs.<sup>81</sup> Those who knowingly generated, stored, treated, transported, disposed of, or otherwise handled any medical waste and who knowingly destroyed, altered, concealed, or failed to file any record, report, or other document in compliance with the regulations violated the law.<sup>82</sup> Upon conviction the penalty would have been a fine of not more than \$50,000 for each day of violation, or imprisonment not to exceed two years.<sup>83</sup> In addition, any person who knowingly committed the above mentioned violations and knew that at that time he was placing another person in imminent danger of death or serious bodily injury upon conviction would have been subject to a fine of up to \$250,000 or imprisonment for a maximum of fifteen years, or both.<sup>84</sup> An organization convicted under the MWTAs could have been subjected to a fine of not more than \$1,000,000.<sup>85</sup>

Although Congress set forth detailed regulations for criminal enforcement, during the length of the demonstration program no criminal charges for violating the MWTAs were ever brought in federal court. In *U.S. v. Paccione*,<sup>86</sup> however, individuals and corporations were convicted of mail fraud and RICO violations for a scheme to illegally dispose of infectious medical waste. *Paccione* demonstrates that the government's

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74. 42 U.S.C. § 6992c(a) (1988).

75. Granite, *supra* note 11, at 274.

76. *Id.* at 275.

77. *Id.* See 42 U.S.C. § 6992d(a).

78. 42 U.S.C. § 6992d(a).

79. Granite, *supra* note 11, at 275.

80. 42 U.S.C. § 6992d(b)(1).

81. *Id.* § 6992d(b)(2).

82. *Id.* § 6992d(b)(3).

83. *Id.* Furthermore, one convicted of knowingly violating the MWTAs could have been imprisoned for up to five years. *Id.*

84. *Id.* § 6992d(c).

85. *Id.*

86. 751 F Supp. 368 (S.D.N.Y. 1990), *aff'd*, 949 F.2d 1183 (2d Cir. 1991).

criminal enforcement options were not limited to bringing criminal charges under the MWTA. The absence of caselaw suggests that the threat of criminal liability under the MWTA and RICO as well as civil liability for improper disposal of medical waste provided an effective deterrent.

#### E. *Relationship to State Law*

Because the MWTA did not preempt state or local law,<sup>87</sup> it was unclear if Congress intended the federal government or the states to implement and enforce the provisions. Congress specifically permitted a state to enforce the provisions of the MWTA to the same extent as the Administrator.<sup>88</sup> In addition, since Congress provided limited funding for enforcement, it appears that Congress intended that the states enforce the MWTA.<sup>89</sup> However, EPA enforcement strategy asserted that state action brought in federal court under the MWTA would not bind the EPA.<sup>90</sup> This strategy thwarted state efforts to enforce the MWTA. A regulated party who knew that the federal government could bring its own suit against him after conclusion of the state action would be unlikely to settle with the state.<sup>91</sup> Furthermore, EPA policy required that the state forward all the penalties it collected under the MWTA to the federal treasury.<sup>92</sup> This policy may further have chilled states' initiative to sue violators under the MWTA.

#### F. *Report to Congress*

The MWTA required that the EPA submit two interim reports and a final report to Congress on twelve topics.<sup>93</sup> The first report was submitted in May 1990.<sup>94</sup> Chapter 1 of the report analyzes the types, number and size of generators of medical waste.<sup>95</sup> Chapter 2 addresses the risk to

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87. 42 U.S.C. § 6992f(b)(1) (1988).

88. *Id.* § 6992f(a). A state which did initiate such a suit was required to notify the Administrator. *Id.*

89. Hubert H. Humphrey III & LeRoy C. Paddock, *The Federal and State Roles in Environmental Enforcement: A Proposal For a More Effective and More Efficient Relationship*, 14 HARV ENVTL. L. REV. 7, 30 (1990).

90. *Id.* at 30 n. 153. Under most environmental laws similar concerns about whether state enforcement precludes a subsequent federal enforcement action arises; however, no other federal law has provided as much direct enforcement authority to the states as the MWTA. *Id.*

91. *Id.* at 30.

92. *Id.*

93. 42 U.S.C. § 6992g(a),(b). The twelve topics the Administrator was to report on are listed in § 6992g(a)(1)-(12).

94. ENVIRONMENTAL PROTECTION AGENCY, MEDICAL WASTE MANAGEMENT IN THE UNITED STATES (FIRST INTERIM REPORT TO CONGRESS, EXECUTIVE SUMMARY, MAY 1990) (NOTIFICATION OF REPORT IN 55 FED. REG. 28,096 (1990)) [hereinafter First Interim Report].

95. See 42 U.S.C. § 6992g(a)(1) (1988); see also First Interim Report, *supra* note 94, at v (specifying the report is structured according to the topics outlined in § 6992g(a)(1) through (12)).

the environment and human health from incineration of medical waste.<sup>96</sup> Chapter 3 estimates the costs of the regulations which implement the MWTAs and the loss of value due to mismanaged medical waste.<sup>97</sup> Chapter 4 explains what steps have been taken to determine the success of the MWTAs.<sup>98</sup> Chapters 5 through 8 evaluate the effectiveness of methods of handling, storing, transporting, disposing and treating medical waste.<sup>99</sup> Chapter 9 studies the uncovered states response to the medical waste disposal problem.<sup>100</sup> Chapter 10 outlines the procedures which will be used to collect information on the appropriateness of penalties.<sup>101</sup> Chapter 11 studies the effect of the MWTAs exclusion of households and small quantity generators from parts of the MWTAs.<sup>102</sup> The final chapter evaluates recycling and reuse techniques.<sup>103</sup>

The second report, issued seven months later in December 1990, updated the twelve topics outlined in the first report.<sup>104</sup> The EPA determined that in seven months it had made substantial progress in the characterization of the generation and management of medical waste and the development of guidelines for home health care waste.<sup>105</sup> Furthermore, the EPA found that an indirect effect of the MWTAs was the encouragement of innovation in treatment technologies.<sup>106</sup>

Although the final report on medical waste was to be submitted to Congress no later than three months after the expiration of the MWTAs,<sup>107</sup> by November 1992 the report had not yet been made available by the EPA. The information gathered during the MWTAs's dura-

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96. First Interim Report, *supra* note 94, at 1-ii. The chapter evaluates the health hazards posed by incineration, landfilling and sewage disposal of medical waste. *Id.*

97. *Id.* at ii. The cost of the regulations which implement the MWTAs were estimated at \$24 million and the preliminary estimate of loss of value to Connecticut, New York, and New Jersey due to mismanaged medical wastes was \$30 million. *Id.*

98. *Id.* The EPA defined the objective of the MWTAs as "ensuring that the wastes subject to the regulations are delivered to treatment or disposal facilities with a minimum of exposure to waste management workers and the public." *Id.* The criteria used to determine the success of the MWTAs were state participation, compliance with the regulations, technical adequacy of the regulations, and the regulations' potential effects on recreational/occupational injuries and disease. In addition, the EPA intended to evaluate the MWTAs's effects on beach washups and beach closings. *Id.*

99. *Id.* at iii. See 42 U.S.C. § 6992g(a)(5)-(8).

100. First Interim Report, *supra* note 94 at iii. Most states required certain packaging and labeling techniques and treatment before land disposal. *Id.*

101. *Id.* at ii-iii.

102. *Id.* at 1. See 42 U.S.C. § 6992g(a)(11). The EPA concluded that home health care waste is likely to contain a significant number of syringes, one of the items of concern to Congress. *Id.*

103. First Interim Report, *supra* note 94, at iii.

104. ENVIRONMENTAL PROTECTION AGENCY, MEDICAL WASTE MANAGEMENT IN THE UNITED STATES IV (Second Interim Report to Congress, Executive Summary, December 1990).

105. *Id.*

106. *Id.* at iii. The EPA also identified the reevaluation of home health care waste management, reduction in the severity of beach wash-ups, and the contribution to program development in non-covered States as indirect effects of the MWTAs. *Id.*

107. 42 U.S.C. § 6992g(a) (1988).

tion was to serve as a data base from which Congress and the EPA could develop a "strong and effective" permanent regulatory scheme to control medical waste.<sup>108</sup> Presumably, since Senator Durenberger has already introduced the Medical Waste Management Act of 1991, the information in the interim reports must have contained sufficient information to develop a national program.

### III. THE NEED FOR NATIONAL REGULATION OF MEDICAL WASTE DISPOSAL

#### A. *The Commerce Clause*

"[Medical] wastes travel across State boundaries so State programs by themselves are inadequate."<sup>109</sup> This single statement reflects the need for nationwide regulation of medical waste disposal. Since the beach scare of 1987, most states have adopted medical waste statutes.<sup>110</sup> These statutes feature subtle differences to which transporters shipping medical waste across state lines must conform.<sup>111</sup> Since the Constitution delegates the power to regulate interstate commerce to Congress,<sup>112</sup> Congress may, by implementing a national policy towards medical waste, prevent states from prohibiting the importation of waste to facilities within their borders. The Supreme Court has consistently upheld this principle that states may not enact legislation which effects economic isolation.<sup>113</sup>

In *City of Philadelphia v. New Jersey*,<sup>114</sup> the Supreme Court first articulated that the Commerce Clause forbids states from prohibiting the importation of waste. New Jersey had attempted to slow the flow of all waste into landfills by prohibiting the importation of most solid or liquid waste originating outside the state.<sup>115</sup> The Supreme Court held that this

108. 134 CONG. REC. S15,327 (daily ed. Oct. 7, 1988) (statement of Sen. Baucus).

