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The New Regulatory Horizon: Regulation of Medical Waste

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THE NEW REGULATORY HORIZON: REGULATION OF MEDICAL WASTE

by Cheryl L. Coon* and Howard L. Gilberg**

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I. OVERVIEW AND INTRODUCTION

THE emergence of environmental regulation is a recent development. Indeed, individuals, certain industries, and service businesses have historically faced minimal, if any, regulation under environmental laws.¹ Beginning particularly in 1988, however, new concern over a special category of waste, namely medical waste ("special" waste in Texas), has emerged. The littering of beaches, particularly on the east coast of the United States, with syringes and other types of medical waste caused a significant public outcry, which was in large part responsible for Congress' enactment of the Medical Waste Tracking Act of 1988 (MWTA).² The MWTA established a demonstration program that was optional in the majority of states.³ The regulatory program officially expired in June 1991.⁴ Incidents involving medical waste have not disappeared, nor has the public demand for increased regulation of medical waste diminished.

Typically, the federal government has taken the lead on environmental issues, enacting statutes which states are authorized to implement and oversee, provided the state requirements are substantially the same as those in the particular federal act.⁵ The past regulation of medical waste, however, has not followed this pattern. Instead, many states have begun to enact laws and regulations relating to medical waste in the absence of a federal mandate. Many of the state programs are based on the MWTA system.

Industrial enterprises are familiar with the intense public debate aroused by attempts to obtain permits for new disposal and treatment facilities. These industries have faced major public opposition and the phenomenon known as "NIMBY" or "Not In My Back Yard." Today, a new sector, consisting of health care services and medical waste destruction, disposal, or treatment facilities (TDDs), is beginning to face the same types of public pressure.⁶ States are enacting prohibitions or moratoriums on the issuance of permits for medical waste incinerators and public opposition is forming against some facilities already in existence in sensitive locations. Thus,

1. For example, 40 C.F.R. § 261.4(b)(1) (1990) defines hazardous waste as expressly excluding household waste under the Resource Conservation and Recovery Act (RCRA) 42 U.S.C.A. §§ 6901-6992k (West 1983 & Supp. 1991).

2. Pub. L. No. 100-582, 102 Stat. 2950 (1988) (codified at 42 U.S.C.A. §§ 6992-6992k (West Supp. 1991)).

3. *Id.* § 6992(a)-(b).

4. *Id.* § 6992(a); see 40 C.F.R. § 259.2 (1990).

5. *E.g.*, 33 U.S.C.A. § 1342 (West 1983 & Supp. 1991) (delegating Clean Water Act or the Federal Water Pollution Control Act to states); 42 U.S.C.A. § 6926 (delegating RCRA to authorized state programs).

6. See Scott B. Goldie, Note, *Blood on North American Soil: A Comparison of United States and Canadian Infectious Waste Disposal Regulations*, 16 SYRACUSE J. INT'L L. & COM. 129, 129-34 (1989).

health care facilities and professionals must learn another principle already familiar to industry — source reduction and pollution prevention, including recycling or waste minimization. As public opposition continues and disposal costs rise, health care facilities and professionals must begin to evaluate new and innovative methods of treatment and disposal. They must also add environmental issues to their public relations agenda.

Finally, another recent trend is increased enforcement of environmental laws on both the federal and state levels. Federal and state governments are bringing growing numbers of civil and criminal cases and they are seeking and collecting larger fines.⁷ This trend has begun to encompass medical waste as well. Already, in the few short years since regulation of medical waste has come to the forefront, there are dramatic examples of civil and criminal enforcement actions in the area.

Unfortunately, the specific individuals or facilities charged with the particular violation are not the only parties affected by enforcement actions. With medical costs already skyrocketing due to other causes, the increased cost of dealing with medical waste merely adds to the burden. All of us, as potential patients, are affected. In Texas, many hospitals, particularly in rural areas, are closing due to increased costs. Decreased availability of medical care is conceivably an indirect effect of higher medical waste costs.

This Article will provide a brief overview of federal and state regulation of medical waste, with a more detailed focus on the regulations under development in Texas. Enforcement actions involving medical waste, as well as instances of public opposition, are briefly examined. The Article will also touch on technological and business aspects of medical waste. Finally, the Article provides some suggestions to health care facilities and providers for dealing with medical waste. Throughout, the reader should keep in mind the parallels between regulation of hazardous waste⁸ and medical waste. The parallels should benefit those associated with medical waste because, in many instances, the experience and learning on issues such as public opposition (or public relations) are transferrable to medical waste. Therefore, health care facilities may not need to reinvent the wheel.

II. FEDERAL REGULATION OF MEDICAL WASTE

A. Overview

Since public recognition of the more severe problems involving medical waste did not begin until approximately 1988, a natural question is why did problems arise at that time? According to one article, problems arose

7. E.g., Judson W. Starr, *Turbulent Times at Justice and EPA: The Origins of Environmental Criminal Prosecutions and the Work that Remains*, 59 GEO. WASH. L. REV. 900, 901 n.3 (1991) (noting that in 1990, indictments were 33% higher than in 1989 with a record high conviction rate of 85%, and that 55% of those indicted received prison sentences); see Pollution Prosecution Act of 1990, Pub. L. No. 101-593, § 202, 104 Stat. 2962 (to be codified at 42 U.S.C. § 4321) (requiring the EPA to increase the number of investigators to at least 200 within five years).

8. See 42 U.S.C.A. §§ 6901-6992; 40 C.F.R. §§ 261.1-.33 (1990).

largely due to a variety of interrelated exacerbations.⁹ Regulations began to appear addressing medical waste. The psychological factors associated with medical waste such as fear of contracting diseases like hepatitis B or AIDS, led some businesses involved in storage, treatment, disposal, or transportation to stop accepting medical waste. With diminishing capacity and increased costs, incentives increased for illegal dumping, whether by the generator or through the development of fraudulent transportation, treatment, or disposal schemes such as in the cases discussed in this Article.¹⁰ At the same time, however, health care industries were, and are, generating more waste due to the increasing population.

In 1988, Congress passed the first significant federal legislation concerning the management of medical waste, the Medical Waste Tracking Act of 1988 (MWTA).¹¹ The United States Environmental Protection Agency (EPA) promulgated regulations pertaining to the proper disposal and transportation of certain medical waste, as required by the MWTA.¹² The initial program was limited in duration and scope, and mandatory via congressional mandate or state election only in Rhode Island, New York, Connecticut, New Jersey, and Puerto Rico.¹³ The five pilot projects began in 1989; they expired in June 1991.¹⁴

Under the EPA regulations, "medical waste" was defined as a solid waste generated in the diagnosis, treatment, or immunization of human beings or animals, research pertaining thereto, or in the production or testing of biologicals.¹⁵ "Regulated medical waste" was a subset of medical waste.¹⁶ Generators that transported more than fifty pounds of medical waste per month off-site had to initiate the tracking system,¹⁷ which was very similar to the manifest requirements imposed for the regulation of hazardous waste

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

10. *Id.* at 562-64; see *infra* text accompanying notes 73-86.

11. Medical Waste Tracking Act of 1988, Pub. L. No. 100-582, 102 Stat. 2950 (1988) (codified at 42 U.S.C.A. §§ 6992-6992k (West Supp. 1991)). The MWTA constitutes subchapter X of RCRA, which regulates solid and hazardous waste.

12. See 40 C.F.R. pt. 259 (1990).

13. 42 U.S.C.A. § 6992(a). Congress originally included the Great Lakes states, but they requested to not participate in the program. Puerto Rico and Rhode Island opted to participate. States which elected, or were required, to participate are generally referred to as "covered" states.

14. In states where the federal demonstration program was not mandatory and the program was not adopted by choice, the only applicable federal guidance for direction was a guidance document published by EPA in 1986. The EPA patterned this guidance, which was not legally binding, and the applicable federal regulations in part after the Center for Disease Control (CDC) guidelines for disposal of medical wastes. U.S. ENVIRONMENTAL PROTECTION AGENCY, EPA GUIDE FOR INFECTIOUS WASTE MANAGEMENT, PB86-199130 (1986) [hereinafter EPA GUIDANCE]; see also Stephan K. Hall, *Infectious Waste Managements: A Multi-faceted Problem*, POLLUTION ENGINEERING, Aug. 1989, at 76; U.S. EPA, MEDICAL WASTE MANAGEMENT IN THE UNITED STATES, SECOND INTERIM REPORT TO CONGRESS, PB91-130187, at 34 (1990) [hereinafter SECOND INTERIM REPORT].

15. 40 C.F.R. § 259.10 (1990). This paper will refer to the federal definition for regulated medical waste, medical waste, and hazardous waste for convenience.

16. *Id.* § 259.30.

17. Originally, the only control of transportation of certain types of medical waste was governed pursuant to the Hazardous Materials Transportation Act of 1972, which regulates

under the Resource Conservation and Recovery Act (RCRA).¹⁸ The federal regulations also controlled transporters and on-site incinerators, primarily requiring records of the amounts of waste incinerated,¹⁹ and imposed recordkeeping requirements on transporters, generators, and TDDs.²⁰

Technically, as previously noted, the EPA regulations expired in June 1991.²¹ At the present time, the EPA has no plans to continue the program. Thus, the only laws and regulations currently applicable to medical waste are state laws. Reference to and discussion of the previous MWTA system is relevant, however, because many state requirements are patterned on the federal system and because the MWTA may be reauthorized. Discussion advocating a mandatory federal system for all states is prevalent, and it is reasonable to assume that such a program, if adopted, would be based on the prior system to some degree.²²

1. Types of Waste Regulated

Under the MWTA, Congress designated the following eleven categories of waste as types of waste to be considered for inclusion in the demonstration program: (1) cultures of infectious and biological agents including live attenuated vaccines of bacteria or viruses, (2) pathological waste including tissues, organs, or body parts, (3) waste human blood and blood products such as plasma, (4) sharps including hypodermic needles, syringes, pasteur pipettes, broken glass, and scalpels, (5) contaminated animal carcasses exposed to infectious agents during research, (6) surgery or autopsy waste, (7) laboratory waste including slides, cover slips, gloves, coats, and aprons, (8) dialysis waste, (9) discarded medical equipment, (10) biological waste and discarded materials contaminated with blood or other human or animal secretions, and (11) other waste that "results from the administration of medical care to a patient by a health care provider . . . [which presents] a threat to human health or the environment."²³

The EPA adopted seven of the eleven categories in its definition of "regulated medical waste."²⁴ These seven categories of wastes are: (1) *contaminated* sharps, (2) cultures and stocks of infectious agents and associated biologicals, (3) human blood and blood products, (4) pathological waste, (5) animal waste, (6) isolation waste, and (7) *unused* sharps.²⁵ Chemotherapy

"etiological agents." See 49 U.S.C. §§ 1801-1813 (1988); see also 49 C.F.R. pt. 172 (1990) (hazardous substances); 49 C.F.R. pt. 173 (1990) (material with more than one hazard).

