

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

URGENT

April 7, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1277

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 - Sonyla Matthews - (202)456-6722 - 429
NSC - William H. Itoh - (202)395-3723 - 249
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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: DEFENSE Proposed Testimony on
Radiation-related Experiments

DEADLINE: 12:00 Noon, Friday, April 8, 1994

COMMENTS: The Department of Defense will testify before the House Administrative Law Subcommittee's field hearing on Monday, April 11, 1994. We understand that Defense will be the only agency to testify; if, however, this information is incorrect (i.e., your agency plans to testify at the hearing), please contact this office as soon as possible. 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.

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CC:

E. Pelton
G. Henry
B. Dorotinsky
T. Grams
J. Fellows
A. Silas
K. Peroff
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✓B. Danus

✓J. Palmieri
✓J. Klein
✓S. Neuwirth
✓C. Varney/P. Caplan
✓B. Burton
T. Thornton
✓J. Podesta

_____	Concur	
_____	No objection	
_____	No comment	
_____	See proposed edits on pages	_____
_____	Other:	_____
_____	FAX RETURN of _____ pages, attached to this response sheet	

APR 7 '94 11:16 FROM OSD-LRS

TO PETERSON

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STATEMENT
OF
GORDON K. SOPER, PRINCIPAL DEPUTY
ASSISTANT TO THE SECRETARY OF DEFENSE
FOR ATOMIC ENERGY
BEFORE THE
SUBCOMMITTEE ON ADMINISTRATIVE LAW
AND GOVERNMENT RELATIONS
CINCINNATI, OHIO
APRIL 11, 1994

Mr. Chairman and Members of the Subcommittee, I am Gordon 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 March 24th to conduct hearings on radiation experiments performed by the University of Cincinnati Medical School which were funded in part by the Department of Defense (DoD).

If I may, Mr. Chairman, I'd like to provide a prelude to my testimony in order to put our efforts into context. Since early January, when the White House called for the formation of a senior level Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation, the Department of Defense has been engaged in an extensive effort to discover the facts surrounding DoD sponsored human radiation experiments.

It goes without saying that the Department takes this action seriously, that it has the complete support of Secretary Perry and that we pledge to you our unqualified commitment to a thorough and complete search of all available records and the

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full public release of the pertinent information in those records. As Dr. Harold Smith, the Assistant to the Secretary of Defense for Atomic Energy, and the DoD focal point for this action, testified to you at your February 2 hearing on this subject, the retrieval of records is a discovery process requiring time intensive "detective work"--we are well into that process now and beginning to make excellent headway. I would be glad to take any questions that you might have regarding the Interagency Working Group process and the results we have obtained so far.

With that as background, I'd like to provide you with as complete a report as I can on the role that the Department of Defense played in the human radiation experiments conducted at the University of Cincinnati College of Medicine from 1960-1972 which were led by the principal investigator, Dr. Eugene L. Saenger, MD. My report to you is based on documents, reports and files that we have thus far been able to locate from wide and varied sources--some of the official Department of Defense records were destroyed long ago as part of the normal regulatory instructions for disposal of contract files.

What I am going to report to you is really not newly uncovered information. The entirely unclassified University of Cincinnati studies have been previously reported in ten technical reports, 17 publications, and 26 presentations at scientific meetings; they were the subject of peer reviews at the University of Cincinnati; discussion of this work appears in the

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Congressional Record in 1971 and 1972; they were the subject of a report by the Comptroller General of the United States in 1972 for Senator Edward Kennedy, Chairman of the Senate Health Subcommittee; they were the subject of a separate investigation in a report by the American College of Radiology in 1972, at the request of U.S. Senator Mike Gravel; and they were--and continue to be--the subject of news articles in the press and other media reports.

In addition, Mr. Chairman, these studies will be further reviewed by the Advisory Committee on Human Radiation Experiments which just recently established by President Clinton. This Committee is composed of eminent scientists, physicians, religious and legal experts and medical ethicists. Its purpose is to advise and guide the government on the larger questions of ethical and scientific standards of any government sponsored experiments 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." A major goal of DoD's "detective work" regarding the University of Cincinnati research is to provide a complete record for review by the Advisory

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Committee.

Next I want to run through a brief chronology of this research, based on the record compiled to date, focusing on the Department of Defense sponsorship.

In September, 1958 Dr. Eugene L. Saenger of the Department of Radiology, University of Cincinnati College of Medicine, as the principal investigator, submitted an unsolicited research proposal to the Research and Development Division of the Army Surgeon General's Office. The research proposal was initiated by the University of Cincinnati and not solicited by the Department of Defense. The application proposed to research metabolic changes in humans following total body irradiation for the purpose of determining whether the presence of amino-aciduria in humans after radiation would provide a reliable biological marker of radiation exposure. Restated less technically, the original goal was to try to develop a simple urine test to detect the amount of radiation exposure. The University of Cincinnati requested approximately \$25,000 for the first year and \$21,000 for two subsequent years. The proposal stated that Dr. Saenger was at that time also conducting pediatric cancer research funded by the National Institutes of Health, and preparing a Handbook on Medical Aspects of Radiation Accidents, under contract from the U.S. Atomic Energy Commission.

This unsolicited proposal was reviewed over the next year within the Department of Defense. Available documentation reveals that at least five Army Medical Corps officers reviewed

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the proposal. They recommended approval of the contract application. In October 1959 staff elements of the Defense Atomic Support Agency (DASA) recommended that DASA negotiate a contract with the University of Cincinnati for the study of the metabolic changes in humans following total body irradiation.

At that time a need existed within the Department of Defense to be able to determine the biological, statistical and clinical features of radiation injury. This was based on the requirements of our military commanders in the field to predict the outcome of human exposure to ionizing radiation, to predict the number of persons requiring hospitalization and to estimate the decrement in work capacity after radiation exposure on a nuclear battlefield. Remembering the context of the late 1950's, where fallout shelters were common in homes and schools and superpower tensions dominated public affairs, this was a real possibility of that time. Furthermore, such information would aid civil defense authorities in their efforts to combat the effects of nuclear explosions on the civilian population. I believe the fairly recent Chernobyl nuclear power reactor explosion underscores the importance of being able to ascertain radiation exposure effects and also understand its impact on a subject population.

So, in early 1960, a contract (DA-49-146-XZ-029, dated 1 January 1960) was signed between DASA and the University of Cincinnati Board of Directors. The contract provided \$25,085 for the study. This contract, with supplements and modifications, funded the study through February, 1964. Another contract

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(DA-49-146-XZ-315) carried the research until April, 1969. The final contract (DASA-01-69-C-0131), effective May, 1969, funded the research until March, 1972 when the University of Cincinnati refused DASA's offer for additional contract funding. Through 1971, the DoD spent \$651,482.79 on this research.

While the search for a biological marker of radiation exposure was one steadfast aim of the University's research effort over the life of the contract, the goals of the Department of Defense were to also understand better the influence of radiation on the combat effectiveness of troops and to develop more suitable methods of diagnosis, prognosis, prophylaxis and treatment of radiation injuries. In order to obtain this information, the Department of Defense provided funds for laboratory, psychological and psychiatric tests to assess the effects of varying doses of whole and partial body irradiation for the treatment of cancer patients. No funds were paid to the University of Cincinnati for direct patient care nor did the Department of Defense play any part in patient selection or choice of treatment.

The University of Cincinnati College of Medicine submitted ten reports to the Department of Defense from 1961 through 1972 in accordance with the terms of the contract. I have provided the committee a copy of these ten reports as well as a number of other relevant documents that we have in our possession. Attachment 1 to my statement is a chronology summarizing major parts of the record compiled to date.

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In reviewing these materials, we at DoD can understand the controversy that arose in the early 1970's, involving the University community, the press, and the Congress, and that which has reemerged this year, regarding this research. Some of the records, especially from the viewpoint of 30 years later, are troubling and raise very understandable concerns. Examples of these include statements in the University's early progress reports to the effect that only patients with non-radiosensitive tumors were selected for the research, which some see as evidence of a non-therapeutic purpose, and that symptoms and side effects were not described to the patients, which some see as evidence of the inadequacy of the informed consent procedures. On the other hand, for example, the 1972 peer review of the American College of Radiology, carried out at the request of Senator Mike Gravel, concluded that the research was validly conceived and executed, that the patient selection conformed with good medical practice, and that consent procedures complied with applicable standards. We at DoD do not at this point seek to resolve these apparent contradictions. Rather, our sole focus regarding this task is to compile a complete record and to make it available to the President's Advisory Committee and to the public.

Before concluding my statement, I want to address the constraints which the Department of Defense imposes on human subject experiments today and how we would respond to an unsolicited proposal, like the 1958 proposal from the University of Cincinnati College of Medicine, for experiments in which

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humans would participate.

Formal DoD policy for the protection of human subjects in research date back to at least 1953, when a then 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 for informed consent, minimization of risk of harm to subjects, and other matters.

Over the years, more detailed procedures were established, including incorporation of the 1974 Department of Health and Human Services regulations for the Protection of Human Subjects, 45 C.F.R. Part 46.

Today, DoD-supported 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, Code of Federal Regulation, 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.

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Under these regulations, a proposal like that from the University of Cincinnati would require much more supporting documentation and justification to be considered for funding. This includes the following:

1. The therapy itself, separate from the research, would require more information on the possible benefits and the known side effects.
2. Several local committees (specifically, scientific, radiation and Institutional Review Boards, or IRBs), would have to review the proposed research protocol package, with proposed consent forms, before DoD would review the proposal for acceptance.
3. It would be required that the sponsor's Institutional Review Board be made up of people from diverse backgrounds, including non-scientific perspectives, who could objectively and fully assess the proposal.
4. The IRB record would have to document that the research design is sound, that risks to subjects are minimized, that the selection of subjects is equitable, and that, if applicable, special protections have been adopted for any vulnerable groups mentioned.
5. A written consent form signed by the patient/subject would be required for participation in the research. This consent form would require an explanation of the proposed therapy, all procedures and studies to be performed, and all expected outcomes and side effects in laymen's terms. The

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consent form must also state that the patient has been counseled about all of the above, and space provided for the patient to sign stating this has occurred and that the patient understands it.

6. The protocol would be required to justify withholding radiation in the control group of patients if such radiation therapy were the standard of care for the cancer each patient had.

7. The investigator would be required to give a more in depth description of the known and suspected risks and the intended benefits of the research for the subject.

In other words, Mr. Chairman, we believe we have in place a set of guidelines for human use experimentation that will preclude 30 years from now, hearings like we are conducting today on experiments that are being conducted today.

So in summary, Mr. Chairman, the DoD received from the University of Cincinnati College of Medicine in 1958 an unsolicited proposal, which resulted in a contract from 1960 to 1971 supporting a human radiation experiment. DoD played no role in the selection of subjects, decisions regarding treatments, or the day-to-day conduct of the research. DoD received a series of reports describing the research results, none of which were ever classified. Data that we obtained from the University of Cincinnati studies were used to enhance our knowledge about the biological response to nuclear warfare--knowledge that we all hope will never have to be put to use. We will understand the

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TO PETERSON

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controversy regarding this research, but make no effort at this time to resolve apparent contractions in the voluminous record compiled to date. Our goal is to compile a complete record for the use of the President's Advisory Committee and ultimate release to the public.

That concludes my prepared remarks. I would be happy to take your questions.

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

Phil
SPECIAL

March 15, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1212

TO: Legislative Liaison Officer -

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NASA - Jeff Lawrence - (202)358-1948 - 219
NEC - Sonyia Matthews - (202)456-6722 - 429
OSTP - Chris Clary - (202)456-7116 - 288
NSC - William H. Itoh - (202)395-3723 - 249
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: ENERGY Qs and As on Human Radiation
Experimentation

DEADLINE: 10:00 A.M., Friday, March 18, 1994

COMMENTS: Attached are Qs and As #1-3, 5-8, 10, 12, 13(b-c),
and 14 (a-c) only; the remaining Qs and As will be sent at a
later date.

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:

B. Damus
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T. J. Glauthier
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B. Dorotinsky
K. Peroff

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: 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

Questions From Senator Glenn

Human Subjects

Question #1

What regulation or law covers research, outside of Federal regulatory or funding programs? For example, if a Federal Contractor, decided to develop a new product which did not require Federal approval or licensure, using their own funds, would the current regulations in the Common Rule apply?

Answer:

The Federal Policy for the Protection of Human Subjects (the so-called "Common Rule") applies to all human subjects research conducted, supported or otherwise subject to regulation by any federal agency or department which takes appropriate administrative action to make the Common Rule applicable to such research. 56 Fed. Reg. 28012 (June 18, 1991). DOE Order 1300.3 (August 23, 1990) and DOE Order 4300.2B (July 16, 1991) makes the Common Rule applicable to all contractors and subcontractors performing work for the Department as provided by law and/or under contract, and as implemented by the appropriate contracting officer. This includes non-DOE funded work at DOE-owned, DOE-leased, or DOE-controlled facilities. Accordingly, the Common Rule would apply to a federal contractor's research at DOE sites, even though the contractor uses its own funds for the research.

Moreover, if the researcher is not a federal agency or federal contractor, state statutes and

/

tort law may govern human research and provide for
civil remedies or criminal penalties for unlawful
research or experimentation.

Prepared by:
Office:
Office phone:
Home phone:
Date:
G.C. initials:

Lisa Schiavo
General Counsel
(202) 586-5289
(202) 686-4755
February 15, 1994

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### Questions From Senator Glenn

Question #2 Under the Common Rule, what sanctions or penalties can be applied for violation of these regulations?

Answer: The Department of Energy's (DOE) regulations provide that Federal funds may not be expended for research involving human subjects unless the requirements of the Common Rule are satisfied. 10 C.F.R. 745.122. Under the DOE regulations, Institutional Review Boards (IRB's) are authorized to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. 10 C.F.R. 745.113. Any suspensions or terminations of approval of research by an IRB must include a statement of the reason for the IRB's actions and must be reported promptly to the Department. Ibid. The DOE regulations further provide that the Department may require that any agency support for a project be terminated or suspended when the Department finds an institution has materially failed to comply with the terms of the Federal Policy. 10 C.F.R. 745.123(a)

In addition to the foregoing sanctions, DOE regulations provide that, in making decisions about supporting or approving applications or proposals for research that would be covered by the Federal Policy, the Department may take into

account whether the applicant has been subject to a termination or suspension, and whether the applicant, or the person or persons who would direct or have directed the scientific and technical aspects of an activity, has materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation). 10 C.F.R. 745.123(b). In situations where a violation of the Federal Policy is sufficiently serious that an organization's or individual's "present responsibility" has been impeached, such as where there has been a willful violation of the regulations for the protection of human subjects, debarment from receiving federal financial and non-financial assistance would also have to be considered. 10 C.F.R. Part 1036.

Civil and criminal sanctions could also be appropriate for some violations of the Federal Policy. For example, institutions engaged in human research are required to certify that their applications or proposals have been reviewed and approved by an IRB (10 C.F.R. 745.103); a false certification could result in civil liability under the Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801-3812, or the False Claims Act, 31 U.S.C. 3729-3733, and criminal liability

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under 18 U.S.C. 1001 and/or 18 U.S.C. 286, 287 and 371. Finally, of course, improper human research activities could also be actionable, both civilly and criminal, under state law.

|                |                   |
|----------------|-------------------|
| Prepared by:   | Marc Johnston     |
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| Date:          | February 15, 1994 |
| G.C. Initials: | W                 |

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## QUESTIONS FROM SENATOR GLENN

Human Subjects

Question #3: Are you now conducting experiments involving human subjects that are classified?

Answer: We are not conducting classified experiments involving human subjects.

Prepared by: Dr. Ari Patrinos  
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Office phone: 301-903-3251  
Home phone: 301-816-1032  
Date: February 24, 1994  
Coordinated with:  
Asst. Sec. initials: *JMK*

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## QUESTIONS FROM SENATOR GLENN

Human Subjects

Question #5: How are the requirements for independence of the Institutional Review Boards (IRBs) maintained for classified experiments? (i.e., is there a member from the subject population?)

Answer: In the case of classified human subjects research, all of which must be reviewed by an IRB, a special board would have to be convened for which the independent community member would also be required to have the appropriate clearance. Because DOE has no classified human subject research, this issue does not apply.

Prepared by: Dr. Ari Patrinos  
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Date: March 2, 1994  
Coordinated with:  
Asst. Sec. initials: JFE

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## QUESTIONS FROM SENATOR GLENN

Human Subjects

Question #6: To what extent do you formally adhere to subparts B, C and D of HHS' guidelines on the use of human subjects?

Answer: The DOE manual entitled, "Protecting Human Research Subjects at the Department of Energy," recommends following subparts "b", "c", and "d" of the Health and Human Services guidelines. The manual provides these 3 subparts for reference.

Prepared by: Dr. Ari Patrinos  
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## QUESTIONS FROM SENATOR GLENN

Human Subjects

Question #7: What mechanism do you employ or have you employed to inform contractors or grantees of this policy?

Answer: The Health and Human Service subpart "b", "c", and "d" has been integrated into the "Protecting Human Subjects Research at the Department of Energy" Manual on protection of human subjects, with an introduction recommending adherence to these added protections. This resource manual has been provided to all DOE laboratories, operations offices, and program offices.

Prepared by: Dr. Ari Patrinos  
Office: Energy Research  
Office phone: 301-903-3251  
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Date: February 15, 1994  
Coordinated with:  
Asst. Sec. initials:

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## QUESTIONS FROM SENATOR GLENN

Human Subjects

Question #8: Please describe generally the system that is in place to ensure that any experiments involving human subjects by the Department are being conducted according to the book?

Answer: The system in place to ensure that experiments involving human subjects by the Department are being conducted according to the regulations includes:

- DOE Orders have been issued to implement the regulation on human subjects, 10 CFR Part 745.  
/They are DOE Order 1300.3 issued on 8/23/90 and  
DOE Order 4300.2B issued on 7/16/91.
- HHS or DOE approved Assurances of Compliance are in place at all sites doing human subject research.
- Individuals responsible for human subject activities at every laboratory, operations office, and program office have been identified.
- Annual DOE-wide human subjects and bioethics meetings are conducted.

- A DOE newsletter and resource manual on protection of human subjects has been distributed to DOE Program Offices, Operations Offices and Laboratories as well as members of the interagency human subjects committee. *A*

Prepared by: Dr. Ari Patrinos  
Office: Energy Research  
Office phone: 301-903-3251  
Home phone: 301-816-1032  
Date: March 2, 1994  
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02/15/94 13:20 GC-01 - 202 586 5497

NO. 692 DO

**Questions From Senator Glenn**

Question #10 As currently understood, there is no Federal law regarding the use of human subjects for experimentation. Requirements are only embodied in Departmental Regulations, Policies or Procedures.

Would you favor establishing Federal Statutes to incorporate and enforce those requirements which are currently only enforced through regulations?

Answer:

As set forth more fully in the Answer to Question No. 2, supra, there are ample administrative, civil, and criminal procedures that may be employed to enforce applicable law. The Department believes that existing regulations and statutes adequately allow the Government to compel compliance with applicable law.

Prepared by:  
Office:  
Office phone:  
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Date:  
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General Counsel  
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February 15, 1994



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## QUESTIONS FROM SENATOR GLENN

Human Subjects

Question #12: 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 federally funded biomedical and behavioral research.

a. Do you see a need for such a panel?

