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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. memo	Ron Peterson to Legislative Liaison Officer [partial] (1 page)	10/08/1996	P3/b(3)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10455

FOLDER TITLE:
Nasopharyngeal Radiation

2014-0046-S
rc1442

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

File NP Radiation

FAX

UNITED STATES SENATOR • CONNECTICUT

Joseph I. Lieberman

Fax to: Elizabeth Drye Date

Fax# Pages

From: Tamara Nameroff

224 9849

Message:

For your information.

Please call me if you have questions.

United States Senate • Washington, D.C. • 20510-4601 • (202) 224-4041 Fax: (202) 224-9750

JOSEPH I. LIEBERMAN
CONNECTICUT

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April 24, 1997

The Honorable Jesse Brown
Department of Veterans Affairs
810 Vermont Avenue NW
Washington, DC 20420

Dear Secretary Brown,

I am writing to urge you to reconsider your decision not to notify the 70 veterans whose nasal radium irradiation (NRI) treatments are documented in the National Personnel Records Center.

As you know, NRI was used widely between the 1940s and the 1960s on military personnel to alleviate pressure changes associated with submarine and flying duties and on civilians, mostly children, in order to alleviate earaches and adenoid problems. The Advisory Committee on Human Radiation Experiment (ACHRE) Final Report found NRI to have the greatest likely excess cancer mortality of any experiments it examined for which people were still alive and might benefit from notice and follow-up.

According to the Department of Health and Human services, individuals who received therapeutic doses of radiation or radium applications to the head, neck, or upper chest for various non-malignant conditions are at increased risk for developing cancer of the thyroid, and to a lesser extent, of the salivary glands and other structures of the head and neck. Secretary to the Cabinet Christine Varney wrote me in May 1994 stating that, "any individual, civilian or military, who has been treated with NRI should contact a physician and ask for a complete examination of the head and neck." Needless to say, a treated individual must first have the knowledge that they were treated in order to notify his or her physician.

I raised the issue of NRI at a January 1994 Senate Government Affairs Committee hearing on radiation experiments. At that hearing you testified that you would be working with the United States Navy to identify veterans who received NRI and notify them about potential health problems associated with the treatment. At a separate hearing I held on NRI in August 1994, Rear Admiral Harold M. Koening, Deputy Surgeon General, U.S. Navy (and also a recipient of NRI) testified that "what we need to do is get people of our Nation just to bring to the attention of their physicians that they had this treatment...." Since these hearings, neither the Navy or the Department of Veterans Affairs has made any effort to notify treated veterans. I urge you to review these commitments.

Some have suggested to me that care needs to be taken about sending out medical alerts without knowing confidently that a risk exists, and without proper techniques available for a physician to

screen for head and neck cancers. In the words of Rear Admiral Koening, "There are a lot of hazards that we're exposed to as we go through our life experience. When we become aware that some of them may have been dangerous, I think it's worth calling that to the attention of our health care provider, and that our health care provider then takes the necessary steps to do at least an initial evaluation." It is my understanding that these initial screening tools, including a manual thyroid examination and an examination of the nasopharynx, are not difficult or expensive. Nonetheless, such simple procedures may provide peace of mind for thousands of treated individuals, and save the lives of those who may develop cancers as a result of NRI.

People have a right to know if they were treated with NRI. How they choose to follow-up on that information is their choice, not the government's. If we truly intend to correct the mistakes of the past, we must warn the former patients whose health and lives may now be at risk. All veterans for whom you are able to document treatment with NRI should be notified; I urge you to start with the 70 identified in your latest records search.

Sincerely,

Joe Lieberman

THANKS

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

07-Jan-1997 00:58am

TO: DRYE_E

FROM: Eric L. Macris

SUBJECT: Budget estimate for nasopharyngeal radiation treatment

Message Creation Date was at 6-JAN-1997 17:13:00

Elizabeth:

I received the attached e-mail earlier today from Alexandra, who is an OMB budget examiner in the VA branch. I just discussed the note with Diane, who is now at the airport, and she asked that I forward the note to you.

---------- Forwarded by Eric L. Macris/OMB/EOP on 01/06/97 05:03 PM ----------

Alexandra Lehr
01/06/97 02:00:19 PM
Record Type: Record

To: Nancy A. Min/OMB/EOP
cc: See the distribution list at the bottom of this message
Subject: Re: URGENT Domestic Policy Council Call on Nasopharyngeal Radiation

On Friday you asked about the cost impact of extending eligibility under VA's Ionizing Radiation Program to veterans treated with nasopharyngeal radiation. According the the estimate submitted by the Department this morning, this will have a 5 year cost of $3 million. This assumes that approximately 1,500 veterans will seek evaluation and/or treatment. Below is a yearly break out of the costs:

Year1	Year2	Year3	Year4	Year5	Total
$488	$732	$732	$732	$246	$2,930

Since we have not seen the legislative proposal, the extension of eligibility remains a policy call. I have informed the Domestic Policy Council to call you if they would like to include the following statement in its report.

The Administration will prepare legislation to make veterans treated with nasopahryngeal radiation eligible for health screening under the Veteran's Administration Ionizing Radiation Program.

Message Copied To:

Toni [redacted] Hustead/OMB/EOP
Bruce D. Long/OMB/EOP
Alexander S. Keenan/OMB/EOP
Eric L. Macris/OMB/EOP
Sarah A. Bianchi/OMB/EOP

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

22-Aug-1996 03:15pm

Copy to Diane
Orginal to Elizabeth

TO: BROSTROM_M

FROM: Jeff Blaylock

SUBJECT: Re: final (?) question on hc eligibility

Message Creation Date was at 22-AUG-1996 15:15:00

As we discussed, it depends on the disability rating & type of care.

Any vet with a service-connected disability (rated 0%-100%) can receive hospital care for any illness, whether related to the SC disability or not.

Any vet with a SC disability rated 50% or more can receive outpatient care for any illness.
Any vet with a SC disability rated 30%-40% can receive outpatient care for that disability, plus any care to prepare him/her for a hospital stay or to prevent ("obviate the need") a hospital stay.
Any vet with a SC disability rated 0%-20% can receive outpatient care for that disability only.

If the vet has no SC disability, but is indigent, then he/she can receive hospital care for any illness but can receive outpatient care only to prepare for a hospital stay or obviate the need for a hospital stay.

Yes, this is very confusing. jb

from "Federal Benefits for Veteran & Dependents" 1996 Edition published by VA Office of Public Affairs

Health-Care Benefits

Hospital Care

Eligibility for VA hospital care is divided into two categories: mandatory and discretionary. VA must provide hospital care to mandatory category veterans at the nearest VA facility capable of furnishing the care in a timely fashion. If no VA facility is available, care must be furnished in a Defense Department facility or another facility with which VA has a sharing or contractual relationship. VA makes an income assessment to determine whether a nonservice-connected veteran is eligible for cost-free VA medical care. This income information is used to determine if nonservice-connected veterans are eligible for mandatory hospital care. If space and resources at VA hospitals are available after caring for mandatory-care patients, VA then may furnish care to veterans in the discretionary category, if they agree to make a copayment to VA for their care.

Mandatory patients: Veterans who must be provided hospital care and are not subject to an income eligibility assessment are: veterans with service-connected disabilities, veterans who were exposed to herbicides while serving in Vietnam, veterans exposed to ionizing radiation during atmospheric testing or in the occupation of Hiroshima and Nagasaki, veterans for a condition which may be related to toxic environmental exposure in the Persian Gulf, former prisoners of war, veterans on VA pension, veterans of the Mexican Border period or World War I and veterans eligible for Medicaid. Nonservice-connected veterans subject to an income eligibility assessment must be provided hospital care if the patient has an income of $21,001 or less if single with no dependents, or $25,204 or less if married or with one dependent. The income maximum is raised $1,404 for each additional dependent.

All others not listed above.

Discretionary patients: Nonservice-connected veterans subject to an income eligibility assessment with income above those listed above for mandatory care are discretionary patients and may be

provided hospital care if space and resources are available. The discretionary patient must agree to pay an amount equal to what would have been paid under Medicare. The Medicare deductible, currently $736, is adjusted annually. VA holds the discretionary patient responsible for the cost of care up to $736 for the first 90 days of care during any 365-day period. For each additional 90 days of hospital care, the patient is charged half the Medicare deductible. In addition to these charges, the patient is charged $10 a day for hospital care and $5 a day for nursing-home care.

Income Assessment

In making an eligibility assessment, the income of the patient, his spouse and dependents is considered. This includes Social Security, U.S. Civil Service retirement, U.S. Railroad Retirement, military retirement, unemployment insurance, any other retirement income, total wages from all employers, interest and dividends, workers' compensation, black lung benefits and any other gross income for the calendar year prior to application for care. Also considered are assets such as the market value of stocks, bonds, notes, individual retirement accounts, bank deposits, savings accounts and cash. Debts are subtracted from income and assets to determine net worth. The patient's primary residence and personal property are excluded from the net worth determination. The patient must fill out VA Form 10-10f, Financial Worksheet, at the time care is requested. VA has the authority to compare income information provided by the veteran with information obtained from the Social Security Administration and the Internal Revenue Service.

Billing Insurance Companies

When applying for medical care, all veterans will be asked to provide information pertaining to health insurance coverage, including policies held by spouses. VA is authorized to submit claims to insurance carriers for the recovery of costs for medical care provided to nonservice-connected veterans and service-connected veterans for nonservice-connected conditions. Veterans will not be held responsible for the deductible requirements and copayments established by their insurance carriers. They also will not be responsible for portions of an insurance claim not covered by the policy. However, veterans above certain income levels are responsible for the copayments required by federal law.

Nursing-Home Care

Nursing care in VA or private nursing homes is provided for veter-

ans who are not acutely ill and not in need of hospital care. VA may, but is not mandated to, provide nursing-home care if space and resources are available in VA facilities. Veterans who have a service-connected disability are given first priority for nursing-home care. Veterans who may be provided nursing-home care without an income eligibility assessment are: veterans with service-connected disability, veterans who were exposed to herbicides while serving in Vietnam, veterans exposed to ionizing radiation during atmospheric testing or in the occupation of Hiroshima and Nagasaki, veterans for a condition which may be related to an environmental exposure in the Persian Gulf, former prisoners of war, veterans on VA pension, veterans of the Mexican Border period or World War I and veterans eligible for Medicaid.

Nonservice-connected veterans must submit an income eligibility assessment form, VA Form 10-10f, to determine whether they will be billed for nursing-home care. Income assessment procedures are the same as for hospital care. Nursing-home care may be authorized for nonservice-connected veterans whose income exceeds the income limit for hospital care, if the veteran agrees to pay the applicable copayment.

Veterans who need nursing-home care may be transferred at VA expense to private nursing homes from VA medical centers, nursing homes or domiciliaries. VA-authorized care normally may not be provided in excess of six months, except for veterans whose need for nursing-home care is for a service-connected disability or for veterans who were hospitalized primarily for treatment of a service-connected disability.

Direct admission to private nursing homes at VA expense is limited to: (1) a veteran who requires nursing care for a service-connected disability after medical determination by VA; (2) a patient in a military hospital who requires a protracted period of nursing care and who will become a veteran upon discharge from the Armed Forces; and (3) a veteran who had been discharged from a VA medical center and is receiving home health services from VA.

Domiciliary Care

Domiciliary care provides rehabilitative and long-term, health-maintenance care for veterans who require minimal medical care but who do not need the skilled nursing services provided in nursing homes. VA may provide domiciliary care to veterans whose annual

income does not exceed the maximum annual rate of VA pension or to veterans the Secretary of Veterans Affairs determines have no adequate means of support.

Outpatient Medical Treatment

Outpatient medical treatment includes medical examinations and related medical services, drugs and medicines, rehabilitation services, and mental health services. As part of outpatient medical treatment, veterans may be eligible for home health services for the treatment of disabilities. The following are the different categories of outpatient eligibility:

1. VA must furnish outpatient care without limitation to veterans for service-connected disabilities, to veterans with a 50 percent or more service-connected disability for any ailment, to veterans who have suffered an injury as a result of VA hospitalization, for that condition only, and to veterans who served in the Persian Gulf War and whose condition the Secretary finds may be the result of exposure to a toxic substance or environmental hazard.

2. VA must furnish outpatient care reasonably necessary for the treatment of any condition necessary in preparation for hospital admission or to prevent hospital admission; to complete treatment after hospital care, nursing-home care or domiciliary care to 30 and 40 percent service-connected disabled veterans; and to veterans whose annual income is not greater than the maximum annual pension rate of a veteran in need of regular aid and attendance of another person.

3. VA may furnish outpatient care without limitation to veterans in a VA-approved vocational rehabilitation program; to former prisoners of war; to World War I or Mexican Border Period veterans; and to veterans who receive increased pension or compensation based on the need for regular aid and attendance of another person, or who are permanently housebound.

4. VA may furnish outpatient care to prevent the need for hospitalization, to prepare for hospitalization, or for a condition for which the veteran was hospitalized to (a) veterans who are 0 to 20 percent service-connected disabled; (b) veterans exposed to a toxic substance during service in Vietnam; (c) veterans exposed to ionizing radiation following the detonation of a nuclear device; (d) mandatory category veterans whose income is more than the pension rate of a veteran in need of regular aid and attendance of another person; (e) discretionary category veterans, subject to a copayment of $11 per outpatient visit; and to allied beneficiaries and employees of other federal agencies for which the Secretary may agree to render

services for which charges shall be made as required by law.

5. VA provides counseling to veterans to overcome psychological trauma resulting from physical assault, battery of a sexual nature or sexual harassment during active duty. VA also can provide care and services for injury, illness or other psychological conditions resulting from such an assault, battery or harassment.

Outpatient Pharmacy Services

Pharmacy services are provided without charge to: (1) veterans receiving medication for treatment of service-connected conditions; (2) veterans rated with 50 percent or more service-connected disability; and (3) veterans whose annual income does not exceed the maximum VA pension. Veterans with a service-connected condition rated less than 50 percent and receiving medication on an outpatient basis from VA facilities for the treatment of nonservice-connected ailments are charged a set amount for each 30-day supply.

Outpatient Dental Treatment

Outpatient dental treatment provided by VA includes examinations and the full spectrum of diagnostic, surgical, restorative and preventive techniques. Nonservice-connected veterans who are authorized outpatient dental care may be billed the applicable copayment if their income exceeds the maximum threshold. The following may be eligible for free dental care:

1. Dental conditions or disabilities that are service connected and compensable will be treated.

2. Service-connected dental conditions or disabilities that are not compensable may receive one-time treatment if the conditions can be shown to have existed at discharge or within 90 days of release from active service. Veterans who served on active duty for 90 days or more during the Persian Gulf Era are included in this category. Veterans must apply to VA for dental care within 90 days following separation. Veterans will not be considered eligible if their separation document indicates that necessary treatment was completed by the military during the 90 days prior to separation.

3. Veterans may receive treatment for service-connected, noncompensable dental conditions resulting from combat wounds or service injuries, and service-connected, noncompensable dental conditions of former prisoners of war who were incarcerated less than 90 days may be treated.

4. Veterans who were prisoners of war for 90 days or more may receive complete dental care.

5. Veterans may receive complete dental care if receiving

disability compensation at the 100-percent rate for service-connected conditions or are eligible to receive it by reason of unemployability.

6. Nonservice-connected dental conditions that are determined by VA to be aggravating a service-connected medical problem may be treated.

7. Veterans participating in a vocational rehabilitation program may be treated.

8. Veterans may be treated for nonservice-connected dental conditions when treatment was begun while in a VA medical center, when it is professionally determined to be reasonably necessary to complete such dental treatment on an outpatient basis.

9. Veterans scheduled for admission to inpatient services or who are receiving medical services may receive outpatient dental care if the dental condition is determined to be complicating a medical condition which VA is currently treating.

Persian Gulf, Agent Orange and Ionizing Radiation

Registry Programs

Veterans who served in the Persian Gulf War or who claim exposure to Agent Orange or atomic radiation are provided with free, comprehensive medical examinations, including base-line laboratory tests and other diagnostic tests deemed by an examining physician necessary to determine current health status. Results of the examinations, which include preparation of the veteran's military service and exposure history, are entered into special, computerized data bases, called registries. These data bases assist VA in analyzing the types of health conditions being reported by veterans. Registry participants are advised of the results of their examinations in personal consultations. Veterans wishing to participate should contact the nearest VA health-care facility for an examination.

Treatment

VA provides treatment to any Vietnam-Era veteran who, while serving in Vietnam, may have been exposed to dioxin or to a toxic substance in a herbicide or defoliant used for military purposes, for medical conditions related to such exposure. Health-care services are available for medical conditions possibly related to any veteran's exposure to ionizing radiation from the detonation of a nuclear device in connection with nuclear tests, or with the American occupation of Hiroshima and Nagasaki, Japan, during the period beginning Sept. 11, 1945, and ending July 1, 1946. Treatment was authorized through June 30, 1995, for veterans exposed to nuclear radiation. VA

also has provided treatment to any Persian Gulf War veteran who may have been exposed to a toxic substance or environmental hazard during the Persian Gulf War, for any disability, even though the medical evidence is insufficient to establish an association between the disability and exposure. Expiration dates have been attached to this authority in recent years.

Beneficiary Travel

Veterans are eligible for payment or reimbursement for travel costs to receive VA medical care. Travel payments are subject to a deductible of $3 for each one-way trip and an $18 per month maximum payment. Two exceptions to this rule are travel for a compensation or pension examination and travel by special modes of transportation, such as an ambulance or a specially-equipped van. Beneficiary travel payments may be made to the following:

1. Veterans whose service-connected disabilities are rated at 30 percent or more.
2. Veterans who are traveling in connection with treatment of a service-connected condition.
3. Veterans who are in receipt of VA pension.
4. Veterans traveling for compensation/pension examinations.
5. Veterans whose income is less than or equal to the maximum base VA pension rate with aid and attendance.
6. Veterans whose medical condition requires use of a special mode of transportation, if the veteran is unable to defray the costs and travel is pre-authorized. If the medical condition is a medical emergency, travel need not be pre-authorized when a delay to obtain authorization would be hazardous.

Alcohol and Drug Dependence Treatment

Veterans eligible for VA medical care may apply for substance abuse treatment. Veterans without service-connected disabilities whose incomes exceed the threshold for free medical care may be authorized treatment for alcohol and drug dependence only if the veteran agrees to make a copayment. After hospitalization for alcohol or drug treatment, veterans may be eligible for outpatient care or may be authorized to continue treatment or rehabilitation at VA expense in private facilities such as halfway houses.

Prosthetic Services

Veterans may apply for prosthetic services for any condition when receiving hospital, domiciliary or nursing-home care in a VA facility.

Veterans who meet the basic requirement for outpatient medical treatment may be provided prosthetic services:

1. For a service-connected disability or adjunct condition.
2. For any medical condition for a veteran with a service-connected disability rated at 50 percent or more, or for a veteran receiving compensation as a result of treatment in a VA facility.
3. For a disability for which a veteran was discharged or released from active service.
4. For a veteran participating in a vocational rehabilitation program.
5. For a veteran receiving outpatient care, to complete treatment of a disability for which hospital, nursing home or domiciliary care was provided.
6. For a veteran in receipt of increased pension or allowance based on needing aid and attendance of another person or being permanently housebound.
7. For a veteran of World War I or the Mexican Border period.
8. For a former prisoner of war.

Services and Aids for Blind Veterans

Veterans with corrected central vision of 20/200 or less in both eyes or field loss to 20 degrees or less in both eyes are considered to be blind. Services are available at all VA medical facilities through the Visual Impairment Services (VIS) coordinator. Blind veterans may be eligible for services at a VA medical center or for admission to a VA blind rehabilitation center or clinic.

In addition, blind veterans entitled to receive disability compensation may receive VA aids for the blind. Benefits for blind veterans may include:

1. A total health and benefits review by a VA Visual Impairment Services team.
2. Adjustment to blindness training.
3. Home Improvements and Structural Alterations to homes (HISA Program).
4. Specially adapted housing and adaptations.
5. Low-vision aids and training in their use.
6. Electronic and mechanical aids for the blind, including adaptive computers and computer-assisted devices.
7. Guide dogs, including the expense of training the veteran to use the dog and the cost of the dog's medical care.
8. Talking books, tapes and Braille literature, provided from the Library of Congress.

Home Improvements and Structural Alterations

The Home Improvements and Structural Alterations program helps pay for home improvements necessary to provide access to the home and its essential sanitary facilities. For alterations, VA will pay up to $4,100 for a veteran being treated for a service-connected disability or a veteran with a disability rating of 50 percent or more. Up to $1,200 will be paid to other veterans eligible for outpatient care. Apply at the nearest VA medical center.

Readjustment Counseling

Veterans who served on active duty during the Vietnam Era or served in the war or conflict zones of Lebanon, Grenada, Panama or the Somalia or Persian Gulf theaters during hostilities or war are entitled to counseling to assist in readjusting to civilian life. Counseling is provided at Vet Centers to help veterans resolve war-related psychological difficulties and to help them achieve a successful post-war readjustment to civilian life. Assistance includes group, individual and family counseling, community outreach and education. Veterans are placed with non-VA agencies if needed.

One common readjustment problem is post-traumatic stress disorder, or PTSD. This refers to such symptoms as nightmares, intrusive recollections or memories, flashbacks, anxiety or sudden reactions after exposure to traumatic conditions. Readjustment difficulties may affect functioning in school, family or work. Counseling also is provided veterans for difficulties due to sexual assault or harassment while on active duty. In areas distant from Vet Centers or VA medical facilities, veterans may obtain readjustment counseling from private-sector professionals who are on contract with VA. To locate a contract provider, contact the nearest Vet Center.

Special Categories for Medical Care

Merchant Marine Seamen

Merchant Marine seamen who served in World War II may be qualified for veterans benefits. When applying for medical care, seamen must present their DD-214 discharge certificate from the Defense Department to the VA medical facility. VA regional offices can assist in obtaining a certificate.

Allied Veterans

VA is authorized to provide reciprocal medical care to veterans of nations allied or associated with the United States during World

War I or World War II. Such treatment is available at any VA medical facility if authorized and reimbursed by the foreign government. VA also is authorized to provide hospitalization, outpatient and domiciliary care to former members of the armed forces of Czechoslovakia or Poland who participated during World Wars I and II in armed conflict against an enemy of the United States, if they have been citizens of the United States for at least 10 years.

Medical Care for Dependents and Survivors (CHAMPVA)

CHAMPVA, the VA Civilian Health and Medical Program, shares the cost of medical services and supplies obtained by eligible dependents and survivors of certain veterans. The following are eligible for treatment through CHAMPVA, provided they are not eligible for CHAMPUS or Medicare:

1. The spouse or child of a veteran who has a permanent and total service-connected disability.
2. The surviving spouse or child of a veteran who died as a result of a service-connected condition, or who, at the time of death, was permanently and totally disabled from a service-connected condition.
3. The surviving spouse or child of a person who died in the line of duty, not due to misconduct, while on active duty.

Dependents are not eligible for medical care under CHAMPVA if they are eligible for medical care under CHAMPUS (Civilian Health and Medical Program of the Uniformed Services) or Medicare, Part A, as a result of reaching age 65.

Beneficiaries age 65 or older who lose eligibility for CHAMPVA by becoming potentially eligible for Medicare, Part A, or who qualify for Medicare, Part A, benefits on the basis of a disability may re-establish CHAMPVA eligibility by submitting documentation from the Social Security Administration certifying they are not entitled to or have exhausted Medicare, Part A, benefits. Persons under age 65 who are enrolled in both Medicare Parts A and B may become eligible for CHAMPVA as a secondary payer to Medicare. Apply to the CHAMPVA Center, P.O. Box 65023, Denver, CO 80206-5023, or call 1-800-733-8387.

to empower individuals and families to help themselves, including our expansion of the earned-income tax cut for low- and moderate-income working families, and our proposals for injecting choice and competition into public and assisted housing and for a new G.I. Bill for America's Workers.

I am determined to end Federal budget deficits, and my balanced budget proposal shows that we can balance the budget without abandoning the investments that are vital to the security and prosperity of the country, now and in the future. I am confident that, working together, we can build common ground on an empowerment agenda while putting our fiscal house in order. I will do everything in my power to make sure this happens.

William J. Clinton

The White House,
August 3, 1995.

Executive Order 12968—Access to Classified Information

August 2, 1995

The national interest requires that certain information be maintained in confidence through a system of classification in order to protect our citizens, our democratic institutions, and our participation within the community of nations. The unauthorized disclosure of information classified in the national interest can cause irreparable damage to the national security and loss of human life.

Security policies designed to protect classified information must ensure consistent, cost effective, and efficient protection of our Nation's classified information, while providing fair and equitable treatment to those Americans upon whom we rely to guard our national security.

This order establishes a uniform Federal personnel security program for employees who will be considered for initial or continued access to classified information.

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

Part 1 Definitions, Access to Classified Information, Financial Disclosure, and Other Items

Section 1.1. *Definitions.* For the purposes of this order: (a) "Agency" means any "Executive agency," as defined in 5 U.S.C. 105, the "military departments," as defined in 5 U.S.C. 102, and any other entity within the executive branch that comes into the possession of classified information, including the Defense Intelligence Agency, National Security Agency, and the National Reconnaissance Office.

(b) "Applicant" means a person other than an employee who has received an authorized conditional offer of employment for a position that requires access to classified information.

(c) "Authorized investigative agency" means an agency authorized by law or regulation to conduct a counterintelligence investigation or investigation of persons who are proposed for access to classified information to ascertain whether such persons satisfy the criteria for obtaining and retaining access to such information.

(d) "Classified information" means information that has been determined pursuant to Executive Order No. 12958, or any successor order, Executive Order No. 12951, or any successor order, or the Atomic Energy Act of 1954 (42 U.S.C. 2011), to require protection against unauthorized disclosure.

(e) "Employee" means a person, other than the President and Vice President, employed by, detailed or assigned to, an agency, including members of the Armed Forces; an expert or consultant to an agency; an industrial or commercial contractor, licensee, certificate holder, or grantee of an agency, including all subcontractors; a personal services contractor; or any other category of person who acts for or on behalf of an agency as determined by the appropriate agency head.

(f) "Foreign power" and "agent of a foreign power" have the meaning provided in 50 U.S.C. 1801.

(g) "Need for access" means a determination that an employee requires access to a particular level of classified information in order to perform or assist in a lawful and authorized governmental function.

(h) "Need-to-know" means a determination made by an authorized holder of classified information that a prospective recipient requires access to specific classified information in order to perform or assist in a lawful and authorized governmental function.

(i) "Overseas Security Policy Board" means the Board established by the President to consider, develop, coordinate and promote policies, standards and agreements on overseas security operations, programs and projects that affect all United States Government agencies under the authority of a Chief of Mission.

(j) "Security Policy Board" means the Board established by the President to consider, coordinate, and recommend policy directives for U.S. security policies, procedures, and practices.

(k) "Special access program" has the meaning provided in section 4.1 of Executive Order No. 12958, or any successor order.

Sec. 1.2. *Access to Classified Information.* (a) No employee shall be granted access to classified information unless that employee has been determined to be eligible in accordance with this order and to possess a need-to-know.

(b) Agency heads shall be responsible for establishing and maintaining an effective program to ensure that access to classified information by each employee is clearly consistent with the interests of the national security.

(c) Employees shall not be granted access to classified information unless they:

(1) have been determined to be eligible for access under section 3.1 of this order by agency heads or designated officials based upon a favorable adjudication of an appropriate investigation of the employee's background;

(2) have a demonstrated need-to-know; and

(3) have signed an approved nondisclosure agreement.

(d) All employees shall be subject to investigation by an appropriate government authority prior to being granted access to classified information and at any time during the period of access to ascertain whether they continue to meet the requirements for access.

(e)(1) All employees granted access to classified information shall be required as a condition of such access to provide to the employing agency written consent permitting access by an authorized investigative agency, for such time as access to classified information is maintained and for a period of 3 years thereafter, to:

(A) relevant financial records that are maintained by a financial institution as defined in 31 U.S.C. 5312(a) or by a holding company as defined in section 1101(6) of the Right to Financial Privacy Act of 1978 (12 U.S.C. 3401);

(B) consumer reports pertaining to the employee under the Fair Credit Reporting Act (15 U.S.C. 1681a); and

(C) records maintained by commercial entities within the United States pertaining to any travel by the employee outside the United States.

(2) Information may be requested pursuant to employee consent under this section where:

(A) there are reasonable grounds to believe, based on credible information, that the employee or former employee is, or may be, disclosing classified information in an unauthorized manner to a foreign power or agent of a foreign power;

(B) information the employing agency deems credible indicates the employee or former employee has incurred excessive indebtedness or has acquired a level of affluence that cannot be explained by other information; or

(C) circumstances indicate the employee or former employee had the capability and opportunity to disclose classified information that is known to have been lost or compromised to a foreign power or an agent of a foreign power.

(3) Nothing in this section shall be construed to affect the authority of an investigating agency to obtain information pursuant to the Right to Financial Privacy Act, the Fair Credit Reporting Act or any other applicable law.

Sec. 1.3. *Financial Disclosure.* (a) Not later than 180 days after the effective date of this order, the head of each agency that originates, handles, transmits, or possesses

classified information shall designate each employee, by position or category where possible, who has a regular need for access to classified information that, in the discretion of the agency head, would reveal:

(1) the identity of covert agents as defined in the Intelligence Identities Protection Act of 1982 (50 U.S.C. 421);

(2) technical or specialized national intelligence collection and processing systems that, if disclosed in an unauthorized manner, would substantially negate or impair the effectiveness of the system;

(3) the details of:

(A) the nature, contents, algorithm, preparation, or use of any code, cipher, or cryptographic system or;

(B) the design, construction, functioning, maintenance, or repair of any cryptographic equipment; but not including information concerning the use of cryptographic equipment and services;

(4) particularly sensitive special access programs, the disclosure of which would substantially negate or impair the effectiveness of the information or activity involved; or

(5) especially sensitive nuclear weapons design information (but only for those positions that have been certified as being of a high degree of importance or sensitivity, as described in section 145(f) of the Atomic Energy Act of 1954, as amended).

(b) An employee may not be granted access, or hold a position designated as requiring access, to information described in subsection (a) unless, as a condition of access to such information, the employee:

(1) files with the head of the agency a financial disclosure report, including information with respect to the spouse and dependent children of the employee, as part of all background investigations or reinvestigations;

(2) is subject to annual financial disclosure requirements, if selected by the agency head; and

(3) files relevant information concerning foreign travel, as determined by the Security Policy Board.

(c) Not later than 180 days after the effective date of this order, the Security Policy Board shall develop procedures for the implementation of this section, including a standard financial disclosure form for use by employees under subsection (b) of this section, and agency heads shall identify certain employees, by position or category, who are subject to annual financial disclosure.

Sec. 1.4. *Use of Automated Financial Record Data Bases.* As part of all investigations and reinvestigations described in section 1.2(d) of this order, agencies may request the Department of the Treasury, under terms and conditions prescribed by the Secretary of the Treasury, to search automated data bases consisting of reports of currency transactions by financial institutions, international transportation of currency or monetary instruments, foreign bank and financial accounts, transactions under $10,000 that are reported as possible money laundering violations, and records of foreign travel.

Sec. 1.5. *Employee Education and Assistance.* The head of each agency that grants access to classified information shall establish a program for employees with access to classified information to: (a) educate employees about individual responsibilities under this order; and

(b) inform employees about guidance and assistance available concerning issues that may affect their eligibility for access to classified information, including sources of assistance for employees who have questions or concerns about financial matters, mental health, or substance abuse.

Part 2 Access Eligibility Policy and Procedure

Sec. 2.1. *Eligibility Determinations.* (a) Determinations of eligibility for access to classified information shall be based on criteria established under this order. Such determinations are separate from suitability determinations with respect to the hiring or retention of persons for employment by the government or any other personnel actions.

