DoD Radiation Experiments
Command Center

6801 Telegraph Road
Alexandria, VA 22310
(703) 556-7300
(703) 847-0890 Fax

Date: 25 MAR 97

Time: 1600

TO: ELIZABETH DRYE / ELLY MELAMED

VERIFICATION: _____

FAX: 202-456-7079 202-536-2360

FROM: CC Bailey

VERIFICATION: _____

FAX: _____

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COMMENTS:

I hope this helps.

CBY

Sent By: CC BAILEY

Please call our office immediately if you did not receive this entire transmission or if you have any questions. Thank you.

DoD Nasopharyngeal Radium Irradiation Update

The Groton study log book contains the names of approximately 1,600 submariner trainees that may have taken part in a 1944-1945 study of various treatment methods for aero-otitis media, including nasopharyngeal radium irradiation (NRI). Of the 1,600, the DoD has reviewed personnel and/or medical records for 1,338 of these individuals and confirmed 84 NRI treatments. Further, researchers from the Department of Defense (DoD) Radiation Experiments Command Center (RECC) reviewed in excess of 110,000 submariner trainee data cards and two years of muster logs for Submarine Base, New London to verify the identities of individuals identified in the log book. The DoD and VA have collected the names of 51,000 submariner trainees and Army Air Forces servicemen that served at military installations that used the NRI treatment. A joint review of 5,500 personnel and medical records from this population is on-going. Information gathered during this effort will be evaluated to determine the efficacy of an epidemiological study.

ACTIONS TO RESPOND TO THE PRESIDENT'S ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
QUESTIONS AND ANSWERS (NOT FOR DISTRIBUTION)
-- DRAFT --

Overview of Advisory Committee Scope, Findings, and Recommendations

Q: What is the universe of experiments studied by the Advisory Committee?

A: The President's directed the Advisory Committee on Human Radiation Experiments (ACHRE) to review government sponsored biomedical experiments on individuals involving intentional exposure to ionizing radiation, focusing on the period from 1944 until 1974. The Committee did not consider common clinical practices that involved incidental exposures to ionizing radiation (e.g. x-rays).

The President's charge also covered intentional releases of ionizing radiation designed to test human health effects or to measure the extent of human exposure. The Committee studied a number of populations exposed to radiation during the government's Cold War activities, including veterans of atomic test blasts, western uranium miners, and residents of the Marshall Islands.

Q: How many experiments does this include?

A: No one knows exactly how many experiments this includes. The Advisory Committee reported that the government had sponsored several thousand human radiation experiments between 1945 and 1974.

Q: How many people were involved in these experiments?

A: Because only fragmentary information has survived about many of these experiments it was not possible for the Advisory Committee to estimate how many people were involved.

Q: How many people were harmed in the experiments?

A: The Advisory Committee was not in a position to answer this question completely. In general, the Committee found that the majority of experiments they studied involved trace amounts of radiation given to adults, similar to those used in research today. These were unlikely to have caused harm. The Committee identified several groups of experiments that may have increased individuals' risks, including total body irradiation experiments on ill patients and iodine-131 experiments involving children.

Q: How many people were not informed in advance that they were the subject of an experiment?

A: Only very limited documentation about consent in individual experiments has survived and no estimates can be made. Generally, the Committee found that researchers obtained consent from healthy subjects, but not from patient-subjects.
The Advisory Committee did look more broadly at issues of informed consent across the government and found that the government did not have comprehensive policies in place before 1974. Although the government has strengthen informed consent procedures significantly since 1974, the Committee recommend -- and the Administration is taking -- additional steps to improve informed consent, including requiring informed consent in all classified research and studying further the inform consent process.

Q: What did the Advisory Committee recommend?

A: The Committee made 18 recommendations to open the record to the public, compensate those who were wronged, and protect human subjects of future research.

Q: What has the Administration done to respond?

A: The Administration has already taken steps in each of these areas. For example, to open up the record, the Administration has put thousands of pages of documents on the Internet and in the National Archives, and has developed document search guides. To better protect human subjects in the future, the President established the National Bioethics Advisory Committee (NBAC) and asked NBAC to examine many of the questions raised by ACHRE. To redress the wrongs of the past, the President apologized to subjects of radiation experiments and their families, and agencies have worked hard to settle compensation claims. These and many other actions responding to the Committee's recommendations are outlined in the report released today.

Today the Administration also announced two new actions -- the President is issuing a directive strengthening protections for subjects of classified research, and the Administration is proposing legislation to improve compensation for uranium miners.

Q: Are current protections for subjects of human research inadequate?