Answer: A biomedical ethics panel would be very useful to the Federal community because so many uncharted areas of research have begun. These include issues raised in the mapping of the human genome, issues of privacy, employer versus employee rights, research conducted in other countries, research related to new fertilization and cloning techniques and a plethora of ethical issues that will need resolution.

b. Would you support its creation?

Answer: We would support the creation of such a commission if it was apolitical and had membership that represented agencies, ethicists, and scientists. It would also be important that, the agenda, deliberations and recommendations of this panel have broad input and appeal rights by those who may disagree.

Prepared by: Dr. Ari Patrinos  
Office: Energy Research  
Office phone: 301-903-3251  
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Date: February 15, 1994  
Coordinated with:  
Asst. Sec. initials:

18 13

## QUESTIONS FROM SENATOR GLENN

QUESTION 13B: Have you revised this order to include archival files?

ANSWER: Yes. Secretary O'Leary has chartered the Department of Energy Records Inventory and Retrieval Coordinating Committee to develop systematic and consistent procedures that can be used by the Department and its contractors to identify and locate, retrieve, inventory, catalogue, categorize, redact, declassify, disseminate, and store all records and information on human radiation experiments from 1944 to the present, or as otherwise indicated by Executive Order.

Prepared by: Glenn Podonsky  
Office: Security Evaluations  
Office phone: (301) 903-3777  
Home phone: (301) 253-1961  
Date: February 28, 1994  
Coordinated with:  
Asst. Sec. initials *[signature]*

*1914*



## QUESTIONS FROM SENATOR GLENN

QUESTION 13.C: What would be involved in expanding the search to include these archival files?

ANSWER: Complete guidance for records inventory and document retrieval has been disseminated DOE-wide. It has been shared with the Interagency Working Group. This guidance covers documentation about human experimentation that can be found in records collections in the custody of the Department of Energy, its contractors, private institutions, and private individuals.

Prepared by: Glenn Podonsky  
Office: Security Evaluations  
Office phone: (301) 903-3777  
Home phone: (301) 253-1961  
Date: February 28, 1994  
Coordinated with:  
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*2015*

## QUESTIONS FROM SENATOR GLENN

QUESTION 14.A: What is the Department doing to ensure there will be uniformity of standards in how this material is collected and reviewed to determine what will be publicly disclosed?

ANSWER: The Department has established a Records Inventory and Retrieval Committee to oversee and the collection and review of relevant records. The work of the Department of Energy committee is coordinated with that of the Interagency Working Group. These committees will work together to ensure the adoption of uniform information management methodologies and standards to support the research needs of the President's Advisory Committee on Human Radiation Experiments. The committee has prepared written guidance for all departmental elements regarding identification, management, declassification, and dissemination of records and information pertaining to human experimentation. Instructions on the how to conduct research, and on how to locate, identify, describe, and furnish information about records relating to human experimentation are being distributed to appropriate officials throughout the Department. The instructions detail what must be done and how it must be done. In addition, specific criteria are established for documenting how experiments were identified and records located. All organizations are being required to use the same form for the collection of information about the records to ensure uniformity in the quality and quantity of information collected. Organizations are directed to put in place procedures and processes to ensure the integrity of

21 16

the records and consistency in information release. Quality control programs specific to this project are being established both at the sites and at Headquarters.

Prepared by: Glenn Podonsky  
Office: Security Evaluations  
Office phone: (301) 903-3777  
Home phone: (301) 253-1961  
Date: February 28, 1994  
Coordinated with:  
Asst. Sec. initials: *mu*

*2/29/94*

*22, 17*



## QUESTIONS FROM SENATOR GLENN

QUESTION 14.B: Will computerized records be made available for easy access on publicly available networks, such as Internet for searching and use?

ANSWER: We have a two-phased approach to identifying and collecting information. First, we will conduct Department of Energy-wide inventories of records of potential value for researching human experiments. These inventories will generate summary facts about specific records collections, such as location, volume, and dates. Second, the inventories will be used to target intensive document-level searches. The findings of both the series inventories and document searches will be automated to facilitate access. We will consult with all appropriate parties to determine what computerized information may be made publicly available. A paramount consideration in this will be protecting the personal privacy of individuals.

Prepared by: Glenn Podonsky  
Office: Security Evaluations  
Office phone: (301) 903-3777  
Home phone: (301) 253-1961  
Date: February 28, 1994  
Coordinated with:  
Asst. Sec. initials

6a  
3/9/94

23, 18

## QUESTIONS FROM SENATOR GLENN

QUESTION 14.C: Will indexes or other search tools be made available for easy access on publicly available networks, such as Internet for searching and use?

ANSWER: We are committed to ensure appropriate access to human experimentation information. The use of indexes and other search tools will be carefully reviewed as we plan, develop, and implement our electronic systems. We are investigating information access alternatives with the objective of making as much information, both about the records and the records themselves, available to the greatest number of people in the shortest possible time. Access through Internet is one of those alternatives.

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Date: February 28, 1994  
Coordinated with:  
Asst. Sec. initials: *AP*

*3/4/94*

*24 19*

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

**URGENT**

February 8, 1994

## LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1091

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 - Chris Clary - (202)456-7116 - 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: ENERGY Proposed Testimony on  
Radiation-related Experiments

DEADLINE: 4:30 P.M., TODAY, Tuesday, February 8, 1994

COMMENTS: On February 10th, the Department of Energy will testify before the House Energy Subcommittee; Energy will be the only Administration witness. 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:

J. Pfeiffer  
G. Henry  
D. Blanchon  
T. Grams  
J. Fellows  
A. Silas  
E. Pelton  
K. Peroff  
T.J. Glauthier  
B. Dorotinsky

B. Damus  
J. Palmieri  
J. Klein  
S. Neuwirth  
C. Varney/P. Caplan  
B. Burton  
T. Thornton  
J. Podesta

1519



**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: ENERGY 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 |

T.O.T.  
2-894

7

JOINT STATEMENT OF  
ASSISTANT SECRETARY FOR ENVIRONMENT, SAFETY AND HEALTH  
TARA J. O'TOOLE  
AND  
DIRECTOR, OFFICE OF ENERGY RESEARCH  
MARTHA A. KREBS  
BEFORE THE  
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY  
U.S. HOUSE OF REPRESENTATIVES  
CONCERNING  
HUMAN RADIATION RESEARCH PROGRAMS

FEBRUARY 10, 1994

## Introduction

**Madam Chairperson and Members of the Committee:**

We are pleased to have the opportunity to appear before the Committee this morning to speak about recent reports of Cold War radiation experiments using human subjects that may have been conducted unethically. As you know, this topic has generated intense public and media attention. This attention has brought about a unique opportunity for the nation to debate important questions raised by some of the human radiation experiments — questions about the role of secrecy in a democratic society, and the need for proper safeguards to ensure the rights of individuals to determine their own fates. We must take the necessary steps to ensure that all Americans — whether they are uneducated or poor or mentally retarded or incarcerated — are not being used unwittingly in Federally-sponsored research.

The Clinton Administration is determined to finally bring to light all information involving ionizing radiation experiments. In a moment, we will discuss the steps being taken to release information as quickly as possible, to ensure that we have a serious, thoughtful debate about the lessons these experiments teach us, and to make sure that the highest standards of ethical and scientific conduct are followed in all research involving human beings.

The Department of Energy contributes to the welfare of the Nation by providing the scientific foundation, technology, policy, and institutional leadership required to achieve energy efficiency, diversity in energy sources, a more productive and competitive economy, improved environmental quality, and a secure National defense. A major contribution to the fulfillment of this mission is the conduct at the Department of outstanding health and environmental



research. One component of this excellent research establishment involves human subjects. It is important to remember that over the years many lives have been saved by knowledge obtained using radiation and chemical agents in the diagnosis and treatment of disease. During the Cold War period when Federal government funds were used to conduct some of the controversial experiments under discussion, other government funds were used to invent vaccines against polio, discover effective treatments for cancer, and develop new ways of visualizing the human body with CAT and cardiac scans. Thus, the benefits brought about by science are many; science itself is not at issue here.

We wish to caution the American people against inordinate fear of current research practices. Significant advances in biomedical ethics have resulted in a widespread recognition of individual rights, the obligation of researchers to obtain informed consent from experimental subjects. The Department of Energy, along with 16 other Federal departments and agencies, is bound by strict regulations governing the conduct of all human subjects research. In addition, as will be described later, the Department has undertaken aggressive efforts to inform and educate the personnel involved in implementing these regulations.

The Clinton Administration is committed to conducting a comprehensive identification and investigation of all experiments sponsored or carried out by Federal government agencies involving intentional human exposure to ionizing radiation. We will use the results of this review to try to repair wrongs that might have been done and will, if necessary, take action to further improve current standards.

### History of Human Radiation Research Programs

On December 7, 1993, Secretary of Energy Hazel O'Leary held a press conference at which important, previously classified, information was released. The Secretary revealed, for example, that 204 previously unannounced nuclear tests - one out of every five United States tests - had been kept secret. The Cold War rationale for this secrecy was the desire to inhibit Soviet monitoring of our weapons testing program. In addition, the Secretary revealed the locations and quantities of the United States weapons grade plutonium stockpile and the amount of mercury used in American nuclear weapons production.

Also during that press conference, the Secretary acknowledged, as was noted in the 1986 Congressional Report by the House Energy, Conservation and Power Subcommittee and as described in recent press accounts, that in the 1940's 18 persons were injected with plutonium as part of an experiment sponsored by the Atomic Energy Commission. The available records indicate that some of these subjects may not have been fully informed of the purpose or risks of the experiment.

We do not yet know if the radiation experiments noted in the 1986 House Subcommittee Report and the experiments involving deliberate environmental releases discussed in the General Accounting Office Report prepared for the Senate Committee on Governmental Affairs in December 1993, comprise the bulk of experiments that might be subject to questions of scientific and ethical propriety. We also do not yet know the full extent of the records pertaining to Department of Energy-sponsored experiments that need to be examined.

The evidence gathered thus far suggests that human experiments involving ionizing radiation conducted or sponsored by the Department of Energy or its predecessor agencies fall into one of four categories:

1. Experiments designed to investigate the effects of radiation on humans or the way the human body metabolizes radioactive substances;
2. Experiments using radioisotopes as tools to study the biochemistry of normal metabolic processes;
3. Experiments designed to investigate the therapeutic uses of radiation in the treatment of diseases such as cancer; and
4. Experiments involving intentional releases of radiation to the environment for purposes of assessing the behavior of such releases.

#### Overview of Steps Taken by the Department of Energy to Identify Human Radiation Subjects

In December 1993, the Department of Energy established a toll-free telephone Helpline. In January, the Department's Helpline was subsequently expanded to capture potential subjects of experiments sponsored by all Federal agencies involved in human radiation testing. The purpose of the Helpline is to aid us in identifying those persons who may have been affected by the activities in question. Since December 24, 1993, we have received more than 17,000 telephone calls and conducted more than 10,000 interviews with callers. Approximately 10% of callers appear to have been subjects of government-sponsored radiation tests.

In addition, over the past two months we have received over 2,000 letters. Less than one half of the letters are from individuals or their relatives who believe that they may have been subjects of human experimentation; approximately one fourth of these are from individuals who believe



that they have been exposed to radiation while serving in the military or while living next to a government facility. The remaining letters express support, offer assistance, or request information about the nature of the Department's efforts.

In addition, Secretary O'Leary has taken action to assure that the records search being conducted by the Department of Energy and its contractors will be thorough and comprehensive as we endeavor to tell the full story. In cooperation with other government agencies, we have developed an action plan to expedite the identification, retrieval, management, declassification, and dissemination of information regarding human radiation experiments. Department of Energy personnel have been directed not to destroy any documents that might be relevant and to identify all pertinent records and information in the Department's possession and in the possession of our laboratories and contractors. In order to accomplish this task, the Secretary established a multi-disciplinary committee under the authority of the Assistant Secretary of the Office of Environment, Safety and Health. The Committee includes specialists in health, environment, legal issues, and other relevant disciplines. The Department, both at Headquarters and in the Field, has already undertaken activities to begin to collect and review the pertinent documents. For example, over 100 cubic feet of files have been collected and are being reviewed at Headquarters.

Our goal is to get all the facts out. We will do our best to provide information as we learn it. All pertinent information that is found regarding human experimentation will be declassified as necessary on an expedited basis and to the maximum extent possible, forwarded to the Independent Advisory Commission on Human Radiation Experiments established by President Clinton, and permanently preserved for public review in an appropriate archive. At the same

time, we are taking appropriate steps to protect the privacy of people who were the subjects of experiments and their families.

#### Current Human Research Program and Regulatory Protections

The Department is currently funding approximately 120 research projects and providing facilities for another 100 projects involving human subjects. Biomedical research under way at the Department of Energy facilities, or with Department of Energy funding, include such lifesaving research as non-invasive diagnostic imaging technologies to see into the human body; advanced cancer therapies using radiation and radio-immuno therapy; nuclear medicine techniques that allow exploration of fundamental and pathological processes; and development of biomarkers and cellular assays for monitoring and protecting the health of Department of Energy workers and the general public.

The research conducted must meet the highest standards of both scientific and technical excellence and bioethical conduct. The Office of Health and Environmental Research within the Office of Energy Research has the responsibility for approval and assurance of all human subjects projects conducted at Departmental facilities or with Departmental funds. That office implements and oversees the Departmental (and Federal-wide) policy for the protection of human subjects.

The Office of Energy Research, is preparing a computerized list of all current Departmental human subjects projects. This list, available on a retrievable data base by March 15, 1994, will provide abstracts, as well as funding and institutional information, for each project being carried out. This data base will be updated annually. We are pleased to make this information available



because we are proud of the science supported by the Department and undertaken in pursuit of Department of Energy missions and National goals.

#### Sufficiency and Adequacy of Current Human Subject Research Guidelines

All current Department of Energy experiments are, we believe, in compliance with the Federal Policy on the Protection of Human Subjects. The Department assisted in drafting this Federal Policy during the 1980s and adopted it along with 16 other Federal agencies in July 1991, when the rulemaking process was complete. The Department also issued two orders addressing the intradepartmental implementation of this Federal policy.

Secretary O'Leary has asked the Department's Health and Environmental Research Advisory Committee to review Department of Energy facilities for compliance with these regulations as well as the adequacy of Departmental oversight. This group of outside experts who advise the Department on health and environmental research matters will report to Dr. Krebs by June 1994.

The Department's Office of Health and Environmental Research has been proactive in identifying contacts in every Laboratory, Field office, and Program office in pursuit of ongoing identification of human subjects projects, oversight of review procedures, and education of staff. This office has held two Departmental-wide meetings since the 1991 regulation was passed. These meetings brought together bioethicists from the academic community, as well as knowledgeable staff from the Department of Health and Human Services, to educate and inform Department of Energy personnel on these important issues. In June 1994, the Departments of Energy, Health and Human Services, Defense, and the Environmental Protection Agency are cosponsoring a large bioethics/human subjects workshop to further educate Laboratory, Field,



and Headquarters personnel on bioethics and implementation procedures. The Office of Health and Environmental Research also has a human subjects newsletter, published twice a year, to assist in education and information dissemination. The office has also prepared a protection of human subjects resource manual for the Department, which is also available for other agencies. This resource manual is in the process of being updated. The Department takes the protection of human subjects very seriously and has been in a position of leadership in implementing the Federal Policy for Protection of Human Subjects.

#### Human Radiation Interagency Working Group

On January 3, 1994, the White House convened a meeting of senior staff from government agencies with potential involvement in human radiation experiments. The White House has established a Human Radiation Interagency Working Group consisting of the Secretaries of Energy, Defense, Health and Human Services, and Veterans Affairs. The Directors of the Central Intelligence Agency and the Office of Management and Budget, the Attorney General, and the Administrator of the National Aeronautics and Space Administration are also on the Working Group.

Five subcommittees have been formed under the Working Group to address the following specific issues: 1) Public Information and Communications; 2) Retrieval and Review of Records; 3) Ethical and Scientific Standards; 4) Congressional Relations; and 5) Legal Issues. These subcommittees are composed of staff from all relevant Federal agencies.

The President's Executive Order, signed on January 15, 1994, established the Advisory Committee on Human Radiation Experiments, consisting of non-governmental experts in the

fields of ethics, science, medicine, and law. The Advisory Committee on Human Radiation Experiments will review records of experiments on ionizing radiation on humans and will advise the Interagency Working Group on whether any lapses of scientific or ethical standards occurred. Dr. Ruth Faden has been appointed by the President to chair the Committee.

The Advisory Committee's scope of review will include:

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 which were designed to test human health effects of ionizing radiation or were designed to test the extent of human exposure to ionizing radiation.

The Advisory Committee will also provide advice, information, and recommendations on the experiments noted in the December 1993 report by the General Accounting Office concerning intentional releases of radiation to the environment. The Advisory Committee may also review other experiments which may later be identified by the Human Radiation Interagency Working Group.

The Advisory Committee will review experiments since 1944. Human radiation experiments undertaken since the 1974 issuance of the United States Government biomedical research guidelines will be sampled to determine their priority for review. Further inquiry into such experiments conducted after 1974 will be pursued if warranted.



### Conclusion

We are committed to a comprehensive airing of the facts surrounding Cold War human radiation experiments. If the government made mistakes or committed wrongs, we, as government officials, must admit them. We are determined to give the American people reason to have greater trust in their government. A serious, thoughtful debate must occur regarding the scientific and ethical propriety of these experiments. If necessary, current federal rules must be further strengthened to protect individuals from future scientific aberrations.

Only by "coming clean" on the details of these experiments and separating Cold War habits of secrecy from proper ethical conduct of scientific research will we eventually reduce the bitterness and suspicion which has surrounded the debate on the health effects of radiation. And only through a careful and balanced review will we be able to emphasize the critical role radiation has played in modern medicine's ability to diagnose and treat disease.

Finally, let us reiterate to you and the American people our commitment to opening up the Department of Energy. We have a tremendous amount of work to do in this area, but we believe we have made a good start.



The Administration is planning to take the following actions in response to individuals affected by the human radiation experiments:

1. All available information will be provided to subjects and their families as soon as possible.

2. When required to protect the health of individuals who were subjects of human radiation experiments or their descendants, the government will notify these subjects, or their descendants, of any potential health risk or the need for medical follow-ups.

3. The Legal Issues Subcommittee is currently examining various models for potentially appropriate federal responses, including those incorporated into other federal programs such as those used to respond to "downwinders," veterans exposed to radiation, and the Japanese-Americans interned in the United States during World War II. The range of federal responses under consideration include potential monetary compensation, medical follow-up, disclosure of detailed information, formal apologies or other recognition, and ongoing research, education and information programs.

4. Specific recommendations for legislative and other action that may be appropriate will be developed once the Working Group and Advisory Committee have completed at least their first phase of work. This will be in six months, when the Advisory Committee's interim report is issued to the Administration's Human Radiation Interagency Working Group.

Throughout all of this activity, the Administration will continue to work closely with the Congress.

The Advisory Committee will make recommendations concerning the need to expand or amend existing Federal guidelines governing human radiation experimentation to the Interagency Working Group, which will then make recommendations, as appropriate, to the President.

Funding of the Advisory Committee is governed by the Federal Advisory Committee Act. The Act only allows one Federal agency to finance the Advisory Committee. The Department of Energy has been chosen as the designated agency. We will not require any special Congressional appropriations for this project. Advisory Committee meetings will be conducted in accordance with the Federal Advisory Committee Act requirements and as such, will be open to the public. Meetings held by the Advisory Committee which require discussion of individual subjects and their records may be closed to protect the subjects' and their families' privacy.

