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"Regulation of Medical Waste in the United States"

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Table of Contents

Introduction	1
I. <u>Chapter One: Characterization and Definition of the Medical Waste Stream</u>	7
A. Historical Background	
B. Defining Infectious Medical Waste	
C. The EPA Definition	
D. The Centers for Disease Control Definition	
E. Characteristics of the Infectious Waste Stream	
1. Amounts of Medical Waste	
2. Sources of Medical Waste	
3. Composition of the Medical Waste Stream	
II. <u>Chapter Two: Medical Waste and the Public Health Debate</u>	24
A. Introduction	
B. ATSDR Findings and the EPA Health Hazard Assessment	
C. Three Types of Risk	
1. Risk to the General Public	
2. Occupational Risks	
3. Risks Associated with Treatment and Disposal	
III. <u>Chapter Three: The Beginning of Federal Regulation</u>	40
A. Background	
B. A Uniform Definition of Medical Waste	
C. The Tracking System	
D. Information Gathering	
E. Enforcement	
F. Critique of the Medical Waste Tracking Act	
IV. <u>Chapter Four: Current Federal Law Governing Medical Waste</u>	54
A. The Resource Conservation and Recovery Act	
B. The Clean Water Act	
C. The Clean Air Act	
V. <u>Chapter Five: State Regulation of Medical Waste</u>	73

VI. Chapter Six: Miscellaneous Federal Regulations, Guidelines, Policies and Work Practice Standards Governing Medical Waste 82

- A. Occupational Safety & Health Administration Regulations
- B. Department of Transportation Regulations
- C. U.S. Postal Service Regulations
- D. EPA Guidelines
- E. Centers for Disease Control Guidelines
- F. Joint Commission for the Accreditation of Health Care Organizations Guidelines

VII. Conclusion 102

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INTRODUCTION

Rising health care costs are focusing national attention on the health care industry. While the current proposed national health care insurance plan is under construction, our health care system is being scrutinized in order to ascertain why medical costs continue growing so rapidly. One overlooked 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.¹

The actual amount of medical waste generated in the United States today is not known.² However, estimates

¹ In 1992 French and German police thwarted 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 drafting a waste directive requiring members to dispose of waste as near as possible to its place of origin. 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 personally liable for breaches of the law. Oliver Tickell & Alan Watson, Hospital Waste: A Case for Treatment, New Scientist, Mar. 28, 1992, at 34-35.

² Office of Technology Assessment, Issues in Medical Waste Management: Background Paper, (Oct. 1988) (hereinafter OTA Background Paper).

indicate that all medical wastes represent a relatively small portion of the municipal solid waste stream.³ Infectious wastes represent an even smaller portion of municipal waste.⁴ The U.S. Environmental Protection Agency (EPA) estimates that 13.2 billion tons of solid waste are generated annually, primarily by hospitals, and comprise approximately 0.3 percent (by weight) of the municipal solid waste stream.⁵ Each year, approximately 500,000 tons of regulated medical waste are produced annually in the United States by about 375,000 generators, as compared to about 160 to 180 million tons of municipal solid waste.⁶

As the amount of medical waste increases, so does the need for lawful, affordable disposal options.⁷ Furthermore,

³ Office of Technology Assessment, Finding the Rx for Managing Medical Wastes, (1990) (hereinafter OTA Report).

⁴ Id. For purposes of this paper, infectious waste shall be assumed to be a subset of the more inclusive term "medical waste." As used by this author, "medical waste" incorporates infectious waste. "Sharps" include needles, hypodermic syringes, scalpels, scalpel blades, etc. See 42 U.S.C. § 6992a(a)(4) (West Supp. 1984-1992).

⁵ Environmental Protection Agency, Medical Waste Management in the United States, First Interim Report to Congress, (May 1990) (hereinafter EPA First Interim Report), and Environmental and Energy Study Institute (EESI) Briefing Book, (hereinafter EESI Briefing Book), 1993 at 55.

⁶ EPA First Interim Report at 1-3.

⁷ Depending on the data source, and the degree of regulation by individual states, estimates of the medical waste market potential vary by industry, from between \$500,000,000 to \$1,000,000,000 annually. Some predict that as these figures continue to climb and more regulations develop, more medical waste

as the demand for medical waste treatment and disposal services grows, so does the cost of managing this waste.⁸ While many generators install incineration units as the most convenient and efficient method of disposal, many hospitals are reluctant to make such a large capital investment in a non-patient care item.⁹ Consequently, many medical waste

generators will face a severe financial burden managing their medical waste. Janet Emmerman, A Prescription for Cleaning Up Medical Waste, USA Today Magazine, Vol. 119, 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. 1992, at 66, and interview of Mr. Tom Goldberg, Director, Medical Waste Institute, NSWMA, Washington, D.C., July 1993.

⁸ See William Marbach, Nuking Nasty Medical Waste--In a Microwave, Bus. Wk., Jul. 23, 1990, at 68. One industry association predicts that the U.S. Occupational Safety and Health Administration's (OSHA) recent bloodborne pathogen standard and the Department of Transportation's newest rule affecting medical waste transporters will also drive costs up. Malloy, supra note 7 at 68. The American Hospital Association projected earlier that, in some cases, increased regulation would raise annual medical waste disposal costs for an average-sized hospital by as much as \$200,000 per year. Jennifer Carlile, Finding Disposal Options for Medical Waste, Am. City & County, Nov. 1989, at 66. See also Leslie Anderson Morales, Managing Medical Wastes: A Bibliography of Periodical Literature, 1987-1989, Jan. 1990, wherein the author notes that where on-site disposal is not possible, finding off-site disposal locations may be difficult, and 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.

⁹ Emmerman, supra note 7 at 78. In addition, forthcoming EPA regulations on incineration and the growing number of state regulations are expected to make incineration a less attractive, economical disposal method, Debra K. Rubin, Mary Buckner Powers, & Bob Boyle, Medical Market Gets Infectious, "ENR, Jan. 7, 1991, at 26-27.

generators may spend more relying on commercial transporter and off-site disposal services, and thereby also increase their exposure to liability.¹⁰ These costs of medical waste management can have a direct impact on patient care costs.¹¹

Contributing to rising costs of medical waste management is the growing amount of medical waste generated.¹² 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

¹⁰ Malloy, supra note 7 "Two Views on Medical Waste," Waste Age, Aug. 22, 1992, at 73. Liability for improper handling and disposal most often attaches under the Resource Conservation Recovery Act (RCRA), Pub. L. 98-616, § 101, 98 Stat. 3224, (1984), codified at 42 U.S.C. §§ 6901-6987 (West 1983 & Supp. 1984-1992), and under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), Pub. L. 96-510, § 101, 94 Stat. 2767, (1980) codified at 42 U.S.C. §§ 9601-9657 (West 1983 & Supp. 1984-1992).

¹¹ Suzan Onel, The Medical Waste Tracking Act of 1988: Will it Protect Our Beaches?, 9 Va. Env'tl. L.J. 225, 230-231 (1989).

¹² United States Environmental Protection Agency, Environmental Backgrounder: Medical Waste (1989). See also Kate Ballen, Zapping Waste, Fortune, Nov. 5, 1990, at 18.

care industry's increased use of disposable products.¹³ Also, in the past five years there has been an increase in both federal and state regulation of medical waste which has, consequently, made more waste susceptible to special treatment and increased costs. Since 1989 the federal government and most states have enacted laws and regulations governing medical waste. While such regulated medical waste does not generally include hazardous or radioactive materials, the volume is also growing because concern over AIDS prompts hospitals and other medical facilities to use more disposables and to classify more waste as infectious.¹⁴

Currently, there is no comprehensive federal law regulating medical waste in the United States. Instead, there exists a patchwork of statutes, regulations, standards and guidelines which 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

¹³ See OTA Background Paper, supra note 2 at 4 concerning increasing use of disposable health care products.

¹⁴ Rubin et al., supra note 9 at 26.

mismanagement poses to human health and the environment. This debate has significantly affected the EPA's and states' approaches to medical waste regulation, and it continues to shape policy regarding medical waste management in the United States. Finally, this paper concludes that minimum federal standards are needed to ensure a uniform definition of medical waste and consistency in the way states regulate medical waste management.

Chapter One

Characterization and Definition of the Medical Waste Stream

Historical Background

Medical waste was first formally recognized as a distinct waste stream in 1978 when EPA considered classifying infectious waste as hazardous waste under the Resource Conservation Recovery Act (RCRA).¹⁵ Then, EPA included regulations for infectious wastes in its proposed hazardous waste regulations. However, in 1979, the agency determined that infectious wastes did not pose a significant health threat, and when EPA promulgated its first RCRA hazardous waste regulations in 1980, it chose not classify infectious waste as hazardous.¹⁶ 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 waste.¹⁷ 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

¹⁵ OTA Background Paper, supra note 2 at 6.

¹⁶ Id. and Nelson A. Rockefeller Inst. of Gov., Perspectives on Medical Waste: A Report 2, 1989, at 1-2 (hereinafter Perspectives on Medical Waste).

¹⁷ See 42 U.S.C. § 6903(5) (West Supp. 1984-1992).

issued the proposed regulations.

By the end of the summer of 1988, following notorious beach wash-ups of medical waste, EPA had changed its position on the threat of medical waste and went on record supporting medical waste regulation.¹⁸ Soon thereafter, Congress passed the Medical Waste Tracking Act (MWTa) demonstration program adding Subtitle J to RCRA, and EPA promulgated implementing regulations at Title 40 Code of Federal Regulations Part 259. 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. Nor has EPA issued any assessment based on epidemiological studies of the degree of risk posed by infectious or other types of medical waste.¹⁹ Consequently, confusion and inconsistency persists regarding medical waste policy, since there are no

¹⁸ Perspectives on Medical Waste, supra note 16 at 2.

¹⁹ OTA Background Paper, supra note 2 at 7. EPA is expected to release a qualitative health assessment based on studies performed pursuant to the 1988 Medical Waste Tracking Act (MWTa), Pub. L. 100-582, 102 Stat. 29050 (1988), codified at 42 U.S.C. §§ 6992-6992k (West Supp. 1984-1992), 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. Interview with Ann Coggington, EPA Office of Solid Waste, Characterization and Assessment Division, Regulatory Development Branch, EPA Headquarters, Washington, D.C., June 1993.

existing federal regulations that comprehensively address the handling, transportation, treatment and disposal of medical waste.²⁰ The major area of inconsistency is in the classification or definition of medical waste and it has broad ramifications.

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," "regulated medical waste," "biohazardous waste," "red bag waste," and "infectious waste" 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.²¹ Presently, health care facilities can follow either EPA or Centers for Disease Control (CDC) Guidelines, or both in

²⁰ OTA Background Paper, supra note 2 at 7.

²¹ Id. According to the Environmental Protection Agency's Second Interim Report to Congress, (Dec. 1990) (hereinafter EPA Second Interim Report), at 26, "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." To date there is no standard that defines the degree of virulence that a waste must attain in order to be classified as infectious waste.

designating medical waste.²² Both agencies have their own definitions of infectious waste and definitional differences between these two contribute to the lack of consistent data on the amount, composition, and types of medical waste in our waste stream. Moreover, how infectious waste is defined affects the cost of waste management and ultimately the choice of waste management disposal options for generators. It is likely that these costs often are be passed on to patients and insurers.

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."²³ 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.²⁴ EPA lists six

²² 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, footnote 9.

²³ United States Environmental Protection Agency, Guide for Infectious Waste Management, (1986) at 2-1, (hereinafter EPA Guide).

²⁴ Id.

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.²⁵ 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. They 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."²⁶ Hence, individual facilities have much discretion in characterizing products in its waste stream as infectious; consequently, there is great disparity in the way health care facilities treat their waste.

The Centers for Disease Control Definition

In 1987 the Centers for Disease Control (CDC) issued

²⁵ Id. at 2-2.

