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Syringes in the Sea: Why Federal Regulation of Medical Waste Is Long Overdue

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SYRINGES IN THE SEA: WHY FEDERAL REGULATION OF MEDICAL WASTE IS LONG OVERDUE

Chryssa V. Deliganis* and Steve P. Calandrillo**

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I. THE MEDICAL WASTE PROBLEM

A. THE CONTOURS OF THE ISSUE

1. Introduction and Overview. The aftermath of Hurricane Katrina in August 2005 brought the dangers of disease from unmanaged hazardous waste to the nation's attention. Floating debris contained drums of hazardous materials, including medical waste from local health care providers. The devastation and threats of disease from these materials serve as a reminder of the dangers involved with hazardous waste and the importance of effective regulation.

Over the past several decades, the handling and disposal of medical waste has become an increasingly urgent problem in our country. In the summer of 1987, well-publicized beach wash-ups of medical waste closed fifty miles of New Jersey coastline and caused an estimated $1 billion loss to the local tourist industry. Since then, syringes and other types of medical waste have washed up in all but two of the twenty-five coastal states and in the Great Lakes region.

Pollution from medical waste disposed into public sewer systems has also created alarming problems. Medical waste improperly disposed into the sewer system has created sewage contamination. In Seattle, Washington, syringes and tampon applicators from a local hospital were recently found flowing from a sewer line into Lake Union.

Of even more concern is the widespread increase in illegal dumping of medical waste inland. Syringes, blood bags, used bandages, and even human body parts are appearing at alarming rates in local dumpsters and residential areas. In Boston, school children discovered containers of hepatitis B-infected "residual

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"blood" outside of their grade school.\footnote{Larry Tye, Brockton Medical Waste Spills in Front of Grade School: Officials to Investigate If the Debris, Apparently from N.E. Medical Center, Is Infectious, \textit{Boston Globe}, Nov. 8, 1988, at 18.} In New York City, a box of medical waste was found sitting on a sidewalk.\footnote{Box of Medical Waste Found on City Sidewalk, \textit{NewSDay}, July 14, 1988, at 27.} And in southern California, two children stumbled upon boxes containing thirty-four fetuses while playing in the Chino Hills.\footnote{Douglas E. Beeman & Tina Dirmann, Officials 'Stumbling in Dark' Over Found Fetuses, \textit{Press-Enterprise} (Riverside, CA), Mar. 18, 1997, at B02.}


Medical waste is produced everywhere that people live and by almost everyone at some point in their lives. Its treatment and disposal implicates the environment, public health, the economy, human dignity, and aesthetics. With the many issues involved, the need for federal regulation of medical waste today is manifest.

This Article examines the problem of medical waste disposal and evaluates the current state-based approach to regulation. Although many states have implemented stringent medical waste programs with some success,\footnote{See infra notes 272–302 and accompanying text.} the absence of direct federal regulation in this area is problematic. The need for national leadership is clear, especially with respect to the unique problems associated with interstate transport and the increasing prevalence of medical waste created by individual sources.\footnote{See generally Michael R. Shumaker, \textit{Infectious Waste: A Guide to State Regulation and a Cry for Federal Intervention}, 66 \textit{Notre Dame L. Rev.} 555 (1990) (advocating necessity of federal regulation for infectious waste management).} At a minimum, federal regulation should include uniform tracking and definitions, minimum
standards for safe handling and disposal, and central collection sites for small generators.  

2. Quantifying the Problem. It is unclear how much medical waste is produced nationwide each year. While medical waste constitutes only a small portion of the total waste stream, it is still a substantial byproduct of our society. The Environmental Protection Agency (EPA) has estimated that around 500,000 tons of regulated medical waste are generated annually by approximately 380,000 regulated generators. Since about 158,000,000 tons of municipal solid waste are produced each year, this means medical waste constitutes only about 0.3% of total output.

3. Lack of a Uniform Definition. Estimates of the amount of medical waste produced, however, vary greatly depending on one’s definition of the term. Some regulatory regimes are extremely inclusive, treating soiled bedclothes and used syringes alike in terms of handling and disposal. Others attempt to limit the materials requiring special treatment by using a more restrictive definition. Although it is obvious that some items—including used hypodermics and body parts—are considered medical waste by almost everyone, it is often unclear whether numerous other items require the same level of care in handling and disposal.

The federal government itself is conflicted on this issue, with the EPA and the Centers for Disease Control (CDC) offering different guidelines for defining medical waste. The EPA generally defines infectious waste as that “capable of producing infectious disease.” The EPA recognizes several infectious waste categories, including

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11 Id. at 600–01.
15 Id.
16 Battle, supra note 13, at 523–24.
human blood and blood products, pathological wastes, contaminated sharps, and animal carcasses. The CDC definition generally agrees with the EPA but differs on the designation of "communicable disease/isolation wastes." The EPA recommends that these categories be treated as infectious while the CDC allows them to be disposed of according to hospital policy.

In its "Final Rule" on medical waste incineration, the EPA adopted the "regulated medical waste" definition from the Medical Waste Tracking Act (MWTA) as the most suitable definition of "medical/infectious waste." This definition includes cultures and stocks of infectious agents from medical laboratories, human pathological waste (tissues, organs, and body parts and fluids removed during medical procedures), human blood and blood products, sharps used in patient care or treatment as well as unused sharps, and isolation wastes including biological waste and discarded materials contaminated with blood. The EPA promulgated a separate definition for "hospital waste" in order to satisfy the Clean Air Act requirement that the agency regulate "units combusting hospital waste, medical waste and infectious waste."

Due to the existence of inconsistent and conflicting definitions of medical waste, it is not surprising that estimates of the quantity produced vary greatly. Indeed, the American Medical Association (AMA) claims that the amount of medical waste produced by hospitals alone is around 800 million pounds. Other estimates are considerably higher than both the AMA's and EPA's and instead put

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18 Id. at 2–2.
19 See Battle, supra note 13, at 525 (discussing scope of CDC and EPA definitions).
20 Battle, supra note 13, at 525.
22 Id. at 810–11.
23 Id. at 811 (quoting 42 U.S.C. § 7429(a)(1)(C) (1994)).
the number as high as 3.2 million tons of medical waste produced annually.\(^{26}\)

While the amount of medical waste generated is uncertain, even less is known about the specific qualities of the waste—including the amount of infectious materials present. The EPA estimates that infectious wastes probably make up about 15% of all medical waste produced.\(^{27}\) Yet since the definition of medical waste varies greatly by jurisdiction and no nationwide studies have been conducted this data is guesswork at best.

4. Generators of Medical Waste.

a. Hospitals and Other Facilities. One reason for the difficulty in estimating the amount of medical waste produced is the lack of data on waste generated by sources other than hospitals. While the EPA has estimated that hospitals produce anywhere from 77% to 90% of regulated medical waste, the contribution of other generators has never been quantified.\(^{28}\) Research institutions, health clinics, and physicians' and dentists' offices are only a few of the numerous individual sources adding to the medical waste stream. Many others, including funeral homes, hospice care, nursing homes, and veterinarians contribute as well but are rarely discussed by the media or commentators.\(^{29}\)

b. Individual Sources. Another category of generators that has not been studied includes the numerous at-home users of sharps. Some four million Americans administer their own injections at home, many due to rising health care costs.\(^{30}\) Numbering in the millions, diabetics alone often require two injections per day.\(^{31}\) It is estimated that over a billion syringes and

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\(^{29}\) Gilbert, supra note 12, at 164.


lancets are disposed of in household trash as the result of self-treatment each year. This occurrence may result from the absence of appropriate disposal options. In addition, for many years the EPA advised self-injectors to dispose of used needles in a household container until full and then throw the container into the household trash. Later, however, concerned community groups encouraged the EPA to provide for safer disposal options, including drop boxes and supervised collection sites, mail-back programs, syringe exchange programs, and at-home needle destruction devices.

Even fewer studies have been conducted regarding the number of illicit drug users who dispose of their needles wherever possible. Though drug addicts produce far less medical waste than hospitals in gross amount, they are potentially a far greater source of the medical waste problem. Wastes produced by illegal drug users are more likely to be in the form of sharps and to be infectious in nature. These factors, combined with the lack of suitable means to dispose of used items properly, indicates that there is an increased possibility that the wastes will end up being dumped illegally and in unsafe places. Indeed, it is now thought that many of the most highly publicized dumpings of used needles may be attributed to drug use.

Aug. 30, 2006).

32 McGrath, supra note 30, at G4.
34 Id.
36 Hospital Waste Attracts Attention, WASH. TIMES, June 3, 1991, at M4 (noting 10% of medical waste that washed up on Northeast beach in 1988 was generated by health care industry, while remainder probably came from home and illegal use).
38 See Gilbert, supra note 12, at 164 (discussing sources of medical waste); see also EPA SECOND INTERIM REPORT, supra note 28, at 10 (EPA estimates over half of wastes that washed up on East Coast in 1988 originated from in-home health care patients and intravenous drug users); A Federal Plan Will Track Medical Waste in 10 States, N.Y. TIMES, Mar. 14, 1989, at B2 (detailing tracking program meant to curb medical waste pollution on beach).
5. **Treatment and Disposal Options.** The methods for treatment and disposal of medical waste may be divided into two broad categories: generally accepted and experimental. The former category encompasses the methods in widespread use, which include incineration, autoclaving, sanitary sewer disposal, and landfills.\(^{39}\) The latter category is growing and reflects market pressure for better alternatives.\(^{40}\) It should be noted that most generators of medical waste employ more than one method of disposal, such as incinerating some wastes at the location where they are generated and sending others to a landfill.\(^{41}\)

   a. **Accepted Treatment Methods.** Incineration is the most widely used method of medical waste disposal.\(^{42}\) In fact, some states (such as Texas) actually require every hospital to either have an on-site incinerator or a contract for waste disposal.\(^{43}\) Incineration utilizes high heat to reduce wastes to a noninfectious or nonhazardous ash.\(^{44}\) The ash may then be transported to a landfill. Benefits include a great reduction in the volume to be transported away, conversion to a more aesthetically pleasing form, and the eradication of pathogens.\(^{45}\) Additionally, this method is suitable for nearly all wastes, and some incinerators have the secondary benefit of generating electrical power from excess heat.\(^{46}\)

   However, incineration itself also poses public health concerns. The resulting ash is sometimes still hazardous and usually requires special disposal under state regulations.\(^{47}\) Incineration also

\(^{39}\) Christina Louise Martini, Comment, Medical Waste Regulation in the United States: A Dire Need for Recognition and Reform, 14 NW. J. INT'L L. & BUS. 206, 209 (1993); see also infra notes 42–82 and accompanying text.

\(^{40}\) See Young, supra note 28, at 18 (discussing rising costs of present medical waste disposal techniques as incentive for less costly disposal technologies).

\(^{41}\) Like many Boston area hospitals, Massachusetts General contracts with a medical waste disposal company (BFI) for waste removal to landfill. The hospital also incinerates certain wastes on-site. Interview with a representative of Mass. Gen. Hosp., in Boston, Mass. (Apr. 9, 1997).


\(^{43}\) Id.

\(^{44}\) Id.

\(^{45}\) Id.

\(^{46}\) Id.; Young, supra note 28, at 16.

\(^{47}\) Young, supra note 28, at 16.
presents an occupational risk for persons operating the incinerator and creates monitoring problems because it may be difficult to ensure that pathogens are consistently destroyed. Furthermore, medical waste is composed of large amounts of plastics, and air pollutants are released when these items are burned. Thus, critics think medical waste incinerators are a significant source of dioxin pollution, and they may release other potentially harmful substances into the air as well.

For the foregoing reasons, public opposition to incineration has grown in the recent past, and some states have imposed moratoriums on the construction of new incinerators. Concerns over the ill effects of incineration prompted a court order requiring the EPA to promulgate strict emission standards to address the problem. The standards are designed to reduce air pollution from medical waste incinerators by 95% and could cost hospitals over $1 billion. It is predicted that around 80% of existing facilities will instead switch to lower cost alternative disposal methods.

