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THE WHITE HOUSE

WASHINGTON

September 30, 1995

ACTION

MEMORANDUM FOR THE PRESIDENT

THROUGH: LEON PANETTA

FROM: PHIL CAPLAN

RE: Advisory Committee on Human Radiation Experiments

I. PURPOSE

To approve several recommended actions to be taken on Tuesday, October 3, when you are scheduled to receive the Advisory Committee's final report.

II. BACKGROUND

You appointed this Committee in January 1994 after Secretary O'Leary made public a number of revelations of the government's conduct during the 1940s and 50s with regard to radiation experiments using human research subjects. You issued an Executive Order charging the Committee with reviewing the records of the Federal agencies and providing expert advice on several issues, including 1) whether human radiation experiments sponsored or conducted by the government from 1944-1974 met the ethical and scientific standards of the time and those that exist today; and 2) whether current human subject research safeguards are adequate to prevent recurrence of such ethical abuses.

The Committee's work essentially falls into three categories: 1) a review of experiments from 1944 -1974, 2) a survey of current human subjects research and 3) a review of secrecy and openness guidelines.

1) 1944 - 1974: The Committee found conclusive evidence that the government sponsored a very large number of human radiation research experiments from 1944-1974. Because of the large number, the Committee did not focus on the particulars of the hundreds of experiments, but rather on identifying the ethical standards that applied to the government and the medical profession. The Committee did examine a few experiments in-depth (those that involved children, vulnerable populations, etc.) and found, (i) that most were not harmful to the subjects, but (ii) that the government did not effectively implement policies to ensure that consent was obtained from the subjects.

The Committee will recommend financial compensation in two categories: 1) For the families of the 18 subjects of the plutonium injection experiments (the *Albuquerque Tribune* won the Pulitzer for uncovering this story). Though it is unlikely physical harm was suffered, this was the most egregious example of the government purposefully concealing the nature of an experiment from an experiment's subjects; 2) For a larger class of people who were subjects of experiments, were harmed to some degree, were not in a position to benefit medically, and did not give the proper informed consent. Experiments in this category include the testicular irradiation of prisoners, and the total body irradiation conducted in Cincinnati. There could be several thousand people in this category, but the number cannot be determined with any precision because many of the records have been destroyed. Nevertheless, the number of people who eventually are compensated will be a small percentage -- probably less than 10% of the total subjects -- because most were not harmed. **OMB is working with the agencies on several options for a compensation scheme. It is premature for you to comment with any specificity at this time, although we recommend that you endorse the Committee's principle of compensating those harmed.**

2) Current Human Subject Research: 1974 - present: The Committee reviewed 125 current or recently federally-funded studies (not limited to radiation research). It interviewed patients at leading hospitals in order to gauge the adequacy of procedures for obtaining informed consent from subjects; evaluated the research risks of the experiments; and sampled attitudes towards human subject research.

While the Committee found that most of the protections and informed consent were up to standard, it did find that some 25% of the experiments were "troubling" in terms of the informed consent and the risks involved in the research. The Committee has notified each of the sponsoring institutions (mostly university research hospitals) of these problems and asked each of the institutions to strenuously review their procedures. **We have prepared a proposed Executive Order directing federal agencies which sponsor human subject research to review their policies and procedures in light of the Committee's report to ensure that such research meets ethical standards.**

3) Secrecy and Openness: The Committee found that there are gaps in the informed consent system that could lead to the conduct of classified research on humans without their knowledge. The Committee's recommendations suggest: 1) additional safeguards for the protection of human subjects involved in classified research, and 2) environmental oversight of classified programs. While you are not in a position to comment on this set of recommendations because DoD and CIA are still reviewing them, preliminary conversations indicate that there should not be any problem in implementing the recommendations easily and quickly.

III. RECOMMENDATIONS

The Administration is officially seeing the final report for the first time, although we have been working closely with the Committee. You are not yet in a position to respond with a great deal of specificity about the Committee's report, but you can lay out a set of

principles that should guide the Administration in implementing the Committee's recommendations. **The theme of your remarks should be that your Administration has "done the right thing," lifting the veil of secrecy on the government's conduct of radiation experiments during the Cold War in order to right the wrongs done to innocent citizens, restore trust in government and ensure that future research meets the highest ethical standards.**

I recommend you take the following actions at the event on October 3rd:

1) Acknowledge the wrong done by the federal government to thousands of Americans and convey your empathy with those who were mistreated. Note that there will be representatives of victims rights groups at the event. By ordering this exhaustive review of the government's conduct, you have placed yourself squarely on the side of those who were wronged and this should come through both at the event and in the press coverage.

2) Endorse the principle that people harmed as subjects in unethical experiments are entitled to compensation, and pledge that your Administration work closely with the Congress to establish a streamlined compensation scheme. **This will be the first time you have substantively commented on this subject and your comments will receive the most media attention out of the event.**

3) Issue an Executive Order that 1) directs all federal agencies to review their policies and procedures with regard to human subject research and 2) establishes the National Bioethics Advisory Committee to, among other things, examine the issue of human subjects research, and develop more rigorous guidelines for informed consent to fill in the gaps that the Committee has found. **A draft Executive Order is attached.**

IV. <u>DECISIONS:</u>

1) _____ Approve general approach: acknowledgement of government's mistakes and endorse principle of compensation

_____ Reject general approach

_____ Discuss further

2) _____ Approve Executive Order

_____ Reject

_____ Discuss

October 2, 1995

RECEIVE FINAL REPORT - ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

Date: October 3, 1995
Time:
Location: Room 450 OEOB
From: Phil Caplan

I. PURPOSE

To receive the final report of the Advisory Committee on Human Radiation Experiments. This marks the end of their 18-month inquiry.

You

II. BACKGROUND

You appointed this Committee in January 1994 after Secretary O'Leary made public a number of revelations of the government's conduct during the 1940s and 50s with regard to radiation experiments using human research subjects. You issued an Executive Order charging the Committee with reviewing the records of the Federal agencies and providing expert advice on many issues, including 1) whether human radiation experiments sponsored or conducted by the government from 1944-1974 met the ethical and scientific standards of the time and those that exist today; and 2) whether current human subject research safeguards are adequate to prevent recurrence of such ethical abuses.

II. Committee's Findings and Recommendations

The Committee's work essentially falls into three categories: 1) a review of experiments from the Cold War, 2) a survey of current human subjects research and 3) secrecy and openness.

1) Cold War: 1944 - 1974

The Committee found conclusive evidence that the government sponsored a very large number of human radiation research experiments from 1944-1974. Because of the large number, the Committee focused on identifying the ethical standards that applied to the

government and the medical profession, not the particulars of the hundreds of experiments, although they focussed on a few in-depth. The basic storyline here is that the Committee found that the vast majority of the experiments were not harmful to the subjects, but, nevertheless, the government did not effectively implement policies to ensure that consent was obtained from the subjects.

The Committee will recommend financial compensation for the families of the 18 subjects of the plutonium injection experiments (the experiments for which the *Albuquerque Tribune* won the Pulitzer) because this was the most egregious example of the government keeping secret an experiment (although it was unlikely physical harm resulted from the experiment itself). The Committee will also recommended compensation for another larger class of people who were subjects of experiments. These people were harmed to some degree, were not in a position to benefit medically, and the experiments were not ethically proper. (There is a staff group led by OMB, Counsel's office and DOE Counsel that is working on the outline of a compensation scheme based on the Committee's broad recommendation.)

2) Current Human Subject Research: 1974 - present

The Committee reviewed 125 current or recently Federally-funded studies (not limited to radiation research) and 1) interviewed patients at leading hospitals in order to gauge the adequacy of procedures for obtaining informed consent from subjects, 2) evaluated the research risks of the experiments and 3) sampled attitudes towards human subject research.

The Committee found that most of the protections and informed consent were up to standard. However, the Committee did find that about 25% of the experiments were "troubling" in terms of the informed consent and the risks involved in the research. The Committee has notified each of the sponsoring institutions (usually a university research hospital) of these problems and asked each of the institutions to strenuously review their procedures. The Committee will recommend 1) enhanced ethics education at med schools and research institutions, 2) a series of measures to ensure that research is clearly distinguished from treatment in obtaining consent, and 3) that Federal oversight be improved and strengthened. (Please see below for how I believe the President should respond to these findings.)

3) Secrecy and Openness

The Committee's recommendations in this section fall generally into two categories: 1) additional safeguards for the protection of human subjects involved in classified research, and 2) environmental oversight of classified programs. The Committee's recommendations are geared to preventing 40s and 50s-style experiments from ever happening again.

September 29, 1995

ACTION

MEMORANDUM FOR THE PRESIDENT

FROM: PHIL CAPLAN

THROUGH: LEON PANETTA

RE: Advisory Committee on Human Radiation Experiments

I. ACTION-FORCING EVENT

To approve several recommended actions to be taken on Tuesday, October 3, when you are scheduled to receive the Committee's final report.

II. BACKGROUND

You appointed this Committee in January 1994 after Secretary O'Leary made public a number of revelations of the government's conduct during the 1940s and 50s with regard to radiation experiments using human research subjects. You issued an Executive Order charging the Committee with reviewing the records of the Federal agencies and providing expert advice on many issues, including 1) whether human radiation experiments sponsored or conducted by the government from 1944-1974 met the ethical and scientific standards of the time and those that exist today; and 2) whether current human subject research safeguards are adequate to prevent recurrence of such ethical abuses.

The Committee's work essentially falls into three categories: 1) a review of experiments from the Cold War, 2) a survey of current human subjects research and 3) secrecy and openness.

1) Cold War: 1944 - 1974: The Committee found conclusive evidence that the government sponsored a very large number of human radiation research experiments from 1944-1974. Because of the large number, the Committee focused on identifying the ethical standards that applied to the government and the medical profession, not the particulars of the hundreds of experiments, although they focussed on a few in-depth. The basic storyline here is that the Committee found that the vast majority of the experiments were not harmful to the subjects, but, nevertheless, the government did not effectively implement policies to ensure that consent was obtained from the subjects.

The Committee will recommend financial compensation for the families of the 18

subjects of the plutonium injection experiments (the experiments for which the *Albuquerque Tribune* won the Pulitzer) because this was the most egregious example of the government keeping secret an experiment (although it was unlikely physical harm resulted from the experiment itself). The Committee will also recommended compensation for another larger class of people who were subjects of experiments. These people were harmed to some degree, were not in a position to benefit medically, and the experiments were not ethically proper. (Experiments in this category include the Fernald school where retarded children were given radioactive milk and cereal.)

- How many people?
- Do we know who they are?

2) Current Human Subject Research: 1974 - present: The Committee reviewed 125 current or recently Federally-funded studies (not limited to radiation research) and 1) interviewed patients at leading hospitals in order to gauge the adequacy of procedures for obtaining informed consent from subjects, 2) evaluated the research risks of the experiments and 3) sampled attitudes towards human subject research.

- How much are we offering?

The Committee found that most of the protections and informed consent were up to standard. However, the Committee did find that about 25% of the experiments were "troubling" in terms of the informed consent and the risks involved in the research. The Committee has notified each of the sponsoring institutions (usually a university research hospital) of these problems and asked each of the institutions to strenuously review their procedures.

3) Secrecy and Openness: The Committee's recommendations in this section fall generally into two categories: 1) additional safeguards for the protection of human subjects involved in classified research, and 2) environmental oversight of classified programs. The Committee's recommendations are geared to preventing 40s and 50s-style experiments from ever happening again.

? What is this? EPA?

III. RECOMMENDATIONS

The Administration is *officially* seeing the final report for the first time, although we have been working closely with the Committee. It would not be correct for you to respond with a great deal of specifity about the Committee's recommendations, but rather lay out a set of principles and then ask the Cabinet to report back to you in 30-60 days with a detailed set of recommendations as to how to implment and respond to the Committee's report. **The theme of your remarks will be that your Administration has done the right thing.**

Therefore, we recommend you take the following actions on October 3rd:

1) apologize on behalf of past governments

2) Endorse the Committee's notion that people subject to unethical experiments should be compensated, and pledge that your Administration work closely with the Congress to establish a streamlined compensation scheme. **This will be the first time you have substantively commented on this subject and your comments**

will receive the most media attention out of the event.

3) Issue a Presidential Memorandum ordering all federal agencies review their policies and procedures with regard to the funding of human subject research and report back to Secretary Shalala.

4) Establish the National Bioethics Advisory Committee to look at, among other things, the whole of issue of human subjects research, and lay out new guidelines for informed consent to fill in the gaps that the Committee has found exist.

5) Pledge that no secret human subject research will ever occur under your watch.

- How is he going to respond to the question about current unethical programs, which he cannot deny ?

REMARKS:

- Acknowledgements: [Secretary O'Leary, for bringing this important issue to light; to Congressman Markey, for working on this issue since 1986, to Senator Glenn, for his vigilance on the protection of human research subjects, to Senator Wellstone, ... and others for their work as well.

- A special thanks to Dr. Ruth Faden and the other members of the Advisory Committee. I bet if you would have known that you would produce a report that was this long and heavy, you might have thought twice about serving on this Committee.

- Dr. Faden, and the rest of you here in the first row, you have done a magnficient and important job and performed a valuable service to your country. We as a nation thank you. You have lifted the veil of secrecy on a sometimes dark chapter in American history and have been able to explain why things operated the way they did during the Cold War.

