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STATEMENT OF

JOHN A. GRONVALL, M.D.

CHIEF MEDICAL DIRECTOR

VETERANS HEALTH SERVICES AND RESEARCH ADMINISTRATION

DEPARTMENT OF VETERANS AFFAIRS

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON VETERANS' AFFAIRS

U.S. HOUSE OF REPRESENTATIVES

JUNE 22, 1989

Mr. Chairman and Members of the Subcommittee:

I am honored to appear before your Committee to give you a progress report on the Department of Veterans Affairs' provision of benefits to the women who served so valiantly in our nation's Armed Forces.

As incredible as it seems to us now, the 1980 Census was the first U.S. Census that ever asked women if they had served in the military. That Census revealed that there were 1.13 million women veterans making up 3.1 percent of the veteran population. This figure is growing and women now comprise over 4 percent of the veteran population. Between 1970 and 1988, the number of women discharged from VA medical centers more than doubled from over 9,000 in 1970 to over 25,000 in 1988 (2.2 percent of all discharges). The Survey of Female Veterans conducted by Louis Harris and Associates in 1964 under contract to the VA, showed that women veterans are better educated than the general population (only 3 percent do not have high school diplomas and 47 percent have some college). Seventy-five percent of women veterans have

private health insurance, perhaps accounting for the underutilization of VA health care (they account for only 2.2 percent of VA medical center discharges despite accounting for 4 percent of the veteran population). Approximately 63 percent of women veterans treated by the VA have nonservice-connected disabilities compared to 62.1 percent of men veterans; most of these of both genders are medically indigent.

In 1982 the General Accounting Office (GAO) published a report that concluded that actions were needed to assure that men and women have equal access to VA treatment programs and medical facilities as well as action to assure that women receive complete physical exams and necessary gynecologic care. The report cited a lack of privacy in some facilities and inadequacies in outpatient gynecologic care. The GAO also pointed to certain special programs such as VA domiciliaries which restricted access by women.

The then Department of Medicine and Surgery concurred with the recommendations of the GAO and in January 1983, a VA directive was published establishing criteria for adequate and equitable care of women veterans. It instructed each facility to develop a written plan for the care of women addressing, at a minimum, four areas:

a. Definition of a complete physical exam for women as including breast and pelvic examination.
b. Provisions for adequate inpatient gynecology services.
c. Provisions for outpatient gynecology services.
d. Referral procedures for necessary services for women unavailable at that facility.

As a result of the GAO recommendations, directives were also issued to VA medical centers to identify privacy problems and propose corrective action in their Five-Year Facility Construction Plans. Construction planning criteria were reviewed and found to be consistent with appropriate privacy standards for men and women.

Prior to 1983, nine facilities had relied on fee-basis care to provide gynecology, thereby limiting the service to service-connected women veterans. A new policy was instituted at that time requiring all VA medical centers to have at least one other method of providing gynecology, such as a staff gynecologist, a consultant to the medical center, a regularly scheduled clinic at the medical center or sharing agreement with a local hospital, in addition to fee-basis care. Now all women veterans using VA facilities have access to gynecologic care.

At the time of the 1982 GAO Report, only six of the 16 domiciliaries admitted women because of privacy considerations. Two years ago, the Chief Medical Director reported to this Subcommittee that all but two domiciliaries were able to provide care for women. I am now pleased to report that all VA domiciliaries are equipped to admit and treat women veterans.

The first VA Mammography Unit was opened at the VA Medical Center, Minneapolis, MN, in 1984, and there are now units at Allen Park, MI; Bronx, NY; Buffalo, NY; Martinez, CA; Portland, OR; and West Roxbury, MA. A mobile unit at Hines (Chicago), IL, provides services to four Chicago-area VA medical centers.

A number of VA medical centers have set up special women's clinics which emphasize early cancer detection, osteoporosis prevention and treatment, gynecology, nutrition, and preventive health.

The health care needs of women veterans are being addressed in the Medical District Initiated Planning Process (MEDIPP). Medical Centers are responsible for assessing their ability to meet the current and future needs of women veterans and to initiate planning when unmet needs are identified. Program initiatives, such as special women's clinics and mammography units, and facility construction or renovation projects to improve privacy, are included in each medical center's MEDIPP plans.

