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Briefing Book
for
HVAC Subcommittee on Compensation, Pension and Insurance
Hearing on
H.R. 1961, Veterans Agent Orange Relief Act.

April 26 and 27, 1983
and
May 3, 1983

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NINETY-EIGHTH CONGRESS

G. V. (SONNY) MONTGOMERY
CHAIRMAN

U.S. House of Representatives

COMMITTEE ON VETERANS' AFFAIRS
335 CANNON HOUSE OFFICE BUILDING
Washington, D.C. 20515

April 5, 1983

Honorable Harry Walters
Administrator of Veterans' Affairs
Veterans' Administration
Washington, D. C. 20420

Dear Mr. Administrator:

The Subcommittee on Oversight and Investigations requests your testimony at a hearing to be held on Tuesday, May 3, 1983 at 8:30 a.m. in Room 334 of the Cannon House Office Building. The subject of the hearing is the status of Federally conducted Agent Orange studies. Additionally, it is requested that Doctor Donald L. Custis, Chief Medical Director, Dr. Barclay M. Shepard, Special Assistant to the Chief Medical Director for Environmental Medicine, and Major Alvin Young, Environmental Scientist, also be present at the hearing.

The Subcommittee requests status summaries on the following studies or reports: remedial actions taken on the recommendations made in GAO Report GAO/HRD-83-6 of October 25, 1982; EPA/VA retrospective study of dioxins and furans in adipose tissue of Vietnam veterans; Chloracne Task Force; twin study; mortality study; survey of patient treatment file for Vietnam veteran inpatient care, as well as an update of any private sector Agent Orange related studies with which the VA is affiliated or cognizant. SEE TAB #3

The Subcommittee would greatly appreciate confirmation of your appearance (or that of your designee) at the earliest possible date, as well as the names and titles of those accompanying you in addition to the individuals listed in the first paragraph. Any questions may be addressed to Barbara Daniel of the Committee staff at 225-3527. Please provide 85 copies of your prepared testimony to Mrs. Arlene Burnett in Room 335, Cannon House Office Building, by close of business on Friday, April 29, 1983.

Sincerely,

G. V. (SONNY) MONTGOMERY
Chairman

1-1

Honorable G. V. (Sonny) Montgomery
Chairman, Committee on Veterans'
Affairs
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This will acknowledge your recent invitation to appear before the Subcommittee on Oversight and Investigations at its May 3 hearing on the status of Federally conducted Agent Orange studies.

The Chief Medical Director, Dr. Donald L. Custis, will be the VA's witness. Dr. Custis will be accompanied by the Acting Director of the Agent Orange Projects Office, Dr. Barclay M. Shepard; and Environmental Sciences Specialist, Agent Orange Projects Office, Dr. Alvin Young.

Every effort will be made to furnish eighty-five copies of our prepared testimony by April 29, as requested. Should that prove impossible, the General Counsel's Office will promptly notify your staff.

Sincerely,

HARRY N. WALTERS
Administrator

MAY 3, 1983

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

GOOD MORNING. WE ARE PLEASED FOR THE OPPORTUNITY TO APPEAR BEFORE YOU TODAY TO DISCUSS THE STATUS OF FEDERALLY-CONDUCTED AGENT ORANGE STUDIES. WITH YOUR PERMISSION, MR. CHAIRMAN, I WILL BRIEFLY SUMMARIZE THE FULL TEXT OF MY STATEMENT WHICH HAS BEEN SUBMITTED FOR THE RECORD.

THE VETERANS ADMINISTRATION HAS UNDERTAKEN A NUMBER OF ACTIVITIES WHICH I THINK DEMONSTRATE OUR COMMITMENT AND RESOLVE TO ADDRESS THE CONCERNS RAISED BY OUR VIETNAM VETERANS. WHEN THE CONTROVERSY FIRST AROSE IN 1978, WE INITIATED A PROGRAM OF OFFERING A FREE EXAMINATION TO ANY VIETNAM VETERAN WHO IS CONCERNED ABOUT THE POSSIBLE HEALTH EFFECTS OF EXPOSURE TO AGENT ORANGE.

A VETERAN COMING TO THE VA UNDER THIS PROGRAM RECEIVES A THOROUGH PHYSICAL EXAMINATION WITH ALL APPROPRIATE LABORATORY TESTS. THE RESULTS OF THE EXAMINATION ARE DISCUSSED WITH THE VETERAN PERSONALLY AND BASIC INFORMATION CONCERNING THE HEALTH STATUS OF THE VETERAN IS ENTERED INTO THE COMPUTERIZED AGENT ORANGE REGISTRY. THE MAIN PURPOSE OF THE REGISTRY IS TO PROVIDE A SYSTEMATIC WAY TO IDENTIFY CONCERNED VIETNAM VETERANS AND TO ASSIST IN DETERMINING WHETHER THERE ARE ANY SIGNIFICANT HEALTH TRENDS AMONG THEM. TO DATE, OVER 106 THOUSAND VETERANS HAVE RECEIVED EXAMINATIONS UNDER THIS PROGRAM.

WITH THE ENACTMENT OF PUBLIC LAW 97-72, THE VETERANS ADMINISTRATION WAS AUTHORIZED TO PROVIDE COMPREHENSIVE HEALTH CARE TO VETERANS FOR CONDITIONS THAT MAY BE ASSOCIATED WITH EXPOSURE TO DIOXINS CONTAINED IN HERBICIDES IN VIETNAM OR TO IONIZING RADIATION FROM ATOMIC WEAPONS TESTING OR AS A RESULT OF SERVICE WITH OCCUPATION FORCES OF HIROSHIMA AND NAGASAKI. APPROXIMATELY 12 THOUSAND VETERANS WERE ADMITTED FOR CARE DURING THE PERIOD FEBRUARY 1982 TO FEBRUARY 1983 AND THERE WERE APPROXIMATELY 440 THOUSAND OUTPATIENT VISITS TO VA HEALTH CARE FACILITIES.

WHILE WE ARE ATTEMPTING TO MEET THE IMMEDIATE HEALTH CARE NEEDS OF VIETNAM VETERANS, WE CONTINUE TO EXPLORE EVERY APPROACH AVAILABLE THAT WILL ASSIST US IN PROVIDING UP-TO-DATE TECHNICAL INFORMATION FOR OUR HEALTH CARE STAFF. A SERIES OF SCIENTIFIC MONOGRAPHS WRITTEN BY RECOGNIZED EXPERTS IN THEIR RESPECTIVE FIELDS ARE BEING PREPARED ON THE TOPICS OF AGENT BLUE, BIRTH DEFECTS, GENETIC SCREENING AND COUNSELING, HUMAN EXPOSURE TO PHENOXY HERBICIDES, AND CHLORACNE. WHEN COMPLETED, THESE MONOGRAPHS WILL BE WIDELY DISTRIBUTED BOTH WITHIN AND OUTSIDE THE VETERANS ADMINISTRATION. ACCOMPANYING THIS EFFORT WILL BE AN UPDATE OF THE REVIEW OF THE LITERATURE ON HERBICIDES THAT WAS COMPLETED IN 1981.

THE VETERANS ADMINISTRATION HAS BEEN MANDATED TO PERFORM AN EPIDEMIOLOGICAL STUDY OF VETERANS WHO WERE EXPOSED IN VIETNAM TO DIOXINS CONTAINED IN HERBICIDES USED IN VIETNAM. TO ENSURE OBJECTIVITY AND CREDIBILITY, THE VETERANS ADMINISTRATION CONTRACTED WITH UCLA TO DEVELOP THE STUDY'S PROTOCOL AND ASKED NON-

VA EXPERTS TO REVIEW IT. WHEN CONCERNS WERE RAISED AND QUESTIONS STILL REMAINED ABOUT THE CREDIBILITY OF A VA-CONDUCTED STUDY, THE VETERANS ADMINISTRATION ASKED THE CENTERS FOR DISEASE CONTROL TO UNDERTAKE THE DESIGN AND CONDUCT OF THE STUDY. THE CDC WILL HAVE COMPLETE INDEPENDENCE IN THIS EFFORT, WHICH IS EXPECTED TO TAKE A NUMBER OF YEARS TO COMPLETE.

