### **Overview**

The ACHRE report reviewed in detail several case studies of government-supported human radiation research including: the injections of plutonium into 18 hospital patients during and after World War II, research with prisoners, and research on patients who were exposed to total body irradiation in clinical settings.

The Advisory Committee also considered issues related to certain radiation exposures associated with government activities that the Advisory Committee concluded should not be considered "human experiments." These exposures were sustained as a result of government activity undertaken for purposes other than human radiation research. The exposed populations include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

The Committee recommended several steps that the government should take to make amends for the specific wrongs for which the government bears moral responsibility.

This section of the report discusses ACHRE's findings and recommendations in the areas of notification, apology, and compensation and presents the Administration's response. Within the discussion of compensation, the report addresses individual cases, uranium miners, other populations covered under the Radiation Exposure Compensation Act, veterans, and Marshall Islanders.

### ACHRE Findings and Recommendations on Notification

The Advisory Committee found "no subjects of biomedical experiments for whom there is a need to provide notification and medical follow-up for the purpose of protecting their health." In addition, the Committee found no evidence that descendants of subjects of human radiation experiments have a greater likelihood of inheriting genetic effects.

The Advisory Committee recommended that (Recommendation 4):

 For any newly-discovered experiments the government should notify participants and provide medical follow-up for "those subjects for whom there is a significant risk of developing a

The ACHRE report reviewed in detail several case studies of government-supported human radiation research. radiation-related disease that has not yet occurred, or has occurred but may still be undetected or untreated, and in whom there might be an opportunity to prevent or minimize potential health risks through detection and treatment."

• The government need not notify subjects of experiments reviewed by ACHRE for public health reasons because they did not meet the recommended criteria for notification.

#### Response

The Administration's view is that, *in general*, ACHRE's recommendation is correct. For public health reasons, the government will notify any identified subjects who meet the criteria in the ACHRE report; these include any subjects placed at a significant risk for development of a radiation-related disease, where there is a recognized medical benefit from early detection and treatment. (Because medical science is not static, neither is the decision as to whether there is a medical benefit.)

Beyond protecting public health, the government will seek to support as fully as possible an individual's right to know about actions that may have affected him/her. Therefore, the government will also notify an identified experimental subject if the subject requests the information; if the government determines that a subject is likely to fall within the criteria for government compensation; and, on a case-by-case basis, if there is uncertainty about the effects of the experiment and notification is necessary to investigate whether subjects were placed at significant risk and whether there is a potential benefit from treatment. The Administration believes that this approach fulfills the government's grave responsibility to inform subjects while maintaining respect for those people who would not want information that has no tangible benefit.

It is important to be clear that notification is not simply the process of taking existing lists of names, current addresses, and phone numbers and contacting people. For most experiments, names are unavailable. Much of the information about past experiments comes from the published literature which does not generally include names. Even where more detailed records have survived, information about individuals is generally fragmentary and does not include anything about their current whereabouts. Much of the information about individuals is in the records of private hospitals and universities where confidentiality and privacy rules prohibit government access.

Beyond protecting public health, the government will seek to support as fully as possible an individual's right to know about actions that may have affected him/her. For all of these reasons, the process of locating individuals or next of kin many years after the experiments took place is difficult, time consuming, costly to the taxpayer, and likely to have limited success. Where individuals can be found, it is difficult to assess their exposure and risk given the limited data available.

Notwithstanding the difficulties of undertaking individual notification, the government reaffirms its continuing commitment to openness. Where the government does not undertake individual notification, it will continue to make material relating to human radiation experiments available to the public, to respond to individual inquiries relating to these experiments, and to carefully review any newly identified experiments in the light of the Advisory Committee notification criteria.

#### Discussion

ACHRE was charged to make a recommendation about notification for the purpose of protecting the health of subjects or their descendants. After careful consideration, however, ACHRE recommended that decisions about notification be based on "evaluation of both the level of risk from radiation exposure and the potential medical benefit from medical follow-up in exposed individuals." In discussing this recommendation, ACHRE observed that notification can impose new burdens on subjects that must be weighed against the potential for medical benefit from notification. These burdens include anxiety; medical harm; inconvenience; possible stigmatization by friends, family, employers, or insurance carriers; and cost of seeking medical testing or follow-up. ACHRE recommended notification in the limited circumstances where the criteria for medical benefit were satisfied or where the individual seeks notification. ACHRE endorsed the principle that citizens are entitled to know if they or a relative were a subject in a radiation experiment. To assist individuals in pursuing answers to this important question, ACHRE included a citizen's guide in its Final Report.