109. 134 CONG. REC. S15,328 (daily ed. Oct. 7, 1988) (statement of Sen. Lautenberg); 137 CONG. REC. S5,898 (daily ed. May 15, 1991) (statement of Sen. Lautenberg).

110. Some comprehensive medical waste programs developed by the states are: ARIZ. REV. STAT. ANN. §§ 49-761, 765 (1992); ARK. STAT. ANN. § 20-32-10 *et seq.* (1992); CAL. HEALTH & SAFETY CODE § 25015 *et seq.* (West 1991); ILL. REV. STAT. Ch. 111 1/2, par. 1056 *et seq.* (1992); MICH. COMP. LAWS § 333.13810 *et seq.* (1991); N.J. REV. STAT. § 13:11-48.1 *et seq.* (1991); N.Y. PUB. HEALTH LAW § 1389-aa to -hh (McKinney 1992); N.C. GEN. STAT. § 130A-309.26 (1991); R.I. PUB. LAWS § 497 (1992); W. VA. CODE § 20-5J-2 *et seq.* (1991).

111. "Infectious waste generators and transporters ship two-thirds of all waste interstate." Schumaker, *supra* note 16, at 558.

112. "The Congress shall have Power [t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes. " U.S. CONST. art. I, § 8, cl.3; "The Congress shall have Power [t]o make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof." *Id.* art. I, § 8, cl.18.

113. See *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935); *H.P. Hood & Sons v. DuMond*, 336 U.S. 525 (1949); *Dean Milk Co. v. City of Madison*, 340 U.S. 349 (1951).

114. 437 U.S. 617 (1978).

115. *Id.* at 625. Chapter 363 of 1973 N.J. LAWS, in pertinent part, provides: "No person shall bring into this state any solid or liquid waste which originated or was col-

practice was unconstitutional because all objects of interstate trade merit Commerce Clause protection.<sup>116</sup> "What is crucial is the attempt by one State to isolate itself from a problem common to many by erecting a barrier against the movement of interstate trade."<sup>117</sup> Thus, New Jersey could not close its doors to out-of-state waste, even under the guise of protecting the health and welfare of her citizens.

In *Government Suppliers Consolidating Services, Inc. v. Bayh*,<sup>118</sup> an Indiana district court applied *City of Philadelphia*<sup>119</sup> to strike down a law requiring transporters of waste to secure certification from a state or local public health or environmental officer stating that a load is not subject to regulation under the SWDA or is not infectious.<sup>120</sup> The court found that health certification would be difficult, if not impossible, to obtain because it is unlikely that officials in other states would be familiar with Indiana law.<sup>121</sup> Furthermore, state officials, occupied with enforcing their own laws and regulations, have neither the time nor the resources to provide these statements.<sup>122</sup> Although states do retain authority under general police powers to regulate matters of legitimate local concern, the disposal of hazardous and infectious waste is a national problem.<sup>123</sup> The purpose of the Commerce Clause is to prevent one state from prohibiting or deterring the residents of other states from sharing in the commerce available in that state.<sup>124</sup> The court held that there simply was not enough evidence that the regulations resulted in "cleaner" state waste to justify a discriminatory treatment of out-of-state waste.<sup>125</sup>

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lected outside the territorial limits of the State, until the Commissioner [of the State Department of Environmental Protection] shall determine that such action can be permitted without endangering the public health, safety and welfare and has promulgated regulations permitting and regulating the treatment and disposal of such waste in this State." *Id.* at 618-19 (quoting N.J. STAT. ANN. § 13:1I-10 (West Supp. 1978)).

116. *Id.* at 622.

117. *Id.* at 628.

118. 753 F Supp. 739 (S.D. Ind. 1990).

119. 437 U.S. 617 (1978).

120. The law in question was enacted under Indiana's medical waste tracking scheme. Indiana had been one of the states covered by the MWTAs, but opted out. The Governor of Indiana wanted an Indiana plan in operation so its effectiveness could be analyzed. The Governor also felt that the cost of the federal program was too high. The federal act covered some wastes which were exempt from Indiana law. Indiana's scheme focused on materials deemed capable of transmitting infections, while the MWTAs covered a broader range of medical waste. *Government Suppliers Consolidating Services v. Bayh*, 753 F Supp. 739, 754 (S.D. Ind. 1990). In addition, Indiana emphasized the treatment of infectious waste, whereas the MWTAs emphasized tracking. *Id.* at 771.

121. *Id.* at 751.

122. *Id.*

123. *Id.* at 763. "The states retain authority under their general police powers to regulate matters of legitimate local concern even though interstate commerce is affected." *Id.*

124. *Id.* at 764-65 n.29.

125. *Id.* at 772. "Regulatory differences are not enough to justify the discriminatory treatment of out-of-state waste, without sufficient evidence that the effect of the regulation actually results in 'cleaner' in-state waste." *Id.*

An ordinance which excluded infectious medical waste generated outside the county was invalidated in *BFI Medical Waste Systems, Inc. v. Whatcom County*<sup>126</sup> The district court held that the ordinance on its face discriminated against commerce solely on the basis of its origin.<sup>127</sup> Further, the court found that the quarantine exception did not apply because the county had its own medical waste, no different from that banned by the ordinance.<sup>128</sup> If the county had been concerned with the ill effects of incineration, it should have directly addressed the issue instead of excluding out-of-county wastes while continuing to process county waste.<sup>129</sup>

In *Diamond Waste, Inc. v. Monroe County Georgia*,<sup>130</sup> the Eleventh Circuit invalidated a Georgia statute which allowed counties to discriminate against interstate waste. Monroe County had rejected the application of Diamond Waste to open a regional landfill in order to prevent the importation of out-of-county refuse.<sup>131</sup> The court held that the county could not prohibit all out-of-county waste, reiterating the proposition set forth by the Supreme Court in *City of Philadelphia*<sup>132</sup> that a state can safeguard the health and safety of its citizens, but may not practice economic protectionism under the Commerce Clause.<sup>133</sup> The court found that the statute violated the Commerce Clause because its impact on interstate commerce could have been substantial and the county could have achieved its objectives in a less burdensome manner.<sup>134</sup>

Last term the Supreme Court reemphasized its belief that a state may not discriminate against out-of-state waste. In *Fort Gratiot Sanitary Landfill, Inc. v. Michigan Dep't. of Natural Resources*<sup>135</sup> the Court stated that "[s]olid waste, even if it has no value, is an article of commerce."<sup>136</sup> Thus, Michigan could not enact a waste management plan discriminating

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126. 756 F Supp. 480 (W.D. Wash. 1991).

127. *Id.* at 484. Ordinance No. 89-61 stated, in pertinent part: "*Restrictions on Importation of Out-of-County Generated Infections [sic] Medical Waste.* Effective January 1, 1990, infectious medical waste generated outside the territorial limits of Whatcom County shall not be accepted for disposal at a waste disposal facility within Whatcom county [sic]." *Id.* at 482.

128. *Id.* at 486. "The Supreme Court rejected the 'quarantine exception' argument in *City of Philadelphia* for the same reason." *Id.*

129. *Id.*

130. 939 F.2d 941 (11th Cir. 1991).

131. *Id.* at 943. The Monroe County Commission passed the following resolution: "[T]he Board of Commissioners resolve[s] to prevent the creation of this Regional Landfill, by legal action if necessary, so that we will prevent garbage, trash, or waste of any kind from being transported into Monroe County from other counties and locations." *Id.*

132. 437 U.S. 617 (1978).

133. *Diamond Waste, Inc.*, 939 F.2d at 944.

134. *Id.* at 945. The court stated that the county could have achieved its goals of preserving existing landfill space and preventing environmental damage by instituting policies of daily tonnage limits, permitting "first come, first served" waste disposal, issuing auction permits, or establishing a lottery system to determine what out-of-county refuse would be accepted by the regional landfill. *Id.*

135. 112 S. Ct. 2019 (1992).

136. *Id.* at 2023.

against out-of-county waste.<sup>137</sup> The Court found that even if the statute purported to regulate inter-county commerce in waste and even if some Michigan counties did accept out-of-state waste, the case presented no factor substantially distinguishing it from *City of Philadelphia*.<sup>138</sup> There were no valid health and safety reasons for limiting the amount of waste accepted from outside the state but not from inside the state.<sup>139</sup>

Supreme Court doctrine thus declares that states may not close their borders to or discriminate against foreign waste. However, the Court has stated that, in limited circumstances, discrimination against waste may be justified for health and safety reasons.<sup>140</sup> Since the Court has not yet addressed the issue of medical waste, it is unclear if the Court would hold that discrimination of medical waste is justified for health reasons. Despite the Supreme Court's prohibition, Congress, through the Commerce Clause, may permit states to discriminate against foreign waste. The Senate began the process of legalizing state waste discrimination by passing the Interstate Transportation of Municipal Waste Bill introduced by Senator Daniel Coates.<sup>141</sup> The Interstate Transportation of Municipal Waste Act of 1992 authorizes any governor to prohibit the disposal of out-of-state municipal waste in any landfill or incinerator under his jurisdiction.<sup>142</sup> The governor is not permitted to exclude any waste if such action would result in the violation of a prior legal contract.<sup>143</sup> The Interstate Transportation of Municipal Waste Act does not cover the transport of medical and other hazardous waste.<sup>144</sup> However, the EPA through RCRA already regulates hazardous waste disposal.<sup>145</sup> If Congress enacts the Medical Waste Management Act of 1991, medical waste will be addressed as a sub-category of federally regulated hazardous waste.<sup>146</sup>

The Interstate Transportation of Municipal Waste Act may provide a feasible means for handling the municipal waste problem, but such a system would wreak havoc upon the medical profession. Medical waste dis-

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137. In 1988, Michigan amended its Solid Waste Management Act of 1978 (SWMA) to require that landfills cannot accept waste generated outside the county unless there is explicit authorization in the county's solid waste management plan. Fort Gratiot Sanitary Landfill applied to St. Clair County Solid Waste Planning Committee for authority to accept 1,750 tons of out-of-state waste. The application was denied. *Id.* at 2022.

