

AGENDA
AGENCY COORDINATION MEETING
January 3, 1993

I. Introductions and Overview

II. History of Experiments/Disclosures

III. Agency Updates

IV. Next steps:

- Review and retrieval of records
- Access
- Notification of subjects
- Ethical review
- Medical follow-up
- Compensation
- Other Issues

V. Organization of Response

Committees

VI. Legislative Strategy

VII. Communications Strategy

VIII. Next Meeting

Monday, January 10, 1993 4:00 PM
Roosevelt Room

→ Put on
my schedule.
We are on schedule
for Roosevelt Rm.
for 5 p.m. that
day. right?



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

JAN 12 1994

MEMORANDUM FOR DESIGNATED AGENCY HEADS
(SEE ATTACHED DISTRIBUTION LIST)

FROM: Robert G. Damus *RGD h/w*
Acting General Counsel

SUBJECT: Proposed Executive Order Entitled "Advisory
Committee on Human Radiation Experiments" *file*

Attached is a proposed Executive order entitled "Advisory Committee on Human Radiation Experiments."

It was prepared by the Human Radiation Interagency Working Group, in accordance with the provisions of Executive Order No. 11030, as amended.

On behalf of the Director of the Office of Management and Budget, I would appreciate receiving any comments you may have concerning this proposal. If you have any comments or objections, they should be received no later than 12:00 noon Thursday, January 13, 1994. Please be advised that agencies that do not respond by the January 13, 1994 deadline will be recorded as not objecting to the proposal.

Comments or inquiries may be submitted by telephone to Mr. Mac Reed of this office (Phone: 395-3563; Fax: 395-7294).

Thank you.

Attachments - Distribution List
Proposed Executive Order

cc: Alice Rivlin
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Isabelle Sawhill
Nancy-Ann Min
Sally Katzen
Steve Kelman
Barry Toiv
Jim Murr

Carol -

Re: Section II - Mack says the working group has already been established, but he (Gibbons) will be added to the Advisory Committee if he's not already on there.

Roz

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Honorable Bernard W. Nussbaum
Counsel to the President

Honorable John Podesta
Assistant to the President
and Staff Secretary

Honorable Jack Quinn
Chief of Staff to the Vice President

EXECUTIVE ORDER NO. _____

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. I.

(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 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 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 the present. 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 such 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) The Advisory Committee shall:

(1) 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 future compliance with recommended 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.

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 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 DOMESTIC POLICY

JAN 5 1977

THE WHITE HOUSE

FROM THE OFFICE OF: **CAROL H. RASCO**
ASSISTANT TO THE PRESIDENT
FOR DOMESTIC POLICY

TO: _____

DRAFT RESPONSE FOR CHR BY: _____

PLEASE REPLY (COPY TO CHR): _____

PLEASE ADVISE BY: _____

LET'S DISCUSS: _____

FOR YOUR INFORMATION: _____

REPLY USING FORM CODE: _____

FILE: _____

RETURN ORIGINAL TO CHR: _____

SCHEDULE: _____

REMARKS:

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HHS:	Kevin Thurm	690-6133	690-7755
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Sylvia Matthews, 2FL WW

THE WHITE HOUSE
WASHINGTON

January 4, 1994

MEMORANDUM FOR PHIL LADER

FROM: CHRISTINE A. VARNEY 
PHIL CAPLAN 

SUBJECT: Agency Coordination of Radiation Experiments

After our interagency meeting yesterday, we have taken several steps to ensure that the review of Cold War-era government sponsored human radiation experiments proceeds smoothly.

As you know, the Agency Coordinating Group will reconvene on Monday, January 10, 1993. As a first step, we have also established several smaller working groups that will meet and discuss mission statements and establish some preliminary timelines for their work. For the moment there are five working groups:

Public Information and Communications Working Group

Retrieval and Review of Records Working Group

Ethical and Scientific Standards Working Group

(Please note that the "Ethical and Scientific Standards" and "Retrieval and Review of Records" groups will work closely together as their missions are closely related and dependent upon each other.)

Congressional Relations Working Group

Legal Issues Working Group

These working groups will convene within the next 1-2 days; we will attend the initial meetings. The groups will be able to make some preliminary reports on Monday.

In a separate attachment, we have outlined 1) an initial mission for each group (the groups have discretion to shape the missions as they see fit), and 2) the members of each group. The membership of each group is fluid and people/agencies may be added or subtracted as needed. Down the line, additional groups may also be appropriate.

Please let us know if you have any questions or comments.

Thank you.

cc: Distribution List

1/4/93

Working Groups:

Public Information and Communications Working Group

This group will 1) establish government-wide guidelines on the intake and distribution of information from 800# phone calls and other means, and 2) coordinate the dissemination of information to the public and the media. ***

DOE: Mike Gauldin (Chair)

DOD: Dennis Boxx

VA: Dave Brigham

HHS: Avis Lavelle

NASA: Jack Vincent

DOJ: Julie Ann Binder

Other: Rachel Levinson, OSTP

Elgie Holstein, NEC

Mark Gearan (or designee), WH Communications

Barbara Chow, WH Leg Affairs

Retrieval and Review of Records Working Group

This working group will establish the government-wide standards for retrieval and handling of records relating to human radiation experiments sponsored by the federal government during the Cold War era.

DOE: Tara O'Toole

DOD: George Soper

VA: Susan Mather

HHS: D.A. Henderson

NASA: Earl Ferguson

DOJ: Dan Metcalfe, Eva Plaza

Other: Steve Neuwirth, WH Counsel (Chair)

Rachel Levinson, OSTP

John Podesta, WH Staff Secretary

Ethical and Scientific Standards Working Group

This group will examine the procedure for establishing an independent, ethical and scientific review board.

DOE: Tara O'Toole

DOD: Jamie Gorelick

VA: Susan Mather

HHS: D.A. Henderson
NASA: Harry Holloway
DOJ: Paul Freidman

Other: Jack Gibbons, OSTP (Chair)
Marcy Greenwood, OSTP

(Please note that the "Ethical and Scientific Standards" and "Retrieval and Review of Records" groups will work closely together as their missions are closely related and dependent upon each other.)

Congressional Relations Working Group

DOE: William Taylor
DOD: Sandi Stuart
VA: Ed Scott
HHS: Jerry Klepner
NASA: Jeff Lawrence
DOJ: Sheila Anthony

Other: Tracey Thornton, WH Leg Affairs (Co-Chair)
Barbara Chow, WH Leg Affairs (Co-Chair)

Legal Issues Working Group

DOE: Bob Nordhaus
DOD: Jamie Gorelick
VA: Jack Thompson
HHS: Beverly Dennis
NASA: Ed Frankel
DOJ: Webb Hubbell, Nancy McFadden

Other: Joel Klein, WH Counsel, (Chair)
Steve Neuwirth, WH Counsel
Holly Gwin, OSTP

*** These brief "mission statements" are by no means definitive. Each group has professional discretion to refine its mission.

*** Membership in each group may change due to the availability of additional information or other circumstances.

Please send any corrections to Phil Caplan, 456-2572, 456-6704 (fax)...apologies in advance.

HUMAN RADIATION EXPERIMENTS HISTORICAL BACKGROUND

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

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

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

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

There are indications that in some cases:

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

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

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

HISTORICAL BACKGROUND ON FEDERALLY-SPONSORED HUMAN EXPERIMENTS INVOLVING IONIZING RADIATION

Human experiments involving ionizing radiation relative to the federal military and civilian nuclear programs have been numerous and span nearly a half century. While several recently publicized experiments raise serious ethical questions, the federal government has and continues to sponsor human studies where there are widely recognized medical benefits. Nonetheless, it is important to examine those studies where ethical questions are raised and where the distinctions between saving lives and damaging them may have been blurred.

TYPES OF EXPERIMENTS

There are several categories of experiments of concern including:

- * Clinical experiments where there was direct federal sponsorship, little or no informed consent, with no medical benefits in mind. These include: (a) injections of plutonium into 18 men women and children in 1945-46 by the Manhattan Engineering District; (b) deliberate internal exposures of radionuclides to workers at Atomic Energy Commission facilities in the 1950's and 1960's; (c) Injecting uranium in terminally ill brain tumor patients to ascertain kidney damage; (d) feeding radium to elderly people in nursing homes; and (e) the irradiation of the testicles of 131 inmates at the Washington and Oregon state prisons between 1960-71.
- * Clinical experiments where there was direct federal sponsorship, where there may have been a medical and non medical benefit, but where misadministration, and little or no informed consent occurred. These include: (a) The irradiation of 194 cancer patients between 1959-75 in specially built facilities at DOE's Oak Ridge facility; and (b) the irradiation of 87 cancer patients at the University of Cincinnati to doses of radiation expected to be found on a nuclear battlefield.
- * Clinical experiments where the federal government provided radioisotopes but did not directly fund the studies themselves. These include: (a) Giving some 800 pregnant women iron-59 in the 1940's to ascertain nutritional information; (b) Feeding retarded children radioactive iron and calcium in the 1950's.

* Studies where military personnel were deliberately exposed to ascertain radiation risks and other information. These include: (a) having manned aircraft fly through radioactive clouds in the Marshall Islands in 1955; and (b) Giving army personnel and Alaskan Natives radioiodine in the 1950's to study how the thyroid effects the human body in cold conditions.

* Studies where radiation was deliberately released to the environment These include: (a) the release of some 8,000 curies of radioiodine in December of 1949 at the Hanford facility as part of a military experiment; (2) releases of radiolanthanum radioprotactinium and radiotantalum at DOE and DOD sites to develop radiological weapons; and (3) the point source detonation of plutonium warhead components a the Nevada test Site and the Marshall Islands.

CATEGORIES OF GOVERNMENT INVOLVEMENT

Over the years, various federal agencies have sponsored and/or provided funds and materials for human experiments involving ionizing radiation. Types of government involvement include, but are not limited to:

* Studies supported by the Department of Energy and its predecessor agencies;

* Studies supported by the Defense Department (Defense Nuclear Agency, Defense Atomic Support Agency, The Armed Forces Special Weapons Project and the Naval Radiological Defense Research Laboratory);

* Studies supported by the National Aeronautical and Space Administration at Atomic Energy Commission facilities (Interagency Agreement 40-35-64).

* Studies supported by the Defense Department at Atomic Energy Commission facilities.

* Studies supported by the Department of Veteran's Affairs.

Hotline Calls

MEDICAL EXPERIMENTS: SUMMARY OF MAJOR CATEGORIES

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

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

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

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

4. DEFENSE EXPERIMENTS INVOLVING EFFECTS OF NUCLEAR WARFARE ON

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

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

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

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

11/15-14/93

THE ALBUQUERQUE TRIBUNE

The Plutonium Experiment

Americans recoiled when the Nazis conducted brutal experiments on humans. But as the world was learning of those horrors, U.S. scientists injected plutonium into 18 people without their informed consent to see how the element that fuels atomic bombs reacts in the body. The identities of these human guinea pigs were hidden for almost 50 years.

Until now.

BY EILEEN WELSOME

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CONTINUED

A SPECIAL REPRINT
OF A THREE-DAY REPORT PUBLISHED
NOV. 15-17, 1993

The Plutonium Experiment

T

he experiment began in the hot, fretful dawn of the Atomic Age in quiet hospitals far removed from the New Mexico desert where scientists were putting the finishing touches on a "gadget" that would

alter the course of history.

In the wards of the sick and dying, syringes were loaded with an ingredient so secret it was known only as "the product." Then, in quick succession, the needles were plunged into the veins of an auto accident victim in Tennessee, a cancer patient in Chicago, a house painter in San Francisco.

The product was plutonium, the highly radioactive substance that would power the brilliant mushroom cloud over Alamogordo three months later. But what did plutonium — the ingredient in a weapon that President Truman would boast harnessed the power of the universe — do in the human body? How long did it circulate in the blood? Where did it lodge in the bone? How quickly was it excreted?

The experiment was approved by the U.S. Army's Manhattan Project, the wartime machine that developed the atomic bomb. Some contemporary scientists compare the project to the human experiments conducted in Nazi Germany. Others defend it.

In all, scientists injected 18 people with plutonium between 1945 and 1947. Even as the plutonium was being administered, the Army colonel listed in documents as primarily responsible for the experiment was describing plutonium as the "most poisonous chemical known."

The patients were ordinary people with one thing in common: life-threatening illnesses that made survival beyond 10 years "highly improbable." They included a boy of slight build who was just two months shy of his fifth birthday, a malnourished alcoholic, an 85-pound woman suffering from widespread cancer.

With the possible exception of one patient, The Tribune found no written evidence that any of the patients were informed of the nature of the experiment or gave consent. Most of them probably went to their graves not knowing they had been injected with one of the most potent cancer-producing chemicals on Earth.

One patient received "many times the so-called lethal textbook dose" of plutonium. That patient and five others received radiation doses to the bone that a scientist 30 years later calculated as being high enough to cause tumors.

One-third of the patients outlived their doctors' grim predictions, and in the early 1970s, four still were living when a follow-up study began. Scientists took urine, blood and stool samples from three to measure the plutonium remaining in their bodies. Scientists also sought exhumations of deceased patients.

Neither the survivors nor the relatives of the deceased plutonium patients initially were told the real reason for the government's interest. In some cases, the relatives were lied to when permission for exhumation was sought.

"This is one of the great, dark stories of the nuclear era," said Arjun Makhijani, president of the Institute for Energy and Environmental Research in Washington, D.C., a non-profit group that studies nuclear issues. "The public is not aware of the depths to which many universities, doctors and scientists descended."

Los Alamos National Laboratory played a major role in the experiment's first phase. The lab analyzed the excretion samples of the patients injected in a Rochester, N.Y., hospital and later published a classified report that has become the definitive source document on the experiment.

The data, some scientists say, helped protect thousands of workers at nuclear facilities from being overexposed to plutonium and did not harm the patients or contribute to their deaths. Others say the experiment was unethical and bad science because, among other reasons, the sample size was too small.

The experiment itself has received limited attention in the media. But to this day, the patients' identities have been known by numbers only.

Six years ago, The Tribune began a search to find them. We thought they deserved to be remembered as something more than numbers, something more than laboratory animals who contributed to science a wealth of data on how plutonium is deposited in the human body — its heart, skeleton, even its

ashes.

Working with scant data from scientific reports and a few clues from government documents, we determined the identities of five of the 18 patients.

In the next few days, The Tribune will tell you how these ordinary Americans unwittingly were swept up by the hot winds of the Atomic Age. We also will tell you about how their families weren't told the truth for almost 50 years.

The first patient we found was a railroad porter named Elmer Allen, identified in records as "Cal-3." Elmer was injected with plutonium in the left calf, and three days later, his leg was amputated for what was thought to be a pre-existing bone cancer.

The second patient was a California house painter named Albert Stevens, known as "Cal-1." Albert received a massive dose of plutonium four days before undergoing surgery for stomach cancer. But he didn't have stomach cancer. Specimens of his spleen, rib and body tissues later show up in a report titled "A Comparison of the Metabolism of Plutonium in Man and the Rat."

The third patient was "HP-6," a man named John Mousso who suffered from Addison's disease and struggled to make ends meet in a small town outside Rochester, N.Y.

The fourth was Eda Schultz Charlton, identified as "HP-3" in official records. Eda's condition was monitored for almost 35 years by the University of Rochester's Strong Memorial Hospital. She underwent dozens of diagnostic tests ranging from X-rays to biopsies and barium enemas, and she developed an obsessive fear of cancer.

And finally, there was "HP-9," a man named Fred C. Sours, a political official in a Rochester suburb whose body was exhumed 31 years after his death and sent to a national laboratory near Chicago. His remains were kept there for more than three years.

Who are the others? The malnourished alcoholic? The auto accident victim in Tennessee?

We don't know. And the government won't say.

We've filed two legal requests under the Freedom of Information Act with the Department of Energy, the sprawling agency that eventually took over many functions of the wartime Manhattan Project.

The first was filed in 1989. The second, filed more than a year ago, was a seven-page request based on the DOE's own documents — including a 1974 report detailing an internal inquiry into the experiment conducted by its predecessor agency, the Atomic Energy Commission.

We've received some documents from the DOE, but it is still withholding many of the most important records, such as medical files and other correspondence that would identify the other patients. The DOE said it doesn't even have a copy of the findings of its own investigation — an investigation that involved teams of officials who reviewed numerous records, conducted interviews with scientists in 14 cities and returned to Washington with 250 documents.

The plutonium experiment began in the hubris of a new age. Among its advocates and architects were some of the brilliant young scientists from Los Alamos who, from behind protective lenses, watched on the morning of July 16, 1945, when a man-made explosion outshone the New Mexico sun.

A half century has elapsed. The Cold War is over, and the bombs are being dismantled. Still, the DOE refuses to relinquish the identities of the victims of one of its darkest secrets.

"This is one of the great, dark stories of the nuclear era. The public is not aware of the depths to which many universities, doctors and scientists descended."

Arjun Makhijani

Institute for Energy and Environmental Research

..... Washington, D.C.

Secret Nuclear Research on People Comes to Light

By KEITH SCHNEIDER A1

For three decades after World War II, top medical scientists in the nation's nuclear weapons industry undertook an extensive program of experiments in which civilians were exposed to radiation in concentrations far above what is considered safe today.

The experiments, at Government laboratories and prominent medical research institutions, involved injecting patients with dangerous radioactive substances like plutonium or exposing them to powerful beams of radiation.

Now the Energy Department is doing an about-face, acknowledging that for the last six years it has ignored evidence of abuses and a Congressional request to uncover the full extent of the experimentation and compensate subjects.

Energy Secretary Hazel R. O'Leary has promised a full investigation, much of it focusing on whether civilians were fully informed of the risks and consented to take part in the experiments. Mrs. O'Leary said it was clear in several cases she had personally reviewed that subjects had not been fully informed. But she and several of her aides also said it was just as clear that other experiments had been conducted in accord with medical and ethical standards of the time.

During the years when much of the research was undertaken, considerably less was known about the hazards of radiation. It was common in the 1950's, for instance, for shoe stores to use X-ray machines to fit customers.

The Government's nuclear scientists, conducting their work as though atomic war were imminent, placed a top priority on research to determine the affect of radiation on soldiers and civilians. And such research clearly advanced nuclear medicine to fight disease and save lives.

Although there have been glimpses of these experiments in the past, most recently in a 1986 Congressional investigation, the Government has long fought efforts by journalists, private investigators and the families of patients to make the full story known.

Now Mrs. O'Leary has vowed to shine a bright light into what her aides say is a dark corner of America's cold war legacy. Prompted by a series of articles last month in The Albuquerque Tribune about one such experiment, Mrs. O'Leary has ordered the most thorough investigation ever of her De-

partment's biomedical experiments.

The investigation will be part of a larger effort by the Energy Department to declassify millions of pages of secret documents on past activities of the nuclear weapons industry. As part of that effort, the Department has hired six archivists to comb classified records at the National Archives. Mrs. O'Leary has also increased the number of employees in her own department who review and declassify documents from three to six, and she has announced plans to train more people to do such work.

In an interview, Mrs. O'Leary said the investigation was motivated by a "an obligation to put the public's mind at rest and expose things that need exposing."

Her initiative, if successful, would help improve the department's image as officials work to resolve huge conflicts over dismantling the nation's nuclear arsenal and cleaning up its weapons plants.