ACHRE's recommendation on notification has generated controversy among stakeholders, including those who participated in the Stakeholders Workshop of February 26–27, 1996, held by the Federal Departments. As the Advisory Committee detailed, many of the wrongs in experimentation involved the failure to obtain consent from subjects or to fully disclose risks and benefits (or lack of benefits) of the experiments, rather than actual adverse health effects from the testing. Some stakeholders believe the government has a responsibility to notify and provide medical follow-up to all who were wronged by the government; not only those who were physically harmed by the government's conduct. Although it is difficult to generalize about the diversity of views presented at the Even where more detailed records have survived, information about individuals is generally fragmentary and does not include anything about their current whereabouts. Workshop, the stakeholders generally advocate that the government pursue some form of notification, and fund medical care by individually chosen physicians. Many subjects and families of subjects do not have confidence that the government can honestly make a judgment about notification, or that the government can, without bias or intimidation of subjects, implement any needed medical follow-up. Others suggested that subjects would want to be notified, whether or not they were harmed.

The Administration agrees that the decision of when and how to notify experimental subjects requires a judgment about whether individuals would want to be notified even if there is no public health reason for notification.

Where the agencies discover new records containing information that would allow notification, the Administration will notify subjects that meet the ACHRE public health criteria, and will also notify those that meet any one of three additional criteria which are intended to shed light on the non-health benefits that may accrue to those who may be notified. As noted above, notification will take place if the subject requests the information; if the government determines that a subject is likely to fall within the criteria for government compensation; and, on a case-by-case basis, if there is uncertainty about the effects of the experiment and notification is necessary to understand whether subjects were placed at significant risk and whether there is a potential benefit from treatment. The Administration believes that these other benefits—where they are present—would cause most subjects to prefer notification.

*Information requests:* Where information is available, it will be provided to the possible experimental subject, if they so request. The government will use all reasonable means to let individuals know that they have the opportunity to ask questions about their own history and a choice about whether to pursue that information.

To make the choice meaningful, the government has provided widespread opportunities for individuals to seek information about their own involvement as subjects of research. Publicity about the existence of experiments, and the widespread availability of information about human radiation experiments, has generated thousands of inquiries from those who want to know whether they were experimental subjects. This response suggests that the government's outreach efforts allowed many possible subjects to choose whether to seek more information.

Based on the response so far, the Administration believes that continued publication of general information and follow-up of individual inquiries satisfies much of the government's obligation to notify experimental subjects.

The government has provided widespread opportunities for individuals to seek information about their own involvement as subjects of research. *Additional research:* In the event that the Departments uncover additional experiments, any newly-discovered subjects will be notified of their participation by the Department that sponsored the research, based on the criteria discussed above.

As experiments are identified, there may be uncertainty about whether initial exposures to radiation significantly increased the risk to subjects. In at least one case, that of members of the armed services exposed to nasopharyngeal radiation, there may be a sufficient number of identifiable subjects to allow for a follow-up study. The follow-up study would be designed to identify any risk to subjects and whether medical follow-up could be beneficial. The Administration's policy does not preclude conducting such a study—even though the government cannot answer with certainty what level of risk is faced by former subjects and whether there is any prospect of medical or other benefit to subjects from a followup study. Any follow-up study should move forward only under the following conditions:

- 1) All care has been taken to minimize any harmful effects of participating in a study.
- 2) Members of the public have been consulted regarding the study and its fairness to individuals who will be notified of their prior participation in an experimental treatment.

### Actions to Date

The most important actions the government has taken to notify subjects are the actions described in Part 1 of this report, Openness in Government. This widespread public availability of information has given individuals the opportunity to choose whether they will seek additional information about their own possible involvement in experiments.

*Individual inquiries:* Those who would like more information about their individual experience can obtain assistance by a phone call; the current number is (202) 586-8439. By calling this number, individuals who think they may have been involved in experiments can have their cases reviewed by the appropriate agency. As of December 1, 1996, DOE has answered over 20,000 information requests, and researched 3,000 cases; DOD has responded to approximately 7,000 case inquiries of which approximately 800 are currently undergoing active research; VA has responded to approximately 1,750 inquiries; and HHS, to approximately 90.

In at least one case, that of members of the armed services exposed to nasopharyngeal radiation, there may be a sufficient number of identifiable subjects to allow for a follow-up study. The Departments are continuing their efforts to research cases. There are several factors beyond the government's control that influence the ultimate success in each individual quest for information. For example, some government records are more complete than others and some individuals can provide more kinds of information (e.g., dates, place and researcher names, and other identifying information) upon which to base a search. In cases where the possible experiment took place in a non-governmental facility (e.g., a hospital or university), access to information may be limited.

*Notification of NASA employees:* Consistent with the effort to provide general information to the widest possible group of people, the National Aeronautics and Space Administration (NASA) has notified approximately 110,000 current and former NASA employees, contractors, and grantees about the human radiation research review. This notification included those universities and institutions at which human radiation research was performed through NASA grants.