- This was a story that needed to be told. Bits of it had slipped out over the years -- largely due to Ed Markey and John Glenn's efforts -- but it was not until Secretary O'Leary made her revelations some 20 months ago that the real story began to unfold.

- When I appointed this Committee, the Vice President and I hosted a reception for them here at the White House before their first meeting. At that time, I told them that their mission was to search for the truth and help restore the trust in government that is so missing in our society by being open, being forthright, and not pulling any punches. I think you have done that.

- I opened the doors of the Administration to you and your staff. The members of my Cabinet here today receive my highest praise for the effort they and their staffs have made to open up their files, blow the dust off, declassify reams of information and make it all available to the Committee and the public.

- Not only has the Committee produced a historic and heroic report, but the government has undertaken a heroic effort to enable the Committee to do so.

- You have found that during the Cold War, the government sponsored or authorized thousands of experiments. Most of these experiments were ok,..... But the ethical standards used in many of those experiments were unacceptable -- researchers did not obtain the proper informed consent -- and many of the subjects were some of the most vulnerable of our society...the poor, the uneducated, minorities. **On behalf of the government and the American people, I want to sincerely apologize to those who participated in radiation experiments without the proper informed consent. It was wrong and the government was**

make virtue of it this risk

wrong to play a role.

- One of these experiments was at the Fernald School in Boston. Congressman Markey has with him as his guest today, Mr. _____. Mr. _____ attended the Fernald School in the 1950s. He joined the Science Club. Doctors fed him, and xx others, radioactive cereal to determine if the body could absorb calcoum calcium inside cereal. But they didn't tell him and didn't tell his parents that he was subject to an experiment. Mr. ____, that shouldn't have happened, and I'm sorry. [I understand that the radiation you ingested was not enough to phsyically harm you, but I'm not sure that matters now.]

- As you can see, this is a long, detailed, report with imporant and serious recommendations. I ask the members of my Cabinet here today to report back to me in 60 days with detailed responses to the Committee's recommendations.

- But let me lay out some guiding principles for my Administration's response. All along, I've said that this inquiry has been about doing the right thing. It was the right thing to ban 17 assault weapons, it is the right thing to curb tobacco use by young people, **and it is the right thing to compensate people who have been involved in unethical experiments.** Not only the families of the plutonium injection experiments that Dr. Faden referred to, but any other person who comes forward to say that they were involved and harmed in a radiation experiment.

- Second, we must always protect humans who participate in research. Human research is critical and has been critical to this country. Human research and science has been of enormous benefit...without it we would not have the cure polio, we would not have CAT scans, we wouldn't be making progress on breast cancer and prostate cancer; any many of these advances are because of the benefits of *radiation.* But still we must adequately protect those who participate in experiments. And this committee has some gaps in our informed consent protection system.

- Today, by Executive Order, I have ordered all government agencies and local institutional review boards responsible for approving experiments, to review their policies and procedures with regard to the rights and welfare of human subjects. Also today, I created the National Bioethics Advisory Committee to review, as its first order of business, the rules that we have in place for human research, and recommend any changes necessary.

- These are important and necessary steps, spurred by this dedicated Advisory Committee. But I say to the American people, you must also look out for yourselves; be healthy skeptics and engage your health care providers over your care. If you are invited to be involved in research, know your rights.

- Close by once again thanking Dr. Faden and the members of your committee, and especially the family members who put up with the

Secrecy...are we doing secret experiments? Should POTUS talk about it?
Can we order IRBs to do something.
Tara to look at latest EO

Depar
Wa

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September 26, 1995

BACKGROUND INFORMATION FOR PHIL CAPLAN

FROM: Tara O'Toole, M.D., M.P.H.
Assistant Secretary
Environment, Safety and Health

SUBJECT: Briefing on the Report of the Advisory Committee on Human Radiation Experiments

The Advisory Committee on Human Radiation Experiments is scheduled to present its final report to the President on Tuesday, October 3rd. Time has been reserved on the President's calendar for a White House event to receive the report. Over the past six (6) weeks, representatives of all agencies involved in this project have been meeting to shape a government-wide response to the Advisory Committee's findings and recommendations.

This memorandum describes the background and process that led to this point, the accomplishments of the Federal agencies acting in cooperation with the Advisory Committee, the Advisory Committee's major findings and recommendations and the proposed Government response thereto, benefits of the project and some potential issues relating to the release of the final report.

BACKGROUND AND PROCESSES

Early Events

- In 1986 Congressman Edward Markey (D.Mass) issued a report entitled *American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens.* This report discussed approximately 30 human radiation studies; it engendered relatively little media interest.

- In November 1993, the Albuquerque Tribune published articles by reporter Eileen Welsome describing experiments during World War II where hospital patients at several locations around the country were injected with

plutonium. Family members interviewed by Welsome denied that the subjects had given their consent.

- In December 1993, Secretary of Energy O'Leary acknowledged the Tribune articles and publicly released additional declassified documents related to the plutonium injections; she committed DOE to locate, declassify and disseminate as much information as possible about human radiation experiments sponsored by the Department of Energy and its predecessors, the Manhattan Project and the Atomic Energy Commission. Media coverage and public response was intense.

- Articles appeared in other newspapers describing other experiments, including some with retarded children in Massachusetts.

- The Secretary established a toll-free hotline to receive inquiries from those who believed they or a family member may have been a radiation experiment subject. This was soon expanded to include other agencies. Over 20,000 calls were ultimately made to the hotline.

Establishment of the Interagency Working Group and the Advisory Committee

- In January 1994, the President established a Cabinet-level Human Radiation Interagency Working Group to provide a coordinated Federal response to this issue. It included the Department of Energy, the Department of Defense, the Department of Veterans Affairs, the Department of Health and Human Services, the National Aeronautics and Space Administration, and the Central Intelligence Agency.

- The President issued an Executive Order (E.O. 12891) establishing an Independent Advisory Committee on Human Radiation Experiments to provide expert advice and recommendations; Federal agencies were directed to provide the committee with the historical records and other information needed to complete its work.

- The Secretary of the Cabinet issued a directive calling for a Government-wide records inventory and retrieval focussing on:

    - Experiments on individuals involving intentional exposure to ionizing radiation, not including common and routine clinical practices; and

    - Intentional environmental releases of radiation designed to test human heath effects or the extent of exposure; and

- Specified releases of radiation to the environment including a series of tests investigated in a 1993 GAO report requested by Senator John Glenn.

- The Advisory Committee, chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University, considered the following issues:

  - the medical and scientific purpose 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 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.

Activities of the Committee

- The Advisory Committee met monthly in public from April 1994 through July 1995 and took testimony from experiment subjects and their advocates, research institutions, and government representatives. Several outreach meetings around the country were also held. The Committee made the drafts of its report publicly available.

- The Committee also reviewed 125 current federally-sponsored studies (not limited to radiation - related research) and interviewed patients at leading hospitals in order to gauge the adequacy of procedures for evaluating the risks of research and for obtaining informed consent from subjects, and 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.

ACHIEVEMENTS FOR OPENNESS

- Given the state of the government's records, we cannot claim to have found every document bearing on human radiation research. Nonetheless, a broad and thorough search has yielded an enormous amount of information and allowed us to see the big picture.

- The historical record of an important part of the history of this country was assembled in an unprecedented exercise in openness.

- 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 scattered at dozens of locations around the country. An estimated 840,000 pages of documents were ultimately delivered by the agencies to the Committee and research was done for them on many topics.

- The Department of Defense and the Department of Energy declassified over 7,000 documents during the course of this project. (Most pertinent documents were not classified; they were unidentified and inaccessible because they were submerged in a sea of government records.)

- The record is being made directly accessible to the public by means of cutting edge technology. Over 250,000 pages of original DOE documents related to human subject radiation research dating back to the Manhattan Project are now available on the Internet. The other agencies will be adding their documents to this database. People can search the documents and print them out at their desks.

- DOE published and widely distributed two volumes describing the general scope and purposes of human radiation research sponsored by the Department and listing and describing some 435 such studies. Other agencies provided lists of experiments.

THE MAJOR FINDINGS OF THE ADVISORY COMMITTEE

Historical Experiments and Population Exposures

- Several thousand government sponsored human radiation experiments were conducted from 1944 to 1974; only fragmentary information survives for most experiments. Few documents survive that shed light on whether

individuals gave informed consent.

- Most experiments were done to advance medical science; the great majority of subjects received low doses unlikely to cause them physical harm.

- Human radiation experimentation during this period contributed significantly to medical advances and thus to the health of the public.

- Some agencies had policies on human subject research as early as the 1950s, but these were generally not effectively implemented.

- Some government agencies required the consent of some research subjects even before 1944, but the government did not have comprehensive policies, covering both healthy subjects and patient-subjects, until 1974.

- It is unlikely that the public was directly harmed solely as a consequence of the environmental releases of radiation. The most severe exposures to non-patients occurred not in biomedical experiments, but to uranium miners.

Trust, Openness, and Secrecy

- Public trust in government is perhaps the biggest casualty of the human radiation experiments and intentional releases.

- Events and data from experiments were sometimes kept secret for reasons of public relations, embarrassment, and concern for legal liability. Examples include: the World War II plutonium injections; secret environmental releases; world-wide fallout studies prior to the 1963 Atmospheric Test Ban Treaty where the amount of such elements as strontium-90 were measured in the human body; and uranium miners.

- The government did not routinely create or maintain records needed to assure that secret programs could be accounted for in later years.

- The management of historical government records in general has contributed to public mistrust of the government. Poor recordkeeping and lack of accessibility has made it difficult to establish facts.

Current Human Subject Protection

- In comparison to the policies and practices of the 1940s and 1960s, there have been significant advances in the protection of the rights and interests of human subjects. However, the current human experiment system is not working as well as it should.

- Most subjects face minimal risks from participation in research but there are problems with, for example, lack of clarity in consent forms, unrealistic expectation by patients of the potential that participation in research will benefit them directly, and the use of persons with diminished mental capacity.

- Environmental releases such as those identified in the Advisory Committee charter could take place in secret today under the current environmental laws and regulations.

THE COMMITTEE'S RECOMMENDATIONS AND THE PROPOSED GOVERNMENT RESPONSE (the full text of all the Advisory Committee recommendations are attached, along with a more detailed discussion of the proposed government response)

Biomedical Experiments and Population Exposures 1944-1974

- The Committee recommends that the government:

  - apologize and compensate the families of World War II era plutonium and zirconium injections and total body irradiation (TBI) because the government misused secrecy to keep the subjects uninformed. (The Committee does not find that these people were physically harmed).

  - apologize and compensate subjects if a court or other forum finds that they were physically harmed.

  - amend the Radiation Exposure Compensation Act (RECA), the law passed in 1990 to provide compensation to persons harmed by nuclear weapons testing and uranium miners, if data shows that additional groups, such as those living downwind of the Hanford plutonium - production complex, are at increased risk of cancer.

- review the fairness of compensation laws related to the uranium miners and the so-called "atomic veterans."

- continue DOE medical programs for Marshall Islanders and consider whether it should be expanded.

- The proposed government response endorses the basic thrust of the Committee's recommendations and suggests a number of specific processes and mechanisms for carrying these out.

Current Human Subject Protection

- The Committee recommends that the government:

  - undertake a national effort to ensure the central importance of ethics in the conduct of researchers whose work involves human subjects.

  - improve the Institutional Review Board (IRB) system, which is the mechanism established by regulation for approval of federally-funded human research.

  - establish an open forum for the continuing review and interpretation of ethical rules as they apply to human subject research.

  - improve the protection of the rights and interests of military personnel with respect to human subjects research, including a review of policies and procedures, better training for officers and investigators in applying the regulations, maximizing voluntariness, and maintenance of a registry of volunteers by all the services.

  - improve oversight, sanctions and scope by 1) conducting regular, periodic applications based on examining outcomes and performance 2) reviewing whether sanctions for violations are adequate; and 3) extending protections to non-federally funded research.

- The proposed government response:

  - remands certain issues to the proposed National Bioethics Advisory Commission which will provide expert advice on issues of ethics;

  - endorses enhanced ethical education in partnership with external

groups such as medical schools, universities, scientific societies, and others;

- involves pooling resources across agencies to conduct pilot projects to improve the efficiency and effectiveness of IRB review and to evaluate the system overall; and

- considers proposing legislation to address some of the gaps in the current system for protecting human subjects such as extending requirements for protection of human subjects of research not funded or conducted by the Federal Government.

Secrecy and Openness

- The Committee recommends:

  - in cases of classified human research, any waiver of informed consent procedures should be prohibited.

  - independent review of classified human research and classified environmental releases; permanent retention of related records.

  - the Interagency Working Group should ensure continued movement toward making historical records accessible by 1) moving records into the Archives more quickly 2) making indexes and finding aids readily available 3) improving public access to records that remain in agencies 4) maintaining records of document destruction and 5) reviewing policies governing access to records of grantees and contractors.

  - review of CIA recordkeeping and high priority to the declassification of CIA records on human research including the MKUltra LSD experiments.

- The proposed government response:

  - includes a Presidential directive that no waivers of full informed consent will be permitted in classified research and disclosure to the subject of the government agency sponsoring the research;

  - requests that EPA review whether additional steps are necessary to ensure robust environmental oversight of classified programs;

- directs the Interagency Working Group, in conjunction with the National Archives, to develop an aggressive plan to increase accessibility of government records;

- redesignates records relating to human subjects research as permanent to prevent future records destruction; and

- involves a high-priority review by the National Archives of the CIA record-keeping system, including addressing means to improve public access and directs CIA to give top declassification priority to human subject research records.

