

**The Administration Announces Actions
Responding to President Clinton's Advisory Committee on
Human Radiation Experiments
March 28, 1997**

Background

In January, 1994 President Clinton established the Advisory Committee on Human Radiation Experiments (ACHRE) to examine reports that the government had supported unethical human radiation experiments and releases of radiation during the Cold War. He asked ACHRE to uncover the truth, recommend ways to right past wrongs, and suggest ways to make sure the government will not repeat past mistakes.

In October, 1995 ACHRE issued its report. ACHRE found that the government had conducted several thousand human radiation experiments from 1945 to 1975 and that the majority advanced biomedical research. The Committee found, however, that some were conducted unethically. For example, scientists injected plutonium into 18 patients without their knowledge, and researchers conducted experiments on indigent patients and children. ACHRE made 18 recommendations to open the public record, protect human subjects of future research, and compensate those wronged by the government's actions.

In October, 1995 the President received the Advisory Committee's report and made it clear that the report would "not be left on a shelf to gather dust" He directed his Cabinet to "use and build on these recommendations." Over the past year and a half, the Administration has acted to implement ACHRE's recommendations to improve openness in government, strengthen ethics in human subjects research, and compensate individuals for the government's mistakes.

Today's Announcement

- **The Administration released *Building Public Trust*, outlining its comprehensive response to the President's Advisory Committee on Human Radiation Experiments (ACHRE). The report summarizes actions to address ACHRE's 18 recommendations.**
- **The Departments of Energy and Justice announced that the government has settled compensation claims with families of all of the known individuals ACHRE recommended for compensation. ACHRE recommended the government compensate the families of 18 subjects of plutonium injection experiments. The government has settled with all 16 families that came forward.**
- **President Clinton signed a memorandum to strengthen the rights and protections of people participating in secret, government-supported research.**

ACHRE recommended that subjects of secret experiments have special protections and information. Acting on that recommendation, the President directed agencies today to propose new rules for secret research that would require scientists to: obtain informed consent from all potential subjects of all secret experiments (current rules allow researchers to waive informed consent in certain cases); disclose the identity of the sponsoring agency to potential subjects; and tell potential subjects that an experiment is classified. The new rules would also establish a more independent review process; require the head of the agency conducting secret human research to approve each project; and require permanent records of secret experiments. The President also directed federal agencies to report annually on the number of classified human research projects and the number of subjects in each project. **A preliminary review by the Administration's human radiation Interagency Working Group indicates that the government is not supporting any classified human research at this time;** today's directive initiates a formal, routine accounting of secret human studies.

- The Administration announced proposed **amendments to the Radiation Exposure Compensation Act of 1990 to compensate hundreds of uranium miners who would not be compensated under current law.** ACHRE found that some deserving miners do not qualify for compensation under the Act. The amendments would establish fairer, science-based criteria for compensation. The Administration will also propose regulatory changes to RECA to facilitate claims processing.

Previous and On-going Actions Described in *Building Public Trust* Include:

Actions to Improve Openness in Government.

- ACHRE transferred more than 4,000 cubic feet of documents to the National Archives. The Administration has made 300,000 fully searchable pages of documents available on the Internet, and will add an additional 200,000 pages shortly. The Departments of Energy and Defense have published document search guides.
- The President signed Executive Order 12958 directing Federal agencies to review and declassify thousands of documents, including documents on radiation experiments.

Actions to Protect human subjects in the future.

- President Clinton established the National Bioethics Advisory Commission (NBAC) to examine bioethical issues, including human research issues. A subcommittee of NBAC will address certain broad questions raised by ACHRE, including how to strengthen Institutional Review Boards -- the local ethics panels for Federally-sponsored research.
- In October, 1995 President Clinton directed agencies to develop plans to

improve their oversight of ethics rules. The agencies have completed their review and upgraded protections, and NBAC will review agency procedures in the coming months.

- Agencies have undertaken nationwide education efforts to raise the profile of ethical considerations, and are funding research to improve our understanding of informed consent.

Actions to Right Past Wrongs.

- In October, 1995 President Clinton apologized to subjects of radiation experiments and their families on behalf of an earlier generation of American leaders and citizens; former Energy Secretary O'Leary made apologies in certain individual cases.
- The Administration will propose legislation to make veterans treated with nasopharyngeal radiation eligible for health care services under the Veteran's Administration's Ionizing Radiation Program.

August 11, 1995

TO: Gordon Soper, DOD
Tara O'Toole, DOE
Pat Glynn, DOJ
Harry Holloway, NASA
T. J. Glauthier, OMB
Rachel Levinson, OSTP
Susan Mather, DVA
Brian Latell, CIA
Phil Caplan, White House

FROM: Deputy Director for Extramural Research
National Institutes of Health, DHHS

SUBJECT: Options Paper from Interagency Subgroup on
Enhancements to Human Subjects Protection

We are sending you a copy of the final options paper that was prepared by our Interagency Subgroup on Enhancements to Human Subjects Protection, addressing Recommendations 8 through 13 in the report of the Advisory Committee on Human Radiation Experiments. I would appreciate the assistance of your office in distributing copies of this paper to appropriate staff in your agency.

The Subgroup consisted of representatives from each of agencies represented on the Interagency Working Group. This final version incorporates the comments that were provided by each agency.

It is my understanding that this option paper as well as those from the other two Subgroups will be discussed at the interagency meeting on August 16, 1995 at the Old Executive Office Building. Please be sure that the representative from your agency who will be attending the meeting has a copy.

Wendy Baldwin, Ph.D.

Attachment

August 11, 1995

Recommendation 8

The Advisory Committee recommends to the Interagency Working Group that efforts be undertaken on a national scale to ensure the centrality of ethics in the conduct of scientists whose research involves human subjects.

Response

The Government has in recent years mounted several activities that address this subject. For example:

- DHHS: The National Institutes of Health (NIH) requires all institutions receiving National Research Service Award institutional training grants to provide pre- and postdoctoral trainees on these grants with instruction in the responsible conduct of research. This curriculum includes, among other things, policies on the appropriate use of human subjects and animals in research.
- DHHS: The NIH completed development of a Core Curriculum in Clinical Research to train young clinical investigators in its Clinical Center. This course, which is mandatory, includes several modules on protection of human subjects and a specific module on bioethics.
- NASA: Established an external Bioethics Task Force to review NASA procedures for all experimentation involving human subjects and to recommend appropriate policy changes. Report to be issued in fall 1995.
- DOE: Holds educational regulatory and bioethics update meetings for the entire DOE system (to which other federal agencies are also invited).
- DOD: Convenes an annual Tri-Service Clinical Investigations Postgraduate Short Course, generally attended by 200-300 physicians, scientists, nurses, pharmacists and other research support personnel, that emphasizes contemporary human subjects protection issues.
- DOE: Has computerized and established worldwide web access to the Department's human subjects newsletter, resource manual and database.
- DOD: Requires investigators' familiarity with the Belmont Report, the Common Rule, DOD Directives and all applicable regulations and instructions through the assurance process with each facility.
- VA: Has established a special office to conduct random site visits to VA medical centers to review local implementation of national VA policy for the protection of human subjects.

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Options

(a) A major effort will be launched to "upgrade" or expand these activities. These will consist of:

- DHHS: In recognition of research initiatives in gene therapy, heterologous and autologous transplantation, adoptive immunotherapy and other emerging areas of clinical investigation, the NIH Clinical Center Clinical Bioethics Program will be expanded. Additional resources, including an SES position, FTEs and space, will be allotted to this program.
- DHHS: Following implementation and assessment in the NIH Clinical Center, the Core Curriculum in Clinical Research may be offered to trainees in extramural institutions and/or further disseminated by publication of the syllabus or making it available on the Internet.
- DOE: Will be requiring educational/ethics updates from all DOE institutions that are involved with human subjects research.
- DOE: Will be establishing an educational plan for all IRBs beginning in FY 1996.
- DOD: Will adopt the investigator assurances of familiarity with the Belmont Report, the Common Rule and related requirements as a standard for all activities involving human subjects research.
- DOD: Will incorporate research ethics into graduate medical education curricula at Military Department teaching hospitals.
- NASA: Works with international partners to enhance the ethical training and understanding of all investigators involved in space-related human research and to ensure an transnational sensitivity to ethical issues in human subjects research.

Issues:

- The activities above reflect federal agencies' ongoing attention and commitment to measures for enhancing the protection of human subjects.
- The public may be expecting more, especially in light of the findings in the ACHRE report regarding contemporary human subjects research.

(b) Invite associations of medical schools and universities as well as scientific societies to join with the Government in launching a broad initiative to heighten the consciousness

of the research community with respect to ethics of human subjects research. These might include the expansion of existing university-based research ethics programs and convening workshops in conjunction with the annual meetings of these different organizations.

Issues:

- This option will require the cooperation of various non-governmental agencies that may have slightly varying views of the need to do this. However, their collaboration would facilitate the process and provide greater credibility vis-a-vis the research community.
- If successfully implemented, this option may yield a high profile activity.
- This option would expand upon what the Government is currently doing but does not make human subjects research ethics a federal requirement.
- Additional resources will be required for implementation of this option.

(c)

OPRR can convene, in conjunction with its counterparts in the other federal agencies, 2-3 regional workshops of IRB chairpersons to allow for the exchange of ideas/approaches, to stimulate the discussions of common problems and to address emerging issues in the arena of human subjects protection.

Issues:

- This approach will highlight for IRB chairs the importance that the Government attaches to the ethics of human subjects research and the need to pay continuing attention to this area.
- The inclusion of IRB chairpersons only limits the audience that needs to be involved in such events.
- This option may be perceived as a low profile activity.
- Additional resources will be required for implementation of this option.

(d)

The President can announce that he will be signing an Executive Order establishing the National Bioethics Advisory Commission and introduce the chairperson of the Commission.

Issues:

- The establishment of NBAC would signal the Administration's commitment to

obtaining expert advice and public input on issues of bioethics, correcting the long absence of such a deliberative body.

- In order to have this scenario materialize, the paperwork and other requirements for establishing NBAC must be completed and the chairperson selected/approved before September 22.
- The NBAC will neither be, nor be seen as, dominated by federal agencies since none of the 15 members may be federal employees.
- The NBAC will be uniquely qualified to carry out this assessment in that it is an advisory body independent of the federal agencies with at least one member from each of the following categories of primary expertise: (i) philosophy/theology; (ii) social/behavioral science; (iii) law; (iv) medicine/allied health professions; and (v) biological research.
- This option can be implemented in conjunction with other options.
- This option may be viewed by some as handing off the recommendations of one committee to another even though by happenstance the NBAC is an ideal mechanism for operationalizing some of the ACHRE's recommendations.
- Funds to support the NBAC must be identified.

Recommendation 9

The Advisory Committee recommends to the Interagency Working Group that the IRB component of the federal system for the protection of human subjects be changed in at least the five critical areas described below.

- 1. Mechanisms for ensuring that IRBs appropriately allocate their time so as to enable adequate review of studies that pose more than minimal risk to human subjects. This may include the creation of alternative mechanisms for review and approval of minimal risk studies.**

Options

- (a) Agencies will remind institutions and their IRBs that the current regulations provide for an expedited review process for certain categories of minimal risk research and for minor changes in ongoing research and emphasize their continued and enhanced use of this mechanism.

Issues:

- Action can be immediate with no change in regulations or federal policy required.
- There is an existing, proven, effective mechanism for implementing this option, i.e., the authoritative OPRR Reports of the Office for Protection from Research Risks which is not only issued and delivered by direct mail to the IRBs and research communities (5,500 addressees worldwide) but also widely reprinted. DOD and DOE have similar newsletters that can also be used for this communication.
- This option may be seen as insufficient since it does not offer a new alternative.

(b)

Consider extending a pilot program to reduce the administrative burdens on award applicants (known at NIH as the "Just-In-Time" experiment) to include a feature that would permit IRBs to delay their review of proposed research until preliminary determinations of the proposals' competitiveness have been made by the agency.

Issues:

- Under this option, IRBs would be relieved of the requirement to review research proposals which will not be sufficiently competitive for agency funding, while preserving the requirement that IRB review be carried out prior to the agency's scientific peer review.
- If the pilot program is effective without diminishing human research subject protections, it can be expanded within NIH and to other federal agencies.
- Even if successful, results would not be available from the pilot testing phase for approximately 18 months.
- There is no guarantee that, even if the IRBs' workload were reduced by this approach, the IRBs would allocate the additional time available to review of studies that involve more than minimal risk to research subjects.
- The closer in time the IRB review is to an agency's decision to fund and the greater the likelihood of funding, the more "pressure" there may be for the IRB to approve the research proposal.
- If IRBs wait for the agency's preliminary determination regarding the

relative competitiveness of research proposals before conducting their own review, IRBs will have less time in which to schedule their review if they are to carry it out prior to the agency's scientific peer review.

- (c) Remove the requirement for IRB review prior to the federal agencies' scientific peer review.

Issues:

- Dramatically reduces the IRBs' workload.
- Dramatically reduces the protections afforded human research subjects in that it puts IRBs in the position of being not only the last but also, at that point, the only obstacle to Federal funding.
- Requires changing the Federal Policy for the Protection of Human Subjects and Federal Regulations.

- (d) Place on the investigator the responsibility for determining if his/her proposed research project is of "minimal risk" and, if it is, the proposal could bypass full IRB review and thus reduce the IRB workload.

Issues:

- This approach of "front-loading" the responsibility would streamline the process and permit administrative rather than full IRB review of minimal risk studies.
- There is a potential conflict of interest in having investigators make this determination.
- Determination of minimal risk is a critical responsibility of IRBs since many studies are in the "gray zone", especially where privacy issues may be involved.

- (e) Ask the Human Subjects Research Subcommittee of the Health, Safety and Food Research Committee of the National Science and Technology Council to consider the implications of implementing this subrecommendation.

Issues:

- All federal agencies that conduct or support human subjects research are

represented on this Subcommittee which will therefore be a reasonable forum in which to discuss this issue.

- The interests of IRBs would not be adequately represented in discussions within the Subcommittee.

- ACHRE language
2. Mechanisms for ensuring that the information provided to potential subjects (a) clearly distinguishes research from treatment, (b) realistically portrays the likelihood that subjects may benefit medically from their participation and the nature of the potential benefit, and (c) clearly explains the potential for discomfort and pain that may accompany participation in the research.
 3. Mechanisms for ensuring that the information provided to potential subjects clearly identifies the federal agency or agencies sponsoring or supporting the research project in whole or in part and all purposes for which the research is being conducted or supported.
 4. Mechanisms for ensuring that the information provided to potential subjects clearly identifies the financial implications of deciding to consent to or refuse participation in research.

Options

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- (a) Implement the above three subrecommendations by instructing IRBs and investigators to address these issues in protocols and consent procedures/forms.

Issues:

- If immediate action is deemed appropriate, the President can announce that these requirements now apply to all recipients of federal research funds, or an interagency working group can develop the appropriate instructions and issue them as a government-wide policy.

- Agencies do not have any objections to these subrecommendations.

- yes
- (b) Announce that on October 2-3, 1995, the Department of Energy, in conjunction with the Subcommittee on Human Subjects Research, Committee on Health, Safety, Food Research & Development, National Science and Technology Council, will convene staff from all federal agencies conducting or supporting human subjects research. Federal officials will be briefed on ACHRE findings and recommendations and caucus for 2 days on at this conference. (The Subcommittee on Human Subjects Research meets bimonthly to coordinate implementation of the Federal Policy for Protection of Human Subjects and

will
be assessing actions to be taken by federal officials subsequent to the October
2-3 conference.)

Issues:

- Demonstrates an ongoing commitment by federal agencies to enhancing the existing system for the protection of human subjects.
- Allows federal agencies to combine their experiences in a public forum, focusing on the issues that are considered important by the ACHRE, including those in these three subrecommendations.
- Some may view this option as either perfunctory or non-responsive since the conference agenda does not directly address the above subrecommendations.

5. **Recognition that if IRBs are to adequately protect the interests of human subjects, they must have the responsibility to determine that the science is of a quality to warrant the imposition of risk or inconvenience on human subjects and, in the case of research that purports to offer a prospect of medical benefit to subjects, to determine that participating in the research affords patient-subjects at least as good an opportunity of securing this medical benefit as would be available to them without participating in research.**

Options

- yes (a) Issue an official reminder to IRBs that they already have the responsibility to review the science in research proposals to determine the appropriateness of the use of human subjects in such research and to stress that patients participating in research should not be denied medical benefits which would otherwise be available to them. IRBs have the authority to call upon external resources for expertise in areas not represented by their members.

Issues:

- This option could be implemented very rapidly and be widely disseminated within a very short timeframe.
- As indicated in Option (a) under Subrecommendation 9.1, there are already existing mechanisms, OPRR Reports as well as similar DOD and DOE newsletters, which have proven to be very effective in communicating policies and policy interpretations to the research community.

- This option, however, may be viewed by some as not doing enough.
- (b) IRBs could be given the authority to provide a conditional approval of a research proposal and once the federal agency has completed its scientific peer review and judged the proposal to be scientifically meritorious, the IRB could then provide the final approval, resolving with the investigator any outstanding issues or questions.

Issues:

- This places the responsibility for scientific merit review where it belongs - with the scientific peer review group. Although IRBs can call upon experts and ad hoc reviewers to supplement the expertise of their own members, some IRBs do not have access to the full range of scientific resources that are available to scientific peer review groups.
- This approach does place implicit pressure on the IRB because the federal agency has in essence determined the proposal to be scientifically meritorious, thus implying that funding is either possible or likely.
- This option does not address the ACHRE's concern about not denying to human subjects medical benefits that would otherwise be available to them.

Recommendation 10

The Advisory Committee recommends to the Interagency Working Group that a mechanism be established to provide for the continuing interpretation and application of ethics rules and principles for the conduct of human subject research in an open and public forum. This mechanism is not provided for in the Common Rule.

Options

- (a) The National Bioethics Advisory Commission would be the ideal body to implement this recommendation. Inasmuch as the NBAC is intended "to consider current and prospective issues pertinent to the conduct of research on human biology and behavior and to identify broad, overarching principles to govern the ethical conduct of such research", this recommendation fits very appropriately with the NBAC's charter. Under provisions of the Federal Advisory Committee Act, all NBAC meetings would be open and provide for public access. (See Recommendation 8, Option d.)

Issues:

- The President must be able to announce that he is or will be shortly signing the charter for NBAC.
- Funds for supporting NBAC must be identified and secured.
- (b) Convene annual or biennial meetings in concert with various organizations interested in human subjects research, major universities, medical schools and scientific societies at which topical issues relevant to human subjects research ethics and/or principles are discussed (e.g., PRIM & R type meeting). These meetings could be structured such that consensus could be achieved on specific questions or issues.

Issues:

- These meetings would not have the benefit of an organized, standing, public body with some accountability and longevity such as NBAC.
- Such deliberations would therefore not include much historical perspective as the group organized each time would be different from the time before.

Recommendation 11

The Advisory Committee recommends to the Interagency Working Group that at least the following four steps be taken to improve existing protections of the rights and interests of military personnel with respect to human subjects research.

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1. **Review of policies and procedures: Policies and procedures governing research involving human subjects should be reviewed to ensure that they (1) clearly state that participation as research subjects by members of the armed services is voluntary and without repercussions for those who choose not to participate; and (2) clearly distinguish those activities that are research and therefore discretionary on the part of the member of the armed services from other activities that are obligatory, such as training maneuvers and medical interventions intended to protect the troops.**

Response

DOD Directives and Military Department regulations require the voluntary and fully informed consent of any person participating as a subject in research projects sponsored or conducted by the Department, as required by 32 CFR 219 (The Common Rule).

2. **Appreciation of regulations:** Education in applicable human subjects regulations should be a routine component of the training of officers and of investigators. Mechanisms are needed to ensure that all officers and investigators have an adequate appreciation of all regulations (including DOD regulations and directives and Service regulations) that bear on the conduct of research involving human subjects, including an appreciation of the conditions under which such regulations apply, the role of officers in interpreting such regulations, and how such regulations are to be implemented.

Response

DOD will incorporate education in human subjects regulations into executive level training for commanders and senior leadership. DOD will also examine methods for providing detailed training for investigators, institutional review board members, research administrators and research support personnel.

Issues:

- Such training would better prepare commanders, senior leadership and all members of research teams to better protect the rights and interests of personnel under their supervision. (It is not effective or efficient to attempt to train every commissioned officer in the Armed Services in research ethics, directives and regulations.)
 - Such training would add to the considerably lengthy training schedule.
 - Implementation of this option would require commitment of diminishing resources.
3. **Maximizing voluntariness:** The Service Secretaries should consider the situations under which it would be appropriate to make obligatory two practices for maximizing voluntariness that have been employed on an *ad hoc* basis in some military research. First, that no unit officers nor noncommissioned officer (NCOs) be present at any subject recruitment session in which members of units are informed of the opportunity and asked to participate in research by investigators; and second, that an ombudsman not connected in any way with the proposed research be present at all such recruitment sessions to monitor that the voluntariness of participation is adequately stressed and that the information provided about the research is adequate and accurate.

Response

- (a) DOD is revising its Directive or Military Department regulations such that officers and senior noncommissioned officers in the chain of command will not be present during research recruitment briefings. This requirement shall apply to research and development studies where briefings are given to potential subjects.

Issues:

- This approach minimizes the risk that military personnel will be influenced to volunteer as research subjects because of the presence of supervisors.
- Measures must be taken to ensure that officers and noncommissioned officers are not inadvertently denied the opportunity to participate as research subjects.

- (b) DOD is also revising its Directive or Military Department regulations to require that an ombudsman be present at group recruitment briefings to monitor that the voluntary nature of participation is stressed and that adequate information is provided about the proposed research.