COMPLEMENTING THE EPIDEMIOLOGICAL STUDY, ARE A NUMBER OF OTHER VETERANS ADMINISTRATION INITIATED STUDIES THAT SHOULD YIELD RESULTS IN A SHORTER TIME FRAME. THESE ARE A MORTALITY STUDY THAT WILL COMPARE MORTALITY PATTERNS AND SPECIFIC CAUSES OF DEATH BETWEEN THOSE WHO SERVED IN VIETNAM AND THOSE WHO DID NOT; A TWIN STUDY THAT WILL EXAMINE PAIRS OF IDENTICAL TWINS (ONE OF WHOM SERVED IN VIETNAM AND THE OTHER OF WHOM DID NOT) TO DETERMINE WHETHER THE CURRENT PSYCHOLOGICAL AND PHYSICAL HEALTH OF VIETNAM VETERANS WAS ADVERSELY AFFECTED; A BIRTH DEFECTS STUDY WHICH IS BEING JOINTLY SPONSORED BY THE DEPARTMENT OF DEFENSE, THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND THE VETERANS ADMINISTRATION TO DETERMINE WHETHER VIETNAM VETERANS ARE AT HIGHER RISK OF FATHERING CHILDREN WITH BIRTH DEFECTS THAN NON-VIETNAM VETERANS. AND FINALLY, A RETROSPECTIVE STUDY OF DIOXINS IN ADIPOSE TISSUE, IN COOPERATION WITH THE ENVIRONMENTAL PROTECTION AGENCY, TO DETERMINE THE BACKGROUND LEVELS OF DIOXIN IN FATTY TISSUE AMONG MALES OF THE VIETNAM-ERA VETERAN AGE GROUP, AND, WHETHER SERVICE IN VIETNAM HAS HAD AN EFFECT ON THE DIOXIN LEVELS.

MR. CHAIRMAN, WE RECOGNIZE ALSO THE NEED TO FULLY INFORM OUR VA STAFF IN THE FIELD OF THESE INITIATIVES AND TO KEEP THEM ADVISED OF THE MANY RESEARCH EFFORTS NOW UNDERWAY. ALSO, WE MUST ASSURE THE VIETNAM VETERAN THAT WE ARE DOING ALL WE CAN TO ADDRESS THE VERY SINCERE CONCERNS THEY RAISE ABOUT EXPOSURE TO AGENT ORANGE. TOWARD THAT END, WE WILL BE VISITING A NUMBER OF VA FACILITIES THROUGHOUT THE COUNTRY AND OFFERING A PROGRAM OF EDUCATION AND INFORMATION TO VA STAFF, VIETNAM VETERANS AND OTHER CONCERNED CITIZENS. WE WILL ATTEMPT TO BE FULLY RESPONSIVE TO QUESTIONS RAISED AND TO ENSURE THAT PROBLEMS THAT MAY BE EXPERIENCED BY VETERANS IN THEIR RELATIONSHIP WITH THE VA ARE PROMPTLY INVESTIGATED AND CORRECTED WHEREVER POSSIBLE.

MR. CHAIRMAN, THIS CONCLUDES MY SUMMARY REMARKS. I AND MY COLLEAGUES WILL BE PLEASED TO ANSWER ANY QUESTIONS YOU OR OTHER MEMBERS OF THE COMMITTEE MAY HAVE.

GAO Report GAO/HRD-83-6
Remedial Actions by Veterans Administration

The Veterans Administration, in response to recommendations contained in the GAO Report, GAO/HRD-83-6 entitled "Improvements Needed in VA's Efforts to Assist Veterans Concerned About Agent Orange" has taken the following remedial actions on those recommendations in which this Agency concurs:

Recommendation: "Revise the exposure history form and use the standard VA physical examination and medical history forms to gather more thorough information during Agent Orange examinations."

Action: DM&S Circular 10-83-38 entitled" Possible Exposure of Veterans to Herbicides During the Vietnam War, RCS 11-49" was issued to all VA health care facilities on March 1, 1983. This directive provided a revision to DM&S Circular 10-81-54, dated March 19, 1981, which was the subject of the GAO recommendation. This circular provides for some modification to Agent Orange Registry procedures and enactment a revised examination code sheet. It also specifies the use of standard history forms SF 504 and SF 505.

Recommendation: "Require environmental physicians to review all examination records to ensure that examinations are thorough and documented."

Action: DM&S Circular 10-81-12, issued January 14, 1981, responds to the recommendation to advise veterans of the results of their examination. This circular required physicians to document, via progress notes in the medical record, the findings of the examination. This was further stressed in the Chief Medical Director's Letter IL 10-81-5 issued February 11, 1981.

Recommendation: "Direct VA medical facilities to ensure that examining physicians are familiar with available information on Agent Orange and that they provide this information to all veterans examined."

Action: Nationwide conference calls with environmental physicians are ongoing and are being held six times annually. In addition to directives which are prepared on VA policy as it develops, significant informational materials are being forwarded on a periodic basis to environmental physicians. Environmental physicians are routinely responding to all veteran inquiries for information which may be raised during the initial examination process or during follow-up examinations.

Recommendation: "Direct VA medical facilities to inform veterans seeking Agent Orange examinations of the examination's limitations."

Action: A Chief Medical Director's Letter, IL 10-82-37, entitled "VA Agent Orange Activities" was issued to VA field facilities on September 30, 1982. This letter advised environmental physicians of the need to make the limitations of the examination known to all registry participants. In addition, a nationwide conference call was made on August 13, 1982, stressing the importance of this procedure.

Recommendation: "Emphasize to VA medical facilities the importance of sending tissue samples taken from veterans who served in Vietnam to the Armed Forces Institute of Pathology.

Action: On September 30, 1982, a Chief Medical Director's Letter, IL 10-82-37, "VA Agent Orange Activities" was sent to all VA health care facilities. In addition to other topics, this letter emphasized the need for active support by those facilities in sending tissue specimens to the Armed Forces Institute of Pathology. This same message was related to all VA health care facilities during a nationwide conference call held on August 13, 1982.

Recommendation: "Develop a monograph on Agent Orange's potential for causing birth defects."

Action: A monograph on "Birth Defects/Genetic Screening" is tentatively scheduled to be published in June 1984. The scope and outline of the monograph is expected to be completed in May 1983 and the final selection of authors by June 1983.

Recommendation: "Direct all VA medical facilities to offer to send the Agent Orange pamphlet to all telephone callers interested in information about Agent Orange, and advise callers when and where they can see the Agent Orange film."

Action: This was accomplished through:

* Chief Medical Director's Letter, IL 10-82-37, entitled "VA Agent Orange Activities" released to VA health care facilities on September 30, 1982.

* Nationwide conference calls with all VA health care facilities held on August 13 and September 27, 1982.

Recommendation: "Use public service announcements to advise veterans of VA Agent Orange services."

Action: The Veterans Administration Office of Public and Consumer Affairs is now in the planning stage for the development of both audio and visual aids which will serve as public service announcements advising veterans of VA Agent Orange services.

Veterans Administration
Department of Medicine and Surgery
Washington, D.C. 20420

Circular 10-83-38

March 1, 1983

TO: Regional Directors; Directors, VA Medical Center Activities, Domiciliary, Outpatient Clinics, and Regional Offices with Outpatient Clinics (136)

SUBJ: Possible Exposure of Veterans to Herbicides During the Vietnam War, RCS 11-49

1. This represents a revision of Circular 10-81-54, dated March 19, 1981. The following circular is referenced: 10-82-37 dated March 15, 1982.