18. 42 U.S.C.A. §§ 6901-6922k (West 1983 & Supp. 1991); see 40 C.F.R. §§ 262.20-.23 (1990) (manifest requirements for hazardous waste); 40 C.F.R. § 259.52 (1990) (medical waste tracking form).

19. 40 C.F.R. §§ 259.60-.62 (1990).

20. *Id.* §§ 259.54-.56 (generators); § 259.61 (incinerators); § 259.77 (transporters); § 259.83 (treatment, destruction, and disposal facilities).

21. 42 U.S.C. § 6992(d) (1988); 40 C.F.R. § 259.2(a) (1990); see 55 Fed. Reg. 27,231 (1990).

22. See Shumaker, *supra* note 9, at 596-601; Goldie, *supra* note 6, at 131.

23. 42 U.S.C.A. § 6992a (West Supp. 1991).

24. See 40 C.F.R. §§ 259.1-.84 (1990).

25. *Id.* § 259.30 (emphasis added). "Sharps" is not defined within the federal regulations; however, the description in the designation of the waste class indicates that "sharps" includes

waste is another category of waste regulated by some states as medical waste.²⁶ Household medical wastes are excluded from regulation however.²⁷

2. Duties

a. Generators

Generators of regulated medical waste were required to segregate the waste (sharps, fluids, other waste), use proper packaging (rigid and leak proof), observe storage rules (sanitary, secure, proper temperature), use only transporters that had notified the EPA of their activity, observe labeling and marking rules, and determine if a waste is indeed a medical waste.²⁸ Generators were also required to initiate the tracking form.²⁹

State laws should concern generators in addition to federal laws and regulations. Wastes such as chemotherapy waste may not be "medical waste" even though the facility is a health care provider. The generator, therefore, is not exempt from the responsibility of determining whether the material might also constitute a "hazardous waste" within the definition of RCRA.³⁰ If, for example, a generator had chemotherapy or pharmaceutical chemicals that were discarded, under the federal system the generator had to initially determine if it was a hazardous waste.³¹ Under the federal definitions, hazardous waste was expressly excluded from the definition of medical waste.³² Thus, a waste was either medical waste or hazardous waste; by definition it could not be both under the federal system. If the material was not a hazardous waste, the generator still had to determine whether or not the material fit within a regulated category of medical waste, and still must do so within the context of particular state laws.³³ Furthermore, because of the varied state regulation, a generator must also examine the laws of every state through which its waste travels or where treatment or disposal occurs to ensure compliance. Finally, generators must consider solid waste rules for materials excluded from being either a hazardous or medical waste.³⁴

If a mixture contains both medical waste and solid waste, the EPA regula-

hypodermic needles, syringes, pasteur pipettes, scalpels, blood vials, needles, culture dishes, and other types of broken or unbroken glassware which were in contact with infectious agents, such as slides or cover slips. *Id.*

26. *See, e.g.*, 25 PA. CODE § 271.1 (1988); ALA. ADMIN. CODE r. 335-13.03; *see also* Shumaker, *supra* note 9, at 573-74.

27. 40 C.F.R. § 259.30(b)(1)(ii) (1990).

28. *Id.* §§ 259.39-.56. Note that generators of less than fifty pounds per month are subject only to certain portions of the regulations such as the packaging requirements. *Id.* §§ 259.50-.51.

29. *Id.* § 259.52. Other duties include the duty to keep specified records, prepare exception reports when a completed tracking form is not received within 35 days after shipment of the waste, and preparation of additional reports under certain circumstances. *Id.* §§ 259.54-.56.

30. 42 U.S.C.A. § 6922; 40 C.F.R. § 262.11 (1990) (duty to determine nature of wastes).

31. 40 C.F.R. § 259.30(b)(1) (1990).

32. *Id.*

33. Several chemotherapeutic agents have been listed by the EPA as hazardous waste, such as mitomycin C, uracil mustard, and chlorambucil. *Id.* § 261.33.

34. *See* Tex. Dep't of Health, 25 TEX. ADMIN. CODE §§ 325.1-.918 (West 1989) (solid waste rules).

tions treat the mixture as a regulated medical waste.³⁵ The same is true of a mixture of regulated medical waste and hazardous waste, meaning it is treated as medical waste "unless the mixture is subject to the hazardous waste manifest requirements in Part 262 or Part 266 [of 40 C.F.R. Chapter 1]."³⁶ Once one deciphers this exemption, it is a narrow one and most mixtures are treated as hazardous waste.³⁷ Only mixtures transported solely on-site or mixtures produced by conditionally exempt small quantity generators are treated as medical waste. Furthermore, a note to section 259.31 states that a mixture of medical and hazardous waste that is exempt from the hazardous waste requirements remains subject to the medical waste regulations.³⁸ Medical waste generators should also check the applicable state laws on hazardous, medical, and solid waste, including any rules for mixtures to determine applicable criteria.

b. Transporters

Transporters were required to use proper vehicles, provide for vehicle security, transport only properly packaged and labeled wastes, and transport only to properly licensed and approved TDD facilities.³⁹ In Texas, transporters must meet similar requirements and also demonstrate financial responsibility.⁴⁰

c. On-Site Incinerators and TDDs

On-site incinerators, defined as generators of regulated medical waste who incinerate only this waste, were required to maintain operating logs and prepare annual reports.⁴¹ Generators that incinerated third party medical waste on-site (as well as owners and operators of TDDs) also had to meet the TDD requirements.⁴² Owners and operators of TDDs had to complete the tracking form, noting any discrepancies, maintain records for three years, and prepare additional reports as required by the EPA.⁴³

3. Enforcement

Congress created specific enforcement provisions applicable to the MWTa.⁴⁴ The EPA may seek an administrative penalty, issue a compliance

35. 40 C.F.R. § 259.31(a) (1990).

36. *Id.* § 259.31(b) (emphasis added).

37. *See id.* §§ 262.20, 262.44, 259.31, 261.5.

38. *Id.* § 259.31, note to paragraph (b).

39. 40 C.F.R. §§ 259.70-.79 (1990).

40. 16 Tex. Reg. 2528-33 (1991); *see infra* notes 139-149.

41. 40 C.F.R. §§ 259.60-.62 (1990).

42. *Id.* § 259.60(b).

43. *Id.* §§ 259.80-.84.

44. This article primarily discusses the MWTa; however, other environmental statutes have provisions relating to medical waste, and a violation of one of the statutes will subject a person to the enforcement authority of that statute. *See, e.g.*, 33 U.S.C.A. § 1362(20) (West Supp. 1991) (Clean Water Act definition of medical waste); 33 U.S.C. § 1311(f) (1988) (illegality of discharge of chemical or biological warfare agents). Under the Clean Water Act provisions, for example, a person may face criminal liability for knowing and negligent violations entailing fines of not less than \$5,000 or more than \$50,000, imprisonment for up to three

order, or both, or may initiate an action for injunctive relief.⁴⁵ The administrative penalty may not exceed \$25,000 per day per violation, and failure to take the required corrective action after issuance of an order may result in additional penalty of up to \$25,000 per day.⁴⁶ Additionally, the MWTA provides for criminal penalties for anyone who: (1) knowingly violates the requirements of the MWTA or the regulations promulgated pursuant to it, (2) knowingly omits material information or makes material false statements in reports or records, or (3) knowingly generates, stores, treats, transports, disposes of, or otherwise handles any medical waste and who knowingly destroys, alters, conceals, or fails to file any required record or document.⁴⁷ The criminal penalty may not exceed \$50,000 per day or imprisonment for up to two years, or upon subsequent convictions, up to twice the specified penalties.⁴⁸ Also, any person who knowingly violates a provision of the MWTA and who knows that such action places another person in imminent danger of death or serious bodily injury may be found guilty of knowing endangerment and subject to a fine of not more than \$250,000, imprisonment for not more than fifteen years, or both.⁴⁹ If the defendant is an organization, such as a corporation, the maximum fine is \$1,000,000.⁵⁰ Finally, the MWTA provides that any person who violates any requirement or regulation may be liable for a civil penalty not to exceed \$25,000 per day per violation.⁵¹

Parties should be aware of other enforcement provisions. State laws, for example, may carry penalties. The MWTA also gives the EPA other enforcement-related authority including the ability to request information concerning the generation, storage, treatment, disposal, or handling of medical waste, the power to conduct monitoring or take samples, and access to all facility medical waste records.⁵²

Moreover, the agency appears more than willing to use its enforcement authority. The EPA recently reported to Congress on medical waste issues and characterized its medical waste enforcement efforts as "aggressive."⁵³ The EPA reported that it conducted approximately 510 inspections, brought 11 administrative enforcement actions, issued 257 warning letters or notices of violation during the first year, and assessed approximately \$690,000 in penalties.⁵⁴ Eventually, the EPA's plan is for states to take the lead role in enforcement of medical waste programs, thereby limiting the EPA's involvement to the start up of state programs, federal facility enforcement, and fol-

years, or both, or fines of not less than \$2,500 or more than \$25,000 per day, imprisonment for up to one year, or both, respectively. 33 U.S.C. §§ 1319(c)(1)(B), 1319(c)(2)(B) (1988).

45. 42 U.S.C.A. § 6992d(a) (West Supp. 1991).

46. *Id.*

47. *Id.* § 6992d(b).

48. *Id.*

49. *Id.* § 6992d(c).

50. 42 U.S.C.A. § 6992d(c).

51. *Id.* § 6992d(d).

52. *Id.* § 6992c.

