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October 23, 1984.

MEMORANDUM FOR BERNADINE BULKLEY

FROM: AL YOUNG

SUBJECT: Veterans Administration Agent Orange Briefing

A briefing has been set for October 23, 1984 at 2:30 p.m. on the Agent Orange and Vietnam Experience Health Studies currently being conducted by the Veterans Administration. John A. Gronvall, M.D., Acting Chief Medical Director, and Barclay M. Shepard, M.D., Director, Agent Orange Projects Office, will present the briefing.

You should be aware of the extensive research program that has been initiated by the Veterans Administration. Three investigations are retrospective epidemiologic studies; namely, the VA Mortality Study (a study of 75,000 deaths), the VA/AFIP (Armed Forces Institute of Pathology) Soft Tissue Sarcoma Study (a study of 400 cases and 800 controls), and the VA/EPA Adipose Tissue Study (a study of the dioxin content of 500 human fat samples). In addition, the VA has health surveillance programs consisting of the Agent Orange Registry and the Patient Treatment File. I have attached a review of the VA studies.

The VA has had difficulty conducting morbidity Studies of Vietnam Veterans. Congress mandated the VA to conduct an epidemiologic study of ground troops exposed to Agent Orange. After more than two years of preparation and protocol development, select members of Congress requested that the Administration transfer the conduct of the study from the VA to the Centers for Disease Control. Although the VA has an extensive program, Veterans have the perception that the Agency has minimal involvement and that the CDC is responsible for the conduct of credible human health studies. It is for that reason that the VA Vietnam Experience Twin Study is so important. This study has been widely advertized by the VA, the twin Registry has been established with the National Academy of Sciences Medical Follow-Up Agency, and the protocol has passed two extensive and comprehensive reviews. As I discussed with you, this study appears to be in peril of cancellation. Its cost is estimated at \$9 million. I believe some internal politics are behind this effort, rather than good science. Dr. Gronvall should give us an update. I believe the Administration, and especially the VA will loose credibility with the Vietnam Veteran if this study is cancelled at this late date.

DEPARTMENT OF MEDICINE AND SURGERY
AGENT ORANGE PROJECTS OFFICE (10A7)
STATUS REPORT OF AGENT ORANGE RESEARCH ACTIVITIES

1. Vietnam Veterans Mortality Study

The Vietnam Veterans Mortality Study is designed to assess mortality patterns of U.S. servicemen in the Army or Marines who served during a portion of the Vietnam era. A sample of 75,000 veteran deaths has been selected from the VA files. For each of the deaths, military service and cause of death information are being collected and coded. The two types of data will be merged and analyzed to compare the mortality experience of veterans who served in Vietnam with veterans of the same era who did not serve in Vietnam. Various analytical approaches are being studied including classical proportionate mortality ratio (PMR) analyses as well as categorical data analyses.

As of August 1984 the military records search and abstracting have been completed for 95% of total cohort of 75,000. Ninety five percent of the expected 72,000 death records have been received. However, about 15% of the records received did not include the cause of death information. Extensive tracing efforts have been made using both internal records and records maintained by other government agencies. Data collection will be completed by the end of 1984 and the final report is expected in June 1985.

2. VA/AFIP Soft Tissue Sarcoma Study (STSS)

The possibility that exposure to phenoxy herbicides may induce rare forms of cancer in humans such as soft tissue sarcoma (STS) has been suggested from recent studies in Sweden. Subsequently, there is much concern in the United States that many veterans who served in Vietnam might have had a significant exposure to the phenoxy herbicides including Agent Orange and, therefore, might be at increased risk of developing STS.

In view of the concern raised by many veterans and conflicting findings in the scientific literature, the VA, in collaboration with the Armed Forces Institute of Pathology (AFIP), is conducting an independent epidemiologic study to determine the relationship of Vietnam service, probable Agent Orange exposure and other factors to the risk of developing STS.