2. The issue of Agent Orange continues to be a genuine concern to a large number of veterans, the scientific community and the chemical industry, and as a result, continues to receive extensive media attention. The VA remains in the forefront of this issue and continues to play a leading role in supporting scientific and educational initiatives in an effort to provide all concerned veterans with the information and guidance they need, as well as any medical care for which they are eligible.

3. The Agent Orange Projects Office (10A7) has the responsibility to coordinate and monitor all DM&S activities relating to the Agent Orange issue including the registry. All policy and clinical questions relating to the potential effects of herbicides should be referred to this office (FTS: 389-5412). Questions relating to eligibility of veterans or treatment of active duty personnel should be referred to Medical Administration Service (136) VACO (FTS: 389-2598/2849).

4. The maintenance of the Agent Orange Registry remains an important function of the VA and is managed centrally by the Agent Orange Projects Office (10A7). The Agent Orange Registry remains our most effective means of identifying concerned Vietnam veterans. The importance of the role of each VA employee, beginning with the initial contact, in providing physical examinations and necessary treatment and advising the veteran of the results of the examination cannot be over-stressed. Any eligible Vietnam veteran expressing a concern relating to exposure to herbicides is encouraged to participate in the registry which includes a thorough medical examination. In addition, any eligible Vietnam veteran currently receiving treatment in VA medical centers and outpatient clinics will be identified and provided with the opportunity to participate in the Agent Orange Registry. Follow-up of the veterans entered into the registry will be conducted over a period of years in an effort to obtain further information regarding any long-term health effects resulting from these chemicals.

THIS CIRCULAR EXPIRES ON FEBRUARY 29, 1984

5. VA Environmental Physicians play a most significant role in determining the perceptions Vietnam veterans have concerning the quality of VA health care services and of their individual treatment by VA health care providers. The Environmental Physician will review the records of every Vietnam veteran examined to assure that a complete physical examination was performed and documented. It is important that each veteran be fully advised of the limitations of an Agent Orange related examination, that is, what the examination can or cannot reveal as regards the presence of dioxin in the body system and/or the relationship to adverse health effects or potential health defects or illnesses which may or may not be related to a veterans exposure to Agent Orange. I wish to strongly encourage your consideration of the best way to accomplish this communication process. The following alternatives might be considered.

(1) Provide each Vietnam veteran reporting to the Outpatient Admissions area with a handout describing the purpose of the examination and its limitations. This can be further clarified by the examining physician during the course of the physical examination, preferably prior to beginning the physical examination process.

(2) Provide each veteran with the opportunity to view the audiovisual "Agent Orange: A Search for Answers." Veterans and/or visitors to VA health care facilities should be informed concerning the film and when and where it can be viewed.

(3) Make all Agent Orange pamphlets and other informational materials available to Vietnam veterans and the public - keeping them displayed in prominent areas and ensuring that sufficient copies are available for distribution. It should be standard operating procedure to provide copies of VA Agent Orange pamphlets to all telephone callers requesting Agent Orange information.

6. It is essential that a complete medical history and physical examination be performed and documented. The medical history should be documented on SF 50 4 and SF 505 and the physical examination should be documented on SF 506 or VAF 10-7978e. The Agent Orange Registry code sheet (VAF 10-9009) does not replace any medical record. In eliciting the medical history and performing the physical examination (which should be conducted by/or under the direct supervision of the Environmental Physician), special attention will be given to those organ systems alleged to be most frequently

affected by exposure to herbicides containing TCDD. These include the liver, kidneys, skin and the reproductive, endocrine, immunologic and nervous systems. Particular attention will be paid to the detection of chloracne, a skin condition which has been associated with acute exposure to TCDD and other dioxins. Evidence will also be sought concerning the following potentially relevant symptoms or conditions: altered sex drive; sterility; congenital deformities among children; repeated infections; neoplasia; and for female veterans, difficulties in carrying pregnancies to term. In gathering these data, it is important to determine and record the time of onset of the symptoms or conditions; their intensity; the degree of physical incapacitation; and the details of any treatment received. The person actually performing the physical exam should be identified with the signature and title (M.D., P.A., etc.). If the examiner is other than a physician, a physician's countersignature is required, preferably the Environmental Physician. When an Agent Orange examination is done as part of a compensation and pension examination, the physical examination will be done by/or under the direct supervision of the Environmental Physician.

7. All veterans participating in the Agent Orange Registry will be given the following baseline laboratory studies: complete blood count, urinalysis, SMA-6, SMA-12, and a chest x-ray if one has not been done within the past 6 months. Appropriate additional diagnostic studies should be performed and consultations obtained as indicated by the patient's symptoms and physical and laboratory findings. Non-routine diagnostic studies, such as sperm counts, should be performed only if medically indicated.

8. The Environmental Physician will personally discuss with each veteran examined the results of the examination and the laboratory studies which are available at the time the physical examination is completed. This personal interview will be conducted in such a way as to encourage the veteran to discuss his/her own health concerns as well as those of his /her family as they relate to exposure to herbicides. In the absence of the Environmental Physician, the interview will be provided by a designated physician familiar with the Agent Orange program. The interviewing physician will document this action in a progress note in the veteran's medical record. In addition to the personal interview, a follow-up letter will be sent to each veteran explaining the results of the examination and laboratory studies. A copy of this letter will be filed in the veteran's administrative medical record. Recommended sample letters are provided in attachments A and B.

9. Particular attention is directed to the Special Registry at the Armed Forces Institute of Pathology (see DM&S Circular, dated 10-82-37 March 15, 1982). All pathological material (autopsy, surgical, cytologic, or other similar tissue) obtained from any Vietnam veteran will be processed in accordance with DM&S Circular 10-82-37 for inclusion in this special registry.

10. It has been determined that the analytical technology for measuring minute levels (parts per trillion) of TCDD in human fat does exist. The results of this study, however, are inconclusive as regards exposure to herbicides in Vietnam. Therefore, no VA medical center will perform any surgical or other procedure for the purpose of obtaining tissue for measuring TCDD in patients without prior approval by VACO (10A7).

11. When a Vietnam veteran requests an Agent Orange examination at a VA medical center, the center's Medical Administration Service will be notified and will initiate the procedures listed below:

a. Prepare a 3x5 card with the following typewritten information:

(1) Veteran's full name
(2) Veteran's address and telephone number
(3) Date of birth
(4) Social Security Number
(5) Date of initial examination
(6) Dates of follow-up examinations

b. The card will be filed alphabetically in a special file, labeled "Agent Orange Registry." This registry card will be maintained until further notice. Every effort should be made to maintain the veteran's current address and telephone number.

c. VA Form 10-10M contains a statement regarding "Possible Exposure." This item should be completed for all veterans applying for the Agent Orange examination.

12. The original records of all examinations performed on Vietnam veterans for possible herbicide toxicity are to be retained in the veteran's Consolidated Health Record (CHR). If a CHR does not already exist for a veteran examined for herbicide toxicity, one will be established, and the results of the examination for herbicide toxicity is to be enclosed in the CHR. A locator card will be created with the establishment of CHR.

13. The following procedures pertain to active duty personnel according to the site of the Agent Orange examination:

a. When active duty members of the uniformed services apply to VA facilities for an Agent Orange examination, the requirements of M-1, Part 1, Chapter 15 regarding the authorization from the

appropriate branch of service and the billing of the appropriate branch of service will apply. The procedures of establishing a 3x5 card, of processing and completing the code sheet for active duty personnel will be the same as those followed for a veteran participating in the Agent Orange registry.

b. However, a military facility may perform the Agent Orange examination according to VA instructions. Military facilities have been informed to obtain a copy of the pertinent VA directive and samples of appropriate forms from the nearest VA facility. The completed physical examination, laboratory tests, and questionnaire will be forwarded to the nearest VA medical center or outpatient clinic. For these individuals the Medical Administration Service personnel at the medical center will:

(1) Prepare a colored 3x5 card with similar data as prepared for a veteran clearly label card as "Active Duty." Insert card in Agent Orange Registry file.
(2) Abstract the data from the medical record documents to the code sheet.
(3) Submit original code sheet to the VA Data Processing Center, Austin, TX as indicated in paragraph 18.
(4) Forward copies of the medical record documents with a copy of the code sheet to VA Central Office (10A7A).
(5) Place the original medical record documents in a plain folder properly identified with the name and social security number and a notation "Active Duty - Agent Orange Exam at _____ military facility." These folders should be maintained in a special location in the file room.
(6) While the medical documents are not placed in the CHR (Type I or II folders), these special folders are subject to the same retention and disposition policies of the CHR.
(7) If an active-duty military person becomes discharged and reports for treatment as a veteran, the Agent Orange examination will be filed in the CHR.