There are occasional inquiries from women concerning care for normal pregnancy and delivery. As you know, the Department of Veterans Affairs does not provide care for pregnancy and delivery since pregnancy is not considered to be a medical disability within the meaning of our medical benefits' laws and regulations. There have also been a few inquiries from women concerning the availability of assistance in overcoming infertility. The scope of VA's medical authority is generally to <u>treat</u> disabilities. However, the inability to become pregnant has not been deemed to be a medical disability and therefore the VA does not <u>treat</u> it. For that reason, VA has not been able to make available new technologies to overcome infertility for either men or women. The Office of Technology Assessment completed a study entitled "Infertility: Medical and Social Choices" in May 1988. The OTA made no specific recommendations for VA action but did summarize some of the considerations: authority to provide care to a nonveteran spouse, responsibility for subsequent obstetrical care, responsibility for offspring with birth defects, and other more general ethical issues facing society as a whole.

The VA Advisory Committee on Women Veterans, which was established in 1983, has closely monitored the progress of the VA in meeting the needs of women in VA facilities. One specific recommendation made by the Committee was the appointment of women veteran coordinators at VA medical centers to make the traditionally male-oriented facilities more accessible and more sensitive to the growing number of women veterans eligible for care in these facilities. The recommendation was accepted and implemented in the field and has been well-received. Many facilities have also set up a committee to assure that the various needs of women can be met and to assist in planning for future needs. The women veteran coordinators continue to meet at the regional and district level to discuss ways in which the VA and the coordinators can better serve the needs of the women veterans.

Since the Advisory Committee's inception, most of their recommendations have been implemented by the Department. For instance, privacy in dressing, bedroom, and examination areas; inclusion of women in statistical information; separate data publications regarding statistics on women veterans; long-range planning for women in nursing homes and domiciliaries; pajamas and robes for women; extensive outreach campaign to inform women veterans of their entitlements; dissemination of "Women Are Veterans, too!" pamphlet for public information; access to substance abuse treatment programs geared specifically to the woman veteran; and, toiletry articles for women available for sale in VA medical center canteens. Members of the Advisory Committee have emphasized the importance of VA outreach to inform women veterans of benefits and to increase awareness of their veteran status.

[redacted]

Several studies of the health effects of service in Vietnam have been completed since the study of women Vietnam veterans was first contemplated. The comprehensive National Vietnam Veterans Readjustment Study conducted by the Research Triangle Institute included an oversample of women veterans. Results indicate significant differences between women who served in Vietnam and those who did not. Nearly 27 percent have had PTSD at some point in their lives and an additional 21 percent have some symptoms of PTSD. The lifetime prevalence of depression and alcohol abuse was also significantly higher for women veterans who served in Vietnam than for those who did not, or for civilians. Another study would certainly give similar results, but would contribute little new information. Further analysis of the extensive data on women collected as a part of that study, however, could expand knowledge of women's reactions to stresses under hostile conditions. The Ranch Hand research of the U.S. Air Force and The Centers for Disease Control Vietnam Experience Study have failed to produce evidence of significant long-term adverse health effects in the thousands of men examined. [redacted] Furthermore, a repeat of the same Vietnam Experience Study in a much smaller group of women veterans is unlikely to contribute any useful information with the possible exception of information on gender specific effects.

While there is little credible evidence that adverse reproductive effects in women can be attributed to the Vietnam experience, it would be possible to conduct an epidemiological study comparing the pregnancy outcomes of women who served in Vietnam with those of women who did not. The Chief Medical Director is exploring with the Office of Technology Assessment whether a scientifically valid study as described in P.L. 99-272 is feasible, or whether alternative studies should be pursued further.

The Veterans Health Services and Research Administration is committed to meeting the needs of women veterans seeking care and is anticipating that the demand will increase as the population of women veterans grows and the significant segment of women who served in World War II ages. Planning to meet their needs is an integral part of VA's planning process.

Although the provision of health care has received the most attention in VA's efforts to better meet the needs of women veterans, the Department of Veterans Affairs provides a full range of other benefits programs which are available for women veterans. The criteria which must be met to qualify for these benefits are the same for men and women. The amount of benefits paid monthly is also the same for women veterans as it is for men.

At present, 35,038 women receive service-connected disability compensation. These women represent 1.6 percent of all veterans on the compensation rolls and nearly 3 percent of all women veterans. Comparatively, 8.3 percent of the male veteran population receives service-connected disability compensation.

Nonservice-connected disability pensions have been granted to 9,200 women veterans (1.5 percent of all veterans on the rolls and 0.76 percent of all women veterans). Approximately 2.3 percent of male veterans are receiving disability pension.

