

The
Advisory
Committee on
Human Radiation
Experiments

PHOTOCOPY
PRESERVATION



ADVISORY COMMITTEE
ON HUMAN RADIATION EXPERIMENTS

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

Ethicists

Ruth R. Faden, Ph.D., M.P.H. - Professor of Health Policy and Management and Director, Program in Law, Ethics and Health, Department of Health Policy and Management, Johns Hopkins University, Baltimore, Maryland; Senior Research Scholar, Kennedy Institute of Ethics, Georgetown University, Washington, District of Columbia.

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Historian

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Nancy L. Oleinick, Ph.D. - Professor of Radiation Biology and Biochemistry, Environmental Health Science and Oncology, School of Medicine, Director, Division of Biochemistry and Oncology, Department of Radiology, Case Western Reserve University, Cleveland, Ohio.

General Scientist

Frank Press, Ph.D. - Fellow, Cecil and Ida Green Fellowship, Carnegie Institution of Washington, Washington, District of Columbia; former President, National Academy of Sciences.

Citizen Representative

Lois L. Norris - Community Representative, Institutional Review Board, University of Nebraska; retired Second Vice President, Omaha National Bank and Omaha National Corporation, Omaha, Nebraska.

RUTH R. FADEN

**CHAIR, ADVISORY COMMITTEE
ON HUMAN RADIATION EXPERIMENTS**

Biographical Sketch

Ruth R. Faden, Ph.D., M.P.H., is the Philip Franklin Wagley Professor of Biomedical Ethics and Director of the Bioethics Institute at Johns Hopkins University. Dr. Faden is also Senior Research Scholar at the Kennedy Institute of Ethics, Georgetown University.

Dr. Faden is the author of many books and journal articles on biomedical and research ethics, health policy, and health behavior, including A History and Theory of Informed Consent, co-authored with Tom L. Beauchamp, Ph.D. In addition to her extensive publications, Dr. Faden has served on numerous national task forces and committees.

Dr. Faden holds a Bachelor of Arts in American Civilization from the University of Pennsylvania and a Master of Arts in Humanities from the University of Chicago. She received a Masters in Public Health (M.P.H.) and a Doctorate (Ph.D.) in Attitudes and Behavior from the University of Chicago-Berkeley.

DAN GUTTMAN

EXECUTIVE DIRECTOR, ADVISORY COMMITTEE
ON HUMAN RADIATION EXPERIMENTS STAFF

Biographical Sketch

Dan Guttman has been a partner at Spiegel & McDiarmid, a Washington, D.C. law firm which represents public agencies, workers and consumers in energy, communication and environmental matters, and human rights issues. He has assisted local governments and worker representatives in the ongoing conversion of the nuclear weapons complex, and Nye County, Nevada, the site of the proposed nuclear waste repository.

Following graduation in 1971 from Yale Law School, he co-authored the Ralph Nader sponsored book, The Shadow Government: The Government's Multibillion Dollar Giveaway of its Decisionmaking Powers to Private Management Consultants, "Experts," and Think Tanks. He served as special counsel to Senator David Pryor in the oversight and investigation of the Federal use of private expertise in the performance of the basic work of government.

He participated on the National Academy of Public Administration's Standing Panel on Executive Organization and Management, and was the recipient of a German Marshall Fund grant to advise on energy conservation in Czechoslovakia.

He has written for publications including The New Republic, The Washington Monthly, Public Power, and The Harvard Journal on Legislation. He served as research assistant to Andy Rooney in the production of "Mr. Rooney Goes to Washington," an award winning CBS news documentary.

He was graduated *phi beta kappa* with highest honors from the University of Rochester in 1968.



ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
1726 M STREET, N.W., SUITE 600
WASHINGTON, D.C. 20036

The Advisory Committee on Human Radiation Experiments is a 14-member committee of nationally recognized experts in the areas of bioethics, epidemiology, law and nuclear medicine. The Committee also includes a public representative. Appointed by the President in April 1994, the members are to prepare a report, due in April 1995, about the use of human beings as subjects of federally funded research using ionizing radiation. Ruth Faden, Ph.D., M.P.H., a bioethicist at Johns Hopkins University, chairs the Advisory Committee.

The Committee's report will be issued to an Interagency Working Group composed of the secretaries of the departments of Defense, Energy, Health and Human Services, Justice, and Veterans Affairs, and the directors of the Central Intelligence Agency and the Office of Management and Budget, and the administrator of the National Aeronautics and Space Administration.

The Committee's charter includes the investigation of experiments conducted since 1942 with ionizing radiation, the investigation of specific intentional releases of radiation into the environment, and the recommendation to the working group of remedies for abuses of human subjects in past experiments, and of policies to improve ethical practices in today's research.

The Committee held its first meeting in April 1994 and has met approximately monthly since. A staff of professionals in history, bioethics, nuclear medicine and epidemiology works in Washington, D.C., under the Committee's direction. The staff is headed by Executive Director Dan Guttman. Stephen Klaidman is spokesman for the Committee and can be reached by telephone at 202/254-9795.

The Advisory Committee's meetings are public and materials presented to members of the Committee at its meetings become public record. The Committee's schedule includes at least one meeting on the West Coast and also includes meetings of panels to hear testimony at other sites in the United States.

Interim Report
of the
Advisory Committee
on
Human
Radiation
Experiments

October 21, 1994

EXECUTIVE SUMMARY

The Advisory Committee on Human Radiation Experiments was created by President Clinton to advise the Human Radiation Interagency Working Group (the "Interagency Working Group") on the ethical and scientific criteria applicable to human radiation experiments carried out or sponsored by the U.S. Government. The Committee is composed of 14 members, including a citizen representative and 13 experts in bioethics, radiation oncology and biology, history of science and medicine, epidemiology, nuclear medicine, and law.

Human radiation experiments are defined by the Committee's charter to include

"(1) experiments on individuals involving intentional exposure to ionizing radiation. This category does not include common and routine clinical practices. . . . (2) experiments involving intentional environmental releases of radiation that (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation.
["Intentional Releases"]

The Committee's Approach

The Committee seeks to answer several fundamental questions: (1) What ethics criteria should be used to evaluate human radiation experiments? (2) What was the Federal Government's role in human radiation experiments? (3) What are the criteria for determining appropriate Federal responses where wrongs or harms have occurred? (4) What lessons learned from studying past and present research standards and practices should be applied to the future?

As a Federal advisory committee, the Committee asks these questions and seeks to answer them in open public meetings. In addition to meetings in Washington, which contain a period for public comment, and a full Committee meeting in San Francisco, the Committee has scheduled at least three other sessions to hear public comment in regions throughout the country.

The Committee's ability to tell the story of past radiation experiments requires more than the will to search through hundreds of boxes for documents and the intuition to recognize which ones are important. It depends on the Committee's ability to find a common language to address the technically complex, often highly emotional issues related to human radiation experimentation. The voices to which the Committee must listen speak in the languages of medicine, a multiplicity of sciences, the military, sick patients, healthy subjects, policymakers, and philosophers. The Committee cannot understand, much less tell, the story unless it seeks out all who can aid its understanding, and works to bridge the cultural and linguistic gaps among them.

The Committee is also convinced that an important determinant of its success will be its

ability to understand the present just as well as, if not better than, it understands the past. Therefore, it has undertaken the task of sampling the ethical practices and standards governing human radiation research today, evaluating them, and deciding whether change is needed.

Finally, in order to focus its own inquiry, and the ability of the public to assist it, the Committee has identified a number of common themes that will guide its work, and give structure to its final report. These themes include:

- *Consent standards and procedures:* A cornerstone of modern research ethics is the requirement that research proceed only with the informed consent of a competent subject or with adequate safeguards to protect the interests of a subject who cannot give consent. The Committee must understand when policies and practices of informed consent were adopted, when, if ever, the requirement was disregarded and why.
- *Risks and benefits of research:* It is inherent in most research that subjects are put at risk of harm in order to obtain desired benefits. It is the Committee's charge to determine whether the risks to which subjects were exposed, however low, were justified.
- *The selection of research subjects:* The ethics of research turn as much on considerations of justice in the selection of subjects as they do on questions of consent or acceptable risk. The Committee deems it essential that it examine whether particular populations were targeted for participation as research subjects because of their relative lack of economic, social, or political power.
- *Responsibility for experiments:* Who decided which experiments were carried out, and who was responsible for assuring that ethics policies, where they existed, were put into practice?

The Committee Begins Its Work

The Committee was created in tandem with a Presidential directive that the executive branch be open to searching inquiry. When it began its work in April 1994, there were few records in hand; the Committee was embarking on a daunting journey into the past and present with neither stars nor compass to chart its course. For example:

- How many human radiation experiments were conducted before 1975? Where could the answer be found? In April it was not clear whether the answer was in the hundreds or the thousands.
- What codes of conduct, if any, existed before 1975 to govern federally sponsored experiments? The prevailing assumption was that until the mid-1960s Federal

agencies, by and large, did not have ethics policies.

- What institutions planned, funded, and conducted experiments, and who had responsibility for ensuring the integrity of experimentation? Where agency organization charts or other road maps existed to guide the way, the fragments at hand were often physically blurred beyond recognition.

Time was short. The Committee therefore had to develop a strategy to quickly gather, organize, and analyze vast amounts of information.

Phase I. The Phase I strategy has three components: (1) the development of a framework for all the information the Committee hoped to collect--the "big picture" into which pieces of the puzzle could be fit; (2) the development of a strategy to mine all available information sources; and (3) the development of an information infrastructure to house and organize all the data. The components of the "big picture" framework include:

- *An experiment database*, to provide a single locale for cataloguing experiments as they are identified;
- *An ethics timeline*, to chart the evolution of Federal and private sector policies and practices pertaining to research ethics;
- *A scientific/medical standards timeline*, to chart the evolution of these standards; and
- *Institutional maps*, to plot the network of public and private institutions that planned, funded, managed, and performed experiments.

Phase II. While Phase I continues, the Committee's brief tenure requires that it turn to the task of evaluating experiments. But on which experiments should it focus? On the one hand, the number of pre-1975 experiments may well be in the thousands, and the number of post-1975 experiments far greater. On the other hand, the Committee may be able to locate only fragments of data about many of these experiments (for example, there is often no information on who subjects were, much less what they were told about the experiment).

The working solution, therefore, is a strategy that seeks to address the basic questions of concern to the Committee and the public by an overlapping set of case studies and samples. First, the Committee is focusing on five groups of biomedical experiments, with each group anchored in one or more specific experiments that have received public attention. Second, the Committee is simultaneously focusing on institutions that conducted the experiments, in order to examine the decisionmaking process and determine responsibility. Third, the Committee's inquiry into intentional releases will focus on determining (1) whether (at this late date) the public can learn who planned the releases, why, and what precautions if any were taken; and (2) whether

intentional releases, which were often shrouded in secrecy, could take place today in the absence of meaningful public notice.

For evaluating the contemporary world of research, the working solution is to conduct three projects: (1) a review of a sample of recently funded research proposals; (2) interviews with subjects of current research; and (3) review of current Federal agency policies for oversight.

Phase III. While Phase I continues, and Phase II has just begun, the Committee is simultaneously turning to Phase III--the tasks of evaluating past and present experiments, recommending policy changes, and developing criteria for a range of remedies that may be appropriate where wrongs or harms have occurred.

Taking Stock: Some Accomplishments and Challenges

Openness: The President's request that the Federal Government open a substantial portion of its Cold War files to the Committee, and the public, was ambitious. There were many reasons for skepticism, including the enormous number of records, the vast number that remained classified, and the potential for bureaucratic delay. These factors remain real. As detailed in this report and agency-specific appendices, the Committee and agency search terms have retrieved important records collections, some of them previously secret, that will provide a new basis for understanding our past and present. In doing so, these collections are producing a road map that should, as present work continues, permit the completion of a substantial search within the Committee's life, and that will remain as a guide for the public in the years to come. It is now clear to the Committee that, with continued public support and interest, the agency commitment to the opening up of a substantial portion of our Cold War archives can continue to be substantial, even unprecedented. It is the Committee's task to help ensure that this search produces results that merit its continuation when the Committee is no longer in existence.

Piecing Together the Secret and Public Worlds of Experiments: The Committee's experiment database presently contains about 400 biomedical experiments conducted before 1975. The Committee possesses at least fragmentary indications of over 1,000 additional experiments. In addition to the 13 intentional releases of ionizing radiation identified in the Charter, the Committee is now aware of hundreds of additional intentional releases.

The Committee is learning that secrecy is not always the primary bar to comprehending the past. A vast amount of data already is public, but it is often widely scattered. For example, piecing together the story of human experimentation in connection with atomic bomb tests requires the Committee to combine discrete collections of public data with newly declassified data while continuing to search for further secret and public pieces of the puzzle.

Piecing Together the Hidden History of Federal Ethics Policy and Practice: Documents delivered by the agencies, and others located by the Committee, have revealed that there was discussion at the highest reaches of government--often in secret--about the need for

human experimentation and for policies to govern it. Committee and agency staff have placed the highest priority on tracking down the twists and turns in these discussions and in the policies and practices that flowed from them.

Discovery of the Past in the Present: When the Committee began its work six months ago, it might reasonably have been assumed that research conducted in the mid-century world was so different from current research that its relevance would be limited. However, the story that is unfolding raises questions of continuing relevance to today. For example:

- At mid-century, ethics policies were discussed and recorded on paper. A key question then, as today, is the relationship between policy and practice.
- Even as policies were put on paper, it was not always clear what they covered. Did they cover sick patients as well as healthy volunteers? In cases involving soldiers and workers, for example, what was understood by responsible decisionmakers to be the difference between experimentation with healthy volunteers and occupational safety monitoring? Then, as today, the boundaries of experimentation may not have been fixed.
- Even with the benefits of openness, basic information on some experiments (notably the intentional releases) remains secret. Could these releases be conducted today without basic public disclosure?

Outreach: The Committee has heard from many members of the public who have written, called, visited its offices, or testified at its open meetings. In many cases these communications have brought important insight and information to the Committee's attention. The Committee's public reading room provides access not only to basic Committee material (e.g., transcripts of meetings) but a collection of important documents that were previously classified or not readily available in an organized form. The Committee's experiment and document collection databases should soon be available to the public on Internet.

Challenges: The primary challenge to the Committee now, as at the onset, is the overwhelming nature of its tasks. Agency and Committee document and information searches are progressing and should result in substantial new information about known experiments, policies, and practices, and perhaps discovery of heretofore unknown experiments, policies, and practices. However, (1) search efforts are necessarily time consuming and uncertain; (2) data on many experiments will likely continue to remain fragmentary; (3) it appears that many important collections have been long since lost or destroyed; (4) a great number of relevant collections contain classified data; the declassification process may be a substantial bottleneck.

Work To Be Done

In the next six months, the Committee will continue with the tasks of data gathering and organizing. The focus of the work, however, will be developing criteria for judging historical and contemporary experiments, policies, and procedures, as well as criteria for remedies that may be appropriate where harms or wrongs have occurred. Based on what the Committee has learned, it will make specific recommendations regarding policies for the future.

**ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
TABLE OF CONTENTS FOR FINAL REPORT**

PREFACE (will be page 1)

INTRODUCTION The Atomic Century

PART I *Ethics of Human Subjects Research: A Historical Perspective*

Overview of Part I
Chapter 1 Government Standards for Human Experiments: The 1940s and 1950s
Chapter 2 Postwar Professional Standards and Practices in Human Experiments
Chapter 3 Government Standards for Human Experiments: The 1960s and 1970s
Chapter 4 Ethics Standards in Retrospect

PART II *Case Studies*

Overview of Part II
Chapter 5 The Plutonium Injections and Related Experiments
Chapter 6 The AEC Program of Radioisotope Distribution
Chapter 7 Nontherapeutic Research on Children
Chapter 8 Total-Body Irradiation: Problems with Dual-Purpose Research
Chapter 9 Prisoners: A Captive Research Population
Chapter 10 Atomic Veterans: Human Experiments at Bomb Tests
Chapter 11 Intentional Releases: Lifting the Veil of Secrecy
Chapter 12 The Ethics of Observational Data Gathering
Chapter 13 Secrecy, Disclosure and Human Radiation Experiments

PART III *Contemporary Projects*

Overview of Part III
Chapter 14 Current Ethics Policies and Oversight Practices for Federally Sponsored Research
Chapter 15 Research Proposal Review Project
Chapter 16 Subject Interview Study
Chapter 17 Contemporary Projects and the Contemporary World

PART IV *Coming to Terms with the Past, Looking Ahead to the Future*

Overview of Part IV
Chapter 18 Findings
Chapter 19 Recommendations

STATEMENTS OF INDIVIDUAL COMMITTEE MEMBERS

EXECUTIVE ORDER

CHARTER

APPENDICES

Acronyms and Abbreviations
Glossary of Terms
Who's Who: A List of Featured Players
Selected Bibliography
List of Public Witnesses
A Citizen's Guide to the Nation's Archives: Where the Records Are and How to Find Them

INDEX

Charter ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

1. Committee's Official Designation

Advisory Committee on Human Radiation Experiments (the "Advisory Committee" or "Committee").

2. Authority

Executive Order No. 12891.

3. Objectives and Scope of Activities

There has been established a Human Radiation Interagency Working Group (the "Interagency Working Group"), the members of which include the Secretary of Energy, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of 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. As set forth in section 4 of this Charter, the Advisory Committee shall provide to the Interagency Working Group advice and recommendations on the ethical and scientific standards applicable to human radiation experiments carried out or sponsored by the United States Government. As used herein, "human radiation experiments" means:

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

Consistent with the provisions set forth in section 4 of this Charter, the Advisory Committee also shall provide advice, information and recommendations on the following experiments:

- (1) The experiment into the atmospheric diffusion of radioactive gases and test of detectability, commonly referred to as "the Green Run test," by the former Atomic Energy Commission (AEC) and the Air Force in December 1949 in Hanford, Washington;
- (2) Two radiation warfare field experiments conducted at the AEC's Oak Ridge office in 1948 involving gamma radiation released from non-bomb point sources at or near ground level;
- (3) Six tests conducted during 1949-1952 of radiation warfare ballistic dispersal device containing radioactive agents at the U.S. Army's Dugway, Utah site;
- (4) Four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and
- (5) Any other similar experiments which may later be identified by the Interagency Working Group.

The Advisory Committee shall review experiments conducted from 1944 to May 30, 1974. Human radiation experiments undertaken after May 30, 1974, the date of issuance of the Department of Health, Education and Welfare

Regulations for the Protection of Human Subjects (45 C.F.R. 46), may be sampled to determine whether further inquiry into experiments is warranted. Further inquiry into experiments conducted after May 30, 1974, may be pursued if the Advisory Committee determines, with the concurrence of the Interagency Working Group, that such inquiry is warranted.

4. Description of Duties for Which Committee is Responsible

- a. The Advisory Committee shall determine the ethical and scientific standards and criteria by which it shall evaluate human radiation experiments, as set forth in section 3 of this Charter. 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.
- b. The Advisory Committee shall evaluate the extent to which human radiation experiments were consistent with applicable ethical and scientific standards as determined by the Committee pursuant to paragraph (a) of this section. If deemed necessary for such an assessment, the Advisory Committee may carry out a detailed review of experiments and associated records to the extent permitted by law.
- c. If required to protect the health of individuals who were subjects of a human radiation experiments, or their descendants, the Advisory Committee may recommend to the Interagency Working Group that an agency notify particular subjects of an experiment, or their descendants, of any potential health risk or the need for medical follow-up.
- d. The Advisory Committee may recommend further policies, as needed, to ensure compliance with recommended ethical and scientific standards for human radiation experiments.
- e. The Advisory Committee may carry out such additional functions as the Interagency Working Group may from time to time request.

5. To Whom the Advisory Committee Reports

The Advisory Committee shall report to the Interagency Working Group

The Advisory Committee shall submit its final report to the Interagency Working Group within one year of the date of the first meeting of the Advisory Committee, unless such period is extended by the Interagency Working Group. The Advisory Committee shall issue an interim report not more than six months after the date of the first meeting of the Advisory Committee. That interim report shall advise the Interagency Working Group on the status of the Advisory Committee's proceedings and the likelihood that the Committee will be able to complete its duties within one year of the date of the first meeting of the Advisory Committee.

6. Duration and Termination Date

The Advisory Committee shall terminate thirty days after submission of its final report to the Interagency Working Group. This Charter shall expire one year plus thirty days after the first meeting of the Advisory Committee, subject to renewal and extension by the President.

7. Agency responsible for providing financial and administrative support to the Advisory Committee

Financial and administrative support shall be provided by the Department of Energy.

8. Estimated Annual Operating Costs

\$3 million.

9. Estimated Number and Frequency of Meetings

The Advisory Committee shall meet as it deems necessary to complete its functions.

10. Subcommittee(s)

To facilitate functioning of the Advisory Committee, subcommittee(s) may be formed. The objectives of the subcommittee(s) are to make recommendations to the Advisory Committee with respect to matters related to the responsibilities of the Advisory Committee. Subcommittees shall meet as the Advisory Committee deems appropriate.

11 Members

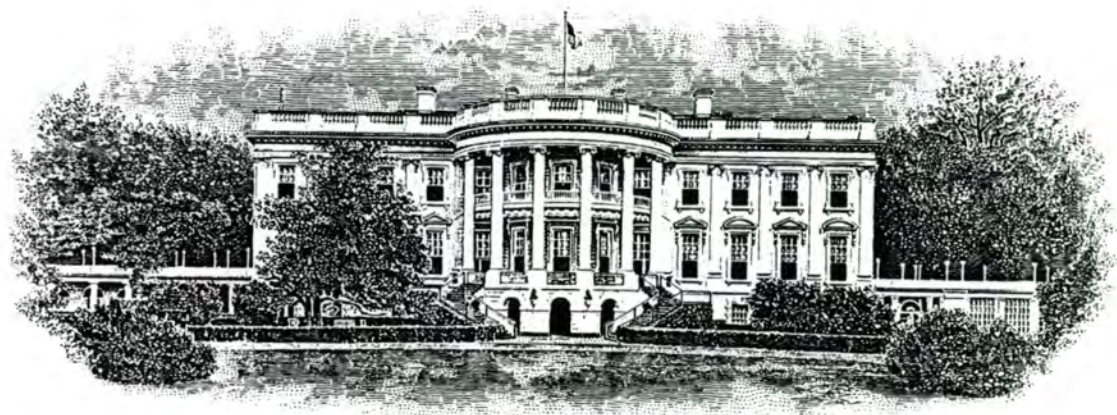
Up to a maximum of fifteen Advisory Committee members shall be appointed by the President for a term of one year, which may be extended by the President. Committee members shall be compensated in accordance with federal law. Committee members may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the government service (5 U.S.C. §§ 5701-5707).

