1ST DRAFT

March 31, 1994

The Honorable Joseph J. Lieberman
United States Senate
Washington D.C. 20510

Dear Senator Lieberman:

Thank you for your letter of March 16, 1994, suggesting the implementation of a dedicated phone line for those individuals who underwent radium nasopharyngeal irradiation treatment.

This treatment, as you know, was a common clinical practice at the time, used by civilian and military physicians alike. Accordingly, this treatment is not within the purview of the charter for the Human Radiation Interagency Working Group as established by Executive Order #12891.

The Department of Defense is conducting an extensive search in an attempt to identify the former members of the Armed Forces who were treated with nasopharyngeal irradiation. Also, if a veteran feels they were treated by nasopharyngeal irradiation they can also obtain the services available through the Department of Veterans Affairs (VA) by contacting the nearest VA medical center or calling 1-800-827-0365 for an examination. An appointment can be arranged, generally within two to three weeks.

In addition, I have forwarded your letter to Secretary Donna Shalala. Your inquiry about non-military subjects of nasopharyngeal irradiation treatment is best handled by HHS (or an agency under HHS jurisdiction). A member of Secretary Shalala's staff will follow up on your request.

I appreciate your taking the time to share your thoughts on this issue. Please do not hesitate to contact me if I can answer any questions or be of further service. Thank you.

Sincerely,

Christine Varney
Secretary to the Cabinet

OFFICE OF CABINET AFFAIRS

THE WHITE HOUSE

WASHINGTON

FAX

TO: Jill Hargis - HHS - 690 7755
Dennis Duffy - VA 273 6791

DATE: 3/31

NO. OF PAGES 4
(Including cover)

PHONE:

FAX:

PRIORITY: (Y) N

FROM: Phil Caplan

PHONE: (202) 456-2572

FAX: (202) 456-6704

MESSAGE:

Thanks for looking at this. I'd love to send it out tomorrow if possible.

Thanks.

VA Office of Congressional Affairs

Facsimile Cover Sheet

To: Phil Caplan
Organization: White House Cabinet Affairs
Phone: 456-2572
Fax: 456-6704

From: Dennis Duffy
Organization: VA Office of Congressional Affairs
Phone: (202) 273-5615
Fax: (202) 273-6791

Date: 4/4/94
Pages including this cover page: 4

Comments: Per your request.

DRAFT

The Honorable Joseph J. Lieberman
United States Senate
Washington, DC 20510

Dear Senator Lieberman:

Thank you for your letter of March 16, 1994, suggesting the implementation of dedicated phone lines for those individuals who underwent radium nasopharyngeal irradiation treatment.

This treatment, as you know, was a common clinical practice at the time, used by civilian and military physicians alike. Accordingly, this treatment is not within the purview of the charter for the Human Radiation Interagency Working Group as established by Executive Order 12891.

In follow-up to your request, the Department of Veterans Affairs initiated a computerized search of the medical literature related to radium nasopharyngeal irradiation treatment and discussed this issue with officials in the Department of the Navy, Department of the Air Force, Department of Defense Command Center investigating radiation research, and the Armed Forces Radiation Biology Research Institute. Scientific publications and other information provided by these officials were reviewed.

During World War II, the United States Navy and Army Air Corps treated service personnel with nasopharyngeal radium treatments to shrink lymphoid tissues blocking the Eustachian tubes and thus to prevent ear problems from occurring following pressure changes associated with submarine and flying duties. Previously such treatments had been used in civilian patients and were felt to be safe and effective in preventing deafness.

The treatment of service personnel was considered to be very successful at achieving its intended purpose and large numbers of service personnel received such radium treatments. Based on numbers and estimates provided by military officials it appears that approximately 5,000 submariners, over 6,000 Army Air Corps personnel, and at least 60 Navy aviators were treated. It should be emphasized that the treatments were considered to be accepted medical care rather than research.

DRAFT

The Honorable Joseph J. Lieberman

Use of nasopharyngeal radium treatments continued until the late 1950s and early 1960s when heightened medical and public concerns over radiation exposure as well as the availability of an alternate form of therapy using tympanostomy tubes led to its curtailment. Apparently the Navy discontinued its use of radium by about 1957.