²⁶ Id. The regulatory definition of "regulated medical waste" promulgated pursuant to the MWTAs at 40 C.F.R. § 259.10 (1989) originally contained ten categories of regulated medical waste. It expired with the MWTAs demonstration program.

recommendations called "universal precautions" to health care facilities for classifying waste as infectious.²⁷ Essentially, the CDC recommended that blood and body fluids from all patients be considered potentially infected with HIV and/or other bloodborne pathogens and that health care workers adhere rigorously to infection control precautions.²⁸ 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.²⁹ As a result of confusion and concern that the recommendations were too broad, in 1988 the CDC attempted to clarify the 1987 guidelines and now limits application of the universal precautions to blood and other body fluids containing visible blood, and other specified fluids.³⁰

Both the CDC and EPA consider pathological waste, blood and blood products, contaminated sharps and microbiological wastes infectious. The major disagreement between the agencies is over designation of communicable disease/isolation wastes because EPA considers communicable disease wastes infectious and the CDC recommends that such wastes be treated

²⁷ Centers for Disease Control, Universal Precautions for Prevention of Transmission of HIV and Hepatitis B Virus, (Aug. 1987), discussed infra at chapter 6.

²⁸ Id.

²⁹ OTA Background Paper, supra note 2 at 4.

³⁰ Id. at 5.

according to hospital policy.³¹ Such disagreements can translate into dollars for 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 four designated by the CDC.³² 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.

Characteristics of the Infectious Waste Stream

Amounts of Medical Waste

Data on the amounts of medical and infectious waste in the U.S. vary. In its second report to Congress under the Medical Waste Tracking Act, the EPA stated that collecting baseline information on medical waste generation, waste

³¹ 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, the EPA, perhaps jointly with the CDC, needs to publish further guidance on these definitional issues.

³² Id. 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.

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.³³ The EPA has estimated that each hospital has a per bed per day generation rate of 13 pounds of medical waste.³⁴ Other independent estimates of medical waste generation range from 16 to 23 pounds per bed per day.³⁵ Not all of this waste 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.³⁶ One study which has distinguished between infectious and medical waste in ascertaining amounts of generation, reports that U.S. hospitals generate a median of 15 pounds of medical waste per patient per day, with

³³ EPA Second Interim Report, supra note 21 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. This study is mentioned in EPA's second interim report at p. 9. However, results of this study will not be available until the final report is released to Congress. Interview of Ann Coggington; supra note 19.

³⁴ 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.

³⁵ See sources cited id. at 3.

³⁶ EPA First Interim Report, supra note 5 at 1-4.

infectious waste making up 15 percent of the total.³⁷ This data is based on a 1985 estimate of 1.3 million hospital beds in 7000 hospitals in the United States, with an average occupancy rate of 69.5 percent.³⁸ Extrapolating from this information, the total generation of infectious waste by hospitals in the United States is 0.375 million tons per year.³⁹ 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.⁴⁰ Most hospitals designate about 15 percent of their wastes as infectious.⁴¹

³⁷ C.C. Lee, George L. Huffman, Richard P. Nalesnik, Medical Waste Management--The State of the Art, *Envtl. Sci. & Tech.*, Mar. 1991 at 360-361; 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).

³⁸ Id.

³⁹ Id. See also Council Report on Infectious Medical Waste, 262 *JAMA*, Sept. 22, 1989, at 1669-1671. If the EPA definition is used, about 15 percent of the 750 to 800 million pounds of total waste generated by U.S. 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.

⁴⁰ OTA Report, supra note 3 at 2.

⁴¹ 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 certain used medical equipment which might otherwise be disposed of as "waste" to developing countries. See William H. Rosenblatt & David G. Silverman, Recovery, Resterilization, and Donation of Unused Surgical Supplies, 268 *JAMA*, Sept. 16, 1992, at

Hospitals are not the sole source of infectious medical waste, however. In fact, it was estimated that hospitals account for less than 2 percent of the total number of facilities with the potential to generate infectious waste.⁴² While there are many other sources of infectious waste in the U.S., much less is known about them.

Sources of Medical Waste

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.⁴³ A Washington State Infectious Waste Project identified funeral homes, nursing homes, veterinarian offices, laboratories, surgery centers, clinics, dentists' offices, and research facilities as the main non-hospital producers of medical waste.⁴⁴ One source states that in terms of the number of facilities that potentially generate medical waste,

1441.

⁴² See Lee et al., supra note 37. 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 21 at 32.

⁴³ OTA Background Paper, supra note 2 at 3.

⁴⁴ Washington State Department of Ecology, Solid and Hazardous Waste Program, Report to the Legislature: Washington State Infectious Waste Project and Attachments, (Dec. 1989).

the categories identified in the Washington study account for more than 98 percent of the total, which is estimated at 340,500 facilities.⁴⁵ By comparison, another source reports that approximately 465,000 tons of infectious waste are generated in the U.S. each year by 377,000 health care facilities including non-hospital sources.⁴⁶

Even less is known about other sources of medical waste like syringes generated in home health care and by illegal drug users. It is estimated that there are 2 million diabetics and 1.2 million intravenous drug abusers nationwide

⁴⁵ Lee et al., supra note 37 at 361. Although hospitals are considered to be the primary generators of medical waste, other sources include approximately 180,000 physicians' offices, 8,400 dentists' offices, 38,000 veterinarians' offices, 15,500 medical clinics, 12,700 long-term health care facilities, 4300 laboratories and 900 free-standing blood banks. William A. Rutala & David J. Weber, Infectious Waste--Mismatch Between Science and Policy, New Eng. J. Med. Aug. 22, 1991, at 578, citing EPA's First Interim Report to Congress, supra note 5. The authors maintain that these sources may have a significant contribution to the medical waste stream; however, reliable data are not available on the amount of waste they produce. Id.

⁴⁶ Alex E.S. Green (ed.), Medical Waste Incineration and Pollution Prevention 43-44 (1992).

who use more than 1 billion insulin-type syringes annually, that are not regulated.⁴⁷ These two waste streams are now receiving more attention. In its Second Interim Report to Congress, the EPA admits that the extent to which these waste streams contribute to the problem of beach wash-ups and other mismanagement incidents is unclear; however some of the medical debris discovered on beaches has been linked to disposal of insulin syringes.⁴⁸ One recent survey indicates that diabetics discard an estimated 1.4 billion needles every year and people with AIDS, cancer and other chronic diseases also frequently receive treatment at home which generates sharps and other medical wastes.⁴⁹ EPA has acknowledged that the home health care community is the most significant unregulated community that EPA has attempted to reach.⁵⁰

⁴⁷ Rutala & Weber, supra note 45 at 579, citing Agency for Toxic Substances and Disease Registry, The Public Health Implications of Medical Waste: A Report to Congress, (Sept. 1990) (hereinafter ATSDR Report).

⁴⁸ EPA Second Interim Report, supra note 21 at 10, 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. citing Environmental Crimes Unit, Maryland Attorney General's Office, Medical Waste Investigation Report, (Dec. 13, 1988).

⁴⁹ Ingfei Chen, Deborah Franklin, Katherine Griffin, John Hastings & Michael Mason, Medical Wastes Come Home, Health, May 1993, at 21-22.

⁵⁰ Id. at 17. 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. EPA First Interim Report, supra note 5 at 11-1 to 11-21.

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 small quantity generators were exempt from reporting under the MMTA. More precise data is needed on non-hospital sources of medical waste and how they may contribute to combined sewer overflows or other types of medical waste mismanagement.

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 classified as infectious, noninfectious solid waste and hazardous waste.⁵¹ 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

⁵¹ 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.

definitions.⁵² Generally, infectious waste includes materials considered to be potential health hazards because of possible contamination with pathogenic microorganisms.⁵³ The typical waste stream components of infectious waste in order of magnitude are paper and cloth items, plastics, glassware and fluids.⁵⁴

Health care facilities also produce noninfectious solid waste which includes many items found in municipal solid waste. Most often these wastes are generated by accounting, engineering, record keeping and other administrative functions. In order of quantity, these noninfectious solid wastes include paper and cardboard, plastics, food scraps, metal glass, inorganic materials and other miscellaneous matter.⁵⁵ Depending on the applicable regulation, most wastes generated from patient care activities may be considered noninfectious as long as no exposure to infectious agents has occurred.⁵⁶

⁵² Frank L. Cross, Infectious Waste Management 8 (1990).

⁵³ Green, supra note 46 at 40.

⁵⁴ 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 52 at 10.

⁵⁵ Green, supra note 46 at 40.

⁵⁶ Cross, supra note 52 at 9-10.

Hazardous waste generated by health care facilities is regulated by RCRA. It 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.⁵⁷ Under RCRA regulations, hazardous waste generators are subject to different standards according to the quantity of waste produced per month. 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 management of infectious wastes.⁵⁸

The medical waste stream has not changed significantly in the past few years.⁵⁹ The most noticeable change is the increase in plastic disposable items.⁶⁰ An increase in

⁵⁷ 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.

⁵⁸ OTA Background Paper, supra note 2 at 7, citing New York State's statute which provides for penalties of up to 4 years in prison and fines of up to \$50,000 for illegal disposal of medical wastes.

⁵⁹ Cross, supra note 52 at 1.

⁶⁰ Id. According to Green, supra note 46 at 45, during the late 1970s only 10 percent of the medical waste stream was plastics. By the late 1980s plastics comprised more than 30 percent. Disposable plastics have replaced many glass items and textiles.

plastics has disposal implications especially if the waste is incinerated because the amount of polyvinyl chloride found in an incinerator's waste feed material is closely related to the production of hydrogen chloride and may influence dioxin and furan emissions.⁶¹

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 fractions.⁶² Infectious waste contains approximately 41 percent plastic and rubber as compared with 12.8 percent in municipal solid waste.⁶³ Municipal solid waste contains 54.1 percent paper and cardboard, compared with 31 percent in infectious waste.⁶⁴ 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

⁶¹ Green, supra note 46 at 45. See discussion of incineration infra at chapter three.

⁶² Green, supra note 46 at 42.

⁶³ Id.

⁶⁴ Id.

infectious waste.⁶⁵ The actual risk posed by infectious waste is still under debate, and the uncertainties of this issue underlies EPA's decision not to regulate the waste as hazardous.

⁶⁵ Council Report on Infectious Medical Wastes, supra note 39 at 1669 and writings cited therein.

Chapter Two

Medical Waste and the Public Health Debate

Introduction

The degree of risk medical waste poses is not clear. Generally speaking there are three main areas of concern: risks to the general public health, risks of occupational exposure and risks associated with disposal and treatment technologies⁶⁶. 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 action⁶⁷. For instance, in 1986 approximately 1400 bags of medical waste were discovered at a warehouse by the New York City Fire Department and in 1987 in Indianapolis, 12 children were found

⁶⁶ 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 public health risks. In the ATSDK Report, supra note 47 at E.11, the agency concluded that "medical 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." Id.

⁶⁷ The legislative history of the MWTAA supports this conclusion and is discussed in more detail infra at chapter 3.

playing with some AIDs-infected vials of blood that came from an unlocked dumpster outside several doctors' offices.⁶⁸

The outcry such incidents have 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 in the Resource Conservation and Recovery Act (RCRA) where "hazardous waste" was defined to include wastes with infectious characteristics.⁶⁹ Despite this, medical waste was not actually regulated until 1988 when Congress passed the Medical Waste Tracking Act, establishing a 2-year demonstration program that was only applicable to four states and Puerto Rico. Despite passage of the MWTA, very little epidemiological study of public health risk associated with medical waste exists.⁷⁰ To date, the most extensive federal research on this issue is reported by the Agency for Toxic

⁶⁸ Lee et al., supra note 37 at 360, citing OTA Background Paper, supra note 2.

⁶⁹ 42 U.S.C. § 6903(5) (West Supp. 1984-1992).

⁷⁰ Interview with Ann Coggington, supra note 19.

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 generation⁷². 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; and, then, infection can occur, but, infection does not always result in disease.⁷³ ATSDR found that an infectious organism's ability to survive outside a host varies

⁷¹ The MMTA, section 11009, required ATSDR to report on the public health implications of medical waste.

