Mr. Chairman and Mr. Markey:

I am Dr. Wendy Baldwin, Acting Deputy Director for Extramural Research at the Public Health Service's National Institutes of Health (NIH). With me today is Dr. Gary Ellis, Director of NIH's Office for Protection from Research Risks. This morning I will provide an overview of the activities that the Department of Health and Human Services (HHS) has undertaken with regard to human experimental exposure to ionizing radiation, and will describe the policies that are in place to prevent such exposures now and in the future.

HHS Activities

The Department is one of the participants on the White House Human Radiation Interagency Working Group, including all the subcommittees. HHS has initiated several actions to support the work of the Working Group.

A memorandum is being prepared by the Office of the General Counsel in coordination with the Deputy Assistant Secretary for Health for all HHS components. This memorandum will:

In response to the directive from the working group

- request that each Departmental division identify an individual who will be responsible for activities related to the Working Group,

- direct each Departmental division to begin immediately to identify records related to human experimental exposure to ionizing radiation, and

- direct each Departmental division to retain and secure any and all records that may pertain to experimental exposure of humans to ionizing radiation.

The memorandum will specify that those employees who identify the records be screened for conflict of interest related to ionizing radiation experiments

In addition, the principal Public Health Service agencies have already been given these directions orally.

It is anticipated that most of the experiments funded by HHS involving human exposure to ionizing radiation were funded by the Public Health Service (PHS). Therefore, a PHS working group has been established with representatives from the Office of the Assistant Secretary for Health, the National Institutes of Health, the Centers for Disease Control, the Indian

Health Service, and the Food and Drug Administration. This group is meeting this week.

The Public Health Service group will:

- o develop a method for identifying relevant records, and determine how and where to search for relevant records,
- o coordinate with other agencies to trace isotope deliveries from the Atomic Energy Commission, and
- o engage in a comprehensive search and review of the medical literature in coordination with other agencies.

The Office of the General Counsel has undertaken a review of recent case law regarding custody and control of grantees' and contractors' records.

Lists of institutions that may have received grants or contracts from PHS during the relevant period (1945-1975) are being compiled and a memorandum is being drafted that will instruct these institutions to retain and secure any records related to human experiments with ionizing radiation.

Preliminary projections indicate that records will be found in many locations. For those experiments conducted by PHS employees, the records are likely to be found within agency files. As you know, much of the research supported by the PHS is conducted by research institutions located throughout the United States. Identifying and locating the records of these grantees and contractors will require additional effort, particularly since pre-1966 grant and contract records consist only of the title of each grant, the recipient institution, the investigator, the amount awarded and a single line description of the project. However, we are committed to seeking out the more detailed records from the research institutions that have been supported by the Department.

Finally, HHS is conducting an assessment of our expertise in providing follow-up to individuals who may have been exposed to radiation. CDC and NIH, in particular the National Cancer Institute, has conducted longitudinal studies on radiation exposure including the DOE workers study, studies of Chernobyl victims, and follow-up studies of patients who have received radiation as a part of a treatment regimen.

Protection of Human Subjects Today

In the United States, regulations protecting human subjects first became

effective on May 30, 1974. Promulgated by the predecessor to HHS, the Department of Health, Education, and Welfare (HEW), those regulations raised to statutory status NIH's Policies for the Protection of Human Subjects, which were first issued in 1966. The Policies and the regulations were based on the concept that freely given consent to participation in research is the cornerstone of ethical experimentation involving human subjects. The regulations established the Institutional Review Board (IRB) as a major mechanism through which human subjects would be protected.

In 1981, in response to the reports and recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, HHS promulgated revisions concerned with some details of what the IRB is expected to accomplish and procedures it must follow.

In 1991, the HHS regulations, further revised, were adopted as the Federal Policy for the Protection of Human Subjects. This Federal Policy (45 CFR 46), or so-called "Common Rule," was promulgated by the sixteen Federal agencies, including those represented here today, that conduct, support, or otherwise regulate human subjects research. The Policy is designed to make

uniform the human protection system in all relevant Federal departments. This Policy is a framework in which investigators, institutional review board members, and others can ensure that serious efforts are being made to protect the rights and welfare of research subjects. The law also holds researchers and IRBs publicly accountable for their decisions and actions.

The Department of Health and Human Services's Office for Protection from Research Risks (OPRR) oversees implementation of the Policy in all domestic and foreign institutions or sites receiving HHS funds. OPPR requires that each institution that conducts or supports research involving human subjects sets forth the procedures it will use to protect human subjects in a policy statement called an "assurance of compliance" commonly referred to as an "assurance."

This is a formal, written commitment (i) to widely held ethical principles, (ii) to the HHS regulations for the Protection of human subjects, and (iii) to institutional procedures adequate to safeguard the rights and welfare of human subjects. The terms of the institution's assurance are negotiated with OPRR.

Let me turn briefly to responsibilities of the institutional review board. IRB review is responsible for assuring that (i) risks are minimized, and

reasonable in relation to anticipated benefits, (ii) there is informed consent, and (iii) rights and welfare of subjects are maintained in other ways as well.

Research investigators have a fundamental responsibility to safeguard the rights and welfare of the people participating in their research activities. In addition, our society has decided by law that an objective review of research activities involving human subjects by a group of diverse individuals is most likely to protect human subjects and promote ethically sound research. IRBs are generally composed of members with expertise in science, ethics and other nonscientific areas. This diversity fosters a comprehensive approach to safeguarding the rights and welfare of human subjects.

Conclusion

In concluding my remarks about human subjects research, I want to assure you that the protections in place are designed to preclude the very problems that we have gathered here today to discuss.

Thank you, Mr. Chairman. We would be glad to answer your questions about our system for safeguarding the human subjects of research.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503

URGENT

September 26, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1838

TO: Legislative Liaison Officer -

CIA - Tom Benjamin - (703)482-6126 - 258
ENERGY - Bob Rabben - (202)586-6718 - 209
HHS - Frances White - (202)690-7760 - 328
JUSTICE - Sheila F. Anthony - (202)514-2141 - 217
NASA - Jeff Lawrence - (202)358-1948 - 219
NEC - Sonyia Matthews - (202)456-6630 - 429
NSC - William H. Itoh - (202)395-3723 - 249
OSTP - Elisa Wynn - (202)456-6020 - 288
VA - Robert Coy - (202)273-6666 - 229

FROM: RONALD K. PETERSON (for) Ronald K. Peterson
Assistant Director for Legislative Reference

OMB CONTACT: MIKE GOAD (395-7301)
Secretary's line (for simple responses): 395-6194

SUBJECT: DEFENSE Proposed Testimony on Human Radiation Experimentation

DEADLINE: 3:00 P.M., Today, Monday, September 26, 1994

THIS TRANSMISSION CONTAINS 12 PAGE(S) (total).

COMMENTS: If you do not respond by the deadline, we will assume that your agency has no comment.

OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

Please advise us if this item will affect direct spending or receipts for purposes of the the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

CC:

✓E. Pelton	B. Damus
✓K. Peroff	J. Klein
T.J. Glauthier	S. Neuwirth
✓A. Keenan	C. Varney/P. Caplan
✓D. Zavada	B. Burton
✓B. Dorotinsky	T. Thornton
✓G. Henry	J. Podesta
✓A. Silas	J. Morall, OIRA
J. Palmieri	

LRM #M-1838

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

If your response to this request for views is **simple** (e.g., concur/no comment) we prefer that you respond by **faxing** us this response sheet. If the response is **simple** and you prefer to call, please **call the branch-wide line** shown below (NOT the analyst's line) to leave a message with a secretary.

You may **also respond** by (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); (2) sending us a memo or letter; or (3) if you are an OASIS user in the Executive Office of the President, sending an E-mail message. Please **include** the LRM number shown above, and the **subject** shown below.

TO: MIKE GOAD (395-7301)
Office of Management and Budget
Fax Number: (202) 395-5691
Branch-Wide Line (to reach secretary): (202) 395-6194

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: DEFENSE Proposed Testimony on Human Radiation Experimentation

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No objection

_____ No comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

DRAFT TESTIMONY FOR DR. SOPER
BEFORE THE COMMITTEE ON GOVERNMENT OPERATIONS
SUBCOMMITTEE ON LEGISLATION AND NATIONAL SECURITY
28 SEPTEMBER 1994

Good Morning, Mr. Chairman and Members of the Subcommittee. I am Gordon K. Soper, the Principal Deputy in the Office of the Assistant to the Secretary of Defense for Atomic Energy. I am here to support your request of August 12th to conduct oversight hearings on Cold War era human subject experimentation. My testimony will focus on radiation experiments.

Before I address the specific questions you asked in your letter of August 12th, I would like to provide you with some background information that will help put our answers into proper context. The use of human volunteers in biomedical research programs in the Armed Forces dates back to the early 1800s. With the advent of the nuclear age and the following Cold War, this research began to include human radiation experiments. There has been Congressional oversight on this topic. For example, in 1972, Senator Edward Kennedy and Senator Mike Gravel held hearings into the Department of Defense involvement in radiation experiments at the University of Cincinnati, and in 1986, Representative Edward Markey published a detailed report on 31 Government-sponsored human radiation studies involving 695 individuals. In December of 1993, Secretary of Energy Hazel O'Leary provided to the public some additional information about the Government's participation in human radiation experimentation during the Cold War era. Secretary O'Leary's statements are a reflection of the Clinton Administration's desire to govern in

a more open manner. In a further demonstration of a full accounting of the Government's past history in this area, President Clinton instructed the Federal Agencies to conduct a comprehensive search for all available records related to Government-sponsored human radiation experimentation, followed by the full public release of the pertinent information in those records.

In order to facilitate this systematic record search and comprehensive review, the President established two major activities: an Interagency Working Group on Human Radiation Experiments and the Independent Advisory Committee on Human Radiation Experiments.

First, the Government-wide Interagency Working Group includes key representatives from the Department of Defense, the Department of Energy, the Central Intelligence Agency, the Department of Veterans Affairs, the Department of Health and Human Services, the National Aeronautics and Space Administration, the Department of Justice, and the Office of Management and Budget. This group is responsible for coordinating and overseeing the Government's search for records of human radiation experimentation. The search strategy for this group is straightforward and all-inclusive. Radiation experiments are defined as those:

(1) Experiments on individuals involving intentional exposure to ionizing radiation. This category does not include common and routine clinical practices, such as established diagnosis and treatment methods, involving incidental exposures to ionizing radiation.

(2) Experiments involving intentional environmental releases of radiation that (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation.

The second activity is the Independent Advisory Committee. It is an outside, independent group composed of eminent scientists, physicians, legal experts and medical ethicists. Its purpose is to advise and guide the government on the larger questions of ethical and scientific standards of government sponsored or conducted research which involved the intentional exposure to ionizing radiation. Specifically, as stated in the Executive Order issued by President Clinton in January: "The Advisory Committee shall consider whether (A) there was a clear medical or scientific purpose for the experiments; (B) appropriate medical follow-up was conducted; and (C) the experiments' design and administration adequately met the ethical and scientific standards, including standards of informed consent, that prevailed at the time of the experiments and that exist today."

These two organizations are working very closely together and obviously will provide guidance that has relevance for the human use experiments that the Department conducts today and in the future.

Within the Department of Defense, we took further steps to ensure that the Department was able to respond positively to the President's challenge. First, then Secretary of Defense, Les Aspin appointed the Assistant to the Secretary of Defense (Atomic Energy), Dr. Harold P. Smith,

Jr. as the Department's focal point for this important initiative. Second, to focus the Department's efforts, we set up a command center structure, initially led by a Flag Officer and now led by a Senior Executive Service civilian, that serves as the central repository for all documents retrieved as a result of our record search. The command center is also responsible for reviewing and analyzing documents found during the search and for responding to public inquiries related to human subject participation in radiation experiments.

Third, DoD established strict records review procedures for all DoD components to ensure a comprehensive record search. Within these procedures, the need to "err on the side of inclusion" when searching for records was emphasized to assure the public that the Government was being open and forthcoming on this issue. We also established guidelines to allow for the expeditious declassification of documents located during the record search.

Five simple and straightforward principles guide the Department's efforts. First, we want the search to be thorough. Second, the search will be done as quickly as possible. Third, all due care is to be exercised to preserve records related to human radiation experiments. Fourth, the integrity of the process must be preserved to insure that it retains its credibility in the long term. Fifth, the process must result in open accounting of the Department's past action in human radiation experiments.

In concert with these principles, the Department's approach to fully respond to this issue has two phases. Phase I has been completed and focused on the identification of DoD

organizations that conducted or sponsored human radiation experiments, together with identifying the archives or records center where records concerning such experiments are stored and a description of the process by which the search was conducted. Phase II is still in progress and deals with identifying each human radiation experiment, providing details of the experiment and locating the relevant records. The Department has also focused its efforts to respond to requests for records and information from the Independent Advisory Committee. The Department has provided information related to Departmental informed consent procedures since the mid-1940's; records on the development of ethics policies since 1944; and policy directives related to the establishment and operation of pertinent research and development bodies; and other data.

The record search has been a massive undertaking and is still in progress. It is truly a box-by-box, page-by-page endeavor. Hundreds of people throughout DoD have been involved in this research task expending considerable effort. Some of the locations where records have been located include: National Archives, Washington, D.C. and Suitland, Maryland; Washington National Records Center, Suitland, Maryland; Federal Personnel Records Center, St. Louis, Missouri; Naval Medical Research Institute, Bethesda, Maryland; Naval Hospital, San Diego, California; Dugway Proving Ground, Utah; the Army Training and Doctrine Command, Fort Monroe, Virginia; and Armstrong Laboratory, Brooks Air Force Base, Texas and Wright-Patterson Air Force Base, Ohio. Since January, we have spent approximately 65,000 man hours on this process; we are making progress, but we still have a long way to go.

Now I would like to address your specific questions. First, concerning DoD sponsored

programs involving human subject ionizing radiation experiments during the 1950s, 1960s and 1970s, the Department has categorized these experiments into four categories: therapeutic/diagnostic, intentional atmospheric releases, total body irradiation, and tracer studies. To give you the flavor of what I am talking about, the following are examples of experiments from each category: **Therapeutic/diagnostic** studies include "The Use of Radioisotopes in Diagnostic Hematologic Procedures (Simultaneous Cr-51 and Fe-59 Studies)" and "The Significance of Positive Ipsilateral Nodes in Resections of Lung"; **intentional atmospheric** releases include "The Green Run Test" conducted in Washington and radiological warfare tests conducted at Dugway Proving Grounds, Utah from 1949-1952; **total body irradiation** research includes the "Metabolic Changes in Humans Following Total Body Irradiation" experiments conducted at the University of Cincinnati and "Systemic and Clinical Effects Induced in 263 Cancer Patients by Whole-Body X-Irradiation with Nominal Air Doses of 15 to 200 Rads"; and **tracer** studies include "The Total Exchangeable Potassium and Chloride and Total Body Water in Healthy Men of Varying Water and Fat Content" and "Assessment of Platelet Function in Patients with Coronary Artery Disease."

In total, approximately 2,000 human radiation experiments with over 52,000 participants were conducted or sponsored by DoD. Most of the experiments identified to date fall into the therapeutic/diagnostic or tracer study categories where radioactive materials were used to assist the experimentation, but effects of the irradiation were not a part of the research. Phase II of the record search is continuing and is expected to be complete by April of 1995. As a result of this continued intensive search, more experiments may be identified in the future.

I will now address your question concerning the potential effects of these ionizing radiation experiments upon human subjects. This is a key focus of the investigation of both the Independent Advisory Committee and the Department of Defense. Since its creation in February 1994, the DoD command center has been compiling information about human radiation experimentation. A detailed questionnaire has been developed and distributed to all individuals who contact or are referred to the command center and come under DoD's purview. This questionnaire includes a section concerning medical problems experienced by these individuals Responses to these questions are helping to determine individuals who may have been affected by radiation experiments. This information will ultimately be helpful in any notification and compensation initiatives. Determining the potential effect of exposure to ionizing radiation will have to be done on a case-by-case basis. Many factors will influence the answer, such as the subject's age and the type, duration and frequency of exposure.

Let me now respond to your question about what efforts DoD has made to notify the subjects of these experiments. As I mentioned earlier, one of the responsibilities of the DoD command center is to respond to public inquiries related to human subjects participation in radiation experiments. Inquiries come to the command center by several means: the Radiation Experiments National Helpline, referrals from other agencies, Congressional referrals, White House referrals, or direct contact. To date the command center has been in contact with more than 4,000 individuals.

You have also enquired about the efforts DoD has made to provide medical care or

compensation for the subjects of these experiments. On this issue, one of the prime responsibilities of the Independent Advisory Committee is to provide recommendations on the need for the Government to compensate and/or provide medical care to participants in human radiation experiments. At this time I believe it is premature to discuss any remedy the Government should apply in this matter until our research is completed and their report and recommendations are evaluated. However, as an example of the Department's response to previous problems related to ionizing radiation exposure, the Department does oversee the Nuclear Test Personnel Review (NTPR) program, which was established in the late 1970s to identify individuals who participated in U. S. atmospheric nuclear testing or participated in the post-war occupation of Hiroshima and Nagasaki, Japan. This program provides the Department with the means to investigate and evaluate each case. Over 205,000 individuals have been identified as participating in the U.S atmospheric nuclear testing program. Another 195,000 DoD personnel have been identified as participating in the occupation of Hiroshima and Nagasaki. Over the last five years an average of 2,000 new program participants have been added to the program annually. To date NTPR has been in contact with more than 70,000 individuals.

