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UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

COMMUNITY AND ECONOMIC
DEVELOPMENT DIVISION

APRIL 5, 1979

B-166506


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The Honorable Douglas M. Costle
Administrator, Environmental
Protection Agency AGC00024

Dear Mr. Costle:

Bck. The General Accounting Office, as part of its continuing assessment of hazardous waste issues, has been reviewing disposal practices for infectious wastes at hospitals, laboratories, and veterinary establishments. However, in view of the Environmental Protection Agency's recent request for comments on proposed hazardous waste regulations, including infectious wastes, and the recent contract award to Enviro Control, Inc. to evaluate the treatment, storage, and disposal methods used for infectious wastes, we have decided to terminate our review and report the findings developed to date.

Rec. Based on the information obtained during this review, ~~we believe~~ the proposed definition of infectious waste could result in government over-regulation. As proposed, much waste will be treated as hazardous even though it does not pose a significant health hazard to those who might accidently come into contact with it. In addition, existing disposal practices for infectious wastes appear adequate and compliance with the proposed changes in the new regulation will be unnecessarily costly and burdensome for health care facilities.

Rec. ~~We believe~~ EPA should revise the proposed infectious waste definition to include only those wastes which, if not properly managed, could result in increased morbidity or mortality. In addition, EPA should consider requiring sterilization of such wastes at the site of generation.

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PROPOSED INFECTIOUS WASTE DEFINITION IS TOO BROAD

The Resource Conservation and Recovery Act of 1976 (RCRA), defines "hazardous waste" as a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may

> "(a) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or
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> "(b) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed."

However, EPA has proposed a regulation which defines infectious hazardous wastes as any waste containing microorganisms or helminths (wormlike organisms) that are listed in Classes 2 through 5 of the Center for Disease Control's (CDC's) Classification of Etiologic (disease causing) Agents and generated by the following hospital departments: obstetrics, including patients' rooms; emergency; surgery, including patients' rooms; morgue; pathology; autopsy; isolation rooms; laboratories; intensive care unit; or pediatrics.

The proposed definition does not consider either an etiologic agent's mode of disease transmission or the severity of the resulting disease. CDC developed this list of etiologic agents as part of its effort to control transmission of diseases for laboratory personnel who work directly with concentrated amounts of these potentially hazardous agents. EPA has, however, taken this same CDC list and used it in the regulations, making it applicable throughout the hospital, in those departments listed above.

Using the CDC list to define as hazardous hospital wastes outside the laboratory is questionable because the the same conditions for disease transmission are not present. In addition, some agents, particularly those in Class 2, do not pose a significant health problem to those who might

accidently come into contact with waste material. Therefore, these agents do not need to be regulated, either because the disease is usually not transmitted this way or because even if one chanced to contract the ailment it is generally mild. The following examples serve to illustrate these points.

> Neisseria gonorrhoea: this is the causative organism of gonorrhoea. It is transmitted only through intimate person to person contact. The bacteria grow only within a narrow temperature range and are rapidly killed by drying or exposure to sunlight.
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> Rhinoviruses: this is a virus group that is believed to be responsible for the common cold. The virus enters through the upper respiratory tract and the resulting symptoms, when they occur, are usually mild.

Another characteristic of these agents, particularly the bacterial agents, is that many are commonly found in the environment. They can often be found on walls, the skin, or in the soil. For example, Escherichea coli, Corynebacterium, diptheriae, streptococci, and staphylococci are all commonly found on the human body. Therefore, it is highly probable that any disposable material from the hospital areas designated in the proposed regulation will contain at least some of these agents. Hospital officials said that it would be impractical to test hospital waste for the presence of all of these micro-organisms and therefore hospitals will have to assume that all hospital wastes are hazardous. This compares with estimates that only 2 to 8 percent of all hospital waste is infectious.

The proposed regulations would require the hospital to (1) annually report the amount of hazardous waste generated, (2) provide a manifest to accompany the waste from the site of generation to the ultimate disposal facility, (3) periodically report on those waste shipments for which a manifest was not returned, and (4) maintain records of all waste generated and its disposition for a period of 3 years. If the hospital disposes of the waste onsite, a permit would also be required. Furthermore, if a landfill is used to dispose of the waste it would have to meet the hazardous waste

landfill standards. EPA is considering designating hazardous infectious waste as a "special waste" and therefore subject to different operating and design criteria than other hazardous wastes.

Considering both the increased volumes of waste which will be treated as hazardous and the new regulatory requirements for handling such wastes, hospital operating costs will probably increase. American Hospital Association officials told us that they estimate the additional cost to comply with the proposed EPA regulation will be about $250 million annually.