⁷² See ATSDR Report, supra note 47. 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. Env'tl. Health, Jul. 1990, at 30.

⁷³ ATSDR Report, supra note 66 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 greatest potential for infectious disease transmission is in the health care setting. Id.

widely and, consequently, its capability to transmit disease varies greatly, depending on its type and form and environmental factors such as temperature and moisture.⁷⁴ 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.⁷⁵

ATSDR arrived at sixteen conclusions based on the data it developed. Most significant, 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.⁷⁶ Outside the health care setting, the potential for hepatitis B virus or HIV infection in the general public following medical waste-related injuries is not likely to be a health concern.⁷⁷ However, the number of persons infected with HIV is expected to increase; likewise, the number of

⁷⁴ Id. at E.2.

⁷⁵ Id. at E.3.

⁷⁶ Id. at E.9.

⁷⁷ Id. Maureen Y. Lichtveld, an ATSDR toxicologist, reports that it is unlikely that anyone has been infected with AIDS as a result of contact with medical waste because the virus is too fragile. But, hepatitis B and bacterial infections may be increasing risks for sanitation workers and home health care providers because of the "explosion in home health care...and there are no regulations on how to deal with those wastes," Chen et al., supra note 49 at 22. Used syringes and intravenous tubing are often tossed into the trash or flushed down the toilet. At least 14 percent of the needle-stick injuries reported by sanitation workers occur in neighborhoods and the number is rising. Id. at 21.

health care workers infected with AIDs is anticipated to rise as a result of contact with waste sharps thereby increasing the potential for medical waste-related HIV transmission in the health care setting.⁷⁸

ATSDR emphasizes that limited data are available on communicable disease potentially attributable to medical waste and theoretical estimates vary extensively due to different study designs, reporting practices and sources of records or case information.⁷⁹ In conclusion, the agency makes eleven recommendations. Among them, ATSDR suggests that research is needed in three specific areas: to evaluate the probably 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.⁸⁰

In addition to ATSDR's report, section 11008(a)(2) of the MMTA required EPA to evaluate the threat posed by medical

⁷⁸ Id.

⁷⁹ Id. 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.

⁸⁰ Id. at E.14-15.

waste. 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.⁸¹ 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 MWTA.⁸² The agency acknowledges that many experts and health care professionals believe 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.⁸³ EPA concludes that determining the potential health hazards of improperly managed medical waste is "one of the most complex and critical issues

⁸¹ EPA Second Interim Report, supra note 21 at 35-37. This analysis focuses on those wastes warranting concern for public exposure. EPA is also collecting information on infective doses and survivability of pathogens, and doing epidemiological data searches (other than those performed by ATSDR) for disease transmission from exposure to medical waste either in the workplace or community. Id.

⁸² Interview with Ann Coggington, supra note 19. Ms. Coggington did not indicate when the report would be released. After preliminary study, the agency has reported that information collected for bacteria and viruses on survivability show rapid die-off of pathogens exposed to various environmental conditions. However, according to Tom Goldberg, supra note 7, the data now available is old and the government is not currently funding any further research in this area.

⁸³ EPA First Interim Report, supra note 5 at 2-1.

requiring resolution."⁸⁴

Three Types of Risks

Risk to the General Public

At least one prominent researcher working in the infectious waste field claims that there is no evidence that medical waste has lead to disease in the hospital or the community, and that the "threat" prompting regulation of medical waste is merely "perceived," fueled by fears of AIDS infection.⁸⁵ 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.⁸⁶ The OTA has stressed that a fundamental policy issue of importance

⁸⁴ 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.

⁸⁵ Rutala & Weber, supra note 45, 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. Regulators have confused protection of the public health with providing an aesthetically pleasing environment and have confused biological agents with toxic chemicals. Id. at 39.

⁸⁶ 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.

which the federal government should address is the extent to which medical wastes are to be regulated on the basis of their potential threat to public health and their aesthetic characteristics.⁸⁷ The data that exists indicates that the majority of waste found on beaches after medical waste wash-ups was general debris; medical waste could not be traced to illegal dumping or specific source, but probably resulted from sewage overflow.⁸⁸ EPA attributed the medical waste problem to illegal disposal, combined sewer overflow, stormwater 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.⁸⁹ Consequently, many believe the likelihood that the general public will contact medical waste appears small. However, the Centers for Disease Control have said that contaminated needles or sharps, human blood and blood products, pathological parts and laboratory wastes possess real

⁸⁷ OTA Report, supra note 3 at 5.

⁸⁸ Rutala, supra note 85 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 came 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.

⁸⁹ 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., at 78 (1988) (statement of Jeffrey D. Denit, Deputy Director, Office of Solid Waste, EPA).

potential to transmit disease.⁹⁰ Nevertheless, the only medical waste that has been associated with infectious disease transmission is contaminated sharps.⁹¹ One theoretical estimate that the sequence of events necessary for infection will occur and that a person will develop HIV infection from a needle on the beach is one in 15 billion to one in 390 trillion.⁹²

Studies which quantify the infectious microbial loads of different hospital wastes are few. Those that exist indicate that hospital waste is no more microbially contaminated than household waste. Some researches have concluded that household waste contains, on the average, 100 times more microorganisms with pathogenic potential for humans than hospital waste.⁹³ The only medical waste that has been associated with infectious disease transmission is

⁹⁰ Mercer, supra note 86 at 513 citing 134 Cong. Rec. S10, 738 (daily ed. Aug. 3, 1988) (statement of Rep. Lautenberg).

⁹¹ Rutala, supra note 85 at 41 citing ATSDR Report.

⁹² Id.

⁹³ Id. at 43. Studies quantifying the infectious microbial loads of different hospital wastes are scarce. Of those that have been conducted, the microbial loads are reported as not greater, and maybe less overall, than those found in general house hold wastes. Id. 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 body flora and a majority of infections occur at home, untreated residential waste may be as infectious as most untreated medical waste. See Wayne L. Turnberg, Infectious Waste Disposal, An Examination of Current Practices and Risks Posed, J. Env'tl. Health, May 1991, at 21, 23.

contaminated sharps.⁹⁴ 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.

Occupational Risks

In the health care setting, the persons most often injured generally are nurse's aides, registered nurses, housekeeping, maintenance and food-preparation workers.⁹⁵ Of all workers contacting medical waste, sanitary service workers report the highest rates of on-the-job-injuries.⁹⁶

Most injuries reported come from contact with sharps. Only one case of infection possibly associated with management of medical waste sharps is reported and it involved a hospital

⁹⁴ Rutala, supra note 85 at 41.

⁹⁵ ATSDR Report, supra note 47 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.

⁹⁶ Id. Sanitary service workers overall injury rate of 180 per 1,000 workers per year is more than double that of the entire U.S. work force combined. Most frequently reported injuries are strains and sprains from overexertion.

housekeeper who developed staphylococcal bacteriaemia and endocarditis from a needle injury.⁹⁷ The two studies of occupational exposure of waste industry workers to medical and municipal waste have not shown an increased risk of bloodborne infections.⁹⁸ But, the Centers for Disease Control once reported that each year 200 to 300 deaths occur among health care workers, often waste handlers, due to hepatitis B.⁹⁹

⁹⁷ Id. According to ATSDR and Rutala, supra note 85, there is no documented evidence on infections resulting from contact with medical waste other than sharps. None of the HIV infections attributed to dermal contact or mucous membrane contamination were associated with medical waste. ATSDR states, based on the data developed in its report, 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. Contact with non-sharp medical waste may make an unknown contribution to the total number hepatitis B virus and HIV cases, but ATSDR says this contribution would be considerably less because a portal of entry must already exist for disease transmission to occur. Id. By comparison, infection resulting from patient contact in the occupational setting is much higher. See e.g. American Dental Association et. al. v. Secretary of Labor, 984 F. 2d 823 (7th Cir. 1993), wherein the court notes that as of 1991 there have been 24 confirmed cases of U.S. health care workers infected with the AIDS virus by patients since AIDS was first diagnosed in 1981. Patient-communicated Hepatitis B virus kills about 200 health workers in the U.S. per year--roughly 100 times the number of such workers infected by patient-communicated HIV. Id. at 824.

⁹⁸ See Rutala, supra note 85 at 44 and studies cited therein.

⁹⁹ 134 Cong. Rec. H9, 541 (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. H9, 536 (daily ed. Oct. 4, 1988) (statement of Rep. Whittaker). The hepatitis B virus can spread through breaks in the skin, mucous membranes, sexual contact, and from mother to infant. The risk of acquiring hepatitis B infection due to a needlestick injury from a needle contaminated by a hepatitis carrier ranges between six to 30 percent within health care settings. See also Michael R. Shumaker, Infectious Waste: A Guide to State Regulation and a Cry for Federal Intervention, 66 Notre

The exact nature and degree of the risk to the public remains in debate with little current empirical data to resolve the dispute. 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 should be collected.¹⁰⁰ This recommendation is supported by the lack of data surrounding occupational risk posed by medical waste and conflicts in the data that does exist.

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 method of treating medical waste. Approximately 64 to 93 percent of hospitals incinerate their waste, about one-third of U.S. 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 disposed of

Dame L. Rev. 555, 561 (1990) at footnote 21.

¹⁰⁰ ATSDR Report, supra note 47 at E.13.

in a sanitary landfill.¹⁰¹ Because of the increased use of plastic disposables, old, less efficient incinerators have the potential to produce incompletely combusted chlorinated products and exposure to these substances may cause adverse health effects.¹⁰² Insufficient data is available to determine if there are proven adverse public health effects associated with medical waste incineration, and the health implications of medical waste incineration are still under vigorous debate.¹⁰³

The ATSDR finds that untreated medical waste can be acceptably disposed of in sanitary landfills because research indicates that medical waste does not contain any greater

¹⁰¹ Rutala, supra note 85 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).

¹⁰² Id. Possible reasons for higher emission levels of dioxins and furans and HCl in medical waste incinerators may be: (1) frequent startups and shutdowns; (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.

¹⁰³ ATSDR Report, supra note 47 at E.13. See also OTA Report, supra note 3 at 15-22, 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. In addition, no national estimates of non-cancer effects associated with hospital incinerator emissions have been undertaken. Id.

quantity of microbial agents than residential waste. Furthermore, viruses present in solid waste tend to adsorb to organic matter and deactivate.¹⁰⁴ 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.¹⁰⁵ Research shows that the chemical and physical characteristics of the landfill environment produce an inactivating effect upon viruses and bacteria; however, they acknowledge it is possible for pathogens to survive.¹⁰⁶ On balance, it appears the risk of groundwater contamination by pathogens in a properly lined and operated landfill is low.¹⁰⁷

Discarding of medical waste via the sewer system is arguably safe assuming that conventional treatment processes

¹⁰⁴ ATSDR Report, supra note 47 at E.11.

¹⁰⁵ Turnberg, supra note 93 at 21, 23.

¹⁰⁶ Id. at 24. See Rutala, supra note 85 and sources at footnotes 39, 48-52.

¹⁰⁷ Turnberg, supra note 93 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. and sources cited at footnotes 5, 57. 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.

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.¹⁰⁸ Proponents who argue that sewer system disposal of medical waste is proper argue that the microbial load added to the sewer via body fluid such as blood is normally negligible compared with already existing major sources of pathogenic microbes in sewage, which include the bacteria and viruses in human feces.¹⁰⁹ The obvious counterargument to this position is the possibility of sewer overflow, bypass or upset of the treatment works, which could create wash-ups exposing the public to infectious wastes. Like incineration, safe disposal of infectious waste in the sewer system continues to be aggressively debated.

In the U.S. the majority of medical waste is incinerated or autoclaved.¹¹⁰ Autoclaving is the preferred method of

¹⁰⁸ Rutala, supra note 85 at 45 citing G. Bitton, Introduction to Environmental Virology at 121-152, 1980. See also OTA Report, supra note 3, chapter 3, Non-incineration Treatment Technologies and Trends.