138. *Id.* at 2025-26.

139. *Id.* at 2027. "[T]he Waste Import Restrictions unambiguously discriminate against interstate commerce and are appropriately characterized as protectionist measures that cannot withstand scrutiny under the Commerce Clause." *Id.* at 2028.

140. See *City of Philadelphia*, 437 U.S. at 624, 628.

141. S. 2877, 102d Cong., 2d Sess., 138 CONG. REC. S10,198 (1992). The specific purpose of the bill was to counter the Supreme Court's ruling in *Fort Gratiot*. 138 CONG. REC. S10,198, S10,200 (daily ed. July 23, 1992) (statement of Sen. Dole).

142. S. 2877, 102d Cong., 2d Sess. § 4011(a)(1)(A)(i); 138 CONG. REC. S10,211 (1992).

143. *Id.* § 4011(a)(C)(i).

144. S. 2877, 102d Cong., 2d Sess. § 4011(d), 138 CONG. REC. S10,211, S10,212 (1992).

145. See 42 U.S.C. §§ 6921-29 (1988).

146. See *infra* note 200.

posal costs would increase dramatically since in many states it is cheaper to ship medical waste out of state rather than to dispose of it internally.<sup>147</sup> However, national concern over health care costs makes it unlikely Congress would allow states to prohibit the disposal of medical waste within their borders.

### B. *The Tenth Amendment*

Although the Commerce Clause clearly authorizes Congress to regulate interstate commerce,<sup>148</sup> the Tenth Amendment limits the requirements Congress can impose upon the states for the purpose of carrying out a federal agenda.<sup>149</sup> In *New York v. United States*,<sup>150</sup> the Supreme Court safeguarded the principle of balance of powers by invalidating portions of the Low-Level Radioactive Waste Policy Amendments Act of 1985.<sup>151</sup> The Court held that although Congress has substantial power under the Constitution to encourage states to provide for disposal of radioactive waste generated within their borders, it cannot compel states to do so.<sup>152</sup> Under Commerce Clause authority Congress can give states the choice of regulating activity according to federal standards or having state law preempted by federal regulation.<sup>153</sup> However, the state residents retain the ultimate decision as to whether or not the state will comply.<sup>154</sup> Thus, the provision in which the state was required to take possession of low-level radioactive waste generated within the state was unconstitutional because it would have "commandeered" state governments to serve federal regulatory purposes.<sup>155</sup>

The Tenth Amendment does not prevent Congress from legislatively

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147. For example, in 1989 the cost of disposing medical waste in New York was \$125 a ton. In Indiana the cost was only \$12 a ton. To ship the refuse from New York to Indiana cost \$33 a ton. Thus, the total cost to ship the waste from Long Island to Indiana was \$45 a ton, which resulted in an \$80 savings. *Government Suppliers Consolidating Services v. Bayh*, 753 F. Supp. 739, 748 (S.D. Ind. 1990).

148. *See supra* note 112.

149. "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. CONST. AMEND. X.

150. 112 S. Ct. 2408 (1992).

151. 42 U.S.C. § 2021b *et seq.* (1991). The amendments provided three incentives to encourage states to comply with their statutory obligation to provide for the disposal of low-level radioactive waste generated within their borders. States which comply with the regulations receive monetary and access incentives. *Id.* §§ 2021e(d)(2)(B), 2021e(d)(2)(C), 2021e(e)(1)(D), 2021e(e)(2)(D). However, states which do not provide for the disposal of low-level radioactive waste by January 1, 1996 are obligated to take possession of the waste. *Id.* § 2021e(d)(2)(C).

152. 112 S. Ct. 2408, 2414 (1992).

153. *Id.* at 2424. The Court used as examples the Clean Water Act, 33 U.S.C. § 1251 *et seq.*, the Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 *et seq.*, and the Resource Conservation and Recovery Act of 1976, 42 U.S.C. § 6901 *et seq.* *Id.*

154. *Id.*

155. *Id.* at 2428. Only the third incentive was ruled unconstitutional and was severed from the Act. The monetary and access provisions are valid incentives for the state to follow federal policy and are constitutional. *Id.* at 2434.

delegating the responsibility for promulgating regulations to safeguard the environment and public health to agencies such as the EPA and OSHA. Unfortunately, implementation of such regulations requires corresponding funds. In the current economic climate, Congress has difficulty finding the resources for their enforcement. As discussed above, the Tenth Amendment prohibits Congress from shifting the economic burden to the states by mandating that they carry out such programs. Nevertheless, states also wish to protect the environment and health of their citizens,<sup>156</sup> and have cooperated with the federal government to implement nationwide programs which protect the health of Americans.<sup>157</sup> This same cooperation is needed to resolve the medical waste dilemma to avoid enactment of onerous federal legislation similar to the Low-Level Radioactive Waste Policy Amendments in order to increase state incentive to address medical waste disposal.

#### IV THE OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS STANDARD

##### A. Background

Even before the 1987 beach scare, health care employees requested that the federal government, through OSHA, require employers to adopt precautionary measures to protect those handling medical waste. Beginning in 1986, health care workers' unions consistently requested that OSHA issue guidelines on the proper treatment of medical waste. However, OSHA did not even propose any rules until 1989.<sup>158</sup> Finally, after health care workers complained of the delay in developing protective standards, Congress passed legislation requiring OSHA to issue guidelines by December 1, 1991.<sup>159</sup> The Standard on Occupational Exposure to Bloodborne Pathogens, effective as of March 6, 1992,<sup>160</sup> is the first set of rules that OSHA has issued in the health care industry.<sup>161</sup> The regulations cover an estimated 4.9 million health care workers and 700,000 Americans who routinely handle blood or bodily fluids on the job.<sup>162</sup>

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156. Even though federal assistance to the states has decreased, state budgets for environmental programs have increased substantially since 1982. Humphrey & Paddock, *supra* note 89, at 36.

157. For example, the Solid Waste Disposal Act (SWDA), under which authority the MWTAA was enacted, has specific guidelines for state implementation of the federal statute. Under the SWDA states regulate the treatment and disposal of medical waste. See 42 U.S.C. §§ 6941-6949 (1988). A future statute on the management of medical waste should be modelled after the successfully implemented legislation on hazardous waste. See *infra* notes 195-278 and accompanying text discussing the Medical Waste Management Act bill.

158. *Anti-Virus Rules Issued for Health Workers*, N.Y. TIMES, Dec. 3, 1991, at C9.

159. Frank Swoboda, *OSHA Mandates AIDS Protection: Agency's New Regulations Cover Health Care Workers, Others*, WASH. POST, Dec. 3, 1991, at A1.

160. See 56 Fed. Reg. 64,048 (1991).

161. Swoboda, *supra* note 159.

162. *Anti-Virus Rules Issued for Health Workers*, N.Y. TIMES, Dec. 3, 1991, at C9. The Standard applies to these industries: physicians' offices, dental offices, hospitals,

The regulations deal only with the handling of medical waste; they do not mandate any procedures regarding medical waste treatment or disposal. The purpose of the Standard is to reduce the chance of workers contracting disease because of exposure to medical waste.<sup>163</sup>

Prior to issuance of the Standard, OSHA published findings on the possibility of workers contracting hepatitis-B and Human Immunodeficiency Virus (HIV) in the absence of any guidelines.<sup>164</sup> The CDC found that annually over 2,100 workers contract hepatitis-B, between 400-440 of those infected require hospitalization, and approximately 200 die.<sup>165</sup> The large amount of infections reflects the ability of the hepatitis-B virus to survive for at least one week, dried, at room temperature, on exposed surfaces.<sup>166</sup> Since the HIV virus can only be transmitted through direct contact with bodily fluids,<sup>167</sup> the risk of contracting HIV is smaller. As of May 1990, however, there were at least 65 reported cases of health care workers whose HIV infections were associated with occupational exposure.<sup>168</sup> OSHA predicted that implementation of the Standard could prevent approximately 200 deaths and 9,200 bloodborne infections per year.<sup>169</sup>

### B. *The Standard*

The Standard begins by defining various terms, providing a generalized definition of regulated medical waste;<sup>170</sup> the definitions are provided so that employers understand exactly what the Standard requires of them.

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medical and dental laboratories, nursing homes, residential care facilities, dialysis centers, drug treatment centers, home health care hospices, government out-patient facilities, blood collectors and blood processors, health clinics in industrial facilities, personnel services, funeral homes and crematories, research laboratories, linen services, medical and dental equipment and repair services, law enforcement, fire and rescue services, correctional institutions, schools for the mentally retarded, lifesaving services, and handlers of medical waste. 56 Fed. Reg. 64,038 (1991).

163. Before issuing regulations, OSHA must determine from the evidence in the record that there is a significant risk of health impairment under existing exposure conditions and that issuance of a new standard will significantly reduce or eliminate that risk. *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 642 (1980).

164. *See* 56 Fed. Reg. 64,004-16 (1991).

165. *Id.* at 64,009 (1991).

166. *Id.* at 64,012.