14. There is a high priority concern for prompt handling and scheduling Agent Orange examinations. Facilities should make every effort not to have 50 or more Agent Orange examinations pending at the end of the month. Facilities having 50 or more examinations pending will be contacted by Agent Orange Projects Office Staff to ascertain the plan of action to be implemented in reducing the backlog and to determine how many examinations are pending beyond 30 days.

15. A monthly submission of medical record documents and code sheets will be sent to VACO, Agent Orange Projects Office (10A7A, Rm B-67) according to the mailing schedule listed in paragraph 17. The monthly submission will contain the following:

a. One legible copy of all the medical record documents relating to the Agent Orange examination. These documents should be placed in alphabetical order with the code sheets stapled on top of the medical record documentation for submission to 10A7A. Pertinent laboratory data and consultations obtained as part of these examinations will be held pending arrival of these data. Only copies of completed examinations should be submitted.

b. Follow-up examinations will be reported in the same manner.

c. The Agent Orange Registry Code Sheet (VAF 10-9009) will be prepared in three copies. One copy will be filed in the veteran's CHR with the documentation from the Agent Orange examination. One copy will be stapled to the corresponding medical record documents that are sent to VACO (10A7A). The original code sheet will be sent to the Austin Data Processing Center in (DPC). See paragraph 18 for instructions for mailing the code sheets to the DPC.

16. Instructions for completing the code sheets (VAF 10-9009) are listed in Attachment C. Effective with the issuance of this circular, the new code sheets (VAF 10-9009) must now be used. The Agent Orange Registry code sheet has been revised. DO NOT USE the VAF 10-9009 with November 1980 and September 1981 dates, they will no longer be accepted. The VAF 10-9009 with the 1982 date will be used. Old stocks of 1980 and 1981 VAF 10-9009 may be destroyed. The VAF 10-20681 (NR) Initial Data Base will no longer be used.

17. The following mailing schedule should be used for mailing the monthly submission to VACO (10A7A) and the Austin DPC.

Region Number	Mailing Date
1	6th of Month
2	10th of Month
3	14th of Month
4	18th of Month
5	22nd of Month
6	26th of Month

18. The following instructions should be followed for the mailing of the original code sheet (VAF 10-9009) to the DPC. These code sheets will be mailed monthly. Code sheets must be received at the DPC according to the mailing schedule listed in paragraph 17.

a. Batching of input documents:

(1) Code sheets should be scanned to ensure all required fields have been completed.

(2) Completed code sheets will be batched in groups of no more than 25 code sheets. Each batch will include code sheets for only one facility as indicated by identical entries in all six positions of the code sheet field one. Different facilities must be batched separately (i.e. VAMC one batch, OPC one batch). Batches of less than 25 code sheets are acceptable.

(3) Attach a transmittal form to each batch of documents. Record the six position facility number and the number of documents on the transmittal.

(4) Using the batch control log (see 18c below) assign the next sequential batch number and record it on the transmittal form. NOTE: Begin batching with batch number 001 in January of each year and continue with sequential numbers throughout the year.

(5) Code sheets should be stapled together in the upper left-hand corner. No medical record documentation should be attached to these code sheets.

(6) Corrected code sheets do not have to be batched separately or handled separately. They can be mailed with the regular code sheets as long as they are for the same facility number.

b. Transmittal form:

(1) Two copies of VA Form 30-7252, "Transmittal Form for the Use in Shipment of Tabulating Data," will accompany each batch of code sheets. One copy will be retained at

the Austin DPC and the other copy will be returned to the transmitting facility with the code sheets and edit analysis lists prepared at the DPC.

(2) The transmittal form will be completed as follows:

Item 2: Name and address of transmitting facility
Item 3: Facility number of transmitting facility and correspondence symbol
Item 6: Date of dispatch
Item 7: Name and telephone number (FTS) of responsible individual at facility
Item 8: Facility Number: The three (3) to six (6) position PTF facility number used on the code sheets of this batch (code sheet field #1)
Batch number: The batch number assigned by the transmitting facility (see below —control log).
Code Sheet Count: The number of code sheets in this batch (25 or less).

(3) The following is an example of the completed transmittal form.

TRANSMITTAL FORM FOR USE IN SHIPMENT OF TABULATING DATA

1. ADDRESSEE
VA Data Processing Center (200/392A)
1615 East Woodward Street
Austin, TX. 78772
ATTN: Agent Orange Clerk

2. STATION NAME AND ADDRESS
VA Medical Center
50 Irving Street, N.W.
Washington, D.C. 20422

3. REPLY REFERENCE (Sta. no./symbol): 688/136B

4. EFFECTIVE DATE OF DATA:

5. NO. OF PACKAGES:

6. DISPATCH DATE:

6A. FINAL BATCH (Check):

7. OFFICIAL RESPONSIBLE FOR SHIPMENT (Name, title and signature): Jane Smith 389-5412

8. TABULATING DATA

REPORTS CONTROL SYMBOL (A)	JOB NUMBER (B)		DESCRIPTION (C)	NO. OF COPIES OF REPORTS (D)	CARD COUNT (E)
	10	20A1	AGENT ORANGE		
			Facility number 688		
			Batch number ØØ2		
			Code sheet count Ø25		

9. REMARKS

VA FORM MAR 1972 30-7252 EXISTING STOCK OF VA FORM 30-7252, MAR 1966, WILL BE USED.

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(4) The encircled area on the copy of the transmittal sheet (the address of the DPC, address of the transmitting facility, station number, and mail symbol, job number, "Agent Orange," facility number, batch number, and code sheet count) should be overprinted on the VA Form 30-7252 at each facility. The facility number entered has to be the PTF or OPC number that is coded on the code sheet.

c. Control log:

As batches are prepared for submission to the DPC an entry should be made on the control log. Instructions for the use of the control log and an example of the control log follows:

FACILITY (1) AGENT ORANGE CONTROL LOG

(2) Batch Number	(3) # Code Sheets	(4) Date Sent	(5) Date Returned			
002	25	10-6-81	10-26-81			

(1) An Agent Orange address control log should be maintained for each facility (Facility Code Number).

(2) The batch number will be assigned sequentially by facility. The batch number will be recorded on the log and on the transmittal sheet (Item 8).

(3) The number of code sheets in the batch will be recorded on the log and on the transmittal sheet (Item 8).

(4) Date the batch was mailed to the DPC.

(5) Date the batch and associated edit output was returned from the DPC.

d. Mailing:

(1) The facilities will establish their own control over the mailing of code sheets to the DPC. In order to ensure that the computer files are current, each facility should submit input at least once each month.

(2) The mailing address for the DPC is:

VA DATA PROCESSING CENTER (200/392A)
1615 East Woodward Street
Austin, TX 78772
ATTN: AGENT ORANGE CLERK

(3) Contact the Agent Orange Clerk at the DPC regarding questions about submitting code sheets, batch control, etc., The telephone number is FTS 770-7281. It is not appropriate to call the DPC in regard to questions on code sheet completion or correction of rejections. These questions should be referred to Nancy Howard, VACO, FTS 389-5412.

e. Processing:

(1) The DPC will keypunch the data from the code sheets and the records twice each month (10th and 25th). Subsequent to editing, the DPC will return all batches and the edit lists to the transmitting facility.

