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## Regulation of Medical Waste in the United States

LAURA CARLAN BATTLE\*

*When wash-ups of syringes and medical vials closed north-eastern beaches, public outcry galvanized Congress to pass the Medical Waste Treatment Act (MWTa). Congress directed the U.S. EPA to investigate whether medical waste should be treated as hazardous or solid waste, and whether a federal regulatory scheme is warranted. In the following article, the author explores varied laws and policies governing the treatment, handling and disposal of medical waste in the United States, the ongoing debate about risks associated with exposure to medical waste, and the ramifications of our current fragmented regulatory approach.*

### I. Introduction

Rising health care costs are focusing national attention on the health care industry. With the proposed national health care insurance plan under construction, our health care system is being scrutinized in order to ascertain why medical costs continue growing so rapidly. One overlooked

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component of burgeoning medical costs is medical waste management. A realistic analysis of present and future health care costs must consider the growing amount of medical waste and the concomitant increase in its regulation. The problems associated with medical waste management are not unique to the United States.<sup>1</sup>

The total amount of medical waste generated in the United States today is difficult to ascertain. Differences in the definition and tracking procedures for medical waste used by different groups, as well as the difficulty in determining the amount of home health care waste which is generated, contribute to this general uncertainty.<sup>2</sup> Most estimates, however, indicate that the volume of medical waste is relatively small when compared to the total municipal solid waste stream.<sup>3</sup> In 1990, for example, the Environmental Protection Agency (EPA) estimated that approximately 500,000 tons of medical waste are produced annually in the United States by regulated generators, such as hospitals and medical offices. This represents 0.3 percent (by weight) of 158,000,000 tons of municipal solid waste originating from all sources.<sup>4</sup> Infec-

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1. In 1992 French and German police discovered an illegal waste dumping network that had transported and dumped in France an estimated 500 tons of medical waste including syringes, empty plastic blood bags and catheters generated in East German hospitals. The European Commission is writing a waste directive requiring members to dispose of waste at a location as close as possible to the place of generation. Tara Patel, *German Syringes Turn up in French Quarry*, NEW SCIENTIST, Aug. 22, 1992, at 7. By comparison, the problem of illegal medical waste disposal in Britain has prompted passage of the National Health Service and Community Care Act of 1990 which removed hospitals' "crown immunity" in 1991, thereby rendering hospital managers and the chief executives of health facilities subject to environmental regulation and personal liability for violations. Oliver Tickell & Alan Watson, *Hospital Waste: A Case for Treatment*, NEW SCIENTIST, Mar. 28, 1992, at 34-35.

2. U.S. CONG. OFFICE OF TECHNOLOGY ASSESSMENT, ISSUES IN MEDICAL WASTE MANAGEMENT: BACKGROUND PAPER 3-4 (1988) [hereinafter OTA BACKGROUND PAPER].

3. OFFICE OF TECHNOLOGY ASSESSMENT, FINDING THE RX FOR MANAGING MEDICAL WASTES (1990) [hereinafter OTA REPORT].

4. OFFICE OF SOLID WASTE, ENVIRONMENTAL PROTECTION AGENCY, MEDICAL WASTE MANAGEMENT IN THE UNITED STATES, FIRST INTERIM REPORT TO CONGRESS 1-3 (1990) [hereinafter EPA FIRST INTERIM REPORT]. A briefing document prepared for Congress in 1993 raised the estimate of municipal solid waste generated annually in the United States to 180,000,000 tons. ENVIRONMENTAL AND

tious medical wastes are believed to represent approximately 15 percent of total regulated medical wastes, although this figure can also vary widely due to differences in definitions, treatments, and disposal practices utilized at different medical facilities.<sup>5</sup>

As the amount of medical waste increases, so does the need for lawful and affordable disposal options.<sup>6</sup> Furthermore, as the demand for medical waste treatment and disposal services grows, so does the cost of managing this waste.<sup>7</sup> While many generators install incineration units as the most convenient and efficient method of disposal, many hospitals

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ENERGY STUDY INSTITUTE, BRIEFING BOOK 55 (1993) [hereinafter EESI BRIEFING BOOK].

5. OTA BACKGROUND PAPER, *supra* note 2, at 4. For purposes of this paper, infectious waste shall be assumed to be a subset of the more inclusive term "medical waste." "Sharps" include hypodermic needles, syringes, scalpel blades, etc. See 42 U.S.C. § 6992a(a)(4) (1983 & Supp. 1992).

6. The medical waste industry estimates the prospective size of the market to be between \$500,000,000 and \$1,000,000,000 annually. Some predict that as these figures escalate and more regulations develop, more medical waste generators will suffer severe financial impacts from managing their medical waste. Janet Emmerman, *A Prescription for Cleaning Up Medical Waste*, USA TODAY MAGAZINE, May 1991, at 78, 79. However, the National Solid Waste Management Association (NSWMA) cites that in the past four years competitive pressures have actually driven prices down. Prices are expected to again rise with new regulations, competitive fallout and consolidation of companies trying to hold their market. The \$500-million-per-year market today is projected to climb to a \$1.5-billion-per-year business by 2000. Michael Malloy, *Medical Waste Treatment: A Status Report*, WASTE AGE, Aug. 22, 1992, at 66; Telephone interview with Tom Goldberg, Director, Medical Waste Institute, NSWMA, Washington, D.C. (July 1993).

7. See William Marbach, *Nuking Nasty Medical Waste—In a Microwave*, BUS. WK., Jul. 23, 1990, at 68. One industry association predicts that the United States Occupational Safety and Health Administration's (OSHA) recent bloodborne pathogen standard and the Department of Transportation's (DOT) newest rule affecting medical waste transporters will also drive costs up. Malloy, *supra* note 6, at 68. The American Hospital Association (AHA) projected earlier that increased regulation could inflate the typical hospital medical waste disposal budget by \$200,000. Jennifer Carlile, *Finding Disposal Options for Medical Waste*, AM. CITY & COUNTY, Nov. 1989, at 66, 76. See also LESLIE ANDERSON MORALES, *MANAGING MEDICAL WASTES: A BIBLIOGRAPHY OF PERIODICAL LITERATURE, 1987-1989* (1990), in which the author notes that where on-site disposal is not possible, finding off-site disposal locations may be difficult, and that generally the greater the distance from point of collection to point of disposal, the higher the cost. Rising costs are exacerbated by dwindling landfill space. *Id.*

are reluctant to make such a large capital investment in a non-patient care item.<sup>8</sup> Consequently, many medical waste generators may reduce short term costs by relying on commercial transporter and off-site disposal services, while simultaneously increasing their potential exposure to liability.<sup>9</sup> These costs of medical waste management can have a direct impact on patient care costs.<sup>10</sup>

The growing amount of medical waste generated contributes to rising medical waste management costs.<sup>11</sup> Estimates on the amount of medical waste generated vary significantly depending on the data source and the way medical waste is defined. A broader definition of "infectious" naturally encompasses more types of waste and affects disposal options. In addition, growth of the waste stream is a product of our increasing population and affluence, the greater accessibility of medical treatment nationwide, and the health care industry's increased use of disposable products.<sup>12</sup> In the past five years, both federal and state regulation of medical waste has increased, which has consequently made more waste susceptible to special treatment and increased costs.<sup>13</sup> While such regulated medical waste does not generally include hazardous or radioactive materials, the volume is also growing because concern regarding transmission of AIDS prompts

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8. Emmerman, *supra* note 6, at 78. In addition, forthcoming EPA regulations on incineration and the growing number of state regulations are expected to make incineration a less attractive and less economical disposal method. Debra K. Rubin, et al., *Medical Market Gets Infectious*, ENR, Jan. 7, 1991, 26, 26-27.

9. Malloy, *supra* note 6, at 73. Liability for improper handling and disposal most often attaches under the Resource Conservation Recovery Act (RCRA), 42 U.S.C. §§ 6901-6992k (1983 & Supp. 1992), and under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. §§ 9601-9675 (1983 & Supp. 1992).

10. Suzan Onel, *The Medical Waste Tracking Act of 1988: Will It Protect Our Beaches?*, 9 VA. ENVTL. L.J. 225, 230-31 (1989).

11. OFFICE OF PUBLIC AFFAIRS, U.S. ENVIRONMENTAL PROTECTION AGENCY, ENVIRONMENTAL BACKGROUNDER: MEDICAL WASTE 1 (1989). See also Kate Ballen, *Zapping Waste*, FORTUNE, Nov. 5, 1990, at 18.

12. See OTA REPORT, *supra* note 3, at 22, concerning increasing use of disposable health care products.

13. See generally OTA REPORT, *supra* note 3.

hospitals and other medical facilities to use more disposables and to classify more waste as infectious.<sup>14</sup>

Governmental regulation of medical waste in the United States is fragmented and uncoordinated. A patchwork of federal and state statutes, regulations, standards and guidelines currently govern the generation, handling, transportation and disposal of medical waste. This paper comparatively analyzes the major sources of regulation of medical waste in the United States, including federal statutes, state statutes and regulations, nonbinding federal guidelines, work practice standards, and hospital accreditation standards. It also examines the ongoing public and scientific debate concerning the risk medical waste mismanagement poses to human health and the environment. This debate has significantly affected EPA and state approaches to medical waste regulation, and it continues to shape policy regarding medical waste management in the United States. Finally, this article concludes that minimum federal standards are needed to ensure a uniform definition of medical waste and consistency in state regulation of medical waste management.

## II. Characterization and Definition of the Medical Waste Stream

### A. Historical Background

Medical waste was first formally recognized as a distinct waste stream by a federal agency in 1978 when EPA considered classifying infectious waste as hazardous waste under the Resource Conservation Recovery Act (RCRA).<sup>15</sup> In fact, when EPA first proposed hazardous waste regulations, infectious wastes were included.<sup>16</sup> However, in 1979, the agency determined that infectious wastes did not pose a significant health threat, and when EPA promulgated its RCRA hazardous waste regulations in 1980, it chose not to classify infec-

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14. Rubin et al., *supra* note 8, at 26.

15. OTA BACKGROUND PAPER, *supra* note 2, at 6.

16. *Id.*

tious waste as hazardous.<sup>17</sup> This is unusual because the language of RCRA specifically includes "infectious" as a characteristic to be considered in determining whether or not a waste is hazardous.<sup>18</sup> The statutory language can be interpreted as requiring these wastes to be classified as hazardous and thus regulated under Subtitle C of RCRA. However, EPA decided to treat medical waste as solid waste and the agency never issued the proposed regulations.<sup>19</sup>

By the end of summer 1988, following notorious beach wash-ups of medical waste, EPA had changed its position on the threat of medical waste to one supporting medical waste regulation.<sup>20</sup> Soon thereafter, Congress passed the Medical Waste Tracking Act (MWTa),<sup>21</sup> adding a demonstration program (Subtitle J) to RCRA, and EPA promulgated implementing regulations.<sup>22</sup> Even so, in the intervening years since passage of the MWTa, EPA has produced no significant research to substantiate a lack of substantial present or potential hazard to human health or the environment when a waste with infectious characteristics is improperly managed. EPA has also not issued any assessments based on epidemiological studies of the degree of risk posed by infectious or other types of medical waste.<sup>23</sup>

Consequently, confusion and inconsistency persists regarding medical waste policy, since no existing federal regulations comprehensively address the handling,

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17. See also NELSON A. ROCKEFELLER INST. OF GOV'T, PERSPECTIVES ON MEDICAL WASTE: A REPORT, 1-2 (1989) [hereinafter PERSPECTIVES ON MEDICAL WASTE].

18. See 42 U.S.C. § 6903(5) (1988).

19. OTA BACKGROUND PAPER, *supra* note 2, at 6 n.14.

20. PERSPECTIVES ON MEDICAL WASTE, *supra* note 17, at 2.

21. 42 U.S.C. §§ 6992-6992k (1988).

22. 40 C.F.R. § 259 (1988).

23. OTA BACKGROUND PAPER, *supra* note 2, at 7. EPA is expected to release a qualitative health assessment in its third and final report to Congress required under the MWTa. The report was due to be released in September 1991 following expiration of the MWTa demonstration program in June 1991, but it has not been issued and EPA does not know when it will come out. Telephone Interview with Ann Coggington, Environmental Protection Specialist, Characterization and Assessment Division, Regulatory Development Branch, EPA Office of Solid Waste (June 1993).

transportation, treatment and disposal of medical waste.<sup>24</sup> The major area of inconsistency is in the classification or definition of medical waste, which has broad ramifications because it dictates the universe of substances subject to an overlapping array of transportation, labor, environmental, and safety regulations.

## B. Defining Infectious Medical Waste

State and federal regulators do not consistently define "medical waste" or its subset "infectious waste." Different terms such as "hospital waste,"<sup>25</sup> "regulated medical waste,"<sup>26</sup> "biomedical waste,"<sup>27</sup> "red bag waste,"<sup>28</sup> and "infectious waste"<sup>29</sup> appear in state and federal laws and guidelines. There is currently no objective test to determine when a solid waste is medical or infectious waste, and a policy debate continues over how to classify infectious and other medical waste.<sup>30</sup> Presently, health care facilities can follow either EPA or Centers for Disease Control (CDC) guidelines, or both in designating medical waste.<sup>31</sup> The two agencies have differing definitions of infectious waste; this contributes to the lack of consistent data on the amount, composition, and types of medical waste in our waste stream. Moreover, the ultimate designation infectious waste receives impacts on the costs of

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24. OTA BACKGROUND PAPER, *supra* note 2, at 7.

25. *Id.* at 4.

26. OTA REPORT, *supra* note 3, at 2.

27. OTA BACKGROUND PAPER, *supra* note 2, at 14.

28. *Id.* at 9.

29. *Id.* at 3.

30. *Id.* According to EPA, "developing a uniform definition of medical waste that is easy for the regulated community (under the Medical Waste Tracking Act) to understand and implement and for EPA to enforce has been problematic." ENVIRONMENTAL PROTECTION AGENCY, MEDICAL WASTE MANAGEMENT IN THE UNITED STATES, SECOND INTERIM REPORT TO CONGRESS 26 (1990) [hereinafter EPA SECOND INTERIM REPORT]. No universally accepted definition exists for infectious waste; as a result, the various terminology used to define these wastes is inconsistent. *United States Environmental Protection Agency, Guide for Infectious Waste Management 2-1* (1986) [hereinafter *EPA Guide*].

31. The OTA reports that a survey for the American Hospital Association showed that 80 percent of the hospitals are following CDC guidelines and 52 percent comply with EPA guidelines. OTA BACKGROUND PAPER, *supra* note 2, at 4 n.9.

waste management and the methods of disposal chosen by generators.<sup>32</sup> It is likely that these costs are often passed on to patients and insurers.

### 1. The EPA Definition

EPA defines infectious waste as waste "that contains pathogens with sufficient virulence and quantity so that exposure to the waste by a susceptible host could result in an infectious disease," or, more simply, "waste capable of producing infectious disease."<sup>33</sup> This definition requires consideration of four factors necessary for the induction of disease: presence of a pathogen of sufficient virulence; dose; portal of entry; and resistance of the host.<sup>34</sup> EPA lists six infectious waste categories: (1) isolation wastes, (2) cultures and stocks of infectious agents and associated biologicals, (3) human blood and blood products, (4) pathological wastes, (5) contaminated sharps, and (6) contaminated animal carcasses, body parts, and bedding.<sup>35</sup> EPA includes additional materials such as contaminated equipment, wastes from surgery and autopsy, laboratory wastes and dialysis wastes as wastes which should be evaluated to determine potential infectiousness.<sup>36</sup> These materials have not been specifically designated as infectious because of a lack of information on the relative risk they pose. EPA therefore recommends that "a responsible authorized person or committee at the individual facility evaluate these wastes to determine which should be managed as infectious waste."<sup>37</sup> Individual facilities thus have much discretion in characterizing products in their waste stream as infectious; there is consequently great disparity in the way health care facilities treat their waste.

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32. *Id.* at 4.

33. *EPA Guide*, *supra* note 30.

34. *Id.*

35. *Id.* at 2-2.

36. *Id.*

37. *Id.* The regulatory definition of "regulated medical waste" promulgated pursuant to the MWTa at 40 C.F.R. § 259.10 (1989) originally contained ten categories of regulated medical waste. It expired with the MWTa demonstration program. 40 C.F.R. 259.10 (1989).

## 2. The Centers for Disease Control Definition

In 1987 the Centers for Disease Control (CDC) issued recommendations called "universal precautions" to health care facilities for classifying waste as infectious.<sup>38</sup> CDC recommended that blood and body fluids from all patients be considered potentially infected with HIV and/or other blood-borne pathogens and that health care workers adhere rigorously to infection control precautions.<sup>39</sup> The recommendations were apparently interpreted by some hospitals as classifying virtually all patient-contact waste as infectious, which could amount to 70 to 90 percent of all hospital waste.<sup>40</sup> As a result of confusion and concern that the recommendations were too broad, in 1988 CDC attempted to clarify the 1987 guidelines and limited application of the universal precautions to blood, body fluids containing visible blood, and other specified fluids.<sup>41</sup>

Both CDC and EPA consider pathological waste, blood and blood products, contaminated sharps and microbiological wastes to be infectious.<sup>42</sup> The agencies disagree over designation of communicable disease/isolation wastes because EPA considers communicable disease wastes infectious and CDC recommends that such wastes be treated according to hospital policy.<sup>43</sup> Such disagreements can have significant financial impacts on a generator attempting to determine how much of its waste is indeed infectious. For example, "one 600-bed hospital found it saved \$250,000 annually by changing its infectious waste designation from 13 categories to the

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38. CENTERS FOR DISEASE CONTROL, UNIVERSAL PRECAUTIONS FOR PREVENTION OF TRANSMISSION OF HIV AND HEPATITIS B VIRUS (1987), discussed *infra* at section VII.