(b) The number of employees that each agency determines are eligible for access to classified information shall be kept to the minimum required for the conduct of agency functions.

(1) Eligibility for access to classified information shall not be requested or granted solely to permit entry to, or ease of movement within, controlled areas when the employee has no need for access and access to classified information may reasonably be prevented. Where circumstances indicate employees may be inadvertently exposed to classified information in the course of their duties, agencies are authorized to grant or deny, in their discretion, facility access approvals to such employees based on an appropriate level of investigation as determined by each agency.

(2) Except in agencies where eligibility for access is a mandatory condition of employment, eligibility for access to classified information shall only be requested or granted based on a demonstrated, foreseeable need for access. Requesting or approving eligibility in excess of actual requirements is prohibited.

(3) Eligibility for access to classified information may be granted where there is a temporary need for access, such as one-time participation in a classified project, provided the investigative standards established under this order have been satisfied. In such cases, a fixed date or event for expiration shall be identified and access to classified information shall be limited to information related to the particular project or assignment.

(4) Access to classified information shall be terminated when an employee no longer has a need for access.

Sec. 2.2. Level of Access Approval. (a) The level at which an access approval is granted for an employee shall be limited, and relate directly, to the level of classified information for which there is a need for access. Eligibility for access to a higher level of classified information includes eligibility for access to information classified at a lower level.

(b) Access to classified information relating to a special access program shall be granted in accordance with procedures established by the head of the agency that created the program or, for programs pertaining to intelligence activities (including special activities but not including military operational, strategic, and tactical programs) or intelligence sources and methods, by the Director of Central Intelligence. To the extent possible and consistent with the national security interests of the United States, such procedures shall be consistent with the standards and procedures established by and under this order.

Sec. 2.3 Temporary Access to Higher Levels. (a) An employee who has been determined to be eligible for access to classified information based on favorable adjudication of a completed investigation may be granted temporary access to a higher level where security personnel authorized by the agency head to make access eligibility determinations find that such access:

(1) is necessary to meet operational or contractual exigencies not expected to be of a recurring nature;

(2) will not exceed 180 days; and

(3) is limited to specific, identifiable information that is made the subject of a written access record.

(b) Where the access granted under subsection (a) of this section involves another agency's classified information, that agency must concur before access to its information is granted.

Sec. 2.4. Reciprocal Acceptance of Access Eligibility Determinations. (a) Except when an agency has substantial information indicating that an employee may not satisfy the standards in section 3.1 of this order, background investigations and eligibility determinations conducted under this order shall be mutually and reciprocally accepted by all agencies.

(b) Except where there is substantial information indicating that the employee may not satisfy the standards in section 3.1 of this order, an employee with existing access to a special access program shall not be denied eligibility for access to another special access program at the same sensitivity level as determined personally by the agency head or deputy agency head, or have an existing access eligibility readjudicated, so long as the employee has a need for access to the information involved.

(c) This section shall not preclude agency heads from establishing additional, but not duplicative, investigative or adjudicative pro-

cedures for a special access program or for candidates for detail or assignment to their agencies, where such procedures are required in exceptional circumstances to protect the national security.

(d) Where temporary eligibility for access is granted under sections 2.3 or 3.3 of this order or where the determination of eligibility for access is conditional, the fact of such temporary or conditional access shall be conveyed to any other agency that considers affording the employee access to its information.

Sec. 2.5. *Specific Access Requirement.* (a) Employees who have been determined to be eligible for access to classified information shall be given access to classified information only where there is a need-to-know that information.

(b) It is the responsibility of employees who are authorized holders of classified information to verify that a prospective recipient's eligibility for access has been granted by an authorized agency official and to ensure that a need-to-know exists prior to allowing such access, and to challenge requests for access that do not appear well-founded.

Sec. 2.6. *Access by Non-United States Citizens.* (a) Where there are compelling reasons in furtherance of an agency mission, immigrant alien and foreign national employees who possess a special expertise may, in the discretion of the agency, be granted limited access to classified information only for specific programs, projects, contracts, licenses, certificates, or grants for which there is a need for access. Such individuals shall not be eligible for access to any greater level of classified information than the United States Government has determined may be releasable to the country of which the subject is currently a citizen, and such limited access may be approved only if the prior 10 years of the subject's life can be appropriately investigated. If there are any doubts concerning granting access, additional lawful investigative procedures shall be fully pursued.

(b) Exceptions to these requirements may be permitted only by the agency head or the senior agency official designated under section 6.1 of this order to further substantial national security interests.

Part 3 Access Eligibility Standards

Sec. 3.1. *Standards.* (a) No employee shall be deemed to be eligible for access to classified information merely by reason of Federal service or contracting, licensee, certificate holder, or grantee status, or as a matter of right or privilege, or as a result of any particular title, rank, position, or affiliation.

(b) Except as provided in sections 2.6 and 3.3 of this order, eligibility for access to classified information shall be granted only to employees who are United States citizens for whom an appropriate investigation has been completed and whose personal and professional history affirmatively indicates loyalty to the United States, strength of character, trustworthiness, honesty, reliability, discretion, and sound judgment, as well as freedom from conflicting allegiances and potential for coercion, and willingness and ability to abide by regulations governing the use, handling, and protection of classified information. A determination of eligibility for access to such information is a discretionary security decision based on judgments by appropriately trained adjudicative personnel. Eligibility shall be granted only where facts and circumstances indicate access to classified information is clearly consistent with the national security interests of the United States, and any doubt shall be resolved in favor of the national security.

(c) The United States Government does not discriminate on the basis of race, color, religion, sex, national origin, disability, or sexual orientation in granting access to classified information.

(d) In determining eligibility for access under this order, agencies may investigate and consider any matter that relates to the determination of whether access is clearly consistent with the interests of national security. No inference concerning the standards in this section may be raised solely on the basis of the sexual orientation of the employee.

(e) No negative inference concerning the standards in this section may be raised solely on the basis of mental health counseling. Such counseling can be a positive factor in eligibility determinations. However, mental health counseling, where relevant to the adjudication of access to classified information,

may justify further inquiry to determine whether the standards of subsection (b) of this section are satisfied, and mental health may be considered where it directly relates to those standards.

(f) Not later than 180 days after the effective date of this order, the Security Policy Board shall develop a common set of adjudicative guidelines for determining eligibility for access to classified information, including access to special access programs.

Sec. 3.2. *Basis for Eligibility Approval.* (a) Eligibility determinations for access to classified information shall be based on information concerning the applicant or employee that is acquired through the investigation conducted pursuant to this order or otherwise available to security officials and shall be made part of the applicant's or employee's security record. Applicants or employees shall be required to provide relevant information pertaining to their background and character for use in investigating and adjudicating their eligibility for access.

(b) Not later than 180 days after the effective date of this order, the Security Policy Board shall develop a common set of investigative standards for background investigations for access to classified information. These standards may vary for the various levels of access.

(c) Nothing in this order shall prohibit an agency from utilizing any lawful investigative procedure in addition to the investigative requirements set forth in this order and its implementing regulations to resolve issues that may arise during the course of a background investigation or reinvestigation.

Sec. 3.3. *Special Circumstances.* (a) In exceptional circumstances where official functions must be performed prior to the completion of the investigative and adjudication process, temporary eligibility for access to classified information may be granted to an employee while the initial investigation is underway. When such eligibility is granted, the initial investigation shall be expedited.

(1) Temporary eligibility for access under this section shall include a justification, and the employee must be notified in writing that further access is expressly conditioned on the favorable completion of the investigation and issuance of an access eligibility approval. Access will be immediately terminated, along with any assignment requiring an access eligibility approval, if such approval is not granted.

(2) Temporary eligibility for access may be granted only by security personnel authorized by the agency head to make access eligibility determinations and shall be based on minimum investigative standards developed by the Security Policy Board not later than 180 days after the effective date of this order.

(3) Temporary eligibility for access may be granted only to particular, identified categories of classified information necessary to perform the lawful and authorized functions that are the basis for the granting of temporary access.

(b) Nothing in subsection (a) shall be construed as altering the authority of an agency head to waive requirements for granting access to classified information pursuant to statutory authority.

(c) Where access has been terminated under section 2.1(b)(4) of this order and a new need for access arises, access eligibility up to the same level shall be reapproved without further investigation as to employees who were determined to be eligible based on a favorable adjudication of an investigation completed within the prior 5 years, provided they have remained employed by the same employer during the period in question, the employee certifies in writing that there has been no change in the relevant information provided by the employee for the last background investigation, and there is no information that would tend to indicate the employee may no longer satisfy the standards established by this order for access to classified information.

(d) Access eligibility shall be reapproved for individuals who were determined to be eligible based on a favorable adjudication of an investigation completed within the prior 5 years and who have been retired or otherwise separated from United States Government employment for not more than 2 years; provided there is no indication the individual may no longer satisfy the standards of this order, the individual certifies in writing that there has been no change in the relevant in-

formation provided by the individual for the last background investigation, and an appropriate record check reveals no unfavorable information.

Sec. 3.4. *Reinvestigation Requirements.* (a) Because circumstances and characteristics may change dramatically over time and thereby alter the eligibility of employees for continued access to classified information, reinvestigations shall be conducted with the same priority and care as initial investigations.

(b) Employees who are eligible for access to classified information shall be the subject of periodic reinvestigations and may also be reinvestigated if, at any time, there is reason to believe that they may no longer meet the standards for access established in this order.

(c) Not later than 180 days after the effective date of this order, the Security Policy Board shall develop a common set of reinvestigative standards, including the frequency of reinvestigations.

Part 4 Investigations for Foreign Governments

Sec. 4. *Authority.* Agencies that conduct background investigations, including the Federal Bureau of Investigation and the Department of State, are authorized to conduct personnel security investigations in the United States when requested by a foreign government as part of its own personnel security program and with the consent of the individual.

Part 5 Review of Access Determinations

Sec. 5.1. *Determinations of Need for Access.* A determination under section 2.1(b)(4) of this order that an employee does not have, or no longer has, a need for access is a discretionary determination and shall be conclusive.

Sec. 5.2. *Review Proceedings for Denials or Revocations of Eligibility for Access.* (a) Applicants and employees who are determined to not meet the standards for access to classified information established in section 3.1 of this order shall be:

(1) provided as comprehensive and detailed a written explanation of the basis for that conclusion as the national security interests of the United States and other applicable law permit;

(2) provided within 30 days, upon request and to the extent the documents would be provided if requested under the Freedom of Information Act (5 U.S.C. 552) or the Privacy Act (3 U.S.C. 552a), as applicable, any documents, records, and reports upon which a denial or revocation is based;

(3) informed of their right to be represented by counsel or other representative at their own expense; to request any documents, records, and reports as described in section 5.2(a)(2) upon which a denial or revocation is based; and to request the entire investigative file, as permitted by the national security and other applicable law, which, if requested, shall be promptly provided prior to the time set for a written reply;

(4) provided a reasonable opportunity to reply in writing to, and to request a review of, the determination;

(5) provided written notice of and reasons for the results of the review, the identity of the deciding authority, and written notice of the right to appeal;

(6) provided an opportunity to appeal in writing to a high level panel, appointed by the agency head, which shall be comprised of at least three members, two of whom shall be selected from outside the security field. Decisions of the panel shall be in writing, and final except as provided in subsection (b) of this section; and

(7) provided an opportunity to appear personally and to present relevant documents, materials, and information at some point in the process before an adjudicative or other authority, other than the investigating entity, as determined by the agency head. A written summary or recording of such appearance shall be made part of the applicant's or employee's security record, unless such appearance occurs in the presence of the appeals panel described in subsection (a)(6) of this section.

(b) Nothing in this section shall prohibit an agency head from personally exercising the appeal authority in subsection (a)(6) of

this section based upon recommendations from an appeals panel. In such case, the decision of the agency head shall be final.

(c) Agency heads shall promulgate regulations to implement this section and, at their sole discretion and as resources and national security considerations permit, may provide additional review proceedings beyond those required by subsection (a) of this section. This section does not require additional proceedings, however, and creates no procedural or substantive rights.

(d) When the head of an agency or principal deputy personally certifies that a procedure set forth in this section cannot be made available in a particular case without damaging the national security interests of the United States by revealing classified information, the particular procedure shall not be made available. This certification shall be conclusive.

(e) This section shall not be deemed to limit or affect the responsibility and power of an agency head pursuant to any law or other Executive order to deny or terminate access to classified information in the interests of national security. The power and responsibility to deny or terminate access to classified information pursuant to any law or other Executive order may be exercised only where the agency head determines that the procedures prescribed in subsection (a) of this section cannot be invoked in a manner that is consistent with national security. This determination shall be conclusive.

(f)(1) This section shall not be deemed to limit or affect the responsibility and power of an agency head to make determinations of suitability for employment.

(2) Nothing in this section shall require that an agency provide the procedures prescribed in subsection (a) of this section to an applicant where a conditional offer of employment is withdrawn for reasons of suitability or any other reason other than denial of eligibility for access to classified information.

(3) A suitability determination shall not be used for the purpose of denying an applicant or employee the review proceedings of this section where there has been a denial or revocation of eligibility for access to classified information.

Part 6 Implementation

Sec. 6.1. *Agency Implementing Responsibilities.* Heads of agencies that grant employees access to classified information shall: (a) designate a senior agency official to direct and administer the agency's personnel security program established by this order. All such programs shall include active oversight and continuing security education and awareness programs to ensure effective implementation of this order;

(b) cooperate, under the guidance of the Security Policy Board, with other agencies to achieve practical, consistent, and effective adjudicative training and guidelines; and

(c) conduct periodic evaluations of the agency's implementation and administration of this order, including the implementation of section 1.3(a) of this order. Copies of each report shall be provided to the Security Policy Board.

Sec. 6.2. *Employee Responsibilities.* (a) Employees who are granted eligibility for access to classified information shall:

(1) protect classified information in their custody from unauthorized disclosure;

(2) report all contacts with persons, including foreign nationals, who seek in any way to obtain unauthorized access to classified information;

(3) report all violations of security regulations to the appropriate security officials; and

(4) comply with all other security requirements set forth in this order and its implementing regulations.

(b) Employees are encouraged and expected to report any information that raises doubts as to whether another employee's continued eligibility for access to classified information is clearly consistent with the national security.

Sec. 6.3. *Security Policy Board Responsibilities and Implementation.* (a) With respect to actions taken by the Security Policy Board pursuant to sections 1.3(c), 3.1(f), 3.2(b), 3.3(a)(2), and 3.4(c) of this order, the Security Policy Board shall make recommendations to the President through the Assistant to the President for National Security Affairs for implementation.

(b) Any guidelines, standards, or procedures developed by the Security Policy Board

pursuant to this order shall be consistent with those guidelines issued by the Federal Bureau of Investigation in March 1994 on Background Investigations Policy/Guidelines Regarding Sexual Orientation.

(c) In carrying out its responsibilities under this order, the Security Policy Board shall consult where appropriate with the Overseas Security Policy Board. In carrying out its responsibilities under section 1.3(c) of this order, the Security Policy Board shall obtain the concurrence of the Director of the Office of Management and Budget.

Sec. 6.4. *Sanctions.* Employees shall be subject to appropriate sanctions if they knowingly and willfully grant eligibility for, or allow access to, classified information in violation of this order or its implementing regulations. Sanctions may include reprimand, suspension without pay, removal, and other actions in accordance with applicable law and agency regulations.

Part 7 General Provisions

Sec. 7.1. *Classified Information Procedures Act.* Nothing in this order is intended to alter the procedures established under the Classified Information Procedures Act (18 U.S.C. App. 1).

Sec. 7.2. *General.* (a) Information obtained by an agency under sections 1.2(e) or 1.3 of this order may not be disseminated outside the agency, except to:

(1) the agency employing the employee who is the subject of the records or information;

(2) the Department of Justice for law enforcement or counterintelligence purposes; or

(3) any agency if such information is clearly relevant to the authorized responsibilities of such agency.

(b) The Attorney General, at the request of the head of an agency, shall render an interpretation of this order with respect to any question arising in the course of its administration.

(c) No prior Executive orders are repealed by this order. To the extent that this order is inconsistent with any provision of any prior Executive order, this order shall control, except that this order shall not diminish or otherwise affect the requirements of Executive Order No. 10450, the denial and revocation procedures provided to individuals covered by Executive Order No. 10865, as amended, or access by historical researchers and former presidential appointees under Executive Order No. 12958 or any successor order.

(d) If any provision of this order or the application of such provision is held to be invalid, the remainder of this order shall not be affected.

(e) This Executive order is intended only to improve the internal management of the executive branch and is not intended to, and does not, create any right to administrative or judicial review, or any other right or benefit or trust responsibility, substantive or procedural, enforceable by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

(f) This order is effective immediately.

William J. Clinton

The White House,
August 2, 1995.

[Filed with the Office of the Federal Register, 12:18 p.m., August 4, 1995]

NOTE: This Executive order was released by the Office of the Press Secretary on August 4, and it was published in the *Federal Register* on August 7.

Memorandum on Assistance to the United Nations Rapid Reaction Force in Bosnia

August 3, 1995

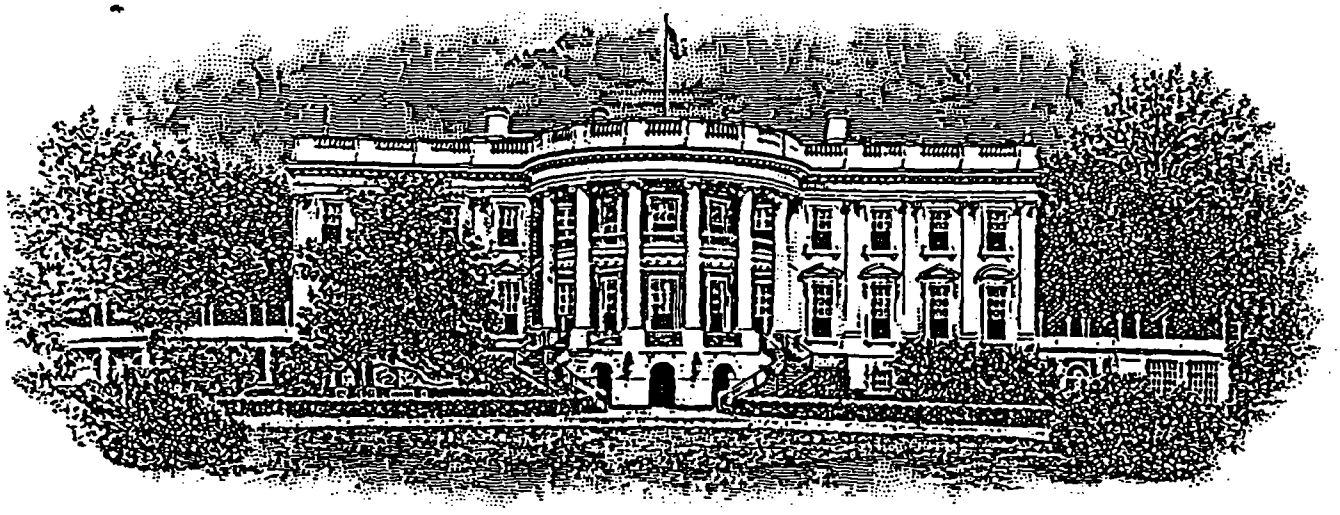
Presidential Determination No. 95–34

Memorandum for the Secretary of State and the Secretary of Defense

Subject: Determination to Authorize the Furnishing of Emergency Military Assistance to the United Nations for Purposes of Supporting the Rapid Reaction Force in Bosnia Under Section 506(a)(1) of the Foreign Assistance Act

Pursuant to the authority vested in me by section 506(a)(1) of the Foreign Assistance Act of 1961, as amended, 22 U.S.C.

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Col. Bailey

FAX NUMBER: 703-847-0890

TELEPHONE NUMBER:

FROM: Elizabeth Drye

TELEPHONE NUMBER: 456-5573

PAGES (INCLUDING COVER): 3

COMMENTS: For your review/edits. Please do by COB today and fax back to 202-456-7028. The report will go into OMB review Tomorrow or Wed.

703-847-0890

in libraries, community centers, schools, and around the world. Paper copies of all documents are at the Coordination and Information Center (CIC) in Nevada.

Making records accessible: DOE has summarized how to find its records in the publication, "Human Radiation Experiments: The Department of Energy Roadmap to the Story and the Records," published in February 1995. The list of experiments in that volume is updated and expanded in, "Human Radiation Experiments Associated with the U.S. Department of Energy and its Predecessors." The text of these documents is also available via the OHRE Homepage (http://www.ohre.doe.gov). DOE also has developed a one-day course on how and where to locate human radiation experiment and related historical records.

Understanding the record: DOE staff interviewed researchers and others possessing first-hand knowledge of the human radiation experimentation and therapy that occurred during World War II and the Cold War. The result is "Human Radiation Studies: Remembering the Early Years." This 29-part series comprises some 1,350 pages of transcripts. This series offers scholars and interested lay persons a vivid glimpse inside one of the most controversial chapters in our nation's postwar history.

The Department is currently developing a plan to fund an oral history project, conducted by a non-Federal institution, which will allow the subjects and their families to tell the story from their perspective. This project will provide a reminder of the importance of protecting individual rights, even in times of national security crisis.

The Department of Defense

Identifying Subjects: The Department of Defense (DOD) is searching records for members of the armed services who may have been experimental subjects. In particular DOD is seeking rosters of those who were treated experimentally or therapeutically with nasopharyngeal radiation. This effort is similar to an effort several years ago to identify those service members who were present at above-ground nuclear tests. (The full story of that effort was chronicled by the Defense Special Weapons Agency in DNA 6041F, "For the Record--A History of the Nuclear Test Personnel Review Program, 1978-1993," March, 1996, which supersedes DNA 6041F, August 1986.)

Please review

Making records accessible: DOD is preparing a guide similar to the DOE *Roadmap* that summarizes DOD involvement in human radiation experiments, describes the search process for the records of those experiments, and provides the result of the search. "The Department of Defense Report on the Human Radiation Experiments Records Search, 1944-1994" is planned for release ~~by the end of~~ in December 1996.

* check date

The National Aeronautics and Space Administration

National database: The National Acronautics and Space Administration

on early radiation research projects for which at least some of the names of research subject were known. These studies were chosen because of the possibility of contacting veterans or family members to encourage medical surveillance or submission of a compensation claim, if warranted. The expert committee did not identify any veterans who warranted special follow-up actions specifically because of their radiation exposure.

Nasopharyngeal Irradiation with Radium (NP) during Military Service: The Departments of Defense (DOD) and Veterans Affairs (VA) have been considering a large group that has attracted public attention: the members of the military who received NP irradiation during and immediately following World War II. Nasopharyngeal irradiation was considered accepted medical treatment at the time, ~~and records identifying individuals receiving this treatment are difficult to locate. DOD has found names of a few members of the service who received nasopharyngeal irradiation and has sent them a fact sheet about the therapy.~~

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

The VA and CDC held a satellite teleconference in September 1996 to provide health professionals information about this issue. Currently, veterans treated with NP radiation do not have special eligibility for VA care. The Administration has proposed legislation that would make veterans treated with NP radium eligible for the VA's Ionizing Radiation Program. The Administration will be resubmitting this legislative proposal in its 1997 legislative package for consideration during the first session of the 105th Congress.

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

Identifying Additional Subjects: DOE notified subjects of the plutonium and uranium injection experiments, or their

Please edit to suggest substantive language.

NP irradiation was considered accepted medical treatment during the cold war, ~~and many~~ individuals, including children

No executive
to - FUND

ACHRE Recommendations 15a and 15b:
Human Subject Protections
in Classified Research

October 9, 1996

AGENDA

1) Review ACHRE recommendations 15a and 15b.

2) Identify areas of continued disagreement.

3) Review existing IRB process for classified research and discuss outstanding issues.

Recommendation 15(a):

i) No waiver of informed consent in classified research. ✓

ii) Inform subjects of the identity of sponsoring agency. ✓ there are non-medical reasons for doing this research
Exec Director — [CIA Director] → General Counsel
Concern (counter-intelligence reason).

iii) Inform subjects that the project involves classified research. ✓

MGen Stofik
John Deutch
engaged in
early days.

Recommendation 15 (b):

Establish independent panel of nongovernmental citizens and representatives with necessary security clearances charged with determining:

1) scientific merit;

2) risks acceptable and benefits justify risks;

3) full disclosure and consent sufficiently voluntary;

4) whether subjects need security clearances and how to get clearances without compromising privacy and voluntariness

- Conflicts of interests
- Truly independent people that hold the necessary ~~of~~ clearances
The President's science advisor — can rule or convene Panel to rule

Call for Secty — convene a non-govt panel —

Head of Agencies has to

Reject a Complaint, & convene a —

panel.

Q's

- President's Commission for the Study of Ethical Problems — Exists? Statutory basis
  US Code 42 USC 300v(1)(b)

- CIA — "deception research" / polygraph —
  - would we want to identify intent

~~Cons~~

- VA — Compensation of injured human subjects.

DoD RADIATION EXPERIMENTS COMMAND CENTER
FACSIMILE LEAD SHEET

6801 Telegraph Road
Alexandria, VA 22310-3398
(703) 556-7300 (Verification)
(703) 847-0890 (Fax)

Date: 18 OCT 96

Time: 2:30

TO: Ms Elizabeth Dreyer

FAX: 202- 456-7028

VERIFICATION: 202-456-5573

FROM: Col Bailey

SUBJECT: ACHRE Critique

Total Number of Pages 8 Including Cover Sheet.

COMMENTS: Per our conversation

Sent By: Col Bailey

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

FACSIMILE COVER PAGE

To : **Claud Bailey**
From : Dr. David Egilman
Sent : 10/10/96 at 1:17:00 PM
Pages : 7 (including Cover)
Subject

just for laughs

Letter to the Editor Submitted for Publication

Title: The Emperor has No Clothes.

October 8, 1996

Carol Mason Spicer
Kennedy Institute Of Ethics Journal
Box 571212
Georgetown University
Washington, DC 20057-1212

Dear Ms. Spicer:

We found your issue of September 1996, on the President's Advisory Committee On Human Radiation Experiments (ACHRE) quite peculiar. First of all, as an ethics journal, we think it is important for you to make plain any possible conflicts of interest that might prevent the editors or writers of your journal from fairly evaluating a given topic.

Your journal is published by the Johns Hopkins University Press, which is owned by Johns Hopkins University. Johns Hopkins University conducted one of the largest of the human radiation experiments. During the course of the ACHRE meetings these experiments became a matter of public debate and litigation against the university was possible and may in fact have occurred. Your issue may be used to defend the university's position in this litigation. I think it was important for your journal to admit to this potential conflict.

After what must have been a thorough international search, your journal managed to find somebody to write a mildly critical analysis of the ACHRE report. However, you did not inform your readers of the fact that this writer, Tom Beauchamp, is married to Ruth Faden, the chairperson of the ACHRE committee. In addition they also share author's credit on a book which was used as the basis for much of ACHRE's discussion of ethical standards for retrospective judgment.

Like ACHRE, whose extensive "oral history project" failed to interview a single victim or victim relative, your journal omits the views of victims and serious critiques of ACHRE.

We think it would be reasonable to infer that Dr. Beauchamp's judgment may have been biased by the fact that he had and has conjugal relations and intellectual collaboration with the chairperson of the committee whose report he reviewed. At any rate, we think this possible source of bias should have been made known to your readers.

We add a few substantive comments here because we have written and will soon be publishing a longer critique of ACHRE:[1]

- Dr. Beauchamp supports his wife and co-author's committee report (ACHRE) by stating that one possible reason they made no judgments of culpability with regard to any of the individual perpetrators, was that they did not have sufficient evidence to condemn them. Perhaps the following statement by Dr. Eugene Saenger (one of the most prominent radiation researchers) will change his mind: "We have had two cases,

[1] Draft available at HTTP://www.brown.edu/Courses/Bio_Community_Health168C.

one at 150 and one at 200 rad. expire while manifesting the hematologic abnormalities of group III of the acute radiation syndrome." This statement is quoted verbatim from a 1962 memo to his funding agency entitled "An Appraisal of Human Studies in Radiobiological Aspects of Weapons Effects". Although they knew of the existence of this memo, his wife and co-author's committee (ACHRE) omitted this statement by Dr. Saenger and instead concluded that they could not tell if Saenger's radiation experiments had harmed anyone. Despite the title of Saenger's reports and the absence of any contemporaneous evidence of therapeutic purpose, Dr. Beauchamp's wife and co-author's committee failed to conclude, due to a "lack of evidence", that Dr. Saenger's had a military rather than therapeutic purpose. Dr. Beauchamp skirts this problem with the "innocent-until-proven-guilty" argument, thereby ignoring one of the key principles of the Nuremberg Code: it is the responsibility of the *researcher*, not the subject (or victim, as the case may be) to prove that ethical principles were followed.

- On a more humorous note, Ruth Macklin reviews some of the hilarious discussion (or rather, intellectual navel contemplation worthy of a Woody Allen movie) on the need for a government apology. We would only comment here that most non-full-time ethicists apologize to people for transgressions as trivial as getting in someone's way -- without demanding evidence of damage. The transcript of the discussion of apology (June 21, 1995) is even funnier than the version published in ACHRE -- which is much funnier than Macklin's sanitized version.[2] At one point Patricia King suggested that a criticism of any individual would be akin to "condemning the profession". When we heard this we wondered if Dr. King meant the profession of war criminal or the profession of medicine. It really was unclear from the discussion. We recommend the transcript of the discussion to the reader.

- Dr. Beauchamp fails to note the unique irony of his wife and co-author's committee's decision to continue the government cover-up of these experiments by not informing the victims of the fact that they had been unknowingly used as human guinea pigs in government sponsored research. Dr. Beauchamp's wife and co-author's committee's own criteria stated that people were to be considered 'harmed', and therefore eligible for notification, apology as well as financial compensation, if there was evidence of "active government cover-up". Dr. Beauchamp's wife and co-author's committee has itself has now implemented an active government cover-up: Therefore, all of the victims whose existence the government is aware of and who have not been informed of their prior unwitting government service now qualify for notification, apology and compensation according to the committee's own criterion. We never understood why an *active* cover-up would trigger an apology and a *passive* one would not, since they both seem to result in the same impact on the victim. But an apology is not a very great intervention. Ironically, even if we were to rely on the committee's own bizarre distinctions, ACHRE's active decision to not notify victims is itself evidence of an "active" government cover-up and the government now has an obligation to notify, apologize and compensate all victims of whom it is aware.

  We note that it takes a big man/woman to admit a mistake and apologize. The government is a big institution and has survived a formal apology. The President, ignored the intellectual navel contemplation of the ACHRE committee, and apologized as his first act upon receiving the ACHRE report. The republic is still standing and this apology has strengthened not weakened our country.

- Dr. Beauchamp fails to note another example of his wife and co-author's committee's excuse-mongering. ACHRE argued that since it might be difficult to determine the names of all the victims, the government should not notify *any of the victims*, including those whose names they knew. ACHRE also argued that notification might cause psychological harm but made no effort to examine ways to mitigate this harm. A variety of psychological counseling mechanisms, programs and projects were suggested to the committee and were ignored. ACHRE cannot and did not claim credit for the "fear of induction of psychological harm" excuse, the original perpetrators first used this excuse to justify the original cover-up.

