January 19, 1995

MEMO TO: **LISA SCHIAVO**
PHIL CAPLAN

FROM: **LORI AZIM 586-5319**
ENVIRONMENT, SAFETY AND HEALTH

SUBJECT: **NOTES ON COMPENSATION**

Attached are some notes that were taken on compensation issues at the December 1994 meeting of the Advisory Committee on Human Radiation Experiments.

If I can get you anything else, or if you have questions, please give me a call.

Thanks!

Compensation Notes Advisory Committee Mtg. December 1994

The Committee is seriously groping with the issues surrounding compensation.

Culpability placed on some but not all instances.

Feinberg is stressing that remedy is not interchangeable with compensation.

Three questions with culpability:

1. **Who? Individual; role responsibilties.**
2. **Why? Deterrent against future; rights protected, wrongs repaired.**
3. **What? Is empirical evidence available to make judgments?**

Moral rightness/wrongness of acts v. culpability of actors, institutions. Can this be separated?

Nine guidelines by the Remedies Subcommittee:

1. **Charter restrictions.**
2. **Lays out a series of remedies.**
3. **Government culpability & harm to the individual**
4. **Discussion of culpability (may not be enough evidence)**
5. **Degree of harm to the individual (may not be enough evidence)**
6. **Causation - Tie harm to exposure; nothing new; merely articulates the problem**
7. **One government - Government culpable if agent does wrong.**
8. **Injuries specific to individual, not applicable to families - Doesn't pass on in estates; remedies sharply curtailed to family if victim is deceased.**
9. **Any evaluation of remedies must be fair, expeditious, equitable, etc.**

Sovereign immunity may be an issue.

Congress will decide remedies.

Some choices for Committee:

1. **Strict liability without deciding culpability**
2. **Go to questions of government culpability**
3. **Forget retrospective remedies, go to prospective remedies.**

Committee may make judgments on government culpability in a few cases.

Remedy does not only mean financial compensation! According to Feinberg.

People in the positions of power and authority at some point, failed to do what that role required morally.

This is clear even if the Committee doesn't know all the facts.

Therefore, the Committee cannot make judgements about culpability and compensation.

The Committee can make a retrospective moral judgement that wrongs were done by irresponsible admission.

Whether or not both oral or written consents were obtained, rights were violated.

A continuum of placing dividing points on equal consents was obtained.

The committee is stating that when enclosure consent was not obtained, it is in doubt that the purpose of consent was ever obtained.

Even though Secretary Wilson's name appears on thousands of documents, four or five documents were brought to the Committee's attention show he may have made the wrong decisions.

This selective choice of documents influences the sort of moral judgement on whether he did what was morally right or morally wrong.

Focusing on culpability and compensation may be difficult for most of the Committee.

The Committee is not judge and jury, and was not designed to be.

The charges that they have is to tell the story and to try and see if they can do something to form guidelines for prevention.

The Committee should be focusing on that kind of remedy.

The issues of culpability and compensation raise questions as to why the Committee still has difficulty getting all the facts.

A number of experiments are still partly classified and is difficult to obtain.

It is believed that there is a bureaucratic desire to protect an agency from culpability and compensation.

The most important thing to do is to get the information out on experiments that took place thirty or forty years ago.

One of the major reasons this Committee was formed was to examine the affects of the Cold War.

The Committee has a right to respond to the violations of individuals affected by radiation exposure.

The Committee should be able to make good judgments in these cases of rights violations.

Also, the Committee may not be able to answer all individual compensation requests.

January 19, 1995

Cabinet Secretary Christine Varney
1600 Pennsylvania Ave. S.W.
Washington, D.C. 20500

Dear Ms. Varney:

Enclosed please find my final appeal for compensation under the Radiation Exposure Compensation Act, 42, U.S.C. 2210 note (Supp. 1994). This request has been ongoing for quite some time, and as you may have guessed, I am having a difficult time in trying to support my claim.

I was diagnosed with cancer of the thyroid and lymph nodes and have spent the better part of two years trying to satisfy the demands of the government.

As of this moment, I have almost given up on any hopes for compensation as letter after letter from the Justice Department has met me with difficulties.

My father worked in southern Utah during the time frame they have mapped, yet they are unbelieving in my testimony.

I hope your feelings are the same as mine, and that the victims of the cold war will not be forgotten. I also wish that there were not so many technicalities to overcome when one tries to be compensated for something that was caused by one's own government. You see Ms. Varney, I was but a small boy when the nuclear testing was done. I found no harm in playing in the dirt with my Tonka truck - dirt that was tainted by acid rain from the inexcusable damage that the goverment had done.

Thank you for taking the time to read my letter. Maybe some type of future legistation might make it possible for people like myself and like my mother who suffers from breast cancer, to be compensated without being made to feel that they are trying to pull one over on the government. After all, the government caused the radiation and perpetrated the "downwind" catastrophe.

Sincerely,

Robert L. Robertson

Robert L. Robertson

January 19, 1995

Radiation Exposure Compensation Program
U.S. Department of Justice
P.O. Box 146
Ben Franklin Station
Washington, D.C. 20044-0146

Re: Defiency Letter, Dec. 27, 1994
RECA File 201-16-4465

Attn: Gerard W. Fischer

Dear Mr. Fischer:

Enclosed please find a rebuttal to the deficiency of my claim and to your denial of my claim for compensation under the Radiation Exposure Compensation Act, 42 U.S.C. 2210 note (Supp. 1994).

After analyzing the reasons for your denial, I once again consulted the "Downwinder's Guidebook". It has come to my attention that your interpretation of "consecutive" and "cumulative" seem to be different from my interpretation of the same. For this I will refer to the guidebook, page 6, b. the Minimum Required Time Periods and Time Frames, which detail - "physical presence totaling two years (any 24 months of cumulative or consecutive presence) in at least one of the designated geographical areas between January 21, 1951, and October 31, 1958; or - physical presence for the entire period beginning June 30, 1962, and ending on July 31, 1962."

You indicated in your letter that summer visits between 1953 and 1958 is less than the required physical presence of two years. What you are neglecting to calculate is the fact that until I was old enough to attend school, at age five, which would be the year 1957, I was with my father continually. I believe that takes care of the adjective "cumulative". I also believe that would total five years and three months. This far exceeds your stipulation of cumulative presence totaling two years.

The entire period of June 30, to July 31, 1962 I was in the designated geographical area, as previous testimony from my uncle states. Summer visits began Memorial weekend and ended Labor Day weekend. If you will once again review the union dues receipts, I will point out a time period that you will find helps explain my presence in southern Utah during the entire months of June and July of 1962. Those with serial numbers 653976-F and 654045-F shows my father's employment as a boilermaker and as I have previously stated, this was in southern Utah.

You indicated on page one of your letter, paragraph three, that the union dues receipts that I submitted in behalf of my claim

showed my father's presence in Salt Lake City, Utah. Understand that at no time did my father work in Salt Lake City, Utah during the time periods under which we are questioning.

Understand that my father belonged to a union. Local number 182 was located and still is located in Salt Lake City, Utah. Union dues were sent to Salt Lake City and receipts were mailed back to their respective members. That was how business was taken care of in the 1950's and 1960's and the practice is still in effect today.

Please find enclosed as well, a letter from Mr. John A. Gallo, Business Manager of the International Brotherhood of Boilermakers and Welders Local 182. Mr. Gallo has written this letter in my behalf to help support my claim that my father did indeed work in southern Utah. He also explains the procedures and territories that Local 182 covers. You might find it interesting to note that under his claim as well as mine, my father worked in White Pine county Nevada as well as various counties in southern Utah.

If you will review the social security papers I have previously submitted, you will find companies that my father was under employ of from all parts of the United States. To aid you in understanding the type of work my father was in, I will explain that a Salt Lake City based company might have sent a crew to southern Utah, or MaGill, Nevada, or wherever the contract for their next job was located. Mr. Gallo's letter emphasizes that fact also.

I would like to explain that I have done extensive research regarding the "Downwinder's" plight and have come to a disturbing conclusion: Most victims of the government's scientific, technical experimentation and nuclear testing have little chance of success in being compensated for their human caused illnesses.

I have read of the efforts of Energy Secretary Hazel O'Leary's vow to compensate participants in the U.S. government's cold war radiation experiments, of Utah Senator Orrin Hatch's 10 year effort to obtain federal aid for the downwinder's victims, of University of Santa Clara's Law Professor Alan Schefflin's research on cold war aftermath, of Cabinet Secretary Christine Varney's quote in U.S. News & World Report, "We need to keep our focus limited to human radiation," or to quote the same article, "Now, the only hope for thousands who were injured or who were experimented on without their informed consent is that President Clinton or Congress will take action to compensate the forgotten casualties of the cold war." The report goes on to suggest that continued secrecy and legal roadblocks erected by the government have made it virtually impossible for victims to be compensated.

Senator John Glenn of Ohio has held hearings on the move to seek justice for all the government's cold war victims.

I must ask of the government if they are aware of how far a

$50,000.00 compensation will cover the expenses that are involved in cancer treatments? The answer is not very far. The benefit is helpful, but is also far to modest to cover the total expenses incurred by ongoing radiation treatments, surgeries, hospitalizations, missed work and continual follow ups from my many physicians who I am under the watchful eye of for the possibility that my cancer which originated in my thyroid gland, spread to my lymph nodes, and may spread to my lungs or brain.

This concludes my appeal of denial for my claim under the Radiation Exposure Compensation Program. Thank you for taking the time to review my appeal.

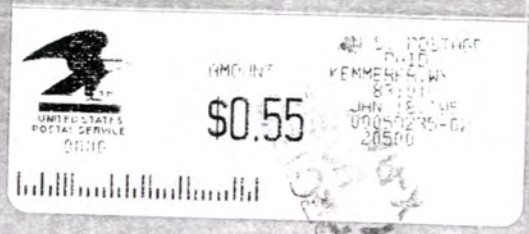
Sincerely,

Robert L. Robertson

Robert L. Robertson

cc. President Bill Clinton
Senator Orrin Hatch
Senator John Glenn
Energy Secretary Hazel O'Leary
Cabinet Secretary Christine Varney

ROBERT L. ROBERTSON
708 BEECH AVE,
KEMMERER, WY.
83101



CABI[illegible] VARNEY

~~1600~~ WASH[illegible] ~~20580~~

CHRISTINE A. VARNEY
ROOM 326
FEDERAL TRADE COMMISSION
WASHINGTON DC 20580

Phil Caplan
111 S 800

Phil -

Let's discuss the attached tomorrow or Monday.

Steve

Marc J.
CC: Lisa S. B.
Ed J.
Jane T.
Dave H.

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BARBARA B. HIRSCH (MD)
MARK A. FREEMAN (MD)

OF COUNSEL
DAVID B. NEWMAN, JR., Ph.D.
INTELLECTUAL PROPERTY MATTERS

Fax to: Brad
Steve H.

DATE: March 7, 1996

ATTENTION:		
Robert R. Nordhaus, Esquire	202	586 1499
Ray Heslin, Esquire	212	481 1722
Dan Berger, Esquire	212	481 1722
Tony Roisman, Esquire	603	795 4245
Cooper Brown, Esquire	212	481 1722
Wally Cummins, Esquire	212	481 1722
Eva Plaza, Esquire	202	514 8071
J. Patrick Glynn, Esquire	202	208 0976 ✓
Kevin Van Wart, Esquire	312	861 2200

FROM: Martin H. Freeman, Esquire
FREEMAN & JENNER, P.C.

RE: Plutonium Injection Cases

PAGES TRANSMITTED (Including this page): four (4)

COMMENTS:

IF THERE ARE ANY QUESTIONS, OR IF YOU DO NOT RECEIVE ALL PAGES, PLEASE CALL: (301) 907-7747 (FAX NO. (301) 907-9877)

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OF COUNSEL
DAVID B. NEWMAN, JR., Ph.D.
INTELLECTUAL PROPERTY MATTERS

March 7, 1996

VIA FACSIMILE AND FIRST-CLASS MAIL

Robert R. Nordhaus, Esquire
General Counsel
Department of Energy
1000 Independence Avenue, S.W.
Room 6A245
Washington, D.C. 20585

Re: Plutonium Injection Cases

Dear Mr. Nordhaus:

We have received your letter dated February 26, 1996, indicating delivery via telecopier and U.S. mail. February 26 was, as you know, the first day of the two day workshop sponsored by the Department of Energy to explain to the Task Force on Radiation and Human Rights how the Department intends to implement the recommendations of the President's Advisory Committee. We did not receive the letter by telecopier. It arrived by mail Thursday, February 29, 1996, with another de minimus offer to settle, left open only until March 1, 1996.

The size of your offer, its timing of delivery (after the workshop and shortly before the Senate hearings), and its manner of delivery (by mail only, with inadequate time to respond), make it clear that the United States has chosen not to implement the policies recommended by the President's Advisory Committee, and instead has opted to pursue a course which:

1. ignores the substantial evidence of liability and damages set out during our extensive written and oral presentations to you, your privately retained counsel, and the Department of Justice over the last three months;

2. continues fifty years of conduct sanctioning the outrageous crimes against humanity committed by the U.S. and its private sector partners;

3. ignores the recommendation of the President's Advisory Committee;

LAW OFFICES
FREEMAN & JENNER, P.C.

4. seeks to "buy out" the aggrieved families for a sum which essentially is zero;

5. commits the expenditure of tens of millions of taxpayers' dollars for costs and fees in defense of human radiation experiment lawsuits;

6. irretrievably, and unnecessarily, exposes our government and its partners to hundreds of millions of dollars in potential jury verdicts, all of which may also have to be funded by tax dollars;

7. has lost the opportunity to join with its aggrieved citizens to demonstrate to the world that our government can and does do more than submit empty apologies for past horrible wrongs, but instead can, and does, stand up with its citizens and correct those wrongs.