39. *Id.*

40. OTA BACKGROUND PAPER, *supra* note 2, at 4.

41. *Id.* at 5.

42. OTA BACKGROUND PAPER, *supra* note 2, at 5.

43. *Id.* at 6. According to the OTA, given the state of confusion at the generator level as to what is infectious waste requiring special handling, EPA, perhaps jointly with CDC, needs to publish further guidance on these definitional issues. *Id.*

four designated by the CDC.”<sup>44</sup> Given the EPA and CDC definitional differences, it is not surprising that accurate, consistent data on the amount of medical waste generated in the United States is difficult to find. This problem is compounded by the fact that other regulatory agencies such as the Occupational Safety and Health Administration and the Department of Transportation also have their own unique definitions of medical waste or infectious substance.<sup>45</sup>

### C. Characteristics of the Infectious Waste Stream

#### 1. Amounts of Medical Waste

Data on the amounts of medical and infectious waste in the United States vary. In its second report to Congress under the Medical Waste Tracking Act, EPA stated that collecting baseline information on medical waste generation and waste management practices and costs has been “problematic” because most facilities, particularly small quantity generators, generally did not maintain records, and because waste management practices vary widely between facilities.<sup>46</sup> EPA estimates that each hospital has a per bed, per day generation rate of 13 pounds of medical waste.<sup>47</sup> Other independent estimates of medical waste generation range from

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44. *Id.* at 4. The OTA reports that most estimates are that 10 to 15 percent of all hospital wastes are infectious. However, depending on the definitions used, the total range of estimates is from 3 to 90 percent of a hospital’s waste. *Id.*

45. OSHA regulations related to medical waste are discussed, *infra*, note 273. Dept. of Transportation regulations on hazardous materials are at 49 C.F.R. §§ 171, 172, 173 (1992).

46. EPA SECOND INTERIM REPORT, *supra* note 30, at 28. As part of its third and final report to Congress, EPA is preparing a Waste Characterization Study which will analyze the generation of medical waste to determine the physical and chemical characteristics of the medical waste stream. See EPA SECOND INTERIM REPORT, *supra* note 30, at 9. However, results of this study will not be available until the final report is released to Congress. Telephone Interview with Ann Coggington, *supra* note 23.

47. OTA BACKGROUND PAPER, *supra* note 2, at 3. These figures apply only to sources producing more than 50 pounds of medical waste per month. Smaller generators, such as medical clinics or dentists’ offices, are not included.

16 to 23 pounds per bed, per day.<sup>48</sup> Not all of this waste, however, is infectious.

To evaluate and define the infectiousness of medical waste requires knowledge of the type of pathogens present, the quantities of those pathogens, potential modes of disease transmission and information on the susceptible host population.<sup>49</sup> One study, which distinguishes between infectious and medical waste in ascertaining amounts of generation, reports that United States hospitals generate a median of 15 pounds of medical waste per patient, per day, with infectious waste making up 15 percent of the total.<sup>50</sup> This data is based on a 1985 estimate of 1,300,000 hospital beds in 7,000 hospitals in the United States, with an average occupancy rate of 69.5 percent.<sup>51</sup> Extrapolating from this information, the total generation of infectious waste by hospitals in the United States is 375,000 tons per year.<sup>52</sup> Clearly, the amount of infectious waste generated by medical facilities as a percentage of their total waste stream varies widely depending on the type of health care facility, the definition of infectious waste used and the procedures used to designate and separate waste types.<sup>53</sup> Most hospitals designate about 15 percent of their wastes as infectious.<sup>54</sup>

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48. *Id.*

49. EPA FIRST INTERIM REPORT, *supra* note 4, at 1-4.

50. C.C. Lee et al., *Medical Waste Management—The State of the Art*, ENVTL. SCI. & TECH., Mar. 1991 at 360-61 (citing P. LAYNE ET AL., REVIEW AND EVALUATION OF EXISTING LITERATURE ON GENERATION, MANAGEMENT AND POTENTIAL HEALTH EFFECTS OF MEDICAL WASTE, DRAFT REPORT OF RESEARCH TRIANGLE INSTITUTE (Nov. 1988)).

51. *Id.*

52. *Id.* See also *Council Report on Infectious Medical Waste*, 262 JAMA 1669 (Sept. 22, 1989). If the EPA definition is used, about 15 percent of the 750 to 800 million pounds of total waste generated by United States hospitals each year is potentially infectious. Assuming such is the case, the daily output of infectious waste is estimated to be 1.5 pounds per bed. *Id.*

53. OTA REPORT, *supra* note 3, at 2.

54. *Id.* In order to reduce its medical waste, one hospital has undertaken a recovery and recycling program called "REMEDY" (Recovered Medical Equipment for the Developing World) whereby it donates to developing countries certain used medical equipment which might otherwise be disposed of as "waste." See William H. Rosenblatt & David G. Silverman, *Recovery, Resterilization, and Donation of Unused Surgical Supplies*, 268 JAMA 1441 (1992).

## 2. Sources of Medical Waste

Hospitals, however, are not the sole source of infectious medical waste. It has been estimated that hospitals account for less than 2 percent of the total number of facilities with the potential to generate infectious waste.<sup>55</sup> In addition to hospitals, other types of health care facilities contribute to the medical waste stream; however, the amount of medical wastes from such non-hospital sources is not known.<sup>56</sup> A Washington State Infectious Waste Project identified funeral homes, nursing homes, veterinarians' offices, laboratories, surgery centers, clinics, dentists' offices, and research facilities as the main non-hospital producers of medical waste.<sup>57</sup> One source states that in terms of the number of facilities that potentially generate medical waste, the categories identified in the Washington study account for more than 98 percent of the total, which is estimated at 340,500 facilities.<sup>58</sup> By comparison, another source reports that approximately 465,000 tons of infectious waste are generated in the United States each year by 377,000 health care facilities including non-hospital sources.<sup>59</sup>

Even less is known about other sources of medical waste, such as syringes generated in home health care and by illegal

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55. See Lee et al., *supra* note 50. But, based on information gathered from five participating states during the initial phase of the MWTa demonstration program, the EPA reported that the vast majority of medical waste (about 90 percent) is produced by hospitals, which comprise about four percent of the generators reporting data. EPA SECOND INTERIM REPORT, *supra* note 30, at 32.

56. OTA BACKGROUND PAPER, *supra* note 2, at 3.

57. WASHINGTON STATE DEPARTMENT OF ECOLOGY, SOLID AND HAZARDOUS WASTE PROGRAM, REPORT TO THE LEGISLATURE: WASHINGTON STATE INFECTIOUS WASTE PROJECT (1989).

58. Lee et al., *supra* note 50, at 361. Other sources include approximately 180,000 physicians' offices, 98,400 dentists' offices, 38,000 veterinarians' offices, 15,500 medical clinics, 12,700 long-term health care facilities, 4,300 laboratories and 900 free-standing blood banks. William A. Rutala & David J. Weber, *Infectious Waste—Mismatch Between Science and Policy*, 325 NEW ENG. J. MED., Aug. 22, 1991, Vol. 325, at 578 (citing EPA FIRST INTERIM REPORT, *supra* note 4). The authors maintain that although these sources may have a significant contribution to the medical waste stream the amount of that contribution is uncertain as no reliable data exists. *Id.*

59. MEDICAL WASTE INCINERATION AND POLLUTION PREVENTION 43-44 (Alex E.S. Green ed. 1992).

drug users. It is estimated that there are 2,000,000 diabetics and 1,200,000 intravenous drug abusers nationwide; between the two groups, more than 1 billion insulin-type syringes are used annually, the disposal of which is not regulated.<sup>60</sup> These two waste streams are now receiving more attention. In its Second Interim Report to Congress, EPA admits that the extent to which these waste streams contribute to the problem of beach wash-ups and other mismanagement incidents is unclear; some of the medical debris discovered on beaches, however, has been linked to disposal of insulin syringes.<sup>61</sup> One recent survey indicates that diabetics dispose of an estimated 1.4 billion needles every year; home health care for people suffering from AIDS, cancer and other chronic diseases also generates medical wastes.<sup>62</sup> EPA has acknowledged that the home health care community is the most significant unregulated medical waste source that it has attempted to reach.<sup>63</sup>

Another component of the medical waste stream is waste produced by small quantity generators. The contribution of this community is nearly impossible to assess since it is not stringently regulated (unless the generator produces hazardous waste regulated under RCRA), and the MWTa exempted small quantity generators from reporting.<sup>64</sup> More precise data is needed on non-hospital sources of medical waste and

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60. Rutala & Weber, *supra* note 58, at 579 (citing AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, THE PUBLIC HEALTH IMPLICATIONS OF MEDICAL WASTE: A REPORT TO CONGRESS (1990) [hereinafter ATSDR REPORT]).

61. EPA SECOND INTERIM REPORT, *supra* note 30, at 17, 26-27. Over half of the medical waste items collected by six states during the 1988 beach season wash-ups were syringe related. A number of states concluded that home health care and illegal intravenous drug use were the most likely sources of this waste. *Id.* at 10 (citing ENVIRONMENTAL CRIMES UNIT, MARYLAND ATTORNEY GENERAL'S OFFICE, MEDICAL WASTE INVESTIGATION REPORT (1988)).

62. Ingfei Chen et al., *Medical Wastes Come Home*, HEALTH, May/June 1993, at 21.

63. EPA FIRST INTERIM REPORT, *supra* note 4, at 11-1 to 11-29. Recognizing the growing significance of this waste stream, EPA has developed a home health care waste education program and published substantive guidance for the disposal of home health care medical waste. *Id.*

64. Medical Waste Tracking Act of 1988, Publ. L.No. 100-582, 102 Stat. 2950 (codified as amended in sections of 69 U.S.C.).

how they may contribute to combined sewer overflows or other types of medical waste mismanagement.

### 3. Composition of the Medical Waste Stream

Waste generated at health care facilities is heterogeneous, varying in composition and in quantity. This is because such facilities offer a variety of services and engage in different activities. The types of wastes produced by a health care facility can be characterized as infectious, noninfectious solid waste and hazardous waste.<sup>65</sup> Since there is no universal definition of the term "infectious waste," there is no clear definition of the category. State, local and federal regulating bodies develop their own definitions.<sup>66</sup> Generally, infectious waste includes materials considered to be potential health hazards because of possible contamination with pathogenic microorganisms.<sup>67</sup> The typical waste stream components of infectious waste in order of magnitude are paper and cloth items, plastics, glassware and fluids.<sup>68</sup>

Health care facilities also produce noninfectious solid waste which includes many items found in municipal solid waste. Most often accounting, engineering, record keeping and other administrative functions generate these wastes. In order of quantity, these noninfectious solid wastes include paper and cardboard, plastics, food scraps, metal glass, inorganic materials and other miscellaneous matter.<sup>69</sup> Depending on the applicable regulation, most patient-care generated waste may be considered noninfectious assuming the absence of exposure to infectious agents.<sup>70</sup>

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65. Low level radioactive wastes are another common hospital waste product; however, they are separately regulated and beyond the scope of this paper. See generally Moira Hayes, *Radioactive Marine Pollution: International Law and State Liability*, 15 SUFFOLK TRANSNAT'L L.J. 674 (1992) for a discussion of radioactive medical waste and the history of radioactive waste regulation.

66. FRANK L. CROSS, *INFECTIOUS WASTE MANAGEMENT* 8 (1990).

67. GREEN, *supra* note 59, at 40.

68. *Id.* at 42. Factors affecting the amount of these elements present in the waste stream include the extent of laboratory and research activities conducted, number of surgeries, and use of disposables. CROSS, *supra* note 66, at 10.

69. GREEN, *supra* note 59, at 40.

70. CROSS, *supra* note 66, at 9-10.

RCRA regulates hazardous waste generated by health care facilities. This waste is frequently produced by chemotherapy units and in the use and disposal of solvents, and may include waste pharmaceuticals, cytotoxic agents, mercury and other heavy metals.<sup>71</sup> RCRA regulations subject hazardous waste generators to different standards according to the quantity of waste produced per month.<sup>72</sup> Some proponents of stringent infectious waste regulation argue that classifying infectious waste as hazardous is desirable in order to prosecute illegal dumping as a felony, to institute a manifest system for infectious wastes which would track off-site movement of these wastes, and to ensure greater comprehensive infectious waste management.<sup>73</sup>

The medical waste stream has not changed significantly in the past few years.<sup>74</sup> The most noticeable change is the increase in plastic disposable items.<sup>75</sup> An increase in plastics has disposal implications, especially if the waste is incinerated, because hydrogen chloride production and furan and dioxin emissions change with the amount of polyvinyl chloride incinerated.<sup>76</sup>

When compared to the municipal waste stream, the composition of the medical waste stream appears very similar. The main differences between the municipal and medical waste stream compositions are in plastic and paper concentrations.<sup>77</sup> Infectious waste contains approximately 41 percent plastic and rubber while municipal solid waste contains

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71. *Id.* at 3. Typical hazardous wastes produced by health care facilities include antineoplastic drugs generated in chemotherapy units, solvents such as xylene and toluene, and certain forms of formaldehyde. *Id.*

72. 42 U.S.C. § 6992b(b) (1988).

73. OTA BACKGROUND PAPER, *supra* note 2, at 7 (citing New York State's statute N.Y. C.L.S. E.C.L. § 71-2713 which provides for penalties of up to 4 years in prison and fines of up to \$50,000 for illegal disposal of medical wastes).

74. CROSS, *supra* note 66, at 1.

75. *Id.* According to GREEN, *supra* note 59, at 45, the use of plastics to replace glass and textiles has caused the amount of plastic in the waste stream to increase from 10 percent in the late 1970s to more than 30 percent in the late 1980s.

76. GREEN, *supra* note 59, at 45. See discussion of incineration *infra* at section IV.

77. GREEN, *supra* note 59, at 42.

12.8 percent.<sup>78</sup> Municipal solid waste contains 54.1 percent paper and cardboard, while infectious waste contains 31 percent.<sup>79</sup>

Not everyone is convinced that infectious waste poses a major health risk to the public. To support this position some argue that certain common pathogens such as group D streptococci are more prevalent in household waste than medical waste, and they further maintain that soiled diapers are a far greater hazard than the typical bag of infectious waste.<sup>80</sup> The actual risk posed by infectious waste is still under debate, and the uncertainty of this issue underlies EPA's decision not to regulate the waste as hazardous.

### III. Medical Waste and the Public Health Debate

#### A. Introduction

The degree of risk posed by medical waste is unclear. There are three main areas of concern: risks to the general public health, risks of occupational exposure, and risks associated with disposal and treatment technologies.<sup>81</sup> Potential risks associated with medical waste were tentatively acknowledged prior to 1988; however, it has been the incidents of medical waste mismanagement that excited public and media attention and forced governmental action.<sup>82</sup> For instance, in 1986 the New York City Fire Department discovered approximately 1,400 bags of medical waste at a warehouse, and in 1987 in Indianapolis, 12 children were found playing with

78. *Id.*

79. *Id.*

80. COUNCIL REPORT ON INFECTIOUS MEDICAL WASTES, *supra* note 52, at 1669 and writings cited therein.

81. There may also be risks to the environment associated with medical waste such as through beach wash-ups of infectious material or incineration of hazardous medical waste; however, the focus of this paper is on public health risks. The EPA concluded that "[m]edical waste adversely affects the environment. Generally, this waste stream contributes to the overall environmental problem of solid waste disposal in the United States. Specifically, beach wash-ups and products of incomplete combustion are among the adverse environmental effects of inadequate medical waste management." ATSDR REPORT, *supra* note 60, at E.11.

82. The legislative history of the MWTA supports this conclusion and is discussed in more detail *infra* at section IV.

AIDS-infected vials of blood that came from an unlocked dumpster outside several doctors' offices.<sup>83</sup>

The outcry such incidents created may have contributed to the recent growth in state legislation regarding medical waste. Nevertheless, the federal government is not convinced that risks associated with medical waste mismanagement warrant a scheme of federal regulation. Congress first addressed the potential hazards of medical waste indirectly in 1976, defining "hazardous waste" in the Resource Conservation and Recovery Act (RCRA) to include wastes with infectious characteristics.<sup>84</sup> Despite this, medical waste was not actually regulated until 1988 when Congress passed the Medical Waste Tracking Act (MWTa). Despite passage of the MWTa, very little epidemiological study of public health risk associated with medical waste exists.<sup>85</sup> To date, the Agency for Toxic Substances and Disease Registry (ATSDR) reports the most extensive federal research on this issue.<sup>86</sup>

#### B. ATSDR Findings and EPA Health Hazard Assessment

ATSDR issued its report in September 1990 describing the "potential for infection or injury from the segregation, handling, storage, treatment or disposal of medical waste" from all sources of generation.<sup>87</sup> The agency found that for infection to happen a chain of events must occur: a person must come into contact with medical waste; an injury must follow, thereby creating a portal of entry (or a portal of entry must already exist); a sufficient number of viable infectious agents must enter a susceptible host via the portal; infection

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83. Lee et al., *supra* note 50, at 360 (citing OTA BACKGROUND PAPER, *supra* note 2).

84. 42 U.S.C. § 6903(5) (1988).

85. Telephone Interview with Ann Coggington, *supra* note 23.

86. The MWTa, *supra* note 64, section 11009, required ATSDR to report on the public health implications of medical waste. 42 U.S.C. § 6992(g)(a)(2).