2. VA/AFIP Soft Tissue Sarcoma Study (STSS) - Continued

The study is conducted in two phases. Phase I of the study will investigate whether service in Vietnam during 1965-1971 increased the risk of developing STS. Providing that the Environmental Support Group of Department of the Army can develop a rough but acceptable exposure ranking scheme based on military records, an attempt will be made to determine a trend in the odds of developing STS with increasing probability of exposure to Agent Orange. In addition, the histopathology and anatomic site of STS will be compared among Vietnam veterans, non-Vietnam veterans and non-veterans. Military service status of cases and controls will be determined through cross-checking the VA BIRLS (Beneficial Identification and Records Location System) file, the National Personnel Records Center files and the military personnel records center files of each branch of service.

Phase II of the study will investigate other host and environmental risk factors for the development of STS based on information obtained from telephone interviews with the subjects or their next-of-kin. Information on risk factors such as occupational and non-occupational exposure to phenoxy herbicides, ionizing radiation, asbestos, arsenic, vinyl chloride, genetic syndromes, and immunologic deficiency will be obtained from the interviews and analyzed individually and jointly with respect to the risk of developing STS.

The study protocol has been reviewed by scientific groups (AOWG, Science Panel; VA Advisory Committee on Health-Related Effects of Herbicides; Armed Forces Epidemiological Board) and the study subject selection process has begun. As of August 1984, a total of 180 hospitals have selected three controls per STS case and sent in requisite patient information.

The RFP for tracing and conducting interviews for the study subjects was approved by the Administrator on May 2, 1984, and announced in the Commerce Business Daily beginning in late May. Evaluation of both technical and business proposals were completed in September and the contract is expected to be awarded in October 1984. The Office of Management and Budget is still reviewing our request for questionnaire approval.

Data collection will be completed by December 1985 and the final report is expected in June 1986.

3. Retrospective Study of Dioxins and Furans in Adipose Tissue

Since 1970, the Environmental Protection Agency (EPA) has been collecting human adipose tissue from the general population to be analyzed for residues of selected pesticide-related chemicals and polychlorinated biphenyls (PCBs). Within the bank of approximately 8,000 tissue specimens available for further chemical analysis there are specimens from 524 males born between 1937 and 1952. Many of these individuals will have served in the military during the Vietnam era and some will have served in Vietnam during the period of Agent Orange use. A retrospective study of selected chlorinated dioxins and furans will provide data on background levels of 2,3,7,8-TCDD in the U.S. male population and will determine if service in Vietnam has had an effect on the levels of TCDD in adipose. The study will be conducted in three phases. In phase I the names and social security numbers of the approximately 524 males noted above will be obtained to determine military service status. Phase II will be the development of analytic methods for the determination of selected rigorous interlaboratory validation by an independent analytic referee, e.g., the Association of Official Analytical Chemists. Phase III will be the analysis of the adipose tissue and the presentation of a final report.

A draft study protocol is being prepared for the AOWG Science Panel review. Once the panel completes its review and necessary resources are secured, the study will take approximately two years to complete.

4. A Review of the Soft Tissue Sarcoma Cases in Patient Treatment File (PTF) for Vietnam Era Veterans

In a parallel effort to the VA/AFIP Soft Tissue Sarcoma Study, the VA's Agent Orange Projects Office (AOPO), in collaboration with VA's Pathology Service and AFIP, is reviewing the soft tissue sarcoma cases in the VA's Patient Treatment File (FY 69-83) for Vietnam era veterans. We are comparing anatomic site, histopathology and frequency of soft tissue sarcoma between Vietnam veterans and non-Vietnam veterans.

A total of 418 patients with International Classification of Diseases (ICD) 171 (malignant neoplasm of connective and other soft tissue) were identified in the PTF between 1969 and 1982. A review of the pathology reports for these cases was made by an "independent" VA pathologist. Military service information for these cases (Vietnam vs. non-Vietnam) was obtained through the National Personnel Records Center in St. Louis. It was found that 36% of the STS cases served in Vietnam whereas in the overall PTF, 41% of the Vietnam era patients served in Vietnam. This

4. A Review of the Soft Tissue Sarcoma Cases in Patient Treatment File (PTF) for Vietnam Era Veterans - Continued

suggests that for Vietnam era veterans treated in the VA Medical Centers the frequency of the STS among veterans who served in Vietnam is not greater than those who did not serve in Vietnam.