53. SECOND INTERIM REPORT, *supra* note 14, at 21.

54. *Id.* at 20-22. These numbers do not include actions taken by states.

low-up or enforcement in states that did not opt into the federal program or where there is no comparable state (or, on Indian lands, tribal) law.⁵⁵

4. *Disposal and Treatment Technologies*

The present means for treatment and disposal of medical waste are essentially the methods that have been used by the health care profession for several years. The most common of these include incineration and steam sterilization or autoclaving. Incineration is by far the most popular treatment/disposal technique.⁵⁶ In Texas, incineration is arguably the most common means of disposal because every licensed hospital must have an on-site incinerator or a contract for disposal of its wastes.⁵⁷ Incineration is the process of using heat for combustion to convert the material into a noninfectious or non-hazardous ash.⁵⁸ The benefits of incineration include reduction in volume, conversion to a more aesthetically appealing type of waste, effectiveness in killing pathogens, compatibility with most types of waste, familiarity with the process, reduced cost by elimination of off-site transportation and disposal fees, and secondary benefits such as the generation of heat for power from the incineration process where large units are involved.⁵⁹

There are, however, potential risks involved with incineration, particularly for certain types of medical waste. Studies show that incineration of plastics commonly present in medical waste can result in the emission of air pollutants such as dioxins and furans.⁶⁰ Incineration of medical waste may also result in increased emissions of hydrogen chloride, sulphur dioxide, nitrous oxides,⁶¹ particulates, carbon monoxide, and trace metals.⁶² Some studies, however, indicate that elimination of a large percentage of these pollutants from the incineration process is possible, provided that certain air pollution equipment is installed and that incinerator operators are properly and thoroughly trained.⁶³ This highlights another disadvantage to incineration — it is highly training and equipment (design and maintenance) depen-

55. *Id.* at 21.

56. According to the EPA, three factors should be considered when determining whether to incinerate medical waste. These are the variation in the waste composition, the waste feed rate, and the combustion temperature. EPA GUIDANCE, *supra* note 14, at 4-7 to 4-8. See *Hospital Waste Combustion Study Data Gathering Phase Final Draft Report*, prepared by Radian Corporation for Ray Morrison of the EPA at 1-2 (Oct. 1987) [hereinafter *Draft Report*].

57. Etter et al., *Medical Waste Combustion: Current and Future Prospects*, WASTE AGE 77 (July 1990); see also Tex. Dep't of Health, 25 TEX. ADMIN. CODE § 133.5 (West 1989).

58. EPA GUIDANCE, *supra* note 14, at 4-7.

59. *Draft Report*, *supra* note 56, at 1-2; EPA GUIDANCE, *supra* note 14, at 4-7, *Medical Waste Treatment Technologies*, F-D-C REPORTS, Apr. 9, 1990, at I&W-10, [hereinafter *Waste Treatment*].

60. WASTE TREATMENT, *supra* note 59, at I&W-10.

61. *Draft Report*, *supra* note 56, at 3-3. Sulfur dioxide and nitrous oxides are constituents of acid rain. *Id.* at 3-1.

62. *Draft Report*, *supra* note 56, at 3-1 to 3-30. Trace metals include arsenic, cadmium, chromium, iron, manganese, nickel, and lead. *Id.* at Table 3-1; see also Hall, *supra* note 14, at 76 (discussing infectious waste management including incineration).

63. Shumaker, *supra* note 9, at 586-87 n.165 (examining the issues related to medical waste treatment and disposal, citing WASHINGTON STATE DEPARTMENT OF ECOLOGY, REPORT TO THE LEGISLATURE: WASHINGTON STATE INFECTIOUS WASTE PROJECT 82 (1989)).

dent.⁶⁴ Further, although an important benefit of incineration is reduction of volume, the issues related to disposal of the byproduct ash remain. Finally, incineration requires a substantial capital investment, poses a risk to the operators, and may create a false sense of security because of the difficulty of testing whether the incineration completely destroys all pathogens.⁶⁵

Another disposal technique for infectious medical waste is steam sterilization, or autoclaving.⁶⁶ Autoclaving is well adapted for treating microbiological cultures and stocks, clothing or other types of items easily penetrable by steam or chemicals, or for instruments where the full exterior of the item is reachable. The advantages of autoclaving are effectiveness in killing pathogens, familiarity with the method, ease of operation, compatibility with many types of medical waste, and low capital costs.⁶⁷ The primary disadvantages of autoclaving are that the waste volume is not reduced, remains are left to be disposed of, it is not effective for all types of medical waste, and the process frequently results in unpleasant odors.⁶⁸ Another concern with autoclaving is the use of ethylene oxide for sterilization because of its potential adverse effect on the ozone layer and its status as a probable carcinogen.⁶⁹ Also, several factors affect the efficiency of autoclaving, including temperature, exposure time, type of waste container, presence of water, and volume and density of the waste.⁷⁰ Other less-used technologies may merit reconsideration and alteration as necessary including thermal inactivation, chemical disinfection,⁷¹ irradiation, microwave treatment, interment, discharge into public sewer systems, and disposal in landfills.⁷²

B. Critique of the Regulations and Issues

Different groups perceive several problems with the now-expired federal program for medical waste. The Health Industry Manufacturers Association's opinion of the MWTA is that the law diverts funds better suited for patient care to management of medical waste, unnecessarily increasing

64. The EPA has published guidance documents aimed at ensuring proper operation. See U.S. EPA, CONTROL TECHNOLOGY CENTER: OPERATION AND MAINTENANCE OF HOSPITAL MEDICAL WASTE INCINERATORS, EPA-450/3-89-002 (Mar. 1989); HOSPITAL INCINERATOR OPERATOR TRAINING COURSE: VOLUMES I-III, EPA-450/3-89-003, EPA-450/3-89-004, EPA-450/3-89-010 (Mar. 1989).

65. *Waste Treatment*, *supra* note 59, at I&W-10.

66. Shumaker, *supra* note 9, at 592-93; EPA GUIDANCE, *supra* note 14, at 4-1 to 4-16.

67. *Waste Treatment*, *supra* note 59, at I&W-10.

68. *Id.*

69. See Elizabeth S. Keische, *Waste And Costs High Among Medical Plastics Concerns*, CHEMICAL WK., June 19, 1991, at 14; EPA GUIDANCE, *supra* note 14, at 4-13; *Waste Treatment*, *supra* note 59, at I&W-10.

70. Hall, *supra* note 14, at 76.

71. EPA indicated that the advantages for chemical disinfection were low capital cost, simplicity of operation, and potential for combination with waste destruction methods to reduce waste volume and render the waste unrecognizable. The disadvantages of chemical disinfection cited by the EPA include potential weight increase in waste following treatment, toxicity of certain disinfection chemicals to humans, existence of sewer discharge limitations, unsuitability for treatment of certain pathological waste, and difficulty in determining whether the treatment was completely effective. *Waste Treatment*, *supra* note 59, at I&W-10.

72. See *infra* notes 198-214.

costs.⁷³ The Association cites the dramatic increase in the cost of transportation and disposal of medical waste. Those costs previously averaged \$9,000 to \$12,000 per month for one hospital, but increased to \$20,000 to \$44,000 per month after the MWTA.⁷⁴ The Association also indicates that hospitals and medical professionals do not understand what falls within the definition of medical waste (or hazardous waste).⁷⁵ Because of this confusion, wastes are improperly characterized as medical waste, thereby increasing costs.⁷⁶ This uncertainty is only exacerbated by the inconsistencies of state laws.

The MWTA also creates effects on the health care industry other than increased costs. In particular, the increasing stringency of regulations for incinerators severely limits, if not prohibits, the use of this disposal technique.⁷⁷ Alternative technology, however, is still in the developmental stages.⁷⁸ According to one article, government officials should enact regulations aimed only at the proven and established risks associated with medical wastes to avoid imposing unnecessary requirements and increasing costs.⁷⁹ Others are re-assessing the need for strict regulation of medical wastes, believing such regulations are overly protective. In 1990 the Alabama Department of Environmental Management proposed new regulations for the management of medical waste based on a study performed by a state task force.⁸⁰ The task force found that the previous medical waste regulations were too broad and that only a small percentage of the waste was truly infectious and should be regulated as such.⁸¹ Others note that the current regulations do not address disposal capacity. One article advises that agencies must support permit actions for incinerator facilities where the genuine issues have been addressed and where the remaining objections by special interest groups rest solely on emotional issues.⁸²

Granted, increased regulation adds costs to the disposal process. Benefits

73. *Medical Waste: Tracking System Called Expensive Burden; Congress Overreacted, Medical Community Says*, [Current Developments] Env't. Rep. (BNA), at 2258-59 (Apr. 19, 1991) [hereinafter *Medical Waste*].

74. *Id.*

75. *Id.*

76. *Id.*; see also *Draft Report*, *supra* note 56, at 1-5. The Draft Report on incineration indicates that in Illinois, for example, only 15% of hospital waste was infectious but that it was mixed with the remaining 85%, at least in 1986. As one article notes, the characterization of "infectious waste" has a substantial effect on the disposal costs of such wastes. Hall, *supra* note 14, at 75. Also, according to American Hospital Association (AHA) studies, disposal of medical waste costs up to 50 times more than disposal costs for reusable waste. *Medical Waste*, *supra* note 73, at 2258-59. For this reason, the AHA opposed any definition of medical waste broader than that originally adopted by CDC, which encompassed microbiological waste, contaminated sharps, pathological waste, and blood and blood products. *Medical Waste*, *supra* note 73, at 2258-59. See also *infra* notes 199-203.

77. Lawrence G. Doucet, *Hospital Infectious-Waste Incineration Dilemma*, HOSPITALS, July 5, 1988, at 80.

78. See *infra* notes 198-214 and accompanying text.

79. Doucet, *supra* note 77, at 80.

80. *Alabama Proposes Update to Medical Waste Rules*, [Current Developments] Env't Rep. (BNA), at 279 (May 25, 1990).

81. *Id.*

82. Doucet, *supra* note 77, at 80.

of the regulatory system, however, should also be considered. The EPA lists increased focus on development of innovative treatment technologies, reevaluation of home health care management practices, a small reduction in the severity of beach washups, and the voluntary development of programs relating to medical waste in states not required to participate in the demonstration program as secondary and indirect benefits of the MWTA demonstration program.⁸³ The EPA also notes that other nations, including Australia, Canada, and Japan, have begun to develop medical waste programs based on the United States' example.⁸⁴

Also, use of the tracking system has several important consequences. First, it assures that the generator, transporter, and disposal or treatment facilities involved in the movement of waste are known and documented. Thus, if a problem arises or illegal disposal occurs, the government and parties will have a "paper trail" to follow back to those potentially responsible. Additionally, the tracking system allows for prompt investigation of matters while the evidence is relatively new and fresh in the minds of the parties involved. A secondary benefit of the tracking system may be that, by requiring parties involved to sign a document, a more conscientious and knowledgeable attitude will develop toward the waste and related issues. The most obvious disadvantage of the paper system is increased time and cost to the parties, thereby increasing already skyrocketing health care costs.