There were 5,350 VA guaranteed home loans made to women veterans during Fiscal Year 1988. This was 2.3 percent of the total 232,640 VA home loans closed.

A proposed regulatory change which would end gender-differentiation in the payment of insurance was published in the Federal Register on March 20, 1989. No public comments were received during the comment period, and, as a result, a final regulatory package has been prepared and submitted for public notice. Implementation of this change will increase the benefits paid to women veteran annuitants in VA insurance programs. It will also implement a recommendation of the VA Advisory Committee on Women Veterans to that effect.

Veterans Benefits Administration personnel in VA regional offices, concerned about women veterans' lack of knowledge about, and their low utilization of, VA benefits programs, pay particular attention to women veteran inquiries and provide comprehensive information and counseling services to women applicants. Pamphlets, newsletters, and public presentations are used for VA outreach to women veterans. Regional offices have developed special mailings and contact lists of women veterans to further this effort.

Women are included in the outreach focus on homeless veterans and in outreach efforts to active duty military personnel who are pending separation or retirement, and to older women veterans and their family members. Women veteran coordinators at all VA regional offices are appointed and are available to provide special services to women as those needs are identified.

Mr. Chairman, this concludes my formal statement. I and members of my staff will be pleased to respond to any questions that you or members of the Committee may have.

Status of Vietnam Veterans Health Studies
VA Office of Environmental Epidemiology

Soft Tissue Sarcomas Studies

In October 1987, the results of a study by the Department of Veterans Affairs (VA) and the Armed Forces Institute of Pathology (AFIP) entitled "Soft Tissue Sarcoma and Military Service in Vietnam: A Case-Control Study" were published in the Journal of the National Cancer Institute. This case-control study was concerned with men who were of draftable age during the Vietnam conflict and examined the association of soft tissue sarcomas with military service in Vietnam as well as with other host and environmental risk factors. A total of 217 cases of soft tissue sarcomas selected from AFIP records were compared to 599 controls for Vietnam service, occupational history, medical history, and life style. The results of the study indicate that Vietnam veterans, in general, did not have an increased risk of soft tissue sarcomas when compared to those men who had never been in Vietnam.

In a parallel study, the VA reviewed the Patient Treatment File (PTF) for soft tissue sarcoma cases among Vietnam era veterans who had been admitted to VA medical centers during the period 1969 to 1983. The soft tissue sarcoma case group were comprised of 234 patients of the Vietnam-era who served in the military between 1964 and 1975. The comparison group consisted of 13,496 patients who were systematically sampled from the same

patient population from which the cases were drawn. This case comparison group analysis of hospital patients indicated no significant association between soft tissue sarcoma and military service in Vietnam. The findings of the study were published in the Journal of Occupational Medicine in December, 1986.

Retrospective Study of Dioxins and Furans in Adipose Tissue

The VA, in collaboration with the Environmental Protection Agency (EPA), completed a very detailed analysis of adipose tissue specimens from approximately 200 males of the Vietnam-era age group. The specimens were analyzed for 2,3,7,8-TCDD and 16 other dioxins and dibenzofurans. The primary reason for concern about the adverse effects of Agent Orange exposure is attributable to the toxic contaminant, 2,3,7,8-TCDD. Because TCDD accumulates preferentially in body fat and has a long half-life in humans, TCDD levels in adipose tissue can serve as a biological marker of exposure to Agent Orange. The adipose tissue collected for the EPA's National Human Adipose Tissue Survey (NHATS) was made available for the study.

A total of 40 Vietnam veterans, 80 non-Vietnam veterans and 80 civilian men were selected and their archived tissues analyzed for dioxins and dibenzofurans. It was found that, with or without adjustment for several demographic variables, the mean level of 2,3,7,8-TCDD in the adipose tissue of Vietnam veterans was not significantly different from that of non-Vietnam veterans or civilian men. Furthermore, the results showed no association

between TCDD levels and Agent Orange exposure opportunity estimations based on military records.