¹⁰⁹ Id. Rutala maintains that, based on epidemiological and microbiological data, only two types of medical waste require special handling and treatment: sharps and microbiological waste.

¹¹⁰ 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. Sometimes chemical or radioactive processes are used to achieve the

treatment for microbiological laboratory cultures and the demand for autoclaving seems to be increasing because it is generally cheaper than incineration and does not produce potentially toxic emissions.¹¹¹ Other potential treatment technologies such as irradiation, microwaving, electrohydraulic disinfection and plasma torch technology are commercially available; however the health risks associated with these technologies have not been thoroughly investigated.¹¹² With the recent growth in alternative technologies for treating and disposing of medical waste, needed research on potential ancillary health risks of alternative technologies may be forthcoming.

same purpose. See generally OTA Report, supra note 3 at 27-28. A further discussion of incineration is contained infra in Chapter Four, "The Clean Air Act."

¹¹¹ Id. at 28, 39.

¹¹² Id. at 38-39. OTA states that further examination of potential health risks is warranted with alternative technologies, particularly for microwaving and irradiation and, 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.

Chapter Three

The Beginning of Federal Regulation of Medical Waste

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.¹¹³ Public concern pressured governmental action and with unusual speed, Congress passed the Medical Waste Tracking Act in November 1988.¹¹⁴ The scope of the Act was limited. It added Subtitle J to RCRA and created a two-year demonstration program that only ultimately applied to four states and Puerto Rico. There may be several reasons why Congress chose to 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

¹¹³ 134 Cong. Rec. S10, 737 (daily ed. Aug. 3, 1988) (statement of Sen. Lautenberg) cited in Mercer, supra note 86 at 509. New York and New Jersey lost at least a billion dollars of tourism revenues due to these closings. Id. at 516.

¹¹⁴ According to Mercer, supra note 86 at 519, 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," citing Nelson A. Rockefeller Institute of Govt., Report of the Medical Waste Policy Committee 2 (June 1989), at 25.

it felt that the medical waste problem was essentially an East Coast malady.¹¹⁵ More likely, Congress concluded that a program of limited time, scope and federal oversight would give Congress an opportunity to view a small-scale program in operation before committing to a national program.¹¹⁶

The statute and its implementing regulations expired on June 22, 1991. Nevertheless, the MWTA remains significant because it is the prototype for many existing state medical waste regulatory programs¹¹⁷. 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.

A Uniform Definition of Medical Waste

EPA created a new definition of medical waste under the MWTA called "regulated medical waste."¹¹⁸ Since there is no

¹¹⁵ See Perspectives on Medical Waste, supra note 16, Supp. 3-7 (July 1989) cited in Mercer, supra note 86 at 520-521.

¹¹⁶ Id.

¹¹⁷ Cheryl L. Coon & Howard L. Gilberg, The New Regulatory Horizon: Regulation of Medical Waste, 45 Sw. L.J. 1099, 1100 (1991-1992).

¹¹⁸ 40 C.F.R. § 259.30(a) (1989).

objective test for medical waste, unlike other types of hazardous wastes addressed by RCRA, the consistent definition provided by the MMTA 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.¹¹⁹ First, the MMTA 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."¹²⁰ Then, the MMTA provided a list of medical waste to be included under the program.¹²¹ With the expiration of the MMTA, federally "regulated medical waste" no

¹¹⁹ For a discussion of these groups' individual viewpoints, see Onel, supra note 11.

¹²⁰ 42 U.S.C. § 6903(40) (West Supp. 1984-1992).

¹²¹ 42 U.S.C. § 6992a(a)(1)-(11) (West Supp. 1984-1992) 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. at § 6992a. 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 MMTA 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, Thomas W. Church, Phillip J. Cooper, A Blip on the Radar Screen: Formulation and Implementation of the Medical Waste Tracking Act, J. Health, Pol., Pol'y & Law 299, 321, (Summer 1992).

longer exists and there are a plethora of state definitions.¹²² 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.¹²³

The Tracking System

EPA has stated that the core of the MWTAs consists of the requirement that medical waste shipped off-site is tracked to its destination.¹²⁴ The tracking system is based upon the hazardous waste manifest system underpinning RCRA Subtitle C.

By making the tracking system the centerpiece of the MWTAs, Congress chose to focus on tracking of existing medical waste rather than to change existing practices regarding disposal or treatment of medical waste.

¹²² For example, Florida uses "infectious, biohazardous waste," Georgia and Connecticut use "biomedical wastes," and Iowa uses "medically hazardous waste." See Shumaker, supra note 99 at 564 for a survey of state laws concerning medical waste.

¹²³ 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. 654 (1991).

¹²⁴ EPA Second Interim Report, supra note 21 at 6.

Under the tracking system, once medical waste is generated, the generator prepares a tracking form to accompany the waste transported offsite from the facility.¹²⁵ 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 at Title 40 Code of Federal Regulations Part 259 also address handling of the waste before transport, treatment, destruction and disposal facilities, generators and transporters. 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.¹²⁶ Transporter vehicle standards are designed to contain the waste and maintain packaging integrity during transport. It was EPA's intention to

¹²⁵ 42 U.S.C. § 6992b(a)(1) (West Supp. 1984-1992). 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 11 at 240-244.

¹²⁶ 40 C.F.R. §§ 259.50(e)(1), 259.52, 259.54(a), 259.55 and 259.50(f) (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.

construct a "closed circle" that facilitates proper management and encourages proper disposal and reveals potential waste mismanagement.¹²⁷ It is an expensive system, however. EPA concluded that the tracking requirement imposed an average annual cost compliance of 12 million dollars or 24 million dollars for the two years the program would be run.¹²⁸ Cost is a major factor weighing against treating medical waste as hazardous waste, and 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.

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, enter sites, and obtain samples.¹²⁹ Information gathering gives EPA a means to gather data it must report to Congress and supports the enforcement provisions of the Act.

¹²⁷ Id.

¹²⁸ EPA First Interim Report, supra note 5 at 3-9. By comparison, EPA estimated the New York, New Jersey and Connecticut alone would lose thirty million dollars because of adverse effects attributable to mismanaged medical waste. Id. at 3-16.

¹²⁹ 42 U.S.C. § 6992c(a) (West Supp. 1984-1992).

According to EPA, one 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.¹³⁰ 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 MWTA requirements.¹³¹ From this data, EPA is required by the MWTA, Sections 6992g-6992h, to report to Congress on specific issues.¹³² 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."¹³³ Yet, with EPA's final report now two years overdue, it is questionable what priority medical waste has on the agency's agenda and, in

¹³⁰ EPA Second Interim Report, supra note 21 at 8.

¹³¹ Id. See note 19, supra.

¹³² 42 U.S.C. § 6992g(a) (West Supp. 1984-1992) requires EPA to prepare a final report to Congress at the end of the MWTA demonstration program.

¹³³ Mercer, supra note 86 at 546.

light of EPA's neglect of the subject, one observer's comments seems apropos:

"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...."¹³⁴

Although the MWTA program has lapsed and may never be revived, its most palpable effect is still seen in some state programs adopting the statute's tracking and controversial enforcement provisions.

Enforcement

During the MWTA demonstration program, some hospitals were accused of overdesignating waste as "regulated medical waste" because the penalties for violating the MWTA rules were so severe.¹³⁵ Indeed, the MWTA contained strong enforcement authorities similar to that in 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

¹³⁴ Nakamura et al., supra note 121 at 322-323.

¹³⁵ Rutala, supra note 85 at 46.

records.¹³⁶ The agency could issue compliance orders and assess civil penalties of up to \$25,000 per day for each violation.¹³⁷ In the event records, reports, documents or material information is knowingly falsified or provisions of the MMTA are knowingly violated, the MMTA 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.¹³⁸ 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 \$1,000,000.¹³⁹ Those who disagreed with the severe penalty structure argued that fines should be assessed relative to the seriousness of the violation; while proponents of the system maintain that the higher the penalties, the stronger the deterrent value.¹⁴⁰

¹³⁶ 42 U.S.C. § 6992c (West Supp. 1984-1992).

¹³⁷ 42 U.S.C. § 6992d (West Supp. 1984-1992) and see Donald W. Steven & Eliza A. Dolin, *Environmental Law and Practice*, Environmental Law Institute, 1992, at 3-186.

¹³⁸ 42 U.S.C. § 6992d (West Supp. 1984-1992).

¹³⁹ *Id.* The orders for penalties were final unless a public hearing was requested within 30 days. 42 U.S.C. § 6992d(3) (West Supp. 1984-1992).

¹⁴⁰ 134 Cong. Rec. H9538 (daily ed. Oct. 4, 1988) (statement of Rep. Whittaker) 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

During the first year of the demonstration program, EPA aggressively pursued serious violations in the form of 11 administrative actions and issued 257 warning letters of notices of violation for less serious infractions.¹⁴¹ As of June 1, 1990, EPA reported it had conducted approximately 510 inspections and had assessed approximately \$690,000 in penalties.¹⁴² The final tally of enforcement actions should appear in EPA's forthcoming final report.

Critique of the MWTA

It has been suggested that the MWTA answered the short-term political needs of Congressmen to act in the face of public demands to do something about 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.¹⁴³ While this is not altogether true, the

Laurence D. Granite, The Medical Waste Tracking Act of 1988: An Analysis of its Provisions and its Effect on New York State, 7 *Touro L. Rev.* 259 (1989-1991).

¹⁴¹ EPA Second Interim Report, supra note 21 at 22.

¹⁴² Id. This is the most recent data available from EPA and the agency states that its final report is will contain a more extensive report of enforcement under the MWTA.

¹⁴³ Perspectives on Medical Waste, supra note 16 at 31 wherein the authors correctly predicted in 1989 that three things would persist after expiration of the MWTA: (1) policy debate over the degree of hazard posed by infectious wastes, (2) the proper role of the EPA in their regulation, and (3) the appropriateness of current handling and disposal practices.

demonstration program had certain weaknesses which adversely affected its efficacy. For instance, the MWTA did not address the long-term risks associated with different treatment and disposal systems, nor did it clearly enunciate a preferred mode of disposal.¹⁴⁴ 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, or, operator training and monitoring specifications and ash disposal requirements.¹⁴⁵ 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 MWTA placed no restrictions on who could handle infectious waste and where the waste should be treated and disposed, and no minimal level was set regarding packaging and labeling or the labeling and disinfection of transport trucks.¹⁴⁶ The Act did not make it clear whether incinerated waste was entirely exempt from the tracking system or whether incinerated waste should have

¹⁴⁴ Onel, supra note 11 at 240.

¹⁴⁵ Id. The MWTA simply requires EPA to gather information, conduct assessment studies and report to Congress.

¹⁴⁶ Id. at 243.

been tracked if it was incinerated off-site.¹⁴⁷ These uncertainties, including the small quantity generator exemption, will influence the accuracy and quality of the data EPA gathered under the MWTa and its conclusions. Also, since there was no pre-MWTa baseline data for comparison it is not clear if EPA will be able to adequately interpret the information it gathers under the MWTa.

If the MWTa is revived and EPA continues to act primarily as administrator of the law, allowing states to take the lead in implementing and enforcing it, it is unclear how states will enforce compliance by haulers and disposal site operators (which the MWTa does not address), particularly those in states different from the generator.¹⁴⁸ Furthermore, the stringent regulations imposed on the generators under the MWTa do not take into account varying risks posed by different types of medical waste, and the Act could have been strengthened by shifting some of the tracking and handling costs onto the waste handlers.¹⁴⁹ In addition, the MWTa 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

¹⁴⁷ Id.

¹⁴⁸ Id. at 244.

¹⁴⁹ Id. at 247.

procedures and agencies intended to deal with the problem."¹⁵⁰ Finally, the program focused on northeastern states with coastlines and beach wash-up problems; consequently, the necessity or practicality of its transferrability to other regions is open to question.¹⁵¹

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, and the 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 collection of essential

¹⁵⁰ 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).