12. Chairperson

The President shall designate a Chairperson from among the members of the Advisory Committee. .



The White House



PRESIDENT OF THE UNITED STATES

Executive Order 12891 of January 15, 1994 Title 3 - The President Advisory Committee on Human Radiation Experiments 59 FR 2935

DATE: Thursday, January 20, 1994

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Establishment.

(a) There shall be established an Advisory Committee on Human Radiation Experiments (the "Advisory Committee" or "Committee"). The Advisory Committee shall be composed of not more than 15 members to be appointed or designated by the President. The Advisory Committee shall comply with the Federal Advisory Committee Act, as amended, 5 U.S.C. App. 2.

(b) The President shall designate a Chairperson from among the members of the Advisory Committee.

Sec. 2. Functions.

(a) There has been established a Human Radiation Interagency Working Group, the members of which include the Secretary of Energy, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of 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. As set forth in paragraph (b) of this section, the Advisory Committee shall provide to the Human Radiation Interagency Working Group advice and recommendations on the ethical and scientific standards applicable to human radiation experiments carried out or sponsored by the United States Government. As used herein, "human radiation experiments" means:

- (1) experiments on individuals involving intentional exposure to ionizing radiation. This category does not include common and routine clinical practices, such as established diagnosis and treatment methods, involving incidental exposures to ionizing radiation;
- (2) experiments involving intentional environmental releases of radiation that (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation.

Consistent with the provisions set forth in paragraph (b) of this section, the Advisory Committee shall also provide advice, information, and recommendations on the following experiments:

- (1) the experiment into the atmospheric diffusion of radioactive gases and test of detectability, commonly referred to as "the Green Run test," by the former Atomic Energy Commission (AEC) and the Air Force in December 1949 at the Hanford Reservation in Richland, Washington;
- (2) two radiation warfare field experiments conducted at the AEC's Oak Ridge office in 1948 involving gamma radiation released from non-bomb point sources at or near ground level;
- (3) six tests conducted during 1949-1952 of radiation warfare ballistic dispersal devices containing radioactive agents at the U.S. Army's Dugway, Utah, site;
- (4) four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and

(5) any other similar experiment that may later be identified by the Human Radiation Interagency Working Group. [*2936]

The Advisory Committee shall review experiments conducted from 1944 to May 30, 1974. Human radiation experiments undertaken after May 30, 1974, the date of issuance of the Department of Health, Education, and Welfare ("DHEW") Regulations for the Protection of Human Subjects (45 C.F.R. 46), may be sampled to determine whether further inquiry into experiments is warranted. Further inquiry into experiments conducted after May 30, 1974, may be pursued if the Advisory Committee determines, with the concurrence of the Human Radiation Interagency Working Group, that such inquiry is warranted.

(b)(1) The Advisory Committee shall determine the ethical and scientific standards and criteria by which it shall evaluate human radiation experiments, as set forth in paragraph (a) of this section. 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.

(2) The Advisory Committee shall evaluate the extent to which human radiation experiments were consistent with applicable ethical and scientific standards as determined by the Committee pursuant to paragraph (b)(1) of this section. If deemed necessary for such an assessment, the Committee may carry out a detailed review of experiments and associated records to the extent permitted by law.

(3) If required to protect the health of individuals who were subjects of a human radiation experiment, or their descendants, the Advisory Committee may recommend to the Human Radiation Interagency Working Group that an agency notify particular subjects of an experiment, or their descendants, of any potential health risk or the need for medical follow-up.

(4) The Advisory Committee may recommend further policies, as needed, to ensure compliance with recommended ethical and scientific standards for human radiation experiments.

(5) The Advisory Committee may carry out such additional functions as the Human Radiation Interagency Working Group may from time to time request.

Sec. 3. Administration.

(a) The heads of executive departments and agencies shall, to the extent permitted by law, provide the Advisory Committee with such information as it may require for purposes of carrying out its functions.

(b) Members of the Advisory Committee shall be compensated in accordance with Federal law. Committee members may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the government service (5 U.S.C. 5701-5707).

(c) To the extent permitted by law, and subject to the availability of appropriations, the Department of Energy shall provide the Advisory Committee with such funds as may be necessary for the performance of its functions.

Sec. 4. General Provisions.

(a) Notwithstanding the provisions of any other Executive order, the functions of the President under the Federal Advisory Committee Act that are applicable to the Advisory Committee, except that of reporting annually to the Congress, shall be performed by the Human Radiation Interagency Working Group, in

accordance with the guidelines and procedures established by the Administrator of General Services.

(b) The Advisory Committee shall terminate 30 days after submitting its final report to the Human Radiation Interagency Working Group. [*2937]

(c) This order is intended only to improve the internal management of the executive branch and it is not intended to create any right, benefit, trust, or responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person.

/s/ WILLIAM J. CLINTON

THE WHITE HOUSE, January 15, 1994.

Rays of Terror

For more than a year now, the President's Advisory Committee on Human Radiation Experiments has been investigating one of the federal government's darkest secrets: human radiation experiments in which sick patients and retarded children, among others, were used as human guinea pigs.

BY MARGARET KRIZ

On April 12, James Tidwell came to the nation's capital to recount the painful death of his grandfather, James Sr., at the hands of a federally financed researcher.

In November 1960, James Sr. went to Cincinnati General Hospital complaining of chest pains. Doctors at the hospital, finding a cancerous spot on his lung, enrolled him in a human radiation experiment financed by the Pentagon.

There is no evidence that James Sr. signed a consent form agreeing to be included in the experiment. As his grandson explained to the President's Advisory Committee on Human Radiation Experiments: "He couldn't read very well and couldn't write. He didn't know what radiation was, and that's why they kept using him as a guinea pig."

Records unearthed by the advisory committee's staff show that Tidwell, an African-American, and more than 80 other poor, uneducated and primarily African-American patients with incurable cancers were exposed to extremely high, full-body doses of radiation. Some patients died within hours of the treat-

ment. Tidwell entered the hospital weighing 180 pounds. When he died 32 days later, his grandson said, he was down to 116 pounds.

Even death didn't end the indignities. The doctors took Tidwell's arms and legs for further study. Unbeknownst to the family, they also removed his brain.

As his grandson related the story of Tidwell's death and the family's subsequent attempts to learn what had happened, his voice filled with long-held sorrow and indignation. "Why did the government let this go on when they knew this was not doing the patients any good?" he asked. "I'm damn mad and furious, and I'm going to stay that way until I get some answers."

The Cincinnati experiments were part of a series of human radiation exposure studies begun under the Manhattan Project, the military's top-secret program to develop the atomic bomb.

But during the Cold War, the military wasn't alone in its hunger for medical research on radiation. The advisory committee's investigators found evidence of human radiation experiments at the CIA,



Ruth R. Faden, who chairs the Advisory Committee on Human Radiation Experiments
"It's very hard to uncover history."

John Eisele

UNEARTHING THE DARK SECRETS

In December 1993, Energy Secretary Hazel R. O'Leary shocked—and shook up—the nation when she acknowledged that the federal government had financed a series of human radiation experiments in which sick patients and retarded children, among others, were used as human guinea pigs—all to learn more about radiation and develop bigger and better weapons. In so doing, she made a lot of enemies in military circles.

O'Leary's revelation triggered a chain of events that has forced federal departments and agencies to divulge other deep, dark secrets of the past.

The Pentagon was initially reluctant to cooperate with the President's Advisory Committee on Human Radiation Experiments, which is assessing the experiments. But in recent months, Defense Department officials have provided the committee with thousands of previously undisclosed documents. That's not the case, however, with the CIA, which, insiders say, continues to stonewall attempts by the advisory committee's staff to unearth evidence of human radiation experiments.

Not surprisingly, the Energy Department has received the highest marks for openness. It's uncovered 150,000 pages of documents related to human radiation experiments, according to Elyn R. Weiss, the director of the department's Office of Human Radiation Experiments, which was created to give the public access to the documents. The documents are now available through the Internet. (The home page electronic address is <http://www.eh.doe.gov/ohre/home.htm>)

"The department has 3.2 million cubic feet of records scattered around the country," Weiss said. "This is the first sustained effort to get some intellectual control over these documents."

To help the next generation of detectives ferret out more information, the Energy Department has published a 300-page road map that outlines the types of studies that were conducted by the national laboratories and where the records on those experiments are housed.

"This is where the rubber meets the road on openness," Weiss said. "There are a lot of people who think this openness is a perfectly horrible idea. There are people who think this is besmirching the reputations of good, honorable researchers. What I say to them is that the level of distrust in big government and big science is pervasive. Without some basic level of public trust, this department can't do what it needs to do into the 21st century to clean up Cold War weapons sites and maintain safe stewardship of the nuclear stockpile."

Weiss and others involved in the openness campaign acknowledge, however, that some records will never be found. In December 1994, an official of the General Accounting Office, in testimony to the Senate Governmental Affairs Committee, said that many documents have been lost because of the government's historically poor record-keeping; old government policies that required records to be destroyed after certain intervals; and "the enormous volume of a variety of records that would have to be manually searched, many of which are not in the possession of the government."

Open to debate is what will happen to the remaining records once the advisory committee and Weiss's office are disbanded later this year. Weiss said that the department is committed to maintaining its Internet files. The advisory committee, too, is making its findings available electronically.

But some congressional aides worry that many citizens still are not able to use the Internet. Some want the Clinton Administration to move all accessible documents to a central location, possibly under the control of the National Archives and Records Administration.

the Energy Department, the Health and Human Services Department, the National Aeronautics and Space Administration and the Veterans Affairs Department. So far, the committee has uncovered more than 4,000 human radiation experiments that were financed by the federal government from 1944-74. The committee estimates that tens of thousands of patients were involved.

In the case of the Cincinnati experiments, committee documents show that the Defense Department agreed to finance the research on sick patients after turning down a request to experiment on healthy subjects.

"What's alarming is that the government funded this research for decades in hopes of getting data useful for fighting a war, but without apparent regard for the

continued value of the effort to the patients," Dan Guttman, the advisory committee's staff director, said in an interview. "At some point someone should have said, 'Gee, enough is enough.' Instead, here is our United States government funding this continually for its own research purposes."

At the committee's April hearing, Tidwell was one of many witnesses who expressed dismay that members of their families had been used as unwitting soldiers of the Cold War. Some relatives brought yellowed photographs of their kin in happier days. All told compelling stories of pain, loss and fear.

"It's a healing process," Gwendon Plair, who heads the Cincinnati-based Concerned Relatives of Cancer Study Patients, told the advisory committee at the hearing. "One of the most important things you can do is to reassure the American citizens that you really are listening to them."

LIFTING THE VEIL

For 12 months, the advisory committee has done a lot of listening as it became a magnet for many citizens who have long known—as well as those who have just discovered—that they or their loved ones were involved in a human radiation experiment.

Composed of 14 nongovernment experts on medicine, ethics and law, the committee is trying to determine the scope of the government-financed radiation experiments and to analyze the wrongs that might have occurred. The committee also is looking to the future, asking the sensitive question of whether similar abuses could happen today.

The panel, which President Clinton created in April 1994, was originally scheduled to disband after a year. But last month, members of the committee agreed that they needed more time to reach a consensus on how the government should react to the new evidence. (For more on the committee's draft recommendations, see box, p. 1104.)

While the committee held a series of field hearings, its staff has been busy knocking down long-closed doors at federal departments and agencies, military facilities, laboratories and hospitals around the country. The 25-person staff has made unprecedented progress in unearthing documents relating to radiation experiments. At the time the committee was created, federal officials knew of about 45 experiments involving 800 persons.

Although many of the experiments were innocuous, the staff has uncovered cases in which basic human rights and freedoms collided head-on with the U.S.

government's rush to gain military superiority and to prepare for a potential nuclear war with the Soviet Union.

"What you're looking at is a story of how the government undertakes to do two very good things: Let's win the war and let's do radiation research for medical and scientific advances," Guttman said. "But the government was using people as the means to these ends."

The committee faces the difficult task of evaluating the value and danger of the Cold War-era experiments at a time when the public has all but forgotten the terror of the Cuban missile crisis and the air-raid drills that sent schoolchildren scrambling under their desks.

The committee is also being asked to assuage the fears of a public that is increasingly suspicious of big government and big science.

"We must address the broad issue of what this country claims to be," said Fred Allingham, the executive director of the National Association of Radiation Survivors, a Sacramento (Calif.)-based victims' group. "It claims to protect its citizens, and yet we have this bizarre history."

Even as the committee tries to address the crimes of yesterday, questions are emerging about the effectiveness of the ethical warning systems in place today within the medical research community.

At the April hearing, for example, members of the committee noted that universities and hospitals conducting government-financed experiments are required to set up independent panels to oversee the research. But the committee members said they were concerned that some panels have not adequately questioned the medical value of the experiments they oversee.

In addition, the committee received a preliminary report suggesting that patients are often unaware that they are taking part in an experiment. According to the early results of a survey conducted in the waiting rooms of medical facilities, 40 per cent of the subjects interviewed didn't know that they were part of an experiment. The report raises serious questions about whether researchers are thoroughly educating and gaining the consent of their subjects.

The chairwoman of the advisory committee, Ruth R. Faden, a bioethics expert who is a professor in the Johns Hopkins University's health policy and management department, maintains that although no one can guarantee that an aberrant scientist might not ignore today's ethical mandates, a repeat of the Cold War human radiation experiments is highly unlikely.

But victims' groups worry that all of the safeguards could easily be eroded or



The photograph above, taken in the mid-1960s, shows a positron emitter detector—which could measure trace amounts of radioactive materials injected into the bloodstream—in use at the Brookhaven National Laboratory. The photograph to the right shows Wright Langham, a chemist at the Los Alamos National Laboratory, being lowered by two colleagues into the facility's first whole-body radiation counter.





Dan Guttman, the staff director of the advisory committee
"At some point someone should have said, 'Gee, enough is enough.'"

overridden if government officials secretly decide that their mission is of critical national importance.

"Take the next national interest," Richard Miller, a policy analyst for the Oil, Chemical and Atomic Workers Union, said. "It may not be national security. It may be being the globally dominant economy. What will we spare to be the global leader in biotechnology, for example? If you ask the question 'Is it possible for these sorts of abuses to happen again today?' the answer is 'Of course.'"

TEST CASES

In 1944, Los Alamos National Laboratory began a series of tests in California's Bayo Canyon in which radioactive material was released into the environment. More than 250 tests were conducted over an 18-year period to evaluate weapons designs.

Two years after the tests began, however, health officials at the laboratory became worried that the chemists who prepared the experiments were being exposed to excessive amounts of radiation. Rather than warn the workers and move them to other jobs, however, the laboratory decided to study whether the radiation was affecting their blood chemistry, according to documents disclosed by the advisory committee.

When the Los Alamos health researchers tried to release the results of their blood study, however, laboratory officials balked, on the ground that doing so would open the federal government to occupational injury claims.

"We can see the possibility of a shattering effect on the morale of the employees

if they became aware that there was a substantial reason to question the standards of safety under which they are working," Clyde E. Wilson, then the chief of the laboratory's insurance branch, wrote in a memo in 1946. "In the hands of labor unions, the results of this study would add substance to demands for extra-hazardous pay. We can also see the definite possibility that general knowledge of the results of this study might increase the number of claims of occupational injury due to radiation and place a powerful weapon in the hands of a plaintiff's attorney."

The document, which the advisory committee obtained last month, was one of several recently discovered records reveal-

ing that the federal government sometimes suppressed employee health studies not for national security reasons, but because officials wanted to avoid lawsuits, union activism and bad public relations.

That's a story that strikes a particularly raw nerve today for some employee groups that are pushing the Energy Department to begin a long-delayed medical surveillance program for some workers who have been part of nuclear programs at the national research laboratories.

Even today, Miller complained, the Energy Department isn't making public the results of health effects studies that use employee exposure data. Such secrecy is particularly alarming, he said, because the department recently approached several employees of national laboratories and offered them early retirement packages if they would agree in writing not to sue the government or its contractors for any future health problems. The department, Miller said, subsequently withdrew the offer.

Federal officials say that the government has instituted several safeguards to prevent the kinds of human experimentation abuses that have occurred in the past. But, Miller asked, "what safeguards exist for workers today who are being studied as part of an epidemiology study but are completely clueless about it?"

WHAT HAPPENED?

When lawyers and scientists search for the code of ethics that should apply to modern medical experimentation, they reach back nearly half a century to the principles applied during the 1947 Nuremberg trials of Nazi Germany's scientists. Among other things, the Nurem-



Energy Secretary Hazel R. O'Leary
A journalist's work prompted her to look into the human radiation experiments.

berg tribunal declared that researchers must obtain the informed consent of all subjects in experiments.

As antiquated as that document may seem, a federal judge cited it in January of this year in refusing to dismiss a lawsuit against the Cincinnati Cold War researchers. The suit was brought by the Tidwells and other families of patients who were subjects of the full-body radiation experiments at Cincinnati General Hospital, now known as University Hospital.

Lawyers for the hospital, the researchers and the federal government sought to have the lawsuit thrown out, arguing that the researchers were immune from liability because they were government contractors and because the law on informed consent was not fully established in the 1960s. But Judge Sandra Beckwith ruled that the Nuremberg doctrine set out the responsibilities of government researchers to

gain the permission of their test subjects.

At the time the advisory committee began its work, the nation's scientific community generally thought that most of the requirements that have to do with ethics in medical and scientific research—informed consent chief among them—were adopted in the 1960s and afterward. But documents obtained by the committee show that shortly after World War II, officials of the federal government told researchers to gain prior permission from test subjects. Some of the orders, however, were classified as top-secret and weren't applied to medical researchers whose work was underwritten or subsidized by the government.

"The most striking single finding is that the government was keenly aware at the highest and most-secret levels that individual dignity had to be protected," Guttman said. "The question then is, what happened?"

Although military leaders were willing to specify strong ethical practices for healthy citizens, the same standards somehow weren't applied to sick patients and to workers, such as the military personnel who were intentionally placed on the Nevada desert during atomic bomb blasts.

As recently as 1986, the government thwarted attempts to investigate its radiation experiments on national security

grounds. In that year, Edward J. Markey, D-Mass., released a list of known human radiation experiments and asked the Energy Department to identify the people involved in the research, to notify the survivors and to compensate those who had been harmed. Although Markey then headed the House Energy and Commerce Subcommittee on Energy and Power, the Energy Department slammed the door in his face.

Using Markey's preliminary information, however, Eileen Welsome, a re-

O'Toole, the assistant Energy secretary for environment, safety and health. O'Toole told Faden that members of the department's staff had just discovered some disturbing research documents, and she wanted Faden's professional opinion.

"I reported back that she had reason to be concerned," Faden recalled in an interview. "If these accounts were accurate, there was a grounding to be worried about violations of human rights in relation to human subjects."

By April 1994, Faden was chairing the advisory committee that is now trying to explain to the nation just what happened in hospitals, laboratories and weapons plants during the Cold War. "It's very hard to uncover history," she said.

Faden heads a panel whose members range from human rights activists to radiation scientists. Some are reluctant to pass judgment on the researchers of another era. Others

want the government to contact the victims of the radiation experiments. Faden's biggest job is to find common ground for the committee's final report.

Organizations that represent victims of the radiation experiments are pushing for a widespread outreach program. Cooper Brown, who heads the Task Force on Radiation and Human Rights, an umbrella group of 20 local organizations, argued that under the Nuremberg code, the government must "do everything in its power to take precautions against even the remotest injury. The prospects of cancer developing in this case takes anywhere from 20-40 years. The government is still responsible today."

The outreach program envisioned by Brown and other victims' rights activists would include retrieving medical records from private hospitals and universities and running a national advertising campaign to find the subjects of the radiation experiments.

The victims' groups also hope that radiation-related horror stories will deter Congress from passing a token compensation bill—as, they say, Congress did for military veterans who were exposed to atomic bomb explosions and who were sent into Hiroshima and Nagasaki after World War II. "Once you put a lot of human faces together with this story,"

"Why did the government let this go on?" asks the grandson of one of the victims.

porter for the *Albuquerque Journal*, began an extensive investigation that resulted in her 1993 Pulitzer prize-winning series on five subjects of the Cold War tests.

Her stories prompted Energy Secretary Hazel R. O'Leary to begin looking into the department's dark history, and O'Leary soon uncovered more evidence of abusive human radiation experiments. In December 1993, O'Leary launched a broad "openness initiative" within the Energy Department that included providing public access to the now-defunct Atomic Energy Commission's records on human radiation experiments. (See box, p. 1100.)

When it became clear that the Energy Department wasn't the only government agency with radiation testing secrets in its closet, Clinton created a Cabinet-level group to coordinate a government-wide inventory of research records. The White House has also proposed creating an National Bioethics Advisory Commission, which would be housed in its Office of Science and Technology Policy, to oversee the federal government's biological and behavioral research.

THE NEXT CHAPTER

In late 1993, Faden received a telephone call at Johns Hopkins from Tara



Cooper Brown, who heads an umbrella group of 20 victims' rights organizations
"It's something that can't be swept under the rug."

Brown said, "then it's something that can't be swept under the rug."

The alarming human rights violations that have been uncovered by the advisory committee are provoking strong feelings among victims' rights groups around the nation. If Brown had his way, for exam-

ple, the committee would ask for the appointment of a special prosecutor to investigate any evidence of criminal wrongdoing in connection with the human radiation experiments. He admitted, however, that the committee is cool to that suggestion.

WHAT SHOULD BE DONE?

The President's Advisory Committee on Human Radiation Experiments is considering eight recommendations in light of recent evidence that the federal government financed thousands of human radiation experiments during the Cold War era, some of which violated basic human rights.