167. *Id.* at 64,032. HIV is the virus which eventually leads to the development of Acquired Immune Deficiency Syndrome (AIDS), a fatal disease.

168. *Id.* at 64,016. In addition, many infections are likely to go unrecognized for several years until the HIV-infected individual develops AIDS. *Id.* at 64,014.

169. *Anti-Virus Rules Issued for Health Workers*, N.Y. TIMES, Dec. 3, 1991, at C9.

170. "Regulated waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials." 56 Fed. Reg. 64,175 (1991) (to be codified at 29 C.F.R. § 1910.1030(b)).

All employers whose employees handle medical waste<sup>171</sup> must establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.<sup>172</sup> The Exposure Control Plan must be reviewed and updated annually. If the employer implements new or modified tasks and procedures or creates new or revised positions which expose employees to medical waste, the employer must update the Plan more frequently.<sup>173</sup>

One of the most important parts of the Exposure Control Plan is the Methods of Compliance Program. In general, employees must follow universal precautions<sup>174</sup> to prevent contact with blood or other potentially infectious materials.<sup>175</sup> Furthermore, generators must adopt specific procedures to minimize workers' risk of contracting infectious diseases. Engineering and work practice controls include providing handwashing facilities,<sup>176</sup> placing contaminated reusable sharps in appropriate containers until properly reprocessed,<sup>177</sup> placing specimens of blood or other potentially infectious materials in containers which prevent leakage during collection, handling, processing, storage, transport or shipping<sup>178</sup> and prohibiting food or drink where blood or other potentially infectious materials are present.<sup>179</sup> During occupational exposure the employer must provide the employee with personal protective equipment.<sup>180</sup> Finally, as a method of compliance, the employer must ensure that the worksite is maintained in a clean and sanitary condition.<sup>181</sup>

The most unique section of the Standard is the hepatitis-B vaccination and post-exposure evaluation and follow-up requirement. This requirement obligates the employer to provide the hepatitis-B vaccine, free of

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171. Occupational exposure is defined as "reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties." *Id.*

172. 56 Fed. Reg. 64,175-76 (1991) (to be codified at 29 C.F.R. § 1910.1030(c)). The Exposure Plan must at least contain exposure determination findings, a schedule and method of implementation for compliance, hepatitis-B vaccination and post-evaluation and follow-up procedures, communication of hazards to employees, record keeping of the Standard, and procedures for the evaluation of circumstances surrounding exposure incidents as required by the Standard. *Id.* at (c)(ii). In addition, there are specific procedures which must be followed for HIV and hepatitis-B research laboratories and production facilities. *Id.* at (c)(ii)(B). Finally, the Plan must be made available to the Assistant Secretary and Director of Labor for Occupational Safety and Health upon request. *Id.* at (c)(v).

173. *Id.* at (c)(iv).

174. "Universal precautions is an approach to infection control [which treats] all human blood and certain human body fluids. . . as if known to be infectious for HIV, [hepatitis-B] and other bloodborne pathogens." *Id.* at 64,175.

175. *Id.* at 64,176(d)(1).

176. *Id.* at (d)(2)(iii).

177. *Id.* at (d)(2)(viii).

178. *Id.* at (d)(2)(xiii).

179. *Id.* at (d)(2)(ix).

180. *Id.* at 64,177 (d)(3)(i). Protective equipment includes, but is not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, mouthpieces, resuscitation bags, pocket masks or other ventilation devices. *Id.*

181. *Id.* at (d)(4)(i).

charge, to all employees at risk of occupational exposure.<sup>182</sup> If the employee refuses the hepatitis-B vaccination he or she must sign a statement indicating that he understands that he or she may contract the disease.<sup>183</sup> In addition, the employer must provide any necessary boosters.<sup>184</sup>

### C. Costs of the Standard

Even before the Standard was issued, both OSHA and the health care industry were concerned about the cost of implementation. OSHA estimated that the annual cost of the new regulations would be \$821 million for all affected industries.<sup>185</sup> Annual incremental costs for waste removal were estimated at \$1.9 million.<sup>186</sup> To control cost increases, OSHA suggested three alternatives to removal of medical waste for off-site treatment.<sup>187</sup> Generators may render the waste non-infectious prior to disposal in order to use the less expensive general waste stream,<sup>188</sup> they may incinerate the waste on site<sup>189</sup> or they may operate autoclaves (steam sterilization equipment) on site.<sup>190</sup> In addition, generators can

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182. *Id.* at (f)(1)(ii).

183. *Id.* at (f)(2)(iv). The statement will be located in Appendix A to 29 C.F.R. § 1910.1030.

184. *Id.* at (f)(2)(v).

185. Swoboda, *supra* note 159.

186. 56 Fed. Reg. 64,077 (1991).

187. Only about fifteen percent of hospitals transport their medical waste off-site for treatment. Schumaker, *supra* note 16, at 586.

188. The cost of disposing infectious waste is five times that of removing routine waste. Lynn Wagner, *REGULATION: Allen Moore: Multitude of Complex Waste Regulation Makes Hospitals' Jobs Harder*, *Costlier*, MOD. HEALTHCARE, Feb. 24, 1992, at 32.

189. Incineration is the conversion by fire or intense heat of infectious waste into non-combustible residue or ash. It is estimated that sixty-seven percent of hospitals in the country use on-site incinerators. Incineration is popular because it reduces the volume and mass of waste material by eighty to ninety-five percent, thereby reducing the cost of transporting the waste. Schumaker, *supra* note 16, at 585-86. However, the large quantities of plastic incinerated causes emission of acids into the atmosphere, which disturbs communities in which incinerators are located. Onel, *supra* note 54, at 244. Recently, incidents of disputes over openings of medical waste incinerators have taken place throughout the country. See Dennis Hevesi, *Bronx Foes Try to Stop Medical Incinerator*, N.Y. TIMES, Nov. 2, 1991, at 25; Ian Fisher, *Judge Orders Temporary Halt to Tests at Medical Waste Incinerator*, N.Y. TIMES, Sept. 1, 1992, at B3 (judge issued temporary restraining order to stop preliminary testing of the same Bronx plant almost a year later). See also Frances Frank Marcus, *Medical Waste Divides Mississippi Cities*, N.Y. TIMES, June 24, 1992, at A16 (Dispute between cities of Pascagoula, which owns incinerator, and Moss Point, where incinerator is located.). Furthermore, Congress is considering proposals which would require incinerators to reduce the amount of dioxins released. But, enactment of such legislation would force hospitals to either retrofit most existing incinerators or build new incinerators to meet the stringent emissions requirements; thereby further increasing the cost of medical waste disposal. Lynn Wagner, *supra* note 188, at 32.

190. 56 Fed. Reg. 64,084-85 (1991). Sterilization, or autoclaving, of medical waste uses the same procedure hospitals use to sterilize equipment. Saturated steam within a pressurized vial is used to kill dangerous pathogens. It is estimated that sixteen percent of hospitals in the country use sterilization. It is probably the second most popular form of treatment since it is simple and the health care industry is familiar with this procedure.

reduce disposal costs by ensuring that workers properly separate infectious waste from routine waste.<sup>191</sup> Finally, the Standard internalizes the external costs of improper waste disposal that society, individual workers and their families would otherwise bear.<sup>192</sup>

While improving employee health, the Standard will also safeguard the environment. It gives industries dealing with infectious waste an incentive to handle it properly, since violations carry fines between \$1,000 and \$70,000.<sup>193</sup> "To the extent that infectious waste in the general waste stream is currently handled improperly, the rule may improve environmental quality as previously mishandled infectious waste is redirected toward preferred disposal alternatives."<sup>194</sup> OSHA seems to imply that an indirect effect of requiring proper *handling* of medical waste will be proper *treatment* and *disposal* of medical waste. Regulation of medical waste disposal goes one step further than the Standard; it protects not only the health of workers, but the health of all Americans. OSHA does not have the authority to mandate disposal methods, but the development and implementation of such methods should not remain within the discretion of the health care industry. Congress must use its authority to ensure the proper disposal of medical waste.

## V. THE MEDICAL WASTE MANAGEMENT ACT OF 1991

### A. Background

The MWTA expired in June 1991<sup>195</sup> and was not reauthorized, although a bill extending the MWTA for an additional two years was proposed in the Senate.<sup>196</sup> A week before OSHA issued the Standard on Occupational Exposure to Bloodborne Pathogens, Senator Dave Durenberger introduced the Medical Waste Management Act of 1991 (MWMA).<sup>197</sup> The MWMA constitutes a complete management program, more comprehensive than the MWTA, describing national standards for storage, treatment, transportation and disposal of medical waste.<sup>198</sup> Senator Durenberger wants the bill to be considered as an

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However, sterilization does not reduce the mass of the waste and often produces offensive odors. Schumaker, *supra* note 16, at 589-92.

191. Wagner, *supra* note 188, at 32.

192. 56 Fed. Reg. 64,079 (1991).

193. Lisa Belkin, *Frustrating Spate of New Rules for Clinics*, N.Y. TIMES, Aug. 30, 1992, at 33, 37.

194. 56 Fed. Reg. 64,088 (1991).

195. See 42 U.S.C. § 6992(d); See also 56 Fed. Reg. 54,064, 3714 (1991) (ending statutory authority of the MWTA).

196. Sen. Lautenberg introduced a bill to the Senate calling for a two-year extension of the MWTA. 137 CONG. REC. S5,898 (daily ed. May 15, 1991) (statement of Sen. Lautenberg).

