

FAX**Date** 01/10/97**Number of pages including cover sheet** 8**TO:***Elizabeth Dwyer***Phone****Fax Phone** 456 - 7028**FROM:**ROBERT DE VESTY
Office of Public Health and
Environmental Hazards (13)
810 Vermont Av. N.W.
Washington D.C. 20420**Phone**

202-273-8453

Fax Phone

202-273-9080

CC:**REMARKS:** ☐ Urgent ☐ For your review ☐ Reply ASAP ☐ Please Comment

Attached is the VA's Questions and Answers as requested. We are also submitting additional information in the form of two 'Fact Sheets' from our Public Affairs Office addressing information on radiation related programs and research in the VA.

Bob D.

Bob

PROPOSED QUESTIONS AND ANSWERS RELATING TO RADIATION REPORT

What is being done to update the radioepidemiological tables?

The Department of Veterans Affairs (VA) and the National Institutes of Health (NIH) presently are discussing the most expeditious way to carry out this project.

How is the VA adjudication process for radiation claims being improved?

As noted above, the radioepidemiological tables used to adjudicate some radiation claims will be updated and expanded. Once updated, VA will be provided with additional information for adjudicating compensation claims.

Also, VA has proposed that additional conditions be considered potentially radiogenic for adjudication purposes. VA is in the process of modifying its regulations to allow veterans to file claims for conditions not currently listed in the regulations (prostate cancer, any other cancers and any other conditions that can be shown by evidence to be radiation induced.)

What is VA doing for veterans treated with nasopharyngeal (NP) radium irradiation during military service?

VA supports a legislative proposal making these veterans treated with Nasopharyngeal radium irradiation eligible for the VA's Ionizing Radiation Program, which includes eligibility to receive an Ionizing Radiation Registry examination and special eligibility for health care for conditions that VA has recognized as being potentially radiogenic. VA is again submitting a legislative proposal to address this matter.

Also VA is evaluating the feasibility of epidemiological studies of Navy and Air Force veterans who received NP radium treatments in service.

What about compensation for these veterans treated with NP radium?

Veterans who received this treatment and have a condition that may be related to their exposure are currently covered under existing regulations.

What actions has VA taken regarding radiation research at VA hospitals?

VA's review of its radiation research showed that most were "tracer" studies that used only low levels of radiation. The presidential advisory committee and an internal VA review committee did not identify any groups of patients in the studies that they reviewed who required special follow-up specifically because of their radiation exposure.

Office of Public Affairs
News Service

Washington, D.C. 20420
(202) 273-5700



VA Fact Sheet

Jan. 1997

RADIATION RESEARCH IN THE DEPARTMENT OF VETERANS AFFAIRS

The Department of Veterans Affairs (VA) took immediate action in response to reports that government-sponsored research involving human subjects and radioactive materials may have been conducted in an inappropriate manner in the 1940s and 1950s. Secretary of Veterans Affairs Jesse Brown immediately ordered that VA medical centers begin a comprehensive search for records on radioisotope nuclear medicine or radiation research that may have involved human subjects between the years 1947 to 1980. VA asked veterans service organizations to help the department raise awareness in the veteran community and urged concerned veterans to call its general toll-free number as well as its special radiation helpline for veterans who were exposed to ionizing radiation during military service. VA also began working with the Department of Energy (DOE), which referred veterans' calls received on the national radiation hotline.

VA's Response

Since those initial actions, VA has conducted a number of other activities in its search for information about possible radiation research involving human subjects:

- Instructions were issued to all VA medical centers concerning the retrieval, preservation and safeguarding of records identified by VA medical centers in their records search.
- A site visit was made to the Boston VA Medical Center, where some radioisotope records from the old Cushing VA Medical Center (closed in 1953) in Framingham, Mass., are located to review a sample of records.
- VA's Nuclear Medicine Service reviewed the licenses issued for radionuclides by the Atomic Energy Commission (now the Nuclear Regulatory Commission) for cross-referencing with research information.
- VA's Office of Research and Development reviewed the protection of human subjects in VA research and reaffirmed the vigorous enforcement of policies and procedures in place to assure that all VA patients who participate in research are fully informed, consenting subjects.
- An additional search for records involving radiation therapy also was conducted.
- VA cooperated fully with the presidential Advisory Committee on Human Radiation Experiments and provided the committee with survey results and historical and other information. This information included results of interviews with current and former VA employees who were pioneers in radioisotope research.
- VA responded to more than 1,700 inquiries forwarded by DOE or from additional sources about possible radiation exposure at a VA medical facility.

-more-

Page 2

- VA contributed funds for a DOE-managed data base containing all available radiation research-related documents for accessing by the general public.
- VA obtained from the Suitland, Md., Federal Records Center 1,772 boxes, or approximately 4 million pages of documents, and reviewed them for any radiation-related research records.

Results of VA's Initiatives

- 137 VA facilities presently have Nuclear Medicine Services. Of those having nuclear medicine capability between 1947 and 1980, 49 had located some protocols used during that period for radioisotope research, 17 had names of patients who participated in at least some research projects, and 54 had some publications available on specific research done during that period. No medical centers found any evidence of research involving plutonium, nor had any contracted out any research.
- Almost all VA radiation research was conducted exclusively for medical purposes, either to improve diagnosis or treat diseases. This research primarily involved tracer amounts of radiation. As best as it can be determined, only one research program appears to have been done primarily for military purposes, i.e., to study strontium which is present in nuclear fallout.
- The site visit to the Boston VA Medical Center found that most radiation records appeared to be related to diagnostic or therapeutic procedures which were part of direct patient care rather than being primarily research. The isotope dosages administered to all the patients reviewed appeared to be within acceptable ranges.
- Decades-old VA documents uncovered by VA referenced a "confidential" Atomic Medicine Division. A review determined that the division was discussed as a means to deal with adjudication issues and civil defense activities relating to radiation but was never activated. VA's Office of Inspector General also conducted a review and came to the same conclusion.
- Most of the radiation hotline and similar inquiries were related to ionizing radiation exposure during military service. Following a review of those inquiries that were related to possible radiation research or treatment in VA facilities, most involved standard diagnostic or treatment procedures, not research using radiation or any other experimental studies.
- Based on discussions with former and current VA employees who were involved with radiation research before VA's formal consent policy was adopted in 1963, patients were informed orally of the effects of the radiation and their consent was obtained. At the time this type of research was conducted, consent forms such as those currently in use were not used in the medical community.

Advisory Committee Recommendation

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 the recommendation, VA Secretary Brown appointed an interagency working group to address the committee's concerns. Members of the working group included representatives from VA, and the Departments of Health and Human Services, and Defense.

-more-

Page 3

The group was tasked with developing a response to the committee's recommendation on whether to update the radioepidemiological tables that VA has been using to determine whether veterans exposed to ionizing radiation in service, or their survivors, are entitled to compensation for resulting disabilities or deaths. By statute, service-connection is presumed for various diseases suffered by certain veterans who participated in nuclear tests; served with occupation forces in Hiroshima or Nagasaki between Aug. 1945 and July 1946; or were exposed to ionizing radiation while a prisoner of war in Japan. VA makes eligibility determinations on other radiation-related claims on a case-by-case basis using the radioepidemiological tables, which were developed by the Department of Health and Human Services' National Institutes of Health (NIH) in 1985. VA agreed that the radioepidemiological tables used in adjudicating VA disability and death claims should be updated and, if appropriate, expanded. VA is coordinating with NIH to update these tables, which has offered its expertise and services to collaborate on the project. When the radioepidemiological tables are updated and expanded, VA will be provided with additional information to use in adjudicating compensation claims.

Existing laws on compensation for atomic veterans also were reviewed to determine whether these laws are administered in ways that produce the best balance in the allocation of resources between financial compensation to these veterans and administrative costs incurred by the Department of Defense, including those related to dose reconstruction. VA determined that the administrative expense of correctly deciding these claims on the basis of individual merit, while significant relative to the number of claims allowed, is a necessary cost of administering the compensation program.

The group also considered related issues not included in the committee's recommendation, and VA is taking the following actions:

- VA is in the process of modifying its regulations to allow veterans to file claims for conditions not currently listed in the regulations (prostate cancer, any other cancers and any other conditions that can be shown by evidence to be radiation-induced).
- When the radioepidemiological tables are updated and expanded, VA will be provided with additional information to use in adjudicating claims.
- VA supports making veterans treated with nasopharyngeal radium irradiation during military service eligible for VA's Ionizing Radiation Program, which includes eligibility for an Ionizing Radiation Registry examination and special eligibility for health care for conditions that VA has recognized as being potentially radiogenic. VA is submitting a legislative proposal to address this matter.
- VA is evaluating the feasibility of epidemiological studies of Navy and Air Force veterans who received nasopharyngeal radium treatments in service.

###



**Department of
Veterans Affairs**

**Office of Public Affairs
News Service**

Washington, D.C. 20420
(202) 273-5700

VA Fact Sheet

Jan. 1997

VA PROGRAMS FOR VETERANS EXPOSED TO RADIATION

VA provides special access to health-care services to any veteran exposed to ionizing radiation in connection with nuclear device tests or with the American occupation of Hiroshima and Nagasaki, Japan, during the period beginning Sept. 11, 1945, and ending July 1, 1946. Since 1981, these veterans have been eligible for care for all conditions except those that VA affirmatively determines have causes other than radiation exposure. As a result of legislation enacted in 1996, special eligibility for care now is limited to those exposed veterans with an illness that VA has recognized as potentially radiogenic through statute or regulation. Health care also is available to veterans determined to have service-connected diseases related to radiation exposure they suffered anytime during their military service. VA also pays compensation to veterans and their survivors if the veteran is determined to have a disability due to radiation exposure while in service.

Radiation Statistics

Some 195,000 servicemembers participated in the post-World War II occupation of Hiroshima and Nagasaki, Japan. In addition, approximately 202,000 servicemembers and another 8,000 civilian and contract personnel participated in 235 U.S. atmospheric nuclear tests in the United States and the Pacific and Atlantic oceans prior to the 1963 Limited Test Ban Treaty. The Defense Special Weapons Agency's Nuclear Test Personnel Review program since 1978 has been identifying participants in various tests. Many test participants received no measurable dose of ionizing radiation, with a total of 1,750 nuclear test participants identified as having a dose of 5 rem or higher. (The current federal guideline for U.S. workplace exposure is 5 rem in 12 consecutive months.)

Disability Compensation

VA may pay compensation for radiogenic diseases under two programs specific to radiation-exposed veterans and their survivors:

- Veterans who participated in nuclear tests by the U.S. or its allies, who served with the U.S. occupation forces in Hiroshima or Nagasaki, Japan, between August 1945 and July 1946, or who were similarly exposed to ionizing radiation while a prisoner of war in Japan, and who develop illnesses specified in the Radiation-Exposed Veterans Compensation Act of 1988 and subsequent legislation.

- more -

Radiation -- Page 2

The 15 types of cancer covered by these laws are:

all forms of leukemia except chronic lymphocytic leukemia; cancer of the thyroid, breast, pharynx, esophagus, stomach, small intestine, pancreas, bile ducts, gall bladder, salivary gland and urinary tract; lymphomas (except Hodgkin's disease); multiple myeloma; and primary liver cancer.

- Veterans who were exposed to ionizing radiation in service and who within specified time periods develop a disease determined to be related to the radiation exposure.

Disability compensation claims of veterans exposed to radiation but who are not covered by the Radiation-Exposed Veterans Compensation Act of 1988 or subsequent presumptive legislation are governed by regulation. Under the regulation, various factors are considered in determining service-connection, including amount of radiation exposure, duration of exposure, and elapsed time between exposure and onset of the disease.

The 22 conditions recognized as radiogenic under the regulation are:

all forms of leukemia except chronic lymphocytic leukemia; cancer of the thyroid, breast, lung, bone, liver, skin, esophagus, stomach, colon, pancreas, kidney, urinary bladder, ovaries, salivary gland, and rectum; posterior subcapsular cataracts; non-malignant thyroid nodular disease; parathyroid adenoma; tumors of the brain and central nervous system; multiple myeloma; and lymphomas other than Hodgkin's disease.

A pending regulation would add the broad category of "any cancer" to the radiogenic list as well as prostate cancer specifically. That proposed regulation followed a review of 53 scientific studies by the Veterans Advisory Committee on Environmental Hazards. VA also will consider evidence that other diseases were caused by radiation exposure.

Rates of compensation depend upon the degree of disability. Additional amounts may be awarded for certain severe disabilities. For deaths in 1993 and after, compensation to survivors is paid based on a flat rate to all eligible claimants. An additional amount may be paid if the veteran had been rated 100-percent disabled for service-connected disabilities, including individual unemployability, for at least eight years prior to death and had been married to the surviving spouse during the same period.

Radiation -- Page 3

Additional amounts may be payable to the surviving spouse for dependent minor children. Claims for compensation may be filed at the nearest VA regional office. Veterans or their survivors can reach the nearest regional office by calling 1-800-827-1000. The Defense Department maintains a helpline at 800-462-3683 to provide veterans information about their test participation.

Medical Care Authorized

Public Law 97-72, the "Veterans Health Care, Training, and Small Business Loan Act of 1981," authorized VA to provide hospital and nursing home care and limited outpatient services to a veteran who was exposed "while serving on active duty to ionizing radiation from the detonation of a nuclear device in connection with such veteran's participation in the test of such a device or with the American occupation of Hiroshima and Nagasaki, Japan, during the period beginning on Sept. 11, 1945, and ending July 1, 1946." The law, however, does not provide for the care of conditions that are found to have resulted from causes other than exposure to ionizing radiation.

Under the Ionizing Radiation Registry program, VA will perform a complete physical examination, including all necessary tests, for each veteran who requests it if the veteran was exposed to ionizing radiation while participating in the nuclear weapons testing program, or if he or she served with the U.S. occupation forces in Hiroshima or Nagasaki. For those who have been examined by VA within the prior six months, only those procedures that are medically indicated by current circumstances will be repeated.

If a veteran has a disorder that has been associated with exposure to radiation, VA will provide hospital and nursing home care in VA facilities. Outpatient care also will be provided at a VA facility to avoid the need to hospitalize the veteran, to prepare the veteran for hospitalization, and to complete care that was initiated during a period of VA hospitalization. These services are provided without regard to the veteran's age, service-connected status, or ability to defray the expenses of medical care. Veterans may receive outpatient care at VA facilities or, when VA facilities cannot provide it, VA may arrange for outpatient services to be provided by a private physician.

###

U.S. DEPARTMENT OF ENERGY

1000 INDEPENDENCE AVE., SW, RM., 7A-075

WASHINGTON, D.C. 20585

UNCLASSIFIED FACSIMILE MESSAGE

Office Fax: (202) 586-2268

Verify Fax: (202) 586-5680

DATE: 7/15/96TO: IAWG MEMBERSFROM: E/11 MELAMED / DOE
202 586-6857No. Of Pages To Follow: 3

COMMENTS: ATTACHED IS MATERIAL
FOR 7/16 MEETING: ① NOTIFICATION
BRIEFING PAPER ② PROPOSED RESPONSE
TO REC. 15. CALL IF QUESTIONS.

PLEASE TELEPHONE _____, AT THE NUMBER
ABOVE TO VERIFY RECEIPT OF THIS FAX

THANK YOU

Briefing Paper on ACHRE Recommendation 4

ASSUMPTIONS:

-Agencies accept ACHRE recommendation 4 and will follow-up in accord with ACHRE criteria for notification - increased lifetime risk for development of a fatal radiation-induced malignancy and recognized medical benefit from early detection and treatment.

-An individual notification effort that goes beyond the ACHRE criteria - attempting to identify, locate, and contact all named individuals who may have been subjects of federally funded human radiation experiments - would be a high cost, low yield endeavor, may not satisfy the groups that are requesting it, and carries potential risks identified by the Advisory Committee as well as the possibility for invasion of privacy.

- in many cases names are not available or hard to extract; even with names the process of locating these individuals many years after the experiments will be very difficult.

- meaningful notification would require a contemporary dose analysis and presentation of risk, which is complicated, expensive and data is often inadequate.

- many stakeholders have indicated that their greatest concern is notification on the basis of records of private hospital and universities where confidentiality and privacy rules prohibit government access.

-Notification has been carried out by agencies in response to specific inquiries that came via the Helpline which was established at the beginning of this effort for those who thought they were potentially subjects of experiments. #5 36,000

-The process the Administration followed in uncovering human radiation experiments - document searches, the ACHRE hearings and report, and agency efforts to make documents publicly available through the National Archives and via the Internet - was predicated on openness and providing as much information to the public as possible and was itself a nationwide notification effort.

ACTIONS:

- In response to Helpline inquiries, DOE has sent over 20,000 replies including intensive research of approximately 3,000 cases; DOD had a caseload of 5,992 inquiries of which 997 are undergoing active research; VA has responded to over 1700 inquiries; and HHS has responded to 88 individuals.

- All Advisory Committee meetings were open; some were held outside of Washington; stakeholders were invited to participate at open forums.

-Agencies carried out an open, thorough and fully documented search for information; provided close to a thousand cubic feet of records to the Advisory Committee; and are in the process of making all documents located available on the World Wide Web as images and with full text searching capabilities.

OPTIONS:

1. Accept Advisory Committee recommendation 4 and frame an IAWG response that makes clear how much the Administration has done to honor the principles of openness throughout all human radiation experiment activities as well as the high costs, feasibility limits, and potential adverse impacts of a major individual notification effort.

There are two additional options:

2. Carry out an individual notification effort as requested by some stakeholders and potentially some members of Congress. This effort would require IAWG member agencies to pull together all reasonably available names of those who were subjects of identified experiments, locate current addresses using the IRS and other methods, develop appropriate information about dose and risk where data is available, and contact the individuals with this information.

3. In terms of meeting the stakeholder desire for medical care rather than medical follow-up, offer Medicare coverage to uncovered members of groups already recognized in law as subjects of government sponsored radiation exposure; these include the atomic veterans (ca. 200,000), Nevada downwinders (ca. 19,000), and uranium miners (ca. 18,000).

3-8-91

SECURITY AND OPENNESS

Recommendation 15: a) No waiver of informed consent for classified research and informing the potential subjects of the identity of the sponsoring agency and that classified research is involved and b) For classified research, establishing an independent panel, whose records are permanent, to review scientific merit, risk/benefit, consent, and whether subjects need a security clearance.

} come from DOD

Summary Response: With regard to 15a, the existing Federal Policy for the Protection of Human Subjects makes no distinction between classified and unclassified research and requires prospective, legally effective informed consent from human subjects, with only very limited exceptions. IRBs may consider altering or waiving informed consent only when four stringent criteria are met. To alter or waive consent, IRBs are required to find and document that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Similarly, the Federal Policy currently leaves to the discretion of IRBs any notification to the prospective subject 1) that classified research is involved, and 2) of the name of the sponsoring government agency.

Changes in IRB authority could be effected by modifications of the Federal Policy. Consideration of modification of the Federal Policy to take into account the Advisory Committee's recommendations will be considered by the Human Subjects Research Subcommittee, Committee on Health, Safety, and Food, National Science and Technology Council. This interagency group meets regularly to ensure uniform implementation of the Federal Policy and to gauge the need for changes.

With regard to 15b, the IAWG staff endorses the current IRB system which already must include at least one member not affiliated with the institution. The IRBs can guarantee participation of non-government persons in reviewing classified research by establishing a dedicated panel for classified research review or by ensuring that all IRB members possess the necessary clearances.

IRBs

FAX**Date** 01/15/97**Number of pages including cover sheet** 4**TO:** Elisabeth Drye
DPC
White House, Washington, DC**Phone**
Fax Phone 456-7028**FROM:** ROBERT DE VESTY
Office of Public Health and
Environmental Hazards (13)
810 Vermont Av. N.W.
Washington D.C. 20420**Phone** 202-273-8453
Fax Phone 202-273-9080**CC:****REMARKS:** ☐ *Urgent* ☐ *For your review* ☐ *Reply ASAP* ☐ *Please Comment*

Attached is an updated copy of the fact sheet on radiation programs in the VA for inclusion in the VA's package for the press conference on the ACHRE recommendations.