Its draft recommendations, which were included in an April 7 staff memorandum, are expected to be reworked before the committee's final report is issued in August. The draft calls on the federal government to:

- develop a several-staged effort to "change the culture of biomedical research" to focus on ethical practices;
- adopt new ways to monitor the effectiveness of procedures that seek to protect the rights of human subjects;
- establish public methods for applying and interpreting ethics rules and principles for conducting human research;
- establish "an express and clear connection between violations of regulations for research involving human subjects and sanctions for those violations";
- review whether research subjects should be compensated for injuries and medical costs arising from their participation in the human radiation experiments (the draft recommends that the government compensate research subjects who did not sign informed consent agreements, whether or not the research caused any harm);
- promote openness in, and public access to, federal records pertaining to human radiation experiments (the draft recommends that private researchers and contractors who receive federal funds be required to provide public access to their records and that the government monitor the CIA to assure that it fulfills legitimate requests for information);
- take steps to improve existing protections of the rights and interests of military personnel with respect to human research;
- better protect the public's rights with respect to intentional releases of radiation into the environment.

Citing widespread public outrage, Allingham, of the National Association of Radiation Survivors, goes so far as to argue that the government should stop financing outside medical research. "I would like to see the government get out of the business of financing human experimentation, period," he said. "If a hospital wants to take that on their own, they can. The national security state has wreaked havoc on people's lives for 50 years."

One thing the victims' groups and the advisory committee agree on, however, is the need to maintain open access to government records. The committee has had the backing of the White House as it pushed for access to previously secret documents. Those who follow in its footsteps may not.

Beyond that, however, Members of Congress who have taken a special interest in the committee's work are awaiting its final report before they take action. Markey's staff, for example, said that he is likely to include the committee's recommendations in legislation he plans to introduce.

When John Glenn, D-Ohio, was the chairman of the Senate Governmental Affairs Committee, he held a series of hearings on the human radiation experiments, including one that was designed to force federal departments and agencies to open their files to the committee's staff. Glenn, too, is likely to introduce legislation in response to the committee's report. So far, however, Sen. William V. Roth Jr., R-Del., the committee's new chairman, hasn't shown any interest in the issue.

Several Republican House Members whose constituents were involved in the radiation experiments have been closely monitoring the committee's work. In April, Steve Chabot and Rob Portman of Ohio and Christopher H. Smith of New Jersey urged the committee to seek more time to sort out the lessons of the Cold War experiments.

A Clinton Administration official who's close to the advisory committee said that Congress is likely to offer bipartisan support for the committee's recommendations if the final report makes a compelling case for the changes it recommends, if it seeks justice for the experiment subjects and if it doesn't suggest budget-busting remedies.

The first order of business may be whether the federal government, at the very least, owes the victims of radiation experiments and their families a full, formal apology. Many of them feel that after years of concealment and cover-up, there needs to be a mea culpa to pave the way for healing the long-hidden wounds of the last victims of the Cold War. ■

John Evelev

Coming Clean After Decades of Dirty Science

Panel urges U.S. apology and payments to subjects of covert radiation tests

When the history of the Cold War is written, the record will show that the period was costly in its damage to basic American legal rights. The FBI and other agencies ran roughshod over anti-war, civil-rights and other dissidents. But probably no governmental violation in that time is more infuriating than the radiation experiments conducted on unwitting subjects—many of them black, poor, imprisoned or gravely ill—without their knowledge or consent.

The President's Advisory Committee on Human Radiation Experiments has now done a signal service in lifting the veil of unnecessary secrecy over an unpleasant reality that extended from 1944 until 1974.

Refreshing in its candor, chilling in its implications, the panel's draft report documents these three decades of ethical abuses by the Atomic Energy Commission, the Defense Department and other agencies. And it recommends steps that governments rarely take: admit the mistakes, apologize and pay financial compensation—at least to some of the unwitting subjects or their families.

Scientists funded by the agencies injected subjects with plutonium, radium and other radioactive substances. Pregnant women were given radioactive potions to drink so researchers could trace the paths of the chemicals in their bodies. Prisoners were made to immerse their testicles in radioactive liquids. The Alaskan tundra near Eskimo settlements was seeded with radioactive debris to see how it spread in the environment. Doctors at the University of Cincinnati exposed indigent cancer patients to radiation 10 times higher than considered safe, and several died as a result.

Some of the studies offered no prospect of direct benefit to the subjects to offset risks.

Although they were not direct subjects of experiments, many thousands more, including uranium miners and residents of the Marshall Islands, were exposed to radiation during the manufacture or testing of early atomic and nuclear weapons. American military personnel

who occupied Hiroshima and Nagasaki shortly after the atomic bomb attacks there 50 years ago also were exposed.

It is perhaps unfair to judge those responsible by today's more refined standards of medical ethics. But the report—demanded by Energy Secretary Hazel O'Leary—found that the agencies violated even then-existing rules governing human experimentation. Perhaps even worse, officials later concealed the information, not out of national security concerns but to avoid embarrassment and legal liability. For example, full details of 250 intentional radiation releases near Pueblo Indian lands in New Mexico were not disclosed until 1994.

The committee recommended public apology and monetary compensation for those subjects of experiments in which the government covered up information to avoid embarrassment or liability and in cases where there was no possible benefit and subjects suffered physical harm. This will not satisfy the exposed miners, service people and their survivors. And, given the distance of time, it will probably be impossible to reconstruct the facts and identities in many cases.

But President Clinton should ratify this important report and ask Congress to appropriate funds to compensate victims. It goes too far to liken these studies to the grotesque medical "experiments" done on concentration camp prisoners by German Nazi doctors. Some of the Cold War studies did advance therapies for prostate cancer and cardiac disease. Scientists involved at the time justified them as crucial to understanding and mitigating the effects of nuclear war on humans.

But Cold War anxiety and hysteria are no excuse for these gross violations of both constitutional rights and basic medical ethics. In the words of the panel's draft report, they undermined "the moral principle, deeply embedded in the American experience, that the government may not use its citizens as mere means to advance its purposes irrespective of citizens' rights to bodily integrity."



Energy Secretary Hazel O'Leary demanded report on acts that occurred from 1944 to 1974.

Chicago Tribune

Circ: 724,257

Atoning for the radiation tests

The staff of a presidential panel looking into the federal government's disgraceful sponsorship of human radiation experiments during the Cold War recommends that Washington issue a broad public apology and compensate those who suffered.

In an age when former Defense Secretary Robert McNamara seeks atonement for the tragedy of Vietnam and the Southern Baptist Convention repudiates racism and slavery, a government apology for its past, inhumane conduct in radiation testing undoubtedly will be greeted by many with cynicism.

Indeed, one can't wash away past transgressions and guilt with *mea culpas* and money, but, in this case, that's an appropriate beginning. It will not excuse the unethical behavior of the past or lessen the pain of those who suffered, but it will help to begin a process of healing and understanding that, it is hoped, will prevent other research abuses from happening.

Because of the nuclear arms race with the former Soviet Union and the fear of imminent nuclear war, Washington authorized thousands of radiation experiments at hospitals, universities and military bases that began in the mid-1940s and stretched into the early 1970s. The goal was to try to understand the effects of radiation exposure on the body. Details of the testing were closely guarded until recently, when press reports led Energy Secretary Hazel O'Leary to open previously secret government files.

Most of the experiments involved small doses of radiation—less than received in an X-ray today—and were harmless, according to a draft report for the President's Committee on Human Radiation Experiments. But, in some cases, the doses were greater and caused significant harm.

In some cases, the tests were designed to see if radiation could fight disease; in others, there was no medical value. Test participants ranged from mentally retarded teenagers to cancer patients in hospitals. Some gave their consent, others did not.

By today's standards, many of the tests would be considered unethical. Some were embarrassingly unethical even considering the unusual circumstances and pressures of the early Cold War period. Although policies were put in place early on to protect people, they were often ignored or themselves kept secret.

Thus, "some people were treated poorly and suffered," the report concludes, "and there's a national duty to express regret." In addition, the report says test subjects (or their survivors), especially those who were not told they were being used as guinea pigs, should be paid for their medical expenses and pain.

A final report will be presented to O'Leary and President Clinton. They must decide whether to apologize and compensate the victims. They should do both. Whatever the political and dollar costs, it will be a small price to pay.

The New York Times

Panel Finds Wide Debate in 40's On the Ethics of Radiation Tests

By PHILIP J. HILTS

Special to The New York Times

WASHINGTON, Oct. 11 — In the early years of the cold war, a systematic effort to gain knowledge of the effects of radiation from experiments on human subjects was secretly planned at the highest levels of the United States Government. The number of experiments was some 10 times larger than known until now, but there was also more discussion than expected on the ethics of experimentation.

That is the outline of the complex picture being developed by the President's Committee on Human Radiation Experiments after six months of sifting through the archives of a dozen Federal agencies. The committee has brought to light a wealth of documents about the Government's behavior — sometimes furtive, sometimes ethical — that will force historians to rewrite part of the history of the dawn of the atomic age.

In particular, the advisory committee has traced the almost continual jostling between the military's desire for data on radiation and the ethical scruples of some senior officials. Since no clear operating policy emerged, the result was that some ethically dubious experiments were

discouraged or disapproved, while others went ahead.

Last year, after The Albuquerque Tribune reported on a group of patients given high doses of radiation treatment for largely experimental purposes, Energy Secretary Hazel R. O'Leary responded by promising to open her agency's files, and President Clinton later ordered the committee to make a detailed inquiry into the experiments.

The Tribune article and the previous instances of unethical radiation experiments discussed by Representative Edward J. Markey, Democrat of Massachusetts, at Congressional hearings in 1984 suggested that a thorough search would stir up many of horrific stories. They also raised questions as to what ethical guidelines, if any, had governed the experiments, and at what point in the Government the research program had been directed.

Dr. Ruth Faden, an ethicist at Johns Hopkins University who is the chairwoman of the committee, said: "Did we find new horror stories? Well, we know now that much more

Continued on Page A12, Column 1

Continued From Page A1

experimental work was done than anyone guessed."

While the radiation doses received by subjects in most cases were not large, at the time the hazards of low levels of radiation were not known, and consent was not usually sought.

But Dr. Faden did express surprise at the apparent deliberateness of the decision making. "Frankly, we did not believe before we started this that there was much debate and planning done in connection with these experiments," she said. "But there was, and it was at a high level of the military and scientific establishment."

"That is not to say what the motive was for these ethical discussions — whether it was high-minded moral reasons, or legal reasons or public relations reasons — but in any case there was an awareness at high levels that one could not proceed in the area of radiation and human experiments just casually. They took it seriously."

Serious Talk About Need for Data

Dr. Faden said that from the level of Secretary of Defense on down through the secretaries of the Army, Navy and Air Force, there was serious discussion of the military's need for information about how dangerous radiation was to troops, how soldiers might react to it and what precautions were needed. The question was how to get that information, and how often were human experiments necessary.

"We are now piecing together the story of the past, an unsuspected past, to help inform the future on these questions," she said.

Among the papers unearthed by the committee are documents that show experiments were debated, planned and carried out in a layer of atomic medical bureaucracy by half a dozen secret committees, which staff members estimate will in-

crease the number of known experiments at least tenfold, to about 600. Most experiments involved exposing troops to varying amounts of radiation, usually without informing them of the risks or seeking their consent.

At the time, the documents suggest, being the subject of experiments was considered as one of the expected hazards of military life and training — not unlike subjecting soldiers to live fire in training exercises — and was not considered to be human experimentation.

The committee also found that, contrary to the belief that there was little debate about the ethics of such experimentation in the 1950's, Army ethical guidelines written in 1953 were in fact far stricter than the current rules.

But the rules — a nearly verbatim copy of the Nuremberg Code, a set of ethical principles that came out of the Nuremberg trials after World War II — did not become operating guidelines, apparently because they were declared top secret.

One of the most important bits of history found in the hundreds of thousands of documents so far received by the committee, Dr. Faden said, is that a fixture of current ethical debates — whether it is possible to offer a patient honest treatment and experiment on him at the same time — appears to have been a consideration in even the earliest documents of cold war experiments.

An Atomic Energy Commission memorandum dated April 17, 1947, recommends that human experimentation not be made public. "It is desired that no document be released which refers to experiments with humans and might have an adverse effect on public opinion or result in legal suits," it says. "Documents covering such work in this field should be classified 'secret.'" The memorandum was also classified secret.

Seeking Tests On Human Beings

In the fall of 1947 the A.E.C., which

later became the Nuclear Regulatory Commission, established a division of biology and medicine and the Advisory Committee on Biology and Medicine, made up of outside experts to consider future human and animal experimentation.

Ten years earlier, 18 patients — the subjects of The Albuquerque Tribune article — were injected with plutonium to help track its course in the body. The committee has found that in 1947 the military proposed that more systematic studies be conducted. While this was disapproved, some individual experiments, including the injection of radioactive material into humans, continued in June and July 1947.

AEC reported requests from the military and private researchers to

conduct radiation experiments on humans. Dr. Shields Warren, the chief medical officer of the A.E.C., said in July 1949 that he was "taking an increasingly dim view of human experimentation."

The debate continued on one track, but so did the experiments on another, in the absence of firm policy to the contrary.

In 1949 a group called the Joint Panel on the Medical Aspects of Atomic Warfare was created to oversee the atomic-related research in the Defense Department. In the minutes of a meeting of the panel, it was noted that if ethical rules were adopted, "then obviously a great deal of our present human tracer studies must be discontinued." Tracer studies involve injecting minute amounts of radioactive chemical to

ack the biochemical pathways of a chemical's metabolism in the body.

The minutes also noted that there were "ethical and medico-legal objections to the administration of radioactive materials without the patient's knowledge or consent." And it said there would be a greater culpability of the Government "if a Federal agency condones human guinea pig experimentation."

The Defense Department tried to initiate experiments using atomic isotopes to conduct total-body irradiation experiments on healthy human subjects. Officials of the A.E.C., chiefly Dr. Warren, protested, but soon relented.

Since the A.E.C. controlled the supply of radioactive materials, Dr. Warren was apparently able to block some of the worst experiments, which called for total body irradiation of healthy subjects.

But some researchers were able to get around the commission's objections. Hundreds of people were irradiated, primarily at universities, by using cancer patients who presumably might have benefited, or at least whose lives would not be greatly shortened by the experiments.

By 1951, it was clear to the military and their medical establishment that it would be necessary to answer in detail many questions about the effects of radiation on humans, and that soldiers would have to be used as the guinea pigs.

In September 1951, the Joint Panel on the Medical Aspects of Atomic Warfare, and that soldiers were to be used as the guinea pigs.

In September 1951 the Joint Panel on the Medical Aspects of Atomic Warfare prepared a memorandum saying that there were numerous reasons to conduct human experiments in atomic bomb explosions, and later documents show that at least four of the human experiments mentioned were carried out.

Using 'Volunteers' In the Military

Among the problems that required experiments on humans, the panel said, were whether atomic explosion caused changes in visual acuity or light-blindness, whether radiation from the explosions could be measured in the body fluids of people near such blasts, whether any psychologi-

cal damage might come from being near an atomic explosion and whether flight crews would have any important exposure if they flew near a nuclear blast. Each of these experiments was carried out.

One of the experiments, called Operation Upshot-Knothole, included, "Subjecting 12 human volunteers and 700 rabbits to the initial light flash from six atomic detonations to investigate its effect on the visual function of the human eyes and to determine the burn injury processes in the dark-adapted rabbit eye," military records show.

The military's use of the word "volunteer" did not imply that informed consent was obtained. In essence, the subjects were ordered to participate; they were not always told what the risks would be.

In other experiments, airplanes flew through radioactive clouds. A report on one such test, called Operation Plum Bob, begins, "The objective of this project was to measure the radiation dose, both from neutrons and gamma rays, received by an air crew delivering an MB-1 rocket." Crewmen swallowed radiation film to help measure their exposure.

Another test was designed to see how well soldiers could perform after exposure to the flash of atomic detonations at night. "Human volunteers were dark-adapted in a light-tight trailer approximately 10 miles from the detonation. Their eyes were exposed to the flash. Some eyes were protected by a red filter, and some were unprotected."

The notes on the experiment said, "The project was terminated after Shot 4 in order to evaluate the significance of lesions of the retina which were produced in two of the subjects."

About 42 officers were included in a "selected volunteer program" in which they watched an atomic blast from 2,000 yards away. In other experiments, troops were brought in within 5,000 or 7,000 yards of ground zero in which atomic explosions, and were then marched to the site of the explosion just after the bomb had gone off.

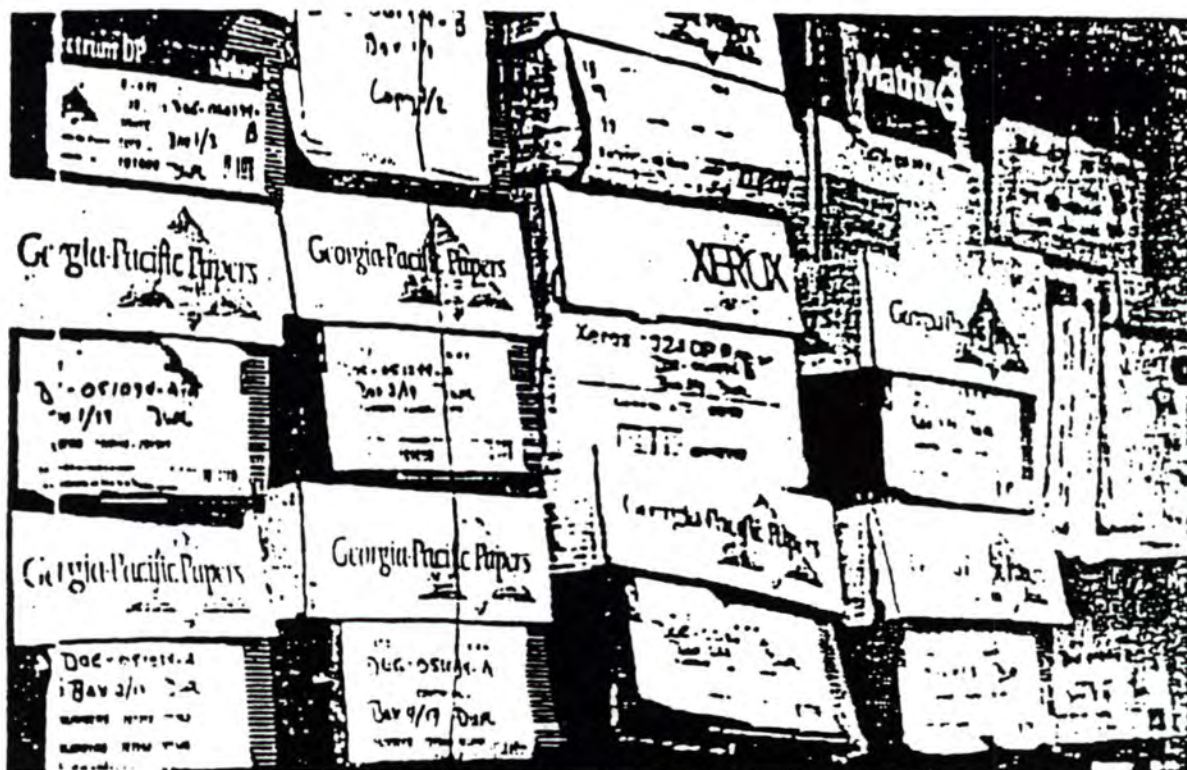
It is not yet known what happened to the subjects of these and other experiments.

In February 1953, after eight years of experiments without a consistent set of rules to govern them, Charles E. Wilson, then Secretary of Defense, prepared a memorandum saying that volunteers should be used as the only "feasible means for realistic evaluation and/or development of effective preventive measures of defense against atomic, biological or chemical agents." The memorandum added, "The voluntary consent of the human subject is absolutely essential."

It recommended using the Nuremberg Code which, if actually applied, would be stricter than current practices because it required detailed

It recommended using the Nuremberg Code which, if actually applied, would be stricter than current practices because it required detailed explanations of the hazards of experiments regardless of any claimed benefits, and allowed the subjects to terminate experiments at any moment. But these guidelines remained so highly classified that few if any people below the secretaries of the Army, Navy or Air Force were aware of them.

Staff members of the advisory committee said this created the zen-like question, "What is the effect of adopting ethical guidelines which are then kept top secret?"



After sifting through the archives of a dozen Federal agencies, the President's Committee on Human Radon Experiments has found that the number

of experiments was 10 times larger than previously known. Above are some of the boxes of research materials that members of the panel have inspected.

U.S. Is Urged To Repay Some in Radiation Tests

Blanket Apology Is Needed, Report Says

By PHILIP J. HILTS

WASHINGTON, July 16 — A draft report prepared for a Presidential panel says that the Federal Government should compensate some of the thousands of people who were made unwitting subjects of radiation experiments by Government researchers during the cold war era and should issue a blanket apology to all involved in the tests.

The report also states that the panel found evidence that the Government covered up several experiments, perhaps illegally, to prevent embarrassing publicity, and it warns that the nation still lacks sufficient safeguards to prevent similar research abuses from being repeated.

The panel, the President's Committee on Human Radiation Experiments, was formed last year after a number of questionable experiments came to light in which human subjects were exposed to radiation. The experiments were conducted between 1944 and 1974 and in some cases were intended to measure the effectiveness of radiation as a therapy for various medical conditions. In others there was no therapeutic rationale.

The committee will begin meeting here on Monday to consider the draft report, which was drawn up by staff members. A final report and recommendations will go to Energy Secretary Hazel R. O'Leary and President Clinton.

The panel found that thousands of radiation experiments had been carried out by the military, universities and medical centers. Many would be considered unethical by today's standards, and some were clearly unethical by any standards, the report said. For instance, high doses of plutonium were injected into 18 patients without their knowledge and for no therapeutic purpose, the report said. These patients were among those that the report recommended for compensation.

In another experiment, prisoners in Oregon were subjected to irradiation of their testicles without their consent. And in hundreds of cases, very small amounts of radioactive substances were fed to or injected into patients.

Most of the experiments had been previously disclosed after news reports on such research persuaded Mrs. O'Leary to order long-secret Government documents opened to the public.

Some of those documents, the panel found, had been classified not because of any compelling concern for national security but "out of concern for embarrassment to the Government, potential legal liability, and concern that public misunderstanding would jeopardize Government programs," the report states.

Such instances amounted to a cover-up, the staff wrote.