Notwithstanding the passing of your March 1, 1996 deadline for response, we have now conveyed it to our plutonium injection clients.

They have instructed us to:

1. decline the offer;

2. make no counter-offer;

3. lift all stays;

4. proceed without further delays or stays.

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FREEMAN & JENNER, P.C.

To the extent you understood that any global "offer" was made to the U.S. by us, your understanding is incorrect. However, we did propose, upon receipt of a satisfactory offer from the government, to recommend it to all of our clients, for approval by them in order to effectuate a settlement.

As the United States, its Departments of Energy and Justice and its partners have embarked on this regrettable and expensive course in the Courts and before Congress, contrary to the President's Advisory Committee recommendations, all of our clients and those who support them will promptly process their grievances.

Very truly yours,

Freeman & Jenner, P.C.

By: Martin H. Freeman /mw

Martin H. Freeman, Esquire,
for Freeman & Jenner , P.C.,
Gold, Farrell & Marks,
Berger & Montague, P.C.,
Cohen, Milstein, Hausfeld
and Toll, and
Cummins and Brown

MHF:mw

cc: Eva Plaza, Esquire
J. Patrick Glynn, Esquire
Kevin Van Wart, Esquire

ADMINISTRATION POSITION ON COMPENSATION
RELATED TO HUMAN RADIATION EXPERIMENTS

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

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

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

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

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

Throughout all of this activity, the Administration will continue active consultations with the Congress.

1/14/94 tjg

DATE: July 26, 1995

ASSISTANT SECRETARY
OFFICE OF ENVIRONMENT, SAFETY AND HEALTH
U.S. DEPARTMENT OF ENERGY
1000 INDEPENDENCE AVENUE, S.W.
WASHINGTON, D.C. 20585

OFFICE: (202) 586-6151 *FAX: (202) 586-0956*

TO: **Brian Latell, Claud Bailey, Gordon Soper, Pat Glynn, Gary Ellis, Lily Engstrom, D.A. Henderson, Harry Holloway, T.J. Glauthier, Susan Mather, Phil Caplan, Rachel Levinson**

FROM: **Tara O'Toole**

NO. OF PAGES TO FOLLOW: 4

___*For your information* ___*Please call upon receipt*

___*As requested* ___*For review and comment*

___*Original copy to follow via mail*

COMMENTS/MESSAGES:

The attached document is for the 10:00 conference call scheduled for July 26th with Tara O'Toole and the Interagency Search Group.

III. Incorporation of Advisory Committee Recommendations into IAWG Compensation Response Framework
(Eligibility Criteria)

CRITERIA	POPULATION AFFECTED	OPTIONS			NEW OPTIONS (ADV. COMMITTEE)
Government Secrecy (New)	Subjects of three lab experiments (listed below)				Apology & financial compensation for subjects of experiments where the government maintained secrecy to avoid embarrassment or liability, (regardless of physical harm).
Type of Exposure	Laboratory subjects/ downwinders	All individuals exposed to radiation in laboratory experiments or through atmospheric testing.	Different responses for individuals exposed to radiation in laboratory setting versus through atmospheric testing.	Individuals who participated in laboratory experiments only.	Individuals who participated in specific laboratory experiments only, (unless dose reconstruction studies later indicate harm to specific downwinder populations).
Informed Consent	Laboratory subjects	No distinction between individuals on basis of provision of informed consent.	All participants in laboratory radiation experiments who did not provide informed consent, based on current ethical standards.	All participants in lab experiments who did not provide informed consent, based on contemporary ethical standards.	
Radiation Dosage/ Exposure Level	Laboratory subjects/ downwinders	No distinction between individuals on basis of radiation doses in laboratory tests.	Distinguish between people exposed to high or low radiation levels, based on lab records.	No coverage of laboratory subjects or downwinders.	

CRITERIA	POPULATION AFFECTED	OPTIONS			NEW OPTIONS (ADV. COMMITTEE)
Contraction of a Potentially Radiation-Related Illness	Subjects of several specific experiments (listed below)	No distinction between individuals based on contraction of a potentially radiation-related illness.	Provide response elements (or higher compensation levels) to individuals with potentially radiation-related illnesses.	No coverage of downwinders or laboratory subjects.	**Apology and cash compensation for medical expenses and other harms** for subjects of experiments where there was no prospect of direct benefits and subjects were physically harmed.
Prospect of Direct Medical Benefit (New)	Subjects of several specific experiments (listed below) and others that may arise.				**Apology** to subjects of experiments where there was no prospect of direct medical benefit to subjects were not physically harmed.

1. **List of subjects covered under recommendation # 1 (Government kept information secret to avoid embarrassment or liability)**

- 18 subjects of plutonium injection experiments;
- 1 subject of a zirconium injection experiment (Cal-Z); and
- Several subjects of specific total body radiation experiments.

2. **List of subjects (potentially) covered under recommendation # 2 (No prospect of medical benefit and subjects were harmed)**

- Subjects of total body irradiation experiments;
- Subjects of Vanderbilt Radioiron nutrition experiments (if government involvement is established);
- Iodine-131 experiments involving native Alaskans;
- Testicular irradiation experiments using prisoners as subjects; and
- Uranium injection experiments at Rochester and Boston.

Note: for many of these experiments, the Committee has not determined whether there was potential for therapeutic benefit. The Committee also has not identified potential physical harms that may have resulted from such experiments, or eligibility requirements for subjects seeking compensation for harms. Three cases are currently under litigation.

3. **List of subjects (potentially) covered under recommendation # 3 (No prospect of direct medical benefit and subjects were not harmed)**

- Children who were subjects of certain experiments (including those conducted at Fernald and Wrentham);
- Experiments involving prisoners in connection with atomic bomb tests; and
- Iodine-131 experiments involving native Alaskans.

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENT
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(202) 254-9827 (Fax)

FAX TRANSMITTAL

NUMBER OF PAGES (including cover): 4

TO: Phil Caplan

FROM: Steve Klaidman

DATE: 7/24/95

RE: Press

If there are any problems with the transmission of this fax, please call (202) 254-9795.

MESSAGE:

Hi Phil,

Thought you'd like to see that they have us in Chicago & Boston

The Boston Globe

July 24, 1995, Monday, City Edition

SECTION: EDITORIAL PAGE, Pg. 10

LENGTH: 348 words

HEADLINE: Nuclear reparations

BODY:

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

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

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

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

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

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

LANGUAGE: ENGLISH

LOAD-DATE: July 25, 1995

Chicago Tribune

July 24, 1995 Monday, NORTH SPORTS FINAL EDITION

SECTION: EDITORIAL; Pg. 8; ZONE: N

LENGTH: 471 words

HEADLINE: ATONING FOR THE RADIATION TESTS

BODY:

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

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

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

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

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

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

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

Thus, "some people were treated poorly and suffered," the report concludes,

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

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

LANGUAGE: ENGLISH

LOAD-DATE: July 24, 1995

Congressional

To: Members of Interagency Working Group
From: Ellyn R. Weiss
Date: July 25, 1995

Subject: ORGANIZING ADMINISTRATION RESPONSE TO FINAL REPORT OF ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

At the conclusion of our meeting last Friday, it was agreed that the group would form smaller subgroups to identify options for the administration's response to the Advisory Committee's final report, focussing on steps that the President can announce when the report is released. The subgroups will report back to the larger group. I was tasked to draft this discussion memo identifying some issues and activities arising from the report and suggesting how these might be divided among the various cognizant parties. Each of you were invited to provide your input.

We are scheduled to have a conference call tomorrow (Wednesday, July 26) to decide how to proceed from here. You will have the opportunity then to add, subtract or modify anything. Please note that it is not the purpose of this memo to lay out the substantive implications of the issues or to identify options; that work will be done by the subgroups. Suggested subgroups and major questions follow:

1. Biomedical experiments in 1944 - 74 (Recommendations 1-5)

Major recommendations: compensation for families of 24 WWII - era "secret" experiments; compensation to subjects of nontherapeutic research if determined to be physically harmed, apology where no physical harm; acknowledgement that no good system in place prior to 1974.

Issues:

-- Relationship with pending litigation
-- Legislation required?
-- In cases where harm is "potential", who decides if it was actual?(leave to individual courts? refer to another entity?)

Subgroup: DOE General Counsel, DOJ, OMB, DOD, VA counsel, VA

2. Population Exposures (atomic vets, uranium miners, downwinders, Marshallese)

Congressional

Major recommendations: work with Congress to consider whether RECA should be amended to add other exposed populations (e.g. Hanford downwinders and uranium millers) and add nonmalignant diseases; update RECA epidemiological tables; address complaints that burden of proof too high and resolution takes too long; compensate all miners with lung cancer and one year or more underground; extend DOE medical monitoring of Marshallese to additional atoll(s).

Issues

-- What can be done administratively - without legislation?
-- How many additional people would be brought within the scope of RECA? Cost?

Subgroup: ~~DOJ, DOE, DOD, VA, White House Counsel~~ OMB

3. Current System for Human Subject Protection

Major recommendations: enhance ethical education for scientific/medical community and public; reform IRB system to focus on high risk research, better inform subjects, review scientific merit, identify government purpose and participation; establish mechanism to interpret ethical rules; address broader issue of compensation for harm to participants in federally-funded research; improve protection of military personnel by ensuring voluntariness, training officers, having ombudsman present when volunteers are sought.

Issues

-- How do we ensure the protection of subjects in ongoing studies where the committee found some problem in consent practices? Is review of all ongoing research necessary? Time frame?
-- Should NBAC be delegated to consider some of these on highest priority basis?
-- Which reforms can be announced immediately?
-- Mobilize support in scientific/medical communities for enhanced education? IRB reform?
-- Effect on military research?

Subgroup: OSTP, DOD, HHS, DOE Harold Jerry Wendy Baldwin

4. Classified Research

Major recommendations: no exemption from consent requirement for classified research; establish two independent panels, one to approve classified research and ensure subjects informed and voluntary, one to review secret intentional releases.

Issues

-- Statement of reasons for continued classified human research needed.

Subgroup: DOD, DOE, NASA

5. Openness

Major recommendations: Improve access to government records by transfer to NARA, designate an entity/person responsible to follow up on openness recommendations, independent review of CIA recordkeeping, declassify records of old CIA research.

Issues

-- What ongoing improvements in openness can be announced immediately?
-- How can we "institutionalize" openness - make lasting change?

Subgroup: DOE, OMB, CIA, DOD, invite participation of National Archives

6. Outreach

It would be the function of this subgroup to develop a plan for contacting groups external to the IWG, briefing them as necessary, identifying and mobilizing support.

Deliverables

Each subgroup should prepare options papers organized by issue and outlining options, pro's and con's, action plan.

Timeline

Options papers should be circulated to the group receiving this memo by Friday, August 11. This group should meet Tuesday, August 15 to consider the papers and endorse a package to go to the full Interagency Group for its consideration so that recommendations are ready for the White House by Friday, August 18.

INTERAGENCY WORKING GROUP ON HUMAN RADIATION EXPERIMENTS
SUBCOMMITTEE ON COMPENSATION

POTENTIAL COMPENSATION RESPONSE OPTIONS

April 19, 1994

TABLE OF CONTENTS

INTRODUCTION

This document is a response to the request made by the Interagency Working Group on Human Radiation Experiments for a preliminary set of compensation response options for individuals potentially affected by incidents involving ionizing radiation identified in the Executive Order on Human Radiation Experimentation. This draft is the result of several weeks of research and discussions conducted by the Compensation Subcommittee of the Interagency group, which includes representatives of the Departments of Energy, Veterans Affairs, and Justice; OMB, and the NEC.

The purpose of this document is to present a potential framework for an Administration response, should the Interagency Group wish to propose compensating individuals affected by radiation experiments or atmospheric radiation releases. The current draft should be considered a preliminary discussion paper, rather than a recommendation about how the Interagency Group should proceed. Throughout the document, legal and ethical issues, and associated implementation concerns, are raised that require further discussions within the Interagency Group, the individual agencies participating in the Interagency process, and the expert Advisory Committee, which will begin its work shortly.

In developing a set of potential compensation elements, the subcommittee relied primarily upon a number of existing models and legal precedents that pertain to issues such as compensation for exposure to ionizing radiation and other toxic substances, and compensation for harmful actions that have been undertaken by the U.S. Government. In addition, the subcommittee considered provisions of bills recently proposed in Congress to compensate subjects of radiation and other government-sponsored tests. Finally, the subcommittee gathered information from agencies about potential implementation issues associated with such compensation programs.

This document provides only an overview of the complex issues involved in determining appropriate compensation for radiation exposure. In the course of its deliberations, the subcommittee learned that there are considerable uncertainties associated with identifying linkages between individual radiation exposure and radiation-related illnesses. Such uncertainties exist even for diseases for which radiation-exposed individuals are currently eligible to receive compensation from the U.S. Government. Other issues that merit further discussions include identifying appropriate ethical standards to apply to laboratory experiments, establishing documentation requirements, and determining whether different responses should be considered for the two types of potentially radiation-exposed populations covered by the Executive Order.

The subcommittee conducted its work with only preliminary data available about the size of the potentially affected population covered under the Executive Order, as this work is currently in progress under the auspices of the Records Retrieval Committee. At this stage of the process, the subcommittee felt that it would be premature to develop cost estimates for any potential overall compensation packages. Such projections will need to await further discussions within the Administration, and estimates from agencies on the cost of each potential compensation element.