A: A strong system of Federal oversight, education, and sanctions is currently in place to ensure the protection of the subjects of government sponsored human research. The Administration has taken a number of steps to further strengthen protections for human subjects based on the Advisory Committee's recommendations. For example, the National Bioethics Advisory Committee is reviewing Institutional Review Board policies -- IRB's are the local boards that review the ethics of individual research projects. And today the President signed a directive to protect subjects of classified research.

The Administration is also working to improve the informed consent process. Despite the vigor with which all parties embrace the informed consent process, the Advisory Committee found that little is actually known about the effectiveness of this transaction between researcher and prospective subject. In response, the NIH and the Departments of Energy and Veterans Affairs are initiating research to develop new knowledge about the informed consent process.

Q: Now that the National Bioethics Advisory Commission has been given a special assignment on cloning, does this mean that there will be a delay in addressing protection of human research subjects.

A: No. the National Bioethics Advisory Commission has already established an ambitious plan of work to address the current status of Federal protection for human research subjects. The work will proceed in parallel with the special assignment on cloning. NBAC is planning to issue a report to the President and to Congress in October and hopes that little or no delay will be incurred as a result of the additional work.

Q: What is being done to provide compensation in connection with the human radiation experiments?

A: The Advisory Committee recommended the government compensate or consider compensate subjects of certain biomedical experiments. The Department of Justice has worked closely with other Departments to resolve individual claims. As announced today, the Administration has resolved all claims brought forward for experiments the Advisory Committee specifically identified for compensation. The Administration has settled with families of 16 plutonium injection subjects. The plutonium injection cases were singled out by the Advisory Committee as being particularly troubling ethically and deserving of compensation because efforts were made by the government to keep information secret from the subjects or their families to avoid government liabilities or embarrassment. The Advisory Committee also identified two other experiments for compensation (see Recommendation 1), but the subjects of those experiments are unknown.

Several other experiments were identified by the Advisory Committee for consideration for possible compensation, subject to further development of the facts surrounding the experiments. That fact-finding continues in a number of these cases. [Refer detailed questions to DoJ].

Some populations exposed to radiation releases studied by the Committee are already eligible for compensation under existing law, including atomic vets and uranium miners. The Committee recommended certain changes to these programs. The Administration has reviewed and acted on those recommendations. For example, today we are announcing new legislation to improve compensation for uranium miners.

Presidential Directive on Classified Human Research

Q: What portion of past experiments was classified?

A: Only a very small number of past experiments were classified, mainly those that took place during the Manhattan Project and were associated with the war effort. However, information about unclassified experiments was not necessarily easily accessible to the public or generally known and made available.

Q: Why is there a need for the Presidential Directive on classified research and what does it do?

A: The Advisory Committee acknowledged that the government should maintain the ability to do secret human research where such research serves national interests, but the Committee found that the subjects of secret research need safeguards beyond those provided for subjects of unclassified research. The President's directive require agencies to propose new protections through regulation. For example, Agencies will propose to require consent from subjects in all classified human research without exception, to require permanent recordkeeping, and to require scientists to tell potential subjects that the research is classified. Agencies will also propose a new review process for classified human research requiring, among other things, that the head of any agency sponsoring secret research personally approve the project. These actions address concerns raised by the Advisory Committee and should prevent the mistakes of the past from occurring again.

Q: How many people are currently involved in classified human research? How many classified experiments are currently taking place?

A: As far as the Administration's Interagency Working Group has been able to determine, there are currently no classified human subject experiments being sponsored by the government and consequently there are no people involved in classified human subject research.

Up to now, there has been no regular reporting requirement in relation to classified human research. Under the President's directive on classified research, the Government will closely monitor and regularly report on any classified human subject research that may be taking place.

Proposed Amendments to the Radiation Exposure Compensation Act / Uranium Miners

Q: What is the purpose of the proposed legislation to amend the Radiation Exposure Compensation Act (RECA)?

A: Uranium miners were exposed to high levels of radon daughters. The government knew the mining conditions were hazardous and how to reduce the hazard, but did not take action. As a result, hundreds of miners have developed preventable lung cancers and other lung diseases, and many have died. Congress passed RECA to provide proper redress, but the Advisory Committee found that the present RECA eligibility criteria for compensation should be improved. This legislation would amend the RECA to incorporate new compensation criteria for lung cancer that reflect the latest scientific data, and better achieve the statutory goal of providing compassionate payments to individuals who suffer or have suffered from lung cancer as a result of their exposure to radiation in uranium mines. The legislation would also expand the existing list of compensable diseases for downwind and onsite participant claimants to reflect current scientific knowledge.