BENEFITS

- Despite occasional media sensationalism and the trepidation of some in the scientific community with the scrutiny associated with this effort, this is a good story for the Administration:

  - when we started down this road, we were aware of a few high-profile and very troubling experiments -- we did not know whether these were aberrational, nor did the government have an idea of the scope and purpose of government-sponsored human radiation research generally.

  - without excusing the dark side of this research, this open examination of the historical record allows the government to acknowledge its mistakes as well as the immense medical benefits achieved by much of this research.

  - people are able to see that the government is committed to preventing the misuse of science and technology, thus creating an environment where good programs can go forward.

- For this Administration, the most likely positive enduring legacy of this project may be the enhancement of openness:

  - large amounts of information were found and cutting edge technology was used to put this information directly into the hands of the people.

  - providing this information has offered an opportunity to begin to heal the wounds that resulted from government projects carried out with

secrecy and deception during the War and the Cold War.

- with the ending of the Cold War, there is an opportunity to frame this project as part of a strong, continuing effort to rebuild trust, and to support and extend democratic government, by making records and information consistently and readily available to the people to whom they belong: the citizens of this country.

POTENTIAL ISSUES/CONSEQUENCES OF THE RELEASE

- In the past, media attention has often focussed on the most controversial or sensational aspects of these experiments and releases, such as the involvement of vulnerable populations; at the same time, the Administration has generally been credited for openness, accountability and rebuilding public trust in government institutions.

- Due to the passage of time and the survival of only parts of the historical records, the Committee has been able to reach very few definitive judgments on the ethics of individual experiments and on the likelihood of harm to individuals. There will be some unmet expectations, but these should be blunted by a commitment to continue the process of openness and dialogue.

- There is a risk that the Committee's criticism of current human subject protection practices could harm the cause of ongoing important human research. The Committee and the agencies are seeking to obtain the support of important elements of the research and scientific communities for their message for more attention to ethics, and the fact that we seek to act in partnership with these institutions should be stressed.

Attachments: *American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens* (the Markey Report); Article by Eileen Welsome from the Albuquerque Tribune; Memorandum from the Secretary of Energy of 12/23/95; Memorandum for Heads of Departments and Agencies from the Secretary to the Cabinet of 1/19/94; *Human Radiation Experiments: the Department of Energy Roadmap to the Story and the Records*; *Human Radiation Experiments Associated with the U.S. Department of Energy and its Predecessors*; Pamphlet: *Human Radiation Experiments 1946-1974, The Clinton*

Administration's effort to find the facts; Pamphlet: *HREX, Human Radiation Experiments Information Management System*; and Recommendations of the Advisory Committee on Human Radiation Experiments.

September 29, 1995

ACTION

MEMORANDUM FOR THE PRESIDENT

FROM: PHIL CAPLAN

THROUGH: LEON PANETTA

RE: Advisory Committee on Human Radiation Experiments

I. ACTION-FORCING EVENT

To approve several recommended actions to be taken on Tuesday, October 3, when you are scheduled to receive the Advisory Committee's final report.

II. BACKGROUND

You appointed this Committee in January 1994 after Secretary O'Leary made public a number of revelations of the government's conduct during the 1940s and 50s with regard to radiation experiments using human research subjects. You issued an Executive Order charging the Committee with reviewing the records of the Federal agencies and providing expert advice on many issues, including 1) whether human radiation experiments sponsored or conducted by the government from 1944-1974 met the ethical and scientific standards of the time and those that exist today; and 2) whether current human subject research safeguards are adequate to prevent recurrence of such ethical abuses.

The Committee's work essentially falls into three categories: 1) a review of experiments from ~~the Cold War~~, 2) a survey of current human subjects research and 3) a review of secrecy and openness guidelines.

1) ~~Cold War:~~ 1944 - 1974: The Committee found conclusive evidence that the government sponsored a very large number of human radiation research experiments from 1944-1974. Because of the large number, the Committee focused on identifying the ethical standards that applied to the government and the medical profession, not the particulars of the hundreds of experiments, although they focussed on a few in-depth. ~~The basic storyline here is that~~ the Committee found that the vast majority of the ~~experiments they examined in-depth were~~ not harmful to the subjects, but, nevertheless, the government did not effectively implement policies to ensure that consent was obtained from the subjects.

The Committee will recommend financial compensation for the families of the 18 subjects of the plutonium injection experiments (the experiments for which the *Albuquerque Tribune* won the Pulitzer), because this was the most egregious example of the government keeping secret an experiment, although it was unlikely physical harm resulted from the experiment itself. The Committee will also recommend compensation for another, larger class of people who were subjects of experiments; approximately 4,000 may deserve compensation, but the number is very, very difficult to determine. These people were harmed to some degree, were not in a position to benefit medically, and the experiments were not ethically proper. Experiments in this category include the testicular irradiation of prisoners, and the total body irradation in Cincinnati. **OMB is working with the agencies on several options for a compensation scheme. It is premature for you to comment with any specificity.**

2) Current Human Subject Research: 1974 - present: The Committee reviewed 125 current or recently Federally-funded studies (not limited to radiation research), and 1) interviewed patients at leading hospitals in order to gauge the adequacy of procedures for obtaining informed consent from subjects; 2) evaluated the research risks of the experiments; and 3) sampled attitudes towards human subject research.

The Committee found that most of the protections and informed consent were up to standard. However, the Committee did find that about 25% of the experiments were "troubling" in terms of the informed consent and the risks involved in the research. The Committee has notified each of the sponsoring institutions (usually a university research hospital) of these problems and asked each of the institutions to strenuously review their procedures. **You will issue an Executive Order directing the agencies to review their policies and procedures.**

3) Secrecy and Openness: The Committee's recommendations in this section fall generally into two categories: 1) additional safeguards for the protection of human subjects involved in classified research, and 2) environmental oversight of classified programs. The Committee's recommendations are geared to preventing 40s and 50s-style experiments from ever happening again.

III. RECOMMENDATIONS

The Administration is *officially* seeing the final report for the first time, although we have been working closely with the Committee. It would not be correct for you to respond with a great deal of specificity about the Committee's recommendations, but you can rather lay out a set of principles and then ask the Cabinet to work on implementing the Committee's recommendations. **The theme of your remarks will be that your Administration has "done the right thing," lifted the veil of secrecy on the government's conduct during the Cold War -- your Administration has taken a risk of exposing deficiencies in the protection of human research subjects in order to improve the system and help restore the trust in government.**

In order to Right the wrong done to innocent citizens, restore trust in government and ensure that future research meets the highest ethical standards.

~~In furtherance of these themes,~~

~~Therefore,~~ we recommend you take the following actions at the event on October 3rd:

1) ~~apologize~~: there will be representatives of victims rights groups at the event. ~~We recommend that, while you don't individually apologize to those present, you issue a heartfelt apology on behalf of the nation to those who were harmed by participating in unethical experiments.~~

2) Endorse the Committee's ~~notion~~ principle that people ~~who were~~ harmed as subjects in unethical experiments ~~should be compensated~~, and pledge that your Administration work closely with the Congress to establish a streamlined compensation scheme. **This will be the first time you have substantively commented on this subject and your comments will receive the most media attention out of the event.**

3) Issue an Executive Order that 1) directs all federal agencies to review their policies and procedures with regard to human subject research and 2) establishes the National Bioethics Advisory Committee to ~~look at~~, among other things, ~~the whole of~~ issue of human subjects research, and ~~lay out~~ new guidelines for informed consent to fill in the gaps that the Committee has found ~~to exist~~.

Ph. I - (3) Is the only decision pt, isn't it?

are entitled to ~~the~~ compensation

examine

draft Exec

~~We~~ [A copy of the Executive Order is attached?]

[When is he supposed to see & approve the E.O.?]

1) Acknowledge the wrong done by the federal government to thousands of Americans and ~~*~~ convey your empathy with those who were mistreated.

Note that

By ~~*~~ ordering this exhaustive ~~government~~ review of the government's conduct you have placed yourself squarely on the side of those who were wronged & this should come through.

September 29, 1995

ACTION

MEMORANDUM FOR THE PRESIDENT

FROM: PHIL CAPLAN

THROUGH: LEON PANETTA

RE: Advisory Committee on Human Radiation Experiments

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III. RECOMMENDATIONS

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1) apologize: there will be representatives of victims rights groups at the event. We recommend that, while you don't individually apologize to those present, you issue a heartfelt apology on behalf of the nation to those who were harmed by participating in unethical experiments.

2) Endorse the Committee's notion that people who were harmed as subjects in unethical experiments should be compensated, and pledge that your Administration work closely with the Congress to establish a streamlined compensation scheme. **This will be the first time you have substantively commented on this subject and your comments will receive the most media attention out of the event.**

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EXECUTIVE ORDER

-- -- -- --

PROTECTION OF HUMAN RESEARCH SUBJECTS AND
CREATION OF NATIONAL BIOETHICS ADVISORY COMMISSION

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Review of policies and procedures. (a) Each executive branch department and agency that conducts, supports or regulates research involving human subjects shall promptly review the protections of the rights and welfare of human research subjects that are afforded by the department's or agency's existing policies and procedures. In conducting this review, departments and agencies shall take account of the recommendations contained in the report of the Advisory Committee on Human Radiation Experiments.

(b) Within [120] days of the date of this order, each department and agency that conducts, supports or regulates research involving human subjects shall report the results of the review required by paragraph (a) of this section to the National Bioethics Advisory Commission, created pursuant to this order. The report shall include an identification of measures that the department or agency plans or proposes to implement to enhance human subject protections. As set forth in section 5 of this order, the National Bioethics Advisory Commission shall pursue, as its first priority, protection of the rights and welfare of research subjects.

(c) For purposes of this order, the terms "research" and "human subject" shall have the meaning set forth in the 1991 Federal Policy for the Protection of Human Subjects.

Sec. 2. Research ethics. Each executive branch department and agency that conducts, supports or regulates research involving human subjects shall, to the extent practicable and appropriate, develop professional and public educational programs to enhance activities related to human subjects protection, to provide forums for addressing ongoing and emerging issues in human subjects research, and to familiarize professionals engaged in nonfederally-funded research with the ethical considerations associated with conducting research involving human subjects. Where appropriate, such professional and educational programs should be organized and conducted with the participation of medical schools, universities, scientific societies, voluntary health organizations, or other interested parties.

Sec. 3. Establishment of National Bioethics Advisory Commission. [add provisions of NBAC executive order.]

DRAFT
9-19-95
11:00 a.m.

EXECUTIVE ORDER

- - - - - -

NATIONAL BIOETHICS ADVISORY COMMISSION

INSERT A

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 3. Establishment. (a) There is hereby established a National Bioethics Advisory Commission ("NBAC"). NBAC shall be composed of not more than 15 members to be appointed by the President. NBAC shall be subject to the Federal Advisory Committee Act, as amended, 5 U.S.C. App. 2.

(b) The President shall designate a Chairperson from among the members of NBAC.

Sec. 4. Functions. (a) NBAC shall provide advice and make recommendations to the National Science and Technology Council and to other appropriate entities regarding the following matters: (1) the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior; and (2) applications, including the clinical applications, of that research.

(b) NBAC shall identify broad principles to govern the ethical conduct of research, citing specific projects only as illustrations for such principles.

(c) NBAC shall not be responsible for the review and approval of specific projects.

(d) In addition to responding to requests for advice and recommendations from the National Science and Technology Council, NBAC may also identify bioethical issues ~~on its own behalf and, subject to the approval of the National Science and Technology Council, deliberate on those issues~~. NBAC may also accept suggestions of issues for consideration from both the Congress and the public, ~~through the National Science and Technology Council~~. Subject to the approval of the National Science and Technology Council, NBAC may also identify other bioethical issues for the purpose of providing advice and recommendations.

Sec. 5. Priorities. (a) As a first priority, NBAC will direct its attention to consideration of: protection of the rights and welfare of research subjects, and issues in the management and use of genetic information, including but not limited to, human gene patenting.

(b) NBAC shall consider four criteria in establishing the other priorities for its activities:

1. the public health or public urgency of the bioethical issue;
2. the relation of the bioethical issue to the goals for Federal investment in science and technology;
3. the absence of another entity able to deliberate on the bioethical issue; and
4. the extent of interest in the issue within the government.

Sec. 6. Administration. (a) The heads of executive departments and agencies shall, to the extent permitted by law, provide NBAC with such information as it may require for purposes of carrying out its functions.

(b) NBAC may conduct inquiries, hold hearings and establish subcommittees, as necessary. The Assistant to the President for Science and Technology and the Secretary of Health and Human Services shall be notified upon establishment of each subcommittee, and shall be provided information on the name, membership (including chair), function, estimated duration, and estimated frequency of meetings of the subcommittee.

(c) NBAC is authorized to conduct analyses and develop reports or other materials. In order to augment the expertise present on the NBAC, the Secretary of Health and Human Services may contract for the services of non-governmental consultants who may conduct analyses, prepare reports and background papers or prepare other materials for consideration by the NBAC, as appropriate.

(d) Members of NBAC shall be compensated in accordance with Federal law. Members of NBAC may be allowed travel expenses,

including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the government service (5 U.S.C. 5701-5707).

