Medical Waste Regulation in the United States: A Dire Need for Recognition and Reform

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I. INTRODUCTION - WHY THE RECENT PUBLICITY REGARDING MEDICAL WASTE?

Environmental issues have been the focus of much public attention and legislative effort over the past decade. One area that has been extremely controversial, especially over the last five years, has been medical waste and its regulation. The recent hype is attributable to numerous events. In 1986, 1400 bags of medical waste were dumped illegally in a New York City warehouse, after the waste had been reported as incinerated.1 In June 1987, twelve children in Indianapolis, Indiana were found playing with vials of blood outside an HMO medical office. Two of the vials were infected with the AIDS virus, and at the time, it was legal for these types of waste to be disposed of in an open dumpster.2 And in 1988, a New Jersey garbage slick a mile long, composed of syringes and empty prescription bottles with New York addresses, was the first of many medical waste washups on beaches along the east coast from Maine to Florida, the west coast, the Great Lakes, and the Gulf Coast. These beaches were temporarily closed.3

1 OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, ISSUES IN MEDICAL WASTE MANAGEMENT - BACKGROUND PAPER 1 1988 [hereinafter ISSUES].
2 Id.
3 There were no reported injuries or deaths. Id.
These are just a few of the numerous incidents which have recently attracted public attention to the handling, treatment, and disposal of medical waste. Though all of these events highlight serious concerns which should be addressed, the actual health risks associated with these events are less imminent than the media, general public, and legislatures believe. Medical waste regulation in the United States, when examined in light of scientific and economic factors, both domestically and abroad, needs to be reevaluated and drastically reformed. No minimum federal standards currently exist to regulate medical waste, which results in the failure of the states and country as a whole to have a legislative regulatory direction to follow. Furthermore, public fervor leads to ad hoc legislation unsubstantiated by any scientific data to justify such regulation. Finally, and most importantly, hospitals are inappropriately subjected to the vast majority of the medical waste regulation and held accountable for the incidents mentioned at the beginning of this Comment. In reality, the smaller medical waste generators are the blameworthy sources.

In contrast, Canada provides a laudable example of how medical waste can be effectively regulated on both federal and local levels. Its provincial governments exercise primary control over the disposal of hazardous biomedical and pathological waste, whereas the federal government regulates the inter-provincial transportation and handling of infectious wastes through its Transportation of Dangerous Goods Act (TDGA). This regime proves to be quite successful in monitoring and controlling medical waste disposal.

This Comment will discuss the current methods by which medical waste is regulated in the United States and how the scientific data regarding medical waste demonstrate a misplaced emphasis on its regulation. Part II of this Comment discusses what constitutes medical waste and current methods for its disposal. Part III discusses the reasons why the medical waste problem began and the real versus perceived risks of medical waste and its disposal. In addition, the current federal and state medical waste regulation in the United States is discussed, and its effects on the states and the health-care industry are examined in closer detail.

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5 Id.

6 For example, “Much of the medical waste that washed ashore in the summer of 1988 was syringe-related (65%) and came from home healthcare, and illegal intravenous drug use.” Id.

Part IV discusses the Canadian approach to medical waste regulation and compares the Canadian system to the American system. Finally, part V poses some suggestions regarding the future of medical waste and how the United States should reform the current system in light of scientific evidence, efficiency considerations, and the Canadian approach to medical waste regulation.

II. WHAT IS MEDICAL WASTE, AND WHAT METHODS OF DISPOSAL ARE CURRENTLY USED?

A. Definitions

To better understand what constitutes medical waste it is important to recognize what hospital waste is and what distinguishes one type from another. Unfortunately, this is where the controversy begins. None of the federal agencies, including the Environmental Protection Agency (EPA) and the Society for Hospital Epidemiology of America (SHEA), just to name a few, seem to have consistent medical waste terminology. What follows is a brief discussion of how these terms are currently employed by some of the various agencies.

Solid waste, also known as hospital waste, is defined by SHEA as "all waste, biological or nonbiological, that is discarded and not intended for further use."9

Medical waste, according to SHEA, is composed of "materials generated as a result of patient diagnosis, treatment, or immunization of human beings or animals."9 On the other hand, the EPA defined medical waste in the context of the Medical Waste Tracking Act of 1988 (MWTA) as "any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals."10 Exemptions from this definition include certain listed hazardous waste and household waste.11

Infectious waste is the most harmful type of waste and proves to be the most difficult to define.12 SHEA defines it as "that portion of medical waste that could transmit an infectious disease."13 The EPA defines it

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8 SHEA, supra note 4, at 39.
9 Id.
10 E.g., the provision of medical services.
12 Id.
13 See generally OFFICE OF SOLID WASTE, U.S. ENVIRONMENTAL PROTECTION AGENCY, GUIDE FOR INFECTIOUS WASTE MANAGEMENT, EPA/530-SW-86-014 (1986).
14 SHEA, supra note 4, at 39.
slightly differently, as "waste capable of producing an infectious disease." However, both SHEA and the EPA agree that there are several factors necessary for the induction of disease: the presence of a pathogen of sufficient virulence, dose, portal of entry, and resistance of the host.

Both the Center for Disease Control (CDC) and the Environmental Protection Agency concluded that infectious waste includes microbiological wastes, pathological wastes, blood and blood products, and contaminated sharps (which is the technical term used by scientists when referring to needles). When these four essential elements are examined more closely, it becomes evident that the potential for infection is virtually nonexistent from non-sharp contact with medical waste. In reality, medical waste is rarely infectious, and the only type of medical waste associated with disease transmission are sharps.

B. Methods of Disposal

Four main types of medical waste disposal currently exist. These are incineration, steam sterilization, sanitary sewer disposal of liquid wastes, and landfill disposal.