Q: Who will benefit from this legislation?

A: This legislation will principally benefit uranium miners who suffered or suffer from lung cancer. The legislation would incorporate new eligibility criteria for lung cancer, including defining eligibility for partial compensation. The new criteria would apply to uranium miners covered by the Act who presently suffer from or contract lung cancer in the future (prior to 2010 when the Program is scheduled to terminate), as well as all uranium miners with lung cancer who previously were denied compensation because they did not meet the present eligibility criteria. The Administration anticipates that most of the claimants who will benefit from this legislation reside in Arizona, Colorado, New Mexico, Utah or Wyoming, the states covered by the RECA.

Q: How many people will benefit from the legislation, and how much compensation will they receive?

A: The Administration estimates that over 500 uranium miners who do not presently qualify for compensation under the RECA would receive either full or partial compensation under the proposed amendments. The Administration estimates that these newly eligible miners would be paid approximately $45 million dollars in compensation over 15 years: over 300 miners would be eligible for full compensation ($100,000 per miner), and over 200 miners would be eligible for partial compensation ($50,000).

Q: What is the budget impact of the proposed changes to RECA? What would be the source of any additional funding made necessary by the proposed changes?

A: The Administration estimates that the proposed changes to RECA will lead to approximately $50 million in additional compensation over the next 15 years. The Administration believes that this estimate is conservative, and that the actual figure may prove to be lower, though such

estimates involve substantial uncertainty. Compensation will be provided through annual appropriations to the Radiation Exposure Compensation Trust Fund, which the original 1990 RECA legislation created to remain active through the year 2012. To date, the Department of Justice has provided about $200 million in compensation through the Trust Fund, which received a replenishment of $30 million in 1997.

Additional Questions on Veterans, Persian Gulf, and Environmental Releases.

Q: Is the government taking any steps to help veterans?

A: The Advisory Committee looked at two types of radiation exposures affecting veterans -- atomic test blasts and nasopharyngeal radium treatments. Hundreds? of veterans were exposed to radiation during atomic test blasts. Congress has already passed legislation to compensate veterans harmed by these exposures. In response to Advisory Committee recommendations, the Administration is taking steps to improve the administration of these programs (see below). Some veterans -- particularly Navy submariners -- were exposed to nasopharyngeal radium treatments during their service. The Department of Defense is working to identify those affected and, if appropriate, will follow up with subjects of the experiments.

Q. What specifically is the Administration doing to improve compensation for atomic vets?

VA recently proposed to expand the list of diseases it recognizes as radiogenic by including all forms of cancer. This means that a veteran with cancer will no longer have to establish that a specific cancer is radiogenic before VA can determine entitlement to benefits based on the estimated level of radiation that the veteran was exposed to while in the military. As recommended by the Advisory Committee, the VA is also updating the "epidemiological tables" to improve the scientific basis for veterans' compensation under the existing compensation system.

In addition, the Department of Veterans Affairs (VA) is drafting legislation to make veterans exposed to nasopharyngeal radium irradiation during military service eligible for VA's Ionizing Radiation Program. This includes eligibility for a screening exam and special eligibility for treatment of conditions recognized by VA by statute or regulation as being potentially radiogenic

Q: Are the controversies surrounding radiation experiments and the Persian Gulf illnesses in any way similar or related?

A: Yes, there are some similarities regarding the Administration's response to public concerns about the two sets of events. President Clinton appointed advisory committees to thoroughly investigate both events and directed complete cooperation from all Federal agencies. Issues of secrecy in government recordkeeping have created a "credibility gap" with the participants and their advocates regarding both events.

The Administration's openness initiatives and related directives will help ensure the future welfare of our nation's military personnel and the American public. In addition, hundreds of thousands of pages of documents on these two events are now openly accessible via the Internet.

Q: What steps is the government taking on environmental releases of radiation?

A: The Advisory Committee made several recommendations to ensure that secret environmental releases could not occur in the present without being appropriately approved and documented. EPA, in conjunction with Federal agencies conducting classified research, is taking steps to improve environmental oversight and enforcement capability over all classified activities. EPA will also establish and maintain a permanent file to document EPA's classified reviews under the National Environmental Policy Act (NEPA).

The Government is also taking a number of steps to improve its program for providing compensation and redress to certain groups of people who developed radiation-related diseases as a result of radiation exposure from the government's Cold War nuclear weapons program, including atomic veterans, uranium miners, and Marshall Islanders.