The Advisory Committee's support staff will consist of both non-governmental individuals and Federal agency workers. An interim report is expected six months from the filing date of the Advisory Committee's Charter. This report will address whether the Advisory Committee believes it is likely that it will be able to fulfill its duties within a one year time-frame.

#### Administration Position on Compensation Related to Human Radiation Experiments

If our review determines that American citizens were treated wrongfully by their government, we believe this Administration owes the American people a full accounting and, where justified, an attempt to right any wrong done.

*Phil*

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

**URGENT**

**February 3, 1994**

**LEGISLATIVE REFERRAL MEMORANDUM**

**LRM #M-1079**

**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 - Chris Clary - (202)456-7116 - 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 Radiation-related  
Experiments**

**DEADLINE: 4:30 P.M., Friday, February 4, 1994**

**COMMENTS: Attached are the prepared remarks of Drs. Yallow, Kapln, and Burrows, VA physicians who will also testify at the Tuesday hearing. 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.

*12 pages*



Page 2  
LRM #M-1079

## CC:

D. Blanchon

T. Grams

G. Henry

K. Scheid

J. Pfeiffer

E. Pelton

K. Peroff

T.J. Glauthier

B. Dorotinsky

A. Silas

J. Fellows

B. Damus

J. Palmieri

J. Klein

S. Neuwirth

C. Varney/P. Caplan

B. Burton

T. Thornton

J. Podesta



FROM: GENERAL COUNSEL PSB IV

TO: 93955691

FEB 4, 1994 11:53AM P.07

02/03/94 11:27

FEB 03 '94 THU 11:50 AM

**TESTIMONY BY DR. ROSALYN S. YALOW**

Nuclear medicine, the use of radioisotopes for medical purposes, now has an important role in medical diagnosis and therapy. My own background in the field goes back to 1948 when I first joined the Bronx Veterans Administration Hospital.

Nuclear Medicine has three roles: treatment with radioisotopes, diagnostic studies using radioisotopic techniques in vivo or in vitro, and medical research employing radioisotopes. Probably the most common role of Nuclear Medicine in the therapy of a nonmalignant disease is in the treatment of hyperthyroidism. It was noted in the press that before he completed his role as our Chief Executive Officer that both the President and Mrs. Bush were shown to have overactive thyroids. The public was informed that both were treated with radioiodine ( $^{131}\text{I}$ ). No information was given about their dose but typical doses for this nonmalignant disease is usually 5,000 - 10,000 microcuries of the radioiodine. Their whole body dose was probably about 5,000 - 10,000 mrem. The dose to their thyroid was about 1,000 times greater. Thus, after a half century of experience in treating the hyperthyroid state with radioiodine the considered medical opinion is that radioiodine is the optimal treatment for the disease in patients like the President and his wife and that doses of those sizes to the thyroid and to the whole body during the treatment are safe. Patients with thyroid cancer have been successfully treated with radioiodine using doses a hundred times as large without obvious deleterious effects.

In the 1950s the diagnosis of overactive or underactive thyroid was based on the 24 hour uptake of radioiodine by the thyroid. It has been estimated that in the United States probably a half million



FROM: GENERAL COUNSEL P86 IU

TO: 93953691

FEB 4, 1994 11:54AM P.08

02/04/94 15:28 ...

people were tested in this way in the 1950s and 1960s before the modern techniques of radioimmunoassay of thyroid related hormones were introduced. Since the doses for the diagnosis of thyroid disease were only a few percent of the doses used for treatment of an overactive thyroid no harmful effects could be expected.

For the past 30 years radioimmunoassay has been the method of choice for measuring a wide variety of hormones, including the thyroid related hormones, without exposing the subject to radiation. Thus, when radioimmunoassay concerns about the administration of radioisotopes for these studies are not relevant. Furthermore, those workers who use radioimmunoassay procedures need not experience even measurable amounts of radiation exposure.

I have not worked extensively with in vivo studies employing radioisotopes over the past quarter century. However from what I note in the literature the doses employed remain small compared to the doses used for the treatment of an overactive thyroid. For the most part the half-lives of the radioisotopes employed in nuclear medicine are short enough that the disposal of the radioisotope should not be a significant problem. The disposal of C14 and H3 used in biomedical investigation does require further description but is not particularly relevant to the hearing today.

It is evident that the use of radioisotopes in nuclear medicine has had major advantages to our medical care. I will end by reminding you that the large dose of radioiodine received by the President for the treatment of his overactive thyroid does not represent a problem to the workers and to the patients.

FROM: GENERAL COUNSEL PSG IV

TO: 93955691

FEB 4, 1994 11:50AM P.03

A Statement to the Veterans Affairs Committee of the  
United States House of Representatives  
ERVIN KAPLAN, M.D.

I preface my statement to the House of Representatives Veterans Affairs Committee, by stating that we owe an incalculable debt to the veterans of our country; in fact, we owe them the very existence of the United States. To treat the veteran population other than with dignity and respect is contrary to the principles upon which this country exists. To violate their trust in us, at a time when they are ill and hospitalized, by using them as experimental subjects without their knowledge or concurrence in random indulgence of our curiosity is an anathema. On the other hand to apply new and promising methodologies to better understand the nature and treatment of their complaints and clinical findings, when these methods are non-invasive and of acceptable, minimum or no risk, and when approved by the veteran, and a highly qualified hierarchy of medical supervision and peer review is highly justified and is often highly beneficial to the patient.

Various aspects of hospital function relevant to patient informed consent in radioisotope research are discussed below as they existed prior to 1967.

The explanation of patient care and its supervision on various bed services;

I. V.A. Hospital, Hines, Illinois, had a professional policy originating with a Deans Committee consisting of the Deans of the University of Illinois, College of Medicine, Northwestern University, School of Medicine, Loyola University School of Medicine and Chicago Medical School. We interacted and collaborated with the University of Chicago by affiliation with the Argonne National Laboratories which was jointly sponsored by the University and the Atomic Energy Commission. The bed services were specialty oriented, consisting of Medical Service, Surgical Service, Neurology Service, Psychiatry Service. Non-bed services were Diagnostic Radiology Service, Therapeutic Radiology Service, Laboratory Service, Nuclear Medicine Service and Research Service. Each Service was headed by a Chief of Service of professional stature and were faculty members of the affiliated medical schools. Medicine and Surgery were divided into subspecialty sections. Section Chiefs were well trained in their subspecialty and mostly had faculty appointments. The subspecialties were staffed with full time and resident physicians. Subspecialty sections were supplied with Consulting and Attending physicians mostly from the affiliated schools' faculty. They made patient rounds with the full time and resident physicians. Referrals were made to other service and sections as indicated. Participation in research was encouraged. Grand rounds and special lectures were very well attended, morale and esprit were high. Patient consent for procedures were obtained and signed for invasive procedures and



FROM: GENERAL COUNSEL PSB IV

TO: 93955691

FEB 4, 1994 11:51AM P.04

02/04/94 08102 1242 000 0000

were not written for non invasive procedures. In the case of research procedures, the patient was informed and participation was voluntary and only made in writing if the risk so indicated. Competent nurses and aids were present on all bed services. Resident physicians were graded on competence and served a formidable hierarchy of supervisors and were directly responsible for assigned patients.

The internal organization of Radioisotope Service:

II. The service was responsible for performing clinical diagnostic and therapeutic procedures for patients using radioisotope methodology. It also had a research and development mission mandated by the VA to define and solve problems applicable to the continuing and growing needs of the field. These investigations were accomplished by a variety of chemical and physical means, among which radioisotope methodology has been prominent. It had been necessary, when seeking answers to specific problems, to deal with the theoretical and fundamental aspects involved; to apply a variety of physical principals and methodology; to develop and modify equipment. The purpose of these varied approaches had been, the definition of specific human anatomy and physiology, delineation and diagnosis of disease states, and in some instances development of specific therapy. To accomplish these ends the broadest and most diverse interdisciplinary team approach had been used. The contributions of biochemists, physicists, physicians in various subspecialties, engineers and physical chemists and others, had stimulated the solution of many difficult problems. My function was to encourage and integrate that work and to correlate it with the clinical and scientific work in the hospital and affiliated institutions.

III. To best serve the hospital patients, it was necessary to interact with the various bed services. It became necessary to know the professional staff, to make rounds with various physicians, to attend meetings at the hospital and medical schools, to formally and informally discuss problems and to stimulate participation of the staff in collaborative research. The professional staff of the Radioisotope Service had to keep current in all aspects of the specialty, by reading the literature, attending and participating in local, national and international meetings and having great familiarity with others in the field and the details of their work.

IV. The development of a research project required a broad knowledge of the frontiers of the investigators specialty and a perspective of those problems which needed investigation and those solvable by the available state of knowledge and technology. Once a research area had been identified by any member of the collaborating group relevant background information had to be obtained, the significance of the study determined and the problem or hypothesis to be proven required precise identification. The



FROM: GENERAL COUNSEL PSG IV

TO: 93955691

FEB 4, 1994 11:52AM P.05

02/04/94 09:02 202 535 8500

VA LONG BEACH

methodology and experimental design to deal with the problem required constant interaction with the multidisciplinary staff. In those instances involving human subjects, those patients fulfilling the study requirements were identified and were entered into the study on a voluntary basis after informing them in all detail of the purpose, the nature of the participation, how they would personally benefit from the information derived and the type and severity of the risk, if any, that might be encountered. In no instance was a patient required to participate. In instances of no risk, such as obtaining urine, blood specimens or if radioactivity were not administered in procedures which were performed in vitro, the patient interaction was minimal. If interaction was invasive and had definable risk the patient was informed in great detail and may have signed an informed consent form. Often, standard and required procedures which were widely accepted as routine were performed on patients and the goal was to evaluate newer instrumentation or methodology patient consent was irrelevant.

A prospective protocol was prepared, discussed, and reviewed and often rewritten several times. When acceptable to the collaborators it was submitted to the institutional Radiation Safety Committee and the institutional Research Committee. If revisions were requested, they were made. If interactions with an affiliated institution, the protocol was examined at that institution. The VA Director of Nuclear Medicine in VA Central Office maintained a research office which passed upon projects for the purpose of approval. The new uses of radioisotopes were reviewed for approval by VACO and the Atomic Energy Commission (AEC) on approval, issued a specific license. A general license was issued by the AEC for routine clinical use of radioisotopes. The general license permitted accepted uses of radioisotope of elements of atomic number 3 through 83 which excluded all nuclear weapon type radioisotopes and all alpha particle emitters.

Some projects were submitted to the National Institute of Health for approval and funding. This then was another and higher level of peer review and required a protocol of exceptional quality. to my knowledge we were in compliance with the then existing protocols and regulations covering human research.

#### V. Informed Consent

*Stricken* The signing of an informed consent document by a patient involved in a radioisotope research project was to my knowledge required after 1968 by the VA. The principal function of informed consent is to protect the institution, the doctor and other participants in a procedure by absolving them from liability from malpractice or injury or accidents during such a procedure. It assumes that a reasonable element of risk exist in the commission of that procedure. Secondly, it assumes that the patient has been informed of the risk and that his consent was obtained. Informed consent is a legal document and in a lesser sense, a

FROM: GENERAL COUNSEL PSG 1U

TO: 93953691

FEB 4, 1994 11:53AM P.06

V. The determination of risk to the patient when a dose of radioisotope is administered. The Radioisotope Service at VA Hospital, Hines, Illinois, employed a full-time health physicist who was to safely receive, store, quantify and dispense radioisotopes. He was aware of the physical and chemical properties of the isotope, this included the physical form, the nature of the radiation, its penetrability, the amount of radiation exposure to the tissue and its distribution when administered. He possessed adequate instrumentation to monitor the patient and his environment, including a whole body monitoring room. He was also aware of the physical and biologic half life and the routes of excretion. With the above information, he could accurately estimate the risk to the patient. He possessed extensive reference documents and know his legal responsibilities. Detailed records were kept by the health physicist.

Patients were often subject to following up if the experimental design so indicated. During the 36 years of my tenure with the Radioisotope Service and as subsequently changed to the Nuclear Medicine Service, there is no evidence that any patient was injured as a consequence of participating in a radioisotope research project.



FROM: GENERAL COUNSEL PSG IV

TO: 93955691

FEB 4, 1994 11:55AM P.09

02/04/94 08:00

**STATEMENT OF  
DR. BELTON A. BURROWS  
BEFORE THE  
HOUSE COMMITTEE ON VETERANS' AFFAIRS**

I am pleased to contribute the enclosed material relevant to the topic of VA research involving the use of radionuclides and other forms of ionizing radiation.

Consistent with my previous training in internal medicine and my research experience in metabolic diseases requiring laborious balance studies before the more accurate radioactive tracer methods became available, I was attracted to the opportunities offered by the establishment of a Radiolotope Unit at the Framingham (Cushing) VA Hospital in July 19--.

Initially, radiiodine was employed for the diagnosis and treatment of hyperthyroidism and cancer. Subsequently, radiosodium, radiopotassium and radio sulfur were used to study body composition changes in a variety of chronic diseases, such as hepatic cirrhosis, hypertension, cardiovascular disease, diabetes and renal insufficiency prevalent in the veteran patient population. With the recruitment of additional staff and the support of a United States Public Health Service training program in radionuclide techniques, the scope of our activities expanded to other medical subspecialties: endocrinology, hematology, gastroenterology, nephrology and oncology, in which scanning devices were becoming useful.



FROM: GENERAL COUNSEL PSB IV

TO: 93555591

FEB 4, 1994 11:55AM P.10

02/04/94 08:30

In the early fifties, there was also a training program in the use of radiation survey monitors to detect areas that might be contaminated with radioactive materials as a result of industrial accidents or military action. In addition, the professional staff was trained in the clinical management of such exposures. From its inception the Radioisotope Unit (later Radioisotope Service and finally Nuclear Medicine Service) was integrated with the similar service at the Massachusetts Memorial Hospital, later the (University Hospital) and its staff held faculty appointments at the Boston University School of Medicine. The Chief was Acting Director of Nuclear Medicine at VACO for its first five years and helped establish training programs in other VA hospitals which materially assisted in the development of a separate and distinct specialty later to be certified by the American Board of Nuclear Medicine under the superb leadership of Dr. Joseph Ross. There was a close working relationship between the VACO office and the Atomic Energy Commission (AEC) in the processing of applications for the authorized use of by-product material in the field.

Many of the published studies resulted from the retroactive compilation and analysis of diagnostic results and their correlation with other clinical and laboratory data, whereas others required the approval of the radioisotope committee to ensure that they complied with AEC, later NRC (Nuclear Regulatory Commission) regulations.

The formal process of "informed consent", with signed forms approved by local human studies committees, was not developed for several years after radioisotope research had become an active pursuit in the majority of the Radioisotope Units. The studies were conducted in an open clinical setting with

02/04/94

14:33

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FROM: GENERAL COUNSEL PSU IV

TO: 93955691

FEB 4, 1994 11:55AM P.11

02/04/94 00:01 0202 000 0000

the full understanding of the nature of the materials, the purpose of the studies, and the potential applicability of the results to the individual patient's problems.

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:

2/2

TO:

Phil Caplan

Cabinet Aff.

FAX #:

6-2983

FROM:

Tracey Thorton

456-6493

RE:

PAGE 1 OF

6

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

FAX SENT:



TELEFAX COVER SHEET

DATE 2/2/94

FROM Dan

OFFICE OF CONGRESSIONAL AND INTERGOVERNMENTAL AFFAIRS  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C. 20585

DANIEL C. TATE, JR.  
DEPUTY ASSISTANT SECRETARY FOR HOUSE LIAISON

TELEPHONE: 202-586-5468

TELEFAX: 202-586-4891

TO Tracy Thornton

TELEFAX NO. 456-2604 CONFIRMATION NO. \_\_\_\_\_

This document contains 4 pages, (not including the cover sheet).

MESSAGE

To be introduced later today. Urgent

IF THERE IS A PROBLEM WITH THE CLARITY OR COMPLETENESS OF THIS DOCUMENT, PLEASE CONTACT OUR OFFICE AT THE ABOVE NUMBER. THANK YOU...

02/02/94 11:50

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H.L.C.

103D CONGRESS  
2D SESSION

**H. RES. \_\_\_\_\_**

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**IN THE HOUSE OF REPRESENTATIVES**

Mr. FROST submitted the following resolution, which was referred to the  
Committee on \_\_\_\_\_

---

**RESOLUTION**

Expressing the sense of the House of Representatives with  
respect to radiation experiments conducted by the Federal  
Government.

Whereas the Federal Government intentionally conducted secret  
radiation experiments on individuals beginning in the  
1940's;

Whereas the experiments were conducted without the informed  
consent or knowledge of the individuals on whom  
the experiments were performed;

Whereas the radiation experiments included, but were not  
limited to, experiments involving injections of plutonium,  
prescription of radioactive medication to pregnant  
women, ingestion of irradiated food, and exposure to atmospheric  
radiation;



02/02/94 11:52

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H.L.C.

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Whereas the Federal Government performed the experiments not in order to achieve medical or health benefits for the individuals who were subjects in the experiments, but for research purposes to allow Federal Government scientists and health specialists to study the effects of radiation on the human body;

Whereas, at the time of the experiments and in the years following the experiments, previous Federal administrations failed to inform the individuals used as subjects, or their families, about the nature and effects of the experiments;

Whereas the failure to inform such individuals and their families persisted even after a 1986 report, issued by the Subcommittee on Energy Conservation and Power of the Committee on Energy and Commerce of the House of Representatives, disclosed the existence of some of the experiments and recommended that individuals used as subjects in the experiments be identified, located, and provided with followup medical care; and

Whereas such experiments conducted on individuals without their consent or permission were wrong and unacceptable in a free and democratic society, and all reasonable steps should be taken to ensure that such experiments never happen again: Now, therefore, be it

1       *Resolved*, That it is the sense of the House of Rep-  
2       resentatives that—

3               (1) the people of the United States deserve a  
4       full accounting of the nature and extent of the radi-  
5       ation experiments conducted by the Federal Govern-  
6       ment;



02/02/94 11:50

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H.I.A.

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1 (2) the Secretary of Energy should be ac-  
2 mended for quickly responding to the disclosures  
3 that secret radiation experiments had been con-  
4 ducted on individuals without their informed consent  
5 by promising to locate and release all relevant  
6 records;

7 (3) the President should be commanded for es-  
8 tablishing a Human Radiation Interagency Working  
9 Group and an independent Advisory Committee on  
10 Human Radiation Experiments to examine the sci-  
11 entific and ethical questions raised by the experi-  
12 ments and to make recommendations to the Presi-  
13 dent;

14 (4) all departments and agencies of the Federal  
15 Government should act expeditiously to locate, re-  
16 trieve, and inventory all records and documents re-  
17 lated to the radiation experiments;

18 (5) once located, retrieved, and inventoried, all  
19 relevant records and documents should be made  
20 available to the individuals who were used as sub-  
21 jects in the experiments, and to their families, to  
22 allow them to learn the truth about the experiments;

23 (6) the individuals who were subjects in the ex-  
24 periments and are still alive should receive appro-  
25 priate followup medical care;

02/02/94 11:52

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4

1 (7) the President should consider whether com-  
2 pensation should be provided to the individuals who  
3 were the subjects of the experiments;

4 (8) the President should consider whether com-  
5 pensation should be provided to the surviving family  
6 members of deceased individuals who were subjects  
7 of the experiments; and

8 (9) an apology should be made by the Federal  
9 Government to the individuals who were subjects in  
10 the experiments, and their families, for the hard-  
11 ships they have endured as a result of the secret ra-  
12 diation experiments.