87. See ATSDR REPORT, *supra* note 60. For a discussion of the methodology ATSDR used, see Sven E. Rodenbeck and Maureen Y. Lichtveld, *Report to Congress: The Public Health Implication of Medical Waste*, J. ENVTL. HEALTH, Jul. 1990, at 30.

can then occur, but does not always result in disease.<sup>88</sup> ATSDR found that "an infectious organism's ability to survive outside a host varies widely and, consequently, its capability to transmit disease varies greatly, depending on its type and form and environmental factors such as temperature and moisture."<sup>89</sup> Viruses such as hepatitis B and the human immunodeficiency virus (HIV), "must be inside a living cell to multiply and once removed from a living cell, their numbers may remain constant or decline, but may never increase."<sup>90</sup>

ATSDR arrived at 16 conclusions based on the data it developed. Most significantly, the agency concluded that the "general public's health is not likely to be adversely affected by medical waste generated in the traditional health care setting."<sup>91</sup> Outside the health care setting, the potential for hepatitis B virus or HIV infection in the general public following medical waste-related injuries is unlikely to be a health concern.<sup>92</sup> However, the number of persons infected with HIV is expected to increase; likewise, the number of health care workers infected with AIDS is anticipated to rise as a result of contact with waste sharps, thereby increasing the potential

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88. ATSDR REPORT, *supra* note 60, at E.5. Of all these requirements, an appropriate portal of entry is the most important determinant in the infectious disease transmission process. Since medical sharps are capable of creating such a portal, injuries from sharps have the greatest potential to cause infection and disease. ATSDR concludes that because most medically related injuries from sharps occur during patient care, the health care setting presents the greatest potential for infectious disease transmission. *Id.*

89. *Id.* at E.2.

90. *Id.* at E.3.

91. *Id.* at E.9.

92. *Id.* Maureen Y. Lichtveld, an ATSDR toxicologist, reports that AIDS infection as a result of contact with medical waste is unlikely because the virus is too fragile. However, risks to sanitation workers and home health care providers as a result of hepatitis B and bacterial infection contamination are rising because of the enormous expansion of the home health care industry and the lack of regulation of home health care waste disposal. Chen et al., *supra* note 62, at 22. Used syringes and intravenous tubing are often tossed into the trash or flushed down the toilet. Of the needle-stick injuries reported by sanitation workers, 14 percent occur in residential neighborhoods and this percentage is increasing. *Id.* at 21.

for medical waste-related HIV transmission in the health care setting.<sup>93</sup>

ATSDR emphasizes that limited data is available on communicable disease potentially attributable to medical waste.<sup>94</sup> Theoretical estimates vary extensively due to different study designs, reporting practices and sources of records or case information.<sup>95</sup> In conclusion, the agency makes eleven recommendations. Among them, ATSDR suggests that research is needed in three specific areas: to evaluate the probability of infection following contact with body fluids previously exposed to the environment; to evaluate the likelihood of medical waste-related diseases caused by infectious agents other than HIV and hepatitis B virus; and to determine the chemical constituents of incinerator stack emission and their mutagenicity.<sup>96</sup>

In addition to ATSDR's report, section 11008(a)(2) of the MMTA required EPA to evaluate the threat posed by medical waste.<sup>97</sup> In its first interim report to Congress, EPA proposed a methodology for assessing the potential health hazards and is currently analyzing approximately 70 classes of pathogenic bacteria, viruses, fungi and protozoa that may be present in health care facilities, focusing on their potential role in infection.<sup>98</sup> Working in consultation with ATSDR, EPA is preparing a Health Hazard Assessment Report which it will release with its third and final report to Congress under the

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93. ATSDR REPORT, *supra* note 60, at E.10.

94. *Id.* at E.11.

95. *Id.* at E.11. ATSDR's report is based on data provided by the New York City Department of Sanitation, Browning-Ferris Industries Corporation, 17 state health departments and the Department of Defense. According to the report, the data were self-reported.

96. *Id.* at E.14-15.

97. MMTA, *supra* note 64.

98. EPA SECOND INTERIM REPORT, *supra* note 30, at 35-37. This analysis focuses on those wastes warranting concern for public exposure. EPA is also collecting information on infective dose and survivability of pathogens, and performing epidemiological data searches (other than those performed by ATSDR) for disease transmission from exposure to medical waste either in the workplace or community. *Id.*

MWTA.<sup>99</sup> The agency acknowledges that "[m]any experts and health care professionals have expressed opinions that any health hazards posed by medical waste are occupational and that actual threats to the general public are unlikely, even when such wastes are mismanaged or improperly disposed."<sup>100</sup> EPA concludes that determining the potential health hazards of improperly managed medical waste is "one of the most complex and critical issues requiring resolution."<sup>101</sup>

### C. Three Types of Risks

#### 1. Risk to the General Public

At least one prominent researcher working in the infectious waste field claims that no evidence exists that medical waste has lead to disease "outside of a healthcare facility," and that the fear of AIDS, "fueled by misleading media coverage," has prompted regulation of medical waste.<sup>102</sup> Some argue the "crisis" in medical waste which spurred regulatory growth in the 1980s and early 1990s is "primarily a function of hysteria brought on by repugnance to the nature of the waste and phobia of infection."<sup>103</sup> The OTA has stressed that

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99. Telephone Interview with Ann Coggington, *supra* note 23. Ms. Coggington did not indicate when the report would be released. After preliminary study, the agency has reported that information collected on survivability of bacteria and viruses show rapid die-off of pathogens exposed to various environmental conditions. However, according to Tom Goldberg, the data now available is old and the government is not currently funding any further research in this area. Telephone Interview with Tom Goldberg, *supra* note 6.

100. EPA FIRST INTERIM REPORT, *supra* note 4, at 2-1.

101. *Id.* at 2-2. According to EPA "[t]he key question is which components of the medical waste stream pose true health hazards and, therefore, require some type of regulatory control." *Id.* at 2-2 to 2-3.

102. Rutala & Weber, *supra* note 58, and William A. Rutala, *Medical Waste, INFECT. CONTROL & HOSP. EPIDEMIOLOGY*, Jan. 1992, at 38. Rutala contends that regulation of medical waste has been based on a lack of understanding of the modes of transmission of infectious agents, the fear of AIDS, and the distrust of health care facilities. He argues that many of the rules developed by states for regulation of medical waste have no scientific basis; therefore, these rules vary widely in content, often conflict, and will ultimately increase health care costs. *Id.* at 39.

103. David R. Mercer, *A Prospectus on the Legislative Response to Medical Waste*, 55 Mo. L. Rev. 510, 515 (1991) and sources cited therein at footnote 40.

an important fundamental policy issue which the federal government should address is the extent of medical waste regulation on the basis of potential threat to public health and aesthetic characteristics.<sup>104</sup> The existing data indicates that general debris comprised the majority of waste found on beaches after medical waste wash-ups; medical waste could not be traced to illegal dumping or a specific source, but probably resulted from sewage overflow.<sup>105</sup> EPA attributed the medical waste problem to illegal disposal, combined sewer overflow, storm water runoff, beach litter, legitimate home use of syringes, illegal drug users and the generally inadequate handling of solid wastes at landfills and coastal transfer facilities.<sup>106</sup> Consequently, many believe it unlikely that the general public will contact medical waste. However, according to the Centers for Disease Control, "contaminated needles or sharps, human blood and blood products, pathological parts and laboratory wastes possess real potential to transmit disease."<sup>107</sup> Nevertheless, contaminated sharps are the only medical waste ever associated with infectious disease transmission.<sup>108</sup> According to one theoretical estimate, the probability of a person developing HIV infection from a needle on the beach is between one in 15 billion and one in 390 trillion.<sup>109</sup>

Few studies quantify the infectious microbial loads of different hospital wastes. Those existing indicate hospital

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104. OTA REPORT, *supra* note 3, at 5.

105. Rutala, *supra* note 102 at 38 (citing INVESTIGATION: SOURCES OF BEACH WASH-UPS IN 1988, NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION REPORT, Albany, New York (1988)). About 65 percent of the waste was syringe-related and was generated from home health care and illegal intravenous drug use. "The amount of medical waste in the form of plastic syringes, collected on the beaches of 23 coastal states, constituted less than 0.1 percent of the total debris found." *Id.* at 41 and sources cited therein.

106. *Health Hazards Posed in the Generation, Handling, and Disposal of Infectious Wastes: Hearing Before the Subcommittee on Regulation and Business Opportunities of the House Committee on Small Business*, 100th Cong., 2d Sess., 78 (1988) (statement of Jeffrey D. Denit, Deputy Director, Office of Solid Waste, EPA).

107. Mercer, *supra* note 103, at 513 (citing 134 CONG. REC. S10,738 (daily ed. Aug. 3, 1988) (statement of Sen. Lautenberg)).

108. Rutala, *supra* note 102, at 41 (citing ATSDR REPORT).

109. *Id.*

waste to be no more contaminated with microorganisms than household waste.<sup>110</sup> Some researchers have concluded that household waste contains on average 100 times more microorganisms with pathogenic potential for humans than hospital waste.<sup>111</sup> In fact, contaminated sharps are the only medical waste that has been associated with infectious disease transmission.<sup>112</sup> In sum, sparse evidence supports a medical waste-disease connection. Based on the data available, it appears the optimum, albeit difficult, way to reduce public exposure through wash-ups is to regulate home health care and intravenous drug use, to ensure proper disposal of municipal waste, and to prevent mechanical failures in sewage systems of coastal cities.

## 2. Occupational Risks

In the health care setting, the persons most often injured are nurse's aides, registered nurses, and housekeeping, maintenance and food-preparation workers.<sup>113</sup> Of all workers contacting medical waste, sanitary service workers report the highest rates of on-the-job injuries.<sup>114</sup> Many medical waste-related injuries reported come from contact with sharps; however, only one case of infection possibly associated with the handling of medical waste sharps has been reported.<sup>115</sup> Ac-

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110. Wayne L. Turnberg, *Infectious Waste Disposal, An Examination of Current Practices and Risks Posed*, J. ENVTL. HEALTH, May 1991, 21, 23.

111. Rutala and Weber, *supra* note 58, at 581. One study conducted by the Seattle/King County Department of Public Health concluded that because organisms capable of causing infection are a part of normal household waste, untreated residential waste may be as infectious as most untreated medical waste. See Turnberg, *supra* note 110. See also WASH. STATE DEPT. OF ECOLOGY, REPORT TO THE LEGISLATURE, WASH. STATE INFECTIOUS WASTE PROJECT (1989).

112. Rutala, *supra* note 102, at 41.

113. ATSDR REPORT, *supra* note 60, at E.3. "The annual injury rates for these occupations vary from 10 to 20 per 1,000 workers. Most work-related injuries among health care workers are sprains and strains due to overexertion." *Id.*

114. *Id.* Sanitary service workers' "overall injury rate of 180 per 1,000 workers per year is more than double that of the entire United States work force combined. Injuries are most frequently reported as strains and sprains caused by overexertion." *Id.*

115. *Id.* at E.6. According to ATSDR and Rutala, *supra* note 102, there is no documented evidence on infections resulting from contact with medical waste

cording to studies, waste industry workers who were exposed to medical and municipal waste did not exhibit an increased risk of bloodborne infections.<sup>116</sup> The Centers for Disease Control, however, once reported that each year 200 to 300 deaths occur among health care workers, often waste handlers, due to hepatitis B.<sup>117</sup>

The exact nature and degree of the risk to medical workers thereby remains an open question, with little current empirical data to resolve the debate. In its report, the ATSDR recommended that work practices of the occupational subgroups frequently contacting medical waste should be evaluated to determine appropriate protective measures and that occupational health and surveillance data for higher risk groups should be collected.<sup>118</sup> Conflicts in the existing data,

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other than sharps. ATSDR REPORT, *supra* note 60, at E.8. None of the HIV infections attributed to dermal contact or mucous membrane contamination were associated with medical waste. ATSDR estimates that there is a theoretical possibility that a maximum of 1 to 4 cases of AIDS per year could occur as a result of contact with medical waste sharps. *Id.* at E.10. Contact with non-sharp medical waste may contribute to the total number of hepatitis B virus and HIV cases, but this contribution is likely to be insignificant, as a portal of entry would already have to exist for disease transmission to occur. *Id.* at E.8. By comparison, infection resulting from patient contact in the occupational setting is much higher. See e.g. *American Dental Association v. Martin*, 984 F.2d 823 (7th Cir. 1993), wherein the court notes that as of 1991, "there had been 24 confirmed cases of United States health care workers infected with the AIDS virus by patients since AIDS was first diagnosed in 1981." About 200 health worker deaths per year are attributable to hepatitis B infection communicated by patients. This figure is approximately 100 times greater than the number of health workers infected each year by patient-communicated HIV. *Id.* at 824.

116. See Rutala, *supra* note 102, at 44 and studies cited therein.

117. 134 CONG. REC. H9541 (daily ed. Oct. 4, 1988) (statement of Rep. Wyden). The study further concludes that many of these deaths can be traced to exposure to infectious materials. Moreover, the CDC reports that each year at least 18,000 people contract hepatitis B through accidental contact with medical wastes. 134 CONG. REC. H9536 (daily ed. Oct. 4, 1988) (statement of Rep. Luken). The hepatitis B virus can spread through breaks in the skin or through contact with mucous membranes. The risk of acquiring hepatitis B infection due to a needlestick injury from a needle contaminated by a hepatitis carrier ranges between 6 to 30 percent within health care settings. Michael R. Shumaker, *Infectious Waste: A Guide to State Regulation and a Cry for Federal Intervention*, 66 NOTRE DAME L. REV. 555, 561 n.21 (1990).

118. ATSDR REPORT, *supra* note 60, at E.13.

and the general lack of data surrounding the occupational risk posed by medical waste, support this recommendation.

### 3. Risks Associated with Treatment and Disposal

Medical waste can be effectively treated by chemical, physical or biological means such as incineration, chemical decontamination, autoclaving, irradiation and sanitary sewage treatment. Incineration is the most common method of treating medical waste, and is the practice of approximately 64 to 93 percent of reporting hospitals. About one-third of United States hospitals steam sterilize their microbial waste, about one-fourth pour liquid blood down a drain connected to a sanitary sewer, and the remaining unregulated medical waste is often dumped in a sanitary landfill.<sup>119</sup> Due to increased disposable plastic use, older and less efficient incinerators have the potential to produce incompletely burned chlorinated by-products. Exposure to these substances may cause adverse health effects.<sup>120</sup> Insufficient data are available to determine the adverse public health effects associated with medical waste incineration, and the health implications of medical waste incineration as compared to municipal solid waste incineration are vigorously debated.<sup>121</sup>

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119. Rutala, *supra* note 102, at 44 (citing his own unpublished research data). See also Rutala & F.A. Sarubbi, *Management of Infectious Waste from Hospitals*, 4 INFECT. CONTROL 198-204 (1983).

120. Possible reasons for higher emission levels of dioxins and furans and HCl in medical waste incinerators may be: (1) frequent startups and shut-downs; (2) less stringent emission controls; (3) poorer combustion controls (e.g., waste mixing and oxygen controls); and (4) differences in the waste feed composition as compared with municipal solid waste. OTA BACKGROUND PAPER, *supra* note 2, at 18. Studies have also shown that dioxins and furans can be formed after leaving the furnace by the catalysts at low temperature of precursors like benzene, and by chlorine atoms on fly ash particles. *Id.*

121. ATSDR REPORT, *supra* note 60, at E.13. See also OTA BACKGROUND PAPER, *supra* note 2, at 22, which states that the few risk assessments which have been performed on individual hospital incinerators have predicted health risks, specifically cancer, that are comparable to those predicted for municipal incinerators. But "no national estimates have been developed for aggregate cancer risks from all hospital incinerators that can be compared with EPA's national estimates for municipal incinerators. Additionally, no national estimates of non-cancer effects associated with hospital incinerator emissions have been undertaken." *Id.*

The ATSDR finds that untreated medical waste can be acceptably disposed in sanitary landfills because research indicates that medical waste does not contain any greater quantity of microbial agents than residential waste. Furthermore, viruses found in solid waste are generally adsorbed to organic matter and become deactivated.<sup>122</sup> The potential hazard of pathogens in landfills is a function of three conditions: (1) the concentration and nature of the pathogen, (2) the pathogen's ability to survive and retain its infectious properties, and (3) the pathogen's ability to migrate through the landfill into the surrounding environment and be a potential human hazard.<sup>123</sup> Research shows that the chemical and physical characteristics of the landfill environment produce an inactivating effect upon viruses and bacteria; however, it acknowledges that it is possible for pathogens to survive.<sup>124</sup> On balance, it appears the risk of groundwater contamination by pathogens in a properly lined and operated landfill is low.<sup>125</sup>

Discarding of medical waste via the sanitary sewer system is arguably safe, assuming that conventional treatment processes such as primary sedimentation, secondary biological treatment and effluent disinfection reduce the microbial content of raw sewage by 90 to 99 percent. But these percentages depend on the type of microorganisms and the effectiveness of specific treatment processes.<sup>126</sup> Proponents of sewer system disposal of medical waste argue that the microbial load added to the sewage flow via body fluid, such as blood, is normally negligible compared with already existing major sources of pathogenic microbes in raw sewage, which include

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122. ATSDR REPORT, *supra* note 60, at E.11.

123. Turnberg, *supra* note 110, at 21, 23.

124. *Id.* at 24. See Rutala, *supra* note 102.

125. Turnberg, *supra* note 110, at 24. "Proper engineering and operation" include use of the necessary liners and leachate collection systems to prevent leaching of landfill contaminants to surface and groundwaters. *Id.* There have been few scientifically designed experiments to measure for pathogens in leachate or waters downstream from a landfill. OTA REPORT, *supra* note 3, at 15.

126. Rutala, *supra* note 102, at 45 (citing G. Bitton, INTRODUCTION TO ENVIRONMENTAL VIROLOGY 121-52 (1980)). See also OTA REPORT, *supra* note 3, ch. 3.

the bacteria and viruses in human feces.<sup>127</sup> The obvious counter argument to this position is the possibility of sewer overflow, or bypass or upset of the treatment works, which could result in wash-ups exposing the public to infectious wastes. Like incineration, the safety of the disposal of infectious waste into the sanitary sewer system continues to be aggressively debated.