(2) While all code sheets will be returned to the transmitting facility, computer listings will reflect only rejected records. For correction of the rejected records, refer to the coding instructions in Attachment C. There will be no published edit list of how to correct errors; carefully following the instructions and double checking the information coded is absolutely essential! Corrections are to be made on the returned code sheet with RED pen or RED felt-tipped pen or a new code sheet can be made with the corrections in the appropriate field(s). If a new code sheet is prepared for the return of a correction, do not just complete the corrected field(s)--all of the fields must be completed as if it were an initial input. DO NOT leave any blank fields.

(3) All returned code sheets should be disposed of only after all information input is verified as correct. Refer to the RCS 10-1 schedule under Medical Administration Service section for the disposition schedule.

(4) There has been a programming change in the editing process for the Agent Orange Registry. Several new error messages are appearing. Examples of the new messages and the corrective action needed are listed below:

(a) ****** - means an error is in a field.
ACTION - correct error and resubmit.

(b) Duplicate Initial Exam - means there already appears on the file an initial Agent Orange examination for this veteran. It may be for the same reporting facility or a different VA facility.
ACTION - No action is necessary.

(c) Warning - No Initial Exam - means the file does not contain an Initial Exam record for this veteran, but the registry has accepted the follow-up record that was previously submitted.
ACTION - Reconstruct the initial exam record and submit to the DPC. DO NOT resubmit the follow-up exam.

19. A monthly statistical report will be sent to VACO, Agent Orange Projects Office, Attn: Nancy L. Howard, RRA (10A7A, Rm, 848). Do not enclose this letter with the medical record documentation and code sheets sent to 10A7, Rm. B-67. This statistical report will be prepared on a monthly basis and should arrive in VACO (10A7) by the tenth workday following the end of the month. Negative reports are required. Please assure that accurate statistics are reported. For Satellite OPC's performing Agent Orange examinations do not submit the statistical report separately. The totals should be combined with the parent facility totals. Do not use the mailing schedule described in paragraph 17 for submission of this statistical report. This transmittal letter should contain:

a. The number of initial examinations performed during the month;

b. The cumulative total of initial examinations performed;

c. The number of follow-up examinations performed during the month;

d. The cumulative total of follow-up examinations performed;

e. The number of initial examinations pending beyond the end of the month;

f. The number of veterans failing to keep an initial examination appointment.

See definitions in Attachment D for an explanation of the monthly report terminology. A copy of the format for the statistical report is illustrated in Attachment E.

It should be noted that the pending examination total (e) and the number of veterans failing to keep an initial examination appointment (f) are not cumulative totals. These apply to the report month only.

20. Special care should be addressed to the completion of the examination code sheets. A black ball-point pen or a black felt-tipped pen should be used. No pencils or blue ink pens should be used as these markings do not reproduce clearly. Carefully follow the instructions for completing the code sheets to assure that all data fields are completed. It is recommended that the Chief, Medical Information Section, be given the responsibility for the coding, completing, mailing of the code sheets to the DPC and the correcting of the code sheets to assure all areas are completed accurately.

21. This circular rescinds DM&S circulars:

10-80-203, dated September 12, 1980;
10-81-12, dated January 15, 1981;
10-81-54, dated March 19, 1981;
10-81-82, dated April 28, 1981;
10-81-115, dated June 4, 1981;
10-81-263, dated December 1, 1981;
10-82-5, dated January 18, 1982; and
10-82-110, dated June 28, 1982.

W. J. JACOBY, JR., M.D.
Deputy Chief Medical Director

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ATTACHMENT A

Circular 10-83-38
March 1, 198^

(FACILITY LETTERHEAD)

Positive Findings -- Recommended Format

Dear Veteran:

We sincerely appreciate your recent participation in the Veterans Administration's Agent Orange Registry. This effort should prove to be very helpful in assisting us to better serve veterans, such as yourself, who are concerned about the possible adverse health effects of exposure to Agent Orange.

A review of the results of your examination indicates that _____
(Use this space to briefly describe any positive findings.)_____
_____

In view of the above findings, we suggest that you contact the Outpatient Admissions Office at extension _____ to schedule a follow-up examination. This will provide us with an opportunity to personally discuss these findings with you and to suggest or provide any essential medical treatment.

Again, your participation in the registry is appreciated.

Sincerely,

(NAME)
Environmental Physician

3-16

ATTACHMENT B

Circular 10-83-38
March 1, 1983

(FACILITY LETTERHEAD)

Negative Findings -- Recommended Format

Dear Veteran:

We sincerely appreciate your recent participation in the Veterans Administration's Agent Orange Registry. This effort should prove to be very helpful in assisting us to better serve you and your fellow veterans who are concerned about the possible adverse health effects of exposure to Agent Orange.

The results of your examination and laboratory tests suggest that you are presently in good health and that you have no reason at this time to be concerned about possible adverse health effects resulting from exposure to Agent Orange. However, if in the future you have a medical condition about which you are concerned, I would encourage you to seek the help and advice of your nearest Veterans Administration Medical Center.

The results of your examination will be maintained by the Veterans Administration and will be available for future use as needed.

Again, your participation in the registry is appreciated.

Sincerely,

(NAME)
Environmental Physician

Attachment C

INSTRUCTIONS FOR ITEMS 1-20 for the Agent Orange Registry Codesheet. (VAF 10-9009).

Item 1 - Facility Number - Suffix - Enter PTF facility code. Use the AMIS Suffix (BY, BZ etc) to indicate your satellite facility. DO NOT USE Q,R,S,

Item 2 - Veteran's Name

Beginning in block 8, enter veteran's last name (please print) using one letter per block. Apostrophes and hyphens in the name should not be used and empty blocks must not be left between the letters of the last name. Do not skip a space or use a comma if the last name is followed with JR, SR, I, II or III, etc.

Beginning in block 34, print the first name, one letter per block. If there is a middle name, enter the middle name beginning in block 49 - otherwise leave this block blank.

Item 5 - Type of Exam - Enter A = initial; C = follow-up. To delete an entire initial examination with a noted error after it has been accepted into the registry, resubmit the original code sheet with a "B" coded in block 59 and submit a code sheet with the correct information with an "A coded in block 59. All fields must be completed on a resubmission. The code sheets can be shipped in the same batch. An example for this usage will be for incorrect spelling of the name, incorrect social security number, changing of address etc.

To delete an entire follow-up examination with a noted error after it has been accepted into the registry, resubmit the original code sheet with a "D" coded in block 59 and submit a code sheet with the correct information with a "C" coded in block 59.

Item 6 - Social Security Number

Block 60 should be left blank. Enter the SSN in blocks 61 through 69. If the veteran does not have a social security number, place the letter "P" in block 60 and assign a pseudo SSN. (See PTF instructions for pseudo SSN). Numerical zeros must be slashed (Ø).

Item 7 - Service Serial Number

Enter the Service Serial Number beginning in block 70, unused blocks remain blank. Numerical zeros must be slashed (Ø).

If the serial number begins with US, blocks 72-79 must contain a number(s).

Fill unused block(s) with zero(s) for this instance only.

If the serial number is unknown, enter a U in block 70. Unused blocks remain blank.

3-18

Example:

70	71	72	73	74	75	76	77	78	79
7	Ø	8	Ø	Ø	Ø				

Service Serial Number
708000

70	71	72	73	74	75	76	77	78	79
U	S	6	6	7	Ø	Ø	Ø	Ø	Ø

Service Serial Number:
US 66700000

70	71	72	73	74	75	76	77	78	79
U									

Veteran does not know serial number

Item 8 - Date of Birth

Enter the numerical equivalent for the month (blocks 80-81) and day (blocks 82-83). Enter the last two digits of the year of birth in blocks 84 and 85. Numerical zeros must be slashed (Ø).