197. S. 2108, 102d Cong., 1st Sess., 137 CONG. REC. S18,334, S18,336 (1991). The bill was sent to the Committee on Environment and Public Works on November 26, 1991.

198. 137 CONG. REC. S18,429 (daily ed. Nov. 26, 1991) (statement of Sen. Durenberger). Because the bill was introduced before OSHA issued the Occupational Exposure to Bloodborne Pathogens Standard, some of the sections which require that the

amendment to the Resource Conservation and Recovery Act of 1976 (RCRA) reauthorization legislation.<sup>199</sup> If passed, the Medical Waste Management Act of 1991 would be added to the Solid Waste Disposal Act (SWDA).<sup>200</sup>

In the bill's national policy announcement, Congress declares that the MWMA will encourage "the proper collection, handling, treatment and disposal of medical waste . . . to the maximum extent achievable."<sup>201</sup> It will curtail improper medical waste management to protect the public health and the environment in the United States.<sup>202</sup> Furthermore, "a comprehensive approach to medical waste management" will be implemented to foster "compliance with standards necessary to protect human health and the environment."<sup>203</sup>

### B. *Medical Waste Definitions*

Following the policy announcement, the bill defines the term regulated medical waste<sup>204</sup> as including, but not limited to, cultures and stocks of infectious agents,<sup>205</sup> human pathological wastes,<sup>206</sup> liquid waste from human blood,<sup>207</sup> sharps,<sup>208</sup> contaminated animal carcasses,<sup>209</sup> biological

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EPA, in conjunction with OSHA, issue regulations regarding the handling of medical waste are no longer necessary. *See infra* notes 219, 233 and 296 and accompanying text.

199. *Id.* RCRA, 42 U.S.C. §§ 6901-6992 (1988), is up for reauthorization this year.

200. *Id.* Subtitle J of the SWDA, 42 U.S.C. §§ 6921-39 (1988), which is the provision on hazardous waste disposal, would be amended to include the Medical Waste Management Act.

201. S. 2108, 102d Cong., 1st Sess. § 11001(a)(A) (1991).

202. *Id.* §§ 11001(a)(B), 11001(a)(C).

203. *Id.* § 11001(b).

204. *Id.* § 11002(1). The section specifically states: "'[R]egulated Medical Waste' means any solid waste or secondary materials generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. Such term does not include any 'hazardous waste' identified or listed under section 3001 or any 'household waste' as defined in regulations under subtitle C . . ." *Id.*

205. *Id.* § 11002(1)(A). The section states: "'Cultures and stocks of infectious agents and associated biologicals, including cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines and culture dishes and devices used to transfer, inoculate, and mix cultures.'" *Id.*

206. *Id.* § 11002(1)(B). The section states: "'Human pathological wastes, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids and their containers.'" *Id.*

207. *Id.* § 11002(1)(C). The section states: "'Liquid waste human blood, items saturated or dripping with human blood, items that were saturated or dripping with human blood that are now caked with dried human blood, and products of blood, including serum, plasma, and other blood components and their containers, which were used or intended for use in either patient care, testing and laboratory analysis or the development of pharmaceuticals and including intravenous bags.'" *Id.*

208. *Id.* § 11002(1)(D). The section states: "'Sharps that have been used in animal or human patient care or treatment or in medical research or industrial laboratories, including hypodermic needles, syringes (with or without attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing and culture dishes (regardless of

waste and discarded materials contaminated with blood,<sup>210</sup> chemotherapy wastes,<sup>211</sup> and unused, discarded sharps.<sup>212</sup> The bill authorizes the Administrator of the EPA “to modify the definition of regulated medical waste. . . as necessary to protect human health and the environment.”<sup>213</sup> In addition, the bill defines an infectious agent as any organism “that is capable of being communicated by invasion and multiplication in body tissue and capable of causing disease or adverse health impacts in humans.”<sup>214</sup>

The bill defines a generator as any person “whose activity or process produces regulated medical waste,” with no consideration of the quantity of the medical waste produced.<sup>215</sup> Storage is considered “the temporary holding of regulated medical waste at a designated accumulation area before treatment, disposal or transport.”<sup>216</sup> A transporter is “a person engaged in the off-site transportation of regulated medical waste by air, rail, highway, or water.”<sup>217</sup> Treatment is defined as “any method, technique or process designed to change the biological character or composition of regulated medical waste so as to reduce or eliminate its potential for causing disease or otherwise render it nonhazardous, or so as to render such medical waste safer for transport or storage.”<sup>218</sup>

### C. Storage and Containment of Medical Waste

The bill provides for the Administrator, in consultation with OSHA, to “promulgate regulations for the storage and containment of regulated

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presence of infectious agents), other types of broken or unbroken glasswares that was [sic] in contact with infectious agents.” *Id.*

209. *Id.* § 11002(1)(E). The section states: “Contaminated animal carcasses, body parts and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals or testing of pharmaceuticals.” *Id.*

210. *Id.* § 11002(1)(F). The section states: “Biological waste and discarded materials contaminated with blood, excretion, exudates or secretions from humans who are isolated to protect others from certain highly communicable diseases or isolated animals known to be infected with highly communicable diseases.” *Id.*

211. *Id.* § 11002(1)(G). The section states: “Chemotherapy wastes, including used intravenous bags and needles, tubing, vials, gloves, gowns, masks, and other disposable material used in the administration of cytotoxic or antineoplastic agents.” *Id.*

212. *Id.* § 11002(1)(H). The section states: “Unused, discarded sharps including hypodermic needles, suture needles, syringes and scalpel blades.” *Id.*

213. *Id.* § 11002(1).

214. *Id.* § 11002(2).

215. *Id.* § 11002(3). The following facilities and activities are examples of generators: general acute care hospital, skilled nursing facility or convalescent hospital, intermediate care facility, in-patient care facility for the developmentally disabled, chronic dialysis clinic, free clinic, community clinic, employee clinic, health maintenance organization (HMO), surgical clinic, urgent care clinic, acute psychiatric hospital, laboratory, medical buildings, physicians’ offices, veterinarians’ offices, veterinary hospital, home health agencies, and federal facilities. *Id.* Note that persons practicing home health care are not included in this definition of generators. See *infra* note 294.

216. *Id.* § 11002(4).

217. *Id.* § 11002(5).

218. *Id.* § 11002(7).

medical waste" not later than twelve months after the enactment of the Medical Waste Management Act.<sup>219</sup> Generators must segregate regulated waste from other waste at the point of origin.<sup>220</sup> They must also store medical waste apart from other waste and mark it with "prominent warning signs."<sup>221</sup> Generators cannot store medical waste in a manner which would allow the waste to putrefy.<sup>222</sup> However, storage at the producing facility for not more than ninety days is permissible without specific approval as long as there is no putrefaction.<sup>223</sup>

All medical waste, "except for sharps capable of puncturing or cutting," must "be contained in disposable plastic bags which are impervious to moisture and have a strength sufficient to preclude ripping, tearing, or bursting under normal conditions."<sup>224</sup> Sharps must be contained in "leakproof, rigid, puncture-resistant containers" sealed to prevent loss of the contents.<sup>225</sup> The disposable bags must be red and conspicuously labeled with a description of the nature of the medical waste.<sup>226</sup>

The bill prohibits the compaction or grinding of medical waste<sup>227</sup> until it is rendered non-infectious.<sup>228</sup> Generators must store, handle or transport the disposal bags in disposable or reusable containers labeled on the lid and the side.<sup>229</sup> The containers must be washed and decontaminated after each use.<sup>230</sup>

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219. *Id.* § 11003(a)(1). This section of the Medical Waste Management Act mandates that certain minimum procedures must be followed when workers store medical waste. However, the Standard on Occupational Exposure to Bloodborne Pathogens already requires employers to submit Exposure Control Plans and to follow certain procedures for the handling of medical waste. See *supra* notes 172-81 and accompanying text. Thus, there would be no need for the Administrator to promulgate additional regulations in this area.

220. *Id.* § 11003(a)(3).

221. *Id.* § 11003(a)(4). The section states: "Containment of medical waste shall be separate from other wastes. Enclosures or containers used for containment of medical waste shall be so secured so as to deny access by unauthorized persons and shall be marked with prominent warning signs on, or adjacent to, the exterior of entry doors, gates, or lids. Each container shall be prominently labeled with a sign using language to be determined by the Administrator and legible during daylight hours from a distance of twenty-five feet." *Id.*

222. *Id.* § 11003(b).

223. *Id.*

224. *Id.* § 11003(c)(1). The section goes on to state: "The bags shall be securely tied so as to prevent leakage or expulsion of solid or liquid wastes during storage, handling, or transport." *Id.*

225. *Id.* § 11003(c)(2).

226. *Id.* § 11003(c)(3).

227. Grinding involves the breaking up of infectious waste into smaller particles. Schumaker, *supra* note 16, at 592 n.214.

228. *Id.* § 11003(d)(1).

229. *Id.* § 11003(d)(2).