Another primary alternative to incineration of medical waste is autoclaving, which is considered an appropriate methodology for treating 90 percent of medical waste, such as microbiological laboratory cultures.<sup>128</sup> The demand for autoclaving seems to be increasing because it is generally cheaper than incineration and does not produce potentially toxic emissions.<sup>129</sup> Other potential treatment technologies such as irradiation, microwaving, electrohydraulic disinfection and plasma torch technology are also commercially available. The health risks associated with most non-incineration technologies, however, have not been thoroughly investigated.<sup>130</sup> With the recent growth in alternative technologies for treating and disposing of medical waste, needed research on potential ancillary health risks of alternative technologies will hopefully become available in the near future.

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127. Rutala, *supra* note 102, at 45. Rutala maintains that, based on epidemiological and microbiological data, only two types of medical waste require special handling and treatment: sharps and microbiological waste.

128. OTA REPORT, *supra* note 3, at 27. Autoclaving or steam sterilization is a process used to sterilize medical wastes prior to disposal in a landfill. It involves the use of saturated steam within a pressure vessel at temperatures high enough to kill infectious agents in the waste. *Id.* at 27-28. See *infra* section V for a further discussion of incineration.

129. OTA REPORT, *supra* note 3, at 31, 39.

130. *Id.* at 38-39. OTA states that further examination of potential health risks is warranted with alternative technologies, particularly for microwaving and irradiation. While many of these alternatives can be viewed as supplements to incineration, pathological wastes are one type of infectious waste for which incineration remains the preferred treatment alternative because destruction is complete. *Id.* at 39.

#### IV. The Beginning of Federal Regulation of Medical Waste

##### A. Background

During the summers of 1987 and 1988 several northeastern beaches were closed due to wash-ups of medical waste, including used syringes, blood vials, rubber gloves, hypodermic needles, and blood bags. In New Jersey, for example, state health officials closed 50 miles of public beaches.<sup>131</sup> Public concern pressured governmental action and with unusual speed, Congress passed the Medical Waste Tracking Act (MWTa) in November 1988.<sup>132</sup> The scope of the Act was limited to adding Subtitle J to RCRA and creating a two-year demonstration program that ultimately only applied to four states and Puerto Rico.<sup>133</sup> There may be several reasons why Congress chose to so limit the MWTa. Perhaps it concluded that there was insufficient support for the legislation to override resistance from the hospital and medical community or, perhaps it felt that the medical waste problem was essentially an East Coast malady.<sup>134</sup> It is more probable that Congress concluded a program of limited time, scope and federal oversight would provide an opportunity to view a small-scale program in operation before national commitment.<sup>135</sup>

The statute and its implementing regulations expired on June 22, 1991.<sup>136</sup> Nevertheless, the MWTa remains signifi-

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131. 134 CONG. REC. S20,111 (daily ed. Aug. 3, 1988) (statement of Sen. Lautenberg). See also Mercer, *supra* note 103, at 509. New York and New Jersey lost at least a billion dollars of tourism revenues due to these closings. *Id.* at 516.

132. Medical Waste Tracking Act of 1988, Pub. L. No. 100-582, 102 Stat. 2950 (codified as amended in sections of 69 U.S.C.). When President Reagan signed the MWTa, his action "marked the culmination of four months of frenzied legislative activity as Congress responded to strong public pressure that arose after medical wastes washed ashore in the northeast." Mercer, *supra* note 103, at 519 (citing NELSON A. ROCKEFELLER INST. OF GOV'T, REPORT OF THE MEDICAL WASTE POLICY COMMITTEE 2, at 25 (1989)).

133. Medical Waste Tracking Act of 1988, Pub. L. No. 100-582, 102 Stat. 2950 (codified as amended in sections of 69 U.S.C.).

134. See PERSPECTIVES ON MEDICAL WASTE, *supra* note 17, Supp. 3-7 (1989).

135. *Id.*

136. Medical Waste Tracking Act of 1988, Pub. L. No. 100-582, 102 Stat. 2950 (codified as amended in sections of 69 U.S.C.).

cant because it is the prototype for many existing state medical waste regulatory programs.<sup>137</sup> The four main features of the Act which are reflected in a number of state statutes today are: (1) a definition of medical waste; (2) a tracking system similar to that for hazardous wastes; (3) information gathering power and requirements; and (4) enforcement capability.<sup>138</sup>

## B. A Uniform Definition of Medical Waste

EPA created a new definition of medical waste under the MWTa called "regulated medical waste."<sup>139</sup> Unlike other types of hazardous wastes addressed by RCRA, there is no objective test for medical waste, therefore a consistent definition provided by the MWTa was critical to determining the ways such waste would be regulated. The definition was hotly disputed, particularly between the American Hospital Association, the Natural Resources Defense Council and certain private parties.<sup>140</sup> First, the MWTa defined medical waste within RCRA as "any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals."<sup>141</sup> Then, the MWTa provided a list of medical waste to be included under the program.<sup>142</sup> With the expiration of the MWTa, federally "regulated medi-

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137. Cheryl L. Coon & Howard L. Gilberg, *The New Regulatory Horizon: Regulation of Medical Waste*, 45 Sw. L.J. 1099, 1100 (1991-92).

138. Medical Waste Tracking Act of 1988, Pub. L. No. 100-582, 102 Stat. 2950 (codified as amended in sections of 69 U.S.C.).

139. 40 C.F.R. § 259.30(a) (1989).

140. For a discussion of these groups' individual viewpoints, see Onel, *supra* note 10.

141. 42 U.S.C. § 6903(40) (1988 & Supp. III 1991).

142. 42 U.S.C. § 6992a(a)(1)-(11) (1988) is a listing of waste categories. In order to exclude a waste from the list, EPA had to determine the specific item did not "pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed." *Id.* § 6992(b). Ultimately, EPA eliminated some of the categories and added a few specific items. The result was a list of seven categories of medical waste subject to the tracking provisions. According to one source, "the MWTa provided Congress with a chance to do something, EPA with the discretion to do relatively little, and the states with the authority . . . to do as much or as little as they cared to do." Robert T. Nakamura et al., *A Blip*

cal waste" no longer exists and there are a plethora of state definitions.<sup>143</sup> Those who argue for a federal definition of medical waste point out that state regulation of medical waste is inconsistent, and since much of our medical waste is transported across state lines, varying definitions create the potential for disparate treatment of generators, transporters and disposers.<sup>144</sup>

### C. The Tracking System

EPA has stated that "the core of the MWTa consists of the requirement that medical waste shipped off-site be tracked to its destination."<sup>145</sup> The tracking system is based upon the hazardous waste manifest system underpinning RCRA Subtitle C.<sup>146</sup> By making the tracking system the centerpiece of the MWTa, Congress chose to focus on tracking of existing medical waste rather than to change existing practices regarding disposal or treatment of medical waste. Under the tracking system, once medical waste is generated, the generator prepares a tracking form to accompany the waste transported offsite from the facility.<sup>147</sup> The form accompanies the waste to the point of treatment and destruction or disposal and a copy of it is returned to the generator. The regulations also address handling of the waste before transport from the generator to the treatment and disposal

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*on the Radar Screen: Formulation and Implementation of the Medical Waste Tracking Act*, J. HEALTH, POL., POL'Y & LAW 299, 321 (Summer 1992).

143. For example, Florida uses "infectious, biohazardous waste," Georgia and Connecticut use "biomedical wastes," and Iowa uses "medically hazardous waste." See Shumaker, *supra* note 117, at 564, for a survey of state laws concerning medical waste.

144. *Id.* at 598. See also B.J. Wynne III & Terri Hamby, *Interstate Waste: A Key Issue in Resolving the National Hazardous Waste Capacity Crisis*, 32 S. TEX. L. REV. 601 (1991).

145. EPA SECOND INTERIM REPORT, *supra* note 30, at 6.

146. 42 U.S.C. 6901(c) (1988).

147. 42 U.S.C. § 6992b(a)(1) (1988). The MWTa tracking forms were similar to manifests used to track Subtitle C wastes. If the generator did not receive the appropriate portion of the tracking form sent with its waste back from the disposal facility, it had to notify EPA as required by "Standards for the Tracking and Management of Medical Waste," 40 C.F.R. § 259.55(b) (1989). For a discussion of divergent opinions on the tracking system, see Onel, *supra* note 10, at 240-44.

facility.<sup>148</sup> The pretransport requirements for medical waste address labeling and marking of containers, segregating, packaging and storing waste, and decontamination of reusable containers. Generators who ship more than 50 pounds of regulated medical waste offsite per month are subject to pretransport, tracking form, recordkeeping and reporting requirements, and they must ship waste with transporters who have notified EPA of their intent to transport medical waste.<sup>149</sup> Transporter vehicle standards are designed to contain the waste and maintain packaging integrity during transport. It was EPA's intention to construct a "closed circle" that facilitates proper management, encourages proper disposal and reveals potential waste mismanagement.<sup>150</sup>

Cost is a major factor weighing against treating medical waste as hazardous waste. EPA concluded that the tracking requirement imposed an average annual cost compliance of \$12,000,000, or \$24,000,000 for the two years the program would be run.<sup>151</sup> While the MWTA's tracking system may have been an effective means of providing baseline data on medical waste, its cost is a potent disincentive which must be weighed against the benefits of tracking.

#### D. Information Gathering

The MWTA provides that "any person who generates, stores, treats, transports, disposes of, or otherwise handles or has handled medical waste" must permit EPA to inspect documents and records relating to that waste, and to conduct monitoring or testing, to enter sites, and to obtain samples.<sup>152</sup> Information gathering gives EPA a means to collect data for reporting to Congress and supports the enforcement provi-

148. 40 C.F.R. § 259 (1989).

149. 40 C.F.R. § 259.50 (1989). *See also* PETER A. REINHARDT & JUDITH GORDON, *INFECTIOUS AND MEDICAL WASTE MANAGEMENT*, 1990, App. A, for a guide to MWTA medical waste tracking regulations.

150. 40 C.F.R. § 259.50 (1989).

151. EPA FIRST INTERIM REPORT, *supra* note 4, at 3-9. By comparison, EPA estimated that New York, New Jersey and Connecticut alone would lose \$30,000,000 because of adverse effects attributable to mismanaged medical waste. *Id.* at 3-16.

152. 42 U.S.C. § 6992c(a) (1988).

sions of the Act. According to EPA, "[o]ne of the primary reasons for developing a demonstration medical waste program was to facilitate the collection and analysis of information and data necessary for an informed discussion of the problems associated with medical waste."<sup>153</sup> There are five "focal points" of EPA's data gathering and research efforts: "[1] the characteristics of the regulated community; [2] the physical, chemical and pathological characteristics of medical waste; [3] the treatment, destruction and disposal methods; [4] costs associated with the mismanagement of medical waste and with the requirements of the Act; and [5] enforcement and compliance with MMTA requirements."<sup>154</sup> From this data, EPA is required by the MMTA to report to Congress on specific issues.<sup>155</sup> According to one commentator, "it is in the information gathering sections of the Act that it becomes most evident that the Medical Waste Tracking Act is not transitory relief to a fleeting crisis, but rather a prototype for permanent federal legislation controlling all aspects of medical waste."<sup>156</sup> Yet in 1992, when EPA's final report was two years overdue, one observer questioned the priority of medical waste on the agency's agenda:

While a crisis can tilt the political balance in favor of regulation, it cannot as readily produce the consensus required to sustain regulation at the levels promised in the legislation. The window of opportunity opened by a convergence of the various policy streams may remain open long enough for authorizing statutes to be enacted. But . . . passage of legislation does not guarantee effective implementation . . . .<sup>157</sup>

Although the MMTA program has lapsed and may never be revived, its most palpable effect is still seen in some state pro-

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153. EPA SECOND INTERIM REPORT, *supra* note 30, at 8.

154. *Id.*

155. EPA is required to prepare a final report to Congress at the end of the MMTA demonstration program. 42 U.S.C. § 6992g-6992h (1988).

156. Mercer, *supra* note 103, at 546.

157. Nakamura, *supra* note 142, at 322.

grams adopting the statute's tracking and controversial enforcement provisions.

### E. Enforcement

During the MWTa demonstration program, some hospitals were accused of overdesignating waste as "regulated medical waste" as protection against the severe penalties for violations.<sup>158</sup> Indeed, the MWTa contained strong enforcement authorities similar to that of RCRA Subtitle C. In addition to the inspection and information gathering authorities discussed, the agency could conduct monitoring or testing, take samples, and have access to all facility medical waste records.<sup>159</sup> The agency could issue compliance orders and assess civil penalties of up to \$25,000 per day for each violation.<sup>160</sup> In the event records, reports, documents or material information are knowingly falsified, or provisions of the MWTa are knowingly violated, the MWTa incorporated criminal sanctions subjecting the convicted violator to a fine of not more than \$50,000 per day of violation, or imprisonment of up to 5 years.<sup>161</sup> If any person knowingly creates a situation that places another person in imminent danger of death or serious bodily injury, a criminal fine of up to \$250,000 or imprisonment of up to 15 years may be imposed; a defendant organization may receive a criminal penalty of up to \$1,000,000.<sup>162</sup> Those who disagreed with the severe penalty structure argued that fines should be assessed relative to the seriousness of the violation. Proponents of the system maintained that higher penalties would provide a stronger deterrent value.<sup>163</sup>

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158. Rutala, *supra* note 102, at 46.

159. 42 U.S.C. § 6992c (1988).

160. 42 U.S.C. § 6992d(a)(4) (1988); see DONALD W. STEVEN & ELIZA A. DOLIN, ENVIRONMENTAL LAW AND PRACTICE, 3-186 (1992).

161. 42 U.S.C. § 6992d(b) (1988).

162. *Id.* The orders for penalties were final unless a public hearing was requested within 30 days. 42 U.S.C. § 6992d(a)(3) (1988).

163. 134 CONG. REC. H9538 (daily ed. Oct. 4, 1988) (statement of Rep. Whitaker) and 134 CONG. REC. H10,106 (daily ed. Oct. 12, 1988) (statement of Rep. Schuette). For a discussion of the merits of stringent federal medical waste legislation and enforcement, see Laurence D. Granite, *The Medical Waste*

During the first year of the demonstration program, EPA aggressively pursued eleven serious violations through administrative actions, and issued 257 warning letters and for less serious infractions, notices of violation.<sup>164</sup> As of June 1, 1990, EPA reported it had conducted approximately 510 inspections and had assessed approximately \$690,000 in penalties.<sup>165</sup> The final tally of enforcement actions should appear in EPA's forthcoming final report.<sup>166</sup>

#### F. Critique of the MWTa

It has been suggested that the MWTa was simply a means by which Congress could temporarily stem constituents' demands for action in the wake of beach wash-ups, and, with the dispersion of these political forces and the expiration of the Act, the MWTa will have no material impact on the problems of medical waste.<sup>167</sup> While this is not altogether true, the demonstration program had certain weaknesses which adversely affected its efficacy. For instance, the MWTa did not address long-term risks associated with different treatment and disposal systems, nor did it clearly enunciate any preferred mode of disposal.<sup>168</sup> While the MWTa suggested that incineration may be the best mode of treatment, it did not address problems surrounding medical waste incinerators and it did not prompt EPA to establish basic parameters such as "air pollution emission standards, operating temperatures and residence times for incinerators and autoclaves, operator training and monitoring specifications, and

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*Tracking Act of 1988: An Analysis of its Provisions and its Effect on New York State*, 7 *TOURO L. REV.* 259 (1989-91).

164. EPA SECOND INTERIM REPORT, *supra* note 30, at 22.

165. *Id.*

166. *See supra* note 23.

167. PERSPECTIVES ON MEDICAL WASTE, *supra* note 17, at 31, wherein the authors correctly predicted in 1989 that three policy debates would persist after expiration of the MWTa: the level of danger inherent in infectious wastes, what role EPA should play in their regulation, and the success of current practices in the handling and disposal of the waste.

168. Onel, *supra* note 10, at 240.

ash disposal requirements.”<sup>169</sup> Nor did the Act prohibit disposal of medical waste through sewage systems.

The problem of beach wash-ups cannot be eradicated until the underlying issues of waste disposal are confronted. The MMTA placed no “restrictions on who could handle infectious waste and where the waste should be treated and disposed,” and no minimal standards were set regarding packaging and labeling, or the labeling and disinfection of transport trucks.<sup>170</sup> The Act was also unclear as to whether incinerated waste was to be completely exempt from the tracking system, or whether waste incinerated off-site was to be tracked.<sup>171</sup> These uncertainties, including the small quantity generator exemption, will influence the accuracy and quality of the data EPA gathered under the MMTA and its conclusions. Also, since there was no pre-MMTA baseline data for comparison it is not clear if EPA will be able to adequately interpret the information it gathers under the MMTA.

While the MMTA permitted the EPA to grant implementation and enforcement authority, it did not address the issue of compliance by haulers and disposal site operators.<sup>172</sup> Furthermore, the stringent regulations imposed on the generators under the MMTA did not take into account varying risks posed by different types of medical waste. The Act could have been strengthened by imposing some of the tracking and handling costs on the waste handlers.<sup>173</sup> In addition, the MMTA did not address the interstate problem of medical waste, leaving states to devise their own disparate regulations. Hence, a “myriad of state responses has resulted in a standardless national definition of infectious waste, and a complex array of procedures and agencies intended to deal with the prob-

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169. *Id.* The MMTA simply requires EPA to gather information, conduct assessment studies and report to Congress.

170. *Id.* at 243.

171. *Id.*

172. *Id.* at 244.