With respect to the risk of cancer following nasopharyngeal irradiation, the Department of Veterans Affairs advises that an article by Sandler et al. cited in your letter to Secretary Brown found no overall increased cancer risk but increases in all head and neck tumors and a slight excess in brain cancer. However, a later similar study from the Netherlands cited in a Navy review of the issue concluded that there was no excess risk of cancer at any site associated with the radium treatments.

Unfortunately, the names of individual service personnel who were treated with radium currently are not available although the Department of Defense is conducting an extensive search for records that might provide this information (such as treatment logs or class rosters). Treatments may have been recorded in individual service medical records but there are many millions of such records in storage. Moreover, medical record keeping was less detailed in the past than it is today and military outpatient records initially were filed separately from inpatient records.

If listings of individual service personnel who received radium treatments can be developed, the Department of Veterans Affairs Environmental Epidemiology Service will consider whether it is feasible to perform follow-up studies to address the question of possible increased risk.

In the mean time, if a veteran believes he or she received nasopharnygeal irradiation while in military service and now suffers from a disability because of that, the Department of Veterans Affairs should be contacted. The veteran may call either the Department of Veterans Affairs Radiation helpline at 1-800-827-0365 for general information or 1-800-827-1000 for information and assistance on applying for medical care and/or initiating a claim for service-connected disability compensation.

In addition, I have forwarded your letter to Secretary Donna Shalala. Your inquiry about non-military subjects of nasopharyngeal irradiation treatment is best handled by HHS (or an agency under HHS jurisdiction). A member of Secretary Shalala's staff will follow up on your request.

3.

DRAFT

The Honorable Joseph J. Lieberman

I appreciate your taking the time to share your thoughts on this issue. Please do not hesitate to contact me if I can answer any questions or be of further service. Thank you.

Christine Varney
Secretary to the Cabinet

DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

FACSIMILE

DATE APR 5 1994

TO: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Phil Caplan
Office of Cabinet Affairs

PHONE: 456-2572

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Jill Hargis
DHHS

PHONE: 690-6133

RECIPIENT'S FAX NUMBER: ( ) 456-2983

NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 4

COMMENTS:

April 5, 1994

Note to Jill Harris

Attached please find language developed by NCI regarding use of radiation as a treatment for various nasal/throat conditions. I suggest that these two paragraphs be inserted in the letter where indicated. I strongly recommend that no reference by made at all to this department as we have nothing more to offer than to direct these individuals to their private physicians.

Please call me if you have any questions.

Kathy Hudson

insert A

4/5/94
Cancer following medical irradiation language

Although it is now known that ionizing radiation is a cause of cancer and other adverse effects, for several decades beginning in the early 1920's, thousands of individuals in the United States received x-ray treatments for a number of noncancerous conditions. Radiation therapy was considered good medical practice and effective treatment for such conditions as ringworm of the scalp, enlargement of the thymus gland, deafness due to lymphoid tissue around the Eustachian tubes, enlargement and inflammation of the tonsils and adenoids, and acne. Individuals who received therapeutic doses of radiation or radium applications to the head, neck, or upper chest for various nonmalignant 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.

A

B

But

If an individual has been treated with radiation to the head, neck, or upper chest they should contact a physician and ask for a complete examination of the head and neck. Following this initial exam, regular examinations should occur every one or two years. It is important to be examined by a physician, whether or not a lump can be felt in the throat or neck. If a lump is discovered between examinations, it should be checked by a physician immediately.

March 31, 1994

The Honorable Joseph J. Lieberman
United States Senate
Washington D.C. 20510

Dear Senator Lieberman:

Thank you for your letter of March 16, 1994, suggesting the implemantation of a dedicated phone line for those individuals who underwent radium nasopharyngeal irradiation treatment.

This treatment, as you know, was a common clinical practice at the time, used by civilian and military physicians alike. Accordingly, this treatment is not within the purview of the charter for the Human Radiation Interagency Working Group as established by Executive Order #12891.

Insert A →

The Department of Defense is conducting an extensive search in an attempt to identify the former members of the Armed Forces who were treated with nasopharyngeal irradiation. Also, if a veteran feels they were treated by nasopharyngeal irradiation they can also obtain the services available through the Department of Veterans Affairs (VA) by contacting the nearest VA medical center or calling 1-800-827-0365 for an examination. An appointment can be arranged, generally within two to three weeks.

delete

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I appreciate your taking the time to share your thoughts on this issue. Please do not hesitate to contact me if I can answer any questions or be of further service. Thank you.