**Department of
Veterans Affairs**

**Office of Public Affairs
News Service**

Washington, D.C. 20420
(202) 273-5700

VA Fact Sheet

Jan. 1997

VA PROGRAMS FOR VETERANS EXPOSED TO RADIATION

VA provides special access to health-care services to any veteran exposed to ionizing radiation in connection with nuclear device tests or with the American occupation of Hiroshima and Nagasaki, Japan, during the period beginning Sept. 11, 1945, and ending July 1, 1946. Since 1981, these veterans have been eligible for care for all conditions except those that VA affirmatively determines have causes other than radiation exposure. As a result of legislation enacted in 1996, special eligibility for care now is limited to those exposed veterans with an illness that VA has recognized as potentially radiogenic through statute or regulation. Health care also is available to veterans determined to have service-connected diseases related to radiation exposure they suffered anytime during their military service. VA also pays compensation to veterans and their survivors if the veteran is determined to have a disability due to radiation exposure while in service.

Radiation Statistics

Some 195,000 servicemembers participated in the post-World War II occupation of Hiroshima and Nagasaki, Japan. In addition, approximately 202,000 servicemembers and another 8,000 civilian and contract personnel participated in 235 U.S. atmospheric nuclear tests in the United States and the Pacific and Atlantic oceans prior to the 1963 Limited Test Ban Treaty. The Defense Special Weapons Agency's Nuclear Test Personnel Review program since 1978 has been identifying participants in various tests. Many test participants received no measurable dose of ionizing radiation, with a total of 1,750 nuclear test participants identified as having a dose of 5 rem or higher. (The current federal guideline for U.S. workplace exposure is 5 rem in 12 consecutive months.)

Disability Compensation

VA may pay compensation for radiogenic diseases under two programs specific to radiation-exposed veterans and their survivors:

- Veterans who participated in nuclear tests by the U.S. or its allies, who served with the U.S. occupation forces in Hiroshima or Nagasaki, Japan, between August 1945 and July 1946, or who were similarly exposed to ionizing radiation while a prisoner of war in Japan, and who develop illnesses specified in the Radiation-Exposed Veterans Compensation Act of 1988 and subsequent legislation.

- more -

Radiation -- Page 2

The 15 types of cancer covered by these laws are:

all forms of leukemia except chronic lymphocytic leukemia; cancer of the thyroid, breast, pharynx, esophagus, stomach, small intestine, pancreas, bile ducts, gall bladder, salivary gland and urinary tract; lymphomas (except Hodgkin's disease); multiple myeloma; and primary liver cancer.

- Veterans who were exposed to ionizing radiation in service and who within specified time periods develop a disease determined to be related to the radiation exposure.

Disability compensation claims of veterans exposed to radiation but who are not covered by the Radiation-Exposed Veterans Compensation Act of 1988 or subsequent presumptive legislation are governed by regulation. Under the regulation, various factors are considered in determining service-connection, including amount of radiation exposure, duration of exposure, and elapsed time between exposure and onset of the disease.

The 22 conditions recognized as radiogenic under the regulation are:

all forms of leukemia except chronic lymphocytic leukemia; cancer of the thyroid, breast, lung, bone, liver, skin, esophagus, stomach, colon, pancreas, kidney, urinary bladder, ovaries, salivary gland, and rectum; posterior subcapsular cataracts; non-malignant thyroid nodular disease; parathyroid adenoma; tumors of the brain and central nervous system; multiple myeloma; and lymphomas other than Hodgkin's disease.

A pending regulation would add the broad category of "any cancer" to the radiogenic list as well as prostate cancer specifically. That proposed regulation followed a review of 53 scientific studies by the Veterans Advisory Committee on Environmental Hazards. VA also will consider evidence that other diseases were caused by radiation exposure.

Rates of compensation depend upon the degree of disability. Additional amounts may be awarded for certain severe disabilities. For deaths in 1993 and after, compensation to survivors is paid based on a flat rate to all eligible claimants. An additional amount may be paid if the veteran had been rated 100-percent disabled for service-connected disabilities, including individual unemployability, for at least eight years prior to death and had been married to the surviving spouse during the same period.

Radiation -- Page 3

Additional amounts may be payable to the surviving spouse for dependent minor children. Claims for compensation may be filed at the nearest VA regional office. Veterans or their survivors can reach the nearest regional office by calling 1-800-827-1000. The Defense Department maintains a helpline at 800-462-3683 to provide veterans information about their test participation.

Medical Care Authorized

Public Law 97-72, the "Veterans Health Care, Training, and Small Business Loan Act of 1981," authorized VA to provide hospital and nursing home care and limited outpatient services to a veteran who was exposed "while serving on active duty to ionizing radiation from the detonation of a nuclear device in connection with such veteran's participation in the test of such a device or with the American occupation of Hiroshima and Nagasaki, Japan, during the period beginning on Sept. 11, 1945, and ending July 1, 1946." The law, however, does not provide for the care of conditions that are found to have resulted from causes other than exposure to ionizing radiation.

Under the Ionizing Radiation Registry program, VA will perform a complete physical examination, including all necessary tests, for each veteran who requests it if the veteran was exposed to ionizing radiation while participating in the nuclear weapons testing program, or if he or she served with the U.S. occupation forces in Hiroshima or Nagasaki

If a veteran has a disorder that has been associated with exposure to radiation, VA will provide, within VA facilities, any necessary medical care including outpatient care. Those services are provided without regard to the veteran's age, service-connected status, or ability to defray the expenses of medical care. When VA facilities cannot provide the necessary care, VA may arrange for services to be provided by a private physician.

###

Ed Scott
Kathy Callier



Department of Veterans Affairs

EXECUTIVE SUMMARY FINAL REPORT RESPONSE TO RECOMMENDATION 6 OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

Presented to the Interagency Working Group on Human Radiation Experiments

Background: The Advisory Committee on Human Radiation Experiments (ACHRE) was established by President Clinton to review records related to human radiation research and provide expert advice to the Cabinet-level Interagency Working Group on Human Radiation concerning scientific and ethical issues related to biomedical experiments involving ionizing radiation. The ACHRE issued its report on October 3, 1995, in which it made several recommendations for possible remedies to individuals exposed to ionizing radiation as the result of the government's activities. Of particular importance to VA is recommendation 6 which states that the Interagency Working Group should 1) consider a review and update of the radioepidemiological tables VA uses in the adjudication of atomic veterans' disability and death claims, and 2) review whether existing laws governing compensation for atomic veterans are now administered in ways that best balance the allocation of resources between compensation to eligible atomic veterans and the administrative costs of determining their eligibility.

VA Working Group: VA's Secretary Jesse Brown established the VA Human Radiation Interagency Working Group (VAWG) to respond to recommendation 6. Secretary of Defense William Perry and Secretary of Health and Human Services Donna Shalala appointed representatives to assist in the review of recommendation 6.

VA's Under Secretary for Benefits, R. J. Vogel, chairs the VAWG and is assisted by Commander Melvin Ely, MSC, USN from the Defense Special Weapons Agency (formerly Defense Nuclear Agency) and Dr. Gilbert Beebe from the National Institutes of Health's National Cancer Institute. These individuals along with other departmental medical,

scientific and program experts and advisors collaborated to focus on the concerns of radiation-exposed veterans and their families. The VAWG met with radiation-exposed veterans and their survivors as well as advocates of the atomic veteran community.

Conclusion: The following report presents VA's response to recommendation 6. It also details our efforts to address other concerns that, while related, go beyond the immediate parameters of the recommendation.

Two exhibits are attached to this report. Exhibit A sets forth the presumptive and non-presumptive lists of radiogenic diseases for which VA provides benefits and services. Exhibit B is a slide presentation capsulizing this Executive Summary.

RECOMMENDATION 6 AND RELATED ISSUES

I. Recommendation 6, Part I:

"The Advisory Committee recommends to the Human Radiation Interagency Working Group that it, 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."

Response: *VA agrees that the radioepidemiological tables used in the adjudicative review of VA disability and death claims should be updated and, if appropriate, expanded.*

Discussion: The current tables were prepared by the National Institutes of Health in 1985, in compliance with Public Law 97-414, The Orphan Drug Act. This public law directed the Secretary of Health and Human Services to devise and publish "tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific [radiation] doses prior to the onset of such disease developed cancer as a result of those doses". The Act specified the tables should show probabilities for each disease associated with doses ranging from 1 millirad to 1,000 rads in terms of such variables as sex, age at time of exposure, time from exposure to onset of disease, and other variables considered relevant, with probabilities of causation displayed as single percentage figures. At the time the tables were published, the Secretary was also to publish evaluations of the tables' credibility, validity and certainty, and a compilation of formulas that yielded them. Public Law 97-414 also specified that the tables were to be updated by Health and Human Services "every four years", or whenever [the Secretary] deems it necessary to insure that they continue to represent the best available scientific data and expertise."

VA is the primary user of HHS's radioepidemiological tables and consults them to adjudicate certain radiation claims. We believe that reviewing and updating the radioepidemiological tables and presenting

the data in the screening dose format are important to ensure that the most current scientific information is incorporated into the adjudication process. Since Public Law 97-414 directs that the tables reflect current scientific and medical knowledge, further Congressional action is unnecessary. We urge HHS's immediate commitment to updating these tables. VA shares in this commitment and offers its expertise and services to collaborate in getting these tables updated.

II. Recommendation 6, Part II:

"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: *VA believes the administrative expense of correctly deciding these claims on the basis of their individual merit, while significant relative to the number of claims allowed, is a necessary cost of credible program administration.*

Discussion: ACHRE's recommendation acknowledges the substantial administrative overhead costs incurred in adjudicating the compensation claims of atomic veterans relative to the benefits paid, and commends to the IAWG an examination of the laws' implementation by VA and DOD.

However, as ACHRE itself acknowledged, the recorded doses for atomic veterans are low. Given current understanding of dose responses in humans, it is not unexpected that substantial numbers of atomic veterans' claims are not approved. Even in a claims system that presumes certain cancers to be service-related if suffered by atomic veterans, and which provides them with the benefit of the doubt in various ways, the low rate of allowance of claims is altogether consistent with scientific knowledge regarding the merits of these claims.

not many at. vets
got harmful
dose? but all
file?

It is, of course, recognized that atomic veterans take issue with both the recorded and reconstructed doses provided to VA by DOD and to the generally accepted assessments of risk VA applies in deciding claims. However, the Nuclear Test Personnel Review dose assessment program has been subjected to rigorous peer review, and VA employs the

do we need?

most current, credible dose-response information available in deciding these claims.

VA doing all they can (Both VA and DOD have devoted considerable resources to ascertaining the circumstances of veterans' radiation exposures and to the careful and systematic adjudication of their claims in order to identify those having merit. VA believes it is doing all the available records and the science permit to try to identify meritorious claims, and is succeeding. In our view, the Nation owes no less to these claimants. If veterans' compensation programs are to retain any credibility, VA must be able to both identify exposed servicemembers and discern which of their claims are meritorious. The relatively low rate of claim allowance and the resulting dissatisfaction of atomic veterans have less to do with problems of program administration than with the claim's lack of merit under currently understood scientific principles. ?

Should new epidemiological information come to light which identifies currently unanticipated adverse health effects of these veterans' exposures, the Government's compensation policies should, of course, be reexamined. However, for now the administration of veterans' compensation laws is appropriate.

Additionally, implicit in this recommendation is information that the costs of administration are so great that it may be better policy for VA to (1) stop adjudicating the claims of veterans who participated in nuclear weapons tests or the occupation of Hiroshima or Nagasaki and have radiogenic diseases and the claims of the survivors of those veterans who die from such diseases, and (2) simply pay all such claims. VA estimates that the net cost of this change, which would be the same as adding all radiogenic cancers to the presumptive list, is \$3.9 billion for the first five years.

III. Other Issues Considered:

During the review of recommendation 6, the VAWG also considered several other issues that, although outside the immediate parameters of the recommendation, are related and have been the subject of concern and criticism from the atomic-veteran community.

1. *Does the list of presumptive radiation-induced (radiogenic) diseases (38 U.S.C. § 1112; 38 C.F.R. § 3.309(d)) adequately reflect the health consequences of veterans exposed to low-level ionizing radiation?*

Response: Public Law 100-321 dated May 2, 1988, created the original list of presumptive radiogenic diseases. This list was later expanded by enactment of Public Law 102-578 on October 1, 1992. The presumptive statute was enacted in response to the scientific and medical uncertainties atomic veterans and their families faced in establishing that post-service diseases and deaths were connected to participation at the atmospheric nuclear tests or the post-war occupations of Hiroshima and Nagasaki, Japan. The legislative history of Public Law 100-321 shows that it was a compromise between different opinions concerning the health consequences likely to result from low-level ionizing radiation exposure. Partly as a result, there are no clearly articulated rationales for the selection of the covered diseases other than the general Congressional intent to establish presumptions for diseases that are relatively strongly and especially associated with radiation exposure.

what were these then? have they changed?

At the present time, there is no additional scientific evidence available that supports blanket presumptions of service connection for other diseases suffered by atomic veterans. Medical and scientific experts in fields associated with ionizing radiation continue to disagree on the health effects of exposure. Accordingly, VA continues to believe that it is preferable to adjudicate claims for other diseases on a case-by-case basis, taking into account the unique facts of each and the latest credible scientific evidence.

substantiating?
over of what std should be?

For this reason, VA does not recommend expanding the list of presumptive diseases, either through legislation or rulemaking.

Additional Considerations: The House of Representatives introduced legislation, H.R. 3673, which, among other things, would add bronchiolo-alveolar carcinoma (a form of lung cancer) to the list of conditions that VA presumes to be the result of ionizing radiation exposure while in the military. On July 16, 1996, the House passed H.R. 3673 and forwarded it to the Senate.

thus, presumptive?

The Veterans' Advisory Committee on Environmental Hazards (VACEH) [see item 5 for specific details about this committee] has reviewed prevailing scientific and medical data to identify additional diseases that may result from low-level ionizing radiation exposure. The VACEH has identified certain diseases likely to result from radiation exposure. However, it has not identified an association between such diseases and veterans exposed to radiation at nuclear weapons tests or Hiroshima or Nagasaki that would warrant including them in the list of presumptive diseases.

how do these studies file?

so why not add to list?

how else would they be exposed?

Additionally, we looked at the possibility of expanding the presumptive list of radiogenic diseases to include all the diseases on the non-presumptive list of radiogenic diseases. [See Exhibit A for these lists.] We estimated that this would cost \$3.9 billion dollars for the first five years to implement.

Lastly, we reviewed the list of diseases that qualifies Marshall Islanders for Federal compensation. Unlike atomic veterans, inhabitants of the Marshall Islands received higher doses of radiation and the health consequences resulting from these larger doses are more predictable.

The Marshall Islands Nuclear Claims Tribunal recognizes 27 medical conditions which are presumed to be caused by exposure to radiation from nuclear testing in persons who were physically present in the Marshall Islands during the period of testing. The first 13 conditions were taken from Public Law 100-321 and from the Radiation Exposure Compensation Act. The additional 14 conditions were based upon research findings of the Radiation Effects Research Foundation in Japan, the conclusions in BEIR V, and the recommendation of Dr. Robert Miller, Chief of Epidemiology at the National Cancer Institute.

how many of 147
In comparing the Marshall Islanders' list to our list, we find that the differences are primarily conclusions based on high-level radiation exposure versus low-level exposure. Further, many of the Marshall Islanders' medical conditions include illnesses that most frequently result from irradiation of very young persons. We believe it is obvious that the situations of the atomic veterans and the Marshall Islanders are not comparable.
not vets

1
x 3 **2. Should the categories of radiation-exposed veterans be expanded for the presumptive service connection rule?** *- i.e. vets serving in clean up*

Response: Public Law 102-578 called for the VACEH to review scientific studies and other relevant information relating to the exposure of veterans to ionizing radiation prior to January 1, 1970, to identify any activity during which significant numbers of veterans received exposure and to make recommendations on the feasibility and appropriateness of any additional investigations with respect to any activity of such veterans.

The VACEH has conducted and continues to conduct reviews of data relating to activities in which veterans may be exposed to ionizing radiation. Its reviews are topical, thorough and cognizant of the broad range of possible exposure to which veterans may have been subjected.

The VACEH's research concerns two essential questions: First, are there activities other than service with the occupational forces of Hiroshima and Nagasaki, Japan, or participation in atmospheric weapons testing where veterans had the opportunity for exposure to ionizing radiation in the course of their military service; and second, if so, would it be feasible or appropriate to study these veteran groups to determine whether adverse health effects were experienced as a consequence of participation in that activity.

The VACEH has concluded that:

1. There are activities other than atmospheric atomic weapons tests and occupation forces activities that resulted in the exposure of veterans to ionizing radiation during their military service prior to 1970. However, in the vast majority of activities for which radiation records exist, the total doses received were small, less than one rem on the average. For the entire group of veterans, the increased risk of developing a radiogenic disease is small. — *what is it?* *→ any sc'fic impact?*

and so? 2. Pre-1970 records of radiation exposure of the majority of participants in these activities are adequate for calculating doses received. There are potentially exposed individuals for whom the records are either inadequate or inaccessible. Some of these records could be improved. There is no reason to believe that any sizable occupational group has been overlooked, or that there were opportunities for exposure that differ substantially from those groups where records exist.

and so? 3. None of the military occupations which were reviewed is likely to provide evidence of adverse health effects associated with radiation exposure due to small numbers of individuals involved, small average dose, or both. The study of nuclear submariners deserves special attention. It was well conducted, but had relatively short follow-up. It may be useful to extend the follow-up, to achieve more meaningful results.

4. There are other studies which may provide information on adverse health effects resulting from exposure not dissimilar to some military exposures. One group study is that of naval nuclear shipyard workers. This group combines reasonably large size, high quality of exposure records, and ready availability of data. This study should be continued, especially if it focuses on exposure above one rem. Another important group of studies is of the Russian workers exposed in the 1940's and 1950's. These results are highly relevant to the risk information at low doses such as those occurring in military exposures. These studies should be pursued.

5. Information pertinent to other military exposures is not always available in the form that the scientific community and others can use. Information such as dose records of military personnel and other pertinent records should be made more readily available. The results of research which involves military groups or other similarly exposed groups should appear in peer-reviewed literature in a timely fashion.

VA strongly endorses the VACEH's conclusions and recommendations regarding the research efforts concerning nuclear submariners and naval nuclear shipyard workers. We encourage the DOD and DOE to support continuation of these studies. While the studies of the Russian workers may be of some interest, we have concerns about the reliability and availability of these data. — why? Consequently, we have no plans to pursue studies of these workers. We certainly support the VACEH's conclusions regarding the importance of more readily available information in usable formats and the prompt publication of study results in appropriate scientific journals. VA, DOD and DOE officials continue to work together to achieve these objectives.

Additional Considerations: While the VACEH report did not make any recommendations regarding radium treatments provided to submariners and aviators that have been described in several scientific papers, we think this matter is worthy of some additional consideration. Substantial interest was voiced when we brought the issue to the VACEH. We have sought their advice as to whether these individuals might constitute a radiation-risk group. The VACEH is also considering whether a scientific investigation of these individuals may be feasible. It is important to keep in mind that the exposures experienced by these individuals are different from that of the nuclear submariner mentioned above.

The definition of "on-site participation in a test involving atmospheric detonation of a nuclear device" was expanded to include atmospheric testing by nations other than the United States.

3. *In lieu of the presumptive service connection rule, are other mechanisms available to atomic veterans and their survivors that would provide disability and death benefits?*

Response: When a claim cannot be approved under the presumptive service-connected rule, it is evaluated under the standards established by Public Law 98-542, dated October 24, 1984. VA

regulation 38 CFR 3.311 implements this public law and describes the specific criteria for deciding these claims.