The remainder of this document has four main sections. Section I identifies issues that could determine eligibility criteria for a compensation program, such as informed consent, proof of illness, and type of radiation exposure. Section II provides an outline of various potential elements of a compensation package, (e.g., monetary compensation, health care, apology). Both sections discuss models and precedents, and include a range of options for how to proceed on each issue. In each case, the Subcommittee has attempted to present a full range of options; not all options are equally feasible, and no alternative presented is intended to serve as a recommendation.

Sections III and IV consist of two tables that graphically present the contents of sections I and II in a "menu" format that suggests how an overall package might be developed. Section V presents two illustrative overall compensation response packages. The subcommittee wishes to emphasize that such options do not represent recommendations. They are intended only to illustrate potential comprehensive combinations of options that could be selected. Finally, Section VI suggests issues that could be addressed by the expert Advisory Committee.

I. POTENTIAL ELIGIBILITY CRITERIA

A. Type of Exposure: Laboratory Experiments Versus Atmospheric Releases

The Interagency investigation covers two distinct populations that may have been exposed to ionizing radiation: individuals who participated in laboratory experiments and those who may have been exposed during intentional atmospheric releases of ionizing radiation that were designed to test human health effects or the extent of human exposure to ionizing radiation. Such populations may require separate compensation responses, due to differences such as: legal precedents governing atmospheric radiation releases; differing quality of data on individual exposure levels; and differing quality of techniques available for estimating individual radiation dose levels, based on radiation exposure levels.

Precedents/Models

- The **Radiation Exposure Compensation Act** (RECA) provides cash compensation to persons who have contracted one of several potentially radiation-related illnesses and fall into one of the following groups: (i) individuals who participated on-site in the atmospheric detonation of a nuclear device conducted by the United States prior to January 1, 1963 ("on-site participants"); (ii) individuals presumably exposed to fallout from the atmospheric detonation of nuclear devices at the Nevada Test Site during specified times in the 1950s and 1962 ("downwinders"); and (iii) certain persons who worked in uranium mines between January 1, 1947 and December 31, 1971.

- The **Compact of Free Association** with the Marshall Islands (1986) provided cash compensation to the government of the Marshall Islands for damages caused by U.S. atomic tests during the 1940s and 1950s. In addition, the United States provides environmental and health monitoring (DOE) and funding for a health care program for residents of Marshall Islands atolls that were contaminated by radiation (DOI).

- The **Department of Veterans Affairs** compensation program provides disability and death benefits to veterans (or their families) who were injured in the line of duty. By statute, veterans are presumed to have contracted certain radiation-related illnesses as a result of their military service if they participated in specified activities that resulted in potentially harmful levels of radiation exposure (e.g., participation in certain nuclear tests or the occupation of Nagasaki or Hiroshima). A similar presumption applies to veterans who were exposed to Agent Orange and contracted certain illnesses.

Alternatives

- Do not distinguish between individuals based on type of exposure (laboratory experiments versus atmospheric releases of ionizing radiation).

- Provide different compensation responses for individuals exposed to radiation in laboratory experiments versus those individuals exposed to ionizing radiation during atmospheric releases.

- Provide compensation response elements only for individuals exposed to radiation in laboratory experiments.

B. Informed Consent (Laboratory Subjects Only)

One eligibility criterion for compensation could be to distinguish between individuals based on whether they provided informed consent before participating in experiments. The Interagency group may wish to ask that the Advisory Committee determine whether current or contemporary standards of informed consent should apply to laboratory experiments.

Precedent/Model

- The sixteen federal agencies that conduct research using human subjects are required to comply with a "**Common Federal Policy for the Protection of Human Subjects**," (or "Common Rule"), which became effective in August 1991. The terms of this policy are incorporated into the Code of Federal Regulations governing each of these agencies. One of the central requirements of the Common Federal Policy is that human subjects must provide informed consent before participating in experiments.[1]

Alternatives

- Do not distinguish between individuals, based on informed consent.
- Provide compensation response elements only for individuals who did not provide informed consent, based on *current* ethical standards.
- Provide compensation response elements only for individuals who did not provide informed consent, based on *contemporary* ethical standards.

C. Level of Radiation Exposure or Dosage

Statutory compensation programs for individuals exposed to ionizing radiation have been based on the assumption that certain groups of people may have contracted their illnesses as a result of their exposure to potentially harmful levels of ionizing radiation. Under these precedents, it would be appropriate to distinguish between individuals, based on their level of potential radiation exposure. DOE representatives have expressed the concern that scientific techniques for linking radiation exposure to illnesses in populations are not pertinent for assessing risk of illnesses for individuals. Moreover, compensating individuals on the basis of their *exposure* to radiation only, without the onset of a radiation-related disease, would establish a new and much more expansive precedent for government liability: an obligation to compensate individuals who have not suffered actual, tangible harm.

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[1] The current federal standard for informed consent requires that all human subjects receive the following information: (i) an explanation of the purpose of the research; (ii) a description of any foreseeable risks or discomforts to the subject; (iii) a description of any potential benefits to the subject; (iv) disclosure of an appropriate alternative procedures; (v) a statement describing confidentiality provisions; (vi) an explanation of compensation or medical remedies available; (vii) a person to contact if any complications develop as a result of the experiments; and (viii) a statement that participation is voluntary. Additional information must be provided for certain types of experiments.

Precedents/Models

- Individuals eligible for compensation for certain illnesses under the **Radiation Exposure Compensation Act** (RECA) are presumed to have been exposed to high levels of ionizing radiation, once they establish the required documentation concerning duration of residence at an exposed location. Members of the three groups covered by RECA are eligible for different amounts of cash compensation, based on their presumed level of exposure.

- **The Department of Veterans Affairs** (VA) extends a statutory "presumption of service-connection" to certain veterans exposed to ionizing radiation through military service who have contracted potentially radiation-related illnesses. Such a presumption entitles a veteran to disability payments (or death benefits for his survivors) that would be available to veterans with other service-connected injuries or illnesses. However, veterans or survivors who accept cash compensation under RECA must forfeit their VA disability or death benefits.

Alternatives

Laboratory Subjects

- Do not distinguish between individuals based on dosage level.

- Distinguish between people, based on whether they were exposed to potentially harmful radiation levels.

- Do not include laboratory subjects.

Downwinders

- Provide compensation response package for local residents who lived within a designated area around sites of (some or all) atmospheric radiation releases identified in the Executive Order.

- Provide compensation response package for local residents who are determined to have been at risk, based on results of future dose reconstruction studies at sites of atmospheric radiation releases.

- Do not include downwinders.

D. Contraction of a Potentially Radiation-Related Illness

Statutes that the subcommittee examined provide compensation to eligible individuals who are believed to have suffered physical harm as a result of their exposure to radiation. Certain diseases have been identified in existing compensation programs as potentially radiation-related; individuals who were exposed to radiation during specified incidents with such diseases have been considered eligible for compensation. Although proof of contraction of a potentially radiation-related illness is the current standard for compensation for radiation exposure, as suggested earlier, scientific techniques for linking radiation exposure in populations may not be pertinent for assessing risk of illnesses for particular individuals. (Under current compensation programs, it is possible that individuals who have contracted illnesses for reasons other than their radiation exposure are eligible for compensation.)

On the other hand, existing compensation programs impose restrictions that can make compensation difficult to obtain for certain legitimate claimants. Documentation requirements, such as proving residence in a certain area during a specified time period or establishing that a person has contracted a potentially radiation-related illness within the latency period of a given disease, can prove extremely difficult in some cases. Individuals seeking compensation under the Radiation Exposure Compensation Act also have been required to establish that they did not participate in certain types of "risky" behavior (e.g. smoking or heavy drinking) that might have caused their diseases.

Precedents/Models

- **The Radiation Exposure Compensation Act** provides compensation to people who were within a specified geographic location during a specified period of time and can prove that they contracted one of approximately a dozen potentially radiation-related illnesses within a specified period of time following their radiation exposure.

- As noted above, a **Veterans Affairs** statutory presumption of service-connected injury entitles a veteran to disability payments (or death benefits for his survivors) only if he contracts one of several specified potentially radiation-related illnesses.

- The **Civil Liberties Act of 1988**, which provided reparations to Japanese-Americans interned during World War Two, compensates individuals based on their loss of liberty, due to forced relocation and internment. No proof of physical harm is required for compensation.

Alternatives

- Do not distinguish between individuals, based on whether they have contracted potentially radiation-related illnesses.

- Provide certain compensation response elements (or a higher grade of compensation) only to individuals who have contracted specified potentially radiation-related illnesses.

- Provide no compensation response package.

II. POTENTIAL COMPENSATION RESPONSE ELEMENTS

A. MONETARY COMPENSATION

1. Payment

In several compensation models the subcommittee considered, different cash compensation amounts are provided to recipients, based on their level of harm. Level of exposure and evidence of physical harm are both possible bases for distinguishing between groups eligible for compensation.

Precedents/Models

- The **Radiation Exposure Compensation Act** provides different lump-sum payments to downwinders ($50,000); on-site participants ($75,000); and uranium miners ($100,000) who have contracted specified radiation-related illnesses.

- **The Department of Veterans Affairs** provides disability payments based on the extent of injury (for radiation-related injuries, as for other types of service-related injuries).

- **The Civil Liberties Act of 1988** provides a uniform $20,000 payment to all eligible claimants, or their survivors.

Possible Responses

- Provide a minimum level of compensation to certain claimants, (e.g., to all participants of laboratory experiments, based on "dignity harm" caused by the experimentation).

- Provide a minimum level of compensation for all participants and higher levels for certain groups, (e.g., individuals exposed to high radiation levels, individuals who did not provide informed consent, individuals with potentially radiation-related illnesses, or individuals who meet some combination of eligibility criteria).

- Do not provide monetary compensation.

2. Extension of Benefits

Most compensation statutes the subcommittee considered as models include provisions to extend benefits to family members in the event that the eligible claimant is deceased. In general, benefits are provided to immediate family members (i.e., spouse and children), although some programs also extend survivors' benefits to two generations (i.e., grandchildren or grandparents). Survivors' benefits are generally provided to compensate a family for lost earning potential. In this case, however, it may be necessary to consider whether extension of benefits is warranted on the basis of any adverse genetic effects that an individual's family may have suffered as a result of exposure.

Precedents/Models

- The **Radiation Exposure Compensation Act** extends compensation to survivors within two generations (i.e., grandchildren or grandparents).
- The **Civil Liberties Act of 1988** extends compensation to survivors' spouses and children.
- **Veterans Affairs** compensation programs provide death benefits to survivors' spouses and children.

Possible Responses

- Extend benefits to survivors within two generations (spouse, children, grandparents, and grandchildren).
- Extend benefits to survivors within immediate family (spouse and children).
- Do not extend benefits to survivors.

B. HEALTH BENEFITS

1. Health Care

Health care benefits are one potential form of compensation for people who have contracted potentially radiation-related illnesses. However, health care programs are extremely expensive to administer and represent an ongoing funding commitment. Only a limited number of federal agencies are set up to implement a health care program as part of a compensation package. Thus, few compensation programs outside VA have included health benefits as a form of compensation.

Precedents/Models

- The **Department of Veterans Affairs** provides radiation-exposed veterans cash compensation is in the form of disability payments. In addition, such veterans are entitled to priority health care at VA hospitals, (meaning that they receive priority over most other eligible groups when receiving medical treatment for potentially radiation-related illnesses).
- Subjects of the **Tuskegee Syphilis Study**, conducted in the 1940s, received full health care benefits for life as compensation for participating in an ethically unsound study that tracked the spread of syphilis in a small community. Several hundred human subjects and their families were covered by this compensation package.[2]

[2] The Tuskegee study was funded by the Health, Education, and Welfare Service, the predecessor of HHS.

1. **Health Care** (continued)

- As noted above, through the **Compact or Free Association**, the Department of the Interior provides funding for a health care program administered by the government of the Marshall Islands Republic. The program was originally established to provide health care for 6,000 residents who were potentially affected by radiation contamination on the islands; the current program enrollment is over 10,000 people.

Possible Responses

- Provide health care benefits to individuals presumed to have contracted potentially radiation-related illnesses as a result of their exposure to potentially harmful levels of radiation.

- Provide health care benefits to individuals presumed to have contracted a radiation-related illness as a result of their exposure to potentially harmful levels of radiation and who do not have access to insurance or adequate Federal health care.

- Provide no health care coverage.

2. **Health Monitoring/Health Screening**

A health monitoring or health screening program could be established to help reduce uncertainties and anxieties that people may feel in connection with their radiation exposures. A screening program could consist of a one-time medical exam either to detect any evidence of a radiation-related illness or to conduct epidemiological tests. An ongoing monitoring program would permit participants to receive periodic exams that could potentially identify early symptoms of a radiation-related illness.

Precedents

- **DOE** provides limited **health monitoring to workers** who are occupationally exposed to hazardous substances such as asbestos, beryllium, or radiation. The Environment, Safety, and Health Division of DOE is promoting a new policy to shift this program more toward prevention, however.

- Through the **Compact of Free Association**, the Department of Energy provides ongoing health monitoring services to residents of four atolls that were contaminated with high levels of radiation. One reason for the ongoing program is that high radiation levels still persist in the areas monitored by DOE.

- As part of the **"Common Rule"** governing treatment of human subjects in federally funded research, scientists are required to monitor the health of human subjects after their participation in a medical experiment.

Possible Responses

- Provide health monitoring and/or one-time health screenings to all individuals who participated in laboratory experiments.

- Provide health monitoring and/or one-time health screenings to all individuals who were presumed to have been exposed to potentially harmful radiation levels (either through laboratory experiments or atmospheric releases).

- Provide no health monitoring or health screenings.