The committee found that as early as 1947 there was substantial discussion among military officials of the ethics of using radiation in experiments on humans. Policies were put in place to protect people in the experiments, but the policies often were kept secret and often were not enforced, the panel found.

The thousands of subjects in the experiments included a broad array of people — children at schools for the retarded, prisoners and patients in hospitals and clinics. The doses of radiation most received were small — less than that commonly received in medical X-rays today. But in some cases the amount of radiation was far greater, especially in cases that were not experiments per se but in which there was unplanned radiation exposure. The report cited as examples the residents of the Marshall Islands who were exposed during bomb tests in the Pacific, and uranium miners who excavated the material used to make bombs.

A warning that safeguards are still insufficient.

The committee found that in many of the experiments it was impossible to determine whether the subjects were informed and gave their consent. But there were some cases in which consent was asked for and received, and others in which consent was not sought.

Many of the experiments were unethical, the draft report concluded. In some of the experiments people were injured, though in most there were no injuries, the committee said.

The report says that perhaps a few hundred of those who got more than minimal doses of radiation are still alive more than two decades after the last experiment was conducted.

The committee found that under current environmental laws and regulations, "events that raise the same concerns" as the radiation experiments could take place in secret today.

There have been significant advances in the policies and practices of research since the 1940's and 1950's, the report said. However, it said, "the advisory committee also finds that there is evidence of serious deficiencies in some parts of the current system for the protection of rights and interests of human subjects."

The draft report said that the Government should make a public apology for the experiments, individualized where feasible, because it did not have — or did not enforce — rules to protect people from unethical experiments. "This recommendation reflects our view that some people were treated poorly and suffered, and that there is national duty to express regret," the report said.

The report recommended that the compensation be given to the subjects of those experiments "in which efforts were made to keep secret from these individuals that they were subjects of research." It said the compensation should cover "relevant medical expenses and associated harms (pain, suffering, loss of income, disability) to the subjects or their survivors."

Among the draft report's other conclusions were these:

¶The great majority of the thou-

sands of experiments that involved trace doses of radioisotopes similar to those used in research today were "not likely to cause physical harm." The committee did find, however, several experiments in which the doses were "in a range capable of causing acute radiation effects or a substantial increase in long-term risks."

¶Some Government agencies required researchers to get the consent of those they studied, but "the Government did not have comprehensive policies requiring the consent of all subjects of research" until 1974, and the policies that existed earlier were not enforced.

¶As early as 1944 it was routine for doctors and scientists to obtain consent from healthy subjects of research, but it was also routine to experiment on sick patients without their consent.

Dr. Ruth Faden, an ethicist from Johns Hopkins University who is the chairwoman of the committee, said the combination of historical fact-finding and moral analysis made the panel's task both unusual and difficult.

"We had a morally charged mission," Dr. Faden said.

"We did get very close to the flavor of the times," she added, "and because it was not so very long ago, the investigation was filled with tension. That is one of the most difficult of all tasks, to make judgments about the actions of others."

Daniel Berger, a lawyer who represents some of the victims of the radiation experiments and is participating in the Human Experiments Litigation Project, which will seek legal redress for victims, said in a telephone interview that the committee's work "may be one of the most important actions of the entire Clinton Administration."

But he was critical of the remedies offered in the preliminary report. For example, he said, the committee concluded that very low doses of radiation were harmless. "That is not known for certain," he said. "The question should be left open."

In addition, he said, "There is no provision for medical surveillance of the victims who are still alive, and that kind of follow up is essential."

SECTION: EDITORIAL PAGE; Pg. 10

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HEADLINE: Nuclear reparations

BODY:

The 50th anniversary of the beginning of the nuclear age this month was invoked in many memorials and testaments but found its most poignant resonance in a draft report issued last week by a panel charged with reviewing the human cost of three decades of American radiation experiments. If the recommendations of the final report, expected in September, bear much resemblance to the conscientious preliminary version, the president would do well to heed them in full.

In November 1993 a reporter in Albuquerque first brought to light the story of 18 hospital patients who were injected, without their knowledge, with large doses of highly radioactive plutonium between 1945 and 1947. Spurred by public outcry, President Clinton established the Advisory Committee on Human Radiation Experiments the following January.

Now the committee has released its first public report. After reviewing the conduct of roughly 4,000 experiments, including the irradiation of 74 children at Fernald State School in Waltham, between 1946 and 1956 and "several hundred" intentional releases of radioactive material into the environment, the committee has recommended "personal, individualized apologies" and the payment of reparations to many of those who served as unwitting guinea pigs for the US nuclear effort.

That is the least the government can do to make up for these reprehensible episodes.

The federal government did not devise comprehensive guidelines for the use of human subjects in scientific experiments until 1976. That is where the committee's survey ends. But its recommendations reach into the present. Noting that many federal environmental impact reviews are still conducted in secret, the panel rightly suggested an enhanced oversight role for the EPA. But with Congress poised to cut millions of dollars from that agency's budget, it seems unlikely to be able to handle such a responsibility.

The committee has undertaken an exhaustive and difficult task. If only by revealing the facts, it should help close the book on a benighted chapter of American history.

EDITORIALS

Radiation Investigation Serves Past and Future

DOCUMENT BY DOCUMENT, individual story by individual story, the White House Advisory Committee on Radiation Experiments is bringing to light the extent of government-sanctioned radiation and nuclear tests between 1944 and 1974.

Just last week, the committee uncovered reports detailing a 1950s international cam-

"We want to be able to say, 'You don't have to worry about surreptitious experiments' "

paign of deception aimed at hiding the fact that the U.S. government gathered human remains and other data to measure fallout from U.S. atomic weapons tests.

In its 10 months of existence, through hearings and reviews of hundreds of thousands of docu-

ments — many of them previously classified — the presidential panel has compiled examples of questionable radiation experiments on humans, both with and without their consent.

A middle-aged woman testified about being pulled out of her second-grade class in Richland, Wash. — where her father worked at the country's main plutonium site — to be given unidentified liquids to drink. She was required to make follow-up doctor visits for the next six years. Service personnel told of seeing the shadow of their bones when they were exposed to Cold War atomic-bomb tests. Former inmates recounted 1960s experiments in which their testicles were deliberately exposed to strong doses of radiation.

The 13-member committee — made up of experts in bioethics, radiation oncology

and biology, history of science and medicine, epidemiology, nuclear medicine and law — is drafting a report, due in May, with an eye toward determining possible compensation, medical follow-up or remedies to people who were victims of past government radiation experiments.

But equally important, the scientists are focusing on the future. Included in the panel's report will be recommendations for an ethics policy for current and future government research experiments based on lessons learned from the Cold War tests as well as from studies of current radiation-related experiments.

"We want the area of radiation therapy to advance," said Dr. Ruth Faden, committee chairwoman and a bioethicist at Johns Hopkins University. "We want to be able to say to the American public, 'When you go into a hospital, you don't have to worry about surreptitious experiments being done.' "

The questions for which the panel sought answers on U.S. action in the three decades following the dawn of the Atomic Age — What ethics criteria were used to evaluate human radiation experiments? What codes of conduct, if any, existed to govern federally sponsored experiments? Who developed them? How were they put into effect? — still apply today, despite more rigorous standards.

Right now, experiments are being conducted that may one day spell the end of certain kinds of cancer or cure other diseases. Both science and humanity will be served if those who take part in such experiments enjoy the peace of mind that comes with the knowledge that they are part of a scientific test being performed in an atmosphere of the highest ethical standards. The committee could make a significant contribution toward that goal.

Radiation Subjects' Stories Tumble Out

Federal panel brings inquiry to S.F.

By Kenneth J. Garcia
Chronicle Staff Writer

Israel Torres knelt in a trench one mile from ground zero during a 1957 atomic bomb test in Nevada. Richard Harley crouched on the deck of an escort carrier 30 miles from a 1953 thermonuclear test at the Eniwetok atoll. Emma Craft was one of 829 pregnant women fed radioactive iron beginning in 1945 at a Tennessee hospital.

Their stories, recounted in a public hearing in San Francisco yesterday, are part of the official record being assembled by the President's Committee on Human Radiation Experiments, the federal panel making a detailed inquiry into tests conducted on people over a 30-year period at scores of

U.S. sites around the world.

The panel was appointed by President Clinton to determine the government's responsibility for harm to human subjects as a result of experiments with radiation. Its first meeting outside Washington underscored the daunting task the committee faces in piecing together the scattered and perhaps most secretive segments of the Atomic Age.

Although many of the victims have detailed memories of their involvement in experiments, in many cases there is no written record of the tests; others are still classified by the federal government for national security reasons. Incredibly, it appears that in some cases the children of military per-

TESTS: Page A15 Col. 1

sonnel were volunteered by their parents for inclusion in experiments that were neither defined nor concluded.

"I just want to get some answers, and that's why I'm here today," Darcy Thrall told the panel at the San Francisco Press Club yesterday. "I want to know what's been done to me and what I can expect to happen . . . whether I have five years or 35 years (to live)."

Thrall's father worked at the Hanford weapons plant in southeastern Washington state, the country's main plutonium production site. She told the panel she was pulled out of her second-grade class in Richland, told to drink some liquids and then monitored periodically by doctors for the next six years. She wore government-issue dog tags for years, but to this day she does not know the reason for the experiment or whether it was responsible for the numerous health problems she has suffered, including hypothyroidism and chronic fatigue syndrome.

Panel members believe that as many as 600 tests may have been conducted on U.S. citizens.

"At our core, we are an ethics committee," said panel chairwoman Dr. Ruth Faden, a bioethicist at Johns Hopkins University. "We are very keen to hear from everyone who thinks they have something to help us with our charge, including the ethics of the work being conducted, whether any government agencies were responsible, and to come up with remedies and recommendations to address this problem."

The panel includes radiation experts, public health specialists, an epidemiologist, a historian and



BY LEA SUZUKI/THE CHRONICLE

Darcy Thrall read to a government panel from the dog tag she was given as a 7-year-old participant in a radiation experiment

a lawyer. Members have searched through hundreds of thousands of documents related to human experiments and have found records from several military committees that discussed the need for radiation data — and secrecy — beginning in the late 1940s.

In 1949, two years after the Atomic Energy Commission established a medical division to consider human and animal experiments, 18 patients were injected with plutonium to help track its path through the human body. The patients were the subject of a series of stories published by the Albuquerque Tribune last year that ultimately led Clinton to establish the committee.

The secret "Atomic Medicine Division" of the Veterans Administration may have been involved in exposing U.S. service personnel to radiation during post-World War II atomic-bomb tests and assessing

the effects. Yesterday, two of the men involved in those tests testified before the panel.

Torres, then a 23-year-old Marine platoon sergeant, was ordered to lead a battalion into a trench at Yucca Flats, Nev., in 1957, where they were told to kneel during the detonation of a weapon, nicknamed "Hood." He said that when the shock wave from the blast hit, the trench began to collapse and the wind nearly sucked them out into the open desert.

"The light was so bright I had to cover my eyes with my hands, and I immediately got blisters on the heat," said Torres, who lives in a small central coast town in California. "Then the trucks and equipment started showing up, and I was placed in a van and taken to a hospital" for a number of lengthy and painful tests.

"All I ask of you is the truth,"

Torres said. "All I ask is for justice for any of the people who died due to this stupidity."

Harley, who was aboard a U.S. naval ship assigned to the Marshall Islands, said he was part of a group of men told to squat on deck during one of the 66 known nuclear tests conducted near the Marshall Islands from 1947 to 1958.

"We were told that any personnel who were to be witnesses should bend down with their backs to ground zero and to remain in that position," he said. "The brightness from the blast was so great that I could actually see the shadow of my bone through my arm."

The very existence of the atomic-medicine unit had been kept secret because of Veterans Administration concerns about disability claims. Numerous victims, and spouses of the victims, have said that their claims have continued to be rejected by the government.

Craft's story, as relayed by her lawyer, Don Arbitit of San Francisco, is the subject of a class-action lawsuit filed against Vanderbilt Hospital in Tennessee and the federal government. She was one of 829 pregnant women given radioactive iron during a two-year study.

It was only in the 1969 publication of a follow-up study in an obscure medical journal that Craft discovered she was one of those included in the study. The story detailed the death of her 11-year-old daughter, who died of a rare form of cancer.

"Her daughter suffered a slow, painful, gruesome death, and Emma always believed it was due to an act of God," Arbitit said. "It wasn't until much after that she believed that this tragedy was due to intervention by humankind."

Ethicist Gets Dream Job in Report on Experiments

By PHILIP J. HILTS

Special to The New York Times

WASHINGTON, Jan. 27 — For a professor of ethics, it is the chance of a lifetime, a chance to, as Dr. Ruth R. Faden puts it, "rewrite the history of ethics and research on human subjects in this country."

Dr. Faden was named by the White House this week as chairwoman of the Federal advisory committee of experts that has been assigned to do a report on the history and ethics of the Government's radiation experiments on humans that have been recently receiving so much attention. It is an opportunity to review in one stroke the ethical practices of doctors and scientists in the United States over the past half-century.

In some ways, for Dr. Faden, 44, a professor at the Johns Hopkins School of Hygiene and Public Health and a scholar at the Kennedy Institute of Bioethics at Georgetown University, her whole life has been preparing her for this chance: she is the daughter of parents who are survivors of the Holocaust; her father spent two years in Auschwitz and her mother two years in Birkenau. She says she has been reflecting throughout her life on "the problems of evil and of right conduct."

Drawn In by Family History

It is easy to see now, she says, how her family's history drew her over the years to the subject of informed consent, which has become her specialty, and to this particular job.

Her field, particularly women's health issues like forced sterilization, has burgeoned over the past three decades, and she has bloomed along with it. In 1986 she and her husband, the philosopher Dr. Tom L. Beauchamp, published "The History and Theory of Informed Consent," (Oxford University Press), widely regarded as the authoritative volume on informed consent.

The new advisory committee will review the radiation experiments before trying to decide what standards of ethics should be used to judge the Government officials and doctors who carried them out, as well as what kind of compensation might be made to the survivors.

As recently as the 1960's the standard that determined when a doctor was obligated to tell patients about the risks of a procedure and ask them for their consent was based on what was "customary" among doctors. A 1972 court case, *Canterbury v. Spence*, radically changed that standard. Since then, doctors have been required to give patients enough information "for a reasonable person to make a decision" about whether to go ahead with a treatment or experiment.

But recently, bioethicists have concluded that while that standard may be acceptable legally, it is not sufficient morally. Many patients have special fears, or need special information to



Marty Katz for The New York Times

Dr. Ruth R. Faden, a professor at the Johns Hopkins School of Hygiene and Public Health, who was named chairwoman of the Federal advisory committee of experts assigned to report on the history and ethics of the Government's radiation experiments on humans.

make a sensible choice, so they need more than the reasonable-person standard. This third standard is the "subjective standard," under which a doctor must be sure that patients understand that their signing consent forms means that they are authorizing a treatment or experiment, that they know what the risks are and that they have an opportunity to say no.

"Morally," said Dr. Beauchamp, "the subjective standard is the right one, but legally it would put doctors in a very precarious situation if they had to meet it in every case. Ruth was working through those issues in the days when no one else had."

Although the experiments using radiation on humans were not secrets and a Congressional committee held

hearings in 1986 on them, they were a surprise to Dr. Faden. The hearings were only sparsely covered by the news media and there was virtually no public discussion. "I did not know about these experiments," she said. "It's my field! And why did this story take off now, years after the committee hearings? It's fascinating."

She was impressed that one reporter, at The Albuquerque Tribune, had uncovered so much of the origin story and also that Hazel O'Leary, the Energy Secretary, had responded with the decision to investigate fully. The committee's job as she sees it is not only backward looking, reviewing the evidence, but looking forward as well. It must judge whether current practices and standards would prevent similar abuses now and recommend what might be done if they do not.

Need to Have a Standard

As she sees it, the most difficult task for the advisory group will be deciding what standard of ethics to measure the experiments against.

Under the customary-practice standard much of the experimentation may be found acceptable. But under the stricter subjective standard, in which each person's knowledge and feeling must be considered separately, many of the experimenters may be accused of misconduct.

Dr. Faden said the opportunity for a scholar to study programs like this with the cooperation of the Government came only rarely. "It is very important that we do it," she said. "Unless people trust doctors, research will not be able to go on. Deception in research, we need to remind doctors, is not in their own interest. We all work at the sufferance of the people. A deceived research subject is an angry person who will shy away from research and tell other people to do that too."

Academically, she said, the opportunity is to "deconstruct some of the myths of medicine and give them meaning in human terms."

The committee is expected to work on the review for a year and submit an interim report six months from the time the group begins meeting, probably in February.

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September 26, 1995

BACKGROUND INFORMATION FOR PHIL CAPLAN

FROM: Tara O'Toole, M.D., M.P.H.
Assistant Secretary
Environment, Safety and Health

SUBJECT: Briefing on the Report of the Advisory Committee on Human Radiation Experiments

The Advisory Committee on Human Radiation Experiments is scheduled to present its final report to the President on Tuesday, October 3rd. Time has been reserved on the President's calendar for a White House event to receive the report. Over the past six (6) weeks, representatives of all agencies involved in this project have been meeting to shape a government-wide response to the Advisory Committee's findings and recommendations.

This memorandum describes the background and process that led to this point, the accomplishments of the Federal agencies acting in cooperation with the Advisory Committee, the Advisory Committee's major findings and recommendations and the proposed Government response thereto, benefits of the project and some potential issues relating to the release of the final report.

BACKGROUND AND PROCESSES

Early Events

- In 1986 Congressman Edward Markey (D.Mass) issued a report entitled *American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens*. This report discussed approximately 30 human radiation studies; it engendered relatively little media interest.
- In November 1993, the Albuquerque Tribune published articles by reporter Eileen Welsome describing experiments during World War II where hospital patients at several locations around the country were injected with



plutonium. Family members interviewed by Welsome denied that the subjects had given their consent.

- In December 1993, Secretary of Energy O'Leary acknowledged the Tribune articles and publicly released additional declassified documents related to the plutonium injections; she committed DOE to locate, declassify and disseminate as much information as possible about human radiation experiments sponsored by the Department of Energy and its predecessors, the Manhattan Project and the Atomic Energy Commission. Media coverage and public response was intense.
- Articles appeared in other newspapers describing other experiments, including some with retarded children in Massachusetts.
- The Secretary established a toll-free hotline to receive inquiries from those who believed they or a family member may have been a radiation experiment subject. This was soon expanded to include other agencies. Over 20,000 calls were ultimately made to the hotline.

Establishment of the Interagency Working Group and the Advisory Committee

- In January 1994, the President established a Cabinet-level Human Radiation Interagency Working Group to provide a coordinated Federal response to this issue. It included the Department of Energy, the Department of Defense, the Department of Veterans Affairs, the Department of Health and Human Services, the National Aeronautics and Space Administration, and the Central Intelligence Agency.
- The President issued an Executive Order (E.O. 12891) establishing an Independent Advisory Committee on Human Radiation Experiments to provide expert advice and recommendations. Federal agencies were directed to provide the committee with the historical records and other information needed to complete its work.
- The Secretary of the Cabinet issued a directive calling for a Government-wide records inventory and retrieval focussing on:
 - Experiments on individuals involving intentional exposure to ionizing radiation, not including common and routine clinical practices; and
 - Intentional environmental releases of radiation designed to test human health effects or the extent of exposure; and

- Specified releases of radiation to the environment including a series of tests investigated in a 1993 GAO report requested by Senator John Glenn.
- The Advisory Committee, chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University, considered the following issues:
 - the medical and scientific purpose for human radiation research sponsored or conducted by the government;
 - whether appropriate medical follow up was undertaken and whether any subjects should be notified now in order to take steps to protect their health;
 - whether experiments met the ethical and scientific standards of the time and those that exist today; and
 - whether current human subject research safeguards are adequate to prevent recurrence of ethical abuses.

Activities of the Committee

- The Advisory Committee met monthly in public from April 1994 through July 1995 and took testimony from experiment subjects and their advocates, research institutions, and government representatives. Several outreach meetings around the country were also held. The Committee made the drafts of its report publicly available.
- The Committee also reviewed 125 current federally-sponsored studies (not limited to radiation - related research) and interviewed patients at leading hospitals in order to gauge the adequacy of procedures for evaluating the risks of research and for obtaining informed consent from subjects, and to sample attitudes toward human subject research.
- At the behest of advocacy groups, the committee considered issues related to some radiation exposures associated with government activity that were not "experiments" - that is, persons who were not exposed for the purpose of research. These include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from a U.S. nuclear weapons test in 1954.

ACHIEVEMENTS FOR OPENNESS

- Given the state of the government's records, we cannot claim to have found every document bearing on human radiation research. Nonetheless, a broad and thorough search has yielded an enormous amount of information and allowed us to see the big picture.
- The historical record of an important part of the history of this country was assembled in an unprecedented exercise in openness.
- Federal agencies mounted a nationwide, coordinated search for records dating back to World War II. These records were often ill-organized and poorly indexed and scattered at dozens of locations around the country. An estimated 840,000 pages of documents were ultimately delivered by the agencies to the Committee and research was done for them on many topics.
- The Department of Defense and the Department of Energy declassified over 7,000 documents during the course of this project. (Most pertinent documents were not classified; they were unidentified and inaccessible because they were submerged in a sea of government records.)
- The record is being made directly accessible to the public by means of cutting edge technology. Over 250,000 pages of original DOE documents related to human subject radiation research dating back to the Manhattan Project are now available on the Internet. The other agencies will be adding their documents to this database. People can search the documents and print them out at their desks.
- DOE published and widely distributed two volumes describing the general scope and purposes of human radiation research sponsored by the Department and listing and describing some 435 such studies. Other agencies provided lists of experiments.

THE MAJOR FINDINGS OF THE ADVISORY COMMITTEE

Historical Experiments and Population Exposures

- Several thousand government sponsored human radiation experiments were conducted from 1944 to 1974; only fragmentary information survives for most experiments. Few documents survive that shed light on whether

individuals gave informed consent.

- Most experiments were done to advance medical science; the great majority of subjects received low doses unlikely to cause them physical harm.
- Human radiation experimentation during this period contributed significantly to medical advances and thus to the health of the public.
- Some agencies had policies on human subject research as early as the 1950s, but these were generally not effectively implemented.
- Some government agencies required the consent of some research subjects even before 1944, but the government did not have comprehensive policies, covering both healthy subjects and patient-subjects, until 1974.
- It is unlikely that the public was directly harmed solely as a consequence of the environmental releases of radiation. The most severe exposures to non-patients occurred not in biomedical experiments, but to uranium miners.