The potential for civil and criminal penalties in the event of a violation arguably results in more circumspect decisions regarding medical waste for all parties involved. In addition to the focus on developing new technologies, recycling and waste minimization are key objectives. The laws also arguably have a secondary benefit of forcing the health care profession to examine its practices and change old habits.⁸⁵

The industrial sector, having faced these same types of regulations and issues, has incorporated them by and large into business practices. The main question remaining is whether continued regulation of medical waste is warranted after adding up the various costs and benefits briefly noted here. Other issues are the level of regulation and proper forum for the regulation, *i.e.*, state or federal government.⁸⁶

C. Pending Federal Legislation

1. Re-authorization of the MWTA

On April 16, 1991, representative James Saxton of New Jersey introduced a bill to extend the MWTA through June 1993.⁸⁷ The last action on the bill was July 10, 1991, adding co-sponsors.⁸⁸ The Senate passed a similar bill

83. SECOND INTERIM REPORT, *supra* note 14, at 23-24.

84. *Id.* at 25.

85. See *infra* notes 198-214 and accompanying text.

86. See Shumaker, *supra* note 9, at 596-61 (arguing for continued regulation on a federal level); see also SECOND INTERIM REPORT, *supra* note 14, at 26-29 (EPA's list of unanswered issues).

87. See H.R. 1816, 102d Cong., 1st Sess. (1991).

88. 137 CONG. REC. H5341 (daily ed. July 10, 1991).

and referred it to the House Energy and Commerce Committee.⁸⁹

2. Other Bills

Congress is currently considering another bill that deals with infectious medical waste. House Report 215, introduced on January 3, 1991, by Representative Robert A. Roe of New Jersey, would require the EPA to research the present management of infectious medical waste.⁹⁰ Tracking services indicate that in its current form this bill has a limited chance of becoming law.⁹¹ Nonetheless, its scope is instructive of the types of issues that Congress is scrutinizing. House Report 215 would require the EPA to develop a research program to: (1) assess the sources, composition, and disposal practices of infectious medical waste, (2) determine the extent of hazards to public health, including occupational exposure, from infectious medical waste, (3) use and compare different disposal processes, such as incinerators and autoclaves, and measure and compare the various emission rates and health risks associated with each disposal option, and (4) assess the status of medical waste management in the United States, including the practices of adding liquid infectious medical waste to municipal sewage systems and mixing low level radioactive waste with other hospital waste.⁹²

Other bills affecting medical waste are also currently pending before Congress. One such bill is House Report 173, introduced on January 3, 1991, by Representative James Olin of Virginia.⁹³ Under this bill, a state is authorized to restrict the transportation of medical waste into the state provided the state has an approved solid waste management plan and justifies the restriction on the basis of a lack of capacity to handle medical waste generated in the state.⁹⁴

Legislation aimed at protecting postal workers from medical waste is also under consideration.⁹⁵ The attention to protection of postal workers has increased in the past few months due to several instances involving puncture wounds of workers from syringes and other types of medical waste transported through the postal service.⁹⁶ Under the bill, persons who ship packages containing medical waste are required to use registered mail, return receipt requested.⁹⁷ According to the bill's proponents, the use of registered mail will reduce the risk to postal workers and provide an automatic track-

89. S. 1083, 102d Cong., 1st Sess. (1991); see also 137 CONG. REC. H3162 (daily ed. May 17, 1991).

90. H.R. 215, 102d Cong., 1st Sess. (1991).

91. *Bill Cast, H.R. 215, available in LEXIS, Legis Library, BLCAS File; Bill Tracing Report, H.R. 215, available in LEXIS, Legis Library, BLTRL File.*

92. H.R. 215.

93. H.R. 173, 102d Cong., 1st Sess. (1991).

94. *Id.*

95. H.R. 2861, 102d Cong., 1st Sess. (1991).

96. Several recent articles have noted the injuries to postal workers. See *Rep. Pallone Introduces Bill To Protect Postal Workers From Hazardous Exposures*, 133 Daily Labor Report (BNA), at A-3 (July 11, 1991) (loading injury of two New Jersey postal workers, one exposed to blood which leaked from a package onto an open wound); Stacy Evers, *No More Hypodermic Needles For Postal Workers*, STATES NEWS SERVICE, July 9, 1991, at 1.

97. H.R. 2861.

ing system for the waste.⁹⁸ Additionally, the bill mandates specific labels for the outside of the packages.⁹⁹ In fact, the Occupational Safety and Health Administration (OSHA) recently cited two postal facilities in Newark and Jersey City, New Jersey, for having unsafe and unhealthy working conditions specifically because of medical waste incidents.¹⁰⁰ At one post office, three postal workers reported injuries from hypodermic needles within a one month period.¹⁰¹ According to the witnesses who testified before the House Post Office and Civil Service Personnel and Modernization Subcommittee on June 11, 1991, the medical waste being transported through the mail belongs to doctors, veterinarians, and dentists who are seeking a cheap means of waste disposal.¹⁰²

D. *Second Interim Report to Congress on Medical Waste*¹⁰³

Under the MWTA, the EPA is required to provide Congress with three reports on medical waste.¹⁰⁴ The second interim report in the series of three was recently completed by the EPA.¹⁰⁵ The second report describes the MTWA's pilot project's results, contains information on the types of medical waste streams, and characterizes medical waste generators.¹⁰⁶

According to the EPA report, some currently unregulated activities contribute in part to the illegal medical waste disposal problem.¹⁰⁷ Specifically, the EPA cites illegal intravenous drug users and home health care facilities as potential generators of improperly disposed medical waste.¹⁰⁸ The EPA also notes that household medical waste, which was excluded from the federal program's definition of regulated medical waste, is the source of a large portion of the improperly disposed medical waste.¹⁰⁹

The EPA also notes that it has established the Compliance Monitoring and Enforcement Information Clearinghouse to collect enforcement data.¹¹⁰ The Clearinghouse collects information on complaints, inspections, press releases, notices of violation, and other relevant materials from both covered

98. Under the expired EPA regulations, use of registered mail was already mandatory. See 40 C.F.R. § 259.51(c) (1990). However, the federal regulations only applied to "covered" states even when they were effective.

99. H.R. 2861; see also Kate McKenna, *Bill Would Curb Risk Of "Hazardous Mail"*, STATES NEWS SERVICE, July 9, 1991, at 1; *USPS Workers Can Be Exposed To AIDS From Unsafe Mail Packages, Panel Told*, [1991] Gov't Emp. Rel. Rep. (BNA), at 756 (1991).

100. McKenna, *supra* note 99, at 1.

101. *Id.*

102. *Id.*; see also *USPS Workers Can Be Exposed To AIDS*, *supra* note 99, at 756.

103. SECOND INTERIM REPORT, *supra* note 14. In addition to the EPA reports, the Agency for Toxic Substances and Disease Registry (ATSDR) must prepare a report for Congress discussing the health impacts of medical waste. 42 U.S.C.A. § 6992h (West Supp. 1991).

104. 42 U.S.C.A. § 6992g.

105. 58 Fed. Reg. 2178 (1991).

106. SECOND INTERIM REPORT, *supra* note 14, at 23-38.

107. *Id.* at 10.

108. *Id.*

109. *Id.* at 11.

110. *Id.* at 15.

and uncovered states.¹¹¹ Clearinghouse information is available to states and EPA regional officials.¹¹²

The EPA, focusing on outreach, education, and training, recognizes that the success of the program requires a thorough familiarity with the regulations and the reasons for the regulations on the part of the regulated community.¹¹³ Thus, the EPA plans to emphasize five main areas: (1) outreach and education for the regulated community, (2) outreach and education for the unregulated universe, which includes the general public and home health care industries, (3) integration and coordination of federal and state agencies, (4) outreach and coordination among EPA headquarters, EPA agents, and the states, and (5) education and training for federal and state personnel who administer the programs.¹¹⁴ The EPA has distributed written materials discussing the requirements, conducted seminars and presentations at trade association meetings, and established programs designed to provide updated information to regulated entities such as transporters and hospitals that operate on-site incinerators.¹¹⁵ Development of effective outreach and training programs is quite a task for the EPA, particularly in view of the breadth of the regulated community, which includes physicians, clinics, dentists, veterinarians, nursing homes, hospitals, and research laboratories, to name a few.

The EPA prepared a list of issues which the final report must address and evaluate for a successful medical waste program.¹¹⁶ These issues include: (1) development of a uniform definition of "medical waste,"¹¹⁷ (2) whether aesthetics is a proper criteria to use in regulating medical waste,¹¹⁸ (3) whether to maintain the current exclusions or to expand regulations to include areas currently exempt such as home health care and household medical waste, (4) whether to implement a different tracking and reporting system,¹¹⁹ (5) whether the agency should develop uniform standards for TDDs based on objective measures rather than the current general definitions, and (6) whether to implement a uniform program addressing all aspects of medical waste similar to the hazardous waste program.¹²⁰ In particular, the EPA acknowledges that generators, transporters, and TDDs

111. SECOND INTERIM REPORT, *supra* note 14, at 15.

112. *Id.*

113. *Id.* at 15-17.

114. *Id.*

115. *Id.* at 16.

116. SECOND INTERIM REPORT, *supra* note 14, at 26-29.

117. *Id.* at 26. The EPA notes, for example, that generators are uncertain of the definition of medical waste, which is often vague and varies somewhat between states. For example, the EPA cites one definition that includes within the blood products category items "which are saturated with and/or dripping with blood." *Id.* Such a subjective standard would make compliance difficult.

118. *Id.* (discarded intravenous bags containing sterile solutions are considered medical waste but present no, or minimal, risks to health or the environment).

119. *Id.* at 27. The EPA indicates, for example, that many "discrepancies" are merely human errors related to improper accounting of hundreds of boxes within a truck, or to confusion when several manifests and generators are involved. *Id.* The agency believes that the time and energy used to resolve the issues caused by such discrepancy reports may be better spent in other areas.