Issues:

- This approach helps ensure that research participation by military personnel is voluntary and that consent is truly informed.
- Under field conditions, an ombudsman with no conflict of interest may be difficult to identify.

4. **Maintenance of a registry:** The Secretaries of the Navy and the Air Force should be directed to adopt the policy of the Army, as detailed in Army Regulation 70-25, to maintain a registry of all volunteers in human studies and experiments conducted under Research and Development programs. Such registries serve to facilitate confirmation of participation in research by subjects and their long-term follow-up.

Response

DOD is revising its Directive on human subjects research to include a provision that each of the Military Departments establish and maintain a registry of volunteers in biomedical studies conducted under research and development programs.

Issues:

- Such registries will facilitate the identification and long-term follow-up of research subjects.
- Development of these registries requires commitment of diminishing resources.
- Issues of privacy must be taken into consideration in the development of these registries.

Recommendation 12

The Advisory Committee recommends that the Interagency Working Group take steps to improve three elements of the current federal system for the protection of the rights and interests of human subjects -- oversight, sanctions and scope.

1. Oversight mechanisms to examine outcomes and performance.

Options

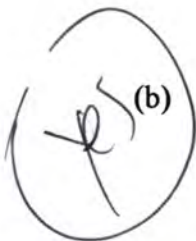


Develop an interagency grants program to stimulate the research community to propose a variety of approaches to evaluating the performance and outcomes of the Government's system for protecting the rights/interest of human subjects, e.g., the recent program announcement of the National Institute of Mental Health seeking proposals for studying the informed consent process in research subjects with mental disorders.

Issues:

- The outcome of such studies will provide a scientific basis for assessing the adequacy and weaknesses of the current informed consent process.
- This strategy allows the Government to solicit a variety of approaches to evaluating the system and select the best for funding.
- This approach permits the pooling of funds so that agencies that might otherwise not be able to award grants in this area can "piggyback" on the interagency effort. This option would be administratively efficient and less costly for all participating agencies.

- Need to identify a lead agency and develop a plan that all participating agencies can endorse. NIH is willing to assume this role.



Strengthen the federal agency offices with responsibility for oversight of human subjects protection.

Issues:

- Investing in the individual offices with oversight responsibilities makes clear the priority the agency is giving to human subjects protection and increases the opportunity and options for providing adequate oversight.
- This approach may not necessarily address all of the Advisory Committee's concerns about the deficiencies at the local level.
- Additional resources may be required by some agencies to implement this option.



Initiate a program of site visits (not for cause) to institutions receiving federal funds for human subjects research.

Issues:

- This approach will allow the Federal Government to review a larger number of institutions than it now does.
- This approach may not address the concerns of the Advisory Committee in that it (a) may still be more process oriented and (b) does not include the patient's perspective.
- Federal agencies that do not have full-time staff devoted to oversight of human subjects protection may find this option very difficult to implement.
- Additional resources will be required to implement this option.



Implement the NIH study to evaluate the implementation of the federally mandated Human Subjects Protection Program, specifically the extent to which the Program provides adequate protection for the rights and well-being of human subjects.

Issues:

- This survey will involve surveys of institutional officials, IRB

chairpersons, IRB administrators, IRB members and investigators as well as extraction of data from IRB records and documents. Because of the size of this effort, this study may yield a large amount of information on the current IRB system.

- Because of its complexity and multitude of surveys, the results of this study will not be available for another two years.

2. Appropriateness of sanctions for violations of human subjects protection.

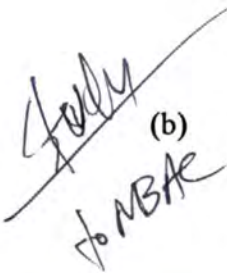
Options

(a) 

Remand this recommendation to the proposed National Bioethics Advisory Commission to determine if the sanctions currently available for violation of human subjects research regulations fit the seriousness of the violations.

Issues:

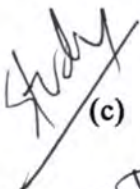
- In view of the charge to the NBAC, it appears to be an appropriate body to review this issue.
- Need, however, to augment the NBAC deliberations with appropriate legal resources.



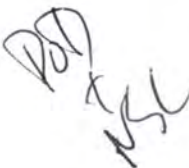
(b) Provide the same sanctions for violation of human subjects regulations as exist for violation of animal welfare regulations.

Issues:

- Enactment of legislation would be required to implement this option.
- This approach would create a parity between the two sets of regulations.
- It took some 10 years for the 16 signatories of the Common Rule to resolve the outstanding issues before issuance of the Rule. Therefore, it is conceivable that enactment of this legislation may be a very lengthy, drawn-out process.
- This may not be necessary since current sanctions, including debarment, whereby an investigator or institution is prohibited from receiving federal research funds for a specified period of time, appear to working adequately.



(c) In the case of DOD, failure to comply with its Directives and Military



Department
regulations can result in administrative and judicial punishment under the
Uniform Code of Military Justice.

3. Extension of human subjects protection to nonfederally funded research.

Options

- (a) Enact legislation that would extend requirements for protection of human subjects to research not funded or conducted by the Federal Government (such as most research involving assisted reproductive technologies).

Issues:

- Enactment of legislation is unlikely in this climate of regulatory reform and cost-benefit risk assessment.
- Enforcement of such legislation would require a rather extensive bureaucratic, regulatory infrastructure because the existing Federal Government infrastructure will not be able to implement such a requirement.
- On the other hand, an aggressive initiative may be an appropriate strategy since it involves the sensitive issue of putting at risk human subjects who participate in non-federally funded research.
- Additional resources would be required to implement this option.

- (b) Work with the American Medical Association, state medical societies and state licensing boards to launch an educational program to familiarize physicians and others engaged in nonfederally funded research with the ethical considerations in conducting human subjects research.

Issues:

- This approach has the advantage of joining with the medical community in raising the consciousness of physicians and others who conduct or plan to conduct human subjects research.
- Part of this approach could involve setting up a helpline that responds to requests for information on appropriate conduct of human subjects research.

Recommendation 13

The Advisory Committee recommends that the federal government review the area of compensation for research injuries of future subjects of federally funded research, particularly reimbursement for medical costs incurred as a result of injuries attributable to a subject's participation in such research, and create a mechanism for the satisfactory resolution of this long-standing social issue.

Options

This issue has been studied off and on over the last 20 years but, because of its complexity, has never reached resolution. With the establishment of the proposed National Bioethics Advisory Commission and the release of the ACHRE report calling for compensation of subjects involved in Cold War era radiation experiments, the time may be right for a definitive examination of the issue and development of recommendations/guidelines for compensation of injured human subjects.

Issues:

- Response to this recommendation should have the input of the Subgroup on Compensation. Although the Compensation Subgroup is addressing compensation for past human subjects, nonetheless, there may be some guiding principles that could also be applicable to future human subjects.
- Need to distinguish between (1) providing appropriate medical care and monitoring and (2) offering monetary compensation to injured human subjects.
- Need to consider if there should be a distinction between dignitary harm and physical harm.

THE WHITE HOUSE
WASHINGTON

December 6, 1995

Peter:

As we have discussed, attached is the report of the Advisory Committee on Human Radiation Experiments and draft material on the Administration response to the report.

The most important parts of the report to focus on are the Findings and Recommendations sections. I believe EPA is implicated in the response to the Committee's recommendation 16.

Once you have looked this over and designated a point of contact at EPA, please let me know so that I can plug that person in to the interagency process for finalizing these responses.

Hope all is well.

Thanks



Peter Robertson
Chief of Staff
EPA

260-4700

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

October 3, 1995

REMARKS BY THE PRESIDENT
IN ACCEPTANCE OF HUMAN RADIATION FINAL REPORT

Old Executive Office Building

11:07 P.M. EDT

THE PRESIDENT: Let me begin with a simple thank you to everyone who participated in this extraordinary project and to everyone who supported them.

I am especially glad to see here today Senator Glenn, who's been so active in working on medical ethics issue, Congressman Markey, who's worked on this issue for a very long time, Congressman Frost, Secretary Shalala, Deputy Secretary of Veterans Affairs Herschel Gober, and of course, the Attorney General who basically tries to get us all to do the right thing all the time. (Laughter.)

I want to thank Secretary O'Leary for her extraordinary devotion to this cause. And you heard in her remarks basically the way that she views this. It's a part of her ongoing commitment to finish the end of the Cold War. And perhaps no Energy Secretary has ever done as much as she has to be an advocate, whether it is for continued reforms within the Energy Department or her outspoken endorsement of the strongest possible commitment on the part of the United States to a Comprehensive Test Ban Treaty, which I believe we will achieve next year in no small measure thanks to the support of the Secretary of Energy.

And, of course, I want to thank Dr. Ruth Faden for her extraordinary commitment of about a year and a half of her life to this unusual but important task.

And all of you who served on the committee -- I remember the first time we put this committee together. I looked -- I said, that's a pretty distinguished outfit. I wish I could give them five or six jobs to do. (Laughter.) I'll expect you back next Monday and then we'll -- (laughter). I do thank you so much for the work you have done.

Let me tell you that, just as this is an important part of the efforts that Secretary O'Leary outlined, I saw this committee as an indispensable part of our effort to restore the confidence of the American people in the integrity of their government. All of these political reform issues to me are integrated. When I became the President, I realized we had great new economic challenges, we

had profound social problems, that a lot of these things had to be done by an energized American citizenry, but that our national government had a role to play in moving our country through this period of transition. And in order to do it, we needed to increase the capacity of the government to do it through political reform, but we also needed, as much as anything else, to increase the confidence of the American people that, at the very least, they could trust the United States government to tell the truth and to do the right things.

So you have to understand that, for me, one reason this is so important is that I see it as part of our ongoing effort to give this government back to the American people -- Senator Glenn's long effort to get Congress to apply to itself the same laws it imposes on the private sector; the restrictions that I imposed on members of my administration in high positions for lobbying for foreign governments; and when the lobby bill failed in the Congress, I just imposed it by executive order on members of the Executive Branch. All these efforts at political reform, it seems to me, are important.

But none of these efforts can succeed unless people believe that they can rely on their government to tell them the truth and to do the right thing. We have declassified thousands of government documents, files from second world war, the Cold War, President Kennedy's assassination. These actions are not only consistent with our national security, they are essential to advance our values.

So, to me, that's what this is all about. And to all those who represent the families who have been involved in these incidents, let me say to you, I hope you feel that your government has kept its commitment to the American people to tell the truth and to do the right thing.

We discovered soon after I entered office that with the specter of an atomic war looming like Armageddon far nearer than it does today, the United States government actually did carry out on our citizens experiments involving radiation. That's when I ordered the creation of this committee. Dr. Faden and the others did a superb job. They enlisted many of our nation's most significant and important medical and scientific ethicists. They had to determine first whether experiments conducted or sponsored by our government between 1944 and 1974 met the ethical and scientific standards of that time and of our time. And then they had to see to it that our research today lives up to nothing less than our highest values and our most deeply-held beliefs.

From the beginning, it was obvious to me that this energetic committee was prepared to do its part. We declassified thousands of pages of documents. We gave committee members the keys to the government's doors, file cabinets and safes. For the last year and a half, the only thing that stood between them and the truth were all the late nights and hard work they had to put in.

This report I received today is a monumental document -- (laughter) -- in more ways than one. But it is a very, very important piece of America's history, and it will shape America's future in ways that will make us a more honorable, more successful and more ethical country.

What this committee learned I would like to review today with a little more detail than Dr. Faden said, because I think it must be engraved on our national memory. Thousands of government-sponsored experiments did take place at hospitals, universities and military bases around our nation. The goal was to understand the effects of radiation exposure on the human body.

While most of the tests were ethical by any standards, some were unethical, not only by today's standards, but by the standards of the time in which they were conducted. They failed both the test of our national values and the test of humanity.

In one experience, scientists -- experiment -- scientists injected plutonium into 18 patients without their knowledge. In another, doctors exposed indigent cancer patients to excessive doses of radiation, a treatment from which it is virtually impossible that they could ever benefit.

The report also demonstrates that these and other experiments were carried out on precisely those citizens who count most on the government for its help -- the destitute and the gravely ill. But the dispossessed were not alone. Members of the military -- precisely those on whom we and our government count most -- they were also test subjects.

Informed consent means your doctor tells you the risk of the treatment you are about to undergo. In too many cases, informed consent was withheld. Americans were kept in the dark about the effects of what was being done to them. The deception extended beyond the test subjects themselves to encompass their families and the American people as a whole, for these experiments were kept secret. And they were shrouded not for a compelling reason of national security, but for the simple fear of embarrassment, and that was wrong.

Those who led the government when these decisions were made are no longer here to take responsibility for what they did. They are not here to apologize to the survivors, the family members or the communities who's lives were darkened by the shadow of the atom and these choices.

So today, on behalf of another generation of American leaders and another generation of American citizens, the United States of America offers a sincere apology to those of our citizens who were subjected to these experiments, to their families, and to their communities.

When the government does wrong, we have a moral responsibility to admit it. The duty we owe to one another to tell the truth and to protect our fellow citizens from excesses like these is one we can never walk away from. Our government failed in that duty, and it offers an apology to the survivors and their families and to all the American people who must -- who must be able to rely upon the United States to keep its word, to tell the truth, and to do the right thing.

We know there are moments when words alone are not enough. That's why I am instructing my Cabinet to use and build on these recommendations, to devise promptly a system of relief, including compensation, that meets the standards of justice and conscience.

When called for, we will work with Congress to serve the best needs of those who were harmed. Make no mistake, as the committee report says, there are circumstances where compensation is appropriate as a matter of ethics and principle. I am committed to seeing to it that the United States of America lives up to its responsibility.

Our greatness is measured not only in how we so frequently do right, but also how we act when we know we've done the wrong thing; how we confront our mistakes, make our apologies, and take action.

That's why this morning, I signed an executive order instructing every arm and agency of our government that conducts, supports or regulates research involving human beings to review immediately their procedures, in light of the recommendations of this report, and the best knowledge and standards available today, and to report back to me by Christmas.

I have also created a Bioethics Advisory Commission to supervise the process, to watch over all such research, and to see to it that never again do we stray from the basic values of protecting our people and being straight with them.

The report I received today will not be left on a shelf to gather dust. Every one of its pages offers a lesson, and every lesson will be learned from these good people who put a year and a half of their lives into the effort to set America straight.

Medical and scientific progress depends upon learning about people's responses to new medicines, to new cutting-edge treatments. Without this kind of research, our children would still be dying from polio and other killers. Without responsible radiation research, we wouldn't be making the progress we are in the war on cancer. We have to continue to research, but there is a right way and a wrong way to do it.

There are local citizens' review boards, there are regulations that establish proper informed consent and ensure that

experiments are conducted ethically. But in overseeing this necessary research, we must never relax our vigilance.

The breathtaking advances in science and technology demand that we always keep our ethical watchlight burning. No matter how rapid the pace of change, it can never outrun our core convictions that have stood us so well as a nation for more than 200 years now, through many different scientific revolutions.

I believe we will meet the test of our times -- that as science and technology evolve, our ethical conscience will grow, not shrink. Informed consent, community right-to-know, our entire battery of essential human protections -- all these grew up in response to the health and humanitarian crises of this 20th century. They are proof that we are equal to our challenges.

Science is not ever simply objective. It emerges from the crucible of historical circumstances and personal experience. Times of crisis and fear can call forth bad science, even science we know in retrospect to be unethical. Let us remember the difficult years chronicled in this report, and think about how good people could have done things that we know were wrong.

Let these pages serve as an internal reminder to hold humility and moral accountability in higher esteem than we do the latest development in technology. Let us remember, too, that cynicism about government has roots in historical circumstances. Because of stonewallings and evasions in the past, times when a family member or a neighbor suffered an injustice and had nowhere to turn and couldn't even get the facts, some Americans lost faith in the promise of our democracy. Government was very powerful, but very far away and not trusted to be ethical.

So today, by making ourselves accountable for the sins of the past, I hope more than anything else, we are laying the foundation stone for a new era. Good people, like these members of Congress who have labored on this issue for a long time, and have devoted their careers to trying to do the right thing, and having people justifiably feel confidence in the work of their representatives. They will continue to work to see that we implement these recommendations.

And under our watch, we will no longer hide the truth from our citizens. We will act as if all that we do will see the light of day. Nothing that happens in Washington will ever be more important in anyone's life affected by these experiments, perhaps, than these reports we issue today. But all of us as Americans will be better off because of the larger lesson we learned in this exercise and because of our continuing effort to demonstrate to our people that we can be faithful to their values.

Thank you very much. (Applause.)

END

11:23 A.M. EDT

Human Radiation Experiment
Update on the Administration's Response

Issue: Compensation

Action: All known individuals who fall within the criteria for compensation will be offered compensation. Settlements in Principle have been reached in XX cases.

Notes:

Major Outstanding Issue:

Issue: Apology

Action: The President apologized on behalf of the government to the victims of human experimentation

Notes: We have gotten inquiries about individual apologies from the President.

Major Outstanding Issue:

Issue: Notification

Action: The government has undertaken a huge effort to identify information related to experiments. This information has been made accessible to the public, and there are continuing efforts to make people aware of the availability of the information. Competing issues of privacy warrant care in notifying people who do not fall within the criteria suggested by ACHRE. We are putting into place guidelines for notification if experiments are identified in the future.

Notes:

Major Outstanding Issue: Should the Administration support legislation to expand medicare eligibility to those who are identified as subjects of government-funded radiation experiments?

Issue: Nasopharyngeal treatment during military service

Action: Public health notification through the medical community.

Proposal to make veterans treated with NP radium eligible for VA's ionizing radiation program.

Notes:

Major Outstanding Issue: Should these veterans be given priority eligibility for VA care.

Issue: Radiation Exposure Compensation Act coverage for exposed populations around Hanford and other federal sites

Action: Agree that this would be appropriate if increase in cancer due to federal activity.

Studies underway at the five major sites to determine if there is an increase in cancer due to federal operations.

Notes: Studies will be completed in XX

Major Outstanding Issue:

Issue: Uranium Miners: Increase Radiation Exposure Compensation Act coverage for uranium miners, improve administration of current program.

Action: Legislation drafted to expand coverage.

Thorough reforms to regulations in draft to respond to issues raised by the public re Navajo non-smokers; b-readers; smoking cessation; CT scans; lung biopsies; ethno-specific pulmonary function; definition of impaired pulmonary function.

Notes: This is one of the major concrete actions we can point to. The administration of this program is still criticized as too slow. Query whether we can promise a specific turn around on claims?

Major Outstanding Issue: How does this affect the budget?

Issue: Atomic vets: Update Epidemiological Tables, consider additions to the list of radiogenic conditions

Action: We have an agreement in principle with the IOM to update the tables.

Notes: The funding for the contract is still in some doubt. VA is committing 1 million in 97 money and asking HHS for 900,000.

Major Outstanding Issue: Are there other changes in the administration of current laws that we should undertake.

Issue: Marshall Islanders

Action: DOE is working with the government of the Marshall Islands to reorient programs to meet the needs of Marshall islanders.

Notes:

Major Outstanding Issue:

Issue: Ensure ethics in Human Subject research

Action: The combination of NBAC and agency investment in improving the ways we seek informed consent respond to this recommendation (there is a long list of specific agency actions).

Notes:

Major Outstanding Issue:

Issue: Reform IRBs, provide a continuing forum for public debate of ethical issues

Action: Guidance to IRBs, letters to researchers, other administrative changes take steps in this direction.

Notes: This issue touches all aspects of human subject research, and full reform of the IRB system is beyond the scope of this response.

Major Outstanding Issue: Should we request a report from Secretary of HHS on status and effectiveness of IRBs in the evolving medical/research system? (with options for process for change?)

Issue: Revise military protocols to better protect military subjects.

Action: This is being done.

Notes:

Major Outstanding Issue:

Issue: Resolve the issue of whether and how all persons injured from federally funded research will be compensated.

Action: The IAWG decided that a case-by-case approach is appropriate and will justify that decision in writing.

Notes:

Major Outstanding Issue:

Issue: No waiver of informed consent for classified research.

Action: Will recommend an Executive order.

Notes: The executive order may cover this issue, and the issue of informing participants that classified research is involved.

Major Outstanding Issue: What is our response to the recommendation that an independent panel review classified human subject research.

Issue: Establish independent oversight and permanent recordkeeping of environmental review of classified research

Action: EPA will undertake to establish permanent recordkeeping. EPA will establish more rigorous oversight procedures.

Notes: We are rejecting the call for an independent panel.

Major Outstanding Issue:

Issue: Make records accessible

Action: The agencies have done a terrific job with this, we can provide solid evidence of the commitment to openness.

Notes:

Major Outstanding Issue:

Issue: Review CIA records and release

Action: the National Archives has undertaken to review, and CIA is giving top priority to declassification of records related to human subject research.

Notes: We need to know what the results are here.

Major Outstanding Issue:

THE WHITE HOUSE
WASHINGTON

95 DEC 7 P1:52

December 7, 1995

Mr. Jeffrey House
Oxford University Press
198 Madison Avenue
New York, New York 10016-4314

Dear Mr. House:

Enclosed are President Clinton's remarks to be published in *The Human Radiation Experiments: Final Report of the Advisory Committee on Human Radiation Experiments*.

As we discussed, you agreed not to use the President's name, title, or image or any reference to the remarks he has provided in marketing or publicizing the book. Additionally, the President's name, title, or image should not be listed or used on the cover of the book. If you have any questions regarding these restrictions, please call me at (202) 456-6229.

Sincerely,

Kathleen M. Whalen

Kathleen M. Whalen
Associate Counsel to the President

Enclosure

cc: Phil Caplan

Package delivered
to Kathy Whalen 1/27
in response to document
request.