¹⁵¹ According to Nakamura et al., supra note 121 at 309, the MWTA's regulatory coverage 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. Thus, Nakamura et al. characterize the MWTA as "an exercise in symbolic politics." Id. at 312.

information.¹⁵² 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, some reduction in the severity of beach wash-ups, and contribution to medical waste program development in noncovered states and foreign countries.¹⁵³ Since enactment of the MWTA, nearly every state has passed some type of medical waste legislation or revised their existing regulations.¹⁵⁴ When EPA at last releases its final report to Congress on the MWTA, the agency will make a recommendation on whether a continuing federal program is needed and, if so, what components the program should include.¹⁵⁵ Meanwhile, management of medical waste in the United States is governed by an eclectic montage of statutes, rules, guidelines and standards.

¹⁵² EPA Second Interim Report, supra note 21 at 23.

¹⁵³ Id. at 23-24.

¹⁵⁴ According to EPA's Second Interim Report, its final report to Congress is expected to address changes in the covered states' program and provide further analysis of the indirect program effects. State regulation of medical waste is discussed infra at chapter five.

¹⁵⁵ EPA Second Interim Report, supra note 21 at 2.

Chapter Four

Current Federal Law Governing Medical Waste

The Resource Conservation and Recovery Act

The EPA was given authority to regulate the handling, storage, treatment, transportation and disposal of medical and infectious waste in 1976 with Subtitle C of the Resource Conservation and Recovery Act (RCRA) which amended the Solid Waste Disposal Act of 1965.¹⁵⁶ RCRA represents Congress' first attempt to control and regulate hazardous waste from creation until disposal. Under RCRA, "hazardous wastes" was defined, in part, as:

"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." (emphasis added)¹⁵⁷

¹⁵⁶ 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) Issue Paper, EESI Briefing Book, 1993, at 55-56.

¹⁵⁷ 42 U.S.C. § 6903(5) (West Supp. 1984-1992). EPA regulates chemical waste if it has a hazardous characteristic or is listed in 40 C.F.R. § 261 (1992). Lists are principally used to regulate toxic chemicals. Chemical waste that has one or more of the described characteristics or is on one of EPA's lists is 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. So, it is possible for some infectious wastes to be considered hazardous. See Reinhardt & Gordon, supra note 126 at 139.

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 under its proposed hazardous waste regulations; however 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.¹⁵⁸ With the release of the rules in 1980, EPA said it would issue separate infectious waste regulations; however, these have never appeared.¹⁵⁹ Instead, EPA issued guidelines for infectious waste management in 1982 and revised these in 1986.¹⁶⁰

Under RCRA, the federal government's role is to provide information, research and financial assistance to the states,

¹⁵⁸ Perspectives on Medical Waste, supra note 16 at 3.

¹⁵⁹ Id. at 4. EPA changed its position on the hazards presented by infectious wastes and chose to make "recommendations" concerning their management.

¹⁶⁰ U.S. Environmental Protection Agency, Draft Guide for Infectious Waste Management (1982) (revised 1986), supra note 23. 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 150 at 157. The Guide addresses problems posed by the infectious characteristics of medical waste but in so doing, it contradicts EPA's original position that regulation of the waste was not warranted because public risks were unproven. Id.

and to initiate a solid waste management policy.¹⁶¹ 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.¹⁶² The EPA has discretion to set standards for hazardous waste handling, transportation and storage and can enforce EPA regulations with civil and criminal penalties.¹⁶³ However, the EPA has chosen not to regulate infectious waste as hazardous waste and, with the expiration of the MWTAA, EPA is treating infectious waste as solid waste, relying on the states to enforce their own infectious waste programs.¹⁶⁴ Since there are currently no regulations for infectious waste management based on RCRA, EPA cannot enforce any national standards for management and disposal, nor can it apply the penalties available under RCRA for infectious waste mismanagement.¹⁶⁵

By granting EPA authority to regulate hazardous waste, Congress presumably intended for EPA to establish a national standard for management of all forms of hazardous waste,

¹⁶¹ 42 U.S.C. § 6902(5) (West Supp. 1984-1992).

¹⁶² 42 U.S.C. §§ 6922-6923 (West Supp. 1984-1992).

¹⁶³ 42 U.S.C. §§ 6921, 6923, 6924, 6928 (West Supp. 1984-1992).

¹⁶⁴ Interview with Ann Coggington, supra note 19.

¹⁶⁵ See Goldie, supra note 150 at 147-148.

arguably including infectious waste by definition. 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 allows prosecution of illegal dumping as a felony and permits 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 along with the fact that the risk associated with medical waste is still vigorously debated. As this debate continues, some look for legislative action to settle the dispute.

In the 102nd Congress one proposed bill amending RCRA, S. 976, was introduced on April 25, 1991 by Senator Max Baucus. 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 Drug Administration and the Secretary of Transportation.¹⁶⁶ 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.¹⁶⁷ 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

¹⁶⁶ S. Rep. No. 102-301, 102d Cong, 2d Sess. (1992). The bill was intended to eliminate use of certain hazardous substances and reduce production of wastes by directing EPA to address toxics use and source reduction; in addition, the bill's other priorities were municipal waste recycling, waste treatment, containment and incineration. "A Tale of Sound and Fury: The Environmental Record of the 102d Congress," Comment, 23 Envtl L. Rep. 10015, 10020 (Jan. 1993). The bill was strongly opposed by industry because of its toxic reduction provisions, and it eventually floundered.

¹⁶⁷ S. Rep. No. 102-301, supra note 166 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," and it also addressed medical waste; 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 MMTA but it never passed. See S. Rep. No. 103-33, 103rd Cong., 1st Sess., (1993) (Report to the Senate on the Activities of the Comm. on Env't. and Public Works for the 102d Congress).

waste and RCRA reauthorization this term appears unlikely.¹⁶⁸

The Clean Water Act

Both the Clean Water Act (CWA), and the Marine Protection, Research and Sanctuaries Act (MPRSA) regulate discharge and disposal of medical waste.¹⁶⁹ These two statutes 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

¹⁶⁸ Much of the pending proposed legislation addressing solid waste concerns interstate transportation and disposal of waste and waste incineration, e.g. see 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 Congressmen to seek legislation giving states and localities authority to restrict importation of medical waste. EESI Briefing Book, supra note 5 at 55. Also, for a list of recent cases addressing interstate transportation of waste, see "A Tale of Sound and Fury," supra note 167 at footnote 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 Natl. Env't'l. Daily (BNA), Jun. 10, 1993, at 1 and 23 Env't. Rep. (BNA) 3108 (Apr. 9, 1993) and 23 Env't. Rep. (BNA) 681, (Jun. 19, 1992).

¹⁶⁹ Federal Water Pollution Control Act (FWPCA) herein referred to as the Clean Water Act, Pub. L. 92-137, 85 Stat. 379 (1972), codified at 33 U.S.C. §§ 1251-1387 (West 1983 & Supp. 1984-1992), and the Marine Protection; Research and Sanctuaries Act (MPRSA), 33 U.S.C. §§ 1401-1445 (West 1983 & Supp. 1984-1992).

frequency.¹⁷⁰ 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.¹⁷¹ It is not known exactly how much improper medical waste disposal contributes to beach closings every year. Nevertheless, recent history confirms that medical waste pollution is a significant factor and both the CWA and 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.¹⁷²

¹⁷⁰ 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. However, because beach monitoring is irregular, it cannot be assumed that increased closures are due to increased beach pollution. NRDC, *Testing the Waters III: Closings, Costs, and Cleanup at U.S. Beaches*, NRDC Rept., (Jun. 30, 1993). This data contradicts EPA's assertion that one beneficial effect of the MWTAs was reduced beach closings.

¹⁷¹ *Id.* See Michael Specter, "Sea-Dumping Ban: Good Politics, But Not Necessarily Good Policy," *The New York Times*, Mar 22, 1993, Sec. A, Pg. 1 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.*

¹⁷² 33 U.S.C. 1311(a) (West Supp. 1984-1992). 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

For instance, disposing of medical waste by wedging it into the rocks of a river bulkhead has been held to constitute an illegal point source discharge actionable under the CWA.¹⁷³ In the case of U.S. v. Villegas, a doctor who co-owned a medical testing laboratory, placed vials of human blood in a river retaining wall purportedly for storage purposes. School children visiting the nearby beach found some of the glass vials laying in the sand. Tests later revealed that five of the vials contained blood infected with hepatitis B, an infectious virus that causes inflammation of the liver and can lead to chronic illness, sometimes even death. The doctor was ultimately convicted by a jury of violating the CWA.¹⁷⁴ In interpreting the statute, the U.S. District Court specifically 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 was deliberately threatening the chemical, physical and biological integrity of the nation's

flows from irrigated agriculture. 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) (West Supp. 1984-1992). The term "pollutant" is broadly defined to include many things including dredged spoil, solid waste, incinerator residue, sewage, garbage, chemical wastes, biological materials. Id. at § 1362(6).

¹⁷³ U.S. v. Villegas, 784 F.Supp. 6 (E.D.N.Y. 1991) 6.

¹⁷⁴ Id.

waters.¹⁷⁵ The court found that the evidence supported a jury finding that the defendant knew the dangers of hepatitis and knew that some of the vials contained hepatitis-infected blood. However, the court said the evidence did not support the conclusion that the defendant knew when he disposed of the vials that there was a high probability that he was placing another person in imminent danger of death or serious injury; therefore he could not be convicted of knowing endangerment under FWPCA § 309(c)(3).

Although the CWA does not directly address medical waste, the Villegas case proves its potential efficacy in protecting our waters, particularly surface water, from medical waste mismanagement. Criminal enforcement of its provisions can result in fines of up to \$250,000 or imprisonment of up to 15 years for individuals convicted of knowing endangerment under the Act, and in the Villegas case the court observed that the range of the sentencing guidelines could be increased because the defendant's conduct was irresponsible and had the potential to cause serious bodily injury.¹⁷⁶ The CWA's sister statute, the MPRSA, is similarly useful in protecting the ocean from illegal dumping of medical waste.

¹⁷⁵ Villegas, 784 F.Supp. at 10, citing 33 U.S.C. § 1251(a). The court added that even if the doctor was not himself a point source, the rocks in the bulkhead were. Id.

¹⁷⁶ 33 U.S.C. § 1319(c)(3)(A) (West Supp. 1984-1992) and id.

The MPRSA is popularly known as the Ocean Dumping Act or the Ocean Dumping Ban Act. Its purpose 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.¹⁷⁷ Specifically, the Act regulates the transportation of material from the United States to a location outside the U.S. for the purpose of dumping the material into ocean waters, and the dumping of material transported by any person from a location outside the U.S., if the dumping occurs in the territorial sea or contiguous zone of the U.S.¹⁷⁸ Among other things, the Act establishes a permit program for the transportation and dumping of material into ocean waters and permits are allowed for only three distinct activities: (1) transportation of any material from the U.S. for the purpose of dumping it into ocean waters; (2) dumping of any material transported from outside the U.S. into the territorial sea of the U.S. or the contiguous zone; (3) transporting any material by a U.S. agency or U.S. registered vessel from outside the U.S. for the purpose of dumping it into ocean waters.¹⁷⁹ The term "material" is broadly defined in the Act and includes chemicals, biological and

¹⁷⁷ 33 U.S.C. § 1401 (West Supp. 1984-1992).

¹⁷⁸ Id. at subparagraph (c).

¹⁷⁹ 33 U.S.C. §1412 (West Supp. 1984-1992).

laboratory waste and "other waste."¹⁸⁰ Medical waste is specifically addressed under the MPRSA and is discreetly defined.¹⁸¹ The Act entirely prohibits ocean dumping of medical waste, radiological, chemical, biological warfare agents and radioactive waste.¹⁸²

Civil penalties for violating the Act, its implementing regulations, or a permit can be assessed up to \$50,000 for each violation.¹⁸³ In addition, any person who violates the Act, its regulations by "engaging in activity in involving the dumping of medical waste" is liable for a civil penalty of up to \$125,000 for each violation.¹⁸⁴ Knowing violation can result in criminal penalties of up to \$50,000 or imprisonment for one year, or both, and knowingly engaging in activity

¹⁸⁰ 33 U.S.C. § 1402(c) (West Supp. 1984-1992).