Example:

MO.		DAY		YR.	
80	81	82	83	84	85
Ø	5	Ø	9	4	7

May 9, 1947

Item 9 - Current Address

Print the veteran's current address in the spaces provided. Use of one block per letter or number. Leave one blank space between street number and name. Print street address in blocks 86-111. Print city or town in blocks 112-137. Print zip code in blocks 138-142. Blocks 143-146 will be blank. Using the PTF codes, assign the proper country and state codes in block 147-151.

Item 10 - Race/ Ethnicity

Enter the appropriate code in block 152.

Item 11-13 - Sex, Martial Status & Current Status of Veteran

Enter appropriate codes.

Item 14 - Branch of Service

Enter appropriate codes in block 156.

If veteran was in more than one branch of service (item 14), code the latest Vietnam service.

Item 15 - Enter the appropriate code for Vietnam service in block 157. If the veteran did not serve in Vietnam, blocks 158-173 should be left blank.

Item 15A - Code the numerical equivalent of the month and code the last two digits of the year of last period of service in Vietnam. Numerical zeros must be slashed (Ø).

Item 15B - If veteran had two or more periods of service in Vietnam, the next to last period of service should be coded in the blocks provided. If only one period of service in Vietnam code this in 17(a) and leave 17(b) blank. Numerical zeros must be slashed (Ø).

Item 16 - Corps or Area Served

Enter the appropriate code (in block 174) for the corps or area in which veteran served. If he served in more than one, use code 6.

Item 17 - Military Unit

Enter the military unit in which the veteran served. Please specify complete unabbreviated title. (Company, battalion, corps, ship, division).

Item 18 - Last Two Periods of Service

Code the month and year of the last two periods of service in 18(a) and (b) regardless of whether or not they were in Vietnam. If veteran did not have more than one period of service, leave (b) blank.

Item 19(a) - (e) Exposure to Agent Orange

Place the most appropriate code that describes veterans exposure to Agent Orange in the block provided. Do not leave any block blank.

Item 20 - Veteran's Health

Enter the code that most appropriately describes veterans health.

INSTRUCTIONS FOR ITEMS 21-34 (THE ITEMS TO BE COMPLETED BY THE EXAMINING PHYSICIAN OR THE DESIGNATED PHYSICIAN)

Item 21 - Date of Exam

Enter the numerical equivalent of the month, day, and year in the appropriate blocks.

Item 22 - Veteran's Complaint(s)

Print the veteran's complaint(s) in the blanks provided. MAS personnel will fill in the blocks for 22(a), (b) and (c), utilizing the ICD-9-CM coding systems. Use the symptoms and signs categories (780-789) for this coding. The "78" has been preprinted for you. For uncodable symptoms, use 78999. For no known complaints use 78ØØØ.

Item 23 - Chief Complaint

Enter appropriate code (1 or 2) in the block.

Item 24 - Number of Complaints

Enter the number of complaints the veteran has in the block provided. If the veteran has 5 or more complaints, enter 5 in the block.

Item 25 - Evidence of Birth Defects in Veteran's Children?

Enter the appropriate code for item 25.

Item 26 - Diagnostic Work-up and/or Consultation

If no work-up and no consultation has been done, enter code 1 in the blocks provided. If a work-up and/or consultation has been done, enter the appropriate code (2,3,4) in the blocks provided. All blocks must have one entry.

Item 27 - Additional Workups/Consultations

Specify any additional workups/consultations performed but not listed in item 26.

Item 28 - Diagnosis

Print the veteran's major medical diagnosis(es) in the spaces provided (a,b,c). For each diagnosis listed, MAS will utilize the ICD-9-CM coding system.

Any diagnosis relating to a neoplasm should be documented in item 29.

Item 29 - Evidence of Neoplasia

Block 240 of ths section must be completed with the appropriate response. If the veteran has a neoplasm or has a known history of a neoplasm, document the appropriate diagnosis and the specific ICD-9-CM diagnostic code must be listed in blocks 241 to 245. If no neoplasm is recorded, leave blank.

Item 30 - No Disease Found

If no disease is found, put a 1 in block 246. Otherwise, leave this block blank.

Item 31 - Years of Onset

For each listed diagnosis in item 28, code the last two digits of the year of onset; leave blank if year of onset is unknown.

Item 32 - Disposition

Place a code (1 or 2) in each block provided. Do not leave any of the blocks blank.

For section d in item 32, if the veteran was referred for VA outpatient care, indicate the two digit code for the clinic in the designated blocks (257-266). Refer to the Outpatient Routing List (VAF 10-2875-1) for the clinic codes to be utilized to code this section.

Item 33 - Remarks

Utilize this space for additional information.

Item 34-36 - Name and Title of Examiner

The name and title of the examiner should be printed in the space provided. The examiner should also sign his/her name.

Information to be abstracted for a follow-up examination:

Items 1 through 13 - must be completed
Items 14 through 20 - no entry
Item 21 - must be completed
Items 22 through 33 - may be blank unless you have follow-up data to report in in any of these items.
Items 34 through 36 - must be completed

PLEASE NOTE: The first time a follow-up visit is recorded on the revised code sheet for a veteran who previously received an initial exam recorded on the old code sheet, every attempt should be made to obtain and record the information to complete Items 14-20.

DEFINITIONS FOR THE MONTHLY REPORT TERMINOLOGY

1. Initial Examination: First time Agent Orange examination given for the purpose of entering a Vietnam veteran into the Agent Orange Registry. The total of initial examinations given during the period of the current report (i.e., 30 initial exams given during January).

2. Cumulative Initial Examination: Includes the total number of "first-time" examinations performed by the medical facility since the beginning of the registry in 1978. Examinations performed by satellite outpatient clinics should be included in the total cumulative figure for the VA medical center of jurisdiction. Independent outpatient clinics should report in a manner similar to the VA medical centers.

3. Follow-up Examination: Any Agent Orange-related examination/visit subsequent to the initial examination.

4. Cumulative Follow-up Examination: Includes the total number of follow-up examinations performed by the medical facility since the beginning of the registry in 1978.

5. Pending Examinations: Initial Agent Orange examinations for which appointments have been scheduled beyond the end of the month.

6. Number of veterans failing to keep an initial examination appointment: number of veterans who failed to keep a scheduled appointment during the month.

EXAMPLE
(FACILITY LETTERHEAD)

Agent Orange Projects Office (10A7)
ATTN: Nancy L. Howard, RRA
VA Central Office, Rm. 848
810 Vermont Avenue, N.W.
Washington, D.C. 20420

SUBJECT: Monthly Report on Possible Exposure of Veterans to Herbicides During the Vietnam War, RCS 11-49

1. The following information is submitted for the month ending _____ _____; facility number_____.

a. Total number of initial examinations performed _____

b. Cumulative total of initial examinations performed _____

c. Total number of follow-up examinations performed _____

d. Cumulative total of follow-up examinations performed_____

e. Number of pending initial examinations at the end of the month _____

f. Number of veterans failing to keep an initial examination appointment _____

2. Comments/problems regarding pending exams:

3. The name and FTS number of the person preparing the report:

_____

(Name)
MEDICAL CENTER DIRECTOR

636481

Veterans Administration

IL-10-81-5

February 11, 1981

CHIEF MEDICAL DIRECTOR'S LETTER

TO: . Directors, VA Medical Centers, Medical and Regional Office Centers, Domiciliary, Outpatient Clinics and Regional Offices with Outpatient Clinics

SUBJ: Follow-Up Activities Related to Agent Orange

1. Last October, at the request of the Administrator, I asked the Office of Environmental Medicine to initiate a sample survey of veterans' satisfaction with the Agent Orange examination process. By the end of November we had received answers from approximately 55% of the 643 veterans to whom the questionnaire was distributed. For the most part these were randomly selected veterans who had been examined in seven VAMC's.