*Notification of veterans:* VA convened an expert committee including specialists in nuclear medicine, radiation oncology, health physics, and radiation dosimetry to review information about certain projects, and to determine whether notification of known subjects was warranted. The VA focused its attention on early radiation research projects for which at least some of the names of research subjects were known. These studies were chosen because of the possibility of contacting veterans or family members to encourage medical surveillance or submission of a compensation claim, if warranted. The expert committee did not identify any veterans who required special follow-up actions specifically because of their radiation exposure.

Nasopharyngeal irradiation with radium (NP) during military service: DOD and VA are reviewing the records of hundreds of Service members who received NP irradiation during and immediately following World War II. In April 1996, DOD discovered a Navy medical log book which lists the names of submariners who were given the NP treatment from 1945 to 1946 under an experimental protocol. Using the log book as the focal point, DOD and VA are conducting intensive research at the National Records Center and other repositories to identify other Service members who received NP treatment and, if feasible, to retrieve medical data for possible cohort or epidemiological studies to notify individuals as appropriate. NP treatment was a widely used conventional therapy, particularly for children, during the 1940s and 1950s. Therefore a study could be valuable to many civilians as well as veterans.

DOD and VA are reviewing the records of hundreds of Service members who received NP irradiation during and immediately following World War II. The VA, along with the Centers for Disease Control (CDC) and Yale University, co-sponsored a workshop on the public health response to NP irradiation which was held in New Haven, Connecticut, in September 1995. Consensus did not support medical screening of asymptomatic individuals but recommended that individuals treated with NP irradiation inform their health care providers when they are examined or evaluated. VA officials have published information on NP irradiation treatments in medical journals and provided it to veterans' newsletters.

The VA and CDC held a satellite teleconference in September 1996 to provide health professionals with information about this issue. Currently, veterans treated with NP irradiation do not have special eligibility for VA care. The Administration will propose legislation that will extend eligibility for the VA's Ionizing Radiation Program to veterans treated with NP irradiation.

Alaskan natives: A number of Alaskan Natives were involved in the U.S. Air Force Arctic Aeromedical Laboratory Iodine-131 thyroid test, which took place in 1956 and 1957. Although both the Advisory Committee and the Institute of Medicine (IOM) determined that there was no evidence of lifetime risk to the participants in these tests, notification and follow-up of the juvenile participants was recommended by the latter as prudent. The Air Force and the Radiation Experiments Command Center (RECC) are following up on the recommendations of the IOM. Efforts are ongoing with representatives of the Native Alaskans to determine appropriate follow-up remedies.

*Identifying additional subjects:* DOE notified subjects of the plutonium and uranium injection experiments, or their next of kin, when these could be located. In addition, DOE asked all its facilities at which human radiation experiments were identified, to provide detailed information about the availability of data relating to individual subjects, the feasibility of notification, and whether any notification process had occurred. Where employees or former employees had been involved in experiments, notification generally had taken place. Otherwise, it was determined that the available data did not warrant notification in light of the Advisory Committee criteria. If new information or experiments come to light, the Department will review these according to the Advisory Committee criteria. DOE notified subjects of the plutonium and uranium injection experiments, or their next of kin, when these could be located.

## ACHRE Findings and Recommendations Regarding Remedies

The Advisory Committee found that:

[T]he government sponsored . . . several thousand human radiation experiments. In the great majority of cases, the experiments were conducted to advance biomedical science; some experiments were conducted to advance national interests in defense or space exploration; and some experiments served both biomedical and defense or space exploration purposes. (Finding 1)

[P]eople who were used as research subjects without their consent were wronged even if they were not harmed." In addition, the Committee was "not persuaded that even where the facts are clear and the identities of subjects known, financial compensation is necessarily a fitting remedy when people have been used as subjects without their knowledge or consent but suffered no material harm as a consequence. (Recommendation 3)

[S]ome government agencies required the consent of some research subjects well before 1944 . . . [and] government agencies did not generally take effective measures to implement their requirements and policies on consent to human radiation research. (Findings 4 and 5)

[T]he government and government officials are morally responsible in cases in which they did not take effective measures to implement the government's policies and requirements....

