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July 27, 1983

ER-73

Fact Sheet on Litigation Pursuant to Human Body Irradiation Program at Oak Ridge

Alvin W. Trivelpiece, Director
Office of Energy Research

The following facts have been prepared to summarize the information relevant to the lawsuit being prepared against the Federal Government (DOE, Department of the Army, and NASA) on behalf of the family of decedent who received medical treatment for acute lymphatic leukemia at the Medical Division of ORAU in July 1964. The lawsuit alleges that the procedures used were inappropriate for the treatment of leukemia, that effective chemotherapy was withheld, and that the claimants were denied information regarding alternative treatment and the hazards of the radiation exposures.

Congressional oversight hearings on this matter before the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology 97th Congress were held on September 23, 1981.

In 1957 under the AEC, the Medical Division of ORAU began a cancer treatment program designed to improve radiation therapies and to assess the health effects of total body irradiation. In 1964, NASA also began providing additional funds to obtain information on the onset of acute radiation sickness. From 1957 to 1974 nearly 200 patients, including , were treated at this facility.

The hearings investigated the allegations that facilities were substandard, that treatments were of little therapeutic value and inferior to other available techniques, that fully informed consent was not given, and finally, that the attempt to gain data for the space program took precedence over proper medical considerations.

The Total Body Irradiation Study at ORAU was initiated with two principal objectives -- the first was to seek information that might lead to improved radiation therapy for leukemias and lymphomas and the second to acquire radiobiologic information.

All patients with these diseases admitted to the Medical Division hospital during this period were considered for this therapeutic program. The diagnoses were established by clinical history, physical examination, and microscopic study of surgical biopsies, bone marrow, and peripheral blood samples. The urgency for treatment was assessed, and those patients whose condition required some other kind of therapy, or no therapy at all, were omitted. If the clinical status was changing rapidly and it was anticipated that other additional treatment might be needed during the postirradiation observation period, these patients were also excluded. If no clearly superior therapy was available for a particular patient and the total-body

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radiation treatment was regarded as an acceptable way of management, the patient was offered this form of treatment, following an explanation of the research protocol. Informed consent was obtained in accordance with ethical practice to protect the rights of the individual as a research subject.

Under an interagency agreement between NASA and AEC, task 9 was begun in 1964 to identify and compile information on effects observed in humans exposed to large doses of ionizing radiation either accidentally or in the course of therapy for disease, and to organize and interpret this information to support NASA's responsibilities for planning and conducting manned space flights. Testimony at the hearings established that NASA's interest in this prospective study was solely in acquiring accurate radiation dose-response data on a non-interference basis from the AEC/ORINS clinical study of the effectiveness of low-level total body radiation in treating persons with certain types of neoplastic diseases (lymphoma, leukemia). No evidence was found that NASA had any role in the selection of patients, selection of therapeutic modality, referral of patients, or any other aspect of the clinical study. NASA was interested only in acquiring data from adult human radiation exposure.

, in the course of his treatment at the Medical Division of ORAU, was treated with several experimental procedures including irradiation of extracted bone marrow, subsequent injection into his mother and reinjection of her serum into him, as well as an experimental total body irradiation in the Medium Exposure Total Body Irradiator. He was then transferred to a second facility -- the Low Exposure Total Body Irradiator -- for intensive monitoring of his acute reactions to the total body irradiation. One witness, Dr. Peter Wiernik of the Baltimore Cancer Research Center, told Gore that the treatment status for leukemia at the time was such that any new treatment could be tried. He had no problem with the treatment, "it was a good idea that didn't work." Besides the scientific and medical experts testifying on the medical need and acceptability of the treatments given, family members of other patients testified that this facility offered their one last hope for saving a relative and also substantiated the quality of good care provided.

After the hearing, in response to questions of reporters, Albert Gore, Jr. stated that he thought that the testimony essentially refuted the charges (The Oak Ridger, September 24, 1981). There has been nothing subsequent to these hearings to alter the situation. This current lawsuit is based on the same information thoroughly and adequately covered in the hearings.

Original signed by
J. W. Thiessen for

Charles W. Edington
Associate Director, Office of
Health and Environmental Research
Office of Energy Research

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