(e) To the extent permitted by law, and subject to the availability of appropriations, the Department of Health and Human Services ("DHHS") shall provide NBAC with such funds as may be necessary for the performance of its functions. The Secretary of Health and Human Services shall provide management and support services to NBAC.

Sec. 7. General Provisions. (a) Notwithstanding the provisions of any other Executive order, the functions of the President under the Federal Advisory Committee Act that are applicable to NBAC, except that of reporting annually to Congress, shall be performed by the Secretary of Health and Human Services, in accordance with the guidelines and procedures established by the Administrator of General Services.

(b) NBAC shall terminate two years from the date of this order unless extended prior to that date.

(c) This order is intended only to improve the internal management of the executive branch and it is not intended to create any right, benefit, trust, or responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person.

THE WHITE HOUSE,

Office for Protection from Research Risks

National Institutes of Health
Suite 3B01
6100 Executive Boulevard
Rockville, MD 20892-7507

Date: SEP 29 1995

To: PHIL CAPLAN FAX: 202-456-2215
Phone: _____

From: Gary B. Ellis FAX 301-402-2071
Phone 301-496-7005 x205

Comments:

THE MISSING "TEETH"

Document consists of 2 pages, including cover sheet.

SEP 28 1995

Research investigators and institutions are the stewards of a trust agreement with the people who volunteer to be research subjects. We have a system in place that to the greatest degree possible minimizes the potential for harm to research subjects; enables and protects individual, autonomous choice by subjects; and promotes the pursuit of new knowledge.

Research involving human subjects is conducted, supported, or regulated by 21 Federal Departments and Agencies, including 16 signatories to regulations promulgated in 1991, the *Federal Policy for the Protection of Human Subjects.* The report of the Advisory Committee on Human Radiation Experiments illuminates the boundaries of our existing Federal regulatory protections for human subjects. I hereby direct the Department of Health and Human Services to develop legislation for transmission to Congress to elevate into statute the fundamental components of these regulatory protections. The Administration seeks new Federal statute that will confer upon all human research subjects in the United States the protections, as warranted, of 1) informed consent, and 2) review of proposed and ongoing research by a local Institutional Review Board.

The report of the Advisory Committee on Human Radiation Experiments provides a timely stimulus for the 16 signatories to the *Federal Policy for the Protection of Human Subjects* and the Department of Labor, Department of the Interior, Nuclear Regulatory Commission, U.S. Postal Service, and Food and Drug Administration to review the protections of the rights and welfare of human research subjects that are afforded by existing policies and procedures.

I hereby direct these Departments and Agencies to report the results of their respective reviews, along with identification of Departmental or Agency measures that should be taken to enhance human subject protections, to the National Bioethics Advisory Commission. Established today by a separate Executive Order, the National Bioethics Advisory Commission will pursue, as its first priority, protection of the rights and welfare of research subjects.

The Federal Government maintains an enduring commitment to ensuring that research involving human subjects is undertaken in accord with the highest ethical standards. By doing so, we protect the rights and welfare of our fellow citizens who make a remarkable contribution to the common good by electing to volunteer for research studies. We owe them our best effort.

William J. Clinton

DATE: 9/29

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: Phil Caplan 456-2015

FROM: Ellyn Weiss

NO. OF PAGES TO FOLLOW: 1

___For your information

___As requested

___Original copy to follow via mail

___Please call upon receipt

___For review and comment

COMMENTS/MESSAGES:

Our suggestions for apology + Compensation language for the President

The following are suggestions for language to address the apology and compensation issues:

The Committee has identified people who were wronged during wartime and the Cold War that followed because the government invoked secrecy improperly and failed to respect the dignity and rights of individuals. The government owes those people a long overdue apology and I give it to their family members on behalf of past governments. I agree with the Committee that fair and reasonable compensation should be made available in these cases.

The committee has also given us an ethical guidepost to apply in other cases: If people were ethically wronged and physically harmed through the fault of the government, fair and reasonable compensation should be offered. I agree with that, too.

From DOE - not been vetted by WH Counsel Use as background

BACKGROUND - WHAT IS THIS ABOUT?

The investigation into the true story human radiation experiments is about:

- what the powerful owe those who are used for power's purpose - however noble those purposes might be;
- the burden and the strain that secrecy imposes on the covenant between a democratic government and the people;
- the tension that inequities in knowledge and authority impose between doctors and their patients, especially when we are sick and at our most vulnerable;
- the fear of radiation: invisible, silent; a force of nature with the power to destroy whole nations and to heal dread disease;
- the Cold War: the twilight years of the twentieth century; a time of furtiveness, of struggle, of secret wars and nuclear brinkmanship, when all the world was on edge to know if the Superpowers, would put an end to history.

WHY DID WE DO THIS?

- Why did we open the door on human radiation experiments?
- Why did I commit the whole Government to a massive records search, declassify thousands of documents, and ask Dr. Faden and her colleagues to devote 18 months of their lives to review these records?
- Why did we risk months of disturbing stories in the newspapers and on television about ethically questionable Government sponsored radiation experiments?

BECAUSE - we believe that no matter what was discovered, it is better to come clean and tell the truth about what the government did.

We did this because it is the right thing to do.

I came to Washington 3 years ago determined to restore the basic relation of trust between government and the American people. Reducing government secrecy, ending deception and making government accountable for its actions are necessary steps towards this all important goal.

Our Administration, with the leadership of Secretary Hazel O'Leary, threw open the Cold War curtains of secrecy to examine the claims of citizens who felt they had been wronged by their government.

The Department of Energy alone has made 250,000 pages of documents covering human radiation experiments available on the Internet. This information alone would cover the national mall from the Washington Monument to the Capitol building to a depth of six inches.

ONLY BY DEALING HONESTLY WITH THE PAST CAN WE TRULY IMAGINE THE FUTURE

The Advisory Committee's report on human radiation experiments is an attempt to learn from our history - to look honestly at the ethical issues raised by the discovery of new forms of energy, of powerful new tools in science and medicine; to recognize the mistakes we made, and to make sure such mistakes are not repeated.

Secrecy is sometimes necessary in the conduct of great nations, especially in the arena of protecting national security. But the need for secrecy to safeguard the country must always be carefully balanced against the strain that government secrecy imposes on a democracy.

Secrecy must never again be used as a shield to protect government from embarrassment or criticism or lawsuits.

Ours is an era of great changes and is alive with the uncertainties and confusion that accompany such millennial change.

We cannot, as a nation, as individuals, effectively face the uncertainties of the next century unless there is a certain trust among the people and between citizens and their government.

The country must acknowledge past mistakes, face up to wrongs committed, before it can honor the achievements of the past.

WHAT HAVE WE LEARNED

- The open examination of this "dark side" of government research has yielded an instructive story of the evolution of radiation science and medicine. As a history buff, I find remarkable the scientific advances such as the increasing use of radionuclides in medicine to diagnose and treat disease told by these documents. This story shows the courage and genius of the pioneers in this new frontier. Few Americans realize that this is a heritage of the Cold War.

- The fruits of this research answered many questions and has saved many lives.

But the good news does not excuse the ethical wrongs or relieve the government of responsibility for harm cause by unethical experiments done at the government's bidding.

The committee's report notes that we have made progress in defining an individual's right to full disclosure about the risks of medical research. We are also more careful these days to protect the especially vulnerable, such as children, the elderly, the poor - though even now, we need to make improvements.

All progress entails risk. We must still confront difficult decisions about how much risk to accept in the search for better treatments and cures for lethal disease.

GOVERNMENT APOLOGY

- I want to express my sincerest apologies to those citizens and families who were wronged by their government in human radiation experiments.

- I endorse my Advisory Committee's recommendations on compensating subjects of these Cold War radiation experiments.

- People to whom the government lied, or from whom the government hid information, or failed to gain adequate consent for participation in radiation experiments, deserve our heartfelt remorse. No excuse is adequate to absolve government from responsibility for betraying its citizens in this manner.

- Today, I pledge that this heavy cloak of past secrecy and deceit in government-sponsored human subjects research will not again burden the American people.

Research investigators and institutions are the stewards of a trust agreement with the people who volunteer to be research subjects. We have a system in place that to the greatest degree possible minimizes the potential for harm to research subjects; enables and protects individual, autonomous choice by subjects; and promotes the pursuit of new knowledge.

Review of Federal protections for human subjects

Research involving human subjects is conducted, supported, or regulated by 21 Federal Departments and Agencies, including 16 signatories to the 1991 *Federal Policy for the Protection of Human Subjects* and the Department of Labor, Department of the Interior, Nuclear Regulatory Commission, U.S. Postal Service, and Food and Drug Administration. The report of the Advisory Committee on Human Radiation Experiments provides a timely stimulus for each of these Departments and Agencies to review the protections of the rights and welfare of human research subjects that are afforded by existing policies and procedures.

I hereby direct these Departments and Agencies to report the results of their respective reviews, along with identification of measures that should be taken to enhance human subject protections, to the National Bioethics Advisory Commission which will pursue, as its first priority, protection of the rights and welfare of research subjects.

Protections in classified research

I hereby direct that no Federal funds be expended to conduct or support classified research involving human subjects where an Institutional Review Board has waived informed consent or where a determination has been made that the research is exempt from Institutional Review Board review. I hereby direct that in all Federally funded classified research, two additional elements of information will henceforth be provided when consent is sought from potential human subjects: 1) the identity of the sponsoring Federal agency, and 2) a statement that the project involves classified information. The National Bioethics Advisory Commission is requested to evaluate whether the *Federal Policy for the Protection of Human Subjects* should be revised to codify these two directives.

I hereby direct all Departments and Agencies to ensure the participation of persons not otherwise affiliated with the Federal government in review of classified research, either by establishing a dedicated review panel for classified research or by ensuring that Institutional Review Board members all have the necessary security clearances.

Federal leadership in enhancing cognizance of research ethics

Among the most important lessons we derive from the deliberations of the Advisory Committee on Human Radiation Experiments is that, of equal import to regulations and oversight mechanisms, is the development of a common understanding among the scientific community and the public of the purposes and limitations of research involving human subjects. I hereby direct Departments and Agencies conducting, supporting, or regulating human subjects research to develop professional and public educational programs in concert with medical schools, universities, scientific societies, voluntary health organizations, 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.

The Federal Government maintains an enduring commitment to ensuring that research involving human subjects is undertaken in accord with the highest ethical standards. By doing so, we protect the rights and welfare of our fellow citizens who make a remarkable contribution to the common good by electing to volunteer for research studies. We owe them our best effort.

William J. Clinton

Office for Protection from Research Risks

National Institutes of Health
Suite 3B01
6100 Executive Boulevard
Rockville, MD 20892-7507

Date: SEP 29 1995

To: STEPHEN R. NEUWIRTH FAX: 202-456-1647
Phone: _____

Copy: LILY O. ENGSTROM

From: Gary B. Ellis

FAX 301-402-2071
Phone 301-496-7005 x205

Comments:

DRAFT OF EXECUTIVE ORDER.

Document consists of 3 pages, including cover sheet.

SSHC
South Shore Health Center

759 Granite Street
Braintree, MA 02184
Phone: (617) 848-1950
Fax: (617) 356-4887

95 SEP 25 A0:01

Date: 9/25/95

To: Phil Caplan

Company:

FAX No: (202) 456-2215

From: Dave Eggleman MD, MPH

Number of pages including cover: ____

Message: A taste! More to come I suggest Negaunee - Call Cooper Bryan - I have budgeted $100,000.00 for a camping to highlight the last 3 sentences of this Article.

DEPARTMENT OF DEFENSE
OFFICE OF GENERAL COUNSEL
1600 DEFENSE PENTAGON
WASHINGTON, DC 20301-1600

OFFICE OF THE DEPUTY GENERAL COUNSEL
(PERSONNEL & HEALTH POLICY)

Fax: (703) 693-7616

fax transmittal

to: PHIL CAPLAN

fax: 202-456-2215

from: Mr. John A. Casciotti, ODGC(P&HP), (703) 697-9657

date: 9/21/95

re: ACHRE #2

pages: [redacted] 4

NOTES:

GENERAL COUNSEL OF THE DEPARTMENT OF DEFENSE

WASHINGTON, D.C. 20301-1600

September 21, 1995

MEMORANDUM FOR THE GENERAL COUNSEL, DEPARTMENT OF ENERGY

SUBJECT: ACHRE Recommendation # 2

Thank you for your memorandum of September 14. I agree with you that the "Defense/Justice preferred version" is too narrow in that it could be interpreted as requiring rigid proof of causation between harm and some specific governmental action. I also agree that the original "Energy proposed version" is too broad in that it seems to call for government compensation even if there was no appreciable governmental involvement in the actions on which the compensation is to be based.

Our major concern relates to therapeutic experiments. In general, the ACHRE recommendations "do not address" whether "remedies should be provided for injuries or offenses related to research that offered a plausible prospect of medical benefit to subjects,"[1] even though informed consent was not typically required or obtained. But, as a limited exception, recommendation 2 calls for compensation in therapeutic cases when "interventions considered to be controversial at the time were presented as conventional or standard practice" and harm resulted. Under the ACHRE recommendations, government compensation in therapeutic experiments is premised not on the lack of informed consent (which might include many cases), but on a misrepresentation of the nature of the clinical intervention (which probably covers only a few cases). Based on this focus, there should be at least some governmental involvement in the misrepresentation on which the government compensation is to be based.