Sincerely,

Christine Varney
Secretary to the Cabinet

OFFICE OF CABINET AFFAIRS

THE WHITE HOUSE

WASHINGTON

FAX

TO: Rudy de Leon

DATE: 3/24

NO. OF PAGES 3
(Including cover)

PHONE:

FAX: 703/697-9080

PRIORITY: (Y) N

FROM: Phil Caplan

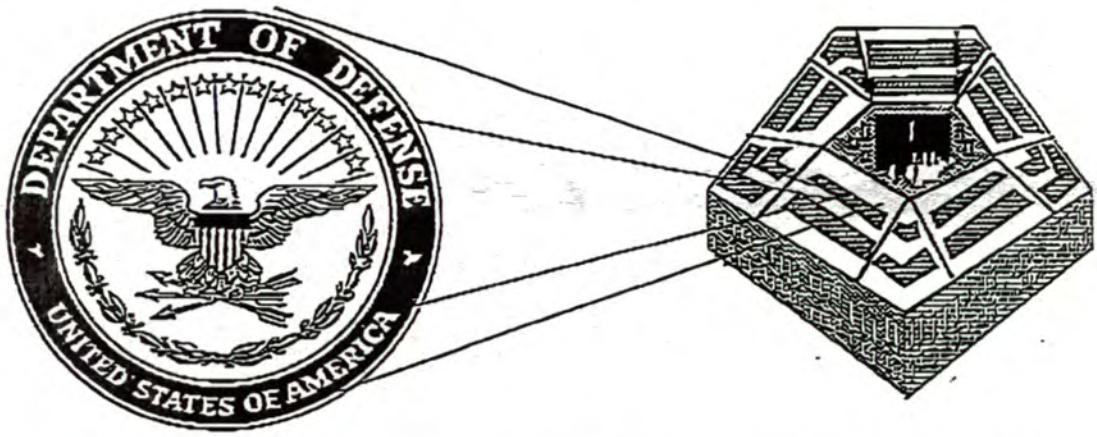
PHONE: (202) 456-2572

FAX: (202) 456-6704

MESSAGE: Rudy -- assuming you are still dealing with all of this, could you advise me on how to answer this letter. I would love to answer it by tomorrow if possible.

Thanks.

FAX FAX



ASSISTANT TO THE SECRETARY OF DEFENSE (ATOMIC ENERGY) WASHINGTON, DC 20301-3050

FAX NOs: *(703) 697-2199 (ROOM 3C120)*
(703) 695-0476 (ROOM 3E1074)

TO: Phil Caplan FAX PHONE NUMBER: 202/456-6704

ATTN:
PHONE:

MESSAGE:

FROM: FAX PHONE NUMBER: *(703) 695-0476*
OATSD(AE) - 697-5561

THIS DOCUMENT CONSISTS OF 3 PAGES, INCLUDING COVER SHEET

Gordon K. Soper
Principal Deputy
Assistant to the Secretary of Defense (Atomic Energy)
3E1074 (703) 697-5161

March 28, 1994

MEMO FOR: Mr. Phil Caplan

SUBJECT: Draft letter for Senator Lieberman

Phil:

I've attached a possible response to Senator Lieberman. I think it skirts around the issue of a separate hot line but I would **strongly** recommend that we discourage such an enterprise. Also note that we've recommended that we punt this puppy to the U.S. Surgeon General. What do you all think about that?

Say hello to Christine.

Warm Regards,

Gordon

cc: Rudy de Leon

The Honorable Joseph J. Lieberman
State Office Building
Washington, DC 20510

Dear Senator Lieberman:

Thank you for your letter of March 16, 1994, suggesting the implementation of a dedicated phone line for those individuals who underwent radium nasopharyngeal irradiation treatment.

This treatment, as you know, was a common clinical practice at the time, used by civilian and military physicians alike. Accordingly, this treatment is not within the purview of the charter for the Human Radiation Interagency Working Group.

The Department of Defense is conducting an extensive search in an attempt to identify the former members of the Armed Forces who were treated with nasopharyngeal irradiation. Those efforts, to date, have been unsuccessful. However, those military veterans treated by this procedure can obtain the services available through the Department of Veterans Affairs (VA) by contacting the nearest VA medical center or calling 1-800-827-0365 for an examination. An appointment can be arranged, generally within two to three weeks.