Claims considered under section 3.311 require a causal nexus between the claimed disease and the level of exposure to ionizing radiation. VA must obtain and assess radiation dose estimates to determine whether the claimed condition is the result of an in-service exposure. The Defense Special Weapons Agency (formerly Defense Nuclear Agency) is VA's source for providing dose assessments for participants of Hiroshima, Nagasaki and atmospheric testing. However, for other types of radiation exposure, dose assessments are determined by official military records or by another credible expert who is certified to have requisite scientific expertise.

The issue of dose assessment is one that receives the most criticism from the atomic-veterans who believe that this is a mechanism designed to deny claims. VA defers to the DOD for in-depth discussion of its dose assessment program, but we understand that DOD's process of obtaining and reporting dose assessments has been subjected to rigorous peer review. Furthermore, even ACHRE acknowledges that the recorded doses of atomic veterans are low. Given current understanding of dose responses in humans, these exposures would be expected to result in very few cancers or other diseases such as cataracts. Thus the rate of claim approvals has more to do with the merits of the individual case than any shortcomings of the process.

Additional Considerations: VA has proposed a change to section 3.311 to add prostate cancer to the list of radiogenic diseases as well as to provide that VA will consider claims based on other diseases if supported by adequate scientific evidence that the claimed disease is radiation-induced.

4. *Should VA eliminate the dose assessment requirement under 38 CFR 3.311, or, at the very least, eliminate the dose assessment requirement for the veterans of Hiroshima, Nagasaki and atmospheric test participants?*

Response: The dose assessment is an essential tool to both ascertaining the circumstances of veterans' exposure and to employing that information in a manner designed to afford claimants the benefit of the doubt. Essentially, without this mechanism, all claimed conditions would fall under the presumptive rule and would be contrary to well-documented scientific data concerning health consequences resulting

from low-level exposure. The adoption of this suggestion would result in multi-billion dollar costs.

Additional Considerations: VA has in the past and will continue to work in unison with the DOD, the Congress and the Administration, as well as the scientific and medical communities to refine the process of analyzing the nexus between the exposure level and health consequence.

5. *There is a mechanism in place that would allow VA to expand the non-presumptive list of radiogenic diseases.*

Response: In addition to the provisions of Public Law 98-542 previously mentioned, VA was required to establish the Veterans' Advisory Committee on Environmental Hazards (VACEH.) This advisory committee consists of 8 members, 5 of whom are experts in biomedical and environmental science in fields, such as epidemiology and other scientific disciplines, pertinent to determining and assessing the health effects of exposure to ionizing radiation in exposed populations. The remaining three members represent the general public, including at least one disabled veteran having a demonstrated interest in, and experience relating to, veterans' concerns regarding exposure to ionizing radiation.

The VACEH held its first meeting in April 1985, and has continued to meet on the average of two times a year. We anticipate the next meeting of the VACEH will be held this fall.

The VACEH's role is to review pertinent scientific and medical evidence relating to the health consequences of individuals exposed to low-level ionizing radiation. VA's Office of Public Health and Environmental Hazards supports the VACEH by providing medical and scientific literature for the committee's consideration. The Office Public Health and Environmental Hazards also reviews the VACEH's recommendations to clarify medical and scientific terminology, if needed.

Further, the VACEH provides advice to the Secretary concerning diseases it feels are associated with ionizing radiation exposure. When considering new or modified regulations to compensate veterans for disabilities resulting from in-service exposures, the Secretary consults the VACEH and considers its recommendations.

have any been raised?

Additional Considerations: The VACEH has played a vital role as the Secretary's advisor on the scientific and medical matters relating to the health consequences of atomic veterans. The list of radiogenic diseases in 38 C.F.R. § 3.311 is an outcome of the VACEH's work. Most

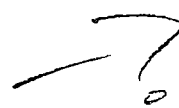
recently, the VACEH recommended the addition of prostate cancer to the list of radiogenic conditions. As mentioned earlier, the Secretary accepted this recommendation, and we have proposed a rule change to add this disease to the list.

6. *The health-care needs of atomic veterans are being met.*

Response: Since 1981, VA has provided free¹, comprehensive medical examinations, including base-line laboratory tests and other diagnostic tests deemed necessary to determine the veterans' current health status, to veterans exposed to ionizing radiation as a result of participation in atmospheric tests or the occupation of Hiroshima and Nagasaki. Also, these veterans are eligible for health-care for conditions possibly related to exposure to ionizing radiation regardless of any determination that the veteran's illness is related to service.

Additional Considerations: VA has proposed legislation to expand the group of veterans eligible for this health-care to include individuals who received nasopharyngeal radium treatments in service. OMB is presently reviewing this proposed legislation.

Additionally, the Under Secretary for Health's Special Committee on Post-traumatic Stress Disorder is investigating the psychological consequences of exposure to ionizing radiation.



Exhibits:

- A: Diseases: 38 CFR 3.309(d) & 3.311
- B: Slide Presentation

1. Veterans are not billed for these services. However, in some instances, VA may bill third party payers.

GONZAGA LAW REVIEW

Volume 30

1994/95

Number 3

CONTENTS

Plaintiffs' Expanding Concepts of
Compensation and the Courts'
Responses

Judith M. Dworkin 487
Janet E. Kornblatt

Hanford: Where Traditional Common
Law Fails

Trisha T. Pritikin 523

The Plaintiff's Perspective: The Need
for Class Certification in Radiation
Cases

Stanley M. Chesley 573
Louise M. Roselle
Paul M. De Marco

Class Actions in Personal Injury
Litigation: At a Crossroads

Anthony Vale 599
Charles H. Carpenter

Service Accepted, Compensation
Denied: The Practice and
Proceedings of the DVA Concerning
Hanford Atomic Veterans

H.W. Cummins, J.D., Ph.D. 629
Thomas J. Fisher, Jr.

The Yakama Nation's Involvement
at the Hanford Nuclear Site

Michael R. Bauer 647

File -
good
article

Service Accepted, Compensation Denied: The Practice and Proceedings of the DVA Concerning Hanford Atomic Veterans

H.W. Cummins, J.D., Ph.D*
Thomas J. Fisher, Jr.**

TABLE OF CONTENTS

I. INTRODUCTION	629
II. THE PRESENT SYSTEM AND DUE PROCESS	637
A. <i>The Opportunity to be Heard</i>	637
B. <i>The Right to be Aware that a Matter Is Pending</i>	639
C. <i>The Right to Make an Informed Choice Whether to Acquiesce or Contest</i>	640
D. <i>The Right to Assert Before the Appropriate Decision-Making Body the Reasons for Such Choice</i>	643
III. CONCLUSION	644

I: INTRODUCTION

In the past decade, much has been learned about the effects of exposure to low-level radiation at our nation's 15 federal nuclear weapons production facilities.¹ Throughout the country, citizens living near these facilities have, with remarkable success, taken part in the national debate about radiation health effects and government accountability. Through organizing, litigation, research, and media attention, the public's awareness of the problems resulting from exposure to radiation released from these facilities has been heightened. The experiences of real people have begun to find their way into the national debate regarding the legacy of nuclear weapons production.²

*H.W. Cummins, Ph.D is the Director of the Radiation Health Effects Public Interest Law (RADLAW) Group and a partner in the Human Experiments Litigation Project. The latter group has partners in New York, Philadelphia, Bethesda, MD, and Washington, D.C. Mr. Cummins is a member of the Pennsylvania Bar.

**Thomas J. Fisher, Jr. is the Director of Programs of the RADLAW Group and currently serves as consultant to the Department of Energy's Office of Human Radiation Experiments.

1. See OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, COMPLEX CLEANUP: THE ENVIRONMENTAL LEGACY OF NUCLEAR WEAPONS PRODUCTION 17 (Feb. 1991) [hereinafter OTA].

2. See MICHAEL D'ANTONIO, ATOMIC HARBOR: HANFORD AND THE LETHAL TOLL OF AMERICA'S

Consistently overlooked in this process, however, is the plight of radiation-exposed veterans. From the beginning of World War II through Operation Desert Storm, they have been the victims of an inaccessible system which has neither adequately acknowledged nor remedied the adverse health effects resulting from their exposure. We as American citizens have an implied contract with these men and women. They serve and defend us in exchange for medical attention and compensation for service-related injuries.³ Veterans have fulfilled their part of this bargained-for exchange. We have not.

It is estimated that more than 450,000 men and women served at Hiroshima, Nagasaki and nuclear test sites in Nevada and the Pacific.⁴ This figure does not include those who served at the 15 nuclear weapons research and production facilities or those exposed to depleted uranium during Operation Desert Storm.⁵ Estimation is necessary as the Department of Defense (DOD) and the Department of Veterans Affairs (DVA) have never performed an accurate count of all radiation-exposed veterans.

One of the most dramatic examples of this abdication of responsibility is the fact that neither the DOD nor the DVA knows the precise number of men and women who served at the largest and most polluted of the federal government's nuclear weapons production facilities, the Hanford Nuclear Reservation (Hanford) in southeastern Washington state. The DVA's most recent official pronouncement on the matter states there were a total, *at all 15 nuclear production sites*, of "as many as 10,000 service personnel."⁶

After being presented with information compiled by the Radiation Health Effects Public Interest Law (RADLAW) Group, the DVA amended that sentence by adding the words "other information . . . suggests that this group may be even larger."⁷ The DVA's disingenuous language dramatically illustrates the quixotic nature of the federal military establishment's approach to radiation-exposed veterans. The DVA's position is effectively contradicted by information available from any public library—information which makes

NUCLEAR ARSENAL (1993).

3. "For disability resulting from personal injury suffered or disease contracted in the line of duty . . . in the active military, naval, or air service during a period of war, the United States will pay to any veteran thus disabled . . . compensation . . ." 38 U.S.C. § 1110 (1992).

4. Keith Schneider, *Ideas and Trends: Opening the Record on Nuclear Risks*, N.Y. TIMES, Dec. 3, 1989, at D6.

5. GENERAL ACCOUNTING OFFICE, OPERATION DESERT STORM: ARMY NOT PREPARED TO DEAL WITH DEPLETED URANIUM CONTAMINATION, GAO/NSIAD-93-90 (Jan. 29, 1993).

6. DVA ADVISORY COMMITTEE ON ENVIRONMENTAL HAZARDS, RADIATION RISK ACTIVITIES REPORT 92 (Aug. 1993) [hereinafter RADIATION RISK REPORT].

7. *Id.*; see also *infra* text accompanying notes 66-68.

it clear that over 50,000 men and women served at or near Hanford.⁸

Whether properly counted or not, when these veterans petition their government for redress, they are consistently told their health problems could not have resulted from radiation exposure. At last count, 91% of all claims for service-connected compensation for radiation exposure had been denied, a total of 14,332 claims of the 15,818 filed.⁹ The denial of these claims, in combination with the number of claims which have not yet been initiated, amounts to one of the most glaring and pervasive violations of due process in recent American history.

To put a discussion of due process into the proper perspective, one must consider the method by which the DVA hears radiation compensation claims.¹⁰ The claims process begins when a veteran submits an application for monthly compensation to one of 58 DVA regional offices located throughout the country.¹¹ The application is completed with the help of a DVA counselor.¹² The counselor's primary duty is to ensure the case enters the system with all the required paperwork, including service records, medical records and the veteran's own "Statement in Support of Claim."¹³

Veterans are entitled to the assistance of a Service Officer from one of the many veterans organizations chartered by Congress. Despite such guidance, however, a typical Statement reads as follows:

8. Yearly troop figures, chosen randomly for the years 1943, 1956, 1959, and 1963, were combined to make a total of 24,336 service personnel. Sources used were: THE UNITED STATES AIR FORCE, DIRECTORY OF UNITED STATES AIR FORCE ORGANIZATIONS, (Jan. 1943, Jan. 1956, Jan. 1959, and Jan. 1963) and UNITED STATES NAVY AND MARINE CORPS BASES, DOMESTIC (Paolo E. Coletta ed., 1985). The two sources cited were obtained by the authors at the Reading Room of the Multnomah County Library in Portland, Or. This 24,336 figure represents veterans who served *off* (downwind from) the Hanford Reservation. This figure combined with the count of 23,000 men who served *on* the Hanford Nuclear Reservation from 1952 through 1962 equals 47,336. This calculation makes it clear that an accurate count of all the men and women who served at or downwind of Hanford for all years since 1943 will be in excess of 50,000. See Memorandum to "Interested Parties" from H. W. Cummins, Director, RADLAW Group, Oct. 21, 1994 (providing government documentation to substantiate the 50,000 figure).

9. Letter from Jesse Brown, Secretary of Veterans Affairs, to John D. Rockefeller IV, Chairman, Committee on Veterans' Affairs, U.S. Senator (July 18, 1994) (on file with the *Gonzaga Law Review*).

10. For an overview of the claims process, see *National Ass'n of Radiation Survivors (NARS) v. Derwinski*, 994 F.2d 583 (9th Cir.), *cert. denied*, 114 S. Ct. 634 (1993); Christopher D. Knopf, *One Last Battle: Reform of the Veterans' Administration Claims Procedure*, 74 VA. L. REV. 937 (1988).

11. DVA ADJUDICATION MANUAL, M21-1, Part III, Change 4, § 5.12 (Aug. 4, 1992).

12. *Id.*

13. *Id.*

I was one of [the personnel stationed at Camp Hanford] from 9-20-50 to 7-27-51. While I was their (sic) one day I saw a dead cat with yellow-green substance emanating from the cat mouth (sic). I told these (sic) to some DVA doctor and one of them said that was radiation poisoning. So if that cat was dead from radiation poisoning what was it doing to me. And this is what has been happening to me in the last years. Saliva glands were enlarged in 1980. DVA doctor removed one of the gland (sic). A year later doctor at DVA found a tumor at the base of my throat. Three years I lost my other saliva gland at this time. I have been put on penicillin (sic) two time in the last [illegible] monuths (sic).¹⁴

Based on the strength of the veteran's statement, in concert with medical and service records, the hearings process is begun. Claims for service-connected compensation resulting from exposure to radiation are heard under the terms of either the Veterans' Dioxin and Radiation Exposure Compensation Standards Act ("Veterans' Act") or the Radiation-Exposed Veterans Compensation Act ("Compensation Act").¹⁵ The Compensation Act provides a presumption of service connection to veterans (and their survivors) who participated either in atmospheric or underwater nuclear tests as part of our nation's weapons testing program or in the American occupation of Hiroshima or Nagasaki, Japan, and who suffer from certain diseases that may be attributable to exposure to ionizing radiation.¹⁶

To be eligible for benefits under the Compensation Act, a veteran needed to meet three criteria: (1) he or she had to have one of the presumed radiogenic diseases, (2) he or she had to show that symptoms first appeared within 40 years of exposure, and (3) he or she had to prove that the disease resulted from participation in a radiation-risk activity.¹⁷ A partial listing of the presumed radiogenic diseases required by the statute includes: leukemia (other than chronic lymphocytic leukemia), thyroid cancer, breast cancer, esophageal cancer, stomach cancer, colon cancer, multiple myeloma, ovarian cancer, and liver cancer.¹⁸

The Compensation Act was later amended by the "Veterans Radiation Exposure Amendments of 1992."¹⁹ These amendments expand the list of diseases presumed to be service-connected to include cancer of the salivary

14. Statement of veteran claimant to Dr. David Price, Mar. 28, 1993 (on file with the *Gonzaga Law Review*).

15. Veterans' Dioxin and Radiation Exposure Compensation Standards Act, Pub. L. No. 98-542, 98 Stat. 2725 (1984); Radiation-Exposed Veterans Compensation Act of 1988, Pub. L. No. 100-321, 102 Stat. 485 (1988).

16. Radiation-Exposed Veterans Compensation Act, § 2, 102 Stat. at 485.

17. 38 C.F.R. § 3.311(b)(1) (1994).

18. *Id.* § 3.311(b)(2).

19. Veterans' Radiation Exposure Amendments of 1992, Pub. L. No. 102-578, 106 Stat. 4774 (1992) (effective Oct. 1, 1992).

glands and cancer of the urinary tract.²⁰ The amendments also eliminate the 40-year latency period limitation previously in effect.²¹ If a veteran cannot meet all the amended criteria, the DVA Adjudication Manual provides that: "the [rating] board will . . . determine that the disease did not result from exposure to ionizing radiation."²²

Cases which do not fit within the DVA's narrow interpretation of the presumed list are adjudicated under the Veterans' Act, which does not contain a presumed list.²³ Rather, compensation under this law depends upon the estimated dose of radiation to which a veteran was exposed.²⁴

Under 38 C.F.R. § 3.311, veterans have the burden of proving that they were exposed to ionizing radiation and that they developed a radiogenic disease within a specified time frame.²⁵ If this burden is sustained at the regional Rating Board level, the claim is automatically referred to the DVA's Chief Benefits Director in Washington, D.C.²⁶ The regulation continues:

(1) When a claim is forwarded for review pursuant to paragraph (b)(1) of this section, the Chief Benefits Director shall consider the claim with reference to the factors specified in paragraph (e) of this section and may request an advisory medical opinion from the Chief Medical Director.

(i) If after such consideration the Chief Benefits Director is convinced sound scientific and medical evidence supports the conclusion *it is at least as likely as not* the veteran's disease resulted from exposure to radiation in service, the Chief Benefits Director shall so inform the regional office of jurisdiction in writing. The Chief Benefits Director shall set forth the rationale for this conclusion, including an evaluation of the claim under the applicable factors specified in paragraph (e) of this section.²⁷

The regulation differentiates between three types of radiation-exposed veterans—those who served at nuclear test sites, those who were stationed at Hiroshima or Nagasaki, and "others."²⁸ "Other" veterans' claims are discussed as follows:

20. *Id.* § 2, 106 Stat. at 4774.

21. *Id.* ("Section 1112(c) of title 38, United States Code, is amended . . . by striking out paragraph (3) . . .") (eliminating latency periods).

22. See DVA ADJUDICATION MANUAL, *supra* note 11, § 5.12(a)(2).

23. Veterans' Dioxin and Radiation Exposure Compensation Standards Act, Pub. L. No. 98-542, 98 Stat. 2725 (1984).

24. 38 C.F.R. § 3.311 (1994).

25. *Id.* § 3.311(b)(1).

26. *Id.* § 3.311(c).

27. *Id.* § 3.311(c)(1) (emphasis added).

28. *Id.* § 3.311(b).

(iii) *Other exposure claims.* In all other (than atmospheric weapons test participation and Hiroshima and Nagasaki) claims involving radiation exposure, a request will be made for any available records concerning the veteran's exposure to radiation. These records normally include but may not be limited to the veteran's "Record of Occupational Exposure to Ionizing Radiation (DD Form 1141)," if maintained, service medical records, and other records which may contain information pertaining to the veteran's radiation dose in service.²⁹

A careful reading of 38 C.F.R. § 3.311 and the DVA's Adjudication Manual could easily lead one to believe that veterans who served at nuclear weapons production facilities are not covered by any claims procedure. The Adjudication Manual incorporates 38 C.F.R. § 3.311(a)(2)(ii) so that administrators who consult the Manual find reference only to veterans who served at nuclear test sites, veterans who served at Hiroshima or Nagasaki, or "other" veterans. The Manual defines "other" veterans as only those who were exposed to radiation "by reason of the nature of military duties (radiologist, x-ray technician, etc.)."³⁰ In short, weapons facility veterans appear to end up being no more than an "etc." in the DVA's Adjudication Manual. This is a key factor in all radiation-exposure claims for claimants such as Hanford veterans since the Manual is the only guide that all DVA decision-makers use in adjudicating these claims.

For veterans whose claims move past the barriers of the DVA Adjudication Manual's vagueness, another set of barriers arises. Both the regulation and the Manual call for a radiation dose estimate.³¹ The Defense Nuclear Agency (DNA) is charged by statute to provide dose estimates *only* for veterans who served at nuclear test sites and Hiroshima or Nagasaki.³² Therefore, estimates of the doses for "other" veterans are usually requested from the individual veteran's branch of service.³³

In the case of the Army, the major recipient of these claims, dose requests are most often furnished by its Office of the Surgeon General.³⁴ The difficulty with this scheme is that few of the veterans exposed at nuclear weapons production facilities had dose records of any kind initiated and maintained.³⁵ This lack of critical evidence is compounded by the Surgeon

29. 38 C.F.R. § 3.311(a)(2)(iii) (1994).