Prisoners Subjected to X-rays

Two of the experiments under review by the department ended in the early 1970's and involved exposing the testicles of more than 100 healthy state prison inmates in Oregon and Washington to very high levels of radiation from X-ray machines. Documents show that the prisoners were paid small sums to participate and were required to sign consent forms in order to take part.

But Robert Alvarez, a special assistant in the Office of Policy Planning and Program Evaluation — and one of the many influential critics of the Energy Department who now work for Mrs. O'Leary — said the consent forms had not fully explained the risks of the experiment, especially the risk of developing testicular cancer. He added that no follow-up studies were conducted on the men who participated.

"These prisoner studies were clearly unethical," Mr. Alvarez said.

But the study was defended by Dr. C. Alvin Paulsen, a retired professor of medicine at the University of Washington School of Medicine who helped conduct the experiments in that state. He said he had kept audio recordings of interviews with inmates that showed they had been well informed about the intent of the research and the possible risks, including cancer.

Needed a Restricted Population

"The question we asked was: What was the minimal effect of radiation that would interfere with the development of sperm?" said Dr. Paulsen, who is now 69 and lives in Seattle. "And given that there might be some decrease in sperm production, would there be full recovery?"

"At that time, the start of the nuclear era, we felt it wouldn't be ethical to expose someone to radiation if we couldn't follow them up. Prisoners provided an opportunity for us to follow these gentlemen for four and five years. We demonstrated that there was recovery of sperm, and we couldn't have done that in the open, mobile population."

He said that even today "there is no evidence that irradiation induces testicular cancer."

But at least one research manager found some of the human experiments so alarming that he warned his colleagues. In a memorandum on Dec. 12, 1963, C. E. Newton Jr., a research manager at the Hanford nuclear weapons plant, warned, "The experiments do not appear to have been in compliance with the criminal codes of the state of Washington, and there is some question as to whether or not the experiments were conducted in compliance with Federal laws."

When asked about this memorandum, a contractor who retains the relevant records said he did not have records of the experiments to which the memo referred.

Other experiments, at the Oak Ridge National Laboratory in Tennessee, exposed patients with leukemia and other cancers to exceptionally high levels of radiation from cesium and cobalt isotopes. Nearly 200 patients, including a 6-year-old boy, were made subjects of the experiments before the Atomic Energy Commission called a halt to them in 1974, saying they had done little to benefit the patients.

Openness Is Applauded

There is no central repository for records on these or other medical research programs, said Dr. Tara O'Toole, the Assistant Secretary of Energy for Environment, Health and Safety, who will be heading the investigation. The records are stored at atomic laboratories, private medical schools and research centers across the country. Among the universities that will be searching for documents are the University of Chicago, the Massachusetts Institute of Technology, the University of Rochester, the University of California system, the University of Washington and Vanderbilt University.

Mrs. O'Leary's interest in such a potentially explosive subject has drawn applause from some of the Department's foremost critics. Tom Carpenter, a Seattle lawyer with the Government Accountability Project, a legal group that represents Energy Department whistle-blowers, said: "She sees this as part of the process of disclosure that is necessary to rebuild public trust in the agency."

CONTINUED

"She's surrounded herself with advisers who were members of the public interest community, and they have told her this kind of stuff needs to get out."

Even so, the Energy Department said it faced legal barriers to disclosing information in its files, especially in complying with laws protecting the privacy of patients or their families.

Just how slow and cumbersome disclosure can become was graphically illustrated over the last six months as the Energy Department sought files from the Argonne National Laboratory outside Chicago on human experiments involving plutonium.

One experiment, conducted from 1945 to 1947, involved injecting 18 patients with plutonium, a dangerous radioactive material developed for use in atomic bombs. The Albuquerque Tribune tracked the stories of five patients, including Eda Schultz Charlton, who was injected without her knowledge in a Rochester hospital in 1945. Apparently not seriously ill at the time, she lived until 1983, when she died at age 85.

Eileen Welsome, a reporter at The Tribune, filed a request under the Freedom of Information Act that the Energy Department make public all its documents relating to the experiment, including the names of people who were injected. In May, Energy Department officials asked Argonne to send the files to headquarters in Washington so they could be made public.

Privacy Issue Looms

But in the last six months, Argonne has sent only a few documents to the Department. Harry Conner, an Argonne spokesman, said lawyers for the University of Chicago, which manages the laboratory, were concerned that disclosing the identities of the people who were injected, all of whom have died, could violate the privacy of family members.

Last week, the University of Chicago agreed to release hundreds of pages of documents but only after officials there were persuaded that the department was sensitive to the privacy issues, Mr. Conner said.

Marc Johnston, an Energy Department lawyer in Washington, said he was expecting the files to arrive over the next few weeks. Before they are made public, the department will review them and remove all names and any other information that could identify the participants, a process that could take weeks more, Mr. Johnston said.

Mrs. O'Leary and Dr. O'Toole said such steps were necessary. The investigation into human experimentation is likely to uncover information that surviving participants, members of their families, and the public will find quite disturbing. "Does the public's right to know include releasing names," Dr. O'Toole asked. "It's not clear to me

that is part of the ethical obligation of the Government."

Administrators at some of the research hospitals and universities involved have said they are worried that unless the Energy Department is careful in how it releases the information, the reputations of their institutions could be harmed. Mrs. O'Leary has appointed a medical ethicist from Johns Hopkins University to help guide the department.

Robert Loeb, the director of public information at Strong Memorial Hospital at the University of Rochester, where some of the studies were conducted, said: "In the 1940's, what was typical in research involving human subjects was for physicians to tell the patients that they would be involved in a study and not always give full details. That is not the standard today. Many of these studies would be impossible to conduct today."

Energy Official Seeks to Assist Victims of Tests

By KEITH SCHNEIDER A1

Energy Secretary Hazel R. O'Leary yesterday called on the Government to compensate Americans who were exposed to radiation from human medical experimentation that the United States conducted for decades after World War II.

Mrs. O'Leary said her appeal on behalf of people who were used as subjects in the medical testing was prompted by the Government's long resistance to providing compensation to thousands of people in the Southwest known as "downwinders" — those who asserted that they or members of their families were harmed by radioactive fallout from open-air testing of atomic bombs in the 1950's and early 1960's.

"I looked at the history of the Energy Department with the downwinders where the department for some years really did battle with these people to hold off their ability to make claims," Mrs. O'Leary said in an interview. "It doesn't occur to me that is the posture I want to be in."

'Make These People Whole'

Referring to the thousand or more subjects of radiation experiments, the Secretary added: "It seems to me that my position ought to be, what does it take to make these people whole? If they can prove there was no consent for the experimentation and harm resulted from the experiments, they or members of their families are going to want something more than a formal apology."

Mrs. O'Leary's first statement on compensation came in an interview on CNN yesterday morning after she was asked if she would consider compensation. She replied: "Many have suggested, and I tend to agree personally, that those people who were wronged need to be compensated. And we ought to go forward and explain to the Congress what has happened, and let the Congress of the United States and the American public determine what would be appropriate compensation."

The Secretary said she was acting largely on her own in calling for compensation for anyone who was harmed during the decades of human medical experimentation conducted by the Atomic Energy Commission. The nu-

clear weapons industry later came under the ownership and management of the Department of Energy. She said she notified the White House on Monday that she would propose a measure to provide compensation.

If approved by the Clinton Administration and Congress, it would be the fifth time since the early 1950's that the Government has compensated people put in jeopardy by radiation from the American nuclear weapons industry. The first four, however, were initiated by foreign governments or the American victims.

Two Departments in Conflict

Secretary O'Leary's comments were the first in which a head of the nuclear weapons industry initiated the Government's effort to apologize and compensate people who may have been harmed by its nuclear materials.

Her appeal for compensation, though, puts the Department of Energy in direct conflict with the Department of Justice. In every other instance in which Congress considered legislation to compensate people exposed to harmful levels of radiation, including the case of the downwinders in the Southwest, the tort branch of the Justice Department's civil division has opposed the effort.

The department has also defended the Government in lawsuits, dating to the early 1950's, in which ranchers, soldiers, uranium miners and the industry's own workers asserted that they had been harmed by radiation from the nuclear weapons industry.

Department lawyers are now defending the Government in a case in Nevada in which the families of more than 200 weapons industry workers, most of whom have died, contend that their relatives were injured or killed by radiation from atomic bomb testing at the Nevada Test Site northwest of Las Vegas.

In that case, which began in Las Vegas on Dec. 13, several of the Government's chief medical witnesses are doctors who conducted the human medical experiments that have come under Mrs. O'Leary's scrutiny.

Three Witnesses Named

One witness is Dr. Constantine Malletskos, a former researcher at the Massachusetts Institute of Technology who performed radiation experiments on retarded teen-age boys at the Fernald State School in Waltham, Mass.

Another is Dr. Clarence Lushbaugh, who directed several human medical experiments, including several in which children were exposed to radiation, at a research institution financed by the Atomic Energy Commission in Oak Ridge, Tenn. Some of Dr. Lushbaugh's studies were halted in the early 1970's after officials of the commission said they had done little to provide medical benefits for the patients involved.

A third witness is Dr. Eugene Saenger, a retired radiologist at the University of Cincinnati College of Medicine, who in the 1960's and 70's exposed indigent cancer patients to levels of radiation that were known to make people acutely ill. According to records of the studies, which were performed for the Defense Department, 9 of the first 40 people exposed to the radiation died within 38 days.

All three doctors have maintained in interviews with Congressional researchers and journalists over the years that their work had been ethical and proper.

Potential for Conflict

Mrs. O'Leary said she had not talked with Janet Reno, the Attorney General, but was aware of the potential for conflict with the Justice Department. "I cannot imagine there would be any other posture that I could take on this," she said. "I am also clear on the fact that the Justice Department may come from another position and point of view."

The Justice Department today said it would not comment on Mrs. O'Leary's proposal.

Mrs. O'Leary's appeal for compensation came three weeks after she directed the Department of Energy to investigate the experiments, determine their ethical and medical propriety, and locate test subjects or members of their families.

Stewart L. Udall, who was Secretary of the Interior in the Kennedy and Johnson Administrations, said yesterday that Mrs. O'Leary's appeal for compensation was breathtaking.

"It's a very bold step," said Mr. Udall, who as a lawyer helped prepare the Nevada Test Site case and two others on behalf of thousands of Americans who believed they had been victimized by the nuclear weapons industry. "Hazel O'Leary is talking to the country. She is saying there were grievous things done to people and, in effect, she is apologizing to the country. But it's not clear anybody else in the Government is listening. The next thing the Clinton Administration ought to do is pull everybody together so they can talk to each other."

MEMORANDUM TO U. S. DEPARTMENT OF ENERGY STAFF

FROM: MICHAEL GAULDIN, DIRECTOR *MG*
OFFICE OF PUBLIC AND CONSUMER AFFAIRS

SUBJECT: REFERRAL NUMBERS FOR PUBLIC CALLS ON RADIATION
EXPERIMENTS AND RELATED SUBJECTS

Many individuals have been calling the U.S. Department of Energy about the radiation experiments conducted by the Atomic Energy Commission and related subjects. The following information should help you direct the callers to the appropriate hotline or office:

If you believe you were the subject of radiation experiments conducted by the Atomic Energy Commission, please call the Human Experimentation Hotline:

1-800-493-2998 (8:30 a.m. - 4:30 p.m. EST M-F)

If you believe that you were a participant in atmospheric nuclear testing or the bombing of Nagasaki or Hiroshima, please call the National Test Personnel Review Hotline:

1-800-462-3683 (8:00 a.m. - 5:00 p.m. EST M-F)

If you have a comment or complaint about the U.S. Department of Energy, please call the Inspector General's Waste and Fraud Abuse Hotline:

1-202-586-4073 (8:30 a.m. - 4:30 p.m. EST M-F)

If you have general questions about the U.S. Department of Energy, please call the Office of Public Information:

1-202-586-5575 (9:30 a.m. - 5:00 p.m. EST M-F)

Post-It™ brand fax transmittal memo 7671		# of pages	1
To	Michael Goodwin		
From	Jesse Brown		
Co.			
Dept.			
Fax #	586-9987		

Office of Public Affairs
News Service

Washington, D.C. 20420
(202) 535-8300



News Release

FOR IMMEDIATE RELEASE

BROWN PLEDGES QUICK ACTION ON REVIEW OF NUCLEAR MEDICINE RESEARCH RECORDS

Washington, Dec. 31 -- Secretary of Veterans Affairs Jesse Brown announced that VA will immediately look into nuclear medicine research conducted at VA facilities in the '40s and '50s.

Said Brown, "We are collecting the records of clinical research conducted at VA hospitals which utilized nuclear medicine. In order to be certain that the research was properly conducted, I have ordered an immediate review of the circumstances surrounding this research at VA facilities."

Brown stated that VA will cooperate fully with all interested agencies and members of Congress. "We plan to leave no stone unturned in our review of this research," said Brown. "If we find that veterans were subjected to improper research, that would be morally and ethically unacceptable to me. We are going to look at all the facts and, if we determine that VA was engaged in any inappropriate research, we will disclose that finding to the American people, notify veterans involved and take appropriate action," he added.

VA is working closely with the Department of Energy and the Department of Defense. This cooperative effort will allow us to expedite our review of records that may contain information on nuclear medicine research.

In addition, VA is asking the veterans service organizations to help the department raise awareness in the veteran community. "Veterans who are concerned should call VA's national toll-free number -- 1-800-827-1000 -- and their cases will be promptly investigated by VA personnel," Brown added.

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EDWARD J. MARKEY, MASSACHUSETTS, CHAIRMAN

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WASHINGTON, DC 20515

October 24, 1986

The Honorable John S. Herrington
Secretary
Department of Energy
1000 Independence Avenue, S.W.
Washington, D.C. 20585

Dear Secretary Herrington:

As you know, the Subcommittee on Energy Conservation and Power has been conducting an investigation into radiation experimentation for human subjects. I am forwarding to you the results of that investigation, a Subcommittee staff report titled, "American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens."

This report reviewed Department of Energy documents, which revealed the frequent and systematic use of human subjects as guinea pigs for radiation experiments sponsored by the Department's predecessor agencies. Some of these experiments were conducted in the 1940s and 1950s, and others were performed during the supposedly more enlightened 1960s and 1970s. The report describes in detail 31 experiments during which about 695 persons were exposed.

In many of these experiments, individuals were exposed to radiation which provided little or no medical benefit to the subjects. The purpose of several of these experiments was actually to cause injury to the participants. Many others sought simply to measure the effects of radiation on humans. American citizens thus became nuclear calibration devices for experimenters run amok.

In a number of experiments, subjects received doses that exceeded presently recognized limits for occupational radiation exposure. Doses were as much as 98 times the body burden recognized at the time the experiments were conducted.

Too many of these experiments used human subjects that were captive audiences or populations that some experimenters frighteningly perhaps might have considered "expendable:" the elderly, prisoners, hospital patients suffering from terminal diseases or who might not have retained their full faculties for informed consent.

5-11-86

The Honorable John S. Herrington
October 24, 1986
Page Two

Some of the more repugnant or bizarre of these experiments include the following:

--From 1945 to 1947, as part of the Manhattan Project, 18 patients believed to have limited life spans were injected with plutonium.

--From 1961 to 1965, at the Massachusetts Institute of Technology, 20 elderly subjects were injected or fed radium or thorium.

--During 1946 and 1947, at the University of Rochester, six patients with good kidney function were injected with uranium salts to determine the concentration which would produce renal injury.

--From 1953 to 1957, at Massachusetts General Hospital, Boston, approximately 12 terminal brain tumor patients were injected with uranium to determine the dose at which kidney damage began to occur.

--From 1963 to 1971, 67 inmates at Oregon State Prison and 64 inmates at Washington State prison received x-rays to their testes to examine the effects of radiation on human fertility and testicular function.

--From 1963 to 1965, at the Atomic Energy Commission's National Reactor Testing Station in Idaho, radioactive iodine was purposely released on seven separate occasions. In one experiment, seven human subjects drank milk from cows which had grazed on iodine-contaminated land.

--From 1961 to 1963, at the University of Chicago and Argonne National Laboratory, 102 human subjects were fed real fallout from the Nevada Test Site; simulated fallout particles containing radioactive material; or solutions of radioactive cesium and strontium.

--During the late 1950s, at Columbia University and Montefiore Hospital, the Bronx, 12 terminal cancer patients were injected with radioactive calcium and strontium.

These experiments, and others described in the Subcommittee staff report, shock the conscience and represent a black mark on the history of nuclear medical research. They raise one major horrifying question: did the intense desire to know the consequences of radioactive exposure after the dawn of the atomic age lead American scientists to mimic the kind of demented human experiments conducted by the Nazis? Did the Department or its

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October 24, 1986
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predecessor agencies fund or sponsor programs which crossed the line that no scientific research can ever be permitted to traverse?

While it is clear that present public and scientific officials are generally not responsible for these experiments, these circumstances nonetheless represent a historical, institutional failure. To compound the evil, in too many experiments, no long term follow up was conducted of subjects. While these experiments cannot be undone, though they must never be repeated, there are potential remedial steps that can be taken to help the victims who served as human nuclear guinea pigs.

I therefore urge the Department of Energy to make every practicable effort to identify the persons who served as experimental subjects, to examine the long term histories of subjects for an increased incidence of radiation-associated diseases, and to compensate these unfortunate victims for suspected damages. A Defense Department program provides a model for such follow up. The Nuclear Test Personnel Review, administered by the Defense Nuclear Agency, is a registry for military personnel exposed to fallout from atmospheric nuclear tests. The primary objectives of the Review are to identify the approximately 200,000 Defense Department personnel involved in such tests, to determine their exposures, to identify incidences of death or illness, and to assist veterans in claims for compensation.

If such an effort can be carried out for military personnel acting in the line of duty, surely a similar effort should be possible for the far smaller number of peaceful atomic soldiers used as unwitting human subjects in radiation experiments. If you feel that new legislation would be necessary, the Subcommittee will be pleased to work with the Department to develop it.

If you have any questions on the material in this letter or the Subcommittee staff report, please contact John Abbotts or Larry Sidman at 202-226-2424. I look forward to receiving by November 15, 1986 a description of the Department's plans for long term follow up of these experimentally irradiated subjects, and your recommendation for what new legislation, if any, might be needed for compensation.

Sincerely,


Edward J. Markey
Chairman



THE SECRETARY OF ENERGY
WASHINGTON, D.C.

February 10, 1987

Honorable Edward J. Markey
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Markey:

This is a further response to your October 24, 1986, letter regarding experiments in which human subjects were subjected to ionizing radiation during the period 1945-1971. An interim response was sent to you by Dr. Charles DeLisi.

My staff has prepared answers to the questions raised in your letter and in your Subcommittee's staff report. Their findings are presented in the enclosed addendum. The conclusion, based on the radiation dosimetry information and for other reasons which follow, is that there is no scientific reason to expect that any of the subjects who are not already being monitored will incur any harmful effects. Therefore, there is neither any reason for attempting any further follow-up studies on these subjects nor to propose new legislation to compensate them.