[G] overnment officials and investigators are blameworthy for not having had policies and practices in place to protect the rights and interests of human subjects who were used in research from which the subjects could not possibly derive medical benefits (nontherapeutic research in the strict sense). By contrast, to the extent that there was reason to believe that research might provide a direct medical benefit to subjects, government officials and biomedical professionals are less blameworthy for not having had such protections and practices. (Findings 11a and 11c)

[S]ince the end of the Manhattan Project in 1946 human radiation experiments (even where expressly conducted for military purposes) have typically not been classified as secret by the government. Nonetheless, important discussions of human experimentation took place in secret, and information was kept secret out of concern for embarrassment to the government, potential legal liability, and concern that public misunderstanding would jeopardize government programs. In some cases, deception was employed. In the case of the plutonium injection experiments, government officials and government-sponsored researchers continued to keep information secret from the subjects of several human radiation experiments and their families, including the fact that they had been used as subjects of such research. Some information about the plutonium injections, including documentation showing that data on these and related human experiments were kept secret out of concern for embarrassment and legal liability, was declassified and made public only during the life of the Advisory Committee. (Finding 17)

## ACHRE Recommendations on Apology

The Advisory Committee recommended

[f]or subjects who were used in experiments for which there was no prospect of medical benefit to them and there is evidence specific to the experiment in which the subjects were involved that (1) no consent, or inadequate consent, was obtained, or (2) their selection as subjects constituted an injustice, or both, the government should offer a personal, individualized apology to each subject. (Recommendation 3)

### Response

The Administration agrees that the subjects identified by the Committee were owed an apology by the government. At the ceremony in which Dr. Faden presented him the report, President Clinton formally apologized on behalf of the government to the victims of human radiation experiments. He said,

So today, on behalf of another generation of American leaders and another generation of American citizens, the United States of America offers a sincere apology to those of our citizens who were subject to these experiments, to their families, and to their communities. The Administration agrees that the subjects identified by the Committee were owed an apology by the government. When the government does wrong, we have a moral responsibility to admit it. The duty we owe to one another to tell the truth and to protect our fellow citizens from excesses like these is one we can never walk away from. Our government failed in that duty, and it offers an apology to the survivors and their families and to all the American people who must be able to rely upon the United States to keep its word, to tell the truth, and to do the right thing.

In addition, former Energy Secretary O'Leary has apologized on behalf of the government as part of the settlements of individual cases. The Administration will continue to apologize to subjects and their families in appropriate cases as they are considered and settled.

At the same time, the Administration believes that, for most subjects, the President's apology on behalf of the government to all subjects of human radiation experiments is sufficient, as opposed to pursuing individualized evidentiary investigations, to fulfill the Committee's admonition that "an apology should be offered only where there is evidence specific to an experiment or subject that no consent, or inadequate consent, was obtained, or the subject's selection constituted an injustice, or both." (Recommendation 3)

## **ACHRE Recommendations on Financial Compensation**

The Advisory Committee recommended that the government provide financial compensation to subjects of human radiation experiments in two cases. First, those cases "in which efforts were made by the government to keep information secret from these individuals or their families, or from the public, for the purpose of avoiding embarrassment or potential legal liability, or both, and where this secrecy had the effect of denying individuals the opportunity to pursue potential grievances." Second, those experiments, "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 Advisory Committee identified three sets of subjects that fit the first class of cases: one set of 18 whose identity is known, and two sets, totaling 52 people, whose identity is not known. The Advisory Committee did not make conclusive findings about which subjects fit the second class of cases. Instead, the committee identified several experiments that might fit the second class of cases, with the expectation that the government would consider the Committee's recommendation in deciding whether to compensate individuals. (Recommendations 1 and 2)

The Administration will continue to apologize to subjects and their families in appropriate cases as they are considered and settled.

#### Response

The Administration agrees with the Advisory Committee's recommendation for both classes of cases. The Department of Justice (DOJ) has worked closely with the Departments to resolve the claims that have been made in connection with human radiation experiments, and will, to the extent permitted by law, offer reasonable financial compensation to subjects of human radiation experiments for which a government agency was responsible and which fall within the Advisory Committee criteria. If compensation cannot be offered under existing law in any case which falls under the ACHRE criteria, the Administration will work with Congress to seek appropriate legislative relief.

DOJ is using the Federal Tort Claims Act (FTCA) claims process, or other existing law, to consider compensation as part of the settlement of relevant claims. Thus, individuals can file claims using a well-established process. At the same time, the government's policy is to seek to resolve these claims quickly and fairly, while avoiding unnecessary litigation. To further these aims, the government's policy is to use alternate dispute resolution, such as mediation, where appropriate. In considering the issue of compensation, the critical factors are the extent of physical injury to the subject, the nature of the experiment, and the degree of government involvement. As needed, agencies seek expert advice on scientific and medical issues.

To date, DOE and DOJ have settled compensation claims with the 16 families of plutonium injection subjects who have come forward, representing compensation to the families of all known subjects recommended for compensation by the Advisory Committee.

## ACHRE Findings and Recommendations on Compensation of Uranium Miners

The Advisory Committee found that "as a consequence of exposure to radon and its daughter products in underground uranium mines, at least several hundred miners died of lung cancer and surviving miners remain at elevated risk."

