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, history of science, radiation biology and oncology, 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 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 1944 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.

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.

WHY DO WE CARE ABOUT HUMAN RADIATION EXPERIMENTS?

o **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.**

o **THIS IS GOOD FOR SCIENCE.**

- **Science and technology are critical engines for the American economy and both have come under attack for disregarding the effects of their activities on citizens.**

  * **The "Not-In-My-Backyard" 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.**

o **THIS IS CUTTING EDGE TECHNOLOGY FOR GETTING INFORMATION DIRECTLY IN THE HANDS OF PEOPLE.**

- **For this project, the Department 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 Freedom of Information Act process obsolete.

o 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 Committee to judge the ethical issues:

  * Millions of pages of documents all over the country, dating back 50 years, have been sifted by the agencies;

  * Hundreds of thousands of pages of documents have been identified as pertinent; and

  * The Advisory Committee will reach its judgments.

- This could never have been accomplished had business-as-usual obtained.

Prepared by Ellyn Weiss, Office of Human Radiation Experiments
February 7, 1995

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

Why was the Advisory Committee formed?

The President of the United States appointed the Committee to analyze these questions: What is the federal government's responsibility for wrongs and harms to human subjects as a result of experiments with ionizing radiation? What remedies are appropriate for those wronged or harmed? And what lessons learned from studying research standards and practices in the past and present can be applied to the future?

Who are members of the Advisory Committee?

The 14 members are nationally recognized experts in bioethics, epidemiology, radiation oncology and biology, history of science, law and nuclear medicine. The Committee also includes a citizen representative. Ruth Faden, a bioethicist at Johns Hopkins University, chairs the Advisory Committee.

What is the Committee authorized to review?

The Committee's charter includes the review of experiments conducted since the 1940s with ionizing radiation and the investigation of specific intentional releases of radiation into the environment.

The Committee's mandate does not include common and routine clinical practices, such as established diagnosis and treatment methods. An important question is how to define the difference between ordinary practice and experimental procedures.

Another important question is whether accidental exposures gave agencies or researchers a chance to conduct "experiments of opportunity."

What will the Advisory Committee do?

The members will prepare a report designed to answer the three questions posed above. The report will be issued in 1995 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.

How will the Advisory Committee evaluate today's practices?

A sample of research protocols funded by federal agencies in fiscal year 1993 is being used to assess ethical standards and procedures in today's environment. Researchers and subjects of research will be interviewed.

How has the Committee looked into past practices?

The President directed federal agencies to search their files for information about research on human subjects in the past. This process has been revised and expanded under the Committee's direction. Literally thousands of documents, many previously unreported and some of them only declassified this year, have been made available to the public as a result of this effort.

Many documents are, of course, fragmentary accounts of experiments. Recreating the ethics policies, standards and practices of 40 or 50 years ago is difficult, much less recreating the conversations between subjects and researchers.

The Advisory Committee has reviewed many private collections left by subjects of experiments and by researchers.

How has the Committee responded to public concern about these experiments?

The Committee recognizes the importance of hearing directly from people throughout the country and including them in its activities. The Committee seeks out participants in past experiments to hear about their experiences and use their recollections to guide its research and inform its judgments.

In addition to soliciting the views of subjects and other interested parties at its Washington meetings, the Committee has scheduled public meetings around the country to hear first-hand from persons involved in research. The Committee has gained valuable documents and insights from working with subjects or their families, as well as researchers, and that process will continue throughout the life of the Committee's work.

What are key questions about experimentation?

The Committee must define the boundaries of experimentation. What is an experiment? How does it differ from innovative treatment? How does it differ from training, as in the case of military units participating in atomic weapons tests in the 1950s? When is an experiment over? Each question bears on the scope of the Committee's endeavors and the way it evaluates the evidence before it.

What are the ethical questions in research?

The issues to be weighed by the Committee are many and complex. These include the risks or harm to the subject, and the benefit to the subject or to society as a whole; whether subject populations have been chosen fairly and appropriately; whether subjects have been fully informed and have fully consented to participate in research.

The Committee has discovered more extensive ethical codes and policies in the government than had previously been known. It's not always clear whether they were applied, or how they were interpreted in different circumstances. These codes and policies, however, are critical to the determination of whether experiment subjects were appropriately informed of risks or harms, and selected fairly for the purposes of experimentation.

How can people contact the Committee?

The Committee staff can be reached by telephone at 202/254-9795 or in writing at 1726 M Street NW, Suite 600, Washington, D.C. 20036.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

PRIVILEGED AND CONFIDENTIAL
FOR DISCUSSION PURPOSES ONLY
DRAFT

OK

CHARTER

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

1. **Committee's Official Designation:**

Advisory Committee on Human Radiation Experiments

2. **Authority:**

Executive Order No. _____

3. **Committee's Objectives And Scope Of Activities:**

To provide advice, information, and recommendations to the Human Radiation Interagency Working Group on the ethical and scientific standards applicable to human radiation experiments carried out or sponsored by the United States Government. The members of the Human Radiation Interagency Working Group include the Secretaries of Energy, Defense, Health and Human Services, and Veterans Affairs; the Attorney General; the Administrator of the National Aeronautics and Space Administration; the Director of the Central Intelligence Agency; and the Director of the Office of Management and Budget.

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 which

(A) were designed to test human health effects of ionizing radiation; or

(B) were designed to test the extent of human exposure to ionizing radiation.

The Advisory Committee shall also provide advice, information and recommendations on the following specific 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 devices containing radioactive agents at the U.S. Army's Duqway, Utah site;

(4) Four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and

(5) Any other experiments which may later be identified by the Human Radiation Interagency Working Group.

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

4. **A Description Of Duties For Which The Committee Is Responsible:**

The duties of the Committee are solely advisory and include:

a. The Committee will determine the ethical and scientific standards and criteria by which human radiation experiments, as defined in paragraph 3 herein, shall be evaluated. The Committee shall consider whether: (1) there was a clear medical or scientific purpose for the experiments; (2) appropriate medical follow-up was conducted; and (3) the experiments' design and administration adequately met the standards of informed consent that prevailed at the time of the experiments and that exist today.

b. The 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 4(a), above. If deemed necessary for such an assessment, the Committee may carry out a detailed review of experiments and associated records.

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

d. The Committee shall assess current federal human experiment subject protection policies and recommend further policies, as needed, to ensure compliance with appropriate ethical and scientific standards.

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

5. **Time Period Necessary For The Committee To Carry Out Its Purpose:**

This Advisory Committee shall submit its final report to the Human Radiation Interagency Working Group one year from the date of the filing of this Charter, unless such period is extended by the Human Radiation Interagency Working Group. The Committee will issue an interim report six months after the filing of this Charter. In its interim report, the Committee shall advise the Human Radiation Interagency Working Group on the likelihood that the Committee will be able to complete its duties within one year.

6. **Official To Whom This Committee Reports:**

The Committee shall report to the Human Radiation Interagency Working Group.

7. **Agencies Responsible For Providing Necessary Financial Support:**

Financial support shall be provided by the Department of Energy.

8. **Estimated Annual Operating Costs:**

$2 million.

9. **Estimated Number And Frequency Of Committee Meetings:**

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

10. **Committee's Termination Date (If Less than Two Years From The Dated Of Establishment):**

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

11. **Subcommittee(s):**

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

12. **Members:**

Up to a maximum of fifteen 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).

13. **Chairperson:**

A Chairperson shall be designated by the President.

PRIVILEGED AND CONFIDENTIAL
DRAFT -- FOR DISCUSSION PURPOSES ONLY

EXECUTIVE ORDER NO. _____

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

By the authority vested in me as President by the Constitution and statutes 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. I.

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

Section 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 the Central Intelligence Agency, 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 which (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation.

The Advisory Committee shall also provide advice, information and recommendations on the following specific 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 devices containing radioactive agents at the U.S. Army's Duqway, Utah, site;

(4) four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and

(5) any other experiments which may later be identified by the Human Radiation Interagency Working Group.

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

(b) The Advisory Committee shall:

(1) Determine the ethical and scientific standards and criteria by which human radiation experiments, as defined in paragraph a of this Section, shall be evaluated. 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 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.

(3) If required to protect the health of individuals who were subject of a human radiation experiment, the Advisory

Committee may recommend to the Human Radiation Interagency Working Group that an agency notify a particular subject of an experiment, or his or her descendants, of any potential health risk of the need for medical follow-up.

(4) The Advisory Committee shall assess current federal human experiment subject protection policies and recommend further policies, as needed, to ensure compliance with appropriate ethical and scientific standards.

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

Section 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.

Section 4. General provisions. (a) Notwithstanding the provisions of any other Executive Order, the functions of the President under the Federal Advisory Committee Act which are applicable to the Advisory Committee, except that of reporting annually to 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.

(c) This Order is intended only to improve the internal management of the Executive Branch and 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.

THE WHITE HOUSE,
January ___, 1994

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release January 18, 1994

EXECUTIVE ORDER

- - - - - - -

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

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:

more

(OVER)

(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.

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.

(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.

WILLIAM J. CLINTON

THE WHITE HOUSE,
January 15, 1994.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release January 18, 1994

EXECUTIVE ORDER

- - - - - - -

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

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:

more

(OVER)

(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.

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.

(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.

WILLIAM J. CLINTON

THE WHITE HOUSE,
January 15, 1994.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release January 18, 1994

EXECUTIVE ORDER

- - - - - - -

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

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:

more

(OVER)

(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.

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.

(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.

WILLIAM J. CLINTON

THE WHITE HOUSE,
January 15, 1994.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release January 18, 1994

EXECUTIVE ORDER

- - - - - - -

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

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:

more

(OVER)

(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.

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.

(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.

WILLIAM J. CLINTON

THE WHITE HOUSE,
January 15, 1994.

# # #

Department of Energy
Washington, DC 20585

OFFICE OF PUBLIC AFFAIRS, PA-1

Facimile Machine Number
202/586-9987

Verification Number
202/586-4940

DATE: 2-22-94

TO: Phil Coplan

Fax Number 456-6704

Verification Number _____

FROM: Gauldin

*This transmittal consists of 1 page(s) excluding this cover sheet.

MEMO

2/21/94

TO: Phil Kaplan
FROM: Gauldin GAULDIN
cc: Dan Reicher
STEVE GALSTON

RE: Radiation survivors

I talked to Fred Abbington of the Radiation Survivors over the weekend and allayed his concerns about the makeup of the Advisory Committee.

He said, however, that he'd already sent letters to Secretary O'Leary and President Clinton. When those are received, I think the response should be something along the line of "I understand that you've been contacted and your concerns have been addressed but encourage you to keep in contact, etc."

I explained the makeup of the Committee and the reasons for not placing advocates of any point of view on it.

I also offered myself as his personal contact through which to communicate to the Working Group.

His root concern is that in the past, when compensation plans have been devised by the government, it's been done with no input from the affected victims and in effect, such plans have been designed to squeeze people out of eligibility and make it nearly impossible to actually get compensation.

I think it would be advisable to plan for some forum when we begin to address the question of compensation in which Abbington and similar advocacy groups can express their concerns.

Whether this is done through the Working Group itself or during the course of the eventual Congressional debate on compensation is one we should talk about.

I have made myself available to Mr. Abbington if he has further concerns or suggestions and I will keep you apprised of anything that should be taken into consideration.

1-13-94
3:15

EXECUTIVE ORDER

- - - - - -

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

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.

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 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 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.

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 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 descendents, 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 services (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 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.

(c) This order is intended only to improve the internal management of the Executive Branch and it 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.

THE WHITE HOUSE,

PRIVILEGED AND CONFIDENTIAL
DRAFT -- FOR DISCUSSION PURPOSES ONLY

EXECUTIVE ORDER NO. _____

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

By the authority vested in me as President by the Constitution and statutes 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. I.

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

Section 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 the Central Intelligence Agency, 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 which (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation.

The Advisory Committee shall also provide advice, information and recommendations on the following specific 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 devices containing radioactive agents at the U.S. Army's Duqway, Utah, site;

(4) four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and

(5) any other experiments which may later be identified by the Human Radiation Interagency Working Group.

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

(b) The Advisory Committee shall:

(1) Determine the ethical and scientific standards and criteria by which human radiation experiments, as defined in paragraph a of this Section, shall be evaluated. 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 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.

(3) If required to protect the health of individuals who were subject of a human radiation experiment, the Advisory

Committee may recommend to the Human Radiation Interagency Working Group that an agency notify a particular subject of an experiment, or his or her descendants, of any potential health risk of the need for medical follow-up.

(4) The Advisory Committee shall assess current federal human experiment subject protection policies and recommend further policies, as needed, to ensure compliance with appropriate ethical and scientific standards.

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

Section 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.

Section 4. General provisions. (a) Notwithstanding the provisions of any other Executive Order, the functions of the President under the Federal Advisory Committee Act which are applicable to the Advisory Committee, except that of reporting annually to 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.

(c) This Order is intended only to improve the internal management of the Executive Branch and 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.

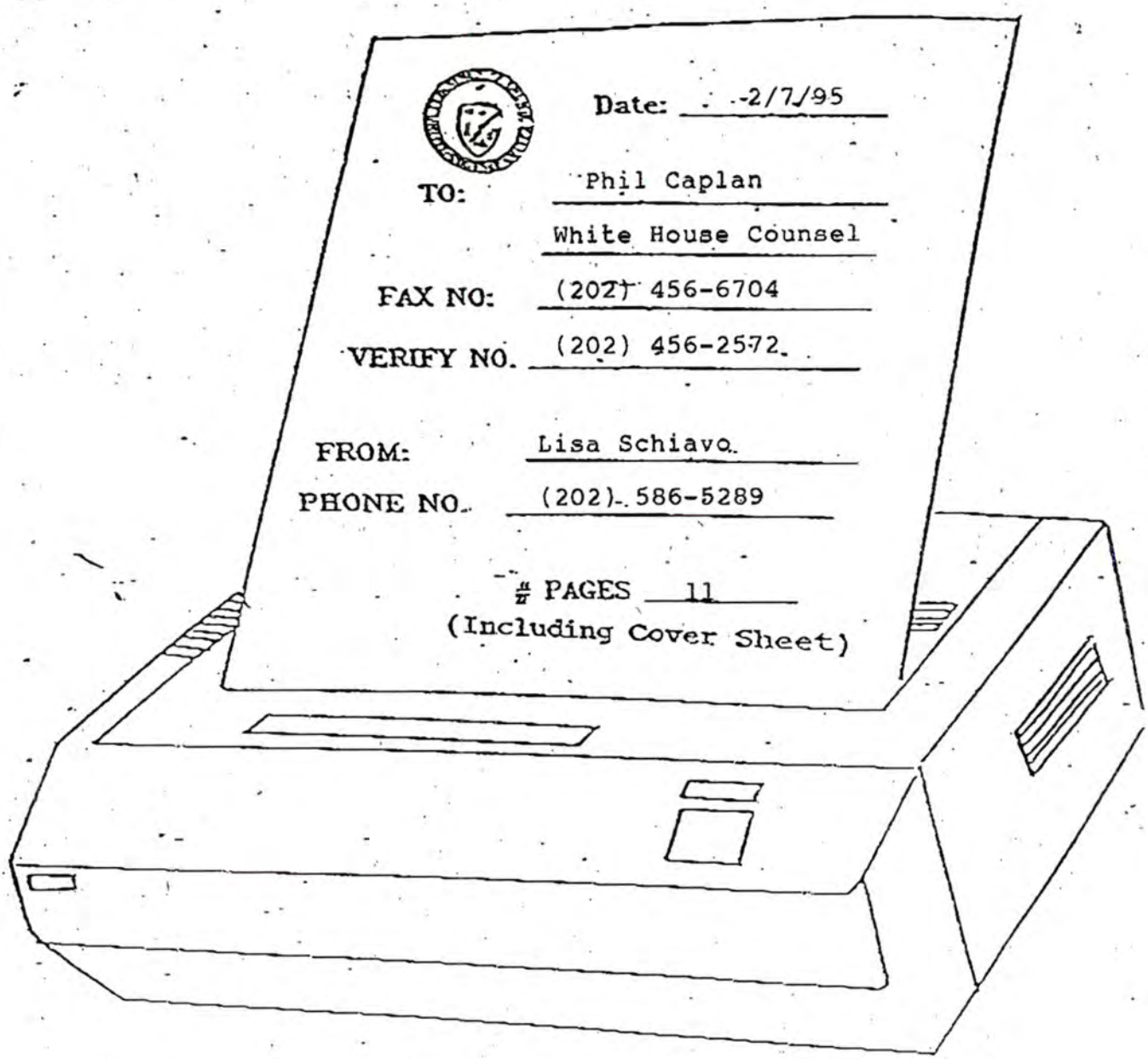
THE WHITE HOUSE,
January ___, 1994

OFFICE OF THE GENERAL COUNSEL

U.S. DEPARTMENT OF ENERGY

WASHINGTON, D.C.

