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Department of Justice

STATEMENT

OF

FRANK W. HUNGER

ASSISTANT ATTORNEY GENERAL

CIVIL DIVISION

BEFORE THE

SUBCOMMITTEE ON ADMINISTRATIVE LAW

AND GOVERNMENTAL RELATIONS

COMMITTEE ON THE JUDICIARY

U.S. HOUSE OF REPRESENTATIVES

CONCERNING

GOVERNMENT-SPONSORED RADIATION TESTS ON HUMANS AND POSSIBLE COMPENSATION FOR PERSONS HARMED IN THE TESTS

PRESENTED ON

FEBRUARY 2, 1994

Mr. Chairman and Members of the Subcommittee:

I am pleased to appear before you today to discuss the role of the Department of Justice in connection with the Administration's commitment to a full and open examination of the nature, extent, and effects of government conducted or sponsored human radiation experiments involving intentional exposure to ionizing radiation.

The Department of Justice has been an active, full-time partner in the Human Radiation Interagency Working Group since the inception of that group on January 3, 1994. Together with the Departments of Energy, Defense, Health and Human Services, and Veterans Affairs, and the National Aeronautics and Space Administration, the Central Intelligence Agency, and the Office of Management and Budget, the Department of Justice shares a commitment to a full and public accounting of the government's human radiation experiments during the past fifty years.

The Interagency Working Group will conduct an investigation of human radiation experiments conducted by or on behalf of the government since 1944, with particular emphasis on experiments conducted prior to May 30, 1974, the date of issuance of the Department of Health, Education, and Welfare Regulations for the Protection of Human Subjects (45 C.F.R. 46). The focus of the investigation will be on experiments on individuals involving intentional exposure to ionizing radiation (excluding common and

routine clinical practices) and experiments involving intentional environmental releases of radiation that were designed to test human health effects of, or the extent of human exposure to, ionizing radiation. In addition, the investigation will examine certain radiation experiments that were noted in the December 1993 report by the General Accounting Office (These experiments generally involved atmospheric releases that were not intended to test human exposure. However, their potential effect on humans will be studied by the Interagency Working Group). Further inquiry into other radiation experiments may be undertaken if warranted.

The task of the Interagency Working Group is to conduct an open and thorough investigation of Cold War-era government sponsored human radiation experiments. The group will coordinate a government-wide effort to uncover the nature and extent of such experiments, to seek answers to questions of whether medical follow-up to the experiments is warranted, and whether compensation or other assistance to those subjected to experiments may be appropriate.

The Interagency Working Group has established five subcommittees to address specific subject issues: Public Information and Communications; Retrieval and Review of Records; Ethical and Scientific Standards; Congressional Relations; and Legal Issues. Representatives of the Department of Justice have participated in the work of these subcommittees to begin the arduous task of

documenting, analyzing, and making public the details of experiments conducted since the onset of the Cold War era.

In the relatively brief span of time since the Interagency Working Group undertook its task, substantial progress has been made in developing mechanisms to gather maximum information from outside and within the government on the nature and extent of human radiation experiments, to preserve that information for deliberate and thorough investigation, and to make the information public to the fullest extent possible while protecting the privacy of the individuals involved.

Through its communications and outreach subcommittee, the Interagency Working Group has developed guidelines for collection of information from the general public concerning incidents and details of human radiation experiments. Information collected through these efforts will be pursued by the Interagency Working Group and compared with information in the files and records of federal agencies to capture the greatest amount of information on the extent of human radiation experiments.

In consultation with the Record Retrieval and Inventory subcommittee, each of the federal agencies that may have conducted or sponsored human radiation experiments has already taken steps to notify its components, as well as outside entities that conducted such experiments under agency contract or grant, to locate and

preserve records of human radiation experiments and to coordinate the retrieval and inventory of such records for further investigation. The Department of Justice has consulted with our partners in the Interagency Working Group to ensure that consistent procedures are employed at each agency and that the scope of these record searches will be comprehensive.

The investigation of human radiation experiments will not be restricted to the government's internal resources. The Interagency Working Group's Ethical and Scientific Standards subcommittee, in which the Department of Justice has participated, offered advice and counsel to the working group on the establishment of a body of citizens from outside the government to assist the working group through independent review of the ethical and scientific standards by which the experiments will be evaluated. To that end, on January 18, 1994, the President signed an Executive Order forming an Advisory Committee on Human Radiation Experiments, to be made up of private citizens, including experts in ethics, medicine, science, and law, that will afford independent advice and recommendations to the Interagency Working Group concerning human radiation experiments. The Advisory Committee will determine the ethical and scientific standards and criteria by which it will evaluate the experiments and the extent to which the experiments were consistent with applicable standards. If required to protect the health of individuals who were subjects of experiments or their descendants, the Advisory Committee may recommend that particular

subjects of an experiment, or their descendants, be notified of any potential health risk or the need for medical follow-up. The Advisory Committee may recommend further policies, as needed, to ensure compliance with recommended ethical and scientific standards for human radiation experiments.

In compliance with the Federal Advisory Committee Act, as amended (5 U.S.C. App. 2), the meetings of the Advisory Committee on Human Radiation Experiments will be open to the public except as to discussions of individual subjects or their records. Such discussions will be closed to protect personal privacy interests. Six months from the filing date of the Advisory Committee's charter, the Advisory Committee will issue an interim report stating whether it anticipates fulfilling its duties within a one-year time frame.

These measures constitute a major initiative on the part of the government to develop a clear and credible record concerning the nature, extent, and effects of human radiation experiments, and to answer questions of whether the experiments comported with applicable ethical and scientific standards. The Interagency Working Group has also undertaken the task of developing recommendations for appropriate responses to those who were affected by these experiments.

The Department believes that if the Administration and Congress determine that relief is warranted after a review of the facts, legislative action by Congress may be necessary to provide for an appropriate federal response. However, I want to emphasize that whether legislation is needed and what the nature of any such legislative proposal would be are questions that must await full development of the facts and details concerning the nature, extent, and effects of human radiation experiments.

The Interagency Working Group's Legal Issues subcommittee is working to develop a broad range of potential responses to individuals affected by human radiation experiments including the following:

1. Taking immediate action to provide information to subjects and their families;

2. Notifying particular subjects of human radiation experiments, or their descendants, of any potential health risk or the need for medical follow-up when required to protect the health of individuals.

3. Examining various models for appropriate federal responses, including those incorporated into other federal programs, such as those for "downwinders," Veterans exposed to radiation, and the Japanese-ancestry interns during World War II. The range of

federal responses under consideration include potential monetary compensation, medical follow-up, disclosure of detailed information, formal apologies or other recognition, and on-going research, education and information programs; and

4. Developing specific recommendations for legislative and other action that may be appropriate once the Working Group and Advisory Committee have completed at least their first phase of work and the interim report is issued.

The Department of Justice has played a unique role in the work of the Human Radiation Interagency Working Group. We have offered legal advice and counsel on a broad range of issues that have arisen in the Working Group's subcommittees since the first week of this year.

We worked closely with our fellow agencies to ensure that procedures for record review and retrieval will be carried out promptly, yet with no sacrifice of the personal privacy interests of individuals subjected to human radiation experiments. Our counsel on matters implicating the Privacy Act and the Freedom of Information Act has been offered in the spirit of the Administration's commitment to making public the greatest amount of information at the earliest possible time while still shielding experiment subjects and their families from embarrassing public exposure in matters of personal privacy.

We have worked to ensure that the mission of the independent Advisory Committee on Human Radiation Experiments is clear and that its membership includes a broad range of experts and persons of varying perspectives. Of primary concern to all of us was that its members be of the highest personal and professional qualifications and devoid of any vested interest or conflict of interest in connection with the crucial role they will play in evaluating the experiments and in making their recommendations.

We have given great attention to ensuring that the investigation entrusted to this interagency working group is comprehensive, that the integrity of records of experiments will be preserved, and that all of the facts will be developed without predisposition as to where those facts should lead us.

This is an opportunity for full and open disclosure of information that has been hidden away or ignored for too long. Once the details of what happened have been made public and judgments can be rendered on the propriety of these experiments, we will join our fellow members or the Working Group in making recommendations to the President and the Congress regarding an appropriate response to those citizens subjected to the experiments, to their families, and to the American people.

Throughout all of this activity, the Administration will continue active consultations with the Congress. However, I want to

emphasize that until the information is collected and analyzed, it would be premature to predict the form of response which will be most appropriate. The Administration has demonstrated its commitment to the subjects of radiation experimentation, and I would urge the Congress to give us an opportunity to complete the review and analysis process so that any legislative proposals can be structured on the basis of the fullest information possible to ensure that our response as a nation is fair.

The Administration is moving forward on all aspects of this important issue, including reviewing many existing compensation programs as potential models for any legislative proposals that may be appropriate once the facts have been developed. The Interagency Working Group's Legal Issues subcommittee is studying various compensation plans, including several administered by the Department of Justice. Those programs are the Radiation Exposure Compensation Act, the National Vaccine Injury Compensation Program, and the Civil Liberties Act of 1988.

The Radiation Exposure Compensation Act

The Radiation Exposure Compensation Act, 42 U.S.C.A. § 2210 note (Supp. 1993), was enacted on October 15, 1990. The Act established an administrative program to provide lump sum compassionate payments to certain individuals, or their survivors, who contracted specified cancers and nonmalignant respiratory diseases as a result of either their exposure to radiation released during above-ground

nuclear weapons tests or their exposure to radiation during employment underground in uranium mines. The procedures established in the implementing regulations are designed to utilize existing records so that claims can be resolved in a reliable, objective, and non-adversarial manner, quickly and with limited administrative costs to the United States or to the person filing the claim.

There are three basic categories of eligible claimants: Downwinders, Onsite Participants, and Uranium Miners. Claimants in each of these categories must meet two major criteria and, depending on the type of disease, several minor criteria in order to establish their eligibility to receive a compensation payment.

"Downwinders" are individuals who were exposed to fallout from atmospheric nuclear weapons testing while residing in certain statutorily designated areas in Utah, Nevada, and Arizona. In order to be eligible for the lump sum compensation payment of $50,000.00, these individuals must establish that they resided in the area affected by fallout for the required length of time, and subsequently developed one of thirteen statutorily specified cancers.

"Onsite Participants" are individuals who participated onsite in a test involving the atmospheric detonation of a nuclear device. In order to be eligible for the lump sum compensation payment of

$75,000.00, these individuals must establish that they participated onsite in the atmospheric detonation of a nuclear device, and subsequently developed one of the thirteen specified cancers.

"Uranium Miners" are individuals who were employed underground in uranium mines in Utah, Colorado, Arizona, New Mexico and Wyoming between 1947 and 1971. In order to be eligible for the lump sum compensation payment of $100,000.00, these individuals must establish that they were exposed to certain levels of radiation while working in the mines, and subsequently developed lung cancer or one of four statutorily designated nonmalignant respiratory diseases.

The regulations implementing the Radiation Exposure Compensation Program were published in the Federal Register on April 10, 1992. The first claims were received on April 1, 1992, and paid on May 11, 1992. Between April 1, 1992 and January 26, 1994, the Department of Justice has received 3,595 claims. Of those, 1,570 claims have been approved for payment for a total amount in excess of $112.5 million dollars. Denied claims total 1,493, and only 532 are pending resolution.

A recent Department of Justice Inspector General's report concluded that the Radiation Exposure Compensation Program was "well managed" and that "Government funds were properly expended for the purposes intended by the [Act]."

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program has been operating for more than five years and has largely accomplished the goals it was set up to achieve. The Program is available to compensate persons who believe they have been injured by receiving one of the standard vaccines administered in childhood. The purpose of the Program is to provide compensation in an equitable manner for persons who suffer vaccine-related injuries, while simultaneously insulating vaccine manufacturers from unpredictable liability in the civil justice system. The end result is a stable supply of critical vaccines.

Claims are resolved in the United States Court of Federal Claims, where the Justice Department represents the Secretary of Health and Human Services, the statutory administrator of the Program. Whether to pay a particular claim -- and how much is appropriate -- is determined by experienced special masters whose exclusive function on the court is to make these determinations.

Although lawyers are involved on both sides, proceedings under the Vaccine Program are less adversarial than traditional tort litigation. The resolution process is less formal, less costly, and moves more quickly than a typical lawsuit once the Secretary's position on a particular claim is made known to the court. To succeed, the process depends upon cooperation between the claimant and the Secretary. However, the resolution process frequently

includes hearings where fact and expert testimony is presented by both sides.

Since the Program started accepting claims in October of 1988, more than 1700 claims have been resolved. More than 500 of those claims were decided in favor of the claimant, resulting in awards between several hundred and several million dollars in compensation. As of the end of 1993, a total of more than $400 million has been paid under the Program. To the extent that the Program has had difficulty, it is largely because many more claims have been filed than were expected. Several thousand claims are at some stage of the resolution process, many have yet to be assigned to a special master. Due to the volume of claims and their complexity and the limited number of court personnel available to resolve vaccine claims, the pace of resolution has been somewhat slower than many people had hoped. Nevertheless, the basic goals of providing equitable compensation to persons who suffer vaccine-related injuries and ensuring a stable supply of critical vaccines have been achieved by the Vaccine Program.

The Office of Redress Administration

The Justice Department's Civil Rights Division administers a compensation program providing for monetary payments and additional services, pursuant to the Civil Liberties Act of 1988 (Public Law 100-383, codified at 50 U.S.C. App. Section 1989).

During World War II, approximately 120,000 Japanese Americans were interned, relocated or evacuated in the U.S. because of their race. Nearly fifty years later, the country apologized for this grave injustice. On August 10, 1988, the Civil Liberties Act of 1988 was signed into law, authorizing payment of $20,000 to each U.S. citizen or permanent resident alien of Japanese ancestry who meets the criteria for eligibility. The Act acknowledges the fundamental injustice of the internment and directs the Attorney General to identify, locate and distribute payment to each eligible individual, without requiring an application. The Act also provides for funding of a public education program to prevent the recurrence of any similar event in the future.

Of the original 120,000 persons interned or evacuated during the war, about 80,000 surviving individuals have received their redress payments. The 1988 Act and its 1992 amendments authorize $1.65 billion for redress payments, of which, not more than $500 million may be disbursed each fiscal year. The program will end in 1998 or when maximum program appropriations are expended, whichever occurs first.

The success of the redress program is due largely to superb research and outreach efforts utilized to identify and locate those who qualify under the Act. The task of identifying and accounting for 120,000 potential redress recipients required extensive research into historical and current information sources including

50-year-old camp rosters of the War Relocation Authority, and other government records retained by the National Archives and the Immigration and Naturalization Service.

Once a potential recipient's historical record is located, the Office of Redress Administration must then track down that person's current address or verify that the individual is deceased. This was accomplished through official sources such as the Social Security Administration and state vital statistics bureaus. Frequently, unofficial sources were utilized including relatives of potentially eligible individuals, civic associations and religious organizations.

Perhaps the most unique aspect of the redress program is that the responsibility of locating redress recipients is placed on the Attorney General. Though the Act makes provisions for accepting voluntary information from the public, it prohibits the Department from requiring internees to submit an application for redress. Specifically, the Act states that the Attorney General "shall, subject to availability of funds appropriated... encourage through a public awareness campaign, each eligible individual to submit his or her own current address..."

Rather than waiting for funding, the Office of Redress Administration began a public outreach campaign immediately. Soon after its opening, the Office opened six toll-free telephone lines

to begin gathering information about potential redress recipients, receiving 1,724 calls in the first week. The Help Line proved to be a main source of communication between the Office of Redress Administration and redress recipients.

Since over 70 percent of redress recipients reside in California, contacting and educating this sector of the Japanese American community about the redress program was a priority for the Office of Redress Administration. On October 11, 1988, a temporary office opened in San Francisco. The office operated for 90 days, distributing and gathering information, publicizing the redress program and making contacts with the Japanese American community on the West Coast. As a result of the opening of the San Francisco office, extensive contacts were made with leaders of the Japanese American community. Outreach continued through public speaking engagements, community workshops, publication of informational materials, press releases and mailings. The Office of Redress Administration has conducted over 50 workshops within the Japanese American community, meeting individually with thousands of redress recipients to provide information and assistance with their cases. These outreach strategies have been an integral part of the philosophy of the Office of Redress Administration and have continued throughout the program. The Office of Redress Administration has also brought three groups of Japanese American community leaders to its office in Washington, D.C. to participate

in a series of meetings and consultations which provide an 'inside view' of the program.

The outreach efforts and community work, in conjunction with the Office of Redress Administration's commitment to the redress effort, have made the redress program a success, fulfilling both the letter and the spirit of the redress law.

Each of these programs was carefully designed and tailored to provide efficient, appropriate compensation for the carefully defined injuries Congress intended to address. Great attention was paid to defining an appropriate recipient population, setting eligibility standards, assessing the availability of relevant evidence, and determining the propriety of monetary and other forms of compensation. We don't have <u>any</u> of that information with regard to the subjects of human radiation experiments at this time. The Human Radiation Interagency Working Group and the independent Human Radiation Advisory Committee are dedicated to developing a record on which the Administration can report to and work with the Congress in crafting the appropriate response the Nation deserves.

DEPARTMENT OF JUSTICE

SUMMARY OF STATEMENT OF FRANK W. HUNGER
ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION
HOUSE JUDICIARY SUBCOMMITTEE ON ADMINISTRATIVE
LAW AND GOVERNMENTAL RELATIONS

FEBRUARY 2, 1994

The Department of Justice has participated in the work of each of the subcommittees of the Human Radiation Interagency Working Group and shares the Administration's commitment to conduct an open and thorough investigation of Cold War-era government sponsored human radiation experiments. The Working Group will coordinate a government-wide effort to uncover the nature and extent of such experiments, to seek answers to questions of whether medical follow-up to the experiments is warranted, and whether compensation or other assistance to those subjected to experiments may be appropriate. The investigation will be aided by a body of citizens from outside the government, appointed by the President as members of the Advisory Committee on Human Radiation Experiments, which will file its initial report in six months. That body will determine the ethical and scientific standards and criteria by which it will evaluate the experiments and may recommend actions to protect public health and to ensure compliance with recommended ethical and scientific standards for human radiation experiments.

The Working Group is developing a broad range of potential responses to individuals affected by human radiation experiments, including taking immediate action to provide information to subjects and their families; notifying particular subjects of human radiation experiments, or their descendants, of any potential

health risk or the need for medical follow-up; and examining various models for appropriate federal responses.

The Department of Justice has offered legal advice and counsel on a broad range of issues that have arisen in the Working Group's subcommittees. Our counsel has been offered in the spirit of the Administration's commitment to making public the greatest amount of information at the earliest possible time while still shielding experiment subjects and their families from embarrassing public exposure in matters of personal privacy.

Once the details of what happened have been made public and judgments can be rendered on the propriety of these experiments, we will join our fellow members or the Working Group in making recommendations to the President and the Congress regarding an appropriate response to those citizens subjected to the experiments, to their families, and to the American people.

The Working Group is reviewing existing compensation programs as potential models, including several administered by the Department of Justice, for any legislative proposals that may be appropriate once the facts have been developed. Those programs are the Radiation Exposure Compensation Act, the National Vaccine Injury Compensation Program, and the Civil Liberties Act of 1988. The provisions of each of these programs are set forth in my prepared Statement.

It should be emphasized that each of these programs was carefully designed and tailored to provide efficient, appropriate compensation for the carefully defined injuries Congress intended to address. Great attention was paid to defining an appropriate recipient population, setting eligibility standards, assessing the availability of relevant evidence, and determining the propriety of monetary and other forms of compensation. We don't have sufficient information with regard to the subjects of human radiation experiments at this time to make any specific proposals.