Agent Orange Registry

The Agent Orange Registry (AOR) program was initiated by the VA in mid-1978 as a service to veterans who were concerned about possible health problems due to exposure to herbicides during service in Vietnam. The AOR provides these veterans an opportunity to receive a complete health evaluation and answers to questions about the current state of knowledge regarding the relationship between herbicide exposure and subsequent health problems. Each veteran who participates in this voluntary program receives a physical examination and a baseline series of laboratory tests and is asked a series of questions about his or her medical history and military service, including their recollections of any contacts with herbicides while in Vietnam. Following the examination, the veterans are provided the results of the physicals in face-to-face discussions with physicians familiar with the health aspects of Agent Orange and by follow-up letters summarizing the findings. Registry participants are placed on a mailing list which enables the VA to provide them with current Agent Orange information. Approximately 230,000 Vietnam veterans have chosen to participate in this program since it began.

A review of data on the first 86,000 AOR participants was published in 1985 ("Chlorinated Dioxins and Dibenzofurans in the

Total Environment II", pp 167-179, Butterworth Publishers). The results of another review of AOR data on 104,000 veterans who received an examination between July, 1982 and October, 1988 were presented at the 22nd Annual Meeting of the Society for Epidemiologic Research in June, 1989. The most prominent diagnoses on initial examination were skin inflammations and dermatitis (8.7%) followed by anxiety (3.6%), depression (3.3%), alcohol dependence (3.2%), and post traumatic stress disorder (PTSD) (3.2%). Prevalence of PTSD was highest among Marine Corps veterans (4.5%) followed by veterans of the Army and the other branches. The distribution of cancer diagnoses by primary site was similar to that of cancer incidence data from the National Cancer Institute SEER (Surveillance, Epidemiology, and End Results) registries. No difference in prevalence for any cancer site was seen between veterans who reported having been exposed to Agent Orange compared to those reporting no exposure. A manuscript is being prepared for submission to a scientific journal for publication.

Vietnam Veterans Mortality Study

The results of the VA's mortality study were released in September, 1987 and published in the Journal of Occupational Medicine in May, 1988.

In this study the patterns of mortality among 24,235 Army and Marine Corps veterans who served in Vietnam were compared with those of 26,685 non-Vietnam veterans using standardized

proportional mortality ratios. The veterans were a random sample of deceased Vietnam-era veterans identified in a VA computerized file used to administer death and other benefits. Military service information was obtained from military personnel records, and cause of death information from death certificates.

Statistically significant excess deaths were observed among Army Vietnam veterans for motor vehicle accidents, non-motor vehicle accidents and accidental poisonings. Similar findings have been reported in other studies of Vietnam veterans. Suicides were not elevated among Vietnam veterans. The Marine Corps Vietnam veterans appeared to have an increased mortality from lung cancer and non-Hodgkin's lymphoma. Although exposure to several environmental factors may be speculated, the study did not investigate possible etiologic factors for these elevated malignancies.

A summary of the comments made by the Science Panel of the Agent Orange Working Group and by the VA's Advisory Committee on Environmental Hazards is provided as follows:

The Science Panel found that the study was well executed but criticized the authors for not advising the necessary caution in interpreting the study's findings. The panel determined that this study could not be used to infer anything about the effects of exposure to Agent Orange and agreed with the authors that further work is needed to evaluate causative factors. In regard to the finding of lung cancer in Marine Corps Vietnam veterans, the panel noted that this had not been seen in other studies and that

the absence of smoking histories made the interpretation of the data difficult. Finally, the panel believed that the small number of statistical departures from expected mortality could be the result of chance alone.

The Advisory Committee on Environmental Hazards concluded that the study was well-designed and well-conducted. The Committee stated that it was their best scientific and professional judgment that the findings concerning non-Hodgkin's lymphoma and lung cancer, while statistically significant, should be interpreted with caution and that the findings are not conclusive. Among the reasons given for this cautionary statement was that a proportionate mortality study by its very nature cannot resolve the question as to whether the observed results constitute a direct cause-and-effect relationship. A study such as this, the Committee noted, can only lead to the identification of issues requiring further study and analysis. With respect to the lung cancer finding, the Committee also noted the absence of any information about the smoking histories of the study's subjects. The Committee recommended no changes in the VA's current guidelines governing the adjudication of claims based upon the findings of this study and exposure to dioxin.

Four Follow-up Studies

In view of the comments made by the Science Panel and the Advisory Committee, the VA has conducted four follow-up studies to confirm or complement the findings of the mortality study.

First, the VA is updating the mortality study by including an additional 11,000 Vietnam-era veterans' deaths which occurred between 1982 and 1984 in the analysis. They will give added statistical power and cases with longer latency periods to the study. This is important because some of the diseases that have been suggested as being associated with Agent Orange exposure or Vietnam service may take a long time to develop. For example, it generally takes as long as 20 years for certain cancers to manifest themselves if they are caused by exposure to environmental chemicals such as Agent Orange. Data analysis are completed and a report is being prepared.