FAX #:
COML:



Date: 2/7/95

TO: Phil Caplan
White House Counsel

FAX NO: (202) 456-6704

VERIFY NO. (202) 456-2572

FROM: Lisa Schiavo

PHONE NO. (202) 586-5289

PAGES 11
(Including Cover Sheet)

REMARKS: See pages 51 & 56 - Let me know if counsel decides that DOE should make the designation and we will do it.

no of may 92.

report, as well as the *Congressional Record* (daily ed. October 10, 1986, pp. S 15865-15868), should provide an adequate basis for an agency to determine which of its employees may be authorized home-to-work transportation.

(b) Additional examples of employees who may perform field work include, but are not limited to, quality assurance inspectors, construction inspectors, customs inspectors, dairy inspectors, revenue officers, compliance investigators, and personnel background investigators. The assignment of an employee to such a position does not, of itself, entitle an employee to receive daily home-to-work transportation. When authorized, such transportation should be provided only on days when the employee actually performs field work, and then only to the extent that such transportation will substantially increase the efficiency and economy of the Government.

(c) Instances may occur when an employee, by the nature of his/her job, is designated as being authorized home-to-work transportation under the field work provision. However, circumstances may require that field work only be performed on an intermittent basis. In those instances, the agency shall establish procedures to ensure that a Government passenger carrier is used only when field work is actually being performed.

(d) In making field work determinations under § 101-6.403(b), an agency head may elect to designate positions rather than individual names, especially in positions where rapid turnover occurs. The determination should contain sufficient information, such as the job title, number, and operational level where the work is to be performed (i.e., five recruiter personnel or positions at the Detroit Army Recruiting Battalion) to satisfy an audit, if necessary.

(e) Situations may arise where it is more cost-effective for the Government to provide an employee a vehicle for home-to-work transportation rather than have the employee travel a long distance to pick up a vehicle and then drive back toward or beyond his/her residence to perform his/her job. In those situations agencies should consider basing the vehicle at a Government facility located near the employee's job site. If such a solution is not feasible, an agency must then decide if the use of the vehicle should be approved under the compelling operational considerations definition. Home-to-work transportation in such cases may be approved only if other available alternatives would involve substantial cost to the Government or expenditure of substantial employee time.

Subparts 101-6.5—101-6.9—[Reserved]

Subpart 101-6.10—Federal Advisory Committee Management

AUTHORITY: Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c); sec. 7, 5 U.S.C., App.; and E.O. 12024, 3 CFR 1977 Comp., p. 158.

SOURCE: 52 FR 45929, Dec. 2, 1987, unless otherwise noted.

§ 101-6.1001 Scope.

(a) This subpart defines the policies, establishes minimum requirements, and provides guidance to agency management for the establishment, operation, administration, and duration of advisory committees subject to the Federal Advisory Committee Act, as amended. Reporting requirements which keep the Congress and the public informed of the number, purpose, membership activities, and cost of these advisory committees are also included.

(b) The Act and this subpart do not apply to advisory meetings or groups listed in § 101-6.1004.

[52 FR 45929, Dec. 2, 1987, as amended at 54 FR 41215, Oct. 5, 1989]

§ 101-6.1002 Policy.

The policy to be followed by Federal departments, agencies, and commissions, consistent with the Federal Advisory Committee Act, as amended, is as follows:

(a) An advisory committee shall be established only when it is essential to the conduct of agency business. Decision criteria include whether committee deliberations will result in the creation or elimination of, or change in regulations, guidelines, or rules affect-

rnment facility located near the oyee's job site. If such a solution t feasible, an agency must then le if the use of the vehicle should ıpproved under the compelling ational considerations definition. e-to-work transportation in such may be approved only if other able alternatives would involve tantial cost to the Government or nditure of substantial employee

Subparts 101-6.5—101-6.9—[Reserved]

ıpart 101-6.10—Federal Advisory Committee Management

UTHORITY: Sec. 205(c), 63 Stat. 390; 40 .C. 486(c); sec. 7, 5 U.S.C., App.; and E.O. 24, 3 CFR 1977 Comp., p. 158.

OURCE: 52 FR 45929, Dec. 2, 1987, unless erwise noted.

01-6.1001 Scope.

a) This subpart defines the policies, ablishes minimum requirements, d provides guidance to agency man- ement for the establishment, oper- on, administration, and duration of visory committees subject to the deral Advisory Committee Act, as ıended. Reporting requirements ıich keep the Congress and the ıblic informed of the number, pur- ose, membership activities, and cost these advisory committees are also cluded.

(b) The Act and this subpart do not pply to advisory meetings or groups sted in § 101-6.1004.

52 FR 45929, Dec. 2, 1987, as amended at 54 R 41215, Oct. 5, 1989]

101-6.1002 Policy.

The policy to be followed by Federal lepartments, agencies, and commis- ions, consistent with the Federal Ad- isory Committee Act, as amended, is as follows:

(a) An advisory committee shall be established only when it is essential to the conduct of agency business. Decision criteria include whether committee deliberations will result in the creation or elimination of, or change in regulations, guidelines, or rules affecting agency business; whether the information to be obtained is already available through another advisory committee or source within the Federal Government; whether the committee will make recommendations resulting in significant improvements in service or reductions in cost; or whether the committee's recommendations will provide an important additional perspective or viewpoint impacting agency operations;

(b) An advisory committee shall be terminated whenever the stated objectives of the committee have been accomplished; the subject matter or work of the committee has become obsolete by the passing of time or the assumption of the committee's main functions by another entity within the Federal Government; or the agency determines that the cost of operation is excessive in relation to the benefits accruing to the Federal Government;

(c) An advisory committee shall be fairly balanced in its membership in terms of the points of view represented and the functions to be performed; and

(d) An advisory committee shall be open to the public in its meetings except in those circumstances where a closed meeting shall be determined proper and consistent with the provisions in the Government in the Sunshine Act, 5 U.S.C. 552(b).

[52 FR 45929, Dec. 2, 1987, as amended at 54 FR 41215, Oct. 5, 1989]

§ 101-6.1003 Definitions.

Act means the Federal Advisory Committee Act, as amended, 5 U.S.C., App.

Administrator means the Administrator of General Services.

Advisory committee subject to the Act means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof, which is established by statute, or established or utilized by the President or any agency official for the purpose of obtaining advice or recommendations on issues or policies which are within the scope of his or her responsibilities.

Agency has the same meaning as in section 551(1) of title 5 of the United States Code.

Committee Management Secretariat (Secretariat), established pursuant to the Act is responsible for all matters relating to advisory committees, and carries out the Administrator's responsibilities under the Act and Executive Order 12024.

Committee member means an individual who serves by appointment on an advisory committee and has the full right and obligation to participate in the activities of the committee, including voting on committee recommendations.

Presidential advisory committee means any advisory committee which advises the President. It may be established by the President or by the Congress, or used by the President in the interest of obtaining advice or recommendations for the President. "Independent Presidential advisory committee" means any Presidential advisory committee not assigned by the President, or the President's delegate, or by the Congress in law, to an agency for administrative and other support and for which the Administrator of General Services may provide administrative and other support on a reimbursable basis.

Staff member means any individual who serves in a support capacity to an advisory committee.

Utilized (or *used*), as referenced in the definition of "Advisory committee" in this section, means a committee or other group composed in whole or in part of other than full-time officers or employees of the Federal Government with an established existence outside the agency seeking its advice which the President or agency official(s) adopts, such as through institutional arrangements, as a preferred source from which to obtain advice or recommendations on a specific issue or policy within the scope of his or her responsibilities in the same manner as that individual would obtain advice or recommendations from an established advisory committee.

§ 101-6.1004 Examples of advisory meetings or groups not covered by the Act or this subpart.

The following are examples of advisory meetings or groups not covered by the Act or this subpart;

(a) Any committee composed wholly of full-time officers or employees of the Federal Government;

(b) Any advisory committee specifically exempted by an Act of Congress;

(c) Any advisory committee established or utilized by the Central Intelligence Agency;

(d) Any advisory committee established or utilized by the Federal Reserve System;

(e) The Advisory Committee on Intergovernmental Relations;

(f) Any local civic group whose primary function is that of rendering a public service with respect to a Federal program, or any State or local committee, council, board, commission, or similar group established to advise or make recommendations to State or local officials or agencies;

(g) Any committee which is established to perform primarily operational as opposed to advisory functions. Operational functions are those specifically provided by law, such as making or implementing Government decisions or policy. An operational committee may be covered by the Act if it becomes primarily advisory in nature. It is the responsibility of the administering agency to determine whether such a committee is primarily operational. If so, it would not fall under the requirements of the Act and this Subpart, but would continue to be regulated under relevant laws, subject to the direction of the President and the review of the appropriate legislative committees;

(h) Any meeting initiated by the President or one or more Federal official(s) for the purpose of obtaining advice or recommendations from one individual;

(i) Any meeting initiated by a Federal official(s) with more than one individual for the purpose of obtaining the advice of individual attendees and not for the purpose of utilizing the group to obtain consensus advice or recommendations. However, agencies should be aware that such a group would be covered by the Act when an agency accepts the group's deliberations as a source of consensus advice or recommendations;

(j) Any meeting initiated by a group with the President or one or more Federal official(s) for the purpose of expressing the group's view, provided that the President or Federal official(s) does not use the group recurrently as a preferred source of advice or recommendations;

(k) Meetings of two or more advisory committee or subcommittee members convened solely to gather information or conduct research for a chartered advisory committee, to analyze relevant issues and facts, or to draft proposed position papers for deliberation by the advisory committee or a subcommittee of the advisory committee; or

(l) Any meeting with a group initiated by the President or one or more Federal official(s) for the purpose of exchanging facts or information.

§ 101-6.1005 Authorities for establishment of advisory committees.

An advisory committee may be established in one of four ways:

(a) By law where the Congress specifically directs the President or an agency to establish it;

(b) By law where the Congress authorizes but does not direct the President or an agency to establish it. In this instance, the responsible agency head shall follow the procedures provided in § 101-6.1007;

(c) By the President by Executive Order; or

(d) By an agency under general agency authority in Title 5 of the United States Code or under other general agency-authorizing law. In this instance, an agency head shall follow the procedures provided in § 101-6.1007.

§ 101-6.1006 [Reserved]

§ 101-6.1007 Agency procedures for establishing advisory committees.

(a) When an agency head decides that it is necessary to establish a committee, the agency must consider the functions of similar committees in the same agency before submitting a consultation to GSA to ensure th
plication of effort will occur.

(b) In establishing or utilizi
visory committee, the hea
agency or designee shall con
the Act and this subpart, and

(1) Prepare a proposed ch
the committee which include
formation listed in section 9
Act; and

(2) Submit a letter and the
charter to the Secretariat pro
establish or use, reestablish,
an advisory committee. Tl
shall include the following
tion:

(i) An explanation of why
mittee is essential to the c
agency business and in the
terest;

(ii) An explanation of why
mittee's functions cannot
formed by the agency, anot
ing advisory committee of th
or other means such as a pu
ing; and

(iii) A description of the
plan to attain fairly balanced
ship. The plan will ensure th
selection of members for th
tee, the agency will conside
section of those directly af
terested, and qualified, as a
to the nature and functio
committee. Committees
technical expertise should in
sons with demonstrated pr
or personal qualifications a
ence relevant to the func
tasks to be performed.

(3) Subcommittees that do
tion independently of th
parent advisory committee
follow the requirements of
(b)(1) and (b)(2) of this sec
ever, they are subject to al
quirements of the Act.

(4) The requirements of
(b)(1) and (b)(2) of this se
apply for any subcommitt
tered advisory committee, v
members are drawn in whol
from the full or parent adv
mittee, which functions ind
of the parent advisory comm
as by making recommendat
ly to the agency rather tha
sideration by the chartere
committee.

)y the Act when an agency ac-
e group's deliberations as a
f consensus advice or recom-
)ns;
meeting initiated by a group
President or one or more
official(s) for the purpose of
ig the group's view, provided
ie President or Federal
) does not use the group re-
as a preferred source of
recommendations;
etings of two or more advisory
ee or subcommittee members
l solely to gather information
ict research for a chartered
committee, to analyze rele-
ies and facts, or to draft pro-
)sition papers for deliberation
advisory committee or a sub-
ee of the advisory committee;

meeting with a group initiat-
he President or one or more
official(s) for the purpose of
ing facts or information.

)05 Authorities for establishment visory committees.

visory committee may be es-
l in one of four ways:
law where the Congress spe-
directs the President or an
o establish it;
law where the Congress au-
but does not direct the Presi-
an agency to establish it. In
tance, the responsible agency
all follow the procedures pro-
§ 101-6.1007;
y the President by Executive
)r
y an agency under general
authority in Title 5 of the
States Code or under other
agency-authorizing law. In
stance, an agency head shall
the procedures provided in
1007.

006 [Reserved]

007 Agency procedures for estab-ng advisory committees.

When an agency head decides
is necessary to establish a com-
the agency must consider the
ns of similar committees in the
gency before submitting a con-

sultation to GSA to ensure that no duplication of effort will occur.

(b) In establishing or utilizing an advisory committee, the head of an agency or designee shall comply with the Act and this subpart, and shall:

(1) Prepare a proposed charter for the committee which includes the information listed in section 9(c) of the Act; and

(2) Submit a letter and the proposed charter to the Secretariat proposing to establish or use, reestablish, or renew an advisory committee. The letter shall include the following information:

(i) An explanation of why the committee is essential to the conduct of agency business and in the public interest;

(ii) An explanation of why the committee's functions cannot be performed by the agency, another existing advisory committee of the agency, or other means such as a public hearing; and

(iii) A description of the agency's plan to attain fairly balanced membership. The plan will ensure that, in the selection of members for the committee, the agency will consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and functions of the committee. Committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed.

(3) Subcommittees that do not function independently of the full or parent advisory committee need not follow the requirements of paragraphs (b)(1) and (b)(2) of this section. However, they are subject to all other requirements of the Act.

(4) The requirements of paragraphs (b)(1) and (b)(2) of this section shall apply for any subcommittee of a chartered advisory committee, whether its members are drawn in whole or in part from the full or parent advisory committee, which functions independently of the parent advisory committee such as by making recommendations directly to the agency rather than for consideration by the chartered advisory committee.

(c) The Secretariat will review the proposal and notify the agency of GSA's views within 15 calendar days of receipt, if possible. The agency head retains final authority for establishing a particular advisory committee.

(d) The agency shall notify the Secretariat in writing that either:

(1) The advisory committee is being established. The filing of the advisory committee charter as specified in § 101-6.1013 shall be considered appropriate written notification in this instance. The date of filing constitutes the date of establishment or renewal. The agency head shall then comply with the provisions of § 101-6.1009 for an established advisory committee; or

(2) The advisory committee is not being established. In this instance, the agency shall also advise the Secretariat if the agency head intends to take any further action with respect to the proposed advisory committee.

[52 FR 45929, Dec. 2, 1987, as amended at 54 FR 41215, Oct. 5, 1989]

§ 101-6.1008 The role of GSA.

(a) The functions under section 7 of the Act will be performed for the Administrator by the Secretariat. The Secretariat assists the Administrator in prescribing administrative guidelines and management controls for advisory committees, and assists other agencies in implementing and interpreting these guidelines. In exercising internal controls over the management and supervision of the operations and procedures vested in each agency by section 8(b) of the Act and by § 101-6.1009 and § 101-6.1017 of this rule, agencies shall conform to the guidelines prescribed by GSA.

(b) The Secretariat may request comments from agencies on management guidelines and policy issues of broad interagency interest or application to the Federal advisory committee program.

(c) In advance of issuing informal guidelines, nonstatutory reporting requirements, and administrative procedures such as report formats or automation, the Secretariat shall request formal or informal comments from agency Committee Management Officers.

(d) The Secretariat shall assure that follow-up reports required by section 6(b) of the Act are prepared and transmitted to the Congress as directed by the President; either by his delegate, by the agency responsible for providing support to a Presidential advisory committee, or by the responsible agency or organization designated pursuant to paragraph (c) of § 101-6.1011. In performing this function, GSA may solicit the assistance of the Office of Management and Budget and other appropriate organizations, as deemed appropriate.

[52 FR 45929, Dec. 2, 1987, as amended at 54 FR 41215, Oct. 5, 1989]

§ 101-6.1009 Responsibilities of an agency head.

The head of each agency that uses one or more advisory committees shall ensure:

(a) Compliance with the Act and this subpart;

(b) Issuance of administrative guidelines and management controls which apply to all advisory committees established or used by the agency;

(c) Designation of a Committee Management Officer who shall carry out the functions specified in section 8(b) of the Act;

(d) Provision of a written determination stating the reasons for closing any advisory committee meeting to the public;

(e) A review, at least annually, of the need to continue each existing advisory committee, consistent with the public interest and the purpose and functions of each committee;

(f) Rates of pay are justified and levels of agency support are adequate;

(g) The appointment of a Designated Federal Officer for each advisory committee and its subcommittees;

(h) The opportunity for reasonable public participation in advisory committee activities;

(i) That the number of committee members is limited to the fewest necessary to accomplish committee objectives;

(j) That the interests and affiliations of advisory committee members are reviewed consistent with regulations published by the Office of Government Ethics in 5 CFR parts 734, 735, and 737, and additional requirements, if any, established by the sponsoring agency pursuant to Executive Order 12674, the conflict-of-interest statutes, and the Ethics in Government Act of 1978, as amended; and

(k) Unless otherwise specified by the President, the preparation and transmittal of a follow-up report to the Congress detailing the disposition of the public recommendations of a Presidential advisory committee supported by the agency, in accordance with sections 6(b) of the Act.

