Report for H.R.3515 Medical Waste Tracking Act of 1988
As finally approved by the House and Senate (Enrolled), AT THE SECOND SESSION
Complete Text of this version

H.R.3515
One Hundredth Congress of the United States of America
AT THE SECOND SESSION
Begun and held at the City of Washington on Monday,
the twenty-fifth day of January, one thousand nine hundred and eighty-eight

An Act

To amend the Solid Waste Disposal Act to require the Administrator of the Environmental Protection Agency to promulgate regulations on the management of infectious waste.

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Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.
This Act may be cited as the "Medical Waste Tracking Act of 1988".

SEC. 2. TRACKING OF MEDICAL WASTE.
(a) Amendment of Solid Waste Disposal Act.--The Solid Waste Disposal Act is amended by adding the following new subtitle at the end:

"Subtitle J--Demonstration Medical Waste Tracking Program

"SEC. 11001. SCOPE OF DEMONSTRATION PROGRAM FOR MEDICAL WASTE.

"(a) Covered States.--The States within the demonstration program established under this subtitle for tracking medical wastes shall be New York, New Jersey, Connecticut, the States contiguous to the Great Lakes and any State included in the program through the petition procedure described in subsection (c), except for any of such States in which the Governor notifies the Administrator under subsection (b) that such State shall not be covered by the program.

"(b) Opt Out.--(1) If the Governor of any State covered under subsection (a) which is not contiguous to the Atlantic Ocean notifies the Administrator that such State elects not to participate in the demonstration program, the Administrator shall remove such State from the program.

"(2) If the Governor of any other State covered under subsection (a) notifies the Administrator that such State has implemented a medical waste tracking program that is no less stringent than the demonstration program under this subtitle and that such State elects not to participate in the demonstration program, the Administrator shall, if the Administrator determines that such State program is no less stringent than the demonstration program under this subtitle, remove such State from the demonstration program.

"(3) Notifications under paragraphs (1) or (2) shall be submitted to the Administrator no later than 30 days after the promulgation of regulations implementing the demonstration program under this subtitle.

"(c) Petition In.--The Governor of any State may petition the Administrator to be included in the demonstration program and the Administrator may, in his discretion, include any such State. Such petition may not be made later than 30 days after promulgation of regulations establishing the demonstration program under this subtitle, and the Administrator shall determine whether to include the State within 30 days after receipt of the State's petition.

"(d) Expiration of Demonstration Program.--The demonstration program shall expire on the date 24 months after the effective date of the regulations under this subtitle.

"SEC. 11002. LISTING OF MEDICAL WASTES.

"(a) List.--Not later than 6 months after the enactment of this subtitle, the Administrator shall promulgate regulations listing the types of medical waste to be tracked under the demonstration program. Except as provided in subsection (b), such list shall include, but need not be limited to, each of the following types of solid waste:

"(1) Cultures and stocks of infectious agents and associated biologicals, including cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures.

"(2) Pathological wastes, including tissues, organs, and body parts that are removed during surgery or autopsy.

"(3) Waste human blood and products of blood, including serum, plasma, and other blood components.

"(4) Sharps that have been used in patient care or in medical, research, or industrial laboratories, including hypodermic needles, syringes, pasteur pipettes, broken glass, and scalpel blades.

"(5) Contaminated animal carcasses, body parts, and bedding of animals that were exposed to infectious agents during research, production of biologicals, or testing of pharmaceuticals.

"(6) Wastes from surgery or autopsy that were in contact with infectious agents, including soiled dressings, sponges, drapes, lavage tubes, drainage sets, underpads, and surgical gloves.

"(7) Laboratory wastes from medical, pathological, pharmaceutical, or other research, commercial, or industrial laboratories that were in contact with infectious agents, including slides and cover slips, disposable gloves, laboratory coats, and aprons.

"(8) Dialysis wastes that were in contact with the blood of patients undergoing hemodialysis, including contaminated disposable equipment and supplies such as tubing, filters, disposable sheets, towels, gloves, aprons, and laboratory coats.

"(9) Discarded medical equipment and parts that were in contact with

infectious agents.

"(10) Biological waste and discarded materials contaminated with blood, excretion, excudates or secretion from human beings or animals who are isolated to protect others from communicable diseases.