Community groups are also increasingly advocating for the elimination of all nonessential incineration of medical waste. Their concerns about incineration are numerous: incineration creates dioxin and mercury air emissions, the air emissions affect the local environment as well as communities miles away, ash residue from the process may leach into the groundwater below

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48 See id. (noting "incinerations pose a moderate occupational risk to operators because of high operating temperatures and the corresponding risk of fire").
49 Id. at 16.
50 See Margaret M. Menicucci & Cheryl L. Coon, Environmental Regulation of Health Care Facilities: A Prescription for Compliance, 47 SMU L. Rev. 537, 547 (1994) (discussing risks of incineration).
51 See Young, supra note 28, at 16 (discussing risks of incineration).
52 Due to extremely stringent dioxin standards promulgated years ago, the entire state of California has approximately two dozen incinerators as opposed to nearly 5,000 nationwide. Karen J. Nardi et al., Environmental Issues and Health Care, 16 WHITTIER L. Rev. 1069, 1072 (1995).
54 Young, supra note 28, at 17.
55 Id.
landfills, and still other pollutants (from arsenic to lead) are present in the air emissions from medical waste incinerators.57

Autoclaving, or steam sterilization, is another commonly used method to decontaminate medical waste.58 Bags of waste are subjected to steam and pressure for a specified period of time, depending on the volume of waste being treated.59 Steam sterilization decontaminates most of the medical waste, but the resulting material is not necessarily "sterilized."60 This method does not produce the high levels of air pollutants that incineration does, and it is a familiar and lower-cost technology for most health care facilities.61 It is believed that steam sterilization is an appropriate method of treatment for as much as 90% of medical wastes, and there are no federal standards with which to comply.62

The primary problem with autoclaving is that the volume of the medical waste is not reduced.63 The material must still be packaged, transported, and disposed of after treatment. Another aesthetic (but often very serious) problem produced by steam sterilization is the emission of extremely noxious odors during treatment.64 Also, some state regulations require that medical waste be rendered unrecognizable.65 Because it leaves the wastes intact, autoclaving is an impermissible means of disposal in many jurisdictions.66 Finally, some concerns exist about the use of

57 Id. at 11. One should be careful to note that not all researchers agree that the risks from incineration are this extreme, and some point out that many of the pollutants mentioned above can actually be filtered out.

58 See Martini, supra note 39, at 210 (explaining that "[a]utoclaving has been a preferred method for treating microbiological laboratory cultures since the mid-1970's").

59 Id. (noting waste is "steamed for fifteen to thirty minutes at 250–270 degrees Fahrenheit").

60 Young, supra note 28, at 17.

61 See Martini, supra note 39, at 211 (discussing steam sterilization process).

62 Id.; Young, supra note 28, at 17.


64 See Menicucci & Coon, supra note 50, at 548 (discussing disadvantages of autoclaving).


66 See Young, supra note 28, at 17 (discussing autoclaving with regards to local pollution regulations).
ethylene oxide during steam sterilization because it may be potentially harmful to the ozone layer or a carcinogen or both.\footnote{Coon & Gilberg, supra note 42, at 1108.}

Public sanitary sewer systems are another disposal option.\footnote{Martini, supra note 39, at 211 (arguing that "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").} Medical wastes are often discharged into sewer systems by hospitals, clinics, laboratories, and blood banks.\footnote{See Gilbert, supra note 12, at 167 (discussing sewer disposal).} Since the medical waste is combined with much larger amounts of residential sewage, it is considerably diluted. Sanitary sewers may remove over 90% of the combined sewage microbial content through treatment methods including filtering, anaerobic digestion, and stabilization ponds.\footnote{Id.} Septic tanks also provide effective treatment of medical wastes because the anaerobic conditions found inside them destroy human pathogens.\footnote{Id.}

Although sanitary sewer systems effectively destroy most infectious agents, they are not a problem-free option for medical waste disposal. Many sewer systems are extremely old and cannot handle the increased capacity that medical waste disposal would require.\footnote{Id.} Temporary shut-downs for maintenance could result in the discharge of untreated medical waste directly into the environment. Moreover, sewer treatment facilities are often inundated by large amounts of storm run-off during heavy rains.\footnote{Id.} This may result in system overflow and the discharge of untreated wastes into neighboring bodies of water.\footnote{Id.}

Landfills continue to be an oft-used method for disposal of medical waste.\footnote{See Battle, supra note 13, at 540–41 (discussing medical waste treatment).} Indeed, almost all other forms of medical waste treatment still result in residual material that must be carted away.\footnote{See Young, supra note 28, at 17 (discussing waste treatment methods).} For years, landfills have provided a simple solution to an unpleasant problem. Although there have been concerns that untreated medical waste will eventually contaminate groundwater,
recent research indicates that medical waste is generally no more contaminating than residential trash.\textsuperscript{77} Moreover, while some viruses have been isolated in commingled waste, they tend to become deactivated when mixed with solid waste in the landfill environment.\textsuperscript{78}

With the passage of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Superfund Amendments,\textsuperscript{79} however, landfills have become an increasingly expensive and unavailable option for waste disposal.\textsuperscript{80} Not only has the cost of dumping increased significantly,\textsuperscript{81} but the specter of possible future liability for clean up has discouraged many generators from using landfills. Moreover, the strict regulation of transportation of medical waste (by the Department of Transportation and the states) has further increased costs.\textsuperscript{82} Of special concern is the added liability for public exposure to medical wastes in the event of an accident during transport.

\textbf{b. Experimental Treatment Methods.} Due to the high costs and problems associated with the preceding “generally accepted” treatment options, alternative methods for medical waste disposal are in high demand.\textsuperscript{83} Most options currently in development involve conversion of the medical waste into “a less hazardous and more easily transported form.”\textsuperscript{84} These alternatives include irradiation, gas sterilization, grinding, shredding, and compaction.\textsuperscript{85}

The high demand for better alternatives has driven the development of new disposal technologies as well.\textsuperscript{86} One of the more eagerly anticipated new methods is electrothermal deactivation, or

\textsuperscript{77} Battle, supra note 13, at 541.
\textsuperscript{78} See id. at 541; see also Mercer, supra note 25, at 512 (discussing qualities and amounts of “infectious waste”).
\textsuperscript{80} See, e.g., id. § 9607 (stating scope and amount of liability for persons covered by CERCLA).
\textsuperscript{81} See Battle, supra note 13, at 540 (noting many U.S. hospitals dump unregulated medical waste in landfills).
\textsuperscript{83} Young, supra note 28, at 18.
\textsuperscript{84} Id.
\textsuperscript{85} Id.
\textsuperscript{86} Young, supra note 65, at 98.
the use of low-frequency radio waves. The radio waves decontaminate the medical waste by causing it to vibrate and heat up to approximately 200 degrees Fahrenheit. Afterwards, the waste is shredded and sent to a landfill. Concerns exist, however, about the safety of this fast-growing industry.

Hydro-pulping provides another new option for medical waste disposal. During this process, medical waste is pulverized and submerged in a disinfecting solution. Any remaining solids are rendered unrecognizable by this process and may then be sent to a landfill, whereas disinfected liquids can be disposed of in a sanitary sewer system. The primary drawback of this approach, however, is the chemical waste created by the disinfectant. This possibly hazardous byproduct may have adverse effects on the environment, and it could potentially overwhelm the sanitary sewer systems in which it is dumped.

Another product that utilizes sanitary sewers for ultimate disposal is “Orex,” or “operating room exit.” This polyvinyl alcohol product may be knitted into operating room paraphernalia including gowns, booties, sponges, and basins. After use, the operating room materials are collected in a red bag made of Orex and placed in a washing wheel. At a high enough temperature, Orex dissolves into a liquid product and the temperature of the water wash disinfects the material. What remains may be washed down the drain and

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87 See id. (discussing new treatment technologies).
88 Young, supra note 28, at 18.
89 Id.
90 For instance, Stericycle, Inc., the primary company using this treatment method, has been cited for workplace safety violations. See generally Diedtra Henderson, Medical-Waste Firm Hit With Violations – Company Building State Treatment Plant Is Cited in Arkansas, SEATTLE TIMES, Aug. 15, 1991, at C10 (discussing various violations cited against Stericycle, Inc.).
91 Gilbert, supra note 12, at 167 (discussing alternative methods of medical waste treatment).
92 Id.
93 Id.
94 Id.
95 Id.
96 Nardi et al., supra note 52, at 1071 (discussing newly discovered ways to dispose of medical waste).
97 Id.
98 Id. at 1072.
99 Id.
will biodegrade in a sewage treatment plant in just thirty hours, whereas toilet paper can take up to thirty days.\textsuperscript{100}

Plasma pyrolysis\textsuperscript{101} has the distinction of being one of the most environmentally friendly of the new technology options for disposal of medical waste.\textsuperscript{102} This system reduces medical waste to a harmless glassy slag by heating it to extremely high temperatures in a machine called a plasma arc.\textsuperscript{103} Since the process does not use oxygen it is not incineration.\textsuperscript{104} Plasma pyrolysis can be used on-site, it reduces waste volume considerably (i.e., on a ratio of about 100 to 1), and the resulting product can be disposed of in landfills or possibly used in road construction.\textsuperscript{105} More importantly, the plasma pyrolysis system produces no measurable pollutants.\textsuperscript{106}

Lastly, one must not forget that recycling provides a promising alternative to disposal of medical waste.\textsuperscript{107} While the use of disposable items was embraced by the health care industry for economic reasons, sorting and recycling many hospital items is not an unrealistic goal.\textsuperscript{108} Items do not necessarily need to be reused but rather could be decontaminated and converted for other uses.\textsuperscript{109} One option is the transformation of medical waste to glass through the process of "vitrification."\textsuperscript{110} In fact, the state of Wisconsin has

\textsuperscript{100} Id.
\textsuperscript{102} See Plasma Processing Update, http://www.plasmaindia.com/PPU%5CUpdate44%5Cupdate44.html (last visited Aug. 30, 2006) (noting "Plasma pyrolysis has been found to be an environmentally benign answer to today's waste disposal dilemma").
\textsuperscript{105} See id. (discussing disposition of medical waste).
\textsuperscript{106} Id.
\textsuperscript{107} Gilbert, supra note 12, at 167.
\textsuperscript{108} Id. at 167–68 (discussing sorting as viable waste treatment); see also Young, supra note 28, at 18 (discussing how several companies are attempting to transform medical waste into reusable products).
\textsuperscript{109} See Gilbert, supra note 12, at 168 (discussing recycling as waste management option).
\textsuperscript{110} Richland Plant to Convert Medical Waste to Glass, J. BUS. SPOKANE, Apr. 23, 1992, at B6 (discussing vitrification technology).
formally recognized the value of recycling by enacting legislation to encourage the practice.\footnote{Medical Waste Source Reduction Policy, WIS. STAT. ANN. § 287.07(8) (West 2004) (delineating medical waste reduction policies).}

6. Public Perception of Medical Waste. The public's perception of the medical waste problem is a key aspect of the issue. Much of the current regulation of medical waste is premised on assumptions concerning health risks, aesthetics, human dignity, and the environment.\footnote{See Gilbert, supra note 12, at 163 (discussing public concerns over waste management).} Public outrage over beach wash-ups can translate into congressional action almost overnight.\footnote{See infra notes 204–53 and accompanying text (discussing MWTA).} By the same token, a successful program can fade just as quickly as public interest wanes. Any analysis of the medical waste problem must address the often conflicting themes of public influence.

a. Health Fears. While medical waste poses significant risks, fear and a lack of information can sometimes lead to unwarranted exaggeration.\footnote{Gilbert, supra note 12, at 163 (discussing public concern over mismanaged medical waste).} Of utmost concern is the risk of transmission for persons who come into contact with infectious medical waste after improper disposal. More research needs to be done in this area, but current studies indicate that the risks to the public may have been overstated.\footnote{See, e.g., MacKnight, supra note 63, at 836 (implying current health care standards overestimate risk of infectious waste). For a full discussion of the public health risks of medical waste, see infra notes 343–58 and accompanying text.}

In light of this uncertainty and lack of information, it is hardly surprising that public fears concerning the infectious qualities of medical waste abound. Some commentators suggest that fear of AIDS, driven by irresponsible media treatment of the issue, has been the driving force behind regulation of medical waste.\footnote{See, e.g., Battle, supra note 13, at 536 (stating "the fear of AIDS 'fueled by misleading media coverage' has prompted regulation of medical waste").} Indeed, the only federal regulation in this area, the MWTA,\footnote{See infra notes 204–53 and accompanying text.} was enacted almost overnight in response to intense public pressure after beach wash-ups on the East Coast.\footnote{Id.} While it might not have reached the
level of hysteria, as some critics argue, it is clear that public sentiment concerning medical waste is strong and politically influential.