[52 FR 45929, Dec. 2, 1987, as amended at 54 FR 41215, Oct. 5, 1989]

§ 101-6.1010 [Reserved]

§ 101-6.1011 Responsibilities of the chairperson of an independent Presidential advisory committee.

The chairperson of an independent Presidential advisory committee shall comply with the Act and this subpart and shall:

(a) Consult with the Administrator concerning the role of the Designated Federal Officer and Committee Management Officer;

(b) Fulfill the responsibilities of an agency head as specified in paragraphs (d), (h) and (j) of § 101-6.1009; and

(c) Unless otherwise specified by the President, consult with the Administrator regarding the designation of an agency or organization responsible for implementing section 6(b) of the Act.

[52 FR 45929, Dec. 2, 1987, as amended at 54 FR 41216, Oct. 5, 1989]

§ 101-6.1012 [Reserved]

§ 101-6.1013 Charter filing requirements.

No advisory committee may operate, meet, or take any action until its charter has been filed as follows:

(a) *Advisory committee established, used, reestablished, or renewed by an agency.* The agency head shall file—

(1) The charter with the standing committees of the Senate and the House of Representatives having legislative jurisdiction of the agency;

(2) A copy of the filed charter with the Library of Congress, Exchange and Gift Division, Federal Documents

Section, Federal Advisor
Desk, Washington, DC 20
(3) A copy of the char
the Congressional filing
Secretariat.
(b) *Advisory committe*
directed by law or auth
Procedures are the sam
graph (a) of this section.
(c) *Presidential advisc*
When either the Preside
gress establishes an ad
tee that advises the Pre
sponsible agency head
of an independent Presi
ry committee, the Presi
shall file—
(1) The charter with t
(2) A copy of the file
the Library of Congress
(3) If specifically dir
copy of the charter inc
of filing with the Secre
standing committees
and the House of
having legislative juri
agency or the indepe
tial advisory committe

§ 101-6.1014 [Reserved]

§ 101-6.1015 Advisory c
tion which must be
Federal Register.

(a) *Committee esta*
tablishment, or renev
in the FEDERAL REGI
when an advisory com
committee specifically
or established by the
ecutive Order, is esta
established, or renew
ing notification of
review from the Secr
ance with paragrap
6.1007, the agency
notice in the FEDER
the committee is
used, reestablished,
new committee, su
describe the nature
committee and the
attain fairly bala
and shall include a
committee is nece
public interest.
(2) Establishmen
ment notices shall
calendar days bef

, and additional requirements, established by the sponsoring pursuant to Executive Order he conflict-of-interest statutes, Ethics in Government Act of amended; and

ıless otherwise specified by the ıt, the preparation and trans- of a follow-up report to the s detailing the disposition of lic recommendations of a Pres- advisory committee supported ıgency, in accordance with sec-) of the Act.

5929, Dec. 2, 1987, as amended at 54 , Oct. 5, 1989]

)10 [Reserved]

)11 Responsibilities of the chair-)n of an independent Presidential :ory committee.

hairperson of an independent ıtial advisory committee shall with the Act and this subpart il:

)nsult with the Administrator ing the role of the Designated Officer and Committee Man- Officer;

ılfill the responsibilities of an ıead as specified in paragraphs ınd (j) of § 101-6.1009; and

less otherwise specified by the ıt, consult with the Adminis- egarding the designation of an or organization responsible for enting section 6(b) of the Act.

5929, Dec. 2, 1987, as amended at 54 , Oct. 5, 1989]

)12 [Reserved]

)13 Charter filing requirements.

visory committee may operate, take any action until its char- been filed as follows:

lvisory committee established, established, or renewed by an The agency head shall file—

ıe charter with the standing ees of the Senate and the f Representatives having legis- risdiction of the agency;

copy of the filed charter with rary of Congress, Exchange t Division, Federal Documents

Section, Federal Advisory Committee Desk, Washington, DC 20540; and

(3) A copy of the charter indicating the Congressional filing date, with the Secretariat.

(b) *Advisory committee specifically directed by law or authorized by law.* Procedures are the same as in paragraph (a) of this section.

(c) *Presidential advisory committee.* When either the President or the Congress establishes an advisory committee that advises the President, the responsible agency head or, in the case of an independent Presidential advisory committee, the President's designee shall file—

(1) The charter with the Secretariat;

(2) A copy of the filed charter with the Library of Congress; and

(3) If specifically directed by law, a copy of the charter indicating its date of filing with the Secretariat, with the standing committees on the Senate and the House of Representatives having legislative jurisdiction of the agency or the independent Presidential advisory committee.

§ 101-6.1014 [Reserved]

§ 101-6.1015 Advisory committee information which must be published in the Federal Register.

(a) *Committee establishment, reestablishment, or renewal.* (1) A notice in the FEDERAL REGISTER is required when an advisory committee, except a committee specifically directed by law or established by the President by Executive Order, is established, used, reestablished, or renewed. Upon receiving notification of the completed review from the Secretariat in accordance with paragraph (c) of § 101-6.1007, the agency shall publish a notice in the FEDERAL REGISTER that the committee is being established, used, reestablished, or renewed. For a new committee, such notice shall also describe the nature and purpose of the committee and the agency's plan to attain fairly balanced membership, and shall include a statement that the committee is necessary and in the public interest.

(2) Establishment and reestablishment notices shall appear at least 15 calendar days before the committee charter is filed, except that the Secretariat may approve less than 15 days when requested by the agency for good cause. The 15-day advance notice requirement does not apply to committee renewals, notices of which may be published concurrently with the filing of the charter.

(b) *Committee meetings.* (1) The agency or an independent Presidential advisory committee shall publish at least 15 calendar days prior to an advisory committee meeting a notice in the FEDERAL REGISTER, which includes:

(i) The exact name of the advisory committee as chartered;

(ii) The time, date, place, and purpose of the meeting;

(iii) A summary of the agenda; and

(iv) A statement whether all or part of the meeting is open to the public or closed, and if closed, the reasons why, citing the specific exemptions of the Government in the Sunshine Act (5 U.S.C. 552(b)) as the basis for closure.

(2) In exceptional circumstances, the agency or an independent Presidential advisory committee may give less than 15 days notice, provided that the reasons for doing so are included in the committee meeting notice published in the FEDERAL REGISTER.

[52 FR 45929, Dec. 2, 1987, as amended at 54 FR 41216, Oct. 5, 1989]

§ 101-6.1016 [Reserved]

§ 101-6.1017 Responsibilities of the agency Committee Management Officer.

In addition to implementing the provisions of section 8(b) of the Act, the Committee Management Officer will carry out all responsibilities delegated by the agency head. The Committee Management Officer should also ensure that section 10(b), 12(a) and 13 of the Act are implemented by the agency to provide for appropriate recordkeeping. Records include, but are not limited to:

(a) A set of approved charters and membership lists for each advisory committee;

(b) Copies of the agency's portion of the Annual Report of Federal Advisory Committees required by paragraph (b) of § 101-6.1035;

(c) Agency guidelines on committee management operations and procedures as maintained and updated; and

(d) Agency determinations to close advisory committee meetings as required by paragraph (c) of § 101-6.1023.

§ 101-6.1018 [Reserved]

§ 101-6.1019 Duties of the Designated Federal Officer.

The agency head or, in the case of an independent Presidential advisory committee, the Administrator shall designate a Federal officer or employee, who may be either full-time or permanent part-time, to be the Designated Federal Officer for each advisory committee and its subcommittees, who:

(a) Must approve or call the meeting of the advisory committee;

(b) Must approve the agenda;

(c) Must attend the meetings;

(d) Shall adjourn the meetings when such adjournment is in the public interest; and

(e) Chairs the meeting when so directed by the agency head.

(f) The requirement in paragraph (b) of this section does not apply to a Presidential advisory committee.

§ 101-6.1020 [Reserved]

§ 101-6.1021 Public participation in advisory committee meetings.

The agency head, or the chairperson of an independent Presidential advisory committee, shall ensure that—

(a) Each advisory committee meeting is held at a reasonable time and in a place reasonably accessible to the public;

(b) The meeting room size is sufficient to accommodate advisory committee members, committee or agency staff, and interested members of the public;

(c) Any member of the public is permitted to file a written statement with the advisory committee; and

(d) Any member of the public may speak at the advisory committee meeting if the agency's guidelines so permit.

§ 101-6.1022 [Reserved]

§ 101-6.1023 Procedures for closing an advisory committee meeting.

(a) To close all or part of a meeting, an advisory committee shall submit a request to the agency head or, in the case of an independent Presidential advisory committee, the Administrator, citing the specific provisions of the Government in the Sunshine Act (5 U.S.C. 552(b)) which justify the closure. The request shall provide the agency head or the Administrator sufficient time to review the matter in order to make a determination prior to publication of the meeting notice required by § 101-6.1015(b).

(b) The general counsel of the agency or, in the case of an independent Presidential advisory committee, the general counsel of the General Services Administration should review all requests to close meetings.

(c) If the agency head or, in the case of an independent Presidential advisory committee, the Administrator agrees that the request is consistent with the provisions in the Government in the Sunshine Act and the Federal Advisory Committee Act, he or she shall issue a determination that all or part of the meeting be closed.

(d) The agency head, or the chairperson of an independent Presidential advisory committee, shall:

(1) Make a copy of the determination available to the public upon request; and

(2) State the reasons why all or part of the meeting is closed, citing the specific exemptions used from the Government in the Sunshine Act in the meeting notice published in the FEDERAL REGISTER.

§ 101-6.1024 [Reserved]

§ 101-6.1025 Requirement for maintaining minutes of advisory committee meetings.

(a) The agency head or, in the case of an independent Presidential advisory committee, the chairperson shall ensure that detailed minutes of each advisory committee meeting are kept. The minutes must include:

(1) Time, date, and place;

(2) A list of the following p who were present:

(i) Advisory committee membe staff;

(ii) Agency employees; and

(iii) Members of the public wi sented oral or written statement

(3) An estimated number of members of the public present;

(4) An accurate description c matter discussed and the resolu any, made by the committee c matter; and

(5) Copies of each report o document received, issued, or ap by the committee.

(b) The chairperson of each a committee shall certify to the cy of all minutes of advisory c tee meetings.

§ 101-6.1026 [Reserved]

§ 101-6.1027 Termination of advis mittees.

(a) Any advisory committe automatically terminate not la 2 years after it is established, lished, or renewed, unless:

(1) Its duration is otherwise for by law;

(2) The President or agen renews it prior to the end period; or

(3) The President or agen terminates it before that tim voking or abolishing its estab authority.

(b) If an agency head term advisory committee, the age notify the Secretariat of the date of termination.

§ 101-6.1028 [Reserved]

§ 101-6.1029 Renewal and rech advisory committees.

(a) Advisory committees s directed by law:

(1) Whose duration exten 2 years shall require rechar the filing of a new charte years after the date of ena the law establishing the com a new charter is not filed, th tee is not terminated, but meet or take any action.

(2) Which would termin the provisions of section 14 and for which renewal wou

2 [Reserved]

3 Procedures for closing an advisory committee meeting.

lose all or part of a meeting, ry committee shall submit a) the agency head or, in the in independent Presidential committee, the Administra- g the specific provisions of rnment in the Sunshine Act 552(b)) which justify the clo- e request shall provide the ead or the Administrator suf- me to review the matter in nake a determination prior to on of the meeting notice re- § 101-6.1015(b).

ie general counsel of the r, in the case of an independ- idential advisory committee, ral counsel of the General Administration should review its to close meetings.

ie agency head or, in the case ependent Presidential adviso- mittee, the Administrator iat the request is consistent provisions in the Government unshine Act and the Federal Committee Act, he or she ie a determination that all or ne meeting be closed.

e agency head, or the chair- f an independent Presidential committee, shall:

ake a copy of the determina- illable to the public upon re- id

te the reasons why all or part eeting is closed, citing the spe- mptions used from the Gov- in the Sunshine Act in the notice published in the FEDER- TER.

024 [Reserved]

025 Requirement for maintaining tes of advisory committee meet-

ie agency head or, in the case dependent Presidential adviso- mittee, the chairperson shall that detailed minutes of each committee meeting are kept. nutes must include:

me, date, and place;

(2) A list of the following persons who were present:

(i) Advisory committee members and staff;

(ii) Agency employees; and

(iii) Members of the public who presented oral or written statements;

(3) An estimated number of other members of the public present;

(4) An accurate description of each matter discussed and the resolution, if any, made by the committee of such matter; and

(5) Copies of each report or other document received, issued, or approved by the committee.

(b) The chairperson of each advisory committee shall certify to the accuracy of all minutes of advisory committee meetings.

§ 101-6.1026 [Reserved]

§ 101-6.1027 Termination of advisory committees.

(a) Any advisory committee shall automatically terminate not later than 2 years after it is established, reestablished, or renewed, unless:

(1) Its duration is otherwise provided for by law;

(2) The President or agency head renews it prior to the end of such period; or

(3) The President or agency head terminates it before that time by revoking or abolishing its establishment authority.

(b) If an agency head terminates an advisory committee, the agency shall notify the Secretariat of the effective date of termination.

§ 101-6.1028 [Reserved]

§ 101-6.1029 Renewal and rechartering of advisory committees.

(a) Advisory committees specifically directed by law:

(1) Whose duration extends beyond 2 years shall require rechartering by the filing of a new charter every 2 years after the date of enactment of the law establishing the committee. If a new charter is not filed, the committee is not terminated, but may not meet or take any action.

(2) Which would terminate under the provisions of section 14 of the Act, and for which renewal would require reauthorization by law, may be reestablished by an agency provided that the agency complies under general agency authority with the provisions of § 101-6.1007.

(b) Advisory committees established by the President may be renewed by appropriate action of the President and the filing of a new charter.

(c) Advisory committees authorized by law or established or used by an agency may be renewed, provided that at least 30 but not more than 60 days before the committee terminates, an agency head who intends to renew a committee complies with the provisions of § 101-6.1007.

§ 101-6.1030 [Reserved]

§ 101-6.1031 Amendments to advisory committee charters.

(a) *Committees specifically directed by law or authorized by law; or established by the President.* The agency head shall be responsible for ensuring that any minor technical changes made to current charters are consistent with the relevant statute or Executive Order. When the Congress by law, or the President by Executive Order, changes the authorizing language which has been the basis for establishing an advisory committee, the agency head, or the chairperson of an independent Presidential advisory committee, shall:

(1) Amend those sections of the current charter affected by the new law or Executive Order; and

(2) File the amended charter as specified in § 101-6.1013.

(b) *Committees established or used by an agency.* The charter of an advisory committee established under general agency authority may be amended when an agency head determines that the existing charter no longer accurately reflects the objectives or functions of the committee. Changes may be minor, such as revising the name of the advisory committee, or modifying the estimated number or frequency of meetings. Changes may also be major such as those dealing with the objectives or composition of the committee. The agency head retains final authority for amending the charter of an advisory committee. Amending any exist-

50-154 O—91——3

ing advisory committee charter does not constitute renewal of the committee under § 101-6.1029.

(1) To make a minor amendment to a committee charter, an agency shall:

(i) Amend the charter language as necessary, and

(ii) File the amended charter as specified in § 101-6.1013.

(2) To make a major amendment to a committee charter, an agency shall:

(i) Amend the charter language as necessary;

(ii) Submit the proposed amended charter with a letter to the Secretariat requesting GSA's views on the amended language, along with an explanation of the purpose of the changes and why they are necessary. The Secretariat will review the proposed changes and notify the agency of GSA's views within 15 calendar days of the request, if possible; and

(iii) File the amended charter as specified in § 101-6.1013.

§ 101-6.1032 [Reserved]

§ 101-6.1033 Compensation and expense reimbursement of advisory committee members, staffs and consultants.

(a) *Uniform pay guidelines for members of an advisory committee.* Nothing in this subpart shall require an agency head to provide compensation, unless otherwise provided by law, to a member of an advisory committee. However, when compensation is deemed appropriate by an agency, it shall fix the pay of the members of an advisory committee to the daily equivalent of a rate of the General Schedule in 5 U.S.C. 5332 unless the members are appointed as consultants and compensated under 5 U.S.C. 3109. In determining an appropriate rate of pay for the members, an agency shall give consideration to the significance, scope, and technical complexity of the matters with which the advisory committee is concerned and the qualifications required of the members of the advisory committee. An agency may not fix the pay of the members of an advisory committee at a rate higher than the daily equivalent of the maximum rate for a GS-15 under the General Schedule, unless a higher rate is mandated by statute, or the head of the agency has personally determined that a higher rate of pay under the General Schedule is justified and necessary. Such a determination must be reviewed by the head of the agency annually. Under this subpart, an agency may not fix the pay of the members of an advisory committee at a rate of pay higher than the daily equivalent of a rate for a GS-18, as provided in 5 U.S.C. 5332.