Ama and your
families (3)

REMARKS BY THE PRESIDENT
IN ACCEPTANCE OF HUMAN RADIATION FINAL REPORT

October 3, 1995

Old Executive Office Building

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What this committee learned I would like to review today because I think it must be engraved on our national memory. Thousands of government-sponsored experiments did take place at hospitals, universities and military bases around our nation. The goal was to understand the effects of radiation exposure on the human body.

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Thank you very much.

JOHNS HOPKINS
UNIVERSITY**Program in Law, Ethics, and Health**

School of Hygiene and Public Health
Department of Health Policy and Management
624 N. Broadway / Baltimore MD 21205-1996

School of Medicine
Division of Internal Medicine
1830 E. Monument Street / Baltimore MD 21205-1966

FAX COVER SHEET**TO:**Phil Caplan**FROM:**Ruth Faden**DATE:**1/5/95**SENDING FAX NUMBER:**

(410) 614-9567

RECEIVING FAX NUMBER:202 1456-2215**NUMBER OF PAGES (INCLUDING THIS COVER SHEET):** _____**NOTES:**

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*Spoke with Kathy
Whalen 1/4 "Final Report of
President's Advisory Committee"
is fine for cover &
book. Told
Ruth*

January 5, 1995

Phil--this is close, but not the latest design. Oxford's proposal is first to make the type somewhat smaller and secondly to change the subtitle to read "Report of the President's Advisory Committee". I'll be out of town on Monday, but I'll try and reach you. Otherwise, please call Sara (410-268-2966), Jeff (414-456-8498), Dan (202-332-0980), or Anna (206-454-8220)

Ruth

The Human Radiation Experiments

Final Report of the Advisory Committee

Jeffrey House

212 / ~~679-7300~~

~~x 7263~~
212 / 726-6204

Oxford Univ Press

198 Madison Ave

NY, NY 10016-4314

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While most of the tests were ethical by any standards, some were unethical, not only by today's standards, but by the standards of the time in which they were conducted. They failed both the test of our national values and the test of humanity.

In one experiment, scientists injected plutonium into 18 patients without their knowledge. In another, doctors exposed indigent cancer patients to excessive doses of radiation, a treatment from which it is virtually impossible that they could ever benefit.

The report also demonstrates that these and other experiments were carried out on precisely those citizens who count most on the government for its help -- the destitute and the gravely ill. But the dispossessed were not alone. Members of the military -- precisely those on whom we and our government count most -- were also test subjects.

Informed consent means your doctor tells you the risk of the treatment you are about to undergo. In too many cases, informed consent was withheld. Americans were kept in the dark about the effects of what was being done to them. The deception extended beyond the test subjects themselves to encompass their families and the American people as a whole, for these experiments were kept secret. And they were shrouded not for a compelling reason of national security, but for the simple fear of embarrassment, and that was wrong.

Those who led the government when these decisions were made are no longer here to take responsibility for what they did. They are not here to apologize to the survivors, the family members or the communities whose lives were darkened by the shadow of the atom and these choices.

So today, on behalf of another generation of American leaders and another generation of American citizens, the United States of America offers a sincere apology to those of our citizens who were subjected to these experiments, to their families, and to their communities.

When the government does wrong, we have a moral responsibility to admit it. The duty we owe to one another to tell the truth and to protect our fellow citizens from excesses like these is one we can never walk away from. Our government failed in that duty, and it offers an apology to the survivors and their families and to all the American people who must be able to rely upon the United States to keep its word, to tell the truth, and to do the right thing.

We know there are moments when words alone are not enough. That's why I am instructing my Cabinet to use and build on these recommendations, to devise promptly a system of relief, including compensation, that meets the standards of justice and conscience.

When called for, we will work with Congress to serve the best needs of those who were harmed. Make no mistake, as the committee report says, there are circumstances where compensation is appropriate as a matter of ethics and principle. I am committed to seeing to it that the United States of America lives up to its responsibility.

Our greatness is measured not only in how we so frequently do right, but also how we act when we know we've done the wrong thing; how we confront our mistakes, make our apologies, and take action.

That's why this morning, I signed an Executive Order instructing every arm and agency of our government that conducts, supports or regulates research involving human beings to review immediately their procedures, in light of the recommendations of this report, and the best knowledge and standards available today, and to report back to me by Christmas.

I have also created a Bioethics Advisory Commission to supervise the process, to watch over all such research, and to see to it that never again do we stray from the basic values of protecting our people and being straight with them.

The report I received today will not be left on a shelf to gather dust. Every one of its pages offers a lesson, and every lesson will be learned from these good people who put a year and a half of their lives into the effort to set America straight.

Medical and scientific progress depends upon learning about people's responses to new medicines, to new cutting-edge treatments. Without this kind of research, our children would still be dying from polio and other killers. Without responsible radiation research, we wouldn't be making the progress we are in the war on cancer. We have to continue to research, but there is a right way and a wrong way to do it.

There are local citizens' review boards, there are regulations that establish proper informed consent and ensure that experiments are conducted ethically. But in overseeing this necessary research, we must never relax our vigilance.

The breathtaking advances in science and technology demand that we always keep our ethical watchlight burning. No matter how rapid the pace of change, it can never outrun our core convictions that have stood us so well as a nation for more than 200 years now, through many different scientific revolutions.

I believe we will meet the test of our times -- that as science and technology evolve, our ethical conscience will grow, not shrink. Informed consent, community right-to-know, our entire battery of essential human protections -- all these grew up in response to the health and humanitarian crises of this 20th century. They are proof that we are equal to our challenges.

Science is not ever simply objective. It emerges from the crucible of historical circumstances and personal experience. Times of crisis and fear can call forth bad science, even science we know in retrospect to be unethical. Let us remember the difficult years chronicled in this report, and think about how good people could have done things that we know were wrong.

Let these pages serve as an internal reminder to hold humility and moral accountability in higher esteem than we do the latest development in technology. Let us remember, too, that cynicism about government has roots in historical circumstances. Because of stonewallings and evasions in the past, times when a family member or a neighbor suffered an injustice and had nowhere to turn and couldn't even get the facts, some Americans lost faith in the promise of our democracy. Government was very powerful, but very far away and not trusted to be ethical.

So today, by making ourselves accountable for the sins of the past, I hope more than anything else, we are laying the foundation stone for a new era. Good people, like these Members of Congress who have labored on this issue for a long time, and

have devoted their careers to trying to do the right thing, and having people justifiably feel confidence in the work of their representatives, they will continue to work to see that we implement these recommendations.

Under our watch, we will no longer hide the truth from our citizens. We will act as if all that we do will see the light of day. Nothing that happens in Washington will ever be more important in anyone's life affected by these experiments, perhaps, than this report we issue today. But all of us as Americans will be better off because of the larger lesson we learned in this exercise and because of our continuing effort to demonstrate to our people that we can be faithful to their values.

Thank you very much.



U. S. Department of Justice

Civil Division

95 AUG 24 P5:14

August 24, 1995
4:59 pm
2 Pages

TO : PHIL CAPLAN

Fax No : 9-456-2215

From : SMART

Subject :

Comments :

PLEASE CALL ME (616-4455) IF YOU DO RECEIVE A ONE PAGE DOCUMENT THAT SHOULD
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GLORIA SMART FOR PAT GLYNN

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Action Plan for Recommendation 1 (Apology Language)

The President may wish to express agreement with the Advisory Committee's denunciation of excessive government secrecy that cloaked many aspects of human radiation experimentation during the Cold War era. The Advisory Committee has provided a valuable public service in advancing the Administration's openness policy, which was the guiding force behind the Administration's unprecedented initiative begun almost two years ago to make public the details of this era of history.

On behalf of the Nation, the President may wish to apologize to the subjects of human radiation experiments from whom information concerning their participation in such experiments was kept secret by the government. Whether caused by paternalistic attitudes of the time or a mistrust by the government of its own citizens, policies and practices during the Cold War era that deprived experiment subjects of information concerning their own bodily integrity should not have been tolerated at the time and rightly are condemned today. Improper secrecy is destructive of the public's trust in their government and inconsistent with the principles that the government must be open, truthful, and accountable to its citizens.

8-23-95

DATE:

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

95 AUG 23 P3:34

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FAX: (202) 586-0956

TO:

Phil Caplan

FROM:

Tara O'Toole

NO. OF PAGES TO FOLLOW:

6

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As you were expecting



Department of Energy
Washington, DC 20585

August 23, 1995

MEMO TO: PHIL CAPLAN
WHITE HOUSE
OFFICE OF STAFF SECRETARY

FROM: TARA O'TOOLE, M.D., M.P.H. *Tara*
DEPARTMENT OF ENERGY
OFFICE OF ENVIRONMENT, SAFETY AND HEALTH

SUBJECT: BACKGROUND ON ADVISORY COMMITTEE ON HUMAN
RADIATION EXPERIMENTS

The President is scheduled to receive the Advisory Committee on Human Radiation Experiments' Final Report on September 22, 1995. This memorandum will describe the process that has led to this point and the major issues raised by the Advisory Committee's work.

BACKGROUND

■ **December 1993:**

- Secretary of Energy Hazel O'Leary released declassified documents concerning 18 persons injected with plutonium by Manhattan Project physicians and promised to find all Departmental records related to human radiation experiments.
- Secretary O'Leary established a hotline to receive inquiries from those who believe they or a family member may have been a radiation experiment subject (20,000 persons ultimately called).

■ **January 1994:**

- President Clinton directed other Federal agencies to search for documents related to human radiation research from World War II to 1974 (when government-wide regulations on human subjects research were adopted).
- The Interagency Working Group was established by President Clinton to coordinate the search for records throughout the Federal government. Members included the Secretaries of the Departments of Energy, Defense, Health and

Prepared by the Department of Energy, August 23, 1995



Printed with soy ink on recycled paper

Human Services and Veterans Affairs, the Attorney General, the Administrator of the National Aeronautics and Space Administration, and the Directors of the Office of Management and Budget and the Central Intelligence Agency.

- President Clinton established the Presidential Advisory Committee on Human Radiation Experiments, chaired by bioethicist Dr. Ruth Faden of Johns Hopkins. The Committee was charged to review the records of the Federal agencies and provide expert advice to the Interagency Working Group on the following issues related both to biomedical experiments and a list of intentional environmental releases of radiation:

- * The medical and scientific purposes for human radiation research sponsored or conducted by the government;
- * Whether appropriate medical follow up was undertaken and whether any subjects should be notified now in order to take steps to protect their health;
- * Whether the experiments met the ethical and scientific standards of the time and those that exist today; and
- * Whether current human subject research safeguards are adequate to prevent recurrence of ethical abuses.

■ **April 1994 through July 1995:**

- The Committee met monthly in public; took testimony from experiment subjects and their advocates, research institutions, several government representatives; and made the drafts of its final report publicly available.
- Federal agencies mounted a nationwide, coordinated search for records dating back to World War II. These records were often ill-organized and poorly indexed and were scattered at dozens of locations around the country. The fruits of this search were an estimated 840,000 pages of documents delivered by the agencies to the Committee.
- The Committee reviewed 125 current or ongoing Federally-sponsored studies (not limited to radiation-related research) and interviewed patients at leading hospitals in order to gauge the adequacy of procedures for both evaluating the risks of research and obtaining informed consent from subjects and also to sample attitudes toward human subject research.
- At the behest of advocacy groups, the Committee considered issues related to some radiation exposures associated with government activity that were not

"experiments" -- that is, persons who were not exposed for the purpose of research. These include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from a U.S. nuclear weapons test in 1954.

COMMITTEE FINDINGS AND RECOMMENDATIONS

The passage of time, inevitable gaps in the historical records -- including the difficulty in finding records documenting consent procedures -- and the sheer volume of human radiation research sponsored by the Federal government, precluded the Committee from reviewing the details of more than a few high profile experiments. The Committee, therefore, focused on identifying the ethical standards that applied to the government and to the medical profession in the post-War period and on looking forward at whether the current system for the protection of human subjects in all areas of Federally-sponsored research is adequate to prevent ethical abuses.

A very abridged version of the Committee's findings and recommendations follows:

- **Biomedical experiments and population exposures, 1944-1974**
 - The Committee finds that the government was aware of the need to obtain informed consent from subjects, particularly for research with no potential benefit to the subjects ("non-therapeutic" research) but did not effectively implement policies to ensure that consent was obtained.
 - The Committee finds that in the area of experimental treatment, where sick persons were the subjects, physicians generally did not recognize a need to obtain consent from patients.
 - Compensation is recommended for the families of a small group of subjects in World War II-era experiments, even though no physical harm apparently resulted, because the government misused secrecy to keep subjects uninformed (the 18 plutonium injection subjects and a few others).
 - The fairness of laws governing compensation of atomic veterans, uranium miners, and other populations put at risk by the nuclear weapons program should be re-assessed.
- **Current human subject protection**
 - The Committee finds that, while improvement has been substantial, serious deficiencies exist in the current system for human subject protection in Federally-funded research.

- The Committee finds that the high level of trust reposed by patients in their physicians can present a conflict of interest when consent is sought for participation in clinical research
- The Committee calls for enhanced education in ethics throughout the medical and research communities. The Committee also recommends a series of measures to ensure that research is clearly distinguished from treatment in obtaining consent, that risks are more clearly stated, that oversight by the Federal agencies is improved, and that a mechanism for continued interpretation of ethical rules is established.
- **Secrecy and openness**
 - Public distrust, while arguably disproportionate to physical harm actually done, has been fueled by decades of secrecy. Extra protections for classified research are recommended, as are steps to make historical records more accessible.

GOVERNMENT RESPONSE TO RECOMMENDATIONS

A group of representatives from the Federal agencies, with participation by OMB and OSTP, has been meeting over the past month to consider government-wide options to address the issues raised by the Committee and propose actions that Federal agencies may take individually and cooperatively, as well as steps that the President may wish to announce. The Group plans to present its product to agency principals by Labor Day and to the President shortly thereafter.

MEDIA INTEREST IN THE FINAL REPORT PUBLIC RELEASE

WHO:

- National and international media interest in the human radiation experiments has been intense. Media covering the issue include medical and science publications as well as consumer electronic and print media.
- Major dailies, including the *Washington Post*, *USA Today* and *New York Times*, regularly cover Department of Energy human radiation-related announcements. Regional media coverage -- whether or not local angles exist -- has been strong as well. Broadcast reporters from ABC, CBS, CNN and NPR keep in touch with the Department of Energy on the issue. The issue also is good "fodder" for editorial coverage and analysis.

- The August announcement has raised interest in the September event; *Time* magazine decided to hold its story for the September announcement. Networks asked about September as well.

HOW:

- Generally speaking, the coverage is "on message": The Administration is credited for openness, accountability and building public trust in government institutions. Coverage of the most recent announcement notes the medical benefits that Americans have derived, partly as a result of these types of tests. Negatives include:
 - There has been comparison among government agencies on level of secrecy/openness, creating distinctions among Cabinet agencies.
 - Some analysis compares the experiments to the Nazis.
 - Coverage always notes the sensational aspects of the experiments, particularly those held on vulnerable populations.
 - Coverage could focus on problems found in current research practices.
- In addition to Administration spokespeople, sources include:
 - Cooper Brown, Task Force on Radiation and Human Rights, who advocates for participants/subject in the experiments;
 - Rep. Edward Markey (D-MA) who has pushed for disclosure since 1986; and
 - Spokespeople from local universities and hospitals where experiments were conducted.

NEXT STEPS:

- We believe that the President's announcement can generate strong, positive attention from the media and the American people. In addition to the event, which is certain to generate extensive media coverage, the White House should consider efforts that make the issue an area of informed discussion by the American people:
 - Town hall meeting with members and staff of the Committee, scientists, radiation subjects advocacy group representatives engaged in the issues, the Secretary of Energy, Cabinet Secretaries, and members of Congress;
 - *Parade* magazine article by [famous doctor?? university president?] that can both credit the President for openness, as well as enumerate medical benefits;

- Opinion editorial by Dr. Ruth Faden for placement in the *Washington Post* or *New York Times*;
- Outreach to columnists in national and local newspapers;
- Outreach to editorial boards;
- Online forum on CompuServe or America Online with ethicist, maybe Dr. Ruth Faden; and
- Radio talk shows throughout the country.



U. S. Department of Justice

Civil Division

August 23, 1995
8:15 pm
8 Pages

TO : PHIL CAPLAN
WHITE HOUSE

Fax No : 9-456-2215

From : SMART

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Comments :

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LEGAL ISSUES PRESENTED BY PROPOSED
HYBRID LITIGATION SCHEME FOR RECOMMENDATION 2

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, individual 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.

I. Criteria for Eligibility Under Recommendation:

1. Proof that the claimant was a subject of a human radiation experiment.
2. Proof that the experiment is among the class identified by the Committee. This requires proof either that:
 - a) the experiment did not involve the prospect of direct medical benefit, and subjects were misled to believe the experiment had a therapeutic purpose;
 - b) the experiment involved intervention considered to be controversial at the time yet presented to the subject as standard or conventional practice.
3. Proof that the claimant suffered physical harm as a result of the experiment.

II. Summary Description of Proposed Hybrid Litigation Scheme

It was the sense of the IAWG at the August 16th meeting that the most politic response to Recommendation 2 would be for the federal government to establish an administrative compensation scheme as an alternative to routine civil litigation. The proposed scheme, modeled on existing compensation programs such as the Radiation Exposure Compensation Act (RECA) and Vaccine Injury Compensation Program (VICP), would resolve the eligibility issues through a combination of administrative review and litigation. A hybrid administrative-litigation program is believed to be the most efficient and expeditious means to compensate the deserving subjects.

The basic elements of the proposed scheme are as follows:

1. Claimant would establish that he/she was the subject of a human radiation experiment through the database assembled by the Advisory Committee, or through submission of privately-held historical documents. The program staff would actively assist a claimant in locating sources and documents to establish this criterion.

2. Claimant would establish that the experiment in which he/she was a subject was among the limited class defined by the Advisory Committee either by relying on a rebuttable presumption or through litigation in a designated forum. The Institute of Medicine, based on a review of the known human radiation experiments compiled by the Advisory Committee, would develop two lists: a list of specific experiments or experimental protocols that are presumed to meet the Advisory Committee's standards; and, a list of specific experiments or experimental protocols that were reviewed by the Institute of Medicine and are presumed to fall outside the class defined by the Advisory Committee. (Note: In light of the large number of interventions that the Advisory Committee characterized as experiments, it is unlikely that the Institute of Medicine could review all radiation "experiments." At least initially, we might refer to the Institute of Medicine only the specific experiments cited by the Advisory Committee in its commentary following Recommendation 2 as examples of suspect experiments.) An experiment on either list would give rise only to a rebuttable presumption: the claimant or the program staff, depending on which list the experiment was placed, could argue in the designated forum that the presumption should be overcome in the case of that individual claimant because of some proven variation in the experimental protocol. In the absence of a challenge by the program staff, however, a claimant could rely solely on the fact of inclusion on the IoM-approved list to meet his/her burden of proof on this criterion.

Claimants who prove that they were the subject of a human radiation experiment not included on either of the presumptive lists -- either because the experiment was not reviewed by the Institute of Medicine or because the experimental protocol differed significantly from those listed by the Institute of Medicine -- would have to prove they meet this criterion through litigation in the designated forum.

3. Claimants would establish that they suffered physical injuries as a result of the human radiation experiment, again, by means of a rebuttable presumption or through individual litigation in the designated forum. The Institute of Medicine would develop a list or chart of adverse human health effects sufficiently associated with exposure to radiation to warrant a rebuttable presumption. Again, the presumption would only be rebuttable: the program staff would have the right to challenge the presumptive causation association and prove to some defined

degree of certainty that some other agent or factor caused the claimant's physical injuries.

Again, a claimant who suffered a physical injury not included on the presumptive list could establish eligibility by litigating the issue in the designated forum.

III. Legal Issues Presented

1. Effect of administrative compensation program on subjects' existing causes of action (i.e., right to seek redress through civil litigation)
 - a. Should the administrative compensation remedy be the exclusive means of redress, extinguishing private rights of action against the United States and/or all private defendants;
 - b. Should a claimant have the option to pursue compensation either through the administrative scheme or civil litigation, but not both; and if so, at what point in each process is the claimant's right to seek redress alternatively extinguished;
 - c. Should a claimant have the right to pursue compensation through both avenues, and if so, may he/she proceed simultaneously or only after one avenue has been unsuccessfully exhausted;
 - d. Should any compensation awarded in the administrative program be reduced by the amount of compensation paid to the claimant from collateral sources (e.g., veteran's benefits, litigation award)?
2. Presumptions arising from IoM-created tables
 - a. Should the presumptions created for resolution of criteria two and three be rebuttable or irrebuttable;
 - b. Should the government be entitled to a disqualifying ("negative") presumption for criteria two and/or three;
 - c. Should the claimant and the government be accorded the same presumption for each criterion;
 - d. What standard(s) of proof will be required to overcome the presumptions, if rebuttable;

- e. How strong must the association be (i.e., how great an increased risk) between exposure and adverse health effect to merit a presumption of causation (and compensation)?

3. Litigation of issues and facts

- a. What forum will decide issues required or permitted to be litigated;
- b. What party will bear the burdens of proof and persuasion on each issue litigated;
- c. What rules of evidence and procedure will govern litigation in the designated forum;
- d. Will there be a right to appeal from decisions of the designated fact-finder, and if so, what decisions and to what authority?