As Phase II of this review, we plan to have the tissue specimens for these cases actually examined by an outside expert pathologist to confirm the original diagnosis. We are in process of selecting an outside expert pathologist and receiving the specimens from the VA medical centers. The final report is expected in May 1985.

5. Other Projects

a. Agent Orange Register Review - The Agent Orange Register is a computerized information retrieval system that abstracts both medical and non-medical information from the Agent Orange Registry. The medical information includes symptoms attributed by the veteran to exposure to Agent Orange and pertinent diagnosis made by VA physicians. The non-medical information includes veterans' demographic data, veterans' self-reported information on their military service and their recollection of exposure to Agent Orange. There are some differences in format between the "old" code sheet and the "new" code sheet, but in general both code sheets cover similar areas.

Because of the self-selective nature of the Registry participants, this group of veterans cannot, with any scientific validity be viewed as being representational of Vietnam veterans as a whole. The information in the Registry can, however, be used to detect suggested health trends and provide some descriptors as to the characteristics of the group itself.

The Agent Orange Register of 86,000 Vietnam veterans was reviewed and results were reported to the VA Advisory Committee on Health-Related Effects of Herbicides in September, 1983. The monitoring of the Agent Orange Register is continuing.

b. Patient Treatment File (PTF) Review - The VA also continues to review health problems of Vietnam veterans treated in its hospitals. Questions have been asked many times by Congress and others whether Vietnam veterans come to the VA hospitals with different or unique health problems as compared to their counterparts who did not serve in Vietnam. An initial review of a sample of 13,000 Vietnam era veterans (FY 69-82) and another review of a random sample of 1,000 veterans' (FY 83) military records and PTF medical data reveal no significant difference in the distribution of diagnoses between Vietnam veterans and non-Vietnam veterans treated in VA hospitals. These findings were also reported to the VA Advisory Committee on June 5, 1984. This effort of monitoring health problems of Vietnam veterans hospitalized in the VA medical facilities will continue.

c. PTF/Cancer Study - In collaboration with the AFIP, the VA plans to conduct a pathological evaluation of malignant neoplasms among Vietnam era veterans treated in the VA medical facilities. There are several published reports which suggest that exposure to phenoxy herbicides may contribute to a higher risk of developing soft tissue sarcoma, lymphoma, nasal cancer, and possibly liver cancer. In general, it takes over a decade for cancer to manifest itself if it is caused by environmental chemicals. It has been more than a decade since the last U.S. troops were exposed to defoliants in Vietnam and about 20 years since the first massive spraying of Agent Orange there. Therefore, the time is about right for evaluating cancer problems in Vietnam veterans. About 5,000 cancer cases among Vietnam era veterans treated in the VA medical facilities in the last 3 years will be selected for this study. The AFIP will make a pathological diagnosis without knowing Vietnam service status of cases and the Army Environmental Support Group will determine military service status and Agent Orange exposure likelihood for each case without knowing the pathological diagnosis. The VA's Agent Orange Projects Office will coordinate this effort and perform data analyses once all the information is collected. This study will serve as a built-in quality control program for the VA's Pathology Service by systematically comparing diagnosis made by the VA pathologist with that of the AFIP experts.

d. The In-depth Review of Suicide Among Vietnam Veterans - In addition to the above on-going research efforts, the VA's AOPO is actively cooperating with the Readjustment Counseling Service in designing an in-depth review of the cases listed as suicide or possible suicide in the mortality study being conducted. This will enable the VA to determine whether the frequency of suicide among Vietnam veterans is higher than among non-Vietnam veterans and also will help to develop a clinical profile of Vietnam veteran suicides which may assist in preventing suicides in the years to come.