

SEP 20 1984

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*See Previous Concurrences

Honorable Richard L. Ottinger
Chairman, Subcommittee on Energy
Conservation and Power
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your letter requesting certain information about project involving human test subjects and radiation that have been funded by the Department of Energy and its predecessor agencies.

An enclosed memorandum outlines the approach that was taken to assemble the pertinent information and lists in chronological order the Government officials responsible for the studies.

Also enclosed are summaries of the projects, grouped by topic.

We trust that this information will be useful to you in your investigation. We continue to search for additional information and will forward such information if it covers projects not reported by this letter.

Sincerely,

DONALD PAUL HODEL

13 Enclosures

cc:

Honorable Carlos J. Moorhead
Ranking Minority Member

bcc: ES (4)
CP-1 (2)
ER-1
ER-2
ER-60
ER-622
ER-70 (2)
ER-71
MA-1
MA-3

REPOSITORY DOE - FORRESTAL
COLLECTION MARKEY FILES
BOX No. 2 OF 6
FOLDER OTTINGER/MARKEY

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ER-73

INFORMATION: Response to Request from Honorable Richard L. Ottinger

The Secretary

This memorandum and the attached summary fact sheets have been prepared in response to Mr. Ottinger's letter, requesting certain information about projects involving human test subjects and radiation that have been funded by the Department of Energy and its predecessor agencies.

Medical radiation research has been conducted for many years for a variety of reasons. In some projects, such as the production and use of plutonium during the war years, there was an urgent need to obtain radiobiological data on certain radionuclides for the purpose of establishing safety criteria for protection of individuals in the workplace. In other research, it was clear that the use of radiation provided considerable improvement in the treatment of certain human diseases, such as cancer. In addition, there was also a need for basic knowledge about the biological effects produced to determine whether repair of biological damage occurred, and to ascertain the treatments necessary to promote recovery of the individuals who had been exposed. Thus, depending upon the magnitude of the problem, there were instances in which humans were exposed to radiation for the purpose of determining the relationship between biological effects and radiation dose, to determine the metabolism, deposition, and elimination of radioactive substances of interest which had been inhaled or ingested by the individual, or to demonstrate the effectiveness of radiation in the treatment of cancer or other diseases.

Prior to the time that formal guidelines were promulgated, there was a general practice to inform participants in human volunteer studies with respect to the purpose of the experiment and the potential hazards involved. In clinical studies related to the use of radiation or radioactivity for medical treatment purposes, such information was provided as a matter of routine. In addition, no proposed treatment protocol by an individual physician could be used without approval of all the clinical staff. In November 1966, the Advisory Committee for Biology and Medicine recommended to the AEC that formal procedures be established in AEC laboratories to ensure that ethical practices then extant were followed with respect to use of human volunteers for research purposes.

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In December of 1966, Dr. Charles L. Dunham, then Director of the Division of Biology and Medicine, directed the program directors of the laboratories to consider current laboratory practices and revise their procedures, if necessary, to comply with the code of ethics which the Surgeon General had instituted.

Subsequently, in 1970, Dr. John R. Totter notified the laboratories that the AEC had officially adopted the National Institute of Health procedures which were described in the booklet entitled "Protection of the Individual as a Research Subject." At an early time, therefore, the AEC and its laboratories were cognizant of and sensitive to the need for implementation of procedures to ensure a responsive code of ethics in their research programs.

The information that is summarized on the attached fact sheets was obtained from several sources. The more recent projects are documented in files at DOE Headquarters in Germantown, Maryland. For others, it was necessary to request our field offices to obtain fact sheets from current or previous contractors. In some instances, the information has been obtained from summary reports or from data published in the open literature. Pertinent information is recorded in the proceedings of two previous congressional investigations: (1) Hon. Chet Holifield (Chairman), Applications of Radio-isotopes and Radiation in the Life Sciences, Hearings before the Subcommittee on Research, Development and Radiation of the Joint Committee on Atomic Energy, March 27-30, 1961, and (2) Hon. Albert Gore, Jr. (Chairman), Oversight - Human Total Body Irradiation (TBI) Program at Oak Ridge, Hearing before the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology, September 23, 1981.