1. Incineration

There are three types of incinerators generally used for hospital waste treatment: controlled air, multiple chamber air, and rotary kiln models. EPA has estimated that approximately 80% of the hospital waste generated per year is incinerated. There are both advantages and disadvantages associated with the incineration process. Incineration provides a significant volume reduction of medical wastes; furthermore, it requires little processing of wastes before treatment. However, incineration is quite costly. Moreover, incinerators appear to have relatively

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16 The key factors include: "presence of a pathogen of sufficient virulence," which refers to the necessity of having an infection present of sufficient strength; "dose," which refers to sufficient quantity; "portal of entry," which refers to proper entrance of the infectious agent into the body (under the right conditions); and "resistance of the host," which refers to the host's ability, or inability, to fight off the infection once it enters the body. See Issues, supra note 1, at 5.
17 Id.
18 SHEA, supra note 4, at 44.
19 Id.
20 Issues, supra note 1, at 15 (citing RADIAN CORP., U.S. Environmental Protection Agency, Hospital Waste Combustion Study, Data Gathering Phase (1987)).
22 Issues, supra note 1, at 15.
23 Id.
high emission rates associated with certain pollutants.\textsuperscript{24} This poses a potentially significant problem, since many hospital incinerators are located in heavily populated areas.\textsuperscript{25} Furthermore, it is imperative that only experienced operators monitor and maintain incinerators because proper operation is a necessity to insure adequate pathogen destruction.\textsuperscript{26} Because of the inherent uncertainty associated with assessing an operator's experience and proper incinerator operation, there is always a possibility that all of the bacteria may not have been adequately treated.

Before incineration is employed, its costs should be weighed against its benefits for the given situation. Primarily, the capital costs associated with purchasing an incinerator must be considered. Furthermore, the stringency of incinerator emission and incinerator ash disposal standards are also key factors in determining whether an incinerator is a sound investment.\textsuperscript{27} Finally, maintenance and retrofitting costs must also be considered.\textsuperscript{28} If the above factors prove to be expensive, it may be more economically advantageous for a given hospital to resort to off-site incineration at a larger regional incinerator. However, before this decision is made final, it is necessary for the hospital to consider the costs associated with off-site incineration, particularly transportation costs associated with medical waste removal from the health care facility under consideration.

2. \textit{Steam Sterilization, or Autoclaving, of Microbiological Waste}

Steam sterilization, or autoclaving, is a process by which medical wastes are sterilized prior to landfill disposal.\textsuperscript{29} Autoclaving has been a preferred method for treating microbiological laboratory cultures since the mid-1970's.\textsuperscript{30} During this process, bags of infectious waste are placed in a chamber and steamed for fifteen to thirty minutes at 250-270 degrees Fahrenheit.\textsuperscript{31} After this treatment, the waste is sterile and can be disposed of in a landfill.\textsuperscript{32}

As with incineration, there are distinct advantages and disadvantages associated with steam sterilization. Autoclave operation and testing procedures are not as complicated as those associated with an

\textsuperscript{24} \textit{Id.}
\textsuperscript{25} \textit{Id.} at 22.
\textsuperscript{26} \textit{Id.} at 21.
\textsuperscript{27} \textit{Id.} at 19.
\textsuperscript{28} \textit{Id.}
\textsuperscript{29} \textit{Id.} at 20.
\textsuperscript{30} \textit{Id.}
\textsuperscript{31} \textit{Id.}
\textsuperscript{32} \textit{Id.}
incinerator. Moreover, an autoclave is less expensive to purchase and operate, takes up less space, and emits fewer toxins than an incinerator. As with an incinerator, however, proper autoclave operation is imperative, and the process is time consuming. Furthermore, autoclaves tend to be smaller and more limited in capacity than incinerators. Most importantly, many landfill and off-site incineration facilities are reluctant to accept post-sterilization medical wastes, possibly due to fear of incomplete sterilization. In light of these factors, it becomes clear why steam sterilization is a less-favored treatment method for medical wastes. A health care facility should consider steam sterilization when pathological tissue, chemotherapy waste, sharps, and other medical wastes are not part of the waste stream, since an autoclave will not properly treat these waste types. It should be noted, however, that 90% of the medical waste stream is suitable for steam sterilization.

Hospitals which must dispose of wastes unsuitable for steam sterilization will often find it more economical to purchase an incinerator and forgo steam sterilization. The types of waste unsuitable for steam sterilization include antineoplastic agents, radioisotopes, solvents, etc. In sum, the costs associated with post-steam sterilization tend to make incinerators a more economical alternative for many hospitals.

3. Sanitary Sewer Disposal of Liquid Wastes

Although this method may seem alarmingly careless and noxious at first, there are several reasons why pouring liquid waste into sanitary sewers is justifiable, even with blood products. For instance, this method of waste disposal rarely leads to infection. The microbial content of raw sewage is reduced by 90% to 99% through conventional sewage treatment processes. The microbial load of blood added to the sewer is very small compared to that of many other sources of pathogenic mi-

33 Id. at 21.
34 Id.
35 Id.
36 Id.
37 Id.
38 Id. at 20.
40 Id.
41 Some post-steam sterilization costs include transportation of resulting waste to the sanitary landfill, as well as possible holdout costs associated with a landfill/incinerator’s refusal to accept the waste.
42 No bloodborne diseases linked to sewage exposure have been documented.
43 SHEA, supra note 4, at 45.
crobes found in sewage. Finally, liquid wastes such as blood tend to be heavily diluted by other liquid municipal waste, which further reduces the likelihood of infection.

However, this method of medical waste disposal seems quite lax and repulsive to the public, despite the fact that it has never been proven to cause infection and poses an insignificant risk to public health. It is this public ignorance which warrants the reform discussed in part V, infra.


According to Subsection D of the Resource Conservation and Recovery Act, nonregulated waste may be disposed of in sanitary landfills. Though this method proves to be less expensive in the short run because of the elimination of pre-treatment methods such as incineration and steam sterilization, landfill disposal is becoming increasingly more difficult and expensive as landfill space vanishes. Another disadvantage is that many waste generators lack incentives to search for alternative methods of disposal, nor will they try to minimize the amount of waste generated while the landfill space continues to cost less than investigating and employing other means of disposal. This facet of the medical waste dilemma is addressed by some of the suggestions discussed in part V, infra—namely, the recycling and reuse of medical products.