Since the scope of this issue is not limited to the Department of Defense or government agencies, I have taken the liberty of forwarding your letter to the U.S. Surgeon General for consideration.

I appreciate your taking the time to share your thoughts on this issue. If I can be of further assistance, please let me know.

Sincerely,

Department of Veterans Affairs

DATE: 10/24

TO: Harold Gracy
Phil Caplen

FAX: 273-4877
456-6704

NUMBER OF PAGES: 1+ cover

PHONE:

MESSAGE:

Here is my draft of a proposed letter to Senator Lieberman. We have been working on the epi study but recently have hit some snags.

I will be in Albuquerque 10/26-28 — back on the 31st. My office can reach me but I wanted to get this off to you before I left.

Susan Mather

FROM: OFFICE OF ENVIRONMENTAL MEDICINE
and PUBLIC HEALTH
VA CENTRAL OFFICE (116)
WASHINGTON, D.C.

FAX: 202-535-7572

PHONE: 202-535-7182

SUGGESTED DRAFT RESPONSE

Dear Senator Lieberman:

Thank you for your letter about the concerns you and many veterans and civilians have about the nasopharyngeal radium treatments they had received to prevent otitis media.

I appreciate your special concern for the Submarine Survivors. I believe that there are still many unanswered questions about their treatment and the potential health risks. These questions were highlighted in the hearings you held on August 29, 1994. After reviewing the information presented at that hearing, it appears to me that the vast majority of this treatment was in the realm of clinical practice and not experimental. Therefore, I do not believe the Advisory Committee on Human Radiation Experimentation or the Human Radiation Interagency Working Group, which was established to support the Committee, are the proper groups to continue the work which you have begun with your groundbreaking hearings.

However, I agree with you that we cannot let the subject drop now. An epidemiologic study of adults who received the treatment, such as the submariners and airmen who were treated while in the service, would be a valuable addition to the scientific knowledge base and would complement the work on children published in the Journal of the National Cancer Institute in 1982. I have encouraged the Secretary of Veterans Affairs to continue to explore ways in which a scientifically valid study of these veterans can be done. I have also asked him to work with the Centers for Disease Control to develop guidelines for medical follow-up.

I do share your concern for these individuals and I am convinced that the Departments which have responsibility for health issues related to all Americans and specifically veterans' health, the Department of Health and Human Services and the Department of Veterans Affairs, are prepared to take on this important project.

Sincerely,

The President

JOSEPH I. LIEBERMAN
CONNECTICUT

COMMITTEES:
ARMED SERVICES
ENVIRONMENT AND PUBLIC WORKS
GOVERNMENTAL AFFAIRS
SMALL BUSINESS

United States Senate

WASHINGTON, DC 20510-0703

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July 19, 1994

The Honorable William J. Clinton
President of The United States
The White House
Washington, DC 20500

Dear Mr. President:

As a result of the Administration's extremely important initiative on human radiation experiments, I have received numerous calls and letters from veterans and civilians from throughout the country who underwent radium nasopharyngeal irradiation during the 1940s through 1970s.

I initially raised this issue at a Senate hearing early this year and was told by Secretary of Veterans Affairs Jesse Brown and Department of Energy Assistant Secretary for Environment, Safety and Health Tara O'Toole that it would be examined by the Administration. Following up on these commitments, I subsequently wrote to Secretary of the Cabinet Christine Varney, asking that the Human Radiation Interagency Working Group look into this treatment and provide help in initiating an epidemiological study. However, Ms. Varney replied in May that radium nasopharyngeal irradiation was not experimental and therefore could not be examined by the working group.

Recently I have obtained contemporary medical documents which describe the treatment conducted on over 7,000 Armed Services personnel as experimental. I have also been provided data indicating that a peer-reviewed epidemiological study of a group of those treated with radium nasopharyngeal irradiation display brain cancer rates equivalent to those of all cancers in the Hiroshima and Nagasaki survivors.

In light of this disturbing new data, I respectfully request that the radium nasopharyngeal irradiation treatment be made part of the purview of the Human Radiation Interagency Working Group and that the Administration move to undertake an epidemiological study to better determine the risks to those treated.