Second, a separate analysis is being completed for Army veterans who served in the I Corps area of South Vietnam. This is an effort to determine whether the Army veterans who were stationed in the same geographic areas as the Marine Corps veterans experienced mortality patterns similar to the Marines. The U.S. Army and Joint Services Environmental Support Group assisted the VA in researching Army unit locations in Vietnam for given time periods. A report is being prepared.

Third, the VA is reviewing its Patient Treatment File (PTF) for non-Hodgkin's lymphoma and Hodgkin's disease among Vietnam era veterans who have been treated in VA medical centers. The case and control patients were compared with respect to service in Vietnam and other military service factors. The hypothesis is that if military service in Vietnam is not associated with an increased risk of non-Hodgkin's lymphoma or Hodgkin's disease,

then the proportion of veterans having served in Vietnam or having certain military characteristics should be similar for both the cases and the controls. Data analysis for the review was completed and the results were presented at the 22nd Annual Meeting of the Society for Epidemiologic Research in June, 1989.

Finally, a separate mortality study has been designed exclusively for Marine Corps Vietnam veterans. To date, the only study providing an overall mortality rate of Vietnam veterans is a cohort mortality study recently published by the Centers for Disease Control, but it was restricted to Army veterans. A substantial portion (approximately 20%) of U.S. ground troops in Vietnam were Marines. Unlike the Army units, the Marine Corps units were located primarily in one geographic area, I Corps. In view of the VA mortality study results and the lack of overall mortality rates as well as cause-specific mortality rates for Marine Vietnam veterans, a separate mortality study for Marine veterans is being conducted.

A contract was awarded in October 1988 to Noblestar Systems Corporation (affiliated with JAYCOR) to abstract military records of 10,000 Marine Vietnam veterans and 10,000 Marine veterans who did not serve in Vietnam. A pilot study was completed in December of 1988 which tested the military records abstraction forms and procedures. Names and social security numbers of Marine veterans are being submitted to the National Personnel Records Center in St. Louis, Missouri, to obtain the military personnel records needed for the study. Approximately 8,000

military records of Marine veterans were abstracted by the end of June 1989. Military record abstraction is expected to be completed in October of 1990.

Current vital status is being ascertained matching identifying information on Marine veterans with records of the Social Security Administration, the Internal Revenue Service, the National Death Index, the VA Beneficiary Identification and Record Locator Subsystem (BIRLS), and military personnel records. Death certificates will be obtained from VA regional offices, Federal Archives Records Centers, and state vital statistic record offices to verify fact of death and determine underlying cause of death. Mortality rates for major cause of death in the study cohort will be compared with those in the comparison cohort.

Suicide in Vietnam Veterans

Potential risks factors for suicide among 38 Vietnam veterans were examined using 46 Vietnam veterans who died from motor vehicle accidents as a comparison group. The veterans were selected from Los Angeles County Medical Examiner's files (1977-1982). Data for these veterans were obtained from military service records, coroners' reports, and psychological autopsies conducted with family members of the decedents. No military service factor was associated with suicide. The characteristics of Vietnam veteran suicide cases were not substantially different from non-Vietnam veteran suicide cases with respect to known

demographic risk factors. The psychological profile of Vietnam veteran suicide cases was also similar to non-Vietnam suicide cases in most instances. Symptoms related to PTSD were observed more frequently among suicide cases than accident cases. However, suicides were not associated with specific combat experiences or military occupations. The extent of combat experience in Vietnam per se as measured in this study is not a good predictor of suicide death. The study has been accepted for publication in the Journal of Nervous and Mental Disease.

OTHER ON-GOING STUDIES

COHORT MORTALITY STUDY OF WOMEN VIETNAM VETERANS

The health effects of military service in Vietnam are being evaluated for women veterans. The study cohort consists of all women who were on active duty in the U.S. Armed Forces at any time during 1964 through 1972 and whose tours of duty included service in Vietnam. Approximately 5,000 women veterans who served in Vietnam were identified from morning reports and their military personnel records have been abstracted to verify Vietnam service dates and military occupations. Mortality rates for major cause of death among women Vietnam veterans will be compared with those of women veterans who did not serve in Vietnam. A comparison cohort of approximately the same size as the study cohort has been identified and their military records have been abstracted.