¹⁸¹ Id. at subparagraph (k). "Medical waste" means 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 such additional medical items as the Administrator prescribes by regulation. Id.

¹⁸² 33 U.S.C. § 1412 (West Supp. 1984-1992). Relevant Congressional oversight hearings include Hearings Before the House Committee on Merchant Marine and Fisheries Subcommittee on Fisheries and Wildlife Conservation and the Environment 100th Cong., 2d Sess. (1988) on the closure of coastal areas due to medical waste and sewage contamination, and Hearing Before the House Committee on Merchant Marine and Fisheries, Subcommittee on Oceanography, 100th Cong., 2d Sess. (1988) on H.R. 3478, a proposed bill to amend the MPRSA and the CWA.

¹⁸³ 33 U.S.C. § 1415 (West Supp. 1984-1992).

¹⁸⁴ Id.

involving the dumping into ocean waters of medical waste can result in a \$250,000 fine or imprisonment for up to 5 years, or both.¹⁸⁵

The Clean Air Act

The Clean Air Act addresses one significant aspect of medical waste: incineration.¹⁸⁶ Historically, incineration was the only method of treatment accepted by regulators for infectious waste because it offers total destruction of the waste, providing an aesthetic benefit and reducing solid waste disposal cost.¹⁸⁷ 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.¹⁸⁸ Other advantages of incineration are that it requires little

¹⁸⁵ Id.

¹⁸⁶ Clean Air Act, 42 U.S.C.A. §§ 7401-7671q (West 1983 & Supp. 1984-1992). "Incineration" is the process by which combustible materials are burned, producing combustion gases and noncombustible residue and ash. U.S. Environmental Protection Agency Handbook, Operation and Maintenance of Hospital Medical Waste Incinerators, January 1990 at 2.1 (hereinafter EPA Incineration Handbook).

¹⁸⁷ Deborah Jessup, Infectious Waste Resource Guide, vol. 2, E-63, containing testimony of Robert A. Spurgin, Vice President, BFI Medical Waste Systems, Inc. Incineration purportedly sterilizes and detoxifies medical waste and converts its to ash, reducing its weight and volume by 90 to 95 percent. Green, supra note 46 at 37.

¹⁸⁸ Green, supra note 46 at 37.

processing of wastes before burning and often it can be done on-site.¹⁸⁹ The main disadvantages are the high cost of incineration and the potential pollution risks associated with incineration processes.¹⁹⁰ Pollutants of concern from medical waste incinerators include particulate matter, toxic metals, toxic organics, carbon monoxide, and acid gases such as hydrogen chloride, sulfur dioxide and nitrous oxides.¹⁹¹ 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

¹⁸⁹ OTA Background Paper, supra note 2 at 15.

¹⁹⁰ Id. According to EPA, "reduction 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 186 at 2.1. A recent study confirmed the increasing use of hospital disposable products and identified numerous ways of reducing medical waste through substitution, minimization and recycling of certain disposable products. Disposable Products in the Hospital Waste Stream, 268 JAMA 2508 (Nov. 11, 1992).

¹⁹¹ Id. at 3.1. Air quality inspection around the nation reveal that few hospital incinerators have the equipment necessary to remove hydrochloric acid and chlorine resulting from burning plastics; few attain the recommended 1,800 degrees Fahrenheit for a minimum of two seconds in the final burn chamber. 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 et al., supra note 9 at 26.

than incremental additional discharges of pollutants linked to incinerators in the New York and New Jersey metropolitan area.¹⁹² 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.¹⁹³ As the debate over health risks intensifies, states are beginning to more aggressively regulate 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 incinerators of the state because of the high cost of retrofitting air pollution control systems to control dioxin and metals.¹⁹⁴ Attempting to avoid costs associated with incineration and its increased

¹⁹² Incineration 2000: Phase II Report, cited in Med. Waste News, Apr. 12, 1993, at 15.

¹⁹³ Id. By comparison, a study for the Florida Department of Environmental Regulation found that municipal solid waste incinerators and medical waste incinerators combined account for 29 percent of all Florida mercury air pollution. It is predicted that the state will 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.

¹⁹⁴ Lee et al., supra note 37 at 360. In Texas v. National Medical Waste of Texas Inc., Texas Dist. Ct. 239th Jud. Dist., No. 91G2902, (Aug. 3, 1992), a corporate defendant which disposes of human body parts and other medical waste agreed to pay \$110,000 in civil penalties 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.

regulation, some hospitals are seeking alternative methods of treatment such as microwaving.¹⁹⁵ 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.¹⁹⁶

The total amount of medical waste incinerated per year is unknown; however, it is still the most prevalent form of infectious waste treatment.¹⁹⁷ Today, incineration accounts for more than 75 percent of the total medical waste treated, with most of the rest being autoclaved.¹⁹⁸ The Clean Air Act Amendments of 1990 specifically address solid waste combustion, and because medical waste is currently

¹⁹⁵ In May 1992 a consortium of 18 Minneapolis and St. Paul hospitals and a coalition of environmental and medical groups agreed to treat some of their combined annual 3 million pounds of infectious waste with steam and microwaves instead of incinerating it. Pathological waste such as human tissue will still be incinerated. Neither steam sterilization or microwave require air emission permits, nor do they require special landfills for disposal of the residual waste. 23 Env't. Rep. (BNA) 408, (May 22, 1992). Prediction of key trends in the medical waste treatment market over the next several years are reduction in on-site incinerators, increase use of non-incineration technology, industry consolidation and leveling out of supply versus demand. New Biomedical Waste Disposal Technologies Predicted at Solid Waste Management Meeting, 23 Env't. Rep. (BNA) 282, (May 8, 1992).

¹⁹⁶ Scott McFetridge, We Really Want Your Medical Waste, Garbage, July 1993 at 19.

¹⁹⁷ EPA estimated 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 U.S. OTA Background Paper, supra note 2 at 15.

¹⁹⁸ Malloy, supra note 7 at 67.

considered solid waste, it is covered by the statute.

Section 129 of the Clean Air Act Amendments of 1990 requires the 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.¹⁹⁹ Under section 129, the EPA is required to 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.²⁰⁰ 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, 2000.²⁰¹ New source performance standards and

¹⁹⁹ 42 U.S.C. § 7429(a) (West Supp. 1984-1992). The EPA Administrator establishes performance standards for each category of solid waste incineration units. Id. New source performance standards are the minimum federal emissions limits set by the 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 § 7429 and EESI Briefing Book, supra note 5 at 13.

²⁰⁰ 42 U.S.C. § 7429 (West Supp. 1984-1992). Solid waste incineration unit is defined at § 7429(g)(1).

²⁰¹ 58 Fed. Reg. 31,358 (1993).

emission guidelines for other types of incinerators including medical waste incinerators are to be developed under separate rulemaking actions.²⁰²

EPA's notice of proposed rulemaking on medical waste incinerators was delayed, ostensibly because of budget cutbacks and internal EPA disagreements regarding monitoring issues.²⁰³ 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 states will have to submit plans for implementing and enforcing the guidelines.²⁰⁴ The EPA is grappling with questions about how it is going to monitor compliance because mandating monitoring devices can be costly; 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.²⁰⁵

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 should fall

202 Id.

203 The latest notice deadline for medical waste incinerators is 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.

204 Id.

205 Id.

under RCRA's household waste exclusion and thus be treated as nonhazardous.²⁰⁶ However, two divergent Circuit Courts of Appeal rulings on this issue have emerged. The U.S. Circuit Court of Appeals for the Second Circuit ruled that municipal solid waste ash is nonhazardous while the U.S. Circuit Court of Appeals for the Seventh Circuit ruled it is hazardous.²⁰⁷ In light of this circuit conflict, the U.S. Supreme Court agreed to decide whether the ash is hazardous or not, and it is probable that medical waste incinerator ash will be covered by this upcoming U.S. Supreme Court ruling.²⁰⁸ If the Court finds the ash is not subject to the exclusion and should

²⁰⁶ This RCRA exclusion derives from 42 U.S.C. § 3001(i) (West Supp. 1984-1992) which states that a municipal resource recovery facility is not deemed to be "treating, storing, disposing of, or otherwise handling" hazardous waste if it receives and burns only household waste.

²⁰⁷ Environmental Defense Fund, Inc. v. Chicago, 948 F.2d 345 (7th Cir. 1991) and Environmental Defense Fund v. Wheelabrator Technologies, 931 F.2d 211 (2d Cir. 1991).

²⁰⁸ The U.S. Supreme Court granted certiorari in City of Chicago, et al. v. Environmental Defense Fund, et al., docket number 92-1639, on June 21, 1993. 61 U.S.L.W. 3851 (Jun. 21, 1993). The U.S. Supreme Court had 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 42 U.S.C. § 3001(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. City of Chicago, 948 F. 2d at 346. The question presented to the U.S. Supreme Court is whether § 3001(i) of RCRA, 42 U.S.C. 6921(i), which provides that "resource recover 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 from hazardous waste regulation ash that is generated by burning municipal solid waste as such facility? 61 U.S.L.W. 3779 (May 15, 1993).

be treated as hazardous, it is possible that treatment prices will soar and the current trend of movement from on-site incineration to autoclaves and alternative technologies will hasten.

Chapter Five

State Regulation of Medical Waste

Congress was aware of the patchwork of state and local laws addressing medical waste when it passed the Medical Waste Tracking Act.²⁰⁹ In the course of its survey of the field prior to the legislation, Congress discovered that medical waste was often unregulated or partially regulated, and even among those states and localities that had medical waste management programs prior to 1988, the scope, intent and effectiveness of the programs varied widely; moreover, because of jurisdictional restrictions on states' authority, they could not adequately address the interstate nature of the medical waste problem.²¹⁰

In enacting the MWTA, Congress charged EPA with responsibility to study existing state and local controls on the handling, storage, transportation, treatment, and disposal of medical waste, including the enforcement and regulatory

²⁰⁹ See generally, 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) See also EPA Second Interim Report, supra note 21 at 5.

²¹⁰ EPA Second Interim Report, supra note 21 at 4.

supervision.²¹¹ EPA responded to this mandate by collecting information on existing medical waste requirements for the five areas covered by the program, and it studied existing and planned medical waste regulations in the seven states that "opted out" of the demonstration program.²¹² The objective of EPA's analysis is to compare the programs and to compile a list of the most important factors for successful medical waste management programs 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.²¹³

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.²¹⁴ By 1989, around 84 percent of all states had bills pending, regulations promulgated or recommendations

²¹¹ 42 U.S.C. § 6992g (West Supp. 1984-1992).

²¹² EPA First Interim Report, supra note 5 at chapter 8 and EPA Second Interim Report, supra note 21 at 40.

²¹³ Id. The key areas EPA is collecting state information about are: the nature of the state medical waste program (regulatory or nonregulatory); the state's treatment of the home health care sector (inclusion or exclusion); and the scope of the state programs. Id.

²¹⁴ Shell J. Bleiweiss & Janice M. Edwards, A Cure for What Ails Us? Environmental Regulation of the Medical Industry, 6 Env't'l. F. 7, 7 (1989).

on the proper disposal of medical waste.²¹⁵ A survey of state laws reveals that nearly every state has some form of medical waste regulation with the exception of Wyoming which has issued general, nonbinding guidelines. As Congress found earlier, the state laws existing today differ significantly in terminology, scope and controls imposed. Such variation can create a burden on those affected who are attempting to comply with the laws and may impose contradictory obligations.²¹⁶ Obviously, the variation in regulatory stringency can lead to forum shopping where generators search for the least expensive and least stringent state to dispose of their waste.²¹⁷ Because of the varied state regulation, a generator must examine the laws of every state through which its waste travels and/or where treatment and disposal occur. Complicating this problem is the fact that states are enacting prohibitions or moratoriums on the issuance of permits for medical incinerators and public opposition to siting of medical waste disposal and treatment facilities is often strident.²¹⁸ In addition, local governments like counties

²¹⁵ See Shumaker, supra note 99 at 556.