4. Compensation and Administration of Program

- a. Will successful claimants receive a pre-determined, standard award or only actual, proven damages;
- b. If a claimant is entitled to actual, proven damages, what types of damages will be compensable (e.g., medical expenses, lost wages, pain and suffering);
- c. If a claimant is entitled only to a set, lump sum award, should the amount of the award vary by the likelihood (degree of risk) exposure caused claimant's physical injuries;
- d. What federal agency will administer the program;
- e. What will be the source of funding for compensation awards (e.g., agency appropriations, trust fund)?

PROPOSED ACTION PLAN FOR RECOMMENDATION 6

Recommendation 6: The Committee recommends that the IAWG work with Congress to amend the provisions of RECA 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 Committee further recommends that the Act 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.

Proposed Response: Agree with the Advisory Committee that the provisions of the Radiation Exposure Compensation Act (RECA) relating to uranium miners should be reviewed to ensure that the criteria for compensation are consistent with the latest scientific data and comparable to compensation standards for other radiation-exposed populations. The Administration will establish a committee of governmental and private experts to review the latest epidemiological data on uranium miners and millers, the present eligibility criteria in the RECA, and Department of Justice's regulations implementing the RECA. The committee will complete its review in 4 to 6 months. Based upon the findings of this committee, the Administration will:

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

The committee of experts will be asked to examine a series of questions, including:

A. Issues relating to Committee recommendation to amend RECA to widen coverage for uranium miners

(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) determine whether it is feasible and appropriate to adopt a duration of employment standard in place of the WLM criterion; if so, define a series of default duration standards, accounting for variables that significantly affected exposure levels, such as the time period in which the claimant mined and the area mined;

(e) 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;

(f) determine whether the right to compensation, and amount of compensation, should vary depending on the statistical probability of causation.

B. Issues relating to Committee recommendation to consider revision of RECA regulations to liberalize standards of proof of statutory criteria

(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 as affidavits) exist to satisfy eligibility criteria, and what means of assuring veracity should be required.

C. Issues relating to Committee recommendation to consider amending RECA to cover Uranium Millers

(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.

DOE F 1325.7

(08 00)

(Exception to SF 14, Approved by NARS, June 1978)

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	WARNER, MICHAEL	703-351-2621	[fax 522-9280]
DEFENSE:	BAILEY, CLAUD.....	703-442-5675	[fax 847-0890]
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	SOPER, GORDON.....	703-697-5561	[fax 695-0476]
DPC:	VYSATOVA, ROMANA..	456-5583	[fax 456-7028]
ENERGY:	AZIM, LORL.....	586-5319	[fax 586-0956]
	HEUSSER, ROGER.....	301-903-3526	[fax 903-6133]
	NORDHAUS, BOB.....	586-5966	[fax 586-1499]
	O'TOOLE, TARA.....	586-6151	[fax 586-0956]
	SCHIAVO, LISA.....	586-5289	[fax 586-1499]
	WEISS, ELLYN.....	254-5020	[fax 254-5056]
JUSTICE:	GLYNN, PAT.....	616-4200	[fax 616-4473]
	PLAZA, EVA.....	514-3309	[fax 514-8071]
HHS:	BALDWIN, WENDY...	301-496-1096	[fax 402-3469]
	ELLIS, GARY.....	301-496-7005	[fax 402-2071]
	ENGSTROM, LILY.....	301-402-2246	[fax 402-3469]
	HENDERSON, D.A.....	410-955-1624	[fax 889-6514]
	VOLKOV, MARINA...	301-496-6123	
NASA:	FERGUSON, EARL.....	358-1894	[fax 358-3038]
	HOLLOWAY, HARRY	358-0122	[fax 358-4174]
	STOKLOSA, JANIS...	358-2209	[fax 358-3038]
NEC:	HOLSTEIN, ELGIE.....	456-2800	[fax 456-7028]
OMB:	GLAUTHIER, T.J.....	395-4561	[fax 395-4639]
	MACRIS, ERIC.....	395-3807	[fax 395-4817]
OSTP:	GWIN, HOLLY.....	456-2735	[fax 456-6049]
	LEVINSON, RACHEL..	456-6137	[fax 456-6027]
VA:	GRACEY, HAROLD.....	273-4808	[fax 273-4877]
	MATHER, SUSAN.....	535-7182	[fax 535-7572]
	OTCHIN, NEIL.....	565-7057	[fax 565-7572]
	TACKETT, NANCY.....	273-5034	[fax 273-5993]
WH:	CAPLAN, PHIL.....	456-2702	[fax 456-2215]



INTERAGENCY WORKING GROUP
Subcommittee on Openness & Classified Research

OPTIONS PAPER

AUGUST 10, 1995

RECOMMENDATION 14a: The Advisory Committee recommends to the Interagency Working Group the adoption of a Federal policy requiring the informed consent of all human subjects of classified research, and that this requirement not be subject to exemption or waiver. In all cases, potential subjects should be informed of the identity of the sponsoring Federal agency and that the project involves classified information.

*only
classified
research*

GOVERNMENT RESPONSE:

OPTION 1: The President directs all departments and agencies that, effective immediately, there will be no waivers of informed consent for Federally funded classified research. President also directs that in all Federally funded classified research, two additional elements of information will henceforth be provided when consent is sought from potential human subjects. (i) the identity of the sponsoring Federal agency, and (ii) a statement that the project involves classified information.

*DoD
+
CIA OK
with*

Implementation: Federal funds be expended for classified research only where: (i) an Institutional Review Board (IRB) has not waived the requirement for informed consent under the 1991 Federal Policy for Protection of Human Subjects, or (ii) a determination has been made in accord with the 1991 Federal Policy for Protection of Human Subjects that the research is not exempt from IRB review.

Pros: Immediate implementation

Implementation of ACHRE recommendation with perfect fidelity.

No opening of the 1991 Federal Policy to extraneous actions.

Avoids need for rulemaking by 16 departments and agencies.

Cons: Informing subjects of classification of research may require security clearance of subjects and bias subject selection.

Presidential directive does not provide for public comment.

OPTION 2: The President refers above (along with all issues of protection of human subjects) to new National Bioethics Advisory ~~Committee~~ (NBAC) for further review and implementation.

Pros: The President is seen as creating an enduring presence (i.e., NBAC) to address concerns of ACHRE.

Full deliberation on issues of protection of human subjects can occur.

Relationship between "classification" and Federal Policy can be examined.

Cons: One committee follows another.

NO OPTION 3: The President directs that rulemaking process be used to revise the 1991 Federal Policy for Protection of Human Subjects as above.

Pros: Opportunity for public comment.

Cons: Opens 1991 Federal Policy to extraneous actions.

Creates need for rulemaking by 16 departments and agencies.

Issue: Sixteen departments and agencies are still grappling with implementation of 1991 Federal Policy. Opening it for revision at this time is likely to be counterproductive.

RECOMMENDATION 14b: Review of classified research by a non-governmental, civilian group with appropriate clearances.

GOVERNMENT RESPONSE:

OK

OPTION: The President directs all agencies to ensure participation of non-government persons in review of classified research, either by establishing a dedicated panel or ensuring the IRB members are all appropriately cleared.

Pros: Since classified research involving human subjects is rare today, refinement of current government system for assurance of protection of human subjects involved in classified research is appropriate.

Stringent mechanisms for protection of human subjects are in place through IRBs, which include non-government and citizen representatives, before any study is approved which involves human subjects.

Additional review and oversight bodies for classified research would be cumbersome, costly, and would have little added benefit to the mechanisms currently in place.

Cons: Not a dramatic action; allowing the agencies to decide how to respond may be seen as business as usual.

RECOMMENDATION 15a: The Advisory Committee recommends that an independent review panel be assigned the task of reviewing any planned or intended environmental releases of substances in cases where the release is proposed to take place in secret, or in circumstances where any aspect of the environmental review process required by law is conducted in secret.

GOVERNMENT RESPONSE:

Study a little bit more any way get EPA to look at

OPTION 1: The President indicates that EPA, in conjunction with Federal agencies conducting classified programs, has an initiative underway to improve environmental oversight and establish more rigorous regulatory procedures for classified facilities. The President indicates that he believes that creating a new regulatory entity would add to the bureaucratic complexities of ensuring environmental safety, but would direct EPA to report on the desirability of the Committee's recommendation before taking action.

"Paranoia pops" very sensitive

Pros: Provides time for further consideration of the recommendation and opportunity to gauge EPA's progress in addressing this issue.

Avoids complexities, budgetary problems, and additional bureaucracy inherent in creating a new, independent panel.

Cons: Could be perceived as balking at recommendation and possibly as ducking the issue.

Issue: Would likely require continuation of Interagency Working Group to evaluate progress on this issue at a later date.

OPTION 2. The President indicates that the Interagency Working Group must explore this recommendation more thoroughly before he takes action, since the results of EPA's efforts to revamp its regulatory system are unclear and budgetary resources are particularly uncertain at this time.

Pros: Would allow time to develop thoroughly-researched, fiscally and politically viable options.

Cons: Could be perceived as avoiding the issue.

Issue: Would require continuation of Interagency Working Group to develop options on this issue at a later date.

RECOMMENDATION 15b: The Advisory Committee recommends to the Interagency Working Group that an appropriate government agency, currently the Environmental Protection Agency, maintain a program directed at the oversight of classified programs, with suitably cleared personnel. This program should maintain critical records, such as environmental impact statements and environmental permits permanently. The agencies subject to regulation should ensure the timely consideration of environmental impacts and oversight and the timely provision of all necessary clearances. EPA should provide regular unclassified reports to Congress describing the extent of its activities as well as any significant problems.

(The Interagency Working Group sought clarification from the Committee on the intent of this recommendation. According to the executive director,

Rec.
Central repository for all classified
BIS

the Committee is not asking here for expansion of EPA's substantive authority under NEPA and other existing environmental laws.)

GOVERNMENT RESPONSE:

OPTION 1: The President may direct EPA to maintain permanent files on classified environmental impact statements and environmental review of classified activities. Pursuant to Executive Order 12958, these records can potentially be declassified when they are 25 years old.

Pros: Can be done immediately. EPA has indicated to the Advisory Committee that they do have facilities to maintain classified documents although they have not done so in the past.

Permanent, centralized recordkeeping enhances accountability.

Fits well with EPA's ongoing initiative to improve oversight of classified installations.

Cons: Does not respond to the Committee's recommendation for reports to Congress.

Issue: Do existing reporting requirements provide sufficient information to Congress?

What gaps need to be filled, if any?

OPTION 2: Option 1 plus EPA is directed by the President to report periodically to Congress on the extent of its review of classified activities and problems encountered.

Pros: Directly responsive to the Committee's recommendations.

Reporting to Congress increases oversight, makes it less likely that a problem would go undetected.

Cons: Additional reporting may be unnecessary and could divert agency resources.

OPTION 3: The President indicates that EPA has an initiative ongoing to improve its oversight of classified installations and directs the agency to report on the desirability of the Committee's recommendations before taking action.

Pros: Provides time for further consideration of the recommendations.

Cons: Would be perceived as ducking the issue.

Issue: If the Interagency Working Group determines it is better to take no action on this recommendation, it may be better to determine that at a later date.

RECOMMENDATIONS 16(1), 16(2), 16(3): The Advisory Committee recommends that the Interagency Working Group take steps to ensure the continued application of the lessons learned from the efforts to organize and make accessible to the public, and the government itself, the nation's historical records.

- (1)** The most important historical collections should be entrusted to the National Archives. The agencies and the National Archives should review the extent to which this is now being done and develop policies to hasten the transfer of agency records to the National Archives.
- (2)** Agencies should make readily available all existing inventories, indices, folder listings and other finding aids to record collections now under agency control. Classified finding aids should undergo declassification review and declassified versions of these finding aids should be also be made available.
- (3)** The Interagency Working Group should ensure the development of policies to improve public access to records held by agencies or deposited in Federal Record Centers.

GOVERNMENT RESPONSE:

OPTION 1: The President can direct all agencies to carry out these recommendations within the existing legal and administrative

structure already in place for records management, records access, and records transfer to the National Archives.

- * The existing system consists of offices and staff that are responsible for managing and controlling agency records. This system includes the identification and transfer of permanent documentation to the National Archives; it also includes a mechanism (under the Freedom of Information Act) for the public to gain access to agency documents.
- * Traditionally, these activities have received low priority and few resources within agencies.
- * The President can cite the successful efforts to transfer, declassify, and make available records as part of the Human Radiation Experiments project at the Department of Energy and other members of the Interagency Working Group.
- * The President can call upon agencies to use similar efforts to give higher priority to the current records system so as to speed the transfer of permanent agency records to the National Archives.
- * Priority will be given to making finding aids and other tools needed for accessing records available to the public. This includes declassifying all indexes to classified collections and moving such indexes to agency public reading rooms.
- * Agencies will give greater emphasis to gaining intellectual control over their records holdings; that is, learning and documenting the location and contents of important records.
- * The President can issue an Executive Order to direct agencies to carry out these actions.

Pros: This is the simplest and easiest response.

It requires no new administrative structures.

It emphasizes what has already been accomplished in this area to the credit of the Administration.

Cons: This does not establish a forceful mechanism to ensure that these recommendations are actually implemented.

It is not fully responsive to the recommendations which call for a new effort to ensure public access to records.

Issue: The President loses an opportunity to institutionalize openness in government.

Need to coordinate with interagency group implementing Executive Order 12958 for records declassification.

This will require some additional resources. (For the Department of Energy, a rough estimate is \$500,000 annually).

OPTION 2: In addition to Option 1, the President can establish an interagency steering group, to provide a driving force to implement the Advisory Committee's recommendations and enhance openness generally.

- * The steering group (consisting at a minimum of the Departments of Energy and Defense) will establish specific priorities and will measure progress toward accomplishment of these goals.
- * In cooperation with the National Archives and other agencies, the group will develop model applications of technology to deliver information directly to citizens, including expanded use of the Internet, automating public reading rooms, and electronic inventories of historical records in agency custody.
- * The goal is to build on lessons learned from the human radiation experiment initiative by institutionalizing tools and systems to empower citizens to find the information they need themselves.
- * Current efforts to manage, declassify, access, and preserve records would be enhanced and improved through centralized coordination and direction.

Pros: This option is fully responsive to the recommendations.

It establishes a basic mechanism to ensure implementation of the recommendations.

Is a forceful, proactive step.

Incorporates theme of reinventing government.

Provides a driving force to achieve change.

Cons: Will entail resource commitment that is not yet defined.

Issue: Agencies, including the National Archives, must work with the steering group for it to succeed.

Need to coordinate with interagency group implementing Executive Order 12958 for records declassification.

Need to define precise structure and mechanism to implement this option.

RECOMMENDATION 16(4): The Advisory Committee recommends that agencies maintain complete records, available to the public, of document destruction.

GOVERNMENT RESPONSE:

OPTION 1: The President should, via Executive Order, institute new policy regarding classified research records of destruction. Such Order should mandate that all records of destruction regarding classified research be maintained by National Records Centers for 25 years.

Pros: Good for public outreach and credibility if destruction records are well documented (content and reasons).

Addresses the area of most public distrust and makes available information which was inaccessible.

Documentation for subject matters of public concern would be maintain but in a limited way (only the classified portions).

Assures management of records.

Narrows the scope, therefore would be more cost effective.

Cons: Huge volumes of records involved, may need to narrow the type/subject retained.

Historically, destruction records do not give adequate reasons for the destruction.

Historically, information on destruction records is of very limited value regarding content of document.

Would require very large commitment of resources to implement.

Issue: Under current records/document destruction requirements, destruction certificates for classified or unclassified documents are not maintained on a permanent basis. Lack of such documents undermines the credibility of the records system and makes an already cynical public even more cynical about government.

Given budgetary and personnel reductions, initiatives undertaken must be done within existing structure.

OPTION 2: The President should, via Executive Order, institute new policy regarding human subjects research records of destruction. Such Order should mandate that all records of destruction regarding classified research be maintained permanently by National records Centers. Disposition instruction of current records should be updated to reflect new policy with specific emphasis on enforcement of records maintenance standards at all levels.

yes
+
option 4

Pros: Good for public access to relevant records.

Good for public credibility, but only if destruction records are well documented for content and reasons.

Addressing an area of the most public interest.

Very subject specific. Manageable volume using limited resources.

Assures management of records.

Documentation for subject matters of public concern would be maintained (drug testing, chem/bio experimentation).

Cons: Historically, destruction records do not give adequate reasons for the destruction.

Destruction done item-by-item on local level and box-by-box at retention centers. Abstracts of boxes of material difficult at a credible level. To be more usable, abstracts of individual documents would be necessary but very resource restrictive.

Proposes a scope much more limited than the recommendation.

Resources required to identify relevant records and process them separately.

Subjective evaluation of the subject matter and its relevance.

OPTION 3: The President should, via Executive Order, institute new policy regarding human subjects in ionizing radiation experiments records of destruction. Such Order should mandate that all records of destruction regarding classified research be maintained permanently by National Records Centers. Disposition instruction of current records should be updated to reflect new policy with specific emphasis on enforcement of records maintenance standards at all levels.

bo
Narrow

Pros: Good for public access to relevant records.

Good for public credibility but only if destruction records are well documented for content and reasons.

Very subject specific. Manageable volume and effort.

Assures management of records.

Given budgetary and resource constraints, is a step in the right direction for openness.

Cons: Historically, destruction records do not give adequate reasons for the destruction.

Destruction done item-by-item on local level and box-by-box at retention centers. Abstracts of boxes of material difficult at a credible level. To be more usable, abstracts of individual documents would be necessary but very resource restrictive.

Proposes a scope much more limited than the recommendation.

Specificity of subject may limit the future use and make it impractical from cost/benefit perspective.

Resources required to identify applicable records and process separately.

Subjective evaluation of the subject matter and its relevance.

OPTION 4: The President directs that all records of classified projects involving human subject testing are to be labeled "permanent retention" in all agencies.

Yes
X
option 2

Issue: Are agencies required to label all existing human subject testing records "permanent retention" or will the directive apply only to records created after its issuance?

RECOMMENDATION 16(5): The Advisory Committee recommends that the Interagency Working Group review and develop policies concerning public access to records generated or held by private contractors and institutions receiving Federal funding.

GOVERNMENT RESPONSE:

*Arthur
Shay*
*for
IACG*
OPTION: The President directs the Interagency Working Group to develop guidelines for implementing this recommendation. The President also directs the Departments of Justice and State to review existing laws and regulations related to the implementation of this recommendation.

Pros: Balances the need for achieving openness in government with the need for preserving the privacy rights of subjects.

Ensures that the recommendation's implementation will not violate the rights of private commercial entities or interfere with vigorous commercial development.

Cons: The Interagency Working Group may not be the best group to undertake the task.

Issue: The privacy rights of subjects must be adequately safeguarded.

Patent rights and intellectual property rights of commercial entities must be adequately safeguarded.

Agreements with international partners should not be inhibited, but must address the rights of human subjects, release of information, access to records and intellectual property rights within the context of presently existing treaties and laws.

RECOMMENDATION 17a: The Advisory Committee recommends that the CIA's recordkeeping system be reviewed to ensure that records are accessible upon legitimate request from the public or governmental sources.

GOVERNMENT RESPONSE:

Yes
OPTION 1: The President directs the National Archives to give priority to its review of CIA's records system that is scheduled for October 1995.

Pros: This would be a high level response and assures an independent review by an organization with the expertise required for the task.

NO
OPTION 2: The President directs CIA to form a task force to review the accessibility of CIA records and recommend ways to improve the Agency's response to outside investigations/reviews.

Pros: This would be a more vigorous high level response that would show the President's and the Agency's commitment to applying the lessons of the Advisory Committee process.

Cons: Such a review would duplicate the national Archives' efforts, and would divert Agency resources already stretched thin by mandatory compliance with the declassification programs required under new Executive Order 12958.

RECOMMENDATION 17b: The Advisory Committee recommends that all CIA records bearing on programs of secret human research, such as MKULTRA and the related CIA human behavior projects from the late 1940s through the early 1970s, become a top priority for declassification review, with the expectation that most, if not all, of these documents can be declassified and made available to the public.

GOVERNMENT RESPONSE:

Yes
OPTION 1: The President directs CIA, as part of its compliance with the Executive Order 12958, to give top priority to the drug testing records.

Pros: This provides a mechanism that is already established to re-review documents that, for the most part, are already declassified.

Cons: This review might be seen by researchers interested in CIA drug testing as not giving the subject sufficient priority.

OPTION 2: The President directs CIA to establish a task force to review and release the drug testing records.

Pros: This is a direct, positive response to the recommendation.

Cons: This could take almost as long as Option 1 to finish and would divert resources needed for other declassification reviews, e.g., the Kennedy assassination records.

NO

DATE: August 23, 1995

95 AUG 23 P 5:36

**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: John Pereira, Claud Bailey, Eva Plaza, Pat Glynn, Paul Yanowitch, Wendy Baldwin, Gary Ellis, Lily Engstrom, D.A. Henderson, Harry Holloway, T.J. Glauthier, Eric Macris, 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:

Attached is the revised remedies response options paper prepared by DOE. Please distribute to other members within your agency who will participate in the Thursday's conference call. Thanks.

August 23, 1995

**TO: INTERAGENCY RADIATION EXPERIMENTS SEARCH GROUP
REPRESENTATIVES**

SUBJECT: COVER MEMO FOR REMEDIES OPTIONS

The Advisory Committee on Human Radiation Experiments found that for the period 1944 - 1974, neither the government nor the medical profession acted effectively to protect the rights of research subjects. While the committee has not identified cases where subjects were physically harmed, it has identified a small number of cases occurring during WW II (less than 25 in total) where the government deliberately kept the true nature of the experiments from the subjects. In those cases, the committee recommends compensation to surviving family members.