30. DVA ADJUDICATION MANUAL, *supra* note 11, § 5.12(c)(4).

31. 38 C.F.R. § 3.311(a); DVA ADJUDICATION MANUAL, *supra* note 11, §§ 5.12(c)(4)-(5).

32. Letter from W.J. Flor, Captain, MSC, USN, Program Manager, Nuclear Test Personnel Review, Defense Nuclear Agency, to J.J. Fitterer, DVA Regional Office, Portland, Or. (Dec. 9, 1991) (on file with the *Gonzaga Law Review*).

33. DVA ADJUDICATION MANUAL, *supra* note 11, § 5.12(c)(5).

34. See Flor, *supra* note 32.

35. The RADLAW Group, *Hanford Veterans Cancer Mortality Study: Direct Contact*

General's inability to provide accurate dose estimates.

In one of the most recent Hanford-related cases, the Surgeon General responded to a request for a dose estimate by saying "this office has no information on Camp Hanford except what we are trying to acquire from the current public media."³⁶ The claim was denied.³⁷ Neither the claimant nor his Service Officer knows if, or where, the DVA went to get a dose estimate or what the estimate was.³⁸ When asked about the case, the DVA merely sent the veteran claimant a letter explaining that he had a right to appeal the denial.³⁹ In the few cases where the DVA does make a dose estimate available, it never explains how it was calculated.⁴⁰

Veterans and their representatives have to take on faith that the Chief Benefits Director has a dose estimate before him when he exercises his judgment. With or without a dose estimate, if the Director is "convinced sound scientific and medical evidence supports the conclusion it is at least as likely as not"⁴¹ that a veteran's medical condition was connected to service, then the claim is granted.

The Chief Benefits Director's opinion, once reached, is sent back down the chain of command to the requesting regional office's Rating Board.⁴² The board has three members—a medical, a legal, and an occupational disease specialist.⁴³ In routine cases such as war wounds, training accidents, and injuries sustained during active duty, the board evaluates the validity of each claim and the degree of disability to determine at what level compensation should be granted.⁴⁴

All claimants have the right to a hearing at any time on any issue in their

List, Contacts Between March 1, 1992 and March 1, 1993 and March 1, 1994. This unpublished data, which contains the results of interviews with over 270 veterans stationed at the Hanford Nuclear Reservation, is available from the RADLAW Group at 7600 Maple Street, Suite 508, Takoma Park, MD 20912.

36. Letter from Russ Zatchuk, Brigadier Gen., Director, Professional Services, U.S. Army, to J. Frank, Adjudication Officer, DVA, Fargo, N.D., 1 (Apr. 19, 1994) (on file with the *Gonzaga Law Review*).

37. Letter from J. Frank, Adjudication Officer, DVA, Fargo, N.D., to Mr. Roy Stola, Jr. (May 19, 1994) (on file with the *Gonzaga Law Review*).

38. *Id.*

39. Letter from J. Frank, Adjudication Officer, DVA, Fargo, N.D., to Mr. Roy Stola, Jr. (Dec. 15, 1994) (on file with the *Gonzaga Law Review*).

40. Letter from Richard S. Christian, C.R.M., Director, Department of the Army, U.S. Army and Joint Services Envtl. Support Group, to Mr. Pfeiffer, Claims Representative, DVA Regional Office, Portland, Or. (Nov. 18, 1985) (on file with the *Gonzaga Law Review*).

41. 38 C.F.R. § 3.311(c)(1)(i) (1994).

42. *Id.*

43. *Id.* § 3.103(c).

44. *Id.*

claim.⁴⁵ The hearing is informal, there is neither governmental opposition nor formal questioning or cross-examination, and formal evidentiary rules do not apply.⁴⁶ The local Board is required to advise claimants what evidence might be advantageous for their claims.⁴⁷ In addition, the Board must resolve any reasonable doubts in the evidence in the claimants' favor.⁴⁸ However, these rights are a chimera given that the veteran never knows when or by whom the case is being considered.⁴⁹

Once the Rating Board has acted, the veteran is notified through a "Notice of Decision" which contains the reasons for the decision and its effective date.⁵⁰ In addition, the Board must inform the claimant of his or her right to a hearing.⁵¹ The claimant may challenge the Rating Board's decision by filing a "Notice of Disagreement" with the regional office.⁵² In response, the regional office will either reconsider the claim or uphold the original adverse determination and issue a "Statement of the Case."⁵³ The latter, which summarizes the decision, is the final action of the regional office.⁵⁴

If the veteran continues to be dissatisfied with the regional office's decision, he or she can file a substantive appeal with the Board of Veterans' Appeals (BVA) after the Statement of the Case is issued.⁵⁵ The BVA is headed by a chairman and a vice chairman, who are responsible to the Secretary of the DVA.⁵⁶ When a claimant raises a medical issue, DVA regulations require a physician to sit on the BVA section which hears the claim.⁵⁷

45. *Id.*

46. 38 C.F.R. §§ 3.103(a)-(c) (1994).

47. *Id.* § 3.103(c).

48. *Id.* § 3.102.

49. Typical examples of this kind of situation are illustrated by numerous letters available through the RADLAW Group. *See, e.g.*, letter from Calvin Post, to J.J. Fitterer, Adjudication Officer, DVA, Portland, Or. (July 30, 1991); letter from Rachel Mecklenburg to H.W. Cummins, Director, RADLAW Group (Sept. 9, 1991); letter from W.F. Byrnes, Adjudication Officer, DVA Regional Office, Pittsburgh, PA, to Frank G. Leonheart (Dec. 4, 1992) (all on file with the *Gonzaga Law Review*).

50. 38 C.F.R. § 3.103(f) (1994).

51. *Id.*

52. *Id.* § 19.26.

53. *Id.*

54. *Id.*

55. 38 C.F.R. § 19.30 (1994).

56. Letter from Jesse Brown, Secretary of Veterans' Affairs, to the President of the Senate and the Speaker of the House of Representatives of the 103rd Cong. (Annual Report as of Sept. 30, 1992). The President of the United States appoints the chairman, and the Secretary of the DVA appoints the vice chairman, deputy vice chairman and 64 other board members. *Id.* at 98.

57. Hearing on Oversight of the DVA's Disability Compensation Programs, Subcommittee on Human Resources and Intergovernmental Relations of the House

In reality, veterans usually complete the Appeals Form included in the letter of denial sent to them. This automatically appeals the decision, thereby moving it to an overburdened BVA which will take, on average, more than a year to hear the case before rendering a decision.⁵⁸

II. THE PRESENT SYSTEM AND DUE PROCESS

Trinity Episcopal School Corp. v. Romney sets forth four elements that the United States Supreme Court has held meet the requirements of due process.⁵⁹ These include "the opportunity to be heard, to be aware that a matter is pending, to make an informed choice whether to acquiesce or contest, and to assert before the appropriate decision-making body the reasons for such choice."⁶⁰ The discussion which follows is based on these four requirements:

A. *The Opportunity to be Heard*

An opportunity to be heard is no opportunity at all if an exposed veteran is unaware that he or she was ever put at risk. Part of the DVA's problem with radiation-exposed veterans is not knowing the number of men and women who were stationed at or downwind of facilities like Hanford. In August 1993, the DVA submitted a mandated "Radiation Risk Activities Report" to Congress.⁶¹ The Report sets out the DVA's count of the number of persons involved in radiation risk activities other than men and women who served at Hiroshima, Nagasaki and/or nuclear test sites.⁶²

Buried in an appendix to the report, as an enclosure to the minutes of one of the Advisory Committee's subcommittee reports, is a January 1993 briefing from the Defense Nuclear Agency.⁶³ The briefing obliquely states that between 20,000 and 30,000 persons were subject to exposure as troops involved in "nuclear weapons development."⁶⁴ Through some sleight of hand by the Advisory Committee, the DVA's 20,000 to 30,000 men and women

Committee on Government Relations, 100th Cong., 2d Sess. (Feb. 18, 1988) (statement of Kenneth E. Eaton, Chairman, BVA).

58. See *Claims Backlog Puts VA in Crisis*, THE VETERANS ADVOCATE, The National Veterans Legal Services Project, June 1994, 89, 89-96; Ken Schamberg, *Claims, Quotas, Chaos*, THE AM. LEGION, Aug. 1994, at 24.

59. 387 F. Supp. 1044, 1084 (S.D.N.Y. 1974), *rev'd on other grounds*, 523 F.2d 88 (2d Cir. 1975).

60. *Id.*

61. RADIATION RISK REPORT, *supra* note 6, at 92.

62. RADIATION RISK REPORT, *supra* note 6, at 92.

63. RADIATION RISK REPORT, *supra* note 6, at Appendix II.

64. RADIATION RISK REPORT, *supra* note 6, at Appendix II.

became "10,000" in the body of the Report.⁶⁵ The Committee told Congress that "the Defense Nuclear Agency has estimated that there may have been as many as 10,000 service personnel in this group."⁶⁶

This statement compounds fault. At the time the Report was being drafted, the 10,000 figure was vigorously challenged by the RADLAW Group.⁶⁷ The Group presented the Committee with incontrovertible evidence, using federal sources, which made it clear that over 50,000 men and women served at or downwind of Hanford.⁶⁸ And Hanford is only one of 15 nuclear weapons production facilities where troops may have served. All the Committee did with the RADLAW information was add one sentence modifying its original "as many as 10,000" figure. The Committee simply added the words "other information provided to the Committee suggests that this group may be even larger."⁶⁹

Moreover, those few radiation-exposed veterans aware of their rights are not necessarily better off than their comrades who not only have no idea they were exposed, but also are unaware they have the right to apply for compensation. Those who do know find themselves confused and frustrated as they attempt to pursue highly technical, complex cases through a system that is not adequately prepared to deal with radiation exposure questions.

The only changes made in the DVA's compensation system since the 1940s have been a series of new legislative proposals designed by a reluctant Congress to deal with health problems like those resulting from Agent Orange, radiation exposure, and Operation Desert Storm.⁷⁰ The result is a system which becomes more inflexible and unresponsive with each legislative addition.

In theory, these legislative revisions were drafted to handle a large number of claims in a non-adversarial, informal manner that is sympathetic to the veteran.⁷¹ In reality, the veteran's first and last personal contact with the DVA system is the intake counselor who helps prepare his or her case. Once the preparation is completed, the system takes over. The result is that the veteran's claim is seldom heard by any triers of fact or decision-makers who make final judgments. All the veteran knows is that he or she filled out forms at the regional office and six, eight or fifteen months pass with no word.

Finally, a key assumption of the "opportunity to be heard" is that the

65. RADIATION RISK REPORT, *supra* note 6, at Appendix II.

66. RADIATION RISK REPORT, *supra* note 6, at 92.

67. RADIATION RISK REPORT, *supra* note 6, at Appendix VI.

68. Cummins, *supra* note 8.

69. See RADIATION RISK REPORT, *supra* note 6, at 92.

70. Brown, *supra* note 9.

71. NARS v. Derwinski, 994 F. 2d 583, 586 (9th Cir.) *cert. denied*, 114 S. Ct. 634 (1993).

hearing officers will be unbiased and have no interest in the outcome of the hearing. It is evident that any DVA decision which relies on the judgment of the Chief Benefits Director does not fit this definition. The Benefits Director's major responsibility is the smooth functioning of the nation's second largest benefits system. The Director is charged with guaranteeing that this system provides maximum service at minimum cost. His responsibility for budget management clearly conflicts with his responsibility for rendering fair decisions in individual compensation cases.

*B. The Right to be Aware that a
Matter Is Pending*

Veteran claimants can seldom track their cases through the DVA system once the case has left the hands of the Service Officer. This lack of knowledge is compounded after the claim is forwarded to the DVA's central office for review by the Chief Benefits Director. Almost without exception, when asked what stage a case has reached, regional office personnel cannot say. All they know is that it has been forwarded to the central office (DVA headquarters) in Washington, D.C.

In one case, a Hanford veteran filed a claim for service-connected disability compensation for lung cancer which he maintains resulted from his service at Hanford.⁷² He assumed his claim was being processed in the Portland, Oregon, regional office, the one nearest his home in Philomath, Oregon. However, the regional office's Adjudication Officer sent a request for dose information to the DNA in Alexandria, Virginia.⁷³ It took 17 months for the DNA to respond to the Adjudication Officer, saying in a letter dated December 9, 1991, that:

the scope of our program is limited to providing information regarding the activities and radiation exposure histories of individuals who participated in atmospheric nuclear tests and the occupation of Hiroshima and Nagasaki . . . Mr. [identity protected]'s exposure is considered occupational in nature . . . Therefore, it falls outside the purview of our office and is being returned without action.⁷⁴

At no time was the veteran told the current status of his case or its future course. No veteran ever gets such notification. The only contact veterans have with the DVA is when they originally file their claims and when the claims are finally denied. The DVA's Compensation Manual contains no

⁷² Flor, *supra* note 32.

⁷³ Flor, *supra* note 32.

⁷⁴ Flor, *supra* note 32.

procedure for keeping veterans apprised of the status of their cases. In the above cited case, the veteran's compensation request was denied on June 7, 1993. He then appealed to the Board of Veterans Appeals. Nobody knows precisely where his case stands at present, and no word is expected from the Board until 1996. However, the DVA recently informed the veteran that he has the "right to appeal," an appeal he already filed after his original claim was denied on June 7, 1993.⁷⁵

*C. The Right to Make an Informed Choice Whether
to Acquiesce or Contest*

In order to make any kind of informed choice regarding a case, a veteran must be well advised. Advocates of the present system point out that the veteran not only has a DVA counselor, but a Service Officer from one of the national veterans service organizations to assist him or her in the claim. What is never mentioned is that veterans are barred from paying fees to legal counsel for services other than in cases before the Court of Veterans Appeals.⁷⁶ This leaves tens of thousands of veterans at the regional office and Board of Veterans Appeals stages of their claims without legal counsel.⁷⁷

Most DVA counselors spend only the amount of time necessary to complete the application for benefits and the veteran's Statement in Support of Claim. They are forbidden to act as advocates.⁷⁸ Thus, they cannot help veterans make informed choices. To quote Gordon Erspamer, an attorney with Morrison and Forrester in San Francisco and a legal advisor to the National Association of Radiation Survivors (NARS), in his testimony to Congress:

[A]ssistance rendered by V.A. adjudicators is limited to attempts to procure medical and service records. The V.A. . . . makes no effort to locate or interview witnesses to the disabling event, obtain additional documentary evidence, refer issues to experts, or perform any other acts to develop key facts. Needless to say, a complex claim supported only by service records is bound to fail. . . . According to V.A. statistics . . . the V.A. spends an average *total* time of but 2.84 hours processing a disability claim.⁷⁹

75. Letter from R.L. Conlee, Adjudication Officer, DVA, to Calvin J. Post (July 25, 1995) (on file with the *Gonzaga Law Review*).

76. 38 U.S.C. § 5904 (Supp. V 1993).

77. For a broader statement of the issues involved, see *Derwinski*, 994 F.2d 583.

78. DVA ADJUDICATION MANUAL, *supra* note 11, § 5.12(c).

79. *Judicial Review of Veterans' Claims, 1986: Hearings on H.R. 585 Before the House Comm. on Veterans' Affairs, 99th Cong., 2d Sess., 193 (1986)* (statement of Gordon P. Erspamer, Esq., Legal Advisory Board, National Ass'n of Radiation Survivors) [hereinafter statement of Gordon Erspamer].

Only the veteran's Service Officer can act as an advocate. One of the primary reasons behind the litigation in *National Association of Radiation Survivors (NARS) v. Derwinski* and *NARS v. Turnage* was the fact that the Service Officers simply do not represent veterans effectively, especially given the fact that they are overburdened and undertrained.⁸⁰ Federal laws mandate only that Service Officers be hired based on their good character, reputation, and familiarity with DVA procedures.⁸¹ They do not require skill in advocacy, the ability to develop complex cases, or any formal training. The DVA has implemented no training for Service Officers and no meaningful accreditation standards for service representatives.⁸² The minimal guidance and accreditation the DVA offers is largely symbolic.

Added to these problems is the fact that the overworked Service Officers often cannot adequately safeguard claimants' rights because they cannot adequately keep up with a system which overwhelms them with regulations, circulars, memoranda, opinions of DVA General Counsel, and even verbal guidelines.⁸³ Even the simplest problems facing them can become critical. For example, Service Officers must sort through a labyrinth of regulations to comply with filing deadlines.⁸⁴ However, the DVA is not required to notify claimants or their representatives of filing deadlines, and failure to meet these deadlines can result in a claim's automatic dismissal.⁸⁵

A veteran must contend not only with his or her overburdened Service Officer, but a number of other roadblocks as well. First, there is no way for persons outside the DOD and DVA systems to assess the accuracy of dose estimates provided by the DOD.

As discussed earlier, dose estimates for Army veterans who served at nuclear weapons production facilities like Hanford are usually prepared by the Department of the Army's Office of the Surgeon General.⁸⁶ The case of a Hanford veteran reinforces the conclusion that evidence of radiation doses provided by the Surgeon General's Office can be wildly inaccurate. In

80. *NARS v. Derwinski*, 782 F. Supp. 1392 (N.D. Cal.), *rev'd*, 1992 Daily Journal D.A.R. 15723 (9th Cir. Cal. 1992); *NARS v. Turnage*, 115 F.R.D. 543 (N.D. Cal. 1987).

81. See 38 U.S.C. § 5904 (1994).

82. See 38 U.S.C. §§ 5901-02 (1992); 38 C.F.R. §§ 14.626-37 (1994) (concerning veteran representation).

83. Statement of Gordon Erspamer, *supra* note 79.

84. Regulations regarding filing deadlines include: 38 C.F.R. § 20.302 (1994) (time limit for filing); *Id.* § 20.303 (extension of time for filing); *Id.* § 20.305 (computing time limit); *Id.* § 20.306 (legal holidays); *Id.* § 19.33 (timely filing of appeal questioned within the agency of original jurisdiction); *Id.* § 19.34 (untimely filing of appeal protested by claimant); *Id.* § 20.400 (notifying claimant).

85. 38 C.F.R. § 3.109 (1994).

86. See *supra* notes 34-35 and accompanying text.

response to an inquiry by a veteran's wife, the Surgeon General's Office wrote:

The U.S. Army Ionizing Radiation Dosimetry Center has no record of Mr. Mecklenburg ever being issued a dosimeter by the U.S. Army, including the period in question while at Camp Hanford. We conclude, therefore, that Mr. Mecklenburg was not involved in activities at Camp Hanford which would have resulted in his receiving occupational ionizing radiation exposures.⁸⁷

This could well be dubbed a "no badge, no dose" approach to dose estimation. Even the help of her Congressman only netted Mrs. Mecklenburg a statement from the Army that her husband "could have received a maximum of 0.5475 rem radiation per year, or 1.095 rem for [the] two year period [of his duty at Hanford]."⁸⁸ Subsequent to this correspondence, a privately funded dose estimate provided by the Institute for Energy and Environmental Research in Takoma Park, Maryland, showed that, based on available evidence, parts of Mr. Mecklenburg's body could have been exposed to doses as high as 300 rem externally on his scalp.⁸⁹ Richard Mecklenburg died in 1987. His case is *still* being pursued by his wife.

In the case discussed above in which a Hanford veteran with colon cancer was told that the Office of the Surgeon General "has no information on Camp Hanford except what we are trying to acquire from the current public media . . .," the correspondence continues: "Based upon what we know about Camp Hanford and exposures received by those who worked there, we believe it is unlikely that [your] colon cancer resulted from [your] military service at Camp Hanford."⁹⁰ Thus, in many cases, a veteran trying to make an informed choice whether to acquiesce or contest is left more confused after having corresponded with the DVA or his or her service branch.

Moreover, not only are veterans hampered in their decision-making process, but one can assume the DVA's Chief Benefits Director is as well. The Director must rely on the same questionable sources as the veteran, making it doubtful the Director can "make an informed choice" or assert compelling "reasons for such choice."