C. RESEARCH PROGRAMS AND PUBLIC OUTREACH

Public outreach and research programs have been included as supplementary elements of some monetary compensation packages. For the Administration's response, one or more research programs could be established to obtain further information about exposure levels, or to conduct medical research that could benefit human subjects covered by the response package. Public outreach programs could serve one or more functions, such as educating the public about the circumstances surrounding experiments or atmospheric tests, promoting ethical scientific experimental methods in the future, or providing affected individuals information that may be relevant to their medical conditions or risks.

1. Research Programs

Precedents/Models

- Public Law 96-151 required the **Department of Veterans Affairs** to conduct an epidemiological study of the health effects experienced by veterans exposed to herbicides containing dioxin, and Public Law 98-160 required, to the extent feasible, such a study of certain radiation-exposed veterans.

- The **Department of Veterans Affairs** also conducts outreach efforts to inform veterans about recent scientific and legal developments regarding their disabilities. For example, Vietnam veterans and "atomic veterans" are notified of developments concerning diseases associated with herbicides or with individual radiation exposures.

- The **Agent Orange Act of 1991** required the National Academy of Sciences to conduct a review of scientific literature evaluating the association between diseases and exposure to dioxin in herbicides. VA also was required to review the feasibility of establishing a program to evaluate dioxin levels in Vietnam veterans' blood serum to facilitate future research.

- The **National Vaccine Injury Compensation Program**, which provides compensation for persons injured by routine pediatric vaccines, includes an ongoing study with the Institute of Medicine about the risks to children posed by specific vaccines.

Possible Responses

- Establish a research program to conduct epidemiological studies of human subjects involved in radiation laboratory experiments included under the Executive Order).
- Establish a program to conduct dose reconstruction studies for areas where radiation was released into the atmosphere (for incidents included under the Executive Order).
- Do not establish any research programs.

2. Public Outreach

Precedents

- The **Civil Liberties Act of 1988** established a Presidentially appointed Civil Liberties Public Education Fund Board. Funds from the Civil Liberties Fund are authorized for use in a public education campaign.
- In 1980, Congress established the **U.S. Holocaust Memorial Council**, which currently awards grants and prizes for education.
- The **National Vaccine Injury Compensation program**, administered by the Departments of Justice and Health and Human Services, includes an outreach program to disseminate information about risks to children from vaccines, and a commission that brings together diverse interest groups for ongoing discussions of national immunization and compensation policy issues.

Possible Responses

- Promote Biomedical Ethics and Public Education. Establish a grant to a leading U.S. research university, (or universities), for a program (or institution) focused on ethical matters arising from the use of human subjects in experiments; or, establish a Board of Directors or foundation to administer grants to other types of organizations to educate the public and to promote ethical scientific experimentation.
- Information Dissemination to Subjects. Establish a program to provide ongoing research and medical information to subjects of experiments.
- Establish No New Programs. Instead, investigate the need for a comprehensive code of conduct for federal agencies or codify current Administration actions to review the ethical standards of Federal research practices in compensation legislation.
- Do not provide public outreach.

D. APOLOGY AND RECOGNITION

1. Apology

Many of the compensation statutes the subcommittee considered included an official apology on behalf of the Nation to individuals receiving compensation. In the case of the Civil Liberties Act of 1988, individuals received letters of apology signed by the President.

Precedents/Models

- The **Radiation Exposure Compensation Act**, the **Civil Liberties Act of 1988**, and the Act that provided compensation for the **Tuskegee Syphilis Study** included official apologies to the individuals covered by each statute.

- **Current Bills**. A compensation bill proposed by Rep. Frost (H.R. 3743) includes an official apology to the subjects of secret Government radiation experiments. A Sense of the House resolution proposed by Reps. Frost and Johnson (H.R. 337) includes an apology to individuals who were the subjects of radiation experiments without providing informed consent.

Possible Responses

- Include an official apology in compensation package that covers all people who have been exposed to radiation through atmospheric releases or during laboratory experiments.

- Include an official apology to individuals who contracted a potentially radiation-related illness through either laboratory experiments or atmospheric releases of radiation, or to individuals who did not provide informed consent to participate in an experiment.

- Include no official apology.

2. Recognition

An alternative to providing a formal apology on behalf of the Government or the Nation is to establish a monument, memorial, or official commendation to individuals affected or harmed by radiation exposure.

Precedents/Models

- A bill proposed by Rep. Goss (H.R. 1055) proposes that DOD provide an official commendation to all individuals exposed to mustard gas in World War Two.

- There are many national monuments to veterans (e.g., the Vietnam Veterans Memorial wall, the adjacent monument to women who served in the military during wartime, and the Iwo Jima memorial in Arlington, VA). The U.S. Holocaust Memorial Museum is a recent example of a national memorial for civilian victims of war.

Possible Responses

- Dedicate a memorial to one or more of the following groups: laboratory test subjects, downwinders, or a broader population of people who have suffered harm from radiation exposures.

- Provide official commendations for veterans who participated in government experiments; (this could apply to radiation experiments only, or also to subjects of LSD, mustard gas, and other types of experiments).

- Provide no official recognition.

III. MENU OF POTENTIAL ELIGIBILITY CRITERIA

CRITERIA	POPULATION	OPTIONS		
Type of Exposure	Laboratory subjects/ downwinders	All individuals exposed to radiation in laboratory experiments or through atmospheric testing.	Different responses for individuals exposed to radiation in laboratory setting versus through atmospheric testing.	Individuals who participated in laboratory experiments only.
Informed Consent	Laboratory subjects	No distinction between individuals on basis of provision of informed consent.	All participants in laboratory radiation experiments who did not provide informed consent, based on current ethical standards.	All participants in laboratory radiation experiments who did not provide informed consent, based on contemporary ethical standards.
Radiation Dosage/Exposure Level	Laboratory subjects	No distinction between individuals on basis of radiation doses in laboratory tests.	Distinguish between people exposed to high or low radiation levels, based on lab records.	No coverage of laboratory subjects.
	Downwinders	Provide compensation response elements for local residents who lived within a designated area around sites of (some or all) atmospheric radiation releases identified in the Executive Order.	Provide compensation response elements for local residents who are determined to have been at risk, based on dose reconstruction studies at sites of atmospheric radiation releases.	No coverage of downwinders.
Contraction of a Potentially Radiation-Related Illness	Laboratory subjects/ downwinders *(different options could be applied to two populations)*	No distinction between individuals based on contraction of a potentially radiation-related illness.	Provide response elements (or higher compensation levels) to individuals with potentially radiation-related illnesses.	No coverage of downwinders or laboratory subjects.

IV. MENU OF POTENTIAL COMPENSATION RESPONSE ELEMENTS

A.	MONETARY COMPENSATION	OPTIONS		
1.	Payment	$XXX minimum; $YYY per person exposed to high radiation levels; $ZZZ per person with specified radiation-related illnesses.	$XXX minimum; $ZZZ per person with specified radiation-related illnesses, subject to restrictions.[3]	$ZZZ per person with specified radiation-related illnesses.
2.	Extension of Benefits	Eligible survivors: spouses, children, grandchildren, parents, and grandparents.	Eligible survivors: spouses and children.	Provide no extension of benefits to survivors.
B.	**HEALTH BENEFITS**	**OPTIONS**		
1.	Health Care	Provide health care coverage to individuals who have contracted specific illnesses presumed caused by radiation exposure.[4]	Provide health care coverage to individuals who have contracted specific illnesses presumed caused by radiation exposure who do not have access to health care.	Provide no health care coverage.
2.	Health Monitoring	Provide health monitoring to all individuals who participated in laboratory experiments.	Provide health monitoring to all individuals exposed to high radiation levels.	Provide no health monitoring program.

[3] In this case, subjects would have to establish that they had been exposed to high levels of radiation. Other restrictions might include a maximum time between radiation exposure and contraction of disease, or evidence that claimant does not engage in risky behavior, such as smoking or heavy drinking.

[4] For this discussion, "radiation exposure" refers to exposure to radiation through either laboratory experiments or atmospheric radiation releases identified in the Executive Order.

B.	HEALTH BENEFITS (continued)	OPTIONS		
3.	Health Screening (one-time)	Provide health screening to all individuals who participated in laboratory experiments.	Provide health screening to individuals exposed to high radiation levels.	Provide no health screening.
C.	**RESEARCH OR OUTREACH PROGRAMS**	**OPTIONS**		
1.	Research Programs	Establish a research program to conduct epidemiological studies of human subjects involved in experiments.	Provide funds for additional dose reconstruction programs at sites of atmospheric releases.	Provide no research program.
2.	Outreach Programs (and other alternatives)	Establish a program to provide information to subjects of experiments or downwinders.	Establish a trust fund to administer grants for programs that promote ethical research practices.	Provide no outreach program.
		Propose a comprehensive code of research conduct (bioethics) for the U.S. Government.	Reference or codify Administration actions to review ethical standards in federal research.	No additional actions to develop standards.
D.	**APOLOGY/RECOGNITION**	**OPTIONS**		
1.	Official Apology	Include an apology that covers entire population covered by Executive Order.	Include an apology to individuals with radiation-related illnesses or who did not provide informed consent.	Provide no official apology.
2.	Recognition	Dedicate a memorial to laboratory subjects, downwinders, or all subjects of ethically questionable government experiments.	Provide a DOD commendation for radiation-exposed veterans (and, possibly, to participants of other ethically questionable government experiments).	Provide no official recognition.

VI. (ILLUSTRATIVE) COMPREHENSIVE COMPENSATION RESPONSE OPTIONS

The following illustrative compensation response options represent combinations of response elements and eligibility criteria identified in Tables III and IV, above. As stated previously, the subcommittee wishes to emphasize that such options do not represent recommendations. They are intended only to illustrate internally consistent combinations of options that could be selected to form the framework for a compensation response package.

Clearly, many other permutations of compensation elements are possible and could be developed, based on the Administration's priorities, the quality of data available, and judgments and recommendations offered by the Advisory Committee. The subcommittee encourages the Interagency Group to develop concrete suggestions as we proceed into the next stage of this process.

OPTION I

ELIGIBILITY

Graded Compensation Levels. Different responses for individuals exposed to radiation in laboratory setting versus through atmospheric testing.

Laboratory Subjects: Provide compensation response package for all participants in laboratory radiation experiments, regardless of consent. No distinction between individuals on basis of radiation doses in laboratory tests. Individuals with specified potentially radiation-related illnesses eligible for higher monetary compensation level.

Downwinders: Provide compensation response package for local residents who lived within a designated area around sites of (some or all) atmospheric radiation releases identified in the Executive Order. Limit eligibility to individuals with specified potentially radiation-related illnesses.

POTENTIAL COMPENSATION RESPONSE ELEMENTS

A. Monetary Compensation

- $XXX minimum (for laboratory subjects without potentially radiation-related illnesses); $ZZZ per person with potentially specified radiation-related illnesses, (subject to restrictions).
- Eligible survivors: spouses and children.

B. Health Benefits

- Provide no health care coverage.
- Provide no health monitoring program.
- Provide each eligible individual who participated in laboratory experiments a one-time health screening.

C. Research Program or Public Outreach

- Establish a program to provide information to subjects of experiments or downwinders.

D. Apology and Recognition

- Include an apology that covers entire population covered by Executive Order.
- Dedicate a memorial to individuals exposed to radiation through tests or atmospheric releases.
- Provide an official DOD commendation for radiation-exposed veterans.

ASSUMPTIONS

Several assumptions are implied in the illustrative example outlined above. The following is intended to provide insight into the arguments and conditions that could form the basis for a response package similar to option I.

Illustrative Compensation Element	Possible Basis for Selection
Provide different types of compensation responses to two populations	If Administration considers differences in legal precedents, types of radiation-exposure, and quality of data significant
Provide minimum cash compensation levels for participants in lab experiments	If Administration elects to compensate based on "dignity harm"
Provide (higher) cash compensation for radiation-exposed individuals with potentially radiation-related illnesses	If Administration wishes to amend Radiation Exposure Compensation Act and avoid change in legal precedent
Make no distinction between individuals, based on informed consent	If data pertaining to informed consent are unavailable or inadequate
Make no distinction between high and low levels or radiation exposure/dosage	If data pertaining to exposure levels are unavailable or if no consensus can be reached on scientific basis for distinction
Provide health screenings, but no health care or monitoring	If screenings are valuable for gathering data; if health care implementation issues are too complex; if Administration wishes to provide higher cash compensation instead
Provide information dissemination but no research programs	If necessary research could be funded from existing programs; if information dissemination would help reduce anxiety and public misconceptions about radiation
Provide apology and public recognition	If Administration wishes to emphasize its commitment to acknowledging wrongful action by government

OPTION II.

The following option provides a more limited compensation response package than illustrative option I. In this case, potential compensation for individuals exposed to radiation from atmospheric releases is delayed until additional scientific and historical data are available.

ELIGIBILITY

- Compensation response for individuals who participated in laboratory experiments only. (Downwinders to be covered through separate venue in the future.)
- No distinction between individuals on basis of level of radiation doses in laboratory tests.
- Cash compensation only for participants who did not provide informed consent, based on current standards, and who have contracted potentially radiation-related illnesses.
- All laboratory participants eligible for limited health benefits, regardless of consent.

POTENTIAL COMPENSATION RESPONSE ELEMENTS

A. Monetary Compensation

- $ZZZ per person with specified potentially radiation-related illnesses who did not provide informed consent.
- Eligible survivors: spouses, children, grandchildren, parents, and grandparents.

B. Health Benefits

- Provide one-time health screenings to all participants in laboratory experiments, (regardless of consent).
- Provide health monitoring to all participants in laboratory experiments, (regardless of consent).
- Provide health care coverage for all laboratory subjects with potentially radiation-related illnesses who do not have private health insurance or access to adequate Federal health care, (regardless of consent).

