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BRIEFING ON PLUTONIUM PROJECT BY DR. JAMES L. LIVERMAN ON
April 29, 1974

The current inquiry seeks to establish (a) whether any of the 18 plutonium and one americium patients or their next of kin were informed about the nature and purpose of the injections at the time they were given or when the recent follow-up studies were undertaken and (b) to provide incidental background information about the studies, including their justification. Interviews and document searches conducted by personnel from DBER and Division of Inspection have established the following:

A. Reasons for undertaking studies

1. Early period (1945-1947)

a. Documentation.

Several documents (dated 1944 and 1945) dealt with the urgent need for information about the metabolism of plutonium in man and the necessity for initiating tracer experiments in humans.

Wright Langham et al. in document no. LA-1151 dated September 20, 1950, provided the following reasons for injecting the patients and conducting the studies:

"The major health problem associated with plutonium processing is, of course, the possibility that small amounts of plutonium accumulated in the skeletal systems of workers may, over a period of from ten to thirty years, cause bone changes similar to those observed in chronic radium poisoning. The possibility is serious enough to justify the adoption of a rigid maximum permissible body burden as is currently done with radium...

Adequate information as to the fixation and excretion of plutonium by man is essential to the evaluation and interpretation of the maximum permissible body tolerance. More specifically such studies seem highly important for the following purposes:

(1) To minimize the degree of uncertainty inherent in extrapolating the vast amount of experimental data to man.

(2) To provide the best possible quantitative basis for the diagnosis of degree of exposure of personnel to plutonium.

(3) To determine the degree of fixation of plutonium by man and establish criteria for the period of retirement from further exposure of workers having received a maximum permissible dose.

(4) To provide more extensive and quantitative data on the deposition and excretion of plutonium by man as a basis for future consideration of maximum permissible body tolerance.

Need for the above information was recognized several years ago. It was also recognized that such information could be obtained only by administering small tracer amounts of plutonium to persons with a relatively short life expectancy."

b. Interviews

In several interviews, physicians expressed the opinion that the studies were undertaken because of uneasiness over extrapolating animal (principally rodent) excretion data to man. The excretion data was of great concern because it was essential to the estimation of body burdens, a vital factor in the control of occupational exposures. The uneasiness was justified by the much greater

retention of plutonium in man than in rodents.

2. Recent period

a. Excretion curves

For more than 25 years, estimates of body burdens of plutonium have been based on the early data collected from the injected patients. The recent information obtained from the survivors permits a more accurate construction of the tail of the excretion curve.

b. Exhumation program

Exhumed bodies were to be studied in order to provide information on late patterns of plutonium deposition in human bone. They would also provide measurements of residual body content of plutonium. Both types of information are contingent upon adequate preservation of the bodies.

B. Informed consent and disclosure to patients

1. Early period (1945-1947)

The issues of disclosure and informed consent must be considered in the light of the prevailing circumstances. Plutonium was a classified term and could not be mentioned publicly. Documents (dated 1947) emphasized that the human plutonium studies were to remain classified. It was not customary at that time to obtain written consent from the patient for any type of clinical experimentation. Rather, consent given in the presence of witnesses was more customary. Finally, information regarding human experimentation in Germany during World War II influenced attitudes toward the use of human subjects

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in the United States only several years after the end of the War.

a. Chicago

According to one witness, plutonium injections at Billings Hospital in Chicago were made after the physician obtained oral consent from each of three patients (in the presence of two witnesses) to administer a radioactive substance that would not necessarily be of benefit to the subject, but might eventually help other people. The physician, who, according to the witness, made the injection, denied administration of the injections to AEC interviewers and could not comment on the disclosure issue. The physician, who was interviewed before contact was made with the witness, has not been available as yet for comment about the statement of the witness.

b. Oak Ridge

According to the physician who administered the injection of plutonium at Oak Ridge Hospital, no consent was obtained from the patient at any time.

c. Rochester

The hospital records of the Rochester patients were examined by a Rochester staff physician, who could find no reference to injections or disclosure to patients. The physician named as having made the injections is deceased, and no other source of direct information regarding disclosure to Rochester patients has been discovered as yet. In view of the large proportion of Rochester patients (eleven), further inquiry may be indicated relative to those patients.