III. THE HEALTH AND COST IMPLICATIONS OF MEDICAL WASTE IN THE UNITED STATES

A. The Medical Waste Problem - How Did It Begin?

Before any comments or criticisms can be made regarding the problem of medical waste regulation in the United States, it is important to understand the reasons why the topic has become so popular over the last several years.

Different businesses, particularly health care facilities, have been concerned with the possibility of infection present at all stages of the treatment process, especially during the treatment and disposal stages of products used in treatment. Furthermore, facilities such as hospitals have realized the operations efficiency yielded by obtaining the necessary equipment and auxiliary treatment products and devices "just in time" from the distributors versus stocking these materials within hospital.

44 Sources of pathogenic microbes include bacteria and viruses present in human feces. Id.
46 "Just in time" refers to those products and devices which are obtained by health care facilities and hospitals immediately before they are needed to treat a patient.
walls, which leads to high inventory costs and inefficient space allocation. “Just in time” is a manufacturing concept which is easily implemented with the use of disposable products, since the distributor in question does not have to concern itself with retrieving the used products from the health care facility or their resterilization.

Because of the popularity of “just in time,” many facilities have increased their use of disposable products, which inevitably leads to an increase in waste disposal. High disposal costs result because of the huge increase in the quantity of waste and the corresponding decrease in available landfill space, and these elevated costs in turn provide an incentive for the midnight, or illegal, dumping phenomenon. This illegal dumping contributes to the waste washing upon the shores of American beaches, which has become the spark to fuel the public’s fire. Citizens cry to their congressmen, who respond promptly with legislation focusing on a zero risk-based approach popular with the public, without prior investigation regarding the actual need for such regulation from a health-based perspective. All the bad publicity leads waste disposal facilities to refuse to handle medical waste because of the perceived health risk and thus increase the incidence of illegal dumping. Furthermore, the small waste generators, namely in-home health care patients and illegal intravenous drug users, are simply not subject to these tough regulations. It is easier for the generators to throw their used syringes in the garbage can, and it is simpler for the regulators to overlook the fact that these “small sources” dispose of more than one billion syringes a year. The end result is inappropriate medical waste regulation which is unduly burdensome on hospitals and allows the small generators to laugh all the way to the trash can.

B. How Dangerous Is Medical Waste? A Closer Look at the Facts and the Fallacies

Despite the recent publicity and outrage over the medical waste issue, the 1988 beach wash-ups were less of a medical waste disposal problem than the public was led to believe. Only 0.1% of the total debris collected in 1988 from the coastal states was plastic syringes, with a total of 1% constituting general medical waste. Most of the beach waste was ordinary trash that had been improperly handled and sewage overflows

48 Id.
49 SHEA, supra note 4, at 40.
50 SHEA, supra note 4, at 40.

Furthermore, it is crucial to note that medical waste poses virtually no risk of infection to the public at large.\footnote{SHEA, supra note 4, at 41.} In fact, the theoretical estimate that a person will acquire HIV from a needle on the beach is between 1 in 15 billion and 1 in 390 trillion.\footnote{SHEA, supra note 4, at 41.} Furthermore, no evidence exists that a member of the public or a waste industry worker has ever acquired an infection from medical waste, with the exception of contaminated sharps.\footnote{SHEA, supra note 4, at 44.} Additionally, all reports of disease transmission by contaminated sharps have reportedly occurred during the administration of treatment within the hospital, during laboratory procedures, or during initial disposal, and are not associated with environmental injuries that occurred after the hospital’s disposal.\footnote{See AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, THE PUBLIC HEALTH IMPLICATIONS OF MEDICAL WASTE: A REPORT TO CONGRESS (1990).}

Household waste, on average, poses at least one hundred times more of an infectious risk\footnote{Household wastes are infectious due to microorganisms with pathogenic potential found in spoiled food, feces, etc.} than medical waste.\footnote{There have been eight studies conducted worldwide which have all found that household waste such as facial tissues, soiled disposable diapers, and dog and cat feces is microbiologically more contaminated than is medical waste from hospitals. SHEA, supra note 4, at 43.} Hence, there is more of a threat during exposure to one’s own garbage than to that of a health care facility. Given that local legislatures are not about to ban, or even regulate, household garbage, efforts to regulate and force medical waste to a level of minimal or zero risk has yet to be justified, either economically or scientifically.

Finally, it is interesting to note that both Congress and the EPA have used the term “medical waste” instead of “infectious waste” in the Medical Waste Tracking Act of 1988 in deference to the remote possibility of acquiring an infectious disease from such waste.\footnote{William A. Rutala, Management of Infectious Waste by U.S. Hospitals, JAMA, Sept. 22-29, 1989, at 1639.}

In light of the above facts, it is evident that medical waste poses much less of a health risk than what the public perceives it to be.
C. The United States Medical Waste Regulations and Their Influence on Hospital Administration

1. The Medical Waste Tracking Act of 1988

The Medical Waste Tracking Act of 1988 amended the Resource Conservation and Recovery Act of 1976 by adding Subtitle J. Congress passed MWTA in the fall of 1988 as a two-year demonstration tracking program for medical wastes to determine the need for such a program on a national level. The purposes of MWTA were: to provide a system to track medical waste to its disposal; to provide a system to assure generators that waste is ultimately received by the proper disposal facility; and to provide a standard form of tracking waste within the applicable states.

Subtitle J defines waste as "any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals..." The program was implemented in New York, New Jersey, Connecticut, and states bordering the Great Lakes.