C. Research Program or Public Outreach

- Establish a research program to conduct epidemiological studies of human subjects involved in experiments.
- Provide funds for additional dose reconstruction studies to address possible need for compensation to downwinders near sites of atmospheric releases cited in Executive Order (and other sites, if necessary).

- Establish a trust fund to administer grants for programs that promote ethical research practices.

D. Apology and Recognition

- Provide an official apology to laboratory test subjects only.
- Provide an official commendation from Secretary of Defense for radiation-exposed veterans.

ASSUMPTIONS

Illustrative Compensation Element	Possible Basis for Selection
Provide compensation for laboratory subjects only	If Administration wishes to minimize changes to legal precedents; if data on atmospheric releases are not definitive
Provide cash compensation only for subjects with illnesses	If Administration follows legal precedent of VA and RECA compensation programs
Provide cash compensation only for individuals who did not provide informed consent	If informed consent documentation is adequate for legal judgments and issue could impact other cases
Make no distinction between high and low levels or radiation exposure/dosage	If there is insufficient data on exposure levels; if no standards can be agreed upon as basis for distinction
Provide health screenings and health monitoring to individuals, regardless of consent.	If Administration wishes to emphasize reducing subjects' anxieties; if adequate health monitoring techniques are available
Establish research program for epidemiological testing of subjects	If research could provide data to benefit laboratory subjects
Provide funds for additional dose reconstruction studies	If more data are necessary to determine risk and exposure of downwinders before providing compensation
Provide apology only to laboratory subjects.	If it is appropriate to delay decisions regarding individuals exposed to radiation during atmospheric releases

VII. POTENTIAL ISSUES FOR CONSIDERATION BY THE ADVISORY COMMITTEE

- Is it possible to assess whether individual experiments or classes of experiments resulted in harm to participants? Is it possible to determine that experiments or classes of experiments did not harm participants?

- Is it possible to distinguish between an acceptable and an "unacceptably high" level of potential radiation exposure? If so, should comparable standards for exposure or risk be applied to the two populations covered in the Executive Order (laboratory test subjects and individuals potentially exposed during atmospheric releases of ionizing radiation)?

- Regarding informed consent:

  - Is it possible to determine whether laboratory radiation experiments complied with ethical standards or perceptions at the time?

  - Should current or contemporary ethical standards be used in determining whether appropriate informed consent was obtained from subjects?

- What level of documentation should be required of claimants regarding health or medical information in order to prove radiation exposure or contraction of a specified potentially radiation-related illness?

- Are there considerations other than radiation exposure or risk, (such as risky personal behavior), that should enter into assessing whether an individual has contracted an illness as a result of radiation exposure?

- Is there a need for additional research that could potentially benefit radiation-exposed individuals?

- Is there reason to believe that the offspring of any of the laboratory test subjects suffered genetic harm as a result of their parents' radiation exposure?

IV. Incorporation of Advisory Committee Recommendations into IAWG Compensation Response Framework
(Potential Compensation Response Elements)

CASH COMPENSATION	OPTIONS			NEW OPTIONS (ADV. COMMITTEE)
1. Payment	$XXX minimum; $YYY per person exposed to high radiation levels; $ZZZ per person with specified radiation-related illnesses.	$XXX minimum; $ZZZ per person with specified radiation-related illnesses, subject to restrictions.	$ZZZ per person with specified radiation-related illnesses.	$XXX per subject in expts where government attempted secrecy; (and cover cost of medical expenses and associated harms where no prospect of medical benefit existed and subjects were physically harmed).
2. Extension of Benefits	Eligible survivors: spouses, children, grandchildren, parents, and grandparents.	Eligible survivors: spouses and children.	Provide no extension of benefits to survivors.	Immediate family members to receive cash compensation.
HEALTH BENEFITS	**OPTIONS**			**NEW OPTIONS (ADV. COMMITTEE)**
1. Health Care	Provide health care coverage to individuals who have specific illnesses presumed caused by radiation exposure.	Provide health care coverage to individuals who have specific illnesses presumed caused by radiation exposure with no access to health care.	Provide no health care coverage.	Provide coverage of medical expenses for subjects of experiments in which no prospect of direct medical benefit existed, and subjects were physically harmed.
2. Health Monitoring	Provide health monitoring to all individuals who participated in laboratory experiments.	Provide health monitoring to all individuals exposed to high radiation levels.	Provide no health monitoring program.	

IV. Incorporation of Advisory Committee Recommendations into IAWG Compensation Response Framework
(Potential Compensation Response Elements – continued)

HEALTH BENEFITS (continued)	OPTIONS			NEW OPTIONS (ADV. COMMITTEE)
3. Health Screening (one-time)	Provide health screening to all individuals who participated in laboratory experiments.	Provide health screening to individuals exposed to high radiation levels.	Provide no health screening.	Provide medical notification and follow-up to subjects for whom: (i) subject was placed at risk & may develop radiation-induced malignancy; and (2) a potential medical benefit for early detection may exist.
RESEARCH OR OUTREACH PROGRAMS	**OPTIONS**			
1. Research Programs	Establish a research program to conduct epidemiological studies of human subjects involved in experiments.	Provide funds for additional dose reconstruction programs at sites of atmospheric releases.	Provide no research program.	The Advisory Committee has recommended that efforts be undertaken at a national scale to ensure the centrality of ethics in scientific conduct and public awareness of the importance of the rights and interests of human subjects. *(This topic should be taken up separately by the new IAWG subcommittee on the current Federal system for human subject protection.)*
2. Outreach Programs (& other options)	Establish a program to provide information to subjects of experiments or downwinders.	Establish a trust fund to administer grants for programs that promote ethical research practices.	Provide no outreach program.	
	Propose a comprehensive code of research conduct (bioethics) for the U.S. Government.	Reference or codify Administration actions to review ethical standards in federal research.	No additional actions to develop standards.	

IV. Incorporation of Advisory Committee Recommendations into IAWG Compensation Response Framework
(Potential Compensation Response Elements -- continued)

APOLOGY/ RECOGNITION	OPTIONS			NEW OPTIONS (ADV. COMMITTEE)
1. Official Apology	Include an apology that covers entire population covered by Executive Order.	Include an apology to individuals with radiation-related illnesses or who did not provide informed consent.	Provide no official apology.	Provide an apology to subjects of experiments where government attempted secrecy or where no prospect of medical benefit existed.
2. Recognition	Dedicate a memorial to laboratory subjects, downwinders, or all subjects of ethically questionable government experiments.	Provide a DOD commendation for radiation-exposed veterans (and, possibly, to participants of other ethically questionable government experiments).	Provide no official recognition.	Provide no memorial or commemoration, but acknowledge that the government did not have a system in place to ensure protection of human subjects of radiation experiments prior to 1974.
OTHER MEASURES	**OPTIONS**			**NEW OPTIONS (ADV. COMMITTEE)**
1. Amend Radiation Exposure Compensation Act (RECA)	_____	_____	_____	Amend RECA to encompass other exposed populations, if appropriate; and amend provisions for radiation exposed uranium miners.
2. Review comp. laws for atomic veterans	_____	_____	_____	Review/update laws determining appropriate relief for atomic veterans
3. Continue Marshall Islanders prog.	_____	_____	_____	Continue DOE medical monitoring for exposed Marshall Islanders.

INTERAGENCY WORKING GROUP ON HUMAN RADIATION EXPERIMENTS

COMPENSATION SUBCOMMITTEE MEETING

Thursday, July 27, 1995

AGENDA

1. **General comments on the Advisory Committee report.**

2. **Discussion of compensation response options recommended by HRE Advisory Committee.**

   a. Comparison to Subcommittee's "Framework" document from last year.

   b. Identification of analysis needed.

3. **Legal issues related to compensation response options, including cost of potential litigation.**

4. **Implementation issues**

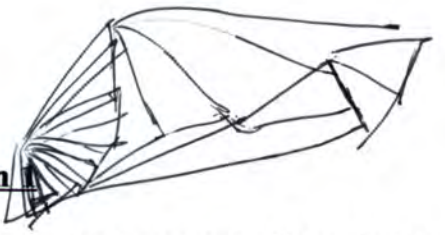
5. **Workplan and schedule for future meetings**

Interagency Working Group on Human Radiation Experiments

Compensation Subcommittee

COMPENSATION RESPONSE OPTIONS

August 14, 1995



Recommendation 1

The Advisory Committee recommends to the Interagency Working Group that the government deliver a personal, individualized apology and provide financial compensation to the subjects of human radiation experiments in which efforts were made by the government to keep information secret from these individuals and from the public for the purpose of avoiding embarrassment and/or potential legal liability, and where this secrecy had the effect of denying individuals the opportunity to pursue alleged grievances.

There are two options for statutory compensation to the affected individuals that would accompany an apology:

Option A

Provide compensation, but require that those compensated terminate suits against government, contractors and employees. This statute would either extinguish claims by legislative fiat or require a release as a condition of getting the money. A range of $75,000 - $125,000 would be offered.

Pro

Terminating the lawsuits is important because DOE expects to reimburse contractors for litigation costs in excess of $1 million per year, and this money is better spent paying subjects' families, not lawyers. Total defense costs (not including judgments or settlements) for these cases could exceed $5 million.

DOE's Office of General Counsel supports Option A, which fully carries out previous DOE commitments to compensate individuals who were wronged by these experiments.

Con

Plaintiffs will object to Option A unless a substantial amount is paid in exchange for termination of suits. Just how much money would persuade counsel representing subjects' families to release their claims is not clear and we can expect a dispute on this issue with the affected families.

Groups claiming injury from, and previous government secrecy of, other experiments and DOE's operations, such as the Hanford downwinders (over 3000 claimants), may ask for compensation comparable to the amounts offered under Option A.

Issues/Concerns

Even if other groups with claims pressed for compensation, DOE should support congressionally-financed compensation schemes as saving DOE millions of dollars in counsel fees, not to mention saving tens of millions of dollars in judgments or settlements. For example, remaining defense costs to try the Hanford downwinders case could add another $7 million to the $32 million in defense costs to date.

Option A is consistent with existing compensation schemes, such as RECA and the Civil Liberties Act of 1988 (Japanese internees), which required a release of claims as a condition of compensation.

Option B

Provide a smaller amount of compensation than in Option A, but allow lawsuits to continue. Compensation money would be in recognition of dignitary harms suffered from cover-up and would not purport to address claims of physical harm. Approximately $20,000 would be offered to correlate with amounts given to Japanese internees and their survivors. Under this option, lawsuits would continue against contractors and, perhaps, the government.

Pro

Up-front compensation costs would be lower than for Option A (though legal expenses would likely be higher).

Option B has the short-term advantage of mollifying plaintiffs' counsel.

Con

Without a termination of lawsuits, a statute apologizing for past wrongs and providing compensation (even if only for dignitary harms) could adversely affect pending litigation, to the extent the government has not already admitted wrongdoing in public documents and previous investigations.

Unlike Option A, Option B would not stem potential criticism over DOE's reimbursement of their contractors' litigation costs.

Recommendation 2

The Advisory Committee recommends to the Interagency Working Group that for subjects of human radiation experiments that did not involve a prospect of direct medical benefit to the subjects, or in which interventions considered to be controversial at the time were presented as conventional or standard practice, and physical injury attributable to the experiment resulted, the government should deliver a personal, individualized apology and provide financial compensation to cover relevant medical expenses and associated harms (pain, suffering, loss of income, disability) to the subjects or their surviving immediate family members.

In developing response options for this recommendation, the Compensation Subcommittee found that the most contentious issues center on the determination that physical injury occurred as a result of an experiment. The following options present a variety of mechanisms through which such causality could be established. All but the second to last of the response approaches outlined (Option D) would require that an entity such as the Interagency Working Group address several other important issues prior to implementing a system for establishing causality. Specifically, the following additional questions must be addressed:

- Was the intervention involved considered to be controversial at the time?
- Was the intervention presented to subjects as conventional or standard practice?
- If the decision to provide the controversial intervention and/or to describe the intervention as conventional or standard practice was all or partially the responsibility of a contractor, rather than the agency, how should liability be allocated between the contractor and the government?

Option A

Propose that the Institute of Medicine of the National Academy of Sciences undertake a study of the experiments identified by the ACHRE in this recommendation to render a determination as to whether physical harm resulted from participation in these experiments. Depending on the results of the study, the government would be in a position to either propose legislation to provide compensation or offer an explanation of why the subjects of these experiments were not physically harmed.

Pro

This approach involves a disinterested third party of experts with a great deal of scientific credibility.

Con

This approach would take at least a year before findings can be made.

In some cases, records providing information on which to make a determination of physical harm will be either unavailable or insufficient. In other cases, such records may be available.

Issues/Concerns

Implementation of this option will require that individual experiments within the categories identified by the ACHRE be reviewed first to determine if they meet the threshold test set forth in the recommendation, i.e., experiments that did not involve a prospect of direct medical benefit to the subjects or controversial interventions that were presented as conventional or standard practice.

If several Federal agencies join in this effort, the amount of resources required from each agency may be within reason.

Option B

Propose development of presumptive criteria, similar to those established for the Radiation Exposure Compensation Act (RECA) of 1990, to establish qualification for compensation. Under this option, compensation would be based on the *presumption* that physical injury resulted for subjects of a fixed list of experiments who later developed at least one of a fixed list of radiation-related injuries.

Pro

A more proactive, faster and predictable solution than litigation; politically more palatable.

Clearly defines universe of eligible participants.

Avoids reliance on precise, case-specific scientific evidence that radiation exposure from research resulted directly in harm to subject -- a causal linkage that has proven difficult, if not impossible, to establish in past cases, including RECA and Agent Orange compensation.