I understand that experimental radium treatments for aerotitis media, which is characterized by middle ear lesions caused by failure to equalize pressure between the middle ear and the atmosphere, were first undertaken by doctors at Johns Hopkins in the late 1920s. Medical papers indicate that the Armed Services began investigating the technique in 1942. In a 1945 paper, Navy physicians H. Haines and J.D. Harris describe what

they term their "experiments" to develop a reliable radium treatment since, as they state, "we had a rich source of material (*human "material" being the 732 Navy personnel who were involved in the experiments*), and since every condition necessary for rigid experimental control was available, we felt it possible to meet rigorous research criteria . . ." Similar experiments were conducted on 6,881 Army Air Force personnel according to a medical journal published in 1945.

The treatment developed by the Armed Services consisted of introducing a sealed radium source of approximately 50 mg of radium-226 through the nose and positioning it in the nasopharyngeal orifice. The experiments involved determining an effective dosage (strength of the radium source and length of exposure) to "burn out" adenoid and lymphoid tissue. Ultimately the Armed Services decided the most effective response resulted from leaving the sources in the orifice for up to 10 minutes, during 2 to 8 bilateral treatments. This treatment resulted in local doses of approximately 2,000 rads. Undoubtedly, significantly higher doses were administered as the treatment was developed.

The apparent short-term success of this treatment led to its application on large numbers of Armed Services personnel. Armed Services' records indicate that 7,000 men underwent this procedure as it was developed and tested. The numbers of individuals who were subsequently treated is not known with certainty. The Submarine Survivors Group, a private organization, set up a hot line in the spring of 1994 to provide information on the treatment to submariners. They have informed me that by early June they had received phone calls and letters from 12,000 veterans, 6,000 dependents of veterans, and 6,000 civilians who underwent the treatment. They estimate that <u>at least</u> 10,000 Navy personnel, 25,000 Army Air Force, and 10,000 family members of veterans were treated by military physicians. Probably largely because military physicians were familiar with the treatment, it was utilized widely on civilians after the Second World War. Although precise numbers may never be known, the press has reported that at least 200,000 individuals, mostly children, received radium treatments from 1943 through 1974. The use of nasopharyngeal irradiation treatments waned during the 1960s as more physicians became aware of potential dangers from radiation exposure. By the mid-1970s treatments appear to have terminated. Johns Hopkins Hospital issued a public service bulletin in 1977 stating that any patient who had received the treatment should be followed by his or her doctor. However, I have been told there was little follow-up to these bulletins in private practice and virtually no recognition of the bulletin in VA hospitals.

The Submarine Survivor Group claims that cancer rates from the radium treatment are comparable to those of Hiroshima and Nagasaki victims. Their claim is based on a 1982 epidemiological study published in the <u>Journal of the National Cancer Institute</u>,

which was cited by the National Academy of Sciences, National Research Council's Committee on the Biological Effects of Ionizing Radiation, and in their 1990 report on the health effects of ionizing radiation. This epidemiological study tracked 904 civilian radium nasal irradiation patients for 25 years. Three of the individuals developed brain tumors versus none in a control group of 2,021 individuals. The medical journal article concludes that this demonstrated "a statistically significant overall excess of malignant neoplasms of the head and neck among exposed subjects." Utilizing this result, the 1990 National Academy of Science report concluded that since approximately 0.57 "natural" brain cancers would be expected in a population of 900, 2.43 of the brain cancers were related to the radium treatment.

The Submarine Survivors Group has compared the risk of brain cancer over 25 years from the radium treatment, as determined by the 1982 study, with the risks of developing cancer in the group of Hiroshima-Nagasaki survivors over 25 years. The number of Hiroshima-Nagasaki victims is 79,856; and the group has 250 excess cancer deaths from all types of cancer. Using the 1982 study risk factor, the Submarine Survivors Group states that the number of excess brain cancer deaths expected in the radium treated group is predicted to be 262. Thus the group concludes that the number of cancer deaths between those who underwent radium nasopharyngeal irradiation and those who were exposed to the atomic bombs in Japan appear to be comparable. They further conclude that if the 1982 study risk factor is applied to the population of 240,000 individuals (the minimum number of individuals they believed to have received the radium treatment), approximately 670 excess brain cancer deaths would be expected over 25 years. The submariners group has told me that radium nasopharyngeal irradiation would be expected to produce illnesses other than brain cancer, such as thyroid illnesses and other types of cancers, which were not examined by the original 1982 epidemiological study.

