Recommendations & Reports of ACHRE (plus responses)

DRAFT

DRAFT

Human Radiation Experiments
Potential Responses to ACHRE Recommendation 2
October 5, 1995

Background

- Almost two years ago, Hazel O'Leary announced to the public that DOE had for years sponsored experiments on humans involving the use of radiation. O'Leary initiated a massive information search on these experiments. Thus far, DOE has documented 435 different experiments with approximately 16,000 individual participants. A small number of these experiments are currently the subject of lawsuits.

- The President then ordered the formation of an Advisory Committee on Human Radiation Experiments. Role: To review past, current and future experiments for ethical abuse and harm to subjects and Federal government involvement. This paper will focus only on compensation of subjects of past experiments.

- OMB has been participating in an Interagency Working Group to develop Administration policy toward those harmed in experiments.

- On October 3, the President officially accept the Advisory Committee's final report. The Administration gave only a general indication of policy with regard to compensation.

Compensation

- The Advisory Committee has found evidence that some experiments may have been ethically questionable, but the committee has not suggested a specific means of compensation.

- The Advisory Committee has indicated that one experiment merits particular attention -- WWII plutonium injection cases -- on the basis that government made efforts to keep information on these experiments secret from the subjects and public. The Interagency Working Group has determined that these subjects should be compensated.

- For other experiments, the Advisory Committee has developed the following criteria that subjects must meet to qualify for compensation:

    1. Experiment offered no prospect of medical benefit, or an intervention considered controversial at the time was presented as conventional to the subject; and

    2. Physical injury attributable to the experiment resulted.

- The question of whether subjects were physically harmed in experiments has proven particularly difficult to answer. In almost all experiments, radiation dosages were so low that a clear line of causality between exposure and harm cannot be drawn.

- In addition, the Compensation Subcommittee of the Interagency Working Group is considering a third, policy criterion that would correlate compensation to the extent of Federal government involvement in each experiment.

The Compensation Subcommittee, while embracing the criteria outlined above, has yet to come to consensus on a specific mechanism for evaluating all radiation experiments. Two different approaches are under consideration:

Option 1

Each agency would establish its own independent mechanism for reviewing personal injury claims brought by experiment subjects. Agencies would base compensation decisions on the criteria outlined above, along with a yet-to-be-determined criterion for establishing physical harm. Agencies could obtain advice from an expert review panel, particularly on medical causation issues. The intent of this approach is to reduce the burden of proof placed on experiment subjects who are currently forced to make their cases through litigation.

- Option 1 requires no legislation, which means the Administration can move now to work on cases. On the other hand, the process of reviewing cases could prove administratively burdensome, expensive and time consuming.

- This decentralized approach could lead to non-uniformity of standards for compensation.

- Does not appear very proactive; sets up what will look like another process with uncertain outcomes. Eighteen months have already passed since the Advisory Committee was formed.

Option 2

This alternative takes a more proactive approach to compensation. While the Advisory Committee has not had the time or resources to review every known experiment in-depth, six experiments have emerged as closest to meeting the committee's criteria regarding ethics (though the ethics of these six is still the subject of debate). Based on these findings, Option 2 entails the following:

1. Provide compensation for those physically harmed in the six experiments named by the Advisory Committee. This approach would override the Advisory Committee's uncertainty about whether two of these experiments meet the criteria listed above.

Sub-option: Compensation for two of the six experiments (Vanderbilt and Saenger) would be contingent upon further study of how or whether they meet the

criteria listed above. This sub-option would more closely follow the Advisory Committee recommendation of further evaluation of the Federal government role in the Vanderbilt experiments, and of whether potential Saenger experiment subjects were misled.

2. In case any other experiments are identified as unethical, subjects could still receive compensation through determinations of an expert panel.

- Option 2 requires legislation, which could take several months. The end result could be a compensation package that bears little resemblance to the original proposal.

- Through negotiations with Congress, Option 2 would allow government-wide consensus to emerge on compensation.