230. *Id.* § 11003(d)(3). Proper methods of decontamination include, but are not limited to: Exposure to hot water of at least 180F for a minimum of fifteen seconds or exposure to a chemical sanitizer by rinsing with or immersion in one of the following for a minimum of three minutes: (I) Hypochlorite solution (500 ppm available chlorine) or (II)

*D. Transfer of Medical Waste to Off-Site Treatment  
or Disposal Facilities*

Generators of regulated medical waste are permitted to transfer the waste to a transporter registered by the Administrator.<sup>231</sup> Transporters must segregate medical waste from other waste during transportation.<sup>232</sup> The MWMA obligates the Administrator, in consultation with OSHA, to promulgate regulations controlling the handling of regulated medical waste by those who may be in contact with it during transport no later than twelve months after its enactment.<sup>233</sup>

*E. Standards Applicable to Transporters of Medical Waste*

The MWMA similarly obligates the Administrator, in consultation with the Secretary of Transportation, to promulgate specific regulations concerning registration for regulated medical waste transporters within twelve months of its enactment.<sup>234</sup> Currently under the MWMA, medical waste transporters must submit an application form to the EPA,<sup>235</sup> demonstrating financial responsibility adequate for any potential clean-up costs or third-party damages.<sup>236</sup> Applicants also must pass an annual inspection by the Department of Transportation.<sup>237</sup> Each truck, trailer, semi-trailer or container used for shipping medical waste must be designed to prevent release of medical waste into the environment under normal transport conditions.<sup>238</sup>

*F Treatment or Disposal of Medical Waste*

The Administrator must promulgate regulations establishing standards for the treatment or disposal of regulated medical waste within twelve months of the enactment of the Medical Waste Management Act.<sup>239</sup> Presently, the MWMA prohibits disposal of untreated medical waste.<sup>240</sup> Medical waste may be treated by incineration<sup>241</sup> or decontamina-

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Idoform solution (100 ppm available iodine), coupled with agitation to remove visible soil. *Id.* § 11003(d)(4).

231. *Id.* § 11004(a).

232. *Id.* § 11004(b).

233. *Id.* § 11004(e). OSHA already requires workers exposed to medical waste to follow certain procedures. *See supra* notes 172-81 and accompanying text.

234. *Id.* § 11005(a).

235. *Id.* § 11005(b)(1).

236. *Id.* § 11005(c)(1). If insurance is the chosen financial alternative the insurance policy must be provided, indicating that minimum coverage has been obtained. *Id.* § 11005(c)(2)(3).

237. *Id.* § 11005(e)(1).

238. *Id.* § 11005(g)(1).

239. *Id.* § 11006(a).

240. *Id.* § 11006(b).

241. *Id.* § 11006(b)(1). The section states: "(1)(A) Such medical waste may be treated by incineration in a controlled-air multi-chambered incinerator which provides complete combustion of the waste to carbonized or mineralized ash. (B) Incinerators shall be capable of providing proper combustion temperatures and residence time and shall be prop-

tion by heating in a steam sterilizer.<sup>242</sup> Generators may discharge non-infectious liquid medical waste through local sewers to a publicly owned treatment facility, unless local or state law prohibits such action.<sup>243</sup> Cultures must be rendered non-infectious by steam sterilization, incineration or another sterilization technique approved by the Administrator.<sup>244</sup> Generators must dispose of recognizable human anatomical remains by incineration or interment.<sup>245</sup>

### G. *Shipping Papers*

Within twelve months of the enactment of the Medical Waste Management Act, the Administrator must establish a system of shipping papers to accompany shipments of regulated waste from the point of generation to any treatment or disposal facility.<sup>246</sup> The MWMA itself requires generators and waste treatment or disposal facilities to maintain records and report at least annually on the types and quantities of regulated medical waste generated or received.<sup>247</sup> No off-site treatment facility may accept any medical waste without the appropriate shipping papers.<sup>248</sup> However, the Administrator may promulgate alternative requirements for facilities generating less than twenty-five kilograms of regulated medical waste per month.<sup>249</sup>

### H. *Treatment, Storage or Disposal Facilities*

Any person who operates a facility for the treatment, storage or disposal of regulated medical waste must have a valid and appropriate permit issued by the Administrator.<sup>250</sup> The Administrator, in consultation with OSHA, must promulgate regulations for such permits.<sup>251</sup> The operator

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erly interlocked to assure that optimum operating parameters are maintained. Emissions shall meet emission limitations established on the basis of the maximum achievable control technology, as determined under section 129 and section 112(d) of the Clean Air Act." *Id.*

242. *Id.* § 11006(b)(2). The section states: "(A) Such medical waste may be treated by decontamination by heating in a steam sterilizer so as to render the waste non-infectious. Medical waste so rendered non-infectious may then be disposed of in accordance with subtitle D or this subtitle, if such decontaminated medical waste is not otherwise identified as a hazardous waste under section 3001." *Id.* § 11006(b)(2)(a).

243. *Id.* § 11006(b)(3).

244. *Id.* § 11006(c).

245. *Id.* § 11006(d). Burial in a landfill may be specifically required by the Administrator if the waste contains a hazardous constituent. *Id.*

246. *Id.* § 11007(a).

247. *Id.*

248. *Id.* § 11007(c). Similarly, a generator would not be permitted to transport, or offer for transport, off-site storage, treatment or disposal, any regulated medical waste unless it was accompanied by the appropriate shipping papers. *Id.*

249. *Id.* § 11007(d). The alternative regulations must assure the protection of human health and the environment. *Id.*

250. *Id.* § 11008(a).

251. *Id.*

must submit an operation plan for the Administrator's approval.<sup>252</sup> The plan must be revised whenever an increase of more than twenty-five percent in the maximum quantity of medical waste treated per year is projected.<sup>253</sup>

### I. State Programs

Within six months of the enactment of the Medical Waste Management Act, the Administrator must promulgate regulations establishing the minimum content for state programs to carry out this subtitle.<sup>254</sup> Eighteen months later, each state intending to operate a regulated medical waste program will be permitted to carry out the provisions of the Medical Waste Management Act.<sup>255</sup> If the Administrator determines that a state program does not comply with the subtitle or that the state lacks the authority or resources to perform its program, that state may not enforce the provisions.<sup>256</sup>

### J. Enforcement and Sanctions

The MWMA's enforcement and sanctions provisions mimic those of the SWDA for violations of hazardous waste disposal.<sup>257</sup> Under current regulations,<sup>258</sup> to ensure proper enforcement any person who generates, stores, treats, transports, disposes of or otherwise handles hazardous waste is required to furnish information to any officer, employee or representative of the EPA or any officer, employee or representative of a state

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252. *Id.* § 11008(b). The plan shall provide for, but is not limited to, the following: (1) A method of receiving wastes which assures that regulated medical wastes are handled separately from other wastes until treatment or disposal is accomplished and which prevents unauthorized persons from having access to or contact with the wastes; (2) A method of unloading and processing of regulated medical wastes which limits the number of persons handling the wastes and minimizes the possibility of exposure of employees and the public using or visiting the facility to the medical waste; (3) A method of decontaminating emptied reusable medical waste containers, transport vehicles or facility equipment which are known or believed to be contaminated with infectious agents or regulated medical waste; (4) The provision and required use of clean gloves and uniforms along with other protective clothing, face masks or respirators to provide protection for employees against exposure to regulated medical waste. [Soiled] protective gear shall be disposed of at the facility or decontaminated; (5) The means of decontamination of any person having had bodily contact with the regulated medical waste while transporting the waste to the treatment or disposal facility or while handling or disposing of the waste at the facility; (6) A calculation of the maximum amount of medical waste that may be treated, stored, or disposed of per month at the facility. *Id.* Compare with *supra* note 172 (OSHA's requirements for Exposure Control Plan under Occupational Exposure to Bloodborne Pathogens Standard).

253. *Id.* § 11008(c).

254. *Id.* § 11009.

255. *Id.*

256. *Id.*

257. *Id.* § 11010. Under this section the term "hazardous waste" includes regulated medical waste. *Id.* Compare with *supra* notes 73-85 and accompanying text (enforcement provisions of MWTA).

258. 42 U.S.C. § 6927 (1988).

having an authorized hazardous waste program.<sup>259</sup> The officers, employees or representatives are authorized to enter the facilities at reasonable times<sup>260</sup> and to inspect and obtain samples of any hazardous waste.<sup>261</sup> Any inspection must be commenced and completed with reasonable promptness.<sup>262</sup>

Each year the Administrator must conduct an inspection of each facility owned or operated by a federal agency for the treatment, storage, or disposal of hazardous waste.<sup>263</sup> In addition, the Administrator must annually inspect all facilities operated by state or local government for the treatment, storage or disposal of hazardous waste.<sup>264</sup> The Administrator or the state must carry out a program which ensures the inspection of every facility for the treatment, storage, or disposal of hazardous waste no less often than every two years.<sup>265</sup>

Under the current federal enforcement regulations<sup>266</sup> the Administrator may issue an order assessing a civil penalty for any past or current violation, requiring compliance immediately or within a specified time period.<sup>267</sup> Any penalty ordered shall not exceed \$25,000 per day of non-compliance for each violation.<sup>268</sup> In the alternative, the Administrator may commence a civil action in the United States district court for the district in which the violation occurred for appropriate relief.<sup>269</sup> If the violation occurs in a state authorized to carry out a hazardous waste program, the Administrator shall give notice to the state before issuing an order or commencing a civil action.<sup>270</sup> An order may include a suspension or revocation of any permit issued by the Administrator or state.<sup>271</sup>

Criminal penalties of not more than \$50,000 for each day of violation, or imprisonment not to exceed five years or both, may be imposed upon conviction of knowingly transporting any hazardous waste to a facility without a permit or knowingly treating, storing, or disposing of any haz-

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259. *Id.* § 6927(a).

260. *Id.* § 6927(a)(1).

261. *Id.* § 6927(a)(2). If any sample is obtained the owner, operator or agent in charge of the premises must be given a receipt. After an analysis is made of such samples, a copy of the results shall be furnished promptly to the owner, operator or agent in charge. *Id.* § 6927(a).

262. *Id.* § 6927(a).