Until the information is collected and analyzed, it would be premature to predict the form of response which will be most appropriate. I urge the Congress to give us an opportunity to complete the review and analysis process so that any legislative proposals can be structured on the basis of the fullest information possible to ensure that our response as a nation is fair. We are dedicated to developing a record so that the Administration and the Congress, should it choose, can craft an informed and appropriate response to a problem which has too long been ignored.

CONGRESSIONAL REFERENCE ACTIONS IN THE UNITED STATES COURT OF FEDERAL CLAIMS

Section 1492 of title 28, United States Code, provides that "[a]ny bill, except a bill for a pension, may be referred by either House of Congress to the chief judge of the United States Court of Federal Claims for a report in conformity with section 2509 of this title." Section 2509 provides the procedure for handling such Congressional reference cases.

The chief judge designates a judge as a hearing officer for the case, and a panel of three judges to serve as a reviewing body. The hearing officer proceeds to determine the facts, and makes findings of fact. Those findings are required to have conclusions sufficient to inform Congress whether the demand is a legal claim, an equitable claim, or a gratuity. The hearing officer also makes findings regarding the amount, if any, that is due from the United States to the claimant.

The findings and conclusions of the hearing officer are then sent to the panel of three judges for review. The panel votes to adopt or modify the findings and conclusions of the hearing officer. The panel then submits its report to the chief judge for transmission to the appropriate House of Congress.

Congress is not required to adopt the recommendations of the court. However, in practice Congress has almost always enacted relief legislation in agreement with those recommendations.

The fact that one House of Congress passes a congressional reference bill does not mean that the United States owes anything to the claimant. By making the reference, Congress only provides an impartial judicial forum to determine the merits of a complex claim. The resulting lawsuit is adversary litigation against the United States. The United States is defended by the Department of Justice.

Various reasons have been suggested why it is better to evaluate such claims in an adversary judicial proceeding rather than in the consideration of a legislative private relief bill. Complex questions of fact and law are better decided in a judicial proceeding. Such claims should be decided based upon competent evidence that is evaluated in court. Furthermore, congressional committees lack the time, expertise, and facilities required to hear the evidence and decide such questions. In addition, resolution of such claims requires a trial proceeding which could be lengthy, and may need to be held in a location other than in Washington, D.C. The court is an impartial and independent tribunal whose processes are careful and evenhanded.

Traditionally, congressional references have tracked the language of section 2509(c), requiring the court to inform

Congress "whether the demand is a legal or equitable claim or a gratuity." The court has always rejected claims found to be gratuities on the basis that such an award would be preferential, and thus inconsistent with justice. In the past "equitable claims" which would not be recognized as "legal claims" were, in some cases, recommended for compensation based upon a perceived moral obligation. In recent decades legal and equitable claims have both been subjected to more similar requirements, with the claimant needing to establish governmental fault in both types of claims. However, where Congress believes that the equities of a claimant's position deserve a hearing Congress can and has waived a defense, such as the statute of limitations, allowing the court to hear evidence and make recommendations, notwithstanding the fact that without such a waiver the claimant would not have a "legal" claim.

DATE:

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COMMENTS/MESSAGES:

Interagency Working Group
Congressional "Wish List"

CIA: Senate Appropriations

- Ted Stevens
- Daniel Inouye

- Steven Cortess, Staff Director
- Charlie Houy, Minority Staff Director

Senate Intelligence

- Charles Battaglia, Staff Director
- Christopher Straub, Minority Staff Director

House Appropriations

- C.W. Young
- John Murtha

- Julie Pacquing, Staff

House Intelligence

- Mark Lowenthal, Staff Director
- Michael Sheehy, Minority Chief Counsel

VA: Veterans Affairs

- Both Committees, all members and staff

- **NAMES WERE NOT SUBMITTED**

HHS: List attached

DOD: List attached

DOE: List attached

NASA: **NOT RECEIVED**

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DOD: List attached

DOE: List attached

NASA: **NOT RECEIVED**

NIH Suggested List of Congressional Contacts for Briefings by Dr. Ruth Faden, Chair of the Advisory Committee on Human Radiation Experiments

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Chairman
House Appropriations Committee
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Washington, D.C. 20515
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(202) 225-3015

Representative David Obey
Ranking Minority Member
House Appropriations Committee
H218 Capitol
Washington, D.C. 20515
Schedulers: Sara Mailander or Carly Burns
(202) 225-3365

Representative John Porter
Chairman
House Appropriations Subcommittee on
Labor, HHS, and Education
2358 Rayburn House Office Building
Washington, D.C. 20515
Scheduler: Lynn Guhse
(202) 225-4835

Representative Michael Bilirakis
Chairman
House Commerce Subcommittee on
Health and the Environment
2125 Rayburn House Office Building
Washington, DC 20515
Scheduler: Douglas Menorca
(202) 225-5755

Representative Henry Waxman
Ranking Minority Member
House Commerce Subcommittee on
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2125 Rayburn House Office Building
Washington, DC 20515
Scheduler: Nora Mail
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Instrumentation

To support the Section 8.0 (Emergency Classes and EALs) symptomatic EAL development, this appendix documents the instrumentation available (and adequacy thereof) to assist operators in the determination of event classification. Indicators for both of the two following categories are obtained (as applicalbe):

1) Release precursor indicators - These are plant/process conditions that indicate an event has the potential to occur.

2) Actual release monitoring - These are conditions that indicate a hazardous material may be releasing.

For each of the release scenarios and their consequences as identified in Sections 6.0 and 7.0 that exceed a PAC (i.e. require an associated EAL), an instrumentation identification and adequacy analysis (qualitative) is performed to determine if they provide quantitative indication of each individual event for inclusion in the EAL basis (Section 8.0).

As the following tables show, the instrumentation identified will only aid in event classification depending on the initiator and its reliability.

EAL/Accident Scenario: Criticality in RBOF (1-RD-2, 2-RD-1, or 2-RD-2).

Description	Tag No.	Units	Range	Alarm Setpoints
Nuclear Incident Monitor (NIM)	—	R/hr	—	0.5 - 3
Stack Monitor AM1 (Picoammeter)	HR-516	Amps	1E-13 - 1E-8	Set by HP
Stack Monitor AM1 (Recorder)	HR-522	Amps µCi/cc	1E-13 - 1E-8 0 - 10	Set by HP

Representative Christopher Shays
Chairman
House Governmental Reform and Oversight Subcommittee
on Human Resources and Intergovernmental Relations
B372 Rayburn House Office Building
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Senator Arlen Specter
Chairman
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(202) 224-4254

Senator Tom Harkin
Ranking Minority Member
Senate Appropriations Subcommittee on
Labor, HHS, and Education and Related Agencies
184 Dirksen Senate Office Building
Scheduler: Rebecca Bass
(202) 224-3254

Senator Nancy Kassebaum
Chairman
Senate Labor and Human Resources Committee
428 Dirksen Senate Office Building
Washington, DC 20510
Scheduler: Jan Vulevich
(202) 224-2774

Senator Edward Kennedy
Ranking Minority Member
Senate Labor and Human Resources Committee
428 Dirksen Senate Office Building
Washington, DC 20510
Scheduler: Stephen Carrigan
(202) 224-4543

Senator William Roth
Chairman
Senate Committee on Governmental Affairs
340 Dirksen Senate Office Building
Washington, DC 20510
Scheduler: Susie Cohen
(202) 224-2441

Senator John Glenn
Ranking Minority Member
Senate Committee on Governmental Affairs
340 Dirksen Senate Office Building
Washington, DC 20510
Scheduler: Kathleen Long
(202) 224-7981

The Honorable Barbara Mikulski
United States Senate
Washington, DC 20510
Scheduler: Ann Norton
(202) 224-4654

The Honorable Constance Morella
U.S. House of Representatives
Washington, DC 20515
Scheduler: Tricia Donnelly
(202) 225-5341

The Honorable Bill Frist
United States Senate
Washington, DC 20510
Scheduler: Gabrielle Forsyth or Ramona Lessen
(202) 224-3344

The Honorable Zach Wamp
U.S. House of Representatives
Washington, DC 20515
Scheduler: Helen Hardin
(202) 225-3271

The Honorable Louis Stokes
U.S. House of Representatives
Washington, DC 20515
Scheduler: Sallie Bell
(202) 225-7032

List to Receive Copy of ACHRE Final Report and Congressional Briefing

Name	Main Area of Interest
Gov. Leavitt, Utah	Radiological Warfare Testing in Utah
Sen. Bennett, Utah	Radiological Warfare Testing in Utah
Sen. Campbell, Colorado	General
Sen. Dingell, Michigan	Marshall Islanders
Sen. Glenn, Ohio	General
Sen. Kennedy, Massachusetts	Involved in Cincinnati Hearings in 1970s
Sen. Liebermann, Connecticut	Nasal Pharyngeal
Sen. Rockefeller, West Virginia	Atomic Veterans and Gulf War Syndrome
Sen. Wellstone, Minnesota	General, NTPR, Depleted Uranium and LAC
Rep. Bryant, Texas	Cincinnati Hearing
Rep. Conyers, Michigan	Chaired Gov Ops Subcommittee hearing on HREs
Rep. Hayes, Louisiana	Tulane
Rep. Markey, Massachusetts	Original General Interest
Rep. Portman, Ohio	Cincinnati Hearing and General Research

DOE

Proposed Briefing List (Group & Personal)

Name	Affiliation	State/Committee	Group	Personal
Markey, Edward	Rep (D)	Massachusetts	X	X
Glenn, John	Sen (D)	Ohio	X	X
Baucus, Max	Sen (D)	Montana	X	
Bliley, Thomas	Rep (R)	Virginia, Chair, House Committee on Commerce	X	X
Boxer, Barbara	Sen (D)	California	X	X
Bryan, Richard	Sen (D)	Nevada	X	
Campbell, Ben Nighthorse	Sen (R)	Colorado	X	
Farr, Sam	Rep (D)	California	X	
Feinstein, Dianne	Sen (D)	California	X	
Gorton, Slade	Sen (R)	Washington	X	
Goss, Porter	Rep (R)	Florida	X	
Graham, Bob	Sen (D)	Florida	X	X
Gramm, Phil	Sen (R)	Texas	X	X
Gregg, Judd	Sen (R)	New Hampshire	X	
Hatch, Orin	Sen (R)	Utah	X	X
Horn, Steven	Rep (R)	California	X	
Hutchison, Kay Bailey	Sen (R)	Texas	X	
Levin, Carl	Sen (D)	Michigan	X	X
Murray, Patty	Sen (D)	Washington	X	
Murkowski, Frank	Sen (R)	Alaska; Chair, Senate Committee on Energy & Natural Resources	X	
Nunn, Sam	Sen (D)	Georgia	X	X
Pressler, Larry	Sen (R)	South Dakota; Chair, Senate Committee on Commerce, Science & Technology	X	X
Shuster, Bud	Rep (R)	Pennsylvania	X	
Stevens, Ted	Sen (R)	Alaska	X	X

DOE

Name	Affiliation	State/Committee	Group	Personal
Upton, Fred	Rep (R)	Michigan	X	
Vucanovich, Barbara	Rep (R)	Nevada	X	
Wellstone, Paul	Sen (D)	Minnesota	X	X

U.S. SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
HEARING ON
HUMAN SUBJECTS RESEARCH: RADIATION EXPERIMENTATION
FERNALD SCHOOL, HOWE HALL
WALTHAM, MASSACHUSETTS
JANUARY 13, 1994
10:30 a.m.

PANEL I

Charles L. Dyer
Former Fernald School Resident
Salem, Massachusetts

Austin LaRocque
Former Fernald School Resident
Beverly, Massachusetts

Belton Burrows, M.D.
Chief, Department of Nuclear Medicine
Boston VA Medical Center

A. Bertran Brill, M.D., Ph.D.
Research Director and Professor of Nuclear Medicine
University of Massachusetts Medical Center

PANEL II

Tara O'Toole, M.D.
Assistant Secretary for Environment,
Safety and Health
Department of Energy

Gordon Soper, M.D
Deputy Assistant Secretary for Atomic Energy
Department of Defense

Marty Albert, M.D.
Director
Medical Research Services
Department of Veterans Affairs Health Administration

Wendy Baldwin
Acting Deputy Director for Extramural Research
National Institutes of Health
Department of Health and Human Services

PANEL II continued

J. David Litster, Ph.D.
Vice President and Dean for Research
Professor of Physics
Massachusetts Institute of Technology

James Adelstein, M.D.
Executive Dean for Academic Programs
in the Faculty of Medicine at Harvard

Frederic Mislio, Jr.
Deputy Commissioner
Department of Mental Retardation
Chairman, Task Force to Review Human Subject Research

PANEL III

George J. Annas, J.D., MPH
Utley Professor and Chair
Health Law Department
Director, Law, Medicine & Ethics Program
Boston University School of Medicine and Public Health

Kenneth Ryan, M.D.
Kate Macy Ladd Distinguished Professor
Department of Obstetrics and Gynecology
Harvard Medical School
Chairman, 1974-1978, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
Chairman, Ethics Committee, Brigham and Women's Hospital

Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. manifest	[Personally Identifiable Information] [partial] (2 pages)	01/13/1994	b(6)

COLLECTION:
Clinton Presidential Records
Staff Secretary
Caplan, Phil
OA/Box Number: 11097

FOLDER TITLE:
Advisory Committee on Human Radiation Experiments-Anything Congressional [1]

2019-0803-S
rs3543

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
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b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
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b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

THE WHITE HOUSE

WASHINGTON

MANIFEST
TRIP TO BOSTON, MA
CONGRESSIONAL HEARING ON HUMAN RADIATION EXPERIMENTS
10:30 AM - January 13, 1993

11 passengers

7:30 AM WHITE HOUSE VAN DEPARTS WEST WING BASEMENT

8:15 AM WHEELS UP DEPARTURE FROM ANDREWS A.F.B.

1) Dr. Wendy Baldwin - Department of Health and Human Services, Acting Deputy Director for Extramural Research, National Institutes of Health

**	Will drive to Andrews
PH:	301/496-1096
FAX:	301/402-3469
HOME:	301/299-4823
SS #:	(b)(6)
VEHICLE:	1991 Honda Prelude - MD 050AVL

2) Dr. Tara O'Toole - Department of Energy, Assistant Secretary for Environment, Safety and Health

**	Will drive to Andrews
PH:	202/586-6151
SS #:	
VEHICLE:	Nissan Maxima - MD AKZ572

3) Mary Louise Wagner - Department of Energy, Deputy Assistant Secretary, Senate Liaison

**	White House Van
PH:	202/586-5450
SS #:	
PAGER:	1-800-946-4646 PIN #2556282
CELL:	301-742-9664
DOB:	

4) Dennis Duffy - Veterans Affairs, Deputy Assistant Secretary for Congressional Affairs

** will drive to Andrews
PH: 202/535-8139
HOME: 703/212-8125
SS #: (b)(6)
VEHICLE: 1983 Honda Accord; Tags: VA NOR-529

5) Kelly Sharbel - Special Assistant to the Asst Secry of Def for Legislative Affairs

** DOD van to Andrews

6) Dr. Gordon Soper - Department of Defense, Deputy Assistant Secretary for Atomic Energy

** DOD van to Andrews

7) Rudy DeLeon - Department of Defense, Special Assistant to the Secretary of Defense

** DOD van to Andrews

8) Christine Varney - White House Cabinet Affairs

** White House Van

9) Phil Caplan - White House Cabinet Affairs

** White House Van

10) Tracey Thornton - White House Legislative Affairs

** White House Van

11) Jocelyn Jolley - White House Legislative Affairs

** White House Van

as of 1/12/94
final 7:10 PM

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

27-Oct-1995 04:52pm

TO: Phillip M. Caplan

FROM: Tracey E. Thornton
Office of Legislative Affairs

CC: Daniel Tate

SUBJECT: Radiation Briefing

As I mentioned to you this morning, we've had hill requests for an update on what's going on within the administration on human radiation experiment follow-up. Our concern now is that folks will start working on hearings and my guess is we ain't nowhere near ready for that. Can you let me know how soon we can have another "conversation" with the hill. I don't think we have to talk about compensation. I also think more attention will be placed on DOD and the VA.

txs

EXECUTIVE OFFICE OF THE PRESIDENT

06-Feb-1996 08:57am

TO: Tracey E. Thornton

FROM: Phillip M. Caplan
Office of the Staff Secretary

SUBJECT: Radiation

Ok...what do we do now?

Give me a call and I'll give you an update on what I know.

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

05-Feb-1996 11:45am

TO: (See Below)

FROM: LORI.AZIM

SUBJECT: Congressional hearing

I have been told that there will be a hearing on human radiation experiments tentatively scheduled for March 12th with the Senate Govt. Oversite Committee - Senator Glenn has proposed this hearing and the majority has bought off on it. Will send more info as it becomes available...

Distribution:

TO: STEVE.GALSON
TO: TARA.O'TOOLE
TO: ELLY.MELAMED
TO: PETER.BRUSH
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TO: hholloway

CC: MARY.ZACCHERO
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CC: BILL.LEFURGY
CC: KEVIN.MONROE
CC: STEVE.LERNER

U.S. DEPARTMENT OF ENERGY
Office of Budget and Administration
EH-71

96 MAR 7 AM 10:31

FAX# (202)586-4059

DATE: 3/7/96

SL-539

NO. OF PAGES TO FOLLOW COVER SHEET: 22

TO: Phil Caplan

FROM: Jan Stubblefield

SUBJ: Statement of Taro O'Toole

REMARKS: Please review and provide your comments to me by 1:00 pm today. Please fax you comments to (202) 586-4059. If you should have any questions, please call me on (202) 586-4350.

Thank you.

STATEMENT OF TARA O'TOOLE, M.D., M.P.H.
BEFORE THE COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE
MARCH 12, 1996

INTRODUCTION AND SUMMARY

Mr. Chairman and Members of the Committee, thank you for the opportunity to appear before the Committee today and to provide you with an update on the continuing work of the Department of Energy (DOE) in response to the human radiation experiments initiative. I will speak to you today both in my capacity as Assistant Secretary of the Office of Environment, Safety and Health of the Department of Energy, and as the chair of the staff of the Interagency Working Group (IAWG), which has been directed by President Clinton to respond to the recommendations of the Advisory Committee on Human Radiation Experiments. The IAWG was established in January 1994 to coordinate the government's response to human radiation experiment issues and consists of the Cabinet Secretaries of the Departments of Energy, Health and Human Services (HHS), Defense (DOD), Veterans Affairs (VA), and Justice (DOJ) and the Directors of the National Aeronautics and Space Administration (NASA), Central Intelligence Agency (CIA), and the Office of Management and Budget (OMB).

My testimony will cover recent activities of the IAWG staff, including preparation of a draft preliminary response to the recommendations of the Advisory Committee and a

two-day stakeholder workshop to receive input to this draft response. The IAWG staff are actively seeking ways to make human radiation experiment information and the research process more useful and accessible to citizens. The Advisory Committee recommendations, to which the IAWG is responding, are the result of 18 months of intense deliberation, the review of thousands of documents, and public meetings in Washington and across the country that involved presentations by many concerned citizens.

I will also discuss the hard work being done by DOE to carry out the human radiation experiments initiative begun over two years ago, and to keep this effort strong. We are working closely with citizens and stakeholders to respond to specific inquiries. We actively continue to locate, release, declassify, and generally improve access to DOE records and information on this and related subjects. We are also providing assistance to affected populations, such as residents of the Marshall Islands.