173. *Id.* at 247.

lem.”<sup>174</sup> Finally, the program focused on northeastern states with coastlines and beach wash-up problems; consequently, the necessity or practicality of its transferability to other regions is open to question.<sup>175</sup>

In spite of its perceived shortcomings, the MWTa has produced beneficial effects. It has contributed to our knowledge of the medical waste stream and will help identify new areas of concern. The program could help in the formulation of a uniform definition of medical waste. In addition, enforcement, inspection and tracking systems could serve as a future model, even if Congress decides medical waste should be left wholly within state purview.

According to EPA's preliminary evaluation of the MWTa, the demonstration program has had several direct and indirect effects. Its direct effects have been “the implementation of a functioning tracking program and the collection of essential information.”<sup>176</sup> The indirect effects of the program include the encouragement of innovation in treatment technologies such as gamma irradiation and microwaving techniques, the reevaluation of home health care waste management, a possible reduction in the severity of beach wash-ups, and a positive stimulus on medical waste program development in noncovered states and foreign countries.<sup>177</sup> Since enactment of the MWTa, nearly every state has passed some type of medical waste legislation or revised its existing regulations.<sup>178</sup> When EPA at last releases its final report to Congress on the MWTa, the agency will make a recommendation

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174. Scott Goldie, *Blood on North American Soil: A Comparison of United States and Canadian Infectious Waste Disposal Regulations*, 16 SYRACUSE J. INT'L L. & COM. 129, 158 (1989).

175. According to one commentary, the MWTa's scope, “was geographically and temporally limited in order to increase its political feasibility . . . . By limiting coverage to those geographical areas where public support was strongest, and by limiting the authorized life of the program, the [Congress] could capitalize on public opinion without risking a battle with the health care establishment.” Nakamura et al., *supra* note 142, at 309. Thus, the MWTa could be characterized as “an exercise in symbolic politics.” *Id.* at 312.

176. EPA SECOND INTERIM REPORT, *supra* note 30, at 23.

177. *Id.* at 23-24.

178. EPA's final report to Congress is expected to address changes in the covered states' program and provide further analysis of the indirect program

on whether a continuing federal program is needed and if so, what components the program should include.<sup>179</sup> Meanwhile, management of medical waste in the United States is governed by an eclectic montage of statutes, rules, guidelines and standards.

## V. Current Federal Law Governing Medical Waste

### A. The Resource Conservation and Recovery Act

EPA was given authority to regulate the handling, storage, treatment, transportation and disposal of medical and infectious waste in 1976 under Subtitle C of the Resource Conservation and Recovery Act (RCRA),<sup>180</sup> which amended the Solid Waste Disposal Act of 1965. RCRA represents Congress's first attempt to control and regulate hazardous waste from creation until disposal. Under RCRA, "hazardous waste" is defined, in part, "a solid waste, or combination of solid wastes, which because of its quantity, concentration, physical, chemical or *infectious* characteristics may . . . pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed."<sup>181</sup> This definition appears to permit inclusion of infectious wastes among the other RCRA-regulated hazardous wastes. In 1978, EPA issued a preliminary rule that placed infectious waste in the category of hazardous waste it proposed to regulate; however,

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effects. *Id.* at 23. State regulation of medical waste is discussed *infra* at section VI.

179. *Id.* at 2.

180. 42 U.S.C. § 6901-6992k (1988 & Supp. III 1991). The main outcome of RCRA has been the creation of a stringent system for regulating hazardous wastes. In practice, there is little federal regulation of other solid wastes such as manufacturing wastes. See ENVIRONMENTAL AND ENERGY STUDY INSTITUTE, EESI BRIEFING BOOK 55 (1993) at 55.

181. 42 U.S.C. § 6903(5) (1988) (emphasis added). EPA will regulate chemical waste only if it has a characteristic defined as hazardous, or is listed in 40 C.F.R. § 261 (1992). Generally, these lists pertain to toxic chemicals. Chemical waste satisfying either condition will be legally identified as hazardous waste. Some chemicals found in medical waste do exhibit at least one of these characteristics, e.g., solvents are often ignitable. It is therefore possible for some infectious wastes to be considered hazardous. See Reinhardt & Gordon, *supra* note 149, at 140.

when comment responses vociferously recommended against regulation of infectious waste as hazardous, EPA decided not to include infectious waste among the RCRA-regulated substances in the 1980 final rules.<sup>182</sup> With the release of the rules in 1980, EPA said it would issue separate infectious waste regulations; however, these have never appeared.<sup>183</sup> Instead, EPA issued draft guidelines for infectious waste management in 1982 and final guidelines in 1986.<sup>184</sup>

Under RCRA, the federal government's role is to provide information, research and financial assistance to the states, and to initiate a solid waste management policy.<sup>185</sup> Congress put the federal government in this role to encourage states and local governments to become active in implementing local waste disposal programs while maintaining minimum national standards.<sup>186</sup> The EPA has the authority to set standards for hazardous waste handling, transportation<sup>187</sup> and storage,<sup>188</sup> and can enforce EPA regulations with civil and criminal penalties.<sup>189</sup> However, EPA has chosen not to regulate infectious waste as hazardous waste. With the expiration of the MWTa, EPA is treating infectious waste as solid waste, relying on the states to enforce their own infectious waste programs.<sup>190</sup> As there are currently no regulations for infectious waste management based on RCRA, EPA cannot enforce any national standards for management and disposal,

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182. PERSPECTIVES ON MEDICAL WASTE, *supra* note 17, at 3.

183. *Id.* at 3-4. EPA changed its position on the hazards presented by infectious wastes and chose to make "recommendations" concerning their management. *Id.*

184. EPA GUIDE, *supra* note 30, at vi. EPA's guide for infectious waste management satisfied RCRA's objective of providing information, but also contributed to the confusion surrounding the hazardousness of infectious waste by not providing a basis for interstate control. Goldie, *supra* note 174, at 156-57. The guide addresses problems posed by the infectious characteristics of medical waste, but in so doing, contradicts EPA's original position that regulation of the waste is not warranted because public risks were unproven. *Id.*

185. 42 U.S.C. § 6902(a) (1988).

186. 42 U.S.C. §§ 6901-02 (1988).

187. 42 U.S.C. § 6923 (1988).

188. 42 U.S.C. § 6924 (1988).

189. 42 U.S.C. § 6928 (1988).

190. Telephone interview with Ann Coggington, *supra* note 23.

nor can it apply the penalties available under RCRA for infectious waste mismanagement.<sup>191</sup>

By granting EPA authority to regulate hazardous waste, Congress presumably intended that EPA establish a national standard for management of all forms of hazardous waste, including, by definition, infectious waste. A national standard would facilitate interstate regulation and control, and would prevent conflicts of policy and enforcement between neighboring states. Moreover, classifying infectious wastes as hazardous could be desirable from the standpoint that it would allow prosecution of illegal dumping as a felony and permit more stringent treatment of violations. Additionally, it would permit tracking of infectious wastes from generation to disposal or destruction, and would thereby ensure greater comprehensive management of infectious wastes. On the other hand, treating infectious waste as hazardous waste under RCRA Subtitle C will likely increase the costs of management and disposal, create further difficulty in siting disposal facilities, impose burdensome requirements on generators, handlers and transporters, and shift non-health care costs to patients. The foregoing factors must be weighed in the balance while recognizing that the risk associated with medical waste is still vigorously debated. Legislative action has been proposed as a means of addressing the issue.

In the 102nd Congress one proposed bill amending RCRA was introduced on April 25, 1991 by Senator Max Baucus.<sup>192</sup> It specifically addressed medical waste and provided, among other things, that the EPA Administrator define medical waste in consultation with the Director of the Centers for Disease Control, the Assistant Secretary of Labor for Occupational Safety and Health, the Commissioner of the Food and

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191. See Goldie, *supra* note 157, at 147-48.

192. S. 976, 102d Cong. 1st Sess. (1991). The bill was intended to eliminate use of certain hazardous substances and reduce production of wastes by directing EPA to address toxic use and source reduction. In addition, the bill also addressed municipal waste recycling, waste treatment, containment and incineration. The bill was strongly opposed by industry because of its toxic reduction provisions, and eventually floundered, never reaching a vote in the Senate. "A Tale of Sound and Fury: The Environmental Record of the 102d Congress," 23 ENVTL. L. REP. 10,015, 10,020 (Envtl. L. Inst.) (Jan. 1993).

Drug Administration and the Secretary of Transportation.<sup>193</sup> In addition, the amendment set standards for medical waste storage and containment, provided treatment options to destroy or sterilize infectious agents or render them unrecognizable, and established transportation requirements including a tracking form maintained by a registered transporter.<sup>194</sup> None of the legislation addressing medical waste proposed in the 102nd Congress passed. Currently, there is no legislation pending in the 103rd Congress specifically addressing management of medical waste and RCRA reauthorization this term appears unlikely.<sup>195</sup>

## B. The Clean Water Act

Both the Clean Water Act (CWA)<sup>196</sup> and the Marine Protection, Research and Sanctuaries Act (MPRSA)<sup>197</sup> regulate discharge and disposal of medical waste. These two statutes

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193. S. REP. NO. 301, 102d Cong. 2nd Sess. at 60 (1992).

194. *Id.* at 61. The section amending RCRA was "designed to assure that a minimum national system for the management of medical wastes is put in place." *Id.* The House RCRA reauthorization bill, H.R. 3865, was introduced on November 22, 1991 as "The National Waste Reduction, Recycling and Management Act," however, it never passed. See H.R. REP. NO. 102-839, 102d Cong. 2d Sess. (1992). Legislation such as S. 1083 was proposed to extend the MWTAA and was approved by the Senate, but no corresponding action was taken by the House of Representatives. See S. REP. NO. 103-33, 103rd Cong., 1st Sess. 12 (1993).

195. Much of the pending proposed legislation addressing solid waste concerns interstate transportation and disposal of waste and waste incineration. See, e.g., H.R. 963, H.R. 1076, H.R. 2488, S. 439, S. 822 and S. 424. Numerous states have enacted statutes to prohibit or restrict imports of solid waste from other states, but courts have struck down several of the laws as unconstitutional because they interfere with interstate commerce. Local opposition to disposal of out-of-state waste has prompted some members of Congress to seek legislation giving states and localities authority to restrict importation of medical waste. EESI BRIEFING BOOK, *supra* note 4, at 55. Also, for a list of recent cases addressing interstate transportation of waste, see "A Tale of Sound and Fury," *supra* note 192, n.133. Superfund reauthorization seems to have a higher priority than RCRA reauthorization in the 103rd Congress, and it appears RCRA is not likely to be addressed this Congressional session; consequently, it is unknown whether RCRA will specifically address medical waste in the future. See 23 Env't Rep. (BNA) 3108 (Apr. 9, 1993) and 23 Env't Rep. [Current Development] (BNA) 681 (Jun. 19, 1992).

196. 33 U.S.C. §§ 1251-1387 (1988 & Supp. IV 1992).

197. 33 U.S.C. §§ 1401-1445 (1988 & Supp. IV 1992).

not only protect surface water from degradation from improper medical waste disposal, but they may also prevent beach wash-ups and closings, which are occurring with more frequency.<sup>198</sup> Most beach closings are caused by beach pollution from combined sewer overflows, polluted runoff, raw sewage overflow, overloaded sewage treatment plants, septic tank pollution and boating wastes.<sup>199</sup> How much improper medical waste disposal contributes to beach closings every year is unknown. Nevertheless, recent history confirms that medical waste pollution is a significant factor. Questions remain whether the CWA and the MPRSA can be used to confront it.

The CWA makes it an offense for any person to discharge a pollutant into navigable waters from a point source.<sup>200</sup> However, in the context of medical waste disposal, the definition of "point source" has been subject to conflicting interpretations. For instance, in *U.S. v. Villegas*, a doctor was originally convicted of being a point source when he unlaw-

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198. In its third annual report on beach closings, the Natural Resources Defense Council (NRDC) found that there were more than 2,600 beach closings or advisories in 1992, which was higher than 1991 figures. NRDC, *Testing the Waters III: Closings, Costs, and Cleanup at U.S. Beaches*, NRDC Report, 3 (June 1993). This data contradicts EPA's assertion that one beneficial effect of the MWTAA was reduced beach closings.

199. *Id.* at 9. See also Michael Specter, *Sea-Dumping Ban: Good Politics, But Not Necessarily Good Policy*, N.Y. TIMES, Mar. 22, 1993, at A1, for a discussion of ocean dumping and medical waste wash-ups. The author maintains that wash-ups were primarily due to combined sewer overflows in New York and New Jersey and that ocean dumping was unrelated to the beach wash-ups and closings. Commenting on the Ocean Dumping Ban Act, he states that the legislation "is a striking triumph of environmental politics over science, a clear demonstration of how environmental policy can often be directed by symbols and fears [rather] than by reasoned discussion of benefit and risk." *Id.*

200. 33 U.S.C. § 1311(a) (1988). A point source is defined in § 1362(14) as "any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged. The term does not include agricultural stormwater discharges and return flows from irrigated agriculture." 33 U.S.C. § 1362(14) (1988). Congress defined "the discharge of a pollutant" as "any addition of any pollutant to navigable waters from any point source. . . ." 33 U.S.C. § 1362(12) (1988). The broad definition of "pollutant" includes dredged spoil, solid waste, incinerator residue, sewage, garbage, chemical wastes, and biological materials. *Id.* at § 1362(6).

fully disposed of vials of blood by wedging them into the rocks of a river bulkhead.<sup>201</sup> School children visiting the nearby beach found some of the glass vials laying in the sand and tests revealed that five of the vials contained blood infected with hepatitis B, an infectious virus that causes inflammation of the liver.<sup>202</sup> In its initial opinion the United States District Court found that Congress intended an expansive reading of the term "point source," and did not exclude a person from within its meaning since the object of a CWA inquiry is whether a defendant's activity deliberately threatened the "chemical, physical and biological integrity of the Nation's waters."<sup>203</sup> However, the case was reversed on appeal and the United States Circuit Court specifically addressed the question whether a human being can be a point source.<sup>204</sup> The appeals court found that human beings are not among the enumerated items that may be a "point source" and that the CWA generally targets industrial and municipal sources of pollutants.<sup>205</sup> According to the court, "this statute was never designed to address the random, individual polluter like Villegas."<sup>206</sup> This ruling raises some unanswered questions about how effectively the CWA can be used addressing unlawful handling and disposal of medical waste.

The CWA's sister statute, the MPRSA may be useful in protecting the ocean from illegal dumping of medical waste. Popularly known as the Ocean Dumping Act or the Ocean Dumping Ban Act, the purpose of the MPRSA is "to regulate the dumping of all types of materials into ocean waters and to prevent or strictly limit the dumping into ocean waters of any material which would adversely affect human health, welfare, or amenities, or the marine environment, ecological systems or economic potentialities."<sup>207</sup> Specifically, the Act regulates the transportation of material from the United

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201. 784 F. Supp. 6 (E.D.N.Y. 1991).

202. *Id.*

203. 784 F. Supp. at 10 (quoting 33 U.S.C. § 1251(a)(1988)).

204. 3 F.3d 643 (Cir. 2 1993).

205. *Id.* at 646.

206. *Id.*

207. 33 U.S.C. § 1401 (1988 & Supp. IV 1992).

States to a location outside the country for the purpose of dumping it into the ocean, and the dumping of material transported by anyone from a location outside the United States if the dumping occurs in the territorial sea or contiguous zone of the United States.<sup>208</sup> Among other things, the Act establishes a permit program for the transportation and dumping of material into ocean waters, and only allows permits for three distinct activities: (1) transportation of any material from the United States for the purpose of dumping it into ocean waters; (2) dumping of any material transported from outside the United States into the territorial sea of the U.S. or the contiguous zone; (3) transporting any material by a United States agency or United States registered vessel from outside the U.S. for the purpose of dumping it into ocean waters.<sup>209</sup> The term "material" is broadly defined in the Act and includes chemicals, biological and laboratory waste, and "other waste."<sup>210</sup> Medical waste is specifically addressed under the MPRSA and is discreetly defined.<sup>211</sup> The Act prohibits ocean dumping of medical waste, radiological, chemical, and biological warfare agents, and radioactive waste.<sup>212</sup>

For each violation, civil penalties of up to \$50,000 can be assessed for violating the Act, its implementing regulations, or a permit.<sup>213</sup> In addition, any person who violates the Act by "engaging in activity involving the dumping of medical waste" is liable for a civil penalty of up to \$125,000 for each

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208. 33 U.S.C. § 1401(c) (1988 & Supp. IV 1992).

209. 33 U.S.C. § 1412 (1988 & Supp. IV 1992).

210. 33 U.S.C. § 1402(c) (1988).

211. According to the Act's definitions, medical waste includes isolation wastes, infectious agents, human blood and blood products, pathological wastes, sharps, body parts, contaminated bedding, surgical wastes and potentially contaminated laboratory wastes, dialysis wastes, and additional items prescribed by regulation. 33 U.S.C. § 1402(6) (1988).

212. 33 U.S.C. § 1412(a) (1988 & Supp. IV 1992). Relevant Congressional oversight hearings include *Hearings Before the Subcommittee on Fisheries and Wildlife Conservation of the House Committee on Merchant Marine and Fisheries* 100th Cong., 2d Sess. (1988) on the closure of coastal areas due to medical waste and sewage contamination, and *Hearing Before the Subcommittee on Oceanography of the House Committee on Merchant Marine and Fisheries*, 100th Cong., 2d Sess. (1988) on H.R. 3478, a proposed bill to amend the MPRSA and the CWA.

