

PATIENTS INJECTED WITH PLUTONIUM (CHRONOLOGY)

1. In 1945-1947, a total of 18 patients were injected with plutonium in hospitals of the Universities of Rochester, Chicago and California as a part of the wartime and postwar activities of the Manhattan Project.
2. The study was conducted for the following reasons:
 - a. Pu was recognized to be a highly toxic substance.
 - b. Many people were handling Pu, and some internal depositions were occurring.
 - c. Need for human metabolic and excretion parameter values was recognized. Injection of known amounts of the element with subsequent distribution and excretion study was considered desirable.
3. Doses were injected that proved to be 7-145 x the current occupational body burden.
4. The injections were carried on in an atmosphere of secrecy, and we do not believe that the patients were informed of either the nature or purpose of the injections.
5. Age greater than 45 years and likelihood of survival of less than 10 years were stated to be the criteria used in patient selection but there were 5 exceptions to the age criterion. The survival criteria was applied loosely so that 6 patients survived for more than 10 years and 4 of those are still alive about 28 years later.
6. After formation of the AEC on August 1, 1946, doubts were expressed concerning the ethics of the study. At one time, consideration was given to referring the matter to the A.M.A. ethics committee but this was not done.

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7. Follow-up metabolic studies were continued for about 5 years after which all contact with the patients was dropped until 1973.
8. In 1972 and 1973, scientists in our laboratories (Drs. Durbin and Rowland) discussed the advisability of obtaining late distribution and excretion values by conducting further studies on the four surviving patients and on any exhumed bodies for which permission could be obtained.
9. The studies were conducted at Rochester and Argonne on 2 of 3 Rochester and 1 California patient between January and July, 1973. The third Rochester patient refused to be studied. A body was exhumed in September 1973 and subsequently studied.
10. Informed consent, including disclosure that plutonium was injected originally, was not obtained from any of the patients studied in 1973. Frank disclosure of the reasons for the studies was not made at any time in spite of the fact that one patient was transported across country to be studied. The studies have not been presented to Human Use Committees of the various institutions for their consideration.
11. Recent DBER involvement:
 - a. Dr. Durbin discussed funding of late studies with Dr. Goldstein in 1972.
 - b. Dr. Rowland discussed with Dr. Marks in June 1973 the matter of guidance in publication of results on his studies. He was advised later to submit papers for review and guidance when they are completed.
 - c. Dr. Sachs of ANL contacted Dr. Liverman about the matter at time of Biomedical Program Directors Meeting as a result of

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discussion that followed presentation of the work to an ANL Advisory Committee by Dr. Rowland.

- d. On January 28, 1974, abstracts of papers to be presented at the International Congress of Radiation Research in July, 1974, were received by DBER.

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