120. *Id.* at 29.

may encounter conflicting or overlapping requirements due to the independent development of state and local programs.¹²¹ Additionally, the EPA argues that since the states lack the power to regulate medical waste traveling through interstate commerce, a federal program may be necessary.¹²²

III. STATE REGULATION OF MEDICAL WASTE

A. Overview

Many states (forty-two as of 1990) have enacted various types of regulations directed at controlling medical or infectious waste.¹²³ States with laws similar to the federal program include Texas, New Mexico, Minnesota, Oregon, California,¹²⁴ Delaware, Louisiana, Maine, Minnesota, North Carolina, Ohio, and Oregon.¹²⁵ The state laws, however, differ significantly in some cases, both in terminology used and regulatory controls imposed.¹²⁶ For example, regulated or medical waste goes by terms ranging from infectious waste, biohazardous waste, biomedical waste, medically hazardous waste, regulated medical waste, or special waste.¹²⁷ Such variation creates a burden on those affected by the laws and may impose contradictory obligations. The differing laws also make compliance substantially more difficult.¹²⁸ In addition to the inconsistent requirements, the varied state legislation may lead to "forum shopping," meaning generators searching for the state with the laxest and least expensive regulatory system to dispose of their wastes.¹²⁹

121. SECOND INTERIM REPORT, *supra* note 14, at 29.

122. *Id.*

123. Shumaker, *supra* note 9, at 556-57 n.4. Of the eight states noted to lack medical waste programs in 1990, West Virginia and Nevada now have programs in place. See W. VA. CODE §§ 20-5J-1 to 20-5J-10 (Supp. 1991); 1991 Nev. Stat. §§ 1-26, chap. 525, at 1667.

124. Under a recent California enactment, California medical waste generators were required to register with local enforcement agencies by April 1, 1991, prepare medical waste management plans, and prepare for inspections. The California definition of medical waste generator, similar to several other state laws, encompasses medical and dental offices, clinics, hospitals, surgery centers, laboratories, veterinary offices, pet shops, and other health facilities required to obtain a license from the state. The California system largely follows the federal system and imposes storage, labeling, transport, and recordkeeping requirements. Generators must register with the state, and storage, treatment, and disposal facilities must obtain permits. Failure to comply may result in civil or criminal fines. CAL. HEALTH & SAFETY CODE §§ 25015-25099.3 (West Supp. 1991).

125. See Shumaker, *supra* note 9.

126. *Id.* at 564-65.

127. *Id.* at 564 n.41.

128. See Goldie, *supra* note 6, at 132, 134-38.

129. See Shumaker, *supra* note 9, at 598-99.

*B. Texas Medical Waste Regulations*¹³⁰*1. Regulations*

Under the Texas Solid Waste Disposal Act (SWDA),¹³¹ medical waste is defined as a type of municipal solid waste.¹³² Medical waste as defined in the federal regulations is defined as "special waste from health care related facilities" in Texas.¹³³ The Texas Department of Health (TDH), the agency with jurisdiction over medical waste, is currently developing a regulatory system for medical waste.¹³⁴ Thus far, the program is almost identical to the federal demonstration program.

Under regulations promulgated on April 20, 1990, the TDH proposed requirements applicable to generators of "special wastes from health care related facilities" such as waste segregation, use of a specified method for any on-site treatment, meeting recordkeeping requirements relating to any on-site waste treatment, and meeting specified disposal requirements.¹³⁵ The specified methods of disposal include chemical disinfection, incineration, en-

130. This Article only discusses the Texas Department of Health (TDH) regulations. It should be noted that in 1990, the Texas Air Control Board (TACB) finalized regulations relating to medical waste incinerators, which make the previous standards stricter. See Texas Air Control Bd., 15 Tex. Reg. 6303 (1990) (to be codified at 25 TEX. ADMIN. CODE §§ 111.121-.129). The new TACB requirements apply to rural hospitals despite specific requests to exempt smaller hospitals that would have a difficult time achieving compliance due to the costs of retrofitting. *Id.* at 6304. The TACB denied any exemptions, waivers, or blanket grandfather clauses, deeming such actions not to be in the best interest of the public. *Id.*

131. TEX. HEALTH & SAFETY CODE ANN. §§ 361.001-.345 (Vernon Supp. 1991).

132. TEX. HEALTH & SAFETY CODE ANN. § 361.003(18). Specifically, the SWDA defines "municipal solid waste" as "solid waste resulting from or incidental to municipal, community, commercial, institutional, or recreational activities and includes garbage, rubbish, ashes, street cleanings, dead animals, abandoned automobiles, and *other solid waste* other than industrial solid waste." *Id.* (emphasis added). Under the new TDH regulations, "special waste from health care related facilities" is regulated in much the same manner as hazardous waste. See Tex. Dep't of Health, 25 TEX. ADMIN. CODE §§ 1.131, 325.136, 325.1001, & 325.1004 (West Supp. Apr. 1, 1991).

133. The TDH regulations define "special waste from health care related facilities" as "solid waste which if improperly treated or handled may serve to transmit infectious disease(s) and which is comprised of the following: (A) animal waste; (B) bulk blood and blood products; (C) microbiological waste; (D) pathological waste; and (E) sharps." Tex. Dep't of Health, 25 TEX. ADMIN. CODE § 1.132 (West Supp. Apr. 1, 1991). Thus, unlike the federal definition, the Texas definition does not appear to include isolation waste and does not separate contaminated versus uncontaminated sharps. *Id.*

Also, under the Texas regulations, certain types of waste are not included within the jurisdiction of the regulations, specifically waste generated by single or multi-family dwellings or hotels, motels, or other accommodations which provide lodging or other services for the public. *Id.* § 1.134.

134. The TDH has authority to promulgate the regulations pursuant to the TSWDA, which grants the TDH authority over municipal solid waste and the power to adopt regulations for management of the same. Tex. Dep't of Health, 25 TEX. HEALTH & SAFETY CODE ANN. §§ 361.011, 361.024 (Vernon Supp. 1991).

135. Tex. Dep't of Health, 15 Tex. Reg. 2240 (1990) (codified at Tex. Dep't of Health, 25 TEX. ADMIN. CODE § 325.1004 (West Supp. Apr. 1, 1991)). For example, certain types of special waste treated in accordance with the regulations may be disposed of in a municipal solid waste landfill. *Id.* (codified at Tex. Dep't of Health, 25 TEX. ADMIN. CODE § 325.1004(d)(1) (West Supp. Apr. 1, 1991)). Other requirements include a duty to place broken glass and pipets in puncture resistant packaging and to use specially designated containers for sharps. *Id.*

capsulation (for sharps in containers), steam sterilization, and thermo-inactivation.¹³⁶ Additionally, generators must observe packaging and labelling rules for any off-site shipment of *untreated* special waste, use only transporters who are registered with the TDH, initiate the tracking system, and maintain shipping records for a period of at least three years.¹³⁷ The range of potential generators is broad — covering blood banks, research centers, home health care agencies, and even funeral establishments.¹³⁸

On May 7, 1991, regulations relating to the transportation of medical waste were finalized.¹³⁹ The effective dates for the regulations were June 1, 1991, for some sections, and July 1, 1991, for others.¹⁴⁰ The new regulations provide that any person who collects for transport, or who transports, *untreated* medical waste from health care related facilities must comply with the regulations.¹⁴¹ Transporters of *treated* waste, therefore, are exempt.

Transporters must register with the TDH and pay an annual registration fee.¹⁴² The regulations also establish standards for the transportation vehicles,¹⁴³ and require transporters to deliver medical waste only to properly

136. A special waste mixed with other regulated medical waste will be deemed a special waste under the proposed generator guideline. Tex. Dep't of Health, 15 Tex. Reg. 2240 (1990) (codified at Tex. Dep't of Health, 25 TEX. ADMIN. CODE § 325.1004(b), (c) (West Supp. Apr. 1, 1991)). Moist heat disinfection was proposed on August 30, 1991. 16 Tex. Reg. 4721 (1991). Proposed changes also encompass use of microwaves and radiowaves with the moist heat. *Id.*

137. Tex. Dep't of Health, 15 Tex. Reg. at 2241 (codified at Tex. Dep't of Health, 25 TEX. ADMIN. CODE § 325.1004(g)-(i) (West Supp. Apr. 1, 1991)).

138. Specifically, the regulations apply to special waste generated by publicly or privately owned or operated health care related facilities including "but not limited to" ambulatory surgical centers, abortion and birthing clinics, blood banks, clinics including medical, dental, and veterinary clinics, clinical, diagnostic, pathological, or biomedical research laboratories, educational institution health center laboratories, emergency medical services, in-stage renal dialysis facilities, funeral establishments, home health agencies, hospitals and long-term care facilities, mental health and retardation facilities including schools and community centers, minor emergency centers, occupational health clinics, pharmacies, pharmaceutical and research laboratories, professional offices including physicians and dentists, special residential care facilities, and veterinary clinics and research labs. Tex. Dep't of Health, 25 TEX. ADMIN. CODE § 1.135 (West Supp. Apr. 1, 1991).

139. See 16 Tex. Reg. 2528 (codified at Tex. Dep't of Health, 25 TEX. ADMIN. CODE § 325).

140. *Id.*

141. *Id.* at 2530 (codified at Tex. Dep't of Health, 25 TEX. ADMIN. CODE § 325.1005(a) (West Supp. Apr. 1, 1991)).

142. *Id.* at 2530, 2532. Transporters should have registered with the TDH no later than the effective date of the regulations, which has already passed, or register with the TDH prior to commencing operations. The registration must contain the name, address, and telephone number of the transporter and the partners, corporate officers, and directors of the transporter, if any, a description of the vehicle to be registered including the license plate number and name of the vehicle owner, and the name and drivers' license numbers for all vehicle operators. *Id.* at 2530-31 (codified at Tex. Dep't of Health, 25 TEX. ADMIN. CODE § 325.1005 (West Supp. Apr. 1, 1991)).