2. An analysis of the survey suggests that in the majority of cases a VA physician did not discuss the results of the physical examination with the veteran, and that in about 80% of cases the veteran did not receive the results of his/her laboratory tests. Even if this is not a totally representative sample, the survey does suggest that we need to make some improvements in our Agent Orange examination procedures.

3. DM&S Circular 10-81-12 which was distributed by teletype on January 15, 1981, provided guidance which when implemented should accomplish some of these needed improvements. I am attaching two recommended sample letters referred to in paragraph 1.B. of the circular. These letters are meant to serve only as a guide. It is likely that in some cases a modification of the sample letter should be made. It is urged that the appropriate follow-up letter be sent to all veterans who have been examined since January 1, 1981. It is recommended that the letter be signed by the environmental physician as the staff member charged with the responsibility of coordinating the Agent Orange Program in your facility.

4. Questions concerning follow-up procedures should be directed to Dr. Barclay M. Shepard, Special Assistant for Environmental Medicine, or to staff members Layne Drash or Nancy Zanis (FTS 389-5412/13).

DONALD L. CUSTIS, M.D.
Chief Medical Director

Attachments

In Reply Refer To:

Distribution: COB: (10) only plus (102) 30
SS (101B1) FSB: MA, DO, OC, OCRO
EX: Boxes 60 and 44-1 ea.

3-25

ATTACHMENT A

IL 10-81-5
February 11, 1981

(STATION LETTERHEAD)

Positive Findings -- Recommended Format

Dear Veteran:

We sincerely appreciate your recent participation in the Veterans Administration's Agent Orange Registry. This effort should prove to be very helpful in assisting us to better serve veterans, such as yourself, who are concerned about the possible adverse health effects of exposure to Agent Orange.

A review of the results of your examination indicates that _____
(Use this space to briefly describe any positive findings.)
_____

In view of the above findings, we suggest that you contact the Outpatient Admissions Office at extension _____ to schedule a follow-up examination. This will provide us with an opportunity to personally discuss these findings with you and to suggest or provide any essential medical treatment.

Again, your participation in the registry is appreciated.

Sincerely,

(NAME)
Chief of Staff

3-26

(STATION LETTERHEAD)

Negative Findings -- Recommended Format

Dear Veteran:

We sincerely appreciate your recent participation in the Veterans Administration's Agent Orange Registry. This effort should prove to be very helpful in assisting us to better serve you and your fellow veterans who are concerned about the possible adverse health effects of exposure to Agent Orange.

The results of your examination and laboratory tests suggest that you are presently in good health and that you have no reason at this time to be concerned about possible adverse health effects resulting from exposure to Agent Orange. However, if in the future you have a medical condition about which you are concerned, I would encourage you to seek the help and advice of your nearest Veterans Administration Medical Center.

The results of your examination will be maintained by the Veterans Administration and will be available for future use as needed.

Again, your participation in the registry is appreciated.

Sincerely,

(NAME)
Chief of Staff

Department of Medicine and Surgery
Washington D.C. 20420

Veterans Administration

IL-10-82-37

September 30, 1982

In Reply Refer To: 102

CHIEF MEDICAL DIRECTOR'S LETTER

TO: Directors, All DM&S Field Activities

SUBJ: VA Agent Orange Activities

1. General: The issues raised by the defoliant Agent Orange continue as a major concern to some Vietnam veterans, the general public and the media. Until some answers surface as a result of intensive Agent Orange related research being undertaken by the Veterans Administration (VA), other Federal agencies and public or private institutions, it can be anticipated that we will need to intensify our efforts to address the specific concerns of these individuals in a compassionate and forthright manner. This letter will serve to advise you of positive actions which can be undertaken at your facilities, actions which will contribute to the effectiveness of our delivery of health care services and assist in improving the perceptions Vietnam veterans may have concerning the VA's traditional role as the veterans' advocate.

2. Agent Orange Registry:

a. The Agent Orange Registry remains our most effective means of identifying concerned Vietnam veterans. The importance of the role of each VA employee, beginning with the initial contact, in providing physical examinations and necessary treatment and finally, advising each veteran of the results of the examination cannot be over-stressed. In this regard, VA environmental physicians play a most significant role in determining the perceptions Vietnam veterans have concerning the quality of VA health care services and of their individual treatment by VA health care providers. DM&S Circular 10-81-12 issued January 15, 1981, directed environmental physicians to advise veterans of the results of their examinations. This was further stressed in a Chief Medical Director's Information Letter, IL-10-81-5 dated February 11, 1981. Implicit in the circular and information letter is the importance of a careful review of each examination record prior to advising the veteran of the

3-25

results of the examination and laboratory studies. This review is also essential to ensure that the details and results of each examination are adequately documented in the veteran's medical record.

b. It is important that each veteran be fully advised of the limitations of an Agent Orange related examination, that is, what the examination can or cannot reveal as regards the presence of dioxin in the body system and/or the relationship to adverse health effects or potential health defects or illnesses which may or may not be related to a veterans exposure to Agent Orange. I wish to strongly encourage your consideration of the best way to accomplish this communication process. The following alternatives might be considered:

(1) Provide each Vietnam veteran reporting to the Outpatient Admissions area with a handout describing the purpose of the examination and its limitations. This can be further clarified by the examining physician during the course of the physical examination, preferably prior to beginning the physical examination process.

(2) Provide each veteran with the opportunity to view the audiovisual "Agent Orange: A Search for Answers." Veterans and/or visitors to VA health care facilities can be informed concerning the film and when and where it can be viewed.

(3) Make all Agent Orange pamphlets and other informational materials available to Vietnam veterans and the public - keeping them displayed in prominent areas and ensuring that sufficient copies are available for distribution. It should be standard operating procedure to provide copies of VA Agent Orange pamphlets to all telephone callers requesting Agent orange information.

3. Pathological Tissue Specimens (AFIP). The need to send tissue samples to the Armed Forces Institute of Pathalogy (AFIP) has been stressed in a series of circulars (DM&S Circulars 10-78-234, 10-79-239, 10-80-229, 10-82-37) and during several nationwide conference calls between Environmental Medicine Office and your facilities.

Although the response to these directives has been most positive in some quarters, it appears that there is a need for each VA health care facility to further review these directives to ensure maximum conformance with the goal of sending pathological materials obtained from all Vietnam veterans to the AFIP. I am confident that you will respond quickly to the necessity of doing so whenever possible.

4. Birth Defects. Vietnam veterans continue to express their concerns and in some instances, fears regarding the possible adverse health effects of exposure to Agent Orange or other environmental substances used in Vietnam. The Veterans Administration does not have legislative authority to provide birth defects counseling, care or treatment to the spouses of Vietnam veterans, for Agent Orange concerns. Nevertheless, in spite of the fact that we have no scientific evidence to relate to veterans concerning possible adverse effects we should take every opportunity to assist them whenever a veteran expresses a concern in this regard. I view this assistance as possible through a referral of these individuals to accredited birth defects/genetic counseling resources within the community. It was for this reason that on September 18, 1981, a copy of the March of Dimes Birth Defects Foundation publication entitled "Birth Defects - Genetic Services" was provided to each environmental physician. This can serve as a directory of genetic counseling services to which Vietnam veterans can be referred. This alternative method of assistance can be of great benefit in relieving many of the anxieties being expressed by Vietnam veterans reporting for an Agent Orange related examination at our facilities. We should view their inquiries as an opportunity to provide them with any available information, including VA Agent Orange pamphlets, which briefly address the issue of Agent Orange and possible birth defects as a result of exposure to this defoliant.

5. In conclusion, I wish to reaffirm my personal commitment to resolving the complex scientific and medical issues as well as many social concerns raised by Agent Orange. This commitment includes the need to assist Vietnam veterans whenever and wherever possible until these issues are resolved and we can effectively ascertain what further steps, if any, need to be taken. I repose great confidence in the support provided by all VA staff to ensure that our Vietnam veterans are given quality health care assistance and are treated with the dignity and respect to which they are entitled.