263. *Id.* § 6927(c). If the state has an authorized hazardous waste program, it may conduct the inspection. *Id.* All records, reports or information obtained during any inspection must be made available to the public. *Id.* § 6927(b).

264. *Id.* § 6927(d).

265. *Id.* § 6927(e)(1).

266. *Id.* § 6928.

267. *Id.* § 6928(a)(1).

268. *Id.* § 6928(a)(3). In addition, the Administrator shall take into account the seriousness of the violation and any good faith efforts of compliance when assessing the penalty. *Id.* § 6928(c).

269. *Id.* § 6928(a)(1). The relief may include a temporary or permanent injunction. *Id.*

270. *Id.* § 6928(a)(2).

271. *Id.* § 6928(a)(3).

ardous waste without a permit.<sup>272</sup> A person convicted of knowingly omitting or making any false material statement for purposes of compliance with regulations promulgated by the Administrator may be subject to a fine of not more than \$50,000 for each day of violation, imprisonment not to exceed two years or both.<sup>273</sup> If the conviction is for a violation after a previous conviction, the maximum punishment shall be doubled with respect to both the fine and imprisonment.<sup>274</sup> If the person commits any of the violations which are subject to a criminal penalty<sup>275</sup> and knows at that time that he thereby places another person in imminent danger of death or serious bodily injury, he may be subject to a fine of not more than \$250,000 or imprisonment for not more than fifteen years or both, upon conviction.<sup>276</sup> An organization may receive a fine of not more than \$1,000,000 upon conviction for knowing endangerment.<sup>277</sup>

### K. Household Medical Waste

The MWMA directs the Administrator to study medical waste generated by households. The MWMA also will cover future development of a system for the collection and management of household medical waste.<sup>278</sup>

## VI. COMPARISON OF THE MEDICAL WASTE MANAGEMENT ACT TO THE MEDICAL WASTE TRACKING ACT

The most obvious difference between the Medical Waste Tracking Act and the Medical Waste Management Act is that the bill now before Congress encompasses a nationwide program. Under the Medical Waste Management Act, states cannot implement separate medical waste plans, such as the one developed by Indiana<sup>279</sup> and numerous other states.<sup>280</sup>

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272. *Id.* §§ 6928(d)(1), 6928(d)(2)(A), 6928(d)(7). A person is also subject to the same penalties for knowingly violating any material condition or requirement of such permit, *id.* § 6928 (d)(2)(B), or knowingly violating any material condition or requirement of any applicable interim status regulations or standards, *id.* § 6928(d)(2)(C).

273. *Id.* §§ 6928(d)(3), 6928(d)(7). The same penalties apply if a person knowingly generates, stores, treats, transports, disposes of, exports or otherwise handles any hazardous waste and knowingly destroys, alters, conceals or fails to file any record, application, manifest, report or other required document, *id.* § 6928(d)(4); knowingly transports hazardous waste without a manifest, *id.* § 6928(d)(5); or knowingly exports a hazardous waste (A) without the consent of the receiving country or, (B) where an international agreement exists between the United States and the government of the receiving country, in a manner which does not conform to the agreement, *id.* § 6928(d)(6).

274. *Id.* § 6928(d)(7).

275. *See supra* notes 272-73 and accompanying text for which violations trigger criminal penalties.

276. 42 U.S.C. § 6928(e).

277. *Id.*

278. S. 2108, 102d Cong., 1st Sess. § 11011 (1991).

279. *See supra* note 120 on Indiana's medical waste tracking scheme which was the subject of dispute in *Government Suppliers Consolidating Sers., Inc. v. Bayh*, 753 F Supp. 739 (S.D. Ind. 1990).

280. Under the Medical Waste Tracking Act states can carry out the provisions en-

Thus, medical waste disposal is no longer viewed as an East coast problem.<sup>281</sup> Congress has affirmatively declared that a comprehensive approach to medical waste management is necessary to protect human health and the environment.<sup>282</sup> Congress has finally heeded the advice which followed the enactment of the MWTA that "[r]egardless of the expense involved, consistency, uniformity and efficiency can only be obtained through a national program."<sup>283</sup>

One of the difficulties in adopting medical waste management guidelines has been determining exactly what types of medical waste deserve regulation.<sup>284</sup> The Medical Waste Management Act's definition of medical waste is more specific than the Medical Waste Tracking Act's because in the MWTA Congress defined medical waste, as opposed to regulated medical waste.<sup>285</sup> The MWMA, however, adopts the Administrator's definition of *regulated* medical waste developed pursuant to Congress' instructions in the MWTA.<sup>286</sup> The MWMA also defines chemotherapy waste as regulated medical waste.<sup>287</sup> Unlike both the MWTA and the subsequent C.F.R. guidelines, the MWMA defines infectious material.<sup>288</sup> However, its definitions of generator, storage, transporter, and treatment are identical to those in the MWTA and the C.F.R. guidelines.<sup>289</sup> The MWMA also mimics the MWTA by allowing the Administrator to modify the definition of regulated medical waste.<sup>290</sup>

Furthermore, most of the instructions to generators, transporters and disposal or treatment facilities are the same in the bill and the MWTA. Both require the segregation of medical waste at the point of generation,<sup>291</sup> placement of medical waste in containers which protect waste handlers and the public from exposure<sup>292</sup> and appropriate labeling of the

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acted by Congress. If states do not wish to do so their law is not preempted by federal law in this area. See *infra* notes 303-305 and accompanying text; see also *supra* notes 254-56 and accompanying text on state implementation of the Medical Waste Management Act.

281. Only Connecticut, New Jersey and New York were required to participate in the MWTA, although Puerto Rico and Rhode Island opted into the program. See *supra* notes 23-32 and accompanying text.

282. S. 2108, 102d Cong., 1st Sess. § 11001(b)(1991).

283. Schumaker, *supra* note 16, at 601.

284. See *supra* note 33 and accompanying text.

285. The MWTA defined medical waste and then the EPA promulgated regulations which defined regulated medical waste. See 42 U.S.C. § 6992a (1988); 40 C.F.R. § 259.30(a) (1989).

286. The bill's definition of medical waste includes the definition of regulated medical waste listed in 40 C.F.R. § 259.30(a) (1989).

287. S. 2108, 102d Cong., 1st Sess. § 11002(1)(G) (1991).

288. See *supra* note 54.

289. See 40 C.F.R. § 259.10(a); S. 2108, 102d Cong., 1st Sess. § 11002 (1991).

290. S. 2108, 102d Cong., 1st Sess. § 11002(1) (1991).

291. See 42 U.S.C. § 6992b(a)(4)(A) (1988); S. 2108, 102d Cong., 1st Sess. § 11003(a)(3) (1991).

292. See 42 U.S.C. § 6992b(a)(4)(B) (1988); S. 2108, 102d Cong., 1st Sess. § 11003(c)(2) (1991).

waste.<sup>293</sup> In addition, both require the establishment of a shipping papers system.<sup>294</sup>

Unlike the MWTA, the MWMA provides for the Administrator, in consultation with OSHA, to promulgate regulations for the storage and containment of medical waste within twelve months of its enactment.<sup>295</sup> Since OSHA has already issued similar regulations,<sup>296</sup> its Standard is a likely template for such subsequent regulations. Thus, it is appropriate to compare the Standard with the C.F.R. regulations promulgated in response to the MWTA. Because the MWTA was a tracking program,<sup>297</sup> the C.F.R. regulations discussed which forms must be filled out and sent to the EPA. The regulations did not require performance of additional handling procedures to safeguard the health of workers. Thus, the Standard is a vast improvement over the C.F.R. regulations in preventing disease.<sup>298</sup>

A major difference between the MWTA and the MWMA is that the latter specifically mandates that medical waste be rendered non-infectious. The MWTA only required that the EPA study various methods of treating medical waste.<sup>299</sup> In contrast, the bill prohibits the disposal of untreated medical waste.<sup>300</sup> Incineration and sterilization are currently

293. See 42 U.S.C. § 6992b(a)(4)(C) (1988); S. 2108, 102d Cong., 1st Sess. § 11003(c)(3) (1991).

294. See S. 2108, 102d Cong., 1st Sess. § 11007(a) (1991); 42 U.S.C. § 6992b(a) (1988). The Administrator is allowed to set up an alternative system for small quantity generators under both provisions. Under the MWTA, the Administrator did not require generators which produced less than fifty pounds of medical waste monthly to fulfill all the general requirements of the tracking program. 40 C.F.R. § 259.50(e)(2)(i) (1989). Similarly under the MWMA, the Administrator can set up an alternative system for generators which produce less than twenty-five kilograms of medical waste per month. S. 2108, 102d Cong., 1st Sess. § 11007(d)(1991). However, there is a small quantity exception for medical waste produced by home health care to the shipping papers regulations. Home health care practitioners also are exempted from following the Occupational Exposure to Bloodborne Pathogens Standard. Thus, there is currently no way to mandate the proper handling and disposal of home medical waste. The problem of household medical waste was supposed to be studied during the MWTA, but presumably no solution was discovered since the Administrator is still studying the problem. See S. 2108, 102d Cong., 1st Sess. § 11011 (1991).

295. S. 2108, 102d Cong., 1st Sess. § 11003(a)(1) (1991).

296. Since OSHA is also a federal agency with the same powers as the EPA in issuing regulations, there is no need to have duplicative regulations on the handling of medical waste by workers. Therefore, there is no need for the Administrator to promulgate additional regulations. See *supra* notes 170-184 and accompanying text on what procedures the Standard requires.