Con

Would involve creating a potentially large array of criteria suitable for all sub-categories of research subjects.

Potential exists for "over-" or "under" compensating a subject population by making qualification criteria too permissive or too restrictive. RECA, for example, has been criticized for the use of highly restrictive presumptive criteria.

Could increase Federal government costs over those for options relying on actual determination of cause and effect.

Issues/Concerns

Who would establish presumptive criteria?

Option C

Propose the establishment of a scientific expert panel that would serve as a screening mechanism to review the documentary records and determine if an experiment fitting the criteria identified by the Committee possibly caused harm. If this threshold issue in resolved in the affirmative, the panel could conduct an individualized fact determination or develop a list of presumptive criteria (such as exposure and illness) and make a recommendation as to appropriate relief.

(a) The government could, as necessary, support private relief bills for the cases the expert panel has recommended compensation; or

(b) The government (and its contractors) could submit to the panel for arbitration the issues of harm and causation for new and existing claims

Issues/Concerns

Legislation needed?

Number of claims?

How much money is involved?

Who administers?

Experiments listed by the Committee lack principle for inclusion with respect to harm/dose (e.g. Vanderbilt and I-131/Alaska)

Option D

Settle compensation cases through the civil justice system.

Pro

Factual questions about the causal linkage between government activity and harm to subjects, on which compensation will depend, have traditionally been resolved in the civil justice system.

Requires no new bureaucracy to administer compensation program.

Con

Could give the appearance that the government is unresponsive to the Advisory Committee recommendation; politically unpalatable.

Unpredictable budgetary impact.

Option E

Implement a hybrid form of litigation, in which the facts necessary to establish entitlement, particularly the establishment of causation, are decided in a judicial forum. For example, if relief is to be by private bill, Congress could refer causation and other factual issues to the Court of Federal Claims for resolution.

Pro

Would likely appear more responsive to the Advisory Committee recommendation than would complete reliance on litigation to establish compensation.

Requires no new bureaucracy to administer compensation program.

Con

Unpredictable budget impact.

Recommendations 2-3 and 3

As of the time this report was prepared, the Advisory Committee had withdrawn these recommendations for revision. The Compensation Subcommittee will not provide response options until the nature of these recommendations is more certain.

Recommendation 4

The Advisory Committee recommends to the Interagency Working Group that it work with Congress to amend the Radiation Exposure Compensation Act of 1990 to encompass other populations environmentally exposed to radiation from government operations in support of the nuclear weapons program, should information become available that shows that areas not covered by the legislation were sufficiently exposed that a cancer burden comparable to that found in geographic areas currently covered by the law may have resulted.

Option

The government also agrees with the Committee that there is an important issue of whether the release of radioactive substances from Hanford's routine operations caused adverse health impacts on those living near the facility. Current studies are underway on this issue.

At Hanford, the Hanford Environmental Dose Reconstruction project, funded by DOE and managed by the Center for Disease Control and Prevention, estimated doses to community residents from environmental releases of radioactive materials. Iodine-131 was identified as the exposure of greatest health concern because it may be associated with an increased risk of thyroid disease. Consequently, the Hanford Thyroid Disease Study, carried out by the Fred Hutchinson Center Research Center under contract by CDC, was initiated to determine the relationship, if any, between doses received from Hanford's operations and the incidence of thyroid disease. Dose reconstruction projects at other DOE sites, such as Fernald, Savannah River, Rocky Flats, and Oak Ridge, will also contribute information on the exposure potential of community residents.

These ongoing efforts seek to provide a scientific basis for assessing the health impact of past DOE operations on community residents. If such information demonstrates negative health impacts resulting from DOE's operations, the government will, consistent with the Committee's recommendations, take appropriate steps to respond to the results of the study, including considering whether existing legislation could be amended to cover the injured individuals.

Issues/Concerns

Consider whether RECA would be the appropriate compensation mechanism if causation were shown.

Application to downwinders of facilities other than Hanford (e.g. the Alaska weapons tests).

Recommendation 5 (1)

The Advisory Committee recommends to the Interagency Working Group that it work with Congress to ensure that epidemiological tables that are relied upon to determine whether relief is appropriate for veterans who participated in atomic testing are reviewed and updated so that all cancers or other diseases for which there is a reasonable probability of causation by radiation exposure are clearly and unequivocally covered by the statutes.

Option A

The Department of Health and Human Services (HHS) could direct the National Institutes of Health (NIH) to assemble another ad hoc working group (like that which, with the aid of a National Academy of Sciences (NAS) oversight committee, developed the 1985 tables) to update the epidemiological tables.

Option B

The NIH Institute of Medicine could be charged with the task of having the tables updated.

Option C

HHS would prefer that the Department of Veterans Affairs (which uses screening doses derived from the tables in its claims adjudications) or another user agency contract with the NAS or another similar entity for the tables revision.

Issues/Concerns

HHS is required by Section 7(b) of the Orphan Drug Act of 1983 (which mandated creation of the 1985 tables by HHS) to update the tables "every four years, or whenever [it is] necessary to insure that they continue to represent the best available scientific data and expertise." HHS, however, has yet to do so.

NIH staff members who assisted in development of the 1985 tables may no longer be available due to retirement or other obligations.

A ballpark estimate of the cost of work to update the tables is $1 million to $2 million, which should be included in the Presidents FY 97 budget request.

Once the tables are updated, policy decisions must be made as to whether the statutes that presume certain cancers to be service connected if suffered by former test participants should be amended to include additional diseases.

Recommendation 5 (2)

The Advisory Committee further recommends to the Interagency Working Group that it review whether existing laws governing the compensation of atomic veterans are now administered in ways that produce the best balance in allocation of resources between financial compensation to eligible atomic veterans and administrative costs, including costs of dose reconstruction.

Option A

The Department of Veterans Affairs (VA), with input from the Defense Nuclear Agency (DNA) regarding dose-reconstruction costs, could provide a written report to the Interagency Working Group by January 1, 1996, describing administration of laws governing the compensation of atomic veterans.

Option B

Upon receiving VA's report, the Interagency Working Group could appoint a subcommittee to evaluate VA and DNA procedures for processing veterans claims, with special attention to the four concerns identified by the Advisory Committee, and report its findings and recommendations to the Interagency Working Group by February 1, 1996. This evaluation could include consideration of both legislative and administrative changes which could be made to address the concerns identified.

Issues/Concerns

Reduction in administrative costs and claim-processing time could have a negative impact on accuracy in evaluation of the merits of claims.

Recommendation 6

The Advisory Committee recommends to the Interagency Working Group that it work with Congress to amend the provisions of the Radiation Exposure Compensation Act of 1990 relating to uranium miners 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 compensation should be extended to include uranium millers, and whether the criteria for compensating nonmalignant respiratory diseases and documentation standards for all claimants should be liberalized.

This recommendation is made up of three separate sub-recommendations:

1. Modification of eligibility criteria
2. Liberalization of Department of Justice RECA regulations
3. Extension of RECA to cover uranium millers

The following options, numbered 1-3, address each sub-recommendation separately.

1. Options relating to recommendation to modify statutory eligibility criteria

Option A

Agree to work with Congress to consider whether to amend RECA to adopt the minimum duration of employment standard in place of the Working Level Months standard for measurement of radon exposure.

Pro

Responsive to Advisory Committee.

May improve parity for uranium miners relative to other classes of eligible recipients.

If Advisory Committee is correct in its assessment of radon-induced cancer risk, amendment would be consistent with data developed since enactment.

Con

Potentially substantial budgetary impact.

May conflict with consensus that led to initial law if same issues were considered at time of initial enactment.

Potential questions of parity relative to other classes of eligible recipients if made too liberal.

Relief may be illusory if miners cannot prove employment for the duration adopted as the standard.

Option B

Agree to work with Congress to consider whether to amend RECA to adopt lower requirements for the number of Working Level Months that must be proved to entitle a miner to compensation.

Pro

Responsive to concern expressed by Advisory Committee.

May improve parity for miners.

Amendment consistent with data developed since enactment.

Can achieve reform without completely revising statutory scheme.

Con

Not precise change Advisory Committee recommended.

Still somewhat dependant upon controversial historical data.

If levels reduced too much, may result in windfalls for some miners.

Issues/Concerns Regarding Options A and B

The Radiation Exposure Compensation Act (RECA) represents Congress' attempt to create an inexpensive, expeditious, and easy-to-administer scheme to compensate those miners whose disease was caused by work-related radiation exposure. In April, 1992, the Department issued final regulations governing claim procedures under the Act.

In drafting the Act, Congress sought to compensate miners who worked in underground

uranium mines for a sufficient period of time that a reasonable association could be drawn between their exposure to radon on the job and their subsequent contraction of a compensable disease. The means by which Congress sought to ensure that compensation was provided only for diseases caused by exposure to radiation while working in an underground uranium mine was the requirement that a miner prove a minimum number of Working Level Months (WLM). A WLM is a measurement of exposure to radiation that combines the length of underground employment (a working month) and the concentration of radiation in the mine where the person worked (working levels). A working level month consists of 170 working level hours.

The Committee has expressed its belief that the latest data suggest that the RECA exposure criteria for compensation are too high relative to probable causation, and thereby exclude miners who should be compensated. The use of WLMs as an eligibility criterion to measure radon exposure has also been criticized because the historical data on which the calculation is based, (radon levels in mines), is imprecise; exposure estimates over worklife (measured in WLMs) can be off by as much as a factor of two. Amending the statute to base eligibility solely on duration of employment has the advantage of accounting for the latest epidemiological data on radon exposure and disease, and minimizes the central problem of reliance on imprecise historical exposure data. Alternatively, simply lowering the minimum number of WLMs that a miner would have to prove to be entitled to compensation would account for the latest epidemiological data and would reduce the adverse impact on miners of the historical data that underestimated concentrations of radiation in the mines.

Adoption of an employment duration standard won't solve all of the perceived problems with the current scheme because it will merely be a rough proxy for specific exposure levels as now mandated. The Committee's recommendation suggests it is concerned that otherwise eligible miners have been disenfranchised simply because they cannot prove a sufficient exposure history. Modifying the eligibility criteria by dispensing with specific WLM levels and substituting a duration of employment, by itself, will not solve this problem.

Under the present regulations, claimants are not required to submit proof of their exposure history; they are required to submit proof of their employment history, from which the RECA staff calculates exposure history (the amount of WLMs). Under the employment duration standard proposed by the Committee, a claimant must still provide proof of employment for the statutory duration. Thus, a claimant denied compensation because he cannot prove sufficient employment history to accumulate the required WLM level may similarly be unable to prove employment for any statutorily-required duration, such as the one year suggested by the Committee.

Reducing the required number of WLMs may solve the problem for disenfranchised miners who can prove only a portion of their total asserted employment history. They may be able to document employment for a sufficient period of time to accumulate a

reduced level of WLMs. Neither of the changes in the statute discussed above will help miners who allege that they cannot prove their employment histories because adequate documentary evidence simply does not exist. To enfranchise that class of claimants, the regulations governing documentation of employment history would need to be substantially modified in ways that may result in numerous unfounded claims.

Finally, the Committee's facile suggestion that one year underground is an appropriate measure masks the difficulties inherent in defining a period of employment. For instance, a one-year employment standard certainly cannot be interpreted as one calendar year during which a miner worked some unspecified number of days. The employment duration period would have to be defined in terms that offer some meaningful measure of the hours of exposure to radiation, such as is now provided by the working level component of the working level months standard. The "one-year" period would likely have to be broken down into work segments (hours, days, etc.) and those segments aggregated to total one year (or such other period as may be suggested) to achieve a reasonable measure of underground work. Further, if a single duration standard (e.g., one year) is applied to all miners, it may fail to account for decreasing levels of radon in the mines over the statutorily designated period (1947-1971). Accordingly, consideration must be given to whether employment duration standards should be different for the later years than for the earlier years, to avoid compensating miners who were not exposed to radon at levels of concern.

2. Option relating to recommendation to liberalize Department of Justice RECA regulations

Agree to review implementing regulations to determine whether the documentation standards for proof of the statutory criteria should be liberalized.

Pro

Responsive to the Committee.

Addresses concern without the need for additional legislation.

Internalizes reform.

Reform can be achieved more rapidly than through legislative process.

Con

If made too liberal, potential for fraudulent claims increases.

Potentially substantial budgetary impact.

Some of the stated deficiencies are statutory, not correctable without legislation.

3. Option relating to Committee recommendation to consider extending RECA to cover uranium millers

Agree to work with Congress to consider whether uranium millers should be eligible for compensation.

Pro

Responsive to Committee.

Potential for parity for a new population of persons adversely affected by exposure.

Con

Potentially substantial budgetary impact.

Levels of exposure may not warrant compensation, or may warrant less compensation than for miners.

Data may be ambiguous and may require more study before a cogent proposal can be made to Congress.

Issues/Concerns

NIOSH recently agreed to conduct an epidemiological study of uranium mill workers. It has conducted two studies of mill workers in the past, but they are somewhat dated (the last study covered workers up to 1977) and the cohorts used were small, so the interpretive power of the studies is minimal. The earlier studies found no statistically significant increase of lung cancer among mill workers, or of renal toxicity associated with exposure to processed uranium ore. The earliest study reported elevated levels of certain lymphatic and hematological diseases; the later study found elevated levels of nonmalignant respiratory disorders. The present study is still in the early stages.

Action Plan for Recommendation 6

Work with Congress to consider whether to amend RECA to adopt a single employment-duration standard for compensation or retain an exposure standard, and to amend the statute to set the standard adopted consistent with the latest scientific data on the risks of radon exposure. Further, work with Congress to consider whether uranium millers should be eligible. Finally, review the existing RECA regulations to determine whether to make appropriate changes in the documentation required to prove statutory criteria.