Current vital status has been obtained by matching identifying information on women veterans with records of the Social Security Administration, the Internal Revenue Service, the National Death Index, the VA Beneficiary Identification and Record Locator Subsystem (BIRLS), and military personnel records. Death certificates are being obtained from VA regional offices, Federal Archives Records Centers, and state vital statistic record offices to verify fact of death and determine underlying cause of death.

Data analysis are expected to be completed by December, 1989 and a report will be available in the summer of 1990.

COHORT MORTALITY STUDY OF ARMY CHEMICAL CORPS VIETNAM VETERANS

The health effects of chemical exposures during military service in Vietnam are being examined among men who were assigned to Army chemical units. These units were responsible for detecting and counteracting enemy chemical warfare by using riot control agents and for defoliating vegetation using phenoxy herbicides. Because they were involved in the mixing and application of these chemicals, they were likely to have had heavier exposure to them than other ground troops. Nearly 1,000 men who served in Army chemical units in Vietnam between 1965 and 1971 have been identified from unit morning reports.

This study will examine mortality and morbidity among the men who served in Army chemical units in Vietnam. Particular

attention will be paid to occurrences of cancer and reproductive disorders and to deaths from cancer and violence.

Military personnel records were located and abstracted for all but a few study subjects. Military occupation specialty codes will be used to distinguish those veterans who could have handled herbicides from those who did not. In addition, unit histories will be obtained for as many of the chemical units as possible in an attempt to determine the extent of herbicide use for each unit.

Current vital status has been obtained by matching identifying information on Army chemical unit veterans with records of the Social Security Administration, the Internal Revenue Service, the National Death Index, the VA Beneficiary Identification and Record Locator Subsystem (BIRLS), and military personnel records. Death certificates are being obtained from VA regional offices, Federal Archives Records Centers, and state vital statistic record offices to verify fact of death and determine underlying cause of death.

Morbidity information will be obtained by matching the Army chemical unit cohort with AOR and PTF records. Prevalence rates for cancer, reproductive disorders, and other conditions noted among the study subjects will be compared with prevalence rates of the same conditions among other Army Vietnam veterans reporting to the AOR and the PTF.

Data analysis are expected to be completed by September, 1989 and a report will be available in the spring of 1990.

STATUS - WOMEN'S HEALTH STUDY

Public Law 99-272, the "Omnibus Budget Reconciliation Act," enacted April 7, 1986, mandates the Veterans Administration to provide for the conduct of an epidemiological study of any long-term adverse health effects experienced by women who served in the Armed Forces in Vietnam. The following chronology describes the status of Agency efforts to comply with the law:

April 7, 1986	P.L. 99-272 enacted
April 15, 1986	In accordance with Section 19031 (a) (1) (A), the VA initiated informal consultation with OTA on feasibility of doing certain aspects of the study.
April 25, 1986	Chief Medical Director transmits memo to Director, Office of Procurement and Supply (90) requesting expedited assistance in issuing RFP for protocol development by July 1, 1986, as mandated by P.L. 99-272.
April 29, 1986	Director, Agent Orange Projects Office (AOPO), transmits memo to VA's Director for Operations (10B1), through ADCMD for Programs, Planning and Policy Development (10X), requesting $250K for development of study protocol for conduct of study in FY 86 and $2.5 million in either FY 87 or 88 for conduct of study.
May 1, 1986	Director, AOPO, transmits memo to Director, Office of Procurement and Supply (93A) relative to the issuance of an RFP for protocol development. Memo forwards "24 Questions and Statement of Work" for the study protocol.
May 2, 1986	Director, AOPO, meets with Director, Office Procurement and Supply, to request support in expediting issuance of RFP by July 1, 1986.
May 6, 1986	Director, AOPO, conferred with Executive Assistant to Director for Operations and Resource Management Staff in effort to identify funding

	source for protocol development and study's conduct.
	Updated "24 Questions and Statement of Work" is provided to Deputy Director, Office of Procurement and Supply. Briefing provided to that office on need to expedite issuance of RFP. Procurement and Supply assures support in meeting July 1, 1986 date.
May 7, 1986	FY 1988-1992 preliminary budget plan for Medical Research sent to Research and Development Service (15B) which includes $2,373,000 for conduct of study.
June 10, 1986	Administrator corresponds with Director, Office of Technology Assessment (OTA), commenting that certain aspects of the study cannot be scientifically conducted. Administrator recommends OTA concurrence on proposal to conduct a Vietnam Experience-related study.
June 23, 1986	Notice of intent to publish RFP is published in Commerce Business Daily.
August 25, 1986	Last date for bidders to submit proposal to VA Central Office.
September 23, 1986	New England Research Institute (NERI) selected as contractor for protocol development.
	Contract cost-$179,000.
	Contract for nine months (to June 23, 1987).
	Protocol development initiated.
May 21, 1987	Contract extended at no additional cost to October 31, 1987 at NERI's request to allow NERI to assist the VA with the submission of data collection forms to the OMB for approval, to allow the NERI Project Director to be available for meetings with the OTA or others and