213. 33 U.S.C. § 1415 (1988).

violation.<sup>214</sup> A knowing violation can result in criminal penalties of up to \$50,000 or imprisonment for one year, or both, and knowingly engaging in activity involving dumping medical waste into ocean waters can result in a \$250,000 fine or imprisonment for up to 5 years, or both.<sup>215</sup>

### C. The Clean Air Act

The Clean Air Act addresses one significant aspect of medical waste: incineration.<sup>216</sup> Historically, incineration was the only method of treatment accepted by regulators for infectious waste because it offers total destruction, providing an aesthetic benefit and reducing solid waste disposal cost.<sup>217</sup> In addition, when incinerators are outfitted with heat recovery capability, they can provide a reduction in the medical waste generator's energy cost by using heat from the incinerator to fire boilers.<sup>218</sup> Other advantages of incineration are that it requires little processing of wastes before burning and can often be done on-site.<sup>219</sup> The main disadvantages are the high cost and the potential pollution risks associated with incineration processes.<sup>220</sup> Pollutants of concern from medical waste incinerators include particulate matter, toxic metals,

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214. *Id.*

215. *Id.*

216. Clean Air Act, 42 U.S.C. §§ 7401-7671q (1988 & Supp. III 1992). "Incineration is the process by which combustible materials are burned, producing combustion gases and noncombustible residue and ash." U.S.E.P.A., OPERATION AND MAINTENANCE OF HOSPITAL MEDICAL WASTE INCINERATORS, at 2.1 (1990) (hereinafter EPA INCINERATION HANDBOOK).

217. Deborah Jessup, INFECTIOUS WASTE: THE COMPLETE RESOURCE GUIDE, 1988, E-63, containing testimony of Robert B. Shaw, Vice President, BFI Medical Waste Systems, Inc. "Incineration sterilizes and detoxifies medical waste and converts it to ash, reducing its weight and volume by 90 to 95 percent." Floyd Hasselris & Laura Constantine, *Characterization of Today's Medical Waste*, in MEDICAL WASTE INCINERATION AND POLLUTION PREVENTION, *supra* note 59 at 37.

218. Green, *supra* note 59, at 37.

219. OTA BACKGROUND PAPER, *supra* note 2, at 15.

220. *Id.* According to EPA, "[r]eduction of atmospheric emissions of constituents that are potentially harmful to human health and the environment is a prerequisite to acceptance of hospital incineration as a feasible disposal alternative by the community." EPA INCINERATION HANDBOOK, *supra* note 216, at 2.1. A recent study confirmed the increasing use of hospital disposable products and identified numerous ways of reducing medical waste through substitution,

toxic organics, carbon monoxide, and acid gases such as hydrogen chloride, sulfur dioxide and nitrous oxides.<sup>221</sup> The issue of risk posed by incineration byproducts is under debate. A recent study found that measured background levels of contaminants posed significantly higher risks to people than incremental additional discharges of pollutants linked to incinerators in the New York and New Jersey metropolitan area.<sup>222</sup> According to the study, hospital infectious waste incinerators were associated with the smallest potential health impacts of all evaluated source categories, whereas municipal solid waste incinerators were associated with the greatest potential health impact.<sup>223</sup> As the debate over health risks intensifies, states are more aggressively regulating medical waste incinerators. For example, California had proposed regulations on new and existing medical waste incinerators that were expected to result in the shutdown of 90% of the state's incinerators because of the high cost of retrofitting air pollution control systems to control dioxin and metals.<sup>224</sup> At-

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minimization and recycling of certain disposable products. *Disposable Products in the Hospital Waste Stream*, 268 JAMA 2508 (Nov. 11, 1992).

221. EPA INCINERATION HANDBOOK, *supra* note 216, at 3.1. For example, hydrochloric acid and chlorine are released from the burning of plastics in generally ill-equipped hospital incinerators. Diane Levetan, *Medical Waste Disposal: A Growing American Crisis*, AM. CITY & COUNTY, May 1990 at 68. For a discussion of the economic impact of incinerator emission regulation, state initiatives, and the growth in alternative treatment technologies, see Rubin, *supra* note 8, at 26.

222. *Incineration 2000: Phase II Report*, cited in MED. WASTE NEWS, Apr. 12, 1993, at 15.

223. *Id.* By comparison, a study for the Florida Department of Environmental Regulation (FDER) found that municipal solid waste incinerators and medical waste incinerators combined account for 29 percent of all Florida mercury air pollution. The FDER wants the state to legislatively ban mercury for medical uses where possible. *Florida DER Finds MSW, Medical Incinerators Causing 29% of Mercury Pollution*, HAZ. WASTE BUS., Feb. 24, 1993, at 20.

224. Lee, *supra* note 50 at 360. In *Texas v. National Medical Waste of Texas Inc.*, Tex. Dist. Ct. 239th Jud. Dist., No. 91G2902, (Aug. 3, 1992), a corporate defendant which disposed of human body parts and other medical waste agreed to pay \$110,000 in civil penalties. The amount was in partial settlement of a lawsuit alleging the company violated the Texas Clean Air Act and the rules and regulations of the Texas Air Control Board by surpassing opacity limits, failing to complete stack testing requirements, and exceeding emission limits for pollutants including oxides of nitrogen, carbon monoxide and hydrogen chloride.

tempting to avoid costs associated with incineration and its increased regulation, some hospitals are seeking alternative methods of treatment such as microwaving.<sup>225</sup> For instance, a new treatment and disposal method called "electrical thermal deactivation" uses high-energy radio waves to cook the medical waste without producing ash or fumes.<sup>226</sup>

The total amount of medical waste incinerated per year is unknown; however, it remains the most prevalent form of infectious waste treatment.<sup>227</sup> Today, incineration accounts for more than 75 percent of the total medical waste treated, while most of the remaining medical waste is autoclaved.<sup>228</sup> The Clean Air Act Amendments of 1990 specifically address solid waste combustion, and because medical waste is currently considered solid waste, it is covered by the statute.

Section 129 of the Clean Air Act Amendments of 1990 requires EPA to develop new source performance standards (NSPS) and emission guidelines (EGs) for four classes of solid waste incineration units: municipal waste combustors, medical waste incinerators, industrial and commercial waste incinerators and categories of other solid waste incinerators.<sup>229</sup>

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225. In May 1992, a consortium of eighteen Minneapolis and St. Paul hospitals and a coalition of environmental and medical groups agreed to treat some of their combined annual 3,000,000 pounds of infectious waste with steam and microwaves instead of incinerating it. Only a relatively small portion of infectious waste will still be incinerated (pathological waste, e.g. human tissue). Environmental advantages to these methods of disposal include a reduction in toxic air pollutants (no emission permits are necessary), and the ability to dispose of the residual waste in regular landfills. 23 Env't. Rep. [Current Developments] (BNA) 408 (May 22, 1992). An increase in these methods of treatment and disposal are but two of the current trends in the waste disposal market. Others include a corresponding decrease in incineration, industry consolidation, and stabilization of supply versus demand. 23 Env't. Rep. [Current Developments] (BNA) 282 (May 8, 1992).

226. Scott McPetridge, *We Really Want Your Medical Waste*, GARBAGE, July 1993, at 19.

227. EPA estimated that the total amount of hospital waste incinerated, when including the waste incinerated off-site, is about 80 percent of the total hospital waste in the United States. OTA BACKGROUND PAPER, *supra* note 2, at 15 n.1.

228. Malloy, *supra* note 6, at 67.

229. 42 U.S.C § 7429(a) (1988 & Supp. III 1992). EPA's Administrator establishes performance standards for each category of solid waste incineration units. *Id.* New source performance standards are the minimum federal emis-

Under section 129, EPA must establish numerical limits for emissions of acid gases (sulfur dioxide and hydrogen chloride), particulate matter, opacity, metals (cadmium, lead, and mercury), organics (dioxins/furans), carbon monoxide, and nitrogen oxides from solid waste incineration units.<sup>230</sup> The agency has issued a list of the types of incinerators to be included under the category of "other solid waste incinerators" (OSWIs) and the scheduled date for promulgating NSPS and EGs for OSWIs is November 15, 2000.<sup>231</sup> New source performance standards and emission guidelines for other types of incinerators, including medical waste incinerators, are to be developed under separate rulemaking actions.<sup>232</sup>

EPA's notice of proposed rulemaking on medical waste incinerators was delayed, ostensibly because of budget cutbacks and internal EPA disagreements regarding monitoring issues.<sup>233</sup> The proposed rule will develop NSPS and EGs for existing sources enforced under Sections 111 and 129 of the Clean Air Act, and it is likely that states will have to submit plans for implementing and enforcing the guidelines.<sup>234</sup> Because mandatory monitoring devices can be costly, EPA is grappling with questions about how to monitor compliance; furthermore, the agency is trying to reach an internal consensus on whether pollution control technology or monitoring should be foremost on the agency's agenda.<sup>235</sup>

The other debate surrounding medical waste incineration is whether or not the ash produced is hazardous. EPA decided in September 1992 that municipal solid waste ash

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sions limits set by EPA for all new or substantially modified sources of air pollution in major polluting industries. The standards are based on the best technology currently available, taking costs into account. See 42 U.S.C. § 7429 and EESI BRIEFING BOOK, *supra* note 4, at 13.

230. 42 U.S.C. § 7429 (1988 & Supp. III 1991). Solid waste incineration unit is defined at § 7429(g)(1).

231. 58 Fed. Reg. 31,358-59 (1993).

232. *Id.*

233. The latest notice deadline for medical waste incinerators was March 1994, moved back from October 1993. Final action is scheduled to take effect in August 1995. See *EPA Medical Waste Incinerator Rule Stuck on Monitoring Issue*, MED. WASTE NEWS, May 12, 1993, at 8.

234. *Id.*

235. *Id.*

should fall under RCRA's household waste exclusion and thus be treated as nonhazardous.<sup>236</sup> However, two divergent Circuit Courts of Appeals rulings on this issue have emerged. The United States Circuit Court of Appeals for the Second Circuit excluded municipal solid waste ash from consideration as a hazardous waste,<sup>237</sup> while the Seventh Circuit ruled that the ash is subject to regulation as a hazardous waste.<sup>238</sup> The Supreme Court upheld the Seventh Circuit, ruling that RCRA Section 3001(i) does not exempt the municipal waste combustion ash generated by the petitioner, City of Chicago, from regulation under RCRA Subtitle C as hazardous waste.<sup>239</sup> Notably, the Court pointed out the petitioners' waste stream was not solely household waste, but consisted of combined household waste and nonhazardous industrial waste, and the Court was not willing to extend the Section 3001(i) exemption to such a waste stream.<sup>240</sup> It is presently unclear how broad an impact this ruling will have.<sup>241</sup>

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236. This RCRA exclusion states that a municipal resource recovery facility is not deemed to be "treating, storing, disposing of, or otherwise managing" hazardous waste if it receives and burns only household waste. 42 U.S.C. § 6921(i) (1988 & Supp. III 1991).

237. *Environmental Defense Fund v. Wheelabrator Technologies*, 931 F.2d 211 (2d Cir. 1991).

238. *Environmental Defense Fund v. Chicago*, 948 F.2d 345 (7th Cir. 1991) *cert. granted*, 61 U.S.L.W. 3851 (U.S. Jun. 21, 1993) (No. 92-1639). The Supreme Court originally remanded the case for consideration in light of a September 1992 EPA memorandum explaining the Agency had changed its position to include municipal incinerator ash within the section 6921(i) exclusion. The 7th Circuit stated that the Agency had changed its view so frequently that it was no longer entitled to the deference normally accorded an Agency's interpretation of the statute it administers. 948 F.2d at 346. The question presented to the Supreme Court was whether section 6921(i) of RCRA, "which provides that [a] resource recovery facility recovering energy from the mass burning of municipal solid waste shall not be deemed to be treating, storing, disposing of, or otherwise managing hazardous wastes, exempt[s] from hazardous waste regulation ash generated by burning municipal solid waste at such facility?" 61 U.S.L.W. 3779 (May 15, 1993).

239. *City of Chicago v. Environmental Defense Fund*, 62 U.S.L.W. 4283 (May 2, 1994).

240. *Id.*

241. *Id.* In his dissent, Justice Stevens concedes that the majority's decision may represent sound policy because requiring cities to spend funds to dispose of incinerator residues in accordance with Subtitle C will provide additional protection to the environment. Nevertheless, he questions the decision's impact on

## VI. State Regulation of Medical Waste

The Medical Waste Tracking Act (MWTa) was enacted by Congress amid concern about the inconsistent regulation of medical waste among the states and local municipalities.<sup>242</sup> State and local laws ranged from comprehensive statutes to a total absence of regulation. Congress's assessment of local regulation also concluded that an overarching federal regulatory scheme was necessary to effectively control the interstate transportation and disposal of medical waste.<sup>243</sup>

In enacting the MWTa, Congress charged EPA with the responsibility to study existing state and local controls on the handling, storage, transportation, treatment, and disposal of medical waste, including enforcement and regulatory supervision.<sup>244</sup> EPA responded by creating a demonstration tracking and management program which collects information on existing medical waste requirements for the five areas covered by the program. EPA is also studying current and proposed medical waste regulations in the states that "opted out" of the demonstration program.<sup>245</sup> The objective of EPA's analysis is to examine what makes a successful medical waste management program by comparing the programs and compiling a list of the most important factors such as tracking, packaging, disposal methods, and comprehensiveness of medical waste definition. The Agency will publish the results of its study in its third and final report to Congress.<sup>246</sup>

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scarce landfill space and on the policy of encouraging resource recovery. Moreover, it is questionable, he asserts, whether the environmental benefits of this decision justify the costs of additional regulation.

242. EPA SECOND INTERIM REPORT, *supra* note 30, at 4. See also, *Health Hazards Posed in the Generation, Handling and Disposal of Infectious Wastes: Hearing Before the Subcommittee on Regulation and Business Opportunities of the House Committee on Small Business*, 100th Cong., 2d Sess. (1988); *Medical Waste and Sewage Contamination: Hearing Before the Subcommittee on Fisheries and Wildlife Conservation of the Committee on Merchant Marine and Fisheries*, 100th Cong., 2d Sess. (1988).

243. EPA SECOND INTERIM REPORT, *supra* note 30, at 4.

244. 42 U.S.C. § 6992g (1988).

245. EPA FIRST INTERIM REPORT, *supra* note 4, ch. 8; EPA SECOND INTERIM REPORT, *supra* note 30, at 40.

246. *Id.* EPA is collecting state information related to several key areas: the nature of the state medical waste program (regulatory or nonregulatory); the

States began acknowledging medical waste as a distinct waste stream in need of regulation around 1988. In 1986 only 57 percent of the states had infectious waste regulations or bills pending.<sup>247</sup> By 1989, around 84 percent of all states had bills pending, regulations promulgated or recommendations made on proper disposal of medical waste.<sup>248</sup> A survey of state laws reveals that some form of medical waste regulation exists in nearly every state except Wyoming, which has issued general, nonbinding guidelines.<sup>249</sup> As Congress found earlier, the state laws existing today differ significantly in terminology, scope and controls imposed. Those who are subject to medical waste regulation may find it difficult to attain full compliance with the variety of statutory schemes in existence.<sup>250</sup> Obviously, the variation in regulatory stringency can lead to forum shopping where generators search for the least expensive and least stringent state in which to dispose of their waste.<sup>251</sup> Because of the varied state regulation, a generator must examine the laws of the state where treatment and disposal occur, as well as the laws of every state through which its waste travels. States enacting prohibitions or moratoriums on the issuance of permits for medical incinerators complicate this problem, as does the often strident public opposition to siting of medical waste disposal and treatment facilities.<sup>252</sup> In addition, local governments like counties and municipalities issue local regulations or "ordinances" and "codes" which restrict medical waste manage-

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state's treatment of the home health care sector (inclusion or exclusion); and the scope of the state programs. *Id.*

247. Shell J. Bleiweiss & Janice M. Edwards, *A Cure for What Ails Us? Environmental Regulation of the Medical Industry*, 6 *Envtl. F.* 7 (1989).

248. See Shumaker, *supra* note 117, at 556.

249. WASTE AGE, *supra* note 6, at 75.

250. Coon & Gilberg, *supra* note 137, at 1114.

251. This issue has received increasing attention recently as evidenced by the proposed legislation on interstate transportation of waste. See *supra* note 195.

252. Coon & Gilberg, *supra* note 137, at 1100. In its state medical waste survey of 1992, NSWMA's WASTE AGE/INFECTIOUS WASTES NEWS found that nine states had current moratoriums on new commercial incinerators. Nearly all states reported they were planning more regulatory action. WASTE AGE, *supra* note 6, at 74. See also Goldie, *supra* note 174, at 129-34.

ment. For instance, local ordinances may specify which types of waste may not be deposited in the local landfill or burned in the county incinerator. These ordinances may also define medical waste in their own way, adding further to the confusion surrounding medical waste handling.

State and local regulations which impact the interstate movement of waste, including medical waste, are a contemporary subject of judicial interpretation and legislation.<sup>253</sup> Judicial disputes frequently arise in the context of a local or state ordinance which prohibits or regulates non-local waste differently than local waste. In *Fort Gratiot Landfill v. Michigan Department of Natural Resources*, the Supreme Court held that an ordinance which regulates imported waste differently from local waste unambiguously discriminates against interstate commerce.<sup>254</sup> When a county ordinance or regulation treats out-of-county wastes differently than local waste, the county bears the burden of showing there is some reason, apart from waste origin, for the unequal treatment. Indeed, the county or state must justify the discrimination with facts "unrelated to economic protectionism."<sup>255</sup> In a recent case involving medical waste, the Ninth Circuit upheld a district court ruling that a Washington county ordinance, which banned importation of infectious medical waste from outside counties, violated the Commerce Clause because it discriminated against interstate commerce. The county also failed to support its claim that the ordinance was a means of protecting county residents from risks associated with medical waste. The court found that the county did not demonstrate that out-of-county medical waste was more hazardous than local medical waste.<sup>256</sup>

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253. See *supra* note 195.

254. 112 S. Ct. 2019 (1992). See also *Diamond Waste, Inc. v. Monroe County*, 796 F. Supp. 1511 (M.D. Ga. 1992), *summ. j. granted*, 828 F. Supp. 52 (M.D. Ga. 1993).