Although many fears about the adverse health effects of medical waste are unfounded, some health fears are valid. In particular, the effects of incineration on air quality create concerns about the emission of dioxins and mercury. One public interest group claims that medical waste incinerators (MWIs) are the third largest known source of U.S. dioxin air emissions and produce about 10% of U.S. mercury emissions. These toxins have proven adverse health effects, which have been recognized by the EPA and the International Agency for Research on Cancer. Nevertheless, "[d]ioxins enter the air from thousands of sources," not just medical waste incinerators, and mercury-containing items may present similar dangers even if not incinerated.

b. The "Yuck" Factor. In addition to the "fear" factor, medical waste engenders strong feelings of disgust in the public at large. Of all the unpleasant waste products produced by our society, medical waste certainly ranks among the most repugnant. Just the thought of discovering a human body part on the beach or in the woods is enough to traumatize most people. In response to this sentiment, many states require that human tissues be rendered unrecognizable before disposal. The state of California, for instance, generally requires disposal of human tissues by incineration or burial, despite the fact that only one company in California is licensed to incinerate such items. This requirement exists for purely aesthetic, rather than health or safety reasons.

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119 See, e.g., MacKnight, supra note 63, at 787 (stating public hysteria is not warranted by properly treated medical waste).
120 See supra note 114 and accompanying text.
121 See Health Care Without Harm, supra note 56 (making purported claim).
122 See id. (discussing EPA and IARC findings).
123 Id.
124 See id. (discussing dangerous effects of mercury).
126 Beeman & Dirmann, supra note 7.
c. Societal Values. Regulation of medical waste is also reflective of our values and beliefs in regard to basic issues of human dignity. For psychological and religious reasons, the public often requires special measures for the disposal of human tissue. When thirty-four fetuses were found off Highway 71 in southern California, for instance, anti-abortion leaders warned officials to "treat the bodies with all the dignity that a human being deserves."128

Fifteen years earlier, 16,500 fetuses had been discovered in the home of a laboratory owner in Los Angeles County. A lengthy court battle ensued at the behest of anti-abortion groups, who wished to bury the fetuses in a religious ceremony. In the end, the U.S. Supreme Court refused to grant certiorari to review a lower court order that the fetuses should be buried without a ceremony. During the burial, however, anti-abortion groups gathered to pray and sing while the fetuses were placed in unmarked graves.

d. Influence on Medical Waste Management Policy. From a practical standpoint, public perception can be a powerful factor influencing the management of medical waste by larger generators. Hospitals in particular are finding that their disposal options may be limited by public opinion. Many community hospitals are located in residential areas, and neighbors are becoming increasingly vocal about the perceived health risks of certain disposal technologies. Caught between an angry public and demanding regulators, some health care providers have found that

128 Kris Lovekin, Probe Ready on Fetuses Found by Road in Chino Hills, PRESS ENTERPRISE (Riverside, CA), Mar. 17, 1997, at A1.
130 See generally id.
132 See Lovekin, supra note 128 (discussing human fetus burial).
134 See Diedtra Henderson, Neighbors Dislike Hospital's Incinerator Plans - Worries Dominate Public Hearing as Northwest Unveils Master Plan, SEATTLE TIMES, May 9, 1991, at G3 (discussing controversy between Northwest Hospital and community).
improving their disposal technology for environmental reasons requires a battle in the arena of public opinion.\textsuperscript{135}

Many hospitals face considerable opposition to on-site incineration from area residents who fear adverse health effects.\textsuperscript{136} This is true even where an incinerator is well within all applicable regulatory requirements. In some cases, organized opposition has had the stymied effect of halting projects aimed at improving public safety and decreasing harm to the environment.\textsuperscript{137} It seems that few residents want an incinerator in their "own backyard," even if overall public health and safety would be improved.\textsuperscript{138}

In New Jersey, for instance, a community hospital fought public opposition in order to obtain a variance to expand its incinerator smokestack.\textsuperscript{139} Ironically, the hospital sought the addition in order to install scrubbing devices which would reduce emissions of sulfur dioxide and hydrogen chloride.\textsuperscript{140} When area residents were unable to persuade zoning officials to reject the variance, they exerted political pressure on the Township Council.\textsuperscript{141} The Council added a covenant prohibiting the burning of outside waste and effectively rendered the plan financially unfeasible for the hospital.\textsuperscript{142} Instead of reducing incinerator emissions, the Council forced the hospital to either send its waste to a landfill or incinerate it at a different location.\textsuperscript{143}

The effort of one hospital to adopt promising new technology offers an even more striking example of the adverse effect public opinion can have on medical waste management. Kaiser Permanente Medical Center in San Diego took the lead in adopting

\footnotesize{\textsuperscript{135} See Gerrard, supra note 133, at 521–22 (noting public opinion impact on waste disposal methods).}

\footnotesize{\textsuperscript{136} See supra note 134 and accompanying text.}

\footnotesize{\textsuperscript{137} See Gerrard, supra note 133, at 521–22 (noting public protest delaying incinerator project).}

\footnotesize{\textsuperscript{138} Id.}

\footnotesize{\textsuperscript{139} Robert Gebeloff, Chilton Hospital to Close Controversial Incinerator, RECORD (Bergen County, N.J.), Jan. 12, 1994, at B3.}

\footnotesize{\textsuperscript{140} Id.}

\footnotesize{\textsuperscript{141} Id.}

\footnotesize{\textsuperscript{142} Id.}

\footnotesize{\textsuperscript{143} Fikes, supra note 104, at 5 (discussing waste processing system approved for Kaiser Permanente).}
plasma pyrolysis technology for disposal of its medical waste.\textsuperscript{144} Since this method of disposal results in almost no measurable pollutants, the hospital had no problem obtaining all applicable permits from state and local regulators.\textsuperscript{145} Despite assurances from scientists and officials, however, community activists immediately began to campaign against the hospital.\textsuperscript{146} Adverse public responses like this can have the unfortunate effect of actually discouraging creative efforts to solve the medical waste problem.

These examples show that the sentiment of "NIMBY" ("not in my backyard") has a substantial effect on medical waste disposal and treatment. Some communities, however, have not been as successful in preventing waste disposal or treatment facilities from being built in their neighborhoods. There have been controversial cases of new medical waste incinerators sited in minority communities, although no studies have examined nationwide patterns of incinerator locations.\textsuperscript{147} Low-income and minority communities are often unaware of the need to make crucial siting decisions to protect their neighborhoods.\textsuperscript{148} Thus, although some communities are successful in preventing the construction of waste disposal facilities in their neighborhoods, the net effect has been to drive the "unwanted facilities toward the more vulnerable groups," perpetuating "privileges for whites at the expense of people of color."\textsuperscript{149}

7. Environmental or Public Health Problem? Considerable debate surrounds the significance of medical waste as both a public health and environmental problem. The lack of data quantifying the risks of disease transmission makes it difficult to assess the danger

\textsuperscript{144} See supra notes 83–111 and accompanying text; see also Fikes, supra note 104, at 5 (discussing waste processing system approved for Kaiser Permanente).

\textsuperscript{145} See generally Fikes, supra note 104 (discussing plasma pyrolysis approval).

\textsuperscript{146} See id. (discussing protest surrounding Kaiser Permanente’s plan).

\textsuperscript{147} See, e.g., Gerrard, supra note 133, at 515 (discussing Bronx incinerator) (citing Ian Fisher, Builders and Foes Using Bronx Incinerator as Test, N.Y. TIMES, Sept. 8, 1992, at B3; Frances F. Marcus, Medical Waste Divides Mississippi Cities, N.Y. TIMES, June 24, 1992, at A16).

\textsuperscript{148} See id. at 522 (explaining need to give minority communities “technical and legal resources they need to participate in crucial siting decisions”).

\textsuperscript{149} Id. at 495 (quoting ROBERT D. BULLARD, DUMPING IN DIXIE: RACE, CLASS AND ENVIRONMENTAL QUALITY 46, 108 (1990)).
that illegal dumping of medical waste poses to the public.  
Similarly, highly divergent estimates of the amount of medical waste produced hinders our ability to determine whether it constitutes an environmental hazard.  

The chain of events necessary for one to acquire a disease from contact with infectious waste is fairly attenuated.  

The person must suffer an injury that creates a portal of entry to their body, or a portal must already exist.  

A sufficient number of infectious agents must then enter through the portal.  

An infection may then occur if the host is susceptible, but disease does not always result.  

The chance that an infectious organism will survive outside of the body long enough to transmit disease varies greatly depending on several factors.  

Once infected material is removed from the body, any viruses it contains will not continue to multiply.  

This means that blood containing HIV or hepatitis B, once removed from the body, may retain its infectious qualities but will not grow more virulent over time.  

Environmental factors, including temperature and humidity, also influence the chance of transmission.  

Although preliminary data has led the government to conclude that there is no significant risk of infection from contaminated medical waste outside of the health care environment, the issue is by no means settled.  

A long-awaited report by the EPA on this

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150 See Mercer, supra note 25, at 513 (noting, unlike other forms of hazardous waste, infectious waste does not create health risks based on threshold level of exposure).

151 See id. at 511–12 (arguing that differences over quantity of waste are “due perhaps to inconsistent and conflicting definitions”).

152 See id. at 514 (noting both quantity and infectious characteristics of medical waste pose significant problems).

153 See Battle, supra note 13, at 533–34 (relying on data from the Agency for Toxic Substances and Disease Registry).

154 Id. at 533.

155 Id.

156 Id. at 533–34.

157 See id. at 534 (discussing hepatitis B virus and HIV).

158 See id. (noting viruses require living cells to multiply).

159 Id.

160 Cf. Martini, supra note 39, at 210 (explaining that autoclaving requires infectious waste to be steamed at 250–270 degrees Fahrenheit to render it sterile).

161 See Battle, supra note 13, at 532–33 (noting “[t]he degree of risk posed by medical
topic was expected after the experimental MWTA, but the final report was never released, and Congress eliminated MWTA's final report requirement in 1998. The agency has admitted that the risk of infection from improperly disposed medical waste is one of the most difficult and important problems that it must address. Two related issues yet unstudied are the added risks posed by the growing number of persons infected with HIV and the vexing problem of intravenous drug users, whose needles are more likely to be infectious or improperly discarded or both.

Commentators also have argued that the amount of medical waste produced each year is such a small fraction of the total amount of solid waste that medical waste itself does not warrant concern from an environmental point of view. The AMA steadfastly downplays the importance of medical waste, citing the release of sewage as a more damaging and frequent reason for beach closings on the East Coast. It is true, for example, that the medical waste that washed up on New Jersey beaches two decades ago was only a small percentage of the total waste that regularly washes ashore. Unlike other wastes, however, generators of medical waste have certain pressures and incentives that militate against proper disposal. Whereas other types of waste can be processed to minimize damage to the environment, medical waste is more likely to be disposed of in an environmentally damaging manner due to the unique enforcement and compliance problems that it presents.

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163 OFFICE OF SOLID WASTE, EPA, supra note 13, at 2-2.

164 It should be noted that the risk of infection in the health care setting appears to be much higher. This topic also requires further study, but the CDC has reported that each year 200 to 300 health care workers die as a result of occupational exposure. 134 CONG. REC. H9531, H9541 (Oct. 4, 1988).

165 See Mercer, supra note 25, at 514-15 (noting "[m]edical waste comprises less than one percent of the total solid waste Americans produce per year").

166 Id. at 514.

167 Id. at 515.
B. ENFORCEMENT AND COMPLIANCE DIFFICULTIES

In their work on regulatory unreasonableness, Eugene Bardach and Robert Kagan discuss the variability of regulated enterprises and an array of factors pertaining to compliance. Bardach and Kagan note that a fundamental problem is the varying degree to which regulatees are motivated and are able to comply with protective regulations. At one end of the spectrum are those amoral actors who will always choose to violate the law in the hopes of gaining a competitive advantage; at the other end are those who will always strive to comply. What is of greater interest are the majority of regulatees who fall somewhere in between these polar opposites. Compliance for these actors is often determined by factors including economic pressure, the threat of litigation, public perception, resources, and education.