Furthermore, the provision of medical care as a result of exposure to ionizing radiation is governed by Public Law 97-72, the "Veterans' Health Care and Small Business Loan Act of 1981," which authorized the Department of Veterans Affairs to provide hospital and nursing home care and limited outpatient services to "veterans who were exposed while serving on active duty to ionizing radiation from the detonation of a nuclear device in connection with each veteran's participation in the test of such a device, or with the American occupation of Hiroshima

and Nagasaki during the period beginning September 11, 1945 and ending July 1, 1946." This law provides for medical care related to radiogenic diseases, but does not authorize care for conditions that are found by the Department of Veterans Affairs to have resulted from other than the exposure to ionizing radiation.

As you are aware, Congress has not passed legislation to direct the Government to provide compensation or medical services to the subjects of human radiation experiments. Several bills are currently before Congress related to compensation and medical care for radiation experiment subjects, including HR 4292, "Radiation Experimentation Victims Act of 1994" introduced by Representative Edward Markey; HR 3743 "Radiation Experimentation Compensation Act of 1994" introduced by Representative Martin Frost. Congress, in concert with the Executive branch, will need to examine and determine the need to establish specific compensation and medical care programs for individual participants in radiation experiments.

As concerns your question regarding informed consent, formal DoD policy for the protection of human subjects in research dates back to at least 1953. At that time a TOP SECRET Memorandum was sent to the Secretaries of the Services from Secretary of Defense C.E. Wilson, titled "Use of Human Volunteers in Experimental Research". This memorandum authorized the voluntary participation of military personnel and civilian employees in DoD conducted research for atomic, biological and chemical warfare defense and established specific standards, based on guidelines from the Nuremberg Code, for informed consent, minimization of risk of harm to subjects, and other matters.

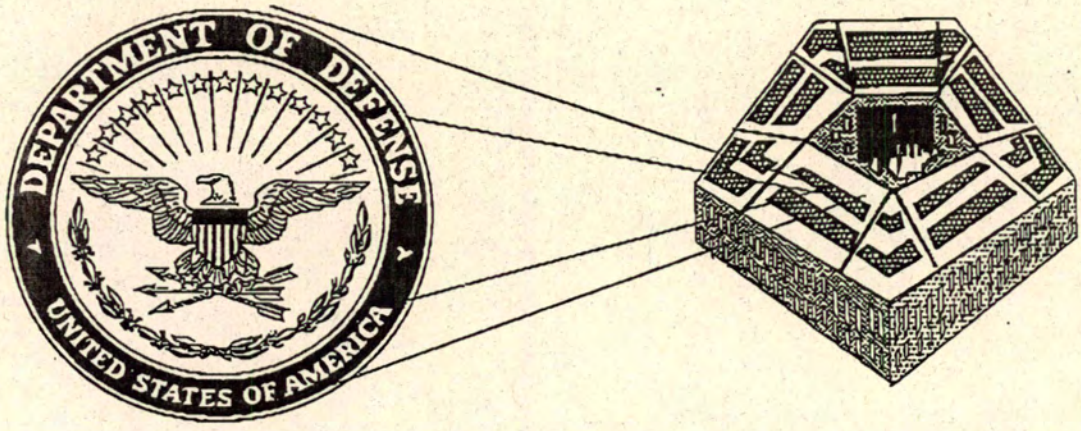
Over the years, more detailed procedures have been established, including incorporation in 1991 of the 1974 Department of Health and Human Services regulations for the Protection of human subjects, 45 Code of Federal Regulation (CFR) Part 46.

Today, DoD-sponsored research is governed by the so-called "Common Rule"--the Federal Policy for the Protection of Human Subjects--which is part of DoD regulations at Title 32, CFR, Part 219. A copy of this regulation is attached to my statement. DoD is a full partner in the government's commitment to this standard and has further defined its human use regulation in DoD Directive 3216.2, "Protection of Human Subjects in DoD Supported Research," January 7, 1983 and Department of Defense Guidance for Assurance of Compliance with the Federal Policy for the Protection of Human Subjects, June 10, 1993.

In closing, I would like to reemphasize that the Department of Defense is committed to a full accounting in this matter and is equally committed to ensuring that any experiments involving human subjects are conducted in accordance with established protocols and the highest ethical standards. I will be happy to answer any questions you might have on this issue.

FAX

FAX



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MESSAGE:

FROM: Gordon K. Soper FAX PHONE NUMBER: *(703) 695-0476*
OATSD(AE) - 697-5561

THIS DOCUMENT CONSISTS OF 11 PAGES, INCLUDING COVER SHEET

DRAFT TESTIMONY FOR DR. SOPER
BEFORE THE COMMITTEE ON GOVERNMENT OPERATIONS
SUBCOMMITTEE ON LEGISLATION AND NATIONAL SECURITY
28 SEPTEMBER 1994

Good Morning, Mr. Chairman and Members of the Subcommittee. I am Gordon K. Soper, the Principal Deputy in the Office of the Assistant to the Secretary of Defense for Atomic Energy. I am here to support your request of August 12th to conduct oversight hearings on Cold War era human subject experimentation. My testimony will focus on radiation experiments.

Before I address the specific questions you asked in your letter of August 12th, I would like to provide you with some background information that will help put our answers into proper context. The use of human volunteers in biomedical research programs in the Armed Forces dates back to the early 1800s. With the advent of the nuclear age and the following Cold War, this research began to include human radiation experiments. There has been Congressional oversight on this topic. For example, in 1972, Senator Edward Kennedy and Senator Mike Gravel held hearings into the Department of Defense involvement in radiation experiments at the University of Cincinnati, and in 1986, Representative Edward Markey published a detailed report on 31 Government-sponsored human radiation studies involving 695 individuals. In December of 1993, Secretary of Energy Hazel O'Leary provided to the public some previously undisclosed information about the Government's participation in human radiation experimentation during the Cold War era. Secretary O'Leary's statements are a reflection of the Clinton Administration's

desire to govern in a more open manner. In a further demonstration of a full accounting of the Government's past history in this area, President Clinton instructed the Federal Agencies to conduct a comprehensive search for all available records related to Government-sponsored human radiation experimentation, followed by the full public release of the pertinent information in those records.

In order to facilitate this systematic record search and comprehensive review, the President established two major activities: an Interagency Working Group on Human Radiation Experiments and the White House Advisory Committee on Human Radiation Experiments.

First, the Government-wide Interagency Working Group includes key representatives from the Department of Defense, the Department of Energy, the Central Intelligence Agency, the Department of Veterans Affairs, the Department of Health and Human Services, the National Aeronautics and Space Administration, the Department of Justice, and the Office of Management and Budget. This group is responsible for coordinating and overseeing the Government's search for records of human radiation experimentation. The search strategy for this group is straightforward and all-inclusive. Radiation experiments are defined as those:

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(2) Experiments involving intentional environmental releases of radiation that (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation.

The second activity is the ~~White House~~ Advisory Committee. It is an outside, independent group composed of eminent scientists, physicians, legal experts and medical ethicists. Its purpose is to advise and guide the government on the larger questions of ethical and scientific standards of government sponsored or conducted research which involved the intentional exposure to ionizing radiation. Specifically, as stated in the Executive Order issued by President Clinton in January: "The Advisory Committee shall consider whether (A) there was a clear medical or scientific purpose for the experiments; (B) appropriate medical follow-up was conducted; and (C) the experiments' design and administration adequately met the ethical and scientific standards, including standards of informed consent, that prevailed at the time of the experiments and that exist today."

These two organizations are working very closely together and obviously will provide guidance that has relevance for the human use experiments that the Department conducts today and in the future.

Within the Department of Defense, we took further steps to ensure that the Department was able to respond positively to the President's challenge. First, then Secretary of Defense, Les Aspin appointed the Assistant to the Secretary of Defense (Atomic Energy), Dr. Harold P. Smith,

Jr. as the Department's focal point for this important initiative. Second, to focus the Department's efforts, we set up a command center structure, initially led by a Flag Officer and now led by a Senior Executive Service civilian, that serves as the central repository for all documents retrieved as a result of our record search. The command center is also responsible for reviewing and analyzing documents found during the search and for responding to public inquiries related to human subject participation in radiation experiments.

Third, DoD established strict records review procedures for all DoD components to ensure a comprehensive record search. Within these procedures, the need to "err on the side of inclusion" when searching for records was emphasized to assure the public that the Government was being open and forthcoming on this issue. We also established guidelines to allow for the expeditious declassification of documents located during the record search.

Five simple and straightforward principles guide the Department's efforts. First, we want the search to be thorough. Second, the search will be done as quickly as possible. Third, all due care is to be exercised to preserve records related to human radiation experiments. Fourth, the integrity of the process must be preserved to insure that it retains its credibility in the long term. Fifth, the process must result in open accounting of the Department's past action in human radiation experiments.

In concert with these principles, the Department's approach to fully respond to this issue has two phases. Phase I has been completed and focused on the identification of DoD

organizations that conducted or sponsored human radiation experiments, together with identifying the archives or records center where records concerning such experiments are stored and a description of the process by which the search was conducted. Phase II is still in progress and deals with identifying each human radiation experiment, providing details of the experiment and locating the relevant records. The Department has also focused its efforts to respond to requests for records and information from the White House Advisory Committee. The Department has provided information related to Departmental informed consent procedures since the mid-1940's; records on the development of ethics policies since 1944; and policy directives related to the establishment and operation of pertinent research and development bodies; and other data.

The record search has been a massive undertaking and is still in progress. It is truly a box-by-box, page-by-page endeavor. Hundreds of people throughout DoD have been involved in this research task expending considerable effort. Some of the locations where records have been located include: National Archives, Washington, D.C. and Suitland, Maryland; Washington National Records Center, Suitland, Maryland; Federal Personnel Records Center, St. Louis, Missouri; Naval Medical Research Institute, Bethesda, Maryland; Naval Hospital, San Diego, California; Dugway Proving Ground, Utah; the Army Training and Doctrine Command, Fort Monroe, Virginia; and Armstrong Laboratory, Brooks Air Force Base, Texas and Wright-Patterson Air Force Base, Ohio. Since January, we have spent approximately 65,000 man hours on this process; we are making progress, but we still have a long way to go.

Now I would like to address your specific questions. First, concerning DoD sponsored

programs involving human subject ionizing radiation experiments during the 1950s, 1960s and 1970s, the Department has categorized these experiments into four categories: therapeutic/diagnostic, intentional atmospheric releases, total body irradiation, and tracer studies. To give you the flavor of what I am talking about, the following are examples of experiments from each category: **Therapeutic/diagnostic** studies include "The Use of Radioisotopes in Diagnostic Hematologic Procedures (Simultaneous Cr-51 and Fe-59 Studies)" and "The Significance of Positive Ipsilateral Nodes in Resections of Lung"; **intentional atmospheric** releases include "The Green Run Test" conducted in Washington and radiological warfare tests conducted at Dugway Proving Grounds, Utah from 1949-1952; **total body irradiation** research includes the "Metabolic Changes in Humans Following Total Body Irradiation" experiments conducted at the University of Cincinnati and "Systemic and Clinical Effects Induced in 263 Cancer Patients by Whole-Body X-Irradiation with Nominal Air Doses of 15 to 200 Rads"; and **tracer** studies include "The Total Exchangeable Potassium and Chloride and Total Body Water in Healthy Men of Varying Water and Fat Content" and "The Evaluation of Pancreatic Exocrine Function and Intestinal Absorption with Radioactive Fat."

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Let me now respond to your question about what efforts DoD has made to notify the subjects of these experiments. As I mentioned earlier, one of the responsibilities of the DoD command center is to respond to public inquiries related to human subjects participation in radiation experiments. Inquiries come to the command center by several means: the Radiation Experiments National Helpline, referrals from other agencies, Congressional referrals, White House referrals, or direct contact. To date the command center has been in contact with more than 4,000 individuals.

You have also enquired about the efforts DoD has made to provide medical care or

compensation for the subjects of these experiments. On this issue, one of the prime responsibilities of the White House Advisory Committee is to provide recommendations on the need for the Government to compensate and/or provide medical care to participants in human radiation experiments. At this time I believe it is premature to discuss any remedy the Government should apply in this matter until our research is completed and their report and recommendations are evaluated. However, as an example of the Department's response to previous problems related to ionizing radiation exposure, the Department does oversee the Nuclear Test Personnel Review (NTPR) program, which was established in the late 1970s to identify individuals who participated in U. S. atmospheric nuclear testing or participated in the post-war occupation of Hiroshima and Nagasaki, Japan. This program provides the Department with the means to investigate and evaluate each case. Over 205,000 individuals have been identified as participating in the U.S. atmospheric nuclear testing program. Another 195,000 DoD personnel have been identified as participating in the occupation of Hiroshima and Nagasaki. Over the last five years an average of 2,000 new program participants have been added to the program annually. To date NTPR has been in contact with more than 70,000 individuals.

Furthermore, the provision of medical care as a result of exposure to ionizing radiation is governed by Public Law 97-72, the "Veterans' Health Care and Small Business Loan Act of 1981," which authorized the Department of Veterans Affairs to provide hospital and nursing home care and limited outpatient services to "veterans who were exposed while serving on active duty to ionizing radiation from the detonation of a nuclear device in connection with each veteran's participation in the test of such a device, or with the American occupation of Hiroshima

and Nagasaki during the period beginning September 11, 1945 and ending July 1, 1946." This law provides for medical care related to radiogenic diseases, but does not authorize care for conditions that are found by the Department of Veterans Affairs to have resulted from other than the exposure to ionizing radiation.

As you are aware, Congress has not passed legislation to direct the Government to provide compensation or medical services to the subjects of human radiation experiments. Several bills are currently before Congress related to compensation and medical care for radiation experiment subjects, including HR 4292, "Radiation Experimentation Victims Act of 1994" introduced by Representative Edward Markey; HR 3743 "Radiation Experimentation Compensation Act of 1994" introduced by Representative Martin Frost. Congress, in concert with the Executive branch, will need to examine and determine the need to establish specific compensation and medical care programs for individual participants in radiation experiments.

As concerns your question regarding informed consent, formal DoD policy for the protection of human subjects in research dates back to at least 1953. At that time a TOP SECRET Memorandum was sent to the Secretaries of the Services from Secretary of Defense C.E. Wilson, titled "Use of Human Volunteers in Experimental Research". This memorandum authorized the voluntary participation of military personnel and civilian employees in DoD conducted research for atomic, biological and chemical warfare defense and established specific standards, based on guidelines from the Nuremberg Code, for informed consent, minimization of risk of harm to subjects, and other matters.

Over the years, more detailed procedures have been established, including incorporation in 1991 of the 1974 Department of Health and Human Services regulations for the Protection of human subjects, 45 Code of Federal Regulation (CFR) Part 46.

Today, DoD-sponsored research is governed by the so-called "Common Rule"—the Federal Policy for the Protection of Human Subjects--which is part of DoD regulations at Title 32, CFR, Part 219. A copy of this regulation is attached to my statement. DoD is a full partner in the government's commitment to this standard and has further defined its human use regulation in DoD Directive 3216.2, "Protection of Human Subjects in DoD Supported Research," January 7, 1983 and Department of Defense Guidance for Assurance of Compliance with the Federal Policy for the Protection of Human Subjects, June 10, 1993.

In closing, I would like to reemphasize that the Department of Defense is committed to a full accounting in this matter and is equally committed to ensuring that any experiments involving human subjects are conducted in accordance with established protocols and the highest ethical standards. I will be happy to answer any questions you might have on this issue.

Gordon K. Soper
Principal Deputy
Assistant to the Secretary of Defense (Atomic Energy)
3E1074 (703) 697-5161

September 23, 1994

MEMO FOR: Phil Caplan, White House
Tara O'Toole, DOE

SUBJECT: Draft Testimony

Help!

I am now scheduled to support testimony before Rep Conyers next Wednesday. My job is to tell the Radiation Experiments story. I've attached my DRAFT testimony and I'd appreciate your critical review. There is some urgency since we gotta get this through the formal review process soon--like **today!**

Avec ma fidèle amitié.

Gordon

GORDON

OFFICE OF THE SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1000

SECRETARY OF DEFENSE TELECOPIER COVER SHEET

Attention: PHIL KAPLAN

Fax Number: 456-6704

From: LAURA MARCUS

Phone Number: 7036934212

Fax contains 2 **pages** *(not including cover sheet)*

Subject: _____

Note: THANKS FOR TAKING A LOOK AT THIS.

SPEAK TO YOU TOMORROW—

LAURA

OFFICE OF THE SECRETARY OF DEFENSE

94 AUG 16 PM 3

ONE HUNDRED THIRD CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT OPERATIONS

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

August 12, 1994

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The Honorable William Perry
Secretary of Defense
The Pentagon
Washington, D.C. 20307-1155

Dear Mr. Secretary:

The Legislation and National Security Subcommittee of the Committee on Government Operations has scheduled an oversight hearing on Cold War era human subject experimentation. The hearing will be held on Wednesday, September 28, 1994, at 10:00 A.M. in Room 2154 of the Rayburn House Office Building.

I am requesting that the Department of Defense present testimony at this hearing through a knowledgeable representative. This testimony should describe the magnitude and possible impact of human subject experimentation conducted during the Cold War and sponsored by components of the Department of Defense, including chemical and biological warfare tests, radiation experiments, and drug testing programs.

Specifically, the Department's testimony should address the following questions:

1. What programs involving human subject experimentation were sponsored by DoD during the 1950s, 1960s and 1970s?

2. How many human subjects were involved in these programs?

3. What are the potential effects of these experiments upon human subjects?

4. What efforts has DoD made to notify the subjects of these experiments and provide medical care or compensation?

5. What measures currently ensure that informed consent is secured from volunteers in DoD sponsored experiments?

16658

In addition, recent news reports indicate that as part of "Operation Large Area Coverage" in the late 1950s the Army sprayed the chemical cadmium from an aircraft flying from Detroit, Michigan to Goodland, Kansas. I am also requesting that the Department provide the Subcommittee with copies of all documents relating to this operation.