²¹⁶ Coon & Gilberg, supra note 117 at 1114.

²¹⁷ This issue has received increasing attention recently as the proposed legislation on interstate transportation of waste mentioned, supra at note 168 attests.

²¹⁸ Coon & Gilberg, supra note 117 at 1100. In its state medical waste survey of 1992, NSWMA's Waste Age/Infectious Wastes News found that nine state had current moratoriums on new commercial incinerators. Nearly all states reported they were planning more regulatory action. Waste Age, supra note 10 at 74.

and municipalities issue local regulations or "ordinances" and "codes" which restrict medical waste management. 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 differently, depending on their purpose, and add further to the confusion attending medical waste handling.

State and local regulation which impacts the interstate movement of waste, including medical waste, is a contemporary subject of judicial interpretation and legislation.²¹⁹ 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, Inc. v. Michigan Department of Natural Resources, the U.S. Supreme Court held that an ordinance which regulates imported waste differently from local waste unambiguously discriminates against interstate commerce.²²⁰ 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, to treat it differently.

Also see Goldie, supra note 150 at 129-134.

²¹⁹ See note 168, supra.

²²⁰ ___ U.S. ___, 112 S.Ct. 2019 (1992) and see Diamond Waste, Inc. v. Monroe County, No. 91-379-2, 1993 WL 311426 (M.D. Ga. Aug. 9, 1993) granting summary judgment in case reported at 814 F.Supp. 83 (M.D. Ga. 1993), with facts reported at 796 F.Supp. 1511 (M.D. Ga. 1992).

Indeed, the county or state must demonstrate that the discrimination is justified by valid factors unrelated to economic protectionism.²²¹ In a recent case involving medical waste, the Ninth Circuit upheld a district court ruling that a Washington county ordinance banning importation of infectious medical waste from outside counties violated the Commerce Clause because it discriminated against interstate commerce. Further, the county 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 any more hazardous than in-county medical waste.²²²

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 states' infectious waste policies often clash and contribute to each other's failures. State regulatory measures that require proving waste delivery to certified disposal sites are confounded by delivery to sites out of state

²²¹ Chemical Waste Management, Inc. v. Hunt, ___ U.S. ___, 112 S.Ct. 2009 (1992) and New Energy Co. of Indiana v. Limbach, 486 U.S. 269, 274 (1988).

²²² BFI Medical Waste Systems v. Whatcom County, 983 F.2d 911 (9th Cir. 1992).

and their inability to tract 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."²²³

Many of the existing state programs are similar to the federal MWTA program. Surveys of the state medical waste laws and regulations reveal that their prominent features are: 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.²²⁴ In attempting to define the universe of regulated medical/infectious wastes, states have drawn from both the EPA Guidelines, the MWTA and the CDC Guidelines. Differences between state statutory definitions are based primarily on the age of the statute, the placement in either state solid waste or public health laws, and the extensiveness of any revisions.²²⁵ Additionally, in developing their medical waste programs, some of the states followed guidelines provided by the Council of State Governments which detail the

²²³ Goldie, supra note 150 at 133.

²²⁴ See Schumaker, supra note 99 at and statutes cited therein.

²²⁵ Goldie, supra note 150 at 136.

components of a medical waste management plan.²²⁶

States which promulgate infectious waste programs in lieu of federal programs are first required to submit written applications of such programs to the EPA for authorization.²²⁷ States must have a program no less stringent than the Federal Government's and since the EPA has not regulated infectious wastes as hazardous, the trend seems to be for the States not to do so either.²²⁸ There are four main arguments against regulating infectious waste as hazardous waste: (1) the public might perceive all medical wastes present the same severity of risk that hazardous wastes present, (2) insurance premiums will become unrealistically high if underwriters perceive regulated medical waste presents the same risks as hazardous wastes, (3) the 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) regulatory, economic and liability

²²⁶ Model Guidelines for State Medical Waste Management, The Council of State Governments, 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 identify alternative, i.e. nonregulatory approaches, to medical waste management.

²²⁷ 42 U.S.C. § 6926 (West 1983 & Supp. 1984-1992).

²²⁸ OTA Background Paper, supra note 2 at 8.

restrictions might be placed on the ultimate treatment and disposal of regulated medical waste precluding on-site treatment by health facilities.²²⁹

Although state infectious waste regulations must adhere to the regulatory requirements of the EPA, they are not required to conform to the EPA's published recommendations, which are intended only to serve as a guide for state policies.²³⁰ Since there are no consistent, binding federal medical waste regulations, states have independently enacted and enforced their own policies. There is little EPA specific direction as to how states should enforce their policies or how they may receive federal funds to initiate a program.²³¹ Consequently, states have had to rely entirely on their own agencies and the result has been a large variety of methods for dealing with medical waste.

States enforce their infectious waste regulations generally through different state departments and bureaus such as the department of health and departments of environmental protection or environmental health. One of the greatest

²²⁹ American Hospital Association Report of the Ad Hoc Committee on Medical Waste and Hazardous Materials, Shaping State and Local Regulation of Medical Waste and Hazardous Materials, May 1990.

²³⁰ 42 U.S.C. § 6926 (West 1983 & Supp. 1984-1992). See also, Goldie, supra note 150 at 148 and notes cited therein.

²³¹ Goldie, supra note 150 at 148 and notes cited therein.

problems facing some states in their efforts to enforce their infectious waste regulations is lack of enforcement in neighboring states.²³² Without national standards, these disparities will likely continue. The Office of Technology Assessment has made this recommendation to Congress in one of its reports:

"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 a 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 protection for humans and the environment."²³³

²³² Id. at 150.

²³³ OTA Report, supra note 3 at 9.

Chapter Six

Miscellaneous Federal Regulations, Guidelines, Policies, and Work Practice Standards Governing Medical Waste

Regulations, guidelines, standards and policies proliferate in the medical waste arena. Regulations are the most stringent. They are normally 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 are usually issued by government or professional organizations and compliance is normally voluntary. Standards are often set by professional organizations such as the Joint Commission on the Accreditation of Health Care Organizations, and although they may not always be enforceable at law, some types of certification are dependent upon meeting the standards.²³⁴ In addition, private organizations such as the American Hospital Association and the National Safety Council 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 suasive of all authority and generally simply set forth a broad statement of intent.

²³⁴ Reinhardt & Gordon, supra note 126 at 19.

Occupational Safety and Health Administration Regulations

The Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor was established by the Occupational Safety and Health Act of 1970 and is responsible for ensuring safe and healthful working conditions for United States workers.²³⁵ The principal function of OSHA 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 which implement federal requirements.²³⁶

²³⁵ Pub. L. 91-596, 84 Stat. 1590-1620 (1970), codified at 29 U.S.C. §§ 651-673 (West 1983 & Supp. 1984-1992). The OSHA regulations are contained in Title 29 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.

²³⁶ The Occupational Safety and Health Act requires the Occupational Safety and Health Administration 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 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 15 O.S.H. Rep. (BNA), State Participation, (Jan.30, 1986), at 81:1001, and see e.g., Los Alamitos Has Introduced A Bloodborne Pathogens Exposure Control Plan, Med. Waste News, 12, Mar. 17, 1993, reporting an example of state OSHA implementation of a federal OSHA requirement.

Generally, there are 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.²³⁷ Secondly, OSHA's Hazard Communication Standard requires employers to develop a written program which lists all hazardous chemicals used in the medical facility and 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 on the hazardous chemical and on appropriate

²³⁷ 29 C.F.R. § 1910.38 (1981), 45 Fed. Reg. 60,703 (1980). 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)(iv)(3) (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.

emergency procedures.²³⁸ OSHA's Chemical Hygiene Standard requires employers to have written policies that establish procedures, equipment, personal protective equipment and work practices which will effectively protect employees from hazardous chemicals in their facilities, plus documentation of medical treatment for exposure, disposal of chemicals, procurement, distribution and storage of chemicals and an employee training plan.²³⁹ Finally, OSHA has recently promulgated a Bloodborne Pathogen Rule which requires employer measures to protect workers from exposure to bloodborne pathogens.²⁴⁰ 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.²⁴¹ Thus, this rule may become a

²³⁸ 29 C.F.R. § 1910.1200 (1983) and revised 52 Fed. Reg. 31,877 (1987). See also Criteria for a Recommended Standard: An Identification System for Occupationally Hazardous Materials, NIOSH, 1974.

²³⁹ 29 C.F.R. § 1910.1450 (1990) and 55 Fed. Reg. 3327, 7967 (Mar. 6, 1990).

²⁴⁰ U.S. Dept. of Labor, OSHA, Occupational Exposure to Bloodborne Pathogens, 56 Fed. Reg. 64,004 (1991) (effective March 6, 1992) (hereinafter Bloodborne Pathogen Rule), codified at 29 C.F.R. § 1910.1030a (1992), as amended 57 Fed. Reg. 12,717 (Apr. 13, 1992) and 57 Fed. Reg. 29, 206 (Jul. 1, 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.

²⁴¹ 29 C.F.R. § 1910.1030a (1992).

consideration in selecting a medical waste disposal option. Naturally, costs are expected to rise as a result of the rule. The waste management industry estimates compliance with the rule will cost it approximately \$1.9 million whereas compliance will cost hospitals around \$321 million.²⁴²

Passage of the Bloodborne Pathogen Rule evidences OSHA's concern that "there is a clear national problem related to occupational safety and health for employees exposed to bloodborne pathogens."²⁴³ 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.²⁴⁴ The OSHA standard for bloodborne pathogens was adopted because exposed employees may face significant health risks, including death.²⁴⁵ The Bloodborne Pathogen Rule is drafted so that employees in every

²⁴² Waste Age, supra note 10 at 68. The Bloodborne Pathogen Rule was recently upheld against a challenge by the American Dental Association in American Dental Association v. Secretary of Labor, supra note 97.

²⁴³ 56 Fed. Reg. 64,004 (1991).

²⁴⁴ Id.

²⁴⁵ "Hepatitis B virus has long been recognized as a pathogen capable of causing serious injury and death....The human immunodeficiency virus, 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." Id. at 64006.

state will be protected by general, performance-oriented standards and, to the extent that there are state or regional differences, 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 state standards to deal with any special problems.²⁴⁶ Compliance with applicable standards is mandatory.

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).²⁴⁷ The HMTA does not define what is or is not a hazardous material. This authority is given to the Secretary of the Department of Transportation, and in the Act Congress preempted any state law, regulation, order, ruling or

²⁴⁶ Id. at 64,004. OSHA specifically recommends that hospitals be careful to 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. Department of Health and Human Services, Guidelines for Protecting the Safety and Health of Health Care Workers, (1988), at 6-1 (hereinafter NIOSH Guidelines).

²⁴⁷ Hazardous Materials Transportation Act (HMTA), Pub. L. 93-633, § 102, 88 Stat. 2156, (1975), codified at 49 U.S.C. §§ 1801-1812 (West 1983 & Supp. 1984-1992), and Hazardous Materials Transportation Uniform Safety Act (HMTUSA), Pub. L. 101-615, § 3(a), 104 Stat. 3277, (1990), codified at 49 U.S.C. §§1801-1819 (West Supp. 1984-1992).

provisions which is not substantively the same as any provision of the HMTUSA.²⁴⁸ The DOT has held several state requirements regarding the definition and shipment of hazardous materials inconsistent with DOT requirements and, therefore, preempted.²⁴⁹ In deciding whether a state regulation is consistent, the 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.²⁵⁰ By using this preemption doctrine, the DOT ensures that the materials which are regulated as hazardous materials during transportation are nationally uniform. These standards are often devised and monitored by the Department of Transportation's Research and Special Programs Administration (RSPA). If the RSPA decides

²⁴⁸ 29 U.S.C. § 1804 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 notification, 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).

²⁴⁹ 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 RSPA found that state regulations authorizing the designation of hazardous materials other than those designated in the HMRs were preempted and unenforceable.