1. Economic and Regulatory Pressures. Many generators of medical waste are operating under a great deal of economic and regulatory pressure. Hospitals, HMOs, and other large providers of medical care have come under increased scrutiny in the past several years due to spiraling health care costs. The move toward managed care has also increased competition among health care providers, who must cut costs in order to remain competitive.

At the same time, state regulation of medical waste has grown considerably. Starting in the late 1980s, the increased prevalence of illegal dumping caused many states to enact legislation detailing comprehensive procedures for the transport, treatment, and disposal of medical waste. Many of these regulations are costly and have
greatly increased the amount of money that hospitals must spend on waste management. 177

Other environmental legislation has further increased pressure on medical waste generators by destroying previously attractive disposal options. Incineration, for instance, has been practically regulated out of existence in California, 178 and the passage of CERCLA and the Superfund Amendments has made landfills an unattractive option for many waste generators for liability reasons. 179 As environmental regulation continues to grow, medical waste disposal will become increasingly difficult.

Many of these same pressures are also felt by smaller generators of medical waste. Although most states do not hold small producers subject to tracking and other specific requirements, these actors must still dispose of their medical waste appropriately. 180 This can be an oppressive financial burden for the small clinic or veterinarian. Unlike the larger generator that can construct an on-site incinerator or autoclave to cut costs, the small producer will have to pay other firms for proper transport and disposal of wastes. 181

Individual sources, including diabetics and intravenous drug users, also usually lack the resources necessary to insure that the wastes they produce will be disposed of properly. Education is one problem; many users are likely unaware that used sharps should not be discarded in municipal trash. Others may wish to dispose of their waste properly but lack a financially feasible method to do so. While some communities have attempted to provide needle recovery programs, 182 no uniform mechanism exists in the United States for

177 See O'Connell, supra note 24, at 1862–63 (discussing increasing costs to manage medical waste).
178 See Nardi et al., supra note 52, at 1072 (discussing regulation of medical waste in California).
180 See, e.g., CAL. HEALTH & SAFETY CODE § 118040 (West 2006).
181 See O'Connell, supra note 24, at 1863–64 (noting that federal regulation ignores small generators even though "[s]maller generators of medical waste require much more . . . assistance").
the collection and appropriate disposal of sharps produced by self-care sources.183

2. Absence of Public Accountability. There is a unique absence of public accountability for medical waste generators in this country. Unlike other industries discussed by Bardach and Kagan,184 health care providers do not have to worry about public or political backlash for their medical waste disposal policies. In the public eye, producers simply are not associated with their medical waste in the way that most companies are associated with their products. In other words, when a person is ill she chooses a hospital on the basis of quality, reputation, and numerous other factors relating to patient care. It is unlikely that the individual patient or the public at large draws the connection between a particular hospital and its method of medical waste disposal.

The only exception to this norm is when a hospital chooses a method that is objectionable to the community in which it is located. As noted earlier, organized public opposition to a hospital’s plan can actually militate against the implementation of cleaner incinerators or new technology.185 Thus, while most hospitals do not have any publicly imposed pressure to dispose of their waste in an environmentally conscious manner, they do have a perverse incentive to avoid making a capital expenditure on expensive on-site technology when it may turn the community against them.

3. Inability to Track Origin of Wastes. Another important aspect of the enforcement dilemma is the inability to track the origin of many medical wastes. Unless it originated in a laboratory, most medical waste items lack any kind of identifying markings by which the user can be traced.186 Syringes, gauze, and other items are generally uniform throughout the industry.187 When illegal dumping of these items takes place, usually the only way to catch

183 See infra note 198 and accompanying text.
184 See BARDACH & KAGAN, supra note 168, at 61–62 (discussing regulatory compliance from industries, such as with OSHA guidelines).
185 See supra notes 133–49 and accompanying text.
187 Id.
the violator is if there are any witnesses able to make a positive identification.

Two cases from California are illustrative. In one, a bag of human fat was dumped in a trash bin outside of a fast food restaurant.\(^\text{188}\) A nurse dining inside the restaurant saw a man throw the large trash bag (which was labeled with medical waste markings) in the dumpster and then jump in a car.\(^\text{189}\) Realizing that this behavior was suspect, the quick-thinking nurse jotted down the license plate number as the car sped away.\(^\text{190}\) The man was later positively identified and charged on a felony count of illegal medical waste disposal.\(^\text{191}\)

The other case concerned a large dumping of medical waste in an unincorporated area of Riverside County, California.\(^\text{192}\) The mess included "tens of thousands of very sharp, large-bore I.V. needles designed to keep veins open."\(^\text{193}\) Here the authorities traced the perpetrator only because he decided to continue dumping in the same area.\(^\text{194}\) Just a few days after the first violation, he returned and was spied by a witness who copied his license number.\(^\text{195}\)

These examples illustrate the severity of the illegal dumping problem but are also just the tip of the iceberg—there are but few cases where witnesses serendipitously happen upon such illegal activity. Presumably, many more violators manage to dump their wastes unnoticed and undisturbed.\(^\text{196}\) Moreover, both large and small generators may dump illegally. This is true even in a state

\(^{188}\) Id.
\(^{189}\) Id.
\(^{190}\) Id.
\(^{191}\) Id.
\(^{193}\) Id.
\(^{194}\) Id.
\(^{195}\) Id.
\(^{196}\) This reality underscores the need for punitive damages in excess of actual harm when violators actually are caught. If offenders are discovered only a small percentage of the time that they commit illegal activity and are asked to pay damages reflecting harm caused only in that particular instance, they will have avoided diluted incentives to take proper care. See generally Steven Shavell, Foundations of Economic Analysis of Law 243–44 (2004) (discussing imposition of punitive damages when it is more likely that injurers will escape suit).
like California, which has some of the most stringent medical waste regulations in the country.197

II. REGULATION OF MEDICAL WASTE

A. FEDERAL REGULATION: PIECemeAL AND PATCHY

The federal government does not directly regulate medical waste. Instead, it provides a limited patchwork of recommendations and rules.198 As noted earlier, the EPA and the CDC have promulgated "guidelines" for handling and disposal, but these contain conflicting definitions of medical waste.199 Additionally, certain regulations govern the transmittal of sharps and other medical devices via the U.S. Postal Service.200 Finally, the government may criminally prosecute under the Clean Water Act (CWA)201 or the Marine Protection, Research, and Sanctuaries Act (MPRSA) persons caught dumping medical waste into waterways.202

The three main sources of federal regulation include a trial program for the tracking of medical waste, safety regulations for the workplace, and rules for the transport of medical waste.203 We shall examine each of these in turn.

1. The Medical Waste Tracking Act: Congress Evaluates the Need for Federal Intervention. Congress enacted the MWTA204 in response to highly publicized wash-ups of medical waste on East Coast beaches.205 The legislation was thrown together quickly and was clearly a response to public outrage over the situation.206 The

197 See infra notes 276–91 and accompanying text.
198 See Mercer, supra note 25, at 516–17 (discussing limited guidelines provided by federal regulations).
199 See supra notes 260–71 and accompanying text.
200 See Battle, supra note 13, at 577 (discussing regulations concerning mailing of sharps and other medical devices).
202 Id. §§ 1401–1445.
203 See infra notes 204–71 and accompanying text.
206 Id.
EPA, which had previously refused to address the issue of medical waste on the grounds that it posed no serious health risks, bent under the weight of political pressure and assisted congressional committees in drafting the Act. 207

Once signed into law, the MWTA amended the Solid Waste Disposal Act, commonly referred to as the Resource Conservation and Recovery Act (RCRA). 208 From the beginning, the MWTA was limited in scope. Although several states were to be covered, 209 many invoked the liberal opt-out provision. 210 In the end, only Connecticut, New Jersey, New York, Rhode Island, and the Commonwealth of Puerto Rico participated. 211 Congress intended the Act to last only two years 212 but later extended it another two years. 213 At least one commentator has suggested that several factors contributed to the short life of the program, including an inability to override resistance from the hospital and medical establishments, the belief that the problem was just an "East Coast" issue, and the idea that it was a scale model for Congress to evaluate the best approach for a national program. 214 Another commentator has argued that by limiting the program to those areas where it was most popular, the authors could "capitalize on public opinion" while avoiding a battle with the health care establishment. 215

The MWTA had four main purposes: (1) to adopt a uniform definition of medical waste, (2) to provide "cradle to grave" tracking of medical wastes, (3) to allow for enforcement, and (4) to allow for better information gathering. 216 Section 11002(a) of the Act lists ten types of regulated medical waste including biologicals containing

207 See id. at 306–07 (noting public concern over medical waste on beaches).
210 See id. § 6992(b) (delineating opt-out provision).
214 Mercer, supra note 25, at 520–21.
215 Nakamura et al., supra note 205, at 309.
216 Mercer, supra note 25, at 521 (citation omitted).
infectious agents, human tissues, sharps, and animal carcasses.\textsuperscript{217} Section 11003(a) sets out the basics of the tracking program, including requirements for tracking of the transportation of waste from the generator to the disposal facility, a system for providing the generator of the waste with assurance that it was received by the disposal facility, use of a uniform tracking form, and provisions for the sorting, packaging, and labeling of medical waste.\textsuperscript{218} Section 11005 provides for enforcement, including civil and criminal penalties for violators.\textsuperscript{219} Sections 11008 and 11009 provide for a series of reports for the EPA to produce on a wide array of topics, including the threat medical waste poses to human health and the success of the demonstration program.\textsuperscript{220} The EPA was to issue its final report no later than three months after the expiration of the demonstration program, but it failed to appear, and Congress subsequently repealed the report requirement in the Federal Reports Elimination Act of 1998.\textsuperscript{221}

The tracking provisions of the MWTA deserve special attention. Considered the core of the program, they were designed to ensure proper handling of medical waste from generation to disposal.\textsuperscript{222} The MWTA was to achieve this goal through a comprehensive paper trail of tracking forms and records, based upon the well-established hazardous waste manifest system.\textsuperscript{223} The waste generator or transporter was to initiate the form and stay with the waste until it reached its destination.\textsuperscript{224} The Act required each actor in the chain to sign off at transmittal of the waste.\textsuperscript{225} In the event that the waste disappeared or failed to make it to its final destination, the generator was responsible for determining the status of the

\textsuperscript{218} Id. § 6992b.
\textsuperscript{219} Id. § 6992d.
\textsuperscript{222} See 42 U.S.C. § 6992b (setting forth requirements dealing with proper handling of waste).
\textsuperscript{223} EPA SECOND INTERIM REPORT, supra note 28, at 6.
\textsuperscript{224} See 42 U.S.C. § 6992b(b) (noting that generators of fifty pounds or more of waste per month were not exempt from tracking requirements).
\textsuperscript{225} EPA SECOND INTERIM REPORT, supra note 28, at 6.
\textsuperscript{226} Id.
In the event that the generator could not solve the problem, the statute required it to notify the EPA and the state. Notification would alert enforcement officials to the problem and, presumably, they would then be hot on the trail of the transgressing party.

Available data indicates that the program was at least partially successful. New Jersey and New York adopted the most extensive programs; the former opted for registration of medical waste generators, while the latter added categories of waste, mailed report forms, and conducted a limited number of on-site inspections. Still, it is believed that none of the states covered by the program provided the administrative attention and resources necessary to fully implement the program.

In its Second Interim Report to Congress, the EPA declined to evaluate the success of the program, which had then been in place approximately a year. The Agency did, however, identify several positive effects stemming from the MWTA, including the development of the tracking program, the implementation of standards for managing medical waste, and the collection of general information on the topic. The EPA also addressed the important issues of outreach, education, and training in regard to both the regulated and unregulated public. With respect to the latter category, the EPA developed and published in brochure form substantive guidelines for the disposal of home health care wastes. These brochures were distributed to health care professionals in the covered states.