Trust, Openness, and Secrecy

- Public trust in government is perhaps the biggest casualty of the human radiation experiments and intentional releases.
- Events and data from experiments were sometimes kept secret for reasons of public relations, embarrassment, and concern for legal liability. Examples include: the World War II plutonium injections; secret environmental releases; world-wide fallout studies prior to the 1963 Atmospheric Test Ban Treaty where the amount of such elements as strontium-90 were measured in the human body; and uranium miners.
- The government did not routinely create or maintain records needed to assure that secret programs could be accounted for in later years.
- The management of historical government records in general has contributed to public mistrust of the government. Poor recordkeeping and lack of accessibility has made it difficult to establish facts.

Current Human Subject Protection

- In comparison to the policies and practices of the 1940s and 1960s, there have been significant advances in the protection of the rights and interests of human subjects. However, the current human experiment system is not working as well as it should.
- Most subjects face minimal risks from participation in research but there are problems with, for example, lack of clarity in consent forms, unrealistic expectation by patients of the potential that participation in research will benefit them directly, and the use of persons with diminished mental capacity.
- Environmental releases such as those identified in the Advisory Committee charter could take place in secret today under the current environmental laws and regulations.

THE COMMITTEE'S RECOMMENDATIONS AND THE PROPOSED GOVERNMENT RESPONSE (the full text of all the Advisory Committee recommendations are attached, along with a more detailed discussion of the proposed government response)

Biomedical Experiments and Population Exposures 1944-1974

- The Committee recommends that the government:
 - apologize and compensate the families of World War II era plutonium and zirconium injections and total body irradiation (TBI) because the government misused secrecy to keep the subjects uninformed. (The Committee does not find that these people were physically harmed).
 - apologize and compensate subjects if a court or other forum finds that they were physically harmed.
 - amend the Radiation Exposure Compensation Act (RECA), the law passed in 1990 to provide compensation to persons harmed by nuclear weapons testing and uranium miners, if data shows that additional groups, such as those living downwind of the Hanford plutonium - production complex, are at increased risk of cancer.

- review the fairness of compensation laws related to the uranium miners and the so-called "atomic veterans."
- continue DOE medical programs for Marshall Islanders and consider whether it should be expanded.
- The proposed government response endorses the basic thrust of the Committee's recommendations and suggests a number of specific processes and mechanisms for carrying these out.

Current Human Subject Protection

- The Committee recommends that the government:
 - undertake a national effort to ensure the central importance of ethics in the conduct of researchers whose work involves human subjects.
 - improve the Institutional Review Board (IRB) system, which is the mechanism established by regulation for approval of federally-funded human research.
 - establish an open forum for the continuing review and interpretation of ethical rules as they apply to human subject research.
 - improve the protection of the rights and interests of military personnel with respect to human subjects research, including a review of policies and procedures, better training for officers and investigators in applying the regulations, maximizing voluntariness, and maintenance of a registry of volunteers by all the services.
 - improve oversight, sanctions and scope by 1) conducting regular, periodic applications based on examining outcomes and performance 2) reviewing whether sanctions for violations are adequate; and 3) extending protections to non-federally funded research.
- The proposed government response:
 - remands certain issues to the proposed National Bioethics Advisory Commission which will provide expert advice on issues of ethics;
 - endorses enhanced ethical education in partnership with external

groups such as medical schools, universities, scientific societies, and others;

- involves pooling resources across agencies to conduct pilot projects to improve the efficiency and effectiveness of IRB review and to evaluate the system overall; and
- considers proposing legislation to address some of the gaps in the current system for protecting human subjects such as extending requirements for protection of human subjects of research not funded or conducted by the Federal Government.

Secrecy and Openness

- The Committee recommends:
 - in cases of classified human research, any waiver of informed consent procedures should be prohibited.
 - independent review of classified human research and classified environmental releases; permanent retention of related records.
 - the Interagency Working Group should ensure continued movement toward making historical records accessible by 1) moving records into the Archives more quickly 2) making indexes and finding aids readily available 3) improving public access to records that remain in agencies 4) maintaining records of document destruction and 5) reviewing policies governing access to records of grantees and contractors.
 - review of CIA recordkeeping and high priority to the declassification of CIA records on human research including the MKUltra LSD experiments.
- The proposed government response:
 - Includes a Presidential directive that no waivers of full informed consent will be permitted in classified research and disclosure to the subject of the government agency sponsoring the research;
 - requests that EPA review whether additional steps are necessary to ensure robust environmental oversight of classified programs;

- directs the Interagency Working Group, in conjunction with the National Archives, to develop an aggressive plan to increase accessibility of government records;
- redesignates records relating to human subjects research as permanent to prevent future records destruction; and
- involves a high-priority review by the National Archives of the CIA record-keeping system, including addressing means to improve public access and directs CIA to give top declassification priority to human subject research records.

BENEFITS

- Despite occasional media sensationalism and the trepidation of some in the scientific community with the scrutiny associated with this effort, this is a good story for the Administration:
 - when we started down this road, we were aware of a few high-profile and very troubling experiments — we did not know whether these were aberrational, nor did the government have an idea of the scope and purpose of government-sponsored human radiation research generally.
 - without excusing the dark side of this research, this open examination of the historical record allows the government to acknowledge its mistakes as well as the immense medical benefits achieved by much of this research.
 - people are able to see that the government is committed to preventing the misuse of science and technology, thus creating an environment where good programs can go forward.
- For this Administration, the most likely positive enduring legacy of this project may be the enhancement of openness:
 - large amounts of information were found and cutting edge technology was used to put this information directly into the hands of the people.
 - providing this information has offered an opportunity to begin to heal the wounds that resulted from government projects carried out with

secrecy and deception during the War and the Cold War.

- with the ending of the Cold War, there is an opportunity to frame this project as part of a strong, continuing effort to rebuild trust, and to support and extend democratic government, by making records and information consistently and readily available to the people to whom they belong: the citizens of this country.

POTENTIAL ISSUES/CONSEQUENCES OF THE RELEASE

- In the past, media attention has often focussed on the most controversial or sensational aspects of these experiments and releases, such as the involvement of vulnerable populations; at the same time, the Administration has generally been credited for openness, accountability and rebuilding public trust in government institutions.
- Due to the passage of time and the survival of only parts of the historical records, the Committee has been able to reach very few definitive judgments on the ethics of individual experiments and on the likelihood of harm to individuals. There will be some unmet expectations, but these should be blunted by a commitment to continue the process of openness and dialogue.
- There is a risk that the Committee's criticism of current human subject protection practices could harm the cause of ongoing important human research. The Committee and the agencies are seeking to obtain the support of important elements of the research and scientific communities for their message for more attention to ethics, and the fact that we seek to act in partnership with these institutions should be stressed.

Attachments: *American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens* (the Markey Report); Article by Eileen Welsome from the Albuquerque Tribune; Memorandum from the Secretary of Energy of 12/23/95; Memorandum for Heads of Departments and Agencies from the Secretary to the Cabinet of 1/19/94; *Human Radiation Experiments: the Department of Energy Roadmap to the Story and the Records*; *Human Radiation Experiments Associated with the U.S. Department of Energy and its Predecessors*; Pamphlet: *Human Radiation Experiments 1946-1974, The Clinton*

Administration's effort to find the facts; Pamphlet: HREX, Human Radiation Experiments Information Management System; and Recommendations of the Advisory Committee on Human Radiation Experiments.



Department of Energy

Washington, DC 20585

August 23, 1995

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MEMO TO: PHIL CAPLAN
WHITE HOUSE
OFFICE OF STAFF SECRETARY

FROM: TARA O'TOOLE, M.D., M.P.H. *Tara*
DEPARTMENT OF ENERGY
OFFICE OF ENVIRONMENT, SAFETY AND HEALTH

SUBJECT: BACKGROUND ON ADVISORY COMMITTEE ON HUMAN
RADIATION EXPERIMENTS

The President is scheduled to receive the Advisory Committee on Human Radiation Experiments' Final Report on September 22, 1995. This memorandum will describe the process that has led to this point and the major issues raised by the Advisory Committee's work.

BACKGROUND

■ **December 1993:**

- Secretary of Energy Hazel O'Leary released declassified documents concerning 18 persons injected with plutonium by Manhattan Project physicians and promised to find all Departmental records related to human radiation experiments.
- Secretary O'Leary established a hotline to receive inquiries from those who believe they or a family member may have been a radiation experiment subject (20,000 persons ultimately called).

■ **January 1994:**

- President Clinton directed other Federal agencies to search for documents related to human radiation research from World War II to 1974 (when government-wide regulations on human subjects research were adopted).
- The Interagency Working Group was established by President Clinton to coordinate the search for records throughout the Federal government. Members included the Secretaries of the Departments of Energy, Defense, Health and

Prepared by the Department of Energy, August 23, 1995



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Human Services and Veterans Affairs, the Attorney General, the Administrator of the National Aeronautics and Space Administration, and the Directors of the Office of Management and Budget and the Central Intelligence Agency.

- President Clinton established the Presidential Advisory Committee on Human Radiation Experiments, chaired by bioethicist Dr. Ruth Faden of Johns Hopkins. The Committee was charged to review the records of the Federal agencies and provide expert advice to the Interagency Working Group on the following issues related both to biomedical experiments and a list of intentional environmental releases of radiation:

- * The medical and scientific purposes for human radiation research sponsored or conducted by the government;
- * Whether appropriate medical follow up was undertaken and whether any subjects should be notified now in order to take steps to protect their health;
- * Whether the experiments met the ethical and scientific standards of the time and those that exist today; and
- * Whether current human subject research safeguards are adequate to prevent recurrence of ethical abuses.

■ **April 1994 through July 1995:**

- The Committee met monthly in public; took testimony from experiment subjects and their advocates, research institutions, several government representatives; and made the drafts of its final report publicly available.
- Federal agencies mounted a nationwide, coordinated search for records dating back to World War II. These records were often ill-organized and poorly indexed and were scattered at dozens of locations around the country. The fruits of this search were an estimated 840,000 pages of documents delivered by the agencies to the Committee.
- The Committee reviewed 125 current or ongoing Federally-sponsored studies (not limited to radiation-related research) and interviewed patients at leading hospitals in order to gauge the adequacy of procedures for both evaluating the risks of research and obtaining informed consent from subjects and also to sample attitudes toward human subject research.
- At the behest of advocacy groups, the Committee considered issues related to some radiation exposures associated with government activity that were not

"experiments" -- that is, persons who were not exposed for the purpose of research. These include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from a U.S. nuclear weapons test in 1954.

COMMITTEE FINDINGS AND RECOMMENDATIONS

The passage of time, inevitable gaps in the historical records -- including the difficulty in finding records documenting consent procedures -- and the sheer volume of human radiation research sponsored by the Federal government, precluded the Committee from reviewing the details of more than a few high profile experiments. The Committee, therefore, focused on identifying the ethical standards that applied to the government and to the medical profession in the post-War period and on looking forward at whether the current system for the protection of human subjects in all areas of Federally-sponsored research is adequate to prevent ethical abuses.

A very abridged version of the Committee's findings and recommendations follows:

■ **Biomedical experiments and population exposures, 1944-1974**

- The Committee finds that the government was aware of the need to obtain informed consent from subjects, particularly for research with no potential benefit to the subjects ("non-therapeutic" research) but did not effectively implement policies to ensure that consent was obtained.
- The Committee finds that in the area of experimental treatment, where sick persons were the subjects, physicians generally did not recognize a need to obtain consent from patients.
- Compensation is recommended for the families of a small group of subjects in World War II-era experiments, even though no physical harm apparently resulted, because the government misused secrecy to keep subjects uninformed (the 18 plutonium injection subjects and a few others).
- The fairness of laws governing compensation of atomic veterans, uranium miners, and other populations put at risk by the nuclear weapons program should be re-assessed.

■ **Current human subject protection**

- The Committee finds that, while improvement has been substantial, serious deficiencies exist in the current system for human subject protection in Federally-funded research.

- The Committee finds that the high level of trust reposed by patients in their physicians can present a conflict of interest when consent is sought for participation in clinical research.
 - The Committee calls for enhanced education in ethics throughout the medical and research communities. The Committee also recommends a series of measures to ensure that research is clearly distinguished from treatment in obtaining consent, that risks are more clearly stated, that oversight by the Federal agencies is improved, and that a mechanism for continued interpretation of ethical rules is established.
- **Secrecy and openness**
- Public distrust, while arguably disproportionate to physical harm actually done, has been fueled by decades of secrecy. Extra protections for classified research are recommended, as are steps to make historical records more accessible.

GOVERNMENT RESPONSE TO RECOMMENDATIONS

A group of representatives from the Federal agencies, with participation by OMB and OSTP, has been meeting over the past month to consider government-wide options to address the issues raised by the Committee and propose actions that Federal agencies may take individually and cooperatively, as well as steps that the President may wish to announce. The Group plans to present its product to agency principals by Labor Day and to the President shortly thereafter.

MEDIA INTEREST IN THE FINAL REPORT PUBLIC RELEASE

WHO:

- National and international media interest in the human radiation experiments has been intense. Media covering the issue include medical and science publications as well as consumer electronic and print media.
- Major dailies, including the *Washington Post*, *USA Today* and *New York Times*, regularly cover Department of Energy human radiation-related announcements. Regional media coverage -- whether or not local angles exist -- has been strong as well. Broadcast reporters from ABC, CBS, CNN and NPR keep in touch with the Department of Energy on the issue. The issue also is good "fodder" for editorial coverage and analysis.

- The August announcement has raised interest in the September event; *Time* magazine decided to hold its story for the September announcement. Networks asked about September as well.

HOW:

- Generally speaking, the coverage is "on message": The Administration is credited for openness, accountability and building public trust in government institutions. Coverage of the most recent announcement notes the medical benefits that Americans have derived, partly as a result of these types of tests. Negatives include:
 - There has been comparison among government agencies on level of secrecy/openness, creating distinctions among Cabinet agencies.
 - Some analysis compares the experiments to the Nazis.
 - Coverage always notes the sensational aspects of the experiments, particularly those held on vulnerable populations.
 - Coverage could focus on problems found in current research practices.
- In addition to Administration spokespeople, sources include:
 - Cooper Brown, Task Force on Radiation and Human Rights, who advocates for participants/subject in the experiments;
 - Rep. Edward Markey (D-MA) who has pushed for disclosure since 1986; and
 - Spokespeople from local universities and hospitals where experiments were conducted.

NEXT STEPS:

- We believe that the President's announcement can generate strong, positive attention from the media and the American people. In addition to the event, which is certain to generate extensive media coverage, the White House should consider efforts that make the issue an area of informed discussion by the American people:
 - Town hall meeting with members and staff of the Committee, scientists, radiation subjects advocacy group representatives engaged in the issues, the Secretary of Energy, Cabinet Secretaries, and members of Congress;
 - *Parade* magazine article by [famous doctor?? university president?] that can both credit the President for openness, as well as enumerate medical benefits;

- Opinion editorial by Dr. Ruth Faden for placement in the *Washington Post* or *New York Times*;
- Outreach to columnists in national and local newspapers;
- Outreach to editorial boards;
- Online forum on CompuServe or America Online with ethicist, maybe Dr. Ruth Faden; and
- Radio talk shows throughout the country.

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INTERAGENCY TALKING POINTS

RELEASE OF THE REPORT OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

October 3, 1995

President's Message: Responsible and Open Government

- o The President came to office determined to repair the trust between the American people and their government.
- o He committed the resources of the government to opening the door to the past; even if wrong did not happen on our watch, we were determined to set it right.
- o This is about what people in power owe to those they serve.
- o We are taking steps to make sure that wrongs never happen again.

Interagency Talking Points

This has been an unprecedented exercise in openness

- o The Federal agencies searched archives, records centers, vaults, libraries, and warehouses around the country.
- o Altogether, the agencies delivered about 840,000 pages of documents dating back to World War II to the Advisory Committee.
- o Over 3,200 documents were declassified.
- o Information and the tools to acquire it have been made accessible to the people: electronic databases were created and over 250,000 pages of original documents were placed on the Internet to date -- thousands more will be added to the Internet by all of the agencies in the coming months.
- o We opened the door on historical human radiation experiments without knowing what was on the other side -- we did it because we believe that, whatever was discovered about the past, it is better to tell the truth in order to rebuild trust with the American people.

- o The combined cost of the interagency effort, including support of the Advisory Committee has been about \$31 million.

The Advisory Committee found some cases of ethical wrongs, laid out an ethical framework for assessing other cases, and found that most radiation experiments were conducted safely and for valid scientific reasons.

- o The Committee identified a discrete set of cases during World War II and the Cold War (about 25) where the government failed to respect the dignity and rights of individuals by misusing secrecy to keep the nature of the experiments from the subjects. (These are the Manhattan Project plutonium injections and a few additional cases)

- The Committee has recommended compensation for the family members of these persons, all now deceased. We agree that fair and reasonable compensation should be made available.

- o The Advisory Committee laid out an ethical framework for the future: They conclude that if ethical wrong and physical harm were done to a subject, the government should make fair and reasonable compensation available.

- o In the coming days, we will consider how best to meet the objectives of these recommendations.

- o The Advisory Committee also found, and for this all Americans can be grateful, that the great majority of human radiation experiments were done safely, for valid and often very important scientific reasons, and that they did not place the research participants at increased risk of health problems.

The Advisory Committee highlighted issues of concern in current research that we will vigorously pursue.

- o The Committee's review of current research highlighted some issues of concern, particularly for research into new medical therapies, including:
 - The clarity and completeness of consent forms in describing the risks of participation and the true potential for benefit to the participants;
 - The need to distinguish clearly between research and therapy when communicating to patients; and

- Fairness in making experimental therapy for disease available to all groups.
- o The Committee also found that current research involving radioisotopes is subject to more safeguards and levels of review than human subjects research generally.
- o In accordance with the Executive Order issued by the President today, all Federal agencies that sponsor human subjects research will immediately review their rules and practices in light of the Committee's findings.

QUESTIONS AND ANSWERS
INTERAGENCY WORKING GROUP ON
HUMAN RADIATION EXPERIMENTS

- Q: How does the government feel about the fact that only 25 people are recommended for compensation in the Committee's report?
- A: It is first of all important to bear in mind that this was a Committee that focused on ethical, not compensation issues. The Committee laid out ethical guidelines for determining compensation for all persons who were harmed by the government. In cases where people were ethically wronged and physically harmed through the fault of the government, we will pursue fair compensation.
- Q: Does the government agree that the people noted in the report as deserving a remedy (such as the plutonium injection cases) should indeed get a remedy?
- A: These cases were singled out by the Committee because it was found that secrecy was misused to keep the facts from the subjects and their families. We agree that this is true and will work to provide these people with a fair remedy.
- Q: How will the government determine if other people were harmed and if they will receive compensation?
- A: The Interagency Working Group will spend the next several weeks reviewing the report and the individual experiments noted by the Committee as candidates for compensation. In addition, many individual cases are now pending in the courts. The bottom line is that if people are found to have been harmed by the government they will be fairly compensated.
- Q: What about criticism that the Committee was biased because its members included radiation doctors and scientists who do not want to embarrass their colleagues or institutions that may have been involved in these experiments?
- A: The members of this Committee were selected because they were the most capable and recognized scientists, doctors, lawyers, and ethicists with knowledge of this area. There is a broad consensus among the various disciplines involved that these are the best people for the job. The Committee

was responsible for finding the truth, not for trying to please every point of view.

Q: How can anyone be sure that all the facts surrounding government sponsored human radiation experiments have been found? What about classified records that are not available?

A: Every document relating to 50 years of government work with radiation has not been found. Our records as a whole are scattered, disorganized, and hard to use. But by any objective standard, it is clear that the agencies and the Committee have made an exhaustive effort to find relevant records. What has been found is adequate to tell a credible, accurate story about what happened and why. In terms of classified human radiation research, the Committee itself states that relatively few such experiments took place. Committee members were allowed access to classified sources of potential value for their study, and what was found has largely been declassified and made public.

Q: Some are saying that this is a "wishy-washy" report that ducks the issues, including who was hurt by these experiments. How does the government feel about this?

A: Again, this Committee was set up to establish an ethical framework for dealing with clear-cut instances where people were harmed. This they did, and did well. The Committee did not have the time or the resources to review individual medical case files thousands of people, nor could the Committee be expected to resolve the many deeply-felt emotions associated with the subject of government radiation uses. Resolution of individual cases will continue, and the government will do everything possible to expedite the process.

Q: Was this whole undertaking a success? A great deal of time and money was devoted to this project -- was it worth it?

A: This has been a very successful project in a number of ways. First and foremost, we are greatly relieved that the Committee found relatively little evidence that a large number of people were physically harmed. You may recall some earlier estimates that thousands of people were put in potential danger from radiation experiments. Nowhere near this number were found by the Committee to be at risk. While it cannot be ruled out that more people will

be determined to have been harmed, the work of the Committee has greatly reduced the number of persons we need to be concerned about.

Another major benefit from this project is increased government openness. From the start, a major concern was that the government had done these experiments in secret and had hidden the facts from the American people. We were sensitive to this and we marshalled all the resources of the national government to find the facts and make them available to the Committee and to the public. This is part of our ongoing work to reestablish trust between the government and its people.

Q: Some scientists claim that this project has given research a bad name. What is the government's view on this?

A: This effort is good for science and especially good for medical research. This research fights disease and saves lives, and we need to have everyone comfortable that it is being done ethically and with the best interest of patients in mind. This project demonstrates that this is the case today, and has largely always been the case in this country.

Q: What about the Committee's findings regarding current research -- does the government agree with them?

A: Let me say again that we are greatly relieved that the Committee's investigation turned up little indication that people were, or are currently, at risk from clinical use of radiation. When the Committee started its review of current biomedical research, they notified the various institutions whose projects would be investigated that if any situation was found where people were at inappropriate risk the matter would be immediately identified. After talking with many, many patients and reviewing over 100 research protocols, no such instance was found. We agree with the Committee that there must be an ongoing, vigilant effort to ensure that the circumstances surrounding human subject research are as safe and as ethical as possible. We have been doing this and we will continue.