A key, unresolved element of Option 2 is the method through which physical harm would be determined to have occurred. Potential methods include:

2A) A. *Presume* that all subjects of the six experiments were harmed if they later developed a radiation-related disease or injury. This approach, while the most "generous," is problematic:

- Some experiment subjects were already terminally ill before the experiment began (If a subject had cancer *before an experiment began*, then compensation for physical harm because the subject still has cancer *after* the experiment would not be appropriate); DOJ is concerned that this presumption, if unrelated to any objective standard regarding radiation exposure level, would set a legal precedent regarding government liability in areas of much broader scope than human radiation experiments.

B) B. Establish panel to review individual subject records to provide compensation based on rigorous scientific/medical evidence. Most restrictive option. Lack of data could make implementation difficult.

C) C. Establish panel to review individual subject records to provide compensation based on a more "generous" standard, such as "probable cause of harm" or "reasonable presumption of harm."

Costs

Proposed compensation for those harmed: $50,000 to $75,000 per subject (or next or kin). Follows precedent set in Radiation Exposure Compensation Act (for uranium miners and "downwinders").

Total estimated cost under either Option: $20-50 million. (Maximum number of compensated subjects assumed to be approximately 1,000)

Would propose to fund in discretionary budget; agency responsible for "unethical" experiment would cover costs. Full funding needed up-front.

Energy and Science Division

9/26/95

Fax For:

PHIL CAPLAN
FAX: x[redacted] 62215

From:

ERIC MACRIS
TEL: x53807

Return Fax: (202) 395-1086

Comments:

ATTACHED IS A SHORT PIECE I'VE PREPARED COMPARING RESPONSE OPTIONS FOR ACHRE REC. 2.

AS WE DISCUSSED, PLEASE DON'T [redacted] SHARE THIS PAPER YET WITH OTHERS ON THE COMPENSATION SUBCOM, SINCE IT'S STILL ONLY A DRAFT.

PLEASE CALL ME AFTER YOU'VE READ THROUGH THE PAPER. KATHY PEROFF [redacted] AND I WOULD LIKE TO DISCUSS WITH YOU HOW TO PROCEED FROM HERE. THANKS, [redacted]

Human Radiation Experiments
Potential Responses to ACHRE Recommendation 2
September 26, 1995

Background

- Almost two years ago, Hazel O'Leary announced to the public that DOE had for years sponsored experiments on humans involving the use of radiation. O'Leary initiated a massive information search on these experiments. Thus far, DOE has documented 435 different experiments with approximately 16,000 individual participants. A small number of these experiments are currently the subject of lawsuits.

- The President then ordered the formation of an Advisory Committee on Human Radiation Experiments. Role: To review past, current and future experiments for ethical abuse and harm to subjects and Federal government involvement. This paper will focus only on compensation of subjects of past experiments.

- OMB has been participating in an Interagency Working Group to develop Administration policy toward those harmed in experiments.

- On October 3, the President will officially accept the Advisory Committee's final report. The Administration will need to give some indication of policy.

- This week, Tracy Thornton (WH Leg Affairs) will be meeting with the Hill to discuss the report's content and, in very general terms, what the Administration is considering.

Compensation

- The Advisory Committee has found evidence that some experiments may have been ethically questionable, but the committee has not suggested a specific means of compensation.

- The Advisory Committee has indicated that one experiment merits particular attention -- WWII plutonium injection cases -- on the basis that government made efforts to keep information on these experiments secret from the subjects and public. The Interagency Working Group has determined that subjects should be compensated for "dignitary harms" at a level of $20,000 per experiment subject. Physical harm would then be evaluated through one of the approaches outlined below.

- For other experiments, the Advisory Committee has developed the following criteria that subjects must meet to qualify for compensation:

1. Experiment offered no prospect of medical benefit, or an intervention considered controversial at the time was presented as conventional to the subject; and

2. Physical injury attributable to the experiment resulted.

- The question of whether subjects were physically harmed in experiments has proven particularly difficult to answer. In almost all experiments, radiation dosages were so low that a clear line of causality between exposure and harm cannot be drawn.