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227 Id.
228 Id.
229 See Mercer, supra note 25, at 527-28 (noting Congressional perception was that tracking system would “work like a burglar alarm”).
230 See Nakamura et al., supra note 205, at 319 (“The program appears to have worked most effectively with hospitals where information regarding the program and the incentives supporting compliance . . . are the highest.”).
231 Id. at 319.
232 Id. (noting limited inspections were conducted).
233 EPA SECOND INTERIM REPORT, supra note 28, at iii.
235 EPA SECOND INTERIM REPORT, supra note 28, at 16.
236 Id. at 17.
The EPA also recognized, in its Second Interim Report, the issue of the nationwide consistency of medical waste management. The Agency acknowledged that it had become clear from the reports already submitted by transporters that generators ship a great deal of medical waste across state boundaries. The Agency also noted that the regulated community will face substantial costs if forced to comply with numerous, potentially conflicting, medical waste programs. Although the EPA refused to address the desirability of a federal program to impose uniformity and consistency, it recognized that any such program would probably contain uniform tracking provisions and enforcement authorities that reach beyond state boundaries.

The MWTA has endured a fair amount of criticism. It does not address the "long-term risks and problems associated with different treatment and disposal systems" or recommend a preferred method of management. The Act does not prohibit disposal of medical waste through sewage systems, nor does it place restrictions on who can handle infectious waste or where it must be treated and disposed. It imposes stringent and expensive regulations on generators instead of permitting cost-sharing with waste handlers. The MWTA's small generator exception also wrongly exempts many polluters. It leaves unregulated numerous individual sources including home health care users and intravenous drug abusers. Finally, the Act does not address the serious problem of interstate transport of medical waste.

237 Id. at 18–19, 29.
238 Id. at 29.
239 Id.
240 Id.
241 See, e.g., Battle, supra note 13, at 549 (noting MWTA contains weaknesses hurting efficacy); Gilbert, supra note 12, at 168 (finding MWTA objectives "largely unmet"); Nakamura et al., supra note 205, at 322 (noting MWTA adopted only in response to "short-term" crisis); O'Connell, supra note 24, at 1865 (identifying five problems with current waste regulations).
242 Battle, supra note 13, at 549.
243 See Nakamura et al., supra note 205, at 315–16 (discussing broad waste disposal regulations).
244 See Gilbert, supra note 12, at 165 (explaining numerous regulations cause high costs of compliance for waste generators).
245 See id. (discussing nonregulated generators).
246 Battle, supra note 13, at 550–51.
The MWTA has not “taken root.”\textsuperscript{247} The EPA’s final report on the program never arrived, and the federal government has no plans at this time to study further the issue of medical waste.\textsuperscript{248} Proposed pieces of legislation to regulate medical waste on a national scale, including a bill to establish a federal policy to replace the MWTA, have failed.\textsuperscript{249}

There are several reasons for the absence of federal legislation in this area. By the time the demonstration program expired, medical waste wash-ups had subsided and seemingly more pressing issues were occupying policymakers and their staffs.\textsuperscript{250} Environmental legislation has instead focused on reauthorization of the Clean Air Act, RCRA, and the Superfund Amendments.\textsuperscript{251} An even stronger factor militating against the adoption of federal regulation of medical waste is the lobbying power of the health care establishment. The MWTA focused on hospitals and other large health care providers, which were already “organized, active, and highly regulated.”\textsuperscript{252} The diffuse group of environmental and health activists who support regulation of medical waste have been no match for their deep-pocket opponents.\textsuperscript{253}

2. \textit{OSHA Regulation: Safety and the Workplace.} OSHA’s provisions for workplace safety are another source of federal regulation of medical waste.\textsuperscript{254} These were adopted in response to the concerns of the health care industry that workers were at risk from handling medical waste on a day-to-day basis.\textsuperscript{255} OSHA defines regulated waste to include blood and blood products, contaminated items (including sharps), and other potentially

\textsuperscript{247} Nakamura et al., \textit{supra} note 205, at 323.
\textsuperscript{248} \textit{Id.} at 318 n.26, 320 (noting EPA had only completed two of three required reports).
\textsuperscript{250} Nakamura et al., \textit{supra} note 205, at 320.
\textsuperscript{251} \textit{Id.}
\textsuperscript{252} \textit{Id.} at 323.
\textsuperscript{253} \textit{See id.} (discussing political context of medical waste regulation).
\textsuperscript{254} \textit{See} Occupational Exposure to Bloodborne Pathogens, 29 C.F.R. \S\ 1910.1030 (2005) (discussing bloodborne pathogens in the workplace).
infectious materials. OSHA also employs the use of universal precautions—all human blood and certain body fluids are treated as if they are infectious. These regulations are primarily concerned with handling requirements aimed at decreasing the risk of injury to health care workers. As with the MWTA, requirements for the proper storing, packaging, and labeling of medical waste are included. Of course, these provisions apply only in the workplace, so they provide no protection to the public at large.

3. Department of Transportation Attempts at Regulation. The Department of Transportation (DOT) initially took the position that infectious medical waste undergoing transportation must conform with Hazardous Materials Regulations. After receiving petitions for reconsideration of this policy, the DOT agreed that medical waste was different from other infectious substances and relaxed packaging and labeling requirements to some extent. In fashioning these amendments to its regulations, the DOT decided to take advantage of the information the EPA gleaned from the MWTA. Thus, the DOT's adopted definition of medical waste and its packaging and labeling requirements were consistent with those in effect under the MWTA.

The DOT extended the compliance date for these regulations several times as the Agency fielded negative comments from health care groups. A major criticism was that OSHA's Bloodborne Pathogens rule already adequately addressed the risks posed to health care workers "in the handling and transporting of medical waste." Presumably, however, the DOT's regulations are necessary to address the added risks associated with transport.

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257 Jensen, supra note 255, at 22.
258 See id. (noting OSHA regulations were "in response to the concerns of the healthcare industry that its workers were at risk for contracting infection").
259 Id.
260 Id. at 23.
261 See id. (noting amended regulations to apply less rigorous requirements to medical waste than infectious waste in December 1991).
262 See id. (noting “DOT looked to the expired MWTA for guidance”).
263 See id. (noting “adoption of the MTWH’s definition of medical waste resurrected the same criticism of vagueness and overinclusiveness originally voiced against the MWTA”).
264 Id.
These could include the risk of contact after accident or derailment, when container integrity may be compromised.

The EPA issued its Final Rule concerning transportation requirements for infectious substances, including regulated medical waste, in 2002. The regulations divide regulated medical wastes into four risk groups and state the transportation safety requirements for medical waste in each risk group. The risk groups indicate the relative ability of particular microorganisms to cause injury through disease. The regulations themselves are focused mostly on specific packaging requirements (such as large packaging, carts, and bulk outer packaging) for medical waste from health care facilities. They delineate the requirements for marking and tagging the packaging with the name and location of the offeror. According to the regulations, "health care facilit[ies] may contract with a waste hauler to perform all offeror functions

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266 Id.
267 49 C.F.R. § 173.134(a)(6) (2005). Risk Group 1 consists of microorganisms unlikely to cause disease, and materials containing such microorganisms are not subject to the requirements of the regulations. Id. The risk such materials create for individuals and the community is characterized as "none or very low." Id. accord 49 C.F.R. § 173.134(b)(1) (finding waste in risk group 1 not subject to regulation). Risk Group 2 consists of pathogens that can cause disease but are unlikely to be a serious hazard. 49 C.F.R. § 173.134(a)(6). Such pathogens are capable of causing serious infection upon exposure, but there are effective treatments and preventive measures available, and the risk of spread of infection is limited. Id. The risk of such materials to individuals is characterized as "moderate," while the community risk is "low." Id. Risk Group 3 consists of pathogens that usually cause serious disease but do not ordinarily spread from one infected individual to another. Id. They are pathogens for which effective treatments and preventive measures are available. Id. Risk to individuals is "high," while risk to the community is "low." Id. Finally, Risk Group 4 consists of pathogens that usually cause serious disease, that can be readily transferred from one individual to another, and for which effective treatments and preventive measures are not usually available. Id. The risk to both individuals and the community is characterized as "high." Id.

269 See 49 C.F.R. § 173.199(d)(1) (noting that all Risk Group 2, 3 and 4 substances must be marked with the OSHA BIOHAZARD symbol and accompanied by appropriate shipping and emergency response documentation).
associated with the transportation of [regulated medical waste]."270 However, the regulations fail to fully address issues concerning medical waste generated from households, only requiring transport of such medical waste according to state, local, or tribal government requirements.271

Although the DOT regulations are more comprehensive than other federal agencies' medical waste requirements, they contribute to a scattered patchwork of regulation on the federal level. When state regulation of medical waste is added to the federal patchwork of regulation, numerous complications and potential conflicts arise.

B. THE STATES RESPOND

In the absence of federal leadership, well over 90% of the states have enacted at least some form of medical waste regulation.272 The EPA has reported that between 1988 and 1990 alone, twenty-two states passed new laws or revised existing provisions.273 Moreover, soon after the passage of the MWTA, at least twelve states began to track medical waste via a manifest system.274

While state regulation of medical waste is widespread, it varies greatly in terms of approach and form. Some states have adopted the MWTA's definition of medical waste while others developed their own definitions.275 Packaging and labeling requirements also

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271 49 C.F.R. § 173.134(b)(10)(v). Furthermore, the transportation requirements differ for medical waste in different risk groups. Waste in Risk Group 1 is not subject to regulation. 49 C.F.R. § 173.134(b)(1). However, "[u]nless an exception is authorized, all Risk Group 2, 3, and 4 infectious substances must be transported in specification triple packagings authorized under the HMR." Hazardous Materials, 67 Fed. Reg. at 53,120 (HMR refers to "Hazardous Materials Regulations"). They must also be marked with the OSHA BIOHAZARD symbol and accompanied by appropriate shipping and emergency response documentation. 49 C.F.R. § 173.199(d)(1). Used health care products that can cut or penetrate skin or packaging material (sharps) must be transported in puncture resistant containers. Id.
272 Shumaker, supra note 10, at 556.
273 EPA SECOND INTERIM REPORT, supra note 28, at 25.
275 See id. at 556 n.4 (discussing various state requirements for waste disposal).
vary from state to state. Almost no data exists to compare the effectiveness of these differing approaches.

1. The Hard Hitters: Comprehensive Regulation in New Jersey and California. New Jersey and California are states which have been hard hit by illegal dumping of medical waste and which understandably now have strict regulation. Although a full analysis of these comprehensive regulatory regimes is not practical here, a brief discussion of key points is helpful.

After years of receiving New York's medical waste, New Jersey enacted its Comprehensive Regulated Medical Waste Management Act\(^{276}\) with the goal of requiring cradle-to-grave tracking of medical wastes\(^{277}\) and the registration of all generators.\(^{278}\) While New Jersey lacked hard evidence to prove that its medical waste problem was due in large part to wastes originating from out of state, it appeared that New York City's mishandling of wastes and illegal dumping from boats contributed to the problem.\(^{279}\) Both New Jersey and New York participated in the MWTA, and New Jersey provided heightened registration and tracking provisions specifically to address the illegal dumping issue.\(^{280}\) Furthermore, New Jersey instituted an informant reward program to encourage citizens to report illegal dumping of medical waste.\(^{281}\) Despite the stringency of its approach, however, New Jersey still has an illegal dumping problem.\(^{282}\) This result appears to be due to the fact that its tracking and registration efforts, though admirable, do not extend beyond the state's borders.\(^{283}\)
California passed its Medical Waste Management Act with the help of over 200 people in industry, government, and other fields. As with other aspects of its environmental legislation, California's medical waste provisions are very strict. Like New Jersey, California utilizes a tracking program and mandates appropriate treatment methods, which include incineration, sewer discharge, or steam sterilization. Due to the state's extremely stringent dioxin standards, however, there are only about two dozen medical waste incinerators left. While the regulations allow the use of alternative treatment methods that receive the express approval of the department, it appears that many materials are transported out of state for disposal. Indeed, California state law almost requires out-of-state dumping of human tissues, since these items must be either incinerated or buried and only one company is licensed to provide incineration.