The Subcommittee requests that you deliver 25 copies of your prepared statement no later than 48 hours prior to the hearing to B-373 Rayburn House Office Building, Washington, D.C. 20515, to the attention of Bennie Williams, clerk; and provide an additional 75 copies on the day of the hearing.

Please contact James C. Turner at (202) 225-5147 to coordinate your response to this request.

Sincerely,

John Conyers, Jr.
Chairman
Legislation and National Security Subcommittee

Jun 02'94 11:38 No.009 P.01

TEL:

THE WHITE HOUSE

WASHINGTON

OFFICE OF LEGISLATIVE AFFAIRS

FAX COVER SHEET

NOTE: **THE INFORMATION CONTAINED IN THIS FACSIMILE MESSAGE IS CONFIDENTIAL AND INTENDED FOR THE RECIPIENT ONLY.**

DATE: _____

TO: Kelly Shrarbel, Faith Burton, Dennis Duffy, William Taylor, Jeff Lawrence, Phil Caplan

FAX #: _____

FROM: TRACEY E. THORNTON

456-6493 (T)/ 456-2604 (F)

RE: FYI

PAGE 1 OF _____

If there are any problems with this transmission, please call (202) 456-6493.

FAX SENT: _____

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUITE 2320 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6301
(202) 225-6371
INTERNET: HOUSE@SCITOHR.HOUSE.GOV

May 24, 1994

The Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Madam Secretary:

As Chairman of the Subcommittee on Investigations and Oversight, I have followed closely the President's initiative to release information on the Federal Government's support for experiments involving the exposure of human beings to radioactive materials. I am writing to seek your assistance in learning more about certain tests described in the enclosed copy of an article published in the Baton Rouge *Sunday Advocate*. Originally published in the Boston *Globe*, it details the use of radioactive materials in patients at the Charity Hospital of New Orleans during the late 1940s and early 1950s.

With the assistance of the National Library of Medicine, the Subcommittee was able to locate a number of scientific publications from the doctors named in this article: Dr. George E. Burch, Dr. C. Thorpe Ray and Dr. Samuel Threefoot. These publications indicate that support for this work was provided by the Public Health Service, specifically through "Grant No. H-143" and, in one instance, a grant from the National Heart Institute (see Burch, *et al.*, "The Urinary Excretion and Biologic Decay Periods of Radiomercury Labeling A Mercurio Diuretic in Normal and Diseased Man," *Journal of Clinical Investigation*, v. 29, Sept. 1950, p. 1131). Copies of the publications are included for your information.

I will hold a field hearing in New Orleans, Louisiana, on this episode on July 8, 1994. I believe the information cited above clearly shows that records of the work conducted at Tulane can be found in the files of your Department. Therefore, I invite you or your designee to attend and testify at this hearing. Should you be unable to attend, I request that you be represented by your primary assistant for this initiative, Dr. Donald Henderson, Assistant Secretary for Health (Science). 94052600019

Your testimony should discuss, and you should be prepared to respond to questions concerning, the following issues:

- How is the Department participating in the Interagency Working Group on Human Radiation Experiments to fulfill the President's instructions to make available to the public all Government records pertaining to experiments funded by the Federal Government that exposed human subjects to radioactive materials?
- How is the Department identifying and processing records in its files that relate to these experiments?

I am concerned by recent reports in the journal *Nature* (April 28, 1994, p. 781) and in the Washington *Post* (May 20, 1994, p. A23) that indicate the Department may not be participating fully in this effort. The strategy for locating and retrieving relevant documents, as described by the *Post*, is deficient if we are to develop a complete understanding of the full range of Government activities in this area. Your testimony should focus on how the Department will comply with both the letter and the spirit of the President's directive to make this information available to the public.

- Using this case as an example, please describe how the Department responds to requests for information and assistance in finding information on particular cases where humans were exposed to radiation.
- What process did the Public Health Service use to determine which institutions received grant support for research using radioactive materials?
- What types of review did the Public Health Service conduct when deciding whether to provide grant support to researchers for research using radioactive materials?
- Did reviews conducted by the Public Health Service include consideration of the researcher's ability to obtain the "informed consent" of human subjects that might be exposed to radioactive materials in the course of research funded by the grant?
- Does the Public Health Service, in funding research activities today, assure that researchers obtain the "informed consent" of those participating as subjects of experiments involving radioactive materials? Are these revised procedures adequate to address the problems noted in protecting the participants in earlier experiments using radioactive materials?

- What responsibility falls on the Public Health Service to review ethical issues raised by the choice of participants in the research that it funds? How does the Service ensure that selection of participants falls within ethical limits? How has the exercise of this responsibility changed over time?
- How has the concern for the protection of human subjects been dealt with in the history of the Public Health Service? Your response to this question should discuss implementation of the so-called "Nuremburg" and "Helsinki Codes" and the steps taken to implement relevant recommendations of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.
- The Department participated in the interagency effort that led to promulgation of the so-called "Common Rule" on human subjects protection in 1991. Under these regulations, what responsibility falls upon Federal agencies funding research with human subjects to ensure that the requirements of current regulations for the protection of human subjects have been met? With these procedures, can the Public Health Service assure that human subjects will not be exposed to unwarranted doses of radiation?
- What responsibility does the Federal Government now have for the patients that were exposed in these tests? Is the Public Health Service assisting in efforts to identify and assist participants in this case? Are the steps to date undertaken by the Federal Government adequate to identify these patients and address their needs?

As part of the preparations for this hearing, the Subcommittee requires the Department's assistance in the following areas:

- Obtaining all records related to Grant Number H-143 issued by the Public Health Service to Dr. George E. Burch or his colleagues at Tulane University;
- Obtaining all records of communications in any form between the Public Health Service with Dr. Burch and his colleagues, particularly those progress reports filed in conformance with the terms of Grant Number H-143;

- Obtaining records of the Department and its subsidiary organizations that describe efforts to establish and enforce protections for human subjects in experiments funded by contracts, grants, or other financial or in-kind means of support provided by the Department.

You should coordinate your activities with James Paul of the Subcommittee staff, who can be reached at (202) 226-3630. Attached for your information are the guidelines for witnesses testifying before the Subcommittee. I would like to take this opportunity to recognize Ms. Kristin Kiser and Ms. Stephanie Niemic in the Division of Legislative Analysis at the National Institutes of Health, and Ms. Eve Marie LaCroix and Ms. Sally Burke of the National Library of Medicine. All have been invaluable in assisting the Subcommittee by locating the scientific publications relevant to this case.

I applaud the President's effort to close the gaps in the historical record and to raise important questions about the Government's relationship with its citizens. I trust the Department and the Subcommittee will cooperate closely in building a public record on this particular case.

Sincerely,

James A. Hayes, Chairman
Subcommittee on Investigations
and Oversight

Enclosures

INFORMATION ON HEARING PROCEDURES FOR WITNESSES
appearing before the
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

Your written statement may be of any length and will be made part of the printed record. To give Members and staff adequate time to review your testimony before the hearing, we request that you provide us with 50 copies of your prepared statement 72 hours before the hearing (July 5, 1994) to: Shirley Watson, Subcommittee on Investigations and Oversight, Room 822, O'Neill House Office Building, Washington, D.C. 20515. In addition, 75 copies of your written statement, for distribution to the public and media, should be provided at least 30 minutes before the hearing, at the hearing location: the Charity Hospital in New Orleans. Your statement may include supplemental materials for inclusion in the hearing record. Should you need audio-visual equipment for your presentation; please let the staff know in advance. We encourage you to transmit your testimony by electronic mail to the Committee address: HOUSESST@HR.HOUSE.GOV. Alternatively, you may provide your testimony on a 3.5" or 5.25" floppy disc in:

- o ASCII format.
- o A Word Perfect 5.2 (or earlier version) document using Courier 10 cpi font.

Key points of your written statement should be summarized in a five minute oral presentation; this will allow time for questions and answers following presentations by you and the other witnesses. It is customary for the Subcommittee on Investigations and Oversight to swear in all witnesses which appear before it in public hearings.

Under Committee rules, hearing proceedings are printed strictly in verbatim form, so that only typographical and transcriptional errors may be edited in the transcript. All other corrections -- insertions or deletions of words and phrases for clarity of meaning or for other purposes -- must be requested in writing (in letter form) by the witness, and these corrections may then only be included as an appendix to the verbatim proceedings. We will provide additional information on these matters when the hearing transcript is mailed to you for editing.

Use of Charity Hospital patients in 1940s radiation tests reported

Editor's note: Reports of radiation experimentation on human subjects have been in the news lately as federal officials have expressed concern about them. This report about Charity Hospital in New Orleans, now known as Medical Center of Louisiana, first appeared in the Boston Globe and was disseminated nationally through the Knight-Ridder news service.

By SCOTT ALLEN
Boston Globe

NEW ORLEANS—People called it "The Big Free," the only hospital where many poor blacks could get medical care in the segregated Louisiana of the 1940s. They flocked to Charity Hospital by the thousands.

But all that free care left Charity Hospital chronically short of cash, and, in 1946, doctors found a way to make it up: radiation research.

Backed by grants from agencies including the U.S. War Department, a team from Tulane University's medical school undertook an ambitious series of human radiation experiments involving at least 300 Charity patients.

For more than a decade, mostly black female patients swallowed or were injected with the radiation equivalent of up to 100 chest X-rays in one experiment as researchers studied how quickly the human body could process radioactivity. The research could be unpleasant, sometimes requiring test subjects to endure 118-degree heat, intentional blisters or diarrhea.

The researchers recall that their test subjects voluntarily took part in the experiments after the doctors told them what was involved. For the patients, the researchers say, radiation experiments were a way out of Charity's overcrowded wards.

"The patients that we used for research really loved us. They really did," Dr. Sam Thevenot, who worked with the researchers from until 1953, said in an interview at his New Orleans home. "They got the most attention. We saw them several times a day. We cared about their diets."

Yet the voices of the test subjects have been lost. They are described obliquely in studies the Tulane team published: a 14-year-old boy who swallowed a tonic dose of radioactive mercury, a woman who remained hospitalized for 70 days so researchers could track a small amount of radioactive chlorine in her body, a "normal subject" who protested after sitting in stifling heat for half an hour so he would sweat before getting a radioactive injection.

Disclosure of the Charity research comes at a time of intense debate over the ethics of government-funded radiation experiments in the early days of nuclear medicine. A congressional subcommittee has focused on human radiation research at federal facilities, and Ea-

☐ See RADIATION, Page 2B

The Sunday Advocate Page 1B
March 6, 1994

Radiation

CONTINUED FROM 1B

ergy Secretary Hazel O'Leary has suggested that some test subjects should be compensated.

The Charity experiments were part of a boom in radiation research that began when the Atomic Energy Commission made radioactive isotopes widely available to labs and hospitals. In a time when the rules governing human experiments were sketchy and informal, at least 1,800 of society's most vulnerable people — the sick, the insane, children and the imprisoned — were among the first to be chosen for experiments.

The Charity subjects were mainly poor blacks in an overtly racist society. It took a major lawsuit in the early 1980s to desegregate New Orleans hospitals, and Charity maintained segregated wards until 1965. "You're talking about a 19th-century society," said Vera Wing, one of the lawyers who brought the case integrating the hospitals.

The hospital, a federal downtown Art Deco tower, at least appears to have tried to avert the ravages of blacks, who made up two-thirds of the patients. But it was desperately understaffed. To survive, it relied on faculty and students at the Tulane and Louisiana State University medical schools, which used Charity as a teaching hospital.

The men who led the research were ambitious, but it appears that they were also devoted to the hospital's mission. Dr. C. Thorpe Rose, a senior researcher, worked six days a week without pay for years as chief of a black female ward, living on his pay as a Tulane faculty member. He and Dr. George H. Burch, Tulane's chairman of medicine, drew their test subjects from the people they treated.

"This had nothing to do with color or sex. I did research on whites, too. ... There was no real interest," said Wasserfirst, 72.

But the researchers were making in a hospital where patients were routinely used in medical experiments unrelated to their conditions. The Sisters of Charity, the nuns who managed the hospi-

Mike photo

Charity Hospital in New Orleans was the site of radiation experiments in the 1940s involving at least 300 patients.

tal, might stop the worst abuses, Tulane faculty members said, but doctors had wide discretion.

"The whole population of the hospital was used for guinea pigs. You could pick anyone you wanted and do any tests you wanted to. No one could ask any questions," said Dr. John Salvaggio, vice chancellor for research at the Tulane Medical Center and a historian of Charity.

Today, education for New Orleans poor say they knew of no one who took part in the experiments, and they were surprised that the experiments occurred. But Dr. Donald Parish, who worked at Charity as a medical student in the 1970s before moving to Georgia, was not surprised. "Some of the saddest things I ever saw in my life were at Charity," he said.

The Tulane researchers got in on the ground floor of the research largely because Burch was one of the first doctors to recognize the medical value of the radioactive isotopes that the Atomic Energy Commission began churning out in 1946. They followed just like the elements they were made from but could be measured in extremely tiny amounts. Placed in the human body, these radioactive "tracers" could be followed wherever they went, from blood to urine.

Burch was particularly interested in the effectiveness of a mercury diuretic then used to relieve fluid build-up from heart disease. By giving a radioactive form of mercury to Charity patients, Burch found that the diuretic could be hazardous if given orally. A 1950 research paper describes how four patients, including a 14-year-old boy, swallowed 10 radioactive mercury capsules apiece and three of them "experienced a toxic reaction manifested by abdominal cramping and diarrhea."

The researchers also discovered the rate at which the mercury diuretic could penetrate human membranes, such as the ones around the heart. They applied a skin irritant to the forearms of patients to create blisters and cut off the top layers of skin. He then applied radioactive mercury to the sores below, to see how fast the mercury penetrated.

"We never had any patient refuse to go on and say, 'I don't want to do that anymore,'" Hay, 76, said in an interview.

The research had medical goals, but it was a business, too, mixing grant money for researchers to gently offset their low pay from the hospital. The doctors received funding from a variety of health organizations, but they also tailored their projects to appeal to the War (now Defense) Department. The military was very interested in the health effects of atmospheric atomic bomb tests.

"We applied for grants in areas they were interested in, particularly in the area of biological half-life," said Hay, referring to the time it takes the concentration of a radioactive isotope in a human body to drop by 50 percent. In one of at least eight studies of the biological half-life of radioactive substances, the researchers say, their data could "throw light upon the problem of radiobiologic injury in both operations and military use of radioelements."

Knowledge of the biological half-life of radioactive elements would have important applications to medicine, as well.

Hay contends that the risks the test subjects faced was very low. He said researchers avoided isotopes that stayed in the body for long periods and kept exposure in general to a minimum. Much of the Tulane research involved isotopes that remain in the body only a few hours.

"We told (patients) it was radiation, like the equivalent of a chest X-ray," Hay said.

But at the time, the researchers could not calculate the radiation exposure, largely because they had only a general idea of how long the radiation would stay in the body. Several of the isotopes had never been tested on people, and the point of the research was to find out how long the body would take to purge the radiation.

In addition, the researchers sometimes used radioactive materials, such as iridium, when they could have gotten the same results with non-radioactive alternatives. Hay said the alternative to using iridium was less convenient.

Today, it appears that most of the Charity experiments involved radiation exposure comparable to the amount people get each year from natural sources, around 300 millirems. However, one history of tests gave four people the equivalent of 100 chest X-rays apiece, a full rem of exposure. Technically, researchers could expose that subject to such levels of radioisotopes today, but "it would have to be very good science," said Dr. Thomas Burch, a radiation authority at Johns Hopkins University in Baltimore.

Poker

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DR. GERALD B. WICKLINE

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503

URGENT

August 26, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1745

TO: Legislative Liaison Officer -

CIA - Tom Benjamin - (703)482-6126 - 258
DEFENSE - Samuel T. Brick, Jr. - (703)697-1305 - 325
ENERGY - Bob Rabben - (202)586-6718 - 209
JUSTICE - Sheila F. Anthony - (202)514-2141 - 217
NASA - Jeff Lawrence - (202)358-1948 - 219
NEC - Sonyia Matthews - (202)456-6630 - 429
NSC - William H. Itoh - (202)395-3723 - 249
OSTP - Roselis D'Allessandro - (202)456-6014 - 288
VA - Robert Coy - (202)273-6666 - 228

FROM: RONALD K. PETERSON (for) Ronald K. Peterson
Assistant Director for Legislative Reference

OMB CONTACT: MIKE GOAD (395-7301)
Secretary's line (for simple responses): 395-6194

SUBJECT: HHS Proposed Testimony on Human Radiation Experimentation

DEADLINE: 2:00 P.M., TODAY, FRIDAY, August 26, 1994

THIS TRANSMISSION CONTAINS 12 PAGE(S) (total).

COMMENTS: Please note that, as HHS will present this statement on Monday, August 29th, this office must clear it today; if you do not respond by the deadline, we will assume that your agency has no comment. HHS advises that the Departments of Defense and Veterans Affairs may also testify at this hearing; at this time, we are attempting to confirm this. If Defense and VA plan to testify on Monday, we will ask that they submit their statements for review and clearance and will forward the statements to you as soon as we receive them.

OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

Please advise us if this item will affect direct spending or receipts for purposes of the the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

CC:
E. Pelton
K. Peroff
T.J. Glauthier
D. Zavada
B. Dorotinsky
G. Henry
A. Silas
J. Palmieri
B. Damus
J. Klein
S. Neuwirth
C. Varney/P. Caplan
B. Burton
T. Thornton
J. Podesta
J. Morall, OIRA

LRM #M-1745

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

If your response to this request for views is **simple** (e.g., concur/no comment) we prefer that you respond by **faxing** us this response sheet. If the response is **simple** and you prefer to call, please **call the branch-wide line** shown below (NOT the analyst's line) to leave a message with a secretary.

You may **also respond** by (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); (2) sending us a memo or letter; or (3) if you are an OASIS user in the Executive Office of the President, sending an E-mail message. Please **include** the LRM number shown above, and the **subject** shown below.

TO: MIKE GOAD (395-7301)
Office of Management and Budget
Fax Number: (202) 395-5691
Branch-Wide Line (to reach secretary): (202) 395-6194

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: HHS Proposed Testimony on Human Radiation Experimentation

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No objection

_____ No comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

TESTIMONY OF

JAMES M. SMITH, PH.D.
CENTERS FOR DISEASE CONTROL AND PREVENTION
PUBLIC HEALTH SERVICE

BEFORE THE

SENATE SUBCOMMITTEE ON CLEAN AIR AND NUCLEAR REGULATION,
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

AUGUST 29, 1994

I am Dr. James Smith, Chief of the Radiation Studies Branch, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC). CDC is pleased to have this opportunity to discuss the potential health effects of nasopharyngeal radium irradiation treatments and the possibility of undertaking new studies.

CDC has recently compiled current and historical literature relating to nasopharyngeal radium irradiation, which was an accepted medical treatment in the past. Most of the reports in the medical literature were about its use in children and military personnel. The goal of the treatment was to reduce swelling of enlarged lymphoid tissue in the nasopharynx, which was thought to cause various problems including conductive hearing loss and aerotitis media[1]. The typical treatment was performed using two radium applicators, each containing 50 mg. of radioactive radium. After a local anesthetic was applied, the applicators were inserted through each nostril, placed near the opening of the eustachian tube, and left in place for approximately 10 minutes. Medical research on the treatment began in the 1920s, following publication of several reports in the late 1930s and early 1940s nasopharyngeal radium irradiation became fairly widely used in the civilian population. Its use was reported in Birmingham Alabama, Baltimore Maryland, Boston

[1] Aerotitis media: a group of symptoms produced by the difference between the atmospheric pressure of the environment and the air pressure in the middle ear.

Massachusetts, Detroit Michigan, Vicksburg Mississippi, New York City, Cleveland Ohio, and Pittsburgh Pennsylvania. The use of nasopharyngeal radium irradiation by general practitioners and pediatricians, as well as otolaryngologists (ear, nose and throat specialists) and radiologists, was reported in the medical literature. Radium treatment was also used by the Army and Navy during World War II for treating aerotitis media. A symposium on its use and the underlying pathology was held by the American Academy of Ophthalmology and Otolaryngology in 1949. The use of nasopharyngeal radium continued into the 1950s, but was discontinued during the 1960s due to concern among physicians about the possibility of malignancy and because of the availability of alternative treatments, such as antibiotics and tympanotomy tubes (plastic ventilation tubes inserted through the ear drum).

Military use of nasopharyngeal radium irradiation treatment began in World War II, due to the sudden increase in military activity, aerotitis media rapidly became a problem for both the Army Air Forces and Navy submarine crews, causing large numbers of divers and flyers to miss missions. Military physicians believed acrotitis was caused by enlarged lymphoid tissue blocking the eustachian tube and preventing equalization of pressure during descent, leading to the complications of aerotitis (pain, fluid in the middle ear, bleeding, and rupture of the drum). Because radium treatments shrank the lymphoid tissue, it was thought to be an appropriate treatment for this condition. Flyers with

aerotitis missed approximately a third of their combat duty time. Thirty percent of men undergoing submarine training developed objective signs of aerotitis. Reports cited the return of personnel to their missions following treatment with nasopharyngeal radium irradiation. It is not documented in the medical literature when or why the military stopped using nasopharyngeal radium irradiation.

At the time nasopharyngeal radium irradiation treatments began to be used, many physicians believed that conductive hearing loss was due to blockage of the eustachian tube by enlarged lymphoid tissue, with subsequent middle ear problems leading to conductive deafness. It was thought best to treat this form of hearing loss in childhood, before the loss became irreversible. Nasopharyngeal radium treatments also were advocated to prevent repeated viral and bacterial infections, for asthma which occurred with repeated viral infections, for recurrent middle ear infections, for sinusitis, and for recurrent tonsillitis.

Early proponents of nasopharyngeal radium irradiation therapy cited several reasons for the advantage of nasopharyngeal irradiation over surgery and conventional X-irradiation. Radium treatment could shrink lymphoid tissues in areas that were inaccessible to surgeons. Compared with surgery, the radium treatment did not require general anesthesia and could be done as an outpatient procedure. In the military, radium applicators were more portable than conventional x-ray equipment, and

therefore radium was the only radiation treatment suitable for treatments in the field during war. It was thought to be safer than conventional X-ray treatment, because the radiation could be more accurately applied to the area of interest and did not have to pass through skin, soft tissue, and bone.

In summary, nasopharyngeal radium irradiation was an accepted medical treatment for hearing loss, aerotitis media, and other middle ear problems in the 1940s and 1950s. It appears to have been used mostly for military personnel and civilian children. It was used by pediatricians and general practitioners as well as ear, nose and throat specialists and radiologists. Nasopharyngeal radium irradiation was believed to be safer than conventional X-ray treatments, and to be useful in situations where surgery was not available.

Concerns about the safety of nasopharyngeal radium therapy began in the late 1940s. Initial concerns were about ulcerations and keratoses (horny projections from the tonsils and nasopharynx) which may require plastic surgery, particularly when they may occur in areas that were not readily observed by patients or physicians. Subsequent concerns were burns, crusting, wasting away of the surface lining of the nasopharynx, lesions of dilated small blood vessels, damage to growing bone and soft tissue, and cancer. Reports of thyroid and other carcinomas following treatments with external sources of radiation began appearing from 1950 to 1960, causing concern about the potential for

nasopharyngeal radium treatments to cause cancer. However, as late as 1978 the medical literature reported that there were no known reports of cancer following nasopharyngeal radium treatments.

Two studies of children who received nasopharyngeal radium irradiation were published in 1982 and 1989, with conflicting results. The first, by Sandler and colleagues in Maryland, found a statistically significant increase in head and neck tumors including brain tumors (four cases in the exposed group of 904 subjects vs. none in the unexposed comparison group), a statistically non-significant increase in lymphatic-hematopoietic and skin cancers, and a statistically non-significant decrease in breast cancer. The second, by Verduijn and colleagues in the Netherlands, found a statistically non-significant decrease in brain and breast cancers, and a statistically non-significant increase in lymphatic-hematopoietic and other cancers. No head and neck tumors other than brain tumors were found in either the exposed or unexposed groups.

Based on our review of the literature, and preliminary estimations of radiation doses received and of the numbers of subjects necessary, it may be possible to perform a meaningful epidemiologic study of persons who received nasopharyngeal radium irradiation. By this we mean a study with the ability to detect an association between exposure and disease if one truly exists, or the ability to prove no association between exposure and

disease if there truly is no association. However, such a study is likely to be difficult and complex. Therefore, it is very important that a feasibility study be undertaken before major resources are committed to a comprehensive study.

If an epidemiologic study were to be conducted, a design known as the retrospective cohort study would probably provide the most information on risks to persons who received nasopharyngeal radium irradiation. Cohort studies can be used to examine a broad array of adverse health effects, which for people exposed to nasopharyngeal radium irradiation would include pituitary and thyroid disease and cancers of the brain, parotid and other salivary glands, pituitary gland, nasal sinus, nasopharynx, soft palate, and thyroid gland. The retrospective cohort method would involve identifying a group, or cohort, of persons who received nasopharyngeal radium irradiation in the 1940s and 1950s. To determine risks for a cancer, the health experience of the cohort of exposed persons would have to be compared with a similar group of persons who did not receive nasopharyngeal radium irradiation. Such a study would take into to account tobacco and alcohol use, which may also cause specific tumors in the head and neck. However, use of the retrospective cohort method could be difficult and complex, because two groups would need to be identified and have their health outcomes tracked over the ensuing years until the present.

Issues that would need to be thoroughly addressed to determine

whether a study of this subject is feasible would include 1) the ability to identify and trace a cohort of persons who received the treatment in the 1940s and 1950s, and the ability to identify and trace a cohort of people who are similar in all respects except that they did not receive the radium treatment; and 2) the ability to ascertain the medical history of all study subjects during the ensuing 40 to 50 years. Because the expected occurrence of the various types of cancers is relatively small, missing just one or two cases could have a major impact on the results of the study. Therefore, for this study to be useful, it would be ideal to identify all cases of cancer that have occurred in cohort members since the 1940s. Locating living persons from records of 40-50 years ago would be very time intensive and would require the use of a variety of information sources, such as voter lists, driver's licenses, birth certificates, tax and property records, and military records. Determining the health status and possible occurrence of disease in those who are alive and can be located could be done through interviews, extensive reviews of medical records, and complete medical examinations. Determining the health history of those who are deceased and therefore unavailable for interview would clearly be more problematic. Therefore, it is very important that a feasibility study be undertaken before major resources are committed to a comprehensive study.

As a point of reference, CDC is currently conducting the Hanford Thyroid Disease Study, which is a retrospective study of person

exposed in the 1940s and 1950s to radioactive iodine emissions from the Hanford Nuclear Facility in the state of Washington. To complete this study CDC and its contractor will need to trace, locate, administer a questionnaire to, and examine more than 3,000 individuals. This study is requiring approximately $17 million, three CDC full time positions, and 40 contractor staff, and 8 years to complete. The pilot phase of this study has taken two years.

CDC would be willing to provide consultation to the Department of Veterans Affairs and the Department of Defense as they pursue the feasibility of a study of individuals exposed to this treatment during military service. The issue of the use of this treatment in the general population is separate from that of the military and would require a substantial effort to determine feasibility. If appropriate staff and funding arrangements can be made, CDC would be willing to explore the feasibility of undertaking a study of the health effects of persons who received nasopharyngeal radium treatments as children. If an epidemiologic study is indeed feasible, it should be realized it would be a very complex undertaking which would require significant effort and resources that would need to be sustained over a long period.

I would be happy to answer your questions.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503

URGENT

August 26, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1747

TO: Legislative Liaison Officer -

CIA - Tom Benjamin - (703)482-6126 - 258
DEFENSE - Samuel T. Brick, Jr. - (703)697-1305 - 325
ENERGY - Bob Rabben - (202)586-6718 - 209
HHS - Frances White - (202)690-7760 - 328
JUSTICE - Sheila F. Anthony - (202)514-2141 - 217
NASA - Jeff Lawrence - (202)358-1948 - 219
NEC - Sonyia Matthews - (202)456-6630 - 429
NSC - William H. Itoh - (202)395-3723 - 249
OSTP - Roselis D'Allessandro - (202)456-6014 - 288

FROM: RONALD K. PETERSON (for) Ronald K. Peterson
Assistant Director for Legislative Reference

OMB CONTACT: MIKE GOAD (395-7301)
Secretary's line (for simple responses): 395-6194

SUBJECT: VA Proposed Testimony on Human Radiation Experimentation

DEADLINE: 4:00 P.M., Today, Friday, August 26, 1994

THIS TRANSMISSION CONTAINS 5 PAGE(S) (total).

COMMENTS: If you do not respond by the deadline, we will assume that your agency has no comment.

OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

Please advise us if this item will affect direct spending or receipts for purposes of the the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

CC:
E. Pelton
K. Peroff
T.J. Glauthier
A. Keenan
D. Zavada
B. Dorotinsky
G. Henry
A. Silas
J. Palmieri
B. Damus
J. Klein
S. Neuwirth
C. Varney/P. Caplan
B. Burton
T. Thornton
J. Podesta
J. Morall, OIRA

LRM #M-1747

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

If your response to this request for views is **simple** (e.g., concur/no comment) we prefer that you respond by **faxing** us this response sheet. If the response is **simple** and you prefer to call, please **call the branch-wide line** shown below (NOT the analyst's line) to leave a message with a secretary.

You may **also respond** by (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); (2) sending us a memo or letter; or (3) if you are an OASIS user in the Executive Office of the President, sending an E-mail message. Please **include** the LRM number shown above, and the **subject** shown below.

TO: MIKE GOAD (395-7301)
Office of Management and Budget
Fax Number: (202) 395-5691
Branch-Wide Line (to reach secretary): (202) 395-6194

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: VA Proposed Testimony on Human Radiation Experimentation

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No objection

_____ No comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

Statement of
Susan Mather, M.D., M.P.H.
Assistant Chief Medical Director for
Environmental Medicine and Public Health
Department of Veterans Affairs
Before the
Committee on Environment and Public Works
Subcommittee on Clean Air and Nuclear Regulation
August 29, 1994
******

Mr. Chairman and members of the Subcommittee, I am pleased to be here today to participate in this hearing and to provide VA's testimony regarding the health effects of radium nasopharyngeal irradiation treatment. We share your concerns for the health and well-being of the veterans who received this kind of treatment during their service, as well as their families, and we very much appreciate your diligent efforts on their behalf.

VA's review including studies and plans for future studies

The use of radium nasopharyngeal irradiation for treatment of aerotitis media in military personnel was common in military facilities as well as non-military facilities during the 1940's and 1950's. The treatments were aimed at shrinking lymphoid tissues blocking the Eustachian tubes and thus helped prevent the occurrence of ear problems following pressure changes associated with submarine and flying duties. While the treatment has since been discontinued because of concerns about long-term health effects and new, alternatives for therapy, it was an accepted medical practice.

We have discussed the issue with both Department of Defense and Department of Health and Human Services officials and we have reviewed scientific publications related to the issue, including two large-scale controlled studies. A paper by Sandler et al., ("Neoplasms following childhood radium irradiation of the nasopharynx", Journal of the National Cancer Institute, 1982, 68:3-8) found no increased overall cancer risk but increased risk of developing benign and malignant head and neck tumors among exposed individuals. A paper by Verduijn et al., ("Mortality after nasopharyngeal radium irradiation for Eustachian tube dysfunction", Annals Otol Rhino Laryngol, 1989, 98:839-844) found no increase in mortality rates due to cancer. These studies indicate that questions remain regarding the possible cancer risks associated with this treatment.

As a result, VA's Office of Environmental Medicine and Public Health has been in contact with the Submarine Survivors Group and we have received the names of some submariners and airmen reported to have received radium

treatments. VA employees are attempting to locate these veterans' military personnel and medical records to determine whether specific information relating to their radium treatments is documented. This will assist in determining the feasibility of a possible epidemiological study.

Documentation of the treatment of the subjects is essential for any valid epidemiological study to be done. If the treatment can be documented, we can then seek to identify an affected population through the examination of training rosters and submarine logs. A comparison group of people with similar characteristics but who did not receive radium treatments will also need to be identified. If two groups (exposed and controls) can be identified that are of adequate size to give statistically valid results, then morbidity and mortality studies can be designed, peer-reviewed, and carried out. A mortality study probably would be the first study to be considered. The suspected health outcomes of concern from previous studies are cancers and most of the head and neck cancers (with the exception of thyroid malignancies) are eventually fatal. Also, the time period which has elapsed is sufficient for radiogenic cancers to have been manifested. Finally, a mortality study can be completed sooner and is generally less costly than a morbidity study. If the mortality study suggests any other health effects related to radium treatments, a morbidity study can be designed to further evaluate those health effects.

VA actions to provide information and guidance to veterans

Initially veterans benefits counselors staffing VA's toll-free radiation help line and VA's general benefits information telephone service line may not have been fully advised about the concerns of submariners and airmen and the specific issues surrounding nasopharyngeal irradiation. However, this situation was corrected last spring, and information about how affected veterans can apply for disability benefits and VA medical treatment has now been disseminated nationwide.

More generally, whenever a veteran alleges involvement in experimental medical treatment during military service, identifying information such as the veterans name, claim number, dates of service, and exposure/experimentation information are taken by veterans benefits counselors and forwarded to the Department of Defense for tracking and further follow-up. Veterans benefits counselors assist veterans in filing claims for service-connected compensation, medical treatment, and other services. When appropriate, the veterans benefits counselors also provide additional information related to military treatment to the involved military service office. VA is committed to

assisting any veteran who believes he or she may have been injured: by exposure to ionizing radiation; by any experimental medical care involving radiation; or by any other examination or treatment.

Status of VA's radiation help line and other referrals and contacts

Of the over 1,500 reports of calls referred to the Veterans Health Administration (VHA) radiation database to date, only seven specifically mentioned these radium treatments.

Since January 1994 VA's radiation help line has referred to the Department of Defense 520 cases where veterans allege that they have undergone experimental treatment during military service. Although separate statistics have not been maintained on cases involving nasopharyngeal irradiation, the number is believed to be minimal, similar to VHA's experience.