The committee also considered issues related to some radiation exposures associated with government activity that were not experiments; that is, persons were not exposed for the purpose of research. These include atomic veterans, uranium miners and residents of the Marshall Islands exposed to the fallout from a 1954 nuclear weapons test. The committee's major recommendation for these groups is that existing laws governing compensation should be reexamined to assure fairness and equity.

Representatives of all agencies that have been a part of this process collectively reviewed the specific recommendations of the committee with a view toward developing a government - wide response that includes actions that agencies can take separately and cooperatively and initiatives that the President may wish to announce. Options were prepared and discussed. The material that follows represents a consensus view of the agencies.

Remedies Response Options (8/23/95 DRAFT)

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.

Response:

Work with Congress to draft and pass legislation to apologize and provide compensation to the affected families for the dignitary harm that may have been suffered by the subjects of the experiments, either because consent of the subjects was not adequately obtained, or the government improperly denied the subjects and their families an opportunity to pursue legal redress.

Compensation would be commensurate with amounts paid to the Japanese internees and their survivors (\$20,000 in 1988) and claimants would be asked to release claims of dignitary harm against the government, its contractors and their employees.

The proposed legislation would explicitly preserve any existing or future claim of physical harm resulting from the experiments. [The government could also defer claims of physical harm in accordance with any decision made respecting recommendation 2.]

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.

Issues:

Scientific complexity of determining criteria for assigning probability of harm --

A cursory review of the experiments listed by the Advisory Committee as candidates for compensation revealed a variety of studies (uptake/distribution/metabolism, injection and total

Do whatever
is politically best

if it is fuzzy,
then maybe refer to DOW

Tam
wait until
final words
of rec.
if 591 "let
courts decide"
then do not

body irradiation studies) involving different types of radiation (external, isotopes, mixtures) and populations (infants, pregnant women, individuals with different medical conditions). This web of variables compounded by the lack of information on subjects, dose and outcome renders the task of establishing criteria for assigning probability of harm extremely complex.

Given the plethora of variables associating with these experiments, the lack of subject data, and limitations of existing scientific methodology, the best outcome that scientific analyses could provide would most likely be range of risks (i.e. the likelihood of cancer/diseases) for categories of subjects with similar attributes. These attributes could be based on some key parameters such as population types, study protocol (i.e. amount and types of radiation materials and route of exposure, and biology (i.e. where the material sequestered and target organ).

Ranges of risks are, however, insufficient to demonstrate causation. The determination and adjudication of individual physical harm would still need to be established on a case by case basis in the courts. A RECA-like compensation scheme is likely to be difficult to formulate because of large and pervasive uncertainties.

The Advisory Committee evaluated the risks of cancer for 19 experiments on children using this kind of an approach (see Chapter 7, "Nontherapeutic Research on Children"). Their analysis revealed a range of risks of excess cancer cases from a maximum of 2.3×10^{-2} to 1×10^{-6} . The committee believed that this analysis captured those experiments with the highest long-term risks. The committee concluded that the overall risks are low for most of the experiments.

The IOM, through their analysis, might be able to certify that the risks from most of these experiments are low. Is it worth asking the IOM to carry out this resource-intensive task for this purpose? Would this appreciably streamline or enhance the existing legal process?

Legal Complexity -- see separate fax from DOJ

Recommendation 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.

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

See separate fax from VA

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.

Response -- See separate fax from DOJ

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 Utirik, 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.

Response:

Extensive analyses of radiation exposures in the Marshall Islands have indicated that the exposures to inhabitants of Ailuk and other atolls were substantially less than exposures on Rongelap and Utirik. However, the Department of Energy will undertake a review of available information, including any new data that has been developed, to determine whether a reconsideration of radiation exposures on Ailuk and other atolls is warranted.

August 22, 1995

TO: Gordon Soper, DOD
Tara O'Toole, DOE
D.A. Henderson, HHS
Pat Glynn, DOJ
Harry Holloway, NASA
T. J. Glauthier, OMB
Susan Mather, DVA
Rachel Levinson, OSTP
Brian Latell, CIA
Phil Caplan, White House

FROM: Deputy Director for Extramural Research
National Institutes of Health, DHHS

SUBJECT: Report on Recommendations from the Interagency Subgroup on
Enhancements to Human Subjects Protection

We are sending you a copy of the revised paper that reflects our interagency discussions on Wednesday, August 16. The options that were not selected have been deleted and some minor revisions in the text have been made in accordance with the consensus of the group. Again, I would appreciate the assistance of your office in distributing copies of this paper to appropriate staff in your agency.

If you have any questions, please do not hesitate to contact Ms. Lily O. Engstrom of my staff at (301-402-2246).

Wendy Baldwin, Ph.D.

Summary of Responses to ACHRE Recommendations 8-13

The responses that have been developed on the following pages to address Recommendations 8 through 13 of the Advisory Committee on Human Radiation Experiments (ACHRE) cover a broad range of approaches, some of which involve activities internal to the agencies and others which call upon external resources for implementation.

Among the responses are activities that can be implemented immediately while others will require some preliminary groundwork prior to full implementation. A third group of responses involve referring certain recommendations to the National Bioethics Advisory Commission, an independent body to be established by the President "to consider current and prospective issues pertinent to the conduct of research on human biology and behavior and to identify broad, overarching principles to govern the ethical conduct of such research".

Generally, the responses to the recommendations cover the following categories of activities:

- Remand specific ACHRE recommendations to the proposed National Bioethics Advisory Commission (NBAC) which will provide expert advice on issues of bioethics.
- Develop educational programs in concert with external groups such as medical schools, universities, scientific societies, and others to strengthen activities in human subjects protection, to provide a forum for addressing ongoing as well as emerging issues in human subjects research, and to familiarize professionals engaged in nonfederally funded research with the ethical considerations in conducting research involving human subjects.
- Implement training programs within federal agencies to educate senior level officials on regulations and policies governing human subjects research, e.g., the activities proposed by the Department of Defense.
- Send official notifications to institutions conducting federally funded research
(a) reminding them of their ongoing responsibilities with respect to IRB review and (b) informing them of their new responsibilities regarding additional requirements to be incorporated into the informed consent procedures and forms.
- Pool resources across agencies to conduct pilot projects to improve the efficiency and effectiveness of IRB review and to evaluate the Government's system for the protection of human subjects.

- Consider proposing legislation to remedy some of the gaps in the current system for protecting human subjects.

August 21, 1995

Recommendation 8

The Advisory Committee recommends to the Interagency Working Group that efforts be undertaken on a national scale to ensure the centrality of ethics in the conduct of scientists whose research involves human subjects.

The Government has in recent years mounted several activities that address this subject. For example:

- **DHHS:** The National Institutes of Health (NIH) requires all institutions receiving National Research Service Award institutional training grants to provide pre- and postdoctoral trainees on these grants with instruction in the responsible conduct of research. This curriculum includes, among other things, policies on the appropriate use of human subjects and animals in research.
- **DHHS:** The NIH completed development of a Core Curriculum in Clinical Research to train young clinical investigators in its Clinical Center. This course, which is mandatory, includes several modules on protection of human subjects and a specific module on bioethics.
- **NASA:** Established an external Bioethics Task Force to review NASA procedures for all experimentation involving human subjects and to recommend appropriate policy changes. Report to be issued in fall 1995.
- **DOE:** Holds educational regulatory and bioethics update meetings for the entire DOE system (to which other federal agencies are also invited).
- **DOD:** Convenes an annual Tri-Service Clinical Investigations Postgraduate Short Course, generally attended by 200-300 physicians, scientists, nurses, pharmacists and other research support personnel, that emphasizes contemporary human subjects protection issues.
- **DOE:** Has computerized and established worldwide web access to the Department's human subjects newsletter, resource manual and database.
- **DOD:** Requires investigators' familiarity with the Belmont Report, the Common Rule, DOD Directives and all applicable regulations and instructions through the assurance process with each facility.
- **VA:** Has established a special office to conduct random site visits to VA medical centers to review local implementation of national VA policy for the protection of human subjects.

Response

(a) A major effort will be launched to "upgrade" or expand these activities. These will consist of:

- DHHS: In recognition of research initiatives in gene therapy, heterologous and autologous transplantation, adoptive immunotherapy and other emerging areas of clinical investigation, the NIH Clinical Center Clinical Bioethics Program will be expanded. Additional resources, including an SES position, FTEs and space, will be allotted to this program.
- DHHS: Following implementation and assessment in the NIH Clinical Center, the Core Curriculum in Clinical Research may be offered to trainees in extramural institutions and/or further disseminated by publication of the syllabus or making it available on the Internet.
- DOE: Will be requiring educational/ethics updates from all DOE institutions that are involved with human subjects research.
- DOE: Will be establishing an educational plan for all IRBs beginning in FY 1996.
- DOD: Will adopt the investigator assurances of familiarity with the Belmont Report, the Common Rule and related requirements as a standard for all activities involving human subjects research.
- DOD: Will incorporate research ethics into graduate medical education curricula at Military Department teaching hospitals.
- NASA: Works with international partners to enhance the ethical training and understanding of all investigators involved in space-related human research and to ensure an transnational sensitivity to ethical issues in human subjects research.

Issues:

- The activities above reflect federal agencies' ongoing attention and commitment to measures for enhancing the protection of human subjects.
 - The public may be expecting more, especially in light of the findings in the ACHRE report regarding contemporary human subjects research.
- (b) Invite associations of medical schools and universities as well as scientific societies

to join with the Government in launching a broad initiative to heighten the consciousness of the research community with respect to ethics of human subjects research. These might include the expansion of existing university-based research ethics programs and convening workshops in conjunction with the annual meetings of these different organizations.

Issues:

- This option will require the cooperation of various non-governmental agencies that may have slightly varying views of the need to do this. However, their collaboration would facilitate the process and provide greater credibility vis-a-vis the research community.
 - If successfully implemented, this option could yield a high profile activity.
 - This option would expand upon what the Government is currently doing but does not make human subjects research ethics a federal requirement.
 - Additional resources will be required for implementation of this option.
- (c) OPRR can convene, in conjunction with its counterparts in the other federal agencies, 2-3 regional workshops of IRB chairpersons to allow for the exchange of ideas/approaches, to stimulate the discussions of common problems and to address emerging issues in the arena of human subjects protection.

Issues:

- This approach will highlight for IRB chairs the importance that the Government attaches to the ethics of human subjects research and the need to pay continuing attention to this area.
 - The inclusion of IRB chairpersons only limits the audience that needs to be involved in such events.
 - This option may be perceived as a low profile activity.
 - Additional resources will be required for implementation of this option.
- (d) The President can announce that he will be signing an Executive Order establishing the National Bioethics Advisory Commission (NBAC) and introduce the chairperson of the Commission.

Issues:

- The establishment of NBAC would signal the Administration's commitment to obtaining expert advice and public input on issues of bioethics, correcting the long absence of such a deliberative body.
- In order to have this scenario materialize, the paperwork and other requirements for establishing NBAC must be completed and the chairperson selected/approved before September 22.
- The NBAC will neither be, nor be seen as, dominated by federal agencies since none of the 15 members may be federal employees.
- The NBAC will be uniquely qualified to carry out this assessment in that it is an advisory body independent of the federal agencies with at least one member from each of the following categories of primary expertise: (i) philosophy/theology; (ii) social/behavioral science; (iii) law; (iv) medicine/allied health professions; and (v) biological research.
- This option can be implemented in conjunction with other options.
- This option may be viewed by some as handing off the recommendations of one committee to another even though by happenstance the NBAC is an ideal mechanism for operationalizing some of the ACHRE's recommendations.
- Funds to support the NBAC must be identified.

Recommendation 9

The Advisory Committee recommends to the Interagency Working Group that the IRB component of the federal system for the protection of human subjects be changed in at least the five critical areas described below.

- 1. Mechanisms for ensuring that IRBs appropriately allocate their time so as to enable adequate review of studies that pose more than minimal risk to human subjects. This may include the creation of alternative mechanisms for review and approval of minimal risk studies.**

Response

- (a) Agencies will remind institutions and their IRBs that the current regulations provide for an expedited review process for certain categories of minimal risk research and for minor changes in ongoing research and emphasize their continued and enhanced use of this mechanism.

Issues:

- Action can be immediate with no change in regulations or federal policy required.
 - There is an existing, proven, effective mechanism for implementing this option, i.e., the authoritative OPRR Reports of the Office for Protection from Research Risks which is not only issued and delivered by direct mail to the IRBs and research communities (5,500 addressees worldwide) but also widely reprinted. DOD and DOE have similar newsletters that can also be used for this communication.
 - This option may be seen as insufficient since it does not offer a new alternative.
- (b) Consider extending a pilot program to reduce the administrative burdens on award applicants (known at NIH as the "Just-In-Time" experiment) to include a feature that would permit IRBs to delay their review of proposed research until preliminary determinations of the proposals' competitiveness have been made by the agency.

Issues:

- Under this option, IRBs would be relieved of the requirement to review research proposals which will not be sufficiently competitive for agency funding, while preserving the requirement that IRB review be carried out prior to the agency's scientific peer review.
- If the pilot program is effective without diminishing human research subject protections, it can be expanded within NIH and to other federal agencies.
- Even if successful, results would not be available from the pilot testing phase for approximately 18 months.
- There is no guarantee that, even if the IRBs' workload were reduced by this approach, the IRBs would allocate the additional time available to review of studies that involve more than minimal risk to research subjects.
- The closer in time the IRB review is to an agency's decision to fund and the greater the likelihood of funding, the more "pressure" there

may be for the IRB to approve the research proposal.

- If IRBs wait for the agency's preliminary determination regarding the relative competitiveness of research proposals before conducting their own review, IRBs will have less time in which to schedule their review if they are to carry it out prior to the agency's scientific peer review.

- (c) Ask the Human Subjects Research Subcommittee of the Health, Safety and Food Research Committee of the National Science and Technology Council to consider the implications of implementing this subrecommendation.

Issues:

- All federal agencies that conduct or support human subjects research are represented on this Subcommittee which will therefore be a reasonable forum in which to discuss this issue.
 - The interests of IRBs would not be adequately represented in discussions within the Subcommittee.
2. **Mechanisms for ensuring that the information provided to potential subjects (a) clearly distinguishes research from treatment, (b) realistically portrays the likelihood that subjects may benefit medically from their participation and the nature of the potential benefit, and (c) clearly explains the potential for discomfort and pain that may accompany participation in the research.**
3. **Mechanisms for ensuring that the information provided to potential subjects clearly identifies the federal agency or agencies sponsoring or supporting the research project in whole or in part and all purposes for which the research is being conducted or supported.**
4. **Mechanisms for ensuring that the information provided to potential subjects clearly identifies the financial implications of deciding to consent to or refuse participation in research.**

Response

- (a) Implement the above three subrecommendations by instructing IRBs and investigators to address these issues in protocols and consent procedures/forms.

Issues:

- If immediate action is deemed appropriate, the President can announce that these requirements now apply to all recipients of federal research funds, or an interagency working group can develop the appropriate instructions and issue them as a government-wide policy.
 - Agencies do not have any objections to these subrecommendations.
- (b) Announce that on October 2-3, 1995, the Department of Energy, in conjunction with the Subcommittee on Human Subjects Research, Committee on Health, Safety, Food Research & Development, National Science and Technology Council, will convene staff from all federal agencies conducting or supporting human subjects research. Federal officials will be briefed on ACHRE findings and recommendations and caucus for 2 days on at this conference. (The Subcommittee on Human Subjects Research meets bimonthly to coordinate implementation of the Federal Policy for Protection of Human Subjects and will be assessing actions to be taken by federal officials subsequent to the October 2-3 conference.)

Issues:

- Demonstrates an ongoing commitment by federal agencies to enhancing the existing system for the protection of human subjects.
 - Allows federal agencies to combine their experiences in a public forum, focusing on the issues that are considered important by the ACHRE, including those in these three subrecommendations.
 - Some may view this option as either perfunctory or non-responsive since the conference agenda does not directly address the above subrecommendations.
5. **Recognition that if IRBs are to adequately protect the interests of human subjects, they must have the responsibility to determine that the science is of a quality to warrant the imposition of risk or inconvenience on human subjects and, in the case of research that purports to offer a prospect of medical benefit to subjects, to determine that participating in the research affords patient-subjects at least as good an opportunity of securing this medical benefit as would be available to them without participating in research.**

Response

Issue an official reminder to IRBs that they already have the responsibility to review the science in research proposals to determine the appropriateness of the use of human subjects in such research, and to stress that patients participating in therapeutic research should have access to the same level of medical care that would have been available to them were they not participating in research. IRBs have the authority to call upon external resources for expertise in areas not represented by their members.

Issues:

- This option could be implemented very rapidly and be widely disseminated within a very short timeframe.
- As indicated in Option (a) under Subrecommendation 9.1, there are already existing mechanisms, OPRR Reports as well as similar DOD and DOE newsletters, which have proven to be very effective in communicating policies and policy interpretations to the research community.
- This option, however, may be viewed by some as not doing enough.

Recommendation 10

The Advisory Committee recommends to the Interagency Working Group that a mechanism be established to provide for the continuing interpretation and application of ethics rules and principles for the conduct of human subject research in an open and public forum. This mechanism is not provided for in the Common Rule.

Response

The National Bioethics Advisory Commission would be the ideal body to implement this recommendation. Inasmuch as the NBAC is intended "to consider current and prospective issues pertinent to the conduct of research on human biology and behavior and to identify broad, overarching principles to govern the ethical conduct of such research", this recommendation fits very appropriately with the NBAC's charter. Under provisions of the Federal Advisory Committee Act, all NBAC meetings would be open and provide for public access. (See Recommendation 8, Option d.)

Issues:

- The President must be able to announce that he is or will be shortly signing an Executive Order to establish the NBAC.

- Funds for supporting NBAC must be identified and secured.

Recommendation 11

The Advisory Committee recommends to the Interagency Working Group that at least the following four steps be taken to improve existing protections of the rights and interests of military personnel with respect to human subjects research.

1. **Review of policies and procedures:** Policies and procedures governing research involving human subjects should be reviewed to ensure that they (1) clearly state that participation as research subjects by members of the armed services is voluntary and without repercussions for those who choose not to participate; and (2) clearly distinguish those activities that are research and therefore discretionary on the part of the member of the armed services from other activities that are obligatory, such as training maneuvers and medical interventions intended to protect the troops.

Response

DOD Directives and Military Department regulations require the voluntary and fully informed consent of any person participating as a subject in research projects sponsored or conducted by the Department, as required by 32 CFR 219 (The Common Rule).

2. **Appreciation of regulations:** Education in applicable human subjects regulations should be a routine component of the training of officers and of investigators. Mechanisms are needed to ensure that all officers and investigators have an adequate appreciation of all regulations (including DOD regulations and directives and Service regulations) that bear on the conduct of research involving human subjects, including an appreciation of the conditions under which such regulations apply, the role of officers in interpreting such regulations, and how such regulations are to be implemented.

Response

DOD will incorporate education in human subjects regulations into executive level training for commanders and senior leadership. DOD will also incorporate methods for providing detailed training for investigators, institutional review board members, research administrators and research support personnel.

Issues:

- Such training would better prepare commanders, senior leadership and all members of research teams to better protect the rights and interests of personnel under their supervision. (It is not effective or efficient to attempt to train every commissioned officer in the Armed Services in research ethics, directives and regulations.)
 - Such training would add to the considerably lengthy training schedule.
 - Implementation of this option would require commitment of diminishing resources.
3. **Maximizing voluntariness:** The Service Secretaries should consider the situations under which it would be appropriate to make obligatory two practices for maximizing voluntariness that have been employed on an *ad hoc* basis in some military research. First, that no unit officers nor noncommissioned officer (NCOs) be present at any subject recruitment session in which members of units are informed of the opportunity and asked to participate in research by investigators; and second, that an ombudsman not connected in any way with the proposed research be present at all such recruitment sessions to monitor that the voluntariness of participation is adequately stressed and that the information provided about the research is adequate and accurate.

Response

- (a) DOD is revising its Directive or Military Department regulations such that officers and senior noncommissioned officers in the chain of command will not be present during research recruitment briefings. This requirement shall apply to research and development studies where briefings are given to potential subjects.

Issues:

- This approach minimizes the risk that military personnel will be influenced to volunteer as research subjects because of the presence of supervisors.
 - Measures must be taken to ensure that officers and noncommissioned officers are not inadvertently denied the opportunity to participate as research subjects.
- (b) DOD is also revising its Directive or Military Department regulations to require that an ombudsman be present at group recruitment briefings to monitor that the voluntary nature of participation is stressed and that adequate information is provided about the proposed research.

Issues:

- This approach helps ensure that research participation by military personnel is voluntary and that consent is truly informed.
- Under field conditions, an ombudsman with no conflict of interest may be difficult to identify.

4. **Maintenance of a registry: The Secretaries of the Navy and the Air Force should be directed to adopt the policy of the Army, as detailed in Army Regulation 70-25, to maintain a registry of all volunteers in human studies and experiments conducted under Research and Development programs. Such registries serve to facilitate confirmation of participation in research by subjects and their long-term follow-up.**

Response

DOD is revising its Directive on human subjects research to include a provision that each of the Military Departments establish and maintain a registry of volunteers in biomedical studies conducted under research and development programs.

Issues:

- Such registries will facilitate the identification and long-term follow-up of research subjects.
- Development of these registries requires commitment of diminishing resources.
- Issues of privacy must be taken into consideration in the development of these registries.

Recommendation 12

The Advisory Committee recommends that the Interagency Working Group take steps to improve three elements of the current federal system for the protection of the rights and interests of human subjects -- oversight, sanctions and scope.

The following three subrecommendations should be collectively referred to the National Bioethics Advisory Commission. However, additional options for implementation are

also outlined below.