255. *New Energy Co. of Indiana v. Limbach*, 486 U.S. 269, 274 (1988); *Chemical Waste Management, Inc. v. Hunt*, 112 S. Ct. 2009 (1992).

256. *BFI Medical Waste Systems v. Whatcom County*, 983 F.2d 911 (9th Cir. 1992).

Because medical waste is disparately regulated at many levels, some argue the need for at least minimum federal regulation of the field. One commentator has opined:

The standardless national definition of infectious waste has lead to a myriad of state responses and a complex array of procedures and agencies intended to deal with the problem at the state level. Neighboring state's [sic] infectious waste policies often clash and contribute to each other's failures. State regulatory measures that require records proving waste delivery to certified disposal sites are confounded by delivery to sites out of state and their inability to track the waste across state lines . . . . Without a consistent basis for state regulatory behavior and enforcement, interstate waste conflicts and illegal dumpings will continue to be a problem.<sup>257</sup>

Many existing state programs are similar to the federal MMTA program. Surveys of state medical waste laws and regulations reveal that their prominent features include a definition of medical/infectious waste; requirements for storing, handling, packaging and shipping medical waste; a medical waste tracking or manifest system; regulations on the treatment of medical waste; and enforcement provisions.<sup>258</sup> In attempting to define the universe of regulated medical/infectious wastes, states have drawn from both the EPA guidelines, the MMTA and the CDC guidelines. These definitions may even vary within the state statutes, depending upon the statute's enactment date, the significance of more recent revisions, and the specific chapter of state law.<sup>259</sup> Additionally, in developing medical waste programs, some states followed guidelines provided by the Council of State Governments which detail the components of a medical waste management plan.<sup>260</sup>

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257. Goldie, *supra* note 174, at 32-33 (footnotes omitted).

258. See Shumaker, *supra* note 117, and statutes cited therein.

259. Goldie, *supra* note 174, at 136.

260. COUNCIL OF STATE GOVERNMENTS, MODEL GUIDELINES FOR STATE MEDICAL WASTE MANAGEMENT, (1992). The Council's Center for Environment prepared the guidelines pursuant to a grant from EPA's Office of Solid Waste. The guidelines are EPA's response to the MMTA's requirement that the Agency

States which promulgate their own infectious waste programs in lieu of federal programs are first required to submit to EPA written applications for authorization of such programs.<sup>261</sup> In order to receive authorization, states must show that their programs are equivalent to the federal program. As infectious wastes are not deemed hazardous under the federal program, equivalency generally is interpreted to mean that the states do not have to regulate these wastes as hazardous.<sup>262</sup> There are four main arguments against regulating infectious waste as hazardous waste:

- (1) [t]he public might inaccurately perceive that medical wastes present the same severity and duration of risk that hazardous wastes present;
- (2) [i]nsurance premiums may become artificially high if underwriters perceive regulated medical [sic] wastes to present the same risks as hazardous chemical wastes;
- (3) [t]he presence of medical waste could be construed as contributing to environmental damage and therefore be subject to the regulations and restrictions of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); and
- (4) [r]egulatory, economic, and liability restrictions might be placed on the ultimate treatment and disposal of regulated medical waste precluding on-site [sic] treatment by health facilities.<sup>263</sup>

EPA's infectious waste management guide offers recommendations for state regulatory programs.<sup>264</sup> However, these recommendations are guidelines only, and do not require states to mirror the EPA guide in order to create an "equivalent" regulatory program.<sup>265</sup> Since no consistent,

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identify alternative, i.e., nonregulatory approaches to medical waste management.

261. 42 U.S.C. § 6926 (1988).

262. OTA BACKGROUND PAPER, *supra* note 2, at 8.

263. AD HOC COMMITTEE ON MEDICAL WASTE AND HAZARDOUS MATERIALS, AMERICAN HOSPITAL ASSOCIATION, SHAPING STATE AND LOCAL REGULATION OF MEDICAL WASTE AND HAZARDOUS MATERIALS 4 (May 1990).

264. 42 U.S.C. § 6926 (1988).

265. EPA GUIDE, *supra* note 30, at 1-1.

binding federal medical waste regulations exist, states have independently enacted and enforced their own policies. There is little specific EPA direction as to how states should enforce their policies or how they may qualify for federal funds to initiate a program.<sup>266</sup> Consequently, states have relied entirely on their own agencies and the result has been a variety of methods for dealing with medical waste.

States generally enforce their infectious waste regulations through different state departments and bureaus such as the department of health and departments of environmental protection or environmental health. Lack of enforcement in neighboring states is one of the greatest problems facing some states in enforcing their infectious waste regulations.<sup>267</sup> Without national standards, these disparities will continue. The Office of Technology Assessment recommended to Congress:

A more comprehensive approach to medical waste management, one consistent with the broader waste management strategy evolving nationally, could be formally established if the issue of medical waste remains part of the current RCRA reauthorization effort. Medical wastes need to be put into a broader frame of reference along with other wastes (e.g. municipal and industrial hazardous and nonhazardous wastes) if we are to establish appropriate levels of protection for humans and the environment.<sup>268</sup>

## VII. Miscellaneous Federal Regulations, Guidelines, Policies, and Work Practice Standards

Regulations, guidelines, standards and policies proliferate in the medical waste arena. Regulations are the most stringent. They normally are issued by governments at the federal, state and local levels; their requirements are mandatory, enforceable by law, and penalties can be assessed for noncompliance. By comparison, guidelines usually are is-

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266. Goldie, *supra* note 174, at 148, and notes cited therein.

267. *Id.* at 150.

268. OTA REPORT, *supra* note 3, at 9.

sued by government or professional organizations and compliance usually is voluntary. Standards often are set by professional organizations such as the Joint Commission on the Accreditation of Health Care Organizations (JCAHO), and although these guidelines may not always be enforceable at law, some types of certification are dependent upon meeting the standards.<sup>269</sup> In addition, private organizations such as the American Hospital Association (AHA) and the National Safety Council (NSC) also develop recommendations and provide materials and assistance to organizations and agencies developing standards and regulations for medical waste management. On the "regulatory" continuum, policies are the least persuasive of all authority and generally set forth a broad statement of intent.

#### A. Occupational Safety and Health Administration Regulations

The Occupational Safety and Health Administration (OSHA) of the United States Department of Labor was established by the Occupational Safety and Health Act of 1970, and is responsible for ensuring safe and healthy working conditions for United States workers.<sup>270</sup> OSHA's principal function is to promulgate and enforce workplace safety and health standards. In addition to federal OSHA regulations, some states have their own OSHA programs approved under Section 18 of the Act.<sup>271</sup>

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269. REINHARDT & GORDON, *supra* note 149, at 19.

270. 29 U.S.C. §§ 651-673 (1988). The OSHA regulations are contained in Title 29 of the Code of Federal Regulations. The Act authorizes the National Institute for Occupational Safety and Health (NIOSH) to develop and establish recommended occupational safety and health standards, and to conduct research and experimental programs to develop criteria for new standards. NIOSH is also authorized to investigate specific workplace hazards in response to requests by workers or employers. Although NIOSH has the same right of entry as OSHA to conduct health hazard inspections and evaluations, NIOSH can only recommend hazard controls and has no enforcement authority.

271. The Occupational Safety and Health Act requires OSHA to encourage states to develop and operate their own workplace and safety and health programs which must be at least as stringent as the federal program. *Id.* A state plan may be approved by OSHA if the state demonstrates that within three years it will meet all the steps necessary to become at least as effective as the

There are generally four OSHA standards which address infectious waste issues in the workplace. The first is OSHA's Emergency Response Standard which requires every employer to supply employees with information on proper actions during an emergency, where emergency equipment is located, how to use it and a location outside of the building where employees will meet after evacuating.<sup>272</sup> Secondly, OSHA's Hazard Communication Standard requires employers to develop a written program which lists all hazardous chemicals used in the medical facility, their physical and chemical ingredients, where they are used, the type of hazard associated with their use, and other related information including the name, address and telephone number of a responsible party who can provide information and emergency procedures for the hazardous chemical.<sup>273</sup> OSHA's Chemical Hygiene Standard requires employers to establish written policies for procedures, equipment, personal protective equipment and work practices which will effectively protect em-

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federal program. After the state has accomplished these steps and has operated its program at a fully effective level for at least one year, federal enforcement activity will cease in those areas over which the state has jurisdiction. *Id.* See also *State Participation*, O.S.H. Rep. (BNA) No. 15, at 81:1001 (Jan. 30, 1986) and see e.g., *Los Alamitos Has Introduced A Bloodborne Pathogens Exposure Control Plan*, MED. WASTE NEWS, No. 12 (Mar. 17, 1993), reporting an example of state OSHA implementation of a federal OSHA requirement.

272. 29 C.F.R. § 1910.38 (1981). OSHA has also promulgated a requirement for a Hazardous Waste Emergency Response Plan, 29 C.F.R. § 1910.120 (1989) applicable to clean-ups required by regulatory agencies, corrective actions, voluntary clean-ups recognized by regulatory authorities, operations involving hazardous wastes at treatment, storage and disposal facilities, and emergency response operations for the release or threatened release of hazardous substances. The Hazardous Waste Emergency Response Plan requirement addresses "hazardous substances" which are defined to include "any biological agent and other disease-causing agent which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any person . . . may reasonably be anticipated to cause death, disease, behavioral abnormalities, etc." 29 C.F.R. § 1910.120(a)(3)(B) (1989). Infectious substances conceivably fall within this definition of hazardous substances, thereby subjecting employers undertaking one of the specified actions to the Hazardous Waste Emergency Plan requirement.

273. 29 C.F.R. § 1910.1200 (1983) and revised 52 Fed. Reg. 31,877 (1987). See also NIOSH, CRITERIA FOR A RECOMMENDED STANDARD: AN IDENTIFICATION SYSTEM FOR OCCUPATIONALLY HAZARDOUS MATERIALS, (1974).

ployees from hazardous chemicals in their facilities.<sup>274</sup> The standard also requires documentation of medical treatment for exposure, disposal of chemicals, procurement, distribution and storage of chemicals and an employee training plan.<sup>275</sup> Finally, OSHA recently promulgated a Bloodborne Pathogen Rule requiring employers to protect workers from exposure to bloodborne pathogens.<sup>276</sup> The rule applies to all persons occupationally exposed to blood and other potentially infectious materials and extends to workers who handle medical waste that is put in red bags and physicians who are employed by a corporation.<sup>277</sup> Thus, this rule may become a consideration in selecting a medical waste disposal option.<sup>278</sup> Naturally, costs are expected to rise as a result of the rule. The waste management industry estimates compliance will cost it approximately \$1,900,000, while compliance will cost hospitals around \$321,000,000.<sup>279</sup>

Passage of the Bloodborne Pathogen Rule evidences OSHA's concern that "employees face a significant health risk as a result of occupational exposure to blood and other potentially infectious materials because they may contain bloodborne pathogens."<sup>280</sup> The Bloodborne Pathogen Rule requires the employer to provide an exposure control plan, training classes, preventive measures (including hepatitis B vaccinations), use of CDC universal precautions, provision of protective equipment, housekeeping programs, and records of exposure incidents.<sup>281</sup> The OSHA standard for bloodborne pathogens was adopted because exposed employees may face

274. 29 C.F.R. § 1910.1450 (1990).

275. *Id.*

276. 29 C.F.R. § 1910.1030a (1992). In addition, the Department of Labor and Department of Health and Human Services published a Joint Advisory Notice, October 19, 1987, Protection Against Occupational Exposure to Hepatitis B Virus and Human Immunodeficiency Virus, which discusses engineering controls and work practices.

277. 29 C.F.R. § 1910.1030 (1992).

278. The Bloodborne Pathogen Rule was recently upheld against a challenge by the American Dental Association. *American Dental Assoc. v. Martin*, 984 F.2d 823 (7th Cir. 1993).

279. WASTE AGE, *supra* note 6, at 68.

280. 56 Fed. Reg. 64,004 (1991).

281. 29 C.F.R. § 1910.1030 (1991).

significant health risks, including death.<sup>282</sup> The Bloodborne Pathogen Rule is drafted so that employees in every state will be protected by general, performance-oriented standards. To the extent that state or regional differences exist, states with occupational safety and health plans approved under Section 18 of the Occupational Safety and Health Act will be able to develop their own standards to deal with any special problems.<sup>283</sup> Compliance with applicable standards is mandatory.

## B. Department of Transportation Regulations

Transportation of hazardous materials is addressed by the Hazardous Materials Transportation Act of 1974 (HMTA) and the Hazardous Materials Transportation Uniform Safety Act of 1990 (HMTUSA).<sup>284</sup> The HMTA does not define hazardous material, but instead gives this authority to the Secretary of the Department of Transportation. In the Act, Congress preempted any state law, regulation, order, ruling or provision which is not substantively the same as the HMTUSA.<sup>285</sup> DOT has held several state requirements regard-

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282. "Hepatitis B virus . . . has long been recognized as a pathogen capable of causing serious illness and death. . . . The human immunodeficiency virus (HIV), the virus that causes AIDS, has only been recognized in the last decade. . . . The consequences of HIV infection are grave, however, because HIV causes the fatal disease AIDS." 56 Fed. Reg. 64,006 (1991).

283. *Id.* at 64,004. OSHA specifically recommends that hospitals comply with state and local regulations when developing an infectious waste treatment plan. Each plan should provide for: (1) designation of the waste that should be managed as infectious, (2) segregation of infectious waste from noninfectious waste, (3) packaging, (4) storage, (5) treatment, (6) disposal, (7) contingency measures for emergency situations and (8) staff training. U.S. Dep't of Health and Human Services, GUIDELINES FOR PROTECTING THE SAFETY AND HEALTH OF HEALTH CARE WORKERS 6-1 (1988), [hereinafter NIOSH GUIDELINES].

284. Hazardous Materials Transportation Act (HMTA), 49 U.S.C. §§ 1801-1812 (1983 & Supp. 1992), and Hazardous Materials Transportation Uniform Safety Act (HMTUSA), 49 U.S.C. §§ 1801-1819 (1988).

285. 49 U.S.C. § 1804 (Supp. 1991) sets forth regulations governing transportation of hazardous materials and expressly preempts any requirement of a state, political subdivision or Indian tribe which is inconsistent with any requirement of the Act or DOT Hazardous Material Regulations (HMRs). The preemption is extensive and includes: (1) designation, description, classification of hazardous materials; (2) packaging, handling, labeling, marking and placarding of hazardous materials; (3) shipping documents; (4) written notifica-

ing the definition and shipment of hazardous materials to be inconsistent with DOT requirements and, therefore, preempted.<sup>286</sup> In deciding whether a state regulation is consistent, DOT considers two factors: (1) whether compliance with both the state requirement and the HMTA or the HMR is possible, and (2) the extent to which the state requirement is an obstacle to the accomplishment and execution of the HMTA and the HMR.<sup>287</sup> By using this preemption doctrine, DOT ensures national uniformity during transportation of materials which are regulated as hazardous. These standards are often devised and monitored by DOT's Research and Special Programs Administration (RSPA). If the RSPA decides to add its own definition of infectious substance or etiologic agent to the list of hazardous materials, it is possible that transportation of medical waste will also be federally preempted.

Recent rulemaking indicates preemption of medical waste may become a reality in the near future. The effective date of the RSPA final rule amending the Hazardous Material Regulations (HMRs), with respect to infectious substances, has been delayed until October 1, 1994 to consider unresolved issues raised in comments, petitions for reconsideration, and exemption applications.<sup>288</sup> The final rule, published in January 1991, adopted a revised definition of "etiologic agent," removed the existing 50 milliliter exception from regulation of etiologic agents, and clarified quantity limitations for etiologic agents transported aboard aircraft.<sup>289</sup> The new regulations apply to any facility that ships regulated medical waste, any company that hauls it, and any maker of packaging for regulated medical waste. The new RSPA rule

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tion, recording and reporting of unintentional releases of hazardous materials; and (5) design, marking, testing, etc. of packages used to transport hazardous materials. *Id.* at § 1804(a)(4)(A)-(B).

286. *See, e.g.* Appeal of Inconsistency Ruling No. IR-31, State of Louisiana, Statutes and Regulations on Hazardous Materials, 55 Fed. Reg. 36,735 (1990) where the Research and Special Programs Administration (RSPA) found that state regulations authorizing the designation of hazardous materials other than those designated in the HMRs were preempted and unenforceable.

287. *See* 49 C.F.R. § 107.209(C) 1992.

288. 58 Fed. Reg. 66,302 (1993). *See also*, 56 Fed. Reg. 197 (1991), 58 Fed. Reg. 12,207 (1993).

289. 58 Fed. Reg. 12,207 (1993).

adopts the MMTA definition of "regulated medical waste" to distinguish between all medical waste and medical waste containing an infectious substance. The rule also specifies packaging requirements for regulated medical waste consistent with those in the expired MMTA regulations. The RSPA has thus created a subcategory of infectious substances—those that are contained in or constitute medical waste. If an infectious substance is being transported then it must be labeled, packaged and transported according to the HMRs. For example, the new rules require all packaging containing infectious substances to be marked "regulated medical waste." It must also bear DOT's "infectious substance label," a set of clearly marked identification numbers, and be accompanied by special shipping papers. If the infectious substance is also medical waste or is contained in medical waste, then the shipper may use less rigorous packaging requirements that are applicable to regulated medical waste. According to the RSPA, if it had not provided some distinction between infectious substances and regulated medical waste, all infectious substances, regardless of how they were generated, would be subject to the full extent of regulation.<sup>290</sup> The cost of this compliance, industry claimed, would be exorbitant.<sup>291</sup>

In response to comments and petitions for reconsideration, the RSPA acknowledged that the HMRs potentially overlap with other federal regulations governing infectious substances, such as OSHA's Bloodborne Pathogen Rule and CDC standards. Both require special packaging and labeling for infectious substances and etiologic agents which differ from the requirements of the HMRs.<sup>292</sup> Critics say that fed-

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290. *Id.* at 12,209-10 and 56 Fed. Reg. 66,142 (1991) wherein the RSPA revised regulations at 49 C.F.R. § 173.197 (1991) to specify less rigorous requirements for infectious substances that are "regulated medical wastes."