	answer questions concerning the protocol, to allow for the time needed by NERI if OTA review requires study design changes in the protocol, to allow time to incorporate the results of CDC's validation study which are expected to be released after June 30, 1987 and to allow for time needed to conduct a further expert panel review if required by any changes resulting from the foregoing.
July 1, 1987	Protocol provided to VA's Office of Environmental Epidemiology (OEE) by New England Research Institute. Protocol was reviewed and approved by an expert panel selected by the contractor.
August 11, 1987	Administrator transmitted protocol to Director, OTA, for review and comment. Director, OTA advised that Science Panel, Agent Orange Working Group (AOWG), to receive a copy of protocol for information purposes also.
August 14, 1987	Acting Director, Agent Orange Projects Office, transmitted copy of protocol to members, Science Panel, AOWG, requesting review and comment.
August 27, 1987	OTA's Advisory Committee conducted formal review of protocol as requested by Administrator.
September 25, 1987	Director, OTA, transmitted comments on review of protocol to Administrator.
October 9, 1987	Director, OEE, briefed VA Advisory Committee on Women Veterans on the status of protocol development.
	Protocol returned to contractor for revision in accordance with OTA recommendations.
October 27, 1987	Existing contract with New England Research Institute extended to April 30, 1988 at an additional

	cost of $77,904 to provide for revision of protocol in accordance with OTA recommendations.
	NERI was requested to investigate the feasibility of an approach to identifying a sample of civilian nurses to serve as a third comparison cohort in the nurses sub-study, to revise the basic study design according to the OTA recommendations, to revise the questionnaire to include a more comprehensive section on stressors, stress outcomes and Post Traumatic Stress Disorders, to conduct additional protesting of sections of the questionnaire, to document which questions measure which variables, to arrange for the review of draft revisions by members of an expert panel and by military and other professional consultants, to submit a final, revised study design and questionnaire, to complete any remaining revision needed for approval, to assist in obtaining OMB approval of the questionnaire and to attend meetings and hearings during the contract period.
March 3, 1988	Revised protocol provided to VA by contractor.
March 8, 1988	Revised protocol submitted to DM&S Research and Publications Committee for their review and comment.
April 28, 1988	VA's DM&S Research and Publications Committee completes review of protocol. Recommendation made by committee that protocol receive further revision.

The Committee's discussions are summarized as follows: The Committee

A. noted that the Study had been mandated by Congress.

B. Recognized the need for such a study.

C. Recommended that it might be helpful if an oversight committee be established to oversee the actual conduct of the study.

D. Suggested that one of the Field HSR&D groups be asked to monitor the Study.

E. Noted that the Questionnaire reflected a lack of medical input. The Committee noted that the study did not address many areas of concern and cited a few examples- namely, hearing, eye care (Glaucoma) (eye pain), dental care, radiation, use of tobacco, head injury, abortion, etc. The Committee also noted that strongyloidiasis is referred to repeatedly without a clear rationale for being suspicious of this problem. Also Lipid analyses are included in the study, but a clear rationale is not stated.

F. Noted the need for the study to address patient privacy rights more forthrightly, the need to obtain a signed "consent" in order to review hospital or medical records and the need to guard against the possible harassment of participants in the process of obtaining information.

G. Recommended that an instrument be developed to measure the effect of drug and alcohol abuse, combat and involvement with herbicides. (The three major stressor groups - drugs, combat and herbicides are not quantified in any way nor is any attempt made to evaluate them.)

H. Identified the need for a comprehensive psychiatric evaluation/examination that would address Cognitive Deficiencies, suicidal thoughts, depression, etc.

I. Recommended that a comprehensive medical examination be designed and perhaps more specific ancillary tests be required, e.g. specific blood tests, etc.