Q: What are the next steps for the government regarding human radiation experiments?

A: We need a chance to go over the report with careful consideration. The Interagency Working Group, which has done a fine job overseeing this matter

for the last year and a half, will be directed to review the Committee's report and develop a plan to address the issues it raises. We expect to receive this plan within the next 30 to 60 days. At that time, we will notify the public about the government's short and long term goals.

Q: In general terms, what major issues will the government address as a result of the report?

A: The report demonstrates that some people were wronged by the government, and we must take steps to address that wrong. We must also ensure that there are protections in place to protect individuals when biomedical research and any other issues associated with personal health and safety intersect with national security. We must also seek ways and means to expand appropriate openness to past, present, and future government activities.

Q: What will the government do regarding openness and to otherwise improve trust between itself and the public?

A: We built a good model for openness with this project. Basically we need to put systems in place to let people go directly to sources of information to draw their own conclusions about how well the government does its job. This is crucial for accountability and for earning trust. All the new developments with information technology such as the internet, television broadcasting, and computers make it possible to present huge amounts of information quickly and cheaply. One of the crucial lessons from this project is that when we put our minds to it, the government can put lots of information into the hands of the American people who are its rightful owners. We will be looking to all parts of the Executive Branch to build on this experience to do a better job getting facts out and to ensure that this information is safely kept for future generations who will want to know what are doing today and why.

E X E C U T I V E O F F I C E O F T H E P R E S I D E

11-Apr-1996 01:38pm

TO: Phillip M. Caplan
FROM: Rachel E. Levinson
 Office of Science and Technology

SUBJECT: nbac

call me if you wish to discuss further.

Talking Points Regarding Appointment of Stakeholders to NBAC

On August 12, 1994, OSTP published a draft charter and request for candidates to be considered for appointment to NBAC.

NBAC was established by the President to provide guidance to all Federal agencies on the ethical conduct of human biological, behavioral and clinical research, and the applications of that research.

One initial charge to NBAC is to develop advice on how to ensure that current and future government-sponsored research adequately protects the rights and welfare of human subject participants.

Although NBAC was established to address the broad scope of all human subject research, it has become associated with human radiation experimentation through Executive Order 12975, which established NBAC and directed Federal agencies funding and conducting human subject research to undertake a review of their human subject protections and report the results to NBAC.

As part of this process, the research agencies have asked that NBAC take up certain issues identified by the Advisory Committee on Human Radiation Experiments. Included among these issues is the question of compensation of subjects injured in the course of government-sponsored research.

As a consequence of this responsibility, deliberations of NBAC may result in recommendations bearing on compensation for injured research subjects, including radiation experiment subjects. Therefore, individuals who have a vested financial interest in seeing that this issue is addressed and resolved in their favor and no stakeholders; people who are known to have a conflict of

interest concerning issues likely to be taken up by NBAC, have been selected as candidates for membership.

However, gathering input from a wide variety of sources, including those who have past and current experience concerning the ethical dimensions of human biological, behavioral and clinical research will be a central focus in all phases of NBAC's deliberations.

More importantly, as dictated by its charter, NBAC membership will be approximately (in fact, exactly, as currently proposed) evenly balanced between scientists and non-scientists. Three of its members will be lay people as community representatives.

Every effort will be made to make the public aware of and be included in NBAC meetings. Suggestions on how to make this an effective, inclusive process are welcome.

Separate note to Phil: An argument may be made the FACA requires affected parties to be represented on an advisory committee. I don't know if such a case would stand up but I would make two comments in this regard:

1) The affected group is really our whole population because we are all potential research subjects. NBAC is intended to be forward-thinking; to guide the way for design of future research protocols. Therefore, it appropriate and necessary to include as members people who truly convey the public attitude, cultural and moral values. Ethics is not static but more a dynamic, moving entity. NBAC will need to build into its recommendations allowance for changes in public values over time. Past research subjects have a small role to play in the formulation of such advice, but not a unique role.

2) Fairness - If a decision was made to include a past subject, and a radiation subject was selected, I believe that other groups, including all those patients who were helped and not injured, would have a compelling argument that they deserve representation also. It would be unjust to raise one group's interest over another.

E X E C U T I V E O F F I C E O F T H E P R E S I D E

30-May-1996 04:09pm

TO: Stephen R. Neuwirth
FROM: Rachel E. Levinson
 Office of Science and Technology
CC: Phillip M. Caplan
CC: Jonathan Foster
SUBJECT: attachment re: NBAC

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**OFFICE OF HUMAN RADIATION EXPERIMENTS
DEPARTMENT OF ENERGY**

**1726 M. STREET, NW
SUITE 200
Washington, D.C. 20036**

**FAX: (202) 254-5056
VERIFY: (202) 254-5026**

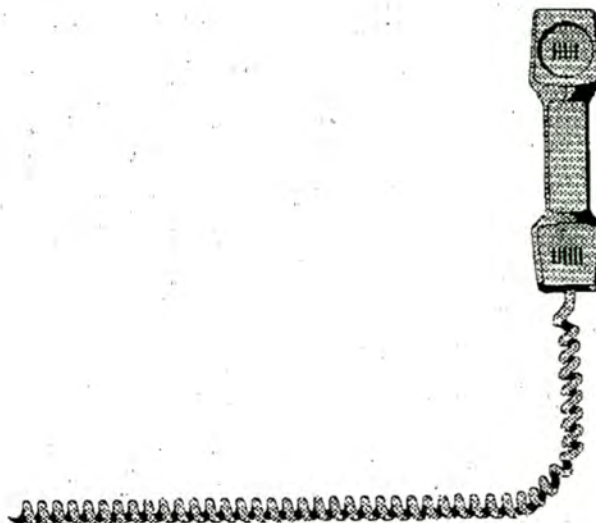
DATE: February 2, 1995

**TO: Phil Caplan
FAX: 456-2572**

**FROM: Ellyn R. Weiss
Special Counsel and Director**

NUMBER OF PAGES (INCLUDING COVER SHEET): 1

COMMENTS:



Why Do We Care About Human Radiation Experiments?

- ▶ **OPENNESS IS NECESSARY TO OUR MISSION.** A basic level of trust between the people and their government is necessary for democracy to function. It has eroded greatly, due at least in part to Cold War secrecy. We have to be open to rebuild trust. This is perhaps most obviously true for the Departments of Defense and Energy, which live so clearly with the legacy of secrecy, but applies with force to the others as well.
- ▶ **THIS IS GOOD FOR SCIENCE.** Science and technology are critical engines for the U.S. economy and both have come under attack for disregarding the effects of their activities on citizens. (The Not-In -My-Back-Yard syndrome afflicts virtually every major project, and is a reflection of people's fear that scientists and the government will barter their welfare for "larger" interests.) People must be able to see that the government is committed to preventing the misuse of science and technology so as to create an environment where good programs can go forward.
- ▶ **THIS IS CUTTING EDGE TECHNOLOGY FOR GETTING INFORMATION DIRECTLY IN THE HANDS OF PEOPLE.** For this project, DOE developed a system, with Argonne National Laboratory, to place images of original documents (some 150,000 pages) on the Internet via Worldwide web. The entire database can be word-searched (e.g. one can call up all documents with the phrase "plutonium injection") and has linkages to other Internet databases both in and outside the government. This represents a revolution in access that could make the FOIA obsolete.
- ▶ **WE PUT PEOPLE FIRST AND CUT RED TAPE.** This entire effort was driven by the demands of Americans to know the truth. In a little over a year after the President directed the agencies to find these records and set up an Advisory Commission to judge the ethical issues, millions of pages of documents all over the country going back 50 years have been sifted by the agencies, hundreds of thousands identified as pertinent and the Advisory Committee has reached its judgments. This could never have been accomplished had business-as-usual obtained.

ADMINISTRATION POSITION ON COMPENSATION
RELATED TO HUMAN RADIATION EXPERIMENTS

The Administration's actions regarding compensation and other responses to individuals affected by the human radiation experiments include the following:

1. Taking immediate action to provide information to subjects and their families;
2. Acting, when required to protect the health of individuals, or their descendants, who were subjects of a human radiation experiment, to notify a particular subject, or his or her descendants, of any potential health risk or the need for medical follow-up;
3. Examining various models for appropriate federal responses, including those incorporated into other federal programs such as those for 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 on-going research, education and information programs; and
4. 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 active consultations with the Congress.

TALKING POINTS FOR THE VICE PRESIDENT

RECEPTION FOR INDEPENDENT ADVISORY COMMITTEE ON HUMAN RADIATION

- Welcome to the White House
- Acknowledge members of the Interagency Working Group on Human Radiation who are present: Secretary Hazel O'Leary, Secretary Donna Shalala, NASA Administrator Dan Goldin, Director of Central Intelligence Jim Woolsey.
- And those who couldn't be with us tonight, Secretary Jesse Brown, Attorney General Janet Reno and Secretary William Perry.
- Thank you to the members of the Advisory Committee for agreeing to serve on this very important body. Your expert advice and information that you will provide to the members of the Cabinet and the Administration will help us immensely in getting to the truth. The facts are what are so vital to this process and your work is critical to that process.
- The President I know is personally very committed to revealing to the American people the nature and extent of the government's involvement in these experiments and without your work we would not be able to achieve that goal.
- And now I would like to introduce the man who appointed you and has given you your charge, President Bill Clinton.

1

LIFTING THE
VEIL
ON COLD WAR
SECRETS

Since World War II several agencies of the U.S. government have conducted or sponsored experiments on human subjects involving radioactive materials.

Many such experiments resulted in valuable medical advances like radiation treatments for cancer and the use of isotopes to accurately diagnose illnesses.

However, the Clinton Administration has questions about whether subjects of some experiments were treated properly.

of these

There are indications that in some cases:

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- (3) subjects gave consent, but were not fully informed of potential health consequences of the experiment;
- (4) experiments were conducted with disturbing frequency on subjects who were vulnerable or disadvantaged or who could not reasonably be expected to

2

fully understand what was being done to them - minorities, elderly people, retarded persons, infants, prison inmates, and hospital patients suffering from terminal conditions.

(5) some experiments served no apparent therapeutic medical purpose.

Information about these experiments has dribbled out over the years, but the government has never made a true accounting to the American people about this period of the Cold War.

The Clinton Administration has now launched a major effort to collect and make public all information we can find about radiation experiments conducted on human subjects by the government.

THE HUMAN RADIATION INTERAGENCY WORKING GROUP

At the direction of *the Administration*
The White House, has formed a working group of senior staff from ~~the~~ *several* government agencies with potential involvement in human radiation research:

The Departments of Energy, Defense, Veterans Affairs, Health and Human Services, the CIA and NASA. Other agencies ~~may~~ be added if necessary.

will

This group will oversee collecting records about human radiation experiments throughout the government.

THE INDEPENDENT ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

In addition, President Clinton has appointed an Advisory Committee on Human Radiation Experiments composed of experts in the fields of ethics, science, medicine, and law from outside the government on whether ^{the experiments} they were conducted properly. Their meetings will be open to ^{the public} ~~press coverage~~. Records will be collected and preserved where they can be studied by the public.

THE HUMAN RADIATION HELPLINE

The call you made to the Human Radiation Research Helpline ^{may help shed} ~~will provide~~ some new light on this little-known part of our past.

Your help is valuable because most of the information we are looking for is very old. We're not sure where it's ^{been preserved} ~~kept~~ after so many years. Your call may help us find ^{additional} ~~information we might have missed~~.

ANSWERS TO YOUR QUESTIONS

I called the Helpline. What happens now?

First we will try to determine which federal agency was responsible for the experiment you described to us.

Information from your call will then be sent to that agency and someone may call you back to get more information.

4

The information you provided will then be combined with information from other callers to give us clues we can use to find records about the experiments you described.

Independent

We will collect all the records we can find and bring them together.

President Clinton has appointed a special Advisory Committee of experts from outside the government to go over the records and determine exactly what was done by the government and if anything was done improperly.

We will also make the records public in one location so they can be studied.

Can I get my own records?

If we find them, yes. We have your current address now and can contact you and provide you a copy of your own records.

Where are these records?

That's the problem. Some of these experiments were conducted 40 or 50 years ago and we don't really know where everything is now. Some records are in government files. Some are at hospitals or universities that did work for the government. Some undoubtedly have been destroyed over the years. We have sent people all over the government to search their files and find any information they can so it can be studied.

5

hen will I know something?

Unfortunately, we can't tell you. We expect it will take many months to locate records and study them properly. We will be giving information to the press on a regular basis, so you should be able to keep up with the progress of our efforts through your local press.

Will you give my name to reporters?

No. We are required by law to keep your name and personal information confidential.

What if you can't find my records?

Unfortunately, we may not, especially if the experiment was conducted decades ago. If you were part of an experiment and your records are missing or have been destroyed, we'll do the best we can to piece together information from other sources, like medical journals and government reports.

Will I get some kind of payment from the government?

We can't answer that yet. When the Advisory Committee finishes its review, Congress may consider some kind of monetary compensation or other assistance, such as medical follow-up. The Administration will work closely with Congress to address this issue.

6

Why are you just looking at records from 1946-1974?

We're looking for all human radiation experiment records from 1946-1974. In 1974 ~~one government agency~~ enacted a set of regulations to protect human subjects in experiments of all kinds. The regulations include setting up Institutional Review Boards to review experiments ~~at each facility~~ ^{at research sites} where they are conducted. We won't look at all records since 1974, but we will look at samples to make sure that the regulations have, in fact, worked to protect people.

the Department of Health, Education and Welfare (now Health and Human Services)

What happens if someone falsely claims participation and seeks compensation?

Providing false information to the Federal Government is a serious crime with serious consequences.

Should I see a doctor?

Do so if you feel like you should to get a check-up or discuss previous treatment. If we find your records and have any reason to believe you face health risks or need medical follow-up, we'll suggest what you might do then.

Should I refuse to be X-rayed or treated with radiation?

No. Radiation has been used safely and beneficially for decades to diagnose and treat many illnesses.

Radiation therapy, as a primary cancer treatment, has been partially

responsible for increasing the overall cure rate for cancer to more than 50 percent. Approximately 20 million radiation therapy procedures are done annually.

MORE INFORMATION AVAILABLE

Many callers to the Helpline expressed concern about issues that are not related to the Human Radiation Experiments inquiry.

RADIATION THERAPY

The National Cancer Institute promotes the correct use of radiation therapy for cancer patients and maintains an information service for patients, their families and health professionals. That information line can be reached by calling 1-800-4-CANCER.

The Food and Drug Administration regulates the manufacturers of radiatgrams to ensure the devices' safety anion therapy devices and employs many prod effectiveness. The FDA's MedWatch program encourages patients and others to report voluntarily problems observed with medical devices by calling 1-800-332-1088.

"DOWNWINDERS"

The Radiation Compensation Act provides compensation for uranium miners and

"downwinders," individuals who lived in Nevada, Arizona and Utah during atmospheric bomb testing who have developed certain kinds of diseases.

For information, call 1-800-729-7327.

"ATOMIC VETERANS"

"Atomic Veterans," those who were exposed to atomic bomb testing as part of military exercises, may be eligible for benefits through the Veterans

Administration. For information,

call 1-800-827-0365.

*Published by the federal Interagency Working Group on Human Radiation
Experiments*

OFFICE OF CABINET AFFAIRS

THE WHITE HOUSE

WASHINGTON

FAX

TO: Mike Gaudin

DATE: 2/28

PHONE: 586-4940

NO. OF PAGES 9
(Including cover)

FAX: 586-9987

PRIORITY: Y N

FROM: Phil Caplan

PHONE: (202) 456-2572

FAX: (202) 456-6704

MESSAGE: _____

Mike - My comments on the pamphlet are
attached -- hope you can read them.

One caveat: I'd have the lawyers look at
this with an eye towards "descendants" or "family
members," etc. There are a couple of places
I thought we might include this -- or even a
separate question.

See you tomorrow



Department of Energy
Washington, DC 20585

Director of Public Affairs

Interagency Group —

Here is copy
for pamphlet.

Pls Review &
SEND BACK comments
by COB tomorrow —
Jan 18.

Thanks.

Koch



Printed with soy ink on recycled paper

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LIFTING THE VEIL OF COLD WAR SECRECY

THE CLINTON ADMINISTRATION'S INVESTIGATION OF GOVERNMENT RADIATION EXPERIMENTS ON HUMAN SUBJECTS

From 1946-1974 several agencies of the U.S. government conducted or sponsored experiments on human subjects involving radioactive materials.

The agencies included the Atomic Energy Commission and several branches of the military services.

Many such experiments resulted in valuable medical advances like radiation treatments for cancer and the use of isotopes to accurately diagnose illnesses.

However, the Clinton Administration has questions about whether subjects of some experiments were treated properly.

There are indications that in some cases:

- (1) subjects were not notified that they were participating in an experiment;
- (2) subjects did not give proper written informed consent;
- (3) subjects gave consent, but were not fully informed of potential health consequences of the experiment;
- (4) experiments were conducted with disturbing frequency on subjects who were vulnerable or disadvantaged or who could not reasonably be expected to fully understand what was being done to them - minorities, elderly people, retarded persons, infants, prison inmates, and hospital patients suffering from terminal conditions.
- (5) some experiments served no apparent therapeutic medical purpose.

Information about these experiments has dribbled out over the years, but the government has never made a true accounting to the American people about this period of the Cold War.

President Clinton and his administration are committed to making government open, honest and responsive to the American people.

The Clinton Administration has now launched a major effort to collect and make public all information we can find about radiation experiments conducted on human subjects by the government.

THE HUMAN RADIATION INTERAGENCY WORKING GROUP

The White House has formed a working group of senior staff from five government agencies with potential involvement in human radiation experiments: the Departments of Energy, Defense, Veterans Affairs, the CIA and NASA. This group will oversee collecting records about human radiation experiments throughout the government.

THE INDEPENDENT ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

In addition, President Clinton has appointed an Independent Advisory Committee on Human Radiation Experiments. This group consists of experts in the fields of ethics, science, medicine, and law from outside the government. They will review records of the experiments and advise the government on whether they were conducted properly. Their meetings will be open to press coverage. Records will be collected and preserved someplace where they can be studied by the public.

THE HUMAN RADIATION HELPLINE

The call you made to the Human Radiation Helpline will help us shed light on this little-known part of our past.

We needed your help because most of the information we are looking for is very old. We're not sure where it's kept after so many years. Your call may help us find information we might have missed.

ANSWERS TO YOUR QUESTIONS

I called the Helpline. What happens now?

First we will try to determine which federal agency was responsible for the experiment you described to us.

Information from your call will then be sent to that agency and someone may call you back to get more information.

The information you provided will then be combined with information from other callers to give us clues we can use to find records about the experiments you described.

We will collect all the records we can find and bring them together. President Clinton has appointed a special Advisory

3

Committee of experts from outside the government to go over the records and determine exactly what was done by the government and if anything was done improperly.

We will also make the records public at one location so they can be studied by

Can I get my own records?

If we find them, yes. We have your current address now and can contact you and provide you a copy of your own records.

Where are these records?

That's the problem. Some of these experiments were conducted 40 or 50 years ago and we don't really know where everything is now. Some records are in government files. Some are at hospitals or universities that did work for the government. Some undoubtedly have been destroyed over the years. We have sent people all over the government to search their files and find any information they can so it can be studied.

When will I know something?

Unfortunately, we can't tell you. We expect it will take many months to locate records and study them properly. We will be giving information to the press on a regular basis, so you should be able to keep up with the progress of this investigation through your local press.

Will you give my name to reporters?

No. We will keep your name and personal information confidential.

Can I call reporters to tell them about my experience?

If you want to, there's no reason you can't.

What if you can't find my records?

Unfortunately, we may not, especially if the experiment was conducted decades ago. If records are missing or have been destroyed, we'll do the best we can to piece together information from other sources, like medical journals and government reports.

Will I get some kind of payment from the government?

We can't answer that yet. When the Advisory Committee finishes its review, Congress may consider some kind of monetary compensation or other assistance, like medical follow-up.

Should I see a doctor?

Not unless you have a health problem or you want to get a check-up to reassure yourself. If we find your records and have any reason to believe you face health risks or need medical follow-up, we'll give you all the information we can then.

Should I refuse to be X-rayed or treated with radiation?

No. Radiation has been used safely and beneficially for decades to diagnose and treat many illnesses. Your doctor should tell you if there are risks or side-effects involved in a particular treatment and you should feel free to ask questions if you are uneasy about any treatment your doctor prescribes.

Why are you just looking at records from 1946-1974?

We're looking for all human radiation experiment records from 1946-1974. In 1974 the government enacted a set of regulations to protect human subjects in experiments of all kinds. The regulations include setting up Institutional Review Boards to review experiments at each facility where they are conducted. We won't look at all records since 1974, but we will look at samples to make sure that the regulations have, in fact, worked to protect people.

A BREAK WITH THE PAST

In the past, the government has been forced by Congress or citizen groups to answer questions about radiation experiments on humans.

This is the first time the government itself has ever launched its own investigation and been willing to make a full and honest accounting. This is an example of the kind of history-making change in government that the Clinton Administration has brought to Washington.

Our goal is to get all the facts out. We will do our best to provide information to the public and congress as we learn it.

This is a tremendous job, but the Clinton Administration is convinced that this is the only right thing to do to keep faith with the American people.

Press
Baker
Sawado
596 4940
HUMAN RADIATION INTERAGENCY WORKING GROUP**UPDATED BACKGROUND INFORMATION**

January 18, 1994

HISTORICAL BACKGROUND

For three decades following World War II, several federal agencies conducted or sponsored experiments on human subjects involving radioactive materials.

Many such experiments resulted in valuable medical advances and were conducted ethically. However, there are questions about whether subjects of some experiments were treated properly.

Experiments on humans during this period were supposed to be conducted according to the "Nuremberg Code." This ethical code was developed in response to disclosures at the Nuremberg War Crimes Trials about Nazi medical experiments conducted on concentration camp prisoners.

There are serious doubts now about whether some of the experiments conducted by the U.S. government on its own citizens did, in fact, meet the criteria of the Nuremberg Code.