A copy of the registration must be maintained at the designated place of business and in each vehicle. *Id.* at 2531. Registrations must be renewed every 12 months, or updated within 15 days of any change if: (1) the amount of untreated medical waste is expanded by 50%, (2) the business changes its address, (3) the registrant or owner changes names, (4) the partners, corporate officers, or directors change, or (5) the business employs additional drivers. *Id.*

143. 16 Tex. Reg. at 2531-32. The regulations require that vehicles used to transport untreated medical waste have a fully enclosed leakproof cargo body, protect the waste from

licensed disposal or treatment facilities.¹⁴⁴ Regulations also prevent "backhauling" and require transporters to clean and disinfect their vehicles before any other cargo is carried after completing a shipment of medical waste.¹⁴⁵ Additionally, transporters must provide evidence of financial responsibility, currently through a general liability policy, a performance bond, or a letter of credit.¹⁴⁶ After receipt of a shipment of medical waste, a transporter must furnish the generator with a signed receipt which includes the address, telephone number, and registration number of the transporter and identifies the generator using the same information.¹⁴⁷ Transporters must maintain a copy of transport documents for at least three years.¹⁴⁸ New regulations also govern transfer of shipments of medical wastes between vehicles.¹⁴⁹

Finally, for sparsely populated areas, the TDH regulations allow a licensed hospital to register as a medical waste collection station to accept untreated medical waste for storage and consolidation from small quantity generators, defined as those who generate less than fifty pounds of waste per month.¹⁵⁰ The new rules, however, do not allow hospitals that act as collection stations to treat the collected waste even if the hospital treats its own waste on-site.¹⁵¹ If a hospital treats third party waste, the TDH's position is that the hospital becomes a *commercial* infectious waste incinerator, subject to the full gamut of regulations including the permit requirements for commercial facilities.¹⁵² Failure to comply with the regulations may result in an administrative penalty of not less than \$100 but not more than \$10,000 per violation, or civil penalties of up to \$25,000 per day per violation, based on the SWDA.¹⁵³

mechanical stress or compaction, carry spill clean-up equipment and personal protective gear, and have a specified identification on the sides and back of the compartment stating the name of the transporter, the registration number, and identifying the contents as "Medical Waste." *Id.* (codified at Tex. Dep't of Health, 25 TEX. ADMIN. CODE § 325.1005(g) (West Supp. Apr. 1, 1991)). The transporter must maintain the cargo compartments in a sanitary condition and lock the vehicle when it is not in motion. The floors and sides must be impervious and non-porous, and all discharge openings must be securely closed during operation of the vehicle. *Id.* at 2532.

144. *Id.* at 2532.

145. *Id.* The operator must maintain records relating to the date and process used to clean and disinfect the vehicle for at least three years, and notify the owner of the vehicle, if not the same as the registrant, in writing that the vehicle has been used to transport medical waste and provide a description of the disinfection process. *Id.*

146. *Id.* However, on October 4, 1991, the TDH proposed an amendment which would only allow use of an irrevocable letter of credit. 16 Tex. Reg. 5404 (1991).

147. 16 Tex. Reg. at 2532. The receipt must also include the weight of the waste and the date of collection. Waste shipping documents must also provide the name and address of the disposal or treatment facility and have a signature of the facility representative. *Id.*

148. *Id.*

149. *Id.* at 2533 (codified at Tex. Dep't of Health, 25 TEX. ADMIN. CODE § 325.1006 (West Supp. Apr. 1, 1991)).

150. *Id.*

151. 16 Tex. Reg. at 2533.

152. *Id.* at 2530.

153. See TEX. HEALTH & SAFETY CODE ANN. §§ 361.223, 361.251 (Vernon Supp. 1991).

2. Discussion

The TDH gave special consideration to cost, realizing that the regulation of medical waste could increase costs of health care, and thereby, decrease the availability of health care, particularly in rural areas.¹⁵⁴ In an effort to accommodate this concern, the TDH considered only the actual disease transmission risk factors and possibility of physical injury to workers.¹⁵⁵ The fewer risks, the fewer restrictions imposed. The TDH also rejected a suggestion that a multi-copy manifest document be required, citing the ineffectiveness of a manifest in some situations and the increased cost to small clinics, physicians, dentists, veterinarians, and other health care providers.¹⁵⁶

The implications for health care providers under the new regulations are myriad. Mobile clinics, industrial facilities, veterinarians, research labs, and office buildings with groups of health care providers are subject to the regulations. Each special waste generator must assess the alternatives. For example, a generator could elect to collect, transport, and arrange for disposal or treatment of its own medical waste. A more cost effective approach, however, may be to use a medical waste collection station where permissible, or where several generators practice together, to use a transporter chosen by the group. Regardless of the compliance method selected, each generator must nevertheless assure itself that an experienced and reputable transporter and TDD are selected. The generator must, for example, examine the storage area, and be sure that packaging and labeling meets regulatory criteria. Special waste generators now face the issues currently faced by industrial hazardous waste facilities, such as the need to assure continuing compliance by the transporter and TDD, not to mention their own facilities. How to assure such compliance will be a major issue. For instance, will a full blown environmental audit be necessary, and if so, how often? If an audit is done, one must assure that those few consultants with experience and expertise in medical or special waste are selected.

Generators have reason for concern because each generator remains liable for the waste it generates.¹⁵⁷ For example, if an errant transporter improperly disposes of the waste, each one of the generators is subject to potential fines and remediation responsibility. The potential fines and attorneys fees do not take into consideration the dramatic public relations impact of being

154. 16 Tex. Reg. at 2528.

155. *Id.*

156. *Id.* at 2529.

157. This is the EPA's position and the TDH would probably follow it. In one EPA guidance booklet, for example, the EPA notes that where there is a group of physicians working together, they may elect one person to transport the waste if it is less than 50 pounds a month, or arrange with a transporter to have the waste removed. However, according to the EPA, each physician is responsible for the segregation, labeling, storage conditions, and the record-keeping requirements. See U.S. EPA, *Managing and Tracking Medical Wastes: A Guide to the Federal Program for Generators*, EPA/530-SW-89-021 (Sept. 1989) (reproduced in SECOND INTERIM REPORT, *supra* note 14, at 67). Thus, delegation to one member of a group is not a defense should a problem arise.

associated with improper disposal, transport, or treatment of medical waste. As discussed below, enforcement is a serious issue.

IV. NEW DEVELOPMENTS - CRIMINAL PROSECUTION FOR MEDICAL WASTE VIOLATIONS

A. Federal Overview

Several recent cases involving medical waste emphasize that the failure to know and follow the law can be a serious mistake, not only for health care entities such as medical waste transporters, but also for the physician or other health care provider.¹⁵⁸ Familiarity not only with the medical waste laws, but with the business practices and regulatory compliance status of the companies used to transport and dispose of such wastes is very important. The statutes relating to medical waste generally do not require any degree of culpability or improper conduct by the health care provider or others in the chain of handling the waste for liability to accrue.

As noted above, the EPA aggressively enforced the medical waste laws.¹⁵⁹ According to a representative of the Justice Department, the Justice Department "will vigorously prosecute individuals who endanger the community and foul the environment with dangerous medical waste."¹⁶⁰ The challenge for health care professionals is to stay abreast of the emerging laws and regulations relating to medical waste, particularly to familiarize themselves with reputable and experienced transporters and TDD facilities.

1. Paccione - Medical Waste Fraud

*United States v. Paccione*¹⁶¹ is a recent case characterized as one of the largest and most serious fraud cases in the United States. Three defendants were convicted of mail fraud, conspiracy, and several Racketeer Influenced and Corrupt Organizations (RICO)¹⁶² charges, based on environmental crimes.¹⁶³ The defendants submitted false information to state agencies which went undetected, and obtained permits and licenses to transport and dispose of hazardous and medical wastes. Rather than properly disposing of the materials, however, the defendants illegally disposed of the wastes. The defendants charged fees for proper transport and disposal while their reported costs were much lower. According to the *Paccione* court, the doctors and hospitals who entrusted medical waste to the defendants are now potentially liable for both civil and criminal fines.¹⁶⁴ The court further noted that

158. See also *infra* notes 161-185.

159. See *supra* note 7 and accompanying text.

160. *Criminal Enforcement, Doctor Convicted Of Water Act Violations For Dumping Medical Waste Into Hudson River*, [Current Developments] *Env't Rep.* (BNA), at 1812-13 (Feb. 8, 1991) (quoting Richard Stewart, Assistant United States Attorney General, Environment & Natural Resources Division in the case *United States v. Villegas*, No. CR-89-338 (E.D.N.Y. Jan. 31, 1991)).

161. 751 F. Supp. 368 (S.D.N.Y. 1990).

162. 18 U.S.C. §§ 1961-1968 (1988).

163. 751 F. Supp. at 371.

164. *Id.* at 372.

this liability existed even though the defendants had assured the generators that they were duly licensed.¹⁶⁵

2. Villegas

*United States v. Villegas*¹⁶⁶ is another recent case involving the criminal conviction of a New Jersey doctor for the improper disposal of medical waste.¹⁶⁷ The physician dumped, or ordered other employees to dump, vials of human blood and other medical waste into the Hudson River. He was convicted of four felony violations of the Clean Water Act and now faces a maximum sentence of a \$1,000,000 fine and thirty-six years in prison.¹⁶⁸

According to the case report, some of the vials were contaminated with hepatitis. The waste was subsequently tracked to the particular physician and laboratory by coded labels on the blood vials. The convictions were based on the knowing endangerment provision of the Clean Water Act, making it unlawful to knowingly place another in danger of death or serious bodily injury,¹⁶⁹ and the Clean Water Act provision relating to knowingly discharging pollutants into waters of the United States without a permit or other authorization.¹⁷⁰

In a related case, the laboratory associated with the physician, Plaza Health Laboratories, Inc., was also indicted based on the same provisions.¹⁷¹ Despite the laboratory's allegation that the actions of Dr. Villegas were done without the knowledge or authorization of the laboratory or its officers or directors, the New York Department of Social Services notified the laboratory that pending the outcome of the criminal action, the laboratory would be suspended from participation in the Medicaid program.¹⁷² The reason for the suspension was stated as crimes "relating to the furnishing or billing for medical care, services, or supplies."¹⁷³ Although the laboratory appealed this decision and sought an injunction to prevent the suspension, the court denied the request, finding that the disposal of waste was sufficiently related to provision of services to permit the suspension.¹⁷⁴

This case serves to reiterate that factors beyond the levying of fines require consideration. The loss of funding for the laboratory will probably be passed

165. *Id.*

166. No. CR-89-383 (E.D.N.Y. January 31, 1991). No opinion on the case is available because of the rules concerning publication of criminal opinions. Such opinions are apparently not published unless a jury verdict has been overruled or there was a ruling on a preliminary motion. The case is still active, however. Telephone Interview with Michelle Roker, Court Docket Clerk (July 30, 1991).

167. *Criminal Enforcement: Doctor Convicted Of Water Act Violations For Dumping Medical Waste Into Hudson River*, [Current Developments] *Env't Rep.* (BNA), at 1812-13 (Feb. 8, 1991).