- Perhaps because of his conjugal and intellectual relationship with the chairperson of ACHRE, Dr. Beauchamp accepts the ACHRE's distinction between the "wrongness of actions" and the "culpability of agents" (p. 252 - 253 of your journal). Although no ethical reference is provided for this excuse we call

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[2] All ACHRE transcripts can be linked from my web site HTTP://www.brown.edu/Courses/Bio_Community_Health168C.

this the construct. He states: "From the fact that an action was wrong or that someone was wronged by the action does not follow that the agents who performed the actions can be fairly blamed, censured or punished. This distinction is of the highest significance and is rightly given a prominent position in the committee's ethical framework." Beauchamp's righteous admiration here is warranted not only by the sight of his wife's committee's good work, but by an even greater delight in the excellence of *his own* scholarship. While some of your readers may think that "this distinction of the highest significance" is derived from their teenagers excuse that "I knew it was wrong but everybody was doing it" or from biblical reference to the preaching of "hate the sin, love the sinner", the passage of ACHRE he cites in your journal references the book he co-authored with wife and ACHRE chairperson Ruth Faden. Perhaps Dr. Beauchamp omitted this reference to his own work out of a false sense of modesty. We take this opportunity to credit him.

- The excuse "My dog ate my homework" has a better foundation in the history of 20th century ethics, and is a better established principle, and follows more closely from Biblical teachings and common sense than Dr. Beauchamp's, and his wife and co-author's committee excuse. Even the Nazi experimenters and the Nazis themselves admitted that some of their actions were wrong and blamed individuals (their superiors). They said they did it because they were ordered to, they were in a war, and they had to follow orders. Of course, Dr. Beauchamp and his wife and co-author's committee could not use this excuse for the American radiation researchers. No one ordered these scientists to conduct unethical research, we were not in a war, and they were not following orders. While Dr. Beauchamp concluded that *some* of the perpetrators were perpetrators, he accepted this bizarre excuse which in essence states that if other people were doing something known to be wrong at the time of commission, it might be wrong, but the perpetrators may be blameless. Dr. Beauchamp and his wife and co-author's committee both seem to forget that the Nazi experiments were punished by criteria written *after the fact*, at a tribunal (Nuremberg) which was *unprecedented* in the history of German or international law. And since the US experiments all occurred after Nuremberg, they were actually *worse* from an ethical and moral standpoint than the Nazi experiments. The US researchers who conducted them had the benefit of the Nuremberg, AMA, and Helsinki codes and had viewed the German experience.

Sincerely yours,

David Egilman MD, MPH
Clinical Associate Professor Department of Community Health Brown University

Statements Of Conflicts Of Interest: David Egilman, MD, MPH

- Financial.

I receive no money from any institution, lawyer, victim or perpetrator of the government radiation experiments.

- Professional

I was a member of the University Cincinnati faculty as a clinical instructor in the Department of Family Medicine in 1984 and 1985. One of the experiments was conducted by the University of Cincinnati Since I have been highly critical of the University of Cincinnati experiments, I do not believe this to be a substantive conflict that has impacted in any way on any of my opinions.

In 1995, the public relations department of the University of Cincinnati contacted several reporters and spread rumors that I was a communist. This included reporters from the Cincinnati Inquirer and the New York Times. But since 1994 is not 1954, the red baiting did not have much impact, and I think a reasonable reader could infer that this comical episode did not substantively change my opinions, particularly since most of my opinions were on record long before the red baiting began. Besides providing some humor and enhancing my credibility and prestige with the reporters, this action did not materially impact on my work. I report this, however, because some people may reasonably suspect that my accusatory comments and activities in relation to the University of Cincinnati radiation experiments were somehow stimulated as a result of their red baiting.

- Intellectual

My father was a victim of German concentration camps and most of my relatives were killed during World War II by Nazis. I have a strong bias against Nazis, Nazi experiments, and Nazi-like experiments. I define "Nazi-like experiments" as those designed to provide information for people other than the ones being experimented on, and that victimize or dehumanize the experimental subjects, or violate the published codes of medical ethics that have been in effect since the German concentration camps were put out of business.

- Sexual

I have not sexual relations with or had sexual advances rejected by any member of ACHRE. I am not married to any member of ACHRE or Johns Hopkins or Georgetown.

Statements Of Conflicts Of Interest: Wes Wallace, BS

- Financial

I am employed by David Egilman, MD, MPH, and work for him in the capacity of research assistant. As his paid assistant it is in my interest to agree with his judgment on matters of professional importance.

I am not now nor have ever been receiving money from any government, academic or other institution connected with the radiation experiments.

- Professional

I have never taught at nor attended Johns Hopkins University or the University of Cincinnati. I have never myself been involved in radiation research, having never risen beyond the undergraduate level, where my studies were unrelated to human radiation research.

- Intellectual

Although I do not oppose the practice of sex out of wedlock, I disrespect its intellectual equivalent: I am strongly opposed to philandering, finessing and surreptitious fiddling in matters of complex importance. I believe the natural place to express our creaturely love of one another is in the privacy of our homes. The impulse to dignify the loved one with undue professional accomplishments is in my opinion a misdirection of sexual and/or emotional energy. As a published poet, I feel certain this impulse can find avenues of expression less fraught with consequences than the pages of an ethics journal.

October 7, 1996

Carol Mason Spicer
Kennedy Institute Of Ethics Journal
Box 571212
Georgetown University
Washington, DC 20057-1212

Dear Ms. Spicer:

I have enclosed a statement of potential conflict of interest and a letter and commentary to Volume 6, no. 3, September 1996 edition of the Kennedy Institute Of Ethics Journal.

While I did note that your journal was printed on acid-free paper, I did not see any information or instruction to authors on a statement of potential conflicts of interest.

I found this omission to be somewhat startling for an ethics journal, but after reading the issue I understood why you maintain this unethical policy.

If you decide to publish my letter and a few of my comments on some of the findings of your authors, I recommend that the accompanying statement of my own potential conflicts of interest also be published. Because your journal has no existing policy to decide whether a potential source of conflict should or should not be mentioned, I think the readers ought to decide for themselves whether a potential conflict is substantive or not.

In addition, I also enclose a statement of endorsement written by my wife. I am unfamiliar with the conventional practices of the ethics-journal editors' community, but since you had Dr. Faden's husband review her committee's work I can only surmise that a letter of evaluation by a spouse or lover is part of your journal's review process. This statement is not in any way meant to suggest that I approve of this practice. It is intended only as a formality to comply with what appears to be the policy of your journal, or perhaps the "standard practice" of your colleagues.

In reviewing Dr. Beauchamp's article I noted seven references. Two of these were cites to the reports he reviewed, two were newspaper articles and three were references to other articles published in the same issue. I have tried to follow what appears to be your policy of publishing unreferenced ideas facts and comments although full citations and documentation can be found at my referenced web site.

Sincerely yours,

David Egilman, MD, MPH
Clinical Associate Professor Department of Community Health Brown University

Naso Pharangyal —

Follow-up research - enough names as we can - socials — go to Cincinatti and pull medical records — get enough people to do Epi / Cohort Studies. w/VA, CDC

Notifications — Stuart Farber — relative ages 20-20 yrs old; Now 72 years old. —

6 month window — to get it done

2.5 million people

Experimental Protocol —

Factual record - was an experiment

Extent that it causes harm —

evidence by Advisory Cmt - no harm —

Names, SSN #'s — minimum — do a cohort study

- Notifications / Compensation

- VA legislation registry

Total # experimented on is ~8000
Army-Corp 6000 < Did find rosters at
Navy – 1,600 ~1,700

Sen. Glenn's office – pushing for notification

St. Louis rec sent 20 records. –
log book gives name, date – but need social

< Did find more Navy rosters at national records ~ 2000+
Croton ~1611 732 were corp of study.

Doc Soper committed to following up –

TO DO Radiation

Diane – do following mtg
Elizabeth – get NP stuff to Molly
Diane – call DOJ –
– Regulation and Legislation
Diane – EO – Draft from HHS. –

Elizabeth – HHS team Thurs –
WH Counsel – assigned to task –

Elizabeth – mtg w/ Kelly Kirkpatrick

– Radiation Experiments –
Evidence – what to do with add'l finds
– Bailey –
– Decision –

KELLY S. KIRKPATRICK
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8 AP 07-29-96 16:51 EST 50 Lines.
Group Takes Look At Children's Programming<
By LAUREN A. BORSA Associated Press Writer

HARTFORD, Conn. (AP) Connecticut's television stations have a chance to lead a new, national push toward improving programming for children, a lawmaker said Monday after meeting with the state's industry representatives.

``I'd love, through this group, to make Connecticut into a model of what local TV stations can do to improve the quality of children's television,'' said U.S. Sen. Joseph Lieberman.

Lieberman, D-Conn., held the meeting the same day President Clinton announced an agreement with the television industry that requires three hours of educational shows a week for children.

The Federal Communications Commission must approve the rule for it to take effect.

The discussion in Hartford touched on several issues, including the impact television has on children and the children's shows now offered. No consensus was reached on what can be done to improve programming, but Lieberman said he does want to meet again.

``I am not here to point fingers today,'' Lieberman said during his meeting at the Legislative Office Building. ``I love television. I'm a child of the television age.''

Representatives of several Connecticut television stations discussed the programs their stations offer children and their continuing efforts to do so.

Gary E. Knell, senior vice president of corporate affairs for the Children's Television Workshop, the creators of ``Sesame Street,'' said children are exposed to more than just television.

``Our kids are getting battered by media from all over'' including the movies and print, he said.

State education chief Theodore Sergi said he would like to see children reading more. ``We want young people to be more active in their learning,'' he said.

Joanne Whitehead, viewer services coordinator for Connecticut Public Television, said broadcasters need to form a strong partnership with parents, ``so that we teach parents and children alike to be more selective.''

Ayesha Wynter, 12, of Hartford, also attended the meeting, sitting in the audience with a group of youths from a Hartford YMCA program.

She said there is a need for more educational programming, but also noted that the work cannot end there.

``How are we going to get more kids to watch educational programming?'' she said to the panel.

144 AP 07-30-96 08:00 EST 65 Lines.
Navy Finds Log Identifying 1,611 Submariners Exposed to Radium<

ALBUQUERQUE (AP) A long-missing naval research log identifying 1,611 subjects of human radiation experiments has been discovered at the Navy submarine base in Groton, Conn., a newspaper reported.

The Albuquerque Tribune, which won a Pulitzer Prize for a 1993 series on human radiation experiments, reported Monday

that researcher Henry Haines had kept the log, which the Navy long had said either didn't exist or couldn't be found.

``We are heartened by this that we now have the log, that we have actual names,'' said Army Col. Claud Bailey, heading a Defense Department investigation of the records found by the Navy.

The experiments were performed at the Navy submarine base in Groton, Conn., where the log was found, the newspaper said. It said the log makes clear these were subjects of research, not merely medical treatment, as the military had claimed.

``There is no doubt,'' Bailey said. ``As a matter of fact, if you look at the document, the words show it was research and, in fact, it says it was an experiment.

``It established the protocol and specifies the doses they got and when they were given,'' he said. ``It's the process, the records and the details of how the scientists went about doing their research.''

Stewart Farber, a Rhode Island medical-radiation physicist who was among the first to raise questions about the Navy experiments, said it's now up to the military to act on the information.

``I think this (discovery) is a very big development,'' Farber said. ``Now the proof is in what they do from here on.''

Bailey told the newspaper that the Pentagon would go all out to track and contact every one of the 1,611. He said the log includes service numbers that may help trace the people.

The experiments involved giving nasopharyngeal radium treatments, which patients contend were unproven and experimental, for such ailments as the inability to adjust to rapid pressure change such as would be experienced in submarines. Radium-tipped rods were inserted into the nostrils for several minutes at a time in an effort to shrink tissue near the eustachian tubes.

The National Centers for Disease Control and Prevention said last year that between 500,000 and 2.5 million Americans received nasal radium treatments for everything from persistent nasal infections to deafness.

Some have questioned whether radium caused such health problems as tumors, endocrine and autoimmune disorders, miscarriages and brittle teeth.

Bailey said veterans should be notified if they're included in the log so they can consult physicians and seek medical advice and care if needed.

His recommendation that the patients be contacted contradicts the Presidential Commission on Human Radiation Experiments, which said no medical benefit could be gained from notification.

``I know what they said, and I know this is contentious in some circles,'' Bailey said, ``but we believe certain people should be notified because they were exposed in certain events like these.''

Bailey said he believes the government is beginning to grasp the significance of the problem, which Farber said dwarfs all other documented human radiation experiments combined.

Employees Banned To Gamble At Foxwoods To Get Chance At Neighboring Casino<

LEDYARD, Conn. (AP) Foxwoods Casino Resort employees who are prohibited from gambling where they work will soon be able to place their bets at a neighboring casino.

On Monday, John B. Meskill, executive director of the state Division of Special Revenue said that Foxwoods employees will be allowed to gamble at the Mohegan Sun Casino which is scheduled to open in October.

``I looked through the Mashantucket gaming procedures and the state statutes, and I don't find anything that would preclude Foxwoods employees from wagering at the Mohegan casino," he said.

Foxwoods' policy, which prohibits licensed employees from gambling there, affects about 11,000 people. The purpose of the ban is to prevent collusion among employees.

Employees of Connecticut's parimutuel facilities, two dog tracks and a jai alai fronton, are prohibited by state regulations from betting where they work, but are allowed to gamble elsewhere.

The Mohegan Sun Casino in Montville, which is being built about 10 miles from Foxwoods, will adopt a similar policy when it opens.

``The gaming not only has to be fair and honest. It has to be perceived that way by the public," said Francis M. Mullin, director of regulations for the Mohegans.

The casino, owned by the Mohegan Indians, plans to employ 4,500 to 5,000 people.

In addition to Mohegan employees, he said, Mohegan tribal members and their families will be prohibited from gambling at the Sun casino. But tribal family members will be allowed to play bingo because the game is so tightly controlled, he said.

At Foxwoods, which is owned by the Mashantucket Pequots, tribal members can gamble as long as they are not members of the tribal council, directors of Foxwoods or casino employees.

In a memo earlier this month, Foxwoods President G. Michael Brown told employees they are free to bet at the new casino.

``Have fun but don't lose your shirts," he wrote.

BC-CT--Day Ahead, TUESDAY, July 30, 1996<

HARTFORD Video conference linking Saint Francis Hospital and Medical Center and Hartford Hospital to mark implementation of new computer network that will link the hospitals' obstetrical facilities. 8:30 a.m. Seery Board, St. Francis Hospital, 114 Woodland St. or 5-South Labor/Delivery Suite, Hartford Hospital, 80 Seymour St. Contact: 714-4511 or 545-2160.

HARTFORD Boston Celtics to hold Summer Jam and basketball clinic with Rick Fox and Eric William. 9 a.m., Willie Ware Community Center, 697 Windsor St., 12:30 p.m. Main St. Market. Contact: 986-7592, 854-8003. Rain sites have been scheduled at the YMCA, 160 Jewell St.

HARTFORD Attorney General Richard Blumenthal and Consumer Protection Commissioner Mark Shiffrin to hold news conference on settlement in lawsuit against the maker of a product marketed as a hearing aid, 12:30 p.m. Attorney General's

Office, 55 Elm St. Contact: 566-8239 or 566-4894.

NEW LONDON Vice Adm. Albert Herberger, administrator of the United States Maritime Administration will join U.S. Rep. Sam Gejdenson, tribal chairman Richard Hayward and other officials for the keel laying for Sassacus, a high-speed ferry, 10 a.m. Pequot River Shipworks, 18 Eastern Ave. Contact: 572-6572.

HARTFORD State Sens. Toni Harp, D-New Haven, and Edith Prague, D-Columbia, will hold a news conference with doctors and members of AARP to celebrate the 31st anniversary of Medicare. Besides celebrating the program, they will criticize Republicans for threats against the program, 12:30 p.m., outside the state Capitol. Contact: Donnie Fowler, 278-5454.

HARTFORD The NHL's Hartford Whalers to hold news conference, 1 p.m. Director's Suite, Hartford Civic Center. Contact: Chris Brown, 728-336 ext. 355.

Tomasso Construction Denies Willful OSHA Violation<

NEW BRITAIN, Conn. (AP) The George A. Tomasso Construction Corp. has denied it willfully violated safety rules at a construction site.

The company said Monday it plans to talk over the allegation with the Occupational Safety and Health Administration, said Jay Malcynsky, court-appointed conservator and acting president of the company.

OSHA last week alleged Tomasso willfully violated safety rules by failing to properly secure a trench and failing to provide a ladder or other means of escape for workers in case the trench caved in.

Malcynsky said Tomasso is conducting an internal investigation of the allegation, and plans to talk it over with OSHA.

``Nothing in what we've discovered so far would indicate if a violation took place, it was willful in nature,'' he said.

OSHA has proposed a $49,500 fine.

Malcynsky said the allegation had nothing to do with Tomasso's recent financial troubles. In September, the company suspended 19 state road projects and laid off most of its workers.

Colonel favors notifying sub students treated with radium

KAD

Pentagon undecided about how to proceed

By ROBERT A. HAMILTON
Day Staff Writer
7/31/96

The deputy director of the Pentagon's Radiation Experiments Command Center said he will urge that submariners who received a controversial nasal radiation treatment be notified of the potential for health effects.

Col. Claud Bailey said a medical log discovered at the Naval Submarine Base in Groton earlier this year identifies 1,611 people who received the treatment as students at the submarine school in the 1940s and '50s.

But Pentagon spokesman Bryan Whitman said the Department of Defense has not decided how it should proceed, and an analysis of the log is continuing. "I can't speculate on what the next step will be, but we're definitely committed to pursuing this," Whitman said.

The Navy announced in May that the log had been found at the Naval Submarine Medical Research Lab at the base, although at the time it was said to list more than 400 names; Bailey said it provides links to hundreds more subjects.

Whitman declined to comment on whether the log contains sufficient information to track down all 1,611 people who received the treatment.

"I can't get into exactly what the log says," Whitman said. "We are investigating the contents of the log, and will pursue it with some vigor."

Treatments not tests

Bailey said the records also show there was no attempt to use the submariners as test subjects to determine the safety of the radiation treatments, as some critics have suggested.

The research being conducted at the base was to determine if a civilian process of shrinking nasal tissue with radiation could be used to treat pressure-induced ailments in the ears of submariners, Bailey said.

"The Navy was not trying to determine if these treatments were dangerous, but whether the treatments could be used for (nasal-related ailments)," Bailey said. "As far as whether it was considered even potentially harmful to the soldiers and sailors, it was not. The report indicates that the procedure was safe."

After World War II, and until the 1960s, physicians often used small amounts of radium to burn off excess tissue causing problems in the inner ear. The practice became common among submariners and Air Force flight crews.

Studies have been inconclusive at proving ill health effects, a conference at Yale University concluded last year. The U.S. Centers for Disease Control has said while there is insufficient evidence to warrant tracking down patients who received the procedure, people who know they received the treatment should tell their doctors.

Critics of the procedure, however, contend that there is enough evidence of ill

See COLONEL, page B2

Dr. Kelly Kirkpatrick
FYI

Colonel urges notifying patients

From B1

health effects, such as head and neck cancers, that a large scale study should be conducted, and the former submarine school students could form the basis of such a study.

The Navy has in the past said the students would be difficult to track down because there were no records, although the discovery of the log could remove that barrier. An additional problem, however, is that many records from that era were lost in a warehouse fire in St. Louis.

Also at issue in the past is whether the Navy knowingly put people at risk to test radiation treatments. The Navy contends that the treatments were accepted practice at the time, and the research at the school would be akin to studying whether Tylenol or aspirin works better on a headache today.

"Looking at the log, it is clear in my mind this was an experiment," Bailey said. "But the debate is, at what point did this become a normal, therapeutic treatment," he said, and the report indicates that it was considered therapeutic in the civilian community before the Submarine Base trials began.

Navy finds the names of radiation 'guinea pigs'

By Lawrence Spohn
TRIBUNE REPORTER

The Navy has found an experimenter's log book that names 1,611 submarine students who were exposed to high doses of radioactive radium more than 50 years ago, a military officer says.

"We are heartened by this, that we now have the log, that we have actual names," Army Col. Claud Bailey said Friday. Bailey is heading a Department of Defense investigation of the records found by the Navy.

The log, which the Navy had long said either did not exist or could not be found, was kept by radiation experimenter Dr. Henry L. Haines.

The students were the first of an estimated 14,000 to 20,000 American military personnel who got what some have called "the treatment." Radium-tipped rods were inserted up their noses as an experimental treatment for certain ailments.

He did the experimental treatments at the Navy submarine base in Groton, Conn., where the log was recently discovered during recent renovations.

"I think this is a very big development," said Stewart Farber, the Rhode Island health-radiation physicist who first raised questions about the Navy experiments. "Now, the proof is in what they do from here on."

Although many of those exposed may be dead or very old, Bailey said, the Department of Defense is going all out to try to contact them because they may be at risk for head and neck cancers.

The discovery makes it undeniable that the military conducted medical radiation experiments on its personnel. The military had previously claimed that nasal pharyngeal irradiation was a common medical procedure.

"There is no doubt," said Bailey, who is deputy director of the DOD's Radiation Experiment Command Center in Alexandria, Va.

"As a matter of fact, if you look at the document, the words show it was research, and in fact, it says it was an experiment.

"It established the protocol and specifies the doses they got and when they were given. It's the process, the records and the details of how the scientists went about doing their research."

The so-called "lost guinea pigs" were the first of an estimated 14,000 to 20,000 American military personnel who ultimately got what some have called "the treatment."

Radium-tipped rods were inserted up their noses for several minutes at a time to deliberately damage tissue. It was an experimental treatment for certain ailments, including the inability to adjust to rapid pressure changes such as in submarines and airplanes.

The experimental subjects are among as many as 2.5 million Americans who got nasal

Please see EXPERIMENTS

EXPERIMENTS *from A1*

radium treatments for everything from persistent nasal infections to deafness. Some argue that acceptance of the treatments was based upon the touted success of the military experiments.

One medical study of adults who got nasal radium as children found a three- to fourfold increase in head and neck cancers and a strong association with thyroid disease.

Bailey said the log contains service numbers that can be used to check individual medical-service records and perhaps to locate those exposed.

"We're going to do everything we can to see if they can be identified and contacted," Bailey said. "We're going to go out and do our damnedest to leave no stone unturned."

If at all possible, veterans who were exposed should be notified so they can seek medical advice and care if needed, Bailey said.

Contacting them would directly contradict the recommendations made last year by the much-criticized Presidential Commission on Human Radiation Experiments.

The commission argued that even if individuals could be identified and were still alive, no medical benefit would be gained by notifying them because there is no successful treatment for brain cancer.

"I know what they said, and I know this is contentious in some circles," Bailey said. "But we believe certain people should be notified because they were exposed in certain events like these."

Bailey said Farber's original estimates on 20,000 servicemen getting nasal radium is close to the mark.

Farber also originally projected conservatively that 200,000 to 400,000 Americans might have received the treatment. Last year, the Centers for Disease Control and Prevention estimated that between 500,000 and 2.5 million people probably got it.

The CDC has announced it will conduct a national satellite video conference Sept. 5 to explore the medical and research issues of nasal radium treatments for government agencies, doctors and medical centers, including veterans hospitals and treatment centers.

Bailey said he believes the government is beginning to grasp the potential significance of the problem, which Farber long has argued dwarfs all of the other documented human radiation experiments combined.

Because so much is known about the exposures the submariners got, they could be the subject of a remarkable case study, Farber said.

July 29, 1996

N E W S R E L E A S E

U.S. SENATOR JOE LIEBERMAN
CONNECTICUT

PRESS OFFICE: (202) 224-4041 or (202) 224-9965 (after 6 p.m.)
Jim Kennedy (202) 583-5697 (H) Kathie Scarrah (703) 845-2874 (H)
Actuality Line : (202) 224-6095

FOR RELEASE

July 20, 1994

Lieberman Urges President To Order Study Of Radium Treatments

Senator Says New Evidence Describes Experimental Nature Of Treatments; Data Indicates Abnormal Cancer Rate

WASHINGTON, DC -- In a letter to President Bill Clinton, Senator Joe Lieberman says newly discovered documents describe radium treatments given to more than 7,000 military personnel from the 1940's to the 1970's as "experimental," and one study states that people receiving the treatments may experience brain cancer at rates comparable to those of all cancers among Hiroshima and Nagasaki survivors.

Citing the "disturbing new data," Senator Lieberman is urging the President to order an epidemiological study of those who received the radium treatments. Senator Lieberman said the treatments should also be made part of the jurisdiction of the Human Radiation Interagency Working Group, which President Clinton established to examine other experiments involving radiation exposure to human beings.

Thousands of military personnel, particularly those who served on submarines and in aircraft, and civilians underwent radium nasopharyngeal irradiation in an effort to treat middle ear lesions caused by failure to equalize pressure between the middle ear and the atmosphere.

(more)

The treatments were first given by doctors at Johns Hopkins in the late 1920's, and medical papers indicate that the Armed Services began investigating the technique in 1942. In a 1945 paper, Navy physicians describe what they term their "experiments" to develop a reliable radium treatment since, as they state, "we had a rich source of material." The "material" refers to 732 Navy personnel who were involved in the experiments. According to a medical journal published in 1945, similar experiments were conducted on 6,881 Army Air Force personnel.

The treatments involved sticking 50 milligrams of radium-226 up a patient's nose and into the nasopharyngeal orifice in an attempt to "burn out" adenoid and lymphoid tissue. "The apparent short-term success of this treatment led to its application on large numbers of Armed Services personnel," Senator Lieberman said. It has been estimated that at least 10,000 Navy personnel, 25,000 Army Air Force personnel, and 10,000 family members of military personnel were treated by military physicians. After World War II, the procedure was used on civilians, with some reports of at least 200,000 individuals, mostly children, receiving radium treatments through 1974.

Senator Lieberman said the Submarine Survivors Group, a private organization of citizens investigating the radium treatment issue, has identified a 1982 study in the "Journal of the National Cancer Institute" that concludes there has been "a statistically significant overall excess of malignant neoplasms of the head and neck among exposed subjects." Using that study, the Submarine Survivors Group states that the number of excess cancer deaths between those who underwent radium nasopharyngeal irradiation and those who were exposed to the atomic bombs in Japan appear to be comparable.

In his letter to President Clinton, Senator Lieberman states, "Your administration has done groundbreaking work on opening long closed doors to bring to light information on radiation experiments by the government. Those veterans who served as subjects in the program to develop the radium nasopharyngeal irradiation treatment, together with the individuals who underwent this radium treatment after the initial Armed Services experiments, deserve to know if their health is at risk and, if so, what steps they should take to minimize that risk." Senator Lieberman's letter to President Clinton is the latest in a series of letters he has sent to various Administration officials about the radium treatment issue, including Veterans Affairs Secretary Jesse Brown, Health and Human Services Donna Shalala, and Centers for Disease Control Director David Satcher.

N E W S R E L E A S E

U.S. SENATOR JOE LIEBERMAN
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FOR RELEASE

July 30, 1996

Lieberman Shocked To Learn Radium Treatments Were Experimental

Washington, D.C. -- Senator Joe Lieberman today said he was shocked to learn that a Department of Defense investigator has uncovered information indicating that nasal radium treatments performed on military personnel in Connecticut and elsewhere were experimental.

"This is an absolute outrageous development," Senator Lieberman said. "We have a moral obligation to find these veterans, notify them of the potential problem, apologize to them and urge them to see their doctor to determine if they have any health problems related to their radium treatments."

Senator Lieberman has been actively involved with this issue, urging the Navy to identify patients treated by Dr. Henry Haines in the mid 1940's. Earlier this year, the Navy discovered a log containing names of military personnel and civilians treated by the Connecticut doctor. A recent investigation of the logs uncovered the experimental dosages given to patients and indicated the treatment was for research.

In 1994, Senator Lieberman, a member of the Senate Armed Services Committee, held a congressional hearing and fought for a VA study of veterans who underwent radium treatments to correct ear problems caused by rapid ascents in submarines. The treatments were designed to "burn out" adenoid and lymphoid tissue, however some evidence indicates the treatments may lead to cancers in the head and neck.

"We ought to learn from this and make sure it never happens again," Senator Lieberman said. "This was a sad chapter in our nation's history."

-- 30 --

THE WHITE HOUSE
OFFICE OF DOMESTIC POLICY

CAROL H. RASCO
Assistant to the President for Domestic Policy

To: ~~Q Citro~~
(2) Diane Ellis CC

Draft ~~response for POTUS~~ and forward to CHR by: Carol - FYI Diane and

Draft response for CHR by: I have been working

Please reply directly to the writer (copy to CHR) by: w/these folks. I'm pleased about the tone

Please advise by: of this letter - Gibbons

Let's discuss: has been good about

For your information: giving them as much

Reply using form code: as he can given

File: consistent with his

Send copy to (original to CHR): goal of a solid

Schedule ? : ☐ Accept ☐ Pending ☐ Regret

Designee to attend: Committee Process

Remarks: - Ellis

AUG - 9 1996

FAX TRANSMISSION

TASK FORCE ON RADIATION AND HUMAN RIGHTS
7006 Carroll Ave., Suite 206
Takoma Park, MD 20912
Ph: 301-891-3992 *Fax: 301-270-3460*

To: MS. Carol Rasco **Date:** August 9, 1996

Fax #: 202-456-7028 **Pages:** 3 , including this cover sheet.

From: Gwendolyn Cloud

Subject: National Bioethics Advisory Commission

COMMENTS:

I thought you might like a copy of our letter to Dr. Gibbons. We look forward to continuing with you in the near future.

* If all pages are not received or if there are any other problems, please call 301-270-3887.

Task Force on Radiation and Human Rights

Washington D.C. Office:
National Committee for Radiation Survivors
6935 Laurel Avenue, Takoma Park, MD 20912
Tel: (202) 775-8786 Fax: (301) 891-3992

July 26, 1996

Dr. John H. Gibbons
Assistant to the President
for Science & Technology
Office of Science & Technology Policy
Washington, DC 20502

Re: National Bioethics Advisory Commission

Dear Dr. Gibbons:

We want to thank you for providing us with the background information on the recent appointments to the National Bioethics Advisory Commission. We also thank you for having earlier provided us with information pertaining to the OTA's utilization of stakeholder advisory panels under your directorship of that office.

As has been mentioned to members of your staff, we are interested in pursuing establishment of an NBAC radiation experiment victims/survivors' stakeholder advisory panel. We note that the NBAC charter issued July 19th appears to authorize the use of such panels. We also understand that the decision to establish such a panel for the radiation experiment victims/survivors is nevertheless within the discretion of the Advisory Commission.

We would like to pursue this matter expeditiously, and for that reason request your assistance in arranging a meeting for the Task Force Executive Committee with Dr. Harold Shapiro, at his earliest convenience.

In closing, we request copies of the *curricula vitae* for each of the recently-appointed members of the National Bioethics Advisory Commission. We also wish to express our appreciation for your willingness -- and that of your staff -- to find constructive solutions to the concerns of our membership that have been raised.