Finally, no matter what the basis for decision, veterans never see the details of the Chief Benefits Director's "rationale for . . . conclusion," or his

87. Letter from Ronald R. Blanck, Brigadier Gen., Office of the Surgeon General, U.S. Army, to Mrs. Richard Mecklenburg (July 20, 1992) (on file with the *Gonzaga Law Review*).

88. Christian, *supra* note 40.

89. BERND FRANKE, A PRELIMINARY RECONSTRUCTION OF THE RADIATION DOSE RECEIVED BY MR. RICHARD MECKLENBURG DURING HIS STAY AT THE HANFORD NUCLEAR RESERVATION 7 (Institute for Energy and Env'tl. Research 1987).

90. Zatchuk, *supra* note 36.

"evaluation of the claim under the applicable factors specified in paragraph (e)."⁹¹ However, the veteran can get a Statement of the Case which provides summary information which lead to a denial, but provides little detail of how the conclusion was reached.⁹² Thus, it is difficult for a veteran to make an informed decision on whether to appeal an adverse ruling. Additionally, if a decision is made to appeal, the veteran has no idea what the key issues are or how they need to be framed. Finally, the regulations do not provide any standard guidelines against which the decision of the Chief Benefits Director can be measured.⁹³ They merely call for the Director to be "convinced."⁹⁴

*D. The Right to Assert Before the Appropriate
Decision-Making Body the Reasons
for Such Choice*

The DVA's Adjudication Manual provides that the Benefits Director's decision is merely advisory and that the regional Rating Board makes final decisions.⁹⁵ However, it is extremely doubtful that regional Rating Boards ever challenge the Benefits Director's "advisory" opinions.

A reading of the DVA's Adjudication Manual leads one to the conclusion that the department's compensation system is based on a command system model. Regional offices are line organizations. In such a scenario, the central office in Washington, D.C. is the headquarters. Information runs up to the central office and orders run down to regional offices. Beyond the effect of the command structure, there is also the fact that the system of referring cases to the Chief Benefits Director is premised upon the belief that regional Adjudication Officers and Boards are unable to develop complex radiation-exposure claims on their own.⁹⁶ Thus, it would be very surprising for a regional board to make a decision contrary to that of the central office's Chief Benefits Director.

Critics argue that even in routine cases the Rating Boards' fact-finding process is incomplete, leading to underdeveloped factual records at the regional level. This is especially true concerning medical records.⁹⁷ At the

91. 38 C.F.R. § 3.311(c) (1994).

92. *Id.* §§ 19.29-31.

93. *Id.* § 3.311(e) (listing factors for consideration).

94. *Id.* § 3.311(c)(1)(i).

95. *Id.* § 3.311(f); DVA ADJUDICATION MANUAL, *supra* note 11.

96. 38 C.F.R. § 3.311(b)(1)(iii) (1994).

97. In addressing Congress, Allen Lynch stated:

[T]he rating board medical specialist often changed the doctor's diagnosis, or just completely disregarded it. On those occasions where more than one diagnosis for the same condition was on record, the claim would often be denied without even asking for a reconciliation of diagnosis [P]rivate medical doctors statements,

regional level, the Rating Board's occupational or legal specialist usually drafts the Board's opinion, which is then routed to the medical specialist to be signed. The medical specialist often renders his or her opinion verbally since there is no requirement that it be put in writing or communicated to the claimant.⁹⁸ In addition, according to Allen J. Lynch, Chief of Veterans Advocacy for the Office of the Illinois Attorney General, in a statement before Congress:

[t]he Rating Board "Medical Specialist" is often a non-licensed physician who has not practiced medicine for years and who is not really a "specialist" in the field of disability that he's rating. [Yet] [t]hese specialists are tasked with rating very complicated cases, while the disabled veterans' livelihood hangs in the balance.⁹⁹

The Rating Board's decision is communicated to the veteran by letter.¹⁰⁰ If the case is turned down, an enclosure to the letter explains that the veteran has a right to appeal to the Board of Veterans Appeals.¹⁰¹ Many veterans do not take advantage of this right. One of the chief reasons for this is that most veterans do not know how to make an appeal. Another reason is that they see the system just as it was meant to be seen—as a command system—that has denied their request for compensation just as it might have denied an in-service request for a two-day pass.

It is not necessary to detail the BVA's process. It suffers from the same due process flaws outlined above. These procedural flaws make a mockery of the DVA's system for hearing compensation requests from radiation-exposed veterans. Further tinkering with the system will simply complicate it more, leading to greater inequity. What is needed is a wholesale restructuring of the system. The goal of the re-structuring must be fair hearings from unbiased administrators.

III. CONCLUSION

This analysis comes to the same basic conclusion reached in *NARS v. Derwinski*, in which the court determined that nuclear weapons production

when placed along side V.A. medical statements, do not carry much weight and were often completely disregarded. . . .

Judicial Review of Veterans' Claims, 1986: *Hearings on H.R. 585 Before the House Comm. on Veterans' Affairs*, 99th Cong., 2d Sess., 36 (1986) (statement of Allen J. Lynch, Chief of Veterans Advocacy, Office of the Ill. Att'y Gen.).

98. *Id.*

99. *Id.*

100. 38 C.F.R. § 3.103(f) (1994).

101. *Id.*

facility veterans, like those who served at or downwind from Hanford, make "an extraordinarily strong showing of the probability of erroneous denial of ionizing radiation claims under the existing (DVA) system"¹⁰²

In short, the DVA's compensation system for radiation-exposed veterans is an overly complex affront to due process and a breach of the statutory mandate that a grateful nation compensate veterans injured in its service. Only wholesale reform of the system will restore due process and allow us to meet our obligations to these veterans. A courageous, responsible Secretary of Veterans Affairs need only look to the President for guidance.

Following his regulatory reform briefing on February 21, 1995, President Clinton moved quickly to let all Department heads know his expectations and timetable for overhauling the federal government's regulatory culture and processes. In a statement on March 4, 1995, the President said that reform of the regulatory system is the "central part of reinventing government" and must be a top priority.¹⁰³

To achieve total regulatory reform, the Secretary of Veterans' Affairs must focus immediately on four steps set out by the President on March 4, 1995:

1) Cut Obsolete Regulations. The Secretary must initiate a page-by-page review of all regulations and eliminate or revise those that are outdated or in need of reform;

2) Reward Results, Not Red Tape. The DVA must change the way it measures performance. It must focus on results, not processes and punishment. DVA Service Officers should not be evaluated by the *number* of claims they handle but by the quality of the advocacy they provide;

3) Get Out of Washington and Create Grassroots Partnerships. The secretary should promptly convene groups of regional regulators and the veterans affected by their regulations; and

4) Negotiate, Don't Dictate. The Secretary should expand considerably his efforts to promote consensual rulemaking. It is time, the President said, to move from a process where lawyers and bureaucrats write volumes of regulations to one where people work in partnership to issue sensible regulations that impose the least burden without sacrificing rational and necessary protections.¹⁰⁴

102. 994 F.2d 583, 591 (9th Cir. 1992) (citation omitted), *cert. denied*, 114 S. Ct. 634 (1993).

103. Memorandum from William J. Clinton, President of the United States, to Heads of Departments and Agencies, 1 (Mar. 4, 1995) (on file with the *Gonzaga Law Review*).

104. *Id.* at 2-3.

Implementation of these recommendations will include Hanford's "atomic veterans" in the nationwide effort to reinvent government, allowing us to fulfill our contractual obligation to provide them due process and just compensation.

URANIUM MINERS: ISSUES FOR DECISION

The Radiation Exposure Compensation Act (RECA) Committee recommended changes to the statute and implementing regulations in its Final Report to the IAWG. The recommendations that raise the more difficult issues or are likely to be controversial are listed below, with salient pro and con points to aid the IAWG in reaching a final decision. The recommendations that are more straightforward and are likely to be widely accepted are listed at the end without additional comment; the explanation in the Executive Summary should prove sufficient.

1. Should the Administration propose legislation amending the RECA by adopting the threshold exposure criteria for lung cancer cases proposed by the Committee?

- the exposure criteria generated and proposed by the Committee reflect the latest credible evidence and scientific methodology;
- the proposed exposure criteria will compensate some miners denied compensation under the present statutory criteria;
- the proposed criteria will significantly raise the exposure criteria for some miners over the current RECA criteria, making it more difficult for these claimants to receive compensation; the affected miners would be those who get lung cancer at age sixty or older, and whose last exposure to radon progeny was more than twenty years ago;
- the Department of Justice will know by the end of the month the approximate percentage of miners who will be newly enfranchised and newly disenfranchised by the Committee's recommended criteria;

Subissue 1(a): Should the Administration propose threshold criteria based on radon progeny exposure (WLMS) or duration of employment?

- employment data is likely to be more accurate than historical mine radon measurements;
- concern about limited historical mine radon measurements led Advisory Committee to recommend use of employment-based criteria;
- radon progeny exposure criteria are more "accurate" -- they better fit the observed data;

- Committee recommends that if duration of employment criteria are proposed by Administration, exposure criteria also be adopted (i.e., a claimant would qualify under either set of criteria);

Subissue 1(b): What "level of assurance" should the Administration require for proposed criteria?

- "levels of assurance" is a crude relative of statistical confidence intervals, and accounts for uncertainty inherent in the statistical process; it denotes the range of values within which, to the defined degree of assurance, the true criterion lies;
- the higher the level of assurance demanded, the lower the resulting criteria imposed on the claimants, and, consequently, the more claimants eligible;
- the Committee generated three sets of criteria for IAWG consideration: without any added level of assurance, with an 80% level of assurance, and with a 90% level of assurance;
- if criteria unmodified for any level of assurance are used, 83% of lung cancer cases in the known study cohorts are eligible; if the 80% level of assurance criteria are used, 85% of lung cancer cases are eligible; if the 90% level of assurance criteria are used, 86% of lung cancer cases are eligible;
- Committee made no recommendation because the selection of the appropriate set of criteria is a policy choice.

2. Should the Administration propose legislation amending RECA by incorporating new threshold exposure criteria for nonmalignant respiratory disorders unrelated to radon progeny exposure?

- Committee concluded that the evidence linking radon exposure and NMRDs is ambiguous and insufficiently persuasive, at best; NMRDs most likely related to dust and agents in mining environment;
- it may be possible to generate more accurate and "fair" criteria based on employment duration;

- Committee recommended that the IAWG task some qualified body or agency to attempt to generate new criteria;
 - legislation proposing new criteria for NMRDs based on duration of employment may have collateral political effect; underground hard rock miners, other than uranium miners, also at risk for NMRDs.
3. Should the Attorney General modify the regulations to create a rebuttable presumption that all Navajo miners were nonsmokers?
- nonsmokers have to meet significantly lower threshold exposure criteria than smokers; rebuttable presumption would aid many Navajo now probably misclassified as smokers;
 - evidence indicating most Navajo smoked at rate less than minimum set in regulations for definition of smoker (one pack-year) comes from wide range of credible sources, including scientific studies performed prior to 1980;
 - use of ethnic-based classifications could pose legal (equal protection problem); could also create political problems among White miners who were light smokers.
4. Should the Attorney General modify in some fashion the regulations that require claimants to submit radiological proof of the presence of a compensable NMRD read by two NIOSH-certified "B"-readers?
- (a) Objections to present regulatory scheme
- (1) the interpretation of chest radiographs for pneumoconiosis is very subjective, and there is reasonable interreader variability, even among "B"-readers;
 - (2) the requirement that claimants have the chest radiograph read by "B"-readers is unnecessarily burdensome and oppressive;
 - (3) the Program's practice of selectively auditing certain "B"-readers, and having their interpretations reevaluated by NIOSH-selected "B"-readers, is unfair and unwarranted;

(b) Potential alternative procedures

(1) Do away with requirement of radiological proof of disease process entirely; require only proof of functional impairment;

- eliminates ambiguous, problematic means of proof, and minimizes burdens on claimants;
- Committee strongly opposes a scheme relying solely on functional impairment as proof of compensable disease
 - tests for functional impairment are not specific to the compensable NMRDs -- if functional impairment alone is required, will compensate many miners with noncompensable restrictive lung diseases and obstructive lung diseases (COPD, emphysema);
 - although radiographic interpretation is subjective and variable, can protect claimants from principal danger -- false negative interpretations -- by allowing claimants with functional impairment to submit high-resolution CT scans;

(2) Do away with requirement that chest radiographs be interpreted by "B"-readers only; accept interpretations of any radiologist or treating physician

- minimizes the burden on claimants
- if physician treating patient for compensable NMRD, should be sufficiently reliable diagnosis
- Committee supports continued exclusive use of "B"-readers to interpret radiographs
 - diagnosis by treating physician insufficient; standard treatment minimal, and difficult to devise effective check to eliminate insufficiently credible relationships
 - subjectivity and interreader variability significant where interpretations are by non-"B"-readers; these drawbacks and dangers of false negatives/positives

minimized where interpretation is by
"B"-readers;

- limited number of "B"-readers submitting interpretations allows for some check on quality and potential fraud; allowing interpretations by any physician or radiologist would make any auditing process minimally effective, if at all;
- burdens on claimants minimal; can send chest radiographs through mail, and many claimants represented by attorneys

X (3) Retain requirement of radiological proof of disease, but require HRCTs instead of chest radiographs:

- HRCTs much more selective and sensitive than chest radiographs; significantly decrease the rate of false negative/positive interpretations;
- Committee recommends retaining chest radiograph requirement in first instance:
 - HRCTs expensive (\$600) and appreciable (and potentially unnecessary) dose of radiation
 - can insure against risk of false negative by allowing claimants with functional impairment and negative chest radiograph to submit HRCTs; gives claimants benefit of false positives;

X (4) Accept diagnosis of compensable NMRD if made by federal physician (i.e., IHS radiologist)

- where diagnosis by federal physician, little risk of fraud;
- meets Program concern with fraudulent or unprofessional interpretations, but does not meet concern that difficulty of interpretation requires experts -- "B"-readers;
- will help only claimants with access to federal medical facilities (Navajo, veterans); will not solve problem for most miner-claimants;
- could impose severe strain on limited federal resources in affected communities -- i.e., one radiologist for all IHS facilities on Navajo reservation

- (5) Modify Program audit procedure to bar selective auditing of specific "B"-readers; instead, have all "B"-readers regularly audited to ensure readings are within the bounds of reasonable professional interpretation

- Committee recommendation
- selective auditing and rereading by Program consultants has resulted in perception in affected community that Program biased against compensation;
- selective audit procedure does not eliminate problematic or biased readers from submitting additional readings;
- modifying audit procedure in tandem with acceptance of HRCTs (if functional impairment and negative chest radiograph) would meet most of claimants' objections to "B"-reader requirement;
- deferential standard of review on audit would allow claimants to continue to choose "B"-readers whose interpretations fall in more "liberal" end of spectrum of acceptable, reasonable interpretations.

Non-controversial Recommendations

5. Should the Administration propose an amendment to the RECA to broaden coverage for silicosis and pneumoconiosis to all miners covered by the statute, not just miners who mined on Indian Reservations?
6. Should the Attorney General be requested to modify the regulations to define the term nonsmoker to include lung cancer claimants who stopped smoking 15 years or more before the date of diagnosis?
7. Should the Attorney General be requested to modify the regulations to accept high-resolution CT scans as proof of the presence of a compensable NMRD?
8. Should the Attorney General be requested to modify the regulations to accept as proof of a compensable disease the results of a lung biopsy?
9. Should the Attorney General be requested to modify the regulations to adopt ethnic-specific pulmonary function.

standards to determine functional impairment in NMRD claimants?

10. Should the Attorney General be requested to modify the regulations to define functional impairment for NMRD claimants consistent with the American Thoracic Society recommended definition of impairment?

RADIATION EXPOSURE COMPENSATION ACT COMMITTEE

FINAL REPORT EXECUTIVE SUMMARY

SUBMITTED TO THE
HUMAN RADIATION INTERAGENCY WORKING GROUP
JUNE 6, 1996

RADIATION EXPOSURE COMPENSATION ACT COMMITTEE

Intens

- RECA

Summary

- which by regulation.

Katherine S. Gruenheck, Esq.
Appellate Section
Civil Division
U.S. Department of Justice

Richard W. Hornung, Ph.D.
Director, Energy-Related Research
National Institute for Occupational
Safety & Health

^ Bruce E. Johnson, M.D. *lung cancer*
Head, Lung Biology Section
Division of Cancer Treatment
National Cancer Institute

^ Jay H. Lubin, Ph.D.
Epidemiological Methods Section
Biostatistics Branch
National Cancer Institute

Dianne S. Spellberg, Esq.
Constitutional & Specialized
Litigation Section
Civil Division
U.S. Department of Justice

Gregory Wagner, M.D. *non-malignant - in DL*
Director, Respiratory Disease Studies
National Institute for Occupational
Safety & Health

* Paul Yanowitch, Esq.
Environmental Torts Section
Civil Division
U.S. Department of Justice

EXECUTIVE SUMMARY

UMRD
Non
mal
1948
Diseases

On October 15, 1990, Congress passed the Radiation Exposure Compensation Act of 1990 (RECA or Act), which provided for compassionate payments to individuals who suffered from specified diseases presumably as a result of exposure to radiation in connection with the federal government's nuclear weapons testing program. Among those eligible for compensation under the Act are individuals who were employed in underground uranium mines in Arizona, Colorado, New Mexico, Utah or Wyoming during the 1947 to 1971 time period, who were exposed to specified minimum levels of radon, and who contracted specified lung disorders. The Department of Justice administers the RECA through the Radiation Exposure Compensation Program (Program).

The provisions of the RECA defining compensation for uranium miners have been characterized by critics as unfair and inconsistent with current scientific information. The regulations of the Department of Justice implementing the statute have also been criticized as being unnecessarily stringent and unreasonably burdensome. These criticisms were noted, and in some cases affirmed, by the President's Advisory Committee on Human Radiation Experiments, charged by the President to investigate the history of human radiation experimentation conducted by the federal government during the Cold War period. In its Final Report, issued on October 3, 1995, the Advisory Committee recommended, among other things, that the Administration review the provisions of RECA governing compensation for uranium miners and the implementing regulations

to ensure that they are fair, consistent with current scientific evidence, and compatible with the objectives of the Act.

In response to this recommendation, the Human Radiation Interagency Working Group established a committee of government scientists and attorneys to study the RECA provisions relating to underground uranium miners and the Department's implementing regulations. The Interagency Working Group charged the committee to respond within six months with a list of recommended statutory amendments and modifications to the regulations. The accompanying Report is intended to fulfill this obligation.

Listed below is a summary of the Committee's recommendations for changes to the statute and implementing regulations.

I. Proposed Amendments to the Statute

RECOMMENDATION 1: Amend the Act to incorporate a new set of compensation criteria for lung cancer based on minimum levels of radon exposure

The legislative history of the RECA convinces us that Congress set the exposure criteria at a level it thought would compensate those miners whose lung cancer more likely than not was caused by their exposure to radon progeny in the mines. The latest epidemiological data suggest that the current exposure criteria do not accurately distinguish among lung cancer cases on a "more likely than not" basis, and, therefore, do not effectively implement congressional intent. The present statutory criteria, we conclude, exclude some deserving miners and inappropriately compensate others.

In place of the present criteria, we recommend alternative exposure-based criteria that more accurately effect congressional intent. To generate these criteria we modified a relative risk model developed by the National Research Council's Committee on the Biological Effects of Ionizing Radiations (BEIR IV), and applied it to updated cohorts of Colorado Plateau and New Mexico underground uranium miners. The model conditions compensation on the variables that the latest data indicate most significantly affect the risk of lung cancer in underground uranium miners: cumulative exposure to radon progeny, attained age (the age at which the claimant developed cancer), and time since last exposure.

RECOMMENDATION 2: Amend the Act to incorporate an alternative set of criteria conditioning compensation on minimum duration of employment

The present RECA criteria and the alternatives discussed in Recommendation 1, above, are based in part on a measure of the claimant's cumulative exposure to radon, which is calculated from historical measurements of radon levels in the mines. These historical measurements are widely believed to be inaccurate and imprecise measures of miners' true exposures; for many mines, measurements either do not exist at all or do not exist for all work areas. Using the modified BEIR-IV risk model, we generated compensation criteria for lung cancer based on duration of employment underground in uranium mines, instead of cumulative exposure.