Last but not least, the Administration is working to improve protections for citizens who are subjects in current human subjects research. DOE's Office of Energy Research has reviewed the entire program of DOE-sponsored current human subjects research in light of the Advisory Committee's recommendations and has recently reported on this review to National Bioethics Advisory Committee (NBAC), as required by the President's October 1995 Executive Order. The Office of Energy Research is now involved in: a

systematic review of DOE site activities in relation to human subjects protection; ongoing improvements to informed consent documentation; and efforts to better educate scientists, administrators, and Institutional Review Board (IRB) members on their responsibilities in the area of human subjects protection.

BRIEF HISTORY OF THE HUMAN RADIATION EXPERIMENTS INITIATIVE

The issue of government sponsored human radiation experiments has been examined with increasing intensity for the past two decades. In the mid-1970s, then Representative Al Gore chaired hearings which focused on whole body irradiation treatments for cancer patients, conducted by the Oak Ridge Institute of Nuclear Studies. However, no final report was ultimately issued and no wrongdoing found.

Representative Ed Markey chaired hearings in 1986 and issued the report, "Human Guinea Pigs", which detailed experiments involving some 600 human subjects. The "plutonium experiments" were first publicly discussed in detail in the report. The research involved in "Human Guinea Pigs" served as a starting point for the exhaustive search to come in the 1990s.

Eileen Welsome's Pulitzer-Prize winning investigative report on the plutonium injection subjects in late 1993 for the Albuquerque Tribune brought the topic to the attention of Energy Secretary Hazel O'Leary. Secretary O'Leary's outrage, expressed in a December

1993 press conference on openness in DOE, inspired tremendous media response and public outcry. The Human Radiation Experiments Helpline was immediately established and received over 17,000 calls from citizens in the first month alone. President Clinton promptly issued an Executive Order directing all relevant Federal agencies to search their records for information on radiation experiments.

This Executive Order also established the IAWG in early 1994. Individual agencies organized research teams to locate and examine records. This was a massive task both because of the age of the documents, which meant that some records were destroyed due to the passage of time, and the disarray of the Federal recordkeeping system -- records were later found in such unlikely places as garages and basements.

In DOE, the universe of records to be searched was over 3.2 million cubic feet. Relevant records were located in the custody of over two dozen DOE sites, private contractors, and non-governmental entities. Over 200 people from the Department were involved in this search process.

The Advisory Committee on Human Radiation Experiments membership was appointed by President Clinton in early 1994. This expert Committee was charged with advising the IAWG and the President of the ethical implications of the experiments. The Committee included medical doctors, university professors, lawyers, ethicists, historians,

and a citizen representative. The Committee's charter required them to review experiments from 1944 to 1974, which was the year of the first Federal regulations protecting human subjects, and sample later experiments for ethical problems.

The Advisory Committee members and staff reviewed hundreds of thousands of documents and spoke with hundreds of citizens and stakeholders. The Committee's meetings and research took them across the country in search of information. They then deliberated for eighteen months and presented the Committee's final conclusions to President Clinton in October 1995.

At the White House ceremony in which the President accepted the Committee's report, he apologized to the victims. "So today," he said, "on behalf of another generation of American leaders and another generation of American citizens, the United States of America offers a sincere apology to those of our citizens who were subjected to these experiments, to their families, and their communities."

The same day, President Clinton signed an Executive Order establishing the National Bioethics Advisory Committee (NBAC), which will continuously review and identify principles governing human subjects research. President Clinton simultaneously directed all Federal agencies sponsoring human subjects research to review and improve their human subjects protections in light of the Advisory Committee's recommendations and to

report on this review to NBAC. He also instructed the Cabinet to use and build on these recommendations to devise promptly a system of relief, including compensation, that meets the standards of justice and conscience.

CURRENT WORK OF THE INTERAGENCY WORKING GROUP STAFF

In response to the 18 recommendations in the Advisory Committee's final report, the IAWG staff has drafted a preliminary paper which lays out a proposed set of government actions. The government continued in its commitment to public involvement by receiving citizen input on this draft during a two-day stakeholder/citizen workshop sponsored by the IAWG staff at the end of February. Over 120 people participated in the workshop, including citizens who believe they were/are experiment subjects and their advocates, government representatives, and invited experts. Discussion was intense and stakeholders were highly critical of the Committee's recommendations, as well as the preliminary proposed government response. Citizens want justice on a wide range of matters relating to radiation exposures, not all of which fall under the category of "human radiation experiments" as defined in the Advisory Committee's charge.

In response to strong citizen concerns expressed at the workshop, the IAWG staff is examining ways to involve the public more extensively in government decisionmaking on the issues of human subjects research. Citizen proposals include:

- The reform of the IRB process to include greater citizen representation and more effective, community-based review of human subjcts research;

- The possibility of citizen/affected party representation on human subjects research-related Federal Advisory Committees and panels;

- Facilitating better access to government decisionmakers for citizen groups; and

- Government working with citizens to develop appropriate search tools to help members of the public access information independently.

Two important and potentially controversial issues raised by the Advisory Committee recommendations, to which the government must respond, are compensation and medical follow-up and notification. As to the issue of compensation, representatives of the families of most, if not all, of the subjects identified by the Advisory Committee have already pursued claims, and the government is currently engaged in discussions with them.

In the areas of subject notification and medical follow-up, citizens at the stakeholder workshop criticized the Advisory Committee recommendations and the IAWG staff draft

responses. They advocated the notification of all subjects who have participated in government sponsored radiation experiments and the provision of funds for comprehensive medical care, managed at the local level, for all persons involved in the experiments.

I would like to explain to you where we currently stand on these issues.

The Advisory Committee recommended against notification and medical follow-up of human radiation experiment participants because two criteria were not met. They concluded that there was a *low level of risk* and a *lack of available interventions*. The Committee advised that these two criteria should form the basis for subsequent decisions for notification and medical follow-up should other experiments of concern come to light in the future. Risk means both the risk of developing cancer as a result of the radiation exposure received in the experiment AND the potential risks from medical procedures that may be part of medical follow-up. The Committee felt that the lifetime risk of developing cancer should be more than 1/1,000 to warrant medical follow-up. The second criteria -- the medical utility of early detection and treatment -- means that there are no medical tests available that would enable doctors to change the course of disease or the quality or length of life in an exposed individual.

Finding participants in past government sponsored radiation experiments would entail an enormously expensive, time-consuming effort that promises to be futile in most cases. The Committee felt that there would be little or no medical benefit to subjects -- and possibly new risks -- from this vast endeavor. These potential risks include medical harm and discomfort, the possibility of incorrect test results, the possibility of stigmatization by friends, family, insurers and employers, and the potential financial costs to the subjects and their families.

Although the Advisory Committee's database includes documentation describing approximately 4,000 government-sponsored human radiation experiments, no list of participants exists for most of the experiments. For example, 3,000 of the 4,000 experiments were sponsored by the VA. According to Advisory Committee staff, there are subject names for only a tiny fraction of these experiments. In the isolated cases where participant lists are available, scores of researchers would be needed to track down persons whose whereabouts have been unknown to the government for several decades. It is probable that most subjects have changed names, died, or moved to other parts of the country and to locations around the globe.

Almost all of the experiments involved small radiation doses, producing less than 1/1,000 remaining lifetime risk of cancer death. This level is minimal compared with the normal risk of dying of cancer (220 out of 1,000). Many of the experiments involved tracer

doses, similar to those used in medical diagnostic procedures today to diagnose cancer and heart disease. Among the experiments involving iodine-131 administration to children or testicular irradiation to prisoners, the Advisory Committee found none that met the 1/1,000 criterion for remaining lifetime risk of dying of cancer.

Effective screening procedures for the detection of an early-stage cancer exist for very few cancer sites. Medicine, with all the progress made over the past 50 years, does NOT have -- with few exceptions -- accepted methods of detecting cancer early that can result in prolongation of life or altering the course of disease. Witness the decades-old debate -- still unsettled -- about whether the radiation doses from mammography are warranted in younger women.

It is therefore not surprising that with regard to the risk of nonfatal thyroid cancer, benign tumors from iodine-131 exposure, and testicular cancer, the Advisory Committee found no evidence that screening and early detection improve the outcome.

With regard to brain, head, and neck cancers among children and military personnel exposed to nasopharyngeal radium treatments, the Advisory Committee did find that these subjects exceeded the 1/1,000 threshold for lifetime cancer risk but they found neither an accepted nor a recommended screening procedure for these tissues. A recent consensus

conference on this subject, sponsored by Yale University, did not recommend notification of these subjects

In addition, the Advisory Committee found no evidence to indicate that subjects of human radiation experiments have greater likelihood than the general population of incurring genetic effects, meaning those passed on to children not directly exposed to radiation. Again, this is not surprising since the decades of research on atomic bomb survivors -- exposed to vastly more radiation -- has not detected genetic effects. Therefore the Advisory Committee did not recommend notification or medical follow-up for descendants of subjects of human radiation experiments.

The position of the IAWG staff on these issues has not been finalized. The provision of government sponsored medical insurance to experiment participants would be fraught with difficulties. Most important are questions of parity with citizens exposed to chemicals, drugs, or radiation from other government activities.

There is currently no Federal program that compensates citizens harmed in the course of Federally-sponsored research. In an era of shrinking Federal resources, a solution to this problem seems more pressing than the problem of providing medical insurance to participants who -- in the judgement of the Advisory Committee -- were not harmed by research.

Notification and follow-up are among the most contentious aspects of the Advisory Committee report. Our efforts to equitably settle pending lawsuits could go a long way toward healing wounds. Our compassion for citizens who were unwitting participants in radiation experiments should -- first and foremost -- fuel efforts to prevent this type of behavior by government and future researchers.

This preliminary draft Federal response to the Advisory Committee recommendations remains a work in progress. A variety of options, including both those generated by government representatives and by stakeholders, are still under discussion. These options are being reviewed for cost-effectiveness, fairness, responsiveness to public concerns, and consistency with Administration policies and with the Department's openness initiative.

DOE HUMAN RADIATION EXPERIMENTS INITIATIVES

DOE wants to take this opportunity to report on our achievements and our continuing hard work in the area of human radiation experiments. We maintain an ongoing program to work closely with citizens and stakeholders to provide useful information. Case managers continue to review DOE records and research constituent inquiries. More than 3,000 cases have been intensively researched, responding to over 16,000 inquiries from the public and members of Congress. DOE has sent more than 20,000 responses to citizens.

The Department continues to locate and make available records and information relating to human radiation research. DOE has already located over 250,000 documents after a massive search of a universe of more than 3.2 million cubic feet of records. These documents are available in hard copy at a number of locations and also on the Internet in such a way that they can be searched, viewed, and printed in their original form. More than 460 cubic feet of records were provided to the Advisory Committee for their review and more than 6,000 documents were declassified for this project.

DOE has published three important reports which serve as useful research tools:

- *Human Radiation Experiments: The Department of Energy Roadmap to the Story and the Records*, released in February 1995, which includes project background, site histories, records series descriptions, topical essays, and a preliminary list of experiments.

- *Human Radiation Experiments Associated with the United States Department of Energy and its Predecessors*, released in July 1995, which contains a listing, description, and selected references for 435 documented human radiation studies dating back to World War II.

- *Human Radiation Studies: Remembering the Early Years*, completed November 1995, which consists of a 29-part series of oral histories whose purpose was to enrich the documentary record, provide missing information, and allow an opportunity for the researchers to provide their perspective.

In addition, we also conducted quality assurance reviews of the search methodologies at 17 field facilities and DOE headquarters to ensure that record searches complied with guidance and that the search was credible and thorough. These reviews resulted from a commitment to the General Accounting Office and to Senator Glenn that DOE would do a quality check on human radiation experiment project activities across the complex. Teams were sent to each site to check whether the site followed the Office of Human Radiation Experiments guidance, whether appropriate documentation existed, and whether any outstanding issues remained. The teams performed random searches through site finding aids and document files to test whether any pertinent collections had been overlooked.

At each stage of this effort, the Department has documented what has been done and why. This will enable those who come after to know where we have been and what we have done. Our goal is not to have the final word, but to leave behind a record of our activities that historians, policymakers, Congress, and the American people can use to understand, debate, and evaluate this aspect of our history.

The activities in which we are now actively engaged are logical extensions of the path we have followed throughout this project. The Advisory Committee recommended that DOE transfer a number of important collections of records to the National Archives, and the two agencies are currently negotiating the transfer of over 3,500 cubic feet of DOE records for the National Archives' permanent collection. Also, in response to an Advisory Committee recommendation, DOE has initiated a project to place finding aids to those records still in DOE custody, and of greatest interest to the public, in agency reading rooms across the country. In addition, DOE, working closely with DOD, is helping to ensure that all documents from IAWG agencies are accessible via the Internet using the same search tools currently employed for the DOE documents.

As additional experiments or documents are located which meet the DOE search criteria, they are incorporated into the DOE information system in both electronic and hard copy format. The Department is continuing an active program of declassification review in response to the President's recent Executive Order.

THE MARSHALL ISLAND'S MEDICAL PROGRAM

[EH will provide more general info on the MI issue by 9 am Thurs]

The Advisory Committee recommended that the Department's medical program for citizens of the Marshall Islands continue, as long as any members of the exposed

population remains alive. There are no plans to discontinue this program of surveillance, screening, and medical care for the Marshallese people.

The Advisory Committee also recommended that DOE's program be reviewed to determine if expansion to include other Marshallese populations is warranted. Radiation doses to the thyroids of the exposed individuals in the mid-belt Atolls (i.e. Ailuk and Likiep) are approximately 10-25 percent of those doses at Utirik. Current radiation exposure data does not indicate the need for expansion of the Marshall Islands medical program. The Centers for Disease Control, funded by a DOE epidemiology budget line, is conducting a feasibility study to determine if they can conduct an epidemiology evaluation of thyroid neoplasia and exposures to radioactive fallout from atomic weapons testing in the Pacific. This will provide a mechanism to determine current incidence of benign and malignant thyroid cancer throughout the Marshall Islands and will provide important information on which to address the Marshall Islands concerns. Ailuk and Likiep Atolls are being considered for such a study.

Finally, the Advisory Committee recommended that the government consider whether the Marshallese people should be involved in future research decisions that affect them and that an independent review be conducted of the current DOE medical program. The government of the Republic of the Marshall Islands has echoed the Advisory Committee in requesting an independent evaluation of DOE's program. The Department is

considering a Blue Ribbon Panel that would include full participation by Marshallese representatives. Any future medical research for Marshall Islands residents will be subject to the rigorous rules governing ethics and human subjects protection.

CURRENT HUMAN SUBJECTS PROTECTION AT DOE

Research on humans performed in accordance with ethical and humanitarian principles allows experiments to be performed that provide medical and scientific benefits to individuals and to the Nation. Medical trials led to the development of the polio vaccine. Radiation research brought us treatments for cancer and diagnostic procedures to pinpoint medical problems. It is important to remember that many lives have been saved and many more will be saved using diagnoses and treatments of diseases derived through medical trials.

Federal regulations have been promulgated to assure that human subjects are fully protected from potential abuses in research experimentation. It is the policy of the Department that the rights and welfare of human subjects involved in research supported or sanctioned by DOE be protected in accordance the Federal Policy for the Protection of Human Subjects; and, until the requirements of DOE policies and orders have been met, no research activity involving human subjects shall be initiated.

DOE is improving protections for citizens who are subjects in DOE-sponsored current human research. This is an ongoing, active DOE program into which the recommendations of the Advisory Committee have been incorporated. Human subjects research at DOE encompasses a variety of studies -- many funded by other agencies in recognition of the expertise and facilities only available at DOE sites. This research encompasses such lifesaving research as non-invasive diagnostic imaging technologies to see into the human body; advanced cancer therapies using radiation and radio-immune therapy; nuclear medicine techniques that allow exploration of fundamental and pathological processes; and development of biomarkers and cellular assays for monitoring and protecting the health of DOE workers and the general public. Studies of de-identified worker records for disease patterns, surveys of occupant comfort in weatherized buildings, security detectors, and studies involving surveys of smokers or runners for health insights are also among the diverse projects that come under the rubric of "human subjects research."

It is important to note that human subjects studies are not done <u>just</u> to test the effects of chemicals or radiation on volunteers. Effects studies just to "see what happens" are not done by DOE or any Federal agency and recent press releases about research conducted many decades ago may have contributed to confusion with regard to the science-based studies and IRB reviewed biomedical research that is currently being conducted. In

contemporary studies, radiation or chemicals are only employed where a therapeutic or diagnostic protocol has been approved by a human studies board following scientific peer review.

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

In December 1993 when Secretary of Energy O'Leary began her "openness initiative," DOE had very well-established links and oversight for its facilities. These were utilized to finally put "on-line" a publicly available electronic human subjects research project database. Prior to the openness initiative, this data existed only in paper copy. The Fiscal Year 1995 database is now ready to go on-line with all research projects involving humans conducted at DOE sites, or performed with DOE funds or personnel. It is widely searched both domestically and abroad. The Fiscal Year 1994 database access information is provided with this report as backup to the testimony.

DOE proactively undertook a review of its sites by the DOE Health and Environmental Research Advisory Committee (HERAC) as part of the DOE openness initiative. The HERAC reported that DOE had quite an excellent system in place. HERAC did make some useful suggestions, the majority of which were adopted by DOE. The primary recommendation was for the establishment of a regular system of performance reviews to evaluate human subjects regulatory compliance by DOE at all sites. This review process began last month at four California sites -- three Laboratories and a DOE field office. These reviews are designed to be interactive and educational between the review team and the site and to suggest local improvements or provide guidance on issues not resolved by the 1991 common rule. In summary, a DOE human subjects performance review was undertaken in 1994, and this process will formally continue. Approximately every three years, using outside ethicists, scientists and laypersons as reviewers, each Laboratory will be revisited. Other details on DOE's activities in current human subject protection can be found in the attached report to NBAC.

CONCLUSION

In closing, let me focus on the central role of openness in the Clinton Administration. Over the past several decades, the American people's trust in the institutions of government has greatly eroded. Many complex factors have contributed to this erosion; not least among them the secrecy associated with our Cold War nuclear competition with the Soviet Union. Without judging the historical necessity of secrecy, it is a fact that the

ability of the government to perform its post-Cold War missions is greatly impeded by pervasive public distrust of its motives and competence.

To help remedy that distrust, we have told the story of human radiation experiments to the best of our ability, even though it required coming clean when necessary on episodes that are embarrassing, discomforting, or even worse. We are now fully engaged in an active, forward-looking effort to continue to provide information and services to the public and to ensure that the mistakes of the past will not be repeated.

Thank you.

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

SPECIAL

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

LRM NO: 3669
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3/5/96

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OMB CONTACT: ~~Victoria WACHINO 395-3845~~

Change of Contact for Comments - Provide all comments to H. Fitter Phone 395-3233 Fax 395-5691

SUBJECT: HHS Proposed Testimony on Protecting Human Subjects in Research (Radiation Experiements)

DEADLINE: 10:00 AM Thursday, March 07,1996

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

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

COMMENTS: DOE and DOD will also be testifying.