Termed a "cradle to grave" approach, MWTA mandated specific packaging, labeling, transporting, and tracking requirements for the following types of wastes: cultures and stocks of infectious agents, pathological wastes, human blood/blood products, sharps, contaminated animal waste, and isolation waste from patients with highly communicable diseases. The tracking aspect of the program proved to be the most innovative. Generators were required to fill out a tracking form which itemized the waste which they were giving to the transporters for disposal. In turn, these transporters, who were required to register with the EPA, took the waste and the form and filled out their designated portion. Each transporter and the owner or operator of the waste disposal facility signed and kept one copy of the tracking form as they received it. The generator was then given the final copy, which indicated where

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64 The Atlantic states could only opt out of the program if they adopted a no less stringent waste-tracking program, whereas the Great Lakes states could opt out of the program unconditionally. 42 U.S.C. § 6992(a)-(b) (1988).
66 Tracking Medical Wastes, supra note 61.
67 Tracking Medical Wastes, supra note 61.
68 Tracking Medical Wastes, supra note 61.
the wastes were ultimately received.\textsuperscript{69}

Unfortunately, MWTA did not address in-home health care, illegal intravenous drug use, or littering; only institutional and commercial sources of medical waste were addressed.\textsuperscript{70} This is because only generators of fifty pounds or more of medical waste per month were within the scope of MWTA.\textsuperscript{71}

The Medical Waste Tracking Act expired in June 1991.\textsuperscript{72} The EPA has since made no proposal to continue the program; however, MWTA has been a driving force behind numerous state and local regulations. A few other effects of MWTA should be considered, as well.

During its short life, MWTA imposed a high cost increase for the transportation and disposal of medical waste, often without any measureable benefits. For example, in order for a New York hospital to comply with MWTA, the amount of waste that became regulated under the Act increased by 315\% between 1984 and 1989, and its total costs went up nearly 700\%.\textsuperscript{73} This dramatic increase is largely due to the huge cost differential between disposing of nonregulated medical waste and regulated medical waste.\textsuperscript{74}

Ironically, the amount of medical waste on the beaches of participating states, particularly syringes, was significantly greater after MWTA's implementation than before the Act went into effect.\textsuperscript{75} A possible explanation for this may be an increase in mismanagement and illegal disposal, so as to avoid the high increase in disposal costs due to the Act.\textsuperscript{76} Hence, the likelihood that MWTA would succeed on a national scale in its original form is slim, since an enormous increase in medical waste disposal costs without a commensurate environmental or public health benefit would be the result.

\section*{2. Resource Conservation and Recovery Act\textsuperscript{77}}

Despite the fact that infectiousness is cited as a possible characteristic of hazardous waste within the Resource Conservation and Recovery Act of 1976 (RCRA), this Act does not contain any provisions for its

\begin{footnotes}
\footnote{69} TRACKING MEDICAL WASTES, supra note 61.\\
\footnote{70} TRACKING MEDICAL WASTES, supra note 61.\\
\footnote{71} TRACKING MEDICAL WASTES, supra note 61.\\
\footnote{72} TRACKING MEDICAL WASTES, supra note 61.\\
\footnote{73} SHEA, supra note 4, at 46.\\
\footnote{74} SHEA, supra note 4, at 46.\\
\footnote{75} SHEA, supra note 4, at 46.\\
\footnote{76} SHEA, supra note 4, at 46.\\
\footnote{77} 42 U.S.C. §§ 6901-6992 (1988).}

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regulation as such. Instead, RCRA gave the EPA the official statutory authority to regulate medical and infectious waste under Subtitle C. However, even with this authority, the EPA has chosen to publish only unenforceable guidelines instead of adopting a definitive position and promulgating regulations pursuant to that stance.

More recently, Congress has been considering various RCRA revisions to require regulation of infectious medical waste as hazardous waste and to require the EPA to further investigate the most effective means of managing medical waste.

3. **Clean Air Act**

With regard to medical waste, the Clean Air Act provisions are of particular interest because of the high percentage of hospital incineration of waste. Dioxin and furan emissions are of particular concern during the incineration process. Furthermore, ash, an incineration by-product, contains hazardous substances, and it is frequently disposed of under open conditions in landfills. As under RCRA, there have been several bills introduced in recent months to address the need for a regulatory program for air emissions from medical waste incinerators.

4. **Occupational Safety and Health Administration Acts and Regulations**

Most health experts believe that medical waste poses a greater hazard to health-care workers and waste handlers than to the environment or the public at large. Notwithstanding the ability of the Occupational Safety and Health Administration (OSHA) to regulate in the area of medical waste, OSHA has instead chosen to concentrate its rulemaking efforts on occupational exposure to two viruses, namely Hepatitis B and HIV. Under the Occupational Safety and Health Act (OSH Act), the Secretary of Labor has express power to regulate the handling and disposal of medical waste and to promulgate standards necessary to assure

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78 *A Cure*, supra note 51, at 10.
80 See SHEA, supra note 4.
81 *A Cure*, supra note 51, at 10.
83 Hospitals currently incinerate 70% of their waste. *A Cure*, supra note 51, at 10.
84 *A Cure*, supra note 51, at 10.
85 *A Cure*, supra note 51, at 11.
86 *A Cure*, supra note 51, at 11.
87 *A Cure*, supra note 51, at 11.
88 *A Cure*, supra note 51, at 11.
89 *Issues*, supra note 1, at 23.
the "attainment of the highest degree of health and safety protection of the employee." Unfortunately, the Secretary's reluctance to provide more regulation for medical waste treatment and disposal has undoubtedly stunted federal progress in this area as well.

5. Center for Disease Control

The Center for Disease Control focuses its energies on medical institutions and generators of infectious waste. Therefore, hospitals tend to be the institutions most frequently subject to its standards. Among other things, the CDC conveys the urgency of correct labeling of infectious waste, classified on the basis of its relative risk of disease transmission. After its research, the CDC showed the EPA that an insufficient amount of evidence existed regarding the effects of medical waste, and neither human health nor environmental safety would be at risk if infectious waste were not regulated. These findings have contributed to the EPA's failure to promulgate regulations regarding medical waste management and its decision to publish guidelines instead.