The information currently available is necessarily incomplete, in part because of the length of time that has elapsed since the beginning of these studies. Many of the original records are currently unavailable because they have been lost or destroyed. However, although it is possible that some additional studies will still be found, it seems unlikely that any significant project has been omitted.

The reports have been grouped into the following categories:

1. Metabolism and Biological Effects of Plutonium, Polonium, Thorium, Uranium, Radium and Lead-212
2. Testicular Irradiation
3. Whole-body Irradiation for Treatment of Leukemia and Lymphoma
4. Teletherapy with Particle Beams
5. Other Teletherapy Studies
6. Treatment of Polycythemia
7. Hematological Effects
8. Neutron Capture Therapy
9. Other Radiation Therapy
10. Biological Effects of Iodine-131
11. Other Biological Effects Studies
12. Metabolic and Physiological Studies

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The responsible government officials for these studies are listed below in chronological order:

<u>Period</u>	<u>Name</u>	<u>Agency</u>	<u>Division or Office</u>	<u>Title</u>
42-45	Stafford L. Warren, M.D.*	MED		
45-47	Robert S. Stone, M.D.*	MED		
47-52	Shields Warren, M.D.*	AEC	DBM	Director
52-54	John C. Bugher, M.D.*	AEC	DBM	Director
54-67	Charles L. Dunham, M.D.*	AEC	DBM	Director
67-72	John R. Totter, M.D.	AEC	DBM	Director
72-77	James L. Liverman, Ph.D.	AEC/ERDA	DBER	Director
77-81	William W. Burr, M.D.	DOE	DBER/OHER	ActDir/Director
81-date	Charles W. Edington, Ph.D.	DOE	OHER	ActDir/ActAssoc Director/Assoc Director

*deceased

Abbreviations:

- MED - Manhattan Engineer District (1942-1945)
- AEC - Atomic Energy Commission (1945-1975)
- ERDA - Energy Research & Development Administration (1975-1977)
- DOE - Department of Energy (1977-date)
- DBM - Division of Biology & Medicine (1945-1974)
- DBER - Division of Biomedical & Environmental Research (1975-1981)
- OHER - Office of Health and Environmental Research (1981-date)

We trust that this information will be useful to Mr. Ottinger in his investigation. We continue to search for additional information and will forward such information if it covers projects not reported by this memorandum.

Alvin W. Trivelpiece
Director, Office of
Energy Research

12 Attachments

ER-73:JSRobertson:lw:353-5355:9-6-84

- bcc: ES (4) ER-622
- CP (2) ER-70 (2)
- ER-1 ER-71
- ER-2 MA-1
- ER-60 MA-3
- ER-61

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Sincerely,

DONALD PAUL HODEL

cc: Honorable Carlos J. Moorhead
 Ranking Minority Member

MA-3

12 Enclosures

8/ /84

bcc: ES (4) Prepared by: JSRobertson/cm:353-5355
 ER-1 8/17/84

MA-1

ER-2
 ER-60 ES84-007251

8/ /84

ER-61
 ER-622 MA-3
 ER-70 (2) MA-1
 ER-71

CONCURRENCES
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DATE 8/17/84
RTG SYMBOL ER-71
INITIALS/SIG. JWhiesse
DATE 8/17/84
RTG SYMBOL ER-70
INITIALS/SIG. CWedington
DATE 8/22/84
RTG SYMBOL ER-61
INITIALS/SIG. IAdler
DATE 8/ /84
RTG SYMBOL ER-60
INITIALS/SIG. RYoung
DATE 8/ /84
RTG SYMBOL ER-2
INITIALS/SIG. JKane
DATE 8/ /84
RTG SYMBOL ER-1
INITIALS/SIG. ATrivelpic
DATE 8/ /84
RTG SYMBOL CP-30
INITIALS/SIG.
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RTG SYMBOL CP-1
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