I do not believe the proposed alternative -- which highlights the "government's knowledge or authorization of the experiment" -- is sufficiently precise because mere knowledge of "the experiment" does not get to the action on which the compensation is based.

---

[1] Part IV Overview, pp.4-5 (9/15/95).

I think better wording of the first sentence of the response would be:

> The Administration agrees with the Advisory Committee that an apology and compensation is warranted for human experiments for which there was governmental involvement in actions falling within the criteria identified by the Advisory Committee.

Two other points about this suggestion are noteworthy. First, it contemplates the need for further elaboration, during the implementation stage, on the nature and extent of governmental "involvement" that would be associated with compensation (or perhaps partial compensation). Second, to the extent the University of Cincinnati case is seen as a model, based on our current impression of the facts, we think that case would be covered by the suggested language.

To facilitate a comparison, attached is a recap of the options for recommendation 2.

Judith Miller

Judith A. Miller

Attachment: Options for Response to Recommendation 2

cc: Eva M. Plaza
Phil Caplan
Eric Macris
Pat Glynn

OPTIONS FOR RESPONSE TO 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, 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.

RESPONSE

The Administration agrees with the Advisory Committee that an apology and compensation is warranted

[Choose 1:

[1. when governmental action caused harm in human experiments

[2. for human experiments sponsored or carried out by the government and

[3. for human experiments either carried out by the government or sponsored by the government with the government's knowledge or authorization of the experiment and

[4. for human 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 [redacted] relief in appropriate cases.

DATE:

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

95 SEP 27 P5:17

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

TO: Phil Caplan, FAX 456-2215

FROM: Ellyn Weiss

NO. OF PAGES TO FOLLOW: [redacted]

__For your information

__Please call upon receipt

__As requested

__For review and comment

__Original copy to follow via mail

COMMENTS/MESSAGES:

Agency talking points as requested in last IAWG Conf. call

Phil Caplan

26 September 1995

NOTE FOR: Lori Azim
Department of Energy

FROM: John F. Pereira
Central Intelligence Agency

SUBJECT: Radiation--Suggested Talking Points

In response to Assistant Secretary O'Toole's request for suggested talking points for use in connection with the Radiation Committee's report, we submit the following for consideration (all related to openness):

1. All agencies undertook major efforts to identify and make available to the Radiation Committee all information--classified and unclassified--that was relevant to the Committee's inquiries.

2. A substantial number of sensitive documents were declassified for purposes of making government records available to the public. In addition, steps are underway to create a comprehensive, government-wide data base for the purpose of improving public access to records related to human radiation testing.

3. CIA is prepared to cooperate fully in implementing the recommendations in the report, including those that propose a review of the Agency's records system and the declassification of records on programs of human behavioral research, such as those from the MKULTRA project.

John Pereira

HHS

Talking Points on
Report of Advisory Committee on Human Radiation Experiments

The Advisory Committee has completed a massive task in reviewing the Government's records on human radiation experiments that took place during the 1944-1974 period.

They are to be commended for undertaking as ambitious an effort as they did. It is understandable, given the breadth and scope of their review, that there was not sufficient time to analyze all the facts related to individual cases.

The Committee's sampling of current research was an attempt to determine how the ongoing system for protection of human subjects is working. The small sample and the limited methodology in the Research Proposal Review Project (RPRP) did not permit a generalization of its findings. We also recognize that, since the study was based on a review solely of paper documentation, the Committee did not have access to other information that was pertinent to the situation they were studying.

However, the study certainly was helpful in identifying some areas within the Governmental structure for oversight of human subjects research that could be improved. We take seriously the Committee's recommendations for enhancing our system for protecting the rights and interests of individuals participating in research and are prepared to respond accordingly.

There are already ongoing efforts within our Department, particularly at NIH which supports the bulk of federally funded human subjects research, to reinforce the ethics of human subjects research. And we will be expanding these efforts to provide for broader participation.

Furthermore, we are prepared to mount new educational initiatives that will focus on federal agency staff, the biomedical research community and health care providers that conduct nonfederally funded human subjects research.

The Department will be assuming the lead role in an interagency effort to conduct pilot projects to improve the efficiency and effectiveness of the review of the use of human subjects in proposed research.

We will be sending notifications to DHHS awardee institutions reminding them of their ongoing responsibilities with respect to human subjects protection and informing them of the Advisory Committee's findings regarding informed consent procedures and forms.

Several of the Advisory Committee's recommendations that address long-term issues will be remanded to the National Bioethics Advisory Commission, an independent body to be established by the President, which will serve as the ideal forum for deliberating these issues.

Department of Health and Human Services

- ✓ Established a multi-agency 16-person working group within the Department to develop search strategies and oversee the search, retrieval and inventory of records pertaining to human radiation.

- ✓ Established an NIH-wide 29-person task force to identify all research conducted or supported by NIH that exposed humans to ionizing radiation.

- ✓ Responsibility for day-to-day coordination for human radiation activities was vested in the NIH Deputy Director for Extramural Research and three full-time staff.

- ✓ Created an electronic database on the approximately 5200 human protocols that have been carried out in the NIH Clinical Center since it opened its doors in 1953. Over 4000 inactive protocols were searched and reviewed, taking eight months and involving 10 persons on the staff of the Clinical Center's Medical Record Department. Over 2700 of these protocols had to be further analyzed in order to appropriately categorize the type of radiation involved. In total, 28 staff members of the Clinical Center and the Institutes/Centers were involved in this effort.

- ✓ Converted to electronic format approximately 60,000 skeletal grant records from the 1940s, 1950s and 1960s that were previously accessible only from print copy or microfiches. This effort involved approximately 40 staff members.

- ✓ Searched several hundred thousand electronic grant records for documentation of human radiation research.

- ✓ Created, for the first time anywhere, an extensive list of scientists supported by NIH whose names match those of scientists who had received radioisotopes from AEC (1946-1954). This list also includes a bibliography of published articles on human radiation authored by these scientists, based on research utilizing the radioisotopes.

- ✓ The National Library of Medicine devoted three individuals to search the scientific literature for articles involving human radiation. In addition to these activities, NLM also completed a comprehensive bibliography on whole-body irradiation, after several months of effort. This bibliography which contains 229 citations from January 1944 through December 1974 is now available on Internet.

- ✓ Files within the Department as well as those at both the Federal Records Storage Center in Suitland and the National Archives have been searched over a period of several months to identify and retrieve documents of interest to the Advisory Committee.

NASA RADIATION REVIEW
TALKING POINTS
September 26, 1995

• Search Structure

NASA performed a comprehensive review of its involvement with human radiation research, including: a literature search; a search of current NASA documents as well as those at Federal Records Centers and National Archives; interviews with former key Centers and National Archives; interviews with former key radiation and life sciences personnel; letters to all current and former employees, contractors and grantees; and public inquiries.

• Review Findings:

NASA identified 147 experiments that fit the criteria for human radiation experimentation as defined by the Advisory Committee on Human Radiation Experiments (ACHRE). These were experiments conducted or funded in part by NASA. They were divided into 7 categories of studies or occupational exposures that have involved human subjects. These were:

- Total Body Calcium Studies
- Radiation Absorption Spectrometry
- Radioisotope Injections in Bedrest and Other Studies
- Oak Ridge Study Data Analysis
- Visual Light Flash Observations
- Human Cataract Data Analysis
- Astronaut Exposures in Space

• Actions Taken as a Result of Review:

1. NASA's Bioethics Task Force has reviewed the ACHRE Report and recommendations. This Task Force is reviewing NASA procedures for all experimentation using human subjects and recommending any appropriate policy changes. It is chaired by Baruch Brody, Ph.D., Leon Jawarski Professor of Biomedical Ethics and Director of the Center for Ethics, Medicine and Public Issues at Baylor College of Medicine.

2. The NASA Management Instruction (NMI) on the Conduct of Human Research has been revised and will incorporate the recommendations reflected in the ACHRE Final Report.

3. NASA has officially changed the name of the Johnson Space Center committee that reviews all NASA human research policy and procedures for space flight and related investigations to Institutional Review Board. This will ameliorate any confusion regarding its function and responsibilities as they relate to the Federal Policy for the Protection of Human Subjects.

4. NASA is working with its international partners to enhance the ethical training and understanding of all investigators involved in space-related human research, particularly to ensure a transnational understanding of the sensitivity to ethical issues in human research.

TALKING POINTS

SUBJECT: Department of Defense Human Subjects Radiation Experiments Review

PURPOSE: To provide an update about DoD human radiation experiments (HREs) research initiatives and the possible outcome of findings of the Advisory Committee on Human Radiation Experiments (ACHRE).

BACKGROUND:

- 7 December 1993, Energy Secretary O'Leary announced openness initiatives about DOE involvement in HRE.
- 24 December 1993, a National Helpline was initiated at DOE to respond to public concern and collect preliminary data regarding reported exposure.
- 3 January 1994, an Interagency Working Group, chaired by the Secretary to the Cabinet, composed of DOE, DoD, CIA, HAS, OMB, DOJ, DVA, and NASA, was established to ensure a coordinated effort.
- 15 January 1994, the ACHRE, comprised of 14 respected professionals of law, ethics, and health, was established by Executive Order 12891. ACHRE is chartered to:
  - Review experiments conducted from 1944 through May 1974 (charter extended in June 1994 to include current experiments)
  - Evaluate ethical and scientific standards and criteria on HREs conducted or sponsored by the U.S. Government
  - Prepare a Final Report to the Interagency Working Group and to the President.

DOD Mission and Scope

- To achieve a full accounting of the DoD involvement in radiation research and experimentation on human subjects during the last 50 years.
- Includes experiments on individuals involving intentional exposure to ionizing radiation, not including common and routine clinical practices such as established diagnosis and treatment methods involving incidental exposures to ionizing radiation.
- Includes experiments involving intentional environmental releases of radiation that were designed to test human health effects of ionizing radiation, or the extent of human exposure to ionizing radiation, and several other specific military research projects.

DoD Initiatives, January 1994 to Present

- SECDEF memo, 7 January 1994, from then SECDEF Les Aspin, affirmed DoD's commitment to openness and appointed Dr. Harold P. Smith, ATSD(AE), as DoD focal point.

- Radiation Experiments Command Center (RECC) established as DoD central repository on 2 February 1994, under ATSD(AE), initially headed by a Flag Officer, now headed by an SES civilian.
- RECC coordinated DoD HRE research in conjunction with the Services and Agencies.
- Conducted research at National Archives and National Records Centers throughout the U.S.
- Declassified more than 1,200 documents.
- Examined approximately 2,600 possible DoD-sponsored HREs (numbers high because of DoD policy to err on the side of inclusion for fairness and openness).
- Processed more than 7,000 inquiries from the Congress and public.
- Collected in a central repository and forwarded copies of approximately 10,000 HRE-related records (200,000 pages) to the ACHRE.
- Total expenditure by DoD is $7.36 million
- Participated in five congressional hearings and briefings on controversial experiments such as total body irradiation and atmospheric releases of radiation.
- Providing input to ACHRE Final Report due for release 3 October 1995.

ACHRE Activities

- Starting in April 1994, conducted document research and held 20 public meetings/hearings in six locations including Washington, DC, and other sites.
- Initially, ACHRE focused on the research of experiments but in June 1994 began an intensive review of HRE policy.
- Scheduled to conclude with release of the *Final Report* 3 October 1995. ACHRE Chair, Dr. Ruth Faden, will formally present Final Report to the President.

ACHRE Findings -- Related to DoD

- From 1944 through 1974 (extended to present), the government sponsored several thousand human radiation experiments. Of this number, DoD conducted several hundred experiments.
- The DoD did not have comprehensive policies requiring the consent of all research subjects, including both healthy subjects and patient subjects, until 1974.
- Agencies did not consistently comply with their requirements and policies on human subjects consent to research.

- Problematic experiments cited in the ACHRE Final Report include:
  - Total body irradiations (TBI) such as those conducted at the University of Cincinnati on which litigation is pending. In conjunction with these experiments, research was funded by DoD on patients exposed to TBI in clinical settings. Key points:
    - -- DoD funds were used solely for laboratory studies and psychological and psychiatric tests of cancer patients who received whole and partial body irradiation.
    - -- No DoD funds were used for direct patient care nor did the DoD play any part in patient selection or choice of treatment.
  - Biomedical research in connection with selected atmospheric nuclear weapons tests, e.g., Desert Rock exercises and Operation REDWING.
    - -- More than 200,000 service personnel participated in nuclear weapons tests from 1945 to the early 1960s; most were engaged in test management, training maneuvers, or data gathering activities.
    - -- About 1,000-2,000 were research subjects.
  - Air Force research in the 1950s on Native Alaskans and military personnel using iodine-131 as a radioisotopic tracer to determine the role of human thyroid activity in acclimatization to extreme cold weather (expected litigation involving 70 participants).

ACHRE Recommendations

- Public apology and compensation to certain HRE participants under particular factual circumstances, including excessive secrecy; injury to healthy subjects in non-therapeutic research projects; and misrepresentation regarding unconventional therapeutic investigations.
- Independent oversight of classified research involving human subjects to create an atmosphere of openness.
- Increased public access to research information. DoD is working closely with the Advisory Committee and the National Record Centers to increase public access to DoD HRE information.
- Better oversight for all government sponsored or conducted human-subject research. Although effective oversight mechanisms are in place, further refinements are indicated.