CURRENT HOSPITAL INFECTION CONTROL PRACTICES APPEAR ADEQUATE

Medical professionals made a distinction between infection and disease risks within a hospital and those outside a hospital. Several factors are present in a hospital that increase the likelihood that patients or hospital staff may become infected or diseased, including increased

--exposure to pathogenic organisms in the hospital environment because of the number of patients with illnesses such as pneumonia, dysentery, etc.,

--susceptibility to infection because of debilitating disease or weakened physical condition or as the result of the use of certain physical or chemical agents, and

--opportunity for infection because medical procedures that break the skin or otherwise enter the body also provide an entry for pathogens.

Therefore, spreading infection from one patient or staff member to another is a real concern within a hospital, but the general population does not face the same risk.

The hospitals we visited had defined procedures for controlling infection within the hospital. These procedures included waste collection and disposal. Wastes from laboratories are autoclaved (steam sterilized) in the laboratory before disposal, rendering them harmless. Both New Jersey

and Pennsylvania license and inspect laboratories in and out of hospitals. The Joint Commission on Accreditation of Hospitals manual requires laboratory wastes to be autoclaved or incinerated.

Patients with suspected or known communicable diseases are usually separated from other patients. Depending on the nature of the etiologic agent and its mode of transmission, various types of isolation procedures are followed. CDC's publication, "Isolation Techniques for Use in Hospitals," is widely used by hospitals. It provides specific recommendations for disposal of dressings, tissues, syringes, and laboratory specimens. For example, dressings and tissue wastes from patients in strict isolation must be double bagged in impervious bags and incinerated.

TRANSPORTATION AND DISCHARGE PRESENTS NO PROBLEMS

None of the health professionals with whom we spoke could recall any instance of disease being linked to hospital waste. The EPA background document supporting the regulation of hospital waste does not present evidence that hospital wastes have caused disease. The paper merely demonstrates that etiologic agents exist in hospital waste. In addition, EPA hazardous waste division officials said that they have been unable to find any cases where damage was related to the transport or disposal of such wastes.

In a December 18, 1978, publication, EPA stated that some infectious waste disposal may not need the higher standards of a hazardous waste landfill. All that would be necessary is a sanitary landfill. Health professionals we spoke with also believe sanitary landfills are sufficient for the following reasons.

--The chance of groundwater contamination appears minimal. In a study of intestinal viruses in leachate from 22 different landfills, only one leachate sample was positive and this landfill did not contain hospital waste. Moreover, seven of the negative samples were from landfills which contained hospital wastes.

--If the waste is buried and covered and access to the landfill is controlled--two items recommended in EPA's sanitary landfill criteria--the risk of rodents spreading disease or scavengers contracting illnesses is sharply reduced.

VETERINARY HOSPITALS ALSO HAVE CONTROLS

We found infectious waste practices at the University of Pennsylvania School of Veterinary Medicine to be similar to those at hospitals. The Chief of Pathology at the school explained that laboratory wastes are autoclaved, diseased carcasses are incinerated, and precautions are taken with patients to prevent speading infection from animal to animal or to man.

Veterinarians stated that very few animal diseases are contagious to man and the worst of these are controlled by the States or the Federal Government. Federal agencies involved included the Department of Agriculture, the Food and Drug Administration, and the Public Health Service.

CONCLUSIONS AND RECOMMENDATIONS

The CDC Classification of Etiologic Agents was designed for laboratory use and is too restrictive to be used for hospital waste as a whole. We believe that using this same classification to define hazardous infectious waste will result in much waste unnecessarily being treated as hazardous. As a result, complying with the regulation will be costly and administratively burdensome for hospitals. Further, existing disposal practices for infectious wastes appear adequate and we found no evidence demonstrating the spread of disease from wastes that have left a hospital.

Rec To determine what is in fact hazardous and therefore regulated, we recommend that you convene a panel of epidemiological and sanitary experts to develop a list of wastes which are truely hazardous to the community and standards for their control.

The New Jersey Department of Environmental Protection has resolved the problem of controlling hazardous infectious waste by requiring it to be rendered noninfectious onsite.

We believe EPA should consider this approach in developing final regulations. If hazardous infectious wastes were treated onsite, the risk of disease to the general public would be eliminated and the cost and administrative burden associated with controlling such wastes would be minimized.

AGENCY COMMENTS

EPA officials told us that commenting on our recommendations would be premature at this time because EPA is evaluating other comments on the proposed regulations. However, these officials did not dispute our findings.

SCOPE OF REVIEW

Our work included a review of regulations and practices relating to the control of infectious waste in New Jersey and Pennsylvania and in the City of Philadelphia. We interviewed State health and solid waste management officials, EPA hazardous waste division officials, Federal health officials at the National Institute of Health and CDC, representatives of national health associations, University of Pennsylvania epidemiologists, and other health professionals. We also visited three hospitals, an independent medical laboratory, and two veterinary establishments.

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As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the Senate Committee on Governmental Affairs and the House Committee on Government Operations not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

Copies of this letter are being sent to the above committees and will be made available to other interested parties who request them.

Sincerely yours,

Henry Eschwege

Henry Eschwege
Director