That concludes my statement Mr. Chairman. I would be pleased to answer any questions that you or other members of the Subcommittee have.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION
HEALTH LEGISLATION
WASHINGTON, D.C. 20201

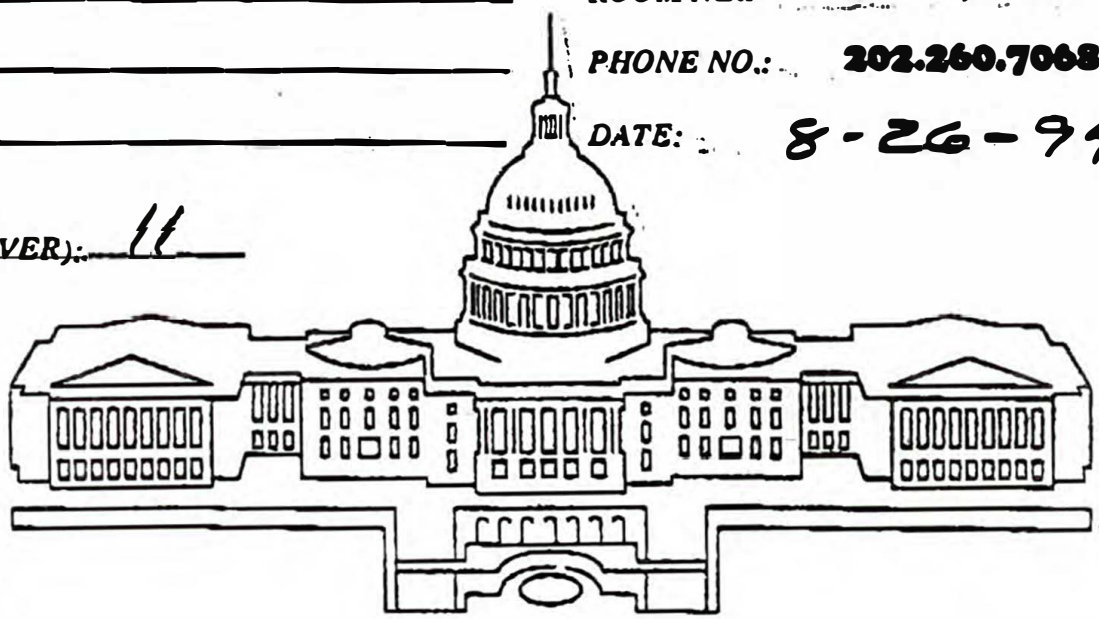
PHONE: (202) 690-7450 **FAX: (202) 690-8425**

TO: **FROM:**

NAME: SEE BELOW
OFFICE:
ROOM NO.:
PHONE NO.:
FAX NO.:

NAME: SEAN DONOHUE
OFFICE: HEALTH LEGISLATION
ROOM NO.: 409 H, HHH
PHONE NO.: 202.260.7068
DATE: 8-26-94

TOTAL PAGES (INCLUDING COVER): 11



REMARKS:

RE: CDC STATEMENT ON NASOPHARYNGEAL IRRADIATION TREATMENTS - ACTION

TO: PHIL KAPLAN - 456-6704
MIKE GOOD - 395-4691
DOUG DOBLIN - 273-6791
VERONICA SANDERS - 703-697-8299

URGENT - PLEASE HAND CARRY !!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Legislation

Washington, D.C. 20201

NOTE TO: Bill Anthony, OASH
Cheryl Austein, ASPE
Glen Harelson, OS/ES
Jill Hargis, IOS/COS
D.A. Henderson, OASH
Don Poppke, ASMB
Paul Spiegel, OGC/L

SUBJECT: Draft Statement--Radium Nasopharyngeal Irradiation Treatment--ACTION

Attached is the draft statement of James M. Smith, Ph.D., CDC. Dr. Smith is scheduled to testify on Monday, August 29 before the Senate Environment and Public Works Subcommittee on Clean Air and Nuclear Regulation (Chairman Lieberman, D-CT). The hearing will focus on the health effects resulting from radium nasopharyngeal irradiation treatment of veterans and civilians. HHS, VA and DoD have been invited to testify.

Please review the attached statement and provide your comments on 260-7068 by 1:00 p.m., Friday, August 26. Your office's clearance will be assumed if comments are not received by the deadline.

Thanks for your assistance.

Sean Donohue

Attachment

cc: Jerry Klepner
Karen Pollitz
Roger McClung
Cam Gardett

TESTIMONY OF

JAMES M. SMITH, PH.D.
CENTERS FOR DISEASE CONTROL AND PREVENTION
PUBLIC HEALTH SERVICE

BEFORE THE

SENATE SUBCOMMITTEE ON CLEAN AIR AND NUCLEAR REGULATION,
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

AUGUST 29, 1994

I am Dr. James Smith, Chief of the Radiation Studies Branch, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC). CDC is pleased to have this opportunity to discuss the potential health effects of nasopharyngeal radium irradiation treatments and the possibility of undertaking new studies.

CDC has recently compiled current and historical literature relating to nasopharyngeal radium irradiation, which was an accepted medical treatment in the past. Most of the reports in the medical literature were about its use in children and military personnel. The goal of the treatment was to reduce swelling of enlarged lymphoid tissue in the nasopharynx, which was thought to cause various problems including conductive hearing loss and aerotitis media[1]. The typical treatment was performed using two radium applicators, each containing 50 mg. of radioactive radium. After a local anesthetic was applied, the applicators were inserted through each nostril, placed near the opening of the eustachian tube, and left in place for approximately 10 minutes. Medical research on the treatment began in the 1920s, following publication of several reports in the late 1930s and early 1940s nasopharyngeal radium irradiation became fairly widely used in the civilian population. Its use was reported in Birmingham Alabama, Baltimore Maryland, Boston

[1] Aerotitis media: a group of symptoms produced by the difference between the atmospheric pressure of the environment and the air pressure in the middle ear.

Massachusetts, Detroit Michigan, Vicksburg Mississippi, New York City, Cleveland Ohio, and Pittsburgh Pennsylvania. The use of nasopharyngeal radium irradiation by general practitioners and pediatricians, as well as otolaryngologists (ear, nose and throat specialists) and radiologists, was reported in the medical literature. Radium treatment was also used by the Army and Navy during World War II for treating aerotitis media. A symposium on its use and the underlying pathology was held by the American Academy of Ophthalmology and Otolaryngology in 1949. The use of nasopharyngeal radium continued into the 1950s, but was discontinued during the 1960s due to concern among physicians about the possibility of malignancy and because of the availability of alternative treatments, such as antibiotics and tympanotomy tubes (plastic ventilation tubes inserted through the ear drum).

Military use of nasopharyngeal radium irradiation treatment began in World War II, due to the sudden increase in military activity, aerotitis media rapidly became a problem for both the Army Air Forces and Navy submarine crews, causing large numbers of divers and flyers to miss missions. Military physicians believed aerotitis was caused by enlarged lymphoid tissue blocking the eustachian tube and preventing equalization of pressure during descent, leading to the complications of aerotitis (pain, fluid in the middle ear, bleeding, and rupture of the drum). Because radium treatments shrank the lymphoid tissue, it was thought to be an appropriate treatment for this condition. Flyers with

aerotitis missed approximately a third of their combat duty time. Thirty percent of men undergoing submarine training developed objective signs of aerotitis. Reports cited the return of personnel to their missions following treatment with nasopharyngeal radium irradiation. It is not documented in the medical literature when or why the military stopped using nasopharyngeal radium irradiation.

At the time nasopharyngeal radium irradiation treatments began to be used, many physicians believed that conductive hearing loss was due to blockage of the eustachian tube by enlarged lymphoid tissue, with subsequent middle ear problems leading to conductive deafness. It was thought best to treat this form of hearing loss in childhood, before the loss became irreversible. Nasopharyngeal radium treatments also were advocated to prevent repeated viral and bacterial infections, for asthma which occurred with repeated viral infections, for recurrent middle ear infections, for sinusitis, and for recurrent tonsillitis.

Early proponents of nasopharyngeal radium irradiation therapy cited several reasons for the advantage of nasopharyngeal irradiation over surgery and conventional X-irradiation. Radium treatment could shrink lymphoid tissues in areas that were inaccessible to surgeons. Compared with surgery, the radium treatment did not require general anesthesia and could be done as an outpatient procedure. In the military, radium applicators were more portable than conventional x-ray equipment, and

therefore radium was the only radiation treatment suitable for treatments in the field during war. It was thought to be safer than conventional X-ray treatment, because the radiation could be more accurately applied to the area of interest and did not have to pass through skin, soft tissue, and bone.

In summary, nasopharyngeal radium irradiation was an accepted medical treatment for hearing loss, aerotitis media, and other middle ear problems in the 1940s and 1950s. It appears to have been used mostly for military personnel and civilian children. It was used by pediatricians and general practitioners as well as ear, nose and throat specialists and radiologists. Nasopharyngeal radium irradiation was believed to be safer than conventional X-ray treatments, and to be useful in situations where surgery was not available.

Concerns about the safety of nasopharyngeal radium therapy began in the late 1940s. Initial concerns were about ulcerations and keratoses (horny projections from the tonsils and nasopharynx) which may require plastic surgery, particularly when they may occur in areas that were not readily observed by patients or physicians. Subsequent concerns were burns, crusting, wasting away of the surface lining of the nasopharynx, lesions of dilated small blood vessels, damage to growing bone and soft tissue, and cancer. Reports of thyroid and other carcinomas following treatments with external sources of radiation began appearing from 1950 to 1960, causing concern about the potential for

nasopharyngeal radium treatments to cause cancer. However, as late as 1978 the medical literature reported that there were no known reports of cancer following nasopharyngeal radium treatments.

Two studies of children who received nasopharyngeal radium irradiation were published in 1982 and 1989, with conflicting results. The first, by Sandler and colleagues in Maryland, found a statistically significant increase in head and neck tumors including brain tumors (four cases in the exposed group of 904 subjects vs. none in the unexposed comparison group), a statistically non-significant increase in lymphatic-hematopoietic and skin cancers, and a statistically non-significant decrease in breast cancer. The second, by Verduijn and colleagues in the Netherlands, found a statistically non-significant decrease in brain and breast cancers, and a statistically non-significant increase in lymphatic-hematopoietic and other cancers. No head and neck tumors other than brain tumors were found in either the exposed or unexposed groups.

Based on our review of the literature, and preliminary estimations of radiation doses received and of the numbers of subjects necessary, it may be possible to perform a meaningful epidemiologic study of persons who received nasopharyngeal radium irradiation. By this we mean a study with the ability to detect an association between exposure and disease if one truly exists, or the ability to prove no association between exposure and

disease if there truly is no association. However, such a study is likely to be difficult and complex. Therefore, it is very important that a feasibility study be undertaken before major resources are committed to a comprehensive study.

If an epidemiologic study were to be conducted, a design known as the retrospective cohort study would probably provide the most information on risks to persons who received nasopharyngeal radium irradiation. Cohort studies can be used to examine a broad array of adverse health effects, which for people exposed to nasopharyngeal radium irradiation would include pituitary and thyroid disease and cancers of the brain, parotid and other salivary glands, pituitary gland, nasal sinus, nasopharynx, soft palate, and thyroid gland. The retrospective cohort method would involve identifying a group, or cohort, of persons who received nasopharyngeal radium irradiation in the 1940s and 1950s. To determine risks for a cancer, the health experience of the cohort of exposed persons would have to be compared with a similar group of persons who did not receive nasopharyngeal radium irradiation. Such a study would take into to account tobacco and alcohol use, which may also cause specific tumors in the head and neck. However, use of the retrospective cohort method could be difficult and complex, because two groups would need to be identified and have their health outcomes tracked over the ensuing years until the present.

Issues that would need to be thoroughly addressed to determine

whether a study of this subject is feasible would include 1) the ability to identify and trace a cohort of persons who received the treatment in the 1940s and 1950s, and the ability to identify and trace a cohort of people who are similar in all respects except that they did not receive the radium treatment; and 2) the ability to ascertain the medical history of all study subjects during the ensuing 40 to 50 years. Because the expected occurrence of the various types of cancers is relatively small, missing just one or two cases could have a major impact on the results of the study. Therefore, for this study to be useful, it would be ideal to identify all cases of cancer that have occurred in cohort members since the 1940s. Locating living persons from records of 40-50 years ago would be very time intensive and would require the use of a variety of information sources, such as voter lists, driver's licenses, birth certificates, tax and property records, and military records. Determining the health status and possible occurrence of disease in those who are alive and can be located could be done through interviews, extensive reviews of medical records, and complete medical examinations. Determining the health history of those who are deceased and therefore unavailable for interview would clearly be more problematic. Therefore, it is very important that a feasibility study be undertaken before major resources are committed to a comprehensive study.

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exposed in the 1940s and 1950s to radioactive iodine emissions from the Hanford Nuclear Facility in the state of Washington. To complete this study CDC and its contractor will need to trace, locate, administer a questionnaire to, and examine more than 3,000 individuals. This study is requiring approximately $17 million, three CDC full time positions, and 40 contractor staff, and 8 years to complete. The pilot phase of this study has taken two years.

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I would be happy to answer your questions.

ASSISTANT TO THE SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

ATOMIC ENERGY

Honorable John Dingell
Chairman, Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is to acknowledge receipt of a copy of your February 17, 1994 letter to Ms. Christine Varney, Deputy Assistant to the President and Secretary to the Cabinet, expressing your concerns regarding human radiation experiments and the residents of the Marshall Islands, specifically the inhabitants of Uterik Atoll. Your committee is to be commended for its efforts to raise the national consciousness regarding this issue, and your commitment to the principles of government accountable to the people it serves.

The Department of Defense (DoD) believes, as you do, in the importance of providing the maximum possible disclosure to the public regarding the government's involvement in radiation exposure to human populations, whether that radiation exposure be nuclear weapons test related, or the result of specific human radiation experiment research.

To this end, the DoD has been working aggressively with other members of the Human Radiation Interagency Working Group, to locate all records of human radiation experiments since 1944. The Human Radiation Interagency Working Group has defined the "human radiation experiment" population to include experiments on individuals involving intentional exposure to ionizing radiation. This includes experiments involving intentional environmental releases of radiation that (a) were designed to test human health effects of ionizing radiation; or (b) were designed to test the extent of human exposure to ionizing radiation. Common and routine clinical practices, such as established diagnosis and treatment methods involving incidental exposures to ionizing radiation are not included in the scope of the Interagency Working Group's mandate.

The Interagency Working Group has also identified several other specific experiments for inclusion within the scope of their records search. They are: the experiment involving the atmospheric diffusion of radioactive gases, commonly referred to as "the Green Run test," conducted by the former Atomic Energy Commission (AEC) and the Air Force in December 1949, at Hanford, Washington; two radiation warfare field experiments, involving gamma radiation released from non-bomb point sources at or near ground level, conducted at the AEC's Oak Ridge office in 1948;

six tests conducted during 1949 to 1952 of radiation warfare ballistic dispersal devices containing radioactive agents at the U.S. Army's Dugway Proving Ground, site in Utah; four atmospheric radiation tracking tests at Los Alamos, New Mexico in 1950. Any other similar human radiation experiments that may later be identified by the Interagency Working Group will be included in the program. Radiation exposures from atmospheric nuclear weapons tests are not included within the Interagency Working Group's mandate. There are established government programs with existing compensation mechanisms, such as the Nuclear Test Personnel Review (NTPR) for individuals falling within this latter category.

It is my understanding, that the White House has determined that the radiation exposure experiences of the residents of the Marshall Islands, as a result of atomic testing in the Pacific, fall outside the Independent Advisory Committee's mandate, as reflected in the Executive Order that established the Advisory Committee. Furthermore, it is also my understanding, that DoE is currently working with other Federal agencies, such as the Department of the Interior (DOI), the Republic of the Marshall Islands (RepMar) and local Marshall Islands government representatives to provide medical surveillance and radiological environmental monitoring on behalf of the Marshall Island people exposed to radioactive fallout from atmospheric nuclear weapons testing. Moreover, Secretary Hazel O'Leary has pledged that the Department of Energy will make available any and all documents relating to atomic tests and has directed that any documents relevant to the Marshall Islands be identified and declassified whenever possible.

Please be assured that the Department of Defense (DoD) is strongly committed to learning all we can about our role in this matter and in sharing that information with the public.

Please do not hesitate to contact me if I can be of any future service.

Sincerely,

Harold P. Smith, Jr.