6. State Activity

Due to the lack of uniform federal regulation, many states have taken it upon themselves to promulgate their own legislation for intrastate waste disposal. The Council of State Governments report, State Infectious Waste Regulatory Programs, found that without a federal standard from which to work and without federal funds "to support the creation of a new environmental regulatory program, states, regardless of size or location, are in the process of meeting the public's demand for protection. It is a clear state-generated initiative . . . ." Additionally, local governments may develop their own standards.

Though these steps reflect an earnest attempt to address the medical waste problem, the resulting variation in regulations is important for several reasons. Because each state addresses its own particular needs through its own legislative process, problems that may be unique or particularly prevalent in a state can be addressed through regulation tailored to those specific problems. However, state standards tend to be promulgated quite hastily; often, there is not enough time to perform the neces-
sary analysis before the standards are adopted, and the necessity of such regulation is often left undisputed. Furthermore, some states regulate on the basis of listed generators versus types of waste generated, which can lead to high requirement differentials between states and regulation targeted at inappropriate sources. Moreover, stricter regulations in one state may encourage the shipment of waste to other states with less stringent regulations. This is another reason why a national standard which establishes a regulatory baseline is favorable; there will be less of an incentive for the states subjected to the more stringent standards to export their waste out of state to the states with less stringent regulation. Thus, a federal standard will result in lower transportation costs, an incentive to research other disposal methods, and an increased awareness among the States regarding what standards to which they can expect to be subjected if interstate disposal is necessary.

IV. CANADIAN REGULATION OF MEDICAL WASTE AND A COMPARISON WITH UNITED STATES REGULATION

A. The Canadian Approach to Medical Waste Regulation

The federal government in Canada has taken more of an active role in medical waste regulation than the United States government. Though the provincial governments of Canada exercise primary control over the disposal of hazardous biomedical and pathological waste, the Canadian federal government regulates the inter-provincial transportation and handling of infectious medical wastes through its Transportation of Dangerous Goods Act (TDGA).

Under TDGA, infectious waste is transported and handled as a dangerous good. The Canadian Ministry of Transportation is given the power to "negotiate for provincial implementation and enforcement of TDGA, which may directly impact intra-provincial transportation." As under the United States' MWTA, provinces are allowed to enact their

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97 Issues, supra note 1, at 24.
98 Issues, supra note 1, at 24.
99 Hospitals are a prime example. Because hospitals tend to be large generators, they tend to be most heavily regulated because members of local and state legislatures sometimes make an erroneous correlation between the total amount of waste generated and the amount of infectious waste generated.
100 Issues, supra note 1, at 23.
101 There is this incentive since one's own landfill space and incinerators are being used.
102 Blood, supra note 7, at 133.
103 Blood, supra note 7, at 133.
105 Id.
106 Blood, supra note 7, at 134.
own legislation, as long as the provincial standards are at least as strict as those promulgated by the federal government. The express purpose of TDGA is to promote public safety through regulation of the inter-provincial movement of dangerous goods by all modes of transportation, except those which are directly controlled by the provinces. Through TDGA, Canada has sought to achieve what the United States still lacks: a uniform standard for medical waste management.

As noted before, TDGA gives the Ministry of Transportation the authority to regulate all handling and transportation of dangerous goods. Dangerous goods are classified as "any product, substance, or organism included by its nature or by the regulations in any of the classes listed in the schedule." Included in the schedule are explosives, flammables, oxidizing substances, radioactives, and poisonous or infectious substances, to name a few. Furthermore, the responsibility for assessing the dangerousness of a given product and the necessary precautions is delegated to the consignor, defined as "any person who manufactures or formulates products containing dangerous goods, or on whose behalf an international or transborder consignment of dangerous goods is brought into the country." However, there are exemptions to TDGA which have narrowed the definition of infectious waste. Low-concentration hospital and medical waste which is not infectious or radioactive is not subject to TDGA's handling and transport provisions. These exemptions muddy the waters a bit, in that the infectious nature of a given article of medical waste may not be easily assessible so as to enable perfect application of the regulations in all cases.

In addition, TDGA specifically addresses the need to regulate medi-
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cal waste disposal for the safety of health-care and sanitary disposal workers. Though there are no specific regulations regarding what adequate training entails, the statute provides that “a person is trained in relation to his assigned duties when his employer is satisfied that the person has received adequate training and has issued a certificate of training to that effect.”\(^{115}\) Hence, the amount of training necessary can be determined by the individual employer.

Moreover, TDGA provides a tracking system analogous to that of the MWTA. Those businesses which are involved in the transport of infectious waste and any other dangerous goods are required by statute to register their activities with the Ministry of Transportation and must register as did American waste transporters under MWTA.\(^ {116}\) The purpose behind these requirements is to insure that enough information is acquired in the event of an accident so that an expedient and equitable clean-up can be achieved with minimal activity. In light of the above, it is clear that the Canadian Transportation of Dangerous Goods Act is comprehensive in scope and attempts to make regulation as uniform and clear as possible.

B. Canadian Regulation vs. United States Regulation

As previously stated in part III, the United States federal government has failed to regulate medical waste on a national level. This is largely due to the EPA’s failure to promulgate medical waste regulations pursuant to its authority under RCRA.\(^{117}\) It may be remembered that the CDC advised the EPA that there is no substantial threat posed to public health by medical waste. Hence, states have been the entities responsible for providing solutions to the medical waste problems that have arisen over the past several years. Without a base standard to draw upon, much of the resulting state standards conflict with one another and often are unnecessary from the very beginning.

However, as noted above, the Canadian federal government has provided a uniform standard for infectious waste management by treating it as a dangerous good. Thus, individual provinces need not establish their own standards from scratch. Furthermore, if a province so desires, it may promulgate stricter standards in accordance with its own individual needs. This is facilitated by the fact that the Ministry’s regulatory actions do not conflict with the recommendations it provides to the prov-

\(^{115}\) *Id.*

\(^{116}\) *Id.*

Thus, there is no real disincentive for provinces to self-regulate, aside from legislative costs normally incurred.