(b) *Pay for staff members of an advisory committee.* An agency may fix the pay of each advisory committee staff member at a rate of the General Schedule in which the Staff member's position would appropriately be placed (5 U.S.C. Chapter 51). An agency may not fix the pay of a staff member at a rate higher than the daily equivalent of the maximum rate for GS-15, unless the agency head has determined that under the General Schedule the staff member's position would appropriately be placed at a grade higher than GS-15. This determination must be reviewed annually by the agency head.

(1) In establishing rates of compensation, the agency head shall comply with any applicable statutes, regulations, Executive Orders, and administrative guidelines.

(2) A staff member who is a Federal employee shall serve with the knowledge of the Designated Federal Officer and the approval of the employee's direct supervisor. If a non-Federal employee, the staff member shall be appointed in accordance with applicable agency procedures, following consultation with the advisory committee.

(c) *Pay for consultants to an advisory committee.* An agency shall fix the pay of a consultant to an advisory committee after giving consideration to the qualifications required of the consultant and the significance, scope, and technical complexity of the work. The compensation may not exceed the maximum rate of pay authorized by 5 U.S.C. 3109, and shall be in accordance with any applicable statutes, regulations, Executive Orders and administrative guidelines.

(d) *Gratuitous services.* In the absence of any special limitations applicable to a specific agency, nothing in this subpart shall prevent an agency

from accepting the gratuito
of an advisory committee
staff member, or consul
agrees in advance to serv
compensation.

(e) *Travel expenses.* Adv
mittee members and staff
while engaged in the perfo
their duties away from thei
regular places of business.
lowed travel expenses, inc
diem in lieu of subsistence,
ized by section 5703 of titl
States Code, for persons
intermittently in the G
service.

(f) *Services for handica
bers.* While performing ad
mittee duties, an advisory
member who is blind or d
qualifies as a handicappe
may be provided services b
assistant for handicapped
the member:

(1) Qualifies as a handi
vidual as defined by sectio
Rehabilitation Act of 197
794); and

(2) Does not otherwise
assistance under 5 U.S.
reason of being an emp
agency.

(g) *Exclusions.* (1) Not
section shall prevent any
(without regard to his o
with an advisory committ
time Federal employee fr
compensation at a rate
she otherwise would be
as a full-time Federal emp

(2) Nothing in this sect
vent any person who
before his or her service
sory committee was a full
employee from receiving
at the rate at which h
compensated as a full-
employee.

(3) Nothing in this
affect a rate of pay or
a rate of pay that is sp
lished by law or a rate
lished under the Gen
classification and pay sy
ter 51 and chapter 5
United States Code.

agency has personally determined a higher rate of pay under the eral Schedule is justified and nec- ry. Such a determination must be wed by the head of the agency ially. Under this subpart, an cy may not fix the pay of the bers of an advisory committee at te of pay higher than the daily valent of a rate for a GS-18, as ided in 5 U.S.C. 5332.

Pay for staff members of an advi- committee. An agency may fix pay of each advisory committee member at a rate of the General dule in which the Staff member's ion would appropriately be placed S.C. Chapter 51). An agency may ix the pay of a staff member at a higher than the daily equivalent he maximum rate for GS-15, s the agency head has deter- d that under the General Sched- ne staff member's position would opriately be placed at a grade r than GS-15. This determina- nust be reviewed annually by the y head.

In establishing rates of compen- , the agency head shall comply any applicable statutes, regula- Executive Orders, and adminis- e guidelines.

A staff member who is a Federal oyee shall serve with the knowl- of the Designated Federal Officer he approval of the employee's supervisor. If a non-Federal em- , the staff member shall be ap- d in accordance with applicable y procedures, following consulta- ith the advisory committee.

Pay for consultants to an adviso- mmittee. An agency shall fix the f a consultant to an advisory ittee after giving consideration qualifications required of the tant and the significance, scope, chnical complexity of the work. ompensation may not exceed the um rate of pay authorized by 5 3109, and shall be in accordance ny applicable statutes, regula- Executive Orders and adminis- guidelines.

Gratuitous services. In the ab- of any special limitations appli- o a specific agency, nothing in bpart shall prevent an agency from accepting the gratuitous services of an advisory committee member, staff member, or consultant who agrees in advance to serve without compensation.

(e) *Travel expenses.* Advisory committee members and staff members, while engaged in the performance of their duties away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons employed intermittently in the Government service.

(f) *Services for handicapped members.* While performing advisory committee duties, an advisory committee member who is blind or deaf or who qualifies as a handicapped individual may be provided services by a personal assistant for handicapped employees if the member:

(1) Qualifies as a handicapped individual as defined by section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 794); and

(2) Does not otherwise qualify for assistance under 5 U.S.C. 3102 by reason of being an employee of an agency.

(g) *Exclusions.* (1) Nothing in this section shall prevent any person who (without regard to his or her service with an advisory committee) is a full-time Federal employee from receiving compensation at a rate which he or she otherwise would be compensated as a full-time Federal employee.

(2) Nothing in this section shall prevent any person who immediately before his or her service with an advisory committee was a full-time Federal employee from receiving compensation at the rate at which he or she was compensated as a full-time Federal employee.

(3) Nothing in this section shall affect a rate of pay or a limitation on a rate of pay that is specifically established by law or a rate of pay established under the General Schedule classification and pay system in chapter 51 and chapter 53 of Title 5, United States Code.

§ 101-6.1034 [Reserved]

§ 101-6.1035 Reports required for advisory committees.

(a) Within one year after a Presidential advisory committee has submitted a public report to the President, a follow-up report will be prepared and transmitted to the Congress as determined under paragraph (d) of § 101-6.1008, detailing the disposition of the committee's recommendations in accordance with section 6(b) of the Act. Reports shall be consistent with specific instructions issued periodically by the Secretariat;

(b) The President's annual report to the Congress shall be prepared by GSA based on reports filed on a fiscal year basis by each agency consistent with the information specified in section 6(c) of the Act. Reports from agencies shall be consistent with instructions provided annually by the Secretariat. Agency reports shall also include information requested to enable the Secretariat to carry out the annual comprehensive review of each advisory committee as required by section 7(b) of the Act. These reports have been cleared in accordance with FIRMR subpart 201-45.6 in 41 CFR chapter 201 and assigned interagency report control number 0304-GSA-XX.

(c) In accordance with section 10(d) of the Act, advisory committees holding closed meetings shall issue reports at least annually, setting forth a summary of activities consistent with the policy of section 552(b) of title 5, United States Code.

(d) Subject to section 552 of title 5, United States Code, eight copies of each report made by an advisory committee, including any report on closed meetings as specified in paragraph (c) of this section, and, where appropriate, background papers prepared by consultants, shall be filed with the Library of Congress as required by section 13 of the Act, for public inspection and use at the location specified in paragraph (a)(2) of § 101-6.1013.

[52 FR 45929, Dec. 2, 1987, as amended at 54 FR 41216, Oct. 5, 1989]

PRIVILEGED AND CONFIDENTIAL
DRAFT -- FOR DISCUSSION PURPOSES ONLY

EXECUTIVE ORDER NO. _____

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

By the authority vested in me as President by the Constitution and statutes 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. I.

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

Section 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 the Central Intelligence Agency, 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 which (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation.

The Advisory Committee shall also provide advice, information and recommendations on the following specific 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 devices containing radioactive agents at the U.S. Army's Duqway, Utah, site;

(4) four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and

(5) any other experiments which may later be identified by the Human Radiation Interagency Working Group.

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

(b) The Advisory Committee shall:

(1) Determine the ethical and scientific standards and criteria by which human radiation experiments, as defined in paragraph a of this Section, shall be evaluated. 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 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.

(3) If required to protect the health of individuals who were subject of a human radiation experiment, the Advisory

Committee may recommend to the Human Radiation Interagency Working Group that an agency notify a particular subject of an experiment, or his or her descendants, of any potential health risk of the need for medical follow-up.

(4) The Advisory Committee shall assess current federal human experiment subject protection policies and recommend further policies, as needed, to ensure compliance with appropriate ethical and scientific standards.

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

Section 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.

Section 4. General provisions. (a) Notwithstanding the provisions of any other Executive Order, the functions of the President under the Federal Advisory Committee Act which are applicable to the Advisory Committee, except that of reporting annually to 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.

(c) This Order is intended only to improve the internal management of the Executive Branch and 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.

THE WHITE HOUSE,
January ___, 1994

EXECUTIVE ORDER

3:15

- - - - - -

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

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.

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 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 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.

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 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 descendents, 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 services (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 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.

(c) This order is intended only to improve the internal management of the Executive Branch and it 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.

THE WHITE HOUSE,

DRAFT January 11, 1994

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES OK

FROM: CHRISTINE A. VARNEY
Secretary to the Cabinet

SUBJECT: Retrieval and Inventory of Records of Human Radiation Experiments

1. Direction to Agencies

Each Agency shall establish forthwith a procedure for retrieval and inventory of records of human radiation experiments conducted by the Agency or under a contract or grant of the Agency. Agencies shall coordinate their procedures with the Human Radiation Interagency Working Group (the "Interagency Working Group") to ensure, where appropriate, that uniform procedures for the retrieval and inventory of records are applied at each Agency. Each Agency shall provide a written copy of the directive initiating the record retrieval to the Interagency Working Group.

2. Definitions

(a) "Agency" means Department of Defense, Department of Energy, Department of Health and Human Services, Central Intelligence Agency, Department of Veterans Affairs, and NASA.

(b) "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 which

(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.

3. In addition, Agencies should retrieve and inventory all records pertaining to:

(a) 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;

(b) 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;

(c) Six tests conducted during 1949-1952 of radiation warfare ballistic dispersal devices containing radioactive agents at the U.S. Army's Duqway, Utah site;

(d) Four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and

(e) Any other experiments which may later be identified by the Human Radiation Interagency Working Group.

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

5. Each Agency Head shall institute procedures for notifying and making records available to subjects of human radiation experiments and their next of kin. Agencies shall coordinate these procedures with the Human Radiation Interagency Working Group.

6. Each Agency Head shall institute procedures for making records on human radiation experiments available to the public. In implementing these procedures, each Agency Head shall immediately issue an order to all elements of the Agency and undertake all appropriate procedures in connection with the Agencies' grantees, contractors or other agents:

(a) Not to destroy any records relating to human radiation experiments.

(b) To locate forthwith all records relating to human radiation experiments in the custody of the Agency, and to identify records and undertake all appropriate procedures with regard to any such records in the possession of grantees, contractors or other agents of the Agency. Agencies shall work together with the Human Radiation Interagency Working Group to standardize the retrieval of these records, which may involve the transfer of files to a designated repository. Until specific instructions are given for the transfer of the records, individual documents shall not be removed from their file series.

7. Each Agency shall:

(a) Review all such records for national security classification and to declassify such records to the maximum extent as soon as possible.

Agencies shall avail themselves of every opportunity to cooperate in expediting this process.

(b) Make any deletions required for the protection of privacy interests of the subjects of the experiments or their next of kin.

8. Agencies shall work together with the Human Radiation Interagency Working Group to standardize the inventory of records of human radiation experiments. Such standards will address methods for describing records, collecting, transcribing and verifying inventory information, and documenting records search strategies.

9. In developing guidelines for retrieval and inventory, Agencies shall take account of advice provided to the Human Radiation Interagency Working Group by the Advisory Committee on Human Radiation Experiments.

PRIVILEGED AND CONFIDENTIAL
FOR DISCUSSION PURPOSES ONLY
DRAFT

OK

CHARTER

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

1. **Committee's Official Designation:**

Advisory Committee on Human Radiation Experiments

2. **Authority:**

Executive Order No. _____

3. **Committee's Objectives And Scope Of Activities:**

To provide advice, information, and recommendations to the Human Radiation Interagency Working Group on the ethical and scientific standards applicable to human radiation experiments carried out or sponsored by the United States Government. The members of the Human Radiation Interagency Working Group include the Secretaries of Energy, Defense, Health and Human Services, and Veterans Affairs; the Attorney General; the Administrator of the National Aeronautics and Space Administration; the Director of the Central Intelligence Agency; and the Director of the Office of Management and Budget.

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 which

(A) were designed to test human health effects of ionizing radiation; or

(B) were designed to test the extent of human exposure to ionizing radiation.

The Advisory Committee shall also provide advice, information and recommendations on the following specific 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 devices containing radioactive agents at the U.S. Army's Duqway, Utah site;

(4) Four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and

(5) Any other experiments which may later be identified by the Human Radiation Interagency Working Group.

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

4. **A Description Of Duties For Which The Committee Is Responsible:**

The duties of the Committee are solely advisory and include:

a. The Committee will determine the ethical and scientific standards and criteria by which human radiation experiments, as defined in paragraph 3 herein, shall be evaluated. The Committee shall consider whether: (1) there was a clear medical or scientific purpose for the experiments; (2) appropriate medical follow-up was conducted; and (3) the experiments' design and administration adequately met the standards of informed consent that prevailed at the time of the experiments and that exist today.

b. The 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 4(a), above. If deemed necessary for such an assessment, the Committee may carry out a detailed review of experiments and associated records.

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

d. The Committee shall assess current federal human experiment subject protection policies and recommend further policies, as needed, to ensure compliance with appropriate ethical and scientific standards.

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

5. **Time Period Necessary For The Committee To Carry Out Its Purpose:**

This Advisory Committee shall submit its final report to the Human Radiation Interagency Working Group one year from the date of the filing of this Charter, unless such period is extended by the Human Radiation Interagency Working Group. The Committee will issue an interim report six months after the filing of this Charter. In its interim report, the Committee shall advise the Human Radiation Interagency Working Group on the likelihood that the Committee will be able to complete its duties within one year.

6. **Official To Whom This Committee Reports:**

The Committee shall report to the Human Radiation Interagency Working Group.

7. **Agencies Responsible For Providing Necessary Financial Support:**

Financial support shall be provided by the Department of Energy.

8. **Estimated Annual Operating Costs:**

$2 million.

9. **Estimated Number And Frequency Of Committee Meetings:**

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

10. **Committee's Termination Date (If Less than Two Years From The Dated Of Establishment):**

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

11. **Subcommittee(s):**

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

12. **Members:**

Up to a maximum of fifteen 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).

13. **Chairperson:**

A Chairperson shall be designated by the President.

OFFICE OF CABINET AFFAIRS

THE WHITE HOUSE

WASHINGTON

FAX

TO: Tara

DATE: 1/13/94

NO. OF PAGES 12
(Including cover)

PHONE:

FAX: 586-0956

PRIORITY: Y N

FROM: Phil

PHONE: (202) 456-2572

FAX: (202) 456-6704

MESSAGE: Please note that the language in the executive order is near final and the language in the other 2 documents will reflect the executive order upon completion.

Radiation

Federal Register
Vol. 58, No. 226
Friday, November 26, 1993

Presidential Documents

Title 3—

The President

Executive Order 12881 of November 23, 1993

Establishment of the National Science and Technology Council

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, it is hereby ordered as follows:

Section 1. *Establishment.* There is established the National Science and Technology Council ("the Council").

Sec. 2. *Membership.* The Council shall comprise the:

(a) President, who shall serve as Chairman of the Council;

(b) Vice President;

(c) Secretary of Commerce;

(d) Secretary of Defense;

(e) Secretary of Energy;

(f) Secretary of Health and Human Services;

(g) Secretary of State;

(h) Secretary of the Interior;

(i) Administrator, National Aeronautics and Space Administration;

(j) Director, National Science Foundation;

(k) Director of the Office of Management and Budget;

(l) Administrator, Environmental Protection Agency;

(m) Assistant to the President for Science and Technology;

(n) National Security Adviser;

(o) Assistant to the President for Economic Policy;

(p) Assistant to the President for Domestic Policy; and

(q) Such other officials of executive departments and agencies as the President may, from time to time, designate.

Sec. 3. *Meetings of the Council.* The President or, upon his direction, the Assistant to the President for Science and Technology ("the Assistant"), may convene meetings of the Council. The President shall preside over the meetings of the Council, provided that in his absence the Vice President, and in his absence the Assistant, will preside.

Sec. 4. *Functions.* (a) The principal functions of the Council are, to the extent permitted by law: (1) to coordinate the science and technology policy-making process; (2) to ensure science and technology policy decisions and programs are consistent with the President's stated goals; (3) to help integrate the President's science and technology policy agenda across the Federal Government; (4) to ensure science and technology are considered in development and implementation of Federal policies and programs; and (5) to further international cooperation in science and technology. The Assistant may take such actions, including drafting a Charter, as may be necessary or appropriate to implement such functions.

(b) All executive departments and agencies, whether or not represented on the Council, shall coordinate science and technology policy through the Council and shall share information on research and development budget requests with the Council.

(c) The Council shall develop for submission to the Director of the Office of Management and Budget recommendations on research and development budgets that reflect national goals. In addition, the Council shall provide advice to the Director of the Office of Management and Budget concerning the agencies' research and development budget submissions.