In order to determine whether those individuals who underwent the treatment are at risk, and to confirm the accuracy of the original epidemiological study, I have written to Secretary of Veterans Affairs Jesse Brown requesting that the Veterans Administration consider undertaking an epidemiological study of a group of veterans who underwent the treatment and provide medical evaluations for these veterans as suggested by the 1977 Johns Hopkins medical bulletin. Secretary Brown responded to my inquiries by stating that if individual veterans could be located, the VA would consider follow-up studies to address possible increased risk. Although over 12,000 veterans have now come forward to the Submarine Survivors Group, no study has been initiated. Secretary Brown did direct veterans who had undergone the treatment to call a Veterans Administration hot line. Unfortunately, I have been told by many who have called the VA hot line that they have been given little assistance and

are instead being referred back to the Submarine Survivors hot line.

I also wrote in March to David Satcher, Director for the Centers for Disease Control, requesting that he investigate the possibility of conducting an epidemiological study of those treated so that potential risks from the treatment could be better quantified and those individuals who had undergone the treatment would be better able to intelligently pursue medical options. Dr. Satcher replied that funding was not available for such a study. I subsequently wrote to Secretary of Health and Human Services Donna Shalala in April requesting that she consider directing CDC to conduct an epidemiological study. I have had no reply from Secretary Shalala.

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. We need to help repair the skepticism about government I have heard from these individuals and give them the information they deserve. Inclusion of this treatment in the purview of the Human Radiation Interagency Working Group and an epidemiological study would help to accomplish this.

I know you share my concern for these individuals, most of whom are simply looking for information on whether or not their health is at risk. I look forward to your reply.

Sincerely,

Joseph I. Lieberman

OFFICE OF CABINET AFFAIRS

THE WHITE HOUSE

WASHINGTON

FAX

TO: Harold Gracy

DATE: 10/24

PHONE:

NO. OF PAGES 5
(Including cover)

FAX: 273-4877

PRIORITY: Y N

FROM: Phil Caplen

PHONE: (202) 456-2572

FAX: (202) 456-6704

MESSAGE:

Harold -

If you could have Susan, or whomever is appropriate, draft a response for the President's signature.

I would think the response should reflect the hearing in August.

If I could get it by Friday, it would be great.

Thanks

8-8-94

Note to Phil Caplan (FAX:456-6704)

Subject: Lieberman letter of 7-19-94

As you know, this letter covers issues that need to be addressed primarily by DOD, VA and DHHS although the radium was likely supplied at some point through DOE or its predecessor agencies.

Two thousand rads applied to the nose would likely increase the risk of developing cancer of various types.

Before deciding whether an epidemiologic study to quantify this increase in risk would be fruitful (that is, whether it would be capable of detecting an increase) one would need to:

1) know how many persons had the therapy and at what radiation dose

2) determine whether those people can be identified

3) determine whether the vital status (alive or dead) of the group can be ascertained

4) determine whether cancer diagnoses among the group can be identified

My understanding is that the Centers for Disease Control has embarked on an effort to determine the feasibility of an epidemiologic study by considering the above questions. Thus the information about CDC in the Lieberman letter does not reflect their current activities.

If the study is deemed feasible it could be done by either of a number of departments including DOD, VA or DHHS.

Please let me know if I can be of any further help on this. You will be able to skip your first year of medical school by the time you leave your job!

Steven Galson

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

Date: August 9, 1994

To: Special Assistant to the Secretary of the Cabinet
The White House

From: Senior Science Advisor
Office of the Assistant Secretary for Health

Subject: Letter to Senator Lieberman of July 19, 1994

I have discussed the Lieberman letter within DHHS and have talked further with Steve Galson since he sent his letter to you. We are all in basic agreement with the following:

- It is a difficult question as to whether the Committee's scope should or should not include military personnel who received nasopharyngeal radiation as part of an experimental protocol. A second order question is whether or not all who received such treatment should be included, as Senator Lieberman proposes. These are questions which we believe should be decided by the Committee.

- My understanding is that the use of nasopharyngeal irradiation to shrink adenoidal tissue was an accepted medical procedure largely used in children, when the military undertook to determine its efficacy in adults in dealing with problems in equalizing pressure between the middle ear and the atmosphere. Technically, one could view this exercise not as a new, experimental therapy but rather as an evaluation of the efficacy of an accepted medical treatment in dealing with a troublesome medical problem in adults. This might well be considered a distinction without a difference, although quite clearly there is a difference. The studies, however, were labeled experimental and they did involve irradiation.