In addition, it appears that the United States has somewhat missed the boat in failing to recognize where the main health risk posed by medical waste lies - with the health care workers themselves. The Secretary of Labor, pursuant to authority delegated by the OSH Act, has authority to promulgate whatever regulations are necessary to ensure the safety of workers. However, the Secretary has failed to issue such regulations with regard to medical waste disposal, much like the EPA has refused to exercise its authority under RCRA. However, TDGA directly addresses the safety of employees who come into contact with infectious waste and requires them to receive appropriate training as determined by their employers. Though this provision is subject to discretion, it addresses the need for awareness of employee safety, while the OSH Act clearly fails to do so.

In light of the above, it becomes clear that the two approaches taken by the United States and Canada are radically different. Unfortunately, the United States has a history of approaching environmental regulation in an ex post manner. The Medical Waste Tracking Act of 1988 is not the only instance in which Congress has waited for someone to steal the horse before it realizes someone should have locked the barn. The enactment of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) in 1980 is another prime example. In 1978, toxic chemical waste began to seep into dozens of homes following heavy rains in the Niagara Falls area. It was later learned that the Hooker Chemical and Plastics Corporation, prior to its transfer of title to this land in 1953 to the city of Niagara Falls, had dumped its toxic waste under the site on which the Love Canal homes were subsequently built. As with the Medical Waste Tracking Act, public fervor prompted congressional action, resulting in CERCLA.

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118 Blood, supra note 7, at 156.
119 29 U.S.C. §§ 651-678 (1982). Specifically, 29 U.S.C. § 651(b)(3) provides, “The Congress declares it to be its purpose and policy . . . to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources, by authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce, and by creating an Occupational Safety and Health Review Commission for carrying out adjudicatory functions under this chapter. . . .”
120 Blood, supra note 7, at 156.
123 Id.
124 Moreover, the Resource Conservation and Recovery Act (RCRA) provides yet another example of Congress’ ex post approach to environmental regulation. RCRA was passed into law in 1976.
By contrast, Canada did not wait until environmental catastrophe struck before it decided to regulate medical waste. Instead, it realized that medical waste, particularly infectious waste, must be clearly and definitively regulated so that all those involved in its production, transport, and disposal would be fully aware of the delegation of responsibilities. Canadian legislators had the time, resources, and foresight to envision the importance of such regulation.

Unfortunately, the ex post approach to medical waste regulation in the United States is a product of the deficiency of these three essential elements to successful legislation. The governmental body with the requisite knowledge to promulgate medical waste regulation is the EPA. However, the EPA is extremely overworked, trying to keep up with the rampant outbreak of environmental concerns which have been brought to its attention, particularly over the past decade. Because of its work overload, the EPA frequently fails to meet the strict regulatory deadlines which Congress imposes upon the Agency. Subsequently, Congress imposes even stricter deadlines upon the EPA as a sanction for its delay. In essence, this vicious circle inevitably sets up the EPA for failure—failure which, in light of the general chaotic state of U.S. environmental law today, digs the country even deeper into its pit of environmental problems.

Ironically, Congress is the body that has the requisite legislative authority to enact a system of medical waste regulation which Canada has succeeded in implementing. Unfortunately, Congress is lacking in the two other essential elements to successful legislation - namely, resources and foresight. Members of Congress, rarely, if at all, have the requisite scientific knowledge to effectively conduct studies and analyses to determine what scope of regulation is really needed. Furthermore, this lack of specialized training, as well as the general congressional need to address a multitude of other matters directly within its scope of knowledge, contributes to Congress' inability to sit down and plan for the future when it legislates. Therefore, the only time Congress addresses an environmental issue such as medical waste regulation is when the public flags a problem and Congress' back is up against the wall.

Clearly, Canadian medical waste regulation should provide a strong incentive for the United States to revise its medical waste program. Specific suggestions for such reform are discussed in part V. Before such changes are implemented, however, it is important to realize that the after congressional committees had received estimates that the amount of solid waste generated in the United States was a much more serious problem than had previously been believed. Id. at 214. Congress acted only after solid waste disposal had become a serious problem.
Canadian system itself is not flawless. The Ministry of Transportation's regulations are quite broad. Though this characteristic helps to minimize the number of loopholes created by an ad hoc, situation-specific approach to regulation (such as that of the United States), it also creates ambiguity. Certain aspects of the Canadian scheme are not detailed enough. Therefore, some doubt is inevitably raised with regard to the standard of care intended by the Ministry of Transportation when it promulgated the Act.

When the United States decides to reform its current medical waste regulation program, it should try to strike that very delicate balance between the slight overbreadth and ambiguity of the Canadians, and the ad hoc, situation-specific regulatory regime which we currently have. This change must take place as soon as possible. Clearly, the implementation of reforms will be costly. Additional research costs will be incurred with regard to the threats associated with the various types of medical waste, in addition to deciding upon the best way to regulate their treatment, transport, and disposal. Moreover, legislative costs will increase, because Congress must essentially start a new national program for medical waste regulation. Congress fortunately has other legislation to draw from and does not have to start completely from scratch. In light of the benefits to be obtained from such a system, and the burdens to be endured without it, it is clear that the United States should bear these costs of reform and should see them as an investment. Not only will medical waste be more effectively regulated, but this country will, hopefully, reform its general attitude and approach towards environmental regulation. The first essential steps are outlined in the next section.

V. RECOMMENDATIONS FOR THE FUTURE OF AMERICAN MEDICAL WASTE REGULATION - HOW CAN THE UNITED STATES REFORM ITS CURRENT MEDICAL WASTE MANAGEMENT SYSTEM?