(d) The Assistant will, when appropriate, work in conjunction with the Assistant to the President for Economic Policy, the Assistant to the President for Domestic Policy, the Director of the Office of Management and Budget, and the National Security Adviser.

Sec. 5. *Administration.* (a) The Council will oversee the duties of the Federal Coordinating Council for Science, Engineering, and Technology, the National Space Council, and the National Critical Materials Council.

(b) The Council may function through established or ad hoc committees, task forces, or interagency groups.

(c) To the extent practicable and permitted by law, executive departments and agencies shall make resources, including, but not limited to, personnel, office support, and printing, available to the Council as requested by the Assistant.

(d) All executive departments and agencies shall cooperate with the Council and provide such assistance, information, and advice to the Council as the Council may request, to the extent permitted by law.

William J. Clinton

THE WHITE HOUSE,
November 23, 1993.

[FR Doc. 93-29263
Filed 11-24-93; 11:50 am]
Billing code 3195-01-P

Presidential Documents

Executive Order 12882 of November 23, 1993

President's Committee of Advisors on Science and Technology

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, and in order to establish an advisory committee on science and technology, it is hereby ordered as follows:

Section 1. *Establishment.* There is established the President's Committee of Advisors on Science and Technology ("PCAST"). PCAST shall be composed of not more than 16 members, one of whom shall be the Assistant to the President for Science and Technology ("Assistant"), and 15 of whom shall be distinguished individuals from the nonfederal sector appointed by the President. The nonfederal sector members shall be representative of the diverse perspectives and expertise in this Nation's investments in science and technology. The Assistant to the President for Science and Technology shall co-chair PCAST with a nonfederal sector member selected by the President.

Sec. 2. *Functions.* (a) The PCAST shall advise the President, through the Assistant, on matters involving science and technology.

(b) In the performance of its advisory duties, PCAST shall assist the National Science and Technology Council ("Council") in securing private sector involvement in its activities.

Sec. 3. *Administration.* (a) The heads of executive departments and agencies shall, to the extent permitted by law, provide PCAST such information with respect to scientific and technological matters as required for the purpose of carrying out its functions.

(b) In consultation with the Assistant to the President for Science and Technology, PCAST is authorized to convene ad hoc working groups to assist the Council.

(c) Members of PCAST shall serve without any compensation for their work on PCAST. However, members may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the government service (5 U.S.C. 5701–5707).

(d) Any expenses of PCAST shall be paid from the funds available for the expenses of the Office of Science and Technology Policy.

(e) The Office of Science and Technology Policy shall provide such administrative services as may be required.

Sec. 4. *General.* (a) I have determined that the Committee shall be established in compliance with the Federal Advisory Committee Act, as amended (5 U.S.C. App.). Notwithstanding any other Executive order, the functions of the President under the Federal Advisory Committee Act, as amended, except that of reporting to the Congress, which are applicable to PCAST shall be performed by the Office of Science and Technology Policy in accordance with the guidelines and procedures established by the Administrator of General Services.

(b) PCAST shall terminate 2 years from the date of this order unless extended prior to that date.

(c) Executive Orders Nos. 12700, 12768, and Section 2 of Executive Order No. 12869 are hereby revoked.

William J. Clinton

THE WHITE HOUSE,
November 23, 1993.

[FR Doc. 93-29264
Filed 11-24-93; 11:52 am]
Billing code 3195-01-P

THE WHITE HOUSE

WASHINGTON

February 18, 1994

FAX MEMORANDUM TO DISTRIBUTION

FROM: Phil Caplan

SUBJ: Press Release and Presidential Memorandum

4 pages to follow

FYI -- Press release on candidates for Advisory Committee on Human Radiation and Presidential Memorandum on review of federal policy for the protection of human subjects.

Please distribute within your agency.

Reminder: Conference call on Tuesday, February 22, at 4:00 PM

Thank you.

DISTRIBUTION LIST:

		Phone:	Fax:
DOE:	Rich Rosenzweig	586-6210	586-7644
DOE:	Tara O'Toole	586-6151	586-0956
DOD:	Rudy DeLeon	703/697-8388	703/697-9080
DOD:	Gordon Soper	703/697-5161	703/695-0476
VA:	Harold Gracey	535-8900	535-8667
HHS:	Kevin Thurm	690-6133	690-7755
NASA:	Chris Dunn	358-1827	358-2810
DOJ:	Nancy McFadden	514-9500	514-4371
Treas:	Alicia Munnell	622-2200	622-2633
CIA:	David Gries	703/351-2698	703/243-8343

DRAFT

[redacted]

~~Office of the Press Secretary~~

For immediate release Date

President announces intention to name experts to Advisory Committee on Human Radiation Experiments

President Bill Clinton today announced that he intends to name 15 experts in several fields to the Advisory Committee on Human Radiation Experiments.

The Committee will review all available records of experiments conducted by the government since 1946 in which humans were intentionally exposed to ionizing radiation. It is to provide advice and recommendations of the ethical and scientific standards that should be applied to such experiments to the Human Radiation Interagency Working Group.

The Committee is to submit an interim report in six months and a final report in one year.

The Committee will be chaired by Dr. Ruth Faden, a medical ethicist from Johns Hopkins University.

Members of the Advisory Committee are:

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, MD; senior research scholar, Kennedy Institute of Ethics, Georgetown University, Washington, D.C.

Ruth Macklin, Ph.D. - head, Division of Philosophy and History of Medicine, professor of bioethics, Shoshanah Trachtenberg Frackman Faculty Scholar in Biomedical Ethics, Department of Epidemiology and Social Medicine, Albert Einstein College of Medicine, Bronx, NY.

Patricia J. King, J.D. - professor of law, Georgetown University Law Center, Washington, DC; adjunct professor, Department of Health Policy and Management, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, MD.

Jay Katz, M.D. - Elizabeth K. Dollard Professor Emeritus of Law, Medicine and Psychiatry and Harvey L. Karp Professorial Lecturer in Law and Psychoanalysis, Yale University, New Haven, CT.

Historian

Susan E. Lederer, Ph.D. - associate professor, Department of Humanities, The Milton S. Hershey Medical Center, Pennsylvania State University, Hershey, PA.

Attorney

Kenneth R. Feinberg, J.D. - Kenneth R. Feinberg & Associates, Washington, DC; adjunct professor of law, Georgetown University Law Center, Washington, DC; member, Presidential Commission on Catastrophic Nuclear Accidents, 1989-90.

Epidemiologist

Duncan Thomas, Ph.D. - professor, Preventive Medicine, University of Southern California School of Medicine, Los Angeles, CA.

Clinicians, radiation therapy/nuclear medicine

Eli J. Glatstein, M.D. - professor and chairman, Department of Radiation Oncology, Simmons Cancer Center, Southwestern Medical Center, University of Texas, Dallas, TX.

Henry D. Royal, M.D. - associate director, Division of Nuclear Medicine, Mallinckrodt Institute of Radiology and professor of radiology, Washington University School of Medicine, St. Louis, MO.

Mary Ann Stevenson, M.D. - assistant professor in radiation therapy, Joint Center for Radiation Therapy and deputy chief, Department of Radiation Oncology, New England Deaconess Hospital, Harvard Medical School, Boston, MA.

Clinician, non-radiation/public health

Reed Tuckson, M.D. - president, Charles R. Drew University of Medicine and Science, Los Angeles, CA.

Military medicine specialist

Phillip K. Russell, M.D. - professor of international health, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, MD.

Radiation biologist

Nancy L. Oleinick, Ph.D. - professor of radiation biology and biochemistry, Environmental Health Science and Oncology, School of Medicine, and director, Division of Biochemistry and Oncology, Department of Radiology, Case Western Reserve University, Cleveland, OH.

HOLDING FOR UPDATED INFORMATION

General scientist

? **Frank Press**, Ph.D. - (title) Carnegie Commission, Washington, DC; former president, National Academy of Scientists.

Community representative

Lois L. Norris - retired businessperson, former second vice president, Omaha National Bank and Omaha National Corporation, Omaha, Nebraska.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **January 18, 1994**

PRESIDENT SIGNS EXECUTIVE ORDER FORMING ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The Clinton Administration today continued efforts to uncover the nature and extent of government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The President today released an Executive Order that will establish an Advisory Committee on Human Radiation Experiments. The Advisory Committee, to be made up of outside-government experts in medicine, science and ethics, will provide to the Human Radiation Interagency Working Group advice and recommendations on human radiation experiments conducted by the government since the 1940's. This Advisory Committee shall comply with the terms of the Federal Advisory Committee Act. (A copy of this Executive Order is attached.)

In other actions:

* On January 3, 1994, the White House called for the formation of a Human Radiation Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The members of the Human Radiation Interagency Working Group 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.

* Christine Varney, Secretary to the Cabinet, will issue a memorandum tomorrow to federal departments and agencies with formal instructions concerning the retrieval and inventory of records on human radiation experiments consistent with discussions by staff of the Human Radiation Interagency Working Group. The memo calls for each agency to establish procedures for document handling and review.

* The Human Radiation Hotline service will soon be upgraded to handle 500 calls an hour.

# # #

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **February 17, 1994**

PRESIDENT ANNOUNCES ETHICAL, SCIENTIFIC AND MEDICAL EXPERTS AS MEMBERS OF ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

WASHINGTON, D.C. - The President today announced his intention to appoint fifteen men and women to serve as members of the Advisory Committee on Human Radiation Experiments, created by an Executive Order on January 18, 1994. The Advisory Committee was created to review the ethical and scientific standards of any government-sponsored human experiments, since 1946, which involved intentional exposure to ionizing radiation.

The Advisory Committee will provide advice and recommendations to the Interagency Working Group on Human Radiation on issues such as whether there was a clear medical or scientific purpose for the experiments, if there was proper informed consent, or if appropriate medical follow-up was conducted.

The Advisory Committee is to submit an interim report in six months after it begins work and a final report in one year. The Advisory Committee will comply with the terms of the Federal Advisory Committee Act.

The Advisory Committee will be chaired by Dr. Ruth Faden, a medical ethicist from Johns Hopkins University. A list of the other members of the Committee is attached.

In other actions:

* The White House today issued a Presidential Memorandum instructing all Executive Departments and Agencies to review their policies on the protection of human subjects in scientific research, and to strictly enforce them. Currently, all human subject research must meet stringent informed consent guidelines that are established by federal regulation. All experiments are reviewed by Institutional Review Boards -- local committees that are required at every research site that ensure adherence to informed consent guidelines and other ethical standards. In light of actions from decades ago that have recently come to light, the Memorandum directs each Executive Department and Agency to exercise constant care in these matters.

(continued))

Clinician, Non-Radiation/Public Health

Reed V. Tuckson, M.D. - president, Charles R. Drew University of Medicine and Science, Los Angeles, CA.

Military Medicine Specialist

Philip K. Russell, M.D. - professor of international health, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, MD.

Radiation Biologist

Nancy L. Oleinick, Ph.D. - professor of radiation biology and biochemistry, Environmental Health Science and Oncology, School of Medicine and director, Division of Biochemistry and Oncology, Department of Radiology, Case Western Reserve University, Cleveland, OH.

General Scientist

Frank Press, Ph.D. - fellow, Cecil and Ida Green Fellowship,
Carnegie Institution of Washington, Washington, D.C.; former president, National Academy of Scientists.

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, NE;

-30-30-30-

CANDIDATES FOR 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, MD; senior research scholar, Kennedy Institute of Ethics, Georgetown University, Washington, D.C.

Ruth Macklin, Ph. D. - head, Division of Philosophy and History of Medicine, professor of bioethics, Shoshanah Trachtenberg Frackman Faculty Scholar in Biomedical Ethics, Department of Epidemiology and Social Medicine, Albert Einstein College of Medicine, Bronx, NY.

Patricia A. King, J.D. - professor of law, Georgetown University Law Center, Washington, D.C.; adjunct professor, Department of Health Policy and Management, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, MD.

Jay Katz, M.D. - Elizabeth K. Dollard Professor Emeritus of Law, Medicine and Psychiatry and Harvey L. Karp Professorial Lecturer in Law and Psychoanalysis, Yale University, New Haven, CT.

Historian

Susan E. Lederer, Ph. D. - associate professor, Department of Humanities, The Milton S. Hershey Medical Center, Pennsylvania State University, Hershey, PA.

Attorney

Kenneth R. Feinberg, J.D. - Kenneth R. Feinberg & Associates, Washington, D.C.; adjunct professor of law, Georgetown University Law Center, Washington, D.C.; member, Presidential Commission on Catastrophic Nuclear Accidents, 1989-90.

Epidemiologist

Duncan Thomas, Ph.D. - professor, Preventive Medicine, University of Southern California School of Medicine, Los Angeles, CA.

Clinicians, Radiation Therapy/Nuclear Medicine

Eli J. Glatstein, M.D. - professor and chairman, Department of Radiation Oncology, Simmons Cancer Center, Southwestern Medical Center, University of Texas, Dallas, TX.

Henry D. Royal, M.D. - associate director, Division of Nuclear Medicine, Mallinckrodt Institute of Radiology and professor of radiology, Washington University School of Medicine, St. Louis, MO.

Mary Ann Stevenson, M.D. - assistant professor in radiation therapy, Joint Center for Radiation Therapy and deputy chief, Department of Radiation Oncology, New England Deaconess Hospital, Harvard Medical School, Boston, MA.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release February 17, 1994

February 17, 1994

MEMORANDUM FOR THE VICE PRESIDENT
THE HEADS OF EXECUTIVE DEPARTMENTS
AND AGENCIES

SUBJECT: Review of Federal Policy for the Protection of Human Subjects

Federally funded biomedical and behavioral research has resulted in major advances in health care and improved the quality of life for all Americans. The pursuit of new knowledge in these fields of research often requires experiments that involve human subjects. Although human subjects research is an essential element of biomedical and behavioral research, bioèthical considerations must influence the design and conduct of such research.

Since 1947, when guidelines for research with human subjects were promulgated, there has been increasingly widespread recognition of the need for voluntary and informed consent and a scientifically valid design of experiments involving human subjects.

Over time, this recognition has evolved into a rigorous and formalized system of regulations and guidelines, which were codified in governmental policies on human subject research, and were included in the former Department of Health, Education and Welfare's regulations in 1974, 45 C.F.R. 46. In 1991, 16 agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects. This Policy requires that all research protocols involving human subjects be reviewed by an Institutional Review Board. This review ensures that (1) risks are minimized and reasonable in relation to anticipated benefits; (2) there is informed consent; and (3) the rights and welfare of the subjects are maintained (56 Fed. Reg. 28003 (June 18, 1991)).

Although these regulations provide the framework for protecting human subjects in research, we must exercise constant care and ensure that these regulations are strictly enforced by departments and agencies. Therefore, I direct each department and agency of Government to review present practices to assure compliance with the Federal Policy for the Protection of Human Subjects and to cease immediately sponsoring or conducting any experiments involving humans that do not fully comply with the Federal Policy.

WILLIAM J. CLINTON

# # #

THE WHITE HOUSE

DRAFT

For Immediate Release February 17, 1994

PRESIDENT ANNOUNCES INTENTION TO NAME ETHICAL, SCIENTIFIC AND MEDICAL EXPERTS TO ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

The President today announced ~~his intention to name~~ fifteen ~~experts in several fields~~ to serve on the Advisory Committee on Human Radiation Experiments. The Advisory Committee was created by Executive Order on January 18, 1994. The Advisory Committee will review the ethical and scientific standards of any government-sponsored experiments since 1946 on individuals involving intentional exposure to ionizing radiation. The individuals he will name to

The Advisory Committee will provide advice and recommendations to the Interagency Working Group on Human Radiation on issues such as whether there was a clear medical or scientific purpose for the experiments, if there was proper informed consent or if appropriate medical follow-up was conducted.

The Advisory Committee is to submit an interim report in six months after it begins work and a final report in one year. The Advisory Committee will comply with the terms of the Federal Advisory Committee Act.

The Advisory Committee will be chaired by Dr. Ruth Faden, a medical ethicist from Johns Hopkins University. A list of the other members of the Committee is attached.

In other actions:

* The White House today issued a Presidential Memorandum instructing all Federal Departments and Agencies to review their policies on the protection of human subjects in scientific research and strictly enforce them. Currently, all human subject research must meet stringent informed consent guidelines that are established by federal regulation. All experiments are reviewed by Institutional Review Boards -- local committees that are required at every research site that ensure adherence to informed consent guidelines and other ethical standards. In light of actions from decades ago that have recently come to light, the Memorandum directs each Federal Department and Agency to exercise constant care in these matters. (A copy of the Memorandum is attached.)

# # #

CANDIDATES FOR 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, MD; senior research scholar, Kennedy Institute of Ethics, Georgetown University, Washington, D.C.

Ruth Macklin, Ph. D. - head, Division of Philosophy and History of Medicine, professor of bioethics, Shoshanah Trachtenberg Frackman Faculty Scholar in Biomedical Ethics, Department of Epidemiology and Social Medicine, Albert Einstein College of Medicine, Bronx, NY.