Specifically, we can take the following steps to develop proposals in anticipation of congressional requests:

Action Plan for portion of Committee recommendation proposing amendment of RECA to widen coverage for uranium miners

Establish a working group of persons from the Department of Justice and experts from NIOSH, NCI, NIESH and other appropriate governmental agencies to:

(a) confirm that the latest credible epidemiological data calls into question the statutorily-designated exposure levels for compensation;

(b) identify, based on the latest credible epidemiological data, an exposure level at which underground miners suffer a sufficiently significant increased risk of lung cancer to merit compensation under the Act;

(c) determine what factors (such as smoking history, date of onset of disease, length of time since last exposure) should be considered by Congress to disqualify an underground miner from compensation or to require elevated eligibility criteria;

(d) calculate a duration of employment standard that will compensate the class of underground miners that suffered a statistically significant elevated risk of lung cancer;

(e) determine whether a uniform duration of employment standard will define the class of entitled miners, or whether it is appropriate to propose a series of employment duration standards tied to variables that significantly affect exposure levels, such as the time period in which the claimant mined, the area mined;

(f) determine how many miners not presently eligible for compensation under the Act will be compensated if a duration of employment standard is adopted, and the resulting budgetary impact.

Action Plan for portion of Committee recommendation to consider revision of RECA regulations to liberalize standards of proof of statutory criteria

Establish a working group of persons from the Department of Justice and experts from NIOSH, NCI, NIESH and other appropriate governmental agencies, to take the following actions:

(a) determine what credible records or sources exist documenting the employment and/or exposure history of miners that have not already been identified by the RECA program;

(b) determine what other documents or means of proof (such a affidavits) exist to satisfy eligibility criteria, and what means of assuring veracity should be required.

Action Plan for portion of Committee recommendation relating to consideration of amendment of RECA to cover Uranium Millers

Establish a working group of persons from the Department of Justice and experts from NIOSH, NCI, NIESH and other appropriate governmental agencies, to take the follow actions:

(a) determine if uranium millers sustained a statistically significant elevated risk of disease as a result of exposure to radon and processed uranium ore;

(b) determine a valid, workable basis for defining the set of millers who sustained a significant increased risk of disease

(c) if there is a statistically significant association between uranium milling and incidence of disease, determine if the increased risk to millers of any identified disease is sufficient to propose compensation, and at what level;

(d) determine what factors should be considered by Congress to disqualify millers from compensation or to require elevated eligibility criteria;

(e) determine for any proposed eligibility criteria the number of claimants potentially entitled to compensation.

Recommendation 7

The Advisory Committee supports the Department of Energy's program of medical monitoring and treatment for the exposed inhabitants of the Marshall Islands atolls of Rongelap and Utirk, and recommends that this program be continued as long as any member of the exposed population remains alive. Furthermore, the Advisory Committee recommends that the program be reviewed to determine if it is appropriate to add to the program the population of Ailuk, and the population of other atolls whose inhabitants may have been received exposure comparable to or greater than those of Ailuk. The Advisory Committee also recommends that consideration be given to the involvement of the Marshall Islanders in the design of any further medical research to be conducted upon them.

Option A

Continue existing Marshall Island program for as long as any member of the exposed population remains alive.

Pro

Status quo, "least cost" approach.

Con

Does not address the Advisory Committee's recommendations to extend the existing program to include other atolls, or to involve Marshall Islanders in the design of research programs.

Option B

Ask the Institute of Medicine to review the comparability of doses received at Ailuk to those received at the other atolls covered by the DOE medical program.

Pro

IOM is a more credible, independent entity than DOE for review of facts.

Con

This option may raise expectations of compensation without a firm prospect of scientific clarity.

More expensive than Option A.

Issues/Concerns

More funding needed to continue current program because program includes lifetime monitoring and treatment of disease regardless of cause.

DOE currently has no evidence that exposures caused adverse health effects at Ailuk. Extension of program would at least triple costs from $2.5 to $7.5 million per year.

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HARMLESS RADIATION? P.55

▶ A forthcoming study of government radiation experiments on hundreds of Americans in the 1950s has found no evidence of significant physical harm. The surprising findings by a panel of experts convened by the Administration are to be released on Sept. 22. Despite a lack of proven injuries, the U.S. will still honor Energy Secretary Hazel O'Leary's December, 1998, vow to compensate the human guinea pigs—many of them unwitting victims—for unjust treatment. The remaining question: How much to pay? Even generous awards may not quell lawsuits by subjects.

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Steve Klaidman: 202-254-9795

FOR RELEASE AT 10:45 A.M.,
OCTOBER 3, 1995

FEDERAL PANEL CITES "LEGACY OF DISTRUST" FROM RADIATION RESEARCH IN THE COLD WAR ERA; RECOMMENDS GUIDELINES FOR COMPENSATING SUBJECTS

Committee Finds Significant Progress in Protecting Human Research Subjects Over Last Fifty Years, But Calls For Improved Safeguards for Children, Incompetent Adults and the Seriously Ill

WASHINGTON October 3, 1995-- Asserting that past experiments and environmental releases of radiation left a profound "legacy of distrust," the Final Report of the Advisory Committee on Human Radiation Experiments urges the government and biomedical researchers to review current practices to ensure that they protect the most vulnerable members of society. At a White House ceremony today, the Presidentially appointed committee presented its 925-page report to President Clinton and the heads of eight federal agencies with jurisdiction over federally funded research.

The Committee was chartered early last year to investigate experiments involving human subjects and ionizing radiation conducted from 1944 through 1974. It was also charged with investigating research related to specific intentional releases of radiation into the environment during the same period.

The Committee's report examines the history of government and professional ethics policies and practices. It presents case studies of experiments including the widely publicized plutonium injections that took place in the late 1940s and intentional releases at the Hanford nuclear facility in Washington state in the early 1950s. The report also describes projects the Committee conducted to assess the current status of research involving human subjects

The Advisory Committee found that important discussions of policies to govern human experiments took place in secret. Information about certain experiments was kept secret out of concern for embarrassment to the government, potential legal liability, and worry that public misunderstanding would jeopardize government programs. The Committee reported that more than two hundred intentional releases of radiation took place in secret. The releases remained secret for decades.

The Committee also found that in the 1940s and 1950s patients were often used as research subjects without their knowledge or consent. This occurred in many areas of research, including human radiation experiments. For example, some patients were injected with plutonium without their consent. Although the doses were not high, government officials kept the truth about the experiments from the subjects and their families, as well as the public. The Committee also studied cases in which prisoners and institutionalized children were used as subjects, and cases in which uranium miners were exposed to excessive amounts of radiation.

"In most of the experiments, the doses were low, and it appears that the government and scientists were concerned about risk, " said Dr. Ruth Faden, chair of the Committee. "But even when they took precautions to avoid harm to subjects, it does not mean that what was done was right.

"What most troubled the Committee was the lack of respect for the American people that seemed to permeate the conduct of research. The period we examined was defined by arrogance. People had great trust in their doctors, but doctors who did research often took advantage of that trust.

"The same can be said for government officials," noted Dr. Faden, who is director of the Bioethics Institute at Johns Hopkins University and a scholar at the Kennedy Institute of Ethics at Georgetown University. "It is clear that federal officials involved in radiation research were managing the release of information to make sure that the public image of the nuclear enterprise would be positive. In some cases, this amounted to deception and withholding of the truth, which the Committee found deeply troubling."

The Advisory Committee on Human Radiation Experiments began its work in April 1994 and held public meetings in Washington, D.C., and cities around the country. It heard more than 200 public witnesses; studied hundreds of thousands of pages of government documents, many of which were declassified for the Committee; and conducted an oral history project aimed at learning from researchers themselves about how research was conducted in the Cold War period.

Based on its findings, the Committee recommended a framework of principles to provide remedies for subjects who were wronged or harmed in past experiments and suggested policies to improve ethical practices in today's research. The Committee urged the government to deliver a personal, individualized apology and provide financial compensation to subjects of radiation experiments under two circumstances:

(1) when efforts were made by the government to keep information secret from subjects, their families, and the public to avoid embarrassment or legal liability; and

(2) when there was no prospect of medical benefit to the subjects, or when interventions considered controversial at the time were presented as standard medical practice and injury resulted.

To determine the extent to which research standards have changed since the Cold War era and to assess current safeguards for protecting human research subjects, the Committee conducted studies to gauge the public's attitudes and understanding about research, to examine current federal regulations and oversight practices, and to review current research protocols.

The Committee found evidence of serious problems in the current research process that warrant immediate attention, though none of these problems approximate those it uncovered about Cold War era research. One problem is that patients with serious illnesses sometimes have unrealistic expectations about the chance that they will personally benefit from participating in research. Some consent forms appear to be overly optimistic in portraying the likely benefits of research. They inadequately explain the impact of research procedures on quality of life and personal finances, and are sometimes incomprehensible to lay people.

The Committee recommended that a mechanism be established to provide for continuing interpretation and application of ethics rules and principles for the conduct of human subject research. This should take place in an open and public forum. The Committee cited particular need for:

(1) clarification of the meaning of "minimal risk" in nontherapeutic research with children;

(2) regulations to cover the conduct of research with institutionalized children; and

(3) guidelines for research with incompetent adults, particularly in more-than-minimal risk research that offers no prospect of direct medical benefit to subjects.

Dr. Faden stressed that the Committee's findings and recommendations should be heeded both by government agencies that oversee human subjects research and by the research community itself. "Our review of the contemporary scene makes very clear that the era of abuse and arrogance is over, that today's research enterprise with human subjects is, by and large, quite healthy. But our review also suggests the importance of being vigilant in protecting the most vulnerable members of society

"We can do more to protect children, institutionalized and incompetent adults, and the seriously ill. Though federal agencies and Congress should take a long look at what they can do to protect the interests of these people, the ultimate responsibility belongs at the universities and research centers where the research takes place. Together, we must do whatever it takes to ensure that the bond of trust is never again broken in the conduct of research with human subjects."

The Advisory Committee found that under current law some biomedical experiments and intentional environmental releases could be conducted in secret today and recommended the adoption of new safeguards to protect the rights and interests of citizens.

The Committee also recommended a series of steps aimed at easing public access to government records. It urged the government to transfer records from individual agencies to the National Archives; to make the process of record retrieval in government collections more "user friendly"; and, where documents have been destroyed, for clear records of the destruction to be available to the public.

Dr. Faden said the Committee had unfettered access to classified and sometimes embarrassing documents. "The White House and federal agencies were completely cooperative, and they let the chips fall where they may," she said. "In doing so, they set a precedent for the future. If the work of this Committee is to mean anything, it has to be that 50 years from now, there doesn't have to be another advisory committee -- that information is not concealed from people in their own time so that it takes two generations for the truth to come out."

The 14 Committee members included a citizen representative and 13 experts in medicine, science, law, history, bioethics, health policy, and epidemiology. (see attached list of Committee members)

Advisory Committee on Human Radiation Experiments

Human Radiation Experiments
Compensation of Past Subjects

Estimate of Maximum Potential Budget Requirements

OMB
February 2, 1996

Experiment	Subjects Max.	Subjects Currently Identified	Notes	Assumed Maximum Compensation/Subject	If Compensation for All Subjects Identified
ACHRE Rec. 1					
Plutonium Inject.	18	12	9 subjects in suits against fed. gov. 3 new claims (cannot sue yet)	$100,000	$1,200,000
ACHRE Rec. 2					
Saenger	88	33	subjects in suits against Cincinnati & doctors, Cincinnati suing fed. gov.	$75,000	$2,475,000
Vanderbilt	829	265	4 subjects in suits against fed. gov. 191 old claims 70 new claims (cannot sue yet)	$50,000	$13,250,000
Native Alaskans	70	70	no suits, only claims	$50,000	$3,500,000
Prisoners	130	2		$50,000	$100,000

Experiment	Subjects Max.	Subjects Currently Identified	Notes	Assumed Maximum Compensation/Subject	If Compensation for All Subjects Identified
Uranium Inject.					
Boston	11	0			
Rochester	6	1	subject suing hospital claim against fed. gov.	$50,000	$50,000
Fernald	74	14	new claims (cannot sue yet)	$50,000	$700,000
Possible New/Additional Cases					
Boron Neutron Capture Therapy	141	3	subjects in suit against hospital, claims against fed. gov.	$50,000	$150,000
New Potential Alaska Experiment	7	7	new claims (cannot sue yet)	$50,000	$350,000
Old: Oak Ridge TBI Therapy	2	2		$50,000	$100,000

Potential Total Compensation: $21,875,000

Privileged and Confidential

DETERMINED TO BE AN ADMINISTRATIVE MARKING INITIALS: MI DATE: 3/30/12
2019-0803-S

Via telecopier to

Eric Macris (395-4817)
Steven Neuwirth (456-1647)
Phil Caplan (456-2215)
Pat Glynn (616-4200)

From: Lisa Schiavo Blatt Lisa Schiavo Blatt

For your review for our Friday meeting on implementing the Advisory Committee's recommendations on compensation, attached is a summary of the status of the pending litigation and settlement negotiations.

cc: Robert Nordhaus
Dr. Tara O'Toole 6-0956

Privileged and Confidential

COMPENSATION FOR HUMAN RADIATION EXPERIMENTS

I. Settlement of Pending Litigation (claims have been filed on behalf of approximately **1275** subjects of human radiation experiments; each claimant seeks between $$1 - 100 million in damages per experiment)

- Counsel for the Human Experimentation Litigation Project (HELP) represent families and subjects of the plutonium and uranium injections, boron neutron capture therapy experiments, the prisoner experiments in Oregon, and the Fernald School Science Club experiment on mentally retarded children. Total potential HELP plaintiffs are the survivors of approximately 369 subjects.