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FOR RELEASE UPON DELIVERY

Testimony of

Dr. Gary B. Ellis

Director, Office for Protection from Research Risks

National Institutes of Health

Department of Health and Human Services

Before the

Committee on Governmental Affairs

United States Senate

Tuesday, March 12, 1996
342 Dirksen Senate Office Building

HHS contact:
Judy Lewis
260-7450

Mr. Chairman and Members of the Committee:

I am Gary Ellis, Director of the Office for Protection from Research Risks (OPRR). The Office for Protection from Research Risks, housed administratively and physically at the National Institutes of Health (NIH), is charged with implementing regulations regarding the Protection of Human Subjects (45 CFR Part 46) that have been promulgated by the Department of Health and Human Services (HHS). In doing so, OPRR oversees a well-developed, yet ever-evolving, system of protection of human research subjects. My testimony today describes the interests of the Department in protecting human subjects in research--a responsibility of enormous weight.

In response to Executive Order 12975 (October 3, 1995), OPRR conducted a February 1996 review of the protections of the rights and welfare of human research subjects that are afforded by existing policies and procedures for HHS-conducted or -supported research.

OPRR's review documents an ever-evolving, dynamic system of protection of human research subjects based on multiple layers of review by expert and lay people exercising their best judgment. As such, this system of protection is highly sensitive to--and readily influenced by--educational efforts. OPRR and the HHS operating divisions that conduct and support research are well-invested in education and have specific plans to enhance that commitment even further. The Department has accepted lead-agency

responsibility for management and support of the new National Bioethics Advisory Commission (NBAC). Taken together, current and planned activities sum to HHS' retaining as a priority continued vigilance over human subjects protection. The recent call by the Secretary, HHS, to make bioethics "as sophisticated as our science" embraces the intent of Executive Order 12975 and reemphasizes OPRR's charge.

HHS Regulations for Protection of Human Subjects

At Title 45, Code of Federal Regulations, Part 46 (45 CFR Part 46), the Department has codified its regulations for Protection of Human Subjects. There are four subparts:

- Subpart A (last revised June 18, 1991) is the Basic DHHS Policy for Protection of Human Research Subjects. Sixteen other Federal Departments and Agencies are also formally bound to identical text by statute, regulation, or Executive Order. OPRR chairs and staffs the interagency body responsible for fostering uniform implementation of this common rule--the Human Subjects Research Subcommittee, Committee on Health, Safety, Food Research and Development, National Science and Technology Council.

- Subpart B (last revised November 3, 1978) identifies Additional DHHS Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization. In October 1995, the Assistant

Secretary for Health transmitted to the Secretary, HHS, a draft Notice of Proposed Rulemaking representing a proposed revision of Subpart B produced by the 1994-95 deliberations of the Public Health Service Human Subject Regulation Drafting Committee.

- Subpart C (last revised November 16, 1978) identifies Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects.

- Subpart D (last revised March 8, 1983) identifies Additional DHHS Protections for Children Involved as Subjects in Research.

The local Institutional Review Board (IRB) at the research site is the cornerstone of this system of protection of human subjects. No human subjects research may be initiated, and no ongoing research may continue, in the absence of IRB approval. HHS cannot provide funds for, or conduct, human subjects research unless one or more IRBs approves the protocol for such studies.

An IRB is, by regulation, to be established at the local level and has a minimum of five people, including at least one scientist, one nonscientist, and one person not otherwise affiliated with that institution.

IRB review is a prospective as well as continuing review of research by a group of individuals with no formal interest in the research. It is a local review, by individuals who are in the best position to know the research site; to know the resources of the institution; to know the capabilities and reputations of the investigators and staff; and to know the prevailing values and ethics of the community and--most important--the likely subject population.

In order to approve research, the IRB must determine that all of the following requirements are satisfied:

1) Risks to human subjects are minimized.

2) Risks to human subjects are reasonable in relation to anticipated benefits, if any, to human subjects, and the importance of the knowledge that may reasonably be expected to result.

3) Selection of human subjects is equitable.

4) Informed consent will be sought from each prospective human subject or the human subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR Part 46.

5) Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR Part 46.

6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of human subjects.

7) When appropriate, there are adequate provisions to protect the privacy of human subjects and to maintain the confidentiality of data.

In addition, when some or all of the human subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these human subjects.

Once research is underway, the IRB must conduct continuing review of the research, at intervals appropriate to the degree of risk--in any event, at least once per year. Continuing review is substantive and meaningful. In approving the continuation of ongoing research, an IRB attests to its satisfaction that the research continues to be conducted in accord with all relevant provisions of the regulations.

I mentioned that IRBs oversee the informed consent process. The regulations specify eight required elements of informed consent:

1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

2) A description of any reasonably foreseeable risks or discomforts to the subject.

3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

OPRR implements these regulations by (i) negotiating formal, written assurances of compliance with institutions engaged in research covered by 45 CFR Part 46; (ii) investigation and oversight of institutional compliance; and (iii) professional and public education.

Assurance of Compliance with 45 CFR Part 46

Each institution engaged in research (i) covered by 45 CFR Part 46 and (ii) conducted or supported by HHS must provide assurance satisfactory to OPRR that it will comply with 45 CFR Part 46. OPRR employs several types of assurance instruments. Institutions with a track record in human subjects protection satisfactory to OPRR are selected for the Multiple Project Assurance (MPA). At present, 448 institutions hold an

active MPA. Of these institutions, 98 percent have voluntarily elected to extend the protections of 45 CFR Part 46 to non-HHS-supported research.

In seeking assurances for their respective research portfolios, the 16 other Federal Departments and Agencies that have embraced Subpart A of 45 CFR Part 46 (also known as the "Federal Policy for the Protection of Human Subjects" and the "Common Rule") are often linked to OPRR. In lieu of requiring institutional assurances for work they conduct or support, they are required to accept assurances, appropriate for the research in question, on file with OPRR and approved for Federal-wide use by OPRR.

OPRR also negotiates Single Project Assurances (3,133 currently active) and Cooperative Project Assurances (1,345 currently active) to meet the varying circumstances of HHS-supported research at other-than-MPA-assured institutions.

The recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE) identify three problems in consent forms reviewed by ACHRE: (i) overly optimistic portrayal of the likely benefits of research; (ii) inadequate explanation of the impact of research procedures on quality of life and personal finances; and (iii) incomprehensibility to lay people. OPRR staff were provided with this ACHRE analysis immediately upon the October 3, 1995 release of the ACHRE report, so that OPRR staff could incorporate this information into OPRR review of IRB handling of informed consent documents prior to approving assurances to comply with 45 CFR Part 46. Additionally,

this ACHRE analysis is being featured in professional and public educational activities described below.

Investigation and Oversight of Institutional Compliance

Under 45 CFR Part 46, there are multiple administrative actions that can be taken for violation of the regulations. OPRR may restrict or suspend its approval of an institution's assurance. Affected research projects cannot be supported by HHS until the terms of the restriction have been satisfied. Examples of such restrictions include, but are not limited to:

- suspending the assurance's applicability relative to some or all research projects until specified protections have been implemented;

- requiring prior OPRR review of some or all research projects to be conducted under the assurance;

- requiring that some or all investigators conducting research under the assurance receive appropriate human subject education;

- requiring special reporting to OPRR.

OPRR may withdraw its approval of an institution's assurance. Affected research projects cannot be conducted or supported by any HHS component until approval of an appropriate assurance is reinstated by OPRR.

OPRR may recommend to appropriate HHS officials or Public Health Service (PHS) agency heads:

- that an institution, a component of an institution (e.g., department or an investigator) be temporarily suspended or permanently removed from participation in specific projects;

- that HHS peer review groups be notified of an institution's or an investigator's past noncompliance prior to review of new projects; or

- that institutions or investigators be declared ineligible to participate in HHS-supported research (i.e., debarment or suspension). If OPRR makes this recommendation, the debarment or suspension process may be initiated in accordance with the procedures specified at 45 CFR Part 76. Debarment or suspension of a participant in a program by one agency has government-wide effect.

OPRR currently has 81 open compliance oversight investigations. One-quarter of these derive from non-HHS-funded research, owing to institutions' voluntary commitment

of all research to HHS rules. Since January 1, 1990, OPRR has initiated 321 human subject compliance oversight investigations, of which 240 were completed as of January 31, 1996. During this period, OPRR conducted 18 "for-cause" site visits (i.e., in the course of compliance investigations) and 10 "not-for-cause" site visits (i.e., for technical assistance).

Corrective actions based on compliance oversight evaluations are intended to remedy identified noncompliance with 45 CFR Part 46 and to prevent reoccurrence. Because each compliance investigation is different, OPRR tailors its corrective actions to the nature of the violation and to the improvements needed in the affected institution's system of protections. The large majority of the 227 investigations completed from 1990 through 1995 involved some corrective action on the part of the institution. Such actions include institutional sanction or increased monitoring of individual investigators, modification of informed consent documents for specific studies, changes in IRB policies and procedures, and revision of the institutional system of protection for human subjects.

The following are examples of additional oversight mechanisms within HHS:

- At NIH, initial scientific and technical review groups must take into consideration the risks to subjects of proposed research, the adequacy of protection against these risks, the potential benefits of the research, and the importance of the knowledge to be gained. This second level of independent review of research involving human subjects, which requires detailed documentation of the consent process and any

additional human subjects concerns, follows local IRB review. OPRR is informed when NIH peer review groups identify concerns about human subject protections, and these concerns must be resolved before an award may be made.

- Cooperative Oncology Group research supported by the National Cancer Institute is monitored through a program of on-site audits which include an evaluation of human subject protections.

- Many NIH-supported, multi-center, clinical trials include provision for monitoring by an independent Data and Safety Monitoring Board which periodically evaluates emerging data to ensure subject safety as the trials progress.

- HHS benefits from the continuing and detailed inspection of IRBs conducted by FDA field staff, where FDA possesses jurisdiction to do so. When an applicable OPRR-approved assurance exists, the findings of such inspections are shared with OPRR, to enhance efficiency of effort within HHS. In turn, OPRR supplies the FDA with lists of institutions at which major clinical trials of Investigational New Drug agents are likely to be in progress.

Professional and Public Education

OPRR responds on a day-to-day and long-term basis to requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects, as required by Section 491(b)(1) of the Public Health Service Act. In addition, OPRR promulgates interpretation of 45 CFR Part 46 by means of periodic "Dear Colleague" letters; sponsorship of 4 to 6 national workshops each year, serving an annual total of approximately 1,000 attendees; free distribution of three instructional videotapes (produced in 1986); production of the comprehensive Institutional Review Board Guidebook (revised 1993); and technical assistance site visits. OPRR fulfills hundreds of requests for educational materials each month via a voice mailbox and FAX-on-demand service. Full-text OPRR materials will soon be electronically retrievable.

In light of the focus of ACHRE recommendations on IRBs, the cornerstone of the HHS response to the ACHRE report is enhanced education directed toward the community of IRB members, IRB administrators, institutional officials, researchers, and potential human subjects. OPRR collaborates closely with Public Responsibility in Medicine and Research (PRIM&R), a Boston-based private, nonprofit organization, to stage an annual public meeting for individuals interested in the governance of human subjects research. More than 600 people attended the October 1995 PRIM&R meeting, at which the ACHRE recommendations were presented for the first time to the IRB community.

OPRR has scheduled presentation and discussion of the ACHRE recommendations at national human subjects protection workshops in Atlanta (April 11-12, 1996), Oklahoma City (June 3-5, 1996), Honolulu (July 26-27, 1996), Peoria IL (September 26-27, 1996), and Houston (November 1-2, 1996). The November 11-12, 1996 PRIM&R annual conference (San Diego) is expected to address IRB implementation of the ACHRE recommendations.

One ACHRE recommendation to IRBs is that they appropriately allocate their time so that they can adequately review studies that pose more than minimal risk to human subjects. Anticipating this recommendation, OPRR issued a May 5, 1995 "Dear Colleague" letter with guidance on this point. OPRR reminded institutions of the procedures described at 45 CFR 46.110 that permit expedited review of activities that involve no more than minimal risk and are identified on a list of 10 research categories promulgated by the Secretary of HHS in 1981. In its letter, OPRR also reminded institutions of the six categories of research at 45 CFR 46.101(b)(1)-(6) that are exempt from IRB review.

The ACHRE demonstrated the utility of first-hand, external examination of institutional oversight of human subjects research, and there is a consensus among experts and regulators about the benefits of such review. Accordingly, OPRR expects to enhance its educational efforts to include a program of technical assistance site visits. Such visits, to number from 12 to 24 per year, are of mutual educational benefit — strengthening both the

institution's program of human subject protections and ensuring the fidelity of OPRR's assurance negotiations and documents.

The ACHRE identified the urgent need for better understanding and implementation of the informed consent transaction between research and subject. The specificity of the language about informed consent in 45 CFR Part 46, its endurance through many years, and the enthusiasm with which all parties adhere to it all belie the fact that little empirical work exists to document the degree of understanding achieved by research participants. There is a paucity of data that bear upon, for example, (i) a research subject's comprehension of a study's methods and procedures; (ii) subject's understanding of relative risks and benefits of participation; (iii) subject's understanding of confidentiality and any exceptions to confidentiality; (iv) subject's understanding of the implications of withdrawal from a study; and (v) subject's ability to distinguish between the roles of clinician and investigator--and the consequences of failure to make that distinction. Such data are desperately needed to aid in designing informed consent procedures that are readily comprehended by prospective participants and, at the same time, impart all critical information.

Announcement came in July 1995 of an important program of the National Institute of Mental Health (NIMH) that will make available NIMH research funds for investigations into the informed consent process in research involving individuals with mental disorders. NIMH has thus taken the lead in stimulating investigations into the informed consent process in research, and OPRR hopes that this is an indication of an increasing investment

by funders in the development of new knowledge related to informed consent. In November 1995, the NIH Office of Extramural Research convened an interagency group to begin pursuit of a broad research agenda in informed consent.

Taken together, these efforts--undertaken on a national scale to ensure the centrality of ethics in human subjects research--maintain and reinforce the trajectory of HHS on the path of preventing misadventures in contemporary human subjects research.

National Bioethics Advisory Commission

There exists a void in our multi-tiered system of human subjects protection, that of a national body that can deliberate and advise on difficult issues in bioethics as they arise. In the past, the Nation has had a demonstrated need for a national, deliberative body of private citizens to offer the Federal Government analysis of the bioethical dimensions of ongoing and new activities and problems. From 1974 to 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was highly productive, laying out much of the philosophical basis for our current regulatory system. Following the National Commission, an Ethics Advisory Board was active in the Department of Health, Education, and Welfare. Then, in the early 1980s, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research served an important role.

The need for such a body is arguably greater today than ever before. The ACHRE recommended establishment of a mechanism to provide for the continuing interpretation and application of ethics rules and principles for the conduct of human subject research in an open and public forum. The ACHRE identified at least three unresolved ethical issues in need of such deliberation:

- clarification of the meaning of minimal risk in research with healthy children;

- development of regulations to govern the conduct of research with institutionalized children; and

- development of guidelines for research involving adults of questionable competence, particularly for research in which subjects are placed at more than minimal risk but are offered no prospect of direct medical benefit.

On October 3, 1995, Executive Order 12975 created the National Bioethics Advisory Commission, to be appointed by the President. OPRR has since been coordinating the initial efforts of management and administration of the NBAC, so that the NBAC can begin operations and begin to address the recommendations of the ACHRE at an early date.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

LRM NO: 3716

FILE NO: 1960

3/8/96

LEGISLATIVE REFERRAL MEMORANDUM

Total Page(s): 26

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OMB CONTACT: Eric MACRIS 395-3807

96 MAR 11 All : 08

SUBJECT: ENERGY Proposed Testimony on Protecting Human Subjects in Research (Radiation Experiements)

DEADLINE: 1:00 P.M., Monday, March 11,1996

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

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RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

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Please include the LRM number shown above, and the subject shown below.

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_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

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GNA S1

STATEMENT OF TARA O'TOOLE, M.D., M.P.H.
BEFORE THE COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE
MARCH 12, 1996

INTRODUCTION AND SUMMARY

Mr. Chairman and Members of the Committee, thank you for the opportunity to appear before the Committee today and provide you with an update on the continuing work of the Department of Energy (DOE) in response to the human radiation experiments initiative. I will speak to you today both in my capacity as Assistant Secretary of Energy for Environment, Safety and Health, and as the chair of the staff of the Interagency Working Group (IAWG), which has been directed by President Clinton to respond to the recommendations of the Advisory Committee on Human Radiation Experiments. The IAWG was established in January 1994 to coordinate the government's response to human radiation experiment issues and consists of the Cabinet Secretaries of the Departments of Energy, Health and Human Services (HHS), Defense (DOD), and Veterans Affairs (VA), the Attorney General (DOJ), and the Directors of the National Aeronautics and Space Administration (NASA), Central Intelligence Agency (CIA), and the Office of Management and Budget (OMB).

My testimony will cover recent activities of the IAWG staff, including preparation of a draft preliminary response to the recommendations of the Advisory Committee on Human

DOE contact
Val Adams
586-2032

Radiation Experiments. These recommendations are the result of 18 months of intense deliberation, the review of thousands of documents, and public meetings both in Washington and across the country that involved presentations by many concerned citizens. Two weeks ago, the Administration sponsored a two-day stakeholder workshop to receive input to this draft response. The IAWG staff are actively seeking ways to make human radiation experiment information more useful and accessible to citizens.

I will also discuss the work being done by DOE to carry out the human radiation experiments initiative begun over two years ago, and to keep this effort strong. We are working closely with citizens and stakeholders to respond to specific inquiries. We actively continue to locate, release, declassify, and generally improve access to DOE records and information on this and related subjects.

Finally, the Administration is working to improve protections for citizens who are subjects in current human subjects research. President Clinton's October 1995 Executive Order required Federal agencies to review their entire program of current human subjects research in light of the Advisory Committee's recommendations and to report on this review to the National Bioethics Advisory Commission. The Office of Energy Research has completed this requirement and is now engaged in: a systematic review of DOE site activities in relation to human subjects protection; efforts to improve informed consent documentation; and efforts to better educate scientists, administrators, and Institutional

Review Board (IRB) members about their responsibilities in the area of human subjects protection.

Let me emphasize the continuing commitment of President Clinton, Secretary O'Leary, and the entire IAWG to make government accountable to the people, make information about government activities easily available, be responsive to citizen concerns, and seek citizen input on the range of issues associated with the human radiation experiments effort.

BRIEF HISTORY OF THE HUMAN RADIATION EXPERIMENTS INITIATIVE

The issue of government sponsored human radiation experiments has been examined with increasing intensity over the past two decades. In the mid-1970s, then-Representative Al Gore chaired hearings which focused on whole body irradiation treatments for cancer patients, conducted by the Oak Ridge Institute of Nuclear Studies. No final report was issued and no wrongdoing found

Representative Ed Markey chaired hearings in 1986 and issued the report, "Human Guinea Pigs", which detailed experiments involving some 600 human subjects. The "plutonium experiments" were publicly discussed in detail in this report. The research involved in "Human Guinea Pigs" served as a starting point for the exhaustive search to come in the 1990s.

In late 1993, Eileen Welsome's Pulitzer-Prize winning investigative report for the Albuquerque Tribune on the plutonium injection subjects brought the topic to the attention of Energy Secretary Hazel O'Leary. Secretary O'Leary's outrage, expressed in a December 1993 press conference on openness in DOE, inspired tremendous media response and public outcry. The Human Radiation Experiments Helpline was immediately established and received over 17,000 calls from citizens in the first month alone. President Clinton promptly issued an Executive Order directing all relevant Federal agencies to search their records for information on radiation experiments.