J. Suggested that all medical diagnosis be recorded and that a total record be sent to the participant's own physician.

K. Identified the need to make provisions for meals, lodgings, transportation and reimbursement for the participants.

L Recognized the value of having a civilian nurse cohort.

M. Suggested that the directions and time for coded input be addressed clearly.

N. Noted the mention of immunosuppression in the discussion which is woven into the protocol. The evidence linking dioxin/herbicides to immune damage is limited and controversial and derived from cell

cultures and animals other than man. Even if evidence was compelling, there are no studies included which will delineate this problem.

O. Noted that no followup is alluded to concerning pathologies discovered in participants in the study.

P. Stated that it was difficult to identify outcome variables. It was noted that variables should be clearly related to recommended evaluations. In addition the power of analysis with respect to the number needed in each cohort and how much of a difference can be detected is not given for individual outcomes.

April 29, 1988	Contract extended to September 30, 1988 at no additional cost. Protocol returned to contractor with DM&S Research and Publications Committee recommendations.
June 8, 1988	Contract extended to October 30, 1988, NERI requested to furnish cost proposal to incorporate DM&S Research and Publications Committee recommendations into protocol.
July 6, 1988	Contract amended to provide for an additional $75,130 to NERI for revising the protocol based on DM&S Research and Publications Committee recommendations.
September 23, 1988	Contractor returns revised protocol to Director, OEE.
September 27, 1988	Director, OEE, transmits revised protocol to Executive Secretary, DM&S Research and Publications Committee, with request that review be expedited in order to get protocol to OTA review committee on or about mid-October 1988.
	Executive Secretary, DM&S Research and Publications Committee, provides for distribution of protocol to committee members for review and comment.
October 18, 1988	Director, OEE, advised that all reviews by DM&S Research and Publications Committee completed. One committee member suggests an

	additional peer review prior to sending protocol to OTA. Director, OEE, schedules meeting with that individual for October 20 to determine if that additional review is necessary.
October 19, 1988	Advised by Ms. Helen Gelband, OTA, that no formal communications were transmitted to Congress by OTA as required by P.L. 99-272 (i.e., report within 180 days of passage of legislation). Further advised that OTA review committee is prepared to review protocol during next meeting scheduled for November 7, 1988.
October 20, 1988	Dr. Kang met with dissenting member of DM&S Research and Publications Committee.
October 27, 1988	Contract extended to December 30, 1988 at no additional cost to allow for OTA review of protocol scheduled for November 7, 1988. The OTA requested Dr. Sonja McKinlay, Principal Investigator, NERI, to attend the meeting to answer questions concerning the protocol. Also allowed for time to further revise the protocol if needed.
October 31, 1988	Dr. John H. Gibbons, Director, OTA, was provided a copy of the revised protocol which incorporated OTA's recommendations of September 25, 1987 and DM&S Research and Publications Committee's recommendations of April 28, 1988.
November 7, 1988	OTA meeting conducted. Dr. Kang and Dr. McKinlay attended.
December 12, 1988	OTA's review comments for the revised protocol sent to Senator Cranston. Recommendations are substantive in nature. In general, OTA recommends a phased approach to the study. VA favors concurrent validation full study approach.

January 4, 1989	Dr. Lawrence Hobson and Dr. Han Kang met with Senate staff and OTA officials to discuss the differences of opinions concerning the study approach. No conclusions reached. Mr. Johnathan Steinburg of the SVAC staff requested that OTA and VA officials continue to meet to resolve problem.
January 9, 1989	Contract with NERI extended to March 31, 1989 at no additional cost.
March 24, 1989	Contract with NERI extended to May 31, 1989 at no additional cost to provide for any changes needed resulting from VA and OTA consultations.
March 30, 1989	Dr. Gronvall informed Dr. Gibbons of our difference of opinion with OTA's December 12, 1988 recommendations and suggested a VA meeting with OTA officials to discuss our plans.
April 19, 1989	FY 1991-1995 budget plan for Medical Research sent to Research and Development Service (15B) which includes an additional $12 million dollars in FY 1991 for conducting the study.
April 27, 1989	Dr. Hobson and Dr. Kang met with OTA staff. OTA said a letter would be sent to both Congressional Veterans' Affairs Committees within two weeks to inform them of OTA's position on the study. OTA said that OTA will not ask for another review of the current study protocol if Congress desires to proceed with the study.

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6-22-1989 DR. GRONVALL'S STATEMENT, PAGES 6, 7, SUBCOM ON OVERSIGHT AND INV., HCVA.