The miners, who were the subject of government study as they mined uranium for use in weapons manufacturing, were subject to radon exposures well in excess of levels known to be hazardous. The government failed to act to require the reduction of the hazard by ventilating To date, DOE and DOJ have settled compensation claims with the 16 families of plutonium injection subjects who have come forward. the mines, and it failed to adequately warn the miners of the hazard to which they were being exposed, even though such actions would likely have posed no threat to national security. (Finding 16)

The Advisory Committee recommended that the Administration,

together with Congress, give serious consideration to amending the provisions of the Radiation Exposure Compensation Act of 1990 relating to uranium miners in order to provide compensation to *all* miners who develop lung cancer after some minimal duration of employment underground (such as 1 year), without requiring a specific level of exposure. The Act should also be reviewed to determine whether the documentation standards for compensation should be liberalized. (Recommendation 7)

#### Response

The Administration agrees that the Radiation Exposure Compensation Act of 1990 (RECA) does not presently ensure that all uranium miners who suffered from lung cancer as a result of their mining employment receive compensation, and that RECA should be amended to better achieve this goal. The Administration is proposing a bill that would make significant and substantial modifications to the statutory compensation criteria for lung cancer. The bill will bring the law into line with current science, and will address some of the issues of fairness that have been raised about the Act's coverage. The Administration will strongly urge the 105th Congress to enact this bill.

*Proposed legislative changes to RECA:* Congress enacted RECA to provide compensation 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 military and civilian nuclear weapons test participants, and people living "downwind" of the Nevada Test Site. In addition, the Act recognizes the tragedy created by the government's failure to use available resources to ensure that the companies and individuals operating uranium mines in Arizona, Colorado, New Mexico, Utah, and Wyoming between 1947 and 1971 provided adequate ventilation in the mines to reasonably reduce the risk of radon-induced lung cancer. The Act provides for compensation to some affected uranium miners, but ACHRE questioned whether the eligibility requirements for compensation were fair and reflected our present scientific knowledge about the effects of radon.

The Administration is proposing a bill that would make significant and substantial modifications to the statutory compensation criteria for lung cancer in uranium miners. The Administration's proposed changes to RECA are supported by an analysis undertaken by an ad hoc committee of government scientists and attorneys with experience in radiation exposure and claims. Their analysis is available in a report, *Final Report of the Radiation Exposure Act Committee*, which was submitted to the Human Radiation Interagency Working Group in July of 1996, and is available on the Internet (www.ohre.doe.gov).

The Administration's bill proposes amendments in three key areas. First, current law requires miners to show that they were exposed to a threshold of 200 working level months of radiation (for nonsmokers) and 300 to 500 working level months (for smokers, depending on the miner's age at the date of diagnosis of disease). The Administration's bill would substitute new criteria for compensation based on an updated scientific analysis of risk factors for lung cancer from uranium mining. Specifically, the criteria include: cumulative exposure, age at which the miner developed cancer, and time since last exposure. These criteria would ensure full compensation to miners with lung cancer where the government's best estimate indicates that the miner's exposure to radiation in the uranium mines is the probable cause of his or her lung cancer. The Administration recognizes, however, that there are documented uncertainties inherent in the process by which the criteria were generated, including uncertainties in the radiation measurements used to calculate miners' exposure. Up to now, the eligibility criteria in RECA have not accounted for these uncertainties. The administration proposes to incorporate known and quantifiable uncertainties into the compensation scheme, so that, in effect, miners are given the benefit of the doubt. In those cases where it can be concluded that a miner's exposure to radiation was the cause of his or her lung cancer only by resolving the uncertainties in favor of the miner, the Administration proposes to provide partial compensation to the miner.

The second major change in the Administration's bill responds to ACHRE's concern that conditioning compensation based on specific radiation exposure levels is too burdensome for some miners to prove and the historical exposure data are too uncertain a base for compensation decisions. Under current law, compensation is based in part on cumulative exposure to radon; the Administration's proposal would continue to allow miners to qualify in this manner, albeit under new, fairer exposure criteria. The Administration's bill would also allow the duration of employment in the mines to be used as a surrogate for exposure in determining whether a miner qualifies for compensation. This change reflects the reality that accurate measurements of radon levels do not exist for many mines, and that the measurements that do exist do not necessarily record the miners' actual exposures. The Administration's proposed changes in RECA are supported by an analysis undertaken by an ad hoc committee of government scientists and attorneys with experience in radiation exposure and claims. ACHRE described concerns from many citizens regarding the administration of RECA. Third, the proposed bill expands the list of compensable diseases for the downwinders and the on-site nuclear test participants to reflect current science. The text of the Administration's proposed bill and an analysis of it are attached to this report in Appendix D.