This Executive Order also established the IAWG in early 1994. Individual agencies organized research teams to locate and examine records. The extensive DOE search for records of Department of Energy and predecessor agency human radiation experimentation was difficult for a number of reasons. The records universe to be searched was huge -- an estimated 3.2 million cubic feet (one cubic foot is about the size of a case of Budweiser longnecks and contains between 2,500 and 3,000 pages!). Moreover, these records were in multiple locations and geographically dispersed from coast to coast.

In addition, there was no single subject index or finding aid to help DOE's Office of Human Radiation Experiments (OHRE) sort through this records universe. Most human experimentation records had been created more than twenty years ago and few in DOE

were familiar with such old records. The records were created by decentralized governmental and contractor institutions with substantial autonomy. As a result, there were few central files arranged according to standardized filing schemes. Some files had been reorganized and moved over the years, so that what were once single collections stored in one place might now be three or four stored in two to four different places. Most of the records had originally been created for purposes other than facilitating a search for documentation on human radiation experiments and therefore did not easily lend themselves to this search. Over 200 people from the Department were involved in this search process.

One important purpose of the records search was to provide the Advisory Committee on Human Radiation Experiments with documents for review. The Advisory Committee membership, appointed by President Clinton in early 1994, was charged with advising the IAWG and the President of the ethical implications of the experiments. The Committee included medical doctors, radiation biologists, lawyers, ethicists, historians, and one citizen representative. When the Advisory Committee was formed, we had no idea of the number of government sponsored radiation experiments or the extent of the documentation that would have to be reviewed. In an attempt to make the Committee's task realistically manageable, the IAWG required the Committee to review experiments from 1944 to 1974, which was the year of the first Federal regulations protecting human subjects, and to sample later experiments for ethical problems. The Advisory Committee

subsequently conducted its own investigation of the adequacy of present-day informed consent documentation by reviewing a sample of current research projects.

The Advisory Committee members and staff reviewed hundreds of thousands of documents and spoke with hundreds of citizens and stakeholders. The Committee's meetings and research took them across the country in search of information. All Advisory Committee meetings were held in public, in accord with the Federal Advisory Committee Act (FACA) and all drafts of the Committee's interim and final reports were also public. The charter of the Committee was extended to 18 months, at the Committee's request, to allow a more thorough review and deliberation. The Committee's final conclusions were presented to President Clinton in a 900 page report on October 3, 1995.

At the White House ceremony in which President Clinton accepted the Committee's report, he apologized to the victims. "While most of the tests were ethical by any standards, some were unethical, not only by today's standards, but by the standards of the time in which they were conducted. They failed both the test of our national values and the test of humanity...So today," he said, "on behalf of another generation of American leaders and another generation of American citizens, the United States of America offers a sincere apology to those of our citizens who were subjected to these experiments, to their families, and their communities."

The same day, President Clinton signed an Executive Order establishing the National Bioethics Advisory Commission (NBAC), which will continuously review and identify principles governing human subjects research. President Clinton simultaneously directed all Federal agencies sponsoring human subjects research to review and improve their human subjects protections in light of the Advisory Committee's recommendations and to report on this review to NBAC. He also instructed the Cabinet to use and build on these recommendations to devise a system of relief, including compensation, that meets the standards of justice and conscience.

where appropriate

CURRENT ACTIVITIES OF THE INTERAGENCY WORKING GROUP STAFF

In response to the 18 recommendations in the Advisory Committee's final report, the IAWG staff has drafted a preliminary paper which lays out a proposed set of government actions. The government continued in its commitment to public involvement by receiving citizen input on this draft during a two-day stakeholder/citizen workshop sponsored by the IAWG staff at the end of February 1996. Over 120 people participated in the workshop, including citizens who believe they were/are experiment subjects, their advocates, government representatives, and invited experts. Discussion was intense and stakeholders were highly critical of the Committee's recommendations, as well as the preliminary proposed government response. Citizens want the government to respond to a wide range of matters relating to radiation exposures, many of which do not fall under

the category of "human radiation experiments" as defined in the Advisory Committee's charge.

In response to strong citizen concerns expressed at the workshop, the IAWG staff is examining ways to involve the public more extensively in government decisionmaking on the issues of human subjects research. Citizen proposals include:

- The reform of the IRB process to include greater citizen representation and more effective, community-based review of human subjects research;

- Facilitation of better access to government decisionmakers for citizen groups; and

- Ways to enable citizens to work with government to develop appropriate search tools to help members of the public independently access information about human radiation experiments..

Two important and potentially controversial issues raised by the Advisory Committee recommendations are compensation and medical follow-up and notification for human radiation subjects. As to the issue of compensation, representatives of the families of most, if not all, of the subjects identified by the Advisory Committee have already

pursued claims against the government and the Administration has engaged or will engage in discussions with them.

In the areas of subject notification and medical follow-up, citizens at the stakeholder workshop criticized the Advisory Committee recommendations and the IAWG staff draft responses. They advocated the notification of all subjects who have participated in government sponsored radiation experiments and the provision of funds for comprehensive medical care, managed at the local level, for all persons involved in the experiments.

The following discussion sets forth the salient issues on this topic.

The Advisory Committee recommended against notification and medical follow-up of human radiation experiment participants because two criteria were not met. The Committee recommended that these two criteria form the basis for decisions on notification and medical follow-up. The criteria were:

1) Risk, including both the remaining lifetime risk of mortality from the exposure and the potential risks from medical follow-up; and

2) The medical utility of early detection and treatment for changing the course of disease or the quality or length of life.

Should other experiments of concern come to light in the future, these criteria should govern the decision to notify subjects and pursue monitoring interventions.

It is an unfortunate fact that the practical, logistical task of identifying, locating, and notifying participants in past government sponsored radiation experiments and/or their descendants would entail an enormously expensive, time-consuming effort that promises to be futile in most cases.

Although the Advisory Committee's database includes documentation describing approximately 4,000 government-sponsored human radiation experiments, no list of participants exists for most of the experiments. For example, 3,000 of the 4,000 experiments were sponsored by the VA. According to Advisory Committee staff, there are subject names for only a tiny fraction of these experiments. In the isolated cases where participant lists are available, scores of researchers would be needed to track down persons whose whereabouts have been unknown to the government for several decades. It is probable that most subjects have changed names, died, or moved to other parts of the country and to locations around the globe.

The Advisory Committee also felt that there would be little or no medical benefit to subjects -- and possibly new risks -- from this vast endeavor. These potential risks include medical harm and discomfort, the possibility of incorrect test results, the possibility of stigmatization by friends, family, insurers, and employers, and potential financial costs to the subjects and their families.

In the Advisory Committee's judgment, almost all of the experiments involved small radiation doses, producing less than 1/1,000 remaining lifetime risk of cancer death. This level is minimal compared with the normal risk of dying of cancer (220 out of 1,000). Many of the experiments involved tracer doses, similar to those used in medical diagnostic procedures today to diagnose cancer and heart disease.

The unfortunate reality is that there are very few effective screening procedures for the detection of an early-stage cancer. Medicine, with all the progress made over the past 50 years, does <u>not</u> have -- with few exceptions -- accepted methods of detecting cancer early that can result in prolongation of life or altering the course of disease in persons who are not known to be at high risk for cancer. Witness the ongoing debate -- still unsettled -- about whether the radiation doses from mammography are warranted in younger women. Our health care system and the vast bulk of medical research efforts emphasize the <u>treatment of disease</u>, not its prevention.

With regard to brain, head, and neck cancers among children and military personnel exposed to nasopharyngeal radium treatments, the Advisory Committee did find that these subjects exceeded the 1/1,000 threshold for lifetime cancer risk but they found neither an accepted nor a recommended screening procedure for these tissues. A recent conference on this subject, jointly sponsored by the VA, Centers for Disease Control, and Yale University, did not recommend notification of these subjects. However, the question of what, if any, follow-up these individuals should receive remains controversial.

In addition, the Advisory Committee found no persuasive evidence to indicate that subjects of human radiation experiments have greater likelihood than the general population of incurring genetic effects, meaning those effects passed on to children of experiment subjects. Again, this is not surprising since the decades of research on atomic bomb survivors -- exposed to vastly more radiation -- have not detected genetic effects. Therefore, the Advisory Committee did not recommend notification or medical follow-up for descendants of subjects of human radiation experiments.

We recognize the anguish that subjects and their descendants may feel, even when there is little the government may be able do for them. The position of the IAWG staff on these issues has not yet been finalized. There is currently no Federal program that compensates citizens harmed in the course of Federally-sponsored research. Our concern and sympathy for those who were subjects of experiments must be balanced against the

fact that the provision of government sponsored medical insurance to experiment participants could be fraught with difficulties. There are also important questions of parity with citizens exposed to chemicals, drugs, or radiation from other government activities.

Notification and follow-up are among the most contentious aspects of the Advisory Committee report. Our compassion for citizens who were unwitting participants should -- first and foremost -- fuel efforts to prevent this type of behavior by government and future researchers.

This preliminary draft Federal response to the Advisory Committee recommendations remains a work in progress. A variety of options, including both those generated by government representatives and by stakeholders, are still under discussion. These options are being reviewed for fairness, cost-effectiveness, responsiveness to public concerns, and consistency with Administration policies and with the Department's openness initiative.

DOE HUMAN RADIATION EXPERIMENTS INITIATIVES

DOE wants to take this opportunity to report on the achievements of the Office of Energy Research and our continuing hard work in the area of human radiation experiments. We maintain an ongoing program to work closely with citizens and stakeholders to provide information about past human radiation experiments. Case

managers continue to review DOE records and research constituent inquiries. More than 3,000 cases have been intensively researched, responding to over 16,000 inquiries from the public and members of Congress. DOE has sent more than 20,000 responses to citizens, from acknowledgement of inquiries to determination of the extent of participation in experiments.

The Department continues to locate and make available records and information relating to human radiation research. DOE has already located over 250,000 pages of documents that are available in hard copy at a number of locations. They are also on the Internet in such a way that they can be searched, viewed, and printed in their original forms. Many more cubic feet of records were provided to the Advisory Committee for their review and more than 6,000 documents have been declassified for this project.

DOE has also published three important reports which serve as useful research tools:

- *Human Radiation Experiments: The Department of Energy Roadmap to the Story and the Records*, released in February 1995, includes project background, site histories, records series descriptions, topical essays, and a preliminary list of experiments.

- *Human Radiation Experiments Associated with the United States Department of Energy and its Predecessors*, released in July 1995, contains a listing, description, and selected references for 435 documented human radiation studies dating back to World War II.

- *Human Radiation Studies: Remembering the Early Years*, completed November 1995, consists of a 29-part series of oral histories whose purpose is to enrich the documentary record, provide missing information, and allow an opportunity for the researchers to provide their perspective.

In addition, we also conducted quality assurance reviews of the search methodologies at 17 field facilities and DOE headquarters to ensure that record searches complied with guidance and that the search was credible and thorough. These reviews resulted from a commitment to the General Accounting Office and to Senator Glenn that DOE would do a quality check on human radiation experiment project activities across the complex. Teams were sent to each site to ensure that the site followed the OHRE guidance, and to determine whether the search was properly documented and any outstanding sources of information remained to be investigated. The teams performed random searches through site finding aids and document files to test whether any pertinent collections had been overlooked.

At each stage of this search effort, the Department has documented what was done and why. This will enable those who come after us to know where we have been and what we have done. Our goal is not to have the final word, but to leave behind a record of our activities that historians, policymakers, Congress, and the American people can use to understand, debate, and evaluate this aspect of our history.

The activities in which we are now actively engaged are logical extensions of the path DOE has followed throughout this project. The Advisory Committee recommended that DOE transfer a number of important collections of records to the National Archives, and the two agencies are currently negotiating the transfer of over 3,500 cubic feet of DOE records for the National Archives' permanent collection. Also, in response to an Advisory Committee recommendation, DOE has initiated a project to place "finding aids," that will improve access to those records still in DOE custody, in agency reading rooms across the country. In addition, DOE is working closely with DOD to help ensure that all documents from IAWG agencies are accessible via the Internet, using the same search tools currently employed for the DOE documents.

As additional experiments or documents are located, they are incorporated into the DOE information system in both electronic and hard copy format. The Department is continuing an active program of declassification review in response to the President's recent Executive Order.

THE MARSHALL ISLANDS MEDICAL PROGRAM

The Department of Energy provides special medical care and logistical support to the remaining population of the Rongelap and Utirik atolls of the Republic of the Marshall Islands (RMI) who were exposed to radiation, resulting from the 1954 United States thermonuclear "Bravo" test. The Marshallese were not specifically included in the Advisory Committee's charter for two primary reasons. First, the Rongelap and Utirik populations were exposed to radiation, not as part of human experimentation, but rather through fallout as a result of the U.S. nuclear weapons testing program. Second, as noted above, a lifetime program of medical care and compensation, supported by the Department, is already in place for these exposed populations.

The Department's medical program currently provides twice a year medical screening and full medical care for radiogenic conditions for the remaining 137 out of 253 exposed Rongelap and Utirik individuals. Any exposed person who has medical findings suggesting a malignant neoplasm, or other radiation-related disease, is referred to secondary or tertiary medical facilities for definitive evaluation and therapy. Those persons with problems that can be effectively managed in Majuro or Kwajalein are referred to the Marshallese Health Services. Those requiring a more extensive evaluation are referred to hospitals in Honolulu or, for the special cases of thyroid and pituitary lesions, the National Institutes of Health in Bethesda, Maryland.

The Department started, during 1995, to transition from previous vessel-based medical missions to land-based medical missions. Vessel-based missions were handicapped by the inability to keep a vessel equipped with state-of-the art medical equipment. The land-based approach will improve the quality and affect cost efficiencies in medical care for the exposed populations in Rongelap and Utirik. This approach will make available, at existing Marshall Islands' medical facilities, more sophisticated diagnostic equipment and improved laboratory analytical capabilities for the aging Rongelap and Utirik populations. Examples of improvements offered by land-based medical capabilities include:

- Year-round use of newly purchased current ultrasound equipment;

- Immediate diagnosis of thyroid nodules, ability to do immediate fine needle aspiration or thyroid surgery locally in the RMI as well as surgical removal of gastrointestinal tumors;

- Availability of certified mammography equipment at Kwajalein which meets the higher more stringent U.S. mammography standards for mammography equipment and technician qualifications; and

- Better radiography capabilities and diagnostics permitting immediate follow-up, additional tests and surgery when needed.

As with vessel-based care, the land-based system will provide continued visits to infirm patients in their homes at Mejatto and Utirik with the added ability to provide full diagnostics and tests of samples taken right after the visit to these remote islands at the newly-established land-based facilities. Because of the limited diagnostic equipment on the vessel, many of these samples were formerly shipped to the U.S. mainland for analysis.

The Advisory Committee recommended that the Department's medical program for citizens of the Marshall Islands continue, as long as any members of the exposed population remain alive. The Department has no plans to discontinue its program of surveillance, screening, and medical care for the Marshallese people.

The Advisory Committee also recommended that DOE's program be reviewed to determine if expansion to include other Marshallese populations is warranted. Based on an evaluation of currently available radiation exposure data, the Department does not believe there is a need for the expansion of the Marshall Islands medical program. For example, current data show that the radiation doses to the thyroids of the exposed individuals in the mid-belt atolls (i.e., Ailuk and Likiep) are only 10 to 25 percent of the doses received by exposed individual at Utirik. Nevertheless, the Department is funding an RMI-requested study by the Centers for Disease Control and Prevention (CDC) to compare the incidence rates of benign and malignant thyroid cancer in populations

throughout the Marshall Islands and to estimate the dose response for radioactive fallout and thyroid neoplasm. This feasibility study is to be completed by June 1996, with a presentation of results to RMI by September 1996. The results of this study will need to be evaluated jointly by CDC, DOE, and the Marshallese in light of existing data to determine the scientific basis for expanding the Department's current medical screening and medical care program.

Finally, the Committee recommended that the government consider whether the Marshallese people should be involved in future research decisions that affect them and that an independent review be conducted of the current DOE medical program. The government of RMI has agreed with the Advisory Committee in requesting an independent evaluation of DOE's program. The RMI government wants a review process in which they can fully participate. The Department is in the process of consulting with the Marshallese on the various approaches which can be used to accomplish this goal. The Department anticipates that its mission in the Marshall Islands will remain a clinical one and will continue not to involve medical research.

CURRENT HUMAN SUBJECTS PROTECTION AT DOE

Research on humans performed in accordance with ethical and humanitarian principles allows experiments to be performed that provide medical and scientific benefits to individuals and to the Nation. Medical trials led to the development of the polio vaccine.

Radiation research brought us treatments for cancer and diagnostic procedures to pinpoint medical problems. It is important to remember that many lives have been saved and many more will be saved using diagnoses and treatments of diseases derived through medical trials.

Federal regulations have been promulgated to assure that human subjects are fully protected from potential abuses in research experimentation. It is the policy of the Department that the rights and welfare of human subjects involved in research supported or sanctioned by DOE be protected in accordance with the Federal Policy for the Protection of Human Subjects and, until the requirements of DOE policies and orders have been met, no site research activity involving human subjects shall be initiated.

DOE is improving protections for citizens who are subjects in DOE-sponsored current human research. This is an ongoing, active DOE program into which the recommendations of the Advisory Committee have been incorporated. Human subjects research at DOE encompasses a variety of studies -- many funded by other agencies in recognition of the expertise and facilities only available at DOE sites. This research encompasses such lifesaving research as non-invasive diagnostic imaging technologies to see into the human body; advanced cancer therapies using radiation and radio-immune therapy; nuclear medicine techniques that allow exploration of fundamental and pathological processes; and development of biomarkers and cellular assays for monitoring

and protecting the health of DOE workers and the general public. Studies of de-identified worker records for disease patterns, surveys of occupant comfort in weatherized buildings, security detectors, and studies involving surveys of smokers or runners for health insights are also among the diverse projects that come under the rubric of "human subjects research."

It is important to note that human subjects studies are not done just to test the effects of chemicals or radiation on volunteers. Effects studies just to "see what happens" are not done by DOE or any Federal agency and recent press releases about research conducted many decades ago may have contributed to confusion with regard to the science-based studies and IRB reviewed biomedical research that is currently being conducted. In contemporary studies, radiation or chemicals are only employed where a therapeutic or diagnostic protocol has been approved by a human studies board following scientific peer review.

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

In December 1993, when Secretary of Energy O'Leary began her "openness initiative," DOE had well-established oversight for its facilities in relation to current human subject research. These were utilized to finally put "on-line" a publicly available electronic human subjects research project database. Prior to the openness initiative, this data existed only in paper copy. It is widely searched both domestically and abroad. The Fiscal Year 1994 database access information is provided with this report as backup to the testimony. The Fiscal Year 1995 database is now ready to go on-line with all research projects involving humans conducted at DOE sites, or performed with DOE funds or personnel.

DOE proactively undertook a review of its sites by the DOE Health and Environmental Research Advisory Committee (HERAC) as part of the DOE openness initiative. The HERAC reported that DOE had an excellent system in place. HERAC did make some useful suggestions, the majority of which were adopted by DOE. The primary recommendation was for the establishment of a regular system of performance reviews to evaluate human subjects regulatory compliance by DOE at all sites. This review process began last month at four California sites -- three Laboratories and one DOE field office. These reviews are designed to be interactive and educational between the review team and the site and to suggest local improvements or provide guidance on issues not resolved by the 1991 common rule. In summary, a DOE human subjects performance review was undertaken in 1994, and this process will formally continue. Approximately

every three years, using outside ethicists, scientists, and laypersons as reviewers, each Laboratory will be revisited. Other details on DOE's activities in current human subject protection can be found in the attached report to NBAC.