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

URGENT

January 31, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1062

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)456-6722 - 429  
NSC - William H. Itoh - (202)395-3723 - 249  
OSTP - Chris Clary - (202)456-7116 - 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: DEFENSE Proposed Testimony on  
Radiation-related Experiments

DEADLINE: 10:00 A.M., Tuesday, February 1, 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:

G. Henry  
J. Pfeiffer  
D. Blanchon  
T. Grams  
J. Fellows  
A. Silas  
E. Pelton  
K. Peroff  
T.J. Glauthier  
B. Dorotinsky

B. Damus  
J. Palmieri  
J. Klein  
S. Neuwirth  
C. Varney/P. Caplan  
B. Burton  
T. Thornton  
J. Podesta

*Fox 6/9*





**DRAFT**

Statement  
of  
Dr. Harold Smith  
to the  
Subcommittee on Administrative Law and Government Relations  
Committee on the Judiciary

February 2, 1994

**DRAFT**



# DRAFT

Mr. Chairman and Members of the Committee, it is an honor for me to appear before you today on behalf of the Department of Defense. I am accompanied by Ms. Joan Pierre of the Defense Nuclear Agency who will be able to respond to your questions about the details of the Nuclear Test Personnel Review. In addition, Ms. Jeanne Fites is here to respond to questions about the Department's effort to identify experiments it has conducted in which humans participated.

## HUMAN RADIATION EXPERIMENTS

You have heard from the Department of Energy's descriptions of the Interagency Working Group now in place to conduct the search and retrieval of records of human radiation experiments. It is not necessary to describe that process again. However, it is important that this committee, your colleagues in the Congress, and the American people, know that the Department of Defense is a full and active participant in that process.

Secretary of Defense Les Aspin has placed a high priority on this project. As the Interagency Working Group was established, he appointed personnel from the highest levels of the Department to serve on the working group. Simultaneously, he charged those persons with the additional duty of serving on a steering committee panel formed to oversee the Department's search and retrieval endeavor.

The steering committee is acting as a "board of directors" for a Command Center which we have established. That center is headed by a Rear Admiral and is to be the collection point and clearinghouse for records discovered in this project. As one might imagine, this retrieval process will require an extensive search. With facilities located all over the country and the world, we cannot be certain where records of experiments will be found. Based upon the experience of DoD's NTPR program, the command center is to be the central point to which records can be referred, cataloged, and reviewed.

While we cannot simply go into the attics or cellars of the Department and pull out boxes labelled "Human Radiation Experiments", the Department will not be deterred by the complexity or difficulty of the task confronting us. We are fully committed to this effort. We are acting as quickly as possible to find and catalogue records. We will collect those records and review them. We will release them as comprehensively and as soon as possible, recognizing that we must proceed in a way that protects the privacy of citizens who may have been participants, knowingly or unknowingly, in those experiments.

## DoD TASK FORCE

Mr. Chairman, the administration's recent pledge to open the files of all radiation experiments conducted or sponsored by government agencies has renewed the interest of the Congress and the American people in other types of human experiments which may have been conducted in the past. This committee should know that eleven months ago, the Department began a records search and retrieval project for chemical, biological, and drug experiments.

The genesis of this effort came in the January 6, 1993 report of the the National Academy of Sciences' Institute of Medicine entitled "Veterans at Risk: The Health Effects of Mustard Gas and Lewisite". Subsequent to the release of that report, Deputy Secretary of Defense William J. Perry established an intra-Department task force to accomplish the task of making all available information available to the Department of Veterans Affairs.

This task force continues its review of records, correspondence, technical reports, scientific notebooks, and other documents. The purpose of this on-going review is to determine the contents of the materials and to determine whether the documents contain personnel identification information which can be extracted for inclusion in a personnel database file. Thus far, the task force has identified five major DoD records holding sites. A preliminary review of records has been made at all sites except one. In addition, the task force has looked at records in certain collections held by the National Archives, and at the University of Chicago.

Most of the collections examined to date are not in the form of personnel or medical records. For the most part, the personnel identifiers have been extracted from scientific notebooks,



# DRAFT

operational orders and plans, administrative correspondence, technical reports, personnel rosters, morning reports, etc. This documentation is housed in historical library collections, warehouse records holding areas, and technical libraries. Many collections are not sorted or indexed, and a large percentage of two of the collections is still classified, requiring a review of each piece of paper in the collections.

Like the search underway for records of human radiation experiments, the task of locating, evaluating, and cataloging records of non-radiation experiments is immense. For example, at one installation, four hundred forty (440) boxes of materials have been identified. At another, 8,465 linear feet of paper has been discovered. In addition, information is stored on microfiche (7,000 sets at one installation, 6,776 sets at another), index cards, and some electronic records.

The personnel information in these holding areas and technical libraries is often contained in documents or reports that are still classified. They often contain weapons schematics, technical drawings, and operational directions as well as scientific formulas. In addition to some of it still being of a national security nature, some also refers to agreements made and exercises conducted with foreign countries. Because of these issues and personnel privacy issues, review of this information must be accomplished by personnel with appropriate security clearances, technical or scientific background, and personnel management expertise literally reviewing each piece of paper in the files.

In addition to instructing the task force to examine records and collect data, Dr. Perry also directed the services and all agencies of the Department to initiate procedures to fully cooperate and locate information, respecting the rights of individual privacy. Moreover, he directed procedures be adopted to declassify documents for chemical weapons research conducted after 1968 and release participants from any oaths of secrecy or other non-disclosure restrictions that may have been placed upon them.

At the end of this process, DoD plans to report on the location of each U.S. chemical weapons research program; whether it was a chamber, field or patch test; the type of chemical tested; the start and finish date of each test; identification of each military unit stationed at each test site; name, service number, and military unit of each individual known to have participated in the test. Though this search is still going on, it is hoped that a preliminary report can be delivered later this month.

## CHEMICAL WEAPONS RESEARCH

The work of the department's task force and the consistent interest of the Congress has resulted in discoveries of other non-radiation experiments. The Army has identified 7,250 Army and Air Force personnel as having participated in experiments involving nerve agents, nerve agent antidotes, psychochemicals, irritants, and blister agents. Some of these experiments have been the subject of Congressional hearings. They include the exposure of humans to mustard gas conducted during World War II by the Navy and the Army and LSD experiments in which conducted in the 1950s and 60s.

The final report of the DoD task force will include a full accounting of other types of non-radiation experiments that have been conducted in the past. We would be happy to provide the committee a copy of that document as soon as it is completed.

## BIOLOGICAL WARFARE ACTIVITIES

In 1977, the Army issued a complete report on its Biological Warfare research activities during the period 1941-69. Those experiments fell into two major areas: 1) offensive biological warfare; and 2) defensive biological warfare. The biological offensive warfare research was concerned principally with antipersonnel and anti crop agents and associated delivery capabilities. Recognizing the civilization's abhorrence of these weapons, the U.S. discontinued this research in 1969 and destroyed its limited stocks of biological weapons.

Defensive biological warfare research was undertaken to develop adequate, effective countermeasures which could be used in the event American military personnel were subjected to



# DRAFT

biological attacks in an armed conflict. That concern arose, of course, during the 1991 war in the Persian Gulf and continues to be of great concern in the post-Cold War era. This research also included safety procedures. Safety and medical aspects of testing with biological material were of overwhelming concern from the inception of the biological warfare program. The U.S. Public Health Service closely followed the progress of biological research and development.

The DoD task force which was described earlier is charged with the responsibility of identifying all of these and like experiments, the agents on which tests were conducted, the sites where they were conducted, and the numbers and names of personnel estimated who participated. The purpose of this effort is to develop the information necessary to respond to claims of former military personnel who were subjected to chemicals, biological agents, and drugs while serving their country.

## NUCLEAR TEST PERSONNEL REVIEW

This program was initiated in the late 1970s to identify and assist veterans and selected DoD civilians who participated in the U.S. atmospheric nuclear testing. In 1988, NTPR was expanded to cover DoD personnel who participated in the post-war occupation of Hiroshima and Nagasaki, Japan. The program provides individuals with participation data and exposure levels to assist them in applying for health care or compensation from the Departments of Veterans Affairs and Labor, which are responsible for determining an individual is eligible for health care or compensation.

As of January 1, 1994, 205,472 individuals were identified as having participated in the U.S. atmospheric nuclear testing program. Another 195,753 DoD were associated with the occupation of post-war Hiroshima and Nagasaki. Over the past five years, about 2,000 new program participants have been added to the program annually.

Reaching out to these individuals has been a challenge. DoD has relied on an outreach program to encourage them to contact us. A key component of that outreach has been a toll free help line. Contact has been established with approximately 70,000 individuals. Help line phone calls have accounted for the most majority of those contacts.

The Department of Defense, the Defense Nuclear Agency remains fully committed to its original philosophy of honesty, candor, and thoroughness in the management of this program.

## SUMMARY

This administration is committed to ensuring that all military members, civilian employees, and contractor of the Department receive the benefits to which they are entitled as a result of their exposure to chemical and biological agents, or radiation. Our full participation in the Human Radiation Experiment Interagency Working Group, the Nuclear Test Personnel Review, and the on-going effort of the Department's task force on chemical weapons research programs represent an intense collective attempt to accumulate information necessary to identify those individuals who participated in experiments. Candor and openness have marked each of these endeavors and will continue to serve as hallmarks by which this administration conducts these efforts.

Those brave military personnel, their families, and the American people deserve no less than a full accounting of experiments in which human subjects were used.

# DRAFT



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

**URGENT**

**January 21, 1994**

**LEGISLATIVE REFERRAL MEMORANDUM**

**LRM #M-1034**

**TO: Legislative Liaison Officer -**

VA - Robert Coy - (202)535-8113 - 229  
HHS - Frances White - (202)690-7760 - 328  
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  
OSTP - Chris Clary - (202)456-7116 - 288  
NSC - William H. Itoh - (202)395-3723 - 249  
CIA - Tom Benjamin - (703)482-6126 - 258

**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: DEFENSE Proposed Testimony on Radiation  
Testing**

**DEADLINE: 11:00 A.M., Monday, January 24, 1994**

**COMMENTS: Please note that the attached testimony will be presented in addition to the testimony circulated under cover of LRM #M-1029. 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.



Page 2  
LRM #M-1034

## CC:

B. Damas  
J. Klein  
S. Neuwirth  
C. Varney/P. Caplan  
B. Burton  
T. J. Glauthier  
J. Palmieri  
T. Thornton

J. Podesta  
E. Pelton  
J. Pfeiffer  
J. Schuhart  
D. Blanchon  
A. Silas  
B. Dorotinsky



01-21-1994 15:18

P.02

**Statement by Major General Kenneth L. Hagemann, USAF**

**Director, Defense Nuclear Agency**

**Department of Defense**

**before**

**Committee on Governmental Affairs**

**United States Senate**

**25 January 1994**



01-21-1994 15:17

P.03

Good morning, Mr. Chairman. I appreciate having this opportunity to appear before the committee. I would like to begin by expressing how important it is that we support those citizens who through their contributions to the Cold War may have been exposed to ionizing radiation. We at the Defense Nuclear Agency are committed to gathering and reviewing any and all data or information related to ionizing radiation research on human subjects.

My statement will concentrate on DNA's management of the Nuclear Test Personnel Review -- or "NTPR" -- program. This is a program initiated in the late 1970s to identify and assist veterans and selected DoD civilians who participated in the U.S. atmospheric nuclear testing program. In 1988, the NTPR program was expanded to also cover DoD personnel who participated in the post-war occupation of Hiroshima and Nagasaki, Japan. The program provides individuals with participation data and exposure levels to assist them in applying for health care or compensation from the Departments of Veterans Affairs and Labor. These departments are responsible for assessing health effects and determining whether an individual is eligible for health care or compensation.

As of 1 January 1994, we had identified 205,472 individuals who participated in the U.S. atmospheric nuclear testing program. Another 195,753 DoD personnel associated with the post-war occupation of Hiroshima and Nagasaki had also been identified. Over the past five years, as a result of individuals contacting us, we have added about 2,000 new program participants annually.

01-21-1994 15:17

P.04

We have learned that doses to most individuals were quite low. In fact, about 25 per cent received no measurable dose. Less than one per cent of the participants -- about 1600 individuals -- received doses in excess of today's Federal guidance for occupational exposure, which is 5 rem per year. The average exposure to NTPR program participants was less than 1 rem.

Reaching out to these individuals and informing them of their potential exposure has proven challenging. We have had to rely on an outreach program to encourage them to contact us. Our outreach efforts include articles in veterans' magazines, media releases, and presentations at veterans' groups and conventions. A key component of our outreach program has been a toll-free helpline. For the benefit of those individuals watching today's hearing, the toll-free number to contact the NTPR program is 1-800-452-3583.

As of today, we have established contact with approximately 70,000 individuals. Phone calls to the NTPR helpline accounted for the vast majority of contacts.

In conclusion, the NTPR program has proven highly effective in meeting the needs of its participants. DNA remains fully committed to its original philosophy of honesty, candidness, and thoroughness in its management of this program.

Again, Mr. Chairman, I appreciate having the opportunity to be here today. I would be pleased to answer questions from the committee members.

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

URGENT

January 21, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1031

TO: Legislative Liaison Officer -

VA - Robert Coy - (202)535-8113 - 229  
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)456-7116 - 288  
NSC - William H. Itoh - (202)395-3723 - 249  
CIA - Tom Benjamin - (703)482-6126 - 258

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 Proposed Testimony  
on Radiation Testing

DEADLINE: 2:00 P.M., TODAY, Friday, January 21, 1994

COMMENTS: Please disregard the testimony sent January 19th under cover of this LRM (#M-1031); the attached testimony will be presented at the hearing tentatively rescheduled for Tuesday, January 25th. 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.

*Hegarty*



Page 2  
LRM #M-1031

## CC:

B. Damus  
J. Klein  
S. Neuwirth  
C. Varney/P. Caplan  
B. Burton  
T. J. Glauthier  
J. Palmieri  
T. Thornton  
J. Podesta

E. Pelton  
J. Pfeiffer  
J. Schuhart  
D. Blanchon  
A. Silas  
B. Dorotinsky  
T. Grams



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| OPTIONAL FORM 89 (7-90)         |                     |
| FAX TRANSMITTAL                 |                     |
| From                            | Mike Lord B. Gaines |
| To                              | OMB                 |
| Phone                           | 386-8687            |
| Fax                             | 386-5497            |
| GENERAL SERVICES ADMINISTRATION |                     |

STATEMENT OF  
SECRETARY OF ENERGY  
HAZEL R. O'LEARY  
BEFORE THE  
COMMITTEE ON GOVERNMENTAL AFFAIRS  
U.S. SENATE  
CONCERNING  
HUMAN RADIATION EXPERIMENTS

JANUARY 20, 1994



Mr. Chairman and Members of the Committee:

The Governmental Affairs Committee has a long-standing and active interest in the well being of the workers and public who are at risk due to radiation and other toxic exposures resulting from nuclear weapons production and environmental cleanup. As such, I feel privileged to come before you to speak about recent reports of potentially unethical conduct involving experiments using radiation on human subjects during the Cold War. As you know, this subject has generated intense public and media attention over the past several weeks. During this time, I have spoken with many Americans around the country, some of whom were experimental subjects or the relatives of subjects. They have been deeply troubled, as I was, by these reports.

The nation has now begun to debate important questions raised by some of these experiments - questions about the role of secrecy in a democratic society as well as the need for proper safeguards to ensure the rights of individuals to determine their own fates. We must prevent anyone in America - whether they are uneducated or poor or mentally retarded or incarcerated - from being used as "guinea pigs."

The Clinton Administration is determined to disclose all records on experiments involving ionizing radiation on humans. In a moment, I will discuss the steps we are taking to release information as quickly as possible, to ensure that we have a serious, thoughtful debate about

the lessons these experiments teach us, and to make sure that the highest standards of ethical and scientific conduct are followed in all research involving human beings.

As we examine this dark and narrow corner of scientific experimentation, we must keep in mind several points. As unsettling as some of these experiments were, and as feared as radiation may be to many people, it is important to remember that many lives have been saved using radiation in the diagnosis and treatment of disease. During the same Cold War period that some scientists were conducting these controversial experiments, other scientists were inventing vaccines against polio, new and effective treatments for cancer, and new ways of visualizing the human body with CAT and cardiac scans. Science itself is not at issue here - the way some scientists may have practiced their craft is.

I also want to caution the American public against inordinate fear of current research practices. Institutional Review Boards enforce strict requirements for informed consent of any human subjects involved in scientific experiments. In fact, scientists today must obtain informed consent just to administer a questionnaire. It is difficult to conceive of the ethical abuses about which we've been hearing occurring today in the U.S.

As I will describe, however, we are committed to a serious review of experiments involving human exposure to ionizing radiation. If necessary, we will use the results of this review to make today's standards even more stringent.

### President Clinton's Commitment to Openness in Government

This Administration recognizes that public trust can only be achieved if American citizens believe that their government is open, truthful, and accountable. Since the earliest days of his campaign, President Clinton has been publicly committed to an open and responsive government. The openness initiative that I began at the Department of Energy last spring was a direct outgrowth of this commitment.

### The Department of Energy's Openness Initiative

On December 7, 1993, I held a press conference at which we released important information that had previously been classified. I revealed, for example, that 204 previously unannounced nuclear tests - one out of every five U.S. tests - had been kept secret. The Cold War rationale for this secrecy was the desire to inhibit Soviet monitoring of our weapons testing program. In addition, we revealed the locations and quantities of the U.S. weapons grade plutonium stockpile and the amount of mercury used in American nuclear weapons production.

Also during that press conference, I acknowledged, as Congressman Markey revealed in a 1986 House Subcommittee Report and as recent press accounts described, that 18 persons were injected with plutonium as part of an experiment sponsored by the Atomic Energy Commission in the 1940's. The records available strongly indicate that some of these subjects may not have been fully informed of the purpose or risks of the experiment.



Experiments using radioactive iron on pregnant women at Vanderbilt University in Nashville, Tennessee were highlighted by the press in recent weeks. These radioisotopes were supplied by the Atomic Energy Commission. As with other press reports on human radiation experiments, the Department of Energy is gathering any relevant records to submit to the Advisory Committee for review.

#### The Department of Energy's Approach to Declassification

Increasing public interest in the activities of the Department of Energy (and predecessor agencies including the Atomic Energy Commission) has resulted in a significant increase in requests over the past few years for Departmental records, many of which are classified or contain restricted data. Nuclear proliferation remains, of course, a national security concern. However, dramatic changes over the past few years in the international arena have significantly reduced the classification requirements for much information and, after proper review, such information will be released to the public.

A significant number of Department of Energy records requiring systematic review, are currently held by the National Archives and Records Administration. The Department of Energy has agreed to transfer additional Atomic Energy Commission records to the Archives. In order to deal with this large volume of classified records, the Department is providing the Archives with authorized reviewers to work in a systematic declassification program. We are also working closely with the Department of Defense to review appropriate information for declassification.