It should be recognized that a comprehensive study which might now accurately quantitate the risk of the procedure would be time-consuming and very costly. It is a formidable task to identify by name a large group who were given a therapy 20 to 50 years previously and then to find them or their health records so as to characterize outcomes. In brief, the prospects for elucidating significant additional information within a reasonable time frame are minimal.

D.A. Henderson, M.D., M.P.H.

cc: Ms. Lily Engstrom, NIH
Mr. Steven Galson, DOE

THE WHITE HOUSE

WASHINGTON

May 3, 1994

The Honorable Joseph J. Lieberman
United States Senate
Washington D.C. 20510

Dear Senator Lieberman:

Thank you for your letter of March 16, 1994, suggesting the implementation of a dedicated phone line for those individuals who underwent radium nasopharyngeal irradiation treatment. I have relied on the Departments of Defense, Health and Human Services, and the Veterans Administration in developing this response.

This treatment, as you know, was a common clinical practice at the time, used by civilian and military physicians alike. Accordingly, this treatment is not within the purview of the charter for the Human Radiation Interagency Working Group as established by Executive Order #12891.

During World War II, the United States Navy and Army Air Corps treated service personnel with nasopharyngeal radium treatments to shrink lymphoid tissues blocking the Eustachian tubes and thus to prevent ear problems from occuring following pressure changes associated with submarine and flying duties. Previously such treatments had been used in civilian patients and were felt to be safe and effective in preventing deafness.

Radiation treatment was considered good medical practice and effective treatment for such conditions as ringworm of the scalp, enlargement of the thymus gland, enlargement and inflammation of the tonsils and adenoids, and acne.

Use of nasopharyngeal radium treatments continued until the late 1950s and early 1960s when heightened medical and public concerns over radiation exposure as well as the availability of an alternate form of therapy using tympanostomy tubes led to its curtailment.

The Department of Defense is conducting an extensive search in an attempt to identify the former members of the Armed Forces who were treated with nasopharyngeal irradiation. If listings of individual service personnel who received the treatments can be developed, the Department of Veterans Affairs Environmental Epidemiology Service will consider whether it is feasible to perform follow-up studies to address the question of possible increased risk.

In the mean time, if a veteran feels he or she received nasopharyngeal irradiation while in military service and now suffers from a disability because of that, the Department of

Veterans Affairs should be contacted. The veteran may call either the Department of Veterans Affairs Radiation helpline at 1-800-827-0365 for general information or 1-800-827-1000 for information and assistance on apllying for medical care and/or initiating a claim for service-connected disability compensation.

According to HHS, 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. As such, any individual, civilian or military, who has been treated with radiation to the head, neck, or upper chest should contact a physician and ask for a complete examination of the head and neck. Following this initial exam, regular examinations should occur every one or two years. It is important to be examined by a physician, whether or not a lump can be felt in the throat or neck. If a lump is discovered between examinations, it should be checked by a physician immediately.

I appreciate your taking the time to share your thoughts on this issue. Please do not hesitate to contact me if I can answer any questions or be of further service. Thank you.

Sincerely,

Christine Varney

Christine A. Varney
Secretary to the Cabinet

JOSEPH I. LIEBERMAN
CONNECTICUT

COMMITTEES:
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ENVIRONMENT AND PUBLIC WORKS
GOVERNMENTAL AFFAIRS
SMALL BUSINESS

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March 16, 1994

Ms. Christine A. Varney
Secretary to the Cabinet
Old Executive Office Building
17th Street and Pennsylvannia Ave.
Washington, D.C. 20500

Dear Ms. Varney:

As a result of the Administration's extremely important initiative on human radiation experiments, I have received numerous calls and letters from veterans and civilians from throughout the country who underwent radium nasopharyngeal irradiation during the 1940's through 1960's. I have been told that a number of these individuals have subsequently experienced brain, neck and thyroid cancers. I am writing to suggest that the Human Radiation Interagency Working Group set up a dedicated phoneline for these individuals, to be operated in conjunction with the Human Radiation Hotline.

Radium treatments for acrotitis media were administered to Navy personnel undergoing underwater escape training. The New England Journal of Medicine reported in 1992 that these men were generally given between 2 to 8 bilateral treatments with approximately 50mg of radium-226. The treatment consisted of positioning a sealed radium source in the nasopharyngeal orifice. I have been told that subjects undergoing this treatment would have been exposed to local doses of approximately 2,000 rads. I have also learned that civilians received similar treatments for enlarged adnoids and tonsilitis.