- In addition, the Compensation Subcommittee of the Interagency Working Group is considering a third, policy criterion that would correlate compensation to the extent of Federal government involvement in each experiment.

The Compensation Subcommittee, while embracing the criteria outlined above, has yet to come to consensus on a specific mechanism for evaluating all radiation experiments. Two different approaches are under consideration:

Option 1

Each agency would establish its own independent mechanism for reviewing personal injury claims brought by experiment subjects. Agencies would base compensation decisions on the criteria outlined above, along with a criterion for proving physical harm that would be less restrictive than a rigorous scientific/medical standard. Agencies could obtain advice from an expert review panel, particularly on medical causation issues. The intent of this approach is to reduce the burden of proof placed on experiment subjects who are currently forced to make their cases through litigation.

- Compared with Option 2, Option 1 could prove administratively burdensome, expensive and time consuming.

- Does not appear very proactive; sets up what will look like another process with uncertain outcomes. Eighteen months have already passed since this issue was raised by Sec. O'Leary.

Option 2

This alternative takes a more proactive approach to compensation. While the Advisory Committee has not had the time or resources to review every known experiment in-depth, six experiments have emerged as closest to meeting the committee's criteria regarding ethics (though the ethics of these six is still the subject of debate). Based on these findings, Option 2 entails the following:

1. Provide compensation for those physically harmed in the six experiments named by the Advisory Committee. This approach would override the Advisory Committee's uncertainty about whether two of these experiments meet the criteria listed above.

Sub-option: Compensation for two of the six experiments (Vanderbilt and Saenger) would be contingent upon further study of how or whether they meet the criteria listed above. This suboption would more closely follow the Advisory Committee recommendation of further evaluation of the Federal government role in the Vanderbilt experiments, and of whether potential Saenger experiment subjects were misled.

2. In case any other experiments are identified as unethical, subjects could still receive compensation through determinations of an expert panel.

A key, unresolved element of Option 2 is the method through which physical harm would be determined to have occurred. Potential methods include:

A. *Presume* that all subjects of the six experiments were harmed if they later developed a radiation-related disease or injury. This approach, while the most "generous," is problematic:

- Some experiment subjects were already terminally ill before the experiment began (If a subject had cancer *before an experiment began*, then compensation for physical harm because the subject still has cancer *after* the experiment would not be appropriate); DOJ is concerned that this presumption, if unrelated to any objective standard regarding radiation exposure level, would set a legal precedent regarding government liability in areas of much broader scope than human radiation experiments.

B. Establish panel to review individual subject records to provide compensation based on rigorous scientific/medical evidence. Most restrictive option. Lack of data could make implementation difficult.

C. Establish panel to review individual subject records to provide compensation based on a more "generous" standard, such as "probable cause of harm" or "reasonable presumption of harm."

Costs

Proposed compensation for those harmed: $50,000 to $75,000 per subject (or next or kin). Follows precedent set in Radiation Exposure Compensation Act (for uranium miners and "downwinders").

Total estimated cost under either Option: $20-50 million. (Maximum number of compensated subjects assumed to be approximately 1,000)

Would propose to fund in discretionary budget; agency responsible for experiment would cover costs. Full funding needed up-front.

8/31/95
weekly
T.J's office

Presumptive Criteria
Illustrative Compensation Estimate

Step 1: Estimate Subject Total

DOE has estimated that the old AEC conducted 435 different radiation experiments on 16,000 men, women and children.

☞ **Subject Total = 16,000**

Step 2: Isolate Ethically "Questionable" Experiments

Tara O'Toole has estimated that about 10 percent of the AEC-sponsored experiments raise ethical questions. Ellyn Weiss indicated that this is only a rough estimate applying *current*, rather than contemporary, ethical standards. While we still must develop a rigorous method of determining ethical appropriateness, the Advisory Committee has focused on whether an experiment offered the prospect of direct medical benefit to the subject, and whether experimenters misled subjects to believe that an intervention considered controversial at the time was actually conventional or standard practice.