The exposure-based criteria we propose better "fit" the observed data, and will, therefore, result in a more valid

characterization of a miner's risk than the proposed employment duration-based criteria. Nonetheless, we recommend a claimant should be allowed to qualify under either the exposure or duration standard.

RECOMMENDATION 3: Amend the Act to condition compensation for nonmalignant respiratory disease on different criteria

The present statutory criteria require that a claimant prove exposure to minimum levels of radon as a condition for compensation for one of the specified nonmalignant respiratory diseases (NMRD) -- pulmonary fibrosis, cor pulmonale related to fibrosis, silicosis and pneumoconiosis. Although it is physiologically plausible that radon causes pulmonary fibrosis, or contributes to the development of silicosis, the two principal compensable NMRDs, the prevailing hypothesis in the scientific community is that the more likely cause of these diseases is exposure to various agents in the mining environment, most notably silica and other dusts. The radon levels in a mine are not believed to be a good proxy for dust levels, so there is no scientifically justifiable reason to tie NMRDs to radon exposure levels.

Unlike the case with lung cancer, above, we do not recommend specific alternative criteria in this case. It is unclear whether and to what extent reliable data are available, and whether appropriate standards can be derived from available data. The Committee did not have the time to identify and analyze the extant data. We recommend that such a project be undertaken.

(Dr. Wagner - a couple of months.)

RECOMMENDATION 4: Amend the Act to extent compensation for silicosis or pneumoconiosis to all miners covered by the Act

The RECA limits compensation for two NMRDs -- silicosis and pneumoconiosis -- to miners who were employed in mines on an Indian reservation. The principal risk factor for silicosis (or pneumoconiosis) is the amount of silica released in the mining environment. The mines both off and on the Navajo Reservation were in silica-bearing rock, and there is no reason to believe the risk of silicosis was any greater in mines on than off the Reservation. We recommend that this statutory limitation be eliminated.

II. Recommended Modifications to the Department of Justice Regulations

RECOMMENDATION 5: Modify the regulations to presume all Native Americans are nonsmokers, absent evidence to the contrary

The existing compensation criteria for both lung cancer and NMRDs set different minimum exposure levels depending on a claimant's smoking status; smokers must meet a higher exposure threshold, presumably to offset the risks from smoking. The regulations define a smoker as one who has smoked one pack-year of cigarettes or more. Smoking status is generally derived from references in historical health records. Most smoking information in the records is self-reported. The overwhelming number of Native American underground uranium miners were Navajo. Navajo generally smoked only for ceremonial purposes or not at all; those who smoked did so at substantially lower rates than their White counterparts. Nonetheless, many Navajo reported themselves as smokers, though their consumption was less than one pack-year. We recommend, therefore, that all Native American's be considered nonsmokers, absent evidence in any individual's record of a smoking rate greater than one pack-year.

pack a day per year.

RECOMMENDATION 6: Modify the definition of nonsmoker in the regulations to include certain ex-smokers

The regulations presume that once a smoker, always a smoker. The latest evidence suggests that the risk of lung cancer in an ex-smoker declines over time, approaching, though possibly never returning, to the background risk of a nonsmoker. The rate of decline of risk depends, among other factors, on the number of cigarettes smoked per day, the number of years the individual smoked, their age at time of cessation, and the years since cessation. We recommend that a claimant be classified as a nonsmoker if he can prove he stopped smoking at least 15 years before diagnosis of lung cancer.

6.11.73?

RECOMMENDATION 7: Modify the regulations to allow proof of NMRD by HRCT scans

The regulations require that a claimant prove both physical changes indicating the presence of a compensable NMRD and functional pulmonary impairment. Proof of the presence of disease is made by submitting chest radiographs (x-rays) interpreted by two "B"-readers, physicians specially certified by National Institute for Occupational Safety and Health (NIOSH) as proficient in the classification of radiographic evidence of pneumoconioses (occupational dust-induced lung diseases). It is

well established that chest radiographs, even when interpreted by "B"-readers, have significant false negative and false positive rates. Thus, a claimant with evidence of functional impairment may be denied compensation because a chest radiograph does not show evidence of disease; conversely, a chest radiograph may falsely be read to show evidence of a compensable disease though that disease is not in fact present. Because of the false negative rate associated with the detection of pneumoconioses by chest radiograph, some critics argue that the Program should dispense with the requirement that the claimant submit radiographic evidence of disease process.

We recommend that the Program continue to require radiographic proof of disease. We further recommend that the Program accept high-resolution computed tomography (HRCT) scans as proof of change to lung structure where the claimant has proven physiological pulmonary impairment yet chest radiographs are negative. HRCT is a more sensitive and specific diagnostic technology: in an appreciable number of cases, it will pick up disease that does not appear on chest radiographs, and allows for more accurate diagnosis.

RECOMMENDATION 8: Modify the regulations to allow proof of disease process by biopsy from all miners

The regulations allow surviving beneficiaries to prove a deceased miner had a compensable NMRD through biopsy results, but do not allow living miners to submit this form of proof. This was done to avoid creating an incentive among living miners for invasive and dangerous surgery. Biopsy results, however, are the "gold" standard for diagnosis. We recommend that where a biopsy is performed for a medically-justified reason independent of the desire for compensation, it be accepted as proof of lung abnormality. We also recommend the Program reserve the right to demand appropriate medical evidence demonstrating the justification for the procedure. — B. Rodas Wagner —

RECOMMENDATION 9: Modify the regulations to establish a random audit procedure for "B"-reader reports

The diagnosis of fibrosis or pneumoconiosis by chest radiograph is an inexact science. It is well established that there is significant variability in radiographic interpretation among readers, including "B"-readers, particularly where the disease is in a mild state. The Program has the interpretive reports of some "B"-readers reviewed by experts selected by NIOSH where there may be a question about the accuracy of the interpretation. Some in the affected community perceive the

Program as selectively reviewing the reports of the most "liberal" "B"-readers, and thus evidencing a bias against compensation. Some critics also recommend dispensing with the "B"-reader requirement as unnecessary.

We recommend that the Program retain the requirement that chest radiographs be interpreted by certified "B"-readers. We further recommend that the Program adopt an audit procedure that will provide for the review of all "B"-readers, and thus protect against the possibility of improper application of the professional diagnostic standards, yet eliminate the possibility of selective enforcement.

RECOMMENDATION 10: Modify the regulations to adopt ethnic-specific pulmonary function standards for proof of impairment

To prove pulmonary impairment, a claimant must demonstrate reduced lung function as measured by pulmonary function tests or arterial blood gas studies. The regulations define impairment on pulmonary function tests as 25% or more reduction in lung function measured against standard values derived from "normal" population, normed by age, gender and height. The regulations use one set of standard values for pulmonary function for all claimants. Pulmonary function can vary by ethnicity and race, however. Standards for Southwest Native Americans are significantly different than those derived from Whites. We recommend that separate pulmonary function criteria derived for Southwest Native Americans be adopted.

RECOMMENDATION 11: Modify the pulmonary function standards in the regulations to define impairment consistent with the recommendations of the ATS

25% → 20%

As noted in Recommendation 10, above, the regulations define impairment as 25% or more reduction in lung function as measured by pulmonary function tests. The American Thoracic Society (ATS) and American Medical Association (AMA) recommend guidelines that define impairment as more than a 20% reduction, measured against standard reference values. We recommend that the regulations be modified to define impairment consistent with the guidelines recommended by the ATS and AMA.

Anything else not considered?

Special process - all come into headquarters
for review -

Ed Scott
Kathy Callahan



Department of Veterans Affairs

EXECUTIVE SUMMARY FINAL REPORT RESPONSE TO RECOMMENDATION 6 OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

**Presented to the Interagency Working Group on
Human Radiation Experiments**

Background: The Advisory Committee on Human Radiation Experiments (ACHRE) was established by President Clinton to review records related to human radiation research and provide expert advice to the Cabinet-level Interagency Working Group on Human Radiation concerning scientific and ethical issues related to biomedical experiments involving ionizing radiation. The ACHRE issued its report on October 3, 1995, in which it made several recommendations for possible remedies to individuals exposed to ionizing radiation as the result of the government's activities. Of particular importance to VA is recommendation 6 which states that the Interagency Working Group should 1) consider a review and update of the radioepidemiological tables VA uses in the adjudication of atomic veterans' disability and death claims, and 2) review whether existing laws governing compensation for atomic veterans are now administered in ways that best balance the allocation of resources between compensation to eligible atomic veterans and the administrative costs of determining their eligibility.

VA Working Group: VA's Secretary Jesse Brown established the VA Human Radiation Interagency Working Group (VAWG) to respond to recommendation 6. Secretary of Defense William Perry and Secretary of Health and Human Services Donna Shalala appointed representatives to assist in the review of recommendation 6.

VA's Under Secretary for Benefits, R. J. Vogel, chairs the VAWG and is assisted by Commander Melvin Ely, MSC, USN from the Defense Special Weapons Agency (formerly Defense Nuclear Agency) and Dr. Gilbert Beebe from the National Institutes of Health's National Cancer Institute. These individuals along with other departmental medical,

scientific and program experts and advisors collaborated to focus on the concerns of radiation-exposed veterans and their families. The VAWG met with radiation-exposed veterans and their survivors as well as advocates of the atomic veteran community.

Conclusion: The following report presents VA's response to recommendation 6. It also details our efforts to address other concerns that, while related, go beyond the immediate parameters of the recommendation.

Two exhibits are attached to this report. Exhibit A sets forth the presumptive and non-presumptive lists of radiogenic diseases for which VA provides benefits and services. Exhibit B is a slide presentation capsulizing this Executive Summary.

RECOMMENDATION 6 AND RELATED ISSUES

I. Recommendation 6, Part I:

"The Advisory Committee recommends to the Human Radiation Interagency Working Group that it, 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."

Response: *VA agrees that the radioepidemiological tables used in the adjudicative review of VA disability and death claims should be updated and, if appropriate, expanded.*

Discussion: The current tables were prepared by the National Institutes of Health in 1985, in compliance with Public Law 97-414, The Orphan Drug Act. This public law directed the Secretary of Health and Human Services to devise and publish "tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific [radiation] doses prior to the onset of such disease developed cancer as a result of those doses". The Act specified the tables should show probabilities for each disease associated with doses ranging from 1 millirad to 1,000 rads in terms of such variables as sex, age at time of exposure, time from exposure to onset of disease, and other variables considered relevant, with probabilities of causation displayed as single percentage figures. At the time the tables were published, the Secretary was also to publish evaluations of the tables' credibility, validity and certainty, and a compilation of formulas that yielded them. Public Law 97-414 also specified that the tables were to be updated by Health and Human Services "every four years", or whenever [the Secretary] deems it necessary to insure that they continue to represent the best available scientific data and expertise."

VA is the primary user of HHS's radioepidemiological tables and consults them to adjudicate certain radiation claims. We believe that reviewing and updating the radioepidemiological tables and presenting

the data in the screening dose format are important to ensure that the most current scientific information is incorporated into the adjudication process. Since Public Law 97-414 directs that the tables reflect current scientific and medical knowledge, further Congressional action is unnecessary. We urge HHS's immediate commitment to updating these tables. VA shares in this commitment and offers its expertise and services to collaborate in getting these tables updated.

II. Recommendation 6, Part II:

"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: *VA believes the administrative expense of correctly deciding these claims on the basis of their individual merit, while significant relative to the number of claims allowed, is a necessary cost of credible program administration.*

- NARS looked
at dose
reconstruction
- GAO Report

Discussion: ACHRE's recommendation acknowledges the substantial administrative overhead costs incurred in adjudicating the compensation claims of atomic veterans relative to the benefits paid, and commends to the IAWG an examination of the laws' implementation by VA and DOD.

However, as ACHRE itself acknowledged, the recorded doses for atomic veterans are low. Given current understanding of dose responses in humans, it is not unexpected that substantial numbers of atomic veterans' claims are not approved. Even in a claims system that presumes certain cancers to be service-related if suffered by atomic veterans, and which provides them with the benefit of the doubt in various ways, the low rate of allowance of claims is altogether consistent with scientific knowledge regarding the merits of these claims.

It is, of course, recognized that atomic veterans take issue with both the recorded and reconstructed doses provided to VA by DOD and to the generally accepted assessments of risk VA applies in deciding claims. However, the Nuclear Test Personnel Review dose assessment program has been subjected to rigorous peer review, and VA employs the

most current, credible dose-response information available in deciding these claims.

Both VA and DOD have devoted considerable resources to ascertaining the circumstances of veterans' radiation exposures and to the careful and systematic adjudication of their claims in order to identify those having merit. VA believes it is doing all ^{that} the available records and the science permit to try to identify meritorious claims, and is succeeding. In our view, the Nation owes no less to these claimants. If veterans' compensation programs are to retain any credibility, VA must be able to both identify exposed servicemembers and discern which of their claims are meritorious. The relatively low rate of claim allowance and the resulting dissatisfaction of atomic veterans have less to do with problems of program administration than with the claim's lack of merit under currently understood scientific principles. ✓

Should new epidemiological information come to light which identifies currently unanticipated adverse health effects of these veterans' exposures, the Government's compensation policies should, of course, be reexamined. However, for now the administration of veterans' compensation laws is appropriate. mechanism for ongoing review?

Additionally, implicit in this recommendation is information that the costs of administration are so great that it may be better policy for VA to (1) stop adjudicating the claims of veterans who participated in nuclear weapons tests or the occupation of Hiroshima or Nagasaki and have radiogenic diseases and the claims of the survivors of those veterans who die from such diseases, and (2) simply pay all such claims. VA estimates that the net cost of this change, which would be the same as adding all radiogenic cancers to the presumptive list, is \$3.9 billion for the first five years.

III. Other Issues Considered:

During the review of recommendation 6, the VAWG also considered several other issues ~~that, although outside the immediate parameters of the recommendation,~~ are related and have been the subject of concern and criticism from the atomic-veteran community. —

- This section should focus on AORE's list of concerns*
1. ***Does the list of presumptive radiation-induced (radiogenic) diseases (38 U.S.C. § 1112; 38 C.F.R. § 3.309(d)) adequately reflect the health consequences of veterans exposed to low-level ionizing radiation?***

Response: Public Law 100-321 dated May 2, 1988, created the original list of presumptive radiogenic diseases. This list was later expanded by enactment of Public Law 102-578 on October 1, 1992. The presumptive statute was enacted in response to the scientific and medical uncertainties atomic veterans and their families faced in establishing that post-service diseases and deaths were connected to participation at the atmospheric nuclear tests or the post-war occupations of Hiroshima and Nagasaki, Japan. The legislative history of Public Law 100-321 shows that it was a compromise between different opinions concerning the health consequences likely to result from low-level ionizing radiation exposure. Partly as a result, there are no clearly articulated rationales for the selection of the covered diseases other than the general Congressional intent to establish presumptions for diseases that are relatively strongly and especially associated with radiation exposure.

and not with other causes

Source?

At the present time, there is no additional scientific evidence available that supports blanket presumptions of service connection for other diseases suffered by atomic veterans. Medical and scientific experts in fields associated with ionizing radiation continue to disagree on the health effects of exposure. Accordingly, VA continues to believe that it is preferable to adjudicate claims for other diseases on a case-by-case basis, taking into account the unique facts of each and the latest credible scientific evidence.

For this reason, VA does not recommend expanding the list of presumptive diseases, either through legislation or rulemaking.

Additional Considerations: The House of Representatives introduced legislation, H.R. 3673, which, among other things, would add bronchiolo-alveolar carcinoma (a form of lung cancer) to the list of conditions that VA presumes to be the result of ionizing radiation exposure while in the military. On July 16, 1996, the House passed H.R. 3673 and forwarded it to the Senate.

The Veterans' Advisory Committee on Environmental Hazards (VACEH) [see item 5 for specific details about this committee] has reviewed prevailing scientific and medical data to identify additional diseases that may result from low-level ionizing radiation exposure. The VACEH has identified certain diseases likely to result from radiation exposure. However, it has not identified an association between such diseases and veterans exposed to radiation at nuclear weapons tests or Hiroshima or Nagasaki that would warrant including them in the list of presumptive diseases.

Additionally, we looked at the possibility of expanding the presumptive list of radiogenic diseases to include all the diseases on the non-presumptive list of radiogenic diseases. [See Exhibit A for these lists.] We estimated that this would cost \$3.9 billion dollars for the first five years to implement.

Lastly, we reviewed the list of diseases that qualifies Marshall Islanders for Federal compensation. Unlike atomic veterans, inhabitants of the Marshall Islands received higher doses of radiation and the health consequences resulting from these larger doses are more predictable.

The Marshall Islands Nuclear Claims Tribunal recognizes 27 medical conditions which are presumed to be caused by exposure to radiation from nuclear testing in persons who were physically present in the Marshall Islands during the period of testing. The first 13 conditions were taken from Public Law 100-321 and from the Radiation Exposure Compensation Act. The additional 14 conditions were based upon research findings of the Radiation Effects Research Foundation in Japan, the conclusions in BEIR V, and the recommendation of Dr. Robert Miller, Chief of Epidemiology at the National Cancer Institute.

In comparing the Marshall Islanders' list to our list, we find that the differences are primarily conclusions based on high-level radiation exposure versus low-level exposure. Further, many of the Marshall Islanders' medical conditions include illnesses that most frequently result from irradiation of very young persons. (We believe it is obvious) that the situations of the atomic veterans and the Marshall Islanders are not comparable.

2. *Should the categories of radiation-exposed veterans be expanded for the presumptive service connection rule?*

Response: Public Law 102-578 called for the VACEH to review scientific studies and other relevant information relating to the exposure of veterans to ionizing radiation prior to January 1, 1970, to identify any activity during which significant numbers of veterans received exposure and to make recommendations on the feasibility and appropriateness of any additional investigations with respect to any activity of such veterans.

The VACEH has conducted and continues to conduct reviews of data relating to activities in which veterans may be exposed to ionizing radiation. Its reviews are topical, thorough and cognizant of the broad range of possible exposure to which veterans may have been subjected.

The VACEH's research concerns two essential questions: First, are there activities other than service with the occupational forces of Hiroshima and Nagasaki, Japan, or participation in atmospheric weapons testing where veterans had the opportunity for exposure to ionizing radiation in the course of their military service; and second, if so, would it be feasible or appropriate to study these veteran groups to determine whether adverse health effects were experienced as a consequence of participation in that activity.

The VACEH has concluded that:

1. There are activities other than atmospheric atomic weapons tests and occupation forces activities that ~~resulted in the exposure of~~^{ed} veterans to ionizing radiation during their military service prior to 1970. However, in the vast majority of activities for which radiation records exist, the total doses received were small, less than one rem on the average. ~~For the entire group of veterans, the increased risk of developing a radiogenic disease is small.~~

2. Pre-1970 records of radiation exposure of the majority of participants in these activities are adequate for calculating doses received. There are potentially exposed individuals for whom the records are either inadequate or inaccessible. Some of these records could be improved. There is no reason to believe that any sizable occupational group has been overlooked, or that there were opportunities for exposure that differ substantially from those groups where records exist.

3. None of the military occupations ~~which were~~^{are} reviewed is likely to provide evidence of adverse health effects associated with radiation exposure due to small numbers of individuals involved, small average dose, or both. The study of nuclear submariners deserves special attention. It was well conducted, but had relatively short follow-up. It may be useful to extend the follow-up, to achieve more meaningful results.

4. ~~There are~~ other studies which may provide information on adverse health effects resulting from exposure not dissimilar to some military exposures. One group study is that of naval nuclear shipyard workers. This group combines reasonably large size, high quality of exposure records, and ready availability of data. This study should be continued, especially if it focuses on exposure above one rem. Another important group of studies is of the Russian workers exposed in the 1940's and 1950's. These results are highly relevant to the risk information at low doses such as those occurring in military exposures. These studies should be pursued.