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d. San Francisco

The hospital records of the first two patients in San Francisco, injected respectively in 1945 and 1946, contained no references to disclosure to the patients or informed consent. However, in both cases the chart contained allusions to special studies involving radioactive materials and the name of a physician who was responsible for specimens and, in one case, could be contacted for information about the case. A person who was then a technician stated in an interview that he delivered the syringe containing the solution to the named physician for injection. However, that physician when interviewed said that he could not remember the cases.

The third case, who is still living and was under study in 1973 in both the Argonne Center for Human Radiobiology (CHR) and the Strong Memorial Hospital in Rochester, was injected intramuscularly into a leg affected by a malignant tumor in July 1947, after AEC came into existence. According to the chart, the amputation of the leg was postponed briefly in order to have the radioactive tracer substances (plutonium) prepared and standardized. Then, the experimental nature of the intramuscular injection of the radioactive tracer sample was explained to the patient, who agreed to the procedure. The patient was stated to be fully oriented and of sane mind. The now deceased responsible physician signed his name. Two other physicians and a nurse witnessed the disclosure and assisted in the procedure. All signed the statement of

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disclosure in the patient's hospital record.

In June 1947, a fourth patient was injected. This individual was given americium intramuscularly into a leg two days before amputation. The injection was made at the Chinese Hospital in San Francisco. The patient was taken to the University Hospital by a now deceased University physician for studies one and six days prior to injection. There was no evidence of disclosure in the chart of this patient.

2. Recent period

a. The present Administration of CHR was not aware of the disclosure, however limited, that had been made to some of the patients at the time of injection. This included lack of knowledge of the disclosure to the third California patient discussed above.

b. That third California case, now living in Texas, was contacted through his personal physician, who had been informed by CHR that they wished to do a follow-up study of treatment that the patient received for his malignant tumor in July 1947. The plutonium injection was not, in fact, given for therapeutic purposes. The standard consent form used for other CHR patients such as radium cases was not signed in this case, apparently not having been presented to the patient.

c. The physician at Rochester involved in the 1973 study of two survivors of the Rochester cases and the above California case did not make any disclosure to the three patients before or during their hospitalization at Rochester. CHR analyzed urine and stool specimens

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from the three patients. Specimens from one patient were also forwarded to LASL. CHR provided funding for hospital costs incurred during the period of collection of specimens from the patients at Strong Memorial Hospital in Rochester.

d. CHR Administration asked personnel of the MIT Radioactivity Center (a CHR satellite) to take the necessary steps to obtain permission to exhume any or all of ten deceased injected persons. Families were to be told that the remains would be examined to determine the microscopic distribution of residual radioactivity from past medical treatment.

Interviews with MIT Radioactivity Center personnel disclosed that they indicated to the families of the deceased that the latter had received injections of mixtures of radioactive isotopes. The principal interviewer told the families that the isotopes were used in an experimental treatment. In one case, the family was given no reason for the injection. The exhumations were to be performed to better characterize the composition of the injected mixture and to study the effects of the isotopes.

e. The study, although initiated in January 1973, was brought to the attention of the Argonne Human Use Committee in stages beginning in November 1973. The Committee met on March 14, 1974, and issued a report dated April 8, 1974, that recommended specific procedures that will bring the CHR in compliance with DHEW guidelines.

f. In interviews, CHR Administration offered the following explanations for failure to present the plutonium studies to the Argonne human

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Use Committee in February 1973:

(1) Their opinion that the studies came under the scope of a protocol approved by that Committee in 1971.

(2) The nature of the studies was to be suppressed to avoid embarrassing publicity for AEC.

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