1. Oversight mechanisms to examine outcomes and performance.

Response

- (a) Develop an interagency grants program to stimulate the research community to propose a variety of approaches to evaluating the performance and outcomes of the Government's system for protecting the rights/interest of human subjects, e.g., the recent program announcement of the National Institute of Mental Health seeking proposals for studying the informed consent process in research subjects with mental disorders.

Issues:

- The outcome of such studies will provide a scientific basis for assessing the adequacy and weaknesses of the current informed consent process.
 - This strategy allows the Government to solicit a variety of approaches to evaluating the system and select the best for funding.
 - This approach permits the pooling of funds so that agencies that might otherwise not be able to award grants in this area can "piggyback" on the interagency effort. This option would be administratively efficient and less costly for all participating agencies.
 - Need to identify a lead agency and develop a plan that all participating agencies can endorse. NIH is willing to assume this role.
- (b) Strengthen the federal agency offices with responsibility for oversight of human subjects protection.

Issues:

- Investing in the individual offices with oversight responsibilities makes clear the priority the agency is giving to human subjects protection and increases the opportunity and options for providing adequate oversight.
- This approach may not necessarily address all of the Advisory Committee's concerns about the deficiencies at the local level.

- Additional resources may be required by some agencies to implement this option.
- (c) Initiate a program for evaluating the cost effectiveness of different approaches for ensuring quality control of institutional systems for protection of human subjects.

Issues:

- This option will allow the Federal Government to review a broader array of approaches and strategies to determine which ones are really cost effective.
 - This option will not address the concerns of the Advisory Committee if it (a) focuses more on process than outcome and (b) does not include the patient's perspective.
 - Additional resources will be required to implement this option.
- (d) Implement the NIH study to evaluate the implementation of the federally mandated Human Subjects Protection Program, specifically the extent to which the Program provides adequate protection for the rights and well-being of human subjects.

Issues:

- This survey will involve surveys of institutional officials, IRB chairpersons, IRB administrators, IRB members and investigators as well as extraction of data from IRB records and documents. Because of the size of this effort, this study may yield a large amount of information on the current IRB system.
- Because of its complexity and multitude of surveys, the results of this study will not be available for another two years.

2. Appropriateness of sanctions for violations of human subjects protection.

- (a) Provide the same sanctions for violation of human subjects regulations as exist for violation of animal welfare regulations.

Issues:

- Enactment of legislation would be required to implement this option.

- regulations.
- This approach would create a parity between the two sets of
 - It took some 10 years for the 16 signatories of the Common Rule to resolve the outstanding issues before issuance of the Rule. Therefore, it is conceivable that enactment of this legislation may be a very lengthy, drawn-out process.
 - This may not be necessary since current sanctions, including debarment, whereby an investigator or institution is prohibited from receiving federal research funds for a specified period of time, appear to working adequately.
- (b) In the case of DOD, failure to comply with its Directives and Military Department regulations can result in administrative and judicial punishment under the Uniform Code of Military Justice.

3. Extension of human subjects protection to nonfederally funded research.

Response

- (a) Enact legislation that would extend requirements for protection of human subjects to research not funded or conducted by the Federal Government (such as most research involving assisted reproductive technologies).

Issues:

- Enactment of legislation is unlikely in this climate of regulatory reform and cost-benefit risk assessment.
 - Enforcement of such legislation would require a rather extensive bureaucratic, regulatory infrastructure because the existing Federal Government infrastructure will not be able to implement such a requirement.
 - On the other hand, an aggressive initiative may be an appropriate strategy since it involves the sensitive issue of putting at risk human subjects who participate in non-federally funded research.
 - Additional resources would be required to implement this option.
- (b) Work with the American Medical Association, state medical societies and

state licensing boards to launch an educational program to familiarize physicians and others engaged in nonfederally funded research with the ethical considerations in conducting human subjects research.

Issues:

- This approach has the advantage of joining with the medical community in raising the consciousness of physicians and others who conduct or plan to conduct human subjects research.
- Part of this approach could involve setting up a helpline that responds to requests for information on appropriate conduct of human subjects research.

Recommendation 13

The Advisory Committee recommends that the federal government review the area of compensation for research injuries of future subjects of federally funded research, particularly reimbursement for medical costs incurred as a result of injuries attributable to a subject's participation in such research, and create a mechanism for the satisfactory resolution of this long-standing social issue

Response

This issue has been studied off and on over the last 20 years but, because of its complexity, has never reached resolution. With the establishment of the proposed National Bioethics Advisory

Commission and the release of the ACHRE report calling for compensation of subjects involved in Cold War era radiation experiments, the time may be right for a definitive examination of the issue and development of recommendations/guidelines for compensation of injured human subjects.

Issues:

- Response to this recommendation should have the input of the Subgroup on Compensation. Although the Compensation Subgroup is addressing compensation for past human subjects, nonetheless, there may be some guiding principles that could also be applicable to future human subjects.
- Need to distinguish between (1) providing appropriate medical care and monitoring and (2) offering monetary compensation to injured human subjects.

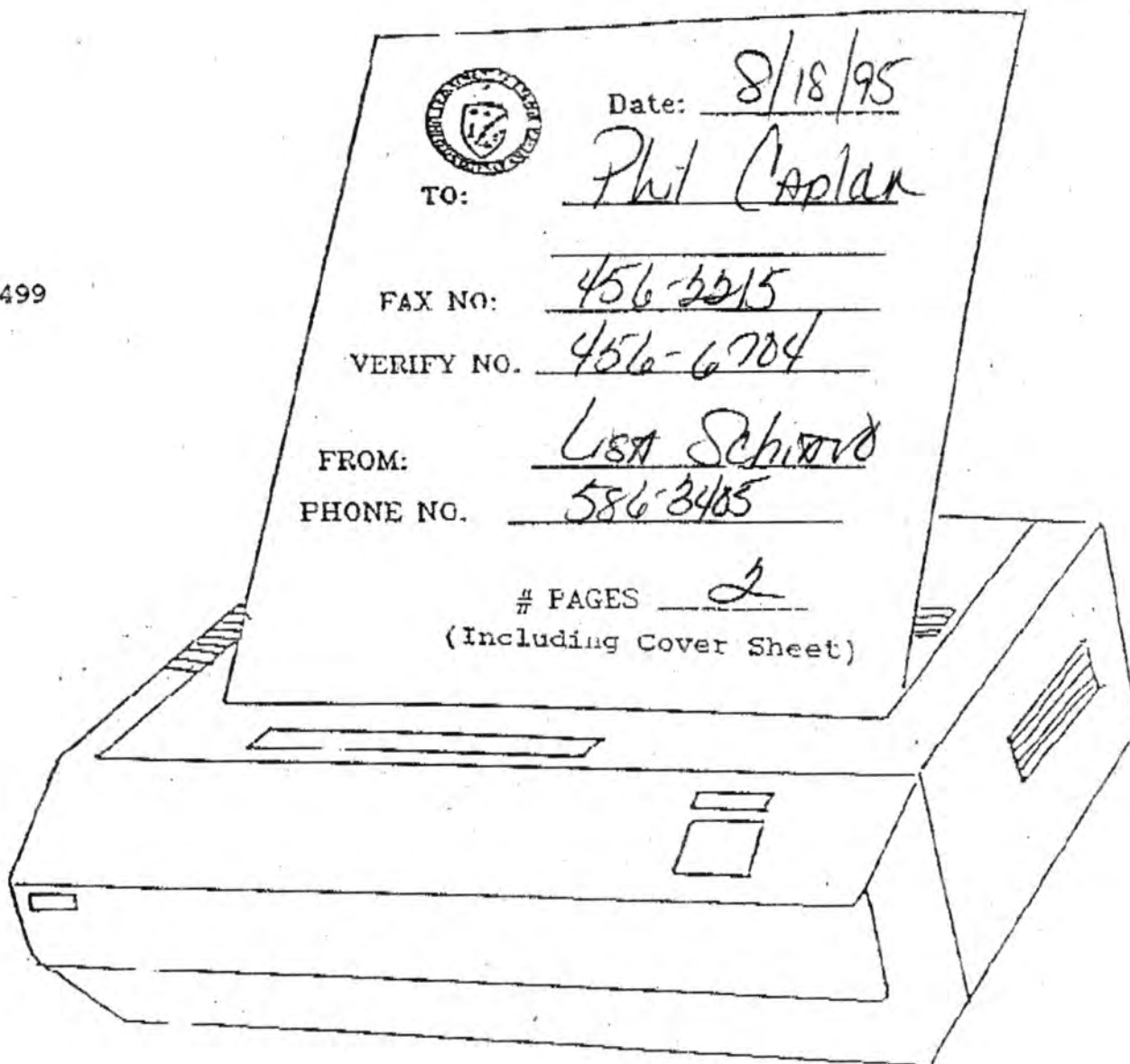
- Need to consider if there should be a distinction between dignitary harm and physical harm.

OFFICE OF THE GENERAL COUNSEL

U.S. DEPARTMENT OF ENERGY

WASHINGTON, D.C.

(202) 586-1499



 Date: 8/18/95

TO: Phil Caplan

FAX NO: 456-5515

VERIFY NO. 456-6704

FROM: Lisa Schiro

PHONE NO. 586-3405

PAGES 2
(Including Cover Sheet)

REMARKS: _____



Department of Energy

Washington, DC 20585

August 18, 1995

To: Ellyn Weiss
Pat Glynn/Paul Yanowitch
Eric Macris

From: Lisa Schiavo 

Re: **New Option for Recommendation 1**

As discussed in the August 16, 1995 meeting, the following additional option was proposed to respond to the Committee's first recommendation, which covers the plutonium injection experiments:

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.

Response: Work with Congress to pass legislation to apologize and compensate the affected families for any dignitary harm that may have been suffered by the subjects of the experiments, either because the subjects' consent was not adequately obtained, or the government improperly denied the subjects and their families an opportunity to pursue legal redress.

Compensation would be commensurate with amounts paid to the Japanese internees and their survivors (\$20,000) and claimants would be asked to release claims of dignitary harm against the government, its contractors and their employees.

However, the proposed legislation would explicitly preserve any existing or future claim of physical harm resulting from the experiments. [The government could also defer claims of physical harm in accordance with any decision made respecting recommendation 2.]

Please let me know if you have any comments or questions (586-5289).

cc: Phil Caplan
Steven Neuwirth



Reports/
Recommendations
of ACHRE
[and responses
to] —



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

November 15, 1994

MEMORANDUM FOR T.J. GLAUTHIER

THROUGH: Kathy Peroff *KP*
FROM: Emily Pelton *EP*
SUBJECT: November 15 Human Radiation Experiments
Advisory Committee Meeting (and related issues)
CC: Phil Caplan

This Morning's Meeting

At a meeting of the Human Radiation Experiments Advisory Committee, held today in Washington, Ken Feinberg presented the initial findings of the Advisory Committee's "Remedies Subcommittee."

Attached is a discussion memo from the Subcommittee to the full Advisory Committee about remedies, and a draft memo from Lisa Schiavo (DOE General Counsel's Office) to Bob Nordhaus, summarizing the Advisory Committee's discussion. I think you will find both documents worth reading.

I have several thoughts on this morning's session, which I would like to discuss with you, at your convenience.

Next Compensation Subcommittee Meeting

I spoke to Phil today about convening the Compensation Subcommittee. As he may have mentioned to you, he would like to first hold a smaller meeting, (to include Joel Klein, yourself, Bob Nordhaus, Pat Glynn, and several others), at which the Advisory Committee could brief the Administration on its approach to remedies. Phil is going to organize this meeting, possibly before Thanksgiving. Any meeting of the Compensation Subcommittee would wait until after this session.

National Bioethics Advisory Committee

Jill Blickstein says that the Health Branch did not provide any input to formulating the proposal published by OSTP in the Federal Register. Although she had not yet briefed Nancy Ann, Jill's sense was that Nancy Ann would probably not want to become substantively involved in this issue unless major budgetary questions arise. According to Sarah, NSF also may have some concerns about the NBAC proposal; (NSF staff with whom Sarah spoke, for example, suggested that it might be preferable to direct the Committee to respond to specific ethics questions raised by the Agencies, rather than having the Committee define issues for its own consideration).

I am not aware of how other Agencies may have reacted to this proposal, or whether the FR notice was cleared through OMB. However, I agree that there are major jurisdictional issues associated with the proposal as currently formulated. (Moreover, the Advisory Committee today discussed the possibility of proposing guidelines that would govern the conduct of research throughout the Federal government, which would raise concerns similar to those you identified.)

I think it might be useful for us to request an OSTP briefing on the proposal (and the process they have followed in developing it). We could do this at the staff level and then discuss the issue with you, or we could include you in the briefing, as you prefer.

TAB L

◆◆◆DRAFT ◆ FOR DISCUSSION PURPOSES ONLY◆◆◆

MEMORANDUM

TO: Members of the Advisory Committee on Human Radiation Experiments

FROM: Remedies Subcommittee

DATE: November 10, 1994

RE: Proposed Methodology for Determining Appropriate Federal Responses Where Wrongs or Harms Have Occurred

A central task for the Committee is to develop an ethical framework in which to construct its recommendations concerning guidelines for appropriate federal responses where wrongs or harms have occurred. The following are initial ideas on how to construct a section on remedies for the Committee's Final Report.

1. The Committee's recommendations should be in guidelines form only. The Committee should not propose specific levels of monetary compensation and should not get in the business of micro-managing specific remedy proposals. Instead, it should recommend to the President and the Congress a road map or blueprint of guidelines that can assist policymakers in deciding whether to provide remedies and, if so, what specific remedies might be appropriate. Such guidelines should be sure to focus on experiments as a class.
2. "Remedies" should be viewed by the Committee to include a broad range of responses. Indeed, the Committee can perform a valuable public service by pointing out that many of its recommendations do not involve direct monetary compensation. For example, the Committee should explore creative alternatives such as the role of a national public apology or other significant symbols of national regret, as well as medical monitoring, health and life insurance, and counseling for emotional distress and anxiety, while recognizing the ethical implications that such responses may themselves engender.
3. The Committee must consider two seemingly distinct groups — those who were exposed to radiation in the course of biomedical research and those who received radiation through intentional releases. Although the Committee's Charter does not include exposures from weapons testing and uranium mining that affected atomic veterans, uranium miners, and Marshall Islanders, subsets of these groups may still come within the purview of the Committee's recommendations on remedies to the extent that they were the subject of "experimentation" in conjunction with mass exposures. Moreover, both groups involve thorny issues associated with medical causation — i.e., was the individual's injury caused by radiation exposure, in the context of latent illnesses, factual disputes over dosage

levels, effects of low-dose radiation, etc. Finally, even if the direct issue of mass exposure from weapons testing and uranium mining is outside of the Committee's mandate, the Committee may still want to review the existing statutory remedies available to radiation exposed persons.

4. Committee guidelines for appropriate responses could be based on a grid that charts the degree of government culpability on one line, and the degree of "harm" to the individual on the other. This grid could be based on the following key principles: 1) the easiest case for a response involves situations where individuals suffered recognized injury or death and the government action was knowing, intentional, and wrongful; 2) the most difficult case for a response involves situations where there is little, if any, evidence of medical and scientific causation of injury and the degree of government culpability is minimal at best; 3) between these two extremes lies a vast "gray area" where there are varying degrees of government culpability (negligent, reckless, knowing) and reasonable evidence of causation demonstrating either a known physical response or a statistically increased incidence of injury; 4) informed consent, or lack thereof, must be factored into this equation -- individuals can be "wronged" when they are the subject of research or experimentation without their consent, even if no attributable physical "harm" results; rather than think of failure to inform as an injury, it may make sense to consider with respect to government culpability -- i.e., the government's failure to inform (obtain informed consent) increases its culpability; 5) where there is no physical injury but the government's conduct is highly culpable, forms of redress may still be reasonable in order to have a deterrent effect on future government conduct and as a matter of justice.
5. The remedies guidelines should avoid any requirement of "dose reconstruction." Not only is it extremely difficult, as an evidentiary matter, to determine such dosage levels from decades ago, but the issue of remedies should not depend on such a provocative problematic effort.

fax draft to

Pat Glynn (DOJ): 616-4473
Emily Felton (OMB): 395-1086

November 15, 1994

MEMORANDUM FOR Robert R. Nordhaus

FROM: Lisa C. Schiavo

SUBJECT: November 15, 1994 Meeting of the Advisory
Committee on Human Radiation Experiments --
Remedies Discussion

Subcommittee Methodology

Ken Reinberg presented the Remedies Subcommittee's methodology for determining appropriate federal responses to past human radiation experiments. He outlined the following elements:

- The Committee will not make recommendations as to specific levels of compensation for various experiments. The Committee will instead issue guidelines, setting forth a blueprint or a set of variables for federal policy-makers to consider in formulating a compensation scheme for Congressional action.
- The Committee will set forth a series of options, ranging from monetary compensation, insurance or medical monitoring, an apology, or no response. There was concern expressed about not raising the expectations of interested members of the public who may not be covered by the Committee's recommendations.
- Any discussion of remedies will distinguish those experiments directed at specific or discrete groups of individuals from those experiments exposing populations to major releases (e.g., the uranium miners, residents of the Marshall Islands, and the atomic veterans). A grey area, however, might be the Green Run.
- The guidelines are likely to come in the form of a "grid" of available remedies, depending on the degree of government culpability on the horizontal axis, and the degree of harm on the vertical axis. Harm would range from disease/injury to a violation of personal integrity from a lack of informed consent. Absence of informed consent would also relate to the culpability axis. The grid would then serve as the guide for a further governmental entity to adjudicate specific cases.
- To attempt to reconstruct the causation question -- whether there was a medical harmful effect from a exposure to

radiation -- would be fool's mission for the Committee. Too much time has past, the Committee lacks the necessary resources for any dose reconstruction or causation determination, and any such endeavor would subject the Committee to criticism. Therefore, the Committee will embrace certain presumptions about the causal impact that radiation exposure had on subjects.

Committee Comment and Discussion

Feinberg acknowledged the Committee has not yet developed specific substantive criteria for determining government culpability and the nature of harm, but offered his personal views. He and other members made the following general comments:

- The Committee should treat differently past conduct that was viewed at the time as appropriate, but when viewed by current standards of ethical behavior, inappropriate. The law generally acknowledges that conduct is not punished when it conformed to then accepted standards. Feinberg commented, however, that some form of response in these cases may still be warranted, but he would be personally troubled about compensation in cases where researchers acted reasonably at the time.
- For the victims who are now deceased, and were not medically harmed by the experiment, but the experiment lacked informed consent, Feinberg believes a serious wrong has occurred. But an appropriate remedy should not go beyond perhaps an apology by the Government to the family. The victim has or her personal integrity violated, but nothing about this wrong should give rise to a remedy inuring to the benefit of the deceased's children or estate. Compensation should be considered for families only where death, disability, lost wages or loss of consortium resulted from the experiments.
- One of the biggest contribution the Committee can make in this area, other than telling the whole story, is to propose a purely prospective remedy, with no retributive value, but one grounded in deterrence. Specifically, the Committee could propose guidelines for procedures to be followed in all future human research. As a result of being put on notice of the way research should be conducted, researchers might henceforth be subject to civil penalties or loss of their license. Criminal penalties might also be fashioned as a result of the Committee's recommendations.
- Several Committee members noted that whatever recommendations are forthcoming should apply to all medical human research, not just human radiation experiments. Although the Committee's charge was limited to radiation experiments, the members agreed that the recommendations

would clearly have broader impact.

- The Remedies Subcommittee felt they lacked the ability to make ethical judgments about the propriety of past experiments, but were urged by other Committee members to make more specific recommendation about remedies next month.
- The Committee needs to be educated further about the usefulness of medical monitoring. Medical monitoring may be a likely candidate for certain classes of experiments (like the Green Run or the prisoners), but members acknowledge that medical monitoring may be a two-edged sword. Although early detection could be a possible benefit for certain conditions, it may be completely ineffective for that purpose, do nothing to prolong life, and cause unintentional consequences to individuals (like cancellation of health insurance).

OFFICE OF THE GENERAL COUNSEL

U.S. DEPARTMENT OF ENERGY

WASHINGTON, D.C.

FAX #:
COML:



Date: 11/17/94

TO:

Phil Caplan
W. H. Counsel

FAX NO:

(202) 456-6704

VERIFY NO.

(202) 456-2572

FROM:

Lisa Schiano

PHONE NO.

(202) 586-5289

PAGES

4

(Including Cover Sheet)

REMARKS: 11/15/94 meeting of the Advisory Committee
on Human Radiation Experiments -
Remedies discussion



Department of Energy

Washington, DC 20585

November 15, 1994

MEMORANDUM FOR Robert R. Nordhaus
General Counsel

Tara J. O'Toole
Assistant Secretary for Environment,
Safety and Health

FROM:

Lisa C. Schiavo *LS*

SUBJECT:

November 15, 1994 Meeting of the Advisory
Committee on Human Radiation Experiments --
Remedies Discussion

Subcommittee Methodology

Ken Feinberg presented the Remedies Subcommittee's methodology for determining appropriate federal responses to past human radiation experiments. He outlined the following elements:

- The Committee will not recommend specific levels of compensation for various experiments. The Committee will instead issue guidelines, setting forth a blueprint or a set of variables for federal policy-makers to consider in formulating a compensation scheme for Congressional action.
- The Committee will set forth a series of options, ranging from monetary compensation, insurance or medical monitoring, an apology, or no response. There was concern expressed about not raising the expectations of interested members of the public who may not be covered by the Committee's recommendations.
- Any discussion of remedies will distinguish those experiments directed at specific or discrete groups of individuals from those experiments exposing populations to major releases (e.g., the uranium miners, residents of the Marshall Islands, and the atomic veterans). A grey area, however, might be the Green Run.
- The guidelines are likely to come in the form of a "grid" of available remedies, depending on the degree of government culpability on the horizontal axis, and the degree of harm on the vertical axis. Harm would range from disease/injury to a violation of personal integrity from a lack of informed consent. Absence of informed consent would also relate to the culpability axis. The grid would then serve as the guide for another governmental entity to adjudicate specific cases.