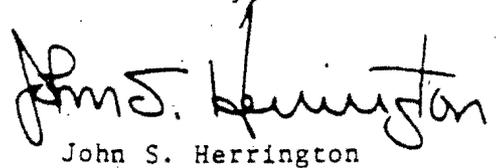
The objections that are emphasized in your letter and in the Subcommittee's staff report appear to have been based on misunderstandings of the basis for occupational standards and of the principles of human experimentation. As is discussed in the National Council on Radiation Protection and Measurements Report No. 39, Basic Radiation Protection Criteria, the basic criteria for the use of radiation in research on human subjects are that radiation is the preferred agent for performing the study, that methods providing maximum information with minimum dose should be utilized, and that the information should be obtained with the smallest practicable levels of radiation. The significant features for all human experimentation are that the propriety and usefulness of the work is assured, that adequate safeguards are provided, and that enlightened consent of the subject is assured.

The requirements for informed consent have undergone considerable development in recent years. At the time of the experiments in question the modern requirements for institutional review boards and signed informed consent had not been established. We have no evidence that the experiments were not conducted in compliance with the ethics as well as the rules for human experimentation that obtained at the time. The current

policies of the Department of Energy are in substantial conformance with the provisions of the Model Federal Policy for the Protection of Human Subjects, which is in the process of being adopted.

Additional comments on the specific experiments are made in the enclosed addendum to this letter.

Yours truly,

A handwritten signature in cursive script, appearing to read "John S. Herrington". The signature is written in dark ink and is positioned above the printed name.

John S. Herrington

Enclosure

ADDENDUM

Comments on October 24, 1986, letter from Congressman Markey and staff report of Subcommittee on Energy Conservation and Power, "American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U. S. Citizens."

In compliance with the request by Congressman Markey that the Department of Energy attempt to identify the persons who served as experimental subjects for certain radiation experiments that were conducted during the period 1945-1971, the cognizant field offices and some individual investigators were asked to evaluate the feasibility and necessity of such an effort. The results of this investigation follow.

General comments. The Subcommittee's staff report is substantially an excellent summary of the radiation experiments that involved human subjects. It is flawed, however, by a pervasive misunderstanding of the applicability of occupational exposure standards to experimental studies that involve only one or a few radiation exposures.

The objections emphasized in the letter and in the Subcommittee's staff report are directed to those experiments in which the radiation dose or the body burden exceeded occupational standards, those that offered little or no direct benefit to the subject, and those for which there is no record of informed consent having been obtained. To a large extent, these objections are based upon misunderstandings of the basis for occupational standards and of the principles of human experimentation.

It should be realized that the standards that have been developed for occupational radiation exposures assume that a large number of people will be exposed, and that the radiation exposures are sustained throughout a working lifetime of several decades. Therefore, because some radiation effects are cumulative, the annual exposure limits are set low enough to insure that the total radiation dose accumulated over many years is safe. Similarly, the standards for body burdens of internally distributed radioactive materials assume chronic exposures that will maintain these body burdens throughout the working lifetime of the individual. These standards are not intended to be applied to research subjects who receive one or a few exposures, or in which the internally distributed radioactivity is present for a relatively short time. The use of radiation in research on human subjects is discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 39, Basic Radiation Protection Criteria, page 104. As is discussed there, the basic criteria are that radiation is the preferred agent for performing the study, that methods providing maximum information with minimum dose should be utilized, and that the information should be obtained with the smallest practicable levels of radiation.

Although desirable, there is no requirement that human experiments provide a direct benefit to the subject. This principle is generally recognized for all types of medical research. The use of placebos in therapeutic trials is a common example. In particular, for radiation studies, again citing NCRP report No. 39, "In many instances, research

involving radiation can be conducted on individuals where the information gained may be directly beneficial to the individual exposed. In other studies, radiation may be employed for the study of populations in which, for example, etiological and developmental factors are being evaluated. The benefits to the individual are primarily indirect, often remote, and, in some instances, nonexistent." The significant features for all human experimentation are that the propriety and usefulness of the work is assured, that adequate safeguards are provided, and that enlightened consent of the subject is assured.

The requirements for informed consent have undergone considerable development in recent years. At the time of the experiments in question, the modern requirements for institutional review boards and signed informed consent had not been established. The first studies of concern were conducted during the Manhattan Project. It was necessary to establish rather quickly and under secret conditions the precautions that would be required to insure the health and safety of people working with new and unfamiliar substances such as plutonium compounds. The physicians and other scientists who were called upon to achieve these goals were highly qualified and well motivated individuals. We have no evidence that the experiments were not conducted in compliance with the ethics as well as the rules for human experimentation that obtained at the time. The Atomic Energy Commission and the Department of Energy have been among the leading agencies in developing better standards for human experimentation. In particular, as a member of the Interagency Human Subjects Coordinating Committee, the DOE Office of Health and Environmental Research has been working since 1982 on the development of a Model Federal Policy for the Protection of Human Subjects. A notice of the Model Policy was published in the Federal Register (Tuesday, June 3, 1986, Part V, Office of Science and Technology Policy, Volume 51, No. 106, page 20204). When adopted by the various agencies, the Model Policy will apply not only to "in-house" research, but also to research that is supported by grants or contracts with non-federal research institutions. In the meantime, the Department of Energy's policies are already in substantial conformance with the provisions of the model policy.

In the comments that follow on specific studies, the category and factsheet numbers correspond to those of the experiments listed on pages 21-22 of the Subcommittee's staff report. The numbers in parentheses after the title are the number of subjects in each of the studies.

Category 1.001, No. 1. Plutonium Excretion Studies. (18)

One subject, who was 36 years old in 1947 and who had a bone sarcoma, is still living and has been contacted recently (November 1986). He has arthritis and high blood pressure, but no ailments that can be ascribed to effects from plutonium. There is no evidence to suggest that the death of any of the other subjects of these studies was related to plutonium exposure or that plutonium influenced the course of their disease.

1.002, No. 118. Relative Uptake of Radium and Thorium. (20)

The files on these subjects are located in Scottsdale, Arizona, in care of the principal investigator. Informed consent statements are available for all of the subjects. The addresses of the subjects are known as of 1964, at which time none had health problems related to radiation exposure. Presumably they could now be located, but their present ages if living would be 85-105 years. The values cited in the committee report for maximum permissible body burdens are for chronic retention in the body and are not applicable to acute exposures. The materials administered in the experiments were retained in the body for relatively short times. On the basis of the low radiation doses involved there is no reason to expect any long-term effects.

1.003, No. 12. Polonium Metabolism. (5)

A spokesman for the University of Rochester stated that the last of the polonium patients died 3 years ago at the age of 80. There is no evidence that the polonium had affected the health of any of these patients.

1.003, No. 119. Excretion of Hexavalent Uranium. (6)

As is stated in the report UR-37, in part the experiments were designed to seek the threshold for minimal renal damage using very sensitive indicators of renal injury. It should be noted that the injury in question was a chemical effect of uranium, not an effect due to radiation. In order to make the possibility of late effects of radiation highly improbable, the doses above 50 micrograms per kilogram of body weight were diluted with non-enriched uranyl acetate. Of the six patients studied, it is stated that patient number 5, aged 51 years in 1947, had a trace of urinary protein which was suspected of being a chance observation. He insisted on being discharged and was not followed further. Patient number 6, then 61 years of age, showed transient traces of urinary protein on days 5 and 6, but none thereafter through day 12. These are minimal effects that would not have significant permanent effects. In none of the other subjects was there any evidence of renal injury. The radiation doses would not be expected to produce long-term effects.

2.001, No. 1. and 2.002, No. 189. Testicular Irradiation. (131)

The principal investigator in the Washington State studies has been contacted. He stated that the main impediment to follow-up studies in these subjects is that the prisoners do not wish to be identified. Medical follow-up information is available on the subjects who remain incarcerated, and no radiation-related illness has been detected in this population. Medical services are available to prisoners who have been released, but "only a handful" have availed themselves of this opportunity in the past 14 years. There is concern that efforts to trace these subjects will violate the privacy of individuals who do not want to be identified, especially since a condition of their participation was that they were promised confidentiality. Although it is true that some of the radiation doses to the testes were substantial, the studies that were conducted showed that eventually there was recovery of testicular function even at the highest doses that were used. Although concern about the possibility of testicular cancer arising

as a result of irradiation has been expressed, all available evidence such as the studies of the Japanese atomic bombing survivors, studies of patients irradiated therapeutically, and animal studies indicate that even for high radiation doses there is not a significant increase in the rate of testicular cancer. None has been seen in the prisoner population that has been available for study.

3.001, No. 49. Blood Changes in Humans Following Total Body Irradiation. (13)

The report cited is concerned only with the effects of total body irradiation on the blood, but except for the three normal volunteers who were laboratory personnel, these observations were incidental to the use of total body irradiation as a therapeutic effort in patients for whom no other therapy was expected to be helpful. The 21 roentgens received by the three normal volunteers is at the borderline of the dose level that will cause transient blood changes, but none were noted. Long term effects are unlikely. For comparison, in studies of the survivors of the Japanese atomic bombings, significant increases in cancer, including leukemia, occurred only at doses above 100 roentgens. In a related study of whole body irradiation for the treatment of leukemia, (3.001, No. 43) conducted at the Oak Ridge Institute for Nuclear Studies (now Oak Ridge Associated Universities), the Department of Energy currently supports a project entitled "Former Patient Care" in which 67 former patients who had been treated at Oak Ridge with whole body irradiation, cobalt-60, radioiodine, or gallium-67 are being provided medical care. This provides a mechanism for obtaining follow-up data without implying that any of their current illnesses are radiation-related.

9.001, No. 166. Hexavalent Uranium. (12)

All subjects were terminally ill with brain tumors. None is still living. There was no evidence that the uranium had affected the course of their diseases.

10.001, No. 173. Controlled Environmental Radioiodine Tests. (17)

Because of the low radiation doses incurred in these studies (maximum 630 millirad) no follow-up was considered to be necessary.

11.001, No. 51. Reactions of Human Skin to Single Doses of Beta Rays. (20)

No long term effects are to be expected from these highly localized irradiations. Although the range of P-32 beta particles in water is 8 mm, 90 percent of the energy is absorbed in the first 1 mm, so the volume irradiated is confined to the skin, which has a relatively rapid recovery rate from acute doses of radiation.

11.001, No. 53. Studies of Thorium X Applied to Human Skin. (3)

These studies were conducted at New York University Hospital in New York City. The three volunteer subjects were followed for three months, at which time they had recovered from the acute effects, erythema, and increased pigmentation. There is no reason to expect long term effects.

11.001, No. 121. Effect of Single Dose X-ray to the Nail-Fold Area of Human Subjects. (15)

The highly localized radiation and small area involved reduce the hazard relative to the occupational standard, which assumes irradiation of the entire hand. The changes seen were transitory, and no long term effects would be expected.

11.001, Numbers 123 and 127, and 12.001, No. 128. Tritium Studies. (18)

Because of the short biological half life of tritium (9 to 14 days) and the small quantities administered, the radiation doses are low (about 200 millirem) and the probability for long term effects is negligibly low.

11.001, No. 133. Exposure of Aircrews in Mushroom Clouds. (NA)

As is indicated in the Subcommittee's staff report the follow-up studies on the Air Force crews involved are being monitored by the Defense Nuclear Agency.

11.001, No. 186B. Lanthanum-140. (54)

The administration of this substance was considered to be part of diagnostic studies for patients with anemia and was not considered to be an experiment. The one normal subject was a scientist who is known to be alive and well. The names of the patients are known and the Former Patient Care Program mentioned above (3.001) is available to them.

12.001, No. 15. Strontium and Calcium Injected in Terminal Cancer Patients. (12)

As indicated in the Subcommittee's staff report, all of the terminal cancer patients involved in the calcium-strontium studies died within less than three years. There was no evidence that the experiments had affected the course of their diseases.

12.001, No. 109. Distribution and Excretion of Technetium. (8)

The whole-body doses associated with these studies is estimated to be about 0.145 rem, in comparison to the annual occupational limit of 5 rem. The probability that these radiation doses could result in long term effects is negligibly low.

12.001, No. 128. Human excretion of Tritium. (6)

The subjects of these studies were personnel who were involved in performing the studies. One died subsequently in an aircraft accident, but the others are known to be in good health. Because of the short biological half life of tritium the radiation dose is negligibly small, and there is no reason to expect any long term effects from these studies.

FOR IMMEDIATE RELEASE
December 29, 1993

Contact: Steve Buttacavoli
(202) 225-2836
Tom Philbin
(617) 396-2900

MARKEY ANNOUNCES ENERGY DEPARTMENT COOPERATION WITH PROBE OF FERNALD RADIATION EXPERIMENTS, CALLS FOR CONGRESSIONAL HEARINGS

Washington -- Congressman Edward J. Markey (D-MA) today announced that the Department of Energy, at his request, will assign staff to investigate the recently revealed radiation experiments on patients at the Fernald State School in Waltham, MA. Markey also stated that he would be recommending that the House Subcommittee on Energy and Power, of which he is a member, hold oversight hearings on the subject of radiation experimentation on humans.

In 1986, Markey released a report on the issue of radiation experimentation on American civilians that detailed a series of 31 experiments on 695 individuals between the mid 1940s and the 1970s. In this report, Markey called on the Department of Energy to further investigate the scope of these experiments, as well as to identify the individuals involved, provide medical follow-up to determine the long-term effects of the experiments, and establish a compensation program for the victims.

Recent reports have indicated that approximately 50 mentally retarded residents of the Fernald State School were fed radioactive materials during the 1940s and 1950s in medical studies on human digestion. Markey stated, "I am deeply concerned by the recent reports of what happened at Fernald in the 40s and 50s. It is disturbing to me that some of society's most vulnerable individuals may have been badly abused by the government that was charged with their care." At Markey's request, the Department of Energy indicated today that they will assign staff to more closely examine the Fernald School experiments. The Massachusetts State Department of Mental Retardation has also instituted an investigation of the Fernald experiments.

"I am pleased by this unprecedented level of openness and cooperation from the Department of Energy," Markey said. "After being stonewalled by the Reagan DOE, it finally appears as if something will be done. Secretary O'Leary's leadership has been vital to our efforts to bring about a meaningful solution to the issue of human radiation experimentation."

Markey also has recommended that the House Subcommittee on Energy and Power hold oversight hearings on this subject early next year. Markey's goal is to assure that: the full scope of the experimentation is ascertained; victims are identified; medical follow-up is provided to determine the long-term effects of these experiments; victims receive compensation; and this type of experimentation has ceased and will never happen again.

"I hope that Congress can act quickly in cooperation with the Department of Energy so that we will finally be able to let the public know to what extent the government was involved in planning these gruesome experiments," Markey said. "We need to see that the victims of these experiments receive justice and also make certain that something like this will never happen again."

SUBCOMMITTEE ON ENERGY CONSERVATION
AND POWER

ROOM: H2-318
HOUSE OFFICE BUILDING ANNEX NO
PHONE (202) 226-2424

EDWARD J. MARKEY
CHAIRMAN

OF THE

COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

LAWRENCE R. SIDMAN
CHIEF COUNSEL AND STAFF DIRECTOR

NEWS RELEASE

FOR IMMEDIATE RELEASE
October 24, 1986

Contact: Raoul Rosenberg
202-225-2836
or John Abbotts
202-226-2424

MARKEY RELEASES REPORT ON THREE DECADES OF RADIATION EXPERIMENTS
ON U.S. CITIZENS

Washington--Congressman Edward J. Markey, Chairman of a House Subcommittee with jurisdiction over nuclear energy programs, today released a staff report titled, "American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens."

The Subcommittee staff report reviewed documents which the Department of Energy supplied to Markey's Subcommittee on Energy Conservation and Power. In a letter to Secretary of Energy John Herrington, Markey noted that the DOE documents "revealed the frequent and systematic use of human subjects as guinea pigs." The experiments were sponsored by the Manhattan Project and the Atomic Energy Commission, predecessors to DOE, and were carried out from the mid-1940s to the early 1970s.

The report described in detail 31 experiments, during which about 695 persons were exposed. In many experiments, individuals were exposed to radiation that provided little or no medical benefit to the subjects. The purpose of several experiments was actually to cause injury to the subjects. Many others sought simply to measure the effects of radiation on humans. As Markey noted to Herrington, "American citizens thus became nuclear calibration devices for experimenters run amok."

Markey also noted that "Too many of these experiments used human subjects that were captive audiences or populations that some experimenters frighteningly perhaps might have considered 'expendable:' the elderly, prisoners, hospital patients suffering from terminal diseases who might not have retained their full faculties for informed consent."

Markey closed his letter by urging the Department of Energy to make "every practicable effort" to identify the persons who served as subjects, to examine their long-term health histories, and to compensate victims of radiation-associated diseases.

Markey's letter to Herrington describes "some of the more repugnant or bizarre" of these human radiation experiments.

EDWARD J. MARKEY, MASSACHUSETTS, CHAIRMAN

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SUBCOMMITTEE ON ENERGY CONSERVATION
AND POWER
OF THE
COMMITTEE ON ENERGY AND COMMERCE
WASHINGTON, DC 20515

October 24, 1986

The Honorable John S. Herrington
Secretary
Department of Energy
1000 Independence Avenue, S.W.
Washington, D.C. 20585

Dear Secretary Herrington:

As you know, the Subcommittee on Energy Conservation and Power has been conducting an investigation into radiation experimentation for human subjects. I am forwarding to you the results of that investigation, a Subcommittee staff report titled, "American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens."

This report reviewed Department of Energy documents, which revealed the frequent and systematic use of human subjects as guinea pigs for radiation experiments sponsored by the Department's predecessor agencies. Some of these experiments were conducted in the 1940s and 1950s, and others were performed during the supposedly more enlightened 1960s and 1970s. The report describes in detail 31 experiments during which about 695 persons were exposed.

In many of these experiments, individuals were exposed to radiation which provided little or no medical benefit to the subjects. The purpose of several of these experiments was actually to cause injury to the participants. Many others sought simply to measure the effects of radiation on humans. American citizens thus became nuclear calibration devices for experimenters run amok.

In a number of experiments, subjects received doses that exceeded presently recognized limits for occupational radiation exposure. Doses were as much as 98 times the body burden recognized at the time the experiments were conducted.

Too many of these experiments used human subjects that were captive audiences or populations that some experimenters frighteningly perhaps might have considered "expendable:" the elderly, prisoners, hospital patients suffering from terminal diseases or who might not have retained their full faculties for informed consent.

Some of the more repugnant or bizarre of these experiments include the following:

--From 1945 to 1947, as part of the Manhattan Project, 18 patients believed to have limited life spans were injected with plutonium.

--From 1961 to 1965, at the Massachusetts Institute of Technology, 20 elderly subjects were injected or fed radium or thorium.

--During 1946 and 1947, at the University of Rochester, six patients with good kidney function were injected with uranium salts to determine the concentration which would produce renal injury.

--From 1953 to 1957, at Massachusetts General Hospital, Boston, approximately 12 terminal brain tumor patients were injected with uranium to determine the dose at which kidney damage began to occur.

--From 1963 to 1971, 67 inmates at Oregon State Prison and 64 inmates at Washington State prison received x-rays to their testes to examine the effects of radiation on human fertility and testicular function.