Patricia A. King, J.D. - professor of law, Georgetown University Law Center, Washington, D.C.; adjunct professor, Department of Health Policy and Management, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, MD.

Jay Katz, M.D. - Elizabeth K. Dollard Professor Emeritus of Law, Medicine and Psychiatry and Harvey L. Karp Professorial Lecturer in Law and Psychoanalysis, Yale University, New Haven, CT.

Historian

Susan E. Lederer, Ph. D. - associate professor, Department of Humanities, The Milton S. Hershey Medical Center, Pennsylvania State University, Hershey, PA.

Attorney

Kenneth R. Feinberg, J.D. - Kenneth R. Feinberg & Associates, Washington, D.C.; adjunct professor of law, Georgetown University Law Center, Washington, D.C.; member, Presidential Commission on Catastrophic Nuclear Accidents, 1989-90.

Epidemiologist

Duncan Thomas, Ph.D. - professor, Preventive Medicine, University of Southern California School of Medicine, Los Angeles, CA.

Clinicians, radiation therapy/nuclear medicine

Eli J. Glatstein, M.D. - professor and chairman, Department of Radiation Oncology, Simmons Cancer Center, Southwestern Medical Center, University of Texas, Dallas, TX.

Henry D. Royal, M.D. - associate director, Division of Nuclear Medicine, Mallinckrodt Institute of Radiology and professor of

radiology, Washington University School of Medicine, St. Louis, MO.

Mary Ann Stevenson, M.D. - assistant professor in radiation therapy, Joint Center for Radiation Therapy and deputy chief, Department of Radiation Oncology, New England Deaconess Hospital, Harvard Medical School, Boston, MA.

Clinician, non-radiation/public health

Reed V. Tuckson, M.D. - president, Charles R. Drew University of Medicine and Science, Los Angeles, CA.

Military medicine specialist

Philip K. Russell, M.D. - professor of international health, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, MD.

Radiation biologist

Nancy L. Oleinick, Ph.D. - professor of radiation biology and biochemistry, Environmental Health Science and Oncology, School of Medicine and director, Division of Biochemistry and Oncology, Department of Radiology, Case Western Reserve University, Cleveland, OH.

General Scientist

Frank Press, Ph.D. - fellow, Cecil and Ida Green Fellowship, Carnegie Institution of Washington, Washington, D.C.; former president, National Academy of Scientists.

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, NE;

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release January 18, 1994

EXECUTIVE ORDER

- - - - - - -

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

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:

more

(OVER)

(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.

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.

(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.

WILLIAM J. CLINTON

THE WHITE HOUSE,
January 15, 1994.

# # #

Will you give my name to reporters?

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

What if you can't find my records?

Unfortunately, we may not. 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 independent 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.

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

We're looking at all human radiation experiment records from 1946-1974. In 1974 the Department of Health, Education and Welfare (now Health and Human Services) enacted a set of regulations to protect human subjects in experiments of all kinds. The regulations include setting up local Institutional Review Boards at research sites to review experiments 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.

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 a need 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 appropriate 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 radiation therapy devices and employs many programs to ensure the devices' safety & 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 Exposure Compensation Act provides compensation for uranium miners and "downwinders," individuals who lived in Nevada, Arizona and Utah during atmospheric nuclear bomb testing and onsite test participants who have developed certain kinds of diseases. For information, call 1-800-729-7327.

"ATOMIC VETERANS"

"Atomic Veterans," those who participated in atomic bomb testing as part of military exercises, may be eligible for benefits through Department of Veteran Affairs, 1-800-827-0365. For exposure data, call 1-800-462-3682

Published by the Federal Interagency Working Group on Human Radiation Experiments

HUMAN RADIATION EXPERIMENTS 1946-1974

The Clinton Administration's effort to find the facts

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.

Much of this research resulted in valuable medical advances like radiation treatments for cancer and the use of isotopes to accurately diagnose illness.

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

There are indications that in some cases:

(1) subjects may not have been notified that they were participating in research;

(2) subjects may not have given proper written informed consent;

(3) subjects gave consent, but may not have been fully informed of potential health consequences of the research;

(4) research was conducted on subjects who were vulnerable or disadvantaged - - minorities, elderly people, persons with mental retardation, infants, prison inmates, and hospital patients suffering from terminal conditions;

(5) some research may have served no apparent diagnostic or therapeutic medical purpose.

Information about this research 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 research conducted on human subjects by the government.

THE HUMAN RADIATION INTERAGENCY WORKING GROUP

At the direction of the White House, the Administration formed a working group of senior staff from 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 will be added if necessary.

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 to investigate the experiments. Their meetings will be open to the public. Records will be collected and preserved in a location 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 some new light on the search for records.

Your help is valuable because most of the information and records we are looking for is very old. We're not sure where it's been preserved after so many years. Your call may help us find additional information.

ANSWERS TO YOUR QUESTIONS

I called the Helpline. What happens now?

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

We will collect all the records we can find and bring them together. President Clinton has appointed a special independent Advisory Committee of experts from outside the government to 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 this research was 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 aren't sure. 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.

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

PUBLIC MEETING

APRIL 21-22, 1994

TENTATIVE AGENDA

Friday, April 22, 1994

9:00 am	Opening Remarks Ruth Faden
9:05 am	Committee Discussion Moderator: Ruth Faden
9:30 am	Briefing by Interagency Working Group: Document Retrieval and Data Collection Efforts
10:30 am	Break
10:45 am	Briefing by Interagency Working Group: Document Retrieval and Data Collection Efforts (**Continued**)
	Committee Question and Answer Period Moderator: Ruth Faden
11:45 am	Committee Staff Structure and Organization Dan Guttman, Executive Director
12:15 pm	Lunch
1:30 pm	Discussion of Committee Strategy and Direction Moderator: Ruth Faden
3:00 pm	Meeting Adjourned

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

PUBLIC MEETING

APRIL 21-22, 1994

TENTATIVE AGENDA

Thursday, April 21, 1994

9:30 am	Call to Order Christine Varney, Secretary to the Cabinet
	Welcome and Introductions Ruth Faden, Chair
9:50 am	Introductory Comments on Committee Mission Ruth Faden
10:00 am	Initial Committee Discussion of Mission Moderator: Ruth Faden
10:45 am	Break
11:00 am	Briefing by Interagency Working Group
12:00 pm	Lunch
1:15 pm	Introductory Comments Ruth Faden
1:30 pm	Comments by Congressional Representatives
2:00 pm	Continued Committee Discussion of Mission Moderator: Ruth Faden
3:00 pm	Break
3:15 pm	Public Comment Period
5:00 pm	Meeting Adjourned

RUTH R. FADEN

CHAIR, ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

Biographical Sketch

Ruth R. Faden, Ph.D., M.P.H., is Professor of Health Policy and Management in the School of Hygiene and Public Health, Johns Hopkins University. Dr. Faden is also Senior Research Scholar at the Kennedy Institute of Ethics, Georgetown University.

Dr. Faden is Director of the Program in Law, Ethics, and Health of Johns Hopkins' School of Public Health. She 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 California-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 EXPERIMENTATION
STAFF

Biographical Sketches

Anna Mastroianni, J.D.
Director of Committee Affairs
Deputy Staff Director
Senior Policy and Research Analyst

Before joining the Advisory Committee staff, Ms. Mastroianni was a study director in the Division of Health Sciences Policy of the National Academy of Sciences' Institute of Medicine. In that position, she most recently directed a study evaluating legal and ethical issues relating to the inclusion of women in clinical studies. Ms. Mastrioanni practiced health care law in Washington, DC, in addition to serving as a legal consultant to the National Research Council's Committee on Contraceptive Development. She received her Juris Doctor and undergraduate degrees from the University of Pennsylvania. Her research interests include legal and ethical issues in the "right to die" area. She currently studies health policy at the Johns Hopkins University School of Hygiene and Public Health, and is a member of the Department of Health and Human Services Advisory Workshop on Women in Medicine.

Jeffrey Kahn, Ph.D., M.P.H.
Acting Staff Director
Senior Policy and Research Analyst

In addition to his Committee duties, Jeffrey Kahn is Assistant Professor of Bioethics and Associate Director for Graduate Studies in the Center for the Study of Bioethics of the Medical College of Wisconsin (MCW). His administrative responsibilities at MCW include directing the College's Master's program in Bioethics. Before joining the faculty at MCW, Dr. Kahn was Assistant Professor of Medical Humanities at East Carolina University School of Medicine, in Greenville, North Carolina. Dr. Kahn's background includes study in both science and the humanities, with a Bachelor degree in Microbiology from the University of California Los Angeles, a Masters in Public Health from the Johns Hopkins University School of Hygiene and Public Health (Health Policy), and a Doctorate (Ph.D.) in Philosophy from Georgetown University, where he studied Bioethics at the Kennedy Institute of Ethics. Dr. Kahn does research and publishes in a variety of areas, including theoretical bioethics, ethics and genetics, dental ethics, ethical issues in health policy, and research ethics. His experience outside the academic setting includes hospital ethics committee memberships and consultations, along with review of proposed human and animal research.

ADVISORY COMMITTEE
ON HUMAN RADIATION EXPERIMENTATION
STAFF

Biographical Sketches

Stephen Klaidman
Director of Communications

In addition to his Committee duties, Stephen Klaidman is currently a visiting professor of journalism at the Pennsylvania State University and a fellow of the Kennedy Institute of Ethics, Georgetown University. He began his career in academia after 23 years as a journalist with The New York Times, The Washington Post, and the International Herald Tribune. Mr. Klaidman has been a columnist, editorial writer, reporterm, and editor. He has been a senior associate of the Institute for Health Policy Analysis at Georgetown, director of the Undergraduate Values Project also at Georgetown, and is currently an Associate in the Department of Health Policy and Management at Johns Hopkins University. He is the author of Health in the Headlines (Oxford, 1991) and The Virtuous Journalist (Oxford, 1987, with Tom L. Beauchamp). Mr. Klaidman has been a Guest Scholar at the Woodrow Wilson Center, where he won First Prize in the Media Studies competition in 1989. In 1992 he won the Lowell Mellett Award for improving journalism through critical evaluation.

Jeremy Sugarman, M.D., M.P.H., M.A.
Senior Policy and Research Analyst

In addition to his Committee duties, Jeremy Sugarman is an Assistant Professor and Co-Director of the Program in Medical Ethics in the Division of General Internal Medicine, Senior Fellow in the Center for the Study of Aging and Human Development, and Assistant Research Professor in the Center for Health Policy Research and Education at Duke University Medical Center. He received his medical degree and residency training at Duke and went on to pursue formal training in medical ethics at Georgetown University, where he received his Master of Arts in Philosophy. Dr. Sugarman also received training in empirical research at the Johns Hopkins University School of Hygiene and Public Health, where he received a Masters in Public Health. Dr. Sugarman is board-certified in Internal Medicine and is a practicing physician at the Duke Medical Center. He has consulted for the U.S. Congress' Office of Technology Assessment on its Defensive Medicine and Use of Medical Technologies Project. His primary research interests relate to the moral issues associated with physician-patient communication, such as advance directives, informed consent, and shared medical decisionmaking.

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.

Ruth Macklin, Ph.D. - Head, Division of Philosophy and History of Medicine, Professor of Bioethics, Shoshanah Trachtenberg Frackman Faculty Scholar in Biomedical Ethics, Department of Epidemiology and Social Medicine, Albert Einstein College of Medicine, Bronx, New York.

Patricia A. King, J.D. - Professor of Law, Georgetown University Law Center, Washington, District of Columbia; Adjunct Professor, Department of Health Policy and Management, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, Maryland.

Jay Katz, M.D. - Elizabeth K. Dollard Professor Emeritus of Law, Medicine and Psychiatry, Harvey L. Karp Professorial Lecturer in Law and Psychoanalysis, Yale University, New Haven, Connecticut.

Historian

Susan E. Lederer, Ph.D. - Associate Professor, Department of Humanities, The Milton S. Hershey Medical Center, Pennsylvania State University, Hershey, Pennsylvania.

Attorney

Kenneth R. Feinberg, J.D. - Kenneth R. Feinberg & Associates, Washington, District of Columbia; Adjunct Professor of Law, Georgetown University Law Center, Washington; Member, Presidential Commission on Catastrophic Nuclear Accidents, 1989-90.

Epidemiologist

Duncan Thomas, Ph.D. - Professor, Preventive Medicine, University of Southern California School of Medicine, Los Angeles, California.

Clinicians, Radiation Therapy/Nuclear Medicine

Eli J. Glatstein, M.D. - Professor and Chairman, Department of Radiation Oncology, Simmons Cancer Center, Southwestern Medical Center, University of Texas, Dallas, Texas.

Henry D. Royal, M.D. - Associate Director, Division of Nuclear Medicine, Mallinckrodt Institute of Radiology, Professor of Radiology, Washington University School of Medicine, St. Louis, Missouri.

Mary Ann Stevenson, M.D., Ph.D. - Assistant Professor of Radiation Oncology, Joint Center for Radiation Therapy, Deputy Chief, Department of Radiation Oncology, New England Deaconess Hospital, Harvard Medical School, Boston, Massachusetts.

Clinician, Non-Radiation/Public Health

Reed V. Tuckson, M.D. - President, Charles R. Drew University of Medicine and Science, Los Angeles, California.

Military Medicine Specialist

Philip K. Russell, M.D. - Professor of International Health, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, Maryland.

Radiation Biologist

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.

MEDIA CONTACTS

Advisory Committee:	Steve Klaidman	202-254-9795
Department of Defense:	Major Bob Potter	703-697-5131
Department of Energy:	Mary Freeman John Donnelly	202-586-6868 -9701
Department of Health and Human Services:	Bill Grigg	202-690-6867
Department of Justice:	Julie Anbender	202-514-2007
Department of Veterans' Affairs:	Donna St. John	202-535-8300
Central Intelligence Agency:	David Christian	703-482-7754
National Aeronautical and Space Administration:	Mark Hess	202-358-1898

WHAT WE KNOW ABOUT RADIATION

1. What is radiation?

We live in a sea of radiation. There are many different types of radiation, some of which are visible light, ultraviolet rays from the sun, infrared from a heat lamp, microwaves, radio waves and ionizing radiation. Radiation is said to be ionizing if it has sufficient energy to displace one or more of the electrons that are part of an atom. This creates an electrically charged atom known as an ion. Common examples of ionizing radiation are x rays and their cousins, gamma rays, which are emitted by radioactive materials. Others include beta rays, which are also emitted from radioactive materials, and neutrons, which are emitted during the splitting (fission) of atoms in a nuclear reactor.

2. When do we encounter ionizing radiation in our daily lives?

Everyone who lives on this planet is constantly exposed to naturally occurring ionizing radiation (background radiation). This has been true since the dawn of time.

Sources of background radiation include cosmic rays from the sun and stars; naturally occurring radioactive materials in rocks and soil; and radioactive isotopes (unstable radioactive counterparts to naturally stable atoms) normally incorporated into our body's tissues; and radon and its products, which we inhale. Radon exists as a gas and is present in soil from which it seeps into the air. Radon gets trapped inside buildings, especially if the ventilation is poor. Levels of environmental radiation depend upon geology, how we construct our dwellings, and altitude. For example, radiation levels from cosmic rays are greater for people on airplanes and those living on the Colorado plateau. However, the risk of cancer has not been shown to vary consistently with the levels of background radiation.

We are also exposed to ionizing radiation from man-made sources, mostly through medical procedures. On the average, doses from a diagnostic x ray are comparable to natural background radiation. Radiation therapy, however, can reach levels many times higher than background radiation but this is usually targeted only to the affected tissues. We are also exposed to ionizing radiation from color televisions, smoke detectors, building materials, mining and agricultural products, and coal-burning. People who smoke receive additional radiation from radioisotopes in tobacco smoke.

3. How do we know about the effects of high doses of ionizing radiation?

The adverse effects of high doses of radiation were seen shortly after the discovery of radioactivity and x rays in the 1890s. In 1902, skin cancers were reported in scientists who were studying radioactivity. Back then, no one took special precautions in working with radioactive materials because their effects were not yet fully recognized. The occupational hazards soon became apparent. For example, a 1931 report described cases of bone cancer in women who wet their brushes on their tongues to get a good "point" for painting radium on watch dials. Radiation's role in causing leukemia in humans was first reported in 1944 in physicians and radiologists.

Much of our data on the effects of high doses of radiation comes from survivors of the 1945 atomic bombs dropped on Hiroshima and Nagasaki and from other people who

received high doses of radiation, usually for treatment. The National Cancer Institute (NCI), part of the National Institutes of Health (NIH), in collaboration with the Radiation Effects Research Foundation, an international group supported jointly by the U.S. Department of Energy and the Japanese Ministry of Health and Welfare, continues to study the long-term effects of radiation on the survivors of the bombs. Only about 12% of all the cancers that have developed among these survivors are estimated to be related to radiation; only about 9% of the fatal cancers in these people are estimated to be related to radiation. Uranium miners and those who lived near the Nevada nuclear weapons test sites used from 1951-1963 are also among those being monitored in order to learn more about the effects of high doses of ionizing radiation. NCI is also helping to set up studies of the people most affected by the Chernobyl nuclear power plant accident, especially the children who lived nearby and the workers who cleaned up the plant after the accident. The information from all these studies has been and will continue to be published--after rigorous review--in medical and scientific journals that are available to everyone.