2. Other Approaches: Nevada and Massachusetts. At the other end of the regulatory spectrum are Nevada and other states that have minimal standards for the handling and treatment of medical waste. Nevada chose to adopt the EPA's definition of medical waste, and its regulations provide generally for storage, treatment, and disposal. Though they may, in the first instance, sound adequate, these requirements are extremely sparse. In order to dump medical waste in a Nevada landfill, for instance, one need only cover the burial area with "suitable cover material compacted

285 See Nardi et al., supra note 52, at 1070 (discussing scope of California Medical Waste Management Act).
286 CAL. HEALTH & SAFETY CODE § 118040 (West 2006).
287 Id. § 118215.
288 Nardi et al., supra note 52, at 1072.
290 See Beeman & Dirmann, supra note 7 (quoting the chief of California's Department of Health Services environmental management branch as stating that because only one California company is licensed to incinerate human tissue, human wastes are transported to Arizona and Utah for disposal; see also Nardi et al., supra note 52 (noting that outdated pharmaceuticals and other wastes are often trucked to Nevada).
291 Beeman & Dirmann, supra note 7.
293 Id. §§ 444.662, .672, .646.
to a uniform depth of 36 inches.\textsuperscript{294} It is not difficult to imagine where much of California's medical waste must end up.\textsuperscript{295}

Interstate dumping of medical waste, moreover, is not limited to situations where a strictly regulated state has a lax neighbor. Massachusetts, for instance, has significant medical waste regulations on the books.\textsuperscript{296} Though a specific tracking program is not employed, generators are required to keep records of the volume and types of waste rendered noninfectious on-site.\textsuperscript{297} Even so, medical waste from as far away as New York has been dumped illegally in Massachusetts municipal landfills.\textsuperscript{298}

Moreover, like all states, Massachusetts faces the unique problems caused by individual sources of medical waste. The town of Stoughton, for instance, grappled with the problem of residents who throw used syringes away in household garbage.\textsuperscript{299} As with most municipalities, the town was unable to process the medical waste due to the risk to employees and did not have the resources to otherwise provide for proper disposal.\textsuperscript{300} The only remaining option was the sale of plastic containers designed for medical waste. The cost of disposal is included in the price of the containers and residents can return them to the place of purchase, which will then pay a company to haul the waste away.\textsuperscript{301} This option, adopted by many municipalities, ignores the needs of those who cannot afford the container (usually $10) and shut-ins who cannot travel to the place of purchase.\textsuperscript{302}

3. Medical Waste as Interstate Commerce: Constitutional Complications. The Commerce Clause of the U.S. Constitution\textsuperscript{303}

\textsuperscript{294} Id. § 444.646(2).
\textsuperscript{295} Battle, supra note 13, at 565 (observing that "[o]bviously, the variation in regulatory stringency can lead to forum shopping where generators search for the least expensive and least stringent state in which to dispose of their waste").
\textsuperscript{296} 105 MASS. CODE REGS. §§ 480.010-.700 (1992).
\textsuperscript{297} Id. § 480.400.
\textsuperscript{298} See Bradford L. Miner, Medical Waste Discovered at Barre Landfill, WORCESTER TELEGRAM & GAZETTE, Mar. 4, 1996, at B1 (discussing medical waste disposal).
\textsuperscript{299} Vicki Ritterband, Selectmen Seek Disposal Plan for Used Syringes, Medical Waste, PATRIOT LEDGER, May 1, 1996, at 16A.
\textsuperscript{300} Id.
\textsuperscript{301} Id.
\textsuperscript{302} Id.
\textsuperscript{303} U.S. CONST. art. I, § 8, cl. 3.
has substantial effects on state and local medical waste regulation. The Commerce Clause states that Congress has the sole power to regulate commerce among the several states. The "Dormant" Commerce Clause prohibits a state from curtailing commerce purely to advance the state's own interests. Various cases have addressed the constitutionality of out-of-area waste bans in state statutes and local ordinances to determine whether they substantially affect interstate commerce and consist of simple economic protectionism.

The problem of interstate dumping of medical waste is a serious one since states with less stringent standards cannot otherwise protect themselves from the importation of out-of-state wastes. For instance, in *BFI Medical Waste Systems v. Whatcom County*, the Ninth Circuit held that a Washington State county ordinance prohibiting disposal of infectious medical waste from outside sources

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304 Id.
305 See the case of *City of Philadelphia v. New Jersey* where New Jersey statute closed its borders to outside waste, other than waste allowed by State Environmental Protection Commissioner. 437 U.S. 617, 629 (1978). Landfill operators and cities in other states brought suit, attacking the statute and regulations on constitutional grounds. *Id.* The U.S. Supreme Court ruled that the statute was per se invalid because New Jersey discriminated against articles of interstate commerce without reason to treat them differently, other than the fact that they were from out of state. *Id.* According to the Court, there is no way to distinguish in-state and out-of-state waste: "If one is inherently harmful, so is the other." *Id.* See also Menicucci & Coon, supra note 50, at 555 (discussing Commerce Clause implications). Menicucci and Coon note:

> Where simple economic protectionism is effected by a state political subdivision, a virtual per se rule of constitutional invalidity has been applied. Where other legislative objectives, such as the health and safety of state citizens, forms [sic] the basis of the ordinance, and there is no patent discrimination against interstate trade, the court may apply the balancing test set forth in *Pike v. Bruce Church, Inc.* Under the *Pike* balancing test, the court must determine whether the ordinance (1) effectuates a legitimate local public interest, (2) has only an incidental effect on interstate commerce, and (3) does not impose a burden on commerce that is clearly excessive in relation to the putative local benefits.

*Id.*


307 983 F.2d 911 (9th Cir. 1993).
was per se unconstitutional. This follows accepted law among the federal courts, which have almost uniformly held similar prohibitions on the interstate transport of wastes to be violative of the Commerce Clause.

However, the Fourth Circuit upheld a similar ordinance in *Medical Waste Associates v. Mayor of Baltimore*, which was decided seven weeks after the Supreme Court decided *Fort Gratiot*. Although some commentators believe the decision was erroneous in light of the Supreme Court's reasoning in *Fort Gratiot*, the court found a "single facility" exception to the per se unconstitutionality rule. The court then utilized the *Pike* balancing test, finding that: (1) the ordinance furthered a legitimate public interest (compliance with state emergency regulations and prevention of improper medical waste disposal in the area), and (2) there was no burden on interstate commerce because the ordinance only restricted disposal at one facility. Nevertheless, the Supreme Court decision in *Fort Gratiot* still holds such ordinances per se unconstitutional as local economic protectionism.

The "Dormant" Commerce Clause challenges to local ordinances and state statutes prohibiting out-of-area medical waste provide examples of the complications that arise when states and localities are left to regulate medical waste on their own. These inconsistencies are evidence of the need for a uniform federal system of medical waste regulation. Only uniform federal regulation can solve the myriad problems concerning medical waste on a nationwide scale.

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308 Id. at 913.
311 Id. at 151 (discussing exclusion of out-of-state waste).
312 See Menicucci & Coon, supra note 50, at 556 (summarizing Medical Waste Assocs.).
313 See supra note 309 and accompanying text.
Numerous government agencies and private entities have created proposals for reform of current medical waste disposal regulation. Although these proposals provide diverse solutions to the problem of medical waste disposal, they find common ground in the goal of uniform federal regulation.

A. THE PRIVATE RESPONSE

1. Underwriters Laboratories. Perhaps the most recent substantial proposal for medical waste regulation reform comes from Underwriters Laboratories. Underwriters Laboratories (UL) is a private company, which provides product compliance standards to manufacturers, consumers, and regulating bodies. In October 2003, the company proposed UL 2334 as the standard with which to evaluate new treatment options for medical waste. The proposed disposal standard examined alternatives to incineration and landfill disposal of medical waste. The proposal covered all methods of microbial inactivation through the use of heat from chemicals and irradiation.

The UL proposed draft standard failed to receive the majority of approval votes required by its members for acceptance as the standard for alternative treatment of medical waste. Thus, the members declined the measure, and UL has not undertaken further standards development work.

2. Health Care Without Harm. Health Care Without Harm (HCWH) is a nonprofit organization dedicated to transforming the health care industry “so it is no longer a source of environmental

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316 See id. at 1 (discussing scope of treatment technologies).
317 See id. at 7–8 (discussing biological indicators).
harm by eliminating pollution in health care practices without compromising safety or care.” The two problem areas in hospital waste on which HCWH focuses are toxicity of waste and volume of waste. The organization is opposed to incineration because, according to its research, MWIs are the third largest known source of U.S. dioxin air emissions and produce about 10% of U.S. mercury emissions. Also, many MWIs burn readily recyclable items. The group documents a list of “problem products” that should be avoided, including polyvinyl chloride (PVC) products. Some examples include I.V. bags, blood bags, and even some sharps containers. Mercury-containing products are also “problem products” according to the group.

In order to quell today’s medical waste problem, HCWH has introduced various opportunities for the use and reuse of alternative products in health care. The organization recommends practicing “dioxin- and mercury-free medicine.” It also recommends environmentally sound procurement policies, minimization of packaging, utilization of reusables instead of disposables, recycling, ongoing “red bag” reduction education, waste segregation, and nonincineration treatment technologies for all wastes.

In addition to these proposed reforms, HCWH also monitors the actions of America’s largest off-site medical waste treatment

company, Stericycle. HCWH attempts to ensure that Stericycle complies with its mission: "to be the leading company dedicated to the environmentally responsible management of infection control and compliance services for the health care community." Despite this noble vision, Stericycle has been subject to fines from OSHA in Rhode Island for knowingly exposing workers to potentially dangerous pathogens as well as in Washington State, where three workers developed tuberculosis after contacting medical waste. HCWH monitors Stericycle facilities and educates communities about the company’s practices.

3. The Coalition for Safe Community Needle Disposal. The Coalition for Safe Community Needle Disposal is a nonprofit organization dedicated to promoting affordable needle disposal options that protect waste workers and the public from disease and injury. The Coalition has addressed the problem of the limited options available for disposal of used needles and other sharps outside the health care setting. The group has identified the negative effects of inconsistent laws and regulations governing medical waste, arguing that these laws and regulations, which are primarily designed for health care facilities and medical waste operations, “hinder community efforts to gather and consolidate household sharps for safe disposal as medical waste.” Options for safe syringe and needle disposal are “limited and poorly understood,” and people who give themselves injections outside the

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326 Health Care Without Harm, supra note 320. For more information on Stericycle, see the company’s website, http://www.stericycle.com (last visited Aug. 30, 2006).
329 Health Care Without Harm, supra note 320.
hospital setting receive "limited and often contradictory guidance" on disposal of used sharps. Moreover, because there are criminal penalties for syringe possession for injection drug users, many are unwilling to participate in safe disposal because of the fear of arrest for possession of drug paraphernalia. For all of these reasons, the Coalition urges dramatic reduction of used sharps from community solid waste in order to protect workers and the general public. The Coalition encourages the development of needle disposal programs at the local level by state and local governments, the solid waste industry, the syringe and pharmaceutical industry, pharmacies and pharmaceutical distributors, and health associations.

The Coalition recently worked in conjunction with the EPA to promote alternative disposal methods for used needles and other medical sharps. Previously, the EPA had advised self-injectors to simply "dispose of their used needles in a household container and throw it in the trash when full." After the Coalition realized that most states were using EPA guidelines as their own, however, the group approached the EPA, and the Agency agreed to offer safer solutions to needle disposal. This cooperation between the EPA and the Coalition signals a newfound concern within the EPA that discarded needles and other sharps pose a health risk to both waste workers and the general public. The EPA now encourages alternatives to placing sharps in the trash: for example, it promotes using drop boxes or supervised collection sites at doctors' offices, hospitals, pharmacies, health departments, or fire stations; mail-back programs requiring special containers returned by mail to

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333 Id.
334 Id.
335 See id. (discussing public health problems regarding needle disposal).
336 Id.
338 See id. (discussing new EPA guidelines).
339 Id. The EPA's new recommendations can be found on the EPA website at http://www.epa.gov/epaoswer/other/medical/sharps.htm.
collection sites (fees usually required); syringe exchange programs; and at-home needle destruction devices.  