"(11) Such other waste material that results from the administration of medical care to a patient by a health care provider and is found by the Administrator to pose a threat to human health or the environment.

"(b) Exclusions From List.--The Administrator may exclude from the list under this section any categories or items described in paragraphs (6) through (10) of subsection (a) which he determines do not pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed.

"SEC. 11003 TRACKING OF MEDICAL WASTE.

"(a) Demonstration Program.--Not later than 6 months after the enactment of this subtitle, the Administrator shall promulgate regulations establishing a program for the tracking of the medical waste listed in section 11002 which is generated in a State subject to the demonstration program. The program shall (1) provide for tracking of the transportation of the waste from the generator to the disposal facility, except that waste that is incinerated need not be tracked after incineration, (2) include a system for providing the generator of the waste with assurance that the waste is received by the disposal facility, (3) use a uniform form for tracking in each of the demonstration States, and (4) include the following requirements:

"(A) A requirement for segregation of the waste at the point of generation where practicable.

"(B) A requirement for placement of the waste in containers that will protect waste handlers and the public from exposure.

"(C) A requirement for appropriate labeling of containers of the waste.

"(b) Small Quantities.--In the program under subsection (a), the Administrator may establish an exemption for generators of small quantities of medical waste listed under section 11002, except that the Administrator may not exempt from the program any person who, or facility that, generates 50 pounds or more of such waste in any calendar month.

"(c) On-Site Incinerators.--Concurrently with the promulgation of regulations under subsection (a), the Administrator shall promulgate a recordkeeping and reporting requirement for any generator in a demonstration State of medical waste listed in section 11002 that (1) incinerates medical waste listed in section 11002 on site and (2) does not track such waste under the regulations promulgated under subsection (a). Such requirement shall require the generator to report to the Administrator on the volume and types of medical waste listed in section 11002 that the generator incinerated on site during the 6 months following the effective date of the requirements of this subsection.

"(d) Type of Medical Waste and Types of Generators.--For each of the requirements of this section, the regulations may vary for different types of medical waste and for different types of medical waste generators.

"SEC. 11004. INSPECTIONS.

"(a) Requirements for Access.--For purposes of developing or assisting in the development of any regulation or report under this subtitle or enforcing any provision of this subtitle, any person who generates, stores, treats, transports, disposes of, or otherwise handles or has handled medical waste shall, upon request of any officer, employee, or representative of the

Environmental Protection Agency duly designated by the Administrator, furnish information relating to such waste, including any tracking forms required to be maintained under section 11003, conduct monitoring or testing, and permit such person at all reasonable times to have access to, and to copy, all records relating to such waste. For such purposes, such officers, employees, or representatives are authorized to--

"(1) enter at reasonable times any establishment or other place where medical wastes are or have been generated, stored, treated, disposed of, or transported from;

"(2) conduct monitoring or testing; and

"(3) inspect and obtain samples from any person of any such wastes and samples of any containers or labeling for such wastes.

"(b) Procedures.--Each inspection under this section shall be commenced and completed with reasonable promptness. If the officer, employee, or representative obtains any samples, prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the sample obtained and, if requested, a portion of each such sample equal in volume or weight to the portion retained if giving such an equal portion is feasible. If any analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge of the premises concerned.

"(c) Availability to Public.--The provisions of section 3007(b) of this Act shall apply to records, reports, and information obtained under this section in the same manner and to the same extent as such provisions apply to records, reports, and information obtained under section 3007.

"SEC. 11005. ENFORCEMENT.

"(a) Compliance Orders.--

"(1) Violations.--Whenever on the basis of any information the Administrator determines that any person has violated, or is in violation of, any requirement or prohibition in effect under this subtitle (including any requirement or prohibition in effect under regulations under this subtitle) (A) the Administrator may issue an order (i) assessing a civil penalty for any past or current violation, (ii) requiring compliance immediately or within a specified time period, or (iii) both, or (B) the Administrator may commence a civil action in the United States district court in the district in which the violation occurred for appropriate relief, including a temporary or permanent injunction. Any order issued pursuant to this subsection shall state with reasonable specificity the nature of the violation.

"(2) Orders assessing penalties.--Any penalty assessed in an order under this subsection shall not exceed $25,000 per day of noncompliance for each violation of a requirement or prohibition in effect under this subtitle. In assessing such a penalty, the Administrator shall take into account the seriousness of the violation and any good faith efforts to comply with applicable requirements.