There are indications that in some cases:

- (1) subjects were not notified that they were participating in an experiment;
- (2) subjects did not give proper written informed consent;
- (3) subjects gave consent, but were not fully informed of potential health consequences of the experiment;
- (4) experiments were conducted with disturbing frequency on subjects who could not reasonably be expected to fully understand what was being done to them - elderly people, retarded persons, infants, prison inmates and hospital patients suffering from terminal conditions.
- (5) some experiments served no therapeutic medical purpose.

In 1986 a comprehensive report, "American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens," was compiled under the direction of Rep. Edward J. Markey, then chairman of the Subcommittee on Energy Conservation and Power of the House Committee on Energy and Commerce. The report identified 31 experiments conducted by Department of Energy predecessor agencies on at least 700 persons.

Rep. Markey's report called on the Reagan-era Department of Energy to track down the subjects of the experiments or their survivors to provide medical follow-up where appropriate, and compensate for wrongful treatment. The Department responded with an explanation of the purpose of each experiment and disagreed with Markey's conclusions that the experiments were conducted improperly or were of no medical value.

HUMAN RADIATION INTERAGENCY WORKING GROUP

The Human Radiation Interagency Working Group was formed by the White House January 3 to collect records about human radiation experiments and design a process to review them.

The agencies which form the working group are: Department of Energy, Department of Defense, the Department of Veterans Affairs, the Department of Health and Human Services, the Department of Justice, the Central Intelligence Agency, the Office of Management and Budget, the National Aeronautics and Space Agency and the Office of the President.

Later this month the Working Group plans a meeting of the Secretaries and Directors of those agencies to report on the work their staffs have done.

THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The White House today released President Clinton's executive order establishing the Advisory Committee on Human Radiation Experiments.

The Advisory Committee will review records of deliberate experimental exposures of human subjects to radiation by government agencies. This group of outside experts in medicine science and law will review the governments records and make determinations on whether they were conducted properly.

A copy is attached.

The Interagency Working Group hopes by the end of January to recommend to President Clinton a list of individuals to be appointed to the Advisory Committee on Human Radiation Experiments.

The advisory group will be formed under the Federal Advisory Committee Act and its meetings will therefore be open to press coverage except for cases in which personal information protected by the Privacy Act must be discussed.

WORKING GROUP COMMITTEES

The Human Radiation Working Group has five committees:

PUBLIC INFORMATION AND COMMUNICATIONS -- This group's initial assignment was to develop a common hotline service to serve all agencies and upgrade the service to properly handle number of calls being received. The group is also assigned to design methods of communicating information to the public and press.

LEGISLATIVE ISSUES -- The group's charge is to work with Congress, keeping Congress involved and informed. The group has conducted several briefing for Members and staff and will continue to do so.

LEGAL ISSUES -- The group has begun to work on compensation models that can be provided to the Interagency Working Group at the end of the Advisory Committee's review.

RECORD RETRIEVAL -- The group has been assigned to develop a government-wide system for retrieving records from agency sites

or contractors.

ETHICS AND SCIENTIFIC STANDARDS -- The group designed the scope of the Advisory Committee and will make recommendations to the Interagency Working Group on the membership of the board.

HUMAN RADIATION EXPERIMENTS HOTLINE (1-800-493-2998)

The hotline has now been upgraded to handle 500 calls an hour and we hope to be in a position now to do a much better job of serving the people who are calling in.

AVAILABILITY OF RECORDS

Although many of these experiments were secret at the time they were conducted, some information about experiments has been public, but little known, for a number of years.

Some results have been published in medical journals.

Documents concerning other experiments have been and are currently available in the public reading rooms of federal agencies.

Because records have been kept individually at locations scattered across the nation, information about these experiments as a whole has not really been accessible to the public.

At this time the report issued by Rep. Ed Markey in 1986 is the most comprehensive known compilation of information on human experimentation.

One of the Clinton Administration's goals is to centralize all available information on this subject so that it can be made available for public study.

PROTECTION OF INDIVIDUALS' PRIVATE RECORDS

Patient records are protected by privacy laws and cannot be made public without consent of the subjects or their survivors.

The identities of callers to the Human Radiation Hotline are also protected.

The Interagency Group will not be able publicly provide the names of individuals who were the subjects of experiments or those who call our hotline.

When records being received by the Advisory Committee are released to the press, they will be released in "redacted" form, with names and identifiers removed.

COMPENSATION

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.

Part of the Advisory Committee's task will be to determine if surviving subjects or their families have received proper medical follow-up.

The Administration will act, when required, to protect the health of individuals or their descendants who were subjects of a human radiation experiment, to notify a particular subject or his or her descendants of any potential health risk or the need for medical follow-up.

The Legal Issues Committee of the Interagency Working Group has begun studying monetary compensation models that have been used before, in the cases of Downwinders or Japanese-Americans displaced during World War II, for example.

Any decision about compensation will ultimately have to be made by Congress.

It is far too early to tell if this review will determine that compensation is warranted.

CURRENT EXPERIMENTATION INVOLVING HUMAN SUBJECTS

Government experiments involving human subjects today are conducted under a Federal-wide policy, 10 Code of Federal Regulations Part 745.

Each agency has enacted this regulation through its own orders. For example, the Department of Energy implements this regulation with two Orders, DOE 1300.3 and 4200.2b.

In 1974 the government began requiring Institutional Review Boards to oversee research involving human subjects funded or supported by government agencies.

Regulations were updated in 1991 and can be found in the Federal Register.

Under the current system, human subject experiments cannot take place until projects are approved by the Institutional Review Board and informed consent written according to very prescriptive guidelines is signed by participants.

Each project must be reapproved each year.

Federal regulations strictly define ethics considerations of experiments on human subjects. Ethical evaluation is the responsibility of the Institutional Review Board, the investigator performing the research and the institution where the research is being performed.

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MEMORANDUM
OF CALL

Previous editions usable

TO:

☐ YOU WERE CALLED BY-- ☐ YOU WERE VISITED BY--

OF (Organization)

☐ PLEASE PHONE ▶ ☐ FTS ☐ AUTOVON

☐ WILL CALL AGAIN ☐ IS WAITING TO SEE YOU

☐ RETURNED YOUR CALL ☐ WISHES AN APPOINTMENT

MESSAGE

RECEIVED BY

DATE

TIME

63-110 NSN 7540-00-634-4018

STANDARD FORM 63 (Rev. 8-81)

Prescribed by GSA

U.S. GOVERNMENT PRINTING OFFICE: 1991 281-781/40014

FPMR (41 CFR) 101-11.6

THE WHITE HOUSE
WASHINGTON
OFFICE OF THE CABINET SECRETARY
(202/456-6280)

TO:

Mike Gaudin / Rich Rosenzweig

FROM:

Phil Cullen

DATE:

NO. OF PAGES

1

MESSAGE:

Call me on 456-6280

do talk about this. I

think this can be merged into

your current language.

The document to follow is intended for the addressee only and should be considered privileged and confidential.

ADMINISTRATION POSITION ON COMPENSATION
RELATED TO HUMAN RADIATION EXPERIMENTS

The Administration's actions regarding compensation and other responses to individuals affected by the human radiation experiments include the following:

1. Taking immediate action to provide information to subjects and their families;
2. Acting, when required to protect the health of individuals, or their descendants, who were subjects of a human radiation experiment, to notify a particular subject, or his or her descendants, of any potential health risk or the need for medical follow-up;
3. Examining various models for appropriate federal responses, including those incorporated into other federal programs such as those for 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 on-going research, education and information programs; and
4. 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 active consultations with the Congress.

1/14/94 tjg

Human Radiation Interagency Working Group
Talking Points
January 11, 1994

- o The Clinton Administration is committed to an honest and open approach in investigating Cold War-era government sponsored ionizing radiation human experiments. The White House has formed an Interagency Working Group to investigate the experiments. This group will coordinate a government-wide effort to uncover the nature and extent of the experiments.
- o Members of the Interagency Working Group include the Secretaries of the Department of Energy, Department of Defense, Department of Veterans Affairs, Department of Health and Human Services, the Attorney General, the NASA Administrator, the Director of the CIA and the Director of OMB. Other federal agencies will be added to the group if necessary.
- o The Interagency Working Group has initially established several subcommittees of the working group to examine issues such as record retrieval and handling, public information and communication guidelines, legal issues and the creation of an Advisory Committee on ethical and scientific standards.
- o The Interagency Working Group ultimately aims to recommend answers to the three questions initially raised in a 1986 report by Rep. Ed Markey (D-MA): What was the extent of the experimentation?; Was there, or should there be, any medical follow-up?; What compensation or assistance may be appropriate?
- o Congress is an essential part of this process. The Administration will fully brief interested Members and staff from committees of jurisdiction or from areas of the country where experiments were conducted.
- o These are the very first steps in what could turn out to be a very lengthy process. Human ionizing radiation experiments, some conducted over forty years ago, may have generated large amounts of documentation, some of which may have been destroyed or may not be easily retrievable. The Administration is fully committed to investigating these experiments quickly, thoroughly and efficiently.

HUMAN RADIATION INTERAGENCY WORKING GROUP**UPDATED BACKGROUND INFORMATION**

January 18, 1994

HISTORICAL BACKGROUND

For three decades following World War II, several federal agencies conducted or sponsored experiments on human subjects involving radioactive materials.

Many such experiments resulted in valuable medical advances and were conducted ethically. However, there are questions about whether subjects of some experiments were treated properly.

Experiments on humans during this period were supposed to be conducted according to the "Nuremberg Code." This ethical code was developed in response to disclosures at the Nuremberg War Crimes Trials about Nazi medical experiments conducted on concentration camp prisoners.

There are serious doubts now about whether some of the experiments conducted by the U.S. government on its own citizens did, in fact, meet the criteria of the Nuremberg Code.

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Rep. Markey's report called on the Reagan-era Department of Energy to track down the subjects of the experiments or their survivors to provide medical follow-up where appropriate, and compensate for wrongful treatment. The Department responded with an explanation of the purpose of each experiment and disagreed with Markey's conclusions that the experiments were conducted improperly or were of no medical value.

HUMAN RADIATION INTERAGENCY WORKING GROUP

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Later this month the Working Group plans a meeting of the Secretaries and Directors of those agencies to report on the work their staffs have done.

THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The White House today released President Clinton's executive order establishing the Advisory Committee on Human Radiation Experiments.

The Advisory Committee will review records of deliberate experimental exposures of human subjects to radiation by government agencies. This group of outside experts in medicine science and law will review the governments records and make determinations on whether they were conducted properly.

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The Interagency Working Group hopes by the end of January to recommend to President Clinton a list of individuals to be appointed to the Advisory Committee on Human Radiation Experiments.

The advisory group will be formed under the Federal Advisory Committee Act and its meetings will therefore be open to press coverage except for cases in which personal information protected by the Privacy Act must be discussed.

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COMPENSATION

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Part of the Advisory Committee's task will be to determine if surviving subjects or their families have received proper medical follow-up.

The Administration will act, when required, to protect the health of individuals or their descendants who were subjects of a human radiation experiment, to notify a particular subject or his or her descendants of any potential health risk or the need for medical follow-up.

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January 18, 1994

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456-0704

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January 18, 1994

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LEGISLATIVE ISSUES -- *the group* primarily concerned working with Congress, *the group* keeping Congress up-to-date; they are conducting the briefings today for congressional staff. *has conducted several briefings for*

LEGAL ISSUES -- Working on the legal requirements to create the Advisory Committee; *the group has been* has begun to work on compensation models that can be provided to Congress at the end of the Advisory Committees review. *will*

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THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

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HUMAN RADIATION EXPERIMENTS HOTLINE 1 - 800 -----

The hotline has now been upgraded to handle 500 calls an hour and we hope to be in a position now to do a much better job of serving the people who are calling in.

We have talked to ----- people since the original hotline was established December 23 by the Department of Energy.

As of (date) we've completed interview reports on () callers who believe they were involved in medical experiments.

About () of our total callers are veterans.

We are not yet able to give you breakdowns of what states or areas our calls are coming from. For the first several weeks we were forced to record all information on paper forms. Part of our upgrade of the service will be to keep information on computer and we expect eventually to be able to provide geographical information to you. As soon as we get the capability to compile that information we'll make it available to you.

AVAILABILITY OF RECORDS

Although many of these experiments were secret at the time they were conducted, some information about experiments has been public, but little known, for a number of years.

Some results have been published in medical journals.

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THE INFORMED CONSENT ISSUE

Many experiments conducted by government agencies in the years after World War II resulted in valuable medical advances and were conducted ethically.

However, there are questions about whether subjects of some experiments were treated properly.

Foremost, there are serious questions about whether the subjects of government radiation experiments gave or were capable of giving "informed consent" as it was defined at the time.

Experiments on humans during this period, 1944-1974, were supposed to be conducted according to the "Nuremberg Code." This ethical code was developed in response to disclosures at the Nuremberg War Crimes Trials about Nazi medical experiments conducted on concentration camp prisoners.

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**PRESENT HUMAN RESEARCH CONDUCTED BY DOE
AND OTHER GOVERNMENT AGENCIES**

Q. IS DOE STILL DOING HUMAN EXPERIMENTS SIMILAR TO THE PLUTONIUM INJECTION EXPERIMENTS OF THE 40'S?

A. No. There is no comparison to the research being conducted in 1993 to that of the plutonium injections of the 40's. There now is a government-wide regulator system in place to protect human subjects from experiments of that sort. The DOE does research involving human subjects as do 17 other Federal agencies including the National Institutes of Health, Food and Drug Administration, the Environmental Protection Agency and the National Science Foundation. The majority of research conducted by the DOE or by other agencies at DOE facilities is of minimal risk, uses informed consent for all participants, and is subject to stringent regulations on human participation. The Department also conducts research on advanced radiation therapy modalities to improve the treatment of cancer and other abnormalities.

Q. WHAT IS DOE'S POLICY ON SUCH EXPERIMENTS? COULD THE TYPE OF EXPERIMENTS CONDUCTED IN THE 40'S AND 50'S EVER HAPPEN AGAIN?

A. Absolutely not. Human subject research today is conducted under a Federal-wide policy (10 Code of Federal Regulations Part 745). DOE implements this regulation with two Orders, DOE 1300.3 and 4200.2b. The experiments done in the 40's have not happened again, and DOE regulation begun in 1975 and updated in 1991 continues to assure that experiments of this sort and/or experiments without informed consent could not happen again.

Q. WHAT SORT OF STUDIES INVOLVING HUMANS IS DOE FUNDING?

A. Many of the studies do not involve direct human volunteers. Examples of these are epidemiologic studies tracking the health and mortality of DOE contractor workers and cancer studies of human tissue samples obtained from hospitals. (DOE identifies these studies as human subjects studies in part because the data may include identifying information about individuals that needs to be protected under privacy statutes.) Other studies do involve direct human volunteers. Examples of these are studies to develop new medical imaging techniques and new nuclear medicine therapies. Experiments involving human subjects funded by DOE programs are all of minimal risk. (The regulations define minimal risk as the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.)

Q. WHY ARE THE STUDIES BEING DONE AT DOE LABS?

A. The Department of Energy has developed a world-class system of laboratories, many with great expertise in biology and medicine. The expertise is recognized by other federal agencies such as NIH that fund DOE labs to do human subject studies. In addition, DOE has its own interests and responsibilities to protect the health and safety of its workers as well as legislative mandates to research and develop new nuclear medical applications.

Q. HOW MANY STUDIES ARE THERE?

A. About 120 studies are conducted with DOE funds at DOE facilities or at academic institutions and medical centers. About 100 studies funded by other agencies are conducted at DOE facilities.

Q. How are the experiments overseen?

Federal regulations now require a local Institutional Review Board at each research facility to oversee the protection of human subjects.

This system is identical to that established by the Department of Health and Human Services and subject to a common rule for all Federal agencies.

The federal regulations were approved in 1991 and agencies are still formulating implementation plans. DOE is second only to DHHS in having a process so firmly in place.

Human Subject experiments cannot take place until projects are approved by the Institutional Review Board and informed consent written according to very prescriptive guidelines is signed by participants.

Each project must be reapproved each year.

Q. How does DOE make sure there is proper informed consent?

Under federal regulations the Institutional Review Board at each research facility is charged with approving a study's procedures for informed consent. (Federal requirements for informed consent are attached.)

Q. How is ethical evaluation of projects carried out?

Federal regulations strictly define ethics considerations of experiments on human subjects.

Ethical evaluation is the responsibility of the Institutional Review Board, the investigator performing the research and the institution where the research is being performed.

Q. What is an Institutional Review Board?

Each has at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

Each is to include one member whose primary concern is science, one whose primary concern is non-scientific and one who is not affiliated with the institution at all. No board may have a member who has a conflict of interest in projects being reviewed.

The board is to be competent to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable laws and standards of professional conduct and practice.

**HUMAN RADIATION EXPERIMENTS
CHRONOLOGY OF RECENT EVENTS
JANUARY 3, 1994**

DRAFT

Spring, 1993:

President Clinton issues Executive Order to begin post Cold War declassification process and "open-up" government to citizens.

Summer, 1993:

Department of Energy initiates massive declassification effort and develops plans to make Departmental information and facilities more accessible to the public.

November 15, 1993:

Albuquerque Tribune begins three-part series about 18 people who were injected with plutonium in a series of government experiments in the late 1940s.

November 19, 1993:

O'Leary responds to press questions about "plutonium experiments" with the following points:

- o information about human experiments not new; available through Markey Report some six years ago.
- o said she was "appalled" and described the experiments as "repugnant".
- o introduced idea of a "third party" examination of all records on human experiments.
- o pledged to make as much information public as legally possible.

December 7, 1993:

O'Leary holds "Openness" press conference; announces that Dr. Ruth Faden, an esteemed medical ethicist at Johns Hopkins, will assist DOE with a review of records on human experimentation.

December 15, 1993:

Senator Glenn releases GAO Report revealing 12 previously secret

DRAFT

intentional radioactive releases during post-WWII nuclear weapons-related tests. DOE pledges full cooperation with GAO to make more information public.

Week of December 20:

December 27 Newsweek cover story: "America's Nuclear Secrets." Large portion of story devoted to human experiments.

December 23, 1993:

O'Leary follows up Dec. 7 announcement by ordering DOE field offices to assemble all relevant records (including those of current and former contractors) pertaining to human medical and scientific experiments.

DOE announces toll-free human experimentation hotline to solicit information from individuals who believe they were subjects in past AEI/DOE experiments.

December 20 - 30, 1993:

O'Leary responds to scores of media interview requests; appears on all major network newscasts and a variety of news talk-shows including "McLaughlin", "Good Morning America", "CNN & Company" and "MacNeil/Lehrer." Human radiation stories appear in virtually every medium/large newspaper across the country.

DOE receives almost 1,000 media queries on this subject since December 7.

December 28, 1993

DOE Hotline overloaded by 10,000 attempted calls in one day. As of Jan. 4, hotline continues to receive 6000-10,000 calls per day.

December 30, 1993:

Departments of Defense and Veterans Administration announce comprehensive records review for human experimentation information.

White House announces January 3 meeting of applicable Cabinet representatives to discuss Administration actions.

HUMAN RADIATION EXPERIMENTS COMMUNICATION ISSUES

DRAFT

SECRECY OF EXPERIMENTS

Although many of these experiments were secret at the time they were conducted, information about most individual experiments has been public, but little known, for a number of years. Some results have been published in medical journals.

AVAILABILITY OF RECORDS

Because records have been kept individually at locations scattered across the nation, information about these experiments as a whole has not been accessible to the public. The Markey report was based on interpretive summaries or original research records, not on the records themselves.

THE INFORMED CONSENT ISSUE

There are serious questions about whether the subjects of these experiments were aware of what was being done to them or gave "informed consent" as it was defined at the time.

THE COMPENSATION ISSUE

If the Administration's review determines that American citizens were treated wrongfully by their government, Secretary O'Leary, with the support of OMB and the Justice Department, has pledged to recommend that Congress enact legislation to provide compensation to the subjects treated wrongfully or their survivors. However, it is too early to tell if this review will determine that compensation is warranted.

THE PRIVACY ISSUE

Patient records are protected by privacy considerations and traditionally not made public without consent of the subjects or their survivors. When records are received, names and identifiers are kept in confidence until consent can be obtained.

CURRENT RESEARCH

Although the government still sponsors research on human subjects, it has adopted strict regulations requiring informed consent and high ethical conduct. All such research is reviewed regularly by oversight panels. Further review of existing federal guidelines on human experimentation may be appropriate.

ADMINISTRATION GOALS

Secretary O'Leary's goal is to collect all information possible about government radiation experiments on humans, making it available at a one location to be freely examined and evaluated.

HUMAN RADIATION EXPERIMENTS**DRAFT****COMMUNICATION MESSAGES**

THE CLINTON ADMINISTRATION IS UNDERTAKING THIS TASK BECAUSE IT IS THE RIGHT THING TO DO.

If American citizens were endangered wrongfully by their own government during the Cold War, this Administration owes it to the American people to give a full accounting, to "come clean," and to issue an apology on behalf of the American people.

THIS HISTORIC EFFORT IS AN EXAMPLE OF THE CHANGE THE CLINTON ADMINISTRATION HAS BROUGHT TO WASHINGTON.

The review of human radiation experiments conducted during the Cold War is in line with several fundamental positions of the Clinton Administration:

REINVENTING GOVERNMENT

- This initiative will make records of government actions available to the public in a way that they can reasonably be studied, rather than ignored in obscure corners all over the country.
- Review of human experiments shows responsiveness to widespread public interest the subject and public desire that this period of our country's history be fully examined.

REDUCING SECRECY

- President Clinton has ordered government to reduce secrecy about past and current operations.

EARNING TRUST AND CREDIBILITY

- The Clinton Administration believes that the American people have a right to trust their government and trust can only be achieved if the government is open and truthful with the people.

CHANGE

- In the past, the government has been forced by Congress or citizen groups to examine the issue of experiments on humans. The response by previous administrations has been grudging and designed to down-play the issue. This is the first broad inquiry generated by the government itself.
- This initiative represents part of the history-making change in government that the Clinton Administration has brought to Washington.

HUMAN SCIENTIFIC AND MEDICAL EXPERIMENTS TASK FORCE

FACT SHEET

DRAFT

Secretary O'Leary has appointed Dr. Ruth Faden, a medical ethicist from Johns Hopkins University, to head a task force of experts from outside the government which will collect and review records of experiments on humans.