Sincerely yours,

Acie Byrd, Jr.
Task Force Executive Committee

Gwendon Plair, Ph.D.
Task Force Executive Committee

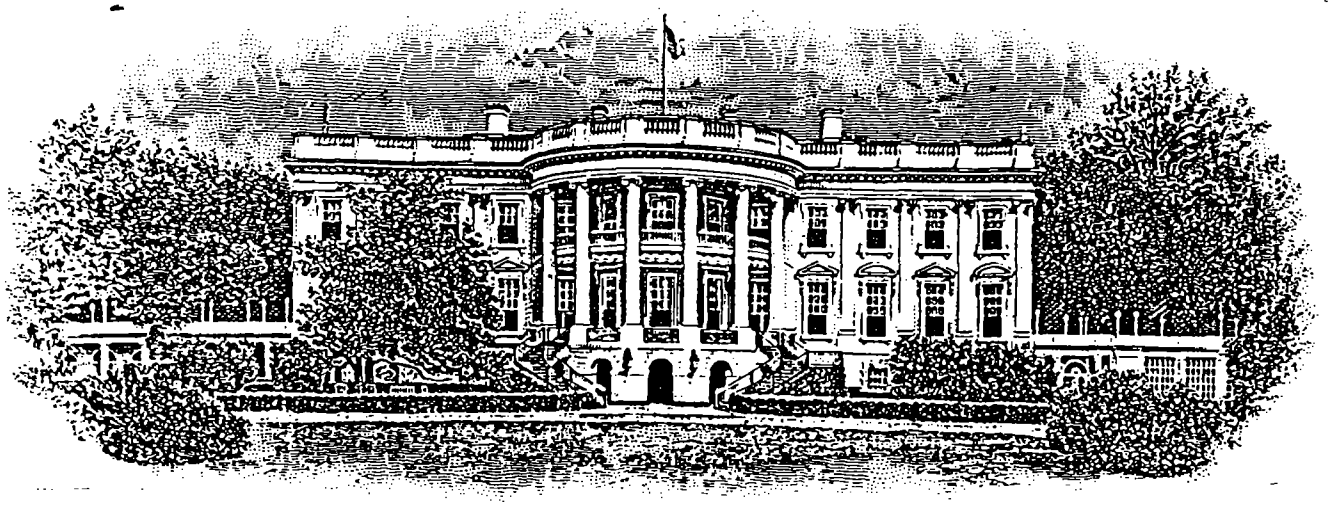
E. Cooper Brown
Task Force Executive Committee

P.S. Please note the new address for the Task Force's Washington office:

Task Force on Radiation & Human Rights
7006 Carroll Avenue, Suite 207
Takoma Park, MD 20912
Phn. No. (301) 891-3990 @ 3992

cc. Senator Ted Stevens, Chairman
Senate Committee on Governmental Affairs
Senator John Glenn
Senate Committee on Governmental Affairs
Secretary Hazel O'Leary
Department of Energy
Secretary Donna Shalala
Department of Health & Human Services
Ms. Carol Rasco, Chair
Domestice Policy Council

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Gordon Soper

FAX NUMBER: 703-695-0476

TELEPHONE NUMBER:

FROM: Elizabeth Drye

TELEPHONE NUMBER: 456-5573

PAGES (INCLUDING COVER):

COMMENTS: Please review bold portions of this draft EO. I'd like to touch base w/you Thursday, 9/19 and get your reaction. Also, I'd like to speak w/you tomorrow about ACHRE's recommendation re DRB's for classified research. I'm setting up a conf. call on that - possibly tomorrow - and will let Marsha know when. Thanks.

DRAFT

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

The report of the Advisory Committee on Human Radiation Experiments identifies the need for certain additional protections when research is classified.

I hereby direct that no Federal funds be expended to conduct or support classified research involving human subjects where an Institutional Review Board has waived informed consent or where a determination has been made that the research is exempt from Institutional Review Board review. I hereby direct that in all Federally funded classified research, two additional elements of information will henceforth be provided when consent is sought from potential human subjects: 1) the identity of the sponsoring Federal agency, and 2) a statement that the project involves classified information.

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

William J. Clinton

— Add anything —

DRAFT

Radiation   Diane   10/29

- Intergov't site internet - not up yet.

- Oral History - researchers. — (on www)
  - researchers only
  -

- Elly pulling out. Transcript commitments

- DOD publications at Internet site. —

- TJ —

Openness.

- EO - - Write something —

- —

RECA — legislation - [20% - 50% probability issue]
- $ estimates - ERIC OMB ~
  → is he making progress on estimates. ←
- Jay Luben - Greg Wagner doing #'s on who would qualify
- expect total of 3,000 - 3,5000 ~~B~~
  - 2,500 compensated. —

Diane sent to Sally Katzen warning her. —

Sept. wit Staff notes

DAV memo

Human Radiation Experiment
Update on the Administration's Response

Issue: Compensation
Action: All known individuals who fall within the criteria for compensation will be offered compensation. Settlements in Principle have been reached in XX cases.
Notes:
Major Outstanding Issue: Need Counsel's help

- Ben Wetherwax
- Pat Glenn.

Issue: Apology
Action: The President apologized on behalf of the government to the victims of human experimentation
Notes: We have gotten inquiries about individual apologies from the President.
Major Outstanding Issue:

Issue: Notification
Action: The government has undertaken a huge effort to identify information related to experiments. This information has been made accessible to the public, and there are continuing efforts to make people aware of the availability of the information. Competing issues of privacy warrant care in notifying people who do not fall within the criteria suggested by ACHRE. We are putting into place guidelines for notification if experiments are identified in the future.
Notes:
Major Outstanding Issue: Should the Administration support legislation to expand medicare eligibility to those who are identified as subjects of government-funded radiation experiments?

N.P. Radiation logs provide opportunity to demonstrate responsiveness.

Issue: Nasopharyngeal treatment during military service
Action: Public health notification through the medical community.

Proposal to make veterans treated with NP radium eligible for VA's ionizing radiation program.
Notes:
Major Outstanding Issue: Should these veterans be given priority eligibility for VA care.

ionizing radiation program - legislation/outs
Thill 3,11 quos.

Issue: Radiation Exposure Compensation Act coverage for exposed populations around Hanford and other federal sites
Action: Agree that this would be appropriate if increase in cancer due to federal activity.

Studies underway at the five major sites to determine if there is an increase in cancer due to federal operations.
Notes: Studies will be completed in XX
Major Outstanding Issue:

Issue: Increase Radiation Exposure Compensation Act coverage for uranium miners, improve administration of current program.
Action: Legislation drafted to expand coverage.
Thorough reforms to regulations in draft to respond to issues raised by the public re navajo non-smokers; b-readers; smoking cessation; ct scans; lung biopsies; ethno-specific pulmonary function; definition of impaired pulmonary function.
Notes: This is one of the major concrete actions we can point to. The administration of this program is still criticized as too slow. Query whether we can promise a specific turn around on claims?
Major Outstanding Issue:

Issue: Update Epidemiological Tables (Atomic Vets)
Action: We have an agreement in principle with the IOM to update the tables.
Notes: The funding for the contract is still in some doubt. VA is committing 1 million in 97 money and asking HHS for 900,000.
Major Outstanding Issue: Are there other changes in the administration of current laws that we should undertake.

Issue: Marshall Islanders
Action: DOE is working with the government of the Marshall Islands to reorient programs to meet the needs of Marshall islanders.
Notes:
Major Outstanding Issue:

Issue: Ensure ethics in Human Subject research
Action: The combination of NBAC and agency investment in improving the ways we seek informed consent respond to this recommendation (there is a long list of specific agency actions).
Notes:
Major Outstanding Issue:

Issue: Reform IRBs, provide a continuing forum for public debate of ethical issues
Action: Guidance to IRBs, letters to researchers, other administrative changes take steps in this direction.
Notes: This issue touches all aspects of human subject research, and full reform of the IRB system is beyond the scope of this response.
Major Outstanding Issue: Do we need to put into place a process/institution beyond the OPRR to address this issue?

- disclosure
- information/
- informed consent
- Science & quality to warrant risk

Issue: Revise military protocols to better protect military subjects.
Action: This is being done.
Notes:
Major Outstanding Issue: check status

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

- Case by case basis
- Administrative process at every Agency

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

Issue: No waiver of informed consent for classified research.
Action: Will recommend an Executive order.
Notes: The executive order may cover this issue, and the issue of informing participants that classified research is involved.
Major Outstanding Issue: How to respond to the recommendation that an independent panel review classified human subject research. Add

Issue: Establish independent oversight and permanent recordkeeping of environmental review of classified research
Action: EPA will undertake to establish permanent recordkeeping. EPA will establish more rigorous oversight procedures.
Notes: We are rejecting the call for an independent panel.
Major Outstanding Issue:

Issue: Make records accessible CIA records process
Action: The agencies have done a terrific job with this, we can provide solid evidence of the commitment to openness.
Notes:
Major Outstanding Issue:

Issue: Review CIA records and release
Action: the National Archives has undertaken to review, and CIA is giving top priority to declassification of records related to human subject research.
Notes: We need to know what the results are here.
Major Outstanding Issue:

The Central Intelligence Agency:

- The CIA is transferring approximately 1,000 pages of declassified documents and a CIA Inspector General report on human subject research procedures to the National Archives. The documents will also be available on the Internet.

- The agency is reviewing for declassification a few documents relevant to the MKULTRA program that had not been previously declassified and released. An independent review of the CIA's record system has been undertaken by the National Archives and will be completed in approximately six months.

Health and Human Services and Veterans Affairs:

- HHS has made its records available on the Internet; VA is preparing documents for availability on the Internet in the fall of 1996. Paper copies have been transferred to the National Archives.

Recommendation 18 : a) Review of CIA recordkeeping by CIA Inspector General or other groups with special attention to facilitating public access and b) Priority given to declassification of CIA historical records such as MKULTRA.

Summary Response: The National Archives has begun a scheduled review of CIA's records management program, including records access issues and the CIA has agreed to give top priority to declassification of human subjects research records.

To: Ely
Fm: Diane R

EVA M. PLAZA
DEPUTY ASSISTANT
ATTORNEY GENERAL
CIVIL DIVISION
(202) 514-3309 (OFFICE)
(202) 514-8071 (FAX)

DATE: 9/17/96

TO: Diane Regas

FAX #: 456-7028 PHONE #: 456-5589

OF PAGES: 15 w/Cover

COMMENTS:

Honorable Albert Gore
President
United States Senate
Washington, D.C. 20510

Dear Mr. President:

Enclosed is a draft bill entitled the "Radiation Exposure Compensation Improvement Act of 1996." The Department of Justice requests that the draft bill be introduced, referred to the appropriate committee, and passed. We are forwarding an identical proposal to the Speaker of the House of Representatives.

This bill would amend various provisions of the Radiation Exposure Compensation Act of 1990, 42 U.S.C. § 2210 note, to ensure that the criteria for compensation are consistent with the latest scientific data and analytical methods. The bill would incorporate new eligibility criteria for uranium miners seeking compensation for lung cancer and specified nonmalignant respiratory diseases, and expand existing eligibility criteria for downwind and onsite participant claimants. The bill would also clarify the circumstances under which an award due to an onsite participant under the Act must be offset by payments from third-parties or the Federal Government, and extend the period of time in which claims for compensation may be filed and payments awarded. The proposed legislation is designed to remedy a series of perceived shortcomings in the Act that may be frustrating congressional intent to provide compassionate payments to individuals who suffer or have suffered from diseases presumably resulting from exposure to radiation in connection with the Federal Government's nuclear weapons testing program.

BACKGROUND

On October 15, 1990, Congress enacted and the President signed into law P.L. 101-426, the Radiation Exposure Compensation Act of 1990 ("RECA" or "Act"). The Act established a procedure to make partial restitution to three classes of individuals who were put at serious risk by the federal government's nuclear weapons testing program during the Cold War era, and who, presumably as a result of exposure to resulting radiation, developed certain diseases. The three classes of eligible claimants recognized in the Act are: individuals who lived a specified duration in certain counties downwind of the Nevada Test Site during defined time periods when above-ground nuclear

tests were conducted, and who suffer(ed) from any of thirteen radiogenic malignant diseases; Department of Defense and Department of Energy personnel and contractors physically present at one of the federal government's nuclear weapons testing sites during an atmospheric detonation of a nuclear device, and who suffer(ed) from any of thirteen radiogenic malignant disease; and individuals employed in underground uranium mines in the states of Arizona, Colorado, New Mexico, Utah and Wyoming during the period January 1, 1947 through December 31, 1971, and who suffer(ed) from either lung cancer or a one of the following nonmalignant respiratory diseases: "fibrosis of the lung, pulmonary fibrosis, and corpulmonale related to fibrosis of the lung; and if the claimant, whether Indian or non-Indian, worked in an uranium mine located on or within an Indian Reservation, the term shall also include moderate or severe silicosis or pneumoconiosis; ...." In addition to the geographic, temporal and medical criteria noted above, the statute requires uranium miner claimants to prove that they were exposed to specified minimum levels of radiation in the course of their employment in underground uranium mines. The prescribed minimum exposure level varies depending on a claimant's smoking status and age at the time of onset of the disease.

The Act provides a set level of compensation to an eligible claimant in each class (defined to include the exposed individual or specified surviving beneficiaries): a "downwinder" receives $50,000; an "on-site participant" receives $75,000; and a uranium miner receives $100,000. The Department of Justice administers the RECA through the Radiation Exposure Compensation Program (Program).

The provisions of the RECA defining the eligibility criteria for uranium miner claimants have increasingly been the subject of criticism by scientists, claimants and interested parties in the affected areas. The principal criticism has been that the threshold radiation exposure criteria are inconsistent with the latest scientific information. Most recently, the Act's provisions relating to uranium miners (and the Department of Justice's implementing regulations) were reviewed by the President's Advisory Committee on Human Radiation Experiments, charged to investigate the history of human radiation experimentation conducted by the federal government during the Cold War period. In its Final Report, the Advisory Committee concluded that much of the criticism of the Act was justified. It recommended that the Administration undertake a review of the provisions of RECA governing compensation for uranium miners 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 Administration created a committee of experts to review the provisions relating to uranium miners in light of the latest epidemiological data nd analytical methods. The Committee concluded, among other things, that the present exposure criteria are problematic in at least

two ways. First, the latest data indicate that the exposure minima misrepresent the risk of lung cancer for many miners. As a consequence, the present criteria have the unfortunate and unjust effect of denying compensation to many miners who were subject to a considerable risk of lung cancer from exposure to radon progeny, and who later developed lung cancer. Second, the data at present do not support the statutory connection between exposure to radiation and the development of the specified nonmalignant respiratory diseases. These nonmalignant lung disorders are most likely caused by silica and other toxic agents in the mining environment, not radiation.

Additionally, through its experience administering the Act, the Department of Justice has identified a number of statutory provisions relating to the downwind and onsite participant populations that should be modified to promote just compensation to deserving claimants. The Department believes that a number of these provisions have caused claimants undue hardship. First, leading scientists at the National Cancer Institute now inform the Department that the list of compensable radiogenic diseases for the downwind and onsite participant populations is no longer comprehensive, and, further, that some of the lifestyle conditions that will preclude recovery for an otherwise compensable disease are not longer accurate. The Department has had to deny compensation to a number of claimants who, based on the information provided by the NCI, should be eligible.

Second, through what is plainly an oversight in the original Act, onsite participants are not entitled to recover for childhood leukemia. While Congress, quite understandably, did not anticipate that any children would be present at a nuclear weapons testing facility during a detonation, the statute define "childhood," for purposes of this section, as exposure before age 21. The Department of Justice has denied claims, albeit a small number, from otherwise eligible veterans and government contractors who were present at a designated testing facility during an official test prior to age 21, and have contracted leukemia.

Third, the statute presently requires the Department to offset any award to an otherwise eligible claimant by any payments the claimant has received from some other source related to injuries covered by the Act. The Act specifically provides, however, that an award to downwinders or uranium miners not be offset by any payments received on a claim for workers compensation benefits. The offset provisions for onsite participants differ: they do not make explicit that workers compensation benefits are excluded from offset, and they require the offset of any payments to the claimant from the Federal Government based on injuries covered by the Act. This lack of parity has proved particularly frustrating to claimants and the Department. Pursuant to the explicit direction of the Act, the Department has had to offset awards to onsite participant claimants by Social Security disability payments; the Department

does not offset awards to downwinders and uranium miners for similar disability payments.

PROPOSED LEGISLATION

The proposed bill would attempt to remedy the shortcomings in the Act relating to uranium miners by incorporating new eligibility criteria for both lung cancer and nonmalignant respiratory disorders based on the latest epidemiological data and analytical methods. The proposed amendments would add two additional sets of eligibility criteria to the existing exposure criteria for lung cancer, one based on minimum radiation exposure levels, the other on minimum duration of employment. These new criteria more accurately reflect the risk of lung cancer from uranium mining, and, therefore, more accurately provide for compensation to claimants whose lung cancer more likely than not was caused by their exposure to radon in uranium mines. The bill would allow a claimant to qualify by meeting either the existing exposure-based criteria, or either of the two new alternative criteria.

The proposed bill would also establish separate threshold eligibility criteria for claimants seeking compensation for a nonmalignant respiratory disorder. These threshold criteria would be based on duration of employment in uranium mines, a surrogate for exposure to the toxic agents in the mining environment known to significantly affect miners' risk of these diseases. The proposed bill would also eliminate some redundancy in the list of compensable nonmalignant respiratory disorders, and eliminate the statutory language limiting compensation for silicosis or pneumoconiosis to claimants employed in uranium mines located on an Indian Reservation.

Additionally, the bill would expand the list of compensable disease for the downwind and onsite participant populations to be consistent with the latest information. The bill would add to the lesit of compensable diseases primary cancer of the male breast, and primary cancer of the salivary gland, if the claimant was not a smoker. It would also modify the list of lifestyle conditions that exclude otherwise eligible claimants by eliminating the requirement that claimants seeking compensation for pancreatic cancer not have a history of heavy coffee drinking.

The proposed bill would also correct an oversight in the initial Act: it would expand the eligible population for childhood leukemia to include any onsite participant first exposed to radiation at one of the designated nuclear weapon detonation sites prior to age 21, and who meets the remaining statutory medical criteria.

Additionally, the proposed bill would modify the offset provisions relating to onsite participants. The bill would

specifically exclude from offset, as it does for downwinders and uranium miners, any payments an onsite participant receives on a claim for workers compensation benefits based on injuries covered by the Act. The bill would also specifically limit the offset for payments by the Federal Government to payments made by the Department of Veteran Affairs. This would include amounts paid to the onsite participant under the Radiation Exposed Veteran's Compensation Act (REVCA), but exclude benefits paid under Social Security disability programs for the same compensable illness. These proposed amendments would put onsite participants on an equal footing with downwinders and uranium miners with respect to federal disability payments.

Finally, the proposed bill would make some technical amendments. The bill would amend the provision setting a twelve month period on the time within which the Department of Justice must process a claim. The bill would clarify that where the Department seeks necessary documentation from the claimant or some third-party, the limitations period is tolled. The bill would amend the statutory provisions defining the period of time in which claims will be accepted and the Trust Fund available for payments. The Administration believes that the changes proposed to the eligibility criteria in this bill will enfranchise many claimants previously denied compensation, as well as some unknown number of claimants who have not submitted claims believing themselves ineligible under the existing criteria. The proposed amendments would give all future potential claimants the 20 years initially envisioned by Congress to file a claim under the amended Act.

We believe that the enactment of the draft bill would be the best way to further promote the congressional objectives stated in the Radiation Exposure Compensation Act of 1990. The proposed bill will ensure that individuals presumably injured as a result of the Federal Government's nuclear weapons testing program are justly compensated.

Thank you for your consideration of this important matter. The Office of Management and Budget advises that there is no objection to the presentation of this draft bill from the standpoint of the Administration's program.

Sincerely,

Andrew Fois
Assistant Attorney General

SECTION-BY-SECTION ANALYSIS

Section (a). This section would amend section 3(d) of the Act to extend the date for termination and dissolution of the Radiation Exposure Compensation Trust Fund consistent with the proposed amendment to section 8 of the Act extending the time period for filing claims.

Section (b). This section would amend section 4 of the Act by expanding the eligibility criteria for downwinder and onsite participant claimants.

Subsection (1) would amend section 4(a)(1) of the Act by expanding the class of claimants eligible for compensation for childhood leukemia. The amendment would add onsite participants who were exposed to radiation before the age of 21 while participating onsite in a test involving the atmospheric detonation of a nuclear device.

Subsection (2) would amend the list of compensable diseases in section 4(b) of the Act to account for the latest scientific findings regarding the effects of radiation exposure. The amendment would add two new diseases that have now been associated with exposure to radiation -- primary cancers of the male breast and salivary gland -- and eliminate the requirement that claimants seeking compensation for pancreatic cancer not have a history of heavy coffee drinking. The bill would limit compensation for salivary gland cancer to claimants who were not heavy smokers.

Section (c). This section would amend the provisions of the Act defining the eligibility criteria for uranium miner claimants.

Subsection 1 would amend section 5(a) of the Act by deleting the present exposure criteria that uranium miners must satisfy to be eligible for compensation for either lung cancer or a nonmalignant respiratory disease, and replacing in lieu thereof separate eligibility criteria for each disease condition. This section would amend the existing exposure criteria for lung cancer by adding two additional sets of criteria -- one also based on exposure to radiation, and one based on duration of employment -- and allow claimants to meet either the existing exposure standards or either of the two new alternative standards. These new sets of criteria were developed by the Administration utilizing the latest epidemiological data and analytical methods, to ensure that the eligibility criteria accurately reflect the risk of lung cancer from uranium mining, and thus provide compensation to deserving claimants.

This subsection would also add new eligibility criteria for the compensable nonmalignant respiratory diseases, based on duration of employment. These new criteria are designed to

incorporate the latest scientific data indicating that the most likely cause of these diseases is not exposure to radiation, but exposure to silica, dust and other toxic agents in the mining environment.

Subsection (2) would amend section 5(b)(3) of the Act by eliminating the redundant reference to pulmonary fibrosis in the list of compensable nonmalignant respiratory disorders. It would also eliminate the limitation on compensation for silicosis and pneumoconiosis to uranium mines on Indian Reservations. This would ensure that miners employed in uranium mines off Indian Reservations (yet within one of the specified mining states) are compensated on the same conditions as miners employed in mines on Indian Reservations; the risk of silicosis due to uranium mining was not restricted to mines on Indian Reservations.

Subsection (3) would amend section 5(b) of the Act by adding two new phrases employed in section 5(a) as shorthand for temporal and geographic eligibility criteria. These new phrases are designed to aid the clarity of the eligibility criteria.

Section (d). This section would amend the provisions of section 6(c)(2) of the Act defining the circumstances in which awards to onsite participants must be offset by payments received to from other parties.

Subsection (1) would amend section 6(c)(2)(B)(i) to clarify that awards under the Act to on-site participants should not be offset by payments to the claimant based on a workers compensation claim for the same injuries. It would also amend section 6(c)(2)(B)(ii) to clarify that an award under the Act should be offset only by payments from the Department of Veteran's Affairs, and not by disability payments from other federal agencies, such as Social Security. These amendments are designed to enhance parity among the eligible populations by ensuring that payments to onsite participants are offset on the same terms as payments to downwinders and uranium miners.

Subsection (2) would amend section 6(d) of the Act by adding explicit authorization for the Attorney General to seek and obtain from claimants, or from any individual or private or public entity on behalf of claimants, any documentation or information necessary to determine eligibility. This section also provides that the time period during which the Attorney General is awaiting the requested information shall not count toward the twelve-month statutory limit on processing claims.

Section (e). This section would amend section 8 of the Act by extending the period of time in which a claimant could file a claim for compensation. The amendment would allow claims to be filed within 20 years of the date of enactment of the proposed amendments, to ensure that all prospective claimants eligible for

compensation under the new proposed criteria would have time to file a claim.

A BILL

To amend the eligibility criteria of the Radiation Exposure Compensation Act (42 U.S.C. § 2210 note (Supp. 1995)), and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, that the Act, as amended, is further amended, as follows:

(a) TRUST FUND.--Section 3(d) of the Act is amended by striking "the enactment of the Act [Oct. 15, 1990]" and inserting "this amendment of the Act".

(b) CLAIMS RELATING TO ATMOSPHERIC NUCLEAR TESTING.--(1) Section 4(a)(1) is amended to read as follows:

"(1) Claims relating to childhood leukemia - Any individual who -

"(A) was physically present in an affected area for a period of at least 1 year during the period beginning on January 21, 1951, and ending on October 31, 1958,

"(B) was physically present in the affected area for the period beginning on June 30, 1962, and ending on July 31, 1962, or

"(C) participated onsite in a test involving the atmospheric detonation of a nuclear device,

and who submits written medical documentation that he or she, after such period of physical presence or such onsite participation (as the case may be), and between 2 and 30 years after first exposure to fallout, contracted leukemia (other then chronic lymphocytic leukemia), shall receive $50,000 (in the case of an individual described in subparagraphs (A) or (B)) or $75,000 (in the case of an individual described in subparagraph (C)), if -

"(i) initial exposure occurred prior to age 21,

"(ii) the claim for such payment is filed with the Attorney General by or on behalf of such individual, and

"(iii) the Attorney General determines, in accordance with section 6, that the claim meets the requirements of this Act."

(2) Section 4(b)(2) is amended--

(i) by inserting "male and" before "female breast"; and

(ii) by striking "and low coffee consumption"; and

(iii) by inserting "salivary gland (provided not a heavy smoker)," after "gall bladder,".

(c) CLAIMS RELATING TO URANIUM MINING.--(1) Section 5(a) of the Act is amended to read as follows:

"(a) Eligibility of Individuals.--Any individual who was employed in a uranium mine located in one of the specified

states at any time during the designated time period, and who--

"(1) submits written medical documentation that he or she developed lung cancer, and

"(A) if a nonsmoker,

"(i) was exposed to 200 or more working level months of radon progeny; or

"(ii) was exposed to at least the amount of radon progeny in working level months prescribed in Table NS1, based on the individual's age at date of cancer incidence and the number of years since his or her last exposure to radon progeny in the designated time period; or,

"(iii) was employed in an underground uranium mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table NS2, based on the individual's age at date of cancer incidence, year of first exposure to radon progeny during the designated time period, and number of years since last exposure to radon progeny during the designated time period; or

"(B) if a smoker,

"(i) submits written documentation that he or she was exposed to 300 or more working level

months of radon progeny and cancer incidence occurred before age 45, or was exposed to 500 or more working level months of radon progeny, regardless of age of cancer incidence; or

"(ii) submits written documentation that he or she was exposed to at least the amount of radon progeny in working level months prescribed in Table S1, based on the individual's age at date of cancer incidence and number of years since last exposure to radon progeny during the designated time period, or

"(iii) submits written documentation that he or she was employed in an underground uranium mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table S2, based on the individual's age at date of cancer incidence, year of first exposure to radon progeny during the designated time period, and number of years since last exposure to radon progeny during the designated time period;

"(2) submits written medical documentation that he or she developed a nonmalignant respiratory disease, and that he or she was employed in an underground uranium

mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table NMD,

"shall receive $100,000, if --

"(i) the claim for such payment is filed with the Attorney General by or on behalf of such individual, and

"(ii) the Attorney General determines, in accordance with section 6, that the claim meets the requirements of this Act.

"Payments under this section may be made only in accordance with section 6.".

(2) Section 5(b)(3) of that Act is amended to read as follows:

"(3) the term "nonmalignant respiratory disease" means pulmonary fibrosis, cor pulmonale related to pulmonary fibrosis, and moderate or severe silicosis or pneumoconiosis;".

(3) Section 5(b)(4) of that Act is amended--

(A) by striking the period at the end of the paragraph and inserting ";" and

(B) by inserting the following at the end:

"(5) the term "specified states" means Arizona, Colorado, New Mexico, Utah, or Wyoming; and

"(6) the term "designated time period" means the period beginning January 1, 1947 and ending on December 31, 1971.".

(d) DETERMINATION AND PAYMENT OF CLAIMS.--(1) Section 6(c)(2)(B) of the Act is amended--

(A) in subparagraph (i) by inserting "(other than a claim for workers compensation)" after "claim"; and

(B) in subparagraph (ii) by striking "Federal Government" and inserting "Department of Veteran Affairs".

(2) Section 6(d) of the Act is amended by inserting at the end the following:

"The Attorney General may request from any claimant, or from any individual or entity on behalf of any claimant, any additional information or documentation reasonably necessary to complete the determination on the claim in accordance with the procedures established under subsection (a). The period of time from the Attorney General's request for additional information or documentation until the time such is provided, or the requested party informs the Attorney General the information or documentation cannot or will not be provided, will not be counted toward the twelve month limit established in this subsection."

Action items for Human Radiation (By Agency, and status)

DOJ

DOJ will explain (recommendation 14)why case by case is appropriate. *Pat Glynn will submit week of Sept. 16.* OMB Review/regs

DOJ to propose regulatory changes re: navajo non-smokers; b-readers; smoking cessation; ct scans; lung biopsies; ethno-specific pulmonary function; modify definition of impaired pulmonary function. *per Eva Plaza; Regulations ready to go week of September 16, to OMB for review.*

RECA amendments: change eligibility req'ts; add compensation for non-malignant respirator disease; add non-reservation mines. *Per Eva Plaza, ready to submit to OMB on 9/12.*

DOE
Update discussion on notification (6/11). *Language to wh week of 9/16.*
Guidelines for designated human subjects research contact to determine. *DOE and HHS have initial draft; will finalize soon.*

HHS
HHS$ for research in ethics in human subject research (6/25)
HHS: Get reports to NBAC from HUD, DOT, DOL, and DOI. (follow up on executive order.)

ALL
Agency info re how they provide a public forum for discussion of ethical issues.

VA

VA legislation to make veterans treated w/ nasoph. radiation eligible for treatment of radium related conditions. [checking]

VA contract in place to update epi tables
Executive order re waiver of consent in classified research

VA: other responses to achre.

EVA M. PLAZA
DEPUTY ASSISTANT
ATTORNEY GENERAL
CIVIL DIVISION
(202) 514-3309 (OFFICE)
(202) 514-8071 (FAX)

DATE: 10/2/96

TO: Diane Regas

FAX #: 456-7028 PHONE #: 456-5589

OF PAGES: _____

COMMENTS: Elizabeth-

This is a very disturbing memo. In particular, the appearance is that DOT does not have enough lawyers assigned to both write new regs & continue to process claims. In addition, it appears that Eva's promises of a quick turnaround on the regs are fraught w/ probs. Let's digest this & talk this afternoon or tomorrow.

Diane.

Date: Wednesday, October 2, 1996 7:00 am
From: SS07(FISCHER)
Subject: RECA -Reply

Eva -- I am sorry that this process is time consuming, and I'd like to explain and answer the concerns you raised.

First, as I understand it, Paul was the agent of the interagency working group/RECA Committee. He has had every draft of the regs, so I do not understand how they, the IAWG, could complain about not having the regs for review. If it is the final version they want, the following explains what we have been doing.

We have been researching, drafting, and discussing internally, and with Paul, every position the Program took with respect to several of the critical issues so that we could avoid direct conflict with the IAWG, where possible. In short, we have met with Paul throughout the process and accepted the committee's recommendations on most issues. Most notably, that the Program use a "panel" approach to reviewing HRCTs.

As you may recall, the committee made a rather strong recommendation in this regard, in favor of a panel review. See, pages 86-89, Final Report of the RECA Committee. This recommendation was universally accepted by every expert with whom we consulted. However, it appears that there may be a legal impediment to such an approach.

Recently, on Monday, 30 September 1996, we were in contact with Bob Hinchman at the Office of Policy Development who reiterated that there may be a Constitutional question with respect to several key points in the new regs. Particularly, he questioned whether there was an conflict with the Federal Advisory Committee Act in creating an HRCT review panel.

Furthermore, he expressed concern that there was a possible "due process" violation with respect to certain limitations that we were placing on claimants' production of evidence. For example, certain technical parameters were defined for HRCTs. These include such things as clarity, collimation, number of pictures, size of the x-ray, and location of the film. They are similar to the restriction we place on chest x-ray B readings.

Frankly, we had not considered that these technical limits would create a Constitutional question, and that it did, required us to re-examine several of the proposed regulations. We are moving through that review with all dispatch.

After our contact with OPD, I met with Helene and we discussed an approach that could avoid these issues. A more simplified approach, one that differently addresses the concerns of uniformity, was the result of that meeting. We are in the process of fleshing out that approach.

This is an incredibly difficult and painful process and one that should really be deliberately engaged. I am certain that at

every step in the DOJ system these regs will be critically evaluated. Therefore, it is in our interests not to forward something that gets shot down at a higher level. More than drafting new regs, we are in essence re-inventing the entire Program in many respects.