"(3) Public hearing.--Any order issued under this subsection shall become final unless, not later than 30 days after issuance of the order, the persons named therein request a public hearing. Upon such request, the Administrator shall promptly conduct a public hearing. In connection with any proceeding under this section, the Administrator may issue subpoenas for the production of relevant papers, books, and documents, and may promulgate rules for discovery procedures.

"(4) Violation of compliance orders.--In the case of an order under this

subsection requiring compliance with any requirement of or regulation under this subtitle, if a violator fails to take corrective action within the time specified in an order, the Administrator may assess a civil penalty of not more than $25,000 for each day of continued noncompliance with the order.

"(b) Criminal Penalties.--Any person who--

"(1) knowingly violates the requirements of or regulations under this subtitle;

"(2) knowingly omits material information or makes any false material statement or representation in any label, record, report, or other document filed, maintained, or used for purposes of compliance with this subtitle or regulations thereunder; or

"(3) knowingly generates, stores, treats, transports, disposes of, or otherwise handles any medical waste (whether such activity took place before or takes place after the date of the enactment of this paragraph) and who knowingly destroys, alters, conceals, or fails to file any record, report, or other document required to be maintained or filed for purposes of compliance with this subtitle or regulations thereunder

shall, upon conviction, be subject to a fine of not more than $50,000 for each day of violation, or imprisonment not to exceed 2 years (5 years in the case of a violation of paragraph (1)). If the conviction is for a violation committed after a first conviction of such person under this paragraph, the maximum punishment under the respective paragraph shall be doubled with respect to both fine and imprisonment.

"(c) Knowing Endangerment.--Any person who knowingly violates any provision of subsection (b) who knows at that time that he thereby places another person in imminent danger of death or serious bodily injury, shall upon conviction be subject to a fine of not more than $250,000 or imprisonment for not more than 15 years, or both. A defendant that is an organization shall, upon conviction under this subsection, be subject to a fine of not more than $1,000,000. The terms of this paragraph shall be interpreted in accordance with the rules provided under section 3008(f) of this Act.

"(d) Civil Penalties.--Any person who violates any requirement of or regulation under this subtitle shall be liable to the United States for a civil penalty in an amount not to exceed $25,000 for each such violation. Each day of such violation shall, for purposes of this section, constitute a separate violation.

"(e) Civil Penalty Policy.--Civil penalties assessed by the United States or by the States under this subtitle shall be assessed in accordance with the Administrator's 'RCRA Civil Penalty Policy', as such policy may be amended from time to time.

"SEC. 11006. FEDERAL FACILITIES.

"(a) In General.--Each department, agency, and instrumentality of the executive, legislative, and judicial branches of the Federal Government in a demonstration State (1) having jurisdiction over any solid waste management facility or disposal site at which medical waste is disposed of or otherwise handled, or (2) engaged in any activity resulting, or which may result, in the disposal, management, or handling of medical waste shall be subject to, and comply with, all Federal, State, interstate, and local requirements, both substantive and procedural (including any requirement for permits or reporting or any provisions for injunctive relief and such sanctions as may be imposed by a court to enforce such relief), respecting control and abatement of medical waste disposal and management in the same manner, and to the same

extent, as any person is subject to such requirements, including the payment of reasonable service charges. The Federal, State, interstate, and local substantive and procedural requirements referred to in this subsection include, but are not limited to, all administrative orders, civil, criminal, and administrative penalties, and other sanctions, including injunctive relief, fines, and imprisonment. Neither the United States, nor any agent, employee, or officer thereof, shall be immune or exempt from any process or sanction of any State or Federal court with respect to the enforcement of any such order, penalty, or other sanction. For purposes of enforcing any such substantive or procedural requirement (including, but not limited to, any injunctive relief, administrative order, or civil, criminal, administrative penalty, or other sanction), against any such department, agency, or instrumentality, the United States hereby expressly waives any immunity otherwise applicable to the United States. The President may exempt any department, agency, or instrumentality in the executive branch from compliance with such a requirement if he determines it to be in the paramount interest of the United States to do so. No such exemption shall be granted due to lack of appropriation unless the President shall have specifically requested such appropriation as a part of the budgetary process and the Congress shall have failed to make available such requested appropriation. Any exemption shall be for a period not in excess of one year, but additional exemptions may be granted for periods not to exceed one year upon the President's making a new determination. The President shall report each January to the Congress all exemptions from the requirements of this section granted during the preceding calendar year, together with his reason for granting each such exemption.

