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Description Notes	In the letter. Young expresses his thanks for the opportunity of serving as a scientific consultant to the Australian Royal Commission. He also summarizes the briefings he gave and shares his specific concerns and suggestions on a morbidity study.

Alvin L. Young, Lt. Col., U.S.A.F., PhD.,
Senior Policy Analyst for Life Sciences,
Executive Office of the President,
Office for Science & Technology Policy,
WASHINGTON, D.C., 20500,
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22 December, 1983.

The Hon. Mr. Justice Phillip Evatt, D.S.C.,
Royal Commissioner,
Royal Commission on the Use & Effects of Chemical
Agents on Australian Personnel in Vietnam,
G.P.O. Box 4842,
SYDNEY, N.S.W., 2001,
AUSTRALIA.

Dear Judge Evatt,

I want to express to you my appreciation for having had the opportunity of serving as a scientific consultant to the Royal Commission on the very complex issues related to Agent Orange and the Vietnam experience. I believe that the week (14-22 December, 1983) spent working with you and your staff has been beneficial to both of our nations. The issues associated with Agent Orange transcend national boundaries, political parties and governmental agencies. Indeed, the success to which our respective governments resolve this controversy satisfactorily will have significant impact on the public's perception of both "responsible government" and the obligations associated with military service.

During my visit I provided briefings in the following areas:

* The use of herbicides & insecticides in Vietnam, 1961-71;
* Development of the Agent Orange controversy in the United States : Scientific and social issues;
* Disposition of Agent Orange, 1972-77;
* Environmental fate of 2,3,7,8-TCDD;
* Exposure analyses of Seveso, Italy; Vietnam and Missouri : Results of Adipose Tissue Analysis;
* On going health studies on Agent Orange Exposure and the Vietnam experience in the United States.

Each of these topics was thoroughly discussed with your staff and members of the staff of the Australian Veterans Health Studies (A.V.H.S.). Perhaps the most important role that I have played, however, this past week is in my assessment of the need for a Morbidity Study. Accordingly, I wish to share with you some specific concerns and suggestions that I have discussed with Mr. John Coombs Q.C. during my service as a consultant to you.

The Australian Forces that served in Vietnam provide a unique population for epidemiologic study of the Vietnam experience. Whereas, United States troops were very hetergeneous as to race, socio-economic class, military service tasks and in-country locations, Australian Forces were more homogenous for these characteristics. For example, Australian personnel served primarily in one area of South Vietnam and they functioned as a unit for tour of duty. U.S. units moved extensively in a large area of operation and rotation for tour of duty was based only on the individual. Thus, I am suggesting that these differences may mean that epidemiologic studies of U.S. veterans as to Vietnam experience

may not provide information sufficiently applicable to Australian veterans. I do not wish to imply, however, that the U.S. studies won't be of value. Indeed these studies may provide some indications to you of the impact of Vietnam service.

Another important aspect of the Australian Forces is that of population size. You have a readily identifiable population of sufficient size for conducting valid epidemiologic studies of the Vietnam experience, but I do not believe that your population is large enough to identify cohorts (groups) having distinctly different magnitudes of chemical exposure (to herbicides or insecticides). Thus, a study of cohorts selected on the basis of exposure to Agent Orange is unlikely to have scientific value. It is my opinion that the United States Air Force Health Study, a carefully conducted epidemiological study of the RANCH HAND personnel, may provide sufficient data on which to identify an Agent Orange Syndrome given that such a syndrome can be identified. If the disease is rare, then the Centers For Disease Control's Agent Orange Epidemiologic Study of Ground Troops will have sufficient population size (18,000) to detect it.

In summary, a scientifically valid epidemiologic study of the Vietnam experience on the morbidity of Australian veterans can be conducted. Moreover, since A.V.H.S. has a study team in-place and the veteran population identified, such a study can be conducted on an acceptable time frame (within two years). To add the necessary assurance that the Scientific and Veteran community will accept such a study, I strongly recommend that a recognised Australian Epidemiologist be appointed principal investigator. Such a superb candidate would be Dr. John D. Mathews. In addition, a Scientific Advisory Panel should be appointed by you that would serve to monitor the scientific progress and assist in the evaluation of the results. I would suggest that you select a small group of scientists representing the Australian, New Zealand and United States experts in the appropriate disciplines.

The careful conduct of this study is critical. Any "short-cuts" or "lack of support" will only decrease the quality of the study. Moreover, only an excellently conducted study will serve the concerns of the nations whose troops fought in Vietnam and who now share in the health concerns of those troops.

Lastly, I wish to express to you my admiration for the superb manner in which Mr. John Coombs, has interacted with me this past week. His concerns for all parties participating in the Royal Commission is worthy of your praise. I also wish to offer my services to you should you feel that I can further contribute to the Commission.

Yours sincerely,

Alvin L. Young.