What are
the studies
trying to
determine?
8
is relevant to
compensation?

5. Information pertinent to other military exposures is not always available in the form that the scientific community and others can use. Information such as dose records of military personnel and other pertinent records should be made more readily available. The results of research which involves military groups or other similarly exposed groups should appear in peer-reviewed literature in a timely fashion.

VA strongly endorses the VACEH's conclusions and recommendations regarding the research efforts concerning nuclear submariners and naval nuclear shipyard workers. We encourage the DOD and DOE to support continuation of these studies. While the studies of the Russian workers may be of some interest, we have concerns about the reliability and availability of these data. Consequently, we have no plans to pursue studies of these workers. We certainly support the VACEH's conclusions regarding the importance of more readily available information in usable formats and the prompt publication of study results in appropriate scientific journals. VA, DOD and DOE officials continue to work together to achieve these objectives.

Additional Considerations: While the VACEH report did not make any recommendations regarding radium treatments provided to submariners and aviators that have been described in several scientific papers, we think this matter is worthy of some additional consideration. Substantial interest was voiced when we brought the issue to the VACEH. We have sought their advice as to whether these individuals might constitute a radiation-risk group. The VACEH is also considering whether a scientific investigation of these individuals may be feasible. It is important to keep in mind that the exposures experienced by these individuals are different from that of the nuclear submariner mentioned above.

The definition of "on-site participation in a test involving atmospheric detonation of a nuclear device" was expanded to include atmospheric testing by nations other than the United States.

3. *In lieu of the presumptive service connection rule, are other mechanisms available to atomic veterans and their survivors that would provide disability and death benefits?*

Response: When a claim cannot be approved under the presumptive service-connected rule, it is evaluated under the standards established by Public Law 98-542, dated October 24, 1984. VA

Conflicts of interest page
- who takes responsibility?

3?

regulation 38 CFR 3.311 implements this public law and describes the specific criteria for deciding these claims.

Claims considered under section 3.311 require a causal nexus between the claimed disease and the level of exposure to ionizing radiation. VA must obtain and assess radiation dose estimates to determine whether the claimed condition is the result of an in-service exposure. The Defense Special Weapons Agency (formerly Defense Nuclear Agency) is VA's source for providing dose assessments for participants of Hiroshima, Nagasaki and atmospheric testing. However, for other types of radiation exposure, dose assessments are determined by official military records or by another credible expert who is certified to have requisite scientific expertise.

The issue of dose assessment is one that receives the most criticism from the atomic-veterans who believe that this is a mechanism designed to deny claims. VA defers to the DOD for in-depth discussion of its dose assessment program, but we understand that DOD's process of obtaining and reporting dose assessments has been subjected to rigorous peer review. Furthermore, even ACHRE acknowledges that the recorded doses of atomic veterans are low. Given current understanding of dose responses in humans, these exposures would be expected to result in very few cancers or other diseases such as cataracts. ~~Thus the rate of claim approvals has more to do with the merits of the individual case than any shortcomings of the process.~~

Additional Considerations: VA has proposed a change to section 3.311 to add prostate cancer to the list of radiogenic diseases as well as to provide that VA will consider claims based on other diseases if supported by adequate scientific evidence that the claimed disease is radiation-induced.

4. *Should VA eliminate the dose assessment requirement under 38 CFR 3.311, or, at the very least, eliminate the dose assessment requirement for the veterans of Hiroshima, Nagasaki and atmospheric test participants?*

Response: The dose assessment is an essential tool to both ascertaining the circumstances of veterans' exposure and to employing that information in a manner designed to afford claimants the benefit of the doubt. Essentially, without this mechanism, all claimed conditions would fall under the presumptive rule and would be contrary to well-documented scientific data concerning health consequences resulting

from low-level exposure. The adoption of this suggestion would result in multi-billion dollar costs.

Additional Considerations: VA has in the past and will continue to work in unison with the DOD, the Congress and the Administration, as well as the scientific and medical communities to refine the process of analyzing the nexus between the exposure level and health consequence.

5. *There is a mechanism in place that would allow VA to expand the non-presumptive list of radiogenic diseases.*

Response: In addition to the provisions of Public Law 98-542 previously mentioned, VA was required to establish the Veterans' Advisory Committee on Environmental Hazards (VACEH.) This advisory committee consists of 8 members, 5 of whom are experts in biomedical and environmental science in fields, such as epidemiology and other scientific disciplines, pertinent to determining and assessing the health effects of exposure to ionizing radiation in exposed populations. The remaining three members represent the general public, including at least one disabled veteran having a demonstrated interest in, and experience relating to, veterans' concerns regarding exposure to ionizing radiation.

The VACEH held its first meeting in April 1985, and has continued to meet on the average of two times a year. We anticipate the next meeting of the VACEH will be held this fall.

The VACEH's role is to review pertinent scientific and medical evidence relating to the health consequences of individuals exposed to low-level ionizing radiation. VA's Office of Public Health and Environmental Hazards supports the VACEH by providing medical and scientific literature for the committee's consideration. The Office Public Health and Environmental Hazards also reviews the VACEH's recommendations to clarify medical and scientific terminology, if needed.

Further, the VACEH provides advice to the Secretary concerning diseases it feels are associated with ionizing radiation exposure. When considering new or modified regulations to compensate veterans for disabilities resulting from in-service exposures, the Secretary consults the VACEH and considers its recommendations.

Additional Considerations: The VACEH has played a vital role as the Secretary's advisor on the scientific and medical matters relating to the health consequences of atomic veterans. The list of radiogenic diseases in 38 C.F.R. § 3.311 is an outcome of the VACEH's work. Most

recently, the VACEH recommended the addition of prostate cancer to the list of radiogenic conditions. As mentioned earlier, the Secretary accepted this recommendation, and we have proposed a rule change to add this disease to the list.

6. *The health-care needs of atomic veterans are being met.*

Response: Since 1981, VA has provided free¹, comprehensive medical examinations, including base-line laboratory tests and other diagnostic tests deemed necessary to determine the veterans' current health status, to veterans exposed to ionizing radiation as a result of participation in atmospheric tests or the occupation of Hiroshima and Nagasaki. Also, these veterans are eligible for health-care for conditions possibly related to exposure to ionizing radiation regardless of any determination that the veteran's illness is related to service.

Additional Considerations: VA has proposed legislation to expand the group of veterans eligible for this health-care to include individuals who received nasopharyngeal radium treatments in service. OMB is presently reviewing this proposed legislation.

— free?
surgery?
only?

Additionally, the Under Secretary for Health's Special Committee on Post-traumatic Stress Disorder is investigating the psychological consequences of exposure to ionizing radiation.

Exhibits:

- A: Diseases: 38 CFR 3.309(d) & 3.311
- B: Slide Presentation

1. Veterans are not billed for these services. However, in some instances, VA may bill third party payers.



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

Diane - Very fond!
let's discuss
- Shiz

Facsimile Cover Sheet

To: Elizabeth Dwyer, DPC
Company: _____
Phone: _____
Fax: 456-~~7028~~ 7431
From: Harold Gracy Co
Company: VA
Phone: 273-4808
Fax: _____

Sandy

Date: 7/17
Pages including this
cover page: 4

Comments:



Putting Veterans First



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

JUL 17 1996

MEMORANDUM FOR: Elizabeth Drye
Chief of Staff,
Domestic Policy Council

FROM: Harold Gracey
Chief of Staff

SUBJECT: ACHRE Recommendation #6

This is in further reference to the white paper I recently sent you regarding ACHRE Recommendation #6, particularly VA's objections to responding to it in a way that commits the Administration to revisiting the scope of current statutory presumptions benefiting atomic veterans and their survivors who file compensation claims with VA.

VA staff who attended the July 9 IAWG meeting and have reviewed Diane Regas' minutes of it advise me there was no consensus among member agencies that the working group should incorporate, in response to the second portion of recommendation 6, a plan for analyzing the adequacy of the statutes regarding VA compensation for atomic veterans. Nevertheless, the minutes indicate VA is expected to present such a plan at the next (July 23) IAWG meeting.

The ACHRE recommendation requires no more than that the IAWG review the *administration* of current veterans-benefit law, not that the benefit statutes themselves be rethought. VA is on record with the Congress, in Administration-cleared testimony, as opposing the creation of additional presumptions of service connection for radiation-exposed veterans. Thus, the response Ms. Regas advocates not only exceeds the scope of the recommendation but conflicts with previously announced Administration policy.



Putting Veterans First

2.

It goes without saying that radiation-exposed veterans -- and literally all veterans were exposed to ionizing radiation in some form during service -- would wish to be compensated for any disease which bears any conceivable relationship to that exposure. The Administration has gone on record as preferring that claims for benefits other than those now covered by statutory presumptions should be decided on their own individual merits using the best available information. We believe the administration of current benefit laws, as reflected in the regulations attached to our white paper, is being carried out in a responsible way. To the extent claims are denied, it is due to their lack of merit -- not because of any inadequacy of the laws' administration.

The legislative history of Public Law 100-321, which first created presumptions of service connection for certain radiation-exposed veterans, shows it was a compromise between very different approaches advocated by the House and Senate. Partly as a result of that, there are no clearly articulated rationales for either the selection of the covered diseases or for why coverage was limited to only certain categories of exposed veterans. To reopen this debate unnecessarily, when there are probably no prospects for resolution that would be both politically and fiscally acceptable, seems to us very unwise.

We recommend that instead of responding to the ACHRE recommendation in a way that puts into play something not even called for, the IAWG reply with a description of the veterans-benefit laws and the manner in which they are being implemented, and respond to the criticism that the administrative costs are too high relative to benefits paid by indicating the Government owes no less to atomic veterans than to carefully investigate and adjudicate their claims on the basis of the best available evidence, regardless of cost. Updating the radioepidemiological tables (in response to the first portion of ACHRE's recommendation #6) will assist VA in keeping current with the science.

3.

Please call if further discussion would prove helpful. For now, VA staff will assume it is not expected to provide the information covered in paragraphs 3. and 4. on page 2 of Ms. Regas' minutes ("The IAWG agreed as follows:") when the IAWG next meets.

Goal Pres — Politically difficult. —

① Memo is wrong

② Process — ~~At~~ other agencies — ~~ending~~
Asst Admin.

— need political person next meeting

Options on Table. —

③ DAS claimed a very positive process

Paul Yarnoch — DAS — worked w/HHS —

Agreed to work with you.



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

Elizabeth -
Re 'testimony'
VA supplied.
Kirsten

Facsimile Cover Sheet

To: Kirsten Hildebrand
Company: DPC
Phone: _____
Fax: 456-7028

From: Sandy Peyton
Company: Harold Gracey's office / VA
Phone: _____
Fax: 273-4808

Date: 7/22
Pages including this
cover page: 9

Comments:

following is additional material
we talked about this morning.
Sandy





THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

NOV 21 1994

The Honorable John D. Rockefeller IV
Chairman, Committee on
Veterans' Affairs
United States Senate
Washington, D.C. 20510-6375

Dear Mr. Chairman:

On October 25 you wrote to express concerns about VA policy regarding the compensation of radiation-exposed veterans, and I am pleased to respond.

First, you are quite right to criticize the white paper enclosed with the February 24, 1994, letter to Ms. Patricia Broudy. I agree that the paper is incomplete insofar as it failed to refer to the controversy that arose concerning the 1985 study by the National Academy of Sciences, and it may leave a misimpression about the study's influence on current VA policy.

That mortality study of certain atomic-test participants was released in May 1985. It had not been published or otherwise made available to VA when, on April 22, 1985, VA formally proposed its regulation (initially 38 C.F.R. § 3.311b, but now 3.311) which requires the consideration of each radiation claim on its individual merits. While the publication of the NAS study undoubtedly had some reinforcing effect on the previously settled VA position, when the study's flaws were identified, its credibility was appropriately discounted and it is not a basis for our current policy. To the extent the white paper sent to Ms. Patricia Broudy may have indicated otherwise, it was in error and I am sorry for any misimpression it has left. We are explaining this to her by separate letter.

I am very glad the data from the 1985 study are being re-analyzed by NAS in response to the critiques you cited. The enclosed fact sheet describes the follow-on study designed to overcome the shortcomings of the initial one. According to the Defense Nuclear Agency, besides employing defined participant and dose information, the new analysis will include approximately 10 additional years' worth of

(1)

2.

The Honorable John D. Rockefeller IV

mortality data concerning the covered atomic-test participants, and compare their cancer rates with those of non-participant servicemen. We understand results should be available in the fall of 1997, but that another NAS mortality study of participants in Operation CROSSROADS should be completed by the spring of 1996.

Should these studies or any other credible evidence establish an elevation in overall cancer rates of atmospheric atomic-test participants, I would certainly agree that the Government's policies regarding their VA benefits eligibility should be rethought.

You also asked whether I believe I would have authority to create, by regulation, radiation-related presumptions of service connection for diseases other than those currently specified in statute. The answer is yes. Pursuant to 38 U.S.C. § 501(a), which permits me to prescribe rules regarding "the nature and extent of proof and evidence" necessary to establish benefit eligibility, I have the authority to issue rules containing evidentiary presumptions. Like all regulations, however, any such rules must have a demonstrably rational basis.

The legislative history of Public Law 100-321, which established the statutory presumptions for radiation-exposed veterans, indicates Congress endeavored to identify those forms of cancer most likely to result from the exposures of concern. I have not recommended the expansion of these presumptions to encompass additional diseases, either through legislation or rulemaking, because I am of the view that it is preferable to adjudicate claims for other diseases on a case-by-case basis, taking into account the unique facts of each. I do not believe available scientific evidence (even leaving aside the questioned 1985 NAS study) supports blanket presumptions of service connection for other diseases suffered by atomic veterans.

The situation involving U.S. veterans exposed to radiation while participating in other nations' atomic-weapons

PHOTOCOPY
PRESERVATION

(2)

01/22/96 12:35 2002 110 1077

3.

The Honorable John D. Rockefeller IV

tests is readily distinguishable. I directed that rule-making be undertaken to afford these veterans the same presumptions available to veterans of U.S. tests because the two classes of veterans are similarly situated -- there is no rational basis for treating them differently.

I hope this clarifies our policies on these important issues.

Sincerely yours,

Jesse Brown

Enclosure

JB/jht

PHOTOCOPY
PRESERVATION

(3)

STATEMENT OF
R. JOHN VOGEL
UNDER SECRETARY FOR BENEFITS
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
SUBCOMMITTEE ON COMPENSATION, PENSION, INSURANCE, AND
MEMORIAL AFFAIRS
OF THE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES
OCTOBER 12, 1995

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to present the views of the Department of Veterans Affairs (VA) on seven bills. They are:

- H.R. 109, a bill to provide that the effective date for discontinuance of compensation and pension paid by the Secretary of Veterans Affairs shall be the date on which the recipient dies, rather than the last day of the preceding month, in the case of a veteran with a surviving spouse, and for other purposes;

★

- H.R. 368, a bill to add bronchiolo-alveolar carcinoma to the list of diseases presumed to be service-connected for certain radiation-exposed veterans;
- H.R. 1482, the "Veterans Programs Amendments of 1995";
- H.R. 1609, a bill to amend the Social Security Act and title 38, United States Code, to provide for sharing of medical information relating to determinations of disability between the Social Security Administration and VA;
- H.R. 2155, the "Veterans' Benefits Reform Act of 1995";
- H.R. 2156, the "Veterans' Insurance Reform Act of 1995"; and
- H.R. 2157, a bill to authorize the termination of Servicemen's Group Life Insurance when premiums are not paid.

1999	10.4
2000	<u>10.7</u>
Total	\$49.7

The estimated cost is based on the assumption that H.R. 109 is not meant to allow duplicate payments under section 5310 and new section 5112(d). These costs would be subject to the pay-as-you-go provisions of the Omnibus Budget Reconciliation Act of 1990 (OBRA).

H.R. 368

H.R. 368 would add bronchiolo-alveolar carcinoma, a type of lung cancer, to the list of diseases presumed to be service-connected for certain radiation-exposed veterans. For this purpose, a "radiation-exposed veteran" includes a veteran who during military service participated on-site in an atmospheric nuclear weapons test, served with the occupation forces of Hiroshima, or Nagasaki, Japan, or who is a former prisoner of war who had an opportunity for exposure to ionizing radiation comparable to that of the occupation forces of Hiroshima, or Nagasaki, Japan.

Several years ago we accepted the recommendation of the Veterans Advisory Committee on Environmental Hazards and included

lung cancer as a radiogenic disease for purposes of 38 C.F.R. § 3.311. Under section 3.311, we adjudicate each radiation-exposure compensation claim on its own merits. In each case, we obtain and analyze a radiation-dose estimate developed for official military records. A claimant may also submit an alternative dose estimate from an individual qualified in the field of health, physics, nuclear medicine, or radiology. Each case is subject to Central Office review by the Veterans Benefits Administration's Compensation and Pension Service.

We believe that the approach under section 3.311, a review of the facts unique to each case, is preferable to one creating a blanket presumption that would necessarily be overinclusive. While we recognize that bronchiolo-alveolar carcinoma may result from radiation exposure, most atomic veterans had low doses of ionizing radiation in service; and other carcinogenic agents can also cause this histologic subtype of lung cancer. In evaluating each lung-cancer claimant, VA currently considers factors such as estimated radiation-dose exposure and, if relevant, smoking history. This case-by-case adjudication remains the appropriate way of recognizing meritorious claims.

The estimated cost of providing medical care to the additional lung-cancer patients service-connected under the proposed presumption would be approximately \$1.9 million per year

over five years. Shown below is the estimated cost of providing medical care and compensation benefits over a five-year period. The additional compensation benefits costs detailed below would be subject to the pay-as-you-go requirement of the OBRA.

<u>Year</u>	<u>Medical Care</u>	<u>Compensation Benefits</u>	<u>Total Estimated Cost (millions)</u>
1996	1.9	1.8	3.7
1997	1.9	1.9	3.8
1998	1.9	2.1	4.0
1999	1.9	2.3	4.2
2000	<u>1.9</u>	<u>2.5</u>	<u>4.4</u>
Total	\$9.5	\$10.6	\$20.1

H.R. 1482

Section 2 of H.R. 1482 would amend section 5303A(b)(3)(F) of title 38 to extend, for the purposes of all benefits under title 38, certain exemptions from the minimum active duty requirements contained in section 5303A(b)(1). Currently, the exception to the minimum active-duty service requirement for individuals discharged or released from active duty for the convenience of the Government and for certain other reasons

*adds
pension
burial,
NSC's
medical
care*



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

- per CFE -
- nature of claim award
- learning on this issue?

Facsimile Cover Sheet

To: Diane Regas
Ann McGuire
Company: _____
Phone: _____
Fax: 456-7028

From: HAROLD GRACEY
Company: _____
Phone: _____
Fax: _____

Date: 7-11-96

Pages including this
cover page: 11

- ① Comments to Diane on draft memo
- ② Call Sam
- Tobacco
- POT reform talk pps.
- ③ ~~11~~ - Her many
fine bloom leaves
- ④ Schie files
- ⑤ 815

Comments:

Please pass this on to Elizabeth
Dryden: ACHRE. We have problems
about implementation of recommendation
as it relates to changing presumptions /
changing law. This explains what we
do now. Very thorny issue.
1 horns,
Harold



Putting Veterans First

ATOMIC VETERANS ISSUES -- ACHRE RECOMMENDATION #6

The second part of ACHRE recommendation #6 is as follows:

The Advisory Committee further recommends to the Human Radiation 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 compensation to eligible veterans and administrative costs, including the costs and scientific credibility of dose reconstruction.

Thus, the recommendation is for an assessment of whether current veterans-benefit laws are being administered in a responsible way, given that overhead costs of adjudicating claims -- including both verification of radiation exposure by the military services and determination of eligibility by VA based on the facts as ascertained -- have been large relative to benefit payouts.

Current Benefit Laws and Their Administration

VA Compensation Presumptions.

