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Response to Query

AEC HUMAN TESTICULAR IRRADIATION PROJECT

Beginning in 1963, AEC funded a series of radiation experiments using as subjects inmates at the Oregon State Prison. The inmates were irradiated at varying levels to determine the effects of such exposures on human fertility. The actual irradiations were completed in 1971. AEC continued to provide support for data analysis, and ERDA is currently providing funds to maintain custody of various medical specimens which were collected ^{for} preparation of scientific reports.

Willamette Week, a small Oregon weekly newspaper, printed a story dealing with the experiments on February 17, 1976.

Background

The experiments involved 67 prisoners at the Oregon State Prison at Salem. Dr. Carl C. Heller of the Pacific Northwest Research Foundation, Seattle, was the senior investigator. In December 1972, Dr. Heller suffered an incapacitating stroke; on February 22, 1973, Mavis J. Rowley, his senior research assistant, was named principal investigator and placed in charge of the numerical data and physical specimens which were collected.

The total funding for the project, by AEC and ERDA, has amounted to approximately \$1.12 million. AEC provided \$1.064 million from June 1963 through July 31, 1973, and \$22,165 additional for August 1, 1973, to July 31, 1974 -- the terminal year for the contact listing both Dr. Heller and Ms. Rowley as investigators. From October 1, 1974, through December 31, 1975, Mavis Rowley, now affiliated with the Swedish Hospital in Seattle,

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has received \$34,550 in operating funds, under a separate contract. She is to assist in publishing parts of the accumulated data, and to oversee the storage and preservation of blood and semen samples, and of material from testicular biopsies. No additional funding has been approved by ERDA.

In the Oregon study, the prisoner volunteers were given x-ray exposures to the testes in doses ranging from 8 to 600 rads, in order to obtain data on specific male sterility caused by radiation. Sixty-one prisoners received a single exposure, five received two exposures, and one received three exposures.

To volunteer and be considered, prisoners were required to be under life sentence. Each inmate agreed to have a vasectomy at the completion of his part of the project; consent of the prisoner's wife was obtained for this procedure. All prisoners involved eventually received a vasectomy. Ages of the irradiated prisoners ranged from 25 to 52.

The consent procedure involved full explanation of the short- and long-term effects, usually in the presence of a chaplain. All participants were required to have a preliminary psychological examination and to sign notices of informed consent. It was made clear to each subject that he could withdraw from the experiment at any time.

Discussion

The justification given for the project at the time was that data drawn from experiments with animals could not be extrapolated to man. The study was approved only after all appropriate human use committees

1000344

and criteria which were then in effect had been satisfied. (A Human Use Committee was established in 1966, in response to the Surgeon General's memorandum of February 8, 1966.) The procedures and standards employed were again reviewed at later stages in the research.

At the time the project began, the question of radiation-induced sterility was considered critical, and it was felt that the objectives of this research were valid. All guidelines governing the use of humans in experiments, which had been set forth at that time by the Department of Health, Education & Welfare (HEW), were strictly observed.

Questions will probably be raised concerning ERDA's position on this specific experiment, and on the general issue of using humans as subjects in medical-scientific experiments. The Oregon prison study was initiated at a time when the use of prisoners in experiments was much more common than at present. The record suggests that for many of the volunteers a prime incentive to participate in the experiments was the feeling that they were performing an important public service.

As to ERDA's current attitude toward such experiments: It is, and will continue to be, ERDA's policy to try to learn as much as possible from the experience of humans who have been subjected to radiation through accidental or occupational exposure. However, it is difficult to imagine circumstances under which ERDA's need for information would be so compelling as to warrant experiments involving the irradiation of humans for the sole or primary purpose of studying effects.

If an occasion were to arise in which information on radiation effects was desperately needed to protect national health and safety, and there were no other way to obtain such information, it is conceivable that ERDA might consider using human subjects. In that event, ERDA would be controlled entirely by HEW or other prevailing national guidelines. It should be emphasized that the possibility for future ERDA involvement in such studies is extremely remote.

(Although the Willamette newspaper is not expected to discuss it, the AEC supported a similar project beginning at the same time in Washington State Prison at Walla Walla. The contract, with Dr. C. Alvin Paulsen, School of Medicine, University of Washington, was terminated in 1970-71, after seven years and a cost of about \$505,000. A total of 63 prisoners were involved in Washington state, and the same basic criteria were observed.)

(Cleared through Dr. Burr, DBER)

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