The benefits of our declassification initiative include: an enhanced ability to fill in the blanks of Cold War history - including the public disclosure of documents relevant to radiation experiments; improved studies of the health and safety of Department workers and the public; and increased trust in government. Also, through this initiative, the U.S. sets an example for other nuclear nations to follow. We recognize, however, that there is a continued need to balance our declassification needs with our nonproliferation objectives.

#### State of Present Knowledge on Radiation Experiments

We do not yet know if the radiation experiments noted in the 1986 Congressional Report by the House Energy, Conservation and Power Subcommittee and the experiments involving deliberate environmental releases discussed in the General Accounting Office Report done for this Committee in December of last year, comprise the bulk of experiments that might be subject to questions of scientific and ethical propriety. We also do not yet know the full extent of the records pertaining to Department of Energy-sponsored experiments that need to be examined.

We do know that the records search being conducted by the Department of Energy -- as well as that of other government agencies -- will be as thorough and comprehensive as possible, as we endeavor to tell the full story. **Our goal is to get all the facts out.** We also will do our best to provide information as we learn it. All pertinent information that is found regarding human experimentation will be declassified as necessary on an expedited basis and permanently preserved for public review in an appropriate public archive. However, we will take appropriate steps to protect the privacy of people who were the subjects of experiments as well as their families.

From what we know thus far, human experiments involving ionizing radiation conducted or sponsored by the Department of Energy or its predecessor agencies fall into one of four categories:

1. Experiments designed to investigate the effects of radiation on humans or the way the human body metabolizes radioactive substances;
2. Experiments using radioisotopes as tools to study the biochemistry of normal metabolic processes;
3. Experiments designed to investigate the therapeutic uses of radiation in the treatment of diseases such as cancer; and
4. Experiments involving intentional releases of radiation to the environment for purposes of assessing the behavior of such releases.

#### Some of the More Troubling Aspects of the Experiments

The radiation experiments that have come to light are disturbing for several reasons. It is not clear that all subjects were properly informed of the purposes or risks associated with the experiments in which they were participants.

Some of the experiments also raise questions about how the experimental subjects were selected. There is, at least on first inspection, the appearance of a pattern of choosing subjects from relatively vulnerable populations such as persons of color, poor people, prisoners, and retarded children. This appearance of treating some citizens as "expendable," to use Congressman Markey's phrase, is especially repugnant in a country that prides itself on its diversity, and that has, as its goal, providing equal opportunity for all its citizens.



### Current Experiments Involving Human Subjects

At present, about 120 studies are conducted with Department of Energy funds at Department of Energy facilities or at medical institutions and centers. Additionally, about 100 studies funded by other agencies are conducted at Department facilities. These studies have a range of purposes, including determining better ways to diagnose and treat disease, and retrospective epidemiologic studies on the long-term effects of radiation on Department of Energy workers. These epidemiological studies are being managed by the Department of Health and Human Services using Department of Energy funds.

Every experiment using human subjects conducted or sponsored by the Department of Energy must be approved by an Institutional Review Board. Each project must be re-approved annually. Changes in project plans or adverse effects among subjects must immediately be reported to Institutional Review Boards. The Department is taking further steps to assure that current studies where human subjects are directly involved, such as those pertaining to medical research, are fully in accordance with the federal regulations and guidelines. A computerized data base is currently being established that will provide complete, accurate, and reliable information on current human subject research in standardized format which will be updated annually. The data base will be complete this spring. We have no reason to believe that any experiments involving human subjects currently being carried out or sponsored by the Department of Energy are in violation of ethical principles or being performed without the subjects' informed consent.

### Human Radiation Interagency Working Group

On January 3, 1994, the White House convened a meeting of senior staff from government agencies with potential involvement in human radiation experiments. The White House has established a Human Radiation Interagency Working Group consisting of myself and the Secretaries of Defense, Health and Human Services, and Veterans Affairs. The Directors of the Central Intelligence Agency and the Office of Management and Budget, the Attorney General, and the Administrator of the National Aeronautics and Space Administration are also on the Working Group. Five subcommittees have been formed under the Working Group to address the following specific issues: 1) Public Information and Communications; 2) Retrieval and Review of Records; 3) Ethical and Scientific Standards; 4) Congressional Relations; and 5) Legal Issues. These subcommittees are composed of staff from all relevant Federal agencies.

The Administration, through an Executive Order signed on January 18, 1994, formed an Independent Advisory Committee on Human Radiation Experiments, consisting of non-governmental experts in the fields of ethics, science, medicine, and law. The Independent Advisory Committee on Human Radiation Experiments, will review records of experiments on ionizing radiation on humans and will advise the Interagency Working Group on whether any lapses of scientific or ethical standards occurred.

The Advisory Committee's scope of review will include:

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 which were designed to test human health effects of ionizing radiation or were designed to test the extent of human exposure to ionizing radiation.

The Advisory Committee will also provide advice, information, and recommendations on the experiments noted in the December, 1993 report by the General Accounting office concerning intentional releases of radiation to the environment. The Advisory Committee may also review any other experiments which may later be identified by the Human Radiation Interagency Working Group.

The Advisory Committee will review experiments since 1944. Human radiation experiments undertaken since the 1974 issuance of the U.S. Government biomedical research guidelines, will be sampled to determine their priority for review. Further inquiry into such experiments conducted after 1974 may be pursued if warranted.

The Advisory Committee will make recommendations concerning the need to expand or amend existing Federal guidelines governing human radiation experimentation to the Interagency Working Group, which will then make recommendations as appropriate to the President.

Funding of the Advisory Committee is governed by the Federal Advisory Committee Act. The Act only allows one Federal agency to finance the Advisory Committee. The Department of Energy has been chosen as the designated agency. We will not require any special Congressional appropriations for this project. Meetings will be conducted in accordance with the Federal Advisory Committee Act requirements and as such will be open to the public. However, meetings which will discuss individual subjects or their records will be closed to protect the subjects privacy.

The Advisory Committee's support staff will consist of both non-governmental individuals and Federal agency workers. An interim report is expected six months from the filing date of the Advisory Committee's Charter. This report will address whether the Advisory



Committee believes it is likely that it will be able to fulfill its duties within a one year time-frame.

#### Gathering and Dissemination of Records by the Department of Energy

The Department has already begun to take several steps to locate and preserve documents relevant to medical and scientific experimentation involving human subjects. Department of Energy personnel have been directed to cease routine and non-routine destruction of documents and to identify all pertinent records and information in the Department's possession and in the possession of our laboratories and contractors. The Department will develop a thorough inventory of records with potential value for investigating human experiments.

A Department of Energy committee has been established to coordinate the retrieval and inventorying of all relevant records. The process used by the Department of Energy will be conducted in conjunction with the guidelines being established by the Interagency Working Group to ensure that, whenever appropriate, uniform procedures for retrieval and inventorying are applied at the Department of Energy as well as other agencies.

Records which are classified will be retrieved for declassification as quickly as possible. It is vitally important that the records be made available to the public while ensuring the privacy of participants in these experiments and their families. Records will be reviewed and deletions made as required to protect the privacy interests involved. Records will then be made available to the public.

### The Human Experimentation Helpline and Correspondence

The Department of Energy has established a toll-free telephone Helpline. The purpose of the Helpline is to aid us in identifying those persons who may have been affected by the activities in question. The number of calls to the Helpline has been overwhelming. We have received more than 15,000 telephone calls since December 24, 1993.

The majority of callers appear not to have been subjects of human radiation experiments. The calls do reflect the concerns of people in every state and of all different backgrounds. The Department is requesting that callers provide additional written information that can be used to identify and locate documents related to these experiments.

In addition, we have received over 1,000 letters in the last two weeks. Approximately one third of the letters are from individuals or their relatives who believe that they may have been subjects of human experimentation and another third of the letters are from individuals who believe that they have been exposed to radiation while serving in the military or while living next to a government facility. The remaining third of the letters express support, offer assistance, or request information on the nature of the Department's efforts.

### Administration Position on Compensation Related to Human Radiation Experiments

If our review determines that American citizens were treated wrongfully by their government, we believe this Administration owes the American people a full accounting and, where justified, an attempt to right any wrong done to individuals.

The Administration is planning to take the following actions regarding compensation and other responses to individuals affected by the human radiation experiments:

1. We will provide information to subjects and their families as soon as it becomes available.

2. When required to protect the health of individuals, or their descendants, who were subjects of a human radiation experiment, the government will notify subjects, or their descendants, of any potential health risk or the need for medical follow-up;

3. The legal issues subcommittee is currently examining various models for appropriate federal responses, including those incorporated into other federal programs such as those used to respond to "downwinders," veterans exposed to radiation, and the Japanese-Americans interned in the United States during World War II. The range of federal responses under consideration include potential monetary compensation, medical follow-up, disclosure of detailed information, formal apologies or other recognition, and ongoing research, education and information programs; and

4. We are also developing specific recommendations for legislative and other action that may be appropriate once the Working Group and Advisory Committee have at least completed their first phase of work. This will be in six months, when the Advisory Committee's interim report is issued to the Administration's Human Radiation Interagency Working Group.

Throughout all of this activity, the Administration will continue to work closely with the Congress.



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

*Phit forced*  
**URGENT**

**January 19, 1994**

**LEGISLATIVE REFERRAL MEMORANDUM**

**LRM #M-1030**

**TO: Legislative Liaison Officer -**

VA - Robert Coy - (202)535-8113 - 229  
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  
OSTP - Chris Clary - (202)456-7116 - 288  
NSC - William H. Itoh - (202)395-3723 - 249  
CIA - Tom Benjamin - (703)482-6126 - 258

**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 Testing**

**DEADLINE: 3:00 P.M., TODAY, Wednesday, January 19, 1994**

**COMMENTS: Please note that the hearing is scheduled for Thursday, January 20th. 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:**

B. Damus  
J. Klein  
S. Neuwirth  
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B. Burton  
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J. Podesta  
E. Pelton  
J. Pfeiffer  
J. Schuhart  
D. Blanchon  
A. Silas  
B. Dorotinsky

*9 pages*





Mr. Chairman and members of the Committee:

I am Dr. D.A. Henderson, Deputy Assistant Secretary for Health-Science in the Department of Health and Human Services. With me today is Dr. Gary Ellis, Director of the Office for Protection from Research Risks. Today I will describe the activities currently underway to identify all experimentation between 1944 and 1974 which was conducted or supported by HHS and which involved human exposure to ionizing radiation. Before doing so, I believe it would be helpful for me to briefly review the actions taken by HHS and its predecessor agency which, over the past 40 years, have evolved into a formal and well-codified administrative structure to assure that research involving human subjects fully takes into account both risks and benefits as well as consent which is voluntary, competent, and informed.

Today, all experiments involving human subjects whether conducted in PHS institutions or by grantees must be reviewed, approved and regularly monitored by a formally constituted Institutional Review Board (IRB).

#### **Protection of Human Subjects Today**

The evolution of requirements for the protection of human subjects begins in 1953 at the National Institutes of Health (NIH). At that time, the NIH Clinical Center produced the first U.S. Federal policy for the protection of human subjects. Its



implementation called for an institutional review board (IRB), now fundamental to the system of human subject protection throughout the United States. On February 9, 1966, the Public Health Service issued a policy that required prior review of research protocols involving human subjects in research supported by the PHS. It required several factors be carefully weighed; 1) the balance of benefits and risk to the individual; 2) methods used to obtain informed consent; and 3) the rights and welfare of the research subjects.

The Department of Health, Education, and Welfare (HEW), the predecessor to HHS, extended and formalized this policy as a regulation on May 30, 1974. The 1966 policy and the regulations that followed in 1974 were based on the concepts that freely given consent to participate in research is the cornerstone of ethical experimentation involving human subjects and that the risks of research need to be balanced against the benefits derived. The regulations established the Institutional Review Board (IRA) as the mechanism through which the adequacy of the informed consent process could be assessed and the rights and welfare of human subjects are otherwise protected. More than 1000 research institutions currently have active IRB programs.

In 1991, the core of the HHS regulations (Subpart A), further revised, was adopted as the Federal Policy for the Protection of Human Subjects. This Federal Policy (HHS, 45 CFR 46), or so-called "Common Rule," was promulgated by the

sixteen Federal departments and 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 regulations also hold 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 HHS facilities as well as domestic and foreign institutions or sites receiving HHS funds. OPRR requires that each HHS agency and extramural research 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."

This is a formal, written commitment (i) to widely held ethical principles, (ii) to the HAS 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.

OPRR has been in operation for over 20 years and employs 8 full time professional staff to ensure compliance with human subjects protections regulations. This office responds to allegations of noncompliance and actively

pursues investigations.

It is now universally accepted that research investigators have a fundamental responsibility to safeguard the rights and welfare of the people participating in their research activities. In addition, it has been decided by law that an objective review of research activities involving human subjects by a diverse group of individuals is most likely to protect human subjects and promote ethically sound research. Ires 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.

### **HHS Activities**

Now I would like to briefly review the efforts we are currently undertaking as a part of the White House Human Radiation Interagency Working Group. HHS is actively participating in the Working Group as well as all of its subcommittees.

We are currently finalizing a memorandum for all HHS components which will:

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



- o direct each Departmental division to begin immediately to identify records related to human experimental exposure to ionizing radiation, and
- o direct each Departmental division to retain and secure any and all records that may pertain to experimental exposure of humans to ionizing radiation.

It is anticipated that most of the experiments funded by HHS involving human<sup>2</sup> exposure to ionizing radiation were funded by the Public Health Service (PHS). Therefore, a PHS Human Radiation Studies 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 and Prevention, the Indian Health Service, and the Food and Drug Administration. This group will provide detailed guidance and oversight to the staff investigating radiation research.

Preliminary projections indicate that PHS research records will be found in many locations. For those experiments conducted by PHS employees, the records that exist are likely to be found within agency files. However, as you know, much of the research supported by the PHS is by research scientists at institutions located throughout the United States. Problematic experimentation, for reasons I have noted, most likely could have occurred prior to the mid 1960's, i.e. more than 30

radiation as a part of a treatment regimen. In addition, CDC has conducted studies of the human health effects of occupational and environmental exposure to radiation.

### **Conclusion**

Mr. Chairman, on February 9, this vigorous system of protecting human volunteers in research supported by HHS enters its 29th year of continuous oversight. In closing, we want to assure you that the projections in place are designed to preclude the very problems that we have gathered here today to discuss.

years ago.

Identifying and locating the records of these grantees and contractors will require additional effort as the overwhelming majority of the records of special interest -- research protocols, documents related to informed consent, and identities of research subjects -- will be located at awardee institutions. Thus, while we are moving forward with all deliberate speed, the task is substantial and must be undertaken with considerable care. For example, we need to be concerned at every step of the way that we do not in anyway place the privacy interests of research subjects at risk.

We will be pursuing multiple leads in our efforts to identify human radiation experiments. First, we will be examining our own records of research and research grants and contracts. At the same time we will be working cooperatively with other agencies to conduct a comprehensive search of the scientific literature, follow up on calls coming in to the 800 number, and use all possible means to identify relevant experiments.

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



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

*August 23, 1994*

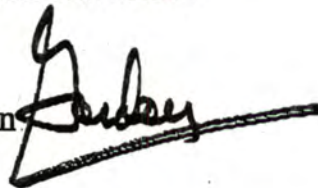
**MEMO FOR:** Dan Guttman

**SUBJECT:** Congressman Portman Letter

Dan:

I am sending you a **DRAFT** copy of the letter (without the enclosures which I believe you have) that we propose to send to Congressman Portman. Apparently Mr. Portman received material from you--see his letter of 25 July to me which I am attaching--which prompted requests for further information. I think it is unfortunate that the Congressman is getting conflicting information on this issue so I'd appreciate any comments you'd care to make on our response. Please forward them either to me or John Casciotti who has been helping on this letter.

Gordon



cf: Mr. Phil Caplan  
Mr. John Casciotti

## DRAFT

Honorable Rob Portman  
House of Representatives  
Washington, D.C. 20515-3502

Dear Mr. Portman:

Thank you for your letter of July 25, 1994, in which you asked follow-up questions concerning the human subject radiation research conducted at the University of Cincinnati from 1960 through 1971. Specifically, you ask whether the 26 February 1953 Secretary of Defense policy memorandum, "Use of Human Volunteers in Experimental Research," applied to the University of Cincinnati research, and, if it did, whether the requirements of this memorandum, such as mandatory written informed consent, were communicated to the University.

Addressing the second question first, we have found copies of the contracts and contract amendments with the University of Cincinnati pertaining to this research. I believe copies of these materials have previously been provided to you. The contracts contain no requirement that the University of Cincinnati follow the 1953 Secretary of Defense memorandum. Nor do the contracts include requirements, such as written informed consent of the individuals involved in the research, that we might assume were premised on the 1953 memorandum. We have found no other documents pertaining to contract administration or the conduct of the research itself that reflect any DoD requirement that the contractor follow the procedures of the 1953 Secretary of Defense memorandum. Noting that this memorandum also required that "[i]n each instance in which an experiment is proposed pursuant to this memorandum," the "Secretary of the military department in which the proposed experiment is to be conducted" must approve of the specific experiment, we have looked for any documentary evidence that this unusual process was recognized as applicable to the University of Cincinnati research. We have found no such documents to date.

You also asked about security clearances. We have thus far found no documents indicating that University of Cincinnati personnel would need a security clearance to carry out any contract requirements. Moreover, none of the contractor's reports was classified, nor was any other aspect of the research. With respect to the security classification issue, it may be noteworthy that, although the 1953 Secretary of Defense memorandum remained classified until 1975, the Army's implementing memorandum, dated 30 June 1953 (attachment 1), was declassified in 1954. This memorandum repeated all of the standards for human subjects protection that were included in the Secretary of Defense memorandum of 26 February 1953. Thus, if these standards were applicable to the University of Cincinnati research, there should not have been a security classification problem in awareness of the policy.



Returning to your first question, whether the standards were, in fact, applicable to this research, we are at this stage of our effort to reconstruct the history of human subject protection requirements unable to state definitively the precise scope of the applicability of the 1953 Secretary of Defense memorandum as of the time of the University of Cincinnati contracts. The Secretary's memorandum authorized a program of "experimental research in the fields of atomic, biological and/or chemical warfare" and stated that "Armed Services personnel and/or civilians on duty at installations engaged in such research shall be permitted to actively engage in all phases of the program, such research shall be subject to" the human subjects protection standards set forth in the memorandum. Taken literally, the reference to military personnel and civilians on duty at military installations does not appear to include members of the public participating in contractor research not on a military installation. But as you point out in your letter, the Army's implementation memorandum, dated 30 June 1953, makes reference to contractors, perhaps suggesting a broader scope.<sup>1</sup>

However, a careful reading of that Army memorandum does not appear to confirm that suggestion. Section 3 of that memorandum summarizes Judge Advocate General opinions on six issues, identified as lettered paragraphs a through f, pertinent to "all participants in research in atomic, biological and/or chemical warfare defense using volunteers." Paragraphs a, b, c and f address military personnel and civilian employees of the Army. Paragraph d addresses private citizens and states that voluntary services from private citizens in research projects "should not be accepted by the Department of the Army." Paragraph e addresses "[c]ontractor employees" and requires (in subparagraph e(1)) that the "terms of the contract must insure that the contractor will observe the conditions and safeguards set forth in this directive." After summarizing all of these Judge Advocate General opinions in section 3, section 4 then states: "Subject to the above conditions, Armed Forces personnel and/or civilians on duty at installations engaged in research in subject fields shall be permitted to actively participate in all phases of the program." Taking sections 3 and 4 of the Army memorandum together, its literal meaning appears to define its scope as applying to personnel "on duty at installations engaged in research," while including as "civilians on duty" not only Army civilian employees but also civilians who are "contractor employees." The literal text of this Army memorandum, thus, does not appear to cover contractor research independent of a research project being conducted on a military installation.