APPENDIX 3

DESCRIPTIONS OF MAJOR EPIDEMIOLOGIC STUDIES OF U.S. VETERANS, AGENT ORANGE EXPOSURE AND THE VIETNAM EXPERIENCE CURRENTLY ON-GOING IN THE UNITED STATES

A.L. Young

1) The U.S. Air Force Health Study

a) Description of the Study

In 1979, the U.S. Air Force established the protocol for a comprehensive epidemiologic study of RANCH HAND personnel, a group of approximately 1260 men who conducted the fixed-wing aerial herbicide spraying missions in Vietnam from 1962 through 1971. The study is designed around the question, "Have there been, are there now, or will there be in the reasonably foreseeable future, any adverse health effects among RANCH HAND personnel caused by repeated exposure to Herbicide Orange?"

The investigation is composed of three integrated elements: 1) a mortality study of those individuals who have died since their exposure, 2) a morbidity study to examine the current health status of the study subjects, and 3) a follow-up study to look for delayed effects over the next 20 years. The mortality and morbidity study elements are being conducted simultaneously on RANCH HAND personnel and on a group of very carefully matched controls using personnel tracking procedures employing the following means: a) an extensive review of military medical personnel records; b) a detailed face-to-face interview using questionnaires to ascertain current and past health events as well as occupational and family data; and c) comprehensive physical examinations, psychological testing, and diagnostic laboratory studies to determine exact health status. Additional questionnaires and physical examinations are to be administered periodically during the follow-up phase.

b) Preliminary Results

In June 1983, a report was released comparing the mortality experience of 1247 RANCH HAND personnel and 6171 comparison subjects. The comparison subjects were individuals assigned to selected Air Force units with the mission of

flying cargo to, from, and in Vietnam during the same period. As of December 31, 1982, 50 RANCH HAND and 250 comparison subjects had died. The mortality experience, including deaths caused by malignant neoplasms, of the RANCH HAND population was almost the same as that of the comparison group. No soft tissue sarcoma deaths were detected in either group. Although there was no indication that the RANCH HAND subjects suffered from any increased mortality or any unusual patterns of death, the study results should not be regarded as final because of the small sample consisting of young, healthy individuals and the relatively short follow-up period. The results of the initial questionnaire, current health status, and reproductive histories are to be released in early 1984.

2) Vietnam Veteran Mortality Study

The US Veterans Administration has initiated a large mortality study that will compare cause-of-death profiles between veterans with service in Vietnam and comparable veterans with no service in Vietnam. Because there are no estimates of the population at risk, the study will provide only proportionate mortality ratio (PMR) data. The study will use existing records to identify a group of approximately 60,000 deceased veterans and determine cause of death and Vietnam service status. The study will also include independent validation of the computer data base used to identify deaths.

Although this study will not provide information specifically related to a reason for greater or lesser relative frequency or specific cause of death, the study will provide a large amount of potentially useful information on Vietnam veteran mortality. In addition, it will provide ideas for future research. The results are to be reported in late 1984.

3) Vietnam Experience Twin Study

a) Description of the Study

The Vietnam Experience Twin Study was begun by a group of research staff members at the US Veterans Administration Medical Center, St Louis, Missouri. The study will identify pairs of identical twin veterans of which one twin served in Vietnam during the period of Agent Orange spraying and the other served in an area other than Southeast Asia. Approximately 600 pairs of twins will be examined using a series of psychologic, physiologic, and biochemical tests.

b) Present Status

The protocol for the study has been completed and approved by a Scientific Advisory Panel. The Twin Registry from which participants will be solicited is being established by the Medical Follow-up Agency of the U.S. National Academy of Sciences. The study will focus primarily on the total Vietnam experience rather than any single factor such as Agent Orange. If sufficient identical twin pairs are identified, there may be an opportunity to draw some conclusions regarding the effects of specific aspects of the Vietnam experience such as combat, herbicide exposure, or use of insecticides. The study is to begin in January 1984. A report on the results is planned for early 1986.

4) Agent Orange Epidemiologic Study of Ground Troops

a) Description of the Study

Public Law 96-151 charged the US Veterans Administration to "design a protocol for and conduct an epidemiological study of persons, who while serving in the

Armed Forces of the United States during the period of the Vietnam conflict, were exposed to any of the class of chemicals known as 'the dioxins' produced during the manufacture of the various phenoxy herbicides (including the herbicide known as 'Agent Orange') to determine if there may be long-term adverse health effects in such persons from such exposure." The Centers for Disease Control (through an interagency agreement with the VA) has completed a protocol for the conduct of this study. This will be a huge research effort that will include interviews and examinations involving 18,000 U.S. Vietnam veterans.

b) Present Status

A major problem in the conduct of such a study is that there are very few records maintained that link specific ground troops to herbicide exposure. Nevertheless, an effort is being made to identify three cohorts, each containing 6,000 veterans. The cohorts will differ by likelihood of exposure to herbicides (high and low) and to combat activity. The pilot study will begin early in 1984 and the study is to be completed by 1987.