☞ **Subjects of Ethically "Questionable" Experiments = 1,6000 x 0.1**
= 1,600

Step 3: Determine Number of Subjects Afflicted with Radiation-Related Illness or Injury

Through consultation with HHS and VA, we can develop a list of illnesses and injuries for which we could *assume* that the experiments in question were the cause. Subjects of ethically questionable experiments who have been afflicted with any of these diseases or injuries could then qualify for compensation. If data and time permit, we could develop a more sophisticated approach taking into account other disease-related factors, such as whether subjects smoke or drink excessively. For illustrative purposes, assume for now that 20 percent of subjects of ethically questionable experiments have contracted a radiation-related illness or injury.

☞ **Subjects Afflicted with disease = 1,600 x 0.2**
= 320

"Cause" is immaterial. If you have lung cancer, doesn't matter how you got it

- If you have any of these diseases: · lung cancer · thyroid cancer (this proves physical harm, but doesn't matter how you got it)
and you

- And you were a subject of these experiments - provable
but we already question it

- You get compensated on a sliding scale based on
Seriousness of the disease

Concerns

- Amt of compensation
- # of total experiments to factor in to equation
- who comes up with list of diseases

Step 4: Determine Compensation Level

Of the 320 subjects determined to be eligible for compensation, some will be afflicted with disease or injury more serious than others. The compensation package we develop could include a framework for distinguishing, for example, between life-threatening and non-life-threatening disease or injury. We could take any of the following approaches:

a: "Worst Case"

Set compensation level at $100,000 per subject, treating all subjects equally, regardless of whether disease or injury is life-threatening.

☞ **Total Compensation: 320 x $100,000 = $32 million**

b: "Best Case"

Upon determining that none of the diseases or injuries are life-threatening, set compensation level at $50,000 per subject.

☞ **Total Compensation: 320 x $50,000 = $16 million**

c: Sliding Scale Compensation

Compensation would depend on statistical survivability rate for each disease or injury. Compensation could vary between $50,000 for diseases or injuries considered virtually never life-threatening, to $100,000 for diseases or injuries that are considered fatal.

☞ **Total Compensation: 320 x (est.) $75,000 = $24 million**

d: Compensation Based on "Survivability Threshold"

We could set a compensation "threshold" distinguishing between diseases and injuries that are life-threatening and those that are not. Provide $50,000 for non-life-threatening, $100,000 for life-threatening disease or injury. Assuming subjects are split evenly between the two categories:

☞ **Total Compensation: (160 x $100,000) + (160 x $50,000) = $24 million**

OFFICE OF THE GENERAL COUNSEL

U.S. DEPARTMENT OF ENERGY 95 SEP 15 P2:18

WASHINGTON, D.C.