Suggestion 1 - Provide a Uniform Definition of Medical Waste

Though providing a uniform definition of medical waste may seem quite simplistic, it is an essential first step. If the United States provides a

125 For example, as discussed earlier, the TDGA provides an exemption from its handling and transport provisions for low-concentration hospital and medical waste which is not infectious or radioactive. However, it is sometimes very difficult to determine at what level particular waste will be infectious or radioactive. Another example is provided by the "adequate training" provisions of the statute discussed earlier. It is within the discretion of a health-care/sanitary disposal employer to decide when its employee has received adequate training in relation to the employee's assigned duties. There are no standards to determine adequate preparedness, so it is possible that an inadequately-trained employee will handle medical waste improperly under the Canadian scheme.
single, distinct definition of what constitutes medical waste, preferably through an organization with some level of expertise (such as the EPA), Congress and/or state legislatures will have a firm basis on which to promulgate medical waste regulations, and health care facilities nationwide will be aware of exactly what they are to dispose and by which means. Though a uniform definition alone will not solve the current medical waste crisis, this is a key step in the right direction.

Suggestion 2 - Waste Reduction and Treatment Before Disposal

By reducing the amount of waste initially generated and recycling when possible those articles which must be used, the magnitude of the medical waste problem can be lessened. Though this recommendation does not directly address the ways in which medical waste is currently treated, it does attempt to reduce the amount of medical waste generated, so that if all else fails, at least the amount of medical waste that American health care facilities have to discard is somewhat diminished.

In a recent study, the volume of total surgical waste in an American hospital was reduced nearly 93% by the removal of disposable linen, paper, and recyclable plastic. Authors of this study contend that recycling and converting from disposable to reusable linens are two of the primary methods by which to reduce the amount of waste a hospital generates. Additionally, technology does exist that is used to decontaminate waste and to separate it into its recyclable components, and recycling practices are generally very effective in reducing both hospital costs and environmental impact. Moreover, reusable medical fabrics and other products have been improved through scientific advances so that they are equal to their disposable counterparts in comfort, liquid repellance, and infection rate. Surveyed hospitals have reported cost savings with no performance problems.

Additionally, it should be noted that recycling methods do not pose any additional risk of infection to health care workers. Hence, the perceived risk is ill-founded and should not be a reason for rejecting recycling as a viable alternative for disposables. Clearly, recyclable and reusable medical products are a viable alternative to disposables, from both health and environmental-based perspectives.

127 Id.
128 Id.
129 Id.
130 SHEA, supra note 4, at 45.
Suggestion 3 - Evaluation of New Medical Waste Treatment Alternatives

With regard to treatment methods, government agencies such as the EPA should promote and perform evaluations for adopting new treatment alternatives based on demonstrated efficiencies and health-based considerations for these methods. For example, interim approval status could be granted while further testing and monitoring is performed. It is only through methods such as this that new technologies will be encouraged and evaluated effectively.

Suggestion 4 - Scientific Analysis and Research Prior to Promulgation of Medical Waste Regulation

Many of the problems associated with medical waste regulation in the United States are attributable to the political interests of congressmen who would rather satisfy their constituents immediately via ad hoc regulation than wait for a scientific rationale to substantiate this regulation. For example, as previously mentioned, disposal methods such as pouring medical waste into sanitary sewers are aesthetically displeasing, but pose a minimal health risk. Nevertheless, the public petitions to their congressmen because the public perceives such methods as hazardous to its health. Legislation is often passed before there is any scientific data presented or risk assessments performed to quantitatively justify the need for such regulation because of the perception that immediate action must be taken.

Furthermore, organizations such as the Natural Resources Defense Council (NRDC) have aggravated the public fervor. NRDC blames the problems associated with medical waste on the medical industry. It places public interest “in the forefront, voices public outrage over beach washups, and frames the problem in a manageable way: regulate the medical waste generators more stringently and the beaches will remain clean.” Because the public welfare is placed in the spotlight, the public tends to advocate this position, and these outcries are what the congressmen tend to hear the most often. However, this view is too simplistic and results in many wastes that are not infectious to be classified as such, and it drastically increases the costs of medical waste dispo-
Moreover, in light of the fact that the only real problem posed by the beach washups is aesthetic, this criterion “establishes a controversial precedent”\textsuperscript{137} that will become a difficult, and costly act for hospitals to follow.

Unless there is a dire emergency requiring immediate regulation, risk assessments, cost-benefit analyses, and scientific data should be employed to the extent that it is economically practicable, or should at least be considered before regulations are promulgated. It is only by subjecting contemplated legislation to such scrutiny that its necessity will be justified and ensured.

Furthermore, federal regulation of medical waste management based on this research is essential. Included in such a program would be minimum regulations which establish packaging, storage, treatment, and disposal methods proven to be most cost effective and necessary through these studies. States could decide to promulgate their own standards, as long as they at least comply with the federal standard. This type of regulation would decrease the amount of money already spent in medical waste treatment and disposal, because the costs incurred due to aesthetically-driven regulation and the inconsistencies resulting from differences found in state regulation will be minimized under this federal strategy.

\textbf{Suggestion 5 - Public Education About the True Risks Posed by Medical Waste and Its Disposal}

Aesthetic concerns have undeniably resulted in the public fear associated with medical waste disposal. As discussed earlier, a prime example is the 1988 beach washups on American coasts. Despite the fact that there are minimal risks associated with these unattractive events, the public nevertheless immediately associates AIDS and death with syringes for several reasons: fear of acquiring HIV or any other infectious disease, lack of personal control, familiarity with the risk of possibly acquiring a disease, perception of fair sharing of the risks and benefits, and the potential for blame.\textsuperscript{138} Furthermore, the public’s ability to imagine the pathway to infection increases as AIDS and other diseases claim more and more lives each year.\textsuperscript{139} As a result, legislative attempts have focused on a zero-risk approach to medical waste regulation\textsuperscript{140}—what the public

\begin{itemize}
\item \textsuperscript{136} SHEA, supra note 4, at 46.
\item \textsuperscript{137} SHEA, supra note 4, at 46.
\item \textsuperscript{138} SHEA, supra note 4, at 42-43.
\item \textsuperscript{139} SHEA, supra note 4.
\item \textsuperscript{140} SHEA, supra note 4, at 42.
\end{itemize}
perceives as extreme atrocities are answered via extreme measures, regardless of actual dangers or resulting costs.