Effects on DoD

- Positive public perception of DoD openness in providing public access to HRE information. Such access should help in reducing public cynicism.
- Anticipate ACHRE Final Report to raise public expectations about possible compensation, at least in several cases.

- Increase in media, public, and congressional interest.
- Congress, the media and interest groups will likely refocus on other experiments, i.e., chemical and biological.

DoD Follow-up

- Review HRE oversight policy. . . make appropriate revisions based on ACHRE recommendations.
- Continue initiatives to increase public access to HRE information.
  - Enter DoD data into INTERNET/World Wide Web.
  - Publish DoD report/book about HRE research in early 1996.
  - Transfer HRE records to National Records Centers.
  - Continue declassification of relevant documents.
- Attempt to resolve pending injury claims under ACHRE's recommendations.
- Continue responsiveness to Congressional and public inquiry.

RECOMMENDATIONS: Continued close coordination with OSD General Counsel, ASD (Public Affairs) and other interested agencies.

POINT OF CONTACT: Colonel Claud Bailey, Jr., USA, (703) 556-7300 or (703) 442-5675

INFORMATION PAPER

SUBJECT: DoD Initiative--Human Radiation Research Review

ISSUE

DoD's efforts to research, document and disclose its involvement in human radiation research from 1944 to the present.

BACKGROUND

DoD actively engaged in an extensive effort to discover the facts about DoD-sponsored human radiation experiments over the last 50 years.

With Secretary Perry's support, the Department is committed to a thorough and complete search of all available records and timely release of pertinent information.

INITIATIVES

- January 7, 1994, Secretary Aspin appoints Dr. Harold Smith as DoD's focal point and calls for moratorium on the destruction of applicable records.
- Soon thereafter the DoD Steering Committee was activated to oversee activities and provide structure and guidance for the Department's actions.
- Detailed guidance was provided on identifying, locating, and retrieving experiment records and reporting results of searches.
- Over 20 major DoD components and agencies rendered initial and final reports. Each report contained two parts:
  - Part I described the search process and identified organizations that may have conducted or sponsored experiments, names of experiments, and the location of associated records.
  - Part II provided a description of the experiments identified in Part I.
- Based on the present requirement to err on the side of inclusion, the DoD has identified about 2,600 possible DoD-sponsored human radiation experiments.
  - It appears that most of these experiments were therapeutic, diagnostic, or tracer studies where radioactive materials or radiation procedures were used to assist the experimentation but the effects of the irradiation were not a central part of the research.
  - However, the DoD chose not to make a judgment regarding the purpose or intent of the possible experiment. Any record that contains three key ingredients, *viz.*, ionizing radiation, humans, and experiments or that relates to intentional environmental releases of radiation is included in the database of possible experiments and submitted to the Advisory Committee on Human Radiation Experiments (ACHRE) for review and study.
  - The organizational distribution of the experiments is as follows:

Army	832
Navy	828
Air Force	918
Agencies	12

- In early 1994, the DoD placed a hold on approximately four million cubic feet of records at Federal Record Centers throughout the nation to ensure no relevant documents were destroyed. In addition, many relevant document collections were identified at DoD facilities. For example,
  - 700 linear feet of records were reviewed at Dugway Proving Grounds, Utah.
  - At the National Records Center, more than 2,000 boxes of Office of the Secretary of Defense records alone have been reviewed for records related to human radiation experiments.
  - More than 1,000 boxes of Office of the Army Surgeon General's records, covering the period from the late 1940s to the late 1960s, were reviewed.
- Based upon the information from the Services and Agencies, many of the experiments identified have one or more of the following characteristics:
  - In some, DoD involvement/sponsorship was "secondary" to the prime motivation for the experiment (e.g., DoD involvement was limited to the documentation of the response of the patient to medical treatment).
  - Many exposures were related to medical treatment (e.g., Navy submariners were treated for ear problems with radium capsules through the nose; the procedure was used extensively by the civilian community).
  - Many studies took place at universities or hospitals as opposed to, for example, prisons, mental institutions and orphanages.
  - Much of the documentation is available in the open literature.
- Some of the experiments that were closely examined by the ACHRE and the public include:
  - University of Cincinnati research experiments conducted from 1960 to 1971, where DoD funds were used for laboratory studies, and psychological and psychiatric tests of cancer patients who received whole and partial body irradiation for the treatment of their disease.
  - Research experiments conducted in the 1950s involving Native Alaskans and using radioisotopic tracer iodine 131 to determine thyroid activity in men exposed to cold.
  - Operation Stoneman II, sponsored by the Navy Radiological Defense Laboratory in 1959, studied dose and radioactive contamination of service personnel (volunteers) who crawled through sand mixed with traces of radioactivity
  - Biomedical experiments possibly conducted in conjunction with atmospheric releases of radiation, such as Hanford, Washington ("the Green Run"); Los Alamos, New Mexico; Oak Ridge, Tennessee; and Dugway Proving Grounds, Utah.
- The Advisory Committee requests for records focused on the development of DoD policy on the use of humans in experiments and biomedical experiments conducted in conjunction with atomic weapons tests that are under the purview of the Nuclear Test Personnel Review (NTPR) Program.
- Detailed experiment information were reported, in a standard format, to the DoD's central repository for human radiation research information--the Radiation Experiments Command Center (RECC). The RECC was initially headed by a Flag Officer and is now headed by an SES civilian.
- Operational since February 1994, the RECC's mission is to consolidate, categorize, and analyze DoD's information. The RECC, which has 20 contractor employees, is DoD's point of contact for radiation experiment matters.
- To date, the approximate cost of DoD-wide research has been $7.36 million.

- Department representatives appeared before five congressional committees investigating human radiation experimentation.
- The RECC is conducting a major research effort concerning policy perspective from 1944 to present.
- DoD is a vigorous participant in the Human Radiation Interagency Working Group (DoD, DOE, HHS, NASA, CIA, VA, DOJ and OMB).
- Approximately 10,000 HRE-related records, consisting of an estimated 200,000 pages, have been collected in a central repository with copies forwarded to the ACHRE.
- The expeditious declassification of relevant material remains a high priority within the Department. Over 1,200 documents have been declassified.
- To date, researchers have logged more than 149,000 personnel hours investigating this subject.
- The RECC has been in contact with more than 7,000 inquirers.

SUMMARY

DoD's actions show its deep commitment to this issue. It will remain a high priority for Secretary Perry and the Department.

POINT OF CONTACT

Colonel Claud Bailey, Jr., USA, Deputy Director, DoD RECC, (703) 556-7300 or (703) 442-5675

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

In Reply Refer To:
103

September 26, 1995

BY FAX

Ms. Ellyn R. Weiss
Special Counsel and Director, Office of Human Radiation Experiments
Department of Energy
Washington D.C. 20585

Dear Ms. Weiss:

In follow up to the Interagency conference call on Friday, September 22, 1995 the VA wishes to include the following items in the Interagency listing of "talking points."

- In its report to the President, the Advisory Committee on Human Radiation Experiments included one recommendation concerning veterans who participated in atomic weapons testing.
- In response to this recommendation, the Secretary of Veterans Affairs will establish an interagency working group representing the Departments of Veterans Affairs, Health and Human Services and Defense to:

  - Review epidemiological tables used to determine whether veterans who participated in atomic testing are eligible for disability compensation and recommend the most feasible way to update these tables to ensure that cancers and other diseases that have a reasonable probability of causation by radiation exposure are included.
  - Review existing laws governing compensation to insure the best balance between allocation of resources and financial compensation to eligible veterans, including review of dose reconstruction.
  - And recommend any needed legislative and administrative changes.

Sincerely,

Susan H. Mather MD

Susan H. Mather, M.D., M.P.H.
Assistant Chief Medical Director for Public Health and Environmental Hazards.

CUMULATIVE STATUS REPORT
VHA RADIATION RECORDS REVIEW PROJECT
AUGUST 1 - OCTOBER 17, 1994

- In early August 1994, MAS, VACO was assigned the task of accessing the amount of radiation records stored at Suitland FRC and developing a plan for their review.

- On August 15, 1994 FTEE detailed to VACO from VAMC's began reviewing records retrieved from Suitland FRC (1772 boxes or approximately 4 million pages of documents)

- As of October 17,1994, all boxes retrieved from Suitland FRC have been reviewed (with the exception of 75 missing boxes) The missing boxes are being reconciled with Suitland FRC.

- A total of 50 FTEE from VAMC's consisted of four separate groups who have worked a total of approximately 45 days since August 15, 1994.

- On October 14, 1994, Group 3 completed review of all boxes sent over from Suitland FRC, with the exception of 75 missing boxes. One full accession remains which is on microfiche. This accession would be approximately 280 boxes if paper.

- On October 17, 1994 Group 4 (12 FTEE) began reviewing the Secretary's records stored on A level of VA Central Office as well as the microfiche. It is anticipated that this phase will be complete by October 28, 1994.

- To date 672 potentially responsive documents have been identified in the boxes retrieved from Suitland FRC and forwarded to ACHRE. These documents include such issues as: correspondence on public information and atomic medicine, VAH's using radioisotope treatment for treating lung disease, radioactive isotope research and researchers, press releases, employment of physicians to perform deep X-ray and radium therapy, radioisotope research funds, purchase of radium for bombs and usage in VAH's and procurement methods, VA methods for release of atomic energy, and accounting procedures and appropriateness of funding in reference to radioisotope research.

- All documents reviewed are being summarized in documents which will permit the indexing and retrieval of all documents reviewed in the future. All responsive documents have been indexed and labeled and copies are being maintained in VACO. All documents and summaries will be electronically stored for future project needs.

TALKING POINTS FOR RELEASE OF FINAL REPORT OF THE PRESIDENT'S ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

THIS IS A MAJOR MILESTONE IN THE PROCESS OF OPENNESS

- The Administration committed to follow this path wherever it would lead in order to rebuild trust with the American people.
- This was a coordinated effort by many federal agencies (Defense, Health and Human Services, Justice, CIA, National Aeronautic and Space Administration, Veterans Affairs, in addition to DOE) and involved searching many thousands of boxes of records scattered throughout the country dating back to the most secret of wartime efforts - the Manhattan Project.
- The federal agencies together delivered some 840,000 pages of records to the Advisory Committee.
- At DOE alone, our search began with records that would cover the Mall 6 inches deep from the Capitol to the Washington Monument.

THE FULL RECORD AS REFLECTED IN THE ADVISORY COMMITTEE'S REPORT ALLOWS US TO EXPRESS REGRET FOR MISTAKES, TO COMPENSATE THOSE WHO WERE WRONGED AND HARMED THROUGH THE FAULT OF THE GOVERNMENT. ONLY THEN CAN WE HONOR THE ADVANCES IN SCIENCE AND MEDICINE THAT WERE MADE POSSIBLE BY GOVERNMENT-SPONSORED RESEARCH

- It is fitting that this story starts with the Manhattan Project plutonium injections since the legacy of secrecy also took root there.
- The Advisory Committee has found that the subjects of these wartime experiments were wronged in an ethical sense because the government failed to inform some of them of the nature of the injections. Secrecy was misused in these cases and we agree that compensation should be paid.
- Persons who were wronged and harmed through the fault of the government should be compensated.
- The Committee has also placed government-sponsored human radiation research in context by concluding that the great majority of the work was for the advancement of science and medicine - we had to acknowledge the wrongs before we could honor the successes.

THE ADMINISTRATION IS RECOMMITTING THE GOVERNMENT TO A RENEWED

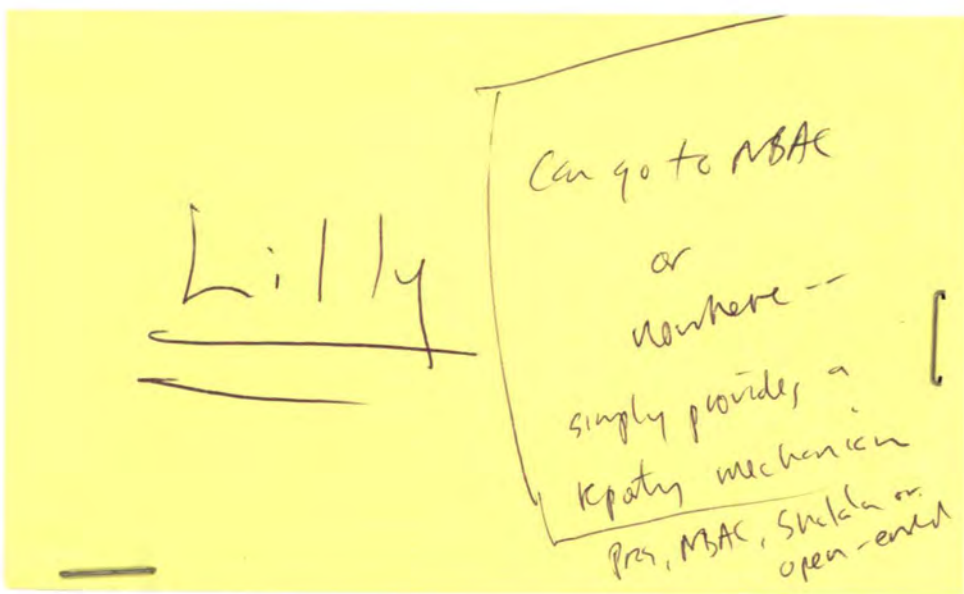
FOCUS ON PROTECTION OF HUMAN SUBJECTS IN RESEARCH

- Human research is a vital element in the development of new drugs and treatments for disease – adherence to the highest ethical standards is necessary for this research to go forward.