297. The MWTA required shipping papers to accompany medical waste from the point of generation until final disposal. See *supra* notes 56-58 and accompanying text.

298. In addition, the Medical Waste Management Act is also an improvement over the MWTA because in the new program Congress calls for the EPA to work in conjunction with OSHA and the Department of Transportation. Finally, Congress is coordinating the efforts of various administrative agencies to deal with a national problem.

299. See 42 U.S.C. § 6992g(a)(6) (1988). Congress stated that the EPA would include in the MWTA Final Report a study on the treatment methods of incineration, sterilization, chemical treatment and grinding. *Id.*

300. S. 2108, 102d Cong., 1st Sess. § 11006(b) (1991).

the only permissible methods of treatment.<sup>301</sup> Medical waste may not be compacted or ground until it is no longer infectious.<sup>302</sup>

Another significant difference between the MWMA and the MWTA is their contrasting relationships with state law. The MWTA did not preempt state or local law.<sup>303</sup> States which were covered by the MWTA could have had their own medical waste program in place simultaneously. Under the Medical Waste Management Act states undertake their own regulated medical waste program only after the Administrator verifies that the state has complied with the relevant subtitle and that the state has the authority and resources to perform the program.<sup>304</sup> If the Administrator determines that a state cannot carry out the program, the Medical Waste Management Act preempts any state legislated program.<sup>305</sup> Thus, Congress will have to find the resources for the EPA to implement and enforce the provisions of the Medical Waste Management Act in the states incapable of implementing the provisions of the Act.

The enforcement provisions of the MWTA and the MWMA are identical, since both were modeled after the SWDA.<sup>306</sup> Both allow the Administrator and the state carrying out a medical waste program to initiate a civil suit for violations of the provisions.<sup>307</sup> However, EPA policy asserted that state suits brought under the MWTA are not binding on the EPA.<sup>308</sup> Administrative ease and efficiency dictate that when either the state or the federal government enforces the provisions of the Medical Waste Management Act the other would forego any further action. Unfortunately, neither Congress nor the Supreme Court has addressed this issue.

By analogizing the Medical Waste Management Act to the Hazardous Waste Management Act, Congress has eliminated most of the deficiencies found in the Medical Waste Tracking Act. The MWMA installs a national medical waste treatment and disposal program but spares the federal government the implementation expenses. The bill also complies with the Tenth Amendment by providing that if the EPA determines that states are complying with the subtitle or have the authority or resources to carry out such a program, they are not "commandeered" to

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301. *Id.* However, the Administrator can qualify innovative technologies for treatment of medical waste in the future. *Id.* § 11006(b)(4).

302. *Id.* § 11003(d)(1).

303. 42 U.S.C. § 6992f(b)(1)(1988).

304. S. 2108, 102d Cong., 1st Sess. § 11009 (1991).

305. Under the Commerce Clause Congress can enact legislation which preempts local law. *See supra* notes 152-55 and accompanying text on the Supreme Court's recent interpretation of this power in *New York v. United States*, 112 S. Ct. 2408 (1992).

306. Mercer, *supra* note 18, at 543. *See supra* note 257 and accompanying text.

307. *See* 42 U.S.C. § 6992f(a)(1988); 42 U.S.C. § 6928(a)(1) (1988). Under the current enforcement provisions of the Hazardous Waste Management Act, if the Administrator commences a civil action within a state which carries out a hazardous waste program, the Administrator must first notify the state. 42 U.S.C. § 6928(a)(2).

308. *See supra* note 90 and accompanying text.

carry out federal policies.<sup>309</sup> States which do not wish to implement EPA policy have the option of allowing the federal government to carry out the program for them. Congress has the authority under the Commerce Clause to enact legislation mandating that the EPA carry out the program for states lacking the authority or resources to do so themselves.

Even though Congress possesses the constitutional authority to enact and implement the Medical Waste Management Act, many in Washington disagreed with the enactment of such environmental legislation. First, the previous Republican Administration was extremely hostile to further burdening businesses with more regulations.<sup>310</sup> Second, the Administration was also adverse to the federal government implementing programs which it felt should be handled by the states.<sup>311</sup> Third, during the past election year Democrats scaled back their legislative agenda in order to concentrate on the presidential campaign.<sup>312</sup> Because of the political climate in Washington, all partisan legislation became a victim of political deadlock at the close of the second session of the 102d Congress. Thus, the Medical Waste Management Act has not yet been voted on by the Senate.

However, with the election of a Democratic President and with a Democratic majority in the House, both claiming to be the protectors of the environment, there is no reason to believe that the Medical Waste Management Act will not be enacted in the near future. The likelihood

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309. In *New York v. United States*, 112 S. Ct. 2408 (1992), the Supreme Court held that Congress cannot coerce states to carry out federal policy. See *supra* notes 150-155 and accompanying text.

310. In President Bush's 1992 State of the Union Address, he announced a 90-day moratorium on any new Federal regulations. *State of the Union*, N.Y. TIMES, Jan. 29, 1992, at A16. The moratorium, in effect during the remainder of President Bush's term, did not apply to those rules deemed necessary because of imminent danger to the public health or those required by deadlines set in law. (OSHA's Standard on Bloodborne Pathogens fits into both of the exceptions.) The White House estimated that during the first eight months of the moratorium between \$15 billion to \$20 billion had been saved. *Consumer Groups Attack Regulations Freeze*, N.Y. TIMES, Aug. 29, 1992, at A10.

311. In addition to state implementation of environmental regulation, many municipalities have moved to the forefront in developing innovative programs to deal with the waste disposal problem. For example, in August, 1992 the New York City Council approved the most aggressive recycling program in the United States. The City was driven by necessity to adopt such a program since its landfill capacity was shrinking, other states threatened to limit garbage exports, and there was little willingness to build new incinerators. Unfortunately, the success of the program may be threatened if the City cannot raise the \$300 million necessary to put the recycling plan in place by 1996. Michael Specter, *Hope, Off the Ash Heap; New York City Fought Over an Incinerator, But Real Focus of Waste Plan Is Recycling*, N.Y. TIMES, Aug. 29, 1992, at A1.

312. See Clifford Krauss, *Democrats Scale Back Aims in Congress to Win at Polls*, N.Y. TIMES, Sept. 18, 1992, at A12. Democratic congressmembers attempted to end the session by October 4, 1992 in order to campaign for their Presidential candidate, Bill Clinton. *Id.* However, in anticipation of the election, the President also reacted to the fear that voters believed that he had not done enough to support environmental concerns. In September, the White House dropped a proposal to allow manufacturers to dispose of hazardous wastes in municipal dumps. Keith Schneider, *Campaign Concerns Prompt White House to Drop Waste Plan*, N.Y. TIMES, Sept. 30, 1992, at A1, A18.

of enactment will increase once the Administration accepts both that environmental standards spark technological innovation, and that America must join the ranks of countries able to compete under stringent environmental regulations.<sup>313</sup> Economic analysis arguing that environmental regulation burdens business ignores the ongoing depletion of natural resources available for future generations occurring in the absence of environmental protection.<sup>314</sup> By allowing the concerns of big business to take precedence over environmental protection, we are sacrificing our future and the future of our children.

Applying the preceding analysis to the Medical Waste Management Act, it becomes clear that despite the increased burden on medical waste disposal and the corresponding elevation in the cost of medical care,<sup>315</sup> the long term benefits clearly outweigh the short term burdens. Precautionary waste disposal methods reduce workers' risk of contracting diseases, and thus relieves society of the costs of curing preventable illnesses. Ensuring proper medical waste disposal also protects the public from accidental exposure to infectious agents. Finally, disposal regulations more effectively safeguard the environment through a national system mandating the proper treatment of medical waste before disposal. All generators, transporters, and disposal facilities throughout the country are thus required to implement the national policy of protecting the health and environment of Americans.

#### CONCLUSION

The Medical Waste Management Act corrects many of the deficiencies which debilitated the Medical Waste Tracking Act. By treating medical waste in the same manner as hazardous waste, Congress clearly recognizes the potential threat of unregulated medical waste to the entire country. Unfortunately, only the public's hysteria to a deadly disease compelled Congress to act. Nonetheless, by developing a medical waste management plan, which addresses the issue of *treatment*, and not merely *disposal*, the United States has taken a step forward in reclaiming its position as a leader in environmental management and preservation. Congress must enact the Medical Waste Management Act to demonstrate that the environment cannot be sacrificed to the pressures of eco-

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313. In addition to forcing existing companies to compete under environmental standards, regulation also creates new markets for companies that make pollution-control equipment and provide environmental services. The United States is in danger of conceding the export-market in environmental goods to Japan and Germany. William K. Stevens, *Environmental Rules May Spur Innovation*, N.Y. TIMES, Sept. 8, 1992, at C8.

314. William K. Stevens, *Economists Strive to Find Environment's Bottom Line*, N.Y. TIMES, Sept. 8, 1992, at C1.

315. Although the medical profession tends to blame the legal system for the increase in the cost of health care, Internal Revenue Service records indicate that the rise in compensation for executives at non-profit hospitals was one of the fastest-growing components of the overall rise in medical costs in the 1980s. Felicity Barringer, *Hospital Executives' Pay Rose Sharply in Decade*, N.Y. TIMES, Sept. 30, 1992, at A14.

conomic concerns. Furthermore, the Medical Waste Management Act shows how inextricably linked the environment is with our health. The passage of the Medical Waste Management Act will mark a metamorphosis in the goals of American environmental legislation from reactive to preventative. Hopefully, instead of correcting past mistakes, we can begin preventing environmental crises from happening.

*Wendy Stynes*