Our concern in the process is that we do not create a legal problem at the Federal District Court level that could have been avoided with more study. Please do not take this to mean that we are purposely delaying the process. Rather we are moving as fast as possible with the limitations we have.

Finally, we have invested a large part of the entire summer on this process and as a result are backlogged by over 300 claims. This time last year, that number was barely one hunderd. Moreover, our nurse consultant, Judy Bragdon, submitted her two week notice last week. As you can imagine, that was quite disruptive of our regular operations as well as the production of a final set of regs, since Judy was an intimate part of the team given the medical issues presented by the regulations.

If you want a short revision of the regs; one that only addresses the question of "former smokers" we can provide that immediately. Also, we can provide a version that simply states the Program will accept HRCTs, and not address how that will happen.

I hope this note answers the concerns you raised. Thank you for your time.

Jerry.

cc: Helene
Paul

- Gary Elles — prefers early or late.
- Rachael Lawrence — Cliff, Carolyn Harrison
- 703-442-5675 — Col Bailey
- ok — John Pereira — 4:00 —
  Tara O'Toole. —

- Albequerque —

— 6-6210 — letter not in mess —

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
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COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
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FOLDER TITLE:
Nasopharyngeal Radiation

2014-0046-S
rc1442

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
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P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

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b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

LRM NO: 5739

FILE NO: 2926

10/8/96

LEGISLATIVE REFERRAL MEMORANDUM

Total Page(s): 17

TO: Legislative Liaison Officer - See Distribution below:

FROM: Ron PETERSON Ron Peterson (for) Assistant Director for Legislative Reference

OMB CONTACT: Holly FITTER 395-3233 Legislative Assistant's Line: 395-6194
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fitter_e@a1.eop.gov
Eric MACRIS 395-4706

SUBJECT: JUSTICE Proposed Draft Bill: Radiation Exposure Compensation Act Amendments Act

DEADLINE: 10:00 AM Tuesday, October 15,1996

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President.

Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

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RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: **5739**

FILE NO: **2926**

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet.
If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.
You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: Holly FITTER 395-3233
Office of Management and Budget
Fax Number: 395-5691
Branch-Wide Line (to reach legislative assistant): 395-6194

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: JUSTICE Proposed Draft Bill: Radiation Exposure Compensation Act Amendments Act

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of ____ pages, attached to this response sheet

U. S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

Honorable Albert Gore
President
United States Senate
Washington, D.C. 20510

Dear Mr. President:

Enclosed is a draft bill entitled the "Radiation Exposure Compensation Act Amendments Act of 1996." We are forwarding an identical proposal to the Speaker of the House of Representatives.

This draft bill would amend various provisions of the Radiation Exposure Compensation Act of 1990, 42 U.S.C. § 2210 note ("the Act" or "RECA"), to ensure that the criteria for compensation are consistent with the latest scientific data and analytical methods. The draft bill would incorporate new eligibility criteria for uranium miners seeking compensation for lung cancer and specified nonmalignant respiratory diseases, and expand existing eligibility criteria for downwind and onsite participant claimants. The draft bill would also clarify the circumstances under which an award due to an onsite participant under the Act must be offset by payments from third parties or the Federal Government, and would extend the period of time in which claims for compensation may be filed and payments awarded. The proposed legislation is designed to remedy a series of perceived shortcomings in the Act that may be frustrating congressional intent to provide compassionate payments to individuals who suffer or have suffered from diseases presumably resulting from exposure to radiation in connection with the Federal Government's nuclear weapons testing program.

BACKGROUND

On October 15, 1990, the President signed into law P.L. 101-426, the Radiation Exposure Compensation Act of 1990. The Act established a procedure to make partial restitution to three classes of individuals who were put at serious risk by the Federal Government's nuclear weapons testing program during the Cold War era and who, presumably as a result of exposure to radiation, developed certain diseases. The three classes of eligible claimants recognized in the Act are: 1) individuals who lived a specified duration in certain counties downwind of the Nevada Test Site during defined time periods when above-ground

nuclear tests were conducted, and who suffer or suffered from any of thirteen radiogenic malignant diseases; 2) Department of Defense and Department of Energy personnel and contractors physically present at one of the Federal Government's nuclear weapons testing sites during an atmospheric detonation of a nuclear device, and who suffer or suffered from any of thirteen radiogenic malignant diseases; and 3) individuals employed in underground uranium mines in the states of Arizona, Colorado, New Mexico, Utah and Wyoming during the period January 1, 1947 through December 31, 1971, and who suffer or suffered from either lung cancer or one of several nonmalignant respiratory diseases. The statute requires uranium miner claimants to prove that they were exposed to specified minimum levels of radiation in the course of their employment in underground uranium mines. The prescribed minimum exposure level varies depending on a claimant's smoking status and age at the time of onset of the disease.

The Act provides a set level of compensation to an eligible claimant in each class (defined to include the exposed individual or specified surviving beneficiaries): a "downwinder" receives $50,000; an "on-site participant" receives $75,000; and a uranium miner receives $100,000. The Department of Justice administers the RECA through the Radiation Exposure Compensation Program ("Program").

The provisions of the RECA defining the eligibility criteria for uranium miner claimants have increasingly been the subject of criticism by scientists, claimants and interested parties in the affected areas. The principal criticism has been that the threshold radiation exposure criteria are inconsistent with the latest scientific information. Most recently, the Act's provisions relating to uranium miners (and the Department of Justice's implementing regulations) were reviewed by the President's Advisory Committee on Human Radiation Experiments, charged with investigating the history of human radiation experimentation conducted by the federal government during the Cold War period. In its Final Report, the Advisory Committee concluded that much of the criticism of the Act was justified. It recommended that the Administration undertake a review of the provisions of RECA governing compensation for uranium miners 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 Administration created a committee of experts to review the provisions relating to uranium miners in light of the latest epidemiological data and analytical methods. The Committee concluded, among other things, that the present exposure criteria are problematic in a number of ways. First, the latest data indicate that the exposure minimum misrepresents the risk of lung cancer for many miners. As a consequence, the present criteria have the unfortunate and unjust

effect of denying compensation to many miners who were subject to a considerable risk of lung cancer from exposure to radon progeny, and who later developed lung cancer. Second, the data at present do not support the statutory connection between exposure to radiation and the development of the specified nonmalignant respiratory diseases. These nonmalignant lung disorders are most likely caused by silica and other toxic agents in the mining environment, not radiation.

Third, through its experience administering the Act, the Department of Justice has identified a number of statutory provisions relating to the downwind and onsite participant populations that should be modified to promote just compensation to deserving claimants. The Department believes that a number of these provisions have caused claimants undue hardship. In particular, leading scientists at the National Cancer Institute (NCI) now inform the Department that the list of compensable radiogenic diseases for the downwind and onsite participant populations is no longer comprehensive, and, further, that some of the lifestyle conditions identified in the Act as precluding recovery for an otherwise compensable disease are no longer accurate. The Department has had to deny compensation to a number of claimants who, based on the information provided by the NCI, should be eligible. In addition, through what is plainly an oversight in the original Act, onsite participants are not entitled to recover for childhood leukemia. While Congress, quite understandably, did not anticipate that any children would be present at a nuclear weapons testing facility during a detonation, the original Act defines "childhood," for purposes of this section, as exposure before the age of 21. The Department of Justice has denied claims, albeit a small number, from otherwise eligible veterans and government contractors who were in fact present at a designated testing facility during an official test prior to age 21, and who later contracted childhood leukemia. Under current law, these individuals are not eligible for payments.

Fourth, the statute presently requires the Department to offset any award to an otherwise eligible claimant by any payments the claimant has received from some other source related to injuries covered by the Act. The Act specifically provides, however, that an award to downwinders or uranium miners not be offset by any payments received on a claim for workers compensation benefits. The offset provisions for onsite participants differ: they do not make explicit that workers compensation benefits are excluded from offset, and they require the offset of any payments to the claimant from the Federal Government based on injuries covered by the Act. This lack of parity has proved particularly frustrating to claimants and the Department. Under the explicit direction of the Act, the Department has had to offset awards to onsite participant claimants by Social Security disability payments. The Department

does not, however, offset awards to downwinders and uranium miners for similar disability payments.

PROPOSED LEGISLATION

The proposed bill would attempt to remedy the shortcomings in the Act relating to uranium miners by incorporating new eligibility criteria for both lung cancer and nonmalignant respiratory disorders based on the latest epidemiological data and analytical methods. The proposed amendments would add two additional sets of eligibility criteria to the existing exposure criteria for lung cancer, one based on minimum radiation exposure levels, the other on minimum duration of employment. These new criteria more accurately reflect the risk of lung cancer from uranium mining, and, therefore, more accurately provide for compensation to claimants whose lung cancer more likely than not was caused by their exposure to radon in uranium mines. The draft bill would allow a claimant to qualify by meeting either the existing exposure-based criteria, or one of the two new alternative criteria.

The proposed bill would also establish separate threshold eligibility criteria for claimants seeking compensation for a nonmalignant respiratory disorder. These threshold criteria would be based on duration of employment in uranium mines, a surrogate for exposure to the toxic agents in the mining environment known to significantly affect miners' risk of these diseases. The proposed bill would also eliminate some redundancy in the list of compensable nonmalignant respiratory disorders, and eliminate the statutory language limiting compensation for silicosis or pneumoconiosis to claimants employed in uranium mines located on an Indian Reservation.

Additionally, the bill would expand the list of compensable diseases for the downwind and onsite participant populations to be consistent with the latest scientific information that we have. The bill would add to the list of compensable diseases primary cancer of the salivary gland, if the claimant was not a smoker, and primary cancer of the male breast. It would also modify the list of lifestyle conditions that exclude otherwise eligible claimants by eliminating the requirement that claimants seeking compensation for pancreatic cancer not have a history of heavy coffee drinking.

The proposed bill would also correct an oversight in the initial Act: it would expand the eligible population for childhood leukemia to include any onsite participant first exposed to radiation at one of the designated nuclear weapon detonation sites prior to age 21, and who meets the remaining statutory medical criteria.

Additionally, the proposed bill would modify the offset provisions relating to onsite participants. The bill would specifically exclude from offset, as it does for downwinders and uranium miners, any payments an onsite participant receives on a claim for workers compensation benefits based on injuries covered by the Act. The bill would also specifically limit the offset for payments by the Federal Government to payments made by the Department of Veterans Affairs. This would include amounts paid to the onsite participant under the Radiation Exposed Veteran's Compensation Act, but exclude benefits paid under Social Security disability programs for the same compensable illness. These proposed amendments would put onsite participants on an equal footing with downwinders and uranium miners with respect to federal disability payments.

Finally, the proposed bill would make some technical amendments. The bill would amend the provision setting a twelve-month limit on the time within which the Department of Justice must process a claim. The bill would clarify that where the Department seeks necessary documentation from the claimant or some third-party, the limitations period is tolled. The bill would amend the statutory provisions defining the period of time in which claims will be accepted and the Trust Fund available for payments.

The Administration believes that the changes proposed to the eligibility criteria in this bill will enfranchise many claimants previously denied compensation, as well as some unknown number of claimants who have not submitted claims believing themselves ineligible under the existing criteria. The proposed amendments would give all future potential claimants the 20 years initially envisioned by Congress to file a claim under the amended Act.

We believe that the enactment of the draft bill would be the best way to promote the congressional objectives stated in the Radiation Exposure Compensation Act of 1990. The proposed bill will ensure that individuals presumably injured as a result of the Federal Government's nuclear weapons testing program are justly compensated.

Thank you for your consideration of this important matter. The Office of Management and Budget advises that there is no objection to the presentation of this draft bill from the standpoint of the Administration's program.

Sincerely,

Andrew Fois
Assistant Attorney General

A BILL

To amend the eligibility criteria of the Radiation Exposure Compensation Act (42 U.S.C. § 2210 note (Supp. 1995)), and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Radiation Exposure Compensation Act Amendments Act of 1996".

SEC. 2. TRUST FUND.

Section 3(d) of the Radiation Exposure Compensation Act (42 U.S.C. § 2210 note (Supp. 1995)) (cited hereinafter as "the Act") is amended by striking "the enactment of the Act [Oct. 15, 1990]" and inserting "this amendment of the Act".

SEC. 3. CLAIMS RELATING TO ATMOSPHERIC NUCLEAR TESTING.

(a) Section 4(a)(1) of the Act is amended to read as follows:

"(1) Claims relating to childhood leukemia - Any individual who --

"(A) was physically present in an affected area for a period of at least 1 year during the period beginning on January 21, 1951, and ending on October 31, 1958;

"(B) was physically present in the affected area for the period beginning on June 30, 1962, and ending on July 31, 1962; or

"(C) participated onsite in a test involving the atmospheric detonation of a nuclear device,

and who submits written medical documentation that he or she, after such period of physical presence or such onsite participation (as the case may be), and between 2 and 30 years after first exposure to fallout, contracted leukemia (other then chronic lymphocytic leukemia), shall receive $50,000 (in the case of an individual described in subparagraphs (A) or (B)) or $75,000 (in the case of an individual described in subparagraph (C)), if --

"(i) initial exposure occurred prior to age 21;

"(ii) the claim for such payment is filed with the Attorney General by or on behalf of such individual; and

"(iii) the Attorney General determines, in accordance with section 6, that the claim meets the requirements of this Act.".

(b) Section 4(b)(2) of the Act is amended --

(1) by inserting "male and" before "female breast";

(2) by striking "and low coffee consumption"; and

(3) by inserting "salivary gland (provided not a heavy smoker)," after "gall bladder,".

SEC. 4. CLAIMS RELATING TO URANIUM MINING.

(a) Section 5(a) of the Act is amended to read as follows:

"(a) Eligibility of Individuals.-- Any individual who was employed in a uranium mine located in one of the specified states at any time during the designated time period, and who--

"(1) submits written medical documentation that he or she developed lung cancer, and

"(A) if a nonsmoker,

"(i) was exposed to 200 or more working level months of radon progeny; or

"(ii) was exposed to at least the amount of radon progeny in working level months prescribed in Table NS1, based on the individual's age at date of cancer incidence and the number of years since his or her last exposure to radon progeny in the designated time period; or,

"(iii) was employed in an underground uranium mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table NS2, based on the individual's age at date of

cancer incidence, year of first exposure to radon progeny during the designated time period, and number of years since last exposure to radon progeny during the designated time period; or

"(B) if a smoker,

"(i) submits written documentation that he or she was exposed to 300 or more working level months of radon progeny and cancer incidence occurred before age 45, or was exposed to 500 or more working level months of radon progeny, regardless of age of cancer incidence; or

"(ii) submits written documentation that he or she was exposed to at least the amount of radon progeny in working level months prescribed in Table S1, based on the individual's age at date of cancer incidence and number of years since last exposure to radon progeny during the designated time period, or

"(iii) submits written documentation that he or she was employed in an underground uranium mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table

S2, based on the individual's age at date of cancer incidence, year of first exposure to radon progeny during the designated time period, and number of years since last exposure to radon progeny during the designated time period;

"(2) submits written medical documentation that he or she developed a nonmalignant respiratory disease, and that he or she was employed in an underground uranium mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table NMD,

"shall receive $100,000, if --

"(A) the claim for such payment is filed with the Attorney General by or on behalf of such individual, and

"(B) the Attorney General determines, in accordance with section 6, that the claim meets the requirements of this Act.

"(3) Payments under this section may be made only in accordance with section 6 of the Act.".

(b) Section 5(b)(3) of the Act is amended to read as follows:

"(3) the term 'nonmalignant respiratory disease' means pulmonary fibrosis, corpulmonale related to pulmonary fibrosis, and moderate or severe silicosis or pneumoconiosis;".

(c) Section 5(b)(4) of the Act is amended --

(1) by striking the period at the end of the paragraph and inserting ";" and

(2) by inserting the following at the end:

"(5) the term 'specified states' means Arizona, Colorado, New Mexico, Utah, or Wyoming; and

"(6) the term 'designated time period' means the period beginning January 1, 1947 and ending on December 31, 1971.".

SEC. 5. DETERMINATION AND PAYMENT OF CLAIMS.

(a) Section 6(c)(2)(B) of the Act is amended --

(1) in clause (i) by inserting "(other than a claim for workers compensation)" after "claim"; and

(2) in clause (ii) by striking "Federal Government" and inserting "Department of Veteran Affairs".

(b) Section 6(d) of the Act is amended by inserting at the end the following:

"The Attorney General may request from any claimant, or from any individual or entity on behalf of any claimant, any additional information or documentation reasonably necessary to complete the determination on the claim in accordance with the procedures established under subsection (a). The period of time from the Attorney General's request for additional information or documentation until the time such is provided, or the requested party informs the Attorney

General the information or documentation cannot or will not be provided, will not be counted toward the twelve month limit established in this subsection.".

SEC. 6. LIMITATION ON CLAIMS AND TRUST FUND.

(a) Section 8 of the Act is amended to read, as follows:

"A claim to which this Act applies shall be barred unless the claim is filed within 20 years after the date of enactment of the Radiation Exposure Compensation Act Amendments Act of 1996.".

(b) The first sentence of section 3(d) of the Act is amended to read, as follows:

"(d) Termination.-- The Fund shall terminate 22 years after the date of enactment of the Radiation Exposure Compensation Act Amendments Act of 1996.".

reca.1
9/17/96

SECTION-BY-SECTION ANALYSIS

Section 1 states short title of the legislation, the "Radiation Exposure Compensation Act Amendments Act of 1996."

Section 2 would amend section 3(d) of the Radiation Exposure Compensation Act ("the Act") to extend the date for termination and dissolution of the Radiation Exposure Compensation Trust Fund consistent with the proposed amendment to section 8 of the Act extending the time period for filing claims.

Section 3 would amend section 4 of the Act by expanding the eligibility criteria for downwinder and onsite participant claimants.

Subsection (a) would amend section 4(a)(1) of the Act by expanding the class of claimants eligible for compensation for childhood leukemia. The amendment would add onsite participants who were exposed to radiation before the age of 21 while participating onsite in a test involving the atmospheric detonation of a nuclear device.

Subsection (b) would amend the list of compensable diseases in section 4(b) of the Act to account for the latest scientific findings regarding the effects of radiation exposure. The amendment would add two new diseases that have now been associated with exposure to radiation -- primary cancers of the male breast and salivary gland -- and eliminate the requirement that claimants seeking compensation for pancreatic cancer not have a history of heavy coffee drinking. The bill would limit compensation for salivary gland cancer to claimants who were not heavy smokers.

Section 4 would amend the provisions of the Act defining the eligibility criteria for uranium miner claimants.

Subsection (a) would amend section 5(a) of the Act by deleting the present exposure criteria that uranium miners must satisfy to be eligible for compensation for either lung cancer or a nonmalignant respiratory disease, and replacing in lieu thereof separate eligibility criteria for each disease condition. This provision would amend the existing exposure criteria for lung cancer by adding two additional sets of criteria -- one also based on exposure to radiation, and one based on duration of employment -- and allow claimants to meet either the existing exposure standards or either of the two new alternative standards. These new sets of criteria were developed by the Administration utilizing the latest epidemiological data and analytical methods, to ensure that the eligibility criteria accurately reflect the risk of lung cancer from uranium mining, and thus provide compensation to deserving claimants.
This subsection would also add new eligibility criteria for the compensable nonmalignant respiratory diseases, based on duration

of employment. These new criteria are designed to incorporate the latest scientific data indicating that the most likely cause of these diseases is not exposure to radiation, but exposure to silica, dust and other toxic agents in the mining environment.

Subsection (b) would amend section 5(b)(3) of the Act by eliminating the redundant reference to pulmonary fibrosis in the list of compensable nonmalignant respiratory disorders. It would also eliminate the limitation on compensation for silicosis and pneumoconiosis to uranium mines on Indian Reservations. This would ensure that miners employed in uranium mines off Indian Reservations (yet within one of the specified mining states) are compensated on the same conditions as miners employed in mines on Indian Reservations; the risk of silicosis due to uranium mining was not restricted to mines on Indian Reservations.

Subsection (c) would amend section 5(b) of the Act by adding two new phrases employed in section 5(a) as shorthand for temporal and geographic eligibility criteria. These new phrases are designed to aid the clarity of the eligibility criteria.

Section 5 would amend the provisions of section 6(c)(2) of the Act defining the circumstances in which awards to onsite participants must be offset by payments received to from other parties.

Subsection (a) would amend section 6(c)(2)(B)(i) to clarify that awards under the Act to on-site participants should not be offset by payments to the claimant based on a workers compensation claim for the same injuries. It would also amend section 6(c)(2)(B)(ii) to clarify that an award under the Act should be offset only by payments from the Department of Veteran's Affairs, and not by disability payments from other federal agencies, such as Social Security. These amendments are designed to enhance parity among the eligible populations by ensuring that payments to onsite participants are offset on the same terms as payments to downwinders and uranium miners.

Subsection (b) would amend section 6(d) of the Act by adding explicit authorization for the Attorney General to seek and obtain from claimants, or from any individual or private or public entity on behalf of claimants, any documentation or information necessary to determine eligibility. This provision also provides that the time period during which the Attorney General is awaiting the requested information shall not count toward the twelve-month statutory limit on processing claims.

Section 6 would amend section 8 of the Act by extending the period of time in which a claimant could file a claim for compensation. The amendment would allow claims to be filed within 20 years of the date of enactment of the proposed amendments, to ensure that all prospective claimants eligible for

compensation under the new proposed criteria would have time to file a claim. Similarly, section 3 of the Act would be amended to extend the date of termination of the Trust Fund to 22 years after the date of enactment of the draft bill.

reca.3
9/17/96

? Interns:
Copy to Diane Regas
Original to Elizabeth

For Your Information

The Department of Energy's Office of Human Radiation Experiments is planning a workshop designed to help people research records located as part of the government-wide human radiation experiments project.

This workshop is part of the Department of Energy's continuing commitment to openness in government. It will be held in Washington DC on September 27, 1996 at the Forrestal Building.

The workshop is directed to members of the public who are interested in researching their own or a family members potential involvement in human radiation experiments. Researchers interested in specific experiments or groups of experiments as well as in the broader historical context in which experiments took place will also find it useful. The focus of the workshop will be on records of the Department of Energy but it will also include some information about records held by other Federal agencies and in private repositories.

The workshop will also provide an opportunity for participants to make suggestions for improving access to this and related material.

There is no fee for the workshop but registration is limited. More information is provided in the enclosed flyer. No travel or lodging assistance is available.

The attached brochure is being sent to key stakeholders to inform them of this opportunity. We welcome your participation. Please let us know if you know if you or your colleagues would like to attend or if you have any suggestions for people to be included in this mailing.

If you would like more information about the human radiation experiments workshop, please contact Karoline Gourley on (202) 586-1988 or Cindy Shindledecker on (202) 586-8230.

Thank you for your support.

Elly Melamed
Director, Office of Human Radiation Experiments
Office of Environment, Safety and Health
Department of Energy

Department of Energy
Assistant Secretary for Environment, Safety and Health
Office of Human Radiation Experiments

Presents

Researching Human Radiation Experiments: A Workshop for the Public

WHO: Anyone interested in researching government records relating to human radiation experiments.

HOW: Please sign up by calling Kim McLeod at (202)586-9024 (seating is limited)
or
Write to: Department of Energy -- 7A-075
Office of Human Radiation Experiments (EH-8)
1000 Independence Ave., SW
Washington, D.C. 20585

WHEN: Friday, September 27, 1996, 9:00 a.m. -- 4:30 p.m

WHERE: Room 6E-081, Department of Energy, 1000 Independence Ave, SW
Washington, D.C. 20585.

WHAT: Topics to be Covered

- Overview of the Department of Energy Human Radiation Experiment Project
- Overview of Research Techniques
- How to Find Records Pertinent to the Individual
- How to Find Records of the Experiments
- How to Find Records in Broad Topics Related to Human Radiation Experiments.
- Using the Internet
- Using the National Archives
- How to perform research in medical literature
- Accessing original records
- Finding Aids -- what are they and how to use them
- Using the records of the Advisory Committee on Human Radiation Experiments
- Discussion of other repositories that may be useful to your research needs.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

01-Oct-1996 02:01pm

TO: Elizabeth E. Drye

FROM: Diane Regas
Domestic Policy Council

SUBJECT: RE: radiation

I have been engaged on this issue. OMB got the legislation today, but because of the number of enrolled bills they can not put it into circulation until early next week. I decided not to try to raise this issue to TJ again, because I know how much pressure they are under and I can not seriously argue that this should take priority over circulating enrolled bills.

The regs are not here yet, I will get the latest eta later today.

Recommendation #1 (biomedical experiments)	Summary Response		
What: • personal, individualized apology; and • financial compensation To: subjects (or next of kin) In the following cases: • subjects of plutonium injection experiments • the subject, Cal-Z, of zirconium injection experiment • subjects of total-body irradiation experiments during World War II	ongoing discussions between agencies, with DOJ, and claimant representatives re: compensation	✓	
Recommendation #2 (biomedical experiments)	Summary Response		
What: • personal, individualized apology; and • financial compensation to cover relevant medical expenses and associated harms To: subjects or surviving immediate family members Conditions: • physical injury AND either experiment did not involve medical benefit to subjects, or interventions considered controversial presented as conventional Other: • could create schedule of projected medical costs for specific diagnoses • decide how strict a causal association required Candidates for remedy: total-body irradiation; testicular irradiation using prisoners; uranium injection at Rochester and Boston; some iodine 131 experiments involving children	ongoing discussions between agencies, with DOJ, and claimant representatives re: compensation	✓	
Recommendation #3 (biomedical experiments)	Summary Response		
What: personal, individualized apology To: each subject In the following cases: a) experiments had no prospect of medical benefit to subjects; and b) evidence specific to experiment that no or inadequate consent obtained; or their selection as subjects constituted an injustice; or both. Specific Candidates: • experiments at Fernald School • candidates for Recommendation 2 if determined subjects not harmed	apology by President on behalf of government to victims of human radiation experiment at ceremony	✓	

Recommendation #4 (biomedical experiments)	Summary Response		Reg / Leg
What: • no current need for notification and medical follow-up • future decisions should be based on guidelines set by Advisory Committee • subjects for whom follow-up recommended in future should be notified of participation and offered voluntary screening programs Guidelines: a) subject placed at increased lifetime risk for fatal radiation-induced malignancy; risk set by Advisory Committee b) benefit from early detection, treatment outweighs risks; public health, financial costs and potential benefits considered before deciding on notification	General Response: general agreement with recommendation and criteria; controversy over recommendation led to further discussion • has been general public notification • NASA notified all its own by letter • interagency helpline leads to individual case review • VA expert committee, reviewing some early radiation research projects, found no veterans who warranted follow-up Agency responses to specific experiments: **a) Treatment with NP Radium during Military Service** • DOD sent letters of notification to a few identified servicemen • VA co-sponsored workshop on public health response to NP irradiation • VA officials published information on NP radium treatments; sent information to veterans' service organizations • VA and CDC planning satellite teleconference to provide health professionals information • legislative proposals being considered to give servicemen subjected to NP radium priority eligibility for VA care **b) Alaskan Natives and Iodine-131 thyroid test** • IOM recommended notification and follow-up of juvenile participants; Air Force and Radiation Experiments Command Center following up on IOMs recommendations **c) DOE Response** • requests to all DOE facilities re: notification	7	Leg
Recommendation #5 (population exposures)	Summary Response		
• work with Congress to amend RECA to cover other populations. • Hanford facility in Washington state should be reviewed	• agreement with Advisory Committee's concern • studies underway in Hanford, Fernald, Savannah River, Rocky Flats, Oak Ridge timing?		Leg
Recommendation #6 (population exposures)	Summary Response		
• update epidemiologic tables that govern relief for veterans (Atomic Vets) • improve administration of laws governing compensation of atomic veterans, including record keeping	• VA established Working Group with representatives from DOD and HHS. Report on how to address recommendations expected mid 1996.		
Recommendation #7 (population exposures)	Summary Response		
• work with Congress to amend RECA re: uranium miners to widen eligibility and loosen documentation requirements	• Committee of scientists and attorneys reviewed RECA re: uranium miners; report almost complete; proposed series of modifications re: certain diseases, a few times not offering alternatives to current system		
Recommendation #8 (population exposures)	Summary Response		
• continue program for exposed inhabitants of Marshall Islands as long as any member still alive • consider expanding program to populations of other exposed atolls • consider involving Marshall Islanders in further research on them • consider establishing panel to review current program	• on-going studies re: exposure and thyroid disease: if new data shows other atolls at increased risk, then Congress would need to consider expansion • planned review of Marshall Island Program suspended; mechanism for review being re-evaluated based on input from RMI • DOE generally working with RMI representatives		

Recommendation #9 (protection of human subjects)	Summary Response		
• *undertake efforts on national scale to ensure centrality of ethics in conduct* of human subject research • list of specific factors to be considered, including how best to balance teaching ethics with encouraging private sector initiatives	• *NBAC will advise government entities re: bioethical issues and will identify* broad principles to govern ethical conduct of research • NIH leading interagency initiative to increase knowledge re: informed consent		
Recommendation #10 (protection of human services)	Summary Response		
IRBs should be changed in 5 areas: • 3 involving ensuring clear information given to individual subjects; • 1 on greater focus on studies that pose more than minimal risk; • 1 on recognition that IRBs must determine if research justifies risk	• IAWG with NBAC and NSTC will oversee compliance with recommendations • OPRR (NIH), through public meetings and presentations, showcases Advisory Committee's message • FDA revised its information sheets in line with recommendations • OPRR (NIH), FDA campaign to address issues on human subjects protection		
Recommendation #11 (protection of human subjects)	Summary Response		
• need mechanism for continuing interpretation of ethical rules in public forum	• NBAC expected to create and maintain such a public forum		
Recommendation #12 (protection of human subjects)	Summary Response		
Improve the protection of rights of military personnel re: human subject research by: reviewing policies and procedures; educating officers and investigators involved in decisions re: human subjects; maximizing voluntariness; maintenance of a registry of volunteers.	• DOD has agreed to specific changes, including revision of regulations and appropriate training for those involved with human subject research • DOD will publish revised human subject protection regulation in summer 1996		
Recommendation #13 (protection of human subjects)	Summary Response		
• Improve 3 elements of current system for protection of human subjects: oversight, sanctions, and scope (extension to non-federally funded research)	• NBAC will fully address recommendation • additionally, federal agencies will undertake specific activities		
Recommendation #14 (protection of human subjects)	Summary Response		
• develop satisfactory resolution to issue of compensation of future subjects of federally funded research	• IAWG recommends NBAC assess compensation for research injury • IAWG, NBAC will also work to protect subjects in non-federal research • *DOE revised handbook; began site visits; reviewing informed consent* documents; drafting model document; requested labs provide plans to improve review system; took steps to publicize information on human subject research • DOD reviewed policies; revised Directive; proposed changes re: training, curricula, familiarity with requirements, review process for some minimum risk research, absence of superiors during research recruitment • NASA established Task Force which issued final report; enhanced condition of human subject research; updated NMI; established oversight process; conducted internal reviews; conducted workshops for domestic and international biomedical community • CIA made ethicist permanent voting member of HSRP; revised regulations and manual to subject all agency human subject research to HSRP approval; informed employees of need for these steps. • DHHS designated OPRR to coordinate NBAC report; began activities to improve protections; ensured FDA response to NBAC • Other: VA planned IRB site visits, policy manual review; EPA planning implementation of Common Rule; Consumer Product Safety Commission revising internal documents		

Recommendation #15 (secrecy and openness)	Summary Response		
15a: no waiver of informed consent for classified research; inform subjects of sponsoring agency and classified nature 15b: subject classified research with human subjects to independent (non-governmental) panel approval; panel determines scientific merit; risk and benefit; disclosure; voluntariness; security clearance. Permanent record keeping.	15a: recommendation should be referred to NBAC for review of whether appropriate 15b: instead proposes using current IRB system which could establish dedicated panel or could ensure needed clearance	✓ ✓	
Recommendation #16 (secrecy and openness)	Summary Response		
16a: independent panel review of any planned environmental release involving secrecy 16b: Government agency (now EPA) to provide environmental oversight of classified programs including permanent recordkeeping, reporting to Congress	16a: reluctance to follow recommendation 16b: EPA does oversee and assure federal agency compliance with environmental laws but does not have record keeping process specific to secrecy; considering MOUs, but suggests each agency responsible for own classified material; EPA sees no need to document NEPA review process	✓ ✓	
Recommendation #17 (on openness)	Summary Response		
Ensure organization and accessibility of historical records by 1. entrusting most important collections to National Archives; hastening transfer of records to Archives 2. make finding aids available, including declassification review or declassified versions of classified aids 3. develop policies to increase public access 4. make records of document destruction publicly accessible 5. review policies re: public access to records of private contractors, institutions	• agreement with 1,2,3,5 • re: 4, investigating feasibility of making all records of classified (and unclassified) human subject research permanent, not just destruction • DOE -- 3 publications of publicly accessible information; making finding aids available; negotiating transfer to National Archives; updating Internet site • DOD preparing guide (mid 1996); access to documents through Internet; home page; expediting response to Freedom of Information Act • NASA maintaining permanent human radiation records; planning access through Internet • CIA transferring documents to National Archives; reviewing declassification of some MKULTRA documents; independent review of record system • HHS and VA preparing document access through Internet	expansion of recommendation	
Recommendation #18 (on openness)	Summary Response		
18a: review of CIA recordkeeping by inspector general or oversight panel re: public accessibility 18b: top declassification priority to secret human research programs (MKULTRA), and related human behavior projects	• National Archives has begun review of CIA's recording program • CIA agreed to give top priority to declassification of human research	?	