--From 1963 to 1965, at the Atomic Energy Commission's National Reactor Testing Station in Idaho, radioactive iodine was purposely released on seven separate occasions. In one experiment, seven human subjects drank milk from cows which had grazed on iodine-contaminated land.

--From 1961 to 1963, at the University of Chicago and Argonne National Laboratory, 102 human subjects were fed real fallout from the Nevada Test Site; simulated fallout particles containing radioactive material; or solutions of radioactive cesium and strontium.

--During the late 1950s, at Columbia University and Montefiore Hospital, the Bronx, 12 terminal cancer patients were injected with radioactive calcium and strontium.

These experiments, and others described in the Subcommittee staff report, shock the conscience and represent a black mark on the history of nuclear medical research. They raise one major horrifying question: did the intense desire to know the consequences of radioactive exposure after the dawn of the atomic age lead American scientists to mimic the kind of demented human experiments conducted by the Nazis? Did the Department or its

The Honorable John S. Herrington

October 24, 1986

Page Three

predecessor agencies fund or sponsor programs which crossed the line that no scientific research can ever be permitted to traverse?

While it is clear that present public and scientific officials are generally not responsible for these experiments, these circumstances nonetheless represent a historical, institutional failure. To compound the evil, in too many experiments, no long term follow up was conducted of subjects. While these experiments cannot be undone, though they must never be repeated, there are potential remedial steps that can be taken to help the victims who served as human nuclear guinea pigs.

I therefore urge the Department of Energy to make every practicable effort to identify the persons who served as experimental subjects, to examine the long term histories of subjects for an increased incidence of radiation-associated diseases, and to compensate these unfortunate victims for suspected damages. A Defense Department program provides a model for such follow up. The Nuclear Test Personnel Review, administered by the Defense Nuclear Agency, is a registry for military personnel exposed to fallout from atmospheric nuclear tests. The primary objectives of the Review are to identify the approximately 200,000 Defense Department personnel involved in such tests, to determine their exposures, to identify incidences of death or illness, and to assist veterans in claims for compensation.

If such an effort can be carried out for military personnel acting in the line of duty, surely a similar effort should be possible for the far smaller number of peaceful atomic soldiers used as unwitting human subjects in radiation experiments. If you feel that new legislation would be necessary, the Subcommittee will be pleased to work with the Department to develop it.

If you have any questions on the material in this letter or the Subcommittee staff report, please contact John Abbotts or Larry Sidman at 202-226-2424. I look forward to receiving by November 15, 1986 a description of the Department's plans for long term follow up of these experimentally irradiated subjects, and your recommendation for what new legislation, if any, might be needed for compensation.

Sincerely,

Ed Markey

Edward J. Markey
Chairman

In: Human Experimentation

EDWARD J. MARKEY, MASSACHUSETTS, CHAIRMAN

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FRED J. ECKERT, NEW YORK
NORMAN F. LINT, NEW YORK
(EX OFFICIO)

LAWRENCE R. SIOMAN
CHIEF COUNSEL AND STAFF DIRECTOR

**U.S. HOUSE OF REPRESENTATIVES
SUBCOMMITTEE ON ENERGY CONSERVATION
AND POWER
OF THE
COMMITTEE ON ENERGY AND COMMERCE
WASHINGTON, DC 20515**

AMERICAN NUCLEAR GUINEA PIGS:

THREE DECADES OF RADIATION EXPERIMENTS ON U.S. CITIZENS

**A Subcommittee Staff Report
for the
SUBCOMMITTEE ON ENERGY CONSERVATION AND POWER
of the
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES**

October 1986

SUMMARY AND CONCLUSIONS

Documents provided by the Department of Energy reveal the frequent and systematic use of human subjects as guinea pigs for radiation experiments. Some experiments were conducted in the 1940s at the dawn of the nuclear age, and might be attributed to an ignorance of the long term effects of radiation exposure, or to the atomic hubris that accompanied the making of the first nuclear bombs. But other experiments were conducted during the supposedly more enlightened 1960s and 1970s. In either event, such experiments cannot be excused.

These experiments were conducted under the sponsorship of the Manhattan Project, the Atomic Energy Commission, or the Energy Research and Development Administration, all predecessor agencies of the Department of Energy. These experiments spanned roughly thirty years. This report presents the findings of the Subcommittee staff on this project.*

Literally hundreds of individuals were exposed to radiation in experiments which provided little or no medical benefit to the subjects. The chief objectives

* This report does not necessarily reflect the views of the Members of the Committee.

of these experiments were to directly measure the biological effects of radioactive material; to measure doses from injected, ingested, or inhaled radioactive substances; or to measure the time it took radioactive substances to pass through the human body. American citizens thus became nuclear calibration devices.

In some cases, subjects willingly participated in experiments, but they became willing guinea pigs nonetheless. In other cases, the human subjects were captive audiences or populations that experimenters might frighteningly have considered "expendable": the elderly, prisoners, hospital patients suffering from terminal diseases or who might not have retained their full faculties for informed consent. For some human subjects, informed consent was not obtained or there is no evidence that informed consent was granted. For a number of these same subjects, the government covered up the nature of the experiments and deceived the families of deceased victims as to what had transpired. In many experiments, subjects received doses that approached or even exceeded presently recognized limits for occupational radiation exposure. Doses were as great as 98 times the body burden recognized at the time the experiments were conducted.

A later section of this report, Description of Human Radiation Experiments, provides details on 31 experiments, during which about 695 persons were

exposed. Experiments are listed by Category and Number as designated by the Department of Energy. Some of the more repugnant or bizarre of these experiments are summarized below.

o During 1945 to 1947, as part of the Manhattan Project, 18 patients who were diagnosed as having diseases which gave them expected survivals of less than 10 years were injected with plutonium, to measure the quantity retained by the human body. These experiments were carried out at the Manhattan District Hospital at Oak Ridge, Tennessee; Strong Memorial Hospital in Rochester, New York; the University of Chicago, and the University of California, San Francisco. Despite the original diagnoses, seven of these patients lived longer than 10 years, and five lived longer than 20 years. Internal investigations by the Atomic Energy Commission found that informed consent was not granted in the initial experiments, since even the word "plutonium" was classified during World War II; and living patients were not informed that they had been injected with plutonium until 1974. (Category 1.001, Number 1).

o From 1961 to 1965 at the Massachusetts Institute of Technology, 20 subjects, aged 63 to 83, were injected or fed radium or thorium to estimate internal doses and to measure passage of these substances through their bodies. Many of these subjects came from the nearby Age Center of New England, a research facility established to investigate the process of aging and the needs of the elderly. These experiments thus represent a perversion of the Center's original purpose, since feeding the subjects radium and thorium did not benefit them as individuals or the elderly population as a whole. (Category 1.002, Number 118).

o During the 1960s, at the Los Alamos Scientific Laboratory, 57 normal adults were fed microscopic spheres containing radioactive uranium and manganese. These experiments were designed to determine how fast such spheres would pass through the human body after ingestion. It was believed that particles of this size could be produced by the atmospheric reentry and burnup of rockets propelled by nuclear reactors, or of radioactive power supplies. (Category 1.003, Number 106).

o During 1946 and 1947, at the University of Rochester, six patients with good kidney function were injected with uranium salts to determine the concentration which would produce renal injury. One patient was diagnosed as being in a "hallucinatory state," another was considered suffering from "emotional maladjustment," and a third, admitted to the hospital for a fifth time, was described as follows: "As he had no home, he agreed willingly to enter the metabolic unit for special studies." (Category 1.003, Number 119).

o From 1963 to 1971, 67 inmates at Oregon State Prison and 64 inmates at the Washington State Prison received x-rays to their testes to examine the effects of ionizing radiation on human fertility and testicular function. These experiments were conducted by the Pacific Northwest Research Foundation and the University of Washington. Subjects had to agree to receive vasectomies after completion of the experiments. The Energy Research and Development Administration planned to begin medical follow up of the irradiated prisoners, but these plans were dropped in 1976 at the request of the U.S. Attorney in Portland after several irradiated inmates filed

suits against state and federal governments. (Category 2.001, Number 2 and Category 2.002, Number 189).

o From 1953 to 1957, at Massachusetts General Hospital, Boston, approximately 12 terminal brain tumor patients were injected with uranium to determine the dose at which kidney damage began to occur. Most of the patients were described as comatose or in a "semi-coma." (Category 9.001, Number 166).

o From 1963 to 1965, at the Atomic Energy Commission National Reactor Testing Station in Idaho, radioactive iodine was purposely released on seven separate occasions. In one of these experiments, seven human subjects drank milk from cows which had grazed on iodine-contaminated land. This experiment was designed to measure the passage of iodine through the food chain into the thyroids of the human subjects. In a second experiment, three human subjects were placed on the pasture during iodine release, and seven subjects were placed on the pasture in a third experiment. In addition, "several" individuals were contaminated during yet another experiment when vials of radioactive iodine accidentally

broke. Cows grazed on contaminated land and their milk was counted in four of the experiments; in the remaining three, radiation measurements were made only on the pasture. (Category 10.001, Number 173).

o During May 1945, at the Clinton Laboratory, Oak Ridge, Tennessee, two groups of 10 subjects were exposed to beta rays, to determine the dose that would begin to cause reddening of the skin. (Category 11.001, Number 51).

o During 1951 and 1952, at least 14 human subjects were exposed to tritium in air, by immersion of body parts in water, or by drinking. These experiments were designed to measure the retention or excretion of tritium by the human body. The experiments were carried out by the Los Alamos Scientific Laboratory, or the General Electric Company in Richland, Washington. (Category 11.001, Numbers 112, 123, 125, 126, 127).

o During 1956, the U.S. Air Force sent manned planes through radiation clouds from atomic bomb tests at Eniwetok and Bikini Atolls in the Pacific to measure radiation doses in the clouds and to

the crew. (Category 11.001, Number 133).

o During the early 1950s, Foster D. Snell, a consulting firm, carried out experiments for the U.S. Army by placing "synthetic" radioactive soil on the hands of about 118 human subjects, and measuring the ability of different cleaning agents to remove the contamination. (Category 11.001, Number 134).

o From 1961 to 1963, at the University of Chicago and Argonne National Laboratory, 102 human subjects were fed real fallout from the Nevada Test Site; simulated fallout particles that contained strontium, barium, or cesium; or solutions of strontium and cesium. This experiment was designed to measure human absorption and retention of these radioactive substances. (Category 11.001, Number 186, Part A).

o During the early 1960s, at the Oak Ridge Institute for Nuclear Studies, 54 hospital patients with normal intestinal tracts were fed lanthanum-140. This experiment was designed to measure the rate at which this radioactive substance passed through the body. (Category

11.001, Number 186, Part B).

o During the late 1950s, at Columbia University and Montefiore Hospital, the Bronx, 12 terminal cancer patients were injected with radioactive calcium and strontium. This experiment was designed to compare the distribution of these two substances among body tissues after autopsy. (Category 12.001, Number 15).

o In 1967 at the Hanford Environmental Health Foundation and the Battelle Memorial Institute, both at Richland, Washington, radioactive promethium was administered to 14 subjects by injection or drinking. These experiments were designed to measure the passage of this substance through the body and the ability of a drug (chelating agent) to increase the removal of promethium. (Category 12.001, Number 110).

o During 1963, at the Battelle Memorial Institute, Richland, Washington, five subjects were injected with radioactive phosphorus. In addition, five subjects were fed fish from the Columbia River which contained radioactive phosphorus, produced and discharged into the river by reactors at the Atomic Energy Commission's

Hanford Site. These experiments were designed to estimate the doses to humans eating contaminated fish. (Category 12.001, Number 111).

In many of the reported experiments, radiation was used as treatment for diseases which were resistant to more conventional methods. Most frequently, radiation was used in attempts to treat cancer, leukemia, or other malignant disorders of the blood. The Subcommittee staff does not question these applications, since patients were irradiated in an attempt to treat their diseases, and in some cases the treatment was successful. In these cases, the radiation exposure was meant to carry some medical benefit for patients, and observation of the effects of exposure, which enhanced understanding of radiation effects, was incidental to the treatment. In some cases, however, long term medical follow up of the surviving patients, which might have provided information for useful comparison with other treatments that might seem promising, was not conducted.

The studies provided by the Department of Energy amply demonstrate the need for long term medical follow up. Category 10.001, Number 69, describes a retrospective study on the health of humans exposed to radioactive iodine, and includes as a study population

the group of Marshallese Islanders exposed to fallout from early atomic bomb tests. This report notes that thyroid nodules, produced by exposure to radioactive iodine, did not first appear among inhabitants of the atoll with the highest fallout until 9 years after the testing. Nodules began appearing some years later among inhabitants of atolls where the doses were lower; and after 22 years, nodules were still being observed.

If there is one thing the government can do for these experimental victims and their families, even at this late date, it is to conduct long term medical follow up of populations exposed to radioactive material. That practice has been adopted by the Defense Department through its Nuclear Test Personnel Review, a registry for military personnel exposed to fallout from atmospheric nuclear tests. The primary objectives of the Review are to identify the approximately 200,000 Defense Department personnel involved in such tests, to determine their exposures, to identify incidences of death or illness, and to assist veterans in claims for compensation. If this effort can be carried out for military personnel acting in the line of duty, surely a similar effort should be possible for the far smaller number of peaceful atomic soldiers used as human subjects in radiation experiments.

RECOMMENDATIONS

1. It seems appropriate to urge the Department of Energy to make every practicable effort to identify the persons who served as subjects for the experiments described below, to examine the long term histories of subjects for an increased incidence of radiation-associated diseases, and to compensate these human guinea pigs for damages they have suffered.

These victims face severe obstacles to compensation under current law, embodied by the Federal Tort Claims Act. The Department of Energy should therefore be encouraged to work with the Subcommittee to develop legislation that provides adequate compensation.

2. Human experiments of this nature must never be repeated. Many of these experiments would not be allowed under current federal guidelines, and it is gratifying that experiments of this nature apparently did not continue after the early 1970s.

Two overriding principles for human experimentation must be followed: The first is that the risks of the experimental treatment must be reasonable in relation to anticipated benefits. The second is that subjects must be fully informed, and capable of understanding the benefits and risks of the treatment. Current federal regulations embody these

principles, with exceptions that are clearly spelled out in cases where knowledge from the treatment might benefit society as a whole. The Appendix to this report describes these federal regulations.

The Subcommittee is gratified that the Department of Energy follows current regulations in its own experiments. However, the sad history of human radiation experimentation makes it clear that standards that were acceptable forty years ago appear repugnant today. It therefore seems appropriate to urge that all applicable federal agencies, including the Department of Energy, frequently review their regulations to ensure that human experimentation is conducted under the highest ethical standards.

BACKGROUND

The investigation into human radiation experiments began as part of an ongoing Subcommittee examination of the health and safety policies of the Department of Energy. In June 1984, Representative Richard Ottinger, then Subcommittee Chairman, requested from the Department a list of experiments involving human test subjects and radiation, which were funded by the Atomic Energy Commission, the Energy Research and Development Administration, or the Department of Energy. The former two agencies were predecessors of the Department of Energy. DOE responded to this initial request in September 1984, enclosing summaries of many different experiments. In October 1984, Chairman Ottinger requested further clarification and information on the human experiments provided. DOE responded to this request in January 1985, providing supporting material and fuller descriptions of many of the experiments, and in some cases reporting more experiments.

In January 1985, Representative Edward J. Markey became Subcommittee Chairman, and initiated an intensive review of all the documents released by the DOE. Chairman Markey also requested further information on individual experiments in August, November, and December 1985, and in March 1986.

REVIEW OF RELEASED DOCUMENTS

The initial information released by the Department of Energy consisted of summary factsheets on each of several human radiation experiments. Each factsheet contained an experiment title, designation of federal agency or agencies funding the experiment, a list of institutions conducting the experiments, description of the experiment objective, a short description of the experiment, and where known, the status of long term medical follow up of experimental subjects.

In response to the Subcommittee's October 1984 request for further information, DOE released additional material including dates when experiments started and ended, names of responsible government officials, and in some cases supporting documents, such as scientific references or project reports. DOE also released some material on experiments not previously reported in the summary factsheets.

DOE placed the experiments reported in 12 different categories:

1. Metabolism and Biological Effects of Plutonium, Polonium, Thorium, Uranium, Radium, and Lead-212.
2. Testicular Irradiation.
3. Whole-body Irradiation for Treatment of Leukemia and Lymphoma.
4. Teletherapy with Particle Beams.

5. Other Teletherapy Studies.
6. Treatment of Polycythemia.
7. Hematological Effects.
8. Neutron Capture Therapy.
9. Other Radiation Therapy.
10. Biological Effects of I-131.
11. Other Biological Effects Studies.
12. Metabolic and Physiological Studies.

In many of the reported cases, radiation was used as treatment for diseases which were resistant to more conventional methods. Most frequently, radiation was used in attempts to treat cancer, leukemia, or other malignant disorders of the blood. The Subcommittee staff does not question these applications, since patients were irradiated in an attempt to treat their diseases, and in some cases the treatment was successful. In these cases, the radiation exposure was meant to carry some medical benefit for patients, and observation of the effects of exposure, which enhanced understanding of radiation effects, was incidental to the treatment. The Subcommittee staff readily acknowledges the scientific advancement produced by such observations and commends those scientists and physicians who engaged in such research.

In many of the cases where radiation was used for

medical treatment, there was little long term medical follow up of the irradiated patients. In part, this may have been due to the fact that the benefits of medical radiation were clear: irradiated patients in some cases showed higher survival rates than patients treated with other methods. But since radiation can also cause cancer, long term follow up on surviving patients may have provided information for a useful comparison with other present treatments or with treatments that might seem promising in the future.

The follow up provisions of one particular experiment, designated Category 4.004, Number 179, should be noted with approval. The objective of this project is to determine the effectiveness of neutron beam irradiation as compared to standard irradiation for the management of certain malignant tumors. This project is funded by the National Cancer Institute and is carried out at the Fermi National Accelerator Laboratory, a facility owned by the Department of Energy.

This project began in 1975 and is continuing today. Approximately 1400 patients have been referred to the program. Prior to treatment, patients must agree to comply with long-term follow up requirements, which include regular physical examinations and laboratory tests. Every effort is made to contact patients who miss scheduled appointments, and fewer

than 1 percent of patients treated at this facility are currently considered lost to follow up. The follow up efforts at this Fermilab project should be applauded, and they represent a model that should be duplicated in other DOE investigations of medical therapy.

In many of the other human experiments which DOE reported to the Subcommittee, however, subjects received little or no medical benefit from their exposure. These experiments fall into two general categories: In one group, human subjects were injected or fed radioactive material, and its passage through the body was monitored. The major objective of these experiments was to compare results with mathematical models predicting radiation doses for occupational or accidental exposure. Although these experiments did provide information on the retention and absorption of radioactive material by the human body, the experiments are nonetheless repugnant because human subjects were essentially used as guinea pigs and calibration devices. In a second group of experiments, the administration of radioactive material was actually intended to cause damage to the human body, and the experimenters sought to correlate the amount of damage done with the dose received.

In some of the experiments described, the human subjects were captive populations: the elderly,

prisoners, and hospital patients who might not have retained their full faculties for informed consent. In other experiments, the subjects were volunteers, but they were willing guinea pigs nonetheless.