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<sup>1</sup> There may be a question as to whether contracts in support of Defense Atomic Support Agency (DASA) activities were covered by the Army's human subjects protection rules. DoD Directive 5158.2, "Administrative Arrangements for the Defense Atomic Support Agency" (February 2, 1960) (attachment 3), provided:

The Department of the Army will provide procurement authority to the Agency, which will be exercised in accordance with Department of Defense policies and regulations, and to the extent appropriate, policies and regulations of the Department of the Army.

Para. III.C. Absent the emergence of indications to the contrary, it seems reasonable to assume that if the Army's human subjects protection rules applied to contracts independent of Army research laboratories, those rules would have applied to Army contracts procured on behalf of DASA. Of the three contracts awarded to the University of Cincinnati in connection with this research, the first two (DA-49-146-XZ-029 and DA-49-146-XZ-315) were Department of the Army contracts.



The policy established by this 1953 Army memorandum appears to have remained in force for some time. In 1962, the Army issued Army Regulation 70-25, "Use of Volunteers as Subjects of Research" (attachment 2). This regulation followed very closely the terms of the 1953 Army memorandum. It applied to all "Department of the Army research." (Sec. 1.) An appendix to the regulation summarized the same Judge Advocate General opinions described in the 1953 memorandum, including guidance regarding "contractor's employees." The last section of the regulation (Appendix, sec. 7) states: "Conclusion. Subject to the above conditions, Armed Forces personnel and/or civilians *on duty at installations engaged in research* in subject fields will be permitted to actively participate in all phases of the program." (Emphasis added.)<sup>2</sup>

We are still searching through archives and records centers for documents relating to the 1953 Secretary of Defense memorandum of the Department's implementation of it. Until we have exhausted all practicable search opportunities, we prefer to withhold conclusive characterizations of the policies in effect at particular times. Based on our review to date, however, we can offer as preliminary observations: 1) the documentary record does not indicate that requirements of the 1953 Secretary of Defense memorandum were included as contract requirements for the University of Cincinnati research project; and 2) this outcome was consistent with a literal reading of the policy issuances of the time, which appeared to focus on research conducted at military research installations. (Please note that in making these preliminary observations, we offer no value judgments on whether this was good or bad policy; our review effort seeks to "just get the facts.") As our records review efforts continue, we expect a more complete picture to emerge.

I hope you find this responsive to your questions.

Sincerely,

Gordon K. Soper  
Principal Deputy

Attachments: As stated

---

<sup>2</sup> We have seen reports suggesting that in the time period of the Secretary of Defense's 1953 memorandum, it would not have been unusual to make a distinction between in-house research and external supported research. The National Institutes of Health (NIH), for example, established in 1953 certain human subjects protection standards applicable to its in-house Clinical Center; in 1966, standards were established for NIH grantees (attachments 4 and 5). See also, Faden and Beauchamp, *A History and Theory of Informed Consent*, Oxford University Press, page 201-202 (1986).



**ROB PORTMAN**  
Second District, Ohio

Committees:  
Small Business  
Government Operations  
Leader's Economic Task Force

## Congress of the United States

House of Representatives

Washington, DC 20515-3502  
July 25, 1994

Washington Office:  
238 Cannon Office Building  
Washington, DC 20515  
(202) 225-3164

Kenwood Office:  
8044 Montgomery Road  
Room 540  
Cincinnati, OH 45236  
(513) 791-0381

Batavia Office:  
350 East Main Street  
Batavia, OH 45103  
(513) 732-2948  
1-800-784-6366

Dr. Gordon K. Soper  
Principal Deputy Assistant to  
the Secretary of Defense for Atomic Energy  
The Pentagon, Room 3E1074  
Washington, D.C. 20301-3050

Dear Dr. Soper:

Thank you for your responses to my April 13 and May 18, 1994 letters concerning the Department of Defense's involvement with the radiation experiments conducted at the University of Cincinnati General Hospital from 1960 through 1971. The information you provided has been very helpful.

We are getting conflicting information, however, with respect to the applicability of the 1953 Memorandum on informed consent to the researchers at the University of Cincinnati General Hospital. In your letter dated July 20, 1994, you conclude that "the policies and procedures established by the 1953 Memorandum do not appear to be applicable" to the researchers who conducted the experiments at the University of Cincinnati. In the attached documentation, however, that we received today from Mr. Dan Guttman, executive staff director for the federal Advisory Committee on Human Radiation Experiments, it appears that the 1953 Memorandum may have applied to DOD contractors such as UC General Hospital. A Memorandum from the Department of the Army (dated 30 June 1953) appears to state clearly that the terms of the informed consent policy do apply to contractors. The document states in Section 3.e(1), "The terms of the contract must insure that the contractor will observe the conditions and safeguards set forth in this directive."

We therefore ask for your prompt responses to the following questions:

1) Did the 1953 Memorandum outlining the DOD's policy on informed consent apply to the researchers conducting the experiments at U.C. General Hospital? Whether the answer is yes or no, would you please provide the documentation that confirms your answer.

2) If the 1953 Memorandum did so apply, was this policy communicated to the researchers at the University of Cincinnati or to other contractors around the country? We understand that the 1953 Memorandum was classified and are trying to understand the extent to which this policy was well-known to the contractors conducting research. Did any of the researchers at UC General

Hospital have DOD clearance to review "classified" documents that would have given them access to this information?

As you can appreciate, it is critically important to understand what the standards for informed consent were at the time and whether, to the extent those standards applied to U.C., the Department enforced its own policies.

Thank you for your continued cooperation in this matter. Please do not hesitate to contact me if you have any questions with respect to this request.

Sincerely,

  
Rob Portman  
Representative

RP/jb



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

URGENT

October 28, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1895

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)456-6630 - 429  
NSC - William H. Itoh - (202)456-9220 - 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: ENERGY Proposed Testimony on Human Radiation  
Experimentation

DEADLINE: 10:00 A.M., Tuesday, November 1, 1994

THIS TRANSMISSION CONTAINS 15 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  
✓ B. Damus

J. Klein  
S. Neuwirth  
P. Caplan  
B. Burton  
T. Thornton  
J. Podesta  
J. Morall, OIRA







STATEMENT OF TARA O'TOOLE, M.D., M.P.H.  
BEFORE THE COMMITTEE ON GOVERNMENTAL AFFAIRS  
UNITED STATES SENATE  
NOVEMBER 4, 1994

INTRODUCTION

Thank you for the opportunity to appear before the Committee to discuss the Administration's progress in revealing the story of Cold War human radiation experiments, an unprecedented venture in open government that began earlier this year. This endeavor has three parts: 1) A search for documents throughout the Federal government and beyond; 2) Ethical evaluation of this historical record by the Advisory Committee on Human Radiation Experiments; and 3) An effort to respond to the thousands of persons who have inquired as to whether they or their family members may have been the subjects of this experimentation.

As you know, the Advisory Committee released its six-month Interim Report on October 21, 1994 and it is therefore timely and appropriate to review the Clinton Administration's progress in opening this important part of the history of the atomic age to the American people.

*Rene Wilhite*  
586-4273



### MOBILIZATION AND ORGANIZATION OF THE EFFORT

In January 1994, President Clinton ordered the Federal government to reveal the story behind human radiation experiments from the outset of the Cold War to the present. In response, senior officials from Federal agencies that may have conducted or sponsored radiation experiments began meeting in January to devise a process for carrying out this assignment. Thus, the Human Radiation Interagency Working Group was formed. This membership of the group includes the Secretaries of Energy, Defense, Health and Human Services, and Veterans Affairs, the Attorney General, the Administrator of the National Aeronautics and Space Administration, the Director of Central Intelligence and the Director of the Office of Management and Budget.

Five subcommittees were initially formed under the Interagency Working Group. The Public Information and Communications Subcommittee coordinated information among agencies and facilitated the transfer of the Department of Energy's human radiation experiment hotline, established in December 1993, to the Interagency Radiation Research Helpline. The Legal Affairs Subcommittee catalogued existing government responses directed to past radiation exposures of uranium miners, atomic veterans, and citizens living downwind of atmospheric nuclear weapons tests.



The Congressional Affairs Subcommittee is responsible for liaison activities between public officials, the Working Group, and the interagency subcommittees. The Scientific and Ethical Standards Subcommittee, chaired by Dr. Jack Gibbons, Science Advisor to the President, drafted the Charter of the independent Advisory Committee on Human Radiation Experiments. The Advisory Committee is composed of eminent ethicists, scientists, physicians and other scholars appointed by President Clinton and is charged with reviewing the ethical propriety and potential harm associated with experiments involving human exposure to ionizing radiation.

The Records Collection and Retrieval Subcommittee, known as the "Search Group", coordinates the massive, nation-wide search for radiation documents needed by the Advisory Committee for their review. The Search Group, which I chair, is comprised of senior officials from the Departments of Energy, Defense, Health and Human Services, and Veterans Affairs. These are the agencies that have the greatest past involvement in human radiation experiments and that consequently face the greatest challenges in identifying and recovering documents that might be relevant to the Advisory Committee's work.



### RECORD COLLECTION AND MANAGEMENT

The Search Group has been meeting regularly to discuss such issues as: coordination of records searches; development of guidelines for referring Helpline inquiries to individual agencies for follow-up; procedures for assuring the integrity of documents; identification of solutions to common problems and concerns; and identification of issues and documents that are of priority interest to the Advisory Committee. The last issue, which also involves locating pertinent records and the recovery of these records has been a particular concern for the Group.

The size and location of the total universe of records or documents associated with the scientific, historic, and policy aspects of human radiation experiments is unknown, but clearly vast - and not well catalogued. The Department of Energy alone has a total agency-wide inventory of some 3.2 million boxes of records distributed throughout the country, many of which are poorly indexed, if indexed at all. The effort to gain what archivists call "intellectual control" of this enormous body of records — to understand what types of documents are likely to be found in what locations and boxes, so as to narrow the search and make it possible within a limited timeframe — is in itself virtually unprecedented. Moreover, the search goes beyond simply the records of



experiments; we are also looking for any indications of the institutional policies and the considerations which drove human subject research. Thus, it is essential that the agencies work closely with the Advisory Committee to map search strategies and a document recovery process that responds to the needs of the Advisory Committee. Historians and archivists on agency staffs have been working with their counterparts on the Advisory Committee staff to formulate these strategies.

Given the magnitude of this challenge, how will we know when we have reached the finish line? First, it would be unrealistic to imagine that the agencies and the Advisory Committee will find all documents related to human subject radiation research. We do believe, however, that a collection sufficient for evaluation will be possible within the one year timeframe of the Advisory Committee.

There are a variety of ways to provide a check on completeness. The large majority of experimentation resulted in publication in the open scientific literature. These publications are being identified and catalogued. The literature thus provides one means to target and check searches. In addition, the agencies' experts work in close cooperation with those on the Advisory Committee staff,



providing guidance to each other on additional search strategies, updates on new discoveries, and sharing insights. Many scientists who were directly involved in experimentation, particularly in the early days after World War II, have been questioned and interviewed, in some cases through formal oral histories. In addition, the search has been extended beyond the Federal complex to include certain key universities and the personal papers of historically important researchers. We intend to keep searching until we have exhausted the avenues opened through all of these overlapping methods.

I understand that the Committee will request each agency to provide a written assessment of its search status for the record. The Department of Energy has organized its search in a "bottom-up" manner. Pursuant to guidance developed early in the year by professional archivists and historians, we began by using all available research tools, including records transfer forms and all indexes and catalogues of records, to identify from the universe of Department of Energy documents those collections (or "series") that might contain relevant material. Early on, we compiled an initial collection of approximately 10,000 documents. These documents were provided to the Advisory Committee. We then examined those series believed to be potentially relevant and prepared "records series descriptions" for each of these collections, describing



the nature of the records in the collection. A copy of a record series description inventory form is attached for illustration. All of those descriptions were also provided to the Advisory Committee. In many cases, individual file folder titles were provided, as well. We are now working with the Advisory Committee staff to review and identify further individual documents within the series. While we do not expect every possibly relevant document to surface, the iterative and logical nature of the search provides a reasonable degree of certainty that important records will be found and reviewed.

#### ASSURING INTEGRITY OF THE DEPARTMENT'S DOCUMENT SEARCH

In addition to the steps outlined above, which provide a check on completeness, perhaps the most effective engine for openness in this process is continued public involvement and oversight. All records provided to the Advisory Committee are, or will soon be, publicly available, with the exceptions of Privacy Act restrictions and a very small minority of documents that must remain classified for legitimate national security reasons. At the Department of Energy, approximately 1,850 documents related to human radiation experiments have been declassified to date. Most relevant documents were never classified. A number of members of the Advisory Committee and staff have been given security clearances and invited to



review classified documents themselves or preview for relevancy before the declassification process begins.

Both the Advisory Committee and the Federal agencies are dedicated to making these records not just available but also easily accessible and searchable. At the Department of Energy, for example, an index of all records currently released is available through the Internet on the Department's Opennet. In addition, publicly accessible computer terminals are located at the Department's Public Reading Room in the Forrestal Headquarters building and also at the Coordination and Information Center in Las Vegas, Nevada. These terminals are fitted with software that permits easy searching of the indexed documents. Upon request, full copies of any available documents are provided. The Department intends to put the full text of all documents on the Internet early in 1995.

The Department of Energy is also preparing a site-by-site description of radiation research using human subjects, which will be published early in 1995, along with the record series descriptions for all relevant collections Department-wide. A "living" list and description of identified experiments is also being prepared. On November 9, 1994, the Department will convene a workshop of prominent non-governmental scholars and historians to review and provide input to our efforts. It is



worthy to note that the level of cooperation we have received from present and former contractors in this endeavor has been very gratifying. The contractors understand from their daily experiences that openness is a necessity.

Finally, each step of the search effort is documented, from Secretary O'Leary's first memorandum December 23, 1993 and the President's January 17, 1994 Executive Order, onward. The Advisory Committee has instituted a system for transmitting its requests in writing so that replies can be tracked and government responsiveness documented. Each significant field site has been visited twice by expert teams from Department of Energy Headquarters and detailed progress reports are prepared periodically. This will enable those who come after to know where we have been and what we have done. Our goal is not to have the final word, but to leave behind a record of our activities that historians, policy-makers, Congress, and the American people can use to understand, debate, and evaluate this aspect of our history.

#### **STATUS OF THE DEPARTMENT OF ENERGY'S SEARCH TO DATE**

The following are some of the significant milestones achieved by the Department of Energy:

1. Teams of professionals trained in disciplines such as health physics, records management, and radiation safety



were set up at each operations office and significant field site to carry out the records search.

2. Guidance for conducting and documenting the search Department-wide was prepared by Headquarters archivists and historians.
3. A new Headquarters Office of Human Radiation Experiments, under the Assistant Secretary for Environment, Safety and Health, was established and staffed, and then developed an aggressive strategy to find records and make them available.
4. Record series descriptions have been completed for over 500 pertinent record collections throughout the Department of Energy, the National Archives, and the Federal Records Centers. This amounts to over 34,000 cubic feet of documents.
5. Over 110,000 pages of documents have been provided to the Advisory Committee and publicly released.
6. Over 1,850 relevant previously classified documents have been declassified for this project.
7. Over 22,000 calls have been received by the Interagency Radiation Research Helpline and distributed among the Federal agencies for response. After compilation of a substantial database, the Department of Energy began preparing substantive responses to constituent inquiries



in September. Interim responses to callers and writers had been completed previously.

Over 200 people have been involved in the Department of Energy radiation experiment records collection and retrieval effort, many dedicated full-time for substantial periods of time. While this challenge is daunting, the search process has already yielded impressive results and we believe that it will provide the documents necessary for the Advisory Committee to perform its evaluative functions.

#### NEXT STEPS

As you know, the final report of the Advisory Committee is scheduled to be provided to the Interagency Working Group in April 1995. We believe that the Advisory Committee should be able to complete its core charge by that time and deliver its views on the ethical propriety of the experiments and on whether harm was done to the subjects of such experiments. The Interagency Working Group will closely review the Advisory Committee's findings and expects to advise President Clinton as to the range of potential Federal responses that may be appropriate based on the facts and opinions developed. We also expect and invite Congressional involvement in consideration of the implications of the Advisory Committee's final report.



It should be noted that a new Bioethics Advisory Committee is being charged by the White House Office of Science and Technology Policy to consider the adequacy of current human research subject protection measures. That group should also have valuable insights on the evolution in ethical standards that will help to place this Advisory Committee's work in full context.

### CONCLUSION

In closing, let me focus on the central role of openness in the Clinton Administration. Over the past several decades, the American people's trust in their institutions of government has greatly eroded. Many complex factors have contributed to this erosion, not least among them the secrecy associated with our Cold War nuclear competition with the Soviet Union. Without judging the historical necessity of secrecy, it is a fact that the ability of the government to perform its post-Cold War missions is greatly impeded by pervasive public distrust of its motives and competence.

The move towards openness, of which this project is a very visible part, is a deliberate effort by President Clinton to rebuild that basic level of trust between the American people and their government that is necessary for democracy to function. It requires coming clean when necessary on episodes



that may be embarrassing or discomfoting or even worse. President Clinton and Secretary O'Leary have championed a very ambitious effort to tell the full story of human radiation experiments. The Department of Energy and other involved Federal agencies have committed significant resources towards this end. Thanks to such support and a remarkable level of interagency cooperation, we have made substantial progress in finding the documents that are necessary for the Advisory Committee's work. We are all committed to making this project succeed and greatly appreciate the support and concern of this Congressional Committee, especially Chairman Glenn's longstanding interest in the area of radiation protection.

Thank you.

I will be pleased to answer any questions the Committee may have.



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

**January 11, 1994**

**LEGISLATIVE REFERRAL MEMORANDUM**

**LRM #M-1012**

**TO: Legislative Liaison Officer -**

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  
OSTP - Chris Clary - (202)456-7116 - 288  
NSC - William H. Itoh - (202)395-3723 - 249  
CIA - Tom Benjamin - (703)482-6126 - 258

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

**OMB CONTACT: Holly FITTER (395-3233)**  
Secretary's line (for simple responses): 395-6194

**SUBJECT: VA Proposed Testimony on The VA use of  
Radionuclides at the Framingham Cushing VA  
Hospital**

**DEADLINE: 12:00 NOON January 12, 1994**

**COMMENTS: You will also be receiving testimony for this  
hearing from Energy, HHS (PHS), and DOD.**

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:**

B. Damus  
J. Klein  
S. Neuwirth  
C. Varney/P. Kaplan  
B. Burton  
T. J. Glauthier  
J. Palmieri  
T. Thornton

E. Pelton  
J. Pfeiffer  
J. Schuhart  
T. Grams  
H. Meyers  
B. Clendenin

*3pgs*





**STATEMENT OF  
BELTON A. BURROWS, MD  
CHIEF, NUCLEAR MEDICINE  
DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER  
BOSTON, MASSACHUSETTS**

I would like to thank you for this opportunity to discuss my involvement in the use of radionuclides at the Framingham Cushing VA Hospital.