Additional Background on Status of Compensation Claims:

In its final report, the Advisory Committee on Human Radiation Experiments recommended, in effect, that the government offer an apology and compensation to the families of eighteen subjects of certain plutonium injection experiments conducted at several hospitals under contracts with a Department of Energy predecessor agency in the mid-1940s. Representatives of sixteen of the eighteen families filed lawsuits against the hospitals, the doctors involved in the experiments, and the United States (or former employees of the United States), or filed administrative claims with the Department of Energy. The United States has now settled all of these lawsuits and administrative claims, providing for compensation for the families of all of the plutonium injection subjects who have come forward and to one additional subject of a uranium injection experiment that was not included in the Advisory Committee recommendation.

The total amount of these settlements was $6,332,500 ($2,755,625 of which is payable from the Judgment Fund, a continuing appropriation to pay settlements by the United States, the balance being paid by the Department of Energy pursuant to its contracts with the hospitals where the experiments took place).

Examples of some of the additional cases that the Advisory Committee identified for further consideration were the following:

In re Cincinnati Radiation Litigation (Southern District of Ohio)

The United States has cooperated with counsel for the plaintiffs and the defendants in this case involving total body irradiation at the University of Cincinnati and has agreed to share in the $4,269,500 in compensation to be paid there. The United States' share will be $1,030,000. That class-action settlement is currently under consideration for preliminary approval by the district court.

Vanderbilt University Nutrition Study

Craft v. United States (M.D. Tenn.)

Plaintiffs are two subjects and the child of one of these subjects, who participated in an iron uptake study among pregnant women in the Vanderbilt University Medical Center. The only defendant is the United States; but Plaintiffs filed a related class action against the State of Tennessee, private institutional entities, individuals, and Monsanto, a government contractor that operated Oak Ridge National Laboratory. Plaintiffs agreed to accept a monetary settlement and dismiss the United States.

Fernald School Cases

Beaulieu v. Blemont, Shattuck v. M.I.T. (District of Massachusetts)

These cases involve claims of 26 individuals arising from experiments in calcium metabolism at the Fernald State School, a residential school in Massachusetts, some of the students of which had special needs. The claimants have sued the State of Massachusetts, Massachusetts Institute of Technology, Quaker Oats Company, individual researchers, and the United States. The United States has joined all of the other parties in court-annexed mediation.

Oregon Prisoner Case

Bibeau v. Pacific Northwest Research Foundation, Inc., et al. (District of Oregon)

A husband and wife, Harold and Melanie Bibeau, have filed an action premised upon Mr. Bibeau's voluntary participation in a testicular irradiation experiment while he was an inmate of the Oregon State Penitentiary from 1963 to 1969. Defendants are Pacific Northwest Research Foundation, Battelle Memorial Institute, Oregon Department of Corrections officials in their individual and official capacities, former federal employees of the AEC in their individual capacities, and the United States.

Message - Human Radiation Experiments Report
Draft - as of 3/24/97

In January 1994, after Cold War-era experiments involving the effects of radiation on humans came to light, I established an independent Advisory Committee on Human Radiation Experiments to investigate these reports. I asked the Committee to shine the light of truth on this aspect of our nation's past.

After taking extensive testimony and conducting numerous public hearings, the Advisory Committee issued its report in October, 1995. The Committee's report made recommendations that spoke to improving ethics in human research today, and righting the wrongs of the past inflicted on unknowing citizens. In my remarks when I accepted the report, I promised that it would not be left on the shelf to gather dust. I made a committment that we would learn from the lessons that the report offered and use it as a road map to lead us to better choices in the future.

This document -- the Administration's response to the Advisory Committee's report -- is a milestone in that commitment. My Administration has been actively at work responding to the important recommendations made by the Advisory Committee through an interagency working group made up of representatives from the Executive Office of the President, the Departments of Energy, Defense, Health and Human Services, Justice, Veterans Affairs, the National Aeronautices and Space Administration, and the Central Intelligence Agency. The Environmental Protection Agency has also joined the effort. This report reflects the joint progress of these agencies on the Advisory Committee's recommendations.

The Administration has made significant achievements in opening government and making information more easily available to the citizens to whom it belongs. Agencies have also improved the protections in place for subjects of future human research. Finally, the government ~~has provided~~ redress to those who have suffered from radiation experiments, as defined by the Advisory Committee.

I emphasize that this document is by no means the end of the journey. Much work remains to be done. I am confident that all of us -- the eminent committee that produced the original report, the Federal officials who worked so hard to support the Committee's efforts and now are implementing its recommendations, and most importantly, the citizens of this great country from whose experiences we have learned so much -- can together help ensure a better world for our children.

My thanks to all of you for a job well done, I pledge my strong support for your continued efforts.