The human radiation experiments are described in detail in the following section.

DESCRIPTION OF HUMAN RADIATION EXPERIMENTS

Category and Number labels below are as designated by the Department of Energy in its responses to the Subcommittee. In many cases, occupational exposure limits are provided for comparison with the doses or amounts of radioactive material received by subjects. Present dose limits are taken from Title 10, Code of Federal Regulations, Part 20. The maximum permissible body burden is an occupational limit for the allowable amount of a given substance that may be internally deposited in an individual. It is generally recognized among the scientific community that doses to the general population should be no more than one tenth the allowable doses to radiation workers. Values presented below for maximum permissible body burdens are taken from NCRP-22, a handbook of the National Committee on Radiation Protection, which is a non-governmental organization that recommends standards for radiation exposure.

In addition to the experiments described in the Summary and Conclusions of this report, many experiments are of special concern because of the circumstances of the persons used as subjects, or because of the doses which some subjects received,

relative to present occupational limits. In experiments where the radioactive material administered was greater than the present maximum permissible body burden, doses are classified as potentially greater than present occupational limits, since not all of the material administered might have remained in the body. These experiments of special concern are listed below, and are followed by descriptions of all experiments.

Category 1.001, Number 1. Subjects were diagnosed as terminal within 10 years; one subject was a child; no evidence of informed consent; potential doses much greater than occupational limits.

1.002, Number 118. Subjects were elderly; potential doses greater than occupational limits.

1.003, Number 12. Subjects were terminal patients; potential doses greater than occupational limits.

1.003, Number 119. Subjects were hospital patients; some doses produced kidney damage.

2.001, Number 2. Subjects were prisoners; doses were greater than occupational limits.

2.002, Number 189. Subjects were prisoners; doses were greater than occupational limits.

3.001, Number 49. Doses were greater than occupational limits.

9.001, Number 166. Subjects were terminal brain tumor patients, and most were comatose; some doses produced kidney damage.

10.001, Number 173. Radioactive iodine was intentionally released to the environment.

11.001, Number 51. Doses were greater than occupational limits.

11.001, Number 53. Doses were greater than occupational limits.

11.001, Number 121. Subjects were hospital patients; doses were greater than occupational limits.

11.001, Number 123. Potential doses were greater than occupational limits.

11.001, Number 127. Potential doses were greater than occupational limits.

11.001, Number 133. Doses were greater than occupational limits.

11.001, Number 186, Part B. Subjects were hospital patients; potential doses were greater than occupational limits.

Category 12.001, Number 15. Subjects were terminal cancer patients; potential doses were greater than occupational limits.

12.001, Number 109. Potential doses were greater than occupational limits.

12.001, Number 128. Potential doses were greater than occupational limits.

Category 1. Metabolism and Biological Effects of Plutonium, Polonium, Thorium, Uranium, Radium, and Lead-212.

Category 1.001, Number 1

Plutonium Injections Into Humans.

During 1945 to 1947, 18 patients were injected with plutonium. These experiments were carried out by the Manhattan Project. The following hospitals were involved in the experiments, with the number of patients involved for each indicated:

Manhattan District Hospital, Oak Ridge, Tennessee

(1)

Strong Memorial Hospital, Rochester, New York (11)

Billings Hospital, University of Chicago (3)

University Hospital, University of California, San Francisco (3).

According to an Energy Research and Development Administration (ERDA) fact sheet of February 1976, the rationale for this experiment was that several thousand Manhattan Project workers had been involved in handling plutonium; accurate information was needed on the retention and excretion of internally deposited plutonium for setting safety criteria, and animal experiments had produced conflicting data which could

not be extrapolated to humans.

In choosing subjects, the original criteria specified that subjects should be older, with relatively short life expectancies. All subjects chosen were diagnosed as having existing diseases that gave them an expected survival of less than 10 years. Most were over 45, but one subject was five years old, and another was 18. The oldest patients were 68. The quantities of plutonium injected ranged from 1.6 to 98 times the body burden value recognized at the time of the experiments, where a body burden is the permissible occupational limit for an internally deposited radioisotope. 13 of the patients received between 7 and 10 body burdens. Patients were monitored for their excretion of plutonium. They received no medical benefits from the injections.

In 1967, a Berkeley radiobiologist learned that one of the injected patients had lived for 20 years. She investigated the whereabouts of other patients, and in 1972 published a scientific paper noting that four patients were then alive. In a subsequent follow up investigation, the Department of Energy determined that 9 patients died within 3 years, one in 8 years, one each in 11 and 14 years, and four after 20 years. One was lost to follow up, and one was still living as of October 1983. In one case, the original diagnosis of disease later proved to be inaccurate.

In 1974, following the report that four patients were still alive, the Atomic Energy Commission conducted internal investigations to determine if the experimental patients had granted informed consent for their exposures. A report transmitted in August 1974 found that experimenters had failed to obtain informed consent in several instances. Formalized standards for patient consent to experimental procedures did not exist prior to 1946. In addition, even the word "plutonium" was classified until the end of World War II. The AEC, which succeeded the Manhattan Project, established a policy of formalized patient consent in 1947. One patient, injected in 1947, was the only subject injected after the AEC had been formed. This patient's hospital record contained a statement by attending physicians that the individual had been properly informed of the experimental nature of the injection. The AEC could find no records of consent for any other patient, and determined from oral testimony that at least one patient had not been informed.

On this issue, a June 1983 Department of Energy memo concluded that:

"The issue of informed consent, if raised, will be difficult to deal with in the light of present DOE and Federal policies and procedures regarding human subjects. These are vastly

more codified and explicit than any guidance available at the time the injections were given, and the procedures used at that time would not meet standards adopted and currently applied by DOE and other federal organizations." (Memo from Nathaniel P. Barr to Alvin W. Trivelpiece, Director, Office of Energy Research, Department of Energy, June 30, 1983.)

In 1973, the Center for Human Radiobiology (CHR), Argonne National Laboratory, initiated a follow up study of surviving patients and a program to exhume deceased patients for whom permission could be obtained. These studies were designed to examine how much plutonium remained in the bodies of subjects. The 1974 AEC investigations found that even by 1973 standards, informed consent had not been obtained for these studies. A memorandum dated December 21, 1972 from [name deleted], Argonne National Laboratory, to [name deleted], Center for Human Radiobiology, contained the following instructions in regard to studies on the surviving patients:

"Please note that outside of CHR we will never use the word plutonium in regard to these cases. 'These individuals are of interest to us because they may have received a radioactive material at some time' is the kind of statement

to be made, if we need to say anything at all" [emphasis in original]. (Quoted in Division of Inspection Report 44-2-326, U.S. Atomic Energy Commission, August 16, 1974, p. 19)

Consequently, patients alive in 1973 were not informed that they had been injected with plutonium in the 1940s. Relatives of deceased patients were told that exhumation was necessary to determine the composition of an "unknown" mixture of injected radioactive isotopes. Injection was also represented as having been an experimental treatment for the patients' diseases, a statement that is not true. As a second AEC investigation concluded:

"Relative to the study undertaken in 1973, informed consent was not obtained from surviving patients who were the subject of the study."

"Consent, following improper disclosure, was obtained from the next of kin of an exhumed patient. Improper disclosure was made to the next of kin of additional deceased patients who have not been exhumed." (Division of Inspection Report 44-2-330, U.S. Atomic Energy Commission, August 12, 1974, pp. 11, 12.)

As a result of the 1974 investigation, the AEC contacted the doctors of the four living patients, and asked the doctors to inform the patients of the nature of the Manhattan Project injections. One doctor did not tell his patient because he felt the information would be detrimental to her health; this patient has since died. The other three patients were informed.

A scientific paper published in 1976 calculated doses to the injected patients, and concluded from these calculations that in spite of the apparent lack of induced tumors among the patients:

"The liver doses do not appear to be high enough to be carcinogenic, but comparison of the bone-surface doses with radium doses that have induced bone tumors indicates that six of these cases have received doses high enough to be considered carcinogenic." (R.E. Rowland and P.W. Durbin, Survival, causes of death, and estimated tissue doses in a group of human beings injected with plutonium, in *The Health Effects of Plutonium and Radium*, J.W. Press, Salt Lake City, 1976)

Category 1.002, Number 118

Administration of Radium and Thorium to Humans.

During the period 1961-1965, doses of the nuclides Radium-224 and Thorium-234 were given to 20

volunteers, 13 men and 7 women, aged 63 to 83. Six subjects were injected with radium, six were injected with thorium, one ingested radium, one ingested thorium, and six ingested both radium and thorium. These experiments were funded by the AEC and carried out at the Massachusetts Institute of Technology.

The experiments were designed to examine the metabolism from radioactive substances that might be similar to those ingested by radium dial painters in the earlier part of the 20th century, many of whom subsequently developed cancer of the jaw or mouth. The specific matter of concern was whether Thorium-228, which may have been present in dial paints, would have contributed a significant dose to painters. After the subjects were fed or injected with the radioactive substances, the substances were monitored by measuring their presence in blood, in the breath, in excreted matter, and by whole-body counting of the subjects. Patients were monitored for up to 120 days.

Doses given to patients were 0.2 to 2.4 microcuries of radium, or 1.2 to 120 microcuries of thorium. For comparison, maximum permissible body burdens are 0.07 microcuries for Radium-224, and 20 microcuries for Thorium-234.

Most of the subjects were obtained from the Age Center of New England, Boston. A few were retired MIT

employees. The subjects received no medical benefits from the experiment.

According to material received from the Department of Energy, the Age Center of New England was a non-profit research facility established in 1954 to investigate the process of aging and the needs of the elderly. The Center's pool of subjects consisted of several hundred "apparently healthy men and women" over the age of 50 who had declared their willingness to be studied in a variety of research projects on aging. These subjects lived elsewhere and had to be active enough to come to the Center to participate in research.

In 1957, the first published annual report of the Age Center described the following ongoing research projects: "Correlates of Anxiety in Older Persons;" "The Nutrition of Apparently Normal Aging Persons;" "Prejudice and Older People," and "A Thematic Analysis of Later Life," which obtained the attitudes of elderly persons through questionnaires and oral interviews. The AEC experiments with Age Center subjects thus represent a perversion of the Center's original purpose: Feeding the subjects radium and thorium was of no direct benefit to the subjects or to the elderly population as a whole, and was not related to phenomena connected to the aging process.

The study was conducted in two phases. In the

first phase, subjects were injected with either radium or thorium, and the passage of the material through the body was measured. The principal reason for these experiments was to calibrate counting equipment that would be used in the second phase, which was the oral ingestion of mixtures of radium and thorium. Excretion and whole body counting was also monitored for the phase two patients. These experiments were reported to the AEC in annual progress reports in 1964 through 1966.

In a January 2, 1985 letter to the Subcommittee Chairman, the Department of Energy reported that no follow up had been conducted on the health of the experimental subjects. The Age Center no longer exists and one professor who conducted the study had "no idea how any records of survival history could be obtained." He stated that finding the patients, if still alive, may be "like doing a missing persons search." The youngest volunteer would be approaching 85 years old today.

Category 1.003, Number 12.

Polonium Administered to Humans.

From 1943 to 1947, radioactive polonium was injected into 4 hospital patients, and given orally to a fifth. Rates of excretion were measured. These studies were funded by the Manhattan Project and the

AEC, and were conducted at the University of Rochester.

The objective of the experiment was to obtain data on human excretion of polonium to obtain a correlation with more extensive data from rats. Hospital patients were used as subjects because the experimenters wanted persons who had not been exposed to polonium through work or accidents.

The experiments were described in a scientific publication: Studies of polonium metabolism in human subjects, Chapter 3 of Biological Studies with Polonium, Radium, and Plutonium, National Nuclear Energy Series, Volume VI-3, McGraw-Hill, New York, 1950. All subjects had incurable diseases. Patient 1 was suffering from lymph cancer, and was injected with 22 microcuries of polonium. Patient 2 had acute leukemia, was injected with 11 microcuries, and died six days later. Patients 3 and 4 suffered from chronic leukemia, and were injected with 12 and 9 microcuries, respectively. Patient 5 suffered from chronic leukemia, and ingested 18 microcuries of polonium. Excretion of polonium was followed, and an autopsy was conducted on the deceased patient to determine which organs absorbed the polonium. The age of the patients ranged from early thirties to early forties.

The isotope administered is not specified, but the

most readily available isotope at the time was Polonium-210. For comparison with the doses, the maximum permissible body burden for Polonium-210 is 0.4 microcuries.

In January 1985, the Department of Energy transmitted to the Subcommittee summary factsheets on this, and many other experiments. The factsheet for this experiment reported no follow up on these experimental subjects.

Category 1.003, Number 21.

Absorption of Lead-212 by the Human Gastrointestinal Tract.

Lead-212 was fed to three human subjects and gastrointestinal absorption and excretion over 24 hours were examined. Similar measurements were made on two human subjects injected with Lead-212, and the results for ingestion and injection were compared. These experiments were conducted to compare experimental results with existing models used by the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection (NCRP), organizations which recommend radiation exposure standards. These experiments were carried out at the University of Rochester, were funded by the AEC, and were reported in UCRL-18140, Lawrence Radiation Laboratory, University of California,

Berkeley, April 1968, pp. 217-232. The material from the Department of Energy on this experiment reported no information on doses, and no follow-up on the experimental subjects.

Category 1.003, Number 106

Some Biological Aspects of Radioactive Microspheres in Humans.

During the 1960s, 57 normal adults were fed very small spheres containing radioactive Uranium-235 and Manganese-54, to determine how long it would take these spheres to pass through the gastro-intestinal tract. The human subjects received no medical benefit from this experiment.

The experiment was designed to assess the potential hazards from atmospheric reentry and burnup of rockets propelled by nuclear reactors, or of radioactive power supplies. Such burnup could produce particles small enough to be inhaled or ingested. In order to estimate internal radiation doses that humans might receive from such accidents, information was needed on the time that radioactive particles might remain in the body. The human subjects were all workers at Los Alamos Scientific Laboratory, except for one individual who was the wife of the principal investigator.

During the experiment, subjects were given a

gelatin capsule containing U-235 and Mn-54, in spheres 100-200 microns in diameter (a micron is one-millionth of a meter). Both U-235 and Mn-54 emit radiation which would penetrate the gelatin. The Mn-54 spheres were coated with ceramic, the U-235 spheres were uncoated. Subjects each swallowed a capsule, and feces were collected and counted to determine how long the capsules remained in the body. One subject repeated ingestion of the sample 10 different times to provide an estimate of variation within the same individual. "Several others" repeated ingestion at different times of the day to provide an estimate of how results might change with time of day.

The experiment was conducted at Los Alamos Laboratory, was funded by the Atomic Energy Commission, and was reported in document LA-3365, Los Alamos Scientific Laboratory, August 1965.

The factsheet which the Department of Energy supplied the Subcommittee reported no follow up on these experimental subjects.

Category 1.003, Number 119.

Injection of Uranium Salts.

During 1946 and 1947, six patients with good kidney function were injected in increasing doses with uranium nitrate, enriched in U-234 and U-235. The objectives of the experiment were to: determine the

dose of uranium salt which produced renal injury; measure the rate of excretion of uranium salts; and observe the effects of modifying rates of excretion. These experiments were carried out at the University of Rochester, Atomic Energy Project.

The experiments are described in UR-37, dated June 1948, which apparently was a project report to the Atomic Energy Commission. The human subjects received no medical benefits from these experiments, and in fact the treatment seemed designed to induce kidney injury in at least one patient. It was recognized that uranium salts could damage the kidney, and the experiment planned to identify the concentration that would produce "just detectable renal injury." (UR-37, p. 7)

The experimental subjects were chosen from a large group of hospital patients; those selected had reasonably normal kidney function. In addition, "The probability that the patient would benefit from continued hospitalization and medical care was also a factor in the choice. When higher levels of dosage were contemplated, individuals from the older age groups were preferred in view of the remote possibility that late radiation effects might occur ..." (UR-37, pp. 8,9).

Patient 1 was in the hospital because of rheumatoid arthritis and urethral strictures.

Patient 2 was hospitalized because of acute alcoholism, "hallucinatory state," cirrhosis of the liver, and possible neural damage. Patient 3 was a young woman "in fairly good physical condition except for mild chronic undernutrition which was thought to be secondary to an emotional maladjustment." (UR-37, p. 18) Patient 4 entered the hospital because of chronic alcoholism and bleeding from the gastrointestinal tract. 12 days after uranium injection, patient 4 was injected with citrate to examine its effect in further removal of uranium. "Unfortunately, this solution was so hypotonic" that blood appeared in the patient's urine and his temperature rose to 39.5 degrees C [103 degrees F]." (UR-37, p. 29).

Patient 5 suffered from chronic cough, had a history of rather high alcohol consumption, and was diagnosed as having pneumonia when he entered the hospital. Uranium doses had been successively increased with each new patient. Patient 5 showed trace amounts of protein in his urine, a sign of kidney disfunction, on the last day before leaving the hospital. He was not followed up. Patient 6 remained in the hospital from October 1946 to April 1947. This was his fifth admission to the hospital. Previous diagnoses had included heart disease, chronic alcoholism, and pneumonia; the present admission was

for an ulcer. "As he had no home, he [Patient 6] agreed willingly to enter the metabolic unit for special studies." (UR-37, p. 41) Patient 6 received the largest dose, 70 microgram of uranium per kilogram weight, and clinical analysis suggested that "tolerance had been reached" for kidney injury. (UR-37, p. 55)

The summary factsheet which the Department of Energy submitted to the Subcommittee reports no follow up on the experimental subjects. Funding for the experiment is not specified, but it presumably would be from the Manhattan Project, since the AEC was not established until 1947.

Category 2. Testicular Irradiation.

Category 2.001, Number 2.

Testicular Irradiation of Inmates at Oregon State Prison.

From August 1963 to May 1971, 67 volunteers at the Oregon State Prison were subjected to testicular irradiation by x-rays. Radiation doses ranged from 8 to 600 roentgen in single acute exposures, except that six prisoners were irradiated a second time, one a third time, and one was given weekly irradiations of 5 roentgen per week for eleven weeks. For comparison,

the present occupational limit for exposure to reproductive organs is 5 roentgen per year. These experiments were carried out by the Pacific Northwest Research Foundation, Seattle; the Atomic Energy Commission provided a total of \$1.08 million for these studies.

The objective of this experiment was to obtain data on the effects of ionizing radiation on human fertility and the function of testicular cells. It was considered that data from animals could not be readily extrapolated to humans. Studies included examination of testicular tissue, sperm counts, and evaluation of urinary or blood steroids and hormones.