202) 586-1499

Date: 09/14/95

TO: Phil Cantor

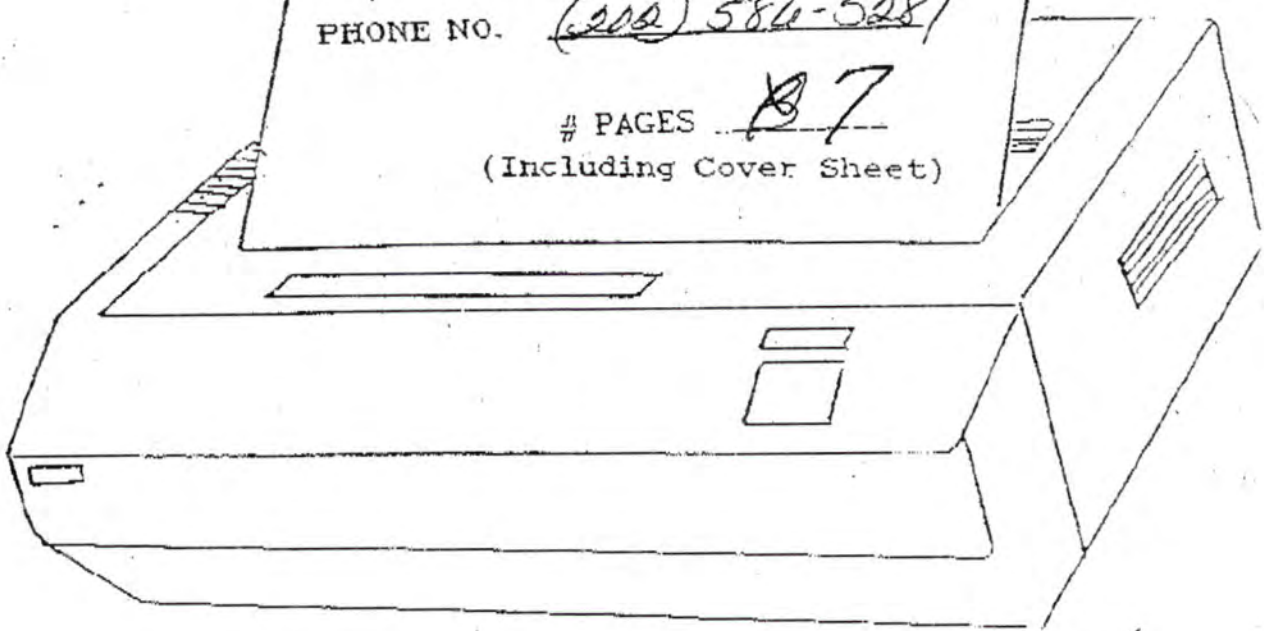
FAX NO: 456-2245

VERIFY NO. 456-2202

FROM: Lisa Schoor

PHONE NO. (202) 586-5281

PAGES 07
(Including Cover Sheet)



REMARKS: Advisory Committee on Human Radiation Experiments. Recommendation No. 2 (Please distribute to appropriate people.)

MEMO

via telecopier

To: Judith A. Miller
Eva M. Plaza

From: Robert R. Nordhaus RNordhaus

Subject: Advisory Committee on Human Radiation Experiments
Recommendation No. 2

Date: September 14, 1995

It is my understanding that the Departments of Justice and Defense have been working with the Department of Energy to reach agreement regarding Recommendation 2 of the President's Advisory Committee on Human Radiation Experiments. That recommendation is as follows:

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 intervention 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.

The two versions under discussion are as follows:

Defense/Justice preferred version:

The Administration agrees with the Advisory Committee that an apology and compensation is warranted <u>when governmental action caused harm</u> in human experiments falling within the criteria identified by the Advisory Committee. Agencies will therefore be encouraged to pursue administrative resolution of such cases and, if necessary, seek expert advice on scientific and medical issues. The Administration is also willing to work with Congress to seek private relief in appropriate cases.

Energy proposed version:

The Administration agrees with the Advisory Committee that an apology and compensation is warranted for human experiments sponsored or carried out by the government and falling within the criteria identified by the Advisory Committee. Agencies will therefore be encouraged to pursue administrative resolution of such cases and, if necessary, seek expert advice on scientific and medical issues. The Administration is also willing to work with Congress to seek private relief in appropriate cases.

The concerns expressed by your agencies relate to the need to link the government's involvement in an experiment before compensation can be justified. After review of this issue, I am concerned by both proposals as currently cast. The Secretary of Energy, as well as others within the Department of Energy, believe that the first proposal is overly narrow, and could be perceived as being unresponsive to the Committee's conclusion that the government did not take adequate steps in ensuring the protection of human subjects in experiments in which the government sponsored or carried out.

However, I share the view that the Committee's broad definition of "sponsorship" sweeps in experiments for which the government should not be held accountable (either legally or morally), such as an unethical experiment conducted without the government's knowledge or authorization.

In order to reach conclusion of this important issue, I would like to suggest another approach, which cabins the breadth of the Committee's recommendation, but sets forth the Administration's policy commitment to seek compensation in the very few cases where harm can be proven. This approach also reflects the fact that, although the government's procedural defenses under existing law may prevent a putative harmed subject from seeking relief, the Administration nonetheless is willing to seek appropriate legislative relief in cases where harm can be shown.