*Proposed regulatory changes to RECA:* ACHRE described concerns from many citizens regarding the administration of RECA. These concerns focussed on the difficulty of the documentation requirements and other burdens on those who seek compensation under the Act. The Administration has undertaken a thorough review of the regulations with the intention of making them fairer and more straightforward. While these are the paramount goals, the regulations must also effectively implement the limitations and requirements in RECA. The result of these efforts is a set of proposed changes to the rules that are designed to relieve some of the burden of those seeking compensation, without sacrificing the accuracy of the decision as to whether particular claimants qualify for compensation. These regulations will be published shortly.

The Administration expects that, as a result of these legislative and regulatory changes, additional uranium miners and others will qualify for compensation.

# ACHRE Finding and Recommendation on Compensation of Other Exposed Populations

The Advisory Committee found "that for both the Green Run (at Hanford) and the RaLa tests (at Los Alamos), where dose reconstructions have been undertaken, it is unlikely that members of the public were directly harmed solely as a consequence of these tests." (Finding 14)

The Advisory Committee recommended that the Administration,

together with Congress, give serious consideration to amending the provisions of the Radiation Exposure Compensation Act of 1990 to encompass other populations environmentally exposed to radiation from government operations in support of the nuclear weapons program, should information become available that shows that areas not covered by the legislation were sufficiently exposed that a cancer burden comparable to that found in populations currently covered by the law may have resulted. (Recommendation 5)

#### Response

The Administration agrees with the Advisory Committee's concern for fair treatment of exposed populations. DOE has undertaken studies of the communities near the Hanford nuclear facility and at other sites including Fernald, Savannah River, Rocky Flats, and Oak Ridge to determine whether there is any increase in cancer resulting from the operation of DOE facilities. If these studies conclude that there is an increase in cancer, the government will work with Congress to amend existing laws to cover those affected. DOE has provided the General Accounting Office with a list of all studies currently in process, and an estimated schedule for their completion.

## ACHRE Findings and Recommendations on Compensation of Veterans

The Advisory Committee found that

some service personnel were used in human experiments in connection with tests of atomic bombs. The Committee finds that such personnel were typically exposed to no greater risks than the far greater number of service personnel engaged in similar activities for training or other purposes. The Committee further finds that there is little evidence that the 1953 Secretary of Defense Nuremberg Code memorandum was transmitted to those involved with human experiments conducted in conjunction with atomic testing. However, some of the requirements contained in the memorandum were implemented in the case of a few experiments, apparently independently of the memorandum. The Committee also finds that the government did not create or maintain adequate records for both experimental and nonexperimental participants. (Finding 12)

The Advisory Committee also concluded that "although there was a real possibility that human subjects research had been conducted in conjunction with the bomb tests, the tests were not themselves experiments involving human subjects." The Advisory Committee further noted that "while the studies all took place in the context of the atomic bomb, and therefore involved some potential exposure to radiation, none of them were designed to measure the biological effects of radiation itself (as opposed to the levels of exposure)." The Advisory Committee recommended that the Administration, together with Congress, give serious consideration to reviewing and updating epidemiological tables that are relied upon to determine whether relief is appropriate for veterans who participated in atomic testing so that all cancers or other diseases for which there is a reasonable probability of causation by radiation exposure during active military service are clearly and unequivocally covered by the statutes. (The Radiation-Exposed Veterans Compensation Act of 1988 and the Veterans Dioxin and Radiation Exposure Compensation Standards Act) (Recommendation 6)

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

### Response

The Administration agrees with these recommendations. The VA will update the epidemiological tables and has reviewed the implementation of these programs to seek ways to make them fairer and more efficient.

Hundreds of thousands of veterans were exposed to radiation those who were present at atomic tests, those who were part of the American occupation of Hiroshima and Nagasaki, and many who were otherwise exposed to radiation in the course of their duties. The President has recognized the special obligation that we owe the men and women who have served their country in the Armed Forces. The President recently said

... [O]ur country can face up to the consequences of our actions ... we will bear responsibility for the harm we do, even when the harm is unintended ... we will continue to honor those who served our country and gave so much. Nothing we can do will ever fully repay the ... veterans for all they gave and all they lost ... but we must never stop trying.

The President has recognized the special obligation that we owe the men and women who have served their country in the Armed Forces. It is in this spirit that the Administration has considered radiation exposure issues related to veterans.

Current law authorizes comprehensive VA health care for veterans who were either atomic test participants or who served in the postwar occupation of Hiroshima or Nagasaki, and who suffer from radiogenic diseases (diseases caused by radiation). This care is provided, free of charge, regardless of whether these veterans' diseases are determined to have resulted from radiation exposure during service.