Prisoners ranged in age from 25 to 52. Each inmate agreed to have a vasectomy at the end of his irradiation; consent of wives was required for this procedure. All prisoners in the Oregon group did eventually have vasectomies. All volunteers were required to sign statements of informed consent. Consent procedures involved an explanation of short term and long term effects, including the possibility of testicular cancer. No Catholics were allowed as subjects. Small sums of money were paid to prisoners: \$5 to \$10 for each treatment, and \$100 at the time of vasectomy. However, according to the Energy Research and Development Administration "records suggest that the prime incentive to participate may have been the

feeling that they were making important contributions to the state of medical knowledge." (ERDA background information on AEC human testicular irradiation projects in Oregon and Washington state prisons, March 19/6, p. 2)

The prisoner irradiation program was terminated in 19/3 after the principal investigator suffered an incapacitating stroke, and because of "subsequent state re-evaluation of correctional institutional involvement in experimental programs." (C.G. Heller et al., "Protection of the rights and welfare of prison volunteers: Policies followed throughout a 17-year medical research program," unpublished manuscript, p. 7) The same document noted that the vasectomies on subjects after the experiment were necessary "to avoid any possibility of contaminating the general population with irradiation-induced mutants." (Ibid., p. 5)

In a summary factsheet provided the Subcommittee in January 1985, the Department of Energy described the follow up of experimental subjects: "Complete recovery as shown by a return to pre-irradiated sperm concentrations and germinal cell numbers was found to be within 9-18 months for doses of 100 rad and below, 30 months for doses of 200 and 300 rad and 5 or more years for doses of 400 and 600 rad."

The need for follow up over a longer term was

recognized as early as 1971, in a letter from an AEC official to Carl Heller, the principal investigator for the experiments. The letter concluded, "Thus, I am suggesting that you prepare a protocol for the long-term follow-up of the irradiated volunteers after their release from the research program." (Frank T. Brooks, Division of Biology and Medicine, AEC, to Carl G. Heller, Pacific Northwest Research Foundation, November 30, 1971).

In its 1976 background information material, the Energy Research and Development Administration noted: "ERDA believes that there is a need for continued medical surveillance of prisoners involved in both sets of experiments [Oregon and Washington], and will explore with prison officials the best methods to achieve this. Among health effects which should be monitored is the possibility of testicular tumors, occurring after a long latency period (25-30 years)." (ERDA background information, March 1976, pp. 2-3.) However, at the request of the U.S. Attorney in Portland, Oregon, this follow up program was cancelled after several irradiated inmates filed suits against state and federal governments. In September 1976, the District Court for the District of Oregon dismissed the suit against federal defendants.

The experiments resulted in the publication of several scientific papers. The most recent one cited

was M.J. Rowley et al, Radiation Research 59, 665-678, 1974.

Category 2.002, Number 189.

Testicular Irradiation of Inmates at Washington State Prison.

During the period June 1963 to May 1970, 64 inmates at the Washington State Prison received testicular irradiation from x-rays. Each subject was irradiated once, and doses ranged from 7 to 400 roentgen. Following irradiation, tissue samples and sperm were examined for indications of damage; urine samples were examined for hormone levels. The Atomic Energy Commission granted \$505,000 to support these studies, which were conducted by University of Washington researchers.

The objective of these studies was to determine the effects of radiation on gonadal function. The studies were reportedly proposed after a radiation accident at the AEC Hanford facility. Three men were overexposed, and no clear scientific data was available to advise them on possible sterility effects. The experiments were designed to determine the minimum effective dose that would render an individual temporarily sterile.

The criteria for selection were similar to the experiments with Oregon inmates: Participants had to

agree to vasectomies after completion of the experiment. However, several of the Washington inmates subsequently did not receive vasectomies: 2 declined and were released from prison; 1 declined and remained in prison; 1 was released before the scheduled vasectomy; 1 did not undergo surgery for psychiatric reasons after mutual agreement with the prison physician; 1 who had heart problems and a life sentence was not vasectomized after mutual agreement. (AEC Contract AT(45-1)-2225, Task Agreement 6, Terminal Report, January 1973, p. 3) Because of the lack of follow up information, it is not known if any experimental subjects subsequently fathered any children.

The experiments were terminated after a Human Subjects review board at the University of Washington refused in July 1969 to authorize further irradiation of prisoners. (George W. Farwell, University of Washington, to John R. Totter, Director, Division of Biology and Medicine, Atomic Energy Commission, July 16, 1969)

In the factsheet submitted to the Subcommittee in January 1985, the Department of Energy had this description for follow up: "Recovery of cell morphology and function were found after a maximum of 501 days. It was concluded that man is very sensitive in regard to temporary sterility, but is very

resistant to complete sterility." As with the Oregon prisoners, there was no long-term follow up of subjects.

Several scientific publications resulted from these experiments. The most recent cited was T.W. Thorslund and C.A. Paulsen, in Proceedings of the National Symposium on Natural and Man-Made Radiation in Space, NASA Document NAS No. 2440, pp. 229-232, January 1972.

Category 3. Whole Body Irradiation

In most of the cases in this category reported to the Subcommittee, whole body irradiation was used as treatment for diseases which were resistant to more conventional methods. Most frequently, whole body irradiation was used in attempts to treat leukemia, cancer, or polycythemia vera (a disorder characterized by excessive levels of red blood cells in the blood). The Subcommittee staff does not question the propriety of these particular applications, since patients were irradiated in an attempt to treat their diseases, and in some cases the treatment was successful. However, one case covered below appeared questionable.

Category 3.001, Number 49.

Blood Changes in Human Beings Following Total-Body Irradiation.

During 1943 and 1944, three groups of persons were given whole body irradiation doses from x-rays. The first group was eight persons with cancer. The second group consisted of one cancer patient and two persons with arthritic conditions. The third group was three normal volunteers. The objective of the study was to observe the changes in blood or blood cells following treatment. Although whole body irradiation was a recognized treatment for malignancies, it provided no benefit to the normal subjects, who received doses which were greater than maximum allowable occupational exposures at the time. In addition, the treatment seemed of little use for arthritis, and the Department of Energy reported in April 1986 that x-ray irradiation for arthritis "is not considered to be standard practice." The experiments were conducted at the University of Chicago and were funded by the Manhattan Project.

The experiment is described in a scientific publication, J.J. Nickerson, Blood changes in humans following total body irradiation, in Industrial Medicine on the Plutonium Project, National Nuclear Energy Series, Vol. IV-20, pp. 308-337, McGraw-Hill, 1951. Page 309 contains the following comment on

clinical treatment:

"The people used in groups 1 and 2 were individuals to whom the medical profession could offer no treatment that was at all specific or known to be helpful. The x-ray exposures that were given were as likely to benefit the patient as any other known type of treatment, or perhaps even more likely than any other. Since this manuscript is concerned only with the effects on the blood, the clinical condition of the patients is not discussed at any length."

Group 1 consisted of 8 patients with cancer of the throat, mouth, breast, or larynx. These patients received total body doses of 27, 60, or 120 roentgen in single doses from x-rays. Group 2 consisted of one patient with cancer of the hand, one patient with chronic arthritis who had received no previous known radiation therapy, and one patient with joint stiffness and pain who had received local radiation therapy to the knee. These patients received 500, 300, and 100 roentgen, respectively of total-body doses in multiple doses from x-rays. The radiation produced no significant change in the arthritis of those two patients. Group 3 consisted of three young male subjects who were normal in every known respect. These subjects received 7 roentgen (r) on three

successive days, for a total of 21 roentgen from x-rays to each of them. Patients in groups 1 and 2 showed a decrease in the number of lymphocytes in the blood following radiation treatment. Group 3 showed no change in blood elements. For Group 3, the experimenters commented that

"These cases were of particular interest to us inasmuch as they indicated that acute exposure to far more than the maximum permissible level of 0.1 r per working day could not be expected to produce diagnostic changes in the elements of the peripheral blood which were studied." (Ibid., p. 336)

The summary factsheet which the Department of Energy submitted to the Subcommittee in January 1985 reported no follow up on these subjects.

Category 4. Teletherapy with Particle Beams.

These experiments consist of applications of cyclotron beams in attempts to treat patients suffering from cancer or other malignancies. The treatment was applied because conventional methods of therapy had often been unsuccessful in arresting the spread of disease. In some cases, the beam therapy proved more effective than conventional methods. In other tests, this therapy offered no advantages over existing methods and was discontinued. One item reported to the Subcommittee did seem disturbing, because experimental subjects received no apparent medical benefits. This item, in Category 4.006, is discussed below.

Category 4.004, Number 179.

Neutron Therapy Facility.

The follow up provisions of this experiment should be noted with approval. The objective of this activity is to determine the effectiveness of neutron beam irradiation as compared to standard irradiation for the management of certain malignant tumors. This project is carried out at the Fermi National Accelerator Laboratory, a facility owned by the Department of Energy, and is funded by the National Cancer Institute.

The project began in 1975 and is continuing.

Approximately 1400 patients have been referred to the program. Prior to treatment, patients must agree to comply with long-term follow up requirements, which include regular physical examinations and laboratory tests. Every effort is made to contact patients who miss scheduled appointments, and fewer than 1 percent of patients treated at this facility are currently considered lost to follow up. The benefits of radiation therapy, when expressed as enhanced survival rates, may be obvious. However, information on longer-term effects of radiation treatment will be useful in comparing results with other techniques in use presently or which may be developed in the future. The follow up efforts at the Fermilab project should be applauded, and should serve as a model that can be duplicated in other DOE investigations of medical therapy.

Category 4.006, Number 93.

Biological Effects of Heavy Ions on Human Nervous System and Vision.

During the early 1970s, human subjects were placed within neutron and ion beams at accelerators in Berkeley and Seattle. These experiments arose because astronauts had observed visual light-streak effects while exposed to cosmic rays in space flight. One objective of the experiments was to explore "visual

sensations" in humans from exposure to ions. Two subjects observed light flashes in neutron beams of peak energy of 640 million electron volts (MeV); six subjects observed light flashes and dim but definite streaks of 25 MeV peak energy; and two subjects observed light flashes and streaks due to helium ions impinging upon human retina.

These experiments were conducted by the Lawrence Berkeley Laboratory and were funded by the Atomic Energy Commission. They were reported in Nuclear Science Abstracts in 1972 and 1973. The summary factsheet provided by the Department of Energy reports no long term follow up on the human subjects.

Category 5. Other Teletherapy.

Projects in this category involved cases where patients whose cancer was not responding to conventional treatment were treated with various types of radiation from accelerators. As before, the Subcommittee staff does not question the propriety of these experiments because they contained a real possibility of benefit for patients.

Category 6. Treatment of Polycythemia.

This project was a ten-year attempt, beginning in 1939, to treat polycythemia vera with radiation. The radiation therapy seemed more successful than conventional means of treatment.

Category 7. Hematological Effects.

Most of the experiments in this category involved examinations of blood changes of patients who were being irradiated for purposes of diagnosis or treatment. The Subcommittee staff does not question these experiments, since the patients benefited or potentially benefited from the treatment, and the examination of blood changes could provide useful information in designing future treatment.

Category 8. Neutron Capture Therapy.

Projects in this category involved the use of beams of neutrons to treat patients with brain tumors. The Subcommittee staff does not question these experiments, since the radiation treatments were meant to benefit patients.

Category 9. Other Radiation Therapy.

Most of these projects involved the examination of radioactive isotopes for their ability to treat malignant diseases or to assist diagnosis by concentrating in tumor cells. One experiment, however, raised issues of concern and is discussed below.

Category 9.001, Number 166.

Uranium Injected Into Brain Tumor Patients.

From 1953 to 1957, approximately 12 terminal brain tumor patients were injected with uranium to determine the dose at which kidney damage began to occur. These experiments were conducted at Massachusetts General Hospital, Boston, with assistance from the Oak Ridge National Laboratory, and were funded by the Atomic Energy Commission.

The experiments were conducted to gain data in deriving tolerance doses for workers in uranium processing and fabrication plants. Inhaled or ingested uranium salts are known to produce kidney damage; these experiments were designed to identify the doses at which kidney damage began to occur. Data were also obtained during these experiments on the excretion and retention of uranium in the body. All subjects were terminal brain tumor patients who died within 18 months of the experiments.

An additional stated reason for conducting the experiment was as an initial evaluation of uranium toxicity in developing therapy to treat brain tumor patients with U-235. However, this does not in fact seem to be an important reason for the experiment, since no effort was made to actually treat the brain tumor patients with this isotope. Moreover, neutron capture therapy with U-235 has never been proven as an effective treatment for brain tumor patients.

Several scientific papers resulted from this experiment. One paper, Bernard et al., Proc. Health Physics Soc., 33-48, June 1956, reported the injection of 11 patients, 10 of whom were in coma or semi-coma. One of these patients died in 2.5 days, and one died 18 days after injection. Doses ranged from 4 to 50 milligrams (mg) of uranium. A second paper, A.J. Lussenhop et al., Am. J. Roentgenol. 79, 83-100, 1958, reported on the injection of five patients, four of whom were in coma or semicoma and remained so until their demise. Patients were injected with 4 to 15 mg uranium. The three patients with the highest doses, 0.12 to 0.28 mg uranium per kg body weight, showed evidence of kidney toxicity. Based on comparisons with animal data, the experimenters determined that a lethal dose for humans would have been 1 mg uranium per kg.

Another paper, S.R. Bernard, Health Physics 1, 288-305, 1958, reports on the injection of eight terminal brain tumor patients, six of whom were comatose. Doses ranged from 4 to 50 mg uranium. There may be some overlap among the patients covered by the three scientific papers. This last paper referred to earlier studies (which were the experiments reported in Category 1.003, Number 119), and notes that these studies lacked some information: "autopsy data were not obtained since none of the subjects were terminal patients." (S.R. Bernard, Ibid., 288) Using terminal subjects thus provided the "advantage" that the distribution of uranium in the body could be determined after autopsy.

Category 10. Biological Effects of I-131.

Category 10.001, Number 69

Study of Changes in Thyroids Irradiated with Radioactive Iodine.

This project, begun in 1951, is a retrospective study of the health of humans exposed to I-131, chiefly for medical reasons. The study has been carried out at Case Western Research University, and has been funded sequentially by the Atomic Energy Commission, the Energy Research and Development

Administration, and the Department of Energy. This is not considered an experiment, but the project shows clearly the necessity and usefulness of long term medical follow up of irradiated populations.

The significant non-patient population in this study is the group of Marshallese Islanders who were exposed to radioactive iodine from atomic bomb test fallout. The findings on this population were described in TID-27160, a June 1976 Progress Report to the Energy Research and Development Administration. The report noted the long latency period for the onset of clinical effects, and commented on the likely relation between exposure and thyroid nodules:

"The lengthy interval in man is clearly shown in the Marshallese where in spite of thorough annual physical examinations the first palpable nodule was not found for 9 years and neoplasms are still appearing at 22 years." (p. 4)

"To date 6 carcinomas have been removed from 10 individuals from several atolls, 3 from an atoll with extremely low exposure. Since this is a population which seldom if ever develops thyroid nodules, the relationship to the radiation which was primarily radioiodine is most impressive." (p. 4)

"At the time of the last annual report we described a 21 year old Marshallese who we had

just operated for multiple benign adenomas. He was 6 months in utero when his mother was exposed to fallout. The special studies of that thyroid tissue showed the bizarre nuclear forms recognized as evidence of radiation effect. At the time of preparation of this report, we have just operated and removed several benign but atypical adenomas from the thyroid of his mother who had developed masses in the last year." (p. 5)

" The factor of long delay in the development of neoplasms is emphasized in both animals and men.... The first Marshallese lesion did not develop for 9 years. Many of the early lesions came from the atoll with the highest fallout (Rongelap). It was quite some years later that lesions began appearing in people who were on the next nearest atoll (Alingnae) where the dose had been somewhat less. While lesions were appearing on the nearer atolls, the low dose received on an atoll much further away (Uterik) seemed to have produced no lesions, but in the most recent years, 8 individuals have been operated and 3 carcinomas found. These observations seem to emphasize the risk of the low dose range."

(p. 5).

"Nine years after the 1954 thermonuclear bomb accident, the first thyroid neoplasm appeared."

(p. 6).

Category 10.001, Number 165.

Milk Containing I-131 Fed to Humans.

In 1962, five human subjects drank milk containing radioactive Iodine-131, for periods of time ranging from 1 to 63 days. In the first experiments all subjects drank daily doses of I-131 milk for periods from 4 to 63 days. Doses each day were 150 or 1840 picocuries. The largest dose was 1840 picocuries per day for 63 days, for a total of 115,920 picocuries. In a second experiment, two of the same subjects drank single doses of 92,000 picocuries each. These experiments were funded by the Atomic Energy Commission and carried out by Oak Ridge National Laboratory.

The objective of the experiment was to validate calculations which standard setting organizations were using to establish occupational radiation exposure limits. Subjects drank the milk, radioactive iodine uptake was measured by counting the area around the thyroid, and excretion of iodine was also measured. Cows milk containing radioactive iodine was obtained from an AEC Agricultural Research Laboratory. The Department of Energy reported that no follow up of

subjects was conducted. These experiments were reported in a scientific paper, S.R. Bernard et al., Health Physics 9, 1307-1323, 1963.

Category 10.001, Number 173.

Planned Radioiodine Exposures to Humans.

From May 1963 to November 1965, radioactive iodine was released intentionally on seven separate occasions. On three occasions, human subjects were exposed. The experiments were funded by the Atomic Energy Commission and were conducted at the National Reactor Testing Station in Idaho.

The experiments were designed to improve knowledge of the transport of radioactive iodine, which is produced by nuclear reactors and nuclear bomb tests, through the air-vegetation-cow-milk sequence in the human food chain. This information was considered desirable in developing reactor siting criteria, in the preparation of safety analysis reports, and as an aid to planning for emergency action after a radiation accident.

Seven separate experiments were conducted. The general design was that radioactive iodine was released in gaseous form, and prevailing winds took the iodine over an area designated the "hot pasture." Monitoring devices in the pasture determined the radioactivity deposited. A herd of cows was then led

to the pasture to graze for several days. The cows were milked and the milk monitored for radioiodine. Humans were exposed either by drinking the milk or by direct exposure to the released iodine gas. The experiments collectively were called the Controlled Environmental Radioiodine Tests (CERT).

During Experiment CERT-1, conducted in May 1963, one curie of radioactive iodine was released into the hot pasture. Six cows were placed on the contaminated pasture. Cows were milked twice a day, and the milk from one cow saved for human ingestion. Seven human subjects each drank 0.5 liter of radioactive milk over a period of 18 days. Radioactive iodine uptake was determined by counting the thyroid of each subject. (IDO-12035, Controlled Environmental Radioiodine Tests at the National Reactor Testing Station, U.S. Atomic Energy Commission, June 1964).

Experiment CERT-2 was conducted in September 1964. Approximately one curie of radioactive iodine was again released over the hot pasture. Milk samples were again tested, but were not consumed by humans. Instead, three human subjects were placed on the pasture during iodine release, and their thyroids counted after exposure. This was not a food chain experiment, but was designed to measure the direct iodine dose from inhalation.

During Experiment CERT-3, conducted in December

1964, and CERT-4 and -5, both conducted in June 1965, no cows or humans were exposed, and measurements were only made on the pasture. Amounts of iodine released were lower than in previous tests. CERT-4 released 0.01 curie; CERT-5 0.1 curie; and the amount released in CERT-3 was not specified. (IDO-12047, Controlled Environmental Radioiodine Tests at the National Reactor Testing Station, 1965 Progress Report, U.S. Atomic Energy Commission, February 1966)

During Experiment CERT-6, conducted in summer 1965, radioactive iodine in the methyl iodide form was released. As the experiment progress report states:

"Unfortunately, several of the vials, each containing 2 curies of methyl iodide-131, were accidentally broken in transit or were leaking when received. Those that were not broken were subsequently opened in the hot cell of the Idaho Chemical Processing Plant (ICPP) and the methyl iodide (2 to 6 curies) escaped to the atmosphere from a 75-meter stack. The stack was located 4 kilometers upwind of the test grid at the Experimental Dairy Farm (EDF)."