168. *Id.* (discussing *United States v. Villegas*, No. CR-89-338 (E.D.N.Y. Jan. 31, 1991)).

169. See 33 U.S.C.A. § 1319(c)(3) (West 1983 & Supp. 1991).

170. *Id.* §§ 1319(c)(2), 1311(a).

171. See *Plaza Health Lab., Inc. v. Perales*, 702 F. Supp. 86 (S.D.N.Y. 1989), *aff'd*, 878 F.2d 577 (2d Cir. 1989).

172. *Id.* at 88.

173. *Id.*

174. *Id.* at 91.

on to the patients through higher medical costs, or worse yet, the patients could face loss of medical services if the laboratory could not continue without the funds. Clearly, therefore, an enforcement action may affect more than the facility charged with a violation.

B. State Cases - *Infergene*

Recently, the state of California alleged that a San Francisco attorney and his law firm were in violation of several provisions relating to the proper disposal of medical waste because of advice allegedly given relating to the disposal of the waste and abandonment of rental property.¹⁷⁵ This case provokes interest for several reasons. It marks perhaps the first time the state of California has prosecuted for the violation of its medical waste disposal provisions. Further, this is one of the first times that attorneys have been charged with responsibility in this arena. The state alleged that an attorney with the firm of Sullivan, Roche & Johnson informed their client's landlord that the client would not clean up medical waste at a laboratory, in part because of pending bankruptcy proceedings.

Even though the attorney and the law firm were dismissed from the case on July 26, 1991, the case is worthy of review.¹⁷⁶ The case demonstrates the difficulties that attorneys may face under competing laws. For example, in a bankruptcy proceeding one could argue that attorneys may violate bankruptcy laws by advising a party to clean up or dispose of waste based on the knowing misuse of assets of a bankruptcy estate. On the other hand, this case demonstrates that attorneys might be charged with a criminal violation of environmental laws if such advice is not given.

In the first amended complaint,¹⁷⁷ the state alleged that: (1) the defendant *Infergene Company* (*Infergene*) knew, or should have known, that it caused the disposal of a hazardous waste at a site not permitted for disposal of such waste in violation of the law, (2) the defendant knew it was disposing of radioactive material at a facility not licensed for such disposal and resulting in a substantial endangerment to public health and safety in violation of the law, and (3) the defendant disposed, or caused to be disposed, medical waste in a manner not authorized by law, at a facility not permitted for the disposal of such waste.¹⁷⁸ Various individuals associated with the company have been charged with the same violations. Named in the first amended complaint are William Dirk Sikkema (*Sikkema*), *Infergene's* chief operating officer, Dan Licon, Michael P. De Mello, an investment banker, Alfonso L. Poire, general counsel for De Mello, De Mello Corporation, Sullivan, Roche

175. See First Amended Complaint at 10-11, *People v. Infergene Co.*, No. 96922 (Solano County Mun. Ct., Cal., filed June 21, 1991).

176. Telephone Interview with Ramona Gordon, Administrative Court Clerk (July 30, 1991). According to the clerk, the discovery for the case had not been filed yet and the deadline was extended to August 16, 1991.

177. The complaint was apparently amended to delete parties, as noted herein. In the original felony complaint filed on May 30, 1991, the state also included Nathaniel Berkowitz, director of *Infergene*.

178. See First Amended Complaint at 1-2, *Infergene*, No. 96922.

& Johnson, the law firm, and William M. Scherer, the attorney. Significantly, each of the alleged violations constitutes a felony. Furthermore, the state standard does not require the state to prove actual knowledge that the act violates the law; rather, the state only needs to prove that the defendant "should have known" that an unlawful disposal or act would occur.¹⁷⁹

In the summary attached to the original complaint, the criminal investigator states that various representatives for Bedford Property, landlord and owner of the property in question, contacted the investigator concerning Infergene, a biotechnology firm. Infergene was experiencing financial difficulties and Bedford Property intended to evict Infergene. Because of the financial problems, Infergene filed for Chapter 11 bankruptcy during this period. According to a representative of the landlord, Sikkema became upset and indicated that Infergene would vacate the property immediately, leaving behind the hazardous and medical waste, when the representative refused to accept a check for overdue rent. The representative also indicated that despite a provision allowing Infergene to have continuing access to the property to remove equipment and hazardous material, Infergene removed only the equipment and personal belongings, leaving the hazardous waste in place. After another representative for Bedford Property contacted Infergene, Infergene allegedly responded that it had been advised by its attorney not to remove any hazardous waste.

Upon visiting the site, the criminal investigator observed improperly sealed containers of radioactive waste, a sharps container, and other pouches labelled "Sharp Objects" which contained used needles. Several bottles of chemical reagents, some containing syringes, culture dishes, test tubes, and other biological agents including bacterial and fungal cultures were also allegedly left behind, as were several drums of butanol. One of the drums of butanol was allegedly cracked, although one party indicates that any butanol that leaked probably evaporated.¹⁸⁰ The investigator also accused Infergene of violating several other provisions of state law and noted that it had received several notices of violation from the State Department of Health.¹⁸¹

According to the docket in the case, the defense sought a continuance for

179. Ruling on Demurrers at 4-5, *Infergene* (No. 96922).

180. However, in interviews, the criminal investigator reports that parties associated with Infergene deny that any waste remained and state that all of the materials from the 433 Industrial Way site were removed. First Amended Complaint at Statement of Berkowitz p.1, *Infergene* (No. 96922). According to another company representative, the hazardous wastes were not removed because disposal and treatment facilities require cash payments up front, a prerequisite which Infergene could not meet because of its cash difficulties. *Id.* Clearly, therefore, there are conflicting stories.

181. According to the inspector, Infergene failed to notify the Department of Health of its change of address after it moved from the 433 Industrial Way, Benicia, California address to a new location after the lease/rent dispute arose. *Id.* at Summary p. 5. The investigator noted that after reviewing agency records, he discovered previous complaints to the Benicia Fire Department and Solano County Health Department. According to the investigator's analysis of the Health Department records, the Health Department, after an inspection on December 7, 1990, noted two violations: (1) improper storage of hazardous waste beyond the permissible accumulation time limits, and (2) improper labelling of hazardous waste containers. *Id.* Infergene apparently requested more time to correct the violations because of its financial condition. *Id.*

further arraignment until June 24, 1991.¹⁸² The discovery motions by the parties were also due by June 24, 1991;¹⁸³ however, no further notations appeared on the docket regarding the same except a note stating that there was a motion for discovery with memorandum of points and authorities filed on June 24, 1991, by Sikkema.¹⁸⁴

Finally, please note that this discussion of federal and state enforcement actions provides only some highlights. Many other enforcement cases are pending or reaching settlement.¹⁸⁵

V. NIMBY - DEALING WITH PUBLIC PERCEPTION

A. Overview

Several states have a moratorium on the issuance of new medical waste incinerator permits. In Iowa, for example, the moratorium was effective until July 1, 1991, and legislation is pending to extend the moratorium through July of 1993.¹⁸⁶ This trend in the management of medical wastes causes grave concern to the EPA and companies that generate medical wastes.¹⁸⁷ Without sufficient available waste disposal capacity, those who create the waste face a bottleneck of considerable operational magnitude.

182. Telephone Interview with Ramona Gordon, Administrative Court Clerk (July 30, 1991).

183. *Id.*

184. *Id.*

185. *EPA Collects \$15,000 for Medical Waste Tracking Act Violation*, P.R. NEWSWIRE ASS'N, Apr. 22, 1991 (noting that the EPA will collect a fine from American Environmental Services in New York for violations relating to the packaging and labeling requirements of the MWTA); *EPA and Freehold Area Hospital, N.J., Sign Agreement for Seven Medical Waste Violations; \$21,600 Penalty Assessed*, P.R. NEWSWIRE ASS'N, Feb. 12, 1991 (violations relating to handling and storage, particularly mixing medical wastes with other wastes and disposal through municipal trash system); *EPA and Ellis Hyde Hospital Association, Malone, N.Y., Sign Agreement for Medical Waste Violations: \$8,997 Fine Assessed*, P.R. NEWSWIRE ASS'N, Feb. 11, 1991 (violations relating to storage, mixture with municipal trash, labeling, and disposal of medical waste); Alan R. Gold, *Garbage Company Faces Charges of Illegal Medical-Waste Storage*, N.Y. TIMES, Jan. 13, 1991, § 1, at 23 (noting that the owner of a transport service had been indicted for illegally storing more than 160,000 pounds of blood vials, fluid samples, used hypodermic needles, and other types of medical wastes with potential prison term and fine of more than \$1 million).

186. *Iowa Bill Will Limit Medical Waste Incinerators*, [Current Developments] Env't Rep. (BNA), at 1907 (Feb. 22, 1991) (proposed bill, H.F. 44, would extend moratorium on medical waste incinerators until 1993).

187. See, e.g., PA. STAT. ANN., tit. 35, § 6019.3(A) (Supp. 1991) (temporary moratorium on issuance of infectious or chemotherapeutic waste incineration construction permit); Tenn. Att'y Gen. Op. No. 90-72 (July 18, 1990) (discussing executive moratorium for medical waste incinerators in Tennessee); *Environmental Release RCRA Wish List: Interstate Transport, Medical Waste Left Out*, [Current Developments] Env't Rep. (BNA), at 334 (1991) (noting that "grass roots" groups want a total moratorium on any new medical waste incinerators as part of RCRA re-authorization); *States Maintain Environmental Enforcement Effort Despite Budget Ills*, [Current Developments] Env't Rep. (BNA), at 1759 (Feb. 1, 1991) (Illinois plans to determine whether a moratorium is needed); *Special Legislative Session Planned to Consider Emergency Waste Proposal*, [Current Developments] Env't Rep. (BNA), at 1567 (Feb. 14, 1990) (noting Kentucky moratorium started on January 16, 1990). This is not a comprehensive list.

B. Case Study

One recent case is proof of the public opposition and growing NIMBY phenomena relating to medical waste.¹⁸⁸ Whatcom County, Washington, enacted an ordinance prohibiting the importation into the county of medical waste generated from outside the county. The impetus for the ordinance was a citizens' group known as "Safe Waste Management Now."¹⁸⁹ The reasons for the enactment, cited by the citizen group and stated in the ordinance, were the increasing lack of capacity and the associated increasing costs for disposal and treatment of infectious medical waste. The ordinance additionally cited the risks involved with the transportation of medical waste over long distances and the new federal and state regulatory systems relating to medical waste which were causing compliance problems at the one facility in the area.