SECRETARY OF DEFENSE ROUTING SLIP	ACT COPY	INFO COPY		ACT COPY	INFO COPY
OFFICE OF THE SECRETARY OF DEFENSE			**MILITARY DEPARTMENTS**		
SECRETARY OF DEFENSE		✓	SECRETARY OF THE ARMY		
DEPUTY SECRETARY OF DEFENSE		✓	SECRETARY OF THE NAVY		
THE SPECIAL ASSISTANT		✓	SECRETARY OF THE AIR FORCE		
EXECUTIVE SECRETARY		✓	**JOINT CHIEFS OF STAFF**		
ESR INTERAGENCY			CHAIRMAN		
/ UNDER SECRETARY FOR ACQUISITION	✓		DIRECTOR, JOINT STAFF		
ASD *(Production & Logistics)*			**DEFENSE AGENCIES**		
Director, Defense Research & Engineering			DEF ADV RSCH PROJ AGENCY		
UNDER SECRETARY FOR POLICY		✓	DEFENSE COMMISSARY AGENCY		
ASD *(International Security Affairs)*			DEFENSE COMMUNICATIONS AGENCY		
ASD *(International Security Policy)*			DEFENSE CONTRACT AUDIT AGENCY		
ASD *(Special Operations / LIC)*			DEFENSE FINANCE AND ACCOUNTING SERVICE		
ASD *(C3I)*			DEFENSE INTELLIGENCE AGENCY		
ASD *(Force Management & Personnel)*			DEFENSE INVESTIGATIVE SERVICE		
ASD *(Health Affairs)*			DEFENSE LEGAL SERVICES AGENCY		
ASD *(Legislative Affairs)*		✓	DEFENSE LOGISTICS AGENCY		
ASD *(Program Analysis & Evaluation)*			DEFENSE MAPPING AGENCY		
ASD *(Public Affairs)*			DEFENSE NUCLEAR AGENCY		
ASD *(Reserve Affairs)*			DEFENSE SECURITY ASSISTANCE AGENCY		
COMPTROLLER, DOD			NSA/CENTRAL SECURITY SERVICE		
GENERAL COUNSEL, DOD			ON-SITE INSPECTION AGENCY		
INSPECTOR GENERAL, DOD			STRATEGIC DEFENSE INITIATIVE ORG		
DIR, OPERATIONAL TEST & EVALUATION			ASD RE		✓
DIR, ADMINISTRATION & MANAGEMENT					

TYPE OF ACTION REQUIRED

	PREPARE REPLY FOR SEC OF DEF SIGNATURE		COMMENTS AND / OR RECOMMENDATIONS
	PREPARE REPLY FOR DEP SEC OF DEF SIGNATURE		INFORMATION AND RETENTION
/	REPLY DIRECT *(Forward copy of reply to CCD, Room 3A948)*	✓	COORDINATE REPLY WITH LA
	APPROPRIATE ACTION		

REMARKS

CONGRESSIONAL

ACTION DUE DATE *(YYMMDD)*	ROUTING DATE *(YYMMDD)*	OSD CONTROL NUMBER	
MAR 9 1994	FEB 23 [illegible]	03847	

SD Form 14, FEB 91 *Previous editions are obsolete.* 25 FEB [illegible] 234/052

ROOM 2323
RAYBURN HOUSE OFFICE BUILDING
PHONE (202) 225-4441

U.S. House of Representatives

Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce

Washington, DC 20515-6116

February 17, 1994

1994 FEB 23 PM 12:20
OFFICE OF THE
SECRETARY OF DEFENSE

The Honorable William J. Perry
Secretary of Defense
U.S. Department of Defense
The Pentagon
Room 3E880
Washington, D.C. 20301-1000

Dear Secretary Perry:

Enclosed for your information is a copy of a February 17, 1994 letter that the Subcommittee on Oversight and Investigations sent to Ms. Christine Varney, Deputy Assistant to the President and Secretary to the Cabinet, concerning human radiation experiments that may have been conducted in the Marshall Islands. As a member of the White House's Human Radiation Interagency Working Group, you will, I am sure, share my concern about the evidence we have received regarding the treatment of the inhabitants of Uterik Atoll. I have expressed to Ms. Varney my view that activities in the Marshall Islands be included in the review being conducted by the Interagency Working Group.

Sincerely,

John D. Dingell
Chairman
Subcommittee on
Oversight and Investigations

Enclosure

cc: The Honorable Dan Schaefer
Ranking Republican Member
Subcommittee on Oversight and Investigations

The Honorable George Miller
Chairman
Committee on Natural Resources

03847

The Honorable Bruce Babbitt
Secretary of the Interior
U.S. Department of the Interior

The Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency

ROOM 2323
RAYBURN HOUSE OFFICE BUILDING
PHONE (202) 225-4441

U.S. House of Representatives

Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce

Washington, DC 20515-6116

February 17, 1994

Ms. Christine Varney
Deputy Assistant to the President and
Secretary to the Cabinet
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Ms. Varney:

On January 11, 1994, members of the staff of the Subcommittee on Oversight and Investigations attended a meeting with you at the Old Executive Office Building concerning government-sponsored radiation experiments and the Administration's plan to address this sorry chapter in our history. In response to questions, an Administration official said that activities in the Marshall Islands would not be included in the review by the Human Radiation Interagency Working Group, which the White House has established, because there is no evidence that radiation experiments were ever conducted on humans living in those islands.

I am sorry to report that the belief that no human experiments were conducted in the Marshall Islands appears to be wrong. Recently, the Subcommittee learned that the inhabitants of Uterik Atoll may have been used as human guinea pigs in an effort to "get a measure of the human uptake when people live in a contaminated environment." This possibility is revealed by the January 13-14, 1956 minutes of the U.S. Atomic Energy Commission's (AEC) Advisory Committee on Biology and Medicine (see attached). For decades, this document was withheld from the public through its "secret" classification.

Not only does this document suggest the existence of yet another previously secret radiation experiment, it also reflects extraordinary callousness on the part of U.S. Government officials. According to the Advisory Committee's minutes, the inhabitants of Uterik Atoll "got initially about 15 roentgens" as the result of a nuclear test in the vicinity. Then, after a temporary evacuation, they were returned to their island which AEC officials characterized as: "safe to live on" but "by far

the most contaminated place in the world...." AEC officials expressed enthusiasm for what they said would be "a very intriguing study" of the effects of a contaminated environment on the bodies of the Atoll's inhabitants:

> "...it will be very interesting to go back and get good environmental data, how many per square mile; what isotopes are involved and a sample of food changes in many humans through their urines, so as to get a measure of the human uptake when people live in a contaminated environment."

The minutes do not reflect what, if anything, the people of Uterik Atoll were told about the level of contamination on their island.

One wonders why anyone, let alone scientists working for the United States Government, would knowingly allow significant numbers of people to live in "the most contaminated place in the world." Sadly, the possible explanation also appears in the Advisory Committee's minutes:

> "While it is true that these people do not live, I would say, the way Westerners do, civilized people, it is nevertheless also true that <u>these people are more like us than the mice."</u> (emphasis added)

I am certain that you find this description of the inhabitants of Uterik Atoll as disturbing as we do. Even more disturbing is the fact that the scientist making the statement was apparently a U.S. Government official.

The Subcommittee trusts that a complete inquiry into the "study" alluded to in the Advisory Committee's minutes will be incorporated into the review being conducted by the Interagency Working Group and that the results will be shared with the Subcommittee, the American public, and, in particular, the people of Uterik Atoll. We request that the Human Radiation Interagency Working Group advise us of its plans with respect to this matter.

Thank you for your attention to this important issue.

Sincerely,

John D. Dingell
Chairman
Subcommittee on
Oversight and Investigations

Enclosure

cc: The Honorable Dan Schaefer
Ranking Republican Member
Subcommittee on Oversight and Investigations

The Honorable George Miller
Chairman
Committee on Natural Resources

Members
Human Radiation Interagency Working Group

Original copy
destroyed by F.K.M
3/24/76

[redacted]

[redacted]

[redacted]

ADVISORY COMMITTEE ON BIOLOGY
and MEDICINE

[redacted]

January 13, 14, 1956
DELETED VERSION
1/28/94

-at-

U.S. ATOMIC ENERGY COMMISSION
NEW YORK OPERATIONS OFFICE
HEALTH and SAFETY LABORATORY
70 Columbus Avenue
New York, New York

CLASSIFICATION CANCELLED
WITH DELETIONS
BY AUTHORITY OF DOE/SA-20
BY R.S. DEWEY, DATE:
1/28/94
1-28-94
1/28/94

[redacted]

some work on fish samples, preferably I presume, taken more or less at the consumer level to see that the levels remain at about what we found for Castle.

Now, there may have been hotter fish found in here right after the test, but in terms of the actual -- probably the most toxic of the isotopes still, we are only dealing with a few per cent of the permissible levels so far. This may not hold, but that is our best estimate to date.

MR. EISENBUD: Thank you, John. Gentlemen, the adjournment time is 5:15, it is now 5:00. I had hoped to be able to make a few summary remarks and project a little bit of this into the future, but I don't need to do this now, I can do this tomorrow.

DR. FAILLA: It might be better to do it now.

MR. EISENBUD: I want to re-emphasize that the program you have heard today is a program that is in progress now.

If you heard it six months ago, it wouldn't be very different with one exception. None of the items have been reported in internal reports.

We have a few things that we are thinking about for the immediate future and I would like to mention a few of these.

We think that one very intriguing study can be made and plans are on the way to implement this — "Uterik" Atoll is the atoll furtherest from the March 1st shot where people were exposed got initially about 15 roentgens and then they were evacuated and they returned.

They had been living on that Island; now that Island is safe to live on but is by far the most contaminated place in the world and it will be very interesting to go back and get good environmental data, how many per square mile; what isotopes are involved and a sample of food changes in many humans through their urines, so as to get a measure of the human uptake when people live in a contaminated environment.

Now, data of this type has never been available. While it is true that these people do not live, I would say, the way Westerners do, civilized people, it is nevertheless also true that these people are more like us than the mice. So that is something which will be done this winter.

ROOM 2323
RAYBURN HOUSE OFFICE BUILDING
PHONE (202) 225-4441

U.S. House of Representatives

Subcommittee on Oversight and Investigations
of the
Committee on Energy and Commerce
Washington, DC 20515-6116

February 17, 1994

Ms. Christine Varney
Deputy Assistant to the President and
Secretary to the Cabinet
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Ms. Varney:

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I am sorry to report that the belief that no human experiments were conducted in the Marshall Islands appears to be wrong. Recently, the Subcommittee learned that the inhabitants of Uterik Atoll may have been used as human guinea pigs in an effort to "get a measure of the human uptake when people live in a contaminated environment." This possibility is revealed by the January 13-14, 1956 minutes of the U.S. Atomic Energy Commission's (AEC) Advisory Committee on Biology and Medicine (see attached). For decades, this document was withheld from the public through its "secret" classification.

Not only does this document suggest the existence of yet another previously secret radiation experiment, it also reflects extraordinary callousness on the part of U.S. Government officials. According to the Advisory Committee's minutes, the inhabitants of Uterik Atoll "got initially about 15 roentgens" as the result of a nuclear test in the vicinity. Then, after a temporary evacuation, they were returned to their island which AEC officials characterized as: "safe to live on" but "by far

the most contaminated place in the world...." AEC officials expressed enthusiasm for what they said would be "a very intriguing study" of the effects of a contaminated environment on the bodies of the Atoll's inhabitants:

> "...it will be very interesting to go back and get good environmental data, how many per square mile; what isotopes are involved and a sample of food changes in many humans through their urines, so as to get a measure of the human uptake when people live in a contaminated environment."

The minutes do not reflect what, if anything, the people of Uterik Atoll were told about the level of contamination on their island.

One wonders why anyone, let alone scientists working for the United States Government, would knowingly allow significant numbers of people to live in "the most contaminated place in the world." Sadly, the possible explanation also appears in the Advisory Committee's minutes:

> "While it is true that these people do not live, I would say, the way Westerners do, civilized people, it is nevertheless also true that <u>these people are more like us than the mice."</u> (emphasis added)

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The Subcommittee trusts that a complete inquiry into the "study" alluded to in the Advisory Committee's minutes will be incorporated into the review being conducted by the Interagency Working Group and that the results will be shared with the Subcommittee, the American public, and, in particular, the people of Uterik Atoll. We request that the Human Radiation Interagency Working Group advise us of its plans with respect to this matter.

Thank you for your attention to this important issue.

Sincerely,

John D. Dingell
Chairman
Subcommittee on
Oversight and Investigations

Enclosure

cc: The Honorable Dan Schaefer
Ranking Republican Member
Subcommittee on Oversight and Investigations

The Honorable George Miller
Chairman
Committee on Natural Resources

Members
Human Radiation Interagency Working Group

OFFICE OF CABINET AFFAIRS

THE WHITE HOUSE

WASHINGTON

FAX

TO: Admiral Wisely

DATE: 3/22

NO. OF PAGES 2
(Including cover)

PHONE: 703 602 1365

FAX: 703 602 5971

PRIORITY: (Y) N

FROM: Phil Caplan

PHONE: (202) 456-2572

FAX: (202) 456-6704

MESSAGE:

As promised — better late than never.

Let me know if you need more.

THE WHITE HOUSE

WASHINGTON

March 18, 1994

The Honorable John Dingell
Chairman, Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter of February 17, 1994, expressing your concerns about the effects of radiation on the residents of the Marshall Islands.

Secretary Hazel O'Leary has pledged that the Department of Energy will soon make available any and all documents relating to these atomic tests and fully comply with all efforts to produce any records dealing with treatment of the residents of the Marshall Islands. This pledge includes the release of previously classified material relating to the Islands.

We will not include these atomic tests in the Human Radiation investigation as they fall outside the Independent Advisory Committee's mandate, as reflected in the Executive Order that established the Advisory Committee. Attached is a copy of the Executive Order for your reference.

It is my understanding that DOE and other Agencies will make every effort to cooperate with you in providing all documents and records and other information relating to the Marshall Islands.

Please do not hesitate to contact me if I can answer any questions or be of future service.

Sincerely,

Christine A. Varney
Secretary to the Cabinet

Enclosure

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503

SPECIAL

June 10, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1546

TO: Legislative Liaison Officer -

CIA - Tom Benjamin - (703)482-6126 - 258
DEFENSE - Samuel T. Brick, Jr. - (703)697-1305 - 325
ENERGY - Bob Rabben - (202)586-6718 - 209
HHS - Frances White - (202)690-7760 - 328
JUSTICE - Sheila F. Anthony - (202)514-2141 - 217
NASA - Jeff Lawrence - (202)358-1948 - 219
NEC - Sonyia Matthews - (202)456-6722 - 429
NSC - William H. Itoh - (202)395-3723 - 249
OSTP - Roselis D'Allessandro - (202)456-6014 - 288

FROM: RONALD K. PETERSON (for) Ronald K. Peterson
Assistant Director for Legislative Reference

OMB CONTACT: MIKE GOAD (395-7301)
Secretary's line (for simple responses): 395-6194

SUBJECT: VA Qs and As on Human Radiation Experimentation

DEADLINE: 10:00 A.M., Wednesday, June 15, 1994

COMMENTS: Please respond by the deadline; if you do not, we will assume that your agency has no comment.

OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

Please advise us if this item will affect direct spending or receipts for purposes of the the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

CC:
E. Pelton
K. Peroff
T.J. Glauthier
D. Zavada
B. Dorotinsky
G. Henry
A. Silas
J. Palmieri
B. Damus
J. Klein
S. Neuwirth
C. Varney/P. Caplan
B. Burton
T. Thornton
J. Podesta
J. Morall, OIRA

7 Page

LRM #M-1546

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

If your response to this request for views is **simple** (e.g., concur/no comment) we prefer that you respond by **faxing** us this response sheet. If the response is **simple** and you prefer to call, please **call the branch-wide line** shown below (NOT the analyst's line) to leave a message with a secretary.

You may **also respond** by (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); (2) sending us a memo or letter; or (3) if you are an OASIS user in the Executive Office of the President, sending an E-mail message. Please **include** the LRM number shown above, and the **subject** shown below.

TO: MIKE GOAD (395-7301)
Office of Management and Budget
Fax Number: (202) 395-5691
Analyst/Attorney's Direct Number: (202) 395-7301
Branch-Wide Line (to reach secretary): (202) 395-6194

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: VA Qs and As on Human Radiation Experimentation

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No objection

_____ No comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

The Honorable John Glenn
Chairman, Committee on
Governmental Affairs
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed are the Department's responses to follow-up questions posed following the January 25, 1994, hearing on radiation and other human subject experiments.

We regret the delay in getting these questions answered and appreciate the opportunity to submit this information for the record.

Sincerely yours,

Jesse Brown

Enclosure
JB/rlh

RHARRIS: (60L) c:1-25LT.DOC (LTR) c:1-25AT.DOC (ATT)

Questions by Chairman John Glenn
Senate Committee on Governmental Affairs Hearing
January 25, 1994

Question 1: How many DoD personnel have been compensated for health effects suffered as a result of the atmospheric testing program?

Answer: As of February 10, 1994, our records indicate that service-connected benefits have been granted to 938 veterans and survivors for disabilities or death alleged to have resulted from exposure to ionizing radiation during U.S. atmospheric testing.

Question 2: How many claims have been filed under this program?

Answer: As of February 10, 1994, 15,587 radiation claims have been filed, of which 7,112 were for disabilities or death alleged to have resulted from exposure during atmospheric testing.

Question 3: What are the general reasons that claims are denied?

Answer: The following denial reasons have been encountered:

(1)The veteran did not claim a disease recognized as radiogenic for VA purposes.

(2) The veteran claimed a disease recognized as radiogenic for VA purposes, but the medical evidence did not disclose the existence of the claimed disease.

(3) Exposure to ionizing radiation could not be established.

(4) The veteran claimed a "recognized" radiogenic disease but the reconstructed estimate of the ionizing radiation dose was determined too small to have resulted in development of the disease (for claims under 38 CFR 3.311, formerly 3.311b, only).

(5) The veteran claimed a "recognized" radiogenic disease, but the disease did not appear within the time period required by regulation (for claims under CFR 3.311, formerly 3.311b, only).

Question 4: Have you seen an increase in the number of claims since the radiation experiments issue began to receive more attention?

Answer: At this time, we have seen no trend indicated an increase in the number of radiation claims filed.

Question 5: Did the VA ever conduct classified radiation experiments on human subjects?

Answer: VA is not aware of any classified experiments involving human subjects which were funded by VA or conducted by VA investigators. However, VA is in the process of identifying research which was conducted between 1947 when VA's research program began and 1980.

Question 6: Are you now conducting experiments involving human subjects that are classified.

Answer: No. The Department of Veterans Affairs does not support any research studies that are classified.

Question 7: What is the total number of grants or contracts administered by VA which involve the use of human research subjects?

Answer: None. The Department of Veterans Affairs Research and Development program is an intramural program. Appropriated funds are utilized by VA investigators with clinical appointments. There are no grants or contracts for research issued.

Question 8: What is the dollar amount of these contracts?

Answer: N/A.

Question 9: What is the total number of FTEs devoted to assurance and compliance with regulations governing the use of human subjects in research?