(IDO-12053, Controlled Environmental Radioiodine Tests, Progress Report Number Two, U.S. Atomic Energy Commission, August 1966, p. 2)

Six cows grazed over the 27 acre area of the EDF,

and iodine concentration in their milk was determined by counting. In addition, "Several individuals were inadvertently exposed to airborne radioiodine from the leaking and broken containers, and efforts were made to obtain data on the retention of this form of iodine in humans." (Ibid., p. 2) These exposures from ruptured vials occurred over a four-day period, and a few people received multiple exposures; thyroids of these individuals were counted.

Experiment CERT-7 was conducted in November 1965; 1 curie of I-131 in the gaseous molecular form was released over the pasture at the EDF. Six cows grazed, and milk samples were counted. In addition, seven human volunteers were placed seated on the pasture area. Uptake of radioactive material was determined by counting the subjects' thyroids.

The Department of Energy reported to the Subcommittee that no medical follow up of the experimental subjects in the CERT tests was performed.

Category 11. Other Biological Effects.

Category 11.001, Number 51.

Reactions of Human Skin to Beta Rays.

During April and May 1945, two groups of 10 human subjects were exposed to plastic disks containing Phosphorus-32, which emits beta rays. These disks were placed directly on the skin to expose subjects. In one set of experiments, 10 persons were exposed to 140 to 250 rep (roentgen equivalent physical); in a second set of experiments, 10 subjects received a series of four exposures each in doses varying from 635 to 1180 rep. In most instances the forearm was the point of exposure, except for three cases in the second series where the inner mid-thigh was exposed. These experiments were funded by the Manhattan Project and were carried out in Clinton Laboratory, Oak Ridge, Tennessee. (One roentgen equivalent physical of beta rays is approximately one rem. For comparison, present occupational exposure limits are 30 rem per year to the skin, and 75 rem per year to hands and forearms.)

The objective of this experiment was to determine the beta ray dose at which skin erythema (reddening of the skin) would first be seen. In the first set of experiments, 8 of 10 subjects showed a "visible reaction" of mild tanning at a dose of 250 rep. In

the second set of experiments, 6 subjects showed erythema at 635 rep, and 8 showed erythema at 813 rep. These experiments were reported in J.E. Wirth and J.R. Raper, Chapter 12, Biological Effects of External Beta Radiation, National Nuclear Energy Series, Volume IV-22E, McGraw-Hill, 1951.

The Department of Energy reported no follow up on these subjects.

Category 11.001, Number 53.

Studies of Radium Applied to Human Skin.

During 1955, experiments carried out on human subjects demonstrated that the biological effects of Thorium X (Radium-224), as judged by erythema and skin pigmentation, can be increased by using an electrical current to cause greater penetration of the skin by radioactive material. These experiments were carried out at New York University and were funded by the Atomic Energy Commission.

Three subjects were exposed in these experiments. During the experiment, squares of blotting paper saturated with Radium-224 were placed on the forearms of each subject. An electric current was applied for 20 minutes to the paper on the left forearm, and no current was applied to the right forearm. For each patient, the left forearm showed intense reddening after 48 hours, and some skin pigmentation at 75 days

after exposure; the right forearms showed no visible reactions at the same times. The Department of Energy estimated that doses to the right forearm were 350 rem, and 1000 rem to the left forearms. Irradiated tissues were surgically removed, and no medical follow up on subjects was conducted. For comparison with the doses, present occupational exposure limits are 75 rem per year to the hands and forearms. These experiments were reported in AECU-3061, Atomic Energy Commission, a publication presented at the Sixteenth Annual Meeting of the Society for Investigative Dermatology, 1955. This publication discusses the application of Thorium X to certain skin diseases, but there is no indication that any of the subjects received medical benefit from the experiment.

Category 11.001, Number 83.

Analysis of Illness of Children Receiving Fetal Irradiation.

In 1948, a program of routine pelvis examination by x-ray early in pregnancy for 1008 mothers who were to bear their first child was carried out at Chicago Lying-In Hospital. The objective of the exposures was to make delivery and labor more predictable and easier by measuring the sizes of pelvis and fetal head. In preceding and succeeding years, no such measurements were made and these groups serve as a control

population. The estimated tissue dose to the pelvis for irradiated mothers was 1.5 to 3 rem. About half of these children were also exposed to 5 x-ray films during the first day of life. The estimated dose to new-born infants was 0.5 rem.

The Atomic Energy Commission subsequently funded the Argonne Cancer Research Hospital to conduct analyses of health of the exposed children. Between 1962 and 1965 the parents of these children were contacted and asked for information on diseases and hospitalization. The first study found an increase in benign hemangiomas, a tumor which produces skin discoloration, but no increase in congenital malformations, eye diseases, or malignant tumors. A second survey made between 1966 and 1970 confirmed the results of the first follow up. The Department of Energy commented in 1985 that, "It is hoped that further data will be obtained from these subjects and if possible from their children."

Category 11.001, Number 112.

Human Absorption of Tritium Oxide Through Skin.

During 1951, 14 human subjects were exposed over a small area (about 10 square centimeters) on the forearm (12 subjects) or abdomen (2 subjects) to a water-vapor atmosphere labeled with tritium oxide (HTO). A single subject was in addition exposed over

his total skin area while breathing uncontaminated air. Absorption of tritium oxide was estimated by measurements of tritium excreted in urine. The data from these experiments indicated that humans absorbed tritium at a rate 4 times faster than measured for rats. These studies were funded by the Atomic Energy Commission and were conducted by the General Electric Company, Richland, Washington.

The objective of these experiments was to determine the rate of absorption of tritium oxide through human skin. This information would assist in evaluating the hazard to individuals who might handle tritium, which had promise of becoming a widely used tracer isotope for hydrogen. The Department of Energy reported that no medical follow up was carried out on these subjects. These experiments were reported in C.W. DeLong et al., Am. J. Roentgenol. Radium Therapy Nucl. Med. 71, 1038-1045, 1954.

Category 11.001, Number 121.

Effects of X-Rays on Human Fingers.

During 1947, fifteen subjects were exposed in the nail fold area of the left fourth finger to doses of 200 to 600 roentgen. (For comparison, present occupational exposure limits are 75 roentgen per year to the hands.) Fourteen of these subjects were patients being treated by x-rays or radium for other

purposes, but none of them had received previous irradiation to the hands. The other subject was a staff member who occasionally prepared radium material for treatments. He was observed before and after the preparation of an item containing 130 milligrams of radium. These experiments were funded by the Atomic Energy Commission and were conducted at the University of Chicago.

The objective of the experiment was to examine the changes which may occur in the fingers of persons occupationally exposed to radiation. The left fourth finger was chosen for irradiation because the skin is fairly thin as compared to other fingers, and this finger is "less likely to have been subjected to previous trauma." Microscopic observations were made of the fingers before and immediately after treatment, and for up to two weeks after treatment. Some irradiated patients showed temporary symptoms such as enlarged or broken blood vessels, or reddening of the skin. The report on the experiment noted no permanent changes to the skin of the finger, and concluded with the statement, "It is proposed that test doses be given at higher levels." (CH-3833, Effect of Single Dose X-Ray to the Nail Fold Area of Human Subjects, Preliminary Report, July 1947, p. 4) However, no further experiments were reported. The Department of Energy reported no medical follow up of the subjects.

Category 11.001, Number 123.

Human Absorption and Excretion of Tritium.

During 1950, human subjects were exposed to tritium in several different experiments. Subjects were exposed to tritium in air for two hours, and the increase in tritium in body fluids was followed over time. In a second experiment, the arm of a man was immersed up to the elbow in water containing tritium, and the tritium in body fluids was again followed. In a third experiment, a man drank tritium in 0.2 liters of water and absorption into the blood stream was followed. Amounts of tritium administered were up to 3 millicuries. (For comparison, the maximum permissible body burden for occupational exposure is 2 millicuries.) These experiments were funded by the Atomic Energy Commission and carried out at Los Alamos Scientific Laboratory.

The objective of the experiment was to obtain information on the human absorption and excretion of tritium, to aid in the setting of occupational exposure limits. The exact number of subjects exposed is not clear, but it appears that one subject immersed an arm in tritiated water, one subject drank tritiated water, and seven subjects were exposed to air containing tritium. These experiments were summarized in AECU-937, The Absorption, Distribution,

and Excretion of Tritium in Men and Animals, U.S. Atomic Energy Commission, November 1950. The Department of Energy reported no medical follow up of subjects.

Category 11.001, Number 125.

Human Absorption of Tritium Liquid and Vapor.

During 1952, the lower arms of subjects were exposed for variable lengths of time to tritiated water vapor and tritium in liquid water. Tritium activity in subjects' urine was monitored. The Department of Energy provided no further details on this experiment, and reported no follow up of subjects.

Category 11.001, Number 126.

Human Absorption of Tritium by Lung.

During 1952, three subjects were exposed in five experiments to tritiated water vapor. Subjects breathed tritium-saturated oxygen for 4 to 5 minutes. The tritium retained in the body during the exposure was obtained by comparing the tritium inhaled with the tritium exhaled. Retention and excretion of tritium with time were monitored through blood and urine samples. This experiment was funded by the Atomic Energy Commission and carried out at Los Alamos Scientific Laboratory.

Subjects inhaled from 0.8 to 1.0 millicuries of tritium. This can be compared with the maximum permissible body burden of 2 millicuries.

The objective of the experiment was to obtain information on absorption and retention of tritium to aid in establishing occupational exposure standards. The experiment is reported in LA-1465, Lung Absorption of HTO by Man Upon Inspiration of HTO Water Vapor, Los Alamos Scientific Laboratory, June 1952. The Department of Energy reported no medical follow up of the subjects.

Category 11.001, Number 127.

Human Absorption of Ingested Tritium Water.

During 1952, five experiments were conducted on three subjects in which the subjects drank water containing tritium. Retention of tritium in the body was examined by taking blood and urine samples over time and counting. The experiments were funded by the Atomic Energy Commission and were carried out at Los Alamos Scientific Laboratory.

The objective of the experiments was to obtain data that would assist in evaluating the hazard of ingested tritium. Two subjects each drank 1.6 millicuries of tritium; the third subject drank 6.2 millicuries in three separate experiments. For comparison, the occupational body burden is 2

millicuries. The experiments are reported in LA-1464, The Absorption of Ingested Tritium Water and the Water Dilution Volume of Man, Los Alamos Scientific Laboratory, June 1952. The Department of Energy reported no follow up on the subjects.

Category 11.001, Number 133.

Radiation Exposure of Aircrews in Mushroom Clouds.

The U.S. Air Force sent manned planes through radiation clouds ("mushrooms and stems") from atomic bomb tests to measure radiation doses in the clouds and to the crews. The detonations were part of Operation Redwing, a series of 17 nuclear tests in the multi-megaton range, at Eniwetok and Bikini Atolls in the Pacific, from May-July 1956. The planes, five different B-57Bs, made 27 passes through clouds from six different nuclear explosions, at times from 20 to 78 minutes after detonation. 16 passes were earlier than 45 minutes and 7 were earlier than 30 minutes after detonation.

Maximum radiation doses in the cloud were 800 roentgens per hour. Total radiation doses to crew members were as high as 15 roentgens by film badge. (For comparison, the present maximum annual dose for workers is about 5 roentgen; one chest x-ray represents 0.02 to 0.04 roentgen.)

The objective of the project was to obtain

radiation dose information, in the event that an "operational situation" required flights through such clouds. The information was to assist Air Force commands in planning to insure the "most-effective utilization, consistent with crew safety, of aircraft in cloud areas."

Earlier operations had been conducted where drone aircraft were sent through clouds to obtain dose information. The report also mentions manned penetrations made during Operation Teapot. These passes were made from 17 to 41 minutes after detonation. The report on Redwing deletes information on doses measured during the Teapot flights, and gives no reference to any other published report on Teapot. The Redwing flights are described in ITR-1320, Preliminary Report, Operation Redwing: Early Cloud Penetrations, Armed Forces Special Weapons Project, May-July 1956.

On November 13, 1985, the Subcommittee chairman released this document to make it available for a hearing before the Senate Veterans Affairs Committee the following day on compensation for veterans exposed to atomic tests. The document was described in subsequent press accounts.

The Department of Energy reported no medical follow up on the exposed aircrews. However, subsequent correspondence between the Subcommittee and

the Defense Department provided more information. The Defense Nuclear Agency (DNA) reported that seven of the Redwing crew members received doses greater than five rem by film badge, and were notified by the Nuclear Test Personnel Review (NTPR), a program to identify veterans exposed during atomic testing. Under this program, persons with exposures greater than five rem per year are notified and encouraged to undergo a special physical examination at the nearest Veterans Administration hospital. None of these seven have reported medical problems attributable to radiation exposure.

In addition, the Redwing aircraft were contaminated with radioactive material as a result of flying through the clouds. The planes were subsequently decontaminated by ground personnel. The DNA retains the exposure records of these personnel, as well as those of all aircrew members, and all these personnel are recorded as part of the NTPR. The DNA maintains a toll free number which veterans who believe they were exposed to atomic tests can call to report their circumstances. (Letter from Lieutenant General John L. Pickitt, Director, Defense Nuclear Agency, to the Subcommittee Chairman, December 11, 1985.)

In December 1985, Chairman Markey joined with Senator Cranston to request a General Accounting Office investigation on atomic cloud fly-through operations. GAO was asked to determine how many air crew members and how many ground personnel were exposed during Redwing and other such operations, what doses these personnel received, and what follow up the Defense Department has conducted on all personnel.

Category 11.001, Number 134.

Radioactive Material Placed on Human Skin.

In 1953, Foster D. Snell, a consulting firm, placed synthetic radioactive soil on the palms of over one hundred human subjects, and examined the ability of different cleaning agents to remove the radioactive material. The objective of this experiment was to determine the efficiency of various cleaning agents in removing radioactive contaminants from "human skin and hair."

These experiments were performed for the Chemical and Radiological Laboratories of the Department of the Army, and were reported in a U.S. Atomic Energy Commission technical publication, Removal of Radioactive Contaminants from Human Skin, NP-4935, June 15, 1953. It appears that at least part of the reason for conducting the experiments was to provide information that could be used on a battlefield during

a nuclear exchange, since there is a reference to decontamination "from the point of view of the soldier in the field." (NP-4935, pp. 165,166)

For the experiments, a drop of a liquid mixture of radioactive material was deposited on the palms or arms of human subjects, allowed to dry, and counted with a Geiger counter. The contamination was then washed off with various cleaning agents, and the skin counted again to determine efficiency of removal. Initial experiments were conducted on metallic surfaces, then on rabbits and pigs. Preliminary work was also done on hair removed from humans, and then on 16 human subjects. Most of this work was done with a suspension of "synthetic soil," a mixture composed chiefly of soil, sand, and clay, mixed with fission products. Some experiments were performed with synthetic soil which had been irradiated in a nuclear reactor, synthetic soil mixed with Carbon-14, or a sample of soil from the Nevada test site. These other mixtures did not adhere well to skin, and were not used in later experiments. In these first human experiments, solutions registering up to 2900 counts per minute were placed on subjects' forearms or palms. These experiments showed that it was most difficult to wash radioactivity from palms, and most subsequent experiments placed the radioactive material on palms only.

Subsequent experiments were conducted on about 102 different human subjects, placing larger amounts of radioactivity, typically 10,000 to 20,000 counts per minute, on subjects' palms. A variety of detergents and hand creams were examined for their ability to remove the radioactive contamination. One set of experiments was conducted with "radiological warfare agents," composed of small pellets of zinc bromide which contained radioactive Tantalum. Droplets containing 13,000 to 49,000 counts per minute of these agents were placed on the palms of six human subjects.

One set of experiments was conducted with employees at the Monsanto Chemical Company's Mound Laboratory, Miamisburg, Ohio. A mixture of contaminants containing alpha emitters, and not further identified, was placed on the palms of four employees and detergents tested for removal. In addition, detergents were tested on the hands of three other employees "whose hands were contaminated in the normal course of work." (NP-4935, p. 152).

Except for the experiments at Mound Laboratory, the Department of Energy has not been able to identify where these experiments were conducted or how the 118 human subjects were obtained. Subjects were male and female, and ranged in age from 18 to 66. The Department of Energy reported no medical follow up on any of these subjects.

Category 11.001, Number 183.

Medical Follow Up Studies.

In its factsheet on this project, the Department of Energy described follow up studies to assess the long range health of several different populations which have been exposed to radiation. These studies have been funded by the Atomic Energy Commission, the Energy Research and Development Administration, and the Department of Energy. Some of them started in the 1950s, and they continue at present. The studies are being carried out at the Argonne Cancer Research Hospital (ACHR), Argonne National Laboratory. The studies are described below:

1. For 20 years, a joint study of more than 400 persons bearing a considerable body burden of radium has been under way. Most of these persons were painters of the radium dials on luminous watches at various plants in the Illinois River valley region during 1920-1930; others received radium chloride by injection or orally as a medical treatment between 1920 and 1933. Persons with a considerable body burden of radium were found to have characteristic defects, destructive changes, and tumors in the skeleton. These studies include accurate estimates of the body content of radium by using a total body counter; through analysis of the expired breath for

the gas radon, a radium decay product; by film exposure from subjects' bodies; and through studies of the blood to reveal if destructive or malignant changes have taken place.

2. A long term follow up study is under way to examine about 1000 children who were exposed before birth to x-rays during pelvic examinations of their mothers. This study, which extended over about 25 years, is described as Category 11.001, Number 83.

3. A follow up study is under way on patients who had received radiation therapy for stomach ulcers. This study was funded by the Department of Energy, and revealed "some positive findings," which are not further specified. The study is now to be resumed under support from the National Institutes of Health.

4. During the 1950s, persons who received short treatments with low-voltage x-rays for benign conditions of the head, neck, and upper thorax during childhood were studied for possible development of carcinoma of the thyroid. All of the children with cancer of the thyroid who had been treated or seen by the investigator had been irradiated previously in such a way that the thyroid gland or portions of it had been included in the radiation field.

Category 11.001, Number 186, Part A.

Human Ingestion of Fallout.

Concern about problems from the ingestion of fallout led to studies using real fallout from the Nevada Test Site; simulated fallout particles that contained Strontium-85, Barium-133, or Cesium-134; and solutions of Sr-85 and Cs-134. During 1961 to 1963, real and simulated fallout and solutions of strontium and cesium were fed to 102 human subjects. Absorption and retention of the ingested radioactivity was measured by counting the bodies of subjects. These experiments were funded by the Atomic Energy Commission and were carried out by the University of Chicago and the Argonne National Laboratory. Subjects were university students or members of the researchers' staffs.

Several different fallout or simulated fallout materials were prepared. One set of experiments used microscopic spheres of radioactive strontium, cesium, or barium. A total of 27 volunteers ingested the spheres. Transit time of the spheres through the gastrointestinal tract was measured by counting excreted matter. A second set of experiments used real fallout, obtained from the Nevada Test Site following land detonation of the nuclear test Small Boy, on July 14, 1962. Fallout samples were placed in gelatin capsules and were fed to 10 subjects. In

these and subsequent experiments, retention of activity was followed by counting subjects' bodies.