- The Advisory Committee has highlighted areas where we need to do better. For example, education in ethics must be enhanced and researchers need to do a more consistent job in conveying clear information about the risks and benefits of participation in research.

- The President is establishing the National Bioethics Advisory Committee as a public forum to address ethical issues of national scope in an ongoing fashion.

- The Department of Energy will begin a proactive performance review in fiscal year 1996 of all DOE laboratories engaged in human subjects research. Just yesterday (October 2), and today, the Department is hosting a Human Subjects Workshop where DOE and other federal representatives will begin addressing the findings of the Advisory Committee. (This is an initiative of the Office of Energy Research)


Lilly
Can go to NBAC
or
nowhere --
simply provides a
Kpathy mechanism
Pres, NBAC, Shalala or
open-ended

DRAFT EXECUTIVE ORDER OR MEMORANDUM

Research investigators and institutions are the stewards of a trust agreement with the people who volunteer to be research subjects. We have a system in place that to the greatest degree possible minimizes the potential for harm to research subjects; enables and protects individual, autonomous choice by subjects; and promotes the pursuit of new knowledge.

Research involving human subjects is conducted, supported, or regulated by 21 Federal Departments and Agencies, including 16 signatories to the 1991 *Federal Policy for the Protection of Human Subjects* and the Department of Labor, Department of the Interior, Nuclear Regulatory Commission, U.S. Postal Service, and Food and Drug Administration. The report of the Advisory Committee on Human Radiation Experiments provides a timely stimulus for each of these Departments and Agencies to review the protections of the rights and welfare of human research subjects that are afforded by existing policies and procedures.

I direct these Departments and Agencies to report the results of their respective reviews, along with identification of measures that should be taken to enhance human subject protections, to the National Bioethics Advisory Commission. Established today by a separate Executive Order, the National Bioethics Advisory Commission will pursue, as its first priority, protection of the rights and welfare of research subjects.

The Federal Government maintains an enduring commitment to ensuring that research involving human subjects is undertaken in accord with the highest ethical standards. By doing so, we protect the rights and welfare of our fellow citizens who make a remarkable contribution to the common good by electing to volunteer for research studies. We owe them our best effort.

William J. Clinton

THE WHITE HOUSE
(date)

COVER SHEET

95 SEP 26 P2:26

FAX

To: Phil Caplan
Fax #: (202) 456-2215
Subject: Draft Executive Order
Date: September 26, 1995
Pages: 2, including this cover sheet.

COMMENTS:

Attached is a draft Executive Order that has been revised along the lines we discussed this morning. If you think it needs additional modifications, please don't hesitate to call. I'll be here most of the afternoon. I have not faxed a copy to Steve Neuwirth, assuming that you would want to see it first. If you want us to send a copy to Steve, just let us know.

From the desk of...

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

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

THE WHITE HOUSE
WASHINGTON

OFFICE OF THE STAFF SECRETARY

Fax Transmittal Sheet

TO: Steve Neuwirth

Fax Number: 61647 **Phone Number:**

FROM: Phil Caplan

SUBJECT:

DATE:

NUMBER OF PAGES (including cover sheet):

MESSAGE:

I asked Hills to re-draft the EO -- this is much later. Pls call ASAP when you get back. I've given a "heads up" copy to Mac Reed. Phil

If all pages are not received, please call 202/456-2702

THE WHITE HOUSE
WASHINGTON

OFFICE OF THE STAFF SECRETARY

Fax Transmittal Sheet

TO: Mac Reed

Fax Number: 57294 **Phone Number:** 53563

FROM: Phil Caplan

SUBJECT:

DATE: 9/26

NUMBER OF PAGES (including cover sheet):

MESSAGE:

This is an early draft -- it may change significantly, but you get the idea. Will need Steve's help.
Phil

If all pages are not received, please call 202/456-2702

6 1647

Office for
Protection from
Research
Risks

National Institutes of Health
Suite 3B01
6100 Executive Boulevard
Rockville, MD 20892-7507

95 AUG 16 P4:39

Date: AUG 16 1995

To: PHIL CAPLAN

FAX: 202-456-2215
Phone: _____

From: Gary B. Ellis

FAX 301-402-2071
Phone 301-496-7005 x205

Comments:

HERE'S THE PREVIOUS STATEMENT ON HUMAN SUBJECTS BY POTUS.

Document consists of 2 pages, including cover sheet.

THE WHITE HOUSE

WASHINGTON

February 17, 1994

MEMORANDUM FOR THE VICE PRESIDENT
THE HEADS OF EXECUTIVE DEPARTMENTS
AND AGENCIES

SUBJECT: Review of Federal Policy for the Protection of Human Subjects

Federally funded biomedical and behavioral research has resulted in major advances in health care and improved the quality of life for all Americans. The pursuit of new knowledge in these fields of research often requires experiments that involve human subjects. Although human subjects research is an essential element of biomedical and behavioral research, bioethical considerations must influence the design and conduct of such research.

Since 1947, when guidelines for research with human subjects were promulgated, there has been increasingly widespread recognition of the need for voluntary and informed consent and a scientifically valid design of experiments involving human subjects.

Over time, this recognition has evolved into a rigorous and formalized system of regulations and guidelines, which were codified in governmental policies on human subject research, and were included in the former Department of Health, Education and Welfare's regulations in 1974, 45 C.F.R. 46. In 1991, 16 agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects. This Policy requires that all research protocols involving human subjects be reviewed by an Institutional Review Board. This review ensures that (1) risks are minimized and reasonable in relation to anticipated benefits; (2) there is informed consent; and (3) the rights and welfare of the subjects are maintained (56 Fed. Reg. 28003 (June 18, 1991)).

Although these regulations provide the framework for protecting human subjects in research, we must exercise constant care and ensure that these regulations are strictly enforced by departments and agencies. Therefore, I direct each department and agency of Government to review present practices to assure compliance with the Federal Policy for the Protection of Human Subjects and to cease immediately sponsoring or conducting any experiments involving humans that do not fully comply with the Federal Policy.

T66065
TRACER

William J. Clinton

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MIN #
130743

COVER SHEET

FAX

To: Phil Caplan
Fax #: (202) 456-2215
Subject: Draft Executive Order
Date: September 25, 1995
Pages: 2, including this cover sheet.

COMMENTS:

Wendy asked me to send you a copy of the draft Executive Order that we prepared. It is being circulated internally at this time for feedback. We will also be sharing this with the Office of the Secretary. If you have any comments or suggestions, please call me. My phone and fax numbers are shown below and I will be the one incorporating changes into the document.

From the desk of...

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

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

DRAFT EXECUTIVE ORDER

The Advisory Committee on Human Radiation Experiments (ACHRE), which was established by Executive Order on January 18, 1994, has recently completed its report. As part of its mandate to provide advice and recommendations on the ethical and scientific standards applicable to human radiation experiments conducted or sponsored by the U.S. Government, the Committee not only reviewed such experiments from the 1944-1974 period but also sampled contemporary research involving human subjects. In its review of present-day research, the Committee found areas within the governmental oversight structure for protection of human subjects that could and should be enhanced. Consequently, it has made a number of recommendations toward this end.

~~In response to these recommendations of the Committee and~~ In recognition of the need for continuing vigilance in the Federal Government's oversight of human subjects protection in research conducted, supported or regulated by the Federal Government, I hereby order both civilian and military agencies whose programs include human subjects research to undertake broad, comprehensive, educational efforts in the ethics of human subjects research, focusing on their own personnel, the biomedical research community, and the health care professions.

Where such efforts are ongoing, they should be further expanded to include broader participation. Where such efforts have already been implemented, they need to be reinforced to heighten the consciousness of those who conduct or oversee the conduct of human subjects research. The Federal Government has a responsibility to ensure that research involving human subjects is conducted in accordance with the highest ethical standards.

To that end, the Federal Government will launch a broad initiative that will include the incorporation of research ethics education into executive level training for senior agency officials with oversight responsibility for human subjects research, expansion of university based research ethics programs, conferences and workshops in conjunction with medical schools and scientific societies, and collaborative efforts with national and state medical associations.

(President's signature)

THE WHITE HOUSE
(date)

326 Dirksen

THE WHITE HOUSE

WASHINGTON

September 5, 1995

MEMORANDUM FOR DISTRIBUTION

FROM: PHIL CAPLAN

SUBJECT: Information on President's event for September 22

The President is scheduled for an event on the afternoon of September 22 where he will publicly receive the report of the independent Advisory Committee on Human Radiation Experiments. We need to discuss several issues and plan for the event on the 22nd, including the press strategy. **Therefore, please come to a meeting on Thursday, September 14, 1995 at 4:00 pm in Todd Stern's office.**

I. Background

The Committee, appointed by the President in January 1994, was charged with reviewing the records of the Federal agencies and providing expert advice on many issues, including 1) whether human radiation experiments sponsored or conducted by the government from 1944-1974 met the ethical and scientific standards of the time and those that exist today; and 2) whether current human subject research safeguards are adequate to prevent recurrence of such ethical abuses.

The event on the 22nd will mark the culmination of the Committee's 18 months of work.

II. Committee's Findings and Recommendations

The Committee's work essentially falls into three categories: 1) a review of experiments from the Cold War, 2) a survey of current human subjects research and 3) secrecy and openness.

1) Cold War: 1944 - 1974

The Committee found conclusive evidence that the government sponsored a very large number of human radiation research experiments from 1944-1974. Because of the large number, the Committee focused on identifying the ethical standards that applied to the government and the medical profession, not the particulars of the hundreds of experiments, although they focussed on a few in-depth. The basic storyline here is that the Committee found that the vast majority of the experiments were not harmful to the subjects, but, nevertheless, the government did not effectively implement policies to ensure that consent was obtained from the subjects.

The Committee will recommend financial compensation for the families of the 18 subjects of the plutonium injection experiments (the experiments for which the *Albuquerque Tribune* won

the Pulitzer) because this was the most egregious example of the government keeping secret an experiment (although it was unlikely physical harm resulted from the experiment itself). The Committee will also recommended compensation for another larger class of people who were subjects of experiments. These people were harmed to some degree, were not in a position to benefit medically, and the experiments were not ethically proper. (There is a staff group led by OMB, Counsel's office and DOE Counsel that is working on the outline of a compensation scheme based on the Committee's broad recommendation.)

2) Current Human Subject Research: 1974 - present
The Committee reviewed 125 current or recently Federally-funded studies (not limited to radiation research) and 1) interviewed patients at leading hospitals in order to gauge the adequacy of procedures for obtaining informed consent from subjects, 2) evaluated the research risks of the experiments and 3) sampled attitudes towards human subject research.

The Committee found that most of the protections and informed consent were up to standard. However, the Committee did find that about 25% of the experiments were "troubling" in terms of the informed consent and the risks involved in the research. The Committee has notified each of the sponsoring institutions (usually a university research hospital) of these problems and asked each of the institutions to strenuously review their procedures. The Committee will recommend 1) enhanced ethics education at med schools and research institutions, 2) a series of measures to ensure that research is clearly distinguished from treatment in obtaining consent, and 3) that Federal oversight be improved and strengthened. (Please see below for how I believe the President should respond to these findings.)

3) Secrecy and Openness
The Committee's recommendations in this section fall generally into two categories: 1) additional safeguards for the protection of human subjects involved in classified research, and 2) environmental oversight of classified programs. The Committee's recommendations are geared to preventing 40s and 50s-style experiments from ever happening again.

III. <u>The September 22 Event</u>

The President has been personally attuned to this issue for quite some time, and has, on several occasions, expressed his desire to do the event. This event will likely get a lot of press attention, even though it is scheduled for a Friday afternoon. *The New York Times, The Washington Post*, and ABC, CBS, CNN and NPR have followed the issue closely and *Time* is also interested in doing a big story.

Likely themes for this event: 1) openness in government, lift the veil of secrecy and ensure that our citizens are never subject to such secret experiments again; righting past wrongs, or 2) add a partisan twist by emphasizing regulatory safeguards; GOP is trying to do away with such protections in many aspects of our lives -- food safety, environment. If they had their way, who knows what would happen (although I don't think this second option is a viable one).

Whatever the theme, I recommend that the President take the following actions on the 22nd:

1) ask the Interagency Working Group on Human Radiation Experiments (eight Cabinet secretaries and staff) to report back to him in 60 days on specific responses to the Committee's recommendations, after he has laid out some guiding principles in his remarks;
2) endorse the Committee's recommendation that those harmed by ethically questionable experiments should be compensated and that the Administration will work with Congress to establish the proper mechanism for doing so.
3) in the meantime, direct (probably by Executive Order) that the Cabinet rigorously review all federally-funded human subject research protections by directing all local Institutional Review Boards to review their procedures and experiments;
4) create the National Bioethics Advisory Committee to set new standards based on the Committee's recommendations (this Committee, known as NBAC, has been on the verge of being created for almost a year -- now would be a good time to get it going)

This is a very positive story for the President and the Administration. The only potential downside to this event is the possibility of raising false alarms. In other words, there is a chance that this report may raise the question of whether our citizens are being experimented on today without their knowledge like in the 40s and 50s. If not explained correctly, the Committee's findings that some current research is "troubling" could be misconstrued. We need to ensure that this aspect of the story is reported accurately and responsibly. At the very least, I think that if the President is reassuring both to the country and the scientific community, we will not face this problem. The President must extol the positive benefits of research -- e.g., cures for disease, chemotherapy -- in the context of his remarks and assure the public that no "secret" research is being conducted by the government.