4. What are some of the beneficial ways in which ionizing radiation is used in medicine and in medical research?

The discovery of x rays in 1895 was a major turning point in diagnosing diseases because physicians finally had an easy way to "see" inside the body without having to operate. Newer x-ray technologies such as CT (computerized tomography) scans have revolutionized the diagnosis and treatment of diseases affecting almost every part of the body. Other sophisticated techniques have provided physicians with low-risk ways to diagnose heart disease. For example, doctors can now pinpoint cholesterol deposits that are narrowing or blocking coronary arteries, information essential for bypassing or unclogging them.

Every major hospital in the United States has a nuclear medicine department, in which radioisotopes are used to diagnose and treat a wide variety of diseases more effectively and safely by "seeing" how the disease process alters the normal function of an organ. To obtain this information, a patient either swallows, inhales, or receives an injection of a tiny amount of a radioisotope. Special cameras reveal where the isotope accumulates briefly in the body, providing, for example, an image of the heart that shows normal and malfunctioning tissue. Radioisotopes are also used in laboratory tests to measure important substances in the body, such as thyroid hormone. Radioisotopes are used to effectively treat thyroid diseases, including Graves disease--one of the most common forms of hyperthyroidism--and thyroid cancer. The use of ionizing radiation has led to major improvements in the diagnosis and treatment of patients with cancer. These innovations have resulted in increased survival rates and improved quality of life. Mammography can detect breast cancer at an early stage when it may be curable. Needle biopsies are more safe, accurate, and informative when guided by x-ray or other imaging techniques. Radiation is used in monitoring the response of tumors to treatment and in distinguishing malignant tumors from benign ones. Bone and liver scans can detect cancers that have spread.

Half of all people with cancer are treated with radiation, and the number of those who have been cured continues to rise. There are now tens of thousands of individuals alive and cured from various cancers as a result of radiotherapy. In addition, there are

many patients who have had their disease temporarily halted by radiotherapy. Radioisotopes are also being used to decrease or eliminate the pain associated with cancer--such as that of the prostate or breast-- which has spread to the bone.

Radioisotopes are a technological backbone for much of the biomedical research being done today. They are used in identifying and learning how genes work. Much of the research on AIDS is dependent upon the use of radioisotopes. Scientists are also "arming" monoclonal antibodies--that are produced in the laboratory and engineered to bind to a specific protein on a patient's tumor cells--with radioisotopes. When such "armed" antibodies are injected into a patient, they bind to the tumor cells, which are then killed by the attached radioactivity, but the nearby normal cells are spared. So far, this approach has produced encouraging success in treating patients with leukemia. Most new drugs, before they are approved by the Food and Drug Administration, have undergone animal studies that use radioisotopes to learn how the body metabolizes them.

Another clinical and research tool, PET scanning (positron emission tomography), involves injecting a small amount of a radioisotope into a person to "see" the metabolic activity and circulation in a living brain. PET studies have enabled scientists to pinpoint the site of brain tumors or the source of epileptic activity, and to better understand many neurologic diseases. Researchers were able to learn how dopamine--the chemical messenger (neurotransmitter) that's involved in Parkinson's disease--is used by the brain.

These are but a few of the many vital uses of ionizing radiation in medicine. About 70 to 80 percent of all research at the National Institutes of Health is performed using radiation and radioactive materials. NIH research has consistently produced results that have improved the health of the American people.

5. What are the adverse effects of ionizing radiation?

Ionizing radiation can cause important changes in our cells by breaking the electron bonds that hold molecules together. For example, radiation can damage our genetic material (DNA) either directly by displacing electrons from the DNA molecule, or indirectly by displacing electrons from some other molecule in the cell, which then interacts with the DNA. A cell can be destroyed quickly or its growth or function may be altered through a change (or mutation) that may not be evident for many years. However, the possibility of this inducing a clinically significant illness or other problem is quite remote at **low** radiation doses.

Our cells, however, have several mechanisms to repair the damage done to DNA by radiation. The efficiency of these repair mechanisms differs among cells and depends on several things, including the type and dose of radiation. There also are biological factors that can greatly modify the cancer-causing effects of **high** doses of radiation.

The severity of radiation's effects depends on many other factors such as the magnitude and duration of the dose; the area of the body exposed to it; and a person's sex, age, and physical condition. A **huge** dose of radiation to the whole body at one time can result in death. Exposure to **high** levels of radiation can increase the risk of developing cancer. Because a radiation-induced cancer is indistinguishable from cancer caused by other factors, it is very difficult to pinpoint radiation as the cause of cancer in a particular individual.

Other effects of **high** doses of radiation include suppression of the immune system and cataracts. Certain tissues of a fetus, particularly the brain, are especially sensitive to

radiation at specific stages of development. An increased rate of severe mental retardation has been found in atomic bomb survivors whose mothers were 8-25 weeks pregnant when the bombs were dropped. However, the children and grandchildren of the atomic bomb survivors so far have shown no greater incidence of genetic problems than unexposed populations.

It is very difficult to detect biologic effects in animals or people who are exposed to **low-level** radiation. Based on studies in animals and in people exposed to **high** doses of radiation such as the atomic bomb survivors, scientists have made conservative estimates of what might be the **highest** doses that would be reasonably safe for a person over a lifetime. But these calculations are estimates only, based on mathematical models. Even so, the U.S. government uses these estimates to set the limits on all potential exposures to radiation for workers in jobs that expose them to ionizing radiation. International experts and various scientific committees have, over the years, examined the massive body of knowledge about radiation effects in developing and refining radiation protection standards.

6. Should patients be concerned about the radiation they may receive from tests that their physicians have ordered?

The doses involved in medical procedures have been decreasing over the past two decades as x-ray films and equipment have been improved. In addition, the ability to target radiation more precisely to one part of the body has resulted in less exposure to the rest of the body.

It is always wise to avoid unnecessary radiation exposure. Physicians routinely compare the risks of radiation to the benefits derived from a diagnostic use of radiation to ensure that there is more benefit to the patient than risk. In many cases, such diagnostic tests enable doctors to treat the patient without invasive and life-threatening procedures.

Radiologists, health physicists, the National Council on Radiation Protection and Measurements--the Congressionally chartered independent advisory group that, among other things, recommends what the U.S. radiation standards should be--and other responsible parties are continually seeking ways of minimizing risk while retaining or improving the benefits from medical uses of radiation.

7. Should patients be concerned about the radiotherapy they undergo for cancer treatment?

Radiation, surgery, and chemotherapy are the mainstays of cancer treatment and are used in combinations depending on the cancer. Certain tumors can be treated successfully with radiotherapy alone. The effectiveness of radiation in killing cancer cells--and, at the same time, the potential for harm to normal tissues--depends on several things, including the type of radiation used, the extent of the body that is treated, and the patient's age or other medical problems. Doctors try to avoid exposure of large parts of the body to radiation because this can cause serious side effects like cancer. However, only about 5% of all secondary cancers--ones that develop after treatment for the initial cancer--have been linked to radiotherapy. The risk of leukemia after **high** doses of radiation to localized areas of the body often is surprisingly low, because the local effect is to kill cells that might, at **lower** doses, undergo transformation --the changes that a

normal cell undergoes as it becomes malignant--eventually leading to leukemia. Other side effects of radiotherapy range from mild to serious; many are temporary.

With the development of better machines and the use of computers to plan the treatment, the safety and efficacy of radiotherapy has steadily improved. Radiologists make every attempt to minimize harmful effects to normal tissues. Thus, a patient's risks from exposure to radiation are far offset by the benefits from the treatment.

8. Should patients or normal volunteers be concerned about participating in medical research studies in which they may be exposed to some radiation?

The U.S. government takes measures to protect the rights and welfare of everyone who participates in medical research studies. By law, studies involving humans and funded by the U.S. government must first be approved by the Institutional Review Board (IRB) of the hospital or university where the study will be conducted. The IRB, composed of a group of individuals with backgrounds in science, ethics, and other fields, must ensure that all risks to the participants are justified on the basis of potential benefits either to themselves or to society and that their rights will be protected. This regulation applies to all studies, including those in which the use of radiation is proposed. It is also the IRB's responsibility to ensure that patients or volunteers are fully and accurately informed of the risks and benefits of participation in the study, are not coerced in any way into participating, and are competent to make the decision to participate. (If the studies will be conducted in children, then parental consent and assent by the child is required.) When the use of ionizing radiation is involved, nearly all such institutions also have a group of radiation health experts (the radiation safety committee) review the proposed research before it can be approved to proceed.

9. Should people be concerned about ionizing radiation?

Most of the radiation that we are receiving is naturally occurring background radiation. Some level of exposure to radiation is unavoidable. It appears, however, that the cancer risk from **very low-dose** exposure is quite low. It is prudent to avoid unnecessary exposure, but not if one loses more--in money, time, convenience, or increased risks from other things--by avoiding radiation rather than ignoring it.

The cancer risk associated with exposure to **high** levels of ionizing radiation is among the best understood of any relationships involving environmental agents that cause cancer; this relationship continues to be studied and reevaluated. This knowledge is constantly used in evaluating the risks and benefits of the uses of radiation in medicine. In the overwhelming majority of cases where it is used, the benefits of medical radiation far outweigh the risks associated with it, but there is a tradeoff. In this sense, radiation is no different than any other diagnostic or therapeutic agent, except that we have more information than usual.

Properly managed, radiation can be used for great benefit to humanity and with minimal risk, a risk comparable to or lower than those commonly accepted as an ordinary part of daily life such as driving to work.

Prepared by the Office of Communications, OD, National Institutes of Health
April 11, 1994

HUMAN RADIATION EXPERIMENTS HELPLINE
APRIL 1994

In December 1993, the Department of Energy established a toll-free Human Radiation Experiments telephone Helpline. The purpose of the Helpline is to aid the Government in identifying those persons who may have been affected by government-conducted or -sponsored radiation experiments. Public response was immediate and the Helpline received thousands of calls within the first two weeks.

The Helpline was subsequently expanded to capture potential subjects of experiments sponsored by all Federal agencies involved in human radiation testing. The Interagency Working Group adopted the Department of Energy's Helpline, beginning January 26, 1994. Government agencies involved in radiation testing have agreed that the consolidated Interagency Helpline best serves the public.

The Helpline staff has received over 21,000 calls and completed over 11,000 surveys.

Each caller provides basic identifying information to the Interagency Helpline. This information is forwarded to the appropriate Federal agency for personal contact and more specific data collection.

The Federal government is trying to learn the scope of what may have occurred. The Helpline is only to be used by persons who suspect they (or family members) were subjects in medical or scientific experiments conducted by the Federal government. However, many others are phoning the Helpline, including:

Medical professionals, worried that patients will refuse legitimate medical radiation treatments;

Individuals who live adjacent to Federal government sites;

Persons who have had cancer, thyroid disease, and other ailments; and

Veterans who believe they were exposed during active military service.

Due to privacy concerns, information about specific callers will not be released.

As data is compiled and analyzed, available information will be shared openly, subject to privacy and ethical requirements.

HUMAN RADIATION EXPERIMENTS

HISTORICAL BACKGROUND

From 1946-1974, several agencies of the United States 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, among others.

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) some subjects may not have been notified that they were participating in an experiment;

(2) some subjects may not have given proper informed consent;

(3) certain subjects gave consent, but may not have been fully informed of potential health consequences of the experiment;

(4) experiments were conducted with disturbing frequency on subjects from vulnerable populations: poor people, elderly people, retarded persons, infants, prison inmates, and hospital patients suffering from terminal conditions; and

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

Information about these experiments has trickled 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 available about radiation experiments conducted on human subjects by the government.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release January 18, 1994

EXECUTIVE ORDER

- - - - - - -

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

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.

Section 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.

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.

Section 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.

Section 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.

(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.

WILLIAM J. CLINTON

THE WHITE HOUSE,
January 15, 1994

# # #

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:

(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 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 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 experiments which may later be identified by the Interagency Working Group.

The Advisory Committee shall review experiments conducted from 1944 to 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

The duties of the Advisory Committee are solely advisory and shall be:

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 experiment, 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. Subcommittees

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.

NEWS RELEASE

OFFICE OF ASSISTANT SECRETARY OF DEFENSE
(PUBLIC AFFAIRS)
WASHINGTON, D.C. · 20301
PLEASE NOTE DATE

No. 200-94
(703)697-5131(media)
(703)697-3189(copies)
(703)697-737(public/industry)

IMMEDIATE RELEASE April 15, 1994

FACT SHEET

DOD'S HUMAN RADIATION EXPERIMENTS REVIEW

In response to the President's guidance of late December 1993, the Secretary of Defense charged the Assistant to the Secretary of Defense (Atomic Energy) Dr. Harold P. Smith to lead DoD's efforts to discover the nature and extent of the Departments involvement in human radiation experimentation. In early January 1994, Dr. Smith organized a DoD Steering Committee of top-level DoD officials to oversee the unprecedented reccrds search and review.

In January 1994, Dr. Smith issued a memorandum to the individual Services and all other DoD components providing detailed guidance on locating, identifying, reviewing, and declassifying records pertaining to human radiation experiments. This guidance instructed DoD components to preserve existing records; manage records in accordance with Freedom of Information Act, Privacy Act and security classification procedures. The memorandum directed that records be declassified to the maximum extent. Further, if a question arose on a particular experiment, DoD components were directed to err on the side of inclusion in the initial identification of a possible experiment.

To ensure the quality, comprehensiveness and integrity of the search process, DoD components were directed to submit a report consisting of two parts. In Part I, each agency was required to identify each subordinate organization that may have conducted or sponsored experiments; records storage locations; a description of the efforts undertaken to confirm if records were at the locations identified; and to report if records had been found. Part II of the report required each organization to describe each experiment identified in the search.

(OVER)

A massive records search was conducted involving hundreds of DoD subordinate agencies, organizations and departments and millions of records. To coordinate this massive search and retrieval effort, the Department established a Radiation Experiments Command Center (RECC). The RECC developed two high-speed automated databases to organize and control the information being gathered. One database is designed to monitor inquiries from the public, other Federal agencies and Congress, and to analyze information received from these and other sources. A second database is designed to compile and organize information on possible experiments identified during the records search. The development of these innovative systems with allow reviewers to quickly cross-reference and match files from the two databases and significantly enhance the Department's ability to respond to inquiries from the Independent Advisory Committee, Congress and the public.

The Department's search has thus far identified approximately 1,760 DoD conducted or supported activities from 1944 to the present that may fall within the scope of the Interagency Working Group definition of human radiation experiments. However, it appears that the overwhelming majority of those cases are clinical research activities conducted by DoD medical components since 1974 involving therapeutic investigations in which radiation was used solely in accordance with established, non-experimental diagnostic procedures.

Secretary of Defense William Perry remains committed to a thorough and complete search of all available records and the full public release of the pertinent information in those records. All retrieved information will be turned over to the Independent Advisory Committee for further review.

-END-

Department of Energy
Washington, DC 20585

U.S. DEPARTMENT OF ENERGY ACTIONS TAKEN FOR INVENTORY AND RETRIEVAL OF RECORDS OF HUMAN RADIATION EXPERIMENTS

The United States Government conducted and sponsored experiments from 1944 to May 1974 involving exposure of humans to radiation, under a variety of circumstances and for a variety of reasons. The existence and nature of these experiments were rarely publicized; in many cases, the people who were exposed may not have been informed about the purposes and risks of the experiments.

Energy Secretary Hazel O'Leary pledged in December 1993 a full review of the scope of the experiments, in line with the Department of Energy's Openness Initiative. President Bill Clinton established an Interagency Working Group in January 1994 to identify and make public the records of Government-conducted or -sponsored radiation experiments, which used human subjects. The Department of Energy is a member of this Working Group.

Recognizing that the Department of Energy is currently responsible for the records of the former Atomic Energy Commission, which sponsored many of the known experiments, Secretary O'Leary directed the Department to set up a telephone Helpline (which later became an Interagency effort, managed by the Department of Energy) and published an address for inquiries concerning the experiments. These actions were complete by January 1994 and the public response was immediate. The Department has established an aggressive program to respond to more than 21,000 Helpline calls and 4,600 letters that have been received to date.

As the Helpline was being activated, the Department also established a Records Inventory and Retrieval Coordinating Committee to facilitate the collection and dissemination of all Departmental records on human radiation experiments. Each element of the Department of Energy was directed to start identifying any records that might be pertinent; elements include operations offices, field offices, area offices, and Headquarters organizations. Assistant Secretary for Environment, Safety and Health Tara O'Toole issued strict guidelines to assure that no information would be lost, overlooked, or otherwise excluded from the process.