B. GOVERNMENT RESPONSE SINCE THE MEDICAL WASTE TRACKING ACT

In 2003, the CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) released guidelines for environmental infection control in health care. One section of these guidelines provided recommendations for categories of medical waste as well as for management, treatment, disposal, handling, transportation, and storage of the waste.

1. Current CDC Guidelines. The CDC guidelines first emphasize that the potential adverse health effects from medical waste are rare and overstated. According to the report, there is no evidence suggesting that most hospital waste is any more infective than residential waste. Moreover, no evidence has shown that medical waste disposal practices cause disease in hospitals or the general community, although sharps injuries often occur before disposal.

Even though the guidelines downplay the health risks inherent in medical waste disposal, they do recommend categorizing medical waste in order to determine which items present the highest risk for infection. The term "regulated medical waste" is distinguished from "infectious waste," since not all regulated medical waste is in fact infectious. Following this logic, the guidelines propose that

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342 Id. at IV.
343 See id. at 112 (stating that no epidemiologic evidence suggests waste from health care facilities is any more dangerous a residential waste).
344 Id.
345 Id.
346 See id. at 112–13 (noting that "[t]he most practical approach to medical waste management is to identify wastes that represent a sufficient potential risk of causing infection").
347 See id. at 113 (discussing categories of medical waste).
it is neither practical nor necessary to treat all items having contact with blood as "infective."\(^{348}\)

The CDC and HICPAC also provided guidelines for the management of medical waste before disposal.\(^{349}\) For most medical waste, a "single, leak-resistant biohazard bag is usually adequate," as long as the bag is sturdy and the exterior is not contaminated.\(^{350}\) Specific procedures for handling sharps are also essential. The guidelines recommend "puncture-resistant containers located at the point of use" for all sharps, and needles and other contaminated sharps should not be recapped, bent, or broken by hand.\(^{351}\)

The CDC guidelines also cover the various treatment methods and discuss whether certain waste should be destroyed on-site. According to the agency, the purpose of medical waste treatment is to reduce the microbial load of the waste and to render byproducts of the waste safe for further handling and disposal.\(^{352}\) The waste need not all be rendered sterile in the treatment process, however, because it will not always be deposited in a sterile site.\(^{353}\) Whether infectious microorganisms should be decontaminated on- or off-site depends on which biosafety level they belong to.\(^{354}\) Certain "select agents" that pose a serious threat to public health and safety must be destroyed on-site before disposal.\(^{355}\) These include certain viruses (e.g., Ebola viruses, herpes B virus, smallpox virus, Lassa fever virus), bacteria, fungi, toxins, genetic elements, recombinant nucleic acids, and recombinant organisms.\(^{356}\) Surprisingly, the guidelines are extremely lenient in allowing the discharge of blood and other fluids into sanitary sewers or septic tanks.\(^{357}\) Contents of vessels that contain over a few milliliters of blood can be inactivated in accordance with state regulations or "carefully poured down a utility

\(^{348}\) Id.

\(^{349}\) Id.

\(^{350}\) See id. (discussing medical waste storage).

\(^{351}\) See id. (noting methods to prevent contamination).

\(^{352}\) Id.

\(^{353}\) Id.

\(^{354}\) See id. at 113–14 (noting different categories of waste pose varying levels of risk for infectious disease transmission).

\(^{355}\) See id. at 114 (discussing federal regulations for laboratories).


\(^{357}\) CDC GUIDELINES, supra note 341, at 116.
sink drain or toilet. . . . No evidence indicates that bloodborne diseases have been transmitted from contact with raw or treated sewage. Thus, disposing blood and other body fluids into the sanitary sewer is considered a safe disposal method, and disposal into septic tank systems appears to be equally safe.

2. **CDC Recommendations.** The CDC and HICPAC also released recommendations concerning regulated medical waste. The first recommendations concern treatment and disposal of regulated medical wastes. Already required by law under Category I.C is "a plan for the collection, handling, predisposal treatment, and terminal disposal of regulated medical wastes." However, the CDC and HICPAC recommend designating "a person or persons to be responsible for establishing, monitoring, reviewing and administering the plan." They also recommend following the precautions for treating microbiological wastes for biosafety level three and four laboratories, as well as for select agents that the Department of Health and Human Services regulates. The recommendations also favor on-site inactivation of microbial cultures and stocks in biosafety levels one and two laboratories rather than packaging and shipping such wastes for off-site treatment and disposal. Finally, they allow disposal of blood and other fluids into sanitary sewers as long as these fluids meet local sewage discharge requirements and the state accepts such method of disposal (Category II).

The CDC and HICPAC also made valuable recommendations concerning the handling, transporting, and storing of regulated medical wastes. The recommendations support compliance with

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358 Id.
359 See CDC GUIDELINES, supra note 341, at 117 (rating recommendations according to various categories: Category I.A: strongly recommended and strongly supported by evidence; Category I.B: strongly recommended and supported by certain evidence and strong theoretical rationale; Category I.C: required by state or federal regulation or representing established standard; Category II: suggested for implementation and supported by suggestive clinical or epidemiological studies or theoretical rationale).
360 Id. at 143.
361 See id. (applying to Category II).
362 Id. at 144 (citing 42 C.F.R. § 73.6 (2005)).
363 Id.
364 Id.
365 Id. at 143.
the OSHA requirements for safe handling of medical waste. For example, the recommendations encourage informing "personnel involved in the handling and disposal of potentially infective waste" of the health and safety risks involved and ensure training of that personnel in the appropriate methods of handling and disposal (Category I.C). The recommendations also encourage compliance with state and local regulations pertaining to the storage of medical wastes awaiting treatment in ventilated areas "inaccessible to vertebrate pests" and using waste containers that "prevent the development of noxious odors." If treatment options are not available on-site, they recommend transporting medical waste in "closed, impervious containers" to the treatment facility (Category I.C).

Another important area of recommendations concerns proper sharps disposal strategies. The CDC and HICPAC recommend compliance with OSHA regulations in this arena. Their recommendations focus on three areas: (1) using sharps containers capable of maintaining impermeability after waste treatment to avoid injury during final disposal; (2) placing disposable syringes with needles into puncture-resistant containers "located as close as possible to the point of use"; and (3) not bending, recapping, or breaking used syringe needles before discarding them into a puncture-resistant container (Category I.C).

Lastly, the CDC and HICPAC also recommend special precautions for wastes generated during care of patients with rare diseases. Federal regulation for such wastes is lacking, and the states provide little guidance concerning care of patients with rare diseases.

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366 See id. (citing 29 C.F.R. § 1910.1030(g)(2)(i) (2005)).
367 Id. at 144 (applying to Category I.C).
368 Id.
369 See id. at 143–44 (citing 29 C.F.R. § 1910.1030(d)(4)(iii)(A) (2005)).
370 Id. at 144.
371 Id.
C. THE ACADEMIC RESPONSE

After the beach wash-ups of medical waste in the late 1980s, many legal professionals began to examine the deficiencies of medical waste regulation. Several commentators have criticized the patchwork system of medical waste regulation since the MWTA expired. However, legal scholarship has practically ignored the issue of medical waste regulation in recent years. It is important to examine the complaints and proposals for reform that legal professionals presented after the MWTA, since the federal government has taken little action since then to improve the situation.

Some of the best legal analysis of the medical waste regulation problem surrounds the decision in the 1993 Second Circuit case, United States v. Plaza Health Laboratories, Inc. In that case, the co-owner of Plaza Health, Geronimo Villegas, had placed containers full of vials of blood outside his condominium along the Hudson River in New Jersey. He placed two containers within the crevice of a bulkhead below the high tide line. The vials of blood were eventually found in New York by a group of school children on a field trip. Some were found to be infected with the hepatitis B virus. A suit was brought against Villegas for violation of the CWA, which provides that it is an offense for any person to discharge a pollutant into navigable waters from a point source without a permit. On appeal, a Second Circuit panel found that

372 See, e.g., MacKnight, supra note 63 (criticizing system of medical waste regulation); Martini, supra note 39 (same); O'Connell, supra note 24 (same); Reitze & Stagg, supra note 21 (same); Shumaker, supra note 10 (same).
373 3 F.3d 643 (2d Cir. 1993).
374 Id. at 644.
375 Id.
376 Id.
377 Id.
a person cannot be considered a point source for purposes of the statute, thus releasing Mr. Villegas from criminal liability.\footnote{See Plaza Health Lab. Inc., 3 F.3d at 649 (dismissing prosecutions against Villegas).}

Unfortunately, the decision in \textit{Plaza Health} was a blow to the enforcement of medical waste regulation. One critic opined:

\begin{quote}
From a medical waste perspective, finding Villegas liable is also important since the CWA is one of a few federal statutes under which the illegal disposal of medical waste can be prosecuted. The CWA not only protects the integrity of water, but also prevents beach wash-ups of medical waste since there is no federal law dealing primarily with the disposal of medical waste. The high-risk nature of infectious medical waste should make prosecution for noncompliance attractive.\footnote{See, e.g., Robin L. Greenwald, What's the "Point" of the Clean Water Act Following United States v. Plaza Health Laboratories, Inc.?: The Second Circuit Acts as a Legislator Rather than as a Court, 60 BROOK. L. REV. 689 (1994) (criticizing Plaza Health decision).}
\end{quote}

Other authors have also criticized the \textit{Plaza Health} decision, not as a failure to take advantage of the rare opportunity to regulate the potential dangers of medical waste, but as an erroneous interpretation of the CWA.\footnote{See, e.g., O'Connell, supra note 24, at 1874 (discussing lack of guidance in medical waste management).}

More importantly, academic analysis has focused our attention on the problems associated with the inconsistent patchwork of regulatory response to the medical waste problem. Analysts have long complained of the lack of uniformity in the definition of medical waste, the lack of national standards, and the problems associated with compliance with a "cornucopia of regulations."\footnote{Ann M. Babigian, Note and Comment, Medical Waste, Loaded Gun on the Verge of Firing: United States v. Plaza Health Laboratories, Inc., 13 PACE ENVTL. L. REV. 1063, 1099–1100 (1996).} When developments in medical waste regulation gathered momentum in the 1990s, legal professionals analyzed the changes and their prospective effects and advocated for reform. One area of resulting change occurred within the EPA. Congress amended the Clean Air Act to regulate the air pollution emissions of hospital/medical/in-
fectious waste incinerators, requiring the EPA to establish emission
guidelines for MWIs. \textsuperscript{384} The EPA failed to promulgate regulations
in a timely manner and the Natural Resources Defense Council sued
the Agency. \textsuperscript{385} The lawsuit led to the establishment of a final rule
for incinerators, establishing federal guidelines for emissions. \textsuperscript{386}

Another area of concern for academics today has been the ad hoc
legislation driven by intermittent public fervor about medical waste
when a reasoned response to the problem is needed. Legislation
should be scientifically based rather than motivated by public outcry
and directed not only at hospitals but also at smaller medical waste
generators, such as in-home health care and illegal intravenous
drug use. \textsuperscript{387} The MWTA failed to address in-home care or illegal
drug use, both of which contribute substantially to the problems
surrounding medical waste. \textsuperscript{388} Others have downplayed the problem
of "hospital waste" and called for lawmakers to focus on the more
dangerous sources of infectious waste such as homes, illegal drug
use, and small clinics. \textsuperscript{389} The focus of sensible, comprehensive
reform should be on the victims and on the sources of improper
medical waste disposal, rather than on dramatic views of waste
washed up on beaches. \textsuperscript{390} Citizens should direct public pressure
concerning the dangerousness of medical waste to often forgotten
sources—primarily homes or illegal drug users. \textsuperscript{391} Aesthetics aside,
perhaps the public hysteria about beach wash-ups of medical waste
was largely unfounded. \textsuperscript{392}

\textsuperscript{384} Reitze & Stagg, supra note 21, at 793 (citing 42 U.S.C. § 7429 (1994)).
\textsuperscript{385} Id. at 794–95 (citing Natural Res. Def. Council v. EPA, Nos. CV-92-2093 & CV-93-0284
(E.D.N.Y. Apr. 15, 1996)).
\textsuperscript{386} See Standards of Performance for New Stationary Sources and Emission Guidelines
for Existing Sources: Hospital/Medical/Infectious Waste Incinerators, 40 C.F.R. § 62 (2000)
(providing source performance standards and emission guidelines).
\textsuperscript{387} See Martini, supra note 39, at 207–16 (blaming public fervor for ad hoc legislation and
calling smaller medical waste generators "the blameworthy sources").
\textsuperscript{388} Id. at 216.
\textsuperscript{389} See, e.g., MacKnight, supra note 63, at 835–36 (finding homes and illegal drug users
most responsible for beach wash-ups).
\textsuperscript{390} Cf. id. (recognizing most beach wash-ups are nonmedical waste).
\textsuperscript{391} Id.
\textsuperscript{392} Id. at 787.
D. A NECESSARY AND COMPREHENSIVE RESPONSE

The need for uniform federal regulation of medical waste is manifest. Congress recognized this when it passed the MWTA, but unfortunately its efforts have been derailed by a loss of enthusiasm and well-organized opposition.