CONCLUSION

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

To help remedy that distrust, we have told the story of human radiation experiments to the best of our ability, even though it required coming clean when necessary on episodes that are embarrassing, discomforting, or even worse. We are now fully engaged in an active, forward-looking effort to continue to provide information and services to the public and to ensure that the mistakes of the past will not be repeated.

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

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

03-Apr-1996 04:35pm

TO: (See Below)

FROM: Melissa Y. Cook
Office of Mgmt and Budget, LRD

SUBJECT: FYI -- Upcoming Hearing on Ionizing Radiation

FYI --

VA has informed me that the H. VA Subcommittee on Compensation, Pension, Insurance, and Memorial Affairs plans hold a hearing on Apr. 30th regarding veterans exposed to ionizing radiation. The hearing invitation states the following:

"There continues to be controversy surrounding access to treatment and compensation for veterans exposed to ionizing radiation. The Subcommittee will review the Department of Veterans Affair's efforts to determine the effects of exposure to this environmental hazard, subsequent treatment, and compensation."

VA plans to have Mr. Vogel, Undersecretary for Benefits, testify with Dr. Mather from VHA in support.

I will keep you posted as to further developments.

Distribution:

TO: Bruce D. Long
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TO: Stephen R. Neuwirth
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'96 APR 18 A10:24

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DATE: 4-18-96

TO: Philip Caplan

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OF PAGES: 8 w/ cover

COMMENTS:

U.S. Department of Justice
Civil Division

Deputy Assistant Attorney General

Washington, D.C. 20530

April 18, 1996

TO: Philip Caplan
Special Assistant to the President
Deputy Staff Secretary

FROM: Eva M. Plaza
Deputy Assistant Attorney General
Civil Division

Subject: RECA Program and Review

On October 15, 1990, Congress enacted and the President signed into law the Radiation Exposure Compensation Act (RECA or Act), P.L. 101-426, 104 Stat. 920 (codified at 42 U.S.C. § 2210 note (Supp. 1993)). RECA establishes an administrative program to provide lump-sum compassionate payments to certain individuals, or their survivors, who contracted certain specified cancers or nonmalignant respiratory diseases presumably as a result of exposure to radiation during the course of the federal government's Cold War-era nuclear weapons testing program. In April, 1992, the Department of Justice issued regulations implementing the Act. The regulations established a compensation system that relies principally on existing historical records, so that claims can be resolved in a reliable, objective, and nonadversarial manner, quickly and with little administrative cost to the United States or to the person filing the claim.

The Act defines three distinct classes of eligible claimants: "downwinders," "onsite participants," and "uranium miners". "Downwinders" are defined in the Act as individuals presumably exposed to fallout from above-ground atmospheric nuclear tests conducted at the Nevada Test Site. To be eligible for compensation as a downwinder, an individual must establish (1) that they resided in certain statutorily designated areas in Utah, Nevada, and Arizona, (2) for a specified length of time, and, (3) subsequently developed one of thirteen statutorily-specified cancers.[1] Qualifying downwinders receive a lump sum compensation payment of $50,000.00.

[1] These cancers include, subject to certain limitations, leukemia, multiple myeloma, lymphomas, and primary cancer of the thyroid, female breast, esophagus, stomach, pharynx, small intestine, pancreas, bile ducts, gall bladder and liver.

"Onsite Participants" are defined to include the employees of the Departments of Defense or Energy, or their contractors, who participated in the atmospheric detonation of a nuclear device, and were presumably exposed onsite to radiation fallout resulting from the detonation. To be eligible for compensation as an "onsite participant" an individual must have been (1) physically present at an official test site, (2) during the atmospheric (above-ground) detonation of a nuclear device; and, (3) subsequently developed one of the same thirteen statutorily-designated cancers for which downwinders receive compensation. Qualifying onsite participants receive a lump sum compensation payment of $75,000.00.

Lastly, the Act creates a class of uranium miners consisting of individuals who were employed in underground uranium mines in specified states during designated time periods, and who were exposed to minimum levels of naturally-occurring radiation[2] in the mines. To be eligible for compensation as a uranium miner, a claimant must have been (1) employed underground in a uranium mine in Arizona, Colorado, New Mexico, Utah, or Wyoming, (2) between January 1, 1947 and December 31, 1971, (3) have been exposed to certain specified minimum levels of radiation,[3] and (4) subsequently developed lung cancer or one of four designated

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[2] Uranium occurs naturally in ore found in the five designated states. Uranium is unstable, and naturally breaks down over time to a stable element through a well defined series of reactions, some of which give off radiation. One of the intermediate products of this so-called "uranium cycle" is radium, which itself decays to radon, a gas. It is the radon that is associated with the increased incidence of lung cancer in uranium miners. The carcinogenic potential of radon derives principally from some of its decay products, which give off alpha radiation.

[3] The Act requires that a nonsmoker have been exposed to 200 working level months of radiation; if the claimant is a smoker and the onset of the compensable disease was before age 45, the required exposure is 300 working level months; if the claimant is a smoker and the onset of the compensable disease was after age 45, the required exposure is 500 working level months. A working level month is a time-weighted measure of radiation exposure.

nonmalignant respiratory diseases.[4] Qualifying uranium miners receive a lump sum compensation payment of $100,000.00.

Since its enactment, the Act has been subject to considerable criticism from scientists and advocates for the various eligible claimants; the overwhelming bulk of the criticism has been directed to the provisions relating to compensation for uranium miners. These groups have argued principally that the exposure criteria for the uranium miners are not supported by current scientific or medical information. Many of the claimants' advocates have also taken issue with the Department's implementing regulations. They contend that the regulations impose unnecessarily strict proof requirements, which have had the effect of denying compensation to numerous deserving claimants.

These concerns were also voiced by the President's Advisory Committee on Human Radiation Experiments in its Final Report, issued on October 3, 1995. The Advisory Committee was charged by the Administration with investigating human radiation experiments conducted by or with the assistance of the federal government during the Cold War period. Among other things, the Advisory Committee investigated the government's relationship to the uranium miners in the West, who supplied uranium ore to the Atomic Energy Commission. The Advisory Committee concluded that the federal government wronged the uranium miners by allowing them unwittingly to be exposed to radiation hazards, and by studying the health effects of their exposures without adequate consent and disclosure. Advisory Committee on Human Radiation Experiments, Final Report 563-83 (Oct. 1995) [hereinafter cited as Final Report]. These conclusions echo in great measure the congressional findings that led to the passage of the RECA. See P.L. 101-426, § 2, 104 Stat. at 920.

The Advisory Committee heard considerable testimony from the groups noted above that was critical of the Act and the Department's administration of the Act. The Advisory Committee

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[4] These respiratory disorders are "fibrosis of the lung, pulmonary fibrosis and corpulmonale related to fibrosis of the lung; and if the claimant, whether Indian or non-Indian, worked in a uranium mine located on or within an Indian Reservation, the term shall also include moderate or severe silicosis or pneumoconiosis." P.L. 101-426, § 5(b)(3), 104 Stat. at 923. "Fibrosis of the lung" and "pulmonary fibrosis" are the same; "corpulmonale" is an enlargement of the right ventricle due to pulmonary disease. "Pneumoconiosis" is an occupational lung disease resulting from the permanent deposition of substantial amounts of particulate matter in the lungs; "silicosis" is the disease caused by the deposition of silica (silicon dioxide) in the lungs.

concluded that scientific information available after 1990 supported the view that exposure to radiation in mines posed a much greater risk of lung cancer than had previously been thought. Final Report, at 814. Consequently, they noted, the present statutory criteria are inaccurate in a number of ways and have the effect of disenfranchising deserving miners. In the Final Report, the Advisory Committee included, as its seventh recommendation, the following:

> The Advisory Committee recommends to the Human Interagency Working Group that it, together with Congress, give serious consideration to amending the provisions of the Radiation Exposure Compensation Act of 1990 relating to uranium miners in order to provide compensation to all miners who develop lung cancer after some minimal duration of employment underground (such as one year), without requiring a specific level of exposure. The act should also be reviewed to determine whether the documentation standards for compensation should be liberalized.

Id. at 813.

In response to this recommendation, the Human Radiation Interagency Working Group (IAWG) requested that the Department of Justice establish a committee of government scientists and attorneys to review the Act and the implementing regulations to ensure that they are fair and consistent with current scientific data. The IAWG requested that the designated committee recommend to the Administration within six months possible statutory changes (to be proposed to Congress) and appropriate amendments to the Department's existing regulations.

Acting upon this request, the Attorney General, through my offices (Deputy Assistant Attorney General for the Civil Division) established a seven-person Committee: three attorneys from the Department of Justice; an epidemiologist and a physician specializing in respiratory diseases from the National Institute for Occupational Safety and Health (NIOSH); and a biostatistician and physician specializing in lung cancer from the National Cancer Institute (NCI). The Committee sought out criticisms of the Act and the implementing regulations; it has to date reviewed testimony submitted during oversight hearings of the RECA before the Senate Committee on Government Affairs in 1993; testimony submitted to the Advisory Committee; spoken with leading scientists studying the effects of radon in underground uranium mines, and with attorneys who represent the majority of Anglo and Navajo uranium miners, miners advocates, officials of the Navajo Nation, physicians who regularly treat uranium miners, and

miners. The Committee expects to submit its final report to the IAWG in the beginning of May.

Based on its investigation, the Committee has identified numerous criticisms of the Act and implementing regulations, many of which have merit. Nonetheless, the criticisms of the Act and regulations that are heard most often, and from almost all quarters, are as follows:

(1) The present minimum exposure criteria for smokers and nonsmokers are not supported by the latest scientific information.

Congress apparently sought to define exposure criteria in RECA that would provide compensation to those uranium miners whose lung cancer was more likely than not caused by their exposure to radon in the mines. Using the latest data on mortality among uranium miners, and the latest accepted statistical methods, it is generally agreed that the present statutory criteria seriously underestimate the risk of radon exposure for many miners, and thus do not accurately give effect to Congress' intent. Based on the latest data and analysis, it is reasonable to expect that the exposure standards for many (<u>but not all</u>) miners will be lower than the present statutory criteria.

(2) The present statutory scheme sets different minimum exposure levels for smokers and nonsmokers; this distinction based on smoking status is not justified by the latest scientific information.

The latest data suggests that it is possible that radon has the same effect on both smokers and non-smokers; that is, that the same dose of radon exposure increases the risk of lung cancer the same amount in both a nonsmoker and a smoker. This would suggest that the exposure distinction based on smoking status be eliminated from the Act. The data are also consistent, however, with the position that radon has a greater effect on nonsmokers, which would suggest that different exposure standards based on smoking status be set. Of course, regardless of which approach the Committee recommends, the minimum exposure standards for many (but not all) miners, smokers or non-smokers, will be lower than the present statutory criteria.

(3) The definition of smoking in the regulations, which defines what exposure standard a miner must meet, is too low.

The regulations define a smoker as an individual who has smoked at least one pack-year (one pack a day for one year) of cigarette products. § 79.31(f). This amount, which is relatively low, fails to distinguish among individuals who rarely or

occasionally smoked and heavy smokers, whose risk of lung cancer may be appreciably increased. There is considerable testimony and data indicating that Navajo (including Navajo miners), smoked only occasionally. Although the risk of lung cancer is linear and has no known "threshold" below which smoking poses no risk, the effect of occasional smoking, such as was common among Navajo miners, may be negligible and appropriately ignored.

(4) The Act inappropriately requires a claimant with a nonmalignant respiratory disease to prove he was exposed to minimum levels of radiation, depending on smoking status.

The Act as presently written ties compensation for the specified nonmalignant respiratory diseases to exposure to radiation. Although there is some evidence from animal studies that radiation can cause the specified nonmalignant diseases, it is not an accepted association in the scientific community. The association between the specified nonmalignant disorders and exposure to dusts generated in hard-rock mining, such as silica, is very well established. Arguably, therefore, compensation for these disorders should be tied to exposure to dust and other agents in the mining environment, not radiation.[5]

(5) To receive compensation for a nonmalignant respiratory disorder, the regulations inappropriately require a claimant to prove the presence of the disease by submitting two chest x-rays read by "B-readers"; the Department compounds the problem by having many of the claimants' readings re-interpreted by B-readers they have selected.

The regulations require that a claimant prove the presence of a compensable nonmalignant disorder by radiographic evidence (chest x-ray). This is done by submitting reports of two "B-readers" verifying the presence of the disorder on a chest x-ray. "B-readers" are physicians specially certified by NIOSH as proficient in the evaluation of x-rays for the presence of certain lung abnormalities, including fibrosis and pneumoconioses (occupationally-related lung diseases, such as silicosis). The presence on chest x-rays of fibrosis or a pneumoconiosis, particularly if the disease is not severe, is quite ambiguous,

---

[5] In a related criticism, it has been noted that the limitation of compensation for silicosis and pneumoconiosis to mines on Indian Reservations makes little sense. The cause of these nonmalignant respiratory diseases is the presence of silica dust in the mining environment; the ore in mines both on and off Indian reservations contained appreciable quantities of silica.

and there is considerable inter-reader variability and difference of interpretation. The Department apparently has identified some B-readers that in their opinion are unusually and consistently liberal in interpreting x-rays in favor of the claimants. Although these readers are still certified by NIOSH, the Department has their interpretations audited and sometimes overruled by B-readers appointed by NIOSH. The discretion in Department officials administering the Act to selectively audit B-reader interpretations, and the lack of authorization in the regulations for submission of more sensitive, advanced radiographic techniques (such as high-resolution computed tomography (CT)) scans, are being examined by the Committee.

EXECUTIVE OFFICE OF THE PRESIDE

27-Jan-1994 05:17pm

TO: (See Below)

FROM: Tracey E. Thornton
Office of Legislative Affairs

SUBJECT: 1/31 briefing for hill staffers

January 27, 1994

TO: BUDGET, APPROPRIATIONS AND INTERESTED STAFF

FR: TRACEY THORNTON, WHITE HOUSE LEGISLATIVE AFFAIRS

RE: OMB BRIEFING ON ISSUES RELATING TO HUMAN RADIATION EXPERIMENTS

Many questions have been raised about how the Administration plans to work with the Congress in developing an appropriate response to issues arising out of our review of government-sponsored experiments on humans involving intentional exposure to ionizing radiation.

To explore some of these questions, including budget and appropriations matters, T.J. Glauthier (Associate Director for Natural Resources, Energy, and Science at OMB) will conduct a **briefing for staff on Monday, January 31, 1994 at 2 p.m. in room 248 Old Executive Office Building (OEOB)**.

The briefing will examine various models for appropriate federal responses, including those incorporated into other federal programs such as those for downwinders, veterans exposed to radiation, and the Japanese interned during World War II. The range of federal responses under consideration include potential monetary compensation, medical follow-up, disclosure of detailed information, formal apologies or other recognition, and on-going research, education and information programs.

Finally, the briefing will cover the time-table for developing specific recommendations for legislative and other action that may be appropriate once the first phase of the Administration's work has been completed.

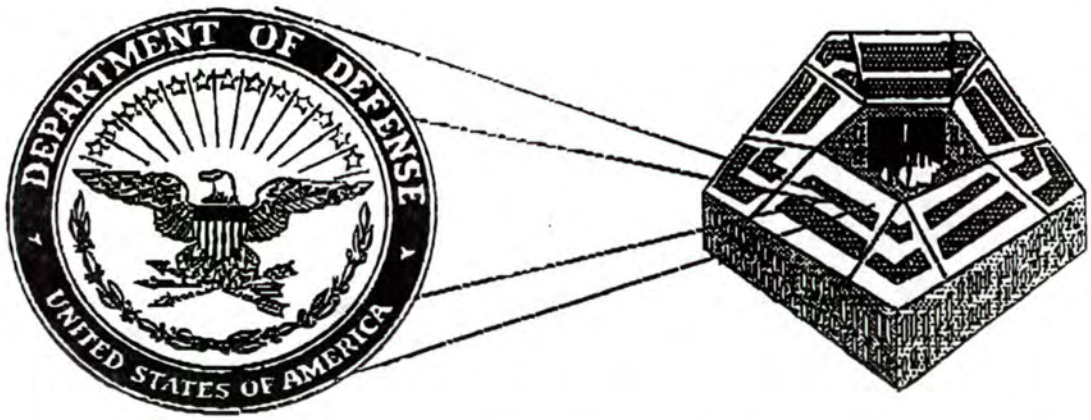
Please call 202-456-6493 to confirm your attendance by leaving your name and date of birth. You may enter the OEOB through the gates on Pennsylvania Avenue, at 17th and G Streets, or through the Southwest gate on the side of the Ellipse.

Thank you.

Distribution:

TO: Martha Foley
TO: Courtney M. Manning
TO: Christine A. Varney
TO: Jocelyn M. Jolley
TO: Lorraine C. Miller
TO: Gordon Li
TO: Phillip M. Caplan
TO: FAX (95358500,dennis duffy)
TO: FAX (93584340,jeff lawrence)
TO: FAX (95149149,faith burton)
TO: FAX (96908425,karen pollitz/judy 1)
TO: FAX (95864891,william taylor)
TO: FAX (97036978299,kelly sharbel)
TO: Tracey E. Thornton
TO: Erin A. O'Connor

FAX FAX



ASSISTANT TO THE SECRETARY OF DEFENSE
(ATOMIC ENERGY)
WASHINGTON, DC 20301-3050

FAX NOs: *(703) 697-2199 (ROOM 3C120)*
(703) 695-0476 (ROOM 3E1074)

TO: Phil Caplan **FAX PHONE NUMBER:**

ATTN:
PHONE:

MESSAGE:

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

THIS DOCUMENT CONSISTS OF 7 PAGES, INCLUDING COVER SHEET

MEMO FOR: PHIL COMEY

SUBJECT: Congressman Markey's memo

Phil:

I have just gotten a fax of a fax copy of the Markey letter to Secretary Perry. I don't know how well it will read after being faxed yet once again--there is probably some law of physics that determines such things.

Anyway, I've got to deal with this and I'll be talking with Margaret Sullivan this afternoon. I'll keep you informed.

Gordon

EDWARD J. MARKEY
7TH DISTRICT, MASSACHUSETTS

CHAIRMAN
SUBCOMMITTEE ON TELECOMMUNICATIONS AND FINANCE
NATURAL RESOURCES
COMMISSION ON SECURITY AND COOPERATION IN EUROPE

Congress of the United States
House of Representatives
Washington, DC 20515-2107

2133 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-2107
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DISTRICT OFFICES
9 HIGH STREET, SUITE 101
MALDEN, MA 02148
(617) 322-1990

188 CONCORD STREET, SUITE 101
FRAMINGHAM, MA 01701
(508) 875-2900

July 27, 1994

The Honorable William J. Perry
Secretary
U.S. Department of Defense
The Pentagon
Washington, D.C. 20301

Dear Secretary Perry:

I commend and support the efforts of the Clinton Administration, through the Human Radiation Interagency Working Group, to disclose all records regarding questionable exposures of human populations to ionising radiation. I recognise that your department, as part of the Interagency Working Group, is involved in an intensive search of archival files to determine the full extent of radiation experiments with human subjects. The Presidential Advisory Committee on Human Radiation Experiments has recently released material relevant to the efforts at the Department of Defense. This material indicated problems with the document collection process in some units of the Department, and also described a program of "close to detonation" exposure of human subjects during atomic bomb testing. The story of atomic veterans is already a national disgrace, but the "close to detonation" program may represent even more severe exposures of servicemen than has previously been recognised. I am writing to request your cooperation on both of these topics.