- To attempt to reconstruct the causation question -- whether a subject was medically harmed from an exposure to radiation -- would be fool's mission for the Committee. Too much time has passed, the Committee lacks the necessary resources for any dose reconstruction or causation determination, and any such endeavor would subject the Committee to criticism. Therefore, the Committee will embrace certain presumptions about the causal impact that radiation exposure had on subjects.

Committee Members' Comments and Discussion

Members acknowledged the Committee has not yet developed specific substantive criteria for determining government culpability and the nature of harm. Feinberg and other members made the following general comments:

- The Committee should treat differently past conduct that was viewed at the time as appropriate, but when viewed by current standards of ethical behavior, inappropriate. The law generally acknowledges that conduct is not punished when it conformed to then accepted standards. Feinberg commented, however, that some form of response in these cases may still be warranted, but he would be troubled about compensation for cases where researchers acted reasonably at the time.
- For the victims who are now deceased, and were not medically harmed by the experiment, but did not give informed consent, Feinberg believes a serious wrong occurred. But an appropriate remedy should not go beyond perhaps an apology by the Government to the family. The victim's personal integrity might have been violated, but nothing about this wrong should give rise to a remedy inuring to the benefit of the deceased's children or estate. Compensation should be considered for families only where death, disability, lost wages or loss of consortium resulted from the experiments.
- One of the biggest contributions the Committee can make in this area, other than telling the whole story, is to propose a purely prospective remedy, with no retributive value, but one grounded in deterrence. Specifically, the Committee could propose guidelines for procedures to be followed in all future human research. As a result of being put on notice of the way research should be conducted, researchers might henceforth be subject to civil penalties or loss of their license. Criminal penalties might also be fashioned as a result of the Committee's recommendations.
- Several Committee members noted that whatever recommendations are forthcoming should apply to all medical human research, not just human radiation experiments.

Although the Committee's charge was limited to radiation experiments, the members agreed that the recommendations would clearly have broader impact.

- The Remedies Subcommittee felt they lacked the ability to make ethical judgments about the propriety of past experiments, but were nonetheless urged by other Committee members to make more specific recommendations about remedies next month.
- The Committee needs to be educated further about the usefulness of medical monitoring. Medical monitoring may be a likely candidate for certain classes of experiments (like the Green Run or the prisoner experiments), but members acknowledged that medical monitoring may be a two-edged sword. Although early detection could be a possible benefit for certain conditions, it may be completely ineffective for that purpose, do nothing to prolong life, and cause unintended consequences to individuals (like cancellation of health insurance).

cc: J. Patrick Glynn, DOJ
Emily D. Pelton, OMB

FACSIMILE TRANSMITTAL SHEET

TO:

FROM:

DELIVERY TIME: 29-AUG-1995 16:25:42

DELIVERY NODE: 2,

SESSION: 2 - 1097

PAGES: 11 (including this page)

INTERAGENCY WORKING GROUP

CIA:	LATELL, BRIAN.....	703-351-2698	[fax 243-8343]
	PEREIRA, JOHN.....	703-351-2802	[fax 243-8343]
	WARNER, MICHAEL	703-351-2621	[fax 522-9280]
DEFENSE:	BAILEY, CLAUD.....	703-442-5675	[fax 847-0890]
	PIERRE, JOAN MA.....	703-325-7302	[fax 325-2959]
	SOPER, GORDON.....	703-697-5561	[fax 695-0476]
JUSTICE:	GLYNN, PAT.....	616-4200	[fax 616-4473]
	PLAZA, EVA.....	514-3309	[fax 514-8071]
HHS:	BALDWIN, WENDY...	301-496-1096	[fax 402-3469]
	ELLIS, GARY.....	301-496-7005	[fax 402-2071]
	ENGSTROM, LILY.....	301-402-2246	[fax 402-3469]
	HENDERSON, D.A.....	410-955-1624	[fax 889-6514]
NASA:	FERGUSON, EARL.....	358-1894	[fax 358-3038]
	HOLLOWAY, HARRY	358-0122	[fax 358-4174]
	STOKLOSA, JANIS...	358-2209	[fax 358-3038]
OMB:	GLAUTHIER, T.J.....	395-4561	[fax 395-4639]
	MACRIS, ERIC.....	395-3807	[fax 395-4817]
OSTP:	GWIN, HOLLY.....	456-2735	[fax 456-6049]
	LEVINSON, RACHEL..	456-6137	[fax 456-6027]
VA:	GRACEY, HAROLD.....	273-4808	[fax 273-4877]
	MATHER, SUSAN.....	535-7182	[fax 535-7572]
	OTCHIN, NEIL.....	565-7057	[fax 565-7572]
	TACKETT, NANCY.....	273-5034	[fax 273-5993]
WH:	CAPLAN, PHIL.....	456-2702	[fax 456-2215]

August 29, 1995

MEMO TO: INTERAGENCY WORKING GROUP
REPRESENTATIVES

FROM: LORI AZIM, DEPARTMENT OF ENERGY
202/586-5319

SUBJECT: ATTACHED INFORMATION ON OPTIONS

I have attached the following items:

1. Overall summary of proposed Federal responses.
2. One page summary of Openness/Classified Research Options paper.
3. Revised draft of the Openness/Classified Research Options paper.

***PLEASE REVIEW THE ATTACHED ITEMS AND RETURN TO
ELLYN WEISS VIA FAX BY 9 AM THURSDAY MORNING,
AUGUST 31ST WITH ANY COMMENTS YOU MAY HAVE.***

Ellyn's FAX number is 202/586-6010. Her phone number is 202/586-0858. Please call Ellyn if you have any questions. I will be out of the office until Tuesday, September 5th.

Thanks!

Thanks!

3/243

SUMMARY

PROPOSED GOVERNMENT RESPONSES TO RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

Background

The Advisory Committee on Human Radiation Experiments, chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University, was established by President Clinton in January, 1994. Acting in cooperation with Federal agencies, which were directed by the President to search for records related to human radiation research and provide them to the Advisory Committee, the Committee was charged to provide expert advice to the Cabinet-level Interagency Working Group on scientific and ethical issues related to biomedical experiments involving ionizing radiation and to a list of intentional environmental releases of radiation. The Committee was to focus on the period 1944-1974 (when government-wide regulations on human subjects research were adopted) but was permitted to go beyond.

Final Report of the Advisory Committee

The Committee report, currently in near-final form, begins by identifying the ethical standards that applied to the government and to the medical and research professions in the post-war period. Several "case studies" are then reviewed in detail, including the injections of plutonium into 18 hospital patients during World War II, research with prisoners, and total body irradiation done in clinical settings but partially funded by the military. Intentional environmental releases of radioactivity are also reviewed.

The Committee also considered issues related to some radiation exposures associated with government activity that are not experiments; that is, persons were not exposed for the purpose of research. These include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

Finally, the Committee reviewed 125 current or recent Federally-funded studies (not limited to radiation research) and interviewed patients at leading hospitals in order to gauge the adequacy of procedures for obtaining informed consent from subjects and evaluating research risks and to sample attitudes toward human subject research.

Advisory Committee Recommendations

The Committee's recommendations fall into the following three major areas:

- **Biomedical Experiments and Population Exposures, 1944-1974**
- **Current Human Subject Protection**
- **Secrecy and Openness**

Government Response to Recommendations

A group of representatives from all agencies represented in the Interagency Working Group, including the Departments of Energy, Defense, Health and Human Services, Veterans Affairs, and Justice, the National Aeronautics and Space Administration, and the Central Intelligence Agency, with participation by the Office of Management and Budget and the White House Office of Science and Technology Policy, has been meeting over the past month to consider government-wide options to address the recommendations of the Advisory Committee. This group divided into three Subcommittees paralleling the three major areas of the Advisory Committee's recommendations. Each Subcommittee developed options, which were presented to the entire group for discussion. The options covered the entire range of potential government responses, from those that agencies can take individually and in cooperation, to those that call for Presidential action.

The following three packages - one from each Subcommittee - represent the consensus view of the group of agency representatives.

INTERAGENCY WORKING GROUP
Subcommittee on Openness & Classified Research

OPTIONS PAPER SUMMARY

The responses described in the following pages address the Advisory Committee on Human Radiation Experiments' findings and recommendations in the areas of secrecy and openness, Recommendations 14 through 17. These Recommendations fall into two general categories. First, additional safeguards are recommended for classified human subjects research and environmental oversight of classified programs. The Recommendations are not limited to radiation-related research or programs. Second, the Committee calls for continued progress in making government records publicly accessible.

The proposed government actions, summarized below, range from those that can be announced immediately and would apply across the government, to those which will require additional development and consultation:

- Presidential directive that no waivers of full informed consent will be permitted in classified research and that sponsoring government agency will be disclosed to potential subjects in all classified research;
- Request that EPA review whether additional steps are necessary to ensure robust environmental oversight of classified programs;
- Direct Interagency Working Group, working with National Archives and Records Administration, to develop aggressive plan to increase public accessibility of government's records, including use of new technological advances and to review policies governing access to records of contractors;
- Redesignate records related to human subjects research to prevent future destruction;
- High-priority review of CIA recordkeeping system, performed by the National Archives, addressing means to improve public access;
- Direct CIA to give top priority in declassification review to human subjects research records.

INTERAGENCY WORKING GROUP
Subcommittee on Openness & Classified Research

OPTIONS PAPER

RECOMMENDATION 14a: The Advisory Committee recommends to the Interagency Working Group the adoption of a Federal policy requiring the informed consent of all human subjects of classified research, and that this requirement not be subject to exemption or waiver. In all cases, potential subjects should be informed of the identity of the sponsoring Federal agency and that the project involves classified information.

RECOMMENDED GOVERNMENT RESPONSE:

The President directs all departments and agencies that, effective immediately, there will be no waivers of informed consent for Federally funded classified research. President also directs that in all Federally funded classified research, two additional elements of information will henceforth be provided when consent is sought from potential human subjects: (i) the identity of the sponsoring Federal agency, and (ii) a statement that the project involves classified information.

The National Bioethics Advisory Committee is requested to evaluate whether the federal rules governing human subjects protection should be revised to codify the President's directive.

RECOMMENDATION 14b: The Advisory Committee recommends to the Interagency Working Group the adoption of a federal policy requiring that classified research involving human subjects be permitted only after the review and approval of an independent panel of appropriate nongovernmental experts and citizen representatives with security clearances, charged with determining: 1) that the proposed experiment has scientific merit; 2) that risks to subjects are acceptable and risk/benefit balance is appropriate; 3) that prospective subjects have been fully informed and participation is voluntary. Records should be kept permanently.

RECOMMENDED GOVERNMENT RESPONSE:

Institutional Review Boards ("IRB") are already required to include non-government and citizen representatives. The President directs all agencies to ensure the participation of non-government persons in review of classified research, either by establishing a dedicated panel for classified research or by ensuring that IRB members all have the necessary security clearances.

RECOMMENDATION 15a: The Advisory Committee recommends that an independent review panel be assigned the task of reviewing any planned or intended environmental releases of substances in cases where the release is proposed to take place in secret, or in circumstances where any aspect of the environmental review process required by law is conducted in secret.

RECOMMENDED GOVERNMENT RESPONSE:

The President indicates that EPA, in conjunction with Federal agencies conducting classified programs, has an initiative underway to improve environmental oversight and establish more rigorous regulatory procedures for classified facilities. Creating a new regulatory entity would add to the bureaucratic complexities of ensuring environmental safety but the President will seek EPA's views on whether additional steps are necessary to ensure robust environmental oversight of classified facilities and programs.

RECOMMENDATION 15b: The Advisory Committee recommends to the Interagency Working Group that an appropriate government agency, currently the Environmental Protection Agency, maintain a program directed at the oversight of classified programs, with suitably cleared personnel. This program should maintain critical records, such as environmental impact statements and environmental permits permanently. The agencies subject to regulation should ensure the timely consideration of environmental impacts and oversight and the timely provision of all necessary clearances. EPA should provide regular unclassified reports to Congress describing the extent of its activities as well as any significant problems.

(The Interagency Working Group sought clarification from the Committee on the intent of this recommendation. According to the executive director, the Committee is not asking here for expansion of EPA's substantive authority under NEPA and other existing environmental laws.)

RECOMMENDED GOVERNMENT RESPONSE:

The President directs that permanent files on classified environmental impact statements and environmental review of classified activities shall be maintained by EPA.

RECOMMENDATIONS 16(1), 16(2), 16(3): The Advisory Committee recommends that the Interagency Working Group take steps to ensure the continued application of the lessons learned from the efforts to organize and make accessible to the public, and the government itself, the nations's historical records.

- (1) The most important historical collections should be entrusted to the National Archives. The agencies and the National Archives should review the extent to which this is now being done and develop policies to hasten the transfer of agency records to the National Archives.
- (2) Agencies should make readily available all existing inventories, indices, folder listings and other finding aids to record collections now under agency control. Classified finding aids should undergo declassification review and declassified versions of these finding aids should be also be made available.
- (3) The Interagency Working Group should ensure the development of policies to improve public access to records held by agencies or deposited in Federal Record Centers.

RECOMMENDED GOVERNMENT RESPONSE:

The President commends the agencies for the progress made through this project in delivering information to people. He commits the administration to continuing aggressively down the path to openness exemplified by this and other initiatives. He directs the Interagency Working Group, working with the National Archives and Records Administration, to advise him on measures to make the government's records genuinely accessible to citizens, which should include consideration of the potential uses of new technology to enhance access. The Interagency Working Group should be asked to report back by a date certain within a few months.

RECOMMENDATION 16(4): The Advisory Committee recommends that agencies maintain complete records, available to the public, of document destruction.

RECOMMENDED GOVERNMENT RESPONSE:

The President should, via Executive Order, institute new policy regarding human subjects research records of destruction. Such Order should mandate that all records of destruction regarding classified research be maintained permanently by National Records Centers. Disposition instruction of current records should be updated to reflect new policy with specific emphasis on enforcement of records maintenance standards at all levels.

The President also directs that all records of classified projects involving human subject testing are to be labeled "permanent retention" in all agencies. This

indicates that they are of historical value, must be reviewed for declassification 10 years after their creation and should go to the National Archives at 30 years.

RECOMMENDATION 16(5): The Advisory Committee recommends that the Interagency Working Group review and develop policies concerning public access to records generated or held by private contractors and institutions receiving Federal funding.

RECOMMENDED GOVERNMENT RESPONSE

The President directs the Interagency Working Group to develop guidelines for implementing this recommendation. The President also directs the Departments of Justice and State to review existing laws and regulations related to the implementation of this recommendation.

RECOMMENDATION 17a: The Advisory Committee recommends that the CIA's recordkeeping system be reviewed to ensure that records are accessible upon legitimate request from the public or governmental sources.

RECOMMENDED GOVERNMENT RESPONSE:

The President directs the National Archives and Records Administration (NARA) to give priority to its review of CIA's records system that is scheduled for October 1995. NARA is specifically directed to address means to improve public access to the agency's records.

RECOMMENDATION 17b: The Advisory Committee recommends that all CIA records bearing on programs of secret human research, such as MKULTRA and the related CIA human behavior projects from the late 1940s through the early 1970s, become a top priority for declassification review, with the expectation that most, if not all, of these documents can be declassified and made available to the public.

RECOMMENDED GOVERNMENT RESPONSE:

The President directs CIA, as part of its compliance with the Executive Order 12958, to give top priority to declassification review of records relating to classified human subject research.



: 59

U.S. DEPARTMENT OF JUSTICE
ENVIRONMENTAL AND OCCUPATIONAL DISEASE LITIGATION SECTION
TORTS BRANCH, CIVIL DIVISION
National Place
1331 Pennsylvania Ave., N.W.
Room 8007S
Washington, D.C. 20004
Fax: (202) 616-4473

DATE:

9-25-95

No. of Pages (Including cover sheet):

8

TO:

PHIL CAPLAN

FAX #:

456-2215WHITE HOUSE

TEL #:

456-2702FROM: J. PATRICK GLYNN, DirectorTEL #: 202-616-4200SPECIAL INSTRUCTION: _____



U.S. Department of Justice

Washington, D.C. 20530

September 25, 1995

MEMORANDUM VIA FACSIMILE

TO: Human Radiation Interagency Working Group
Representatives

FROM: J. Patrick Glynn
Director
Torts Branch, Civil Division

SUBJECT: Proposed Responses from Remedies Subcommittee

The attached document, circulated by Lisa Schiavo of DoE's Office of General Counsel, contains the proposed wording for the Administration's responses to Recommendations 1 through 7, as set forth in the most recent version of the final report of the Advisory Committee on Human Radiation Experiments. The wording for the proposed response to Recommendation 2 has been agreed upon by DoE, DoD, and DoJ following last Friday's telephone conference call.

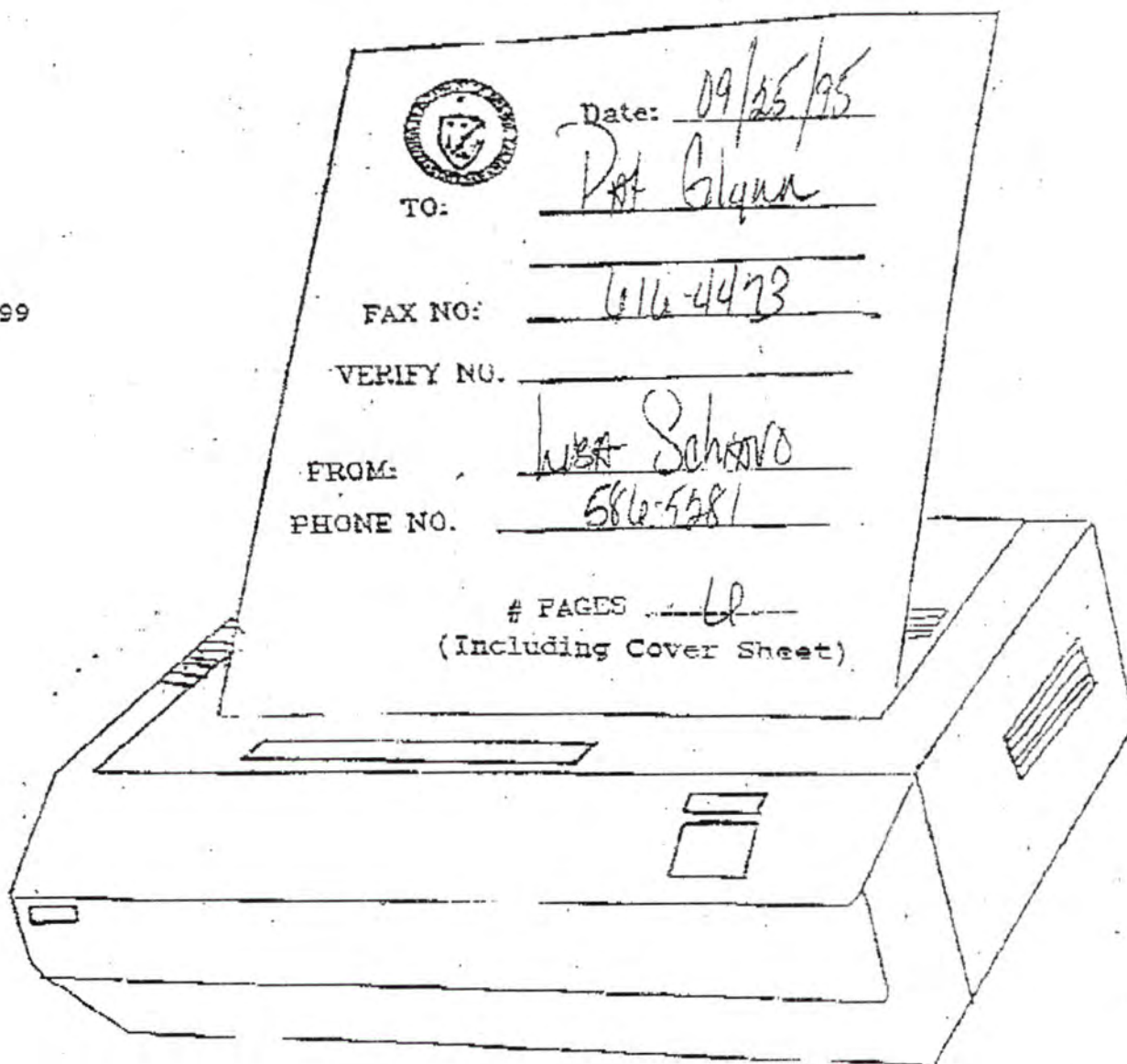
Attachment

OFFICE OF THE GENERAL COUNSEL

U.S. DEPARTMENT OF ENERGY

WASHINGTON, D.C.

202) 586-1499




TO: Date: 09/25/95
Pat Gilman

FAX NO: 616-4473

VERIFY NO. _____

FROM: West Schenck

PHONE NO. 586-5581

PAGES 62
(Including Cover Sheet)

REMARKS: _____

Remedies Subcommittee

**PROPOSED GOVERNMENT RESPONSES TO ADVISORY COMMITTEE
RECOMMENDATIONS ON REMEDIES FOR BIOMEDICAL EXPERIMENTS AND
POPULATION EXPOSURES FROM 1944-1974 (as of 9/25/95)****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.