²⁵⁰ See 49 C.F.R. § 107.209(C) 1992.

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 be a reality in the near future. The RSPA has published a final rule amending the Hazardous Material Regulations (HMRs), including those for infectious substances, but, it has delayed its effective date until January 1, 1994 to consider unresolved issues raised in comments, petitions for reconsideration, and exemption applications.²⁵¹ The final rule was published in January 1991, and it 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.²⁵² 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. In the new rule, the RSPA adopts the MMTA definition of "regulated medical waste" to distinguish between all medical waste and medical waste containing an infectious substance. It also specifies packaging requirements for regulated medical waste that are consistent

²⁵¹ 56 Fed Reg. 197 (1991), 58 Fed. Reg. 12,207 (1993).

²⁵² Id.

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 offered for transportation or being transported then it must be labeled, packaged and offered for transportation according to the Department of Transportation's (DOT) Hazardous Material Regulations. 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 and industry claimed the cost of compliance would be exorbitant.²⁵³

In response to comments and petitions for reconsideration, the RSPA acknowledged that the HMRs

²⁵³ Id. at 12,209-12.210 and 56 Fed. Reg. 66142 (1991) wherein RSPA revised regulations at 49 C.F.R. § 173.197 (1991) to specify less rigorous requirements for infectious substances that are "regulated medical wastes."

potentially overlap with other Federal regulations governing infectious substances such as OSHA's Bloodborne Pathogen Rule and CDC standards, both of which require special packaging and labeling for infectious substances/etiologic agents which differ from those of the HMRs.²⁵⁴ Critics say that federal agencies are unnecessarily duplicating each other's requirements; for example, DOT's black-on-white "infectious substance" label conveys the same things as OSHA's orange "biohazard" label.²⁵⁵ In short, frequently each agency involved requires one or more different labels on packages containing medical or infectious waste. Complicating this scheme is the fact that the RSPA is attempting to align U.S. standards with the United Nations Recommendations on the Transport of Dangerous Goods standards.²⁵⁶ Currently the

²⁵⁴ See e.g. 42 C.F.R. § 72 (1992). 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.* CDC's regulations set forth packaging and labeling requirements for the transportation of diagnostic specimens, biological products and materials containing certain etiologic agents. According to § 72.2 "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."

²⁵⁵ See Karen Pallarito, New Packing, Shipping Rules may be Shelved, *Modern Healthcare*, Sept. 28, 1992 at 33-34.

²⁵⁶ Interview with Ms. Eileen Martin, Regulatory Advisor, RSPA, Department of Transportation, July 1993.

RSPA is evaluating answers to its extensive request for comments; in particular, it is concerned with comments addressing the potential overlap or inconsistency of the new DOT standards with other federal regulations governing infectious substances such as those issued by OSHA, CDC, the Food and Drug Administration, and the United States Postal Service.²⁵⁷

U.S. Postal Service Regulations

Concern about exposure of postal workers to contaminated sharps being shipped in the U.S. mail lead to promulgation of new regulations on the mailability of sharps and other medical devices.²⁵⁸ The new regulations require that used sharps and other medical devices be sent as first class or priority mail effective June 30, 1992.²⁵⁹ The Postal Service also

²⁵⁷ 56 Fed. Reg., supra note at 12210. Since the new rule would officially add regulated medical wastes to the hazardous materials table, industry is concerned with the rules ramifications to the medical waste hauling industry. See DOT Packaging Rule Draws Concern from Medical Waste Industry, Waste Age, March 1992 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 has 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 246.

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

²⁵⁹ Id.

requires that used sharps be packaged in a primary container that is securely sealed, leak and puncture resistant and pass 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 now required to obtain an authorization from the U.S. Postal Service for their products to be transported in the U.S. mails, all packaging must be "type-tested" and certified by an independent company before application for U.S. Postal Service mailing authorization, and there is a financial responsibility requirement necessitating a bond.²⁶⁰ The Postal Service states that the bond is essential to avoid or minimize expenses of cleaning up spills and leaks occurring on postal property, in addition to disposing of regulated medical waste addressed for delivery at closed delivery sites.²⁶¹ Other medical devices that do not contain sharps must now be packaged in a securely sealed, leak resistant primary container which is enclosed in a shipping container similar to those used for mailing sharps.

The Postal Service only received 17 comments in response

260 Id.

261 Id.

to the new rule.²⁶² 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. The regulation has its own definition of terms such as "sharps," "medical devices" and "infectious substance" which the regulated community must consult and reconcile with other, sometimes conflicting, definitions promulgated by other regulatory agencies.

EPA Guidelines

The Resource Conservation and Recovery Act of 1976, as amended, requires EPA to develop and evaluate environmentally sound methods for solid waste management, and EPA is to provide information, research and financial assistance to states.²⁶³ Congress intended that RCRA 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.²⁶⁴ In fulfilling this charter EPA has published hazardous waste regulations but chosen not to include infectious waste among them because the agency believes "considerable evidence that these wastes cause harm

²⁶² The proposed rule is at 57 Fed. Reg. 9404 (1992).

²⁶³ 42 U.S.C. § 6902 (West 1983 & Supp. 1984-1992).

²⁶⁴ Id.

to human health and the environment is needed to support Federal rulemaking."²⁶⁵ Absent such evidence, the EPA has chosen to regulate infectious wastes as hazardous. Instead, in response to numerous requests for technical information and guidance on infectious waste management, 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 on the manual, the agency decided to revise it and in May 1986 issued the EPA Guide for Infectious Waste Management. Since the expiration of the MMTA, this EPA guide is the main agency pronouncement on this subject and it represents the EPA'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. It is intended to provide guidance to persons responsible for infectious waste management decisions at facilities such as hospitals, laboratories, animal experimentation units, industrial plants and other facilities which generate infectious wastes such as biotechnology companies.²⁶⁶

²⁶⁵ EPA Guide, supra note 23 at vi.

²⁶⁶ Id. at 1-1.

One of the most significant aspects of the guide is EPA's definition of infectious waste. The guide's definition has been adopted by many states and agencies regulating medical waste; however, it is nonbinding at the federal level.²⁶⁷ The EPA "strongly" suggests that agencies use its guide only as reference material.²⁶⁸

The guide has been criticized on more than one ground. 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. While the EPA provided suggested components of an infectious waste management plan in its guide, it failed to recommend how the states should enforce their policies, primarily because EPA wrote the guide for persons managing infectious waste treatment for private facilities, not state and local agencies.²⁶⁹ So, the guide 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.²⁷⁰

²⁶⁷ See OTA Report, supra note 3 at 5 for a comparison of the components of EPA's definition and the CDC's definition.

²⁶⁸ EPA Guide, supra note 23 at 1-1.

²⁶⁹ Goldie, supra note 150 at 148 and Sue Markland Moreland, State Infectious Waste Regulatory Programs, The Council of State Governments, 1988.

²⁷⁰ Goldie, supra note 150 at 156, footnote 184.

Finally, EPA's original position that regulation of infectious waste is premature and unnecessary until its risks are proven seems contradicted by suggestions it makes in the guide for private management and state regulation.²⁷¹ Possibly, some of the findings EPA releases in its final report to Congress under the MMTA will clarify some of these issues.

Centers for Disease Control Guidelines

Like the EPA, the Centers for Disease Control (CDC) of the United States Public Health Service have issued guidelines addressing certain aspects of infectious waste. The CDC is a federal public health agency charged with the surveillance and investigation of infectious diseases in hospitals.²⁷² The CDC collects weekly, monthly and yearly statistics on many infectious diseases, on control programs for health care facilities, and the agency makes recommendations necessary for disease control.²⁷³

The CDC has most directly addressed medical waste in two publications: "Recommendations for Prevention of HIV Transmission in Health Care Settings," and "Guidance for

²⁷¹ Id. at 157.

²⁷² NIOSH Guidelines, supra note 242 at 2-21.

²⁷³ Id.

Handwashing and Hospital Environmental Control."²⁷⁴ The 1987 "Recommendations" stated that blood and body fluid "universal precautions" be consistently used for all patients regardless of their bloodborne infection. Thus, blood and certain body fluids of all patients were considered potentially infections for HIV, hepatitis B and other bloodborne pathogens. In response to numerous questions about the universal precautions, the CDC updated its "Recommendations" in 1988 with a publication entitled "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings."²⁷⁵ 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 removal and disposal. One commentator posits that the CDC's 1987 "Recommendations for Prevention of HIV Transmission" quelled the urgency of

²⁷⁴ CDC, Recommendations for Prevention of HIV Transmission in Health Care Settings, Morbidity & Mortality Weekly Rep. (Supp.), Vol. 36, (Aug. 21, 1987). CDC Guidelines for the Prevention and Control of Nosocomial Infections: Guideline for Handwashing and Hospital Environmental Control, (1985).

²⁷⁵ CDC, 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, (Jun. 24, 1988). The CDC now limits the application of universal precautions to blood and other body fluids containing visible blood, to semen and other specified body fluids. Id.

labeling most medical waste as infectious because the CDC chose to recommend classifying waste material based on its risk of disease transmission.²⁷⁶ Indeed, the "Recommendations" state that identifying wastes for which special precautions are required is a matter of judgment about the relative risk of disease transmission and, while any item that has had 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.²⁷⁷ 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 in chapter one, determining which portion of medical waste is infectious goes to the heart of the definitional problem associated with medical waste management. Thus, until the 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

²⁷⁶ Goldie, supra note 150 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 244.

²⁷⁷ CDC Recommendations, supra note 267.

disseminate advice on how to prevent or control specific infections acquired while in the hospital, called "nosocomial infections." The Guidelines offer recommendations regarding handwashing technique, 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.

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. The JCAHO conducts inspections and requires hospitals to establish policies and procedures for monitoring and responding to safety and health hazards.²⁷⁸ In its manual, the JCAHO designates infectious wastes and sharps as hazardous wastes, along with chemical, chemotherapeutic and radioactive wastes.²⁷⁹ The manual outlines methods for handling each type of waste and the JCAHO requires that a system to handle all such hazardous wastes exist and be in compliance with

²⁷⁸ Joint Commission on Accreditation of Healthcare Organizations, Accreditation Manual for Hospitals (1990) (hereinafter JCAHO Manual).

²⁷⁹ Id.

Federal, State and local regulations.²⁸⁰

The JCAHO has recognized that hospitals must manage their hazardous materials and infectious waste from point of origin to final disposal.²⁸¹ Under its accreditation standard, a hospital's infectious waste management program must, among other things: (1) protect patients, personnel, visitors and the environment, (2) control the waste from generation to disposal, (3) include policies and procedures for identifying and managing hazardous materials and waste, including the substitution of less hazardous agents, (4) review operational policies and procedures at least annually, (5) provide job training to its waste handlers.²⁸²

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.

²⁸⁰ Id. If there are no existing federal regulations, 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 Report, supra note 3 at 7.

²⁸¹ Id.

²⁸² Id. and Infectious Medical Wastes, JAMA, supra note 39 at 1670-71.

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 waste 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 only medical waste that can be identified as truly infectious and which has proven capacity to inflict substantial harm to the public or the environment. In order to identify such waste, EPA needs to devise an objective test for infectious waste that can be uniformly used by health care organizations and other medical waste generators in their management of this waste stream. Such a test is the necessary first step to 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 addressing 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 agencies such as the CDC and the JCAHO, attempt to reconcile definitional and policy differences, and strive to issue compatible, uniform guidance. Or, EPA could simply defer to the CDC definition and cross-reference it in its regulations. Likewise, OSHA and the DOT should attempt to bring their definitions and policies concerning infectious waste into concert with the 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 more nationally cohesive regulation of medical waste, EPA needs to take the lead, first, in issuing its overdue MWTA 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. Moreover, the agency should 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 MWTA in 1988 and its expiration in 1991, states and localities have aggressively undertaken to regulate 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 the 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 federal oversight, perhaps via state-delegated RCRA programs, is 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 provides 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 attributable to irregularities in its regulation. Our national interest would be best served by a more unified, science-based medical waste management policy.