"(b) Definition of Person.--For purposes of this Act, the term 'person' shall be treated as including each department, agency, and instrumentality of the United States.

"SEC. 11007. RELATIONSHIP TO STATE LAW.

"(a) State Inspections and Enforcement.--A State may conduct inspections under 11004 and take enforcement actions under section 11005 against any person, including any person who has imported medical waste into a State in violation of the requirements of, or regulations under, this subtitle, to the same extent as the Administrator. At the time a State initiates an enforcement action under section 11005 against any person, the State shall notify the Administrator in writing.

"(b) Retention of State Authority.--Nothing in this subtitle shall--

"(1) preempt any State or local law; or

"(2) except as provided in subsection (c), otherwise affect any State or local law or the authority of any State or local government to adopt or enforce any State or local law.

"(c) State Forms.--Any State or local law which requires submission of a tracking form from any person subject to this subtitle shall require that the form be identical in content and format to the form required under section 11003, except that a State may require the submission of other tracking information which is supplemental to the information required on the form required under section 11003 through additional sheets or such other means as the State deems appropriate.

"SEC. 11008. REPORT TO CONGRESS.

"(a) Final Report.--Not later than 3 months after the expiration of the demonstration program, the Administrator shall report to Congress on the following topics:

"(1) The types, number, and size of generators of medical waste (including small quantity generators) in the United States, the types and amounts of medical waste generated, and the on-site and off-site methods currently used to handle, store, transport, treat, and dispose of the medical waste, including the extent to which such waste is disposed of in sewer systems.

"(2) The present or potential threat to human health and the environment posed by medical waste or the incineration thereof.

"(3) The present and potential costs (A) to local economies, persons, and the environment from the improper handling, storage, transportation, treatment or disposal of medical waste and (B) to generators, transporters, and treatment, storage, and disposal facilities from regulations establishing requirements for tracking, handling, storage, transportation, treatment, and disposal of medical waste.

"(4)(A) The success of the demonstration program established under this subtitle in tracking medical waste,

"(B) changes in incineration and storage practices attributable to the demonstration program, and

"(C) other available and potentially available methods for tracking medical waste and their advantages and disadvantages, including the advantages and disadvantages of extending tracking requirements to (i) rural areas and (ii) small quantity generators.

"(5) Available and potentially available methods for handling, storing, transporting, and disposing of medical waste and their advantages and disadvantages.

"(6) Available and potentially available methods for treating medical waste, including the methods of incineration, sterilization, chemical treatment, and grinding, and their advantages, including their ability to render medical waste noninfectious or less infectious, and unrecognizable and otherwise protect human health and the environment, and disadvantages.

"(7) Factors affecting the effectiveness of the treatment methods identified in subsection (a)(5), including quality control and quality assurance procedures, maintenance procedures, and operator training.

"(8) Existing State and local controls on the handling, storage, transportation, treatment, and disposal of medical waste, including the enforcement and regulatory supervision thereof.

"(9) The appropriateness of using any existing State requirements or the requirements contained in subtitle C as nationwide requirements to monitor and control medical waste.

"(10) The appropriateness of the penalties provided in section 11006 for insuring compliance with the requirements of this subtitle, including a review of the level of penalties imposed under this subtitle.

"(11)(A) The effect of excluding households and small quantity generators from any regulations governing the handling, storage, transportation, treatment, and disposal of medical waste, and

"(B) potential guidelines for the handling, storage, treatment, and disposal of medical waste by households and small quantity generators.

"(12) Available and potentially available methods for the reuse or reduction of the volume of medical waste generated.

"(b) Interim Reports.--The Administrator shall submit two interim reports to Congress on the topics listed in subsection (a). The interim reports shall contain the information on the topics available to the Administrator at the time of submission. One interim report shall be due 9 months after enactment of this subtitle and one shall be due 12 months after the effective date of

regulations under this subtitle.

"(c) Consultation.--In preparing the reports under this section, the Administrator shall consult with appropriate State and local agencies.

"SEC. 11009. HEALTH IMPACTS REPORT.