Two types of simulated fallout were also prepared. They were distinguished by the size of microscopic spheres used, which simulated the size of fallout particles close to or far from the site of detonation. 21 subjects were fed simulated local fallout, and 22 simulated distant fallout. Finally, 22 subjects were fed solutions of strontium or cesium. The amounts of radioactive material fed to subjects in all experiments ranged from 0.4 to 2.5 microcuries of Strontium-85, or 0.5 to 14 microcuries of Cesium-134. These values can be compared with the maximum permissible occupational body burdens of 60 microcuries for Strontium-85, and 30 microcuries for Cesium-134.

The Department of Energy reported no long term medical follow up on these subjects. These experiments were reported in a scientific paper, G.V. LeRoy et al., Health Physics 12, 449-473, 1966.

Category 11.001, Number 186, Part B.

Lanthanum-140 Administered to Humans.

The paper cited in Number 186, Part A, G.V. LeRoy et al., reported an earlier study in which 54 hospital patients were fed radioactive Lanthanum-140, and the passage of material through the gastrointestinal tract

was measured by counting excreted matter. It appears that the Department of Energy did not report to the Subcommittee on this experiment, but it was published in R.L. Hayes et al., Health Physics 9, 915-920, 1963, and the Subcommittee obtained a copy of the original reference from the Library of Congress, Congressional Research Service. This experiment was carried out at the Oak Ridge Institute of Nuclear Studies, and was funded by the Atomic Energy Commission.

The objective of this experiment was to measure the movement of radioactive material through the human body, and estimate the dose to the lower large intestine from materials that the body does not absorb. The experimenters noted that movement through the body varied with individuals, and these experiments attempted to measure the extent of such variation.

Subjects were fed 10 or 20 microcuries of Lanthanum-140. (For comparison, the maximum permissible body burden for occupational exposure is 10 microcuries.) Movement of this substance through the body was examined by collecting fecal samples and counting. Subjects were patients from the clinical program at the Oak Ridge Institute, and ranged in age from 7 to 76. All subjects were selected because they had normal intestinal tracts, which were not affected by their diseases. Subjects thus received no medical

benefit from the experiment. To measure variability in individuals, 8 subjects were fed lanthanum twice, and one was fed three times.

Category 12. Metabolic and Physiological Studies.

Category 12.001, Number 15.

Strontium and Calcium Injected in Terminal Cancer Patients.

The material which the Department of Energy submitted to the Subcommittee on this project included ANL-6104, a 1959 report from the Argonne National Laboratory. This report summarized data on the retention by humans of calcium, strontium, and radium. One of the references cited was Schulert et al., Int. J. Applied Radiation and Isotopes 4, 144-153, 1959. The Department of Energy did not supply this reference, but the Subcommittee obtained a copy of the original through the Library of Congress, Congressional Research Service.

In these particular experiments, radioactive Calcium-45 or Strontium-85 were injected into twelve terminal cancer patients, and the distribution of each substance in tissue and bone was determined at autopsy. These experiments were carried out at Columbia University and the Montefiore Hospital,

Bronx, New York.

The objective of these experiments was to measure the absorption by different parts of the body of strontium, a product of nuclear fission and a component of nuclear weapons fallout. In order to help evaluate the hazards of strontium to humans, the experimenters desired to determine the retention by different tissues of strontium compared to calcium; strontium mimics calcium chemically and concentrates in bone. As the scientific paper explained, subjects were chosen so they could be autopsied fairly soon after injection: "Since autopsy analyses were employed, the patients were, of necessity, of limited life expectancy with cancer involvement, and cannot be considered as normal healthy adults." (Schulert et al., 145)

Ten patients were injected with about 1.5 microcurie per kilogram body weight of Strontium-85, and about 0.4 microcurie per kilogram of Calcium-45. Total doses would have been 64 to 114 microcuries of strontium, and 17 to 30 microcuries of calcium. For comparison, the occupational maximum permissible body burdens are 60 microcuries for Strontium-85, and 200 microcuries for Calcium-45. These patients lived from 3 hours to 124 days. An additional terminal patient injected with strontium only survived for 251 days, and one patient injected with calcium only survived

for 960 days. Patients ranged in age from 49 to 72.

Category 12.001, Number 109.

Technetium Administered to Humans.

During 1965, Technetium-95 (metastable) and -96 were administered to 8 subjects. Retention and absorption of technetium were monitored by counting the bodies of subjects and by counting excretions. Doses were administered to subjects at the University of Washington, counting was carried out by the Pacific Northwest Laboratory, Richland, Washington. The Atomic Energy Commission funded the work of the Pacific Northwest Laboratory.

Technetium is a product of nuclear fission and is present in rather high concentrations in wastes from nuclear reactors. At the time of these experiments, technetium was being separated from nuclear wastes at the federal facility near Richland, Washington. In addition, technetium was also used for medical diagnoses. The objective of these experiments was to obtain information on the retention of technetium in the body, to help assign occupational exposure limits.

Four subjects were injected, and four subjects were fed technetium. Each subject received 20 microcuries of Tc-95m and 60 microcuries of Tc-96. (For comparison, the occupational maximum permissible body burdens are 70 microcuries for Tc-95m and 10

microcuries for Tc-96.) Samples of sweat, plasma, tears, urine and feces were collected, and observations were made for up to 60 days on some subjects.

These experiments were reported in a scientific paper, T.M. Beasley et al., Health Physics 12, 1425-1435, 1966. The Department of Energy reported there was no long term follow up of these subjects.

Category 12.001, Number 110.

Promethium Administered to Humans.

In 1967, Promethium-143 was administered to 14 subjects. Absorption and retention were followed by counting the bodies of subjects, and by measuring the activity in blood and excretion samples. 6 subjects were injected with promethium and observed for retention. 2 subjects drank orange juice with promethium in solution. 6 subjects were injected with promethium and then injected with the chelating agent diethylenetriaminepentaacetate (DTPA), and the ability of DTPA to remove promethium from the body was examined. These experiments were funded by the Atomic Energy Commission and were carried out by the Hanford Environmental Health Foundation and the Battelle Memorial Institute, both at Richland, Washington.

The experiments were conducted to determine the uptake, retention, distribution, and excretion of

promethium in humans. The information obtained would help to develop an excretion model for diagnosis of promethium in humans, to form a basis for radiation exposure, and to determine the dose from accidental exposures. These considerations were relevant to occupational exposure of persons handling promethium.

Injected subjects received 0.1 microcuries of promethium. Two subjects drank 10 microcuries of promethium. Administered preparations were mostly Pm-143, but some Pm-144 was also present. Little promethium was retained by the two subjects who drank it. However, about half of the injected promethium deposited in the liver within a few minutes, and most of the remaining promethium deposited in the bone within the next 5 hours. Subjects were followed for one year, during which this distribution remained unchanged. The effectiveness of DTPA in enhancing excretion of promethium declined with time: When DTPA was injected 30 minutes after promethium, it removed 90 percent of the radioactive material; after 24 hours, it removed only 25 percent; and after 80 days, it removed only 5 percent.

These experiments were reported in a scientific paper, H.E. Palmer and I.C. Nelson, Health Physics 18, 53-61, 1970. The Department of Energy reported that no follow up was conducted beyond the one year observation after the experiment.

Category 12.001, Number 111.

Phosphorus-32 Injected into Humans.

During 1963, five subjects were injected with Phosphorus-32. Three of the subjects were patients at the University of Oregon Medical School who received the P-32 as part of the therapy for blood diseases. The other two subjects were injected at the Swedish Hospital in Seattle for purposes only of calibrating equipment. These experiments were funded by the Atomic Energy Commission and carried out by the Battelle Memorial Institute, Richland, Washington.

The reasons for carrying out these experiments were described in a scientific paper:

"Fish and waterfowl that feed in the Columbia River downstream from the Hanford reactors acquire some radionuclides that enter the river with the effluent water (1). ^{32}P and ^{65}Zn are the principal nuclides found, and suckers and whitefish usually contain the greatest concentration of these nuclides. Since sportsmen obtain and eat the waterfowl and fish from the Columbia River below Hanford, a method of measuring the low level body burden of these nuclides in humans is needed. Since ^{65}Zn is a gamma emitter, body burdens down to 1 nc [nanocurie] can easily be measured in a

whole-body counter. Foster (2) has described an experiment in which a subject ate a weekly meal of whitefish and the accumulation of the $^{65}\text{-Zn}$ in the body was studied. $^{32}\text{-P}$ does not emit a gamma ray and it is much more difficult to measure. This paper describes a method by which body burdens of $^{32}\text{-P}$ down to 40 nc can be measured."

(H.E. Palmer, Health Physics 12, 605-608, 1966. References 1 and 2 are publications designated HW-80991, 1964; and HW-SA-3060, 1963. These are probably Atomic Energy Commission documents.)

One subject was injected with 425 nc of P-32. A second subject was injected with 500 nc, then reinjected after 28 days with 425 nc more. Injection doses for the other subjects were not reported. This same scientific paper reported another experiment where humans ate radioactive fish:

"One reason for developing a sensitive, in vivo counter for $^{32}\text{-P}$ was to measure people who eat Columbia River fish. The significance of this intake with relation to the maximum permissible body burden has been discussed in another publication. (1) Five subjects ate 3/4 lb each of whitefish which had been caught in the Columbia River. After allowing 1 day for

absorption of the 32-P, the subjects were measured for 20 min with the [radiation] counter and showed body burdens of 70, 110, 89, 72, and 93 nc.... The maximum permissible body burden for occupational exposure is 6000 nc.: (Ibid., 607. Reference 1 is HW-80991.)

The Department of Energy reported that no follow up was conducted on these experimental subjects.

Category 12.001, Number 128.

Humans Inhaled Tritium.

During 1950, six subjects each inhaled "a few" millicuries of tritium. (For comparison, the maximum permissible occupational body burden for tritium is 2 millicuries.) Tritium concentration in urine was monitored for the following 15 days. These experiments were funded by the Atomic Energy Commission and were carried out at the Los Alamos Scientific Laboratory, New Mexico.

The objective of this experiment was to investigate the rate of appearance of tritium in urine. This knowledge would help in the establishment of occupational exposure limits. No follow up on these subjects was reported.

Category 12.003, Number 174.

Radioactive Material Administered to Humans to Calibrate Equipment.

Between 1965 and 1972, 8 individuals were involved in 13 different human experiments. All eight were employees of the Idaho Division of the Atomic Energy Commission. In four experiments, subjects inhaled Argon-41; in nine experiments, subjects swallowed capsules containing microcurie amounts of radioactivity. These experiments were funded and carried out by the Atomic Energy Commission.

The objective of this experiment was to calibrate instruments that measure radioactive substances inside the human body; such instruments are usually used to examine workers accidentally exposed or hospital patients receiving radioactive material for diagnostic purposes. A secondary objective of the experiments was to examine the metabolism of radionuclides ingested or inhaled by humans.

Some of these experiments were reported in scientific papers. In the first set of experiments, one subject was fed one microcurie of Manganese-54; another subject was fed an unspecified amount of Iodine-131 (J.I. Anderson and D.G. Olson, Health Physics 13, 719-732, 1967) In a second set of experiments, individual subjects were fed 3.5 microcuries of Cesium-132, 1.9 microcuries of

Potassium-42, or 1.1 microcuries of Manganese-54. In addition, 4 subjects inhaled Argon-41 in amounts of 1.3 to 2.2 microcuries (D.G. Olson, Health Physics 14, 439-447, 1968). In a third experiment, one subject was fed 1.5 microcuries each of Cobalt-60 and Cesium-137 (J.I. Anderson and D.G. Olson, Health Physics 23, 325-332, 1972).

The Department of Energy reported there was no medical follow up of any of these experimental subjects.

APPENDIX

Current Federal Regulations on the Protection of Human
Subjects

Current regulations on the use of human subjects for experiments are described in Title 45, Code of Federal Regulations, Part 46 (45 CFR 46), revised as of October 1, 1985. These regulations call for special requirements when prisoners, children, or other specified categories of persons are used as subjects.

General Provisions:

Experiments on human subjects must satisfy the following criteria:

- 1) Risks to subjects should be minimized.
- 2) Risks to subjects should be reasonable in relation to anticipated benefits, and the importance of the knowledge that may reasonably be expected to result.
- 3) Subjects should be selected in an equitable manner.
- 4) Informed consent shall be sought from each prospective subject or the subject's legally authorized representative. Informed consent includes a clear description of the risks and benefits of the experimental procedure. (45

CFR 46.111)

Prisoners:

Biomedical or behavioral research may involve prisoners as subjects only if the purpose of the proposed research is to:

- 1) study the possible causes, effects, and processes of incarceration or of criminal behavior;
- 2) study prisons as institutional structures or prisoners as incarcerated persons;
- 3) conduct research on conditions particularly affecting prisoners as a class (for example, vaccine trials or other research on hepatitis, which is more prevalent among prisoners than the general population);
- 4) examine practices, both accepted and experimental, which have the intent and reasonable probability of improving the health or well-being of the subject. (45 FR 46.306)

Children:

A child is an individual who has not attained the legal age for consent to treatments or procedures involved in the research, under the applicable laws of the location where the research is to be conducted (45 FR 46.402)

A child may be used as a subject only upon receipt of permission from parents and assent from the child, under conditions where the child is judged capable of providing assent (45 FR 46.408). If permission and assent are obtained, research can be conducted only if one of the following conditions is met:

- 1) The research poses no greater than minimal risk (45 FR 46.404).
- 2) The research presents more than minimal risk, but the procedure holds out the prospect of direct benefit for the individual subject or is likely to contribute to the subject's well-being (45 FR 46.405).
- 3) The research presents more than minimal risk, does not hold out the prospect of direct benefit to the subject, but the procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for understanding the disorder or condition (45 FR 46.406).
- 4) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children (45 FR 46.407).

Other Subjects:

Where some or all of the human subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards must be included in the study to protect the rights and welfare of these subjects. (45 FR 46.111)

It should be noted that under these regulations, the experiments previously described with prisoners, and which used minors as subjects, would have been strictly prohibited. In addition, many other experiments used patients with severe illnesses or who were disadvantaged, and there is no indication that safeguards were incorporated into the experiments to protect these subjects.

JAN 14 REC'D 10:25am

Carol is name
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GAP

WHITE HOUSE STAFFING MEMORANDUM

ACTION/CONCURRENCE/COMMENT DUE BY: 1-14 NDDM

REC. ORDER ESTABLISHING RADIATION
ADVISORY Comm. file

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	GRIFPIN	<input type="checkbox"/>	<input checked="" type="checkbox"/>
McLARTY	<input checked="" type="checkbox"/>	<input type="checkbox"/>	QUINN	<input type="checkbox"/>	<input type="checkbox"/>
NEEL	<input type="checkbox"/>	<input type="checkbox"/>	RASCO	<input checked="" type="checkbox"/>	<input type="checkbox"/>
PANETTA	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RUBIN	<input type="checkbox"/>	<input type="checkbox"/>
BAGGETT	<input type="checkbox"/>	<input type="checkbox"/>	SEGAL	<input type="checkbox"/>	<input type="checkbox"/>
EMANUEL	<input type="checkbox"/>	<input type="checkbox"/>	SEIDMAN	<input type="checkbox"/>	<input type="checkbox"/>
GEARAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	STEPHANOPOULOS	<input type="checkbox"/>	<input type="checkbox"/>
GERGEN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	TYSON	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GIBBONS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	VARNEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
HALE	<input type="checkbox"/>	<input checked="" type="checkbox"/>	WATKINS	<input type="checkbox"/>	<input type="checkbox"/>
HERMAN	<input type="checkbox"/>	<input type="checkbox"/>	WILLIAMS	<input type="checkbox"/>	<input type="checkbox"/>
LAKE	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Clerk	<input checked="" type="checkbox"/>	<input type="checkbox"/>
LINDSEY	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
McGINTY	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
MYERS	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
NUSSBAUM	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

REMARKS: Any comments on this E.O. must come in promptly. Plan is to have it

RESPONSE: cleared and executed today.
TODD

JOHN D. PODESTA
Assistant to the President
and Staff Secretary
Ext. 2702



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

January 13, 1994

94 JAN 14 09:10

MEMORANDUM FOR THE PRESIDENT

FROM: Leon E. Panetta
Director 

SUBJECT: Proposed Executive Order Entitled "Advisory
Committee on Human Radiation Experiments"

SUMMARY: This memorandum forwards for your consideration a proposed Executive order that was prepared by the Human Interagency Radiation Working Group ("Group"). The proposed Executive order would establish an advisory committee to provide advice and recommendations to the Group.

BACKGROUND: The proposed order would establish the "Advisory Committee on Human Radiation Experiments" ("Committee"). The Committee would be composed of not more than 15 members to be appointed or designated by the President and would report to the Group. The Committee would provide advice and recommendations to the Group on the ethical and scientific standards applicable to human radiation experiments carried out or sponsored by the United States Government. It could review experiments conducted from 1944 to the present.

Among other things, the Committee would determine the ethical and scientific standards and criteria by which it would evaluate the human radiation experiments as defined in the order. It may recommend policies to ensure compliance with recommended ethical and scientific standards for human radiation experiments. It would carry out such additional functions as the Group may request. The Committee would be funded by the Department of Energy and it would terminate 30 days after submitting its report to the Group.

None of the affected agencies objects to the proposed Executive order.

RECOMMENDATION: I recommend that you sign the proposed Executive order.

Attachment



U.S. Department of Justice

Office of Legal Counsel

Office of the
Deputy Assistant Attorney General

Washington, DC 20530

January 13, 1994

MEMORANDUM

Re: Proposed Executive Order Entitled "Advisory
Committee on Human Radiation Experiments"

The attached proposed Executive Order was prepared by the Human Radiation Interagency Working Group ("Working Group"). The Office of Management and Budget, with the approval of the Director, forwarded it to this Department for review with respect to form and legality.

The proposed Order will establish the Advisory Committee on Human Radiation Experiments ("Committee"). The Committee would be composed of not more than 15 members, all appointed by the President. The Committee would provide to the Working Group advice and recommendations on the ethical and scientific standards applicable to certain human radiation experiments carried out or sponsored by the United States Government. It would terminate thirty days after submitting its final report to the Working Group.

The proposed Order is approved with respect to form and legality.

A handwritten signature in cursive script that reads "Dawn E. Johnsen".

Dawn E. Johnsen
Deputy Assistant Attorney General



U.S. Department of Justice

Office of Legal Counsel

Office of the
Deputy Assistant Attorney General

Washington, DC 20530

January 13, 1994

The President,

The White House.

My dear Mr. President:

I am herewith transmitting a proposed Executive Order entitled "Advisory Committee on Human Radiation Experiments." This proposed Executive Order was prepared by the Human Radiation Interagency Working Group. The Office of Management and Budget, with the approval of the Director, has forwarded it to this Department for review with respect to form and legality.

The proposed Executive Order is approved with respect to form and legality.

Respectfully,

A handwritten signature in cursive script that reads "Dawn E. Johnsen".

Dawn E. Johnsen
Deputy Assistant Attorney General

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 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 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 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,