Answer: All VA research utilizing human subjects, both funded and unfunded, undergoes rigorous review at the local facility level. Protocols are reviewed for their scientific merit by the Facility Research and Development Committee. A review to assure appropriate informed consent and a risk/benefit analysis is conducted by the Human Studies Subcommittee. Members of this committee include VA researchers, clinicians, ethicists or clergymen, non-VA patient advocates and legal consultants. A minimum committee membership of five persons is required. When these studies are submitted for Central Office review for funding, the Merit Review (peer review) process includes an additional review of the impact of the study on human subjects. Due to the variety in expertise required for appropriate evaluation and analysis, FTE cannot be devoted solely to assurance and compliance. Nonetheless, a close estimate of the number of VA and non-VA people involved yields a figure in excess of 700.

Question 10: How many compliance investigations pertaining to regulations governing the use of human subjects in research have been conducted by VA over the past 3 years?

Answer: All research conducted at a VA Medical Center is reviewed annually by the Research and Development Committee. Those pertaining to human subjects receive further review by the Human Studies Subcommittee. Within the Cooperative Studies program, compliance with Human Subject protocols must be uniform among the participating facilities.

Question 11: How many and what corrective actions were taken based on those investigations?

Answers: Responsibility for assuring that corrective action is taken in cases of non-compliance with regulations governing the conduct of human studies has been delegated to the Research and Development Committee at the local level. Site visits were conducted to oversee compliance of Cooperative Studies with human subject regulations.

Question 12: Has the agency made any announced or unannounced site visits in the past 3 years to evaluate its compliance program? How many of each? What were the results?

Answer: Site visits are regularly carried out on all human subject research within the Cooperative Studies Program. In FY 1993 12 such visits were made. In all instances, the facilities were found to be in full compliance and conformance with regulations.

Question 13: A recent OTA study, Biomedical Ethics in U.S. Public Policy, has strongly recommended the creation of a permanent, ongoing, national research review board to consider the ethical implications of certain protocols or clauses of federally funded biomedical and behavioral research. Such a panel might resemble earlier efforts at integrating ethics, science and public policy, like the Ethics Advisory Board established by NIH but disbanded in 1980.

Do you see the need for such a panel?

Would you support its creation?

Answer: As we understand it, the national research review board discussed by OTA would consider two general classes of issues: (1) those involved in biomedical or behavioral research proposals involving human subjects, and (2) broad-based issues related to medical practices, health care, or the social implications of research. We believe that a national board is likely to contribute more to the second category of issues rather than to the first. VA, and the other departments and agencies following the Federal Policy for the Protection of Human Subjects, already possess very adequate mechanisms and procedures for dealing with ethical issues involving specific research proposals.

VA supports the creation of a national bioethics board.

Question 14: What are you doing to ensure there will be uniformity of standards in how the VA records will be collected and reviewed to determine what will be publicly disclosed?

Answer: The Department of Veterans Affairs has been actively participating in the White House Human Radiation Interagency Working Group. A major concern of this body has been thorough search and uniform inventory and retrieval of these records in each of the affected agencies, e.g., Department of Defense, Department of Energy. Records search instructions for the operating components of these agencies were discussed and coordinated within the interagency working group; VA instructions have been comprehensive and in conformance with the considerations identified in the group.

The interagency body is now engaged in establishing a uniform system for inventorying the records found in the search. It is anticipated that uniform retrieval standards will be developed thereafter. The VA will continue to

participate in and cooperate with these efforts.

Question 15: What role should the National Archives be playing? Do you think it would be advisable to include them in on the Task Force level to oversee the whole records collection and review effort?

Answer: A senior representative of the National Archives has already met with the interagency working group at its initial meeting dealing with the establishment of uniform inventory guidelines. The information provided was of significant assistance and it appears that continued assistance from that agency will be available.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503

Phil
SPECIAL

May 4, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1396

TO: Legislative Liaison Officer -

CIA - Tom Benjamin - (703)482-6126 - 258
DEFENSE - Samuel T. Brick, Jr. - (703)697-1305 - 325
HHS - Frances White - (202)690-7760 - 328
JUSTICE - Sheila F. Anthony - (202)514-2141 - 217
NASA - Jeff Lawrence - (202)358-1948 - 219
NEC - Sonyia Matthews - (202)456-6722 - 429
NSC - William H. Itoh - (202)395-3723 - 249
OSTP - Roselis D'Allessandro - (202)456-6011 - 288
VA - Robert Coy - (202)273-6666 - 229

FROM: RONALD K. PETERSON (for) Ronald K Peterson
Assistant Director for Legislative Reference

OMB CONTACT: MIKE GOAD (395-7301)
Secretary's line (for simple responses): 395-6194

SUBJECT: ENERGY Qs and As on Human Radiation Experimentation

DEADLINE: 10:00 A.M., Monday, May 9, 1994

COMMENTS: Please respond by the deadline; if you do not, we will assume that your agency has no comment.

OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

Please advise us if this item will affect direct spending or receipts for purposes of the the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

CC:
E. Pelton
K. Peroff
T.J. Glauthier
T. Grams
B. Dorotinsky
G. Henry
A. Silas
J. Palmieri
B. Damus
J. Klein
S. Neuwirth
C. Varney/P. Caplan
B. Burton
T. Thornton
J. Podesta
J. Morall, OIRA

18 pages

LRM #M-1396

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

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TO: MIKE GOAD (395-7301)
Office of Management and Budget
Fax Number: (202) 395-5691
Analyst/Attorney's Direct Number: (202) 395-7301
Branch-Wide Line (to reach secretary): (202) 395-6194

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: ENERGY Qs and As on Human Radiation Experimentation

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No objection

_____ No comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

HEARING: HUMAN RADIATION EXPERIMENTATION
FEBRUARY 10, 1994
ADDITIONAL QUESTIONS FOR THE RECORD

DR. MARTHA KREBS:

- Does DOE conduct its human research in more openness and public scrutiny today than in the past, and does this peer review contribute to better science?

- Are DOE facilities now regulated by HHS standards with human research? Aren't some of the DOE labs now independently certified by HHS?

- For current research, would you explain the Institutional Review Board (IRB) procedures and DOE's role in that review process?
  – What happens, for instance, if the desired medical or therapeutic benefit is not realized – is the research stopped?
  -- What exactly are the procedures, and accountability of DOE in current research programs?

- To what extent do your current efforts on DOE human subject research monitoring and data collection need to be strengthened?

- Your testimony notes that DOE will have a database available March 15 on DOE's human subject research. Please provide the database and any accompanying report to the Subcommittee. In addition to the database, what strategic review has been given to radiation research?

  For example, -- after several decades of continuing Federally funded research at national laboratories, colleges and universities and hospitals, what distillations have been made of the results of all of this research; what aspects of the biological effects of radiation exposure remain to be investigated?

  -- What are the present goals for federally funded research into biological effects of radiation?

  -- Is the present balance satisfactory between basic and directed research in this field?

  – How is this federally funded and conducted research coordinated, why and by whom?

QUESTIONS FOR MARTHA KREBS

Human Radiation Experimentation

Question #1: Does DOE conduct its human research in more openness and public scrutiny today than in the past, and does this peer review contribute to better science?

Answer: The Department of Energy (DOE) conducts its human subject research under the auspices of Institutional Review Boards (IRB) that have been approved by either DOE or the Department of Health and Human Services. All of these Boards are required to have at least one member from the community. In addition, since 1991, all DOE facilities and indeed all research supported by the Federal government follow a common regulation for the protection of human research subjects (10 CFR 745). Prior to 1991, Federally supported human subjects research, including that of DOE, was conducted under regulations that were not uniform across DOE or any other Federal agencies.

Scientific peer review usually refers to the independent scientific evaluation of the proposed research. At the Department of Energy, scientific peer review is required for all research projects and contributes to better science.

Prepared by: Ari Patrinos
Office: Energy Research
Office phone: 301-903-3251
Home phone: 301-816-1032
Date:
Coordinated with:
Asst. Sec. initials:

2

QUESTIONS FOR MARTHA KREBS

Human Radiation Experimentation

Question #2: Are DOE facilities now regulated by HHS standards with human research? Aren't some of the DOE labs now independently certified by HHS?

Answer: Department of Energy (DOE) facilities are regulated by DOE regulations for the protection of human subjects (10 CFR 745). These regulations are identical to those of the Department of Health and Human Services and other relevant Federal agencies that fund research involving human subjects.

The Department of Health and Human Services (HHS) provides assurances of compliance for those facilities where HHS funded research is conducted. Many of the DOE National Laboratories receive HHS funding for research and, therefore, have received HHS assurances for compliance with human subjects regulations. Under the common rule protecting human research subjects, other agencies, including DOE, must recognize these HHS assurances and not require separate documentation. In this sense, some DOE laboratories are certified by HHS.

Prepared by: Ari Patrinos
Office: Energy Research
Office phone: 301-903-3251
Home phone: 301-816-1032
Date:
Coordinated with:
Asst. Sec. initials:

3

QUESTIONS FOR MARTHA KREBS

Human Radiation Experimentation

Question #3: For current research, would you explain the Institutional Review Board (IRB) procedures and DOE's role in that review process? What happens, for instance, if the desired medical or therapeutic benefit is not realized -- is the research stopped? What exactly are the procedures, and accountability of DOE in current research programs?

Answer: The Institutional Review Board (IRB) at each participating institution operates under the "common rule" protecting human subjects research (10 CFR 745). This rule spells out membership requirements, review requirements, informed consent documentation, and recordkeeping requirements. The Department of Energy (DOE), as well as the Department of Health and Human Services and other relevant Federal agencies, approve the IRB membership, the operating procedures, and the documentation of compliance. Federal agencies do not interfere in the autonomy of these review boards.

The desired medical or therapeutic outcomes of the research project as well as conditions for early termination are detailed in the protocols which must receive scientific and IRB approval before research begins. Scientific oversight continues during the course of the project and all adverse effects and changes suggested to the protocol must be brought to the immediate attention of the IRB.

Prepared by: Ari Patrinos
Office: Energy Research
Office phone: 301-903-3251
Home phone: 301-816-1032
Date:
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Asst. Sec. initials: mek

4

QUESTIONS FOR MARTHA KREBS

Human Radiation Experimentation

Question #4: To what extent do your current efforts on DOE human subjects research monitoring and data collection need to be strengthened?

Answer: The new database on human subjects research and its annual updating will go a long way toward improving DOE oversight of human subjects research. In addition, we will continue to educate staff of the laboratories, program offices, and operations offices on the bioethical and implementation issues surrounding research involving human subjects.

Prepared by: Ari Patrinos
Office: Energy Research
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Home phone: 301-816-1032
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Coordinated with:
Asst. Sec. initials:

5

QUESTIONS FOR MARTHA KREBS

Human Radiation Experimentation

Question #5: Your testimony notes that DOE will have a database available March 15 on DOE's human subject research. Please provide the database and any accompanying report to the Subcommittee. In addition to the database, what strategic review has been given to radiation research?

Answer: Radiation research has had many strategic reviews, often by discipline, over the decades. These are available in many books and review articles. One notable compendium is Radioactivity and Health: A History, by J. Newell Stannard, October 1988, a Department of Energy, Office of Health and Environmental Research publication. A copy of the database of current DOE's human subject research was provided to the subcommittee.

Prepared by: Ari Patrinos
Office: Energy Research
Office phone: 301-903-3251
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Date:
Coordinated with:
Asst. Sec. initials: Mak

6

QUESTIONS FOR MARTHA KREBS

Human Radiation Experimentation

Question #6 What are the present goals for federally funded research into biological effects of radiation?

Answer: The goals for Federally funded research into biological effects of radiation focus on the large remaining area of uncertainty about health effects at low levels of exposure. In order to answer these questions, a thorough understanding of biological mechanisms at low exposure levels must be obtained. The current research program in the Department of Energy, Health Effects and Life Sciences Research Division, is focused on developing understanding of molecular mechanisms of radiation damage and repair.

Prepared by: Ari Patrinos
Office: Energy Research
Office phone: 301-903-3251
Home phone: 301-816-1032
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Coordinated with:
Asst. Sec. initials:

7

QUESTIONS FOR MARTHA KREBS

Human Radiation Experimentation

Question #7: Is the present balance satisfactory between basic and directed research in this field?

Answer: Yes, we feel that the present federal program is well balanced. Several agencies are major participants in this field: The Department of Energy conducts radiation measurements and determines occupational and environmental exposures, as well as performing basic and applied research on the health effects and risks associated with exposures to radon, defense- and energy-related radiation, and nuclear waste clean up. The Environmental Protection Agency carries out directed research to develop and implement radon control strategies (EPA is also responsible for developing radon policy). The National Institutes of Health's National Cancer Institute supports basic and applied research that relates to the late effects (e.g., cancer, fibrosis, etc.) of medical treatments and radiation therapy. The National Institute of Environmental and Health Sciences supports research on nonionizing radiation such as electromagnetic effects.

The National Aeronautics and Space Administration (NASA) currently supports research directed at understanding the adverse health effects of exposures to highly energetic charged particles, e.g., protons or heavy ions. Research is conducted to characterize the nature and mechanisms of radiation-induced DNA damage and repair, carcinogenesis, and

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mutation. No human subjects studies are supported by NASA except for some retrospective analyses of human exposure data from the National Counsel of Radiation Protection. Some animals (mice) are used in studies supported by NASA.

The Department of Defense (DoD) currently supports research than can be categorized into five general areas: 1) performance studies to determine the effects of radiation exposures on physical and mental performance; 2) risk assessment studies to estimate health-risks following radiation exposures from fallout-contaminated areas; 3) radiation casualty management research to determine appropriate action following exposure accidents; 4) cellular and molecular radiobiology to determine the mechanisms of radiation effects at the cellular and molecular levels; and 5) research support for scientists in the former Soviet Union.

The research in the fifth area involves the use of human subjects in the former Soviet Union. Animals (predominantly rats and mice) are used in other DoD-supported radiation research.

These efforts are all Federally coordinated by the State Department to prevent overlaps or duplications of effort.

Prepared by: Ari Patrinos
Office: Energy Research
Office phone: 301-903-3251
Home phone: 301-816-1032
Date:
Coordinated with:
Asst. Sec. initials: Mike

QUESTIONS FOR MARTHA KREBS

Human Radiation Experimentation

Question #8: How is this federally funded and conducted research coordinated, why and by whom?

Answer: The two agencies conducting the vast majority of radiation biology are NIH and DOE. The programs are well coordinated at both the scientific and managerial levels. In addition, all Federal radiation policies and science are coordinated through the Office of Science and Technology Policy Committee on Interagency Radiation Research and Policy Coordination. Finally, there are strong links with the Commission of European Communities.

Prepared by: Ari Patrinos
Office: Energy Research
Office phone: 301-903-3251
Home phone: 301-816-1032
Date:
Coordinated with:
Asst. Sec. initials:

10

HEARING: HUMAN RADIATION EXPERIMENTATION
FEBRUARY 10, 1994
ADDITIONAL QUESTIONS FOR THE RECORD

DR. TARA O'TOOLE:

- How is the Advisory Committee actually going to review these experiments? What documentation will the Committee use? Will they review complete files? Summaries? Is data being gathered in a consistent format across the agencies for the review? What is being done to protect peoples rights to privacy as the files are reviewed?

- There has been some concern that the individuals who were either directly experimented on or their offspring have not received data on the experiments except by press accounts. What progress is being made to provide the information to patients or relatives. Is there a formal process for its release?

- You mention a public fear and misunderstanding of radiation which was also alluded to by other witnesses. What is DOE doing to reassure the public regarding the beneficial uses of radiation? What public outreach or program initiatives are needed since over 10 million patients each year have nuclear medicine studies or therapy for diagnosis or management of a variety of diseases?

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QUESTIONS FOR DR. TARA O'TOOLE

Human Radiation Experimentation

Question: How is the Advisory Committee actually going to review these experiments? What documentation will the Committee use? Will they review complete files? Summaries? Is data being gathered in a consistent format across the agencies for the review? What is being done to protect peoples rights to privacy as the files are reviewed?

Answer: The Advisory Committee is now being established. The committee will have available to it all the information collected on human radiation experiments. Once the committee meets, it will determine how it wishes to proceed. The committee may undertake their review by whatever means they determine will be most efficient. They can view individual files if they wish or summaries if they prefer. At DOE we are collecting, cataloging, and abstracting all documents collected, so that the committee members can choose what records they wish to review individually and which they do not. Guidance has been provided by the White House in a Memorandum for Heads of Departments and Agencies from Christine A. Varney, Secretary to the Cabinet on January 19, 1994, on the records retrieval process. In addition, DOE is sharing the procedures it develops with the other Federal agencies. Interagency working groups meet at regular intervals to share information on their records retrieval process. The Advisory Committee and their staff must have access to individually identified data to complete their review of the experiments effectively. The Advisory Committee and their staff granted access to identified records shall be subject to the same restrictions applicable to Federal employees under the Privacy Act. All information to be made publicly available will be

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redacted to protect the confidentiality of participants and their families.

QUESTIONS FOR DR. TARA O'TOOLE

Question: There has been some concerns that the individuals who were directly experimented on or their offspring have not received data on the experiments except by press accounts. What progress is being made to provide the information to patients or relatives. Is there a formal process for its release?

Answer: All information collected on experiments will be made available to participants or their families. At DOE a procedure is being established that will ensure that the participants or their families are contacted as soon as the information is available. DOE has already contacted the families of the participants in the plutonium injection experiments wherever possible.

QUESTIONS FOR DR. TARA O'TOOLE

QUESTION: You mention a public fear and misunderstanding of radiation which was also alluded to by other witnesses. What is DOE doing to reassure the public regarding the beneficial uses of radiation? What public outreach or program initiatives are needed since over 10 million patients each year have nuclear medicine studies or therapy for diagnosis or management of a variety of diseases?