"Within 24 months after the enactment of this section, the Administrator of the Agency for Toxic Substances and Disease Registry shall prepare for Congress a report on the health effects of medical waste, including each of the following--

"(1) A description of the potential for infection or injury from the segregation, handling, storage, treatment, or disposal of medical wastes.

"(2) An estimate of the number of people injured or infected annually by sharps, and the nature and seriousness of those injuries or infections.

"(3) An estimate of the number of people infected annually by other means related to waste segregation, handling, storage, treatment, or disposal, and the nature and seriousness of those infections.

"(4) For diseases possibly spread by medical waste, including Acquired Immune Deficiency Syndrome and hepatitis B, an estimate of what percentage of the total number of cases nationally may be traceable to medical wastes.

"SEC. 11010. GENERAL PROVISIONS.

"(a) Consultation.--(1) In promulgating regulations under this subtitle, the Administrator shall consult with the affected States and may consult with other interested parties.

"(2) The Administrator shall also consult with the International Joint Commission to determine how to monitor the disposal of medical waste emanating from Canada.

"(b) Public Comment.--In the case of the regulations required by this subtitle to be promulgated within 9 months after the enactment of this subtitle, the Administrator may promulgate such regulations in interim final form without prior opportunity for public comment, but the Administrator shall provide an opportunity for public comment on the interim final rule. The promulgation of such regulations shall not be subject to the Paperwork Reduction Act of 1980.

"(c) Relationship to Subtitle C.--Nothing in this subtitle shall affect the authority of the Administrator to regulate medical waste, including medical waste listed under section 11002, under subtitle C of this Act.

"SEC. 11011. EFFECTIVE DATE.

"The regulations promulgated under this subtitle shall take effect within 90 days after promulgation, except that, at the time of promulgation, the Administrator may provide for a shorter period prior to the effective date if he finds the regulated community does not need 90 days to come into compliance.

"SEC. 11012. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated to the Administrator such sums as may be necessary for each of the fiscal years 1989 through 1991 for purposes of carrying out activities under this subtitle.".

(b) Table of Contents.--The table of contents for the Solid Waste Disposal Act is amended by inserting the following after the items relating to subtitle I:

"Subtitle J--Demonstration Medical Waste Tracking Program

"Sec. 11001. Scope of demonstration program for medical waste.

"Sec. 11002. Listing of medical wastes.
"Sec. 11003. Tracking of medical waste.
"Sec. 11004. Inspections.
"Sec. 11005. Enforcement.
"Sec. 11006. Federal facilities.
"Sec. 11007. Relationship to State law.
"Sec. 11008. Report to Congress.
"Sec. 11009. Health impact report.
"Sec. 11010. General provisions.
"Sec. 11011. Effective date.
"Sec. 11012. Authorization of appropriations.".

SEC. 3. DEFINITION.

Section 1004 of the Solid Waste Disposal Act (42 U.S.C. 6903) is amended by adding the following at the end thereof:

"(40) Except as otherwise provided in this paragraph, the term 'medical waste' means any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. Such term does not include any hazardous waste identified or listed under subtitle C or any household waste as defined in regulations under subtitle C.".

SEC. 4. EPA LAW ENFORCEMENT POWERS.

(a) Conferral of Law Enforcement Powers.--Chapter 203 of title 18, United States Code, is amended by adding at the end the following:

"Sec. 3063. Powers of Environmental Protection Agency

"(a) Upon designation by the Administrator of the Environmental Protection Agency, any law enforcement officer of the Environmental Protection Agency with responsibility for the investigation of criminal violations of a law administered by the Environmental Protection Agency, may--

"(1) carry firearms;

"(2) execute and serve any warrant or other processes issued under the authority of the United States; and

"(3) make arrests without warrant for--

"(A) any offense against the United States committed in such officer's presence; or

"(B) any felony offense against the United States if such officer has probable cause to believe that the person to be arrested has committed or is committing that felony offense.

"(b) The powers granted under subsection (a) of this section shall be exercised in accordance with guidelines approved by the Attorney General.".

(b) Clerical Amendment.--The table of sections at the beginning of chapter 203 of title 18, United States Code, is amended by adding at the end the following:

"3063. Powers of Environmental Protection Agency.".

Speaker of the House of Representatives.

Vice President of the United States and
President of the Senate.