- HELP suits are brought against former and current Department of Energy contractors and former employees of the contractors and government, and Federal Tort Claims Act claims have been brought against the United States.

- Cooperative settlement meetings with HELP, DOE and DOJ are ongoing; case discussions are proceeding in the order listed above; parties have agreed to stay several of the cases; settlement range will vary depending on the claim and experiment.

- The status of other human radiation experiment cases brought by other counsel involving about 906 subjects:

  Cincinnati Total Body Irradiation; 33 out of 88 subjects have sued; DOJ is handling with DOD and case is close to settlement

  Vanderbilt nutritional experiments; class action for 800 subjects; trivial government involvement; case proceeding against state and private entities; plaintiffs have raised settlement possibility

  Oak Ridge Total Body Irradiation experiments; 2 subjects; TBI was an experimental treatment on cancer patients

  Washington prisoners; 1 subject filed claim (60 in experiments)

Alaska natives exposed to Iodine-131 by Air Force; 70 FTCA claims; NAS report just released this week concluding no physical harm but inadequate consent

II. Process for Reviewing Future Claims Against the Government

- Administrative process
- Agency decision-making will follow Advisory Committee criteria

III. Possible Impediments for Both Filed and Unfiled-Future Claims

Statute of limitations (i.e., no government cover-up)
Limited government involvement
Lack of Harm (Advisory Committee concluded that only a few individuals may have been harmed by the experiments)
Claimant wants more money than is offered or litigation is worth

IV. Public Statement Regarding Compensation (follows Christmas paper by staff of Interagency Working Group to the White House)

As recommended by the Advisory Committee, and to the extent permitted by law, the affected agencies will work with the Department of Justice to offer reasonable financial compensation to subjects (or their surviving immediate family members) of human radiation experiments in which a government agency was involved in actions falling within any of the following three criteria outlined by the Advisory Committee:

1. experiments in which excessive secrecy deprived individuals of the opportunity to pursue potential grievances;

2. experiments in which there was no prospect of direct medical benefit to the subject and physical injury resulted; or

3. experiments in which interventions considered controversial at the time were presented as conventional or standard practice and physical injury resulted.

A streamlined administrative process, based on Federal Tort Claims Act procedures or other applicable law, will be used to offer compensation in settlement of relevant claims. Maximum effort will be made to avoid lengthy litigation, including use of alternative dispute resolution, such as mediation or arbitration, where appropriate. The amount of compensation will be based on the extent of physical harm to the subject, the nature of the experiment, and the degree of government involvement. As needed, agencies will seek expert advice on scientific and medical issues. If compensation cannot be offered under existing law in any case under the stated criteria, the Administration will work with Congress to seek legislative relief in appropriate cases.

ADMINISTRATION POSITION ON COMPENSATION
RELATED TO HUMAN RADIATION EXPERIMENTS

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

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

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

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

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

Throughout all of this activity, the Administration will continue active consultations with the Congress.

1/14/94 tjg

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1/14/94 tjg

THE WHITE HOUSE

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

WASHINGTON

20-Mar-1994 01:44pm

TO: (See Below)

FROM: T J Glauthier
Office of Mgmt and Budget, NRES

SUBJECT: Next Meeting of the Radiation Compensation Subcommittee

The next meeting of the Compensation Subcommittee will be held this Wednesday, March 23, from 10:30am to 12:00pm, in Room 248 of the Old Executive Office Building.

Clearance into the OEOB: my assistant, Courtney Manning, will clear in the following people:

Anita Capoferri
Patrick Glynn
Rosemary Hart
Robin Henderson
Lucy Huffman
Eva Plaza
Jack Thompson

If you plan on sending a representative not on this list please call her at 395-4561.

Distribution:

TO:	Bob Damus	(OMB)
TO:	Lucy Huffman	(Treasury)
TO:	Nancy McFadden	(DOJ)
TO:	Bob Nordhaus	(DOE)
TO:	Heather Ross	(NEC)
TO:	Jack Thompson	(VA)
TO:	Christine Varney	
TO:	Phil Caplan	
TO:	Kathy Peroff	(OMB)
TO:	Emily Pelton	(OMB)
TO:	John Pfeiffer	(OMB)

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

~~February 17, 1994~~

MEMORANDUM

TO: Bob Damus (OMB)
Lucy Huffman (Treasury)
Nancy McFadden (DOJ)
Bob Nordhaus (DOE)
Heather Ross (NEC)
Jack Thompson (VA)

FROM: Emily Pelton

SUBJECT: Materials for the next meeting of the radiation compensation subcommittee

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As you know, the next meeting of the Compensation Subcommittee will be held on Wednesday, March 23, from 10:30 a.m. to 12:00 p.m. in Room 248 of the Old ~~Executive Office Building.~~ Attached are two documents we have prepared as background for the meeting.

First, we are providing some additional background on potential models for health monitoring and health care compensation options. Second, we are providing a set of draft options for monetary compensation in a format that we hope will be appropriate for making recommendations to the full Interagency Group. Please take a few moments to review these materials before the meeting.

Finally, we request that you bring with you the materials distributed for last week's meeting to help guide our ongoing discussions.

I look forward to seeing you on Wednesday.

CC: Christine Varney
Philip Caplan
Joel Klein

Health Monitoring and Health Care Options

Models for Health Care

Only three compensation models that the subcommittee has considered provide health care coverage: the Marshall Islands Compact, the Tuskegee syphilis study, and the Veterans Affairs health care program.

- **Marshall Islands Compact (DOI).** Under Section 177 of the Compact of Free Association, the United States funds a health care program in the Republic of the Marshall Islands (RMI) for residents of four atolls judged to have been affected by U.S. nuclear tests. The so-called 177 Health Care Program is funded through the U.S. Department of Interior. In recent years, the RMI government has expanded the program from an original population of roughly 6,000 people to 10,000 people. Total funding of $30 million ($2 million per year for 15 years) for the Marshall Islands Section 177 Health Care Program was provided as part of the total amount agreed to under the Compact.

- **Tuskegee Study (HHS).** Subjects of the Tuskegee syphilis study and their families (extended to two generations) were provided full health care coverage under the HHS compensation program. All medical expenses for subjects and their families, regardless of any connection to syphilis, were covered by the government, (including all doctor and hospital fees, and transportation to and from medical facilities). The population of subjects eligible for this program was approximately 450 people.

- **Department of Veterans Affairs (VA).** VA provides health care to all veterans. Radiation-exposed veterans are entitled to "priority care" at VA hospitals, but main benefits for radiation-exposed veterans are disability and death compensation payments.[1] No estimates are currently available of the average cost of treatment for a radiation-exposed veteran with a radiation-related illness. Veterans who accept cash compensation under the Radiation Exposure Compensation Act are required to forfeit any death or disability payments to which they would otherwise be entitled from VA as a result of a radiation-related injury or illness.

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[1] Veterans seeking health care at VA hospitals receive priority based on a number of different factors. Veterans seeking health care for an ionizing radiation-related illness are among the highest priority group of patients eligible for care at VA hospitals.

Models for Health Monitoring

- **Worker Health Monitoring (DOE).** DOE is required to provide health monitoring for workers occupationally exposed to hazardous or radioactive substances. The following information was recently provided by Assistant Secretary Tara O'Toole at a March 17 hearing:

  Inadequate Monitoring Program. The Environment, Safety, and Health Program at DOE is currently launching a joint initiative with the Cleanup program to assess risks at DOE sites and to develop procedures to protect workers. One reason for this is that current DOE monitoring programs are considered to be under-funded and ineffective (for example, improperly calibrated instruments have been used and many workers have not been regularly checked). As a result, DOE worker exposure data have been incomplete and unreliable. Ongoing lawsuits by former DOE workers claiming to have radiation-related illnesses have focused attention on the inadequacy of DOE data in this area.

  Pilot Programs. Funding for DOE worker monitoring activities has been extremely limited; however, DOE is conducting pilot programs at Rocky Flats and Oak Ridge to monitor workers who may be at risk for Chronic Beryllium Disease. The program consists of a one-time medical evaluation and, where appropriate, a definitive diagnostic workup. To date, 4,200 individuals have been examined; 50 were found to have the disease. The program cost is approximately $1,000 per employee monitored.

- **Marshall Islands Compact (DOE).** As part of the U.S. Government's ongoing commitments under the 1986 Compact of Free Association, DOE conducts health monitoring, dose assessment activities, and environmental monitoring in the Marshall Islands. The former two activities are discussed below. The total cost of DOE health monitoring and dose assessment activities from FY 1980 - FY 1994 was $64.7 million. Current annual funding for such activities is $6 million.

  Health Monitoring. DOE laboratory personnel and 177 Health Care Program physicians provide health monitoring to residents of the Rongelap and Utrik atolls of the Marshall Islands. DOE conducts two field medical missions annually to examine and provide medical surveillance and follow-up medical care for residents exposed to radiation during the so-called BRAVO atomic weapons test of 1954.

Dose Assessment Program. In addition to health monitoring, DOE is involved in a radiological monitoring program of the Marshallese people to determine and quantify the presence of radioactive material which may have been taken into their bodies. DOE also participates in the Marshall Islands Nationwide Radiological Study, which includes studies of thyroid conditions of residents and should provide data concerning the potential for radiation exposure that still exists on the islands.

- **Hanford Environmental Dose Reconstruction Project (DOE).** The Hanford Environmental Dose Reconstruction Project (HEDER), initiated in 1987, will estimate radiation doses people may have received as a result of radioactivity released from Hanford's nuclear weapons production plants. The initial study will identify radiation doses corresponding to "profiles" of people, (based on their lifestyle, dietary habits, and geographic location). Results will not provide information for specific individuals. DOE eventually expects to turn over the HEDER data base to the Washington State Health Agency; the State may attempt to develop computer models that could estimate radiation doses for individuals. The HEDER project was funded at roughly $5 million per year during FY 1988 - 1994 and is projected to cost $2 million per year in FY 1995 and FY 1996. Preliminary HEDER results are expected to be released on April 21, 1994.

- **Human Subjects (All Federal agencies conducting research with human subjects).** Under the so-called Common Federal Policy that governs treatment of human subjects in all Federally sponsored research, human subjects must be monitored to ensure subjects' safety and the adequate collection of data. One possibility for health monitoring could be to extend this provision to human radiation experiment subjects in the past through the agency responsible for conducting the original experiment.

INTERAGENCY WORKING GROUP ON HUMAN RADIATION EXPERIMENTS
SUBCOMMITTEE ON COMPENSATION

COMPENSATION OPTIONS

OPTION I: MONETARY COMPENSATION

LABORATORY EXPERIMENTS

I. ELIGIBILITY

All participants in government or government-sponsored laboratory experiments involving intentional exposure to ionizing radiation (not including routine clinical practices), with or without informed consent.

II. PAYMENT

$XXX per person minimum;

$YYY per person exposed to high levels of radiation; and

$ZZZ per person with specified radiation-related illnesses, independent of exposure level and independent of period within which illness was contracted.

III. EXTENSION OF BENEFITS

Benefits extend to two generations (i.e., immediate family, parents, grandchildren, and grandparents) if claimant is deceased.

ATMOSPHERIC RELEASES OF RADIATION

I. ELIGIBILITY

Amend the Radiation Exposure Compensation Act (RECA) to include all "downwinders" within a specified geographic area surrounding locations of atmospheric releases identified in the Executive Order.[1]

II. PAYMENT (specified in the Radiation Exposure Compensation Act)

$50,000 for civilian downwinders; and

$100,000 for military test personnel.

III. EXTENSION OF BENEFITS

Benefits extend to two generations (i.e., immediate family, parents, grandchildren, and grandparents) if claimant is deceased.

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[1] In order to receive compensation under RECA, claimants must have been exposed to radiation during specified radiation releases (atomic tests conducted in Nevada during the 1950s) or during uranium mining activities. People covered are civilians living downwind of specified tests, military personnel involved in the tests, and uranium miners. To receive compensation, claimants must: (i) prove that they were present within a specific geographic area near the tests during a specified time period; (ii) document that they have contracted one of thirteen radiation-related illnesses; (iii) document that they contracted their illness within a specified period of time following their exposure.

OPTION II: MONETARY COMPENSATION

DRAFT

LABORATORY EXPERIMENTS

I. ELIGIBILITY

All participants in government or government-sponsored laboratory experiments involving intentional exposure to ionizing radiation (not including routine clinical practices), with or without informed consent.

II. PAYMENT

$XXX per person minimum;

$ZZZ per person with specified radiation-related illnesses who were exposed to high levels of radiation, subject to restrictions (e.g. time period between exposure and contraction of disease, or evidence of risky behavior).

III. EXTENSION OF BENEFITS

Benefits extend to immediate family, (i.e., spouse or children) if claimant is deceased.

ATMOSPHERIC RELEASES OF RADIATION

I. ELIGIBILITY

Amend the Radiation Exposure Compensation Act to certain "downwinders" surrounding locations of atmospheric releases identified in the Executive Order. Eligibility for compensation contingent on results of radiation dose reconstruction studies that estimate potential human radiation exposures resulting from atmospheric releases.

II. PAYMENT (specified in the Radiation Exposure Compensation Act)

$50,000 for civilian downwinders exposed to dangerous radiation levels; and

$100,000 for military test personnel exposed to dangerous radiation levels.

III. EXTENSION OF BENEFITS

Benefits extend to two generations (i.e., immediate family, parents, grandchildren, and grandparents) if claimant is deceased.