Departmental elements have identified approximately 2,500 records of human radiation experiments and placed them in public reading rooms throughout the country. The Department has also established a centralized Information Center at its Headquarters in the Forrestal Building in Washington, D.C. The Forrestal Information Center holds copies of all records of human radiation experiments identified by the Department of Energy, along with a large number of additional records that will facilitate the identification and analysis of relevant records. These additional records include 270,000 records on nuclear testing and some 7,000 records on human experiments that may or may not involve radiation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

Search for Records of Human Radiation Experiments

The Department of Health and Human Services (DHHS) is actively participating with the other Agencies of government in the search to discover all instances in which human subjects have been experimentally exposed to ionizing radiation. The identification of all relevant documents and their public dissemination has been given high priority.

On January 27, 1993, Secretary Shalala instructed all components of the Department of Health and Human Services to identify all records related to experimental human exposure to ionizing radiation conducted between 1944 and 1974. Since most of these experiments were funded by the Public Health Service (PHS), PHS established a working group to coordinate the DHHS records retrieval effort. This working group is co-chaired by Dr. D.A. Henderson, Deputy Assistant Secretary for Health--Science, and Dr. Wendy Baldwin, Deputy Director for Extramural Research, NIH, and includes representatives from the National Institutes of Health, the Centers for Disease Control and Prevention, the Indian Health Service, and the Food and Drug Administration. The working group is responsible for providing ongoing guidance and oversight for the search activities to assure the quality, comprehensiveness, and integrity of the records collection process.

The working group is pursuing several strategies to identify relevant records, including:

1) All records of all PHS agencies are being carefully and systematically scrutinized for relevant information.

2) Past and present PHS employees are being interviewed for their recollections of this type of experimentation.

3) National Library of Medicine staff are searching the medical and scientific literature for articles involving the experimental use of ionizing radiation on humans.

4) PHS staff are contacting people who have either written the government or called the toll-free hotline with information related to possible PHS funded studies.

Each of the principal PHS agencies has established special search strategies tailored to the types of research activities and records maintained by each agency. For those experiments conducted by PHS employees, the records that exist are likely to be found within agency files. However, because much of the research supported by the PHS is conducted by research institutions located throughout the United States, the majority of the records of special interest -- research protocols, documents related to informed consent, and identities of research subjects -- will be located at awardee institutions. On March 7, 1994, HHS sent a letter to 27,000 research institutions asking that any records related to human exposure to ionizing radiation not be destroyed, even in the course of routine records destruction. Methodologies are now being developed to identify individual institutions or investigators involved in human experimentation with ionizing radiation.

U.S. Department of Justice

Office of Public Affairs

Washington, D.C. 20530

HUMAN RADIATION EXPERIMENTS
HUMAN RADIATION INTERAGENCY WORKING GROUP
DEPARTMENT OF JUSTICE SUMMARY

The Department of Justice did not conduct nor sponsor human radiation experiments. Nevertheless, it is participating in the work of the subcommittees of the Human Radiation Interagency Working Group. The Department shares the Administration's commitment to conduct an open and thorough inquiry of Cold War-era government sponsored human radiation experiments.

The Department provides the Working Group with legal advice and counsel on a broad range of issues. That counsel rests on the Administration's commitment to make public the greatest amount of information at the earliest possible time, while mindful of the personal privacy of those involved in the experiments and their families.

The Working Group is developing a broad range of potential responses for those who may have been affected by human radiation experiments. It is reviewing existing compensation programs as potential models, including several administered by the Department, in the event legislation is proposed after the facts have been determined. The Department's current programs include the Radiation Exposure Compensation Act, the National Vaccine Injury Compensation Program, and the Civil Liberties Act of 1988.

It should be emphasized that each of these programs was carefully designed and tailored to provide efficient, appropriate compensation for the carefully defined injuries Congress intended to address. Great attention was paid to defining an appropriate recipient population, setting eligibility standards, assessing the availability of relevant evidence, and determining the propriety of monetary and other forms of compensation. The Department, with the same attention to detail, is approaching the challenge of crafting an appropriate framework for the Administration's response to the subjects of human radiation experiments should it become appropriate to consider compensation.

The Department will join its fellow members on the Working Group in making recommendations to the President and the Congress regarding these matters.

Component Contact: J. Patrick Glynn (501-7040)

NASA REVIEW OF HUMAN RADIATION EXPERIMENTS

NASA is continuing its review of human radiation experiments involving NASA investigators or NASA funding. Dr. Harry Holloway, Associate Administrator, Life and Microgravity Sciences and Applications, has been appointed to oversee this review. Dr. Earl W. Ferguson, Director, Aerospace Medicine and Occupational Health, will provide Headquarters coordination of the review. Dr. Donald E. Robbins, Acting Director, Space and Life Sciences, Johnson Space Center, is leading the team conducting this review.

Daniel Goldin, Administrator, and Dr. Holloway have each issued guidance to Directors of NASA field centers instructing them to direct all NASA employees to take all necessary steps to locate, safeguard and report all records and other documentation related to human radiation experimentation. In addition, Mr. Goldin has sent a letter to all current and retired NASA employees requesting that any relevant information that they have be conveyed to Dr. Robbins.

Dr. Robbins and his team are conducting a search of NASA records concerning human experiments involving humans. This search includes a search of the Federal Records Centers data bases. The team has also contacted current and retired investigators, research managers, and program managers at NASA Headquarters and NASA field centers who would have knowledge about previous radiation research and radiation research funding. The latter efforts are particularly important because most official documents covering research efforts during and prior to the 1970s have been retired and destroyed in the normal course of documents management. A computer search of published scientific literature related to radiation research is also underway. The computer search initially identified 1777 articles for screening, 384 articles were selected for further review and 50 of those articles have been selected for detailed analysis.

NASA has thus far received less than 20 Helpline calls, FOIA requests and other inquiries related to its radiation review.

- More -

Our review is on-going, but thus far the following studies which fall under the purview of this review have been clearly identified as involving NASA:

1. Oak Ridge Institute for Nuclear Research: NASA contributed to the funding of both a retrospective study and a prospective study of human effects of radiation exposure in individuals who were exposed to whole body radiation for medical treatment or who were accidentally exposed. NASA provided less than 10% of the funding for these Atomic Energy Commission studies. The data on approximately 3000 human subjects from 45 different institutions were reviewed (approximately 100 subjects from the prospective study at Oak Ridge itself).
2. Two studies involving low levels of whole body radiation in experiments to measure total body calcium.
3. Studies in which investigators put their own heads in high energy particle beams to observe visual light flashes like those experienced by astronauts.

4/13/94

- end -

Editor's Note: Questions should be directed to Michael Braukus, NASA Headquarters at 202/358-1979

Office of Public Affairs
News Service

Washington, D.C. 20420
(202) 273-5700

Department of Veterans Affairs

VA Fact Sheet

April 1994

RADIATION RESEARCH IN THE DEPARTMENT OF VETERANS AFFAIRS

The Department of Veterans Affairs (VA) responded swiftly to reports that government-sponsored research involving human subjects and radioactive materials may have been conducted in an inappropriate manner in the '40s and '50s. Secretary of Veterans Affairs Jesse Brown immediately ordered VA medical centers to begin a comprehensive search for records on radioisotope nuclear medicine or radiation research that may have involved human subjects between the years 1947 and 1980. VA asked veterans service organizations to help the department raise awareness in the veteran community and urged concerned veterans to call its general toll-free number. VA regional offices began tracking those calls as well as calls to its special radiation helpline for veterans who were exposed to ionizing radiation during military service. In addition, VA began working with the Department of Energy (DOE), which is referring to VA veterans' calls received on its radiation hotline.

Status of VA's Response

VA medical centers were asked to search records for information about radioisotope and other nuclear medicine and radiation research between 1947, the year the radioisotope/nuclear medicine program was begun in VA, and 1980, when institutional review procedures for the protection of human subjects were well established. VA's emphasis on radioisotope/nuclear medicine research resulted from an initial search of historic records indicating that this was where VA research using ionizing radiation was focused. Of VA facilities with nuclear medicine capability between 1947 and 1980, 49 have located some protocols used during that period for radioisotope research, 24 have names of patients who participated in at least some research projects and 54 have some publications available on specific research projects done during that period. No medical centers found any evidence of research involving plutonium, nor had any contracted out any research.

In addition to the searches, VA's Nuclear Medicine Service is reviewing the licenses issued for radionuclides by the Atomic Energy Commission (now the Nuclear Regulatory Commission) for cross-referencing with research information. VA's Office of Research and Development reviewed protection of human subjects in VA research and reaffirmed the vigorous enforcement of policies and procedures in place to assure that all VA patients who participate in research are fully informed, consenting subjects. VA also is continuing to investigate the activities of the Atomic Medicine Division, established in the '40s but not in existence today.

VA's next step is to retrieve and inventory these records prior to review. A rigorous "chain of custody" is being established. An additional search for records on research involving ionizing radiation also will be done, and medical institutions affiliated with VA are being queried about the availability of records related to radiation research involving VA patients but not done at VA facilities. Procedures are being developed for the inventory of records, which will begin in the near future. All federally sponsored research will be reviewed by the Advisory Committee on Human Radiation Experiments, made up of nongovernmental scientists, physicians and ethicists.

Of the 800 inquiries DOE has forwarded to VA, some 650 are related to ionizing radiation exposure during military service. Some 150 are related to possible radiation research or treatment in VA facilities. Since mid-January 1994, VA regional offices have taken approximately 8,117 calls from individuals concerned with radiation exposure either while on active duty or at a VA medical center. Approximately 800 were concerned with possible radiation exposure at a VA medical facility. VA is in the process of reviewing these cases and will contact each individual. Inquiries related to radiation exposure during military service are being referred to the Department of Defense and the Department of Health and Human Services, or will be handled by VA.

Central Intelligence Agency

Washington, D.C. 20505

13 April 1994

The Central Intelligence Agency's Search for Records on Human Radiation Testing

On 4 January 1994 the Central Intelligence Agency began searching for records relating to any experiments that used ionizing radiation on human subjects. As this search nears completion, CIA has found no evidence that the Agency ever deliberately exposed anyone to toxic radiation.

The Agency's search took its initial guidance from statements made in the reports of two probes of CIA conducted in the 1970s. The Rockefeller Commission (1975) and the Church Committee (1976) discussed the Agency's testing of drugs on unwitting subjects in the 1950s and 1960s, particularly the MKULTRA program. MKULTRA, according to the investigators, authorized Agency officials to explore "additional avenues to the control of human behavior," including "*radiation*, electroshock, various fields of psychology, psychiatry, sociology, and anthropology, graphology, harassment substances, and paramilitary devices and materials" (emphasis added).

Agency officials tried to determine whether MKULTRA researchers actually experimented with radiation. No one associated with MKULTRA or the investigations of the 1970s recalled why the word "radiation" was used by the Rockefeller and Church reports. We found no documents indicating MKULTRA researchers used ionizing radiation on human subjects (most MKULTRA documents have been in the public domain for over a decade). Both reports used language from the CIA Inspector General's 1963 investigation of MKULTRA, and we believe the language might have originated in early documents mentioning radiation as a potential research field for Technical Services Division (which ran the MKULTRA program).

CIA officers in all the directorates are searching relevant Agency records for any evidence of radiation experiments. Throughout this search, CIA has based its inquiries on the broadest usage of the term "radiation." CIA officials have queried dozens of current and former employees, ranging from former DCIs to scientists and medical personnel most likely to have conducted or been aware of radiation testing, if it occurred. Without exception, Agency veterans knew of no such experiments or operations. No documents found to date suggest that CIA conducted experiments or operations using ionizing radiation on human subjects.

Since the 1970s, all Agency research involving human subjects has been conducted in accordance with all relevant guidelines issued by the Department of Health, Education and Welfare and the Department of Health and Human Services.

THE WHITE HOUSE

WASHINGTON

January 19, 1994

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES

FROM: CHRISTINE A. VARNEY
Secretary to the Cabinet

SUBJECT: Retrieval and Inventory of Records of Human Radiation Experiments

1. Each Agency should establish forthwith an initial procedure for locating records of human radiation experiments conducted by the Agency or under a contract or grant of the Agency. Agencies should coordinate the development of procedures for the retrieval and inventory of records with the Human Radiation Interagency Working Group (the "Interagency Working Group")[1] to ensure, where appropriate, that common procedures for the retrieval and inventory of records are applied at each Agency. Each Agency should provide to the Interagency Working Group a written copy of its initial directive and other documents implementing the Agency's record location, retrieval and inventory procedures.

2. (a) As used herein, "Agency" means Department of Defense, Department of Energy, Department of Health and Human Services, Central Intelligence Agency, Department of Veterans Affairs, and National Aeronautics and Space Administration.

(b) 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.

---

[1] The members of the Human Radiation Interagency Working Group 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.

(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.

3. In addition, Agencies should establish forthwith a procedure for retrieval and inventory of records of the following experiments:

(a) 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;

(b) 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;

(c) Six tests conducted during 1949-1952 of radiation warfare ballistic dispersal devices containing radioactive agents at the U.S. Army's Dugway, Utah site;

(d) Four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and

(e) Any other similar human experiments that may later be identified by the Interagency Working Group.

Each agency should include in the directive described in paragraph 1 above a directive initiating the Agency's retrieval and inventory procedure for records of the experiments set forth in this paragraph.

4. The procedures to be established pursuant to paragraph 1 above should address records for human radiation experiments conducted from 1944 to the present. 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 such experiments is warranted. Further inquiry into such experiments conducted after May 30, 1974, may be pursued if the Advisory Committee on Human Radiation Experiments (to be established pursuant to Executive Order 12891 (Jan. 15, 1994)) determines, with the concurrence of the Interagency Working Group, that such inquiry is warranted.

5. To the extent permitted by law, each Agency Head should institute procedures, consistent with paragraphs 6 and 7 below, for notifying and making records available to individuals subjected to human radiation experiments or the experiments set forth in paragraph 3 above, and/or their next of kin. Agencies should coordinate the development of these procedures with the Interagency Working Group.

6. Each Agency Head should institute procedures, consistent with existing statutes and regulations, for making records on human radiation experiments, and the experiments set forth in paragraph 3 above, available to members of the public. In implementing these procedures, each Agency Head should immediately issue an order to all elements of the Agency, and undertake all appropriate procedures to instruct and inform the Agency's grantees, contractors or other agents:

   (a) Not to destroy any records relating to human radiation experiments or the experiments set forth in paragraph 3 above.

   (b) To locate forthwith all records relating to human radiation experiments and the experiments set forth in paragraph 3 above and to identify, and undertake all appropriate procedures with regard to, any such records in the possession of grantees, contractors or other agents of the Agencies. Agencies should work together, in coordination with the Interagency Working Group, to standardize the retrieval of such records, which may involve the transfer of files to one or more designated repositories.

7. Each agency should also:

   (a) Upon locating the records, review all records of human radiation experiments, and the experiments set forth in paragraph 3 above, for national security classification and declassify such records as soon as practicable and to the maximum extent possible. Agencies should avail themselves of every opportunity to cooperate in expediting the declassification process.

   (b) Before making any copies of such records available to the public, make any redactions required for the protection of personal privacy interests of individuals subjected to human radiation experiments or the experiments set forth in paragraph 3 above, and/or their next of kin.

8. Agencies should work together with the Interagency Working Group to standardize, where appropriate, the inventory of

records of human radiation experiments and the experiments set forth in paragraph 3 above.

9. Agencies should document the procedures implemented to search for, retrieve and inventory records of human radiation experiments and the experiments set forth in paragraph 3 above.

10. In developing guidelines for retrieval and inventory of records, Agencies should consider advice and information provided to the Interagency Working Group by the Advisory Committee on Human Radiation Experiments.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release February 17, 1994

February 17, 1994

MEMORANDUM FOR THE VICE PRESIDENT
THE HEADS OF EXECUTIVE DEPARTMENTS
AND AGENCIES

SUBJECT: Review of Federal Policy for the Protection of Human Subjects

Federally funded biomedical and behavioral research has resulted in major advances in health care and improved the quality of life for all Americans. The pursuit of new knowledge in these fields of research often requires experiments that involve human subjects. Although human subjects research is an essential element of biomedical and behavioral research, bioethical considerations must influence the design and conduct of such research.

Since 1947, when guidelines for research with human subjects were promulgated, there has been increasingly widespread recognition of the need for voluntary and informed consent and a scientifically valid design of experiments involving human subjects.

Over time, this recognition has evolved into a rigorous and formalized system of regulations and guidelines, which were codified in governmental policies on human subject research, and were included in the former Department of Health, Education and Welfare's regulations in 1974, 45 C.F.R. 46. In 1991, 16 agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects. This Policy requires that all research protocols involving human subjects be reviewed by an Institutional Review Board. This review ensures that (1) risks are minimized and reasonable in relation to anticipated benefits; (2) there is informed consent; and (3) the rights and welfare of the subjects are maintained (56 Fed. Reg. 28003 (June 18, 1991)).

Although these regulations provide the framework for protecting human subjects in research, we must exercise constant care and ensure that these regulations are strictly enforced by departments and agencies. Therefore, I direct each department and agency of Government to review present practices to assure compliance with the Federal Policy for the Protection of Human Subjects and to cease immediately sponsoring or conducting any experiments involving humans that do not fully comply with the Federal Policy.

WILLIAM J. CLINTON

# # #