ANSWER: The Secretary of Energy and I, as well as other senior Administration officials, have taken every opportunity to emphasize the importance of properly conducted medical research and the importance of professional medical care involving radiation. We have conveyed this message in Congressional hearings, in public appearances nationwide, and in the media, and will continue to do so. In addition, the Department of Energy will continue to support outstanding health and environmental research that, over the years, has saved many lives by knowledge obtained using radiation in the diagnosis and treatment of disease.

Our experience with the concerns raised by many members of the public confirms the need for an open approach to the human experimentation initiative. In pursuit of this goal, the President's Advisory Committee on Human Radiation Experiments will carry out its activities under the Federal Advisory Committee Act, including full opportunity for public involvement. The work of

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the Committee - including its interim and final reports - will be widely publicized. We believe that this process will aid in presenting a full and credible public information process.

Prepared by: Dr. Heather G. Stockwell
Office: Epidemiology and Health Surveillance
Office phone: 301-903-3721
Home phone: 703-683-0586
Date: April 18, 1994
Coordinated with:
Assistant Secretary initials: 4-21-94

16

Phil

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503

SPECIAL

May 20, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1471

TO: Legislative Liaison Officer -

CIA - Tom Benjamin - (703)482-6126 - 258
DEFENSE - Samuel T. Brick, Jr. - (703)697-1305 - 325
HHS - Frances White - (202)690-7760 - 328
JUSTICE - Sheila F. Anthony - (202)514-2141 - 217
NASA - Jeff Lawrence - (202)358-1948 - 219
NEC - Sonyia Matthews - (202)456-6722 - 429
NSC - William H. Itoh - (202)395-3723 - 249
OSTP - Roselis D'Allessandro - (202)456-6014 - 288
VA - Robert Coy - (202)273-6666 - 229

FROM: RONALD K. PETERSON (for) Ronald K. Peterson
Assistant Director for Legislative Reference

OMB CONTACT: MIKE GOAD (395-7301)
Secretary's line (for simple responses): 395-6194

SUBJECT: **REVISED** ENERGY Qs and As on Human Radiation Experimentation

DEADLINE: 10:00 A.M., Tuesday, May 24, 1994

COMMENTS: The Department of Energy has revised its answers to questions #4 and #8 that were originally circulated under cover of LRM #M-1396. Please review and respond by the deadline; if you do not, we will assume that your agency has no comment.

OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

Please advise us if this item will affect direct spending or receipts for purposes of the the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

CC:
E. Pelton
K. Peroff
T.J. Glauthier
T. Grams
B. Dorotinsky
G. Henry
A. Silas
J. Palmieri
B. Damus
J. Klein
S. Neuwirth
C. Varney/P. Caplan
B. Burton
T. Thornton
J. Podesta
J. Morall, OIRA

LRM #M-1471

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

If your response to this request for views is **simple** (e.g., concur/no comment) we prefer that you respond by **faxing** us this response sheet. If the response is **simple** and you prefer to call, please **call the branch-wide line** shown below (NOT the analyst's line) to leave a message with a secretary.

You may **also respond** by (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); (2) sending us a memo or letter; or (3) if you are an OASIS user in the Executive Office of the President, sending an E-mail message. Please **include** the LRM number shown above, and the **subject** shown below.

TO: MIKE GOAD (395-7301)
Office of Management and Budget
Fax Number: (202) 395-5691
Analyst/Attorney's Direct Number: (202) 395-7301
Branch-Wide Line (to reach secretary): (202) 395-6194

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: **REVISED** ENERGY Qs and As on Human Radiation Experimentation

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No objection

_____ No comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

2/

QUESTIONS FOR MARTHA KREBS

Human Radiation Experimentation

Question #4: To what extent do your current efforts on DOE human subjects research monitoring and data collection need to be strengthened?

Answer: DOE has been an active participant in the Interagency Committee for the Protection of Human Subjects for 14 years. DOE has continued to strengthen and broaden its human subjects research monitoring since adoption in 1991, along with 16 other Federal agencies and departments, of the "common rule" on the Protection of Human Subjects. DOE has adopted two orders to implement the 1991 Federal policy as well as a resource manual containing all relevant materials on human subjects protections. The Department has underway an advisory committee review of human subjects activities at major DOE laboratories as well as a review of the adequacy of the monitoring efforts. The DOE human subjects database, completed April 4, 1994, and its annual updating will contribute greatly to the oversight process within and external to the Department. Lastly, to further strengthen bioethical education within the Department, DOE is updating its resource manual and sponsoring a major meeting on June 14, 1994, entitled, "Research Using Human Subjects: Past and Present Viewpoints," for the DOE community as well as other interested interagency guests. DOE is also cosponsoring with the Department of Health and Human Services, the Department of Defense, and the Environmental

Protection Agency a meeting for the staff from all Federal agencies, field offices and laboratory personnel entitled, "Focus on Protecting Human Subjects in the Federal Government." The academic and bioethics communities have been sought and included in the facility of both meetings. We feel the sum of these efforts adequately strengthens DOE human subjects research monitoring and data collection.

Prepared by: Ari Patrinos
Office: Energy Research
Office phone: 301-903-3251
Home phone: 301-816-1032
Date: May 13, 1994
Coordinated with:
Asst. Sec. initials:

QUESTIONS FOR MARTHA KREBS

Human Radiation Experimentation

Question #8: How is this federally funded and conducted research coordinated, why and by whom?

Answer: The two agencies conducting the vast majority of radiation biology are NIH and DOE. The programs are well coordinated at both the scientific and managerial levels through joint research collaborations, joint funding, joint publications, workshops, interagency briefings, and representative membership on both Federal and international radiation committees. NIH and DOE as well as other Federal agencies involved in radiation policy or research activities also share membership on the Office of Science and Technology Policy Committee on Interagency Radiation Research and Policy Coordination (CIRRPC). This committee provides a formal mechanism for discussion of research needs and the programs designed to meet these needs. This is done through periodic panel meetings and publication of CIRRPC reports. CIRRPC panels also address radiation policy issues of multiagency interest.

Prepared by: Ari Patrinos
Office: Energy Research
Office phone: 301-903-3251
Home phone: 301-816-1032
Date: May 13, 1994
Coordinated with:
Asst. Sec. initials:

6

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503

SPECIAL SPECIAL

March 22, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1248

TO: Legislative Liaison Officer -

CIA - Tom Benjamin - (703)482-6126 - 258
DEFENSE - Samuel T. Brick, Jr. - (703)697-1305 - 325
HHS - Frances White - (202)690-7760 - 328
JUSTICE - Sheila F. Anthony - (202)514-2141 - 217
NASA - Jeff Lawrence - (202)358-1948 - 219
NEC - Sonyia Matthews - (202)456-6722 - 429
OSTP - Chris Clary - (202)456-6011 - 288
NSC - William H. Itoh - (202)395-3723 - 249
VA - Robert Coy - (202)535-8113 - 229

FROM: RONALD K. PETERSON (for)
Assistant Director for Legislative Reference

OMB CONTACT: MIKE GOAD (395-7301)
Secretary's line (for simple responses): 395-6194

SUBJECT: VA Qs and As on Human Radiation Experimentation

DEADLINE: 10:00 A.M., Friday, March 25, 1994

COMMENTS: If you do not respond by the deadline, we will assume that your agency has no comment.

OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

Please advise us if this item will affect direct spending or receipts for purposes of the the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

CC:
E. Pelton
K. Peroff
T.J. Glauthier
T. Grams
B. Dorotinsky
G. Henry
A. Silas
J. Palmieri
B. Damus
J. Klein
S. Neuwirth
C. Varney/P. Caplan
B. Burton
T. Thornton
J. Podesta

LRM #M-1248

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

If your response to this request for views is **simple** (e.g., concur/no comment) we prefer that you respond by **faxing** us this response sheet. If the response is **simple** and you prefer to call, please **call the branch-wide line** shown below (NOT the analyst's line) to leave a message with a secretary.

You may **also respond** by (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); (2) sending us a memo or letter; or (3) if you are an OASIS user in the Executive Office of the President, sending an E-mail message. Please **include** the LRM number shown above, and the **subject** shown below.

TO: MIKE GOAD (395-7301)
Office of Management and Budget
Fax Number: (202) 395-5691
Branch-Wide Line (to reach secretary): (202) 395-6194

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: VA Qs and As on Human Radiation Experimentation

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No objection

_____ No comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

Chairman, Committee on Veterans' Affairs
US House of Representatives
335 Cannon House Office Building
Washington, DC 20515

Dear Mr. Chairman:

In accordance with your letter of February 14, 1994, enclosed are our responses to your questions based on comments by Belton Burrows, M.D., Chief, Nuclear Medicine Service, at our facility. Please direct any questions to Ms. Janice Boss, Health System Specialist, at (617) 278-4590/4591. We appreciate your continued interest in the welfare of America's veterans.

Sincerely,

SMITH JENKINS, JR.
Medical Center Director

cc: Regional Director (131)
DAS for Congressional Liaison (60C)

Enclosure

VAMC BOSTON

Question 1: In conducting radiation related research in the VA, what were the highest dosage levels to which your subjects were exposed? What was your understanding at the time as to what risks were entailed in such dosage levels? Can you recall whether you described those risks to the research subjects and, if so, how would you have described them?

The highest dose levels to which subjects were exposed were below the limits of Atomic Energy Commission regulations: 350 microcuries for potassium-42; 150 microcuries for sodium-24; 15 microcuries for sodium-22; and 300 microcuries for tritium. Those dosage levels were insignificant compared to environmental and body burden exposures from naturally occurring radionuclides. The risks to the subjects were described to the subjects in those terms.

Question 2: If by the term "informed consent" we mean freely given consent following a full and careful explanation of the research project, whether or not the subject is given a form and asked to sign it, did you conduct research in the VA which did not seek your subjects' informed consent?

No.

Question 3: Who was responsible for informing patients of the possible risks of participating in a particular study and who was responsible for determining this risk? How was the risk determined?

Physicians were responsible for informing patients about possible risks of participating in a particular study and for determining the risks. In patient studies the risk-to-benefit relationship was determined by the physician's knowledge of the patient's medical problem. Consideration was given to other radiation, such as X-rays, to which the patient might be exposed. For diagnostic studies and particularly for therapeutic procedures, such as iodine-131 administration for hyperthyroidism and thyroid cancer, patients were also informed about precautions to be taken and possible side effects, such as hypothyroidism.

Question 5: Would you have had the cooperation of so many patients if the current restrictions had been in place back in the 1940s and 1950s?

Dr. Burrows is of the opinion that, had current restrictions for research been in place in the 1940s and 1950s, it is unlikely the restrictions would have discouraged or prevented patients from participating in research activities

Question 6: Dr. Rothman cites the principle set forth at Nuremburg that calls for voluntary consent of research subjects and for the subjects to have "sufficient knowledge and comprehension of the elements of the subject matter involved as to make an enlightened decision." Would you comment on how one insures that patients have achieved that level of understanding?

Any level of patients' understanding will be dependent on patients' general knowledge and physicians' communication skills. For clinical research using tracer doses (which are not considered to be of physiological significance), patients can readily understand physicians' explanations.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503

April 15, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1315

TO: Legislative Liaison Officer -

CIA - Tom Benjamin - (703)482-6126 - 258
DEFENSE - Samuel T. Brick, Jr. - (703)697-1305 - 325
ENERGY - Bob Rabben - (202)586-6718 - 209
JUSTICE - Sheila F. Anthony - (202)514-2141 - 217
NASA - Jeff Lawrence - (202)358-1948 - 219
NEC - Sonyia Matthews - (202)456-6722 - 429
NSC - William H. Itoh - (202)395-3723 - 249
OSTP - Roselis D'Allessandro - (202)456-6011 - 288
VA - Robert Coy - (202)535-8113 - 229

FROM: RONALD K. PETERSON (for) Ronald K Peterson
Assistant Director for Legislative Reference

OMB CONTACT: MIKE GOAD (395-7301)
Secretary's line (for simple responses): 395-6194

SUBJECT: HHS Proposed Testimony on Radiation-related Experiments

DEADLINE: 4:30 P.M., TODAY, Friday, April 15, 1994

COMMENTS: The attached is a statement for the record. The House Administrative Law Subcommittee held the field hearing on Monday, April 11, 1994. If the Subcommittee has requested that your agency submit a statement for the record, please contact this office. If you do not respond by the deadline, we will assume that your agency has no comment.

OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

Please advise us if this item will affect direct spending or receipts for purposes of the the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

CC:
E. Pelton
B. Dorotinsky
T. Grams
J. Fellows
G. Henry
A. Silas
K. Peroff
T.J. Glauthier
B. Damus
J. Palmieri
J. Klein
S. Neuwirth
C. Varney/P. Caplan
B. Burton
T. Thornton
J. Podesta

LRM #M-1315

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

If your response to this request for views is **simple** (e.g., concur/no comment) we prefer that you respond by **faxing** us this response sheet. If the response is **simple** and you prefer to call, please **call the branch-wide line** shown below (NOT the analyst's line) to leave a message with a secretary.

You may **also respond** by (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); (2) sending us a memo or letter; or (3) if you are an OASIS user in the Executive Office of the President, sending an E-mail message. Please **include** the LRM number shown above, and the **subject** shown below.

TO: MIKE GOAD (395-7301)
Office of Management and Budget
Fax Number: (202) 395-5691
Analyst/Attorney's Direct Number: (202) 395-7301
Branch-Wide Line (to reach secretary): (202) 395-6194

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: HHS Proposed Testimony on Radiation-related Experiments

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No objection

_____ No comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

Statement for the Record

Dr. Donald A. Henderson

Deputy Assistant Secretary for Health -- Science

U.S. Public Health Service
Provided to the Subcommittee on
Administrative Law and Governmental Relations
Committee on the Judiciary
United States House of Representatives
April 14, 1994

Mr. Chairman and Members of the Subcommittee:

I am pleased to provide information related to U.S. Public Health Service (PHS) support of research conducted by Eugene L. Saenger, M.D., at the University of Cincinnati. Dr. Saenger received PHS funds to conduct several research and training activities beginning in 1957 and continuing through 1974.

Dr. Saenger was one of many investigators associated with a General Clinical Research Center supported by PHS grants RR- 00068, RR-00123, and RR-05408 from the Division of Research Resources to the University of Cincinnati. These grants spanned the period Fiscal Year (FY) 1963 through FY 1984.

In FY 1970, Dr. Saenger was the senior investigator for two of some 30 subprojects of the General Clinical Research Center awards; "Radioisotope Metabolism Studies" (RR-00123), and "Metabolic Studies of Gamma-Emitting Radiopharmaceuticals" (RR-00068). In 1973, Dr. Saenger acknowledged support from the third award, a General Research Support award, PHS grant RR-05408, in his journal publication on "Whole Body and Partial Body Radiotherapy of Advanced Cancer" (American Journal of Roentgenology, Radiation Therapy & Nuclear Medicine 117:670-685, 1973).

The actual dollar support for Dr. Saenger's subprojects are not listed in existing grant records. In FY 1970, for example, there were some 28 other subprojects which were conducted using funds from RR-00068, sharing the total grant of $258,105. One other subproject of interest, "Nuclear and Immunologic Changes Following Total and Partial Irradiation," was under the direction of Ben I. Friedman, M.D.

It is possible that, prior to FY 1970, Dr. Saenger may have directed other subprojects involving human irradiation experiments. However, subproject investigators and research topics were not recorded under General Clinical Research Center awards prior to FY 1970.

Additional information about the grants is not available from the files because all relevant grant files prior to FY 1986 were destroyed in keeping with normal record retention policies.

The majority of PHS funds received by Dr. Saenger supported his conduct of (i) research on the incidence of neoplasia in irradiated children, and (ii) training in radiological sciences.

The National Cancer Institute provided two grants to the University of Cincinnati with Dr. Saenger as Principal Investigator; grant CA-0297 ($48,924, FY 1957-FY 1959) and grant CA-06500 ($165,640, FY 1962-FY 1966). These two successive grant awards carried the same title: "Incidence of Neoplasia in Irradiated Children." These grants supported Dr. Saenger's studies of the late effects of radiation on persons who had been irradiated years earlier, in childhood, for benign conditions. A representative scientific report by Dr. Saenger is found in Radiology 74:889-904, 1960 ("Neoplasia Following Therapeutic Irradiation for Benign Conditions in Childhood").

Dr. Saenger received two grants in support of training programs in the radiological sciences

and radiobiology. The first grant (CA-05049) was for $254,012 for the period FY 1959 through FY 1963. This training grant provided stipends and equipment for graduate students in physics and medical students seeking assistance in learning radioisotope techniques. A wide variety of projects were pursued by the students. At least one publication derived from training under grant CA-05049 describes whole- or partial-body irradiation: "Endoreduplication in Leucocyte Chromosomes. Preliminary Report of its Relation to Cancer and Whole-Body Irradiation" (Lancet, Sept. 5, 1964, pp.494-495.)

A second training grant (GM-01247) provided $543,691 from FY 1964 through FY 1974. The two successive training grant awards carried the same title: "Radiological Sciences." Publications resulting from these awards are wide-ranging. At least one report of work supported by training grant GM-01247 describes whole- or partial- body irradiation: "Active Bone-Marrow Dose Related to Hematological Changes in Whole-Body and Partial Body Co Gamma Radiation Exposures" (Radiology 103:651-656, 1972).

We are continuing to search our records for additional information to increase our understanding of the work of Dr. Saenger and the involvement of the Public Health Service in these activities. We will keep the Subcommittee informed as to additional findings as they become available.