RECOMMENDED GOVERNMENT RESPONSE

The Administration agrees with the Advisory Committee that an apology and compensation is warranted for human radiation experiments for which there was governmental involvement in actions 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 legislative relief in appropriate cases.

RECOMMENDATION 3

The Advisory Committee recommends to the Interagency Working Group that for subjects who were used in experiments for which there was no prospect of medical benefit to them and there is evidence specific to the experiment in which the subjects were involved that (1) no consent, or inadequate consent, was obtained, or (2) their selection as subjects constituted an injustice, or both, the government should offer a personal, individualized apology to each subject.

RECOMMENDED GOVERNMENT RESPONSE

[The preliminary Administration response is to thank the Committee for the recommendation, but to explain that the recommendation is unworkable given incomplete records, and a lack of criteria as to what constitutes an injustice.]

SECOND 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 from 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 than 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 Utrik, 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 Utrik 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.

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

12-Jul-1995 05:43pm

TO: (See Below)

FROM: Phillip M. Caplan
Office of Cabinet Affairs

SUBJECT: Human Radiation Advisory Committee Report

The Advisory Committee's report will be completed shortly after Labor Day and it is likely that the President will be involved with the release of the report. I've scheduled Ruth Faden, chair of the committee, to brief WH and agency staff on the findings and recommendations in the report next Friday, July 21 at 1:00 pm in 472 OEOB. We have the room for two hours if need be.

We (the government) need to figure out how to respond to the report...or more importantly we need to figure out what the President will say. Therefore, once we are briefed, there will probably be some number of "assignments" to complete in advance of release of the report. My guess is we might want to issue an Executive Order/Presidential Memorandum of some sort, or take some other similar action.

By Monday, I will have distributed to you a draft copy of the Findings and Recommendations section for your perusal before the meeting.

For those of you on this e-mail list who haven't been involved in this issue yet, it is thankfully coming to a close. While the Committee has gone beyond its charter and will get into areas that we would rather not have them address, this will be a very, very positive story for the President and the rest of the Administration and it will get a huge amount of press come September. So, please try to come to the meeting if at all possible so that we can plan accordingly.

Don't hesitate to call if you have any questions.

Thanks.

Distribution:

TO: Jeremy D. Benami ✓
TO: Virginia M. Terzano
TO: Mary Ellen Glynn ✓
TO: Richard L. Siewert ✓
TO: Julia Moffett ✓
TO: Holly L. Gwin ✓
TO: Elgie Holstein ✓

TO: Stephen R. Neuwirth /
TO: T J Glauthier
TO: Emily D. Pelton /

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

12-Jul-1995 05:45pm

TO: T J Glauthier

FROM: Phillip M. Caplan
 Office of Cabinet Affairs

SUBJECT: Radiation

T.J.

Could you give me a call about radiation. I think OMB will play a critical role in this over the next two months. I'm now on 62702. Thanks.

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

20-Jul-1995 07:04pm

TO: (See Below)

FROM: Phillip M. Caplan
 Office of Cabinet Affairs

SUBJECT: REMINDER

Briefing by Dr. Ruth Faden on Human Radiation report, Friday, July 20 in 472
OEOB at 1:00 pm.

Thanks.

Distribution:

TO: Bruce R. Lindsey ✓
TO: Virginia M. Terzano ✓
TO: Mary Ellen Glynn ✓
TO: Richard L. Siewert ✓
TO: Holly L. Gwin ✓
TO: Elgie Holstein ✓
TO: Stephen R. Neuwirth ✓
TO: T J Glauthier ✓
TO: Alice E. Shuffield ✓
TO: Emily D. Pelton ✓
TO: Todd Stern ✓

Anna, called,
will know answer
by 1:00 pm

date - Sept 27 is
okay

needs to talk to

Philly
#1 = 25 (45) time
100
#2 = 40 (45) per
car time

THE WHITE HOUSE

WASHINGTON

July 18, 1995

MEMORANDUM FOR

BRUCE LINDSEY 2 FL - WW
T.J. GLAUTHIER 246 OE03
STEVE NEUWIRTH 130 OE03
JEREMY BEN-AMI 218 OE03
HOLLY GWIN 428 1/2 OE03
ELGIE HOLSTEIN 721 OE03
JAKE SIEWERT 169 OE03
MARY ELLEN GLYNN/GINNY TERZANO 1 FL/WW

FROM: PHIL CAPLAN

SUBJECT: Human Radiation Report

As promised, please find attached three sections of the final report:

- 1) Draft "Preface"
- 2) Draft "Findings"
- 3) Draft "Recommendations"

Ruth Faden, chair of the Committee, will brief on the findings and recommendations on Friday, July 21, 1995 at 1:00 pm in the Room 472 OE0B. It would be helpful if you could read over (or at least glance at) this material before then so that the meeting can move quickly.

In short order, the Administration must figure out how to respond to the Committee's recommendations; this meeting is the beginning of that process. The President will likely receive the final report the last part of September.

As noted in yesterday's *New York Times*, the Committee will recommend financial compensation for a very small number of people (30 or so) harmed by several narrowly-defined groups of experiments. While we need to address this and other legal issues, the briefing on Friday will only touch upon these topics; we will set up another, separate meeting to discuss more fully the legal implications of the Committee's work

Please call me on 6-2702 if you have any questions.

Thanks.

cc: Todd Stern

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.

Subjects covered:

- ▶ 18 subjects of plutonium injection experiments
- ▶ 1 subject of a zirconium injection experiment (Cal-Z)
- ▶ Several (3-6) subjects of specific total body irradiation experiments conducted during WWII

Subject total: 22-25

ISSUES/CONCERNS

- ▶ In the absence of actual injury to either the experiment subjects or their survivors, the justification for compensation to the survivors is tenuous (VA).
- ▶ What would the measure of "damages" be where there is no actual injury? (VA)

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.

Subjects potentially covered (contingent upon establishment of harm. Otherwise, Rec. 2-3 applies):

- ▶ Subjects of total body irradiation experiments (89-90 from Sanger experiments)
- ▶ Subjects of Vanderbilt Radioiron nutrition experiments (if government involvement is established) (approx. 800, according to DOE) (10-20 likely to establish harm)
- ▶ Native Alaskans involved in Iodine-131 experiments (60-70 total divided between Rec's 2 and 3)
- ▶ Prisoners involved in testicular radiation experiments (approx. 120, according to DOE)
- ▶ Subjects involved in uranium injection experiments at Rochester and Boston (less than 25)

Subject total: Maximum approx. 1050

ISSUES/CONCERNS

- ▶ Unclear whether the measure of compensation to a survivor would be based on harm to subject or harm to survivor. (VA)
- ▶ To preclude double recovery, any new remedy should require offsets or credits for Government benefits already paid to the same individual for the same injury under other authority and an election-of-remedies requirement regarding future payments. (VA)
- ▶ Tax treatment of any such payments should be specified. (VA)
- ▶ Determination of whether identified subjects suffered physical harm (option: Institute of Medicine could conduct study) (HHS)

RECOMMENDATION 2-3

The Advisory Committee recommends to the Interagency Working Group that -- even where there is no harm attributable to experimentation -- individualized apologies should still be made to those people (or their families) who are known and can now be located who were subjects in experiments specifically reviewed in the Committee's case studies that offered no prospect of direct medical benefit or that involved controversial treatments that were presented as conventional or standard practice. These apologies should be understood to be a symbol of the country's expression of regret to all others who were similarly situated but who may not now be identifiable.

Subjects potentially covered (if harm established, Rec. 2 would apply):

- ▶ Children who were subjects of certain experiments (including those conducted at Fernald and Wrentham) (300-700 total)
- ▶ Soldiers involved in experiments connected with atomic bomb tests
- ▶ Native Alaskans involved in Iodine-131 experiments (60 total divided between Rec's 2 and 2-3)

Subject total: Depends on establishment of harm in Rec. 2

ISSUES/CONCERNS

- ▶ Apologies should not be issued where there clearly was informed consent. (VA)

RECOMMENDATION 3 (Under Revision. Formerly Rec. 4)

The Advisory Committee recommends to the Interagency Working Group that medical notification and follow-up be offered to subjects of government-sponsored human radiation experiments based on the following guidelines:

1. Determination that the subject was placed at significant (lifetime) risk as well as demonstration of a significant remaining (future) risk for the development of a radiation-induced malignancy.
2. A recognized potential medical benefit from early detection and treatment of the cancer.

Subjects potentially covered:

The Advisory committee has not yet been able to identify any subjects falling in this category. (Advisory Committee is still looking at children in nasopharyngeal experiments)

ISSUES/CONCERNS

- ▶ Who would administer program -- single agency?
- ▶ Cost, including administrative, staffing costs
- ▶ Source of funding
- ▶ Relationship to health insurance/collateral sources
- ▶ Relationship to/disposition of pending or future litigation
- ▶ Government-administered health care follow-up vs. payment/reimbursement for private follow-up/treatment
- ▶ Bases/standards/procedures for factual determinations: risk significance, what diseases/types of cancers, whether potential medical benefit is recognized
- ▶ Limitation of compensation to tests beyond those recommended for general population
- ▶ Form and content of notification
- ▶ Means of delivery of the notice

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.

Subjects potentially covered:

Directed at Hanford, where some small fraction of a population in the tens of thousands may be covered, depending on criteria established.

ISSUES/CONCERNS

- ▶ Identification of eligible populations, potential size/geographic coverage
- ▶ Bases/standards/procedures for determining whether cancer burden "may have resulted" from exposure and what level is comparable to that found in presently covered areas.
- ▶ Cost, including administrative, staffing costs
- ▶ Identification of any Committee recommendations previously considered by the Congress in enacting the current law and what has changed since then.
- ▶ Parity with other RECA beneficiaries; dates/duration of residency in covered area; exclusion factors

RECOMMENDATION 5

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.

ISSUES/CONCERNS

- ▶ Congressional policy has been to limit presumption of causation for "atomic veterans" to cancers most likely to result from radiation and not other causes (e.g. smoking). Extension of presumptions would be problematic. (VA)
- ▶ Does this recommendation cover both RECA and VA benefits?
- ▶ Bases/standards/procedures to determine sufficiency/currency of epidemiological tables and reasonable probability of causation
- ▶ Determination of proper body to review current administration
- ▶ Identification of potential areas in administration that could be improved
- ▶ Cost
- ▶ Identification of any Committee recommendations previously considered by Congress in enacting current laws and what has changed since then

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.

Subjects potentially covered:

Of 3000-4000 miners, 400 have died of lung cancer. Advisory Committee estimates that several hundred more may be eligible.

ISSUES/CONCERNS

- ▶ Number of potentially eligible miners
- ▶ Number of potentially eligible millers
- ▶ Cost, including administrative, staffing costs
- ▶ Legislation needed versus administrative changes possible, especially on documentation and duration requirements
- ▶ Identification of any Committee recommendations that were previously considered by the Congress in enacting the current law and what has changed since then
- ▶ Effect on exclusion factors, e.g. smoking, if coverage is liberalized
- ▶ Effect of adding millers on residential populations adjacent to mill tailings, or housing constructed on fill from mill tailings.



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 Utirik, 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 received exposures 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.

Subjects potentially covered:

Ailuk: less than 200 likely

Other atolls: potential max. less than 1000, but probably far fewer

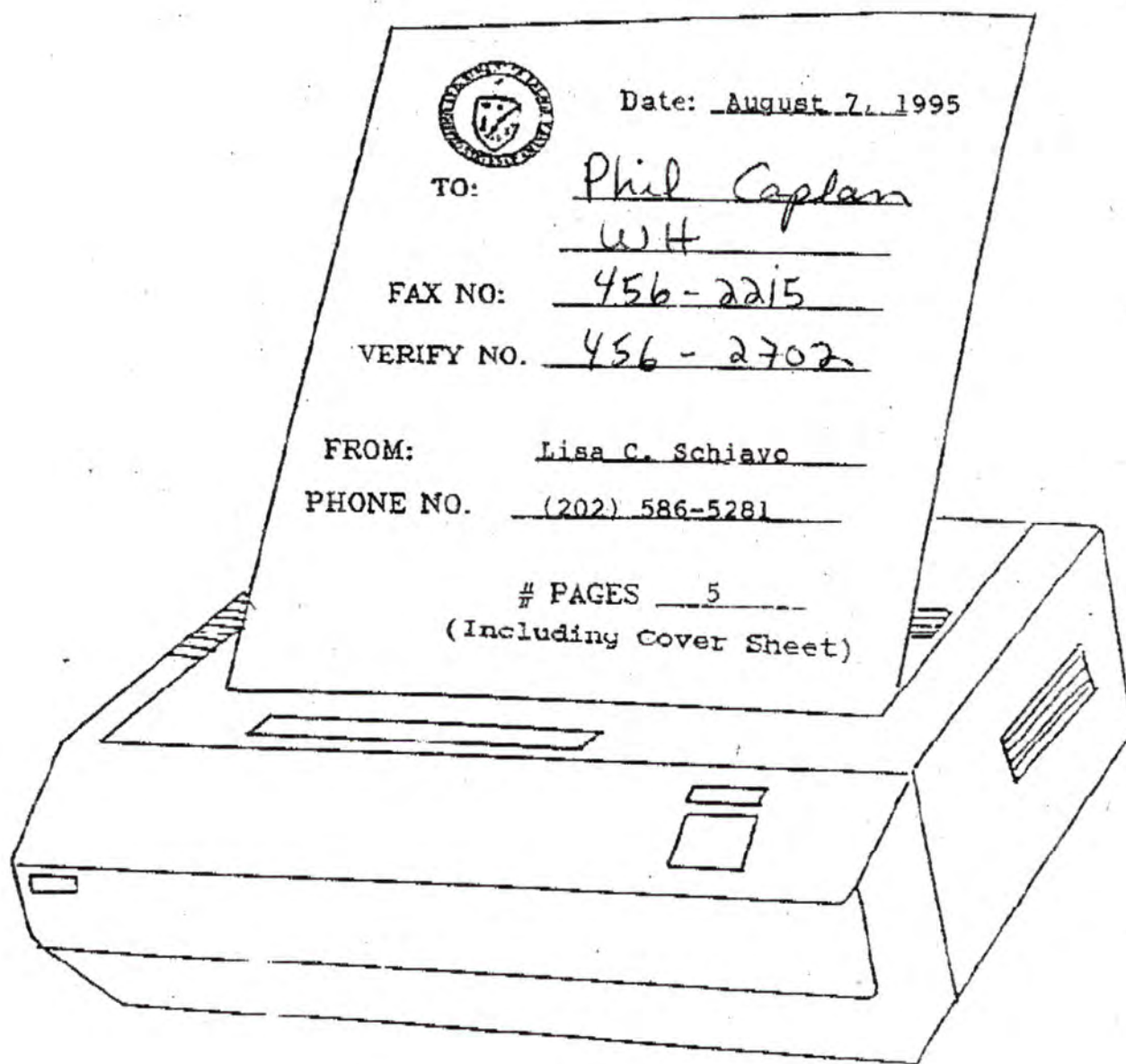
ISSUES/CONCERNS

- ▶ Number of potentially eligible inhabitants
- ▶ Cost, including administrative, staffing costs
- ▶ Exposure levels on various atolls
- ▶ State Department role

OFFICE OF THE GENERAL COUNSEL

U.S. DEPARTMENT OF ENERGY

WASHINGTON, D.C.



REMARKS:

Please call with any comments by 2:00 p.m.

on Wed., Aug. 9, as I will be out from Aug.

10 through Aug. 16. My fax no. is (202) 586-1499

FROM THE DEPARTMENT OF ENERGY

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.

Option 1: To the extent that experimental subjects and their families were deprived of the opportunity to seek legal redress because the experiments were improperly kept secret, the government apologizes for using classification procedures in the 1940s - 1950s to avoid embarrassment and potential legal liability. This apology reflects the Administration's policy of public accountability and commitment to openness. [Can be combined with other options.]

Option 2: Work with Congress to pass legislation (private relief bill) that compensates classes of individuals identified by the Committee and either extinguishes any claims against government, contractors and their employees or requires a release as a condition of compensation.

Option 3: Work with Congress to pass legislation that offers a relatively smaller amount of compensation for the dignitary harm suffered by the individuals and their families and defer the question of appropriate relief for any physical harm that may have been suffered in accordance with the response to recommendation 2. This option would not require a release of pending judicial claims of physical harm but may require a release for other types of claims.

ISSUES/CONCERNS

range of compensation should considered now

avoided litigation costs by U.S.

pay subjects' families rather than counsel

plaintiffs will strongly object to Option 2 unless the payments are substantial

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.

Options 1-3: [from other agencies]

Option 4: 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 is 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?

pending constitutional issue if government can agree to binding arbitration (but DOE contractors can)

number of claims?

how much money is involved?

who administers?

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 v\burden comparable to that found in geographic areas currently covered by the law may have resulted.

Option: We fully support the Committee's view that there is a continual need to review the data on the health of populations that may have been exposed to radiation and other hazardous substances from the nation's weapon-related activities. 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, and that 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 will thus provide a scientific basis for assessing the health impact of past DOE operations on community residents. If such information reveals negative health impacts, 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 No. 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 Utirik, 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: Consistent with the Committee's recommendations, the government is committed to continuing the medical programs for the Marshall Islanders, and will consider whether expansion of the program is warranted. (more information to follow)

ISSUES/CONCERNS

need to insure the existence of adequate funding for current program because current program includes life-time monitoring and treatment of disease regardless of cause.

costs including administrative and staffing costs

exposure levels of Ailuk are 1/1000 of Rongelap



U. S. Department of Justice

Civil Division

August 9, 1995
12:42 pm
10 Pages

TO : PHIL CAPLAN
WHITE HOUSE

Fax No : 9 456-2215

From : SMART

Subject :

Comments :

Attached is Justice's proposed options in response to Recommendation 6. Please submit any comments before 1:00 p.m. THURSDAY, AUGUST 10th. If you wish to make comments by phone, please call Paul Yanowitch (616-4448), who is handling this matter while Pat Glynn is on leave.

Other Recipients:

TO: T.J. GLAUTHIER	OMB
TO: JACK THOMPSON	VA
TO: DICK HIPOLIT	
TO: LISA SCHIAVO	DOE
TO: TARA O'TOOLE	DOE
TO: NORDHAUS	DOE
TO: WEISS	
TO: CASCIOTTI	DOD
TO: CONTENTO	DNA

Department of Justice Submission**Recommendation 6. Amended Provisions for Uranium Miners¹**

The Committee recommends that the IAWG work with Congress to amend the provisions of RECA 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 Committee further recommends that the Act 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.

Summary: The Committee's sixth recommendation is designed to broaden RECA's coverage of uranium miners by liberalizing the criteria for eligibility and standards of proof. For miners seeking compensation for lung cancer, the primary reform proposed is to change from a radon exposure criterion, calculated from data found in historical records on employment and mine radon levels, to a simple criterion of some minimal duration of underground mining employment. The Committee also proposed considering extending the Act's coverage to include uranium millers, and considering adoption of liberalized standards for compensation for nonmalignant respiratory diseases and liberalized documentation standards for all prospective claimants.

Issues Presented by Recommendation 6: The Committee's proposals regarding the RECA uranium miners provisions present the following issues:

A. Issues presented by recommendation to modify statutory eligibility criteria

1. Determination of a minimum duration of underground mining employment, by mining area and time period, to qualify for compensation. (The Committee claims the current scheme, which requires claimants to document exposure to specified minimum levels of radon (measured in Working Level Months (WLMs) is too stringent, and should be replaced by a minimum duration of employment standard.);

2. Determination whether concerns expressed by the Committee can be met by adoption of a new, lower, exposure level requirement;

3. Identification and effect of potentially disqualifying factors, e.g., smoking, age at onset of disease, if legislative criteria for compensation are modified;

¹ This was recommendation 8 in the prior version.

4. Determination whether any recommendations for modification of statutory eligibility (and disqualifying) criteria were previously considered and rejected by Congress in enacting RECA, and identification of any new data that might affect prior congressional decisions;

5. Number of potentially eligible miners under revised eligibility criteria;

6. Cost, including administrative, staff costs;

B. Issues presented by recommendation to liberalize Department of Justice RECA regulations

7. Determination of liberalized documentation standards for proof of statutory eligibility criteria, including proof of radon exposure and proof of nonmalignant respiratory disease;

8. Number of potentially eligible miners under liberalized proof criteria;

9. Cost, including administrative, staff costs;

C. Issues presented by recommendation to consider extending RECA to cover uranium millers

10. Determination of eligibility criteria and disqualifying factors;

11. Effect of compensating millers on other populations potentially exposed to uranium tailings, e.g., residential populations adjacent to mill tailings piles, residents of housing constructed on or with fill containing mill tailings;

12. Number of potentially eligible miners under liberalized proof criteria;

13. Cost, including administrative, staff costs.

Options

A. Options relating to Committee recommendation to modify statutory eligibility criteria

Option 1. 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 Committee; may improve parity for uranium miners relative to other classes of eligible recipients; if 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 2. 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 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 Committee recommended; still somewhat dependant upon controversial historical data; if levels reduced too much, may result in windfalls for some miners.

Discussion Regarding Options 1 and 2:

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.

B. Option relating to Committee recommendation to
liberalize Department of Justice RECA regulations

Option 3. 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.

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

Option 4. 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 perhaps not at the same level as miners); data may be ambiguous and may require more study before a cogent proposal can be made to Congress.

Discussion: 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 amendment of RECA to adopt a single employment-duration standard or a lower required level of working level months, and to consider whether uranium millers should be eligible, and whether other changes in the medical and documentation criteria should be liberalized by amendment of the statute or regulations.

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

A. 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, NIOSH 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 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.

B. 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 follow 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 veracity should be required.

C. 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.