PROPOSED RESPONSE

The Administration agrees with the Advisory Committee that an apology and compensation is warranted for human experiments either carried out by the government or sponsored by the government with the government's knowledge or authorization of the experiment and falling within the criteria identified by the Advisory Committee. Agencies will therefore be encouraged to pursue administrative resolution of such cases and, if necessary, seek expert advice on scientific and medical issues. The Administration is also willing to work with Congress to seek private relief in appropriate cases.

cc: Phil Caplan
Eric Macris
Pat Glynn
John Casciotti

Remedies Subcommittee

PROPOSED GOVERNMENT RESPONSES TO ADVISORY COMMITTEE RECOMMENDATIONS ON REMEDIES FOR BIOMEDICAL EXPERIMENTS AND POPULATION EXPOSURES FROM 1944-1974 (as of 9/15/95)

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.

RECOMMENDED GOVERNMENT RESPONSE

The President directs the Department of Energy to work with Department of Justice and the affected Department of Energy contractors to pursue reasonable compensation for, and apology to, the families of individuals identified by the Advisory Committee, either through settlement of outstanding claims or other forms of dispute resolution, such as the use of a neutral mediator or arbitrator.

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 intervention 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.

See Nordhaus 9/14/95 memo

[APOLOGY RECOMMENDATION (OPEN ISSUE)]

RECOMMENDATION 3

The Advisory Committee has found no subject of biomedical experiments for whom there is a need to provide active notification and medical follow-up for the purpose of protecting their health. In the event that other experiments of concern come to light in the future, we recommend to the Interagency Working Group that subsequent decisions for notification

be based on evaluation of both the level of risk from radiation exposure and the potential benefit form medical follow-up in exposed individuals.

Additionally, the Advisory Committee has found no evidence to indicate that the subjects of human radiation experiments we reviewed would have had greater likelihood of incurring heritable (genetic) effects that the general population, and thus does not recommend notification or medical follow-up for descendants of subjects of human radiation experiments.

RECOMMENDED GOVERNMENT RESPONSE

Agree with the Advisory Committee that no further response is warranted at this time and that the criteria set forth by the Committee is appropriate for evaluating future cases.

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.

RECOMMENDED GOVERNMENT RESPONSE

The government agrees with the Committee's concern about treating exposed population fairly. Studies are underway that look at communities near the Hanford nuclear facility and at other sites including Fernald, Savannah River, Rocky Flats and Oak Ridge. If information is forthcoming showing increased cancer resulting from the operation of DOE facilities, the government will consider whether existing law should be amended to cover those affected.

RECOMMENDATION 5(1)

The Advisory Committee recommends to the Interagency Working Group that it work with Congress to ensure that the 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.

RECOMMENDATION 5(2)

The Advisory Committee further recommends to the Interagency Working Group that it review whether existing laws governing 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.

RECOMMENDED GOVERNMENT RESPONSE

The Secretary of Veterans Administration will appoint a Working Group that will include representatives from the Department of Veteran Affairs, the Department of Health and Human Services and the Department of Defense to provide a written report to the Interagency Working Group by January 31, 1995. The report will

- Recommend that most feasible way to accomplish updating the epidemiological tables to develop a budget request for the President's FY 1997 budget;
- Describe the administration of laws governing compensation of Atomic Veterans; and
- Recommend legislative and administrative changes that address the concerns identified by the Advisory Committee.

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 documentation standards or all claimants should be liberalized.

RECOMMENDED GOVERNMENT RESPONSE

Agree with the Advisory Committee that the provisions of the Radiation Exposure Compensation Act of 1990 (RECA) relating to uranium miners should be reviewed to ensure that they are fair, comparable to compensation standards for other radiation-exposed populations and consistent with current scientific data. The Administration will establish a committee of experts to review the eligibility criteria of RECA in light of these concerns. The committee will also review the Department of Justice's implementing regulations under RECA to ensure that they are not unduly restrictive, and review existing data to determine whether further study of uranium millers and open-pit miners is warranted. The committee will be asked to complete its review within 6 months. Based on the committee's findings, the Administration will work with Congress to enact

appropriate statutory changes, and amend the existing Department of Justice regulations as appropriate.