Veterans are also eligible for compensation based on their radiation exposure during their service if they have radiogenic diseases and their claims otherwise meet the criteria for benefits. In determining whether certain claimants qualify for compensation, VA uses radioepidemiological tables. The Advisory Committee recommended that these epidemiological tables be updated to reflect the latest scientific information. The government will contract with preeminent scientists to update the tables. The project is expected to take approximately 2<sup>1</sup>/<sub>2</sub> years. The Departments are considering a proposal from the Institute of Medicine, part of the National Academy of Sciences, to accomplish this update. The updated tables will more accurately identify whether there is a reasonable probability that certain diseases were caused by radiation exposure.

*Implementing existing law:* The Advisory Committee also recommended that the Administration examine and respond to the criticisms that have been made of VA's implementation of existing compensation laws. The Advisory Committee noted numerous concerns voiced about the claims process. The Administration takes these concerns seriously, and has taken several steps to respond. At the same time, the Administration has found that in some cases the system strikes a reasonable balance among the legitimate goals of fairness, speed, and accuracy in the decisions made by VA.

First, reported concerns included whether the list of diseases for which compensation is available is fair. VA currently provides benefits for veterans exposed to radiation based on two separate statutory schemes. The Radiation-Exposed Veterans Compensation Act of 1988 provides that if a veteran has a disease listed in the statute, and meets the criteria for exposure, the veteran is entitled to benefits. Thus, for qualified veterans, the list of compensable diseases establishes a presumption of a service connection. This approach has the advantage of simplicity and goes as far as possible toward providing the benefit of doubt to the claimant. It does, however, qualify some people for benefits for whom there is a low The government will contract with preeminent scientists to update the epidemiological tables used for determining probability of radiation-induced disease. probability of a connection between their in-service exposure to radiation and their disease.

Radiation-exposed veterans may also seek benefits under the Veterans Dioxin and Radiation Exposure Compensation Standards Act. Regulations issued pursuant to this Act require a determination that the disease is both radiogenic and connected to the type and amount of radiation the veteran was exposed to during service. The implementing regulations include a list of diseases that claimants do not have to prove were caused by radiation. HHS' epidemiological tables then provide additional information to help VA adjudicate claims and provide some measure of predictability for claimants. This approach has the potential to be scientifically more accurate in determining service connection. It has, however, been criticized for a variety of reasons, including that the epidemiological tables are out of date, the system creates a difficult burden of proof, and the process is expensive for claimants and the government.

The Administration has taken steps to make this claims process work better. In September of 1996, the Department of Veterans Affairs proposed to include all forms of cancer in the list of diseases recognized as radiogenic. This proposal would mean that each claim will be evaluated based on an individual's estimated dose and all other pertinent information, but will no longer require a showing that the cancer is radiogenic. In addition, the Administration has worked with the Veterans Advisory Committee on Environmental Hazards (VACEH), an independent panel that reviews the scientific literature related to radiation-induced disease, to determine whether other diseases should be added to the list of diseases. Transcripts of VACEH's discussions and citations to the scientific papers they considered are available from VA. As new information becomes available, the VACEH will review it carefully and advise the Secretary if changes in VA's regulations are warranted.

ACHRE noted that many have raised questions about the level of investment in dose reconstruction and scientific investigation compared to the amount spent compensating veterans. The Administration's view is that we owe veterans both a complete look at the facts and compensation for service-connected disease. VA and DOD have invested heavily in making sure that full and fair information is available for every veteran who may have been exposed to radiation during service. The dose reconstructions, including their methodology, have been independently peer-reviewed. Every veteran who seeks compensation needs this information, and it can be enormously frustrating for veterans when the information is incomplete or indeterminate. The principal reason the government has spent more on dose reconstruction than on compensation is that the

The Administration's view is that we owe veterans both a complete look at the facts and compensation for service-connected disease. dose reconstruction has suggested that most veterans were exposed to levels not expected to cause a significant increase in risk for disease. Unfortunately, there is no shortcut to this information, and it has been expensive to develop.

ACHRE noted that complaints have been raised about the appeals process for radiation-related claims. VA recognizes it must do a better job to meet veterans' needs, and is taking steps to improve compensation claims processing. For example, VA is redesigning the claims process to provide a partnership among the veteran making a claim, the veteran's representative, and the VA employees processing the claim. VA will discuss the claim, issues that arise, and evidence needed. Once a decision is made, VA will discuss it with the veteran and the veteran's representative, and if necessary, will provide help framing the claim for any appellate review. VA believes that this personal interaction will lead to better and faster decisions and will provide a transparent claims process.

VA remains open to other reforms that will make the process of deciding claims fairer and more streamlined.