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

15-Sep-1996 09:45am

TO: Diane Regas

FROM: T J. Glauthier
Office of Mgmt and Budget, NRES

CC: Sally Katzen
CC: Elizabeth E. Drye
CC: Ronald K. Peterson

SUBJECT: RE: Human Radiation Experiments

Diane, we need to discuss this quickly. I understand that a very "draft" and incomplete legislative package was sent over here Thurs or Fri by DOJ and that it is far from ready for prime time. In particular, I have been told that it was not even run thru DOJ's legislative review process, that it is not all in final legislative language, and that the agencies and perhaps we in the WH offices are going to raise serious questions about whether we should send it up at this time.

I will check further with my staff, but I need more background on just what process this has gone through so far, what the agencies' involvement has been, etc.

I have not seen the package yet, but from my staff's comments and all of our history on this topic, I expect that it will seem a lot more conservative and less "victim friendly" than we may want to spring out publicly right now.

I certainly support our demonstrating follow through on the Advisory Committee's report and recommendations, but am not clear enough on the overall strategy.

I would like to have this kind of discussion early this week, before you schedule an interagency meeting. Maybe a couple of us could sit down with you for 20 to 30 minutes on Monday or Tuesday. Have Phil Caplan, Kris Balderston, and Elena Kagan been involved already? They've been involved a lot in the past.

National Bioethics Advisory Commission

6100 Executive Boulevard • Suite 3C01
Rockville, MD 20892-7508

Telephone: (301) 402-4242
Facsimile: (301) 480-6900

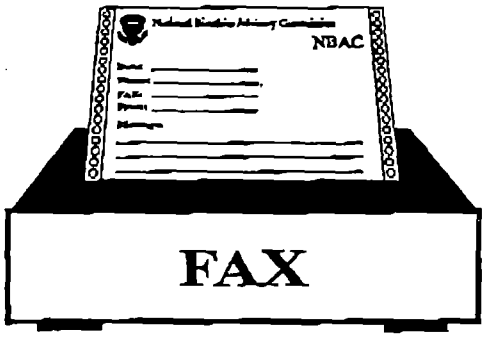
To: Ms. Elizabeth Drye

Date: Oct. 3, 1996

Phone:

FAX #: 202/456-7028

From: Ms. Margaret Jenkins



Message:

As requested by Rachel Levinson on your behalf, attached is the agenda for the inaugural meeting of the National Bioethics Advisory Commission

Number of pages (including cover): 2

If there are any problems receiving this transmission please call: (301) 402-4242

INAUGURAL MEETING

NATIONAL BIOETHICS ADVISORY COMMISSION

OCTOBER 4, 1996

Location: National Institutes of Health
9000 Rockville Pike, Building 31, Conference Room 10
Bethesda, Maryland

Final Agenda

8:30 a.m. **CALL TO ORDER, OPENING REMARKS, AND INTRODUCTIONS**
Ms. Rachel E. Levinson, Designated Federal Official
Dr. Harold T. Shapiro, NBAC Chair, and NBAC Members

9:00 a.m. **CHARGE TO THE COMMISSION**
Dr. John H. Gibbons
Assistant to the President for Science and Technology

9:30 a.m. **PRESENTATIONS FROM THE CONGRESS**
Mr. Aaron Menikoff
Legislative Assistant to Senator Mark O. Hatfield
Dr. Leonard Weiss
Minority Staff Director, U.S. Senate Committee on Governmental Affairs

10:00 a.m. **PRESENTATION ON ETHICS IN GOVERNMENT**
Ms. Michelle Russell-Einhorn
Assistant Special Counsel for Ethics

10:15 a.m. **BREAK**

10:30 a.m. **VISIONS FOR THE COMMISSION**
Chair and Members

11:45 a.m. **LUNCH**

1:00 p.m. **PERSPECTIVES**
Dr. Francis S. Collins
Director, National Center on Human Genome Research

2:30 p.m. **BREAK**

2:45 p.m. **RESEARCH INVOLVING HUMAN SUBJECTS**
Dr. Gary B. Ellis
Chair, Human Subjects Research Subcommittee, Committee on Health, Safety, and Food, National Science and Technology Council

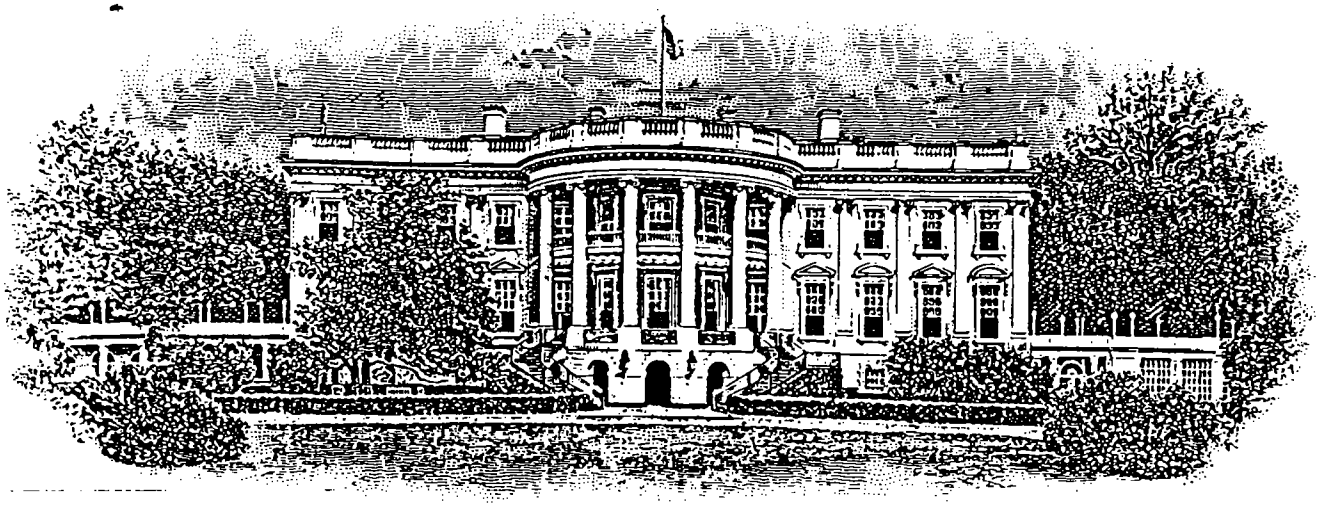
3:15 p.m. **DISCUSSION OF CONFLICT OF INTEREST GUIDELINES**
Chair, Members, and Ms. Russell-Einhorn

3:30 p.m. **DISCUSSION OF FUTURE PLANS**
Chair, Members, and Staff

4:00 p.m. **PUBLIC COMMENT**

4:30 p.m. **ADJOURN**

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: John Pereira

FAX NUMBER: 703-243-8343

TELEPHONE NUMBER:

FROM: Elizabeth Drye

TELEPHONE NUMBER: 456-5573

PAGES (INCLUDING COVER):

COMMENTS: Draft EO, for your review.

6

Tara O'Toole — doesn't make sense to get Security Clearance

- Bureaucracy — only going to meet

Advisory cmt — NBAC — all got Security clearances — could

[redacted]

{last episode of X-files — Aug 1996 — govt did do these experiments}

— IRB [redacted] for classified research.

Medical devices — FDA approves their safety and efficacy — People are marketing w/out approval —

relied on
— social and ethical concerns —

1988 convened a panel of medical experts

— 1988 Guideline paper at FDA

— Purpose of screening process

— We know there's one pending

—

Total Pages: 9

LRM ID: MYC140

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

Thursday, July 24, 1997

LEGISLATIVE REFERRAL MEMORANDUM

TO:	Legislative Liaison Officer - See Distribution below
FROM:	Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT:	Melissa Y. Cook PHONE: (202)395-3924 FAX: (202)395-6148
SUBJECT:	VETERANS AFFAIRS Draft Bill on Authorize Care for Veterans Treated with Nasopharyngeal Radium Irradiation
DEADLINE:	10:00am Tuesday, July 29, 1997

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: The attached contains provisions that were originally included as part of another VA draft bill ("Health-Care Related FY 1998 Budget Proposals"); however, they have been pulled out of that bill.

DISTRIBUTION LIST

AGENCIES:
29-DEFENSE - Samuel T. Brick Jr. - (703) 697-1305
32-ENERGY - Bob Rabben - (202) 586-6718
95-Office of Science and Technology Policy - Maria Reff - (202) 45/6-6098

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Gary L. Bennethum
David H. Morrison
Mary Jo Siclari
Suzanne L. White
Elizabeth Drye
Robert W. Schroeder

JUL-24-1997 11:59 TO:E DRYE FROM:JULIA YUILLE

Phillip Caplan
James C. Murr
Janet R. Forsgren
E. Holly Fitter

LRM ID: MYC140 **SUBJECT:** VETERANS AFFAIRS Draft Bill on Authorize Care for Veterans Treated with Nasopharyngeal Radium Irradiation

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RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:

(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or

(2) sending us a memo or letter

Please include the LRM number shown above, and the subject shown below.

TO: Melissa Y. Cook Phone: 395-3924 Fax: 395-6148
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 396-7362

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

The following is the reponse of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this reponse sheet

THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

The Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

There is transmitted herewith, a draft bill, "To authorize provision of care to veterans treated with nasopharyngeal radium irradiation." We request that it be referred to the appropriate committees for prompt consideration and enactment.

The draft bill would authorize participation in VA's ionizing radiation program by veterans who were treated with nasopharyngeal radium irradiation many years ago. During the 1940s and 1950s, the military administered nasopharyngeal radium treatments to thousands of submariners and air crew members to prevent ear injury during the severe pressure changes they encountered on the job. Scientific study now suggests that treated individuals may be at increased risk for development of head and neck malignancies. It is also possible that the treatment may cause other types of diseases such as endocrine disorders.

With the current state of knowledge regarding the possible consequences of nasopharyngeal radium treatment, it is appropriate for the VA to provide needed health care for disabilities that might be associated with the treatment. The draft bill would authorize such treatment. It would also authorize VA to examine any veteran treated with radium irradiation and include any findings in the Department's radiation registry.

[illegible] Congress
1st Session

A BILL

To amend title 38, United States Code, to authorize provision of care to veterans treated with nasopharyngeal radium irradiation.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That except as otherwise expressly provided, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of title 38, United States Code.
shall be considered to be made to a section or other provision of title 38, United States Code.

Sec 2. (a) The Secretary may examine, and include in the Department's Ionizing Radiation Registry Program, any veteran who received nasopharyngeal radium irradiation treatments while serving in the active military naval or air service.

(b) Section 1710 is amended--

(1) in subsection (a)(2)(F), by inserting "or who received nasopharyngeal radium irradiation treatments," after "environmental hazard,"; and

(2) in subsection (e)--

(A) by adding at the end of paragraph (1) the following new subparagraph:

"(D) Subject to paragraph (2) of this subsection, a veteran who the Secretary finds was given nasopharyngeal radium irradiation treatments while serving in the active military, naval, or air service is eligible for hospital care, medical services, and nursing home care under subsection (a)(2)(F) for any disability, notwithstanding that there is insufficient medical evidence to conclude that such disability may be associated with such exposure."

(B) in paragraph (2)(B), by inserting "or (1)(D)" after "(1)(C)".

SECTION BY SECTION ANALYSIS

Section 2

Section 2 of the draft bill would amend 38 U.S.C. § 1710 to expand eligibility for VA's ionizing radiation program to include veterans who were treated with nasopharyngeal radium irradiation during service and to authorize treatment of those veterans for any disability that might have resulted from the nasopharyngeal radium irradiation treatment during service. This proposal would authorize VA to examine veterans who received the treatment to ascertain whether they may have a disability, regardless of whether they have any symptoms of disability, and to provide hospital and nursing home care and outpatient medical services for any disability found. Care may be furnished where there is insufficient medical evidence to conclude the disability is associated with the radiation treatment, but cannot be furnished for a disability found to have resulted from a cause other than the treatment. Enactment of this provision would result in a cost of $3,000,000 for FYs 1997-2001.

CHANGES IN EXISTING LAW MADE BY DRAFT BILL

Changes in existing law made by this bill are shown as follows (existing law proposed to be omitted is enclosed in brackets and struck through, new matter is underlined in italics, existing law in which no change is proposed is shown in courier):

TITLE 38-UNITED STATES CODE

* * * * * * *

PART II-GENERAL BENEFITS

* * * * * * *

CHAPTER 17-HOSPITAL, NURSING HOME, DOMICILIARY, AND MEDICAL CARE

* * * * * * *

SUBCHAPTER II--HOSPITAL, NURSING HOME OR DOMICILIARY CARE AND MEDICAL TREATMENT

* * * * * * *

§ 1710. Eligibility for hospital, nursing home, and domiciliary care

(a)(1) The Secretary (subject to paragraph (4)) shall furnish hospital care and medical services, and may furnish nursing home care, which the Secretary determines to be needed-

* * * * * * *

(2) The Secretary (subject to paragraph (4)) shall furnish hospital care and medical services, and may furnish nursing home care, which the Secretary determines to be needed to any veteran-

* * * * * * *

(F) who was exposed to a toxic substance, radiation, or environmental hazard, *or who received nasopharyngeal radium irradiation treatments,* as provided in subsection (e) of this section; or

* * * * * * *

(e)(1)(A) A Vietnam-era herbicide-exposed veteran is eligible (subject to paragraph (2)) for hospital care, medical services, and nursing home care under subsection (a)(2)(F) for any disability, notwithstanding that there is insufficient medical evidence to conclude that such disability may be associated with such exposure.

* * * * * * *

(D) Subject to paragraph (2) of this subsection, a veteran who the Secretary finds was given nasopharyngeal radium irradiation treatments while serving in the active military, naval, or air service is eligible for hospital care, medical services and nursing home care under subsection (a)(2)(F) for any disability, notwithstanding that there is insufficient medical evidence to conclude that such disability may be associated with such exposure.

* * * * * * *

(2)(A) In the case of a veteran described in paragraph (1)(A), hospital care, medical services, and nursing home care may not be provided under subsection (a)(2)(F) with respect to--

* * * * * * *

(B) In the case of a veteran described in paragraph (1)(C)[,] *or (1)(D),* hospital care, medical services, and nursing home care may not be provided under subsection (a)(2)(F) with respect to a disability that is found, in accordance with guidelines issued by the Under Secretary for Health, to have resulted from a cause other than an exposure described in that paragraph.

FAX

Date 07/17/96

Number of pages including cover sheet 2

TO: Elizabeth Drye
Domestic Policy Council

Phone

Fax Phone 202-456-7028

FROM: Robert De Vesty
Office of Public Health and Environmental Hazards
(13) DVA

Phone 202-273-8453

Fax Phone 202-273-9080

CC:

REMARKS: ☐ Urgent ☑ For your review ☐ Reply ASAP ☐ Please Comment

Elizabeth:,

Attached is a copy of the VA's legislative proposal to include Veterans who received Nasopharyngeal Radium Irradiation Treatment in the VA's Ionizing Radiation Program. According to our General Counsel the proposal is currently in OMB for review. If you have any additional questions please call myself or Dr. Otchin at the number above. Thanks.

Bob

: submitted as part of Dept's A-19 package

: HR 2080: moved to next year's leg. session?

5-0435

VHA Inclusion of Veterans Who Received Nasopharyngeal Radium Irradiation Treatment in VA's Ionizing Radiation Program

This proposal would authorize the Secretary to include in VA's ionizing radiation program, veterans who received nasopharyngeal radium irradiation treatment during service. That would allow examination of these veterans to determine if they have disabilities resulting from the treatment, and inclusion in a registry. The proposal would also amend 38 U.S.C. § 1710(e) to authorize treatment of those veterans for any disability that might have resulted from the treatment during service. Treatment authority would be the same as for those veterans receiving treatment for disabilities possibly related to exposure to ionizing radiation during weapons testing or in Japan at the end of World War II

During the 1940's and 1950's, nasopharyngeal radium irradiation was a relatively common medical procedure for the treatment of persons who had difficulty equalizing pressure in the inner ear. The procedure, which involved insertion of radium-tipped rods into the nasal cavities to remove tissue, was widely used by military physicians for servicemen who were involved in both submarine and aviation activities. There is now evidence that some of those individuals may have disabilities which may be associated with that exposure to radiation. Those disabilities include benign and malignant head, neck, and brain tumors, and other diseases such as endocrine disorders.

This proposal would authorize VA to examine veterans who received the treatment to ascertain whether they may have a disability, regardless of whether they have any symptoms of disability. It would also authorize hospital and nursing home care, and outpatient medical services for the treatment for any disability found. Care could be furnished even if there is insufficient medical evidence to conclude that the disability is associated with the radiation treatment. However, care could not be furnished for a disability found, in accordance with guidelines issued by the Under Secretary for Health, to have resulted from a cause other than the treatment.

Estimated costs of this proposal are as follows:

Fiscal Year	Cost
1997	$500,000
1998	$750,000
1999	$750,000
2000	$750,000
2001	$250,000

KELLY S. KIRKPATRICK
CONGRESSIONAL SCIENCE AND TECHNOLOGY FELLOW

JOSEPH I. LIEBERMAN
UNITED STATES SENATOR
CONNECTICUT

316 SENATE HART BUILDING
WASHINGTON, DC 20510
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8 AP 07-29-96 16:51 EST 50 Lines.
Group Takes Look At Children's Programming<
By LAUREN A. BORSA Associated Press Writer

HARTFORD, Conn. (AP) Connecticut's television stations have a chance to lead a new, national push toward improving programming for children, a lawmaker said Monday after meeting with the state's industry representatives.

``I'd love, through this group, to make Connecticut into a model of what local TV stations can do to improve the quality of children's television,'' said U.S. Sen. Joseph Lieberman.

Lieberman, D-Conn., held the meeting the same day President Clinton announced an agreement with the television industry that requires three hours of educational shows a week for children.

The Federal Communications Commission must approve the rule for it to take effect.

The discussion in Hartford touched on several issues, including the impact television has on children and the children's shows now offered. No consensus was reached on what can be done to improve programming, but Lieberman said he does want to meet again.

``I am not here to point fingers today,'' Lieberman said during his meeting at the Legislative Office Building. ``I love television. I'm a child of the television age.''

Representatives of several Connecticut television stations discussed the programs their stations offer children and their continuing efforts to do so.

Gary E. Knell, senior vice president of corporate affairs for the Children's Television Workshop, the creators of ``Sesame Street,'' said children are exposed to more than just television.

``Our kids are getting battered by media from all over'' including the movies and print, he said.

State education chief Theodore Sergi said he would like to see children reading more. ``We want young people to be more active in their learning,'' he said.

Joanne Whitehead, viewer services coordinator for Connecticut Public Television, said broadcasters need to form a strong partnership with parents, ``so that we teach parents and children alike to be more selective.''

Ayesha Wynter, 12, of Hartford, also attended the meeting, sitting in the audience with a group of youths from a Hartford YMCA program.

She said there is a need for more educational programming, but also noted that the work cannot end there.

``How are we going to get more kids to watch educational programming?'' she said to the panel.

144 AP 07-30-96 08:00 EST 65 Lines.
Navy Finds Log Identifying 1,611 Submariners Exposed to Radium<

ALBUQUERQUE (AP) A long-missing naval research log identifying 1,611 subjects of human radiation experiments has been discovered at the Navy submarine base in Groton, Conn., a newspaper reported.

The Albuquerque Tribune, which won a Pulitzer Prize for a 1993 series on human radiation experiments, reported Monday

that researcher Henry Haines had kept the log, which the Navy long had said either didn't exist or couldn't be found.

``We are heartened by this that we now have the log, that we have actual names," said Army Col. Claud Bailey, heading a Defense Department investigation of the records found by the Navy.

The experiments were performed at the Navy submarine base in Groton, Conn., where the log was found, the newspaper said. It said the log makes clear these were subjects of research, not merely medical treatment, as the military had claimed.

``There is no doubt," Bailey said. ``As a matter of fact, if you look at the document, the words show it was research and, in fact, it says it was an experiment.

``It established the protocol and specifies the doses they got and when they were given," he said. ``It's the process, the records and the details of how the scientists went about doing their research."

Stewart Farber, a Rhode Island medical-radiation physicist who was among the first to raise questions about the Navy experiments, said it's now up to the military to act on the information.

``I think this (discovery) is a very big development," Farber said. ``Now the proof is in what they do from here on."

Bailey told the newspaper that the Pentagon would go all out to track and contact every one of the 1,611. He said the log includes service numbers that may help trace the people.

The experiments involved giving nasopharyngeal radium treatments, which patients contend were unproven and experimental, for such ailments as the inability to adjust to rapid pressure change such as would be experienced in submarines. Radium-tipped rods were inserted into the nostrils for several minutes at a time in an effort to shrink tissue near the eustachian tubes.

The National Centers for Disease Control and Prevention said last year that between 500,000 and 2.5 million Americans received nasal radium treatments for everything from persistent nasal infections to deafness.

Some have questioned whether radium caused such health problems as tumors, endocrine and autoimmune disorders, miscarriages and brittle teeth.

Bailey said veterans should be notified if they're included in the log so they can consult physicians and seek medical advice and care if needed.

His recommendation that the patients be contacted contradicts the Presidential Commission on Human Radiation Experiments, which said no medical benefit could be gained from notification.

``I know what they said, and I know this is contentious in some circles," Bailey said, ``but we believe certain people should be notified because they were exposed in certain events like these."

Bailey said he believes the government is beginning to grasp the significance of the problem, which Farber said dwarfs all other documented human radiation experiments combined.

Employees Banned To Gamble At Foxwoods To Get Chance At Neighboring Casino<

LEDYARD, Conn. (AP) Foxwoods Casino Resort employees who are prohibited from gambling where they work will soon be able to place their bets at a neighboring casino.

On Monday, John B. Meskill, executive director of the state Division of Special Revenue said that Foxwoods employees will be allowed to gamble at the Mohegan Sun Casino which is scheduled to open in October.

``I looked through the Mashantucket gaming procedures and the state statutes, and I don't find anything that would preclude Foxwoods employees from wagering at the Mohegan casino,'' he said.

Foxwoods' policy, which prohibits licensed employees from gambling there, affects about 11,000 people. The purpose of the ban is to prevent collusion among employees.

Employees of Connecticut's parimutuel facilities, two dog tracks and a jai alai fronton, are prohibited by state regulations from betting where they work, but are allowed to gamble elsewhere.

The Mohegan Sun Casino in Montville, which is being built about 10 miles from Foxwoods, will adopt a similar policy when it opens.

``The gaming not only has to be fair and honest. It has to be perceived that way by the public,'' said Francis M. Mullin, director of regulations for the Mohegans.

The casino, owned by the Mohegan Indians, plans to employ 4,500 to 5,000 people.

In addition to Mohegan employees, he said, Mohegan tribal members and their families will be prohibited from gambling at the Sun casino. But tribal family members will be allowed to play bingo because the game is so tightly controlled, he said.

At Foxwoods, which is owned by the Mashantucket Pequots, tribal members can gamble as long as they are not members of the tribal council, directors of Foxwoods or casino employees.

In a memo earlier this month, Foxwoods President G. Michael Brown told employees they are free to bet at the new casino.

``Have fun but don't lose your shirts,'' he wrote.

BC-CT--Day Ahead, TUESDAY, July 30, 1996<

HARTFORD Video conference linking Saint Francis Hospital and Medical Center and Hartford Hospital to mark implementation of new computer network that will link the hospitals' obstetrical facilities. 8:30 a.m. Seery Board, St. Francis Hospital, 114 Woodland St. or 5-South Labor/Delivery Suite, Hartford Hospital, 80 Seymour St. Contact: 714-4511 or 545-2160.

HARTFORD Boston Celtics to hold Summer Jam and basketball clinic with Rick Fox and Eric William. 9 a.m., Willie Ware Community Center, 697 Windsor St., 12:30 p.m. Main St. Market. Contact: 986-7592, 854-8003. Rain sites have been scheduled at the YMCA, 160 Jewell St.

HARTFORD Attorney General Richard Blumenthal and Consumer Protection Commissioner Mark Shiffrin to hold news conference on settlement in lawsuit against the maker of a product marketed as a hearing aid, 12:30 p.m. Attorney General's

Office, 55 Elm St. Contact: 566-8239 or 566-4894.

NEW LONDON Vice Adm. Albert Herberger, administrator of the United States Maritime Administration will join U.S. Rep. Sam Gejdenson, tribal chairman Richard Hayward and other officials for the keel laying for Sassacus, a high-speed ferry, 10 a.m. Pequot River Shipworks, 18 Eastern Ave. Contact: 572-6572.

HARTFORD State Sens. Toni Harp, D-New Haven, and Edith Prague, D-Columbia, will hold a news conference with doctors and members of AARP to celebrate the 31st anniversary of Medicare. Besides celebrating the program, they will criticize Republicans for threats against the program, 12:30 p.m., outside the state Capitol. Contact: Donnie Fowler, 278-5454.

HARTFORD The NHL's Hartford Whalers to hold news conference, 1 p.m. Director's Suite, Hartford Civic Center. Contact: Chris Brown, 728-336 ext. 355.

127 AP 07-30-96 03:37 EST 26 Lines.

Tomasso Construction Denies Willful OSHA Violation<

NEW BRITAIN, Conn. (AP) The George A. Tomasso Construction Corp. has denied it willfully violated safety rules at a construction site.

The company said Monday it plans to talk over the allegation with the Occupational Safety and Health Administration, said Jay Malcynsky, court-appointed conservator and acting president of the company.

OSHA last week alleged Tomasso willfully violated safety rules by failing to properly secure a trench and failing to provide a ladder or other means of escape for workers in case the trench caved in.

Malcynsky said Tomasso is conducting an internal investigation of the allegation, and plans to talk it over with OSHA.

``Nothing in what we've discovered so far would indicate if a violation took place, it was willful in nature,'' he said.

OSHA has proposed a $49,500 fine.

Malcynsky said the allegation had nothing to do with Tomasso's recent financial troubles. In September, the company suspended 19 state road projects and laid off most of its workers.

Colonel favors notifying sub students treated with radium

KAD

Pentagon undecided about how to proceed

By ROBERT A. HAMILTON
Day Staff Writer
7/31/96

The deputy director of the Pentagon's Radiation Experiments Command Center said he will urge that submariners who received a controversial nasal radiation treatment be notified of the potential for health effects.

Col. Claud Bailey said a medical log discovered at the Naval Submarine Base in Groton earlier this year identifies 1,611 people who received the treatment as students at the submarine school in the 1940s and '50s.

But Pentagon spokesman Bryan Whitman said the Department of Defense has not decided how it should proceed, and an analysis of the log is continuing. "I can't speculate on what the next step will be, but we're definitely committed to pursuing this," Whitman said.

The Navy announced in May that the log had been found at the Naval Submarine Medical Research Lab at the base, although at the time it was said to list more than 400 names; Bailey said it provides links to hundreds more subjects.

Whitman declined to comment on whether the log contains sufficient information to track down all 1,611 people who received the treatment.

"I can't get into exactly what the log says," Whitman said. "We are investigating the contents of the log, and will pursue it with some vigor."

Treatments not tests

Bailey said the records also show there was no attempt to use the submariners as test subjects to determine the safety of the radiation treatments, as some critics have suggested.

The research being conducted at the base was to determine if a civilian process of shrinking nasal tissue with radiation could be used to treat pressure-induced ailments in the ears of submariners, Bailey said.

"The Navy was not trying to determine if these treatments were dangerous, but whether the treatments could be used for (nasal-related ailments)," Bailey said. "As far as whether it was considered even potentially harmful to the soldiers and sailors, it was not. The report indicates that the procedure was safe."

After World War II, and until the 1960s, physicians often used small amounts of radium to burn off excess tissue causing problems in the inner ear. The practice became common among submariners and Air Force flight crews.

Studies have been inconclusive at proving ill health effects, a conference at Yale University concluded last year. The U.S. Centers for Disease Control has said while there is insufficient evidence to warrant tracking down patients who received the procedure, people who know they received the treatment should tell their doctors.

Critics of the procedure, however, contend that there is enough evidence of ill

See COLONEL page B2

Colonel urges notifying patients

From B1

health effects, such as head and neck cancers, that a large scale study should be conducted, and the former submarine school students could form the basis of such a study.

The Navy has in the past said the students would be difficult to track down because there were no records, although the discovery of the log could remove that barrier. An additional problem, however, is that many records from that era were lost in a warehouse fire in St. Louis.

Also at issue in the past is whether the Navy knowingly put people at risk to test radiation treatments. The Navy contends that the treatments were accepted practice at the time, and the research at the school would be akin to studying whether Tylenol or aspirin works better on a headache today.

"Looking at the log, it is clear in my mind this was an experiment," Bailey said. "But the debate is, at what point did this become a normal, therapeutic treatment," he said, and the report indicates that it was considered therapeutic in the civilian community before the Submarine Base trials began.

Re: Kelly Kirkpatrick
From Ken M

Navy finds the names of radiation 'guinea pigs'

By Lawrence Spohn
TRIBUNE REPORTER

The Navy has found an experimenter's log book that names 1,611 submarine students who were exposed to high doses of radioactive radium more than 50 years ago, a military officer says.

"We are heartened by this, that we now have the log, that we have actual names," Army Col. Claud Bailey said Friday. Bailey is heading a Department of Defense investigation of the records found by the Navy.

The log, which the Navy had long said either did not exist or could not be found, was kept by radiation experimenter Dr. Henry L. Haines.

The students were the first an estimated 14,000 to 20,000 American military personnel who got what some have called "the treatment." Radium-tipped rods were inserted up their noses as an experimental treatment for certain ailments.

He did the experimental treatments at the Navy submarine base in Groton, Conn., where the log was recently discovered during recent renovations.

"I think this is a very big development," said Stewart Farber, the Rhode Island health-radiation physicist who first raised questions about the Navy experiments. "Now, the proof is in what they do from here on."