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.

RECOMMENDED GOVERNMENT RESPONSE

Extensive analyses to date of radiation exposures in the Marshall Islands have indicated that the exposures to inhabitants of Ailuk and other northern Marshall Islands atolls were a factor of 30-90 times less than at Rongelap and about 10-25 percent of those at Utirik based upon external dose measurements and on estimates of thyroid dose. The connection between radiation exposure and thyroid disease is the subject of several ongoing studies sponsored by the U.S. Department of Energy and managed by the Centers for Disease Control. If new data is developed to indicate that residents of atolls other than Utirik and Rongelap are at increased health risk, the Department will consider including them in an appropriate medical surveillance program.

The Department will embark in November, 1995, on an independent review of the Brookhaven National Laboratory Marshall Islands medical program. This independent review will be conducted by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and is designed to address the adequacy of the current medical monitoring and medical care programs.

LARRY C. WALLACE
425 WEST CAPITOL, SUITE 3801
LITTLE ROCK, ARKANSAS 72201
501-375-2000
FAX 501-375-4350

September 15, 1995

FAX MESSAGE

Thomas F. "Mack" McLarty
The White House
Washington, D.C.
Fax 456-2215

Dear Mack,

Thanks for your note. I am sorry that I missed you. Call on me if I can ever help. Everyone is doing a great job.

Thank You!

Sincerely,

Larry

FAX SHEET

To: See Below
Fax #:
Subject: Option for Recommendation 2
Date: August 8, 1995
Pages: 2, including this cover sheet.

COMMENTS:

Please let me have your comments, if any, as soon as possible but **NO LATER THAN NOON, THURSDAY, AUGUST 10.** You may either fax or phone in your comments.

Eric Macris
Gary Bennethum
Jack Thompson
Lisa Schiavo
T. J. Glauthier
Phil Caplan
Tara O'Toole
R. Nordhaus
Ellyn Weiss
Pat Glynn
John Casciotti
Denise Contento

From the desk of...

Lily O. Engstrom
Assistant Director
Office of Extramural Research, NIH
Shannon Building, Room 150
Bethesda, Maryland 20892

(301) 402-2246
Fax (301) 402-3469

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 experiments 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.

Option

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 on why the subjects of these experiments were not physically harmed.

Issues

- The advantage of this approach is that it involves a disinterested third partyof experts with a great deal of scientific credibility.
- The disadvantage is that it will take at least a year before findings can be made.
- In some cases, records that would provide information on which to make a determination of physical harm will be either unavailable or insufficient. In other cases, such records may be available.
- If several federal agencies join in this effort, the amount of resources required from each agency may be within reason.

95 AUG 10 P5:52

Energy and Science Division

Fax For:

SEE BELOW

From:

ERIC MACRIS

TEL: 202-395-3807

Return Fax: (202) 395-~~1058~~ 4817

Comments:

ATTACHED IS A DRAFT OUTLINE OF AN OPTION ADDRESSING RECOMMENDATION 2 FROM THE HRE ADVISORY COMMITTEE REPORT. PLEASE PROVIDE COMMENTS BY C.O.B. **FRIDAY.** (8/11/95)

DISTRIBUTION:

JACK THOMPSON (VA)
LILY ENGSTROM (HHS)
LISA SCHIAVO (DOE)
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TARA O'TOOLE (DOE)
BOB NORDHAUS (DOE)
ELLYN WEISS (DOE)
PAT GLYNN (DOJ) ⇒ PAUL YANOWITCH
JOHN CASCIOTTI (DOD)
DENISE CONTENTO (DOD)

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.

Option

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

Who would establish presumptive criteria?