Since the passage of the MWTA, state regulation of medical waste has increased and the need for federal leadership has grown as well. A waste transporter conducting business across state lines now faces numerous, potentially conflicting, medical waste regulations with which it must comply. Variations in regulatory stringency among the states can also lead to forum shopping with less stringent states becoming dumping grounds for their neighbors. While many states have adopted tracking programs, their effectiveness is undercut by the inability to track wastes across state boundaries, both due to a lack of uniformity in tracking methods and the inability of states to enforce regulations beyond their borders. Finally, individual generators of medical waste, including diabetics and intravenous drug users, are almost always overlooked by state programs. The absence of appropriate disposal methods for these sources results in billions of sharps discarded in municipal trash bins each year, which endangers waste disposal workers every day.

For these reasons, a federal system of medical waste regulation should provide a uniform definition; minimum standards for handling, disposal, and treatment; nationwide uniform tracking; a regulatory framework for individual sources of medical waste; and civil and criminal liability for individuals who violate certain medical waste regulations.

1. Uniform Definition of Medical Waste. Almost all commentators on the subject agree that the federal government should provide a uniform definition of medical waste. The lack of a standard definition is an important cause of inconsistencies among the states and contributes to many of the interstate enforcement problems. Indeed, one of the primary reasons that the data on medical waste is so incomplete stems from the fact that we cannot measure what we cannot describe (or at least agree on how to describe).
Promulgating a uniform definition of medical waste will not be a simple task. The EPA noted that its definition under the MWTA was the subject of considerable inquiry by the regulated community. For instance, many regulatees questioned the status of items generated by a patient that are unrelated to medical care. This evinces both a desire to comply and illustrates the complexity of the issue. If there was not so much confusion, a uniform definition might not be necessary.

2. Minimum National Standards for Handling, Disposal, and Treatment. As in the MWTA, the federal government should promulgate minimum standards for the handling and disposal of medical waste. These standards must cover the basics of safe handling, including segregation of wastes, packaging, storage, labeling, and transportation. While states will be free to expand on these requirements, by insuring that minimum standards are adopted by the least stringent states, the EPA can help prevent waste handlers from shopping for cheaper dumping grounds.

Minimum standards should not constrain the regulated community to a particular technology but rather should encourage research and development of new methods for dealing with medical waste. Indeed, by making it more difficult to send wastes to an out-of-state landfill, these standards should result in renewed efforts to find better alternatives. Thus, provisions should be included that address the method by which generators may request evaluation and certification of new technologies for waste disposal.

While the EPA and CDC have made some progress in promulgating standards for medical waste handling, disposal, and treatment, more interagency cooperation is necessary for an effective, comprehensive solution. First, different agencies should simplify the regulations by using the same terminology when describing categories of medical waste. Today, there is an unfortunate diversity of terminology, from "biosafety levels" to "risk groups." The federal government should adopt uniform

\[392\] EPA SECOND INTERIM REPORT, supra note 28, at 26.
\[394\] Id.
\[396\] CDC GUIDELINES, supra note 341, at 114.
terminology based on the four “risk groups” of the EPA, which focus on the relative ability of microorganisms to cause injury through disease.\textsuperscript{397} In this way, dangerous medical waste can be distinguished from harmless waste materials.

Moreover, the government should require systems of protection from the dangers of infectious medical waste in health care facilities and should promote general awareness of such dangers. As recommended by the CDC, each health care facility should have a designated person responsible for the facility’s medical waste plan. This person should be responsible for monitoring, administering, and reviewing the plan, as well as for training and educating workers who will come into contact with medical waste. Regulations should also require training and education for all health care personnel who deal with medical waste. Such training must involve the appropriate methods for handling and disposing of waste, as well as education concerning all potential health and safety risks involved in handling medical waste. Designated medical waste specialists in each facility must teach new employees the proper procedures for spills, exposures to infection, and other medical waste emergencies, and these procedures should also be available in employee handbooks.

Additionally, the federal government should implement uniform federal regulation concerning safe storage of medical waste prior to treatment. The regulations should include time limits for storage of infectious medical waste before treatment. They should also follow CDC recommendations for safety and protection from pests and temperature changes.

Finally, in order to achieve compliance with medical waste regulations, there must be incentives for health care facilities. The federal government could provide tax incentives for health care providers that practice safe medical waste handling, disposal, and treatment. Incentives should be available for hospitals that minimize packaging (within federal requirements), practice safe recycling and re-use methods, and practice nonincineration treatment technologies for all wastes. The government should award grants to facilities that transition from incineration to

\textsuperscript{397} Id.
alternative, safer methods of medical waste treatment. Also, regulatory agencies should strictly enforce existing incineration requirements under the Clean Air Act. Lastly, agencies should publish reports of medical waste-related violations by health care facilities each year so that surrounding residents are aware of the problems in their communities.

3. Nationwide Uniform Tracking. The government should adopt a nationwide program for the tracking of medical waste. This program could be based on the tracking provisions of the MWTA with specific changes. While states may design their own tracking forms, the preliminary section of all forms should be the same for all of the states. A uniform tracking form would insure that transporters record necessary information, including the names and addresses of all parties coming into contact with the waste. The tracking forms should be simple, easy to use, and convenient for medical waste transporters in order to avoid slowing the safe and efficient transportation of medical waste.

Unlike when the MWTA, all handlers and generators of medical waste should be potentially responsible for ultimate disposal. While the generator could still retain the primary responsibility for notifying government officials when waste goes missing, regulations should not completely absolve other handlers. Generators who produce small amounts of waste (e.g., fifty pounds per month) may be exempt from the tracking forms, but regulations should still call for those producers to keep a log of waste shipments. Federal regulations should then require transporters who accept waste from these small producers to initiate tracking.

4. Federal Regulation of Individual Sources. Importantly, the federal government should break its long-standing regulatory silence on the issue of individual sources. In-home care and illegal intravenous drug use have traditionally been areas left to the states and localities, but the problems associated with these sources of medical waste signal a need for uniform regulation at the national level. The federal government has largely ignored individual sources in its regulation of medical waste, but it is clear that the

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398 49 C.F.R. § 173.134(b)(10)(v) (2002) (noting EPA regulations for transport of medical waste do not address waste generated from households, which must be transported in
dangers of continued ignorance of such a prevalent source of waste, particularly used sharps, warrant federal regulation.

In response to this growing concern, the government should provide alternative disposal options for used sharps in order to avoid today’s common practice of unsafe disposal in the household trash. Although the EPA has worked in conjunction with the Coalition for Safe Community Needle Disposal, its goal should not be to merely “promote” alternative disposal methods for used needles and other sharps but to create official regulation and requirements for disposal. Also, since people who self-inject often receive limited guidance on disposal of used sharps, the government should provide greater education on safe methods of disposal.

There are several viable options for federal action. As with glass bottles and other recyclables, the government could place a redemption value on used sharps. Although this could have the unfortunate effect of increasing exposure among scavengers who will attempt to collect these items, more likely it will remind home users to bring their old needles in when purchasing new ones. The government could also initiate a national registry for home users of sharps. In order to purchase the items, one would be required to present an identification number, and those who do not have an account “credit” of returned sharps would not qualify for a discount. Alternatively, federal law could require that the purchase of sharps requires a concurrent purchase of a biohazard box for the safe collection of used sharps. Such boxes are already in use in some municipalities and come with the guarantee that when returned to the place of purchase they will be disposed of properly.

There are many options for possible collection sites of home medical waste. Existing hazardous waste dropoff sites, hospitals, pharmacies, and nursing homes are all viable possibilities. Private entities could be enticed to provide the service through financially attractive tax breaks. In order to reach shut-ins, mobile collection units could be organized to visit remote neighborhoods. Intravenous drug users could be reached through needle exchange programs and collection sites in underprivileged areas. Still other options for alternative disposal include mailback programs and at-home needle
destruction devices. A safe, well-organized and easy to understand mailback program for used sharps would be effective for the elderly and others who may be unable to travel to the nearest collection site. The government could also approve at-home needle destruction devices that are safe and easy to use. With these programs in place and available to all in-home users, the government could assess fines for people who continue to knowingly dispose of needles and other sharps in the household trash, or who illegally dump used sharps.

Public outreach and education should be another priority in addressing the problem of individual sources. Under the MWTA, the EPA developed materials on proper disposal techniques for sharps used in self-care, but these brochures were only distributed to persons in the five covered states. The government needs to do far more to educate the public on safe handling procedures. Moreover, agencies tasked with educating the public need to produce a diverse array of materials to insure that persons of differing language and literacy skills will understand. Preferably, those agencies should distribute such materials to health care providers, pharmacies, and the media.

Despite these aggressive recommendations for reform, federal regulation of medical waste need not incur oppressive expenses. Much of what is needed can be accomplished through existing facilities and methods of state enforcement. The primary goal is to insure uniformity and consistency in order to remedy the factors currently militating against effective state enforcement of medical waste regulation.

5. Civil and Criminal Liability for Medical Waste Law Violators. Finally, in order to provide consistent and uniform enforcement of medical waste regulations, violators must be held liable for the damage they cause. In serious cases, violators should be criminally prosecuted. Strict penalties should be assessed in order to deter violations of medical waste regulations.

Civil liability should be imposed when individuals, health care providers, and treatment companies violate medical waste regulations. The government should create a system of fines against

399 EPA SECOND INTERIM REPORT, supra note 28, at 17.
health care facilities for violations of handling or disposal regulations. The government should also assess fines for egregious violations of tracking requirements, including large fines against treatment companies for violations of treatment standards, particularly Clean Air Act violations by operators of MWIs. Individuals should receive fines for disposing of used sharps and other potentially dangerous in-home medical waste in the household trash.

As a last resort, criminal liability should attach to especially egregious violations of medical waste regulations. The decision in United States v. Plaza Health Laboratories, Inc. demonstrates the current difficulties in holding someone criminally liable for medical waste violations, even when that person knowingly endangers the environment and public health. New enforcement regulations should provide criminal liability for such actions. The government should focus on persons who "knowingly" violate medical waste regulations when assessing criminal penalties. Particularly, regulations should criminalize illegal dumping of medical waste with large fines and potential imprisonment. Such criminal provisions should include illegal dumping of syringes used for illegal drugs. Also, knowing violations of treatment standards and especially egregious violations of tracking requirements (e.g., "knowingly" making false statements on tracking forms) should warrant criminal liability.

The presence of severe civil and criminal penalties for violating medical waste regulations will serve to prevent medical waste disasters from occurring. Only with enforcement options will medical waste regulation be truly effective. Thus, a system of strict penalties is an important component to solving the medical waste problem.

IV. CONCLUSION

The problems inherent in medical waste disposal are not new but nonetheless continue to persist and have never been adequately

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400 3 F.3d 643, 650 (2d Cir. 1993) (acquitting violator of criminal liability for dumping vials of blood in waterway due to ambiguities in CWA).
addressed. Intermittent public outcry in response to national news events like Hurricane Katrina or needles washing up on East Coast beaches appears to influence regulators, politicians, and the public far more than actual science does. There must be consistent federal regulation of medical waste if we are ever to systematically address our scattered patchwork of laws and regulations. A uniform approach will be far more effective at avoiding future tragedies than the haphazard state and federal efforts that have been put forth so far. If we do not address this issue in a uniform manner today, the problem will only grow worse tomorrow.