As you probably know, in October 1986 I released a staff report of the House Subcommittee on Energy Conservation and Power, describing experiments funded by predecessor agencies of the Department of Energy, in which human subjects were exposed to ionising radiation that provided little or no medical benefit to those exposed. This report was essentially ignored by the Reagan Administration. But when these and other experiments came to the attention of the Clinton Administration, the President in January 1994 initiated the Human Radiation Interagency Working Group, and established the Advisory Committee on Human Radiation Experiments to provide advice and recommendations to the Working Group.

The Honorable William J. Perry
Page 2
July 27, 1994

At the Advisory Committee's public meeting during July 25 and 26, 1994, Committee Chair Ruth Faden noted deficiencies with the document collection process at some branches of the Defense Department. Specifically, Dr. Faden reported that the Defense Nuclear Agency (DNA) has not complied with Department directives to locate documents on experimental exposures to humans. She also noted that the Department of the Army has identified approximately 1000 experiments in which human subjects may have been exposed, but has yet to provide information on these experiments.

A previous memo of June 3, 1994, from the Advisory Committee Staff described DOD-wide instructions of January 31, 1994 from the Assistant to the Secretary of Defense for Atomic Energy. The January 31 instructions directed completion by February 28 of the identification of DOD organizations that might have conducted or sponsored human radiation experiments, and the identification of each possible human radiation experiment and the location of records regarding each such experiment. The June 3 memo from the Advisory Committee staff also noted that the Defense Nuclear Agency had not searched for intentional releases of radioactive material that could have exposed human populations. Advisory Committee staff have informed my staff that this deficiency has not been rectified, leading Chairperson Faden to conclude that DNA has yet to comply with Department directives that should have been fulfilled before March.

I have no doubt about your personal commitment for meeting the goals of President Clinton's Executive Order on Human Radiation Experiments. But there should be no doubt that resistance by the bureaucracy, if left unchallenged, can defeat the commitment of a cabinet member to full disclosure. I am gratified that Dr. Faden also reported that the problems described above have been brought to the attention of officials at the highest levels of the Pentagon. I urge you to correct this situation promptly.

At its latest meeting, the Advisory Committee released additional material relevant to human radiation exposures. The Department of Defense administers the Nuclear Weapons Test Personnel Review Program (NTPR), which maintains records on approximately 400,000 servicemen who were exposed to ionizing radiation from atomic bomb tests. My staff has previously received allegations that prior to atomic tests, some human subjects were placed at locations significantly closer to the site of detonation than the majority of troops exposed during a test. Material released by the Advisory Committee would tend at least partially to confirm such allegations.

A July 19, 1994, memo from the Advisory Committee staff contained a preliminary list of intentional releases of radioactive material, and "experiments of opportunity," scientific studies of human biological effects that make use of opportunities created by other events, including atmospheric nuclear tests (see Attachment). This memo describes notes from a January 1994 meeting convened by the Defense Nuclear Agency to discuss human experimentation. As a potential experiment of opportunity, the staff memo cites DNA notes that the NTPR database should include approximately "800 personnel who volunteered to occupy close-to-detonation positions during bomb events." (Attachment, third page)

At its latest meeting, the Advisory Committee also released a written statement, submitted for the record, from Ms. Patricia Broudy, National Legislative Director, National Association of Atomic Veterans. Ms. Broudy described eight "volunteer officers" at atomic test SMOKY, on April 25, 1953. The group leader of these officers had participated in a similar manner in the previous test. These officers were located in a trench 2000 yards from group zero, while the main body of troops was 4000 yards from ground zero. Ms. Broudy reported that when one officer volunteer regained his eyesight following the bomb flash, he read a local dose of 100 roentgen/hr. The officers climbed out of their trenches and moved to a location 4000 yards from ground zero, at which point the registered dose had declined to 1 roentgen/hr, presumably due to a combination of time, distance, and decay of short-live isotopes. At this point, the main body of troops started marching toward ground zero. (Patricia Broudy, Statement of July 18, 1994 before the Advisory Committee) This testimony suggests that the volunteer officers, because of their closer distance to ground zero and earlier exit from the trenches, would have experienced significantly higher exposures to heat, blast, and radiation than the bulk of the troops at atomic tests.

As you probably know, the Advisory Committee has identified a 1981 Defense Department memo, describing biomedical information that can only be obtained from atomic weapons testing, and suggesting that exposure of military personnel during atomic tests would be one method of obtaining such information. Committee deliberations have included discussions over the exposures of servicemen during weapons tests, and how such exposures should be considered in light of the Committee's charter. If personnel involved in the "close to detonation" program were positioned similarly to those described as "volunteer officers," then they may represent a small portion of all atomic veterans, but they may have received significantly higher exposures. Information on this program should assist the Advisory Committee in its consideration of "experiments of opportunity," and would also benefit the Congress as it considers appropriate corrective action for victims of radiation

experiments. Release of information on the "close to detonation" program would also be consistent with a more aggressive document collection effort by the Defense Nuclear Agency. I therefore request your response to the following questions:

1. Please provide, at the earliest practicable date, the notes from the DNA meeting of January 1994 described in the Attachment. It is my understanding that the notes were based on a discussion of unclassified experiments. If this is not correct, then I request unclassified excerpts, or an unclassified summary.

2. Please provide any documents which describe the "close to detonation" program, and the rationale for placing personnel at such close locations.

3. Please provide details on the "close to detonation" exposures, including the how close personnel were placed to detonation sites, the atomic tests involved, the numbers of personnel exposed, ionizing radiation doses received, and how these doses compared generally with those of other groups of servicemen who may have been exposed during the same tests. I do not at this time request the names of servicemen exposed during any test.

4. Please describe what measures were implemented for informed consent among personnel participating in "close to detonation" operations.

5. Please describe what medical follow-up has been conducted on personnel who received "close to detonation" exposures. How does the health of these persons compare to match groups of other atomic veterans and veterans who received minimal exposure to ionizing radiation?

I appreciate your cooperation on this matter. Please provide the information requested here as soon as it becomes available. I reiterate my commendation of the Clinton Administration for your efforts to provide full disclosure of improper activities that may have been conducted during the history of government atomic energy programs.

Sincerely,

Edward J. Markey
Member of Congress

Attachment: Advisory Committee Staff memo of 7/19/94

The Honorable William J. Perry
Page 5
July 27, 1994

cc: The Honorable G.V. (Sonny) Montgomery, Chairman
Committee on Veterans' Affairs

The Honorable Ronald V. Dellums, Chairman
Committee on Armed Services

Dr. Ruth R. Faden, Chair
Advisory Committee on Human Radiation Experiments

EXECUTIVE OFFICE OF THE PRESIDENT
Office of Management and Budget
Legislative Reference Division
Labor, Welfare and Personnel Branch
Washington, DC 20503

Facsimile Transmission

Sender's FAX Number (202) 395-6148
Sender's Phone Number (202) 395-3803

TO:	AGENCY:	FAX Phone	Recipient's Phone
PHIL CAPLAN	OCA		

* * * * * * *

FROM: *Connie J. Bowers*

DATE: **Fri Aug 26, 1994 10:26am**

No. of Pages (including transmittal sheet): 4

COMMENTS:

AIR FORCE TESTIMONY - RADIUM NASOPHARYNGEAL IRRADIATION

Attached is the Air Force testimony on health effects of this irradiation. If you have any comments, please call Alex Keenan, of the VA branch in OMB 5-4500.

Thanks.

DEPARTMENT OF THE AIR FORCE

PRESENTATION TO THE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

SUBCOMMITTEE ON CLEAN AIR AND NUCLEAR REGULATION

UNITED STATES SENATE

SUBJECT: Health Effects of Radium Nasopharyngeal Irradiation

STATEMENT OF: Major General Robert A. Buethe, Jr.
Acting Surgeon General of the Air Force

August 1994

NOT FOR PUBLICATION UNTIL
RELEASED BY THE SENATE
COMMITTEE ON ENVIRONMENT
AND PUBLIC WORKS,
UNITED STATES SENATE

Good morning Mister Chairman and members of the committee. I am Major General Robert A. Buethe, Jr., acting Surgeon General of the United States Air Force. It is my pleasure to be with you this morning to address your concerns regarding radium nasopharyngeal irradiation treatment.

Irradiation of lymphoid tissue in the nasopharynx using radium was widely practiced by physicians in the U. S. beginning in the 1920's and well into the 1960's. This therapy was designed to improve the function of the eustachian tube by shrinking excessive lymphoid tissue in and around the tubal orifice. Hundreds of thousands of civilians were treated; primarily children with recurrent ear infections. The advent of myringotomy tubes led to discontinuation of this therapy.

During WWII a large number of aviators developed a condition known as aerotitis media. Aerotitis media is an inflammation of the middle ear caused by atmospheric pressure changes. Aerotitis media was a problem for the Air Force during WWII due to two main factors (1) rapid pressurization of the middle ear during descent in combat aircraft and (2) high rates of upper respiratory tract infections, particularly during winter months in England and Italy. Some flying personnel experienced this condition on a recurrent basis, leading to subsequent grounding for days to weeks. One report stated that such patients were unavailable for combat duty 30% of the time. Nasal pharyngeal irradiation with radium rods was one treatment option used in these patients. The number of patients treated with radium rods during WWII was approximately 7000. We believe that such therapy was reserved for patients who expressed a desire for the therapy. There were a number of other treatment options used prior to considering radium rod therapy. It is important to note that nasopharyngeal irradiation treatments were considered standard of practice at the time and not experimental

There are no consolidated listings of patients who received radium rod therapy. Some individuals have identified themselves to the Department of Energy's ionizing radiation hot line. In such cases, it may be possible to locate the serviceman's medical records and confirm the treatment.

It is our intention to fully support any efforts by the Department of Veterans Affairs to study any medical complications which may be associated with this form of therapy.

Facsimile Cover Sheet

Department of Veterans Affairs

To: Phil Caplan
Organization:
Phone:
Fax: 456-6704

From: Doug Dembling
Organization: VA Office of Congressional Affairs
Phone: (202) 273-5615
Fax: (202) 273-6791

Date: 08/25/94
Pages including this cover page: 4

Comments: VA testimony for 8/29 radium treatments hearing.

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

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

VA's review including studies and plans for future studies

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

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

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

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

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

<u>VA actions to provide information and guidance to veterans</u>

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

More generally, whenever a veteran alleges involvement in experimental medical treatment during military service, identifying information such as the veterans name, claim number, dates of service, and exposure/experimentation information are taken by veterans benefits counselors and forwarded to the Department of Defense for tracking and further follow-up. Veterans benefits counselors assist veterans in filing claims for possible entitlement to service-connected compensation, medical treatment, and other

services. When appropriate, the veterans benefits counselors also provide additional information related to military treatment to the involved military service office. VA is committed to assisting any veteran who believes he or she may have been injured: by exposure to ionizing radiation; by any experimental medical care involving radiation; or by any other examination or treatment.

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

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

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

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

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

22-Mar-1994 04:44pm

TO: (See Below)

FROM: Tracey E. Thornton
Office of Legislative Affairs

SUBJECT: radiation meeting

Our next radiation meeting will be thursday, march 24 at 11am in room 472 OEOB. We will discuss the following:

follow-up on issues raised by hill staffers at OMB briefing
- contractor indemnification
- downloading of info from hotline
- compilation of hotline data
- how each agency is managing records retrival
- how agencies are handling classified experiments

FOIA requests

Hearings/briefing schedule

Glenn request for GOA inquiry

Courtesy calls for Ruth Faden (Advisory Committee)

Any other issues group needs to discuss

Prior to our meeting, I will talk to Cabinet Affairs, OMB and Legal Working Group. Please consult with folks at your agency about these issues as well.

PLEASE CALL ME IF YOU WILL NOT BE ABLE TO ATTEND THIS MEETING.

THANKS

Distribution:

TO: Phillip M. Caplan
TO: Jocelyn M. Jolley
TO: Lorraine C. Miller
TO: FAX (92736791,dennis duffy)
TO: FAX (93584340,jeff lawrence)

TO: FAX (95149149,faith burton)
TO: FAX (96908425,karen pollitz/judy l)
TO: FAX (95864891,william taylor)
TO: FAX (97036978299,kelly sharbel)
TO: Tracey E. Thornton

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

29-Mar-1994 01:23pm

TO: (See Below)

FROM: Tracey E. Thornton
Office of Legislative Affairs

SUBJECT: radiation meeting wednesday

I neglected to note the time of the meeting tomorrow--it is at 2:00 pm in room 180 OEOB.

Thanks

Distribution:

TO: Phillip M. Caplan
TO: Emily D. Pelton
TO: Jocelyn M. Jolley
TO: Lorraine C. Miller
TO: FAX (92736791,dennis duffy)
TO: FAX (93584340,jeff lawrence)
TO: FAX (95149149,faith burton)
TO: FAX (96908425,karen pollitz/judy l)
TO: FAX (95864891,william taylor)
TO: FAX (97036978299,kelly sharbel)
TO: Tracey E. Thornton

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

15-Mar-1994 10:46am

TO: (See Below)

FROM: Tracey E. Thornton
Office of Legislative Affairs

SUBJECT: OMB briefing; materials will be provided at the br

March 11, 1994

TO: BUDGET, APPROPRIATIONS AND INTERESTED STAFF

FR: TRACEY THORNTON, WHITE HOUSE LEGISLATIVE AFFAIRS

RE: OMB BRIEFING ON ISSUES RELATING TO HUMAN RADIATION EXPERIMENTS

Many questions have been raised about how the Administration plans to work with the Congress in developing an appropriate response to issues arising out of our review of government-sponsored experiments on humans involving intentional exposure to ionizing radiation.

To explore some of these questions, including budget and appropriations matters, T.J. Glauthier (Associate Director for Natural Resources, Energy, and Science at OMB) will conduct a **briefing for staff on Monday, March 21,1994 at 2 p.m. in room 248 Old Executive Office Building (OEOB)**.

The briefing will examine various models for appropriate federal responses, including those incorporated into other federal programs such as those for downwinders, veterans exposed to radiation, and the Japanese interned during World War II. The range of federal responses under consideration include potential monetary compensation, medical follow-up, disclosure of detailed information, formal apologies or other recognition, and on-going research, education and information programs.

Finally, the briefing will cover the time-table for developing specific recommendations for legislative and other action that may be appropriate once the first phase of the Administration's work has been completed.

Please call 202-456-6493 to confirm your attendance by leaving your name and date of birth. You may enter the OEOB through the gates on Pennsylvania Avenue, at 17th and G Streets, or through the Southwest gate on the side of the Ellipse.

Thank you.

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TO: Phillip M. Caplan
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TO: FAX (95864891,william taylor)
TO: FAX (97036978299,kelly sharbel)
TO: Tracey E. Thornton

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

07-Mar-1994 06:27pm

TO: (See Below)

FROM: Tracey E. Thornton
Office of Legislative Affairs

SUBJECT: compensation/administrative costs breifng

OMB will conduct another compensation briefing march 21 from 2-3 in the OEOB. i will send out the notices later this week. This will be the last staff briefing on this subject for a while so please make sure you get the information out to your authorizing committee or let me know who you'd like me to send a notice to. my list has appropriations, budget, judiciary--house and senate, minority and majority. It aslo contains leadership and the names of people who complained about not having been invited to the last one. You will need to inform your authorizers of the briefing because you know who the the specific staffers are who need to be invited.

I will keep you posted.

Distribution:

TO: Phillip M. Caplan
TO: Jocelyn M. Jolley
TO: Lorraine C. Miller
TO: FAX (92736791,dennis duffy)
TO: FAX (93584340,jeff lawrence)
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TO: FAX (96908425,karen pollitz/judy l)
TO: FAX (95864891,william taylor)
TO: FAX (97036978299,kelly sharbel)
TO: Tracey E. Thornton

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

07-Mar-1994 05:33pm

TO: Tracey E. Thornton

FROM: Courtney M. Manning
Office of Mgmt and Budget, NRES

CC: Emily D. Pelton

SUBJECT: RE: Briefing for the Hill re: Radiation Compensation

I have reserved Room 248 (Director's Conference Room) from 2:00pm to 3:30pm on March 21st. Our staff will have to provide you with updated briefing materials.

Advisory Committee on Human Radiation Experiments
1726 M Street NW, Suite 600, Washington, DC 20036
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FAX COVER SHEET

NUMBER OF PAGES (INCLUDING COVER SHEET): 4

TO: Phil Caplan

FROM: Ama Mastoranni

DATE: May 5, 1994

RE: Ken Fernberg

Here is the document we discussed.

CITIZEN SOLDIER
175 Fifth Ave. #808
New York, N.Y. 10010
(212) 777-3470

For release:
May 4, 1994

Statement of Tod Ensign, Director of Citizen Soldier before the House Veterans Affairs Subcommittee on Oversight and Investigation, May 4, 1994, Washington, D.C.

* * *

Mr. Chairman, it's a privilege to testify before your subcommittee today. Citizen Soldier was organized in the midst of the Vietnam war to advocate for veterans. Unlike most veterans groups at the time we opposed the Vietnam war and called for the immediate withdrawl of our troops.

At the same time, we advocated for VA healthcare and disability compensation for ailing veterans. For instance, we raised the issue that large numbers of Vietnam vets were suffering from post-traumatic stress disorder years before the VA finally established special programs for these veterans.

I will use my few minutes today to highlight special problems which continue to plague atomic veterans and Agent Orange vets and to urge this committee to take corrective action. While some progress has been made, much more must be done if these two groups are going to receive the assistance they deserve.

Atomic veterans Since new disclosures were made about human radiation experiments last November 1993, atomic vets have been hopeful that long-classified reports and documents about their exposure to radiation would finally see the light of day.

While the Department of Energy seems to be making an honest effort to locate and release secret data on radiation experiments, I don't believe that the Department of Defense nor the Department of Veterans Affairs are making a comparable effort. For example, a recent newsletter of the National Association of Atomic Veterans contains a detailed account by a Navy officer who, along with seven other "volunteers" witnessed the detonation of a 55 kiloton bomb (three times the Hiroshima bomb) just a mile from ground zero. My research has convinced me that there were many such experiments using GIs as "volunteers" during America's 200+ atmospheric bomb tests. I urge this committee to take a strong public position in support of releasing all data on these tests.

Although Congress adopted legislation to make it easier for some of our 205,000 atomic veterans to obtain disability awards, the DVA's handling of their claims is a scandal. It has approved 1,401 claims out of a total of 15,369 that were filed by January 1994. One barrier many claimants face is obtaining

accurate information about the levels of radiation to which they were exposed. The DVA relies heavily on dose-construction prepared by Science Applications International, a private contractor.

I would urge this committee to conduct oversight hearings on the activities of this contractor. Its work product bears directly on the fact that fewer than one in ten atomic veterans has been able to win a disability claim from the DVA. Incidentally, SAI has been paid over $1.5 billion to date for these radiation estimates; far in excess of what atomic vets have received as compensation!

This committee would be performing a great public service by probing that whole issue of radiation exposure records. I recall a New York Times story (2/8/1982) which published an account of a former Army medic, Van R. Brandon of Sacramento, CA that his unit kept two sets of books on radiation readings during the 1956-57 tests. "One set was to show that no one received an (elevated) exposure," Brandon stated. "The other set of books showed...the actual reading. That set was brought in a locked briefcase every morning," he recalled.

If the DVA is going to base its disability decisions in part on veterans' radiation exposure, then this committee has a duty to insure that that data is as accurate and complete as possible.