Although many of those exposed may be dead or very old, Bailey said, the Department of Defense is going all out to try to contact them because they may be at risk for head and neck cancers.

The discovery makes it undeniable that the military conducted medical radiation experiments on its personnel. The military had previously claimed that nasal pharyngeal irradiation was a common medical procedure.

"There is no doubt," said Bailey, who is deputy director of the DOD's Radiation Experiment Command Center in Alexandria, Va.

"As a matter of fact, if you look at the document, the words show it was research, and in fact, it says it was an experiment.

"It established the protocol and specifies the doses they got and when they were given. It's the process, the records and the details of how the scientists went about doing their research."

The so-called "lost guinea pigs" were the first of an estimated 14,000 to 20,000 American military personnel who ultimately got what some have called "the treatment."

Radium-tipped rods were inserted up their noses for several minutes at a time to deliberately damage tissue. It was an experimental treatment for certain ailments, including the inability to adjust to rapid pressure changes such as in submarines and airplanes.

The experimental subjects are among as many as 2.5 million Americans who got nasal

Please see EXPERIMENTS

EXPERIMENTS *from A1*

radium treatments for everything from persistent nasal infections to deafness. Some argue that acceptance of the treatments was based upon the touted success of the military experiments.

One medical study of adults who got nasal radium as children found a three- to fourfold increase in head and neck cancers and a strong association with thyroid disease.

Bailey said the log contains service numbers that can be used to check individual medical-service records and perhaps to locate those exposed.

"We're going to do everything we can to see if they can be identified and contacted," Bailey said. "We're going to go out and do our damndest to leave no stone unturned."

If at all possible, veterans who were exposed should be notified so they can seek medical advice and care if needed, Bailey said.

Contacting them would directly contradict the recommendations made last year by the much-criticized Presidential Commission on Human Radiation Experiments.

The commission argued that even if individuals could be identified and were still alive, no medical benefit would be gained by notifying them because there is no successful treatment for brain cancer.

"I know what they said, and I know this is contentious in some circles," Bailey said. "But we believe certain people should be notified because they were exposed in certain events like these."

Bailey said Farber's original estimates on 20,000 servicemen getting nasal radium is close to the mark.

Farber also originally projected conservatively that 200,000 to 400,000 Americans might have received the treatment. Last year, the Centers for Disease Control and Prevention estimated that between 500,000 and 2.5 million people probably got it.

The CDC has announced it will conduct a national satellite video conference Sept. 5 to explore the medical and research issues of nasal radium treatments for government agencies, doctors and medical centers, including veterans hospitals and treatment centers.

Bailey said he believes the government is beginning to grasp the potential significance of the problem, which Farber long has argued dwarfs all of the other documented human radiation experiments combined.

Because so much is known about the exposures the submariners got, they could be the subject of a remarkable case study, Farber said.

July 29, 1996

N E W S R E L E A S E

U.S. SENATOR JOE LIEBERMAN
CONNECTICUT

PRESS OFFICE: (202) 224-4041 or (202) 224-9965 (after 6 p.m.)
Jim Kennedy (202) 583-5697 (H) Kathie Scarrah (703) 845-2874 (H)
Actuality Line : (202) 224-6095

FOR RELEASE

July 20, 1994

Lieberman Urges President To Order Study Of Radium Treatments

Senator Says New Evidence Describes Experimental Nature Of Treatments; Data Indicates Abnormal Cancer Rate

WASHINGTON, DC -- In a letter to President Bill Clinton, Senator Joe Lieberman says newly discovered documents describe radium treatments given to more than 7,000 military personnel from the 1940's to the 1970's as "experimental," and one study states that people receiving the treatments may experience brain cancer at rates comparable to those of all cancers among Hiroshima and Nagasaki survivors.

Citing the "disturbing new data," Senator Lieberman is urging the President to order an epidemiological study of those who received the radium treatments. Senator Lieberman said the treatments should also be made part of the jurisdiction of the Human Radiation Interagency Working Group, which President Clinton established to examine other experiments involving radiation exposure to human beings.

Thousands of military personnel, particularly those who served on submarines and in aircraft, and civilians underwent radium nasopharyngeal irradiation in an effort to treat middle ear lesions caused by failure to equalize pressure between the middle ear and the atmosphere.

(more)

The treatments were first given by doctors at Johns Hopkins in the late 1920's, and medical papers indicate that the Armed Services began investigating the technique in 1942. In a 1945 paper, Navy physicians describe what they term their "experiments" to develop a reliable radium treatment since, as they state, "we had a rich source of material." The "material" refers to 732 Navy personnel who were involved in the experiments. According to a medical journal published in 1945, similar experiments were conducted on 6,881 Army Air Force personnel.

The treatments involved sticking 50 milligrams of radium-226 up a patient's nose and into the nasopharyngeal orifice in an attempt to "burn out" adenoid and lymphoid tissue. "The apparent short-term success of this treatment led to its application on large numbers of Armed Services personnel," Senator Lieberman said. It has been estimated that at least 10,000 Navy personnel, 25,000 Army Air Force personnel, and 10,000 family members of military personnel were treated by military physicians. After World War II, the procedure was used on civilians, with some reports of at least 200,000 individuals, mostly children, receiving radium treatments through 1974.

Senator Lieberman said the Submarine Survivors Group, a private organization of citizens investigating the radium treatment issue, has identified a 1982 study in the "Journal of the National Cancer Institute" that concludes there has been "a statistically significant overall excess of malignant neoplasms of the head and neck among exposed subjects." Using that study, the Submarine Survivors Group states that the number of excess cancer deaths between those who underwent radium nasopharyngeal irradiation and those who were exposed to the atomic bombs in Japan appear to be comparable.

In his letter to President Clinton, Senator Lieberman states, "Your administration has done groundbreaking work on opening long closed doors to bring to light information on radiation experiments by the government. Those veterans who served as subjects in the program to develop the radium nasopharyngeal irradiation treatment, together with the individuals who underwent this radium treatment after the initial Armed Services experiments, deserve to know if their health is at risk and, if so, what steps they should take to minimize that risk." Senator Lieberman's letter to President Clinton is the latest in a series of letters he has sent to various Administration officials about the radium treatment issue, including Veterans Affairs Secretary Jesse Brown, Health and Human Services Donna Shalala, and Centers for Disease Control Director David Satcher.

N E W S R E L E A S E

U.S. SENATOR JOE LIEBERMAN
CONNECTICUT

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FOR RELEASE

July 30, 1996

Lieberman Shocked To Learn Radium Treatments Were Experimental

Washington, D.C. -- Senator Joe Lieberman today said he was shocked to learn that a Department of Defense investigator has uncovered information indicating that nasal radium treatments performed on military personnel in Connecticut and elsewhere were experimental.

"This is an absolute outrageous development," Senator Lieberman said. "We have a moral obligation to find these veterans, notify them of the potential problem, apologize to them and urge them to see their doctor to determine if they have any health problems related to their radium treatments."

Senator Lieberman has been actively involved with this issue, urging the Navy to identify patients treated by Dr. Henry Haines in the mid 1940's. Earlier this year, the Navy discovered a log containing names of military personnel and civilians treated by the Connecticut doctor. A recent investigation of the logs uncovered the experimental dosages given to patients and indicated the treatment was for research.

In 1994, Senator Lieberman, a member of the Senate Armed Services Committee, held a congressional hearing and fought for a VA study of veterans who underwent radium treatments to correct ear problems caused by rapid ascents in submarines. The treatments were designed to "burn out" adenoid and lymphoid tissue, however some evidence indicates the treatments may lead to cancers in the head and neck.

"We ought to learn from this and make sure it never happens again," Senator Lieberman said. "This was a sad chapter in our nation's history."

-- 30 --

OFFICE OF MANAGEMENT AND BUDGET

Legislative Reference Division

Labor-Welfare-Personnel Branch

Telecopier Transmittal Sheet

FROM: Melissa Cook **PHONE:** 395-3924

DATE: 8/14/96 **TIME:** _____

Pages sent (including transmittal sheet): 9

COMMENTS:

Per our conversation

TO:

Molly Brostrom

=no action on HR 2080 → Stump bill would treat nasoph. diff from other radiation exposed

Registry: allows + but + can

=? abt leg. status of proposal

PLEASE CALL THE PERSON(S) NAMED ABOVE FOR IMMEDIATE PICK-UP.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

LRM NO: 3841

FILE NO: 2036

3/20/96

LEGISLATIVE REFERRAL MEMORANDUM

Total Page(s): 8

TO: Legislative Liaison Officer - See Distribution below:

FROM: Janet FORSGREN Janet Forsgren (for) Assistant Director for Legislative Reference

OMB CONTACT: Melissa COOK 395-3924 Legislative Assistant's Line: 395-7362
C=US, A=TELEMAIL, P=GOV+EOP, O=OMB, OU1=LRD, S=COOK, G=MELISSA, I=Y
cook_my@a1.eop.gov

SUBJECT: VETERANS AFFAIRS Proposed Report RE: HR2080, Priority Health Care for Nasopharyngeal Irradiation Treated Veterans

DEADLINE: C.O.B. Friday, March 29,1996

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President.

Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

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Mary Jo Siclari
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Al Maldon
OMB LA
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Janet Forsgren
Phil Caplan

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: **3841**

FILE NO: **2036**

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet.
If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.
You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: Melissa COOK 395-3824
Office of Management and Budget
Fax Number: 395-6148
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: VETERANS AFFAIRS Proposed Report RE: HR2080, Priority Health Care for Nasopharyngeal Irradiation Treated Veterans

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of ____ pages, attached to this response sheet

THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

The Honorable Bob Stump
Chairman, Committee on Veterans Affairs
U.S. House of Representatives
335 Cannon House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

You have requested our views on H.R. 2080, a bill "to amend title 38, United States Code, to provide priority health care by the Department of Veterans Affairs for veterans who received nasopharyngeal irradiation treatments while serving in the Armed Forces." H.R. 2080 would require the Secretary to provide priority health care, for any disability, to a veteran whom the Secretary finds received nasopharyngeal irradiation treatments during active military service, notwithstanding that the medical evidence is insufficient to determine a causal relationship between the radiation exposure and disability. Priority health care would be available to these veterans on both an inpatient and outpatient basis through December 31, 1998.

In the 1940's and 1950's, physicians considered the administration of nasopharyngeal irradiation treatments to be acceptable medical practice for shrinking lymphoid tissues that blocked the Eustachian tubes. The procedure prevented hearing loss, aerotitis medical, and other middle ear problems. Military physicians administered this treatment to alleviate medical conditions caused by rapid pressure changes associated with submarine and aviation duties. Since the late 1940's, physicians have raised concerns about the safety of such therapy and possible adverse long-term effects associated with its use, including the possibility of an increased risk of cancer of the head and neck. It is also possible that the treatments may result in other types of diseases such as endocrine disorders. However, the scientific evidence is still inconclusive as to any such associations.

The Honorable Bob Stump

VA supports H.R. 2080, as discussed below, which would expand eligibility for VA priority health care to include veterans for disabilities possibly associated with the receipt of nasopharyngeal irradium treatments. Although this treatment was considered to be a medically acceptable procedure at the time it was used, military personnel did not receive these radium treatments in response to their individual medical needs. Rather, nasopharyngeal irradiation treatments were used solely to enable them to perform their military duties. VA is committed to helping any veteran who believes he or she may have been injured by any procedure or treatment that the Government rendered as part of the veteran's military service. H.R. 2080 would allow VA to meet the special medical needs of this population by placing them on a par for priority health care with veterans who may have been exposed to Agent Orange during the Vietnam War era, ionizing radiation during World War II, or a toxic substance or environmental hazard during the Persian Gulf War.

In contrast to VA's other priority health care authorities, H.R. 2080 would allow these veterans to receive all care, even when their disabilities are clearly due to causes other than nasopharyngeal irradium treatments. As a result, the scope of priority care available to these veterans would be greater than that which is available to Agent Orange veterans, radiation-exposed veterans, and Persian Gulf War veterans. To be equitable, VA recommends amending H.R. 2080 to make it similar in all respects to VA's other priority health care authorities. We further recommend that the Committee amend the bill to provide that veterans who received nasopharyngeal irradium treatments be included in VA's Ionizing Radiation Registry Program so that they, similar to "atomic veterans," are eligible for radiation-related registry examinations.

If H.R. 2080 is amended, as recommended, the total cost to the Department is estimated to be approximately $3 million for Fiscal Years 1997-2001. However, if H.R. 2080

is not so amended, the total five-year cost to the Department over that time period is estimated to be $22.5 million. (We have projected costs over a five-year period notwithstanding that this treatment authority, if enacted, would terminate after December 31, 1998.)

I

104TH CONGRESS
1ST SESSION

H. R. 2080

To amend title 38, United States Code, to provide priority health care by the Department of Veterans Affairs for veterans who received nasopharyngeal irradiation treatments while serving in the Armed Forces.

IN THE HOUSE OF REPRESENTATIVES

JULY 20, 1995

Mr. GEJDENSON introduced the following bill; which was referred to the Committee on Veterans' Affairs

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A BILL

To amend title 38, United States Code, to provide priority health care by the Department of Veterans Affairs for veterans who received nasopharyngeal irradiation treatments while serving in the Armed Forces.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. PRIORITY HEALTH CARE FOR VETERANS WHO RECEIVED NASOPHARYNGEAL IRRADIATION TREATMENTS WHILE SERVING IN THE ARMED FORCES.

(a) INPATIENT CARE.—Section 1710 of title 38, United States Code, is amended—

(1) in subsection (a)(1)(G), by inserting "or who received nasopharyngeal irradiation treatments," after "environmental hazard,";

(2) in subsection (e)—

(A) by adding at the end of paragraph (1) the following new subparagraph:

"(D) Subject to paragraphs (2) and (3) of this subsection, a veteran who the Secretary finds was given nasopharyngeal irradiation treatments while serving in the active military, naval, or air service is eligible for hospital care and nursing home care under subsection (a)(1)(G) for any disability, notwithstanding that there is insufficient medical evidence to conclude that such disability may be associated with such exposure."; and

(B) in paragraph (3), by striking out the period at the end and inserting in lieu thereof ", or in the case of care for a veteran described in paragraph (1)(D), after December 31, 1998.".

(b) OUTPATIENT CARE.—Section 1712(a)(1) of such title is amended—

(1) by striking out "and" at the end of subparagraph (C);

(2) by striking out the period at the end of subparagraph (D) and inserting in lieu thereof "; and"; and

(3) by adding at the end the following new subparagraph:

"(E) during the period before Janaury 1, 1999, for any disability in the case of a veteran who the Secretary finds was given nasopharyngeal irradiation treatments while serving in the active military, naval, or air service, notwithstanding that there is insufficient medical evidence to conclude that such disability may be associated with such exposure.

(c) CONFORMING AMENDMENT.—Section 1712(a)(7) of such title is amended by inserting "or (1)(E)" after "paragraph (1)(D)".

○

NASOPHARYNGEAL RADIUM IRRADIA' 'ION
Current Medical Issues

A Public Health Training Network Satellite Videoconference
September 5, 1996 12:30 - 2:30 PM EDT

Program Description
Between 1940 and the mid 1960's, **nasopharyngeal radium irradiation** was used to treat children with chronic ear infections and hearing loss, and World War II submariners and aviators with otic barotrauma. An estimated 500,000 people were given the treatment. This live, interactive videoconference will educate health care professionals about the **emerging medical problems** which may result from past practice. Physicians will learn to recognize the symptoms and problems which may develop, and will be informed about circumstances requiring referral.

Who Should Attend
Physicians in general practice, family practice, internal medicine, otolaryngology, radiology, and nuclear medicine; nurse practitioners and physician assistants in the same fields.

Objectives
As a result of attending, physicians will be able to:
- describe the medical use of an historic radiation treatment;
- describe the radiation dose and possible adverse health outcomes for five nearby areas of the body: nasopharynx, pituitary, brain, salivary glands, and thyroid;
- describe how to take an accurate medical history from a patient who had this treatment;
- describe how to perform a thorough head and neck exam, and know when to refer to a specialist.

Sponsors and Partners
The Centers for Disease Control and Prevention (CDC), National Center for Environmental Health (NCEH), in partnership with the Department of Veterans Affairs, the Department of Defense, the Association of State and Territorial Health Officials (ASTHO), and the Public Health Training Network (PHTN)

Faculty
Richard Jackson, MD, MPH, CDC, NCEH
Susan Mather, MD, MPH, Department of Veteran Affairs
Anne Mellinger-Birdsong, MD, MPH, CDC, NCEH
Douglas Ross, MD, Yale University
Donald Proctor, MD, Johns Hopkins University
Henry Royal, MD, Mallinckrodt Institute Of Radiology, Washington University
L e Sandler, PhD, National Institute of Environmental Health Sciences
Capt. Steven R. Warlick, MD, Portsmouth Naval Medical Center

Registration After June 1
To receive registration materials, clearly PRINT your name, complete address, day phone #, Fax phone #, and the word "NASO" on white paper. Fax to PHTN: **(800) 553-6323**. Materials will be sent in August, including satellite technical specifications.

Accreditation
A variety of continuing education credit will be offered based on two hours of instruction. Specific details will be sent with the registration materials.

How to View the Program
Participation requires a satellite downlink site that has a steerable antenna which can receive either Ku- or C-band channels. A telephone in the viewing room will allow for interaction with the presenters. Most schools, hospitals, community colleges, universities, and county extension offices have the required equipment. All VA hospitals will receive this program.

Test Date and Time
September 3, 1996 12:30 PM EDT

Program Test Time
C-band: TBA **Ku-band:** TBA

Satellite Technical Specifications

C-band	Ku-band
Satellite: TBA	Satellite: TBA
Transponder: TBA	Transponder: TBA
Polarization: TBA	Polarization: TBA
Video Freq: TBA	Video Freq: TBA
Audio Freq: TBA	Audio Freq: TBA

Satellite tech specs are same for Test Date and Program.

Satellite 800 Numbers
Voice: (800) 432-2306 FAX: (800) 553-6323
TTY: (800) 815-8152 Tech. Trouble: (800) 728-8232

(V-6/11)

peratures, opportunities for cross-contamination were detected. Measures for preventing cross-contamination include washing hands and surfaces after contact with raw ground beef, storing raw ground beef to ensure that drippings do not contaminate other foods, and using different utensils to handle raw and cooked meat.

As of January 1996, reporting of *E. coli* O157:H7 infection was required by 38 states (W. Keene, Oregon Department of Human Resources, personal communication, 1996), including Georgia and Tennessee; neither state had required reporting of *E. coli* O157:H7 at the time of this outbreak. The outbreak described in this report underscores the need for clinical laboratories to screen stool specimens for *E. coli* O157:H7 on sorbitol-MacConkey (SMAC) agar. In this outbreak, *E. coli* O157:H7 was detected by a laboratory in Georgia that routinely screened for this pathogen. In a recent survey of clinical microbiology laboratories in the United States, only 54% screened all bloody stool specimens on SMAC agar.[4] CDC recommends that laboratories in all states screen at least all bloody stools for *E. coli* O157:H7.

References 4 available.

Workshop on the Public Health Response to Nasopharyngeal Radium Irradiation

MMWR. 1995;45:254-256

DURING September 27-28, 1995, a workshop entitled "Public Health Response to Nasopharyngeal Radium Irradiation" was convened in New Haven, Connecticut, to address issues regarding possible adverse health effects of this former medical treatment. Workshop participants discussed the strengths and weaknesses of possible epidemiologic studies.

From 1940 through the mid-1960s, nasopharyngeal (NP) radium was used to treat hearing loss, chronic otitis, and other conditions in children and was used to treat aerotitis media in submariners and aviators in the military. The goal of this approach was to reduce swelling of enlarged lymphoid tissue, which was believed to be a cause of both hearing loss and aerotitis media. Treatment usually included insertion of an applicator with a capsule of radium through each nostril and placement of the radium near the eustachian tube opening for 8-12 minutes.

Workshop participants presented estimates of the numbers of persons treated and of the doses to nearby organs. An estimated 500 000-2 million persons may have received NP radium treatments. Radiation doses to nearby organs were estimated on the basis of bilateral use in an adult of 50 mg of radium sulfate in a 0.5-mm platinum capsule for 12 minutes per session for three sessions. Estimates were 2000 rads to local tissue, 24 rads to the pituitary gland, 5 rads to the brain, and 2 rads to the thyroid.

Based on a cohort study in Maryland of 904 exposed and 2021 unexposed persons during 1943-1960, the risk for all head and neck cancers combined was higher among persons who had received the treatment than among persons who had not[1]; however, this finding was based on small numbers of cancers (three brain and one soft palate cancer) and was statistically significant only after categories were combined. A cohort study in the Netherlands of 2510 exposed and 2199 unexposed persons did not document a statistically significant increase in head and neck cancers in the exposed group.[2] Follow-up studies of both cohorts are under way.

A panel of medical and public health experts and representatives of veterans' and civilians' groups then discussed and provided comments for a workshop report. The report encouraged CDC and the U.S. Department of Veterans Affairs (VA) to collaborate on the following public health activities:

- 1. Continue the follow-up studies of existing cohorts, and if possible, combine the data from these studies, include noncancer endpoints in the follow-up studies, and evaluate the results of the follow-up studies before considering an additional cancer incidence study of persons who received NP radium treatments. Although studies of persons who self-report exposure to the treatment are useful in generating hypotheses, such self-reporting should not be the means of identifying formal "case-subjects" in epidemiologic studies.
- 2. Veterans who received NP radium treatments should be provided access to the Ionizing Radiation Registry maintained by the VA and to priority medical care at VA medical facilities.
- 3. Rather than screening asymptomatic persons, physicians should be educated about how to obtain more complete and accurate histories from patients who received NP radium treatments. Subspecialists should be provided specific information about NP radium exposure.

Reported by: J Stolwijk, PhD, A Saftlas, PhD, Dept of Epidemiology and Public Health, Yale Univ School of Medicine, New Haven. ML Fleissner, DrPH, Connecticut Dept of Public Health. Association of State and Territorial Health Officers, Washington, DC. S Mather, MD, Office of Public Health and Environmental Hazards, US Dept of Veterans Affairs. Radiation Studies Br, Div of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC.

CDC Editorial Note: Nasopharyngeal radium was one of several radiation treatments used to treat benign conditions before 1950. Other approaches included use of external x-irradiation to treat hearing loss, acne, tinea capitis, and enlarged thymus, and the use of radon and radium to treat hemangiomas.[3-7] When radium treatments were developed and used, other options were either not available, were considered more invasive, or involved external irradiation. Following the publication during the 1950s of findings regarding long-term effects of radiation, health-care providers reserved therapeutic radiation only for serious or life-threatening conditions.

Because most of the radiation from NP radium was in the form of beta particles, the highest dose was delivered to the soft tissue of the nasopharynx, in which the background rate of cancer is low (0.6 per 100 000 persons)[8] and which has not been documented to be as sensitive to radiation as thyroid or brain tissue.

In collaboration with workshop cosponsors, CDC plans wider published dissemination of the proceedings of the workshop. The VA is seeking legislation to provide veterans who received NP radium treatments with access to the VA Ionizing Radiation Registry and priority medical care at VA medical facilities. CDC, VA, and the Association of State and Territorial Health Officers are developing a live satellite videoconference for physicians on NP radium, which will be aired on September 5, 1996, from 12:30 p.m. to 2:30 p.m. eastern daylight time.

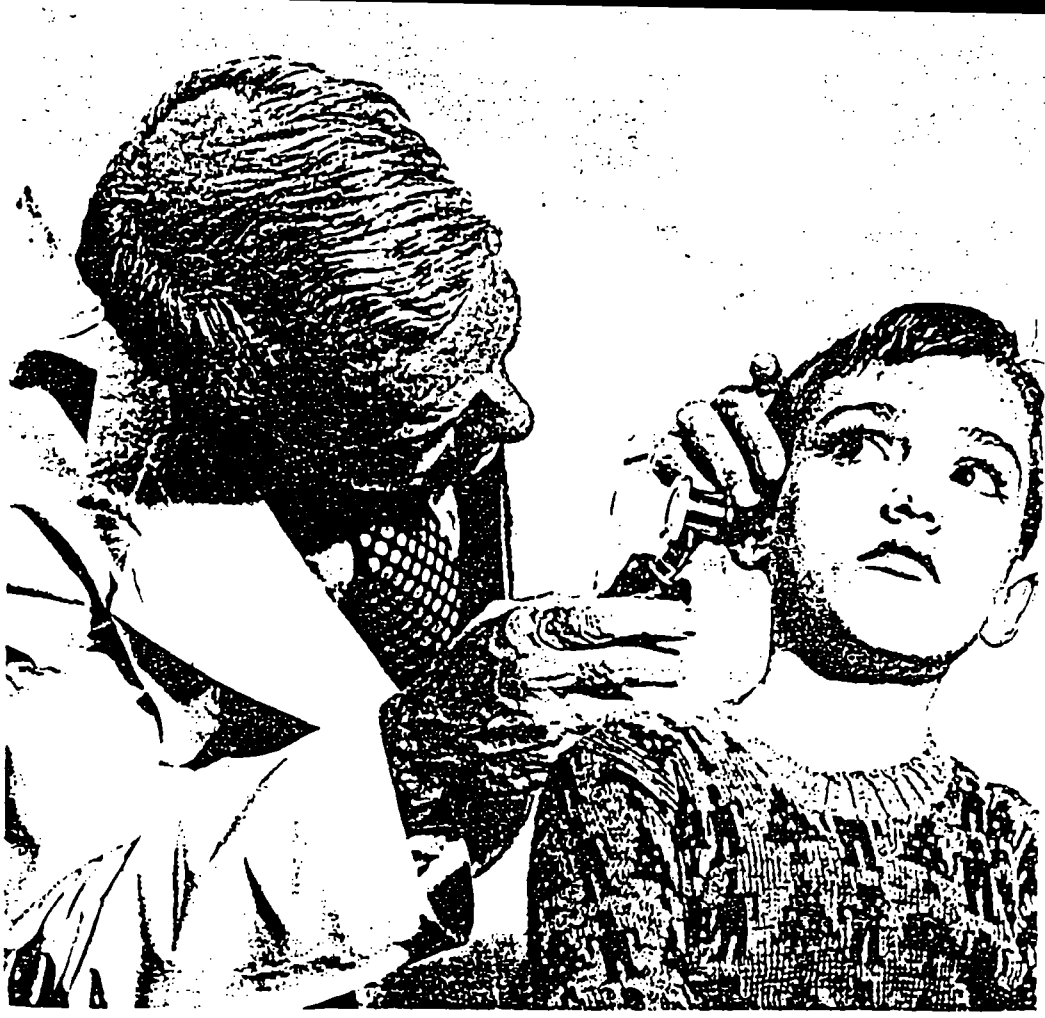
Current studies do not indicate substantial increases in risks for neoplastic or other disease among those who received NP radium treatments. Because the workshop discussion discouraged medical screening, diagnostic tests and procedures for asymptomatic persons are not warranted. However, physicians may consider performing thorough head and neck examinations of patients with a history of NP radium treatments. In addition, physicians who provide care for patients aged ≥35 years with head and neck complaints should ask the patients whether they have a history of NP radium treatments or other head and neck radiation. Persons who recall being treated or believe they were treated with NP radium should inform their physicians of the exposure.

References 8 available.

Will Your Child Be Deaf?

By MYRON STEARNS

An estimated 4,000,000 American children have middle-ear defects that will lead to varying degrees of deafness in later life. But something can be done about it—if it's done in time.



PHOTOS BY BOB JONES

Dr. Samuel J. Crowe, of Johns Hopkins, and a patient. This otologist, a leader in the war on impaired hearing, says: "The public should be taught to think of most deafness as a preventable disease."

KATHLEEN, my friend Don Cooley's daughter, is eight years old. Last winter, when she was seven, Don and his wife began to be a little worried about her, because she had had so many colds. She seemed to be unduly susceptible to them. nose would be blocked, and for days her whole head would be stuffy. Since Don is an unusually posted citizen who has written a good deal on medical subjects, he wondered if her hearing was being affected. She was dropping behind a little in schoolwork. So he took her to a good otologist, which is the tall name medicos give to ear doctors.

Kathleen's examination showed that her hearing in the higher tones—far up above high C—which usually makes no difference at all in understanding ordinary conversation, wasn't quite so good as it ought to be. Fortunately, her doctor was thoroughly familiar with the amazing but still little-known y that this article is going to tell you. So he knew what that drop in high-tone-hearing ability might mean, and suggested treatment with radon, which can be described as a gas given off by radium.

There were three treatments, about twenty days L. The radon was in a tiny cylinder at the end of a wire called an applicator. Kathleen's nose was given a quick spray with a mild local anesthetic—whiff, whiff—so that she wouldn't be bothered by the wire, which was then gently inserted along what doctors call "the floor of the nose" until it rested on little bulges of tissue near the entrance to the Eustachian tube, which leads from the throat cavity to the middle ear. It was left there a few minutes, then taken out. That was all. She was allowed to go home and play.

Treatment is for an expert: A radon (radium extract) applicator is in in the nostril.

Kathleen has shown no particular change since the treatments, except that her hearing in those seemingly unimportant higher tones has improved She is doing a little better in her schoolwork, and this last winter had only a single slight cold. But Don and his wife are greatly pleased, because they have headed off, and with occasional re-examination will continue to head off, what would very likely have developed into middle-age—and possibly much earlier—deafness for their daughter. Kathleen's case is typical of hundreds of pioneer cases that are the forerunners of a new treatment which eventually may prevent millions of cases of deafness that have hitherto been considered unavoidable.

Take the more spectacular story of Hattie Euell, who is an orphan at a Catholic home in upstate New York. In 1942, when Hattie was eleven, a short, blond little girl with glasses, she began having trouble with her schoolwork. Like Kathleen Cooley, she had many colds. Sometimes she would miss hearing what her teachers said or get directions wrong. All through 1943 and 1944 her hearing got worse, and she dropped almost to the bottom of her class. She began to be listless and discouraged. The Sisters who had charge of her became more and more worried about her. Finally they decided to risk the expense of a trip to New York for her, to see an otologist at the New York Eye and Ear Infirmary.

The otologist found that she had lost more than half the hearing in both ears, even in the middle range of spoken tones. Her adenoid tissue had grown back after an lier operation, and had begun to block the Eustachian tubes. She had three treatments similar to those given to Kathleen.

Within a few weeks Hattie began a complete amorphosis. Her hearing improved wonderfully, so that, though still handicapped, she could understand most conversation readily. Her schoolwork began to get better. Never a beauty, she became far more attractive. Today, at seventeen, she has blossomed out. She is getting ready for high school. Instead of being shy, afraid and discouraged, she is brighter, more confident, cheery. The Sisters are delighted with her transformation.

I went into the office of the specialist who had treated her, to see how it is done. Another patient, an eleven-year-old boy, was lying comfortably on his back on a padded examining table. He holding a comic magazine over his head, reading it interestedly, with the end of a wire applicator sticking out of one nostril. His mother was sitting beside him, also reading a magazine. A little alarm clock went off, the doctor checked the time by his watch, drew out the applicator, and the boy sat up.

"Bother you any?" I asked him.

"Nah!" he answered.

I was told of another boy who had asked, a day or so previously, not to have his nose sprayed before the applicator was put in place for his second treatment: the spray had bothered him more than the careful insertion of the applicator.

These cases all followed a wide investigation of hearing conditions undertaken by Dr. Samuel J. Crowe, of Johns Hopkins Hospital, and his associates, in the late '30's, of 1365 Baltimore school children, eight to thirteen years old. The findings were reported by Doctor Crowe and Dr. John W. Baylor in the Journal of the American Medical ciation in 1939. Although only three children in 100 had badly impaired hearing for all tones or in understanding of the human voice, nearly 40 per cent impaired hearing for some or all tones in the higher registers, beginning at about the upper level of ordinary conversation.