Dr. Tara O'Toole, assistant secretary of energy for environment, safety and health, will direct the Department of Energy's efforts on behalf of Secretary O'Leary.

The Task Force will include distinguished professionals from a wide variety of relevant disciplines, including radiation biology, medical ethics, law and health physics.

The Task Force's review will be conducted as openly as possible (some meetings may have to be closed to protect the confidentiality of individuals).

The Task Force will review materials now being assembled by each DOE field office.

The Department of Energy has contacted the National Archives to establish a central location for retention of the records for use by the Task Force.

TASK FORCE MACRO TIME LINE

Task Force Operational
Membership, procedures announced

January, 1994

Periodic releases of records as
they are reviewed

January - June 1994

Status report to Secretary O'Leary
Recommendations for future
operation of Task Force

June 1, 1994

PROPOSED STATEMENT

The White House today directed federal agencies to conduct a complete investigation of experiments the government conducted on humans using radioactive materials in the early decades of the Cold War.

The Departments of Energy, Defense and Veteran's Affairs have already launched independent inquiries into whether such experiments were conducted ethically. At a meeting late today, the White House directed all agencies to coordinate their efforts under a (presidential commission; advisory board; task force) created _____.

White House officials said the (presidential commission; advisory board; task force) will focus its study on experiments that fail to meet any of three important criteria: (1) documented informed consent by subjects; (2) clear therapeutic benefit; or (3) appropriate medical follow-up for subjects.

"If American citizens were treated wrongfully by their own government in the past," said _____, "the Clinton Administration feels a clear responsibility to make that information public so that the American people can clearly understand what happened and insure that any wrongs committed in the past can't happen again."

The (presidential commission; advisory board; task force) will be headed by _____.

The group will:

- * attempt to identify all experiments that were conducted;
- * attempt to identify and contact all subjects or their survivors;
- * collect and review all available records of the experiments;
- * provide a central repository where records can be made easily available to the public;
- * recommend appropriate medical follow-up for subjects or their survivors;
- * examine current federal guidelines governing human experimentation and determine if they are sufficient to prevent future abuses of test subjects;
- * draft an appropriate apology to the American people;
- (* make recommendations on compensation or other assistance to subjects or their survivors.)

The (presidential commission; advisory board; task force) is to make an interim report by June 1.

("It's too early now to speculate about the possibility of compensation or other assistance to experiment subjects or their families," said _____. "Those questions will have to be addressed after the task force has determined that we have learned enough to have informed discussions of those issues.")

HUMAN EXPERIMENTATION ISSUES FOR DISCUSSION

I. Brief Review of History of Human Radiation Experimentation

II. Response to Date to Current Disclosures

- o DOE
- o Other Agencies
- o Congress
- o Press

III. Possible Next Steps

- o Determine Scope of Inquiry -- Government sponsored experiments exposing human subjects to radiation
- o Agency Retrieval of Records
- o Independent Review of Scientific and Ethical Issues
- o Notification of Subjects and Next of Kin
- o Medical Follow-up
- o Apology by Government
- o Compensation or Other Assistance to Subjects or Next of Kin
- o Review Current Guidelines for Human Experiments

IV. Organization of Federal Government Response

- o Review of Experiments
- o Compensation Issues

V. Public Affairs Strategy

- o White House Statement
- o Public Affairs Contacts
- o Congressional Follow-up



DEPARTMENT OF ENERGY
Washington, DC 20585

OFFICE OF THE SECRETARY

December 29, 1993

NOTE TO PHIL CAPLAN
STEVE SILVERMAN

FROM: RICH ROSENZWEIG

Here is the appropriate potential statement, information on the experiments, and some press articles which recently increased the visibility of the story. Please distribute to appropriate White House officials.

Attachments

DRAFT STATEMENT FOR POTENTIAL USE BY THE WHITE HOUSE

We are deeply troubled that the climate of the Cold War allowed our government to sanction in secrecy human experimentation that had no apparent scientific merit and that violates our fundamental sense of ethics. This information has come to light as I had ordered all Cabinet Agencies to declassify information that no longer requires classification for National Security purposes. The Secretary of Energy has already set up an independent panel to gather information and release it to the public as soon as possible, consistent with the privacy interests of the affected individuals.

The Department of Energy has set up this process to gather information on past experiments that may have violated ethical standards. Nothing in this activity casts doubt on the validity of current medical therapies being administered to patients by qualified physicians or medical institutions. Persons receiving such therapy should feel comfortable in discussing their therapy with their physician.

The Department of Energy has established a toll-free hot line (1-800-493-2998), which interested members of the public may call with questions or information. The Secretary has also been in contact with members of Congress and other officials within the Administration. After reviewing the matter, the Administration will make recommendations to Congress for appropriate compensation to any individuals who were injured by the experiments.

MEDICAL EXPERIMENTS: SUMMARY OF MAJOR CATEGORIES

1. THE PLUTONIUM EXPERIMENTS. CONDUCTED DURING THE CLOSING DAYS OF THE MANHATTAN PROJECT, MASSIVE DOSES OF PLUTONIUM WERE INJECTED INTO 18 MEN, WOMEN AND CHILDREN. THE SECRET EXPERIMENTS WERE CONDUCTED ACROSS THE COUNTRY, INCLUDING NEW YORK CITY AND SAN FRANCISCO. IT IS UNCLEAR WHETHER THESE SUBJECTS WERE INFORMED AS TO THE NATURE OF THE EXPERIMENTS.

INFORMATION ON THIS AND SOME OF THE OTHER ITEMS LISTED BELOW WAS PUBLICLY RELEASED IN THE MID-1980'S AS PART OF CONGRESSIONAL INVESTIGATIONS CONDUCTED BY MR. MARKEY AND THEN-REPRESENTATIVE AL GORE.

2. PRISONER EXPERIMENTS. STUDIES IN THE 1960'S, SPONSORED BY NASA AND THE DEFENSE DEPARTMENT, INVOLVED IRRADIATION OF THE TESTICLES OF APPROXIMATELY 130 PRISONERS IN THE STATES OF WASHINGTON AND OREGON. ALTHOUGH THE PRISONERS WERE APPARENTLY GIVEN SOME INFORMATION ON THE NATURE OF THE EXPERIMENTS AND WERE PAID SMALL SUMS FOR THEIR PARTICIPATION, THE ADEQUACY OF THIS "INFORMED CONSENT" WILL BE AT ISSUE. THIS WORK WAS ALSO RELEASED IN THE 1980'S.

3. EARLY NUCLEAR MEDICINE EXPERIMENTS. IN THE 1950'S AND 1960'S, FACILITIES FOR THE IRRADIATION OF PATIENTS WITH CANCER AND LEUKEMIA WERE CONSTRUCTED AT OAK RIDGE. THEY WERE PART OF THE HUMAN EXPERIMENTATION PROGRAM FROM 1960 - 1975 IN WHICH APPROXIMATELY 200 PATIENTS LIVED IN THESE FACILITIES AND RECEIVED VARYING - BUT SOMETIMES VERY LARGE - DOSES IN AN ATTEMPT TO PROVIDE IMPROVED RADIATION THERAPY FOR MALIGNANT DISEASES. THIS INFORMATION WAS ALSO RELEASED IN THE 1980'S.

4. DEFENSE EXPERIMENTS INVOLVING EFFECTS OF NUCLEAR WARFARE ON

TROOPS. BETWEEN 1960 - 1971, THE DEFENSE DEPARTMENT SPONSORED A PROGRAM AT THE UNIVERSITY OF CINCINNATI. SOME 87 TERMINALLY ILL PATIENTS WERE EXPOSED TO LARGE DOSES OF RADIATION COMPARABLE TO THOSE EXPECTED TO BE FOUND ON THE BATTLEFIELD.

5. THE FERNALD SCHOOL EXPERIMENTS. IN THE PAST FEW DAYS THE PRESS HAS REVEALED EXPERIMENTS CONDUCTED ON "SCORES" RETARDED YOUTHS AT THIS BOYS' SCHOOL NEAR BOSTON. APPARENTLY UNDER THE SPONSORSHIP OF THE ATOMIC ENERGY COMMISSION, THE EXPERIMENTS INVOLVED THE INGESTION OF RADIOACTIVELY-CONTAMINATED MILK AS A FORM OF A TRACER TO EXAMINE DIGESTIVE PROCESSES. WE ANTICIPATE LEARNING MORE ABOUT THIS IN OUR REVIEW.

6. VANDERBILT UNIVERSITY EXPERIMENTS. IN THE LAST FEW DAYS, THE PRESS HAS REVEALED EXPERIMENTS CONDUCTED AT THE VANDERBILT UNIVERSITY HOSPITAL FREE PRE-NATAL CLINIC AND FUNDED BY THE ATOMIC ENERGY COMMISSION. THE EXPERIMENTS INVOLVED INGESTION OF RADIOACTIVE MATERIALS IN PILL FORM BY HUNDREDS OF PREGNANT FEMALES ENTERING THE CLINIC FOR FREE PRE-NATAL CARE. THEY APPARENTLY WERE GIVEN NO NOTICE OF THE EXPERIMENTS, AND APPARENTLY NO CONSENT WAS RECEIVED. AT LEAST THREE CHILDREN OF THESE PREGNANCIES ARE REPORTED TO HAVE DIED AT A PREMATURELY-YOUNG AGE AND WE ARE RECEIVING HOT LINE CALLS FROM PERSONS WHO MAY HAVE BEEN INVOLVED WITH THIS WORK.



7. **RADIOACTIVE IODINE INFANT EXPERIMENTS.** RECENT NEWS REPORTS INDICATE THAT HUNDREDS OF INFANTS WERE INJECTED WITH LOW LEVELS OF RADIOACTIVE IODINE AROUND THE COUNTRY. THE EXPERIMENTS WERE DESIGNED TO DISCOVER METHODS OF DETECTING THYROID DISEASE IN INFANTS AND YOUNG CHILDREN. WE HAVE INCOMPLETE INFORMATION AS TO ANY CONSENT RECEIVED.



HUMAN SCIENTIFIC AND MEDICAL EXPERIMENTS
EXPERT TASK FORCE

- ◆ TASK FORCE SET UP UNDER SHIELD OF SECRETARY OF ENERGY ADVISORY BOARD.
- ◆ DR. RUTH FADEN ("FAY-DIN"), MEDICAL ETHICIST FROM JOHNS HOPKINS UNIVERSITY, TO HEAD TASK FORCE:
 - OPERATIONAL IN EARLY 1994
 - WILL INCLUDE DISTINGUISHED PROFESSIONALS FROM A WIDE VARIETY OF RELEVANT DISCIPLINES SUCH AS RADIATION BIOLOGY, MEDICAL ETHICS, LAW, HEALTH PHYSICS, ETC.
 - ANALYSIS WILL BE CONDUCTED AS OPENLY AS POSSIBLE (SOME MEETINGS MAY HAVE TO BE CLOSED TO PROTECT CONFIDENTIALITY OF INDIVIDUALS)
- ◆ TASK FORCE WILL REVIEW MATERIALS NOW BEING ASSEMBLED BY EACH DEPARTMENT OF ENERGY FIELD LOCATION:
 - FIELD OFFICES HAVE BEEN DIRECTED TO ASSEMBLE AND RETAIN ALL RELEVANT DOCUMENTS
 - THE DEPARTMENT IS CASTING THE NET WIDELY
 - ALL NECESSARY STAFF AND RESOURCES WILL BE PROVIDED
- ◆ WORK IS UNDERWAY WITH THE NATIONAL ARCHIVES TO ESTABLISH A CENTRAL LOCATION FOR RETENTION OF RECORDS FOR USE BY THE TASK FORCE

HUMAN SCIENTIFIC AND MEDICAL EXPERIMENTS
HOTLINE

- ◆ 340 CALLS ON VOICE MAIL AS OF 2:00 PM, MONDAY, DECEMBER 27, 1993:
 - NUMBER OF PERSONS STAFFING HOTLINE HAS TRIPLED SINCE THE TELEPHONE LINE OPENED THURSDAY AFTERNOON, DECEMBER 23, 1993, DUE TO THE LARGE NUMBER OF CALLS.
- ◆ CONCERN THAT THE MEDIA MAY BE MISUNDERSTANDING THE PURPOSE OF THE HOTLINE. THE DEPARTMENT IS TRYING TO LEARN THE SCOPE OF WHAT MAY HAVE OCCURRED.
 - HOTLINE ONLY TO BE USED BY PERSONS WHO SUSPECT THEY (OR FAMILY MEMBERS) WERE SUBJECTS IN MEDICAL OR SCIENTIFIC EXPERIMENTS CONDUCTED BY THE DEPARTMENT OF ENERGY OR ITS PREDECESSOR AGENCIES.
 - IF, AT A LATER TIME, OUR RESEARCH SHOWS THAT OTHER POPULATIONS MAY HAVE BEEN AFFECTED, WE WILL THEN SOLICIT INFORMATION FROM THE POTENTIAL SUBJECT GROUP.
- ◆ DUE TO PRIVACY CONCERNS, THE DEPARTMENT WILL NOT RELEASE INFORMATION ABOUT SPECIFIC CALLERS.
 - AS DATA IS COMPILED AND ANALYZED, THE DEPARTMENT WILL OPENLY SHARE AVAILABLE INFORMATION, SUBJECT TO PRIVACY AND ETHICAL REQUIREMENTS.

The New York Times

Circulation 1,068,217

DEC 27 1993

Paper Says Radiation Test Used 19 Retarded Youths

A14

Nineteen mentally retarded boys who thought they were participating in a science club in the 1940's and 1950's were actually fed radioactive milk by scientists, who wanted to learn about the digestive system, The Boston Sunday Globe reported.

The experiment is one of several radiation studies from that time that have come under ethical scrutiny this year. The growing number of questionable experiments has led to a Federal investigation of radiation experiments done on people.

The Massachusetts experiments, carried out from 1946 to 1956, were done on retarded boys at the Fernald State School in Waltham, Mass. Scientists from Harvard University and the Massachusetts Institute of Technology fed radioactive forms of iron and calcium to the boys, sometimes in their breakfast milk, to study the body's ability to digest minerals. The Globe reported, quoting a scientist who participated in the studies and old school records.

While one researcher said that the radiation levels to which the boys were exposed were not harmful, other experts said there was no such thing as a safe level of exposure. The experiment exposed the boys to radiation that was at least the equivalent of 50 chest X-rays, The Globe reported.

The school sent a letter to parents but did not mention radiation. "We are considering the selection of a group of our brighter patients, including your son, to receive a special diet," said a portion of the letter printed in The Globe. The boys were told that they were part of a science club.

Energy Secretary Hazel R. O'Leary promised earlier this month to undertake an investigation of radiation experiments on civilians to learn if the volunteers gave consent and if they fully understood the risks.

A toll-free telephone line, (800) 493-2998, has been set up by the Department to gather information from people who think they may have been used in radiation experiments financed by the Federal Government.

Radiation used on retarded

Postwar experiments done at Fernald school

By Scott Allen
GLOBE STAFF

WALTHAM - Records at the Fernald State School list them as "morons," but the researchers from MIT and Harvard University called the retarded teen-age boys who took part in their radiation experiments "the Fernald Science Club."

In the name of science, members of the club would eat cereal mixed with radioactive milk for breakfast or digest a series of iron supplements that gave them the radiation-equivalent of at least 50 chest X-rays. From 1946 to 1956, scores of retarded teen-agers consumed radioactive food to help the researchers better understand the human digestive process.

"There is absolutely no ground for caution regarding the quantities of radioactive substances which we would use in our experiments," Massachusetts Institute of Technology biochemist Robert S. Harris assured Fernald's superintendent in a letter proposing the research in December 1945. At least some consent forms sent home to parents or guardians do not mention radiation.

The experiments at the Fernald School, which almost certainly would not be permitted today, are one of the darker corners of Massachusetts' atomic legacy. Along with pioneering the field of nuclear medicine, some of the state's leading academic institutions and hospitals also subjected the terminally ill, the elderly and others to radiation doses that are considered unsafe today, often with no possible benefit to the test subjects.

RADIATION, Page 45

BOSTON GLOBE DEC 26 1993

Though never secret - researchers published the results of the Fernald studies in scholarly journals - details of the research effort, funded partly by Quaker Oats Co. and the US Atomic Energy Commission, have sat in a jumble of boxes in the Fernald School library until now.

The Albuquerque Tribune of New Mexico sparked new interest in human radiation experiments last month with harrowing accounts of prisoners, mental patients and even pregnant women who were given plutonium and other radioactive material in government-supported research after World War II. US Energy Secretary Hazel O'Leary has started a federal review of human radiation experiments, promising to declassify government documents that shed light on the subject.

"It's very important that the public begin to see that secrecy at bottom is what lets this happen," said David Rush of Tufts University's Human Nutrition Research Center, who has written a book on radiation exposure to defense workers. He called the Fernald experiments "something of which American medicine should be ashamed."

But Constantine Maletskos, a former MIT researcher who studied how teen-agers at Fernald metabolized radioactive calcium, defended the experiments, saying they yielded important information about nutrition.

"I feel just as good about it today as the day I did it," he said. "The attitude of the scientists was we're going to do this in the best way possible. ... They would get the minimum radiation they could possibly get and have the experiment work."

The Fernald participants, who were between 15 and 17 years old at the time, would be in their 50s and 60s today.

11313
BURRELLE'S

NEWSPRESS

PAGE 3 OF 1

Maletskos does not know of any follow-up health studies on the Fernald subjects, but he maintains to this day that the children were not harmed because the radiation levels were so low. However, other radiation researchers, such as Richard Clapp of JSI in Boston, an epidemiology research group, believe there is no such thing as a safe level.

The experiments at Fernald grew out of nutritionists' concern that a diet heavy in cereal might slow down the body's ability to digest two important minerals, iron and calcium. The best way to study this problem, team leader Harris concluded, was to use a radioactive form of the two minerals, which are easy to detect in blood and human waste.

Harris told Malcolm Farrell, superintendent of Fernald at the time, that the boys would be eating radioactive food. But Farrell's 1946 letter to parents and guardians, still in a file at the Fernald library, makes no mention of radiation. "We are considering the selection of a group of our brighter patients, including your son, to receive a special diet rich in iron and vitamins, the form letter reads.

Authorities at Fernald referred questions to the Department of Mental Retardation, which now runs the school. State officials last week said they were unaware of the tests, and they said such work would be extremely unlikely today.

"We should always be concerned that these things can happen to a population that's been devalued. We have to continually have safeguards in place to reduce the chance that it will ever happen again," said mental retardation Commissioner Philip Campbell.

The federal review is likely to involve a number of research institutions in Massachusetts, which received more shipments of radioactive isotopes for research than any other state except New York from 1946 to 1961, according to federal records.

Much of the radioactivity was used for health-related research - for example, MIT discovered that radioactive paint used on luminous watches was making workers sick. But sometimes the subjects of the research were little more than "human guinea pigs," as US Rep. Edward J. Markey, Democrat of Malden, said in a 1986 report. Markey found that MIT researchers studying the watch workers' plight fed 20 elderly people radium to see how it passed through their bodies. He also found that Massachusetts General Hospital in Boston injected radioactive uranium into terminally ill patients in the 1950s to measure its effect on kidneys.

A US Atomic Energy Commission index of where it shipped radioactive isotopes, obtained by the Center for Atomic Radiation Studies of Brookline, suggests that human experimentation in Massachusetts may have been more widespread. The index, which covers 1946 to 1951, lists experiments at the Framingham Veterans Administration hospital, tests of "the long-term toxic effects of radio-iodine" at Beth Israel Hospital in Boston, as well as the research at Fernald.

"What we are seeing in the local experimentation is that sometimes the face of evil can turn out to be authority infected by opportunism and arrogance," said Dan Bernstein, president of the Center for Atomic Radiation Studies, a small, nonprofit group that follows use of radioactive material.

But Philip Reilly of the Shriver Center for Mental Retardation in Waltham, author of a book on forced sterilization of the retarded, cautions against applying today's standards to experiments done decades ago. After all, the US Public Health Service conducted its Tuskegee syphilis experiment - in which black men were denied treatment to see how the disease affected them - until it came to public attention in 1972.

Still, Reilly said, the human radiation researchers can be held accountable. "They had to realize that any radiation beyond background radiation involved some risk," Reilly said. At Fernald, he said, "they were not being up front by their own standards at that time."

Researchers called the teen-agers who

2/3 14
BURRELLE'S

NEWS EXPRESS

PAGE 8 OF 11

took part in the Fernald experiments a "science club" even though they had the "mental age" of 8-year-olds. "I guess they were calling all these kids who were doing this a club to make them develop a rapport among themselves," said Maletskos, who was not involved in recruiting participants.

In the first battery of tests, conducted in 1946 before Maletskos arrived, 17 adolescent boys ate meals laced with radioactive iron, an isotope that can harm blood and the spleen. Based on figures in an unpublished report on the project, the children's spleens were exposed to between 544 and 1,024 millirems of radiation over the course of seven meals. By comparison, the typical American receives about 300 millirems of radiation from natural sources each year.

Next, the team studied calcium digestion by adding a radioactive form of calcium to the breakfast milk of 19 boys. This time, each child had only one radioactive meal, exposing each child's bones to 35 millirems of radiation. By comparison, during their lifetimes, most Americans will receive 110 millirems of radiation on their bones from the fallout of nuclear weapons testing, according to Jacob Shapiro, director of radiation protection at Harvard University.

Maletskos said the research team did everything possible to minimize exposure using animals to develop test procedures first and then limiting each boy's participation. "If you could do it any other way, we did not recommend radiation," said Maletskos, a biophysicist who is still researching the effects of radium and thorium on health.

Shapiro declined to say whether the experiments were dangerous, but he added, "I would ask a colleague of mine, would you let your child get that dose?"

Records at the Fernald library are incomplete, but they are dotted with references to radiation research from 1946 to 1956, including a list of 49 children invited to an annual Christmas party at MIT as a reward for taking part in the experiments. "I can remember vividly the kids singing the red-nosed reindeer song, and it was very well done," recalled Maletskos.

Even if the radiation levels were trivial, mental health experts today say that the Fernald experiments probably could not be repeated. Today, human experiments must win approval from two independent review boards that force researchers to consider alternatives and calculate the risks. And in any human tests, subjects or their guardians must have all the facts before they can agree to participate.

15
313
BURRELLE'S

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PAGE 4 OF 11