The plaintiffs in this suit, collectively referred to as "BFI," were in the business of collecting, hauling, and disposing of waste principally from the area of Vancouver, British Columbia, and Washington and Oregon states. Most of the waste transported by BFI originated in Canada. BFI alleged that the ordinance violated the Commerce Clause of the United States Constitution.¹⁹⁰ Procedurally, both sides moved for summary judgment, arguing that no genuine issues of material fact existed for development and that the case turned solely on questions of law.

In addressing the severe disposal capacity problems, the court noted that since the passage of the ordinance, the only landfill located in the county had reached capacity and closed and that the county's municipal wastes were being shipped to the eastern part of Washington.¹⁹¹ The court also stated, however, that the local incinerator had incorporated significant technological developments, meaning that the operation was now presumably safer.¹⁹²

The court adopted the two part analysis developed in previous cases interpreting the Commerce Clause. First, the court must determine whether the ordinance or act in question falls within the "virtually per se rule of invalidity."¹⁹³ Under this test, a rule with a protectionist purpose and the effect of an overt and total block on the flow of interstate commerce is per se invalid.¹⁹⁴ The court recognized that the county ordinance was based solely on

188. See *BFI Medical Waste Sys., Inc. v. Whatcom County*, 756 F. Supp. 480 (W.D. Wash. 1991).

189. *Id.* Ordinance No. 89-61 reads as follows: "Section 2. *Restrictions on Importation of Out-of-County Generated Infectious Medical Waste.* Effective January 1, 1990, infectious medical waste generated outside the territorial limits of Whatcom County shall not be accepted for disposal at a waste disposal facility within Whatcom County." *Id.* at 482. The ordinance defined infectious medical waste as "infectious and noninfectious waste from medical and intermediate care facilities, research centers, veterinarian clinics, and other similar facilities." *Id.* (emphasis added).

190. *Id.* at 483; see also U.S. CONST. art. I, § 8, cl. 3.

191. 756 F. Supp. at 472.

192. *Id.*

193. *Id.* at 483.

194. *Id.* The *Whatcom County* court relied principally upon the seminal case, *City of Philadelphia v. New Jersey*, 437 U.S. 617 (1978). Interestingly, the *Philadelphia* case involved a New Jersey law which prohibited the import of any solid or liquid waste into the state from

the origin of waste and placed a total prohibition on the entry of such waste into the county, whether the waste was generated in another Washington county or out-of-state.¹⁹⁵ The court, however, found that even if the ordinance had not fallen under the per se rule of invalidity, it would nonetheless have fallen under the less restrictive balancing test because the potential legitimate local purposes for the ordinance did not outweigh the harm to interstate commerce.¹⁹⁶ The court also indicated that less restrictive means could be used to address the local concerns.¹⁹⁷

VI. RELATED DEVELOPMENTS

As hazardous waste fell under increasing regulation, industries were forced to develop new treatment or disposal alternatives. Similarly, the medical waste arena is beginning to see the development of new technologies by companies who foresee a profit to be made in the area of medical waste treatment and disposal. A review of recent articles, for example, reveals items such as notices that new "consultant" companies are developing to address specific medical waste issues.¹⁹⁸

An article describing a recycling program initiated in Vermont stated that other persons are aggressively pursuing new and innovative technologies.¹⁹⁹ According to the article, the recycling program is the first in the nation to address the issue of recycling medical waste and is intended as a demonstration program and model for other hospitals.²⁰⁰ A ton of medical waste was recycled in the first two weeks of the pilot plant's operation, consisting primarily of paper and plastics. Under the program, wastes are sorted, with the hazardous and infectious medical waste removed and disposed of separately.²⁰¹ To facilitate the recycling, barrels and recycling bags are placed throughout a hospital and the hospital employees are given training and instruction on the recycling program.²⁰² An independent recycling consultant associated with the effort asserts that the effort thus far has reduced the medical waste from the hospital by seventy-five to eighty percent.²⁰³

outside its territorial limits. The Supreme Court found in *Philadelphia* that the law was invalid and served no legitimate local purpose which could not have been served by other, less intrusive means. 437 U.S. at 626-27.

195. 756 F. Supp. at 484.

196. *Id.* at 485-86.

197. *Id.*

198. *Arima Is Formed To Provide Medical Waste Consulting Services*, INTEGRATED WASTE MANAGEMENT, Jun. 12, 1991, at 5. Arima is forming to provide recommendations for managing medical waste. Acting in much the same manner as typical environmental consultants, the company intends to visit particular facilities, analyze the wastes and physical arrangement of the site, and then work with the company to elicit proposals from the treatment and disposal facilities tailored at addressing the specific needs of the client. Other services which Arima intends to provide are transportation of waste and a mail disposal service for small quantity generators. *Id.*

199. *A Medical Waste Recycling Program Tested In Vermont*, REUTERS, June 5, 1991.

200. *Id.*

201. *Id.*

202. *Id.*; see also *Study Looks At Ways To Recycle Medical Waste*, AP DOMESTIC NEWS, May 29, 1991.

203. *Id.*

Other businesses are beginning to build and plan for treatment and disposal facilities, seeing the new regulatory horizon as a boon for such facilities. One article notes that Biomedical Waste Systems, Inc. developed plans to acquire a company with a permit to build and operate a medical waste incinerator in Arkansas, and hopes to generate \$6,000,000 through a public offering of the shares.²⁰⁴ Another article indicates that medical waste management and biotechnology may provide an economic boon for states with economic problems.²⁰⁵ Biotechnology is itself a hot industry which results in a relatively small amount of medical waste when compared to hospitals. The type of medical waste generated, however, is typically of a type creating greater concern, such as materials contaminated with the AIDS virus or radioactive isotopes.²⁰⁶ One article also states that biotech businesses are developing at a rapid pace, citing for example the tripling of the start up of such firms in Massachusetts between 1976 and 1985.²⁰⁷ However, as discussed in this Article,²⁰⁸ such enterprising entrepreneurs will join the health care professionals who face an increasing amount of opposition to medical waste.

Also, a Connecticut company announced recently that it had successfully developed a large microwave disposal unit which allegedly has the benefits of zero air emissions, volume reduction, and nonhazardous residue.²⁰⁹ According to the company, the residue can be landfilled. The company, ABB Sanitec, Inc., sells the microwave units for approximately \$500,000 to \$600,000 each and has obtained regulatory approval in two states, with approval pending in six other states.²¹⁰ The article affirms that California and North Carolina have approved this system, and New Jersey, Ohio, New York, Massachusetts, Pennsylvania, and Texas are taking the system under consideration for approval.²¹¹ The system has also been sold in France, Germany, Switzerland, and Italy since 1986.²¹² An additional significant benefit of the use of the microwave system is that disposal costs between seven and ten cents per pound, whereas hospitals typically pay up to fifty cents per pound for other types of medical waste disposal.²¹³ Finally, another article notes that other plastics and resin producers in the medical market are beginning to focus on alternative means, such as gamma radiation, for disposal

204. STATES NEWS SERVICE, Apr. 25, 1991. Bio-Medical Waste Systems announced plans to make a public offering of stock for an organization to construct and operate medical waste incinerator facilities and transfer stations throughout the country. F-D-C REPORTS, Jul. 2, 1990, at 13-14.

205. Wendy Hower, *Medical-Waste Specialists Loom as Biotech Ally*, BOSTON BUSINESS JOURNAL, Feb. 25, 1991, at 13.

206. *Id.*

207. *Id.*

208. *See supra* note 175 and accompanying text.

209. *Connecticut Company Cooks Up A Solution For Hospital Waste*, CHICAGO TRIBUNE, Jan. 6, 1991, at 9C.

210. *Id.*

211. *Id.*

212. *Id.*

213. *Id.*

and treatment of medical waste.²¹⁴

VII. PRACTICAL CONSIDERATIONS AND CONCLUSION

Those in the health care field and their counsel should take stock of their medical waste management and disposal practices and take a proactive approach toward the trend of increased regulation. Materials are available from the EPA and states explaining the regulatory programs. Parties might also attend seminars or presentations on medical waste to become familiar with the issues. A medical waste education is the first step, however attained. In this regard, those with management powers should consider implementing an employee training program. Having one employee who is familiar with all environmental matters for the facility is helpful, as is a central location for records and related documents. The investigation should also include exploration of new treatment and disposal technologies as they develop.

The attention to detail must be carried over to the decision of selecting transporters and disposal or treatment facilities. Select only companies with expertise and a good reputation. Do not hesitate to check references and investigate the administrative history of the facility — for example, does it have notices of violation in its agency files? Make sure any notices, registrations, or permits have been given or obtained. Check the financial condition and insurance coverage as well. Counsel may assist in such inquiries, or the information may be available through various state open records acts.²¹⁵ Moreover, do not hesitate to visit the location of the transporter or TDD facility.

In selecting a transporter or TDD facility, one should also consider employing the services of a third party consultant. As noted in this Article, consultant firms are beginning to emerge, specializing in medical waste issues. Just as care should be used in selecting a TDD, care should also be taken in selecting a consulting firm. Particularly when the market is new, the lack of competition may create unreasonable fees, or it may mean that few experienced firms are available to meet the needs of health care providers. Again, investigate carefully, and if possible, obtain proposals from more than one consulting firm before making the final decision. Determine initially your own medical waste disposal needs. Consider performing an internal audit of your environmental compliance status, using in-house personnel or a consultant. If an audit is performed, be sensitive to issues such as confidentiality and privilege.

Finally, hospitals and other health care service providers must stay informed of the issues and take an active role in the initial development of laws and regulations pertaining to medical waste. An opportunity is available today to get in on the ground floor of an area that will continue to impact

214. Elizabeth S. Kiesche, *Waste and Costs High Among Medical Plastics Concerns*, CHEMICAL WEEK, June 19, 1991, at 14.

215. See TEX. REV. CIV. STAT. ANN. art. 6252, § 17a (Vernon Supp. 1991) (Texas Open Records Act).

the health care industry for years to come. Such groups should offer constructive suggestions, whether challenging or proposing legislation. By participating in the development of the new laws and sharing their experience with the process, health care providers have a unique advantage at the present time. Their participation in the debate may be the best means to assure that effective and manageable laws are enacted that protect human health and the environment.