DONALD L. CUSTIS, M.D.
Chief Medical Director

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98TH CONGRESS
1ST SESSION

H. R. 1961

To amend title 38, United States Code, to provide a presumption of service connection for the occurrence of certain diseases related to exposure to herbicides or other environmental hazards or conditions in veterans who served in Southeast Asia during the Vietnam era.

IN THE HOUSE OF REPRESENTATIVES

MARCH 8, 1983

Mr. DASCHLE (for himself, Mr. PANETTA, Mr. BONIOR of Michigan, Mr. EDGAR, Mr. LONG of Maryland, Mr. WILLIAMS of Ohio, Mr. RICHARDSON, Mr. APPLEGATE, Mr. GARCIA, Mr. KASTENMEIER, Mr. OLIN, Mr. SMITH of New Jersey, Mr. MOAKLEY, Mr. OTTINGER, Mr. WHITEHURST, Mr. BARNES, Mr. KASICH, Mr. LELAND, Mr. FEIGHAN, Mr. RATCHFORD, Mr. DUNCAN, Mr. FORD of Michigan, Mr. SMITH of Florida, Mr. FRANK, Mr. TALLON, Mr. YOUNG of Alaska, Mr. MURTHA, Mr. STARK, Mr. MORRISON of Connecticut, Mr. OWENS, Mr. SIMON, Mr. ROE, Mr. FAUNTROY, Mr. MITCHELL, Mr. SCHEUER, Mr. STUDDS, Mr. DORGAN, Mr. LAFALCE, Mr. ERDREICH, Mr. CORRADA, Mr. ECKART, Mr. FORD of Tennessee, Mr. TRAXLER, Mr. SPRATT, Mr. WILLIAMS of Montana, Mr. OBERSTAR, Ms. MIKULSKI, Mr. PERKINS, Mr. LOWRY of Washington, Mr. MCKINNEY, Mr. HERTEL of Michigan, Mr. WIRTH, Mrs. SCHNEIDER, Mr. LANTOS, Mr. MARTINEZ, Mr. BERMAN, Mr. SHANNON, Mr. KILDEE, Mr. D'AMOURS, Mrs. COLLINS, Mr. FOGLIETTA, Mr. LEVINE of California, Mr. WEISS, Mr. HARRISON, Mr. FAZIO, Mr. MINETA, Mr. STOKES, Mr. DWYER of New Jersey, Mr. MURPHY, Mr. WEAVER, Mr. MCHUGH, Mr. HOWARD, Mr. DURBIN, Mr. MARKEY, Mr. BATES, Mr. SEIBERLING, Mr. VENTO, Mr. BORSKI, Mr. DONNELLY, Mr. SUNIA, Mr. MRAZEK, Mr. ADDABBO, Mr. RODINO, Mrs. KENNELLY, Mr. BEREUTER, Mr. DELLUMS, Mrs. BOXER, Mr. EDWARDS of California, Mr. JEFFORDS, Mr. BROWN of California, Mr. SHARP, Mr. PENNY, Mr. FISH, Mr. ASPIN, Mr. KEMP, Mr. FLORIO, Ms. OAKAR, Mr. GORE, Mr. HARKIN, Mr. OXLEY, Mr. DE LUGO, Mr. MCCLOSKEY, Mr. GUNDERSON, Mr. GILMAN, Mr. KOGOVSEK, Mr. TORRICELLI, Mr. HORTON, Mr. DIXON, Mr. EVANS of Illinois, Mr. MILLER of California, Mr. WOLPE, Mr. GLICKMAN, and Mr. SLATTERY) introduced the following bill; which was referred to the Committee on Veterans' Affairs

A BILL

To amend title 38, United States Code, to provide a presumption of service connection for the occurrence of certain diseases related to exposure to herbicides or other environmental hazards or conditions in veterans who served in Southeast Asia during the Vietnam era.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Vietnam Veterans Agent Orange Relief Act".

SEC. 2. The Congress finds that—

(1) certain adverse health effects occurring among persons who served in the Armed Forces in Southeast Asia during the Vietnam era, and certain birth defects occurring among the children of such persons, may be the result of the exposure of such persons during such service to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced during the manufacture of such herbicides or to other factors involved in such service including exposure to other herbicides, chemicals, medications, or environmental hazards or conditions; and

(2) a comprehensive review and scientific analysis of the literature covering studies relating to whether there may be long-term adverse health effects in

humans from exposure 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), as required by section 307(a)(1)(B) of Public Law 96–151, has been completed and submitted to the Veterans' Administration.

SEC. 3. Section 312 of title 38, United States Code, is amended by adding at the end the following new subsection:

"(d)(1) For the purposes of section 310 of this title and subject to the provisions of section 313 of this title, in the case of a veteran who served in Southeast Asia during the Vietnam era and who after such service suffers from a disease described in paragraph (2)(A) of this subsection, such disease shall be considered to have been incurred in or aggravated by such service, notwithstanding that there is no record of evidence of such disease during the period of service.

"(2)(A) The diseases referred to in paragraph (1) of this subsection are the following:

"(i) Soft-tissue sarcomas.

"(ii) Porphyria cutanea tarda.

"(iii) Active and residual chloracne and chloracneform lesions.

"(iv) A disease listed in a regulation prescribed by the Administrator under subparagraph (B) of this paragraph.

"(B) The Administrator may determine, and prescribe by regulation, diseases (in addition to those listed in subparagraph (A) of this paragraph) that medical research has shown may be due to exposure to herbicides, chemicals, medications, or environmental hazards or conditions. The Administrator shall include in such regulations a specification of the standards used by the Administrator in making such determination.

"(3) Paragraph (1) of this subsection shall terminate on the first day of the first month beginning after the end of the one-year period beginning on the date the Administrator submits to the appropriate committees of Congress the first report required by section 307(b)(2) of the Veterans Health Programs Extension and Improvement Act of 1979 (Public Law 96-151; 93 Stat. 1098).".

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VIETNAM VETERANS IN CONGRESS

Chairman: Tom Daschle, South Dakota
439 Cannon Building, Washington, D.C. 20515
Vice Chairman: Leon Panetta, California
431 Cannon Building, Washington, D.C. 20515

1/31/83

FEB 02 1983 AGENT ORANGE

STEERING COMMITTEE:

Don Bailey Pennsylvania
David Bonior Michigan
Hal Daub Nebraska
Allen Ertel Pennsylvania
James Florio New Jersey
H. John Heinz Pennsylvania
John LaFalce New York
Denny Smith Oregon

Dear Colleague:

The deadly contaminant, dioxin, present in certain herbicides used in Vietnam, including Agent Orange, has been called the most toxic synthetic chemical known to man. You may be aware that dioxin was the chemical recently discovered in Times Beach, Missouri.

Public Law 96-151 mandated the Veterans Administration to conduct a world-wide literature review of research conducted on phenoxy herbicides and dioxin. This review has documented a number of adverse health effects resulting from exposure to dioxin and related compounds. These include soft-tissue, lymphatic and stomach cancer, liver abnormalities, nerve damage, neuroasthenia (fatigue, insomnia, etc.) and others.

Yet, the VA for years has dismissed veterans' claims that their adverse health effects result from exposure to dioxin and other chemicals in Vietnam. We believe it is time to begin compensating Vietnam veterans who suffer from these illnesses. We feel the best way to do so is to establish a series of presumptions that certain illnesses and conditions are related to Vietnam service and are therefore compenseable. As a result, we will be introducing legislation that will allow the VA to compensate Vietnam veterans for diseases and illnesses which the literature has linked to herbicide exposure. In the 97th Congress, similar legislation enjoyed widespread bi-partisan support.

This legislation is not precedent setting as the VA already lists over 40 diseases it presumes to be service related. Despite possessing more evidence and knowledge of dioxin's effects on humans than many of the other 40 presumptions, the agency continues to deny claims.

It is time for Congress to act and we invite you to join with us as an original cosponsor of this legislation. Please call Ryan at 5