The "Radiation-Exposed Veterans Compensation Act of 1988" was enacted in response to the difficulties atomic veterans and their families were having establishing that postservice diseases and deaths were connected to their participation either at the atmospheric nuclear tests or the postwar occupations of Hiroshima and Nagasaki. Under the Act, veterans so exposed who later contracted any of 13 cancers were entitled to a rebuttable presumption that their disease was caused by their exposure. Later enacted legislation would add two more cancers.

VA's regulation implementing this act, 38 C.F.R. § 3.309(d) (copy attached), lists the diseases covered and broadly defines who is to be considered an "onsite" test participant. The latter includes not only presence on the

onsite "

test site during official operational periods, but also:

- o performance of official military duties in connection with ships, aircraft or other equipment in direct support of a test;
- o during the six month period following the official operational period of a test, presence at the test site or other test ~~staging~~ area for duties related to the test (including decontamination of equipment);
- o service as a member of the garrison or maintenance forces on Eniwetok during periods relevant to the Pacific tests; and
- o duties at Naval shipyards involving the decontamination of ships participating in Operation Crossroads.

Some 470 claims have been allowed to date under this authority. VA obtains verification of qualifying military service from DoD's "NTPR" program, and then verifies the existence of a qualifying disease through available clinical records. If necessary to determine current degree of disability, VA will provide for a physical examination.

Other Radiation-Related Compensation Claims.

If a veteran or survivor claims benefits on the basis of ionizing radiation exposure other than as an atomic test participant or Hiroshima/Nagasaki occupation veteran, or for a disease other than those presumed service connected under Public Law 100-321, the claim is adjudicated on its individual merits pursuant to fairly elaborate procedures set forth at 38 C.F.R. § 3.311 (copy attached). These rules specify the diseases VA will consider to be potentially radiation-induced (radiogenic), but provides that VA will entertain claims based on other diseases if competent evidence is submitted that they can be radiogenic.

The regulation is designed to facilitate the identification of claims with merit, i.e. those in which the evidence indicates it is at least as likely as not the disease contracted is related to in-service exposure to

ionizing radiation. It provides for a sophisticated claims review, to include obtaining expert testimony regarding the relevant scientific issues. However, very few claims (probably no more than 50) have been approved under this regulation.

POLICY DISCUSSION

The ACHRE recommendation is in response to criticism from the atomic-veteran community that the many millions of dollars the Government has spent to process and deny the vast majority of their 18,000 VA claims should instead have been spent to compensate them. ACHRE's recommendation acknowledges this high administrative overhead relative to benefits paid, and commends to the interagency working group an examination of the laws' implementation by VA & DoD.

There appears to be relatively little controversy over VA's implementation of the statutory presumptions of service connection, i.e. no suggestion that VA is denying claims for qualifying diseases brought by or on behalf of veterans covered by the terms of the act. Controversy concerning the act relates to its terms, i.e. criticism that it covers too few diseases and too few radiation-exposed veterans. *Significantly, ACHRE does not ask the working group to analyze the statutory presumptions for their adequacy, but rather only their administration.*

As ACHRE itself acknowledged (@ p. 482 of its report), the recorded doses for atomic veterans are low. Given current understanding of dose responses in humans, these exposures would be expected to result in very few additional cancers. Thus the low rate of allowance of claims not covered by the presumptions is unsurprising and, in fact, altogether consistent with scientific knowledge regarding the merits of these claims. Atomic veterans take issue with both the recorded and reconstructed doses provided to VA by DoD, and to the generally accepted assessments of risk VA applies in deciding claims. However, the NTPR dose assessment program has withstood rigorous peer review, and

← DoD

VA employs the most current, credible dose-response information available in deciding these claims. [Note: VA

advocates that the working group adopt the other part of ACHRE's Recommendation #6, i.e. that the HHS radioepidemiological tables be updated, since VA relies on this dose-response information in its claims adjudications.]

ACHRE is apparently suggesting one of two things: either that VA is failing to identify some claims having merit, or that it is imprudent to spend considerable resources to identify from among large numbers of claims those having merit. VA believes it is doing all the available records and science permit to try to identify meritorious claims, and succeeding. Furthermore, the Nation owes no less to these claimants than a thorough investigation of their claims to determine their merit; it is simply a necessary cost of doing business. If veterans' compensation programs are to retain any credibility, VA must be able to both identify exposed servicemembers and discern which of their claims are meritorious. The bottom line is that the relatively low rate of claim allowance has less to do with problems of program administration than with the claims' lack merit under currently understood scientific principles. Should the state of the science change -- for example, if ongoing epidemiological research, including the major mortality analysis of atomic-test participants being undertaken by the Medical Followup Agency of the National Academy of Sciences, identify currently unanticipated adverse health outcomes in this population -- then of course Government policies must be rethought. However, for now the administration of veterans-compensation laws seems altogether appropriate.

§ 3.309 Diseases subject to presumptive service connection.

* * * * *

(d) Diseases specific to radiation-exposed veterans. (1) The diseases listed in paragraph (d)(3) of this section shall be service-connected if they become manifest in a radiation-exposed veteran as defined in paragraph (d)(3) of this section, provided the rebuttable presumption provisions of § 3.307 of this part are also satisfied.

(2) The diseases referred to in paragraph (d)(1) of this section are the following:

- (i) Leukemia (other than chronic lymphocytic leukemia).
- (ii) Cancer of the thyroid.
- (iii) Cancer of the breast.
- (iv) Cancer of the pharynx.
- (v) Cancer of the esophagus.
- (vi) Cancer of the stomach.
- (vii) Cancer of the small intestine.
- (viii) Cancer of the pancreas.
- (ix) Multiple myeloma.
- (x) Lymphomas (except Hodgkin's disease).
- (xi) Cancer of the bile ducts.
- (xii) Cancer of the gall bladder.
- (xiii) Primary liver cancer (except if cirrhosis or hepatitis B is indicated).
- (xiv) Cancer of the salivary gland.
- (xv) Cancer of the urinary tract.

NOTE: For the purposes of this section, the term "urinary tract" means the kidneys, renal pelvis, ureters, urinary bladder, and urethra.

(3) For purposes of this section:

(i) The term radiation-exposed veteran means either a veteran who while serving on active duty, or an individual who while a member of a reserve component of the Armed Forces during a period of active duty for training or inactive duty training, participated in a radiation-risk activity.

(ii) The term radiation-risk activity means:

(A) Onsite participation in a test involving the atmospheric detonation of a nuclear device.

(B) The occupation of Hiroshima or Nagasaki, Japan, by United States forces during the period beginning on August 6, 1945, and ending on July 1, 1946.

(C) Internment as a prisoner of war in Japan (or service on active duty in Japan immediately following such internment) during World War II which resulted in an opportunity for exposure to ionizing radiation comparable to that of the United States occupation forces in Hiroshima or Nagasaki, Japan, during the period beginning on August 6, 1945, and ending on July 1, 1946.

(iii) The term atmospheric detonation includes underwater nuclear detonations.

(iv) The term onsite participation means:

(A) During the official operational period of an atmospheric nuclear test, presence at the test site, or performance of official military duties in connection with ships, aircraft or other equipment used in direct support of the nuclear test.

(B) During the six month period following the official operational period of an atmospheric nuclear test, presence at the test site or other test staging area to perform official military duties in connection with completion of projects related to the nuclear test including decontamination of equipment used during the nuclear test.

(C) Service as a member of the garrison or maintenance forces on Eniwetok during the periods June 21, 1951, through July 1, 1952, August 7, 1954, through August 7, 1957, or November 1, 1958, through April 30, 1959.

(D) Assignment to official military duties at Naval Shipyards involving the decontamination of ships that participated in Operation Crossroads.

(v) For tests conducted by the United States, the term operational period means:

(A) For Operation TRINITY the period July 16, 1945 through August 6, 1945.

(B) For Operation CROSSROADS the period July 1, 1945 through August 21, 1945.

(C) For Operation *SANDSTONE* the period April 15, 1948 through May 28, 1948.

(D) For Operation *RANGER* the period January 27, 1951 through February 8, 1951.

(E) For Operation *GREENHOUSE* the period April 8, 1951 through June 22, 1951.

(F) For Operation *BUSTER-JANGLE* the period October 22, 1951 through December 22, 1951.

(G) For Operation *TUMBLER-SNAPPER* the period April 1, 1952 through June 28, 1952.

(H) For Operation *IVY* the period November 1, 1952 through December 31, 1952.

(I) For Operation *UPSHOT-KNOT-HOLE* the period March 17, 1953 through June 28, 1953.

(J) For Operation *CASTLE* the period March 1, 1954 through May 31, 1954.

(K) For Operation *TEAPOT* the period February 18, 1955 through June 16, 1955.

(L) For Operation *WIGWAM* the period May 14, 1955 through May 15, 1955.

(M) For Operation *REDWING* the period May 5, 1955 through August 6, 1955.

(N) For Operation *PLUMBBOB* the period May 22, 1957 through October 22, 1957.

(O) For Operation *HARDTACK I* the period April 22, 1958 through October 31, 1958.

(P) For Operation *ARGUS* the period August 27, 1958 through September 18, 1958.

(Q) For Operation *HARDTACK II* the period September 19, 1958 through October 31, 1958.

(R) For Operation *DOMINIC I* the period April 25, 1962 through December 31, 1962.

(S) For Operation *DOMINIC UPFLOW-SHARE* the period July 8, 1962 through August 15, 1962.

(vi) The term "occupation of Hiroshima or Nagasaki, Japan, by United States forces" means official military duties within 10 miles of the city limits of either Hiroshima or Nagasaki, Japan, which were required to perform or support military occupation functions such as occupation of territory, control of the population, stabilization of the government, demilitarization of the Japanese military, rehabilitation of the infrastructure or deactivation

and conversion of war plants or materials.

(vii) Former prisoners of war who had an opportunity for exposure to ionizing radiation comparable to that of veterans who participated in the occupation of Hiroshima or Nagasaki, Japan, by United States forces shall include those who, at any time during the period August 8, 1945, through July 1, 1946:

(A) Were interned within 75 miles of the city limits of Hiroshima or within 100 miles of the city limits of Nagasaki, or

(B) Can affirmatively show they worked within the areas set forth in paragraph (d)(vii)(A) of this section although not interned within those areas, or

(C) Served immediately following internment in a capacity which satisfies the definition in paragraph (d)(vi) of this section, or

(D) Were repatriated through the port of Nagasaki.

(Authority: 28 U.S.C. 111A, 1112, 1151)

§ 2.211 Claims based on exposure to ionizing radiation.

(a) *Determinations of exposure and dose—(1) Dose assessment.* In all claims in which it is established that a

radiogenic disease first became manifest after service and was not manifest to a compensable degree within any applicable presumptive period as specified in § 2.307 or § 2.309, and it is contended the disease is a result of exposure to ionizing radiation in service, an assessment will be made as to the size and nature of the radiation dose or doses. When dose estimates provided pursuant to paragraph (a)(2) of this section are reported as a range of doses to which a veteran may have been exposed, exposure at the highest level of the dose range reported will be presumed.

(Authority: 38 U.S.C. 601)

(2) *Request for dose information.* Where necessary pursuant to paragraph (a)(1) of this section, dose information will be requested as follows:

(i) *Atmospheric nuclear weapons test participation claims.* In claims based upon participation in atmospheric nuclear testing, dose data will in all cases be requested from the appropriate office of the Department of Defense.

(ii) *Hiroshima and Nagasaki occupation claims.* In all claims based on participation in the American occupation of Hiroshima or Nagasaki, Japan, prior to July 1, 1946, dose data will be requested from the Department of Defense.

(iii) *Other exposure claims.* In all other claims involving radiation exposure, a request will be made for any available records concerning the veteran's exposure to radiation. These records normally include but may not be limited to the veteran's Record of Occupational Exposure to Ionizing Radiation (DD Form 1141), if maintained, service medical records, and other records which may contain information pertaining to the veteran's radiation dose in service. All such records will be forwarded to the Under Secretary for Health, who will be responsible for preparation of a dose estimate, to the extent feasible, based on available methodologies.

(3) *Referral to independent expert.* When necessary to reconcile a material difference between an estimate of dose, from a credible source, submitted by or on behalf of a claimant, and dose data derived from official military records, the estimates and supporting docu-

mentation shall be referred to an independent expert, selected by the Director of the National Institutes of Health, who shall prepare a separate radiation dose estimate for consideration in adjudication of the claim. For purposes of this paragraph:

(1) The difference between the claimant's estimate and dose data derived from official military records shall ordinarily be considered material if one estimate is at least double the other estimate.

(2) A dose estimate shall be considered from a "credible source" if prepared by a person or persons certified by an appropriate professional body in the field of health physics, nuclear medicine or radiology and if based on analysis of the facts and circumstances of the particular claim.

(4) *Exposure.* In cases described in paragraph (a)(3)(1) and (1) of this section:

(i) If military records do not establish presence at or absence from a site at which exposure to radiation is claimed to have occurred, the veteran's presence at the site will be conceded.

(ii) Neither the veteran nor the veteran's survivors may be required to produce evidence substantiating exposure if the information in the veteran's service records or other records maintained by the Department of Defense is consistent with the claim that the veteran was present where and when the claimed exposure occurred.

(b) *Initial review of claim.* (1) When it is determined:

(i) A veteran was exposed to ionizing radiation as a result of participation in the atmospheric testing of nuclear weapons, the occupation of Hiroshima or Nagasaki, Japan, from September 1945 until July 1945, or other activities as claimed;

(ii) The veteran subsequently developed a radiogenic disease; and

(iii) Such disease first became manifest within the period specified in paragraph (b)(5) of this section; before its adjudication the claim will be referred to the Under Secretary for Benefits for further consideration in accordance with paragraph (c) of this section. If any of the foregoing requirements has not been met, it shall not be determined that a disease has resulted from

exposure to ionizing radiation under such circumstances.

(2) For purposes of this section the term "radiogenic disease" means a disease that may be induced by ionizing radiation and shall include the following:

(i) All forms of leukemia except chronic lymphatic (lymphocytic) leukemia;

(ii) Thyroid cancer;

(iii) Breast cancer;

(iv) Lung cancer;

(v) Bone cancer;

(vi) Liver cancer;

(vii) Skin cancer;

(viii) Esophageal cancer;

(ix) Stomach cancer;

(x) Colon cancer;

(xi) Pancreatic cancer;

(xii) Kidney cancer;

(xiii) Urinary bladder cancer;

(xiv) Salivary gland cancer;

(xv) Multiple myeloma;

(xvi) Posterior subcapsular cataracts;

(xvii) Non-malignant thyroid nodular disease;

(xviii) Ovarian cancer;

(xix) Parathyroid adenoma; and

(xx) Tumors of the brain and central nervous system.

(Authority: 38 U.S.C. 363)

(3) For purposes of paragraphs (a)(1) and (b)(1) of this section, "radiogenic disease" shall not include polycythemia vera.

(4) If a claim is based on a disease other than one of those listed in paragraphs (b)(1) or (b)(3) of this section, VA shall nevertheless consider the claim under the provisions of this section provided that the claimant has cited or submitted competent scientific or medical evidence that the claimed condition is a radiogenic disease.

(5) For the purposes of paragraph (b)(1) of this section:

(i) Bone cancer must become manifest within 20 years after exposure;

(ii) Leukemia may become manifest at any time after exposure;

(iii) Posterior subcapsular cataracts must become manifest 6 months or more after exposure; and

(iv) Other diseases specified in paragraph (b)(2) of this section must be

come manifest 5 years or more after exposure.

(Authority: 38 U.S.C. 801; Pub. L. 92-603)

(c) *Review by Under Secretary for Benefits.* (1) When a claim is forwarded for review pursuant to paragraph (b)(1) of this section, the Under Secretary for Benefits shall consider the claim with reference to the factors specified in paragraph (e) of this section and may request an advisory medical opinion from the Under Secretary for Health.

(i) If after such consideration the Under Secretary for Benefits is convinced sound scientific and medical evidence supports the conclusion it is at least as likely as not the veteran's disease resulted from exposure to radiation in service, the Under Secretary for Benefits shall so inform the regional office of jurisdiction in writing. The Under Secretary for Benefits shall set forth the rationale for this conclusion, including an evaluation of the claim under the applicable factors specified in paragraph (e) of this section.

(ii) If the Under Secretary for Benefits determines there is no reasonable possibility that the veteran's disease resulted from radiation exposure in service, the Under Secretary for Benefits shall so inform the regional office of jurisdiction in writing, setting forth the rationale for this conclusion.

(3) If the Under Secretary for Benefits, after considering any opinion of the Under Secretary for Health, is unable to conclude whether it is at least as likely as not, or that there is no reasonable possibility, the veteran's disease resulted from radiation exposure in service, the Under Secretary for Benefits shall refer the matter to an outside consultant in accordance with paragraph (d) of this section.

(3) For purposes of paragraph (c)(1) of this section, "sound scientific evidence" means observations, findings, or conclusions which are statistically and epidemiologically valid, are statistically significant, are capable of replication, and withstand peer review, and "sound medical evidence" means observations, findings, or conclusions which are consistent with current medical knowledge and are so reasonable

and logical as to serve as the basis of management of a medical condition.

(d) *Referral to outside consultants.* (1) Referrals pursuant to paragraph (c) of this section shall be to consultants selected by the Under Secretary for Health from outside VA, upon the recommendation of the Director of the National Cancer Institute. The consultant will be asked to evaluate the claim and provide an opinion as to the likelihood the disease is a result of exposure as claimed.

(2) The request for opinion shall be in writing and shall include a description of:

(i) The disease, including the specific cell type and stage, if known, and when the disease first became manifest;

(ii) The circumstances, including date, of the veteran's exposure;

(iii) The veteran's age, gender, and pertinent family history;

(iv) The veteran's history of exposure to known carcinogens, occupationally or otherwise;

(v) Evidence of any other effects radiation exposure may have had on the veteran; and

(vi) Any other information relevant to determination of causation of the veteran's disease.

The Under Secretary for Benefits shall forward, with the request, copies of pertinent medical records and, where available, dose assessments from official sources, from credible sources as defined in paragraph (a)(3)(ii) of this section, and from an independent expert pursuant to paragraph (a)(3) of this section.

(3) The consultant shall evaluate the claim under the factors specified in paragraph (e) of this section and respond in writing, stating whether it is either likely, unlikely, or approximately as likely as not the veteran's disease resulted from exposure to ionizing radiation in service. The response shall set forth the rationale for the consultant's conclusion, including the consultant's evaluation under the applicable factors specified in paragraph (e) of this section. The Under Secretary for Benefits shall review the consultant's response and transmit it with any comments to the regional office of jurisdiction for use in adjudication of the claim.

(e) *Factors for consideration.* Factors to be considered in determining whether a veteran's disease resulted from exposure to ionizing radiation in service include:

(1) The probable dose, in terms of dose type, rate and duration as a factor in inducing the disease, taking into account any known limitations in the dosimetry devices employed in its measurement or the methodologies employed in its estimation;

(2) The relative sensitivity of the involved tissue to induction, by ionizing radiation, of the specific pathology;

(3) The veteran's gender and pertinent family history;

(4) The veteran's age at time of exposure;

(5) The time-lapse between exposure and onset of the disease; and

(6) The extent to which exposure to radiation, or other carcinogens, outside of service may have contributed to development of the disease.

(f) *Adjudication of claim.* The determination of service connection will be made under the generally applicable provisions of this part, giving due consideration to all evidence of record, including any opinion provided by the Under Secretary for Health or an outside consultant, and to the evaluations published pursuant to §1.17 of this title. With regard to any issue material to consideration of a claim, the provisions of §1.102 of this title apply.

(g) *Willful misconduct and supervening cause.* In no case will service connection be established if the disease is due to the veteran's own willful misconduct, or if there is affirmative evidence to establish that a supervening, nonservice-related condition or event is more likely the cause of the disease.

(Authority: Pub. L. 92-603)

50 FR 3688, Aug. 21, 1985, as amended at 54 FR 4288, Oct. 18, 1989; 55 FR 1888, Mar. 21, 1990. Redesignated at 50 FR 5307, Feb. 1, 1985, and amended at 50 FR 4573, Sept. 4, 1985; 50 FR 5388, Feb. 21, 1985.