In light of the fact there is no scientific evidence that medical waste has ever infected anyone outside the health-care setting, nor has any waste industry worker ever been infected by any type of medical waste other than sharps, it is necessary to put legislative and agency efforts into perspective. Instead of promulgating ad hoc regulation as a knee-jerk response to public fervor, resources may be more wisely spent on educating the public of the real risks associated with medical waste and its methods of proper disposal. Additionally, legislative efforts should be focused where the only real health threat is posed by medical waste—within the actual confines of the health care facility.

**Suggestion 6 - Focus Legislative Efforts on Small Generators of Medical Waste**

Some organizations, such as the Society for Hospital Epidemiology and the American Hospital Association (AHA), agree that small generators of medical waste, in aggregate, account for a considerable amount of this type of waste. Notwithstanding that there are 180,000 private physicians’ offices, 98,400 private dentists’ offices, 38,000 veterinarians’ offices, 15,500 medical clinics, 12,700 long-term care facilities, 4,300 laboratories, and 900 free-standing blood banks, there is no reliable data available on the amount of waste small generators produce. Furthermore, two million diabetics and 1.2 million intravenous drug users generate over one billion insulin-type syringes per year, but are not regulated either. Given these data, the AHA believes medical waste efforts (including the MWTA and similar legislation) should be directed at small-quantity generators. In light of these factors, it is clear that small-quantity generators cannot be ignored as were those generating 50 pounds of waste or less a month under the Medical Waste Tracking Act of 1988. Unfortunately, regulation on such a local scale is costly. However, ignoring these sources because of high regulation costs is simply burying one’s head in the sand. Instead, the EPA and legislatures on federal and state levels should focus their energies on devising a cost-

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141 SHEA, supra note 4, at 46.
142 U.S. ENVIRONMENTAL PROTECTION AGENCY, MEDICAL WASTE MANAGEMENT IN THE UNITED STATES: FIRST INTERIM REPORT TO CONGRESS (1990).
143 SHEA, supra note 4, at 40.
beneficial plan by which small generators of medical waste can be regulated without incurring overly burdensome costs.

One possible plan would be to impose a local tax on landfill users or generators of waste. Governments could increment the tax so that there would be a direct correlation between the amount of waste generated by a particular source and the corresponding amount of tax imposed. The revenues from this tax would be set aside in a fund to be disbursed as an aid to the smaller generators that find compliance with established medical waste disposal regulations too financially burdensome and who would otherwise go out of business. Not only would this tax enable the smaller waste generators to properly handle their waste, but it would also serve to deter waste generators from endlessly discharging medical waste. Furthermore, a regional tax on landfill users and waste generators would encourage reuse and recycling on the most effective level—the local level.

Suggestion 7 - Retain Parts of Previous Legislation During the Regulation Drafting Process

Not all medical waste regulations are doomed to fail. Hence, it is wise to retain certain aspects of previous legislation which have been crucial to the modest success of medical waste management to date. For example, MWTA’s tracking system is arguably the most important aspect of the Act. Under the tracking system, the government and the involved parties have a “paper trail” to determine who the potentially responsible parties are if a problem arises or midnight dumping occurs. In addition, the tracking system may result in increased awareness or conscientiousness by parties involved in waste disposal, given that they are required to sign their name as part of the process. Though the system does result in a time and cost increase for the involved parties, these may be relatively small burdens in light of the potential benefits of a system that may decrease the amount of waste generated at the source.

Suggestion 8 - The EPA Should Be More Authoritative About Medical Waste Regulation

EPA, in its Second Interim Report to Congress on Medical Waste, cited several ways to control the medical waste dilemma. Its points of

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147 Id.
148 I.e., deterrence of illegal dumpings.
149 U.S. ENVIRONMENTAL PROTECTION AGENCY, MEDICAL WASTE MANAGEMENT IN THE UNITED STATES: SECOND INTERIM REPORT TO CONGRESS (1990).
emphasis include: outreach and education for the regulated community; outreach and education for the regulated universe;\textsuperscript{150} integration and coordination of federal and state agencies; outreach and coordination among the EPA headquarters, its agents, and the states; and education and training for federal and state personnel who administer the programs. Many of these issues have already been addressed in this Comment. However, none of these objectives will come to fruition unless the EPA assumes a more authoritative role, namely, to regulate as well as to educate. Unfortunately, it has been extremely difficult for the United States to realize an overall view of the national medical waste problem because of the EPA's failure to establish a set of minimum federal standards through its delegated authority under environmental statutes such as RCRA. As a result, statutes such as MWTA will be ignorantly passed on both federal and state levels without the assistance of the EPA's expertise and scientific data. This research is essential so that the actual threat posed by medical waste is properly assessed. While hospitals continue to be the main target of medical waste regulation, their costs will continue to needlessly skyrocket, other health care facilities will lack substantial incentive to reduce the amount of waste they generate, and syringes will continue to wash up on our shores.

VI. CONCLUSION

It is quite clear that medical waste treatment and disposal is one of the most controversial issues today in the area of environmental law. Unfortunately, there will be no end to the public fervor associated with medical waste management until the United States federal government and its agencies play a more authoritative role in the promulgation of a uniform national standard similar to that found in Canada. The federal government should make an effort to educate the public of the true threats posed by medical waste. Until then, the vicious regulation/midnight dumping cycle will continue, leaving American hospitals and beaches the inevitable losers and small waste generators the undeniable winners.

\textsuperscript{150} I.e., small generators.