Again, we need to discuss these issues more thoroughly and plan for the 22nd. See you on Thursday, September 14, 1995 at 4:00 pm. I'll be out of town until the 13th.

Thank you.

DISTRIBUTION:
John Angell
Jeremy Ben Ami
Elgie Holstein
Cathie Woteki
Jake Siewert
David Shipley
Kitty Higgins
Ginny Terzano
Billy Webster
Tracey Thornton
T.J. Glauthier
Steve Neuwirth

not only today but set new policies

burden falls mostly on R. Faden during her ed boards

April 20, 1994

RECEPTION FOR INDEPENDENT ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

DATE: April 21, 1994
LOCATION: Diplomatic Reception Room
TIME: 5:45 pm - 6:15 pm
From: Christine Varney
Phil Caplan

I. PURPOSE

To thank the members of the Independent Advisory Committee for agreeing to serve their country to fulfill this important mission. To let the members of the Committee know how important it is to you that they complete a thorough and independent investigation of the government's involvement in human radiation experiments during the Cold War-era.

II. BACKGROUND

This past January, you issued an Executive Order creating the Independent Advisory Committee on Human Radiation Experiments. The committee, chaired by Dr.Ruth Faden, an ethicist from Johns Hopkins, is in Washington to hold its first meeting. The mission of the committee is to establish the scientific and ethical standards used in the human radiation experiments conducted or sponsored by the government from 1944 - 1974. Experiments after 1974 will be sampled to test their adherence to human subject guidelines established that year.

In addition to investigating the experiments, the Advisory Committee was created to advise members of the Cabinet who sit on the Interagency Working Group. The Interagency Group consists of Secretary O'Leary, Secretary Shalala, Secretary Perry, Secretary Jesse Brown, Attorney General Reno, NASA Administrator Dan Goldin and Director Woolsey.

The Advisory Committee is made up of experts from the fields of medicine, ethics, science and history. They will make an interim six-month report to the Interagency Working Group on the progress of the Committee and will then determine if it is feasible to complete the investigation in one year.

III. PARTICIPANTS

Interagency Working Group:

Secretary O'Leary
Secretary Shalala
Administrator Dan Goldin
Director Woolsey

Members of the Advisory Committee

(A complete list is attached.)

Advisory Committee Staff

Interagency Working Group Staff

IV. PRESS PLAN

Closed. White House Photographer only.

V. SEQUENCE OF EVENTS

- You will enter the Diplomatic Reception Room from the Cross Hall with the Vice President.
- The Vice President will proceed directly to the lectern in front of the fireplace and make brief remarks and then introduce you.
- You will make brief remarks thanking the committee.
- You will first greet the members of the committee and have informal photos taken.
- You will spend the remaining time mingling with other guests and having informal photos taken.

VI. REMARKS

Talking Points Attached

ATTACHMENT #1

Members of Independent Advisory Committee on Human Radiation Experiments

Ethicists

Ruth Faden, Ph.D., Chair - Professor of Health Policy and Management and Director, Program in Law, Ethics and Health, Johns Hopkins University, Baltimore.

Ruth Macklin, Ph.D. - Head, Division of Philosophy and History of Medicine, Albert Einstein College of Medicine, Bronx, New York.

Patricia J. King, J.D. - Professor of Law, Georgetown University Law Center; Adjunct Professor, Department of Health Policy and Management, School of Hygiene and Public Health, Johns Hopkins University, Baltimore.

Jay Katz, M.D. - Professor Emeritus of Law, Medicine and Psychiatry, Yale University **(Professor Katz had the First Lady as a student at Yale Law School)**

Historian

Susan Lederer, Ph.D. - Associate Professor, Department of Humanities, Hershey Medical Center, Penn State University, Hershey, Pennsylvania.

Attorney

Kenneth Feinberg, J.D. -partner, Kenneth R. Feinberg & Associates, Washington, D.C.; adjunct professor of law, Georgetown University Law Center, Washington, D.C.; member, Presidential Commission on Catastrophic Nuclear Accidents, 1989-90.

Epidemiologist

Duncan Thomas, Ph.D. - professor, Preventive Medicine, University of Southern California School of Medicine, Los Angeles, CA.

Clinicians, radiation therapy/nuclear medicine

Eli J. Glatstein, M.D. - professor and chairman, Department of Radiation Oncology, Simmons Cancer Center, Southwestern Medical Center, University of Texas, Dallas, TX.

Henry D. Royal, M.D. - associate director, Division of Nuclear Medicine, Mallinckrodt Institute of Radiology and professor of radiology, Washington University School of Medicine, St. Louis, MO.

Mary Ann Stevenson, M.D. - assistant professor in radiation therapy, Joint Center for Radiation Therapy and deputy chief, Department of Radiation Oncology, New England Deaconess Hospital, Harvard Medical School, Boston, MA.

Clinician, non-radiation/public health
Reed V. Tuckson, M.D. - president, Charles R. Drew University of Medicine and Science, Los Angeles, CA.

Military medicine specialist
Philip K. Russell, M.D. - professor of international health, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, MD.

Radiation biologist
Nancy L. Oleinick, Ph.D. - professor of radiation biology and biochemistry, Environmental Health Science and Oncology, School of Medicine and director, Division of Biochemistry and Oncology, Department of Radiology, Case Western Reserve University, Cleveland, OH.

General scientist
Frank Press, Ph.D. - fellow, Cecil and Ida Green Fellowship, Carnegie Institution of Washington, Washington, D.C.; former president, National Academy of Scientists.

Citizen Representative
Lois L. Norris - community representative, Institutional Review Board, University of Nebraska; retired second vice president, Omaha National Bank and Omaha National Corporation, Omaha, NE;

ATTACHMENT #2
TALKING POINTS

RECEPTION FOR INDEPENDENT ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

- Welcome to the White House.

- Thank you to Secretary O'Leary for bringing these important issues to light. Thank you to Secretary Shalala, Director Woolsey, Administrator Goldin, for your commitment to the truth and thank you to the staffs of the various agencies who have worked so hard over these last 4 months to put this whole effort together.

- Thank you most of all to the members of the Advisory Committee, and especially, Dr. Ruth Faden, Chair of the Committee, for serving your country and putting so much of your time and energy into this important effort.

- This mission you are undertaking is critical to helping restore the trust in government that is so missing in our society . Years ago, our government may have done things to people in the name of national security or science that today we find unacceptable. It is your mission to advise Members of my Cabinet on how to deal with such hard truths.

- This is not an easy task. Without gutsy scientific research we would not have found the cure for polio or smallpox or other sicknesses. We would not today be making progress on cancer cure rates or AIDS or Alzheimers or other current-day diseases. We would not have developed MRIs or CAT Scans or other diagnostic tools.

- But, from what I know, some of the issues you will confront will be different. The experiments may not have served a proper purpose. That is for you to review. It will be difficult at times to criticize scientific colleagues, but in the end you will have done right. And the American people will thank you.

- I know that you began your meetings today. I am sure it is the first step on the road to the truth.

- Thank you for your commitment, your time and energy. We all appreciate it.

TALKING POINTS FOR THE VICE PRESIDENT

RECEPTION FOR INDEPENDENT ADVISORY COMMITTEE ON HUMAN RADIATION

- Welcome to the White House

- Acknowledge members of the Interagency Working Group on Human Radiation who are present: Secretary Hazel O'Leary, Secretary Donna Shalala, NASA Administrator Dan Goldin, Director of Central Intelligence Jim Woolsey.

- And those who couldn't be with us tonight, Secretary Jesse Brown, Attorney General Janet Reno and Secretary William Perry.

- Thank you to the members of the Advisory Committee for agreeing to serve on this very important body. Your expert advice and information that you will provide to the members of the Cabinet and the Administration will help us immensely in getting to the truth. The facts are what are so vital to this process and your work is critical to that process.

- The President I know is personally very committed to revealing to the American people the nature and extent of the government's involvement in these experiments and without your work we would not be able to achieve that goal.

- And now I would like to introduce the man who appointed you and has given you your charge, President Bill Clinton.

DRAFT TALKING POINTS
CALL TO ORDER
Meeting of Independent Advisory Committee on Human Radiation Experiments

- Good Morning, my name is Christine Varney. I am Deputy Assistant to the President and Secretary to the Cabinet and the designated federal official for this first meeting of the Independent Advisory Committee on Human Radiation Experiments. I hereby call this meeting to order.

- The Advisory Committee was established by the President by Executive Order on January 18 of this year. This expert panel of ethicists, medical doctors, research scientists, lawyers and clinicians is appointed and charged by the President with a very important mission: to provide expert advice and information to the members of the Interagency Working Group. Members of the Working Group include Secretary Hazel O'Leary, Secretary Donna Shalala, Attorney General Janet Reno, Secretary Jesse Brown, NASA Administrator Dan Goldin, CIA Director James Woolsey and OMB Director Leon Panetta. Shortly we will hear presentations from the Interagency Group.

- The work of the Committee is critically important to the President and to his Administration. It is about being open and forthright and getting to the bottom of some troubling issues that the American people are concerned about.

- On behalf of the Administration, I would like to thank the members of the Committee for agreeing serve and commit so much time to this effort. It will not be easy.

- The President asked me, as Secretary to the Cabinet, to help coordinate the efforts of the Interagency Working Group. We have strived to be very open and accommodating in this whole endeavor. The Interagency Group has conducted several congressional briefings and made every effort to accommodate public interest in any experiments that were conducted. The Advisory Committee will operate under the Federal Advisory Committee Act and its meetings will be open to the public -- as they are today and tomorrow.

- According to the President's Executive Order, the Committee should consider, among other things, whether there was a clear medical or scientific purpose for the experiments, whether appropriate medical follow-up was conducted, and whether the experiments' design and administration adequately met scientific and ethical standards, including standards of informed consent. Other questions you should answer include by what criteria should you judge these experiments? Were wrongs committed, was harm done and how might the Administration intervene to avoid further harm? You are to review experiments from 1944-1974. You may also review experiments conducted after 1974 to determine if federal rules adopted that year adequately protected human subjects. We hope you will do

this.

- The Advisory Committee is a free standing, independent body. The Interagency Working Group will rely very heavily on you the Committee for expert advice on a wide range of issues; speaking for the Interagency Group, I want to emphasize the importance we place on the independence and frankness of your work.

- I am not a scientist but I am familiar with the work of scientific advisory committees. This committee, you should realize, may be different than previous committees on which you may have served. As you can see by the media here today, you will be observed closely. Congress will be very, very interested in your work. You will not just address scientific research issues but a range of potentially far-reaching policy implications involving ethics and the history of science.

- You are an impressive line-up of experts and Dr. Faden has assembled an impressive and very professional staff. You have a difficult but very important job ahead of you. And you have license to hold the government's "feet to the fire. Thank you and good luck.

- The first order of business is for the Advisory Committee to be sworn in. Tim Sanders. Deputy Executive Clerk at the White House will do the honors. Tim....

95 SEP 27 P5:27

FAX Transmittal Sheet

DATE: September 27, 1995

TO: Phil Caplan

ORGANIZATION: Office of Staff Secretary

TELEPHONE: 62702

FAX: 62215

FROM: RACHEL E. LEVINSON

TELEPHONE: 202-456-6137

FAX: 202/456-6027

NUMBER OF PAGES, INCLUDING COVER PAGE: 2

SPECIAL INSTRUCTIONS: As promised. Note: still says "in consultation with"

NATIONAL BIOETHICS ADVISORY COMMISSION
FACT SHEET

The Office of Science and Technology Policy (OSTP), in consultation with members of the National Science and Technology Council and interested members of Congress, has developed a proposal to create a standing body of experts to consider bioethical issues arising from research on human biology and behavior, including clinical research, and the applications of such research. The goal is to establish a panel of non-government experts in the relevant scientific disciplines, law, and ethics, as well as community representatives, to provide advice and recommendations to the Federal government. To engage broader public participation in the discussion of such a group's role and composition, a draft charter for a National Bioethics Advisory Commission was published on August 12, 1994, in the *Federal Register* for comment. Comments received in response to this Notice have been incorporated into the final document. The Commission will report to the President's National Science and Technology Council and will operate under the provisions of the Federal Advisory Committee Act.

BACKGROUND: OSTP began developing this proposal at the request of the Departments of Energy and Health and Human Services, in October 1993. These agencies had been considering establishment of a joint advisory panel to examine issues related to maintaining the confidentiality of genetic information resulting from the Human Genome Project. It became clear that there were a number of other bioethical issues that would benefit from consideration by an expert, standing advisory body. Thus, the informal interagency working group was expanded to include representatives of DOD, NASA, VA, NSF and Justice. The products of these discussions are the draft charter and preamble that were published in the *Federal Register.*

The key points of the charter are:

- The immediate charge to the Commission will be to consider issues in the protection of the rights and welfare of human research subjects and management and use of genetic information.

- The general charge to the Commission will be 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. The Commission will have the authority to establish its own priorities and agenda, in accordance with four criteria described in the charter, and in consultation with the National Science and Technology Council.

- The Commission will be composed of experts in the fields of philosophy and theology, social and behavioral science, law, medicine and biological research, in addition to representatives of the general public. Its members will be appointed by the President.

For further information contact: Rachel E. Levinson (202) 456-6137.