To [illegible] and adenoids of more than half of the [illegible] children had been removed, but had grown again in the majority of

In three quarters of all the children who had not been operated upon, there was enough of what doctors call ex[illegible] lymphoid tissue partially to block the Eustachian tubes.

In nearly 40 per cent of all those eight-to-thirteen-year-old school children, in other words, and in about 75 per [illegible] of those who had never been operated on for tonsils or adenoids, there existed throat-cavity conditions that endangered their hearing to an ex[illegible]; that in later life might handicap [illegible] with at least partial deafness.

Yet because these children—all except the 3 per cent whose hearing in all [illegible] already been affected—still had [illegible] hearing in the middle of the scale where human speech is—say from 250 to 3000 cycles, or vibrations, a second—there was no outward evidence, either at home or at school, to indicate the danger.

Even though, in many of these children, as in hundreds of thousands of other children the country over, there [illegible] the beginning of deafness in the middle tones, it was likely to be thought of, by both parents and teachers, as simply inattention. Untreated, the impairment of hearing gradually progresses, involving one octave after another.

Treatment by radon was undertaken on 209 of the Baltimore children and followed over a two-year period on 152 of [illegible] with numerous re-examinations to make sure of the results.

In [illegible] cases, results were as spectacular as they were with Hattie Euell. [illegible] was Johnny, for example, who unable to keep up with his class because of bad hearing. He had frequent colds, and breathed through his mouth. In 1937 his tonsils and adenoids had been taken out. The next winter his symptoms were worse than ever. He was transferred to a class for handicapped children and taught lip reading. When he was examined, both Eustachian tubes were found completely closed, and he was almost totally deaf. Five months after he been treated with radon his ing was almost normal.

"During this short period," wrote the doctors in their report, "he had transformed from a dull, listless child who had been in a lip-reading class for nearly a year to a bright, alert, healthy-looking boy."

With only a few children, of course, there such a noticeable gain. In [illegible] cases there was no improvement in hearing at all; the damage had already been done. In others, the deaf- kept right on increasing, in spite of all the doctors could do. But in all instances the improved condition of the Eustachian tubes was retained, giving nature as good a chance as possible to [illegible] at further middle-ear deafness. In [illegible] cases susceptibility to colds decreased markedly. Seasonal varia- [illegible] in hearing, from summer to winter, became much less in children who received the treatment.

The experiment convinced Doctor Crowe and his associates that parents, teachers and school nurses must be told how much damage can come from the neglect of bad middle-ear condi- [illegible] and how readily the condition today be improved. "The general public," Doctor Crowe wrote, "should be taught to think of most deafness as a preventable disease, not as a condition for which a specialist should be consulted after the damage is done."

Doctor Crowe's long research, which preceded the Baltimore examinations of school children's hearing, began in 1912. At that time he had already graduated from the University of Georgia and taken his medical degree at Johns Hopkins; he had assisted two famous surgeons, Dr. William S. Halsted and Dr. Harvey Cushing, for four years. He was coming to be known as a brilliant young brain surgeon. Then he was invited to establish a brand-new department for Johns Hopkins University and Hospital—an ear, nose and throat department. Although up to that time he had not specialized in such knowledge, he decided to accept.

Europe, in 1912, led the world in ear-and-throat science. Doctor Crowe, besides setting up the new department for Johns Hopkins, found time for study at Vienna, Leipzig and Berlin until he had mastered about all that was known concerning hearing and the diseases that impair it. He decided that not nearly enough was known on the subject. By 1924, twelve years after he had begun his work at Johns Hopkins, he established, with the assistance of funds from the Rockefeller Foundation, an otological research laboratory to study the causes and prevention of deafness.

Until that time doctors had tested hearing by such methods as asking patients to listen for the ticking of a watch; then they measured the distance the watch was from the ear when it was first heard. Examination of the upper portions of the throat cavity was made with the help of a reflecting mirror.

Doctor Crowe felt that he needed more accurate tests for hearing than anything then in existence. The Bell Telephone Laboratories lent him a testing machine, or audiometer, with tones that ran from 32 cycles, or vibrations, a second up to 16,384. Commercial audiometers, without having so wide a range, are today patterned after it. They are about the size of table radio sets, with headsets for the patient's ears. Each tone starts at zero when it is turned on, and increases until the patient can hear it. Then it is gradually turned down until the patient can no longer hear it, and the number of decibels when the patient first hears the tone and when he can no longer hear it is recorded. A decibel is the smallest change in the amount of sound recognizable by a normal ear. If you can't hear thirty-five decibels of sound, you are pretty deaf and do not have practical conversational hearing. After the first tone has been tested, another, an octave higher, is tried, and so on throughout the entire range of hearing.

You probably know that the human ear is divided into three parts. The outer ear, with its twisty little channel going into the eardrum, you can see and feel. The middle ear is a chamber in which three tiny bones connect the outer eardrum with a smaller, inner eardrum, or window. Ventilation of this middle-ear chamber is possible only through the Eustachian tube. When you swallow or yawn, the Eustachian tube opens and air pressure in the middle-ear chamber becomes the same as that outside. The inner ear, behind the inner eardrum, or window, is given over to vastly complicated, infinitesimal hearing mechanisms more marvelous than any church organ.

"The ultimate purpose of all investigations of the causes of impaired hearing," Doctor Crowe says, "is to learn how to prevent the development of the impairment and how to restore the hearing." With his improved instruments for measuring varying degrees of deafness, he began to find out things that had never been suspected before.

For 200 years it had been known that when the Eustachian tube is blocked, so that ventilation of the middle ear and the equalization of atmospheric pressure between it and the air outside is impossible, hearing is impaired. But until Doctor Crowe and his associates proved otherwise, it was believed that hearing of low tones, in the range of the speaking voice and below, was chiefly affected. Impairment of high tones was believed to result from nerve or inner-ear damage or incapacity, about which nothing could be done.

It took nearly twenty years of observation and research before that little thing—that high tones were affected by middle-ear changes before low tones were—could be demonstrated. Doctor Crowe began to collect records, made with the improved hearing testers, until he had accumulated more than 15,000 of them, illustrating every known type and degree of deafness, and leading "to conclusions that could not have been foreseen."

Presently he was able to show that impairment of high-tone hearing is far more common, among children as well as grownups, than had ever been realized. Also, that whenever ventilation of the middle ear through the Eustachian tube is seriously interfered with, impairment of high-tone hearing results.

That comes about in this way: Blockage of the Eustachian tube causes a partial vacuum in the middle ear, and this in turn brings about a swelling of blood vessels there, and an outpouring of serum. These circumstances "dampen" the action of the three little bones—the hammer, anvil and stirrup—which carry the sound vibrations across the middle ear from the eardrum to the inner ear. It's something like putting a mute on a violin bridge or stuffing cotton into the doorbell. In time, if the condition isn't rectified, the three little bones become permanently affected.

To show how promptly and definitely Eustachian-tube blockage interferes with hearing, one of Doctor Crowe's associates, Dr. Walter E. Loch, made a painful experiment on himself. He shut off his own Eustachian tubes with small rubber balloons, inserted through his nostrils before being inflated. He found that after the tubes had been closed for as little as twenty minutes, impairment of high-tone hearing became evident. After forty-five, sixty and seventy-five minutes, it became progressively worse—as the oxygen in the inner ear was absorbed and the vacuum increased—until there was a loss of at least twenty decibels at 13,004 cycles.

While this new knowledge was being gained, Doctor Crowe was also learning more about the manner in which the Eustachian tubes can be blocked. Here another invention came along to help out—the nasopharyngoscope, which looks a little like a tiny flashlight, so slender that it can be inserted through a nostril to illuminate the Eustachian-tube entrances.

A study of the results of tonsil and adenoid operations had already been made, showing that in some cases the hearing improved after the operation, and in others it didn't. The nasopharyngoscope helped show why: around the tube entrances excess tissue often grows right back after the operations, blocking it as much as before; sometimes even more.

Doctor Loch's experiments showed what youngsters with Eustachian-tube stoppages through colds have to endure. The main difference is that with children the blockage is often so gradual that, unless there is extreme pain resulting from the partial vacuum in the middle ear, they don't realize that anything in particular has happened, and don't complain. Since their low-tone hearing is often not affected at all, neither they nor their parents know anything about the trouble. In this way the most common kind of middle-ear deafness in adults begins in childhood, between the ages of five and ten.

To get rid of the extra amounts of tissue that so often grow around the entrance to the Eustachian tubes—sometimes from colds, sometimes after tonsil or adenoid operations—Doctor Crowe thought of radium. He talked the matter over with the late Dr. Curtis F. Burnam, who was a physicist and early radium experimenter as well as a doctor, and who worked with the Kelly Radium Clinic in Baltimore. As a result of their conversation Doctor Burnam worked out the idea of a radon applicator that could be inserted through the nostrils and placed right on the spot where it was needed.

Radon can be secured from radium by an extremely complicated prc Its life, compared to radium's, is extremely short. The radon in applicator tubes or cartridges lasts only about thirty days, and half its strength is gone in less than four days. But, for the Johns Hopkins doctors and others who were within reach of the Kelly clinic, it did the trick.

Next came the first large-scale examinations and treatments for Baltimore school children, corroborating Doctor Crowe's theories beyond anything that had gone before. The number of children with hearing defects who having nothing done for them was obviously appalling. Applying the Baltimore percentages to school children all over the country would mean that at least 4,000,000 children are suffering from middle-ear hearing defects that may, unless preventive measures are taken to correct them, cause in later life varying degrees of deafness that might easily have been avoided. It is not the size, but the location of the excess tissue at the mouth of the Eustachian tubes and the frequency of infection that are important.

The new treatment so affects the obstructing, spongelike lymphoid [illegible] that it is gradually absorbed by the system. It also flattens out the folds and crypts in this tissue, and thus removes a favorite lodging place for viruses. This latter effect, Doctor Crowe says, explains why the frequency and severity of colds are reduced in [illegible]y children who have received the irradiation treatment. It also explains why children often have fewer colds for a time following the removal of tonsils and adenoids, which are lymphoid tissue. We need some lymphoid tissue to filter out and destroy bacteria, but we can have too much of it; in which case it harbors and does not destroy viruses.

All these findings were new to the medical world. But the time limitation of radon made the use of the new applicators difficult in parts of the country distant from Johns Hopkins and Baltimore.

Then along came the war. It b [illegible]t an entirely new middle-ear develop-

ment. In aviation, ventilation of the middle-ear chamber is particularly important. Unless, by swallowing or in some other manner managing to open the Eustachian tube, pilots can equalize the pressure in the ear chamber with the varying air pressures at different altitudes outside, they suffer from attacks of what is known as serotitis. This is a disturbance caused when the middle-ear air pressure becomes less than that outside, so that the eardrum is pushed inward, as when a plane descends. It can be extremely painful. Sometimes it inflicts such agony that gunners, navigators, bombardiers or pilots may be completely incapacitated. It is sometimes accompanied by loud crackling or popping noises in the ears, sometimes by deafness that lasts for days. Sometimes there is even a pouring of blood and serum into the ear chamber. And though efforts were made to weed out, while still in training, airmen who were likely to suffer from it, there were plenty of victims who got through their preliminary work and went overseas. In England, during the winter of 1942–43, and in Italy during the following winter, there were many colds that made matters worse.

One surgeon wrote: "We deal constantly with flying personnel who have, or develop, a chronically recurring serotitis. Frequently this involves key personnel, whose utility to the service becomes seriously impaired. The usual story is that a mission is flown, followed by subsequent grounding for several days or weeks because of serotitis, and then the cycle is repeated. In the end, these men take up a lot of time of the unit surgeons, occupy hospital beds, and are not available for combat duty a third of the time."

To improve such conditions Doctor Crowe suggested to Maj. Gen. David N. W. Grant, the Air Surgeon, that a wide program be instituted to test and treat either potential or actual sufferers from serotitis. About fifty carefully selected otologists were called to Washington and trained for the work.

Since it necessitated an applicator more practical for large-scale work at varying distances than the radon apparatus, Dr. Donald Proctor, of Johns Hopkins, went to New York and suggested to the Radium Chemical Company, through Mr. George W. Loftus, that they make, *if possible*, a radium applicator that could accomplish what had so far been done successfully only with radon. After various experiments, a solution of the problem was reached: a thin radium applicator carrying fifty milligrams of radium—about $1200 worth—in a tiny metal cylinder. Instead of having a life of only about four days, like radon, radium keeps on going strong almost indefinitely. Its strength is only half gone in 16,000 years.

As with the first radon applicator, the new device was carefully tested, over and over again, to make sure that the amount of radium was exactly right, that the metal sheath was a satisfactory filter, and what the correct dosage, in minutes, should be. For safety and practicability, the applicators were carried from airfield to airfield, as needed, in a lead case shaped like a black cheese and weighing perhaps eighty pounds.

In all, during the last months of the war, when the whole serotitis program was functioning, some 25,000 Army and Navy airmen in training were examined, and as many as necessary of them were treated with radium.

At Westover Field, for example, one of the Air Force training centers in Massachusetts, 44 per cent of 3523 airmen examined were found to need treatment. At Southern airfields, where the climate is milder, the proportion was somewhat smaller.

There were no bad effects whatever from the treatment. On the other hand, some amazing results, in individual cases, were secured. At Mitchel Field, to cite a single instance, two pilots were examined who had constantly been having trouble with their ears. They experienced severe pain when descending even at the rate of as little as 300 feet a minute, and were in danger of being washed out altogether. Yet within a few months after being treated they were able to descend 6000 feet a minute.

Twenty-four hundred dollars in two tiny cylinders of radium less than half an inch long and only a few millimeters in thickness is a lot of money. Yet when a plane carrying a set—two applicators—crashed and burned, with the lead of the container melting in the heat, 99 of the 100 milligrams were recovered by the use of Geiger counters.

From the standpoint of treating children for middle-ear trouble to prevent deafness, the war experience was valuable. It rounded out Doctor Crowe's researches by making available a new and extremely practical radium applicator, which, in spite of its initial cost, is readily available, since it can be leased, radium and all, by properly qualified physicians for about fifteen dollars a month.

Doctor Crowe emphasizes the fact that his far-reaching new treatment is not a panacea. "Irradiation," he says, "is not a treatment for deafness, but for conditions that cause deafness." It is important to differentiate between different kinds of ear damage; that in the middle ear itself may already be beyond recall. But where middle-ear symptoms—like the loss of hearing in high tones—come from the mere blockage of the Eustachian tube, the trouble may be cured by the new treatment.

This means that every child should have, beginning not later than the age of eight, an annual hearing test with an expertly used audiometer, as a part of a regular physical examination. But before this can be done, a number of careful steps must be taken. As Doctor Crowe has put it:

1. Fight acute middle-ear trouble. Educational campaigns will give all physicians a chance to help.

2. Use radon or radium to reduce lymphoid obstructions of the Eustachian tubes.

3. The hearing of many children at present greatly handicapped by deafness can be cured, thus simplifying the educational problem for their p[illegible], their teachers and their communities. Candidates for treatment are those in whom lack of hearing is combined with observable tube obstruction, recognizable by any ordinary physician after a short course of training.

4. Get adequate hearing aids for children with permanently impaired hearing, for the sake of the children, who need a normal education and a normal life.

5. For children with high impairment only, first the community must make preparations to a[illegible] audiometer into the hands of a well-trained examiner, and have a good otologist ready and willing to examine, to treat and to re-examine large [illegible] bers. Then—and not until then—it is both wise and practical to [illegible] the search for such children.

In Maryland, where Doctor Crowe's influence has been felt directly, [illegible] are already five counties w[illegible] state, county and city health departments have authorized the treatment of school children by radium.

But, although both radon and radium applicators have been so perfected that they are apparently 100 per cent safe in the hands of experts, they should never be used by [illegible]. Early X-ray therapy was at [illegible] with many bad results. This time, with such great possibilities in sight for improving the hearing of thousands [illegible] dreds of thousands of children, there should be no bad results. Every effort is being made by the manufacturers to see that none of the hundreds of radium-sulfate applicators already made fall into the hands of [illegible] or other unqualified persons. Parents and community leaders [illegible] be equally careful.

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Workshop on Public Health Response to Nasopharyngeal Radium Irradiation: Summary Report of the Panel

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SUMMARY REPORT

Workshop on Public Health Response to Nasopharyngeal Radium Irradiation

From about 1940 to the mid-1960s, nasopharyngeal radium was used to treat hearing loss, chronic otitis, and other conditions in children; in the military it was used to treat aerotitis in submariners and aviators. Aerotitis is a group of symptoms including bleeding from the ear, ear pain, and rupture of the ear drum, caused by changing ambient air pressure. The typical radium treatment consisted of two applicators containing encapsulated radioactive radium being inserted thought each nostril and placed near the opening of the eustachian tube for 8-12 minutes. The goal of the treatments was to reduce swelling of enlarged lymphoid tissue in the nasopharynx. The swelling was thought to cause both hearing loss and aerotitis media.

On September 27-28, 1995, a Workshop on Public Health Response to Nasopharyngeal Radium Irradiation was conducted at the Quality Inn and Conference Center, 100 Pond Lily Avenue, New Haven, CT. The Workshop was presented by the Department of Epidemiology and Public Health of the Yale University School of Medicine, as local organizers, the National Center for Environmental Health of the Centers for Disease Control and Prevention, and the Office of Public Health and Environmental Hazards of the Department of Veterans Affairs. The Workshop was also sponsored by the Connecticut State Department of Public Health and the Association of State and Territorial Health Officers.

Invitations to this Workshop were sent to all Ear-Nose-and-Throat Physicians and Therapeutic Radiologists in the states of Connecticut, Massachusetts, Rhode Island, New York, to all State Health Departments in the U.S. and to members of the Association of State and Territorial Health Officers, and to all Schools of Public Health and their Environmental Health Departments. Additional invitations were extended to known organizations advocating for patients who had received nasopharyngeal radium irradiation (NRI) treatments. The program for the Workshop had been prepared by a Planning Committee organized by the Centers for Disease Control and Prevention, and the local organization was the responsibility of the Department of Epidemiology and Public Health of the Yale University School of Medicine. There were 94 participants in the workshop; the panel of experts, the speakers and the organizers numbered a total of 28, and 66 participants were patients who had been exposed, or representatives of such patients or physicians who might treat such patients.

The public health response has as its objective the reduction, where possible, of any adverse outcomes. Another objective is the dissemination of information about NRI and what is known about the possible adverse endpoints.

The panel of experts developed conclusions and recommendations based on the information presented during the Workshop. The Panel split into three sub-panels, with responsibility to formulate conclusions and recommendations in the areas of Public Health, Epidemiology and Medical Practice. These conclusions and recommendations are presented below, in the form developed by each of the sub-panels. Each of the professions provided a perspective, and, as would be anticipated, there is some overlap. To preserve these perspectives the conclusions and recommendations have not been consolidated. Dr. Alan

Ducatman, a member of the Epidemiology Sub-Panel wished to dissociate himself from parts of the Epidemiology Sub-Panel report because he feels that studies based on veterans self-report should be encouraged.

Public Health Sub-panel: Henry Anderson, Richard Jackson, Mary Lou Fleissner, Fran Keneally, Mark Fox, and Susan Mather

Summary and Recommendations:

The Committee felt that the Centers for Disease Control and Prevention (CDC) should take the lead in coordinating the response for the civilian population. The response for those exposed while in the military would be coordinated by the Department of Veteran Affairs (VA). The responses and activities will be coordinated by the two agencies so that messages are consistent and resources maximized. The following recommendations apply to veterans:

- VA should be authorized to provide veterans who received nasopharyngeal radium treatment access to the Ionizing Radiation Registry;

- VA should look into the possibility of priority care for veterans who received nasopharyngeal radium treatment;

- VA should develop an educational program for VA physicians as to the issues involved in nasopharyngeal radium treatment.

The following recommendations were made for civilians who were exposed to nasopharyngeal radium treatment:

- CDC should form partnerships with local and state health departments where these treatments were used, to coordinate the public health response;

- CDC should work with VA in expanding the VA educational program to other physicians in areas most heavily impacted by this treatment. In addition, information on this Workshop will be published in the Morbidity and Mortality Weekly Report (MMWR). Scientific presentations from the Workshop should be published in a journal representing physicians likely to see patients treated with nasopharyngeal irradiation. The *Journal of Otolaryngology - Head and Neck Surgery* has expressed an interest in publication of these reports. Information from the Workshop will be sent to the Veterans of Foreign Wars (VFW), the American Legion (AL), AMVets and the Fleet Reserve Association for inclusion in military newsletters and magazines. Consideration should be given for another Senate hearing to address the concerns raised in the previous hearing and answer these questions.

- Consideration should be given to fund adequately the follow-up cohort study in Washington County in Maryland so that other end points and/or additional persons can be included in the study;

- Since the CT tumor registry is the oldest and one of the most complete tumor registries in the country, and since many of these treatments were given in Connecticut, consideration should be given to funding a study of cancer cases in the CT tumor registry of those sites that may be related to this radiation exposure;

- The medical advisory sent to physicians in 1977 from Johns Hopkins should be reviewed to see if additional information should be forwarded to physicians, and to whom it should be sent;

- Fran Kenneally, who ran the civilian hotline in Connecticut, will identify questions most frequently asked by concerned treated persons and relatives. These questions will be used to develop a fact sheet that will be available to both those exposed as civilians and in the military. The fact sheet will be in the format of questions and answers.

Epidemiology Sub-panel: Alan Ducatman, Roy Shore, Elaine Ron, Carl Shy, and Dale Sandler

Summary and Recommendations:

The extent of treatment with nasopharyngeal radium irradiation has not been documented but use of this treatment may have been more common than previously appreciated. Various estimates were presented for military and non-military use of the treatment. Whether or not an epidemiologic study is recommended, it will be important to determine the number of exposed persons in order to devise an appropriate public health response. Documentation of the use of this treatment in the military is hampered by the lack of systematically maintained records. Reasonable estimates can, however, be made based on reports in the literature. Use in children is also difficult to document. An estimate as high as 2.5 million persons treated was presented, but this figure was based on advertisements that cited the number of applicators sold and the assumption that applicators were in constant use. In practice, applicators might have been in use only a small percentage of the time. Alternative approaches to estimating the number of exposed children were proposed, including determining the number of tympanic tubes that are placed (the treatments reach the same segment of the ENT patient population) or extrapolating from population data from the Netherlands (where 25,000 were treated in a base population of 11 million) should be pursued.

The following points were considered as a basis for the discussion and recommendations of the Epidemiology Sub-panel:

- 8,000-20,000 US military veterans have been treated with nasopharyngeal radium irradiation. Approximately 8,000 uses during WWII have already been reported among Naval submariners and Army/Air-Force pilots, but identities of these individuals are mostly unknown.

- Childhood exposure was much more common. Estimates presented ranged from between 100,000 and 500,000 to as many as 500,000 to 2,500,000 children treated.

- Persons exposed as children are at greater risk of any possible untoward effects. There is evidence that many of the exposed tissues are more sensitive (at least in terms of cancer) to radiation when exposures occur in childhood. Because of the importance of distance in calculating tissue-specific dose, the exposures of children from the same treatment dose will have been greater than those for persons exposed as adults, for whom the distances to various organs, such as the thyroid, were much greater.

- There is nothing fundamentally different about irradiation from nasopharyngeal radium treatments that would make it inappropriate to predict risks based on studies of low-dose exposure to gamma or x-ray irradiation from other sources. The contribution of the beta irradiation to dose is only important in the first few millimeters. While tissue

exposures from this treatment were generally low-dose, radiation exposure to the nasopharynx in the areas immediately surrounding the applicators may have been substantial.

- It should be possible, using data from other radiation-exposed cohorts, to estimate cancer risk for persons treated with nasopharyngeal radium irradiation. Ranges of risk can be calculated based on differing estimates of tissue dose received.

- Persons who have received this treatment have concerns about the possibility of a wide range of effects from nasopharyngeal radium irradiation. A lack of understanding of what this treatment involved may have resulted in some physicians not appreciating that this treatment involved gamma irradiation or that doses to other tissues were not negligible. This may have caused some individuals to feel that their medical complaints were not being taken seriously.

- While much is known about radiation carcinogenesis, little is known about effects of pituitary irradiation, other than from experimental studies and studies of cancer patients who, in addition to being exposed to much higher doses, have underlying medical conditions which may be directly or indirectly related to endpoints of interest. Besides cancer, persons who have been treated report a wide variety of problems that may or may not be plausibly related to irradiation. These include impaired growth, nervous disorders, dental problems, salivary gland disorders, emotional problems, thyroid

disease, immunologic dysfunction and hearing loss.

- If a cohort study were to be undertaken, possible *a priori* hypotheses include increased risk for cancers of the head and neck including salivary glands, nasopharynx, brain, and thyroid; hematopoietic cancers; pituitary adenomas; thyroid disease; manifestations of pituitary dysfunction including infertility and premature menopause; hearing loss; dental changes and other conditions related to radiation necrosis (although such effects are not expected at these low doses); and decreased risk for breast cancer (which has been reported for several irradiated populations including those treated with nasopharyngeal radium).

- Only three studies of this treatment have been published. One, by Hazen et al., involved 400 children included in a much larger cohort of other head and neck irradiation treatments. Follow-up of this cohort may have been extended, but data have not been published. The other two studies, Washington County, Maryland and The Netherlands, were described at this Workshop and continued follow-up is ongoing. None of these studies demonstrated statistically significant increases in risk for any cancers, but if results were to be pooled, significant results or consistent patterns may emerge. Only the Washington County study reported results for non-cancer outcomes that might be related to pituitary irradiation. Suggestive results were observed for several outcomes, although alternative explanations including weaknesses in data collection (e.g. for specific thyroid diseases) or inadequate control for underlying

differences between those who were or were not treated (e.g. for hearing loss or ENT surgeries) must be considered.

- Doses used in Washington County were, on average, greater than those used in the Netherlands, and in the New York group reported by Hazen or by the military. This could explain differences in observed risks, but because of small sample sizes, results from any of these studies could have been due to chance.

A study of persons treated as children may be the most productive. Possibilities and recommendations include:

Non-cancer endpoints -

- The ongoing follow-up of the Washington County study may provide additional information on pituitary effects of irradiation that may justify further studies. These efforts should be supported. If not already part of the follow-up, collection of information on thyroid disease and other non-cancer endpoints is recommended for the study in The Netherlands.

- The feasibility of conducting clinical studies within the existing cohorts should be explored. The sample sizes needed to evaluate menstrual or hormonal disturbances, hearing loss, or thyroid dysfunction are substantially smaller than those needed for cancer follow-up. However, care should be taken to include samples large enough to

detect clinically relevant differences. Medical evaluations should include dental exams, hearing evaluations, and measurement of pituitary hormones. The use of more sensitive measures of infertility and menstrual dysfunction should be considered.

- Data on reproductive outcomes have been collected for the tinea capitis cohort in Israel. Additional studies of this cohort could be undertaken to investigate effects of pituitary irradiation at doses similar to (or slightly greater than) those resulting from nasopharyngeal radium irradiation.

Cancer Endpoints -

- Data from the existing studies could be pooled.

- Follow-up of existing cohorts should be continued. Data from the follow-up of the Hazen et al. study should be pursued and published.

- A feasibility study should assess the possibility of assembling a large enough cohort for study. An approach similar to that used in The Netherlands could be used. Namely, ENT physicians who practiced during the 1940s through the 1960s could be surveyed to identify those who used this treatment. Emphasis could be placed on areas where the treatment was known to have been used, but this treatment may have been used in more areas than previously appreciated. Long-term records may be most likely to exist for ENT clinics in hospitals and health departments. ENT physician organizations might

facilitate such a survey.

- Dose estimates need to be established for children and associated excess relative risk estimates need to be calculated. A wide range of estimates were presented. To the extent possible, these differences should be reconciled. Some differences can be explained on the basis of uncertainty about the distances to various tissues, but assumptions used about treatment dose and applicator characteristics also varied.

- Based solely on scientific grounds, there is no need for a large cohort study of cancer incidence in treated individuals. A study of nasopharyngeal radium irradiation is not likely to contribute any new information about low-dose radiation carcinogenesis. If there are compelling public health and political reasons for carrying out a study, the cancer endpoints listed above, as well as non-cancer endpoints should be pursued.

- A population-based case-control study of a particular cancer or of pituitary adenomas could be carried out in an area where the treatment was commonly used. However, it should be recognized that the frequency of exposure is likely to be low even in areas where the treatment was used, and the likelihood of being able to document exposures and dose-levels is remote.

- Questions about nasopharyngeal radium irradiation should be added to ongoing studies of brain cancer, breast cancer, and other relevant cancers.

Recommendations regarding studies of the military:

- Based on the reports given, it appears that a study of the military may not be feasible. However, attempts thus far to locate records to confirm self-reported exposures or to identify an exposed cohort only focused on the Navy and only covered a narrow time window that may have missed the peak use. The VA should be encouraged to locate records that might exist for the Army/Air-Force, including, but not limited to, researching the military and medical records for self-identified exposed pilots.

- Studies based on veterans' self reports of treatment should be discouraged. Because persons with medical concerns are most likely to have come forward, studies based solely on such an unrepresentative sample will yield biased results regarding the relationship between exposure and disease. Limited surveys of self-identified veterans could, however, yield leads to be followed up with formal studies, particularly when there is consistency between reports, and new effects of head and neck irradiation are suggested.

- If an exposed cohort cannot be assembled from existing records, it might be possible to identify a complete cohort of persons who trained or worked at a particular military facility where nasopharyngeal radium irradiation was used. If the entire cohort could be traced and contacted, it might be possible to survey the cohort to ascertain exposure and evaluate exposure/disease relationships. Limitations of this approach include the

possibility of self-selection or over-reporting of exposures, even in the face of high response rates, that could lead to bias, and the fact that information to validate exposures or establish radiation dose is not likely to be available.

- In view of the lower risks associated with adult versus childhood radiation exposure, and the lower doses received, the numbers needed to carry out a study of adequate statistical power may exceed the numbers treated or available for study.

Medical sub-panel: Natasha Mirza, Douglas Ross, Henry Royal, and Arthur Schneider

Preamble

Scope:
1) Whether screening was indicated for individuals who were exposed to nasopharyngeal radium irradiation.
2) What should be physician educational goals with respect to nasopharyngeal radium irradiation?

The Sub-Panel considered individually children and adult veterans, and in each case whether whether they are symptomatic or asymptomatic. The body of evidence considered was the information presented at this public conference

Summary and Recommendations:

- If a physician has a record that a current patient was treated with nasopharyngeal radium irradiation, the physician should notify the patient. A public health fact sheet should be sent.

- Screening of asymptomatic patients, whether they were treated with nasopharyngeal radium as children or adults is not recommended.

- The studies so far on nasopharyngeal radiation are consistent with other studies on radiation. They do not clearly show a greater risk of neoplastic or other disease from nasopharyngeal irradiation, but the statistical power to detect elevated risks was limited by the relatively small sample sizes.

- Some observations related to hormonal function have been presented, but the associations are unlikely because the range of doses is too low based on studies of other populations who received higher doses. In addition, some of the proposed associations lack biological foundation.

- Screening itself may disclose incidental findings which could lead to inappropriate treatment and morbidity.

- Patients with symptoms should receive usual care including evaluation and treatment. There is no evidence that nasopharyngeal radium irradiation changes the approach a physician should take to these symptomatic patients.

Goals of physician education:

- to allow a primary care physician to obtain an accurate history of nasopharyngeal radium irradiation or other radiation exposure.

- to have a primary care physician focus history taking based on their knowledge of plausible effects of radiation

- to provide subspecialists who may be consulted with special information with relation to nasopharyngeal radium irradiation or other radiation exposure