Finally, I urge this subcommittee to investigate the circumstances surrounding the appointment of Kenneth R. Feinberg, Esq., to the White House Advisory Committee on Human Radiation Experiments. I believe that once you have examined Mr. Feinberg's history you will join Citizen Soldier and other veteran groups in calling for his removal from this panel.

The only attorney on the committee, Feinberg is widely reviled by Vietnam veterans for his role, as federal judge Jack Weinstein's emissary, in pressuring an eleventh-hour settlement of the Agent Orange class action lawsuit for $180 million in 1984. Although he played no part in preparing the six year old litigation for trial, he received an enormous legal fee for his role in securing a settlement.

Veterans are asking why the White House would chose Feinberg to sit on a panel which will be asked to make important decisions about which groups of radiation exposure victims should be considered for compensation. Given his history, there is a deep suspicion that he has been placed on the panel so that, once again, he can minimize the assistance provided to ailing veterans.

Feinberg is not an expert on radiation effects; he's an expert at settling lawsuits for a penny on the dollar. It's appointments like these that reinforce the cynicism and distrust of so many of our military veterans!

Agent Orange As I noted, these vets were left with a pittance when the class action suit against the manufacturers was settled

behind their backs in 1984. In February, the US Supreme Court refused to hear an appeal of judge Weinstein's ruling that veterans who developed injuries after 1984 cannot sue the manufacturers, even in state courts. The attorney generals of all fifty states filed an amicus brief in support of this appeal.

I believe that it's significant that only when a scientific task force appointed by the National Academy of Science published a major report last July 1993 finding "significant associations" between Agent Orange exposure and certain cancers, did the DVA finally agree to recognized several cancers as "service-connected." While the maxim "better late than never" applies here, I would urge this committee to closely monitor how the DVA actually processes Agent Orange claims in the future.

In November, 1993, I attended the Second International Symposium on the Human Health Effects of Herbicides in Hanoi, Vietnam. The Vietnamese scientists who participated expressed a strong desire to work cooperatively with American researchers to study the long-term health effects of Agent Orange on citizens of both countries. Now that President Clinton has ended the economic embargo of Vietnam, I would urge you to take an active part in encouraging and funding research that will benefit veterans in both countries.

Independent scientists such as Drs. Jeanne and Steven Stellman, who co-authored the American Legion Study, have continued to urge Congress to support new studies which focus on the most highly-exposed veterans. They also argue that the CDC's original idea to organize veteran groupings by their level of exposure is sound and deserves to be revived and implemented.

This panel has a special responsibility to serve as an advocate for ailing veterans. The past seventeen years have taught us that powerful interests are arrayed in defense of the status quo. You must serve as the uncorruptible advocate for these deserving men and women. Thank you.

Ensign, an attorney, is co-author of G.I. Guinea Pigs: How the Pentagon Exposed Our Troops to Dangers More Deadly Than War Playboy Press (1980) and author of Military Life: The Insider's Guide, Arco/Simon & Schuster (1990) He has written on these issues for numerous magazines and newspapers, including forthcoming articles in Covert Action and The Progressive.

OFFICE OF CABINET AFFAIRS

THE WHITE HOUSE

WASHINGTON

FAX

TO: Tracey Thornton

DATE: 3/23

NO. OF PAGES 2
(Including cover)

PHONE:

FAX: 6-[redacted] 2604

PRIORITY: Y N

FROM: Phil

PHONE: (202) 456-2572

FAX: (202) 456-6704

MESSAGE: could you read this and let me know if it is accurate. Christine insists that we send a response under Patsy's name. I'll run it by Newsirth next.

I'm trying to leave at 5:30 tonight so page me [redacted] so we can talk about other stuff -- most importantly Ruth Faden.

Thanks.

DRAFT #1 3.23.94

March 24, 1994

Mr. William M. Hunt
Director, Federal Management Issues
General Accounting Office
Washington, D.C. 20548

Dear Mr. Hunt:

Thank you for your letter of March 8, 1994, concerning a request from the Senate Committee on Governmental Affairs for the GAO to examine federal plans and efforts for disclosing information concerning radiation-related experiments and releases from the Cold War era.

In our discussions with Senator Glenn, Chair of the Committee, we have determined that the most appropriate way for you to proceed is to begin at the Departments and Agencies involved in the Interagency Working Group on Human Radiation. The Departments and Agencies are just beginning their work; while they will be very cooperative, it might be most productive to wait several weeks before beginning your review. (should we attempt to delay like this???)

Dr. Ruth Faden, Chair-designate of the Independent Advisory Committee on Human Radiation, will be meeting with Senator Glenn [this/next] week to brief him on the Advisory Committee. The members of the Advisory Committee have not yet been officially appointed by the President and the first meeting of the Committee will not occur until mid-late April. The time, date and location will be published in the Federal Register soon.. The meeting will be open to the public as required by the Federal Advisory Committee Act.

Thank you.

Sincerely,

Patsy Thomasson
Special Assistant to the President and
Director, Office of Administration

66704

MEMORANDUM

SUBJECT: RADIATION EXPERIMENTS AT UNIVERSITY OF CINCINNATI

A radiation therapy project for the treatment of cancer, under the cognizance of the University of Cincinnati commencing at least as early as 1955, existed for some five years prior to Department of Defense involvement. Department of Defense participation, starting in 1960, resulted from an unsolicited proposal from a staff member of the University of Cincinnati General Hospital. Cost of the U of C program in therapy and patient care was borne entirely by the U of C General Hospital. The DoD funds were used to pay for supplemental laboratory analyses of patients who had received total body irradiation therapy. These experiments have been extensively reported in the open literature and were the subject of a Government Accounting Office report sponsored by Sen. Ted Kennedy in 1972.

(A copy of the GAO report will be faxed to Tracy Thornton in the morning, 2/15/94).

Today, Congressman Mann (Cincinnati) and Congressman Portamn (Cincinnati suburbs) held a press conference with the local U.S. Attorney and Members of the local City Council in Cincinnati to discuss the role of the hospital in these experiments and whether any criminal prosecution is warranted. The hospital is now a part of the University of Cinicinnati.

Since the statute of limitations has tolled there cannot be criminal prosecution even though some claim the experiments were clearly performed without informed consent on terminally ill patients.

TT
- Fact Sheet gold citations
- letter
- tomorrow - release
- clear - heads up

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

MAY 8 0 1972

B-164031(2)

Dear Mr. Chairman:

Pursuant to your request of December 23, 1971, and discussions with your office, we obtained documents relating to (1) the whole-body irradiation program at the University of Cincinnati Medical Center and (2) the policy of the Department of Defense on the subject of the protection of humans used in medical research projects under contract. The enclosure to this letter identifies the documents obtained by us and made available to your office during our work.

Concerning the policy on the subject of the protection of humans used in medical research projects, an official of the Department advised us that the policy of the Department was set forth in Department of Defense Instruction 5030.29, dated May 12, 1964. The instruction, which is applicable to all components of the Department and to its contractors or grantees, states that:

"The Department of Defense assumes full responsibility for the protection of humans involved in research under its sponsorship whether this involves investigational drugs or other hazards.

"Each Military Department will establish within the office of its Surgeon General a formal Review Board of professional personnel to consider each research proposal from within that Military Department or from its contractors or grantees which may involve the use of human subjects in the clinical investigation of new drugs. Before a clinical test with an investigational drug may be performed under the sponsorship of a Military Department--

"1. the plan of the test and other pertinent details must be submitted to the appropriate Review Board,

"2. the Board must indicate its approval, and

"3. the approval must be confirmed by the respective Surgeon General."

With the exception of certain reports that were required to be filed with the Food and Drug Administration of the Department of Health, Education, and Welfare in the case of investigational new drugs, no procedures were specified in the instruction with regard to the use of human subjects for other research purposes. The reports to be filed with the Food and Drug Administration were set forth in a Memorandum of Understanding between the Department of Health, Education, and Welfare and the Department of Defense, dated February 1964, which contained the procedures to be followed to ensure that the requirements of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 355), and the regulations issued under the act are fully met.

Although the instruction appeared to be directed primarily toward the investigational use of drugs, an official of the Department of Defense advised us that the instruction applied to all medical research projects. He stated also that each service directed its own research projects without control from the Department.

We contacted officials of the Departments of the Army, Navy, and Air Force and of the Defense Nuclear Agency, formerly known as the Defense Atomic Support Agency (the organizational entity within the Department of Defense that had contracts with the University of Cincinnati relating to the whole-body irradiation program), to determine whether they had any instructions or regulations that were applicable to the use of humans in medical research work under contract. The officials were not aware of any instructions or regulations, other than the instructions and regulations implementing Instruction 5030.29, involving the use of human subjects that would apply to contractors conducting medical research for their organizations.

An official of the Department of the Air Force advised us that the Air Force did not conduct medical research under contract. Officials of the Departments of the Army and Navy stated that, although most medical research had been conducted in-house, some had been performed under contract. They stated also that, when work is to be performed under contract, they must be satisfied that patient consent forms will be used and that human subjects will be adequately protected before a contract is executed.

B-164031(2)

An official of the Defense Nuclear Agency advised us that, although the Defense Nuclear Agency did not have any contracts for the use of human subjects for medical research, the following language had been included in all medical contracts after August 1971.

> "The COR [Contracting Officer's Representative] shall be informed in writing of any project plans on the part of the Contractor to employ new, experimental, and investigational drugs or other hazards in research involving human subjects, and such experimentation shall be specifically authorized by the Contracting Officer in writing prior to the prosecution of such research. Without the concurrence and authorization by the Contracting Officer for the specified drug or other hazard involved, such research shall not be performed. (The purpose of this clause is to insure compliance with the Department of Defense Instruction, 5030.29, 1964 May 12, entitled 'Investigational Use of Drugs or Other Hazards by the Department of Defense', a copy of which is furnished to the Contractor with this Contract)."

Concerning the contract with the University of Cincinnati, officials of the Defense Nuclear Agency stated that the cost of radiation treatment and patient care had not been borne by their agency. They stated also that funds of the Defense Nuclear Agency had been used only to pay for supplementary laboratory analyses of patients who had received whole-body irradiation in order for the Defense Nuclear Agency to gain information in areas that were relative to national defense.

We plan to make no further distribution of this report unless copies are specifically requested, and then we shall make distribution only after your agreement has been obtained or public announcement has been made by you concerning the

B-164031(2)

contents of the report. We trust these comments will serve the purpose of your inquiry.

Sincerely yours,

Comptroller General
of the United States

Enclosure

The Honorable Edward M. Kennedy
Chairman, Subcommittee on Health
Committee on Labor and Public Welfare
United States Senate

THE WHITE HOUSE

WASHINGTON

January 31, 1994

MEMORANDUM FOR CHRISTINE VARNEY DEPUTY ASSISTANT TO THE PRESIDENT AND SECRETARY TO THE CABINET

PHILIP CAPLAN SPECIAL ASSISTANT TO THE CABINET SECRETARY

FROM: STEPHEN NEUWIRTH for SN SNN
ASSOCIATE COUNSEL TO THE PRESIDENT

David Greis, of the CIA, is planning to provide the attached statement to a subcommittee of the House Judiciary Committee. Among other things, this proposed statement will assert that the CIA took no part in any radiation testing on humans and that the CIA has already undertaken extensive records searches.

Please let me know as soon as possible if you have any comments on this proposed statement.

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On a separate matter, we should decide as soon as possible when we want the Advisory Committee to have its first meeting. Normally, the FACA requires 15 days' notice in the Federal Register of any such meeting.

Attachment

STATEMENT OF DAVID GRIES

Before the Subcommittee on Administrative Law
and Governmental Relations

Committee on the Judiciary
U.S. House of Representatives

Wednesday, February 2, 1994

Good afternoon, Mr. Chairman. My name is David Gries, and I am the Director of the Center for the Study of Intelligence, Central Intelligence Agency. The Director of Central Intelligence has appointed me as the CIA's representative to the interagency working group on radiation testing. I am pleased to testify today on the CIA's efforts to determine whether the Agency ever took part in any radiation testing on human beings. As I will explain, based on our searches to date, I believe that the answer to that critical question is "no".

I would like to describe the extensive efforts we have made to search our records. On Tuesday, 4 January 1994, CIA started an Agency-wide search for records bearing on any possible CIA involvement in testing the effects of radiation on humans. We focussed our efforts initially on records pertaining to the MKULTRA program, which I will briefly describe.

The MKULTRA program was established to counter perceived Soviet and Chinese advances in brain washing techniques. Between 1953 and 1964, the program consisted of some 149 subprojects which the Agency contracted out to various universities, research foundations and similar institutions. A few of the subprojects involved drug testing on unwitting human subjects, but most involved other areas of behavior. In 1963, the Agency's Inspector General inspected the program and issued a report on MKULTRA. The Agency destroyed most of its MKULTRA records in 1973.

In 1974 and 1975, the Rockefeller Commission and Church Committee conducted extensive investigations of CIA human research activities, relying on extant documents, interviews and testimony. Both of these bodies issued public reports that discussed the MKULTRA program in some detail and noted that "radiation" was one area within the MKULTRA program charter. In 1977, CIA's discovery of boxes of program financial papers enabled CIA to reconstruct files on

virtually all MKULTRA subprojects and led to another Congressional investigation and testimony before the Senate Select Committee on Intelligence and Senate Committee on Human Resources. Once again, these Committees issued public reports discussing the MKULTRA program in detail.

These extensive and public investigations made it possible for our current researchers to assess virtually every one of the 149 subprojects and to follow up those that looked of interest. In addition, CIA researchers have reviewed the extant records from other programs (largely drug related) that may have conducted intrusive research on humans. We also reviewed and checked the voluminous documentation on intrusive research compiled in response to the Rockefeller Commission, Church Committee and SSCI/SCHR investigations, as well as the approximately 11,000 pages of documents released in response to Freedom of Information Act requests.

We also studied the 1963 Inspector General's report on MKULTRA and a 1973 compendium of employee reports of improper or illegal activities. We interviewed more than 40 current and former employees, ranging from former DCI's to the scientists and medical personnel most likely to have conducted or been aware of radiation testing, had it occurred. Simultaneously, Agency records managers and offices are carrying out wide ranging searches for any indication whatsoever of radiation testing. I should emphasize that we have based our search inquiries on the broadest and most comprehensive usage of the term "radiation".

To date, CIA has found no evidence of any ionizing radiation testing on humans ever carried out under its auspices. Further, none of the employees or senior officers whom we consulted, and who were in a position to know, have ever heard of the Agency conducting such an activity.

We believe the statement appearing in the Rockefeller Commission and Church Committee Reports originated as standard phraseology in early documents mentioning radiation as a potential area of MKULTRA research. However, we have not located any documents thus far showing that radiation testing was pursued.

That was the past, what about now? Since they took effect, the Agency has strictly followed HHS regulations pertaining to the conduct of human subject research. We have established an internal review board and rigorous procedures to ensure that any proposal for such research complies in every respect with these guidelines. In recent years, very few proposals have been considered and certainly none have involved radiation or drug testing on human beings.

In conclusion, although our search continues, CIA has found no evidence of any kind that the Agency has ever deliberately exposed any person to ionizing radiation, whether for research into human behavorial modification or for any other purpose.

Thank you, Mr. Chairman.

3

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

27-Jan-1994 05:33pm

TO: (See Below)

FROM: Tracey E. Thornton
Office of Legislative Affairs

SUBJECT: MEMO FOR OMB BRIEFING

THE MEMO I SENT TO EACH OF YOU ABOUT THE MONDAY BRIEFING FOR HILL STAFFERS WILL BE DELIVERED COB TODAY.
IT WENT TO ABOUT 75 INDIVIDUALS--HOUSE AND SENATE, MINORITY/MAJORITY OF APPROPRIATIONS, BUDGET, LEADERSHIP AND JUDICIARY (FULL AND SUB ON COURTS).

ALONG WITH THE INVITE, THE PACKAGE INCLUDED ALL THE SAME INFORMATION ABOUT THE WORKING GROUP THAT WENT TO EACH CONGRESSIONAL OFFICE EARLIER THIS WEEK.

IF YOU HAVE OTHERS YOU WANT TO INVITE JUST GET DOB'S AND CALL THEM IN TO MY OFFICE AT 456-6493.

LET ME KNOW IF THERE'S ANYTHING ELSE I NEED TO DO TO PREPARE FOR THIS.

THANKS.

Distribution:

TO: Courtney M. Manning
TO: Christine A. Varney
TO: Martha Foley
TO: Jocelyn M. Jolley
TO: Lorraine C. Miller
TO: Gordon Li
TO: Phillip M. Caplan
TO: FAX (95358500,dennis duffy)
TO: FAX (93584340,jeff lawrence)
TO: FAX (95149149,faith burton)
TO: FAX (96908425,karen pollitz/judy l)
TO: FAX (95864891,william taylor)
TO: FAX (97036978299,kelly sharbel)
TO: Tracey E. Thornton
TO: Erin A. O'Connor

EXECUTIVE OFFICE OF THE PRESIDE

31-Jan-1994 09:57am

TO: (See Below)

FROM: Tracey E. Thornton
Office of Legislative Affairs

SUBJECT: CONGRESSIONAL RELATIONS SUBCOMMITTEE LIST

HUMAN RADIATION INTERAGENCY WORKING GROUP

Subcommittee on Congressional Relations

Department of Defense

Kelly Sharbel	703-695-1868(T)	703-697-8299(F)

Department of Energy

William Taylor	202-586-5450(T)	202-586-4891(F)

Health and Human Services

Judy Lewis	202-690-7450(T)	202-690-8425(F)

Department of Justice

Faith Burton	202-514-1653(T)	202-514-9149(F)

NASA

Jeff Lawrence	202-358-1948(T)	202-358-4340(F)

Department of Veterans Affairs

Dennis Duffy	202-273-5615(T)	202-273-5994(F)

White House

Tracey Thornton	202-456-6493(T)	202-456-2604(F)

Distribution:

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TO: FAX (97036978299,kelly sharbel)
TO: Tracey E. Thornton
TO: Erin A. O'Connor

EXECUTIVE OFFICE OF THE PRESIDENT

Washington, D. C.

FAX TRANSMITTAL COVER SHEET

DATE: 11-Jan-94

TO: PHIL CAPLAN

SUBJECT: FOR YOUR IMMEDIATE ATTENTION

FROM:

TRACEY E. THORNTON (202) 456-7557
OFFICE OF LEGISLATIVE AFFAIRS

If there are any problems receiving this transmission, please call the sender, or (202) 395-7370.

TO: KELLY SHARBEL (DOD)
WILLIAM TAYLOR (DOE)
JERRY KLEPNER (HHS)
SHEILA ANTHONY (DOJ)
JEFF LAWRENCE (NASA)
DENNIS DUFFY (VA)

FR: TRACEY THORNTON 456-6493
LORRAINE MILLER 456-6620

DA: JANUARY 11, 1994

RE: CONGRESSIONAL SUBCOMMITTEE RADIATION MEETING

The next meeting of the Congressional Working Group is Wednesday January 12, at 10:30 am in room 107 of the East Wing (Lorraine's office). For this meeting please bring a list of every requests for documents you have received from congressional committees/offices and the status of that request; a list of every significant congressional inquiry you have had and your response to it; a list of all request for witnesses for congressional hearings and the status; and a list of all request for congressional briefings.

We are trying to set up a general briefing for all congressional offices for Wednesday for the House and Senate separately.

Thanks for your cooperation.

cc: Susan Brophy
Phil Caplan