It is my understanding that potential dangers from this procedure were recognized by doctors during the late 1940's. In 1977, The Johns Hopkins Hospital issued a public service bulletin stating that any patient who had received nasopharyngeal irradiation should be followed by his or her physician. A 1982 paper in the Journal of the National Cancer Institute described a study on a group of 904 children who received radium nasopharyngeal irradiation treatments between 1943 and 1960. This study showed that 4 had died of malignant head and neck tumors by 1980, although no such tumors were detected in an untreated clinic population.

Secretary Brown testified at the Senate hearing that his Department and the Department of Defense would seek to identify veterans who received radium nasopharyngeal irradiation treatment, notify them about potential problems associated with the treatments, aid veterans in obtaining medical care and, where appropriate, compensation under existing programs. I also have written to Mr. David Satcher at the Center for Disease Control and Prevention suggesting that the Center investigate and report on these treatments. However, the number of calls I have received from individuals who are not veterans, but who underwent radium nasopharyngeal irradiation, seeking information and wishing to be part of a study on the effects of this treatment suggests that government outreach in the form of a phone hotline for non-veterans would also be appropriate.

I know you share my concern for these individuals, most of whom are simply looking for information on whether they are at risk. I look forward to your reply.

Sincerely,

Senator Joseph I. Lieberman

Date: 07/21/94 Time: 08:48

More Than 7,600 Servicemen Subjected to Radium Studies, Documents

WASHINGTON (AP) More than 7,600 U.S. military fliers and divers were given nasal radium treatments in the mid-1940s to see if radium could prevent ear ailments caused by severe pressure, recently unearthed documents show.

Nasal radium was commonly given to people in the 1940s, 1950s and 1960s to prevent and treat colds, adenoid and ear problems and hearing loss. Since then, thousands of former patients have blamed radium for range of health problems, including head and neck cancers, thyroid disorders, brittle teeth and miscarriages.

But while the treatments may have been misguided, they have never been viewed as experimental. That's a test they must meet in order to be studied by the Advisory Committee on Human Radiation Experiments, which is scheduled to report to the Clinton administration next year.

Sen. Joseph Lieberman, D-Conn., said Wednesday the cases should be included in the administration's work and asked President Clinton to order an epidemiological study of radium patients.

The Pentagon says military personnel were treated with radium as early as 1944 because it was a commonly accepted medical treatment.

Radium applicators were developed in the 1930s at Johns Hopkins Hospital in Baltimore. But at that time, they were used mostly to treat children for impaired hearing, said Stewart Farber, a public health scientist in Pawtucket, R.I., who has researched the issue.

Moreover, reports published in medical journals in 1945-46 indicate that 6,881 men in the Army Air Force and 732 Navy divers were given radium so military doctors could determine if the therapy would prevent ailments, such as broken ear drums, that were grounding pilots.

One report on the Navy study, which took place at the U.S. submarine base in Groton, Conn., states specifically that an experiment was conducted on divers to better understand and develop radium therapy.

''Merely another clinical study would not meet the need,'' wrote Dr. Henry L. Haines and J. Donald Harris of New London, Conn., in the Annals of Otology, Rhinology and Laryngology in 1946.

Reports are less explicit on the Army Air Force study, in which more than 14,000 radium treatments were given to 6,881 men at Mitchell Field in New York, Westover Field in Chicopee, Mass., Drew Field in Tampa, Fla., and in the Mediterranean and European theaters.

However, medical officers repeatedly referred to studying their subjects, listed in detail their objectives, observations and conclusions, and supplied photographs of irradiation clinics, patients undergoing treatment and even leaden storage containers for the radium.

Based on the studies, officers concluded that nasal radium therapy which involved inserting radium pellets in the nostrils to shrink tissues near the Eustachian tubes was well-suited for military use because it required little time and did not interfere with combat or training schedules.

''The use of the nasopharyngeal radium applicator is a safe, practical and effective method,'' concluded one report on the Army Air Force study published in the annals in 1945.

Haines and Harris, after their study, concluded ''radium is effective in about 9 out of 10 men.''

The reports' descriptions of research procedures do not spell out whether the men were fully informed about the nature of the treatments.
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