291. *DOT Packaging Rule Draws Concern from Medical Waste Industry*, WASTE AGE, Mar. 1992, at 8.

292. *See e.g.*, 42 C.F.R. § 72 (1992), identifying CDC's requirements for the transportation of etiologic agents in interstate traffic. These regulations specify that they "are in addition to and not in lieu of any other packaging or other requirements for the transportation of etiologic agents in interstate transportation prescribed by the Department of Transportation and other agencies of the Federal Government." *Id.* at n.1. CDC's regulations set forth packaging and

eral agencies are unnecessarily duplicating each other's requirements; for example, DOT's black-on-white "infectious substance" label conveys the same information as OSHA's orange "biohazard" label.<sup>293</sup> In short, each agency requires one or more different labels on packages containing medical or infectious waste. Complicating this scheme is the fact that the RSPA attempts to align United States standards with those of the United Nations Recommendations on the Transport of Dangerous Goods.<sup>294</sup> The RSPA is currently evaluating answers to its extensive request for comments; in particular, it is concerned with comments addressing the potential overlap or inconsistency between the new DOT standards and other federal regulations governing infectious substances including those issued by OSHA, CDC, the Food and Drug Administration, and the United States Postal Service.<sup>295</sup>

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labeling requirements for the transportation of materials containing etiologic agents:

No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material including, but not limited to, diagnostic specimens and biological products which such person reasonably believes may contain an etiologic agent unless such material is packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

*Id.* at § 72.2.

293. See Karen Pallarito, *New Packing, Shipping Rules May Be Shelved*, MODERN HEALTHCARE, Sept. 28, 1992, at 33-34.

294. Interview with Eileen Martin, Regulatory Advisor, RSPA, Department of Transportation, July 1993.

295. 56 Fed. Reg. 12,207, 12,210 (1993). Since the new rule would officially add regulated medical wastes to the hazardous materials table, the medical waste hauling industry is concerned with the rule's ramifications. See *DOT Packaging Rule Draws Concern from Medical Waste Industry*, WASTE AGE, Mar. 1992, at 8, and Renee Blankenau, *Medical Waste Transport Issues Aired*, J. OF AMER. HOSP. ASSOC., Apr. 20, 1993, at 12. One hygienist at the American Hospital Association observed that the amount of waste affected by the new RSPA rule will depend on how individual hospitals interpret the definitions of regulated medical waste and infectious substance. He estimated that the new rule "would increase waste haulers' costs 12 to 18 cents per pound, which would most likely be passed on to hospitals." Pallarito, *supra* note 293, at 34.

### C. U.S. Postal Service Regulations

Concern about exposure of postal workers to contaminated sharps being shipped in the United States mail led to new regulations on the mailability of sharps and other medical devices.<sup>296</sup> Effective June 30, 1992, the regulations require that "used sharps and other used medical devices be sent as First-Class or Priority Mail."<sup>297</sup> The Postal Service also requires that used sharps be packaged in a securely sealed primary container that is leak and puncture resistant and has passed a vibration test. The package must also have a secondary containment system, and both containers must be enclosed in a specific type of shipping container which includes absorbent material. To ensure compliance with the detailed standards, all distributors and manufacturers of sharps containers are required to obtain authorization from the United States Postal Service in order to transport their products through the mail. To obtain authorization, all packaging must have been "type-tested" and certified by an independent company. In addition, a bond is required to ensure financial responsibility.<sup>298</sup> The Postal Service states that the "bond is essential to avoid or minimize the expenses incurred for containing and cleaning up spills and leaks that occur on postal property, in addition to disposing of regulated medical waste addressed for delivery at closed disposal sites."<sup>299</sup> Other medical devices that do not contain sharps must be packaged in a securely sealed, leak resistant primary container, which is then enclosed in a shipping container similar to those used for mailing sharps.

The Postal Service received only 17 comments in response to the proposed rule.<sup>300</sup> Those organizations objecting to the rule were concerned about the cost of complying with the labeling, manifest, and testing requirements, and challenged the need for a bond.<sup>301</sup> The regulation has its own def-

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296. 57 Fed. Reg. 29,028 (1992) (to be codified at 39 C.F.R. pt. 111).

297. *Id.*

298. *Id.*

299. *Id.*

300. *Id.* The proposed rule is at 57 Fed. Reg. 9404 (1992).

301. 57 Fed. Reg. 29,028 (1992).

inition of terms such as "sharps," "medical devices," and "infectious substance" which the regulated community must reconcile with other, sometimes conflicting definitions promulgated by other regulatory agencies.

#### D. EPA Guidelines

The Resource Conservation and Recovery Act of 1976 (RCRA), as amended, requires EPA to develop and evaluate environmentally sound methods for solid waste management, and to provide information, research and financial assistance to states.<sup>302</sup> Congress intended RCRA to provide for the promulgation of guidelines for solid waste collection, transport, separation, recovery and disposal practices, and a "cradle-to-grave" management system for solid wastes identified as hazardous.<sup>303</sup> In fulfilling this charter, EPA has published hazardous waste regulations, but has chosen not to include infectious waste under the hazardous waste definition because the agency believes "considerable evidence that these wastes cause harm to human health and the environment is needed to support [f]ederal rulemaking."<sup>304</sup> Instead, in response to numerous requests for technical information and guidance on infectious waste management, EPA published its findings regarding infectious waste management techniques in September 1982 as a guidance manual, the *Draft Manual for Infectious Waste Management*. After receiving and considering comments, the agency decided to revise the manual and issued the *EPA Guide for Infectious Waste Management* in May 1986. Since the expiration of the MWTa, this EPA guide represents the agency's current perspective on acceptable infectious waste management practices. In summary, it addresses infectious waste characterization, infectious waste management, treatment of infectious wastes, and recommendations for development of an infectious waste management plan.<sup>305</sup> It is designed to guide those persons responsible for managing infectious waste at facilities such as hospitals, lab-

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302. 42 U.S.C. § 6902(a) (1988).

303. *Id.*

304. EPA GUIDE, *supra* note 30, at vi.

305. *Id.*

oratories, animal experimentation units, industrial plants, biotechnology companies, and others which generate infectious wastes.<sup>306</sup>

One of the most significant aspects of the guide is EPA's definition of infectious waste as waste capable of producing an infectious disease, taking into account four factors: (1) presence of a pathogen of sufficient virulence, (2) dose, (3) portal of entry, and (4) resistance of the host. The guide's definition has been adopted by many states and agencies regulating medical waste; however, it is nonbinding at the federal level.<sup>307</sup> EPA "strongly" suggests that agencies use its guide only as reference material.<sup>308</sup>

The guide has been criticized on two grounds. First, because EPA was uncertain of the health risks posed by infectious wastes, it failed to set forth a minimum national standard for the management and disposal of infectious waste.<sup>309</sup> Because EPA wrote the guide for persons managing infectious waste treatment for private facilities, not for state and local agencies, it provided only suggested components of an infectious waste management plan and failed to recommend how the states should enforce their policies.<sup>310</sup> One author has observed that the guide thus technically satisfies RCRA's objective of providing information, but it may have added to the confusion surrounding the risk associated with infectious waste by not providing a basis for interstate control.<sup>311</sup> In addition, EPA's original position, that regulation of infectious waste is premature and unnecessary until its risks are proven, seems contradictory to the guide's suggestions for private management and state regulation.<sup>312</sup> It is possible that the findings EPA releases in its final report to Congress under the MMTA will clarify these issues.

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306. *Id.* at 1-1.

307. *Id.* See OTA REPORT, *supra* note 3, at 3 for a comparison of the components of EPA's definition and the CDC's definition.

308. EPA GUIDE, *supra* note 30, at 1-1.

309. Goldie, *supra* note 174, at 132.

310. Goldie, *supra* note 174, at 148 n.125. See also THE COUNCIL OF STATE GOVERNMENTS, STATE INFECTIOUS WASTE REGULATORY PROGRAMS 4 (1988).

311. Goldie, *supra* note 174, at 156.

312. *Id.* at 157.

## E. Centers for Disease Control Guidelines

Like EPA, the Centers for Disease Control (CDC) of the U. S. Public Health Service has issued guidelines addressing certain aspects of infectious waste. CDC is a federal public health agency charged with the surveillance and investigation of infectious diseases in hospitals.<sup>313</sup> CDC collects weekly, monthly and yearly statistics on many infectious diseases and on control programs for health care facilities. The Agency also makes recommendations necessary for disease control.<sup>314</sup>

CDC has most directly addressed medical waste in two publications: "Recommendations for Prevention of HIV Transmission in Health Care Settings,"<sup>315</sup> and "Guidance for Handwashing and Hospital Environmental Control."<sup>316</sup> The 1987 "Recommendations" suggested that "universal precautions" relating to blood and body fluid be consistently used for all patients regardless of their bloodborne infection.<sup>317</sup> Thus, blood and certain body fluids of *all* patients were considered potentially infectious for HIV, hepatitis B and other bloodborne pathogens. In response to numerous questions about the universal precautions, the CDC updated its "Recommendations" in 1988.<sup>318</sup> These "precautions" apply primarily to health care workers and medical institutions; consequently, the guidelines reach the generators of infectious waste and their on-site handling and treatment, and have not had as much impact as the EPA guidelines on medical waste re-

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313. NIOSH Guidelines, *supra* note 283, at 2-21.

314. *Id.*

315. The Center for Disease Control, *Recommendations for Prevention of HIV Transmission in Health Care Settings*, MORBIDITY & MORTALITY WEEKLY REP. (Supp.), Vol. 36 (Aug. 21, 1987) [hereinafter *Recommendations*].

316. Center for Disease Control, *CDC Guidelines for the Prevention and Control of Nosocomial Infections: Guideline for Handwashing and Hospital Environmental Control* (1985) [hereinafter *Handwashing Guidelines*].

317. *Recommendations*, *supra* note 315.

318. Center for Disease Control, *Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health Care Settings*, MORBIDITY & MORTALITY WEEKLY REP., Vol. 37 (June 24, 1988). The CDC now limits the application of universal precautions to blood and other body fluids containing visible blood, and to semen and other specified body fluids. *Id.*

moval and disposal.<sup>319</sup> One commentator posits that CDC's 1987 "Recommendations" quelled the urgency of labeling most medical waste as infectious because the CDC chose to recommend classifying waste material based on its risk of disease transmission.<sup>320</sup> Indeed, the "Recommendations" state that identifying wastes which require special precautions is a matter of judging the relative risk of disease transmission. While any item that has contact with blood or body fluids may be potentially infective, it is not usually considered practical or necessary to treat all such waste as infective.<sup>321</sup> A hospital's calculation of its total amount of infectious waste can vary vastly, depending on whether it uses CDC or EPA definitions of infectious waste. As discussed, determining which portion of medical waste is infectious goes to the heart of the definitional problem associated with medical waste management.<sup>322</sup> Thus, until CDC and EPA can reach consensus on the definition of infectious waste, generators may continue to be confused regarding proper classification and management of medical wastes.

The purpose of the CDC "Handwashing Guidelines" is to disseminate advice on how to prevent or control specific infections acquired while in the hospital, called "nosocomial infections."<sup>323</sup> The guidelines offer recommendations regarding handwashing techniques, handwashing with antimicrobial products, cleaning, disinfecting and sterilizing patient-care equipment, and handling infective waste. According to the guidelines, handwashing is the single most important procedure for preventing hospital-acquired infections.<sup>324</sup>

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319. Goldie, *supra* note 174, at 143.

320. Goldie, *supra* note 174, at 143. Goldie maintains that this CDC policy for treatment of infectious waste may have convinced EPA that insufficient evidence of risk existed. In reality, "CDC's recommendation to EPA did not mean infectious waste is not hazardous, only that not all hospital waste should be classified as infectious." EPA may have misinterpreted this recommendation when it made its decision not to regulate infectious waste disposal. *Id.* at 144.

321. *Recommendations*, *supra* note 315.

322. See discussion in Chapter 1.

323. *Handwashing Guidelines*, *supra* note 316.

324. *Id.*

## F. Joint Commission on Accreditation of Healthcare Organizations Standards

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), formerly the Joint Commission on Accreditation of Hospitals, accredits health care organizations and reevaluates the accreditation every 3 years. JCAHO conducts inspections and requires hospitals to establish policies and procedures for monitoring and responding to safety and health hazards.<sup>325</sup> In its manual, JCAHO designates infectious wastes and sharps as hazardous wastes along with chemical, chemotherapeutic and radioactive wastes.<sup>326</sup> The manual outlines methods for handling each type of waste and requires a system to handle all such wastes that complies with Federal, State and local regulations.<sup>327</sup>

JCAHO has recognized that hospitals must manage their hazardous materials and infectious waste from point of origin to final disposal.<sup>328</sup> Under its accreditation standard, a hospital's infectious waste management program must, among other things:

- (1) control the waste from its point of origin to its final disposal; (2) protect patients, personnel, visitors and the environment; (3) include policies and procedures for identifying and managing hazardous materials and waste, including the substitution of less hazardous agents, process changes, isolation, and ventilation; (4) review operational policies and procedures at least annually by the respective safety or control committees, with recommendations, conclusions, and actions referred to those persons responsible for the hospital's quality assurance program; (5) provide job training to its waste handlers . . . .<sup>329</sup>

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325. JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, ACCREDITATION MANUAL FOR HOSPITALS (1990).

326. *Id.*

327. *Id.* If federal regulations do not exist, the hospital must comply with state and local regulations and if these do not exist then hospitals should comply with either CDC or EPA guidelines. OTA BACKGROUND PAPER, *supra* note 2, at 7 n.18.

328. JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, ACCREDITATION MANUAL FOR HOSPITALS (1990).

329. *Infectious Medical Wastes*, JAMA, *supra* note 52 at 1670-71.

Obtaining JCAHO accreditation is critical for most hospitals. Therefore, even though the organization's recommendations and policies are not legally binding or enforceable, they can have significant effect on hospital operation and procedure.

### VIII. Conclusion

The putative risks to public health and the environment posed by the mismanagement of medical waste have not been adequately demonstrated to warrant federal regulation of this waste stream to the extent it was under the MMTA. To treat all medical waste as hazardous without substantive evidence that it indeed presents a viable threat will produce unnecessary costs for medical waste managers and, ultimately, for health care patients. Stringent RCRA Subtitle C requirements should be reserved for medical waste that can be identified as truly infectious and which has a proven capacity to inflict substantial harm upon the public or the environment. In order to identify such waste, EPA needs to devise a uniform objective test for infectious waste that can be used by health care organizations and other medical waste generators in their waste management. Such a test is the necessary first step toward developing a uniform definition of infectious waste which is, in turn, an absolute necessity for consistent regulation. Without a scientifically based, national definition of infectious medical waste, an inconsistent, inequitable scheme of regulation is likely to prevail. Therefore, federal intervention to this extent alone is needed. EPA already has authority under RCRA to regulate Subtitle C and Subtitle D wastes. The Agency could most appropriately address this issue and maintain flexibility by promulgating regulations which address several areas of confusion. For instance, EPA should define and distinguish medical waste and infectious waste, and clarify when infectious waste meets the characteristics of hazardous waste as defined in 42 U.S.C. § 6903. Insofar as possible, EPA should consult with others such as CDC and JCAHO, in order to reconcile definitional and policy differences and to attempt to issue compatible, uniform guidance. Or, EPA could simply defer to CDC's definition and

cross-reference it in its regulations. Likewise, OSHA and DOT should bring their definitions and policies concerning infectious waste into concert with EPA and CDC so that generators, employers and transporters are complying with a coherent, predictable scheme of regulation instead of a conflicting panoply of requirements.

In order to achieve nationally cohesive regulation of medical waste, EPA needs to take the lead. First, it must issue its overdue MMTA report to Congress, which purportedly explores further the risks of infectious waste. Then, EPA should sponsor or encourage more intensive study of the safety and efficiency of various treatment and disposal methods of infectious waste, particularly incineration, land disposal, disposal via the sanitary sewer system and alternative technologies. The existing studies of medical waste treatment and disposal do not adequately examine the toxic persistence of agents such as the HIV virus or its mutagenicity in different disposal environments over a long-term period.

Finally, EPA needs to recommend to the states appropriate methods of handling and treating medical waste. The Agency should also provide guidance on cogent ways states can enforce their own medical waste regulatory programs, including home health care medical waste management. To accomplish this the Agency could issue more current special guidelines.

Since the passage of the MMTA in 1988 and its expiration in 1991, states and localities have aggressively regulated the medical waste stream. In the absence of clear federal guidance as to what constitutes infectious medical waste, and when or whether it should be treated as solid or hazardous waste, states have promulgated a diverse array of laws and regulations. The disparity among states' regulation of medical waste often causes inequitable or conflicting treatment of waste at different levels and complicates interstate waste shipment. Although states have demonstrated in recent years that they are the most suitable regulators of this waste stream, federal guidance and some regulation, perhaps via state-delegated RCRA programs, are essential to effective medical waste management.

Even though the alarming beach wash-ups which precipitated medical waste regulation have long passed, the current national preoccupation with AIDS infection and rising health care costs provide another opportunity to consider the medical waste stream. Medical waste management often constitutes a hidden cost of health care, and some of these costs may be attributed to irregularities in its regulation. Our national interest would best be served by a more unified, science-based medical waste management policy.