That facility was one of 14 around the country which were designated radioisotope units. One function of these units was to train professional staff and other personnel in radiation surveys and the evaluation of possible radiation exposures following industrial accidents or military action. The same facilities could be used for diagnostic studies, therapy and medically-related research with established procedures using radionuclides. Veterans were not subjects for studies of radiation effects. They received tracer doses of radionuclide for thyroid disorders and other radionuclides for evaluation of their hematological and metabolic problems. Therapeutic doses of radioiodine were given for hyperthyroidism and thyroid cancer.

The tracers given to the subjects were small amounts of radioactive material, lower than the background radiation that everyone receives from the environment because of natural radioactivity in the atmosphere and the earth's crust. Consistent with state-of-the-art medical research procedures during this time period, there was no formal process to document the patient's knowledge of and consent to the studies; it was the established practice to verbally explain what was being done and why.

From a preliminary review, it appears we have records of all studies performed at Cushing and the Boston VA Medical Center in approximately 150 ledgers, loose leaf notebooks and other clinical files from 1949. These include organ scans obtained after 1963.

*Jack Thompson 523-6372*



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

URGENT

January 19, 1994

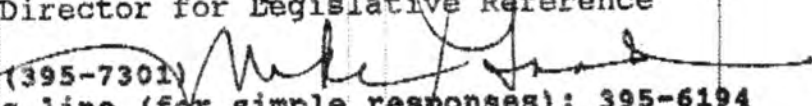
LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1028

TO: Legislative Liaison Officer -

DEFENSE - Samuel T. Brick, Jr. - (703)697-1305 - 325  
HHS - Frances White - (202)690-7760 - 328  
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  
OSTP - Chris Clary - (202)456-7116 - 288  
NSC - William H. Itoh - (202)395-3723 - 249  
CIA - Tom Benjamin - (703)482-6126 - 258

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 Proposed Testimony on Radiation Testing

DEADLINE: 3:00 P.M., TODAY, Wednesday, January 19, 1994

COMMENTS: Please note that the hearing is scheduled for Thursday, January 20th (see attached invitation). 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:

B. Damus  
J. Klein  
S. Neuwirth  
C. Varney/P. Caplan  
B. Burton  
T. J. Glauthier  
J. Palmieri  
T. Thornton

J. Podesta  
E. Pelton  
J. Pfeiffer  
J. Schuhart  
D. Blanchon  
A. Silas  
B. Dorotinsky

LRM #M-1028

**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 Proposed Testimony on Radiation Testing

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



FROM: GENERAL COUNSEL PSG IV

TO: 93955691

JAN 19, 1994

8:45AM

P.02

AM

DRAFT  
01/19/94 08:27

**STATEMENT OF  
THE HONORABLE JESSE BROWN  
SECRETARY OF VETERANS AFFAIRS  
BEFORE THE  
SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS**

**January 20, 1994**

Mr. Chairman and Members of the Committee, I appreciate the opportunity to appear before you to discuss the steps we are taking to determine if inappropriate radiation-related research has ever occurred at any facilities for which the Department of Veterans Affairs (VA) has responsibility. In response to recent reports that government-sponsored research involving radioactive materials may have been conducted in an inappropriate manner many years ago, I have pledged to veterans, their families and the American people that VA will initiate a full and comprehensive review of its nuclear medicine activities and records. At my direction, a review to assess the conduct of nuclear medicine research at any VA facility is now underway. If evidence indicates subsequently that any research abuses have occurred, VA is fully prepared to take whatever action is necessary to address the possible health care and other needs of veterans who may have suffered adversely from the effects of such experimentation.

I wish to assure you at the outset that every possible action is now being taken by VA, in concert with other concerned Federal Departments and Agencies including, among others, the Department of Energy, Department of Defense, Health and Human Services and NASA, to determine the nature, location and possible effects of radiation-

FROM: GENERAL COUNSEL PSG IV

TO: 93955591

JAN 19, 1994

8:45AM

P.03

related experimentation. A special Interagency Task Force has been established by the President to provide for a coordinated review by all concerned Federal Departments and Agencies, of all human radiation research conducted since the advent of the nuclear age and to assess all radiation research that involved the intentional exposure of individuals to radioactive substances or the intentional release of radiation into the environment. VA will be a full participant in the activities of this Task Force and we will cooperate fully with all interested agencies and Congress in addressing this issue.

During these early years of the Nuclear Age, VA was a pioneer in nuclear medicine and a great deal of research, with major benefits for patient care, was carried out in VA facilities using radioisotopes. A review of centrally held research and nuclear medicine records has revealed no information on specific research projects, protocols, or human subjects. Therefore, I found it necessary to require each VA medical center to conduct a search of its research and other files to determine if that information exists locally. Attached to my testimony are copies of the documents directing this undertaking. All VA facilities are now engaged in this effort. Our review includes any research that VA conducted in conjunction with our affiliated medical schools and any research that VA, as some documentation indicates, contracted out to other entities. We will be compiling and analyzing their reports as received in order to ascertain the level of VA participation in any human-related radiation research. We expect to complete an initial review by the end of the month.

As part of our outreach to veterans, we have asked the veterans service organizations to help us locate veterans who might have been subjects of this research. We have also announced a toll-free line (1-800-827-1000) for veterans to contact us if they have concerns about their possible participation.



FROM: GENERAL COUNSEL PSG 1U

TO: 93955691

JAN 19, 1994

8:46AM

P.04

Mr. Chairman, we share your concern for the protection of human subjects in any research, radiation-related or otherwise. Clinical research directed toward improvement in disease prevention, diagnosis and treatment often requires the participation of patients in carefully designed studies. It is VA policy, and this policy is rigorously enforced, that all participants in research studies be fully informed, consenting subjects and that they must be protected by all legal and ethical safeguards pertaining to human subject research. In addition to human rights reviews conducted at local VA medical centers, there are two additional reviews undertaken routinely as part of the national VA peer review process involving any proposed human research. These reviews are designed to resolve any potential problems and assure compliance of the proposed research with appropriate human rights standards before any research is undertaken. VA was a key player in the development of current federal policies in this area. We believe that our regulations and procedures meet appropriate ethical, scientific and medical standards, and still permit us to maintain an excellent program of research.

Mr. Chairman, as I previously noted, VA has led the way in the development of modern nuclear medicine discipline. Historical documents show that in 1947 VA established a program employing radioisotopes for the purpose of medical research, clinical diagnosis and medical treatment of patients. VA medical centers were required to comply fully with standards established by the Atomic Energy Commission for health protection of patients receiving isotopes as well as for individuals working with them, and we are aware of nothing to indicate that these standards were not strictly observed from the beginning. By December 31, 1953, there were 33 radioisotope units either established or in the process of activation in VA hospitals. By 1958, the number had risen to 48. VA pioneered the medical use of radioisotopes and for many years VA researchers led the field in such research in this country.

FROM: GENERAL COUNSEL PSG IV

TO: 93955691

JAN 19, 1994 8:47AM

P.05

All projects were to be reviewed at the local level by a Radioisotope Committee that included individuals from outside the VA and also had access to one of three radiation experts of international stature appointed by the then Chief Medical Director to serve as consultants to a Central Advisory Committee and to individual hospital programs. Research projects were not reviewed at the Central Office level until the 1960s. A separate review by a human subjects committee probably did not occur at the time of the early studies as that did not become a practice until about 1962. However, currently we have no evidence to suggest that VA ever engaged in radioisotope studies that were not medically sound and designed to benefit patients.

VA also had an "Atomic Medicine Division." According to a 1952 Bulletin of the Committee on Veterans' Medical Problems, which was a component of the National Academy of Sciences, in 1947, VA's Chief Medical Director became deeply concerned about the problems that atomic energy might create for the Veterans Administration due to the fact that the Armed Services were so actively engaged in matters of atomic energy. The Director, out of concern for problems VA might have in connection with alleged service-connected disability claims, classified the existence of VA's Atomic Medicine Division as "confidential." Mr. Chairman, it is extremely upsetting to me that VA apparently did not reveal for an undetermined length of time the existence of this Atomic Medicine Division, and I have ordered a thorough review of the records to attempt to piece together why this was done; what, if any, secret activities it engaged in; and the consequences of those activities.

We do know that one purpose of the Atomic Medicine Program was to teach techniques of nuclear preparedness to the nation. VA was named the lead agency in that endeavor. The employment of radiation scientists allowed VA to conduct this training mission in connection with the Civil Defense program and at the same time launch an



FROM: GENERAL COUNSEL PSG IV

TO: 93955691

JAN 19, 1994

8:47AM

P.06

important pioneering program on the medical use of isotopes. Information on VA's role in civilian defense is outlined in a December 15, 1950, "Brief of Training Plan, U.S. Veterans Administration: Medical Aspects of Atomic Warfare, Medical Aspects of Radiological Defense, Radiological Defense (Monitors)."

At the local VA hospital level, radiation specialists held courses in their communities on atomic preparedness and taught fire and police personnel how to use radiation monitoring devices like the Geiger counter. The Atomic Medicine Program also produced a Training Guide for a Course in Radiobiological Defense that was used extensively in the Civil Defense program of the 1950s.

Mr. Chairman, as you can see, this is a very complex issue made more difficult to some degree by the passage of time. However, let me again assure you that I will leave no stone unturned in our review of any VA involvement in the research in question. Should the final evidence indicate that there was research detrimental to the health and welfare of veterans, we will take the necessary action to provide for their care as well as addressing any other concerns they may have.

VA is perhaps unique among the concerned Federal agencies in already having statutory authority to compensate for injuries to veterans occurring as a result of radiation exposure either during their military service or during VA hospitalization or treatment following service. In the event any such veterans or their survivors are identified during the ongoing interagency review, we are committed to seeing they are compensated to the full extent authorized by law.

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OMB LRD/RDI

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FROM: GENERAL COUNSEL PSB IV

TO: 93955691

JAN 19, 1994

8:48AM

P.07

Mr. Chairman, this concludes my remarks. I will be glad to answer any questions which you or Members of this committee have concerning VA's role in radiation-related research.

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FROM: GENERAL COUNSEL PSB IV

TO: 93955691

JAN 18, 1994

6:23PM

P.07

JOHN GLENN, OHIO, CHAIRMAN

SAM MANN, GEORGIA  
EARL LAYNE, MICHIGAN  
JIM SANCHEZ, TENNESSEE  
DAVID PRYOR, ARKANSAS  
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JOHN MCCAIN, ARIZONA

LEONARD WEISS, STAFF DIRECTOR

FRANKLIN D. FOLE, MINORITY STAFF DIRECTOR AND CHIEF COUNSEL

## United States Senate

COMMITTEE ON  
GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-8250

January 12, 1994

The Honorable Jesse Brown  
Secretary  
Department of Veterans Affairs  
Washington, DC 20420

Dear Secretary Brown:

On January 20, 1994 at 9:30 a.m., the Senate Committee on Governmental Affairs will convene to hear testimony on radiation and other scientific experiments conducted by the U. S. government on its citizens. The Committee is exploring this issue across government, and is interested in understanding the Department of Veterans Affairs past and present role in conducting scientific experiments on U.S. veterans. I am therefore requesting you or your designee to testify before the Committee.

I would like your testimony to discuss the role that the Department of Veterans Affairs is currently playing on the Interagency Working Group chartered by President Clinton to examine the radiation experiments issue. I am also interested in learning about past or ongoing internal Departmental reviews which address human experiment issues beyond the scope of the Interagency Working Group.

While it is clear to me that, in the past, our government sponsored human radiation experiments which did not necessarily invoke the highest ethical and medical standards, I am concerned about the practices, regulations and procedures which are in place today to prevent such experiments from recurring. In addition to radiation experiments, I am concerned about human experimentation generally -- whether it involves drugs, other toxic chemicals, or psychological testing. For instance I am aware of allegations that veterans have been subjected to tests involving mustard gas, and other chemical warfare agents. What assurances do we have that human experiments are currently being conducted according to the highest ethical, scientific and medical standards, as well as established regulations?

The Committee also has jurisdiction over federal recordkeeping and the National Archives and Records Administration. Many Federal agencies participated in these experiments; consequently, relevant records are spread throughout

FROM: GENERAL COUNSEL PSG IV

TU: 93955691

JAN 18, 1994

6:24PM

P.08

The Honorable Jesse Brown  
January 12, 1994  
Page Two

government. In order to fully understand the magnitude and impact of these experiments, it may be necessary to establish a central clearinghouse of government records, possibly within NARA, that is fully accessible to the public. Public access to these records is imperative, but also raises significant ethical and logistical problems. The Committee would be interested in your thoughts on these recordkeeping issues.

With these thoughts in mind, I would also like for your testimony to address the following questions:

- What is being done to identify, contact, and assist those people who unwittingly participated in radiation or other experiments sponsored by the Department? How many of these people have been identified?

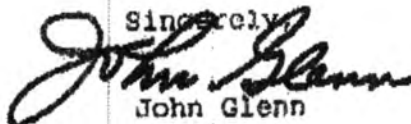
- Has any determination been made regarding possible medical followup that may be necessary as a result of the experiments?

- Does the Department as yet have a position on the issue of compensation of human experimentation participants?

Finally, I would appreciate your assistance in arranging for a briefing of my staff on the issues to be addressed at the Committee hearings as soon as is practicably possible. Committee rules require that 100 copies of your prepared testimony be submitted 48 hours prior to the hearing date. Should you have any questions about this hearing, please do not hesitate to contact me. My staff contact is Chris Kline (224-4751).

Best regards.

Sincerely,

  
John Glenn  
Chairman

JHG/ck

UOI



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

**URGENT**

January 19, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1029

TO: Legislative Liaison Officer -

VA - Robert Coy - (202)535-8113 - 229  
HHS - Frances White - (202)690-7760 - 328  
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  
OSTP - Chris Clary - (202)456-7116 - 288  
NSC - William H. Itoh - (202)395-3723 - 249  
CIA - Tom Benjamin - (703)482-6126 - 258

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 Radiation  
Testing

DEADLINE: 3:00 P.M., TODAY, Wednesday, January 19, 1994

COMMENTS: Please note that the hearing is scheduled for  
Thursday, January 20th. 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:

B. Damus  
J. Klein  
S. Neuwirth  
C. Varney/P. Caplan  
B. Burton  
T. J. Glauthier  
J. Palmieri  
T. Thornton

J. Podesta  
E. Pelton  
J. Pfeiffer  
J. Schuhart  
D. Blanchon  
A. Silas  
B. Dorotinsky

*Tracy*





# DRAFT

## Testimony of Dr. Harold Smith

Assistant to the Secretary of Defense for Atomic Energy

to the

Senate Committee on Government Affairs

January 20, 1994

Mr. Chairman and Members of the Committee, it is an honor for me to appear before you today on behalf of the Department of Defense. I am accompanied by Major General Kenneth Hageman, Director of the Defense Nuclear Agency, who testify about the Nuclear Test Personnel Review; and Col. John Fraser Glenn of the Department's Human Subject Research Review Board, who can provide you with expert testimony on how the Department of Defense, the military services, and all DoD agencies currently conduct experiments involving human subjects and the human protections under which those experiments are allowed to be conducted. With the permission of the committee, their statements will follow mine.

At the outset of my remarks, let me compliment you and this committee for the continued and persistent interest you have demonstrated over the years on the broad issues of the use of humans in experimentation, radiation protection and informed consent. You have been in the forefront of those concerns and have made a real contribution to elevating our national consciousness to the need for more accountability for all sponsors of experiments in which humans are used. Indeed, you and your colleague Senator Sasser have been firm in your longstanding commitment to government that is open and accountable to the people it serves. You are to be commended for all of your efforts in that regard. This hearing is yet another stage in this committee's effort to open up a part of government which has, for too long, remained closed to the American people. We applaud your persistence and share your dedication to these principles.

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The Department of Defense shares with its partners in the Human Radiation Experiment Inter-Agency Working Group a commitment to a comprehensive search of its records and the release of information it discovers. DoD has been a full partner in the Inter-Agency Working Group and has been active in all discussions of the group since its inception. Secretary of Defense Les Aspin has appointed personnel from the highest levels of the department to each of the subcommittees organized by the Inter-Agency Working Group. Each appointee serves in a dual capacity. Each is deeply involved in the work of his or her inter-agency subcommittee and is also an integral part of the Department's effort.

I cannot emphasize enough the high priority placed upon this project by Secretary Aspin. As appointments were made to the Inter-Agency working group, he also established within the Department a working group which I direct under the guidance of the Undersecretary of Defense for Acquisition. Our task is to coordinate the Department's research and retrieval effort. In constituting that group, the Secretary charged it to "move quickly and thoroughly on this matter---it should be given high priority." At every opportunity, he has reemphasized the seriousness of our task and the need to cooperate in this important undertaking.

Our effort is being driven by five principles. First, we want it to be thorough. Every agency should take every possible action to insure that its search is comprehensive and omits nothing. Secondly, it should be done as quickly as possible. Records of human radiation experiments should be collected and catalogued as soon as possible. Thirdly, all due care should be exercised to preserve the records. Fourth, the integrity of the process must be preserved to insure that it retains its credibility in the long term. Finally, the process must result in an open accounting of the Department's past action in human radiation experiments.

To achieve those goals, Secretary Aspin initially directed all military services and other DoD agency heads to retain all documents relating to human ionizing radiation experiments. Furthermore, he directed them to instruct persons responsible for routine

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document disposal to preserve any such records which they may discover. When the Inter-Agency Working Group issued its formal directive outlining the scope of the search, DoD convened an "all hands" meeting to insure that all DoD agencies fully understood the tasks to be undertaken. Secretary Aspin and Undersecretary John Deutch attended that meeting to provide specific instructions to all DoD agencies on the exact execution of the tasks at hand.

It is important to understand that this is a discovery process requiring some time before a full report can be provided to the Congress and the people of this country. We have all read or heard media reports of these types of experiments. They all will be part of our overall search. In the interim, we want to make it clear and emphasize to you that we are fully committed to this effort. We are acting as quickly as possible to find and catalogue records. We will collect those records and review them. We will release them as comprehensively and as soon as possible, recognizing that we must proceed in a way that protects the privacy of citizens who may have been participants, wittingly or unwittingly, in those experiments. Let me give you some specifics.

We have attempted to organize our effort to meet both short and long term objectives. The Department has established a command center, headed by a Rear Admiral, to be the collection point and clearinghouse for records discovered in this project. As one might imagine, this retrieval process will require an extensive search. With facilities located all over the country and the world, we cannot be certain where we might find records of experiments. This is not a situation where we can go to the dark cellars or attics of the department or its agencies, find a box labelled "Human Radiation Experiments", dust it off, and release the documents inside. It is going to be much more difficult and labor intensive as each of the many agencies within the department search their files and their archives. The Department will not be deterred by the complexity or the difficulty of this project.

We are committed to that search. The command center was established based upon the experience of the Department in the Nuclear Test Personnel Review. It provides a central point to which agencies will send records they may discover. We felt we needed a

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place for these records to be sent, catalogued, and reviewed. That will be the purpose of the command center. Overseeing the work of center will be a steering group composed of DoD personnel who are also involved with the work of the Inter-Agency Working Group. We think this represents a serious commitment of resources to this project and an organization that can efficiently and effectively oversee it.