5) Epidemiologic Study of the Vietnam Experience

The "exposure" of military service in Vietnam comprises numerous factors, many of which are unknown, poorly defined, or not quantifiable. Nevertheless, the Vietnam "experience" could have influenced anyone who served there. The Centers for Disease Control, Atlanta, Georgia, have initiated a study of two cohorts of U.S. Army draftees and single-term enlistees who served in the infantry. Each cohort will consist of six thousand men. For the Vietnam service cohort, soldiers will be selected so as to provide a year-of-tour distribution which is proportional to the year by year Army troop strength in Vietnam over the period 1966-1971. The selection procedure for the control cohort will be such that its period of service distribution is equivalent to

the Vietnam cohort. However, this latter group will have served either in the U.S., Europe or Korea. The morbidity of the men in both cohorts will be determined. The study is to be completed in 1987.

6) Centers for Disease Control Birth Defects Study

In 1981, the Centers for Disease Control (CDC) in Atlanta, Georgia, began a study designed to determine if U.S. veterans are at an increased risk of having children with birth defects. Since 1968, CDC has maintained a registry of all babies born with structural or functional defects in the greater metropolitan Atlanta area. Of the more than 15,000 children in this registry, approximately 7,500 had significant anatomical defects at birth. The investigators will locate and interview both parents of approximately 5,400 of the children in this group. In addition, the parents of 3,000 matched control normal babies born during the same time period will be interviewed.

Since the major objective of this study will be to determine whether an unusually high proportion of fathers of babies born with defects served in Vietnam, information will be gathered about Vietnam service, as well as on other factors that may be associated with occurrence of birth defects. If results demonstrate that a Vietnam veteran has an increased risk of fathering a child with a defect, then an attempt will be made to determine whether the increase is associated with Agent Orange exposure or with some other factor(s). An index of herbicide exposure has been prepared for use in this study. The study is scheduled to be completed by the end of 1983 and results are to be reported in early 1984.

7) Soft Tissue Sarcoma Studies

a) Kansas Study

In view of concern raised by many veterans that their contact with phenoxy herbicides and TCDD during Vietnam service may increase the risk of developing soft tissue sarcoma (STS), and because of the conflicting research findings reported in the scientific literature regarding association between exposure to phenoxy herbicides and STS, many epidemiological studies have been initiated in the US to determine host and environmental risk factors for STS. The National Cancer Institute is conducting a case-control study in the state of Kansas to evaluate the effects of occupational and environmental risk factors including herbicide exposure on the development of STS, non-Hodgkin's lymphoma, and Hodgkin's disease. A minimum of 100 white male cases of each type of such cancers drawn from the Cancer Data Service of the University of Kansas Medical Center will be compared to controls matched to each case (3:1) by age, race, sex, and area of residence. Results of this study are due in mid-1984.

b) U.S. Veterans' Administration/Armed Forces Institute of Pathology Study

The VA, in collaboration with the Armed Forces Institute of Pathology (AFIP), has started a case-control study of STS. A minimum of 500 STS cases selected from the AFIP registries will be compared to controls matched (2:1) to each case by age ($\pm$ 5 years), race, sex, and place of initial diagnosis. Phase I of the study will investigate whether military service in Vietnam increases the risk of developing STS. Phase II of the study will investigate other host and environmental risk factors for STS based on information obtained from interviews with subjects or their next of kin. Phase I of the study is scheduled for completion in the fall of 1984; Phase II will be completed in late 1985.

c) NIOSH Dioxin Registry Study

Since 1979, NIOSH has begun to develop a registry of US workers involved in production of herbicides possibly contaminated with dioxin. As of May 1, 1983, about 4,000 workers have been included in the registry. The enrollment of an expected number of 6,000 workers will be completed by the end of 1983, and their mortality pattern, including deaths caused by STS, will be available in early 1985.

8) Studies of Chlorinated Dioxins and Furans in Adipose Tissue in the U.S.A.

The U.S. Veterans Administration in cooperation with the US Environmental Protection Agency (EPA) has initiated a study of the levels and the frequency of occurrence of 2,3,7,8-TCDD in adipose tissue from a selected group of U.S. males.

Since 1968, the EPA has been collecting adipose tissue from the US general population by region, age, sex, and race in a National Adipose Tissue Bank which now contains specimens from over 12,000 individuals. Adipose tissue from approximately 550 males born between 1937 and 1953 is available from this bank. Many of these men served in the military during the Vietnam era, and some served in Vietnam during the period of Agent Orange use. A retrospective study of their adipose tissue may establish data on background levels of 2,3,7,8-TCDD in the U.S. male population, as well as whether service in the military and especially in Vietnam has had an effect on the levels of TCDD in adipose tissue.

The study will be conducted in three phases. Phase I will obtain the name and social security number for the approximately 550 males noted above. This information will be used to determine military service status. Phase II will

be the development of analytic methods for the determination of selected chlorinated dioxins (especially 2,3,7,8-TCDD) and furans in human adipose tissue. The method will be subjected to rigorous interlaboratory validation by an independent analytic referee, such as the Association of Official Analytical Chemists. Phase III will be the analysis of the adipose tissue and the preparation of a final report. Phases I and II should be completed within the 1983 calendar year, and the report from Phase III should be available in early 1985.