## ACHRE Finding and Recommendations on Compensation of Marshall Islanders

The Advisory Committee found that

[a]s a consequence of a U.S. hydrogen bomb test conducted in 1954, several hundred residents of the Marshall Islands and the crew of a Japanese fishing boat developed acute radiation effects. Some of the Marshall Islanders subsequently developed benign thyroid disorders and thyroid cancer as a result of the radiation exposure. Surviving Marshallese also may remain at elevated risk of thyroid abnormalities. (Finding 16)

The Advisory Committee recommended that the U.S. Government should continue the current medical monitoring and treatment program for citizens of the Marshall Islands as long as any member of the exposed population remains alive. In addition, ACHRE recommended that the Administration consider adding the populations of other exposed atolls to the south and east; that the Administration involve the Marshall Islanders in the design of any further medical research conducted on them; and that the Administration establish an independent panel to review the adequacy of the current monitoring and treatment program. (Recommendation 8) VA recognizes it must do a better job to meet veterans' needs, and is taking steps to improve compensation claims processing.

### Response

The Administration recognizes the difficulties and inequities in the current program of medical care for the Marshall Islands and fundamentally agrees with ACHRE's recommendations. The recommendations address the scope and effectiveness of programs designed to provide benefit to citizens of the Marshall Islands because of their exposure to radioactive fallout from atmospheric tests. Before discussing the particular recommendations that ACHRE put forward, it is appropriate to set out the Administration's vision for the implementation of these programs. DOE has undertaken a reorientation of the Republic of the Marshall Islands (RMI) programs to support more local involvement and control over the resources made available as a part of this program. This reorientation means open discussion between the U.S. Government and the Marshallese regarding resources available for, and realistic goals of, this program, along with better coordination of DOE and Department of Interior (DOI) programs. These tasks are underway.

The heads of delegations of the Government of RMI, the DOE, and the U.S. Departments of State and Interior held a meeting in May 1996. A Joint Communiqué was signed that outlined a path forward to address the basic ACHRE issues of concern to the Marshall Islands people.

At a subsequent meeting on June 7, 1996, a 30-day action plan was mutually agreed upon. This action plan establishes objectives for eight working groups and a time table for achieving these defined objectives. These objectives include how best to include RMI in decisionmaking on future direction of programs and in evaluating the DOE Marshall Islands medical program.

The Republic of the Marshall Islands decided to address all eight working group issues by hosting a meeting in Majuro, Marshall Islands, on January 29–31, 1997. The U.S. Government (USG) agreed to fully address four of the working group issues and to discuss issues in the other four working groups, with meetings of these working groups to follow at a later time. The meeting was conducted as bilateral discussions with decisions reached, successes achieved, and forward actions identified to meet the objectives of the four working groups held. The meeting was attended by the leaders of the RMI Government and Local Atoll Government Councils. The U.S. Government was represented by the DOE and their contractors, as well as the Departments of State and Defense.

The major outcome of the January Majuro meeting was the development of a joint USG/RMI committee to deal collectively with the four working groups issues related to the redesign of the current medical delivery process for the Rongelap and Utirik exposed

DOE has undertaken a reorientation of the Republic of the Marshall Islands (RMI) programs to support more local involvement and control over the resources available as a part of this program. community. The Marshall Islands called for an open competitive process that would provide a more community-based medical delivery program on a more frequent basis than the current twice-yearly medical missions. The Committee set an accelerated time-table to have an instrument for open competition published in the *Federal Register* by mid-1997 with a new medical delivery process in place by the latter part of calendar year 1998.

An independent review of the DOE Marshall Islands Medical Program is still under discussion. At the request of the Government of RMI, the mechanism for such a review is being reevaluated. RMI has requested a broader historical review that might be done by the National Research Council/National Academy of Sciences. The Department is considering the use of a Blue Ribbon Panel as another possible mechanism for this review.

DOE is also working with the RMI to systematically review and collect historical documents which will help to complete the record of U.S. atmospheric testing in the Marshall Islands and the impact on its people. As part of this effort, DOE is also providing support to facilitate Marshallese access to these and previously collected documents. Documents are being scanned into an electronic retrieval system available via the Internet that makes it possible to search many documents of direct pertinence to the RMI concerns.

As ACHRE recommended, the Administration plans to continue to support the current monitoring and treatment program. This program is an important element of our nation's commitment to those who were harmed by the atomic testing program.

As ACHRE recommended, the Administration has considered whether additional populations should be included in this program. Extensive analyses to date of radiation exposures in the Marshall Islands have indicated that the exposures to inhabitants of Ailuk and other northern Marshall Island atolls were a factor of 30 to 90 times less than at Rongelap and about 10 to 25 percent of those at Utirik, based upon external dose measurements and on estimates of thyroid doses. Consequently, the Administration does not believe that additional populations should be added to the medical surveillance program. The connection between radiation exposure and thyroid disease is the subject of several ongoing studies sponsored by DOE and managed by CDC. If these or other studies reveal new data to indicate that residents of atolls south and east of Bikini, other than Rongelap and Utirik, are at a significantly increased health risk, DOE will propose any needed expansion of the current medical surveillance program.

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