As you know, the Department of Health and Human Services issued in 1974 the definitive federal policy regarding controls to be exercised in government sponsored experiment in which humans are involved. All, I repeat all, Department of Defense experiments are subject to that policy. Investigators in these experiments use rigorous protocols to insure that individual consent is truly informed, that Institution Review Boards are independent and assertive, and that all scientific and medical research standards are met. My Department of Defense colleagues on this panel, Major General Hagaman and Colonel Glenn, are here to describe an on-going DoD program related to radiation experiments involving humans and address protocol issues from the perspective of those within the Department who oversee research projects and those who execute those projects.

Finally, questions have arisen about government's ethical responsibility to those citizens who may have participated in human radiation experiments. Principally, those questions have focused on possible compensation and/or medical follow-up treatment. At this early stage in the process, that is an issue that requires review and discussion among a number of agencies as well as requiring the involvement of the Congress. We will certainly participate in those discussions.

Mr. Chairman, we think we have in place a process that will produce answers to the many questions being asked by you, your colleagues in the Congress, and the American people. We are committed to making that process work and work well to achieve two primary objectives: 1) provide the American people with full disclosure of the Department's role in human radiation experiments it may have sponsored; and 2) by doing so, help restore the confidence of the American people in its government. If our review determines

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JAN 19 '94 9:12 FROM OSD-LRS

TO PETERSON

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**DRAFT**

that American citizens were treated wrongfully by their government, we believe this Administration owes the American people a full accounting and, where justified, an attempt to right any wrong done to individuals.

There are those who may argue about the mindset of the times or how the ethics of scientific research have progressed since the early days of the Cold War. They do not speak for the Department of Defense. We want to learn all we can about the department's role in human radiation experiments that took place and share that information with the people whom we serve.

**DRAFT**

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

URGENT

January 18, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-1021

TO: Legislative Liaison Officer -

DEFENSE - Samuel T. Brick, Jr. - (703) 697-1305 - 325  
HHS - Frances White - (202) 690-7760 - 328  
VA - Robert Coy - (202) 535-8113 - 229  
JUSTICE - Sheila F. Anthony - (202) 514-2141 - 217  
NASA - Jeff Lawrence - (202) 358-1948 - 219  
NEC - Sonya Matthews - (202) 456-6722 - 429  
OSTP - Chris Clary - (202) 456-7116 - 288  
NSC - William H. Itoh - (202) 395-3723 - 249  
CIA - Tom Benjamin - (703) 482-6126 - 258

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

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

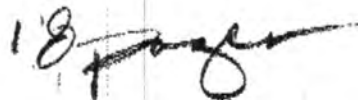
SUBJECT: ENERGY Proposed Testimony on Radiation  
Testing

DEADLINE: 10:30 A.M., TODAY, Tuesday, January 18, 1994

COMMENTS: Please note that the hearing is scheduled for 1:00 P.M., TODAY, Tuesday, January 18th (see attached invitation). 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.

18 



Page 2  
LRM #M-1021

## CC:

B. Damus  
J. Klein  
S. Neuwirth  
C. Varney/P. Caplan  
B. Burton  
T. J. Glauthier  
J. Palmieri  
T. Thornton

J. Podesta  
E. Pelton  
J. Pfeiffer  
J. Schuhart  
D. Blanchon  
A. Silas  
B. Dorotinsky





## DRAFT STATEMENT OF HAZEL O'LEARY

SECRETARY  
U.S. DEPARTMENT OF ENERGY

JANUARY 18, 1994

Mr. Chairman and Members of the Committee:

The topic that brings us together this afternoon -- reports of unethical conduct involving experiments using ionizing radiation on human subjects during the Cold War - has generated intense public interest and media attention over the past weeks. During this time, I have met and spoken with many Americans around the country, some of whom were experimental subjects or the relatives of subjects, and they have been troubled, as I was, by these reports.

The nation has now begun to debate important questions raised by these stories - questions about the role of secrecy in a democratic society, and the need to have proper safeguards in place to ensure the rights of individuals to determine their own fates. We must prevent anyone in America - whether they are uneducated or poor or mentally retarded or incarcerated - from being used as "guinea pigs", as means to an end.

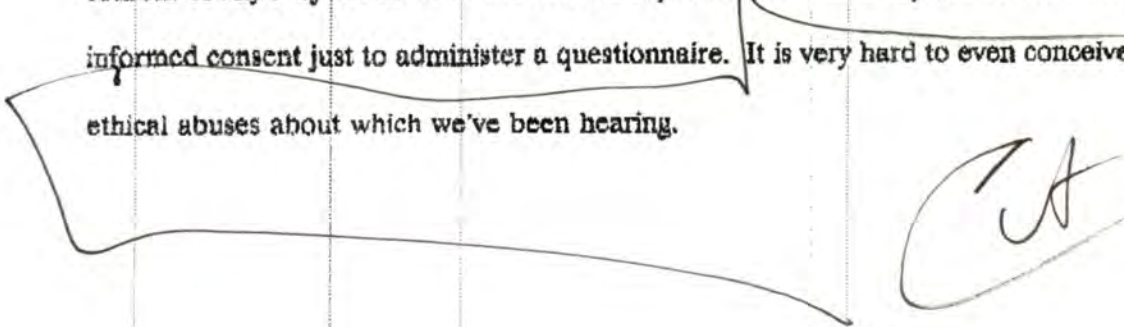
The Clinton Administration is determined to disclose all records of questionable experiments involving ionizing radiation on humans. In a moment, I will discuss the steps we are taking to get all the information out as quickly as possible, to ensure that we have a serious,

2

thoughtful debate about the lessons these experiments have to teach us, and to make sure that the highest standards of ethical and scientific conduct are followed in all research involving human beings.

As we examine this dark and narrow corner of scientific experimentation, we must keep in mind several points. First, as unsettling as some of these experiments were, and as fearful as radiation is to many who associate it with the destructive power of nuclear weapons, it is important to remember that many lives have been saved from the use of radiation in the diagnosis and treatment of disease. During the same Cold War period that some unscrupulous scientists were conducting these reprehensible experiments, other scientists were inventing vaccines against polio, new and effective treatments for cancer, and new ways of visualizing the human body with CAT scans and cardiac scans. Science itself is not on trial here - the way some scientists practiced their craft is.

I also want to caution the American public against entertaining an inordinate fear of current research practices. Institutional Review Boards enforce strict requirements for informed consent of any subjects involved in scientific experiments. These days, scientists must obtain informed consent just to administer a questionnaire. It is very hard to even conceive of the ethical abuses about which we've been hearing.





As I will describe, however, we are committed to a serious review of experiments involving human exposure to ionizing radiation. If necessary, we will use the results of this review to make today's standards even more stringent.

#### President Clinton's Commitment to Openness in Government

This Administration recognizes that public trust can only be achieved if American citizens believe that their government is open, truthful, and accountable. Since the earliest days of his campaign, President Clinton has been publicly committed to an open and responsive government. The openness initiative that I began at the Department of Energy last spring was a direct outgrowth of this commitment.

#### The Department of Energy's Openness Initiative

On December 7, 1993, I held a press conference at which we released a mountain of information that had previously been classified. Only a small part of this information pertains to human experimentation. During this press conference, I revealed, for example, that 204 previously unannounced nuclear tests - one out of every five tests - had been kept secret. The Cold War rationale for this secrecy was the desire to inhibit Soviet monitoring of our weapons testing program. In addition, we revealed the locations and volume of the United States weapons grade plutonium stockpile, and the amount of mercury used in American weapons production.

Also during that press conference, I acknowledged, as was revealed in a 1986 House Subcommittee Report and in recent news accounts, that in the 1940s, 18 persons had been injected with plutonium as part of an experiment sponsored by the Atomic Energy Commission. The records available strongly indicate that these subjects were not fully informed of the purpose or risks of the experiment.

State of Present Knowledge on Radiation Experiments

We do not yet know if the radiation experiments noted in the 1986 Congressional Report and the experiments involving deliberate environmental releases discussed in the December 1993 General Accounting Office Report requested by Senator Glenn, comprise the bulk of experiments that might be subject to questions of scientific and ethical propriety. We do not yet know the full extent of the universe of records pertaining to Department of Energy-sponsored experiments that needs to be examined. The records search being conducted by the Department of Energy and other government agencies will be as thorough and comprehensive as possible, as we endeavor to ensure that the full story is told.

Our goal is to get all the facts out. We will do our best to provide information as we learn it. All appropriate steps will be taken to protect the privacy of people who were the subjects of experiments and their families. But all pertinent information that is found regarding human experimentation will be declassified as necessary on an expedited basis and permanently preserved for public review in an appropriate public archive.



From what we know thus far, human experiments involving ionizing radiation conducted or sponsored by the Department of Energy or its predecessor agencies fall into one of four categories:

1. Experiments designed to investigate the effects of radiation on humans or the way the human body metabolizes radioactive substances;
2. Experiments using radioisotopes as tools to study the biochemistry of normal metabolic processes;
3. Experiments designed to investigate the therapeutic uses of radiation in the treatment of diseases such as cancer; and
4. Experiments involving intentional releases of radiation to the environment for purposes of assessing the behavior of such releases.

#### Some of the More Troubling Aspects of the Experiments

The radiation experiments that have come to light are disturbing for several reasons. First, it is not clear that all subjects were properly informed of the purposes or risks associated with the experiments in which they were participants.

Second, some of the experiments raise questions about how the experimental subjects were selected. There is, at least on first inspection, the appearance of a pattern of choosing subjects from relatively vulnerable populations such as persons of color, poor people, prisoners, and retarded children. This appearance of treating some citizens as "expendable",

6

to use Congressman Markey's phrase, is especially repugnant in a country that prides itself on its diversity, and that has, as its goal, providing equal opportunity for all its citizens.

#### Human Radiation Interagency Working Group

On January 3, 1994, the White House convened a meeting of senior staff from government agencies with potential involvement in human radiation experiments. The White House has established an Human Radiation Interagency Working Group consisting of myself and the Secretaries of Defense, Health and Human Services, and Veterans Affairs. The Directors of the Central Intelligence Agency and the Office of Management and Budget, the Attorney General, and the Administrator of the National Aeronautic and Space Administration are also on the Working Group. Five subcommittees have been formed under the Working Group to deal with the following specific issues: 1) Public Information and Communications; 2) Retrieval and Review of Records; 3) Ethical and Scientific Standards; 4) Congressional Relations; and 5) Legal Issues. These subcommittees are composed of staff from all relevant Federal agencies. In addition, the Administration is establishing an Independent Advisory Committee on Human Radiation Experiments, consisting of non-governmental experts in the fields of ethics, science, medicine, and law.

The Independent Advisory Committee on Human Radiation Experiments, will review records of experiments on ionizing radiation on humans and will advise the Interagency Working Group on whether any lapses of scientific or ethical standards occurred.



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The Advisory Committee charter of activities will include:

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 which were designed to test human health effects of ionizing radiation; or were designed to test the extent of human exposure to ionizing radiation.

The Advisory Committee shall also provide advice, information and recommendations on the experiments noted in the December 1994 report by the General Accounting office that involved intentional releases of radiation to the environment, and any other experiments which may later be identified by the Human Radiation Interagency Working Group.

The Advisory Committee shall review experiments since 1944. Human radiation experiments undertaken since the date of issuance (1974) of the U.S. Government biomedical research guidelines will be sampled to determine their priority for review. Further inquiry into such experiments conducted after 1974 may be pursued if warranted.

The Advisory Committee will make recommendations concerning the need to expand or amend existing Federal guidelines governing human experimentation to the Interagency Working Group, which will then make recommendations as appropriate to the President.

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Funding of the Advisory Committee is governed by the Federal Advisory Committee Act. The Act only allows one Federal agency to finance the Advisory Committee. The Department of Energy has been chosen as the designated agency. We will not require any special Congressional appropriations for this project.

The Advisory Committee's support staff will consist of both non-governmental individuals and Federal agency workers. An interim report is expected six months from the filing date of the Advisory Committee's Charter. This report will address whether the Advisory Committee believes it is likely that it will be able to fulfill its duties within a one year time-frame.

Information-Gathering and Dissemination by the Department of Energy

The Department has already begun to take several steps to locate and preserve documents relevant to medical and scientific experimentation involving human subjects. Department of Energy personnel have been directed to cease routine and nonroutine destruction of documents and to identify all pertinent records and information in the Department's possession and in the possession of our laboratories and contractors. The Department will develop a thorough inventory of records with potential value for investigating human experiments.



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EH BUDGET/ADMIN

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### The Human Experimentation Helpline

The Department of Energy has established a toll-free telephone Helpline. The purpose of the Helpline is to aid us in identifying those persons who may have been affected by the activities in question. The number of calls to the Helpline has been overwhelming. We have received more than 12,000 telephone calls since December 24, 1993.

However, the majority of callers appear not to have been subjects of human radiation experiments. The calls do reflect the concerns of people in every state, and of all different backgrounds. The Department is requesting that callers provide additional written information, which can be used to help us identify and locate documents related to these experiments.

### Administration Position on Compensation Related to Human Radiation Experiments

The Administration has made plans to take the following actions regarding compensation and other responses to individuals affected by the human radiation experiments:

1. We will provide information to subjects and their families as soon as it becomes available.
2. When required to protect the health of individuals, or their descendants, who were subjects of a human radiation experiment, the government will notify subjects, or their descendants, of any potential health risk or the need for medical follow-up;

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3. The legal issues subcommittee is currently examining various models for appropriate federal responses, including those incorporated into other federal programs such as those used to respond to "downwinders," veterans exposed to radiation, and the Japanese interns during World War II. The range of federal responses under consideration include potential monetary compensation, medical follow-up, disclosure of detailed information, formal apologies or other recognition, and ongoing research, education and information programs; and

4. We are also developing specific recommendations for legislative and other action that may be appropriate once the Working Group and Advisory Committee have at least completed their first phase of work. This will be in six months, when the Advisory Committee's interim report is issued to the Administration's Human Radiation Interagency Working Group.

Throughout all of this activity, the Administration will continue to work in close collaboration with the Congress.

#### The Department of Energy's Approach to Declassification

Classification review of documents is a function of the Department of Energy mandated by statute and Executive order. Increasing public interest in the activities of the Department of Energy (and precursor agencies including the Atomic Energy Commission) has resulted



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in a significant increase in requests over the past few years for Departmental records, many of which are classified or contain restricted data.

A significant number of Department of Energy records requiring systematic review, are currently held by the National Archives and Records Administration. The Department of Energy has agreed to transfer additional Atomic Energy Commission records to the National Archives and Records Administration. In order to deal with this large volume of classified records, the Department of Energy will provide the National Archives and Records Administration with authorized declassification reviewers to work in a systematic review program.

Nuclear proliferation remains, of course, a national security concern. However, dramatic changes over the past few years in the international arena have significantly reduced the classification requirements for much information; and after proper review, it could be released to the public.

The benefits of our declassification initiative will include an enhanced ability to fill in the blanks of Cold War history - including the public disclosure of documents relevant to radiation experiments; improve studies of the health and safety of Department workers and the public; and increased trust in government. It is also my belief that by doing this, the United States sets an example for other nations to follow. We recognize that there is a continued need to balance our declassification needs with our nonproliferation objectives.

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We are also working with the Department of Defense to review appropriate information for declassification.

### Conclusion

We are committed to do right by the subjects of the experiments and their families. If the government made mistakes or committed wrongs, we, as government officials, must admit them. We want to give the American people reason to trust their government again. A serious, thoughtful debate must occur regarding the scientific and ethical propriety of these experiments. If necessary, current federal rules must be further strengthened to protect individuals from future scientific aberrations.

Only by "coming clean" on the details of these experiments and separating Cold War habits of secrecy from proper ethics in scientific and medical research will we eventually reduce the bitterness and suspicion which has surrounded the debate on the health effects of radiation. Investigations into these experiments must not be conducted as "witch-hunts" against scientists, but as legitimate and fair searches for the truth behind these experiments.

Science must not and will not be destroyed by this process. Radiation has played a critical role in modern medicine's ability to diagnose and treat disease. I believe that the investigations into the experiments will highlight the importance of science in bettering the lives for all human beings.



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Let me assure you and the American people that the Department of Energy and I will take whatever steps are necessary to bring openness to the Department. We have a tremendous amount of work to do, but we have begun.

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# U.S. House of Representatives

Committee on Energy and Commerce

SUBCOMMITTEE ON ENERGY AND POWER

Washington, DC 20515-6117

January 13, 1994

The Honorable Hazel R. O'Leary  
 Secretary  
 U. S. Department of Energy  
 1000 Independence Avenue, SW  
 Washington, DC 20585

Dear Secretary O'Leary:

I am pleased to invite you and Assistant Secretary O'Toole to testify at an Energy and Power Subcommittee hearing on federally assisted experiments involving radiation and human subjects, and on the Department of Energy's (DOE) connection with the Human Radiation Interagency Working Group. The hearing will be on Tuesday, January 18, 1994, and begin at 1:00 p.m. in Room 2123 of the Rayburn House Office Building.

The purpose of the hearing is to gain an understanding of the current state of knowledge regarding the purpose of these experiments, the parties involved, the impact on the subjects' wellbeing, and the degree of consent obtained from or on behalf of the subjects. In addition, the hearing will give the Subcommittee a focussed opportunity to learn about the Department's plans for responding to recent concerns about these experiments.

In your testimony, please respond to the following questions:

1. Please summarize, to the extent of your present knowledge, the human experiments involving radioactive materials which were done by, or at the behest of, the federal government.
2. Please describe the charter of the Human Radiation Interagency Working Group; the makeup of the Group; the role of the proposed Advisory Committee; your responsibilities as a principal in the Group, the ramifications for DOE in terms of workload and budget; the timetable for the Group, including any scheduled reports.



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3. Please outline your actions regarding declassification of Cold War information, and your plans for revamping the Department's approach to classification. It would be helpful for us to understand the philosophy behind the changes you are instituting, particularly in distinguishing information which must be protected from that which should be made public.
4. While the Subcommittee does not have legislative jurisdiction over the issue of compensation, I would appreciate any observations you might have on the need for recompense, monetary or otherwise, to persons who were subjects of these experiments or members of their families.

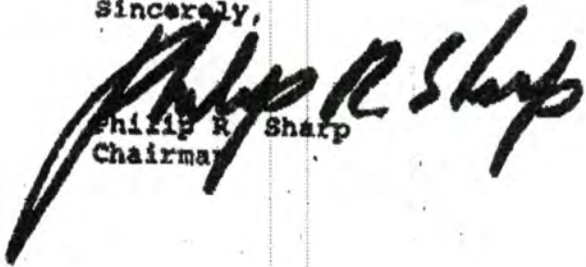
We request that 150 copies of your prepared testimony be brought with you to the hearing room.

Your written testimony may be of any length but House printing rules may require us to exclude statements that are in excess of seven single-spaced pages from the printed hearing record. Additional background material can be submitted and will be noted in the record but kept on file at the Subcommittee's office. Your statement should include an attached one-page abstract which summarizes major points of your testimony without detailed justification. I would also appreciate your best efforts to couch scientific information in terms understandable to non-scientists.

In order to allow sufficient time for members of the Subcommittee to ask questions of all witnesses, your oral statement should be limited to 5 minutes.

I appreciate your interest in participating and look forward to seeing you on the 18th. If you have any questions with respect to the hearing or your preparation, please call Sue Sheridan at 202/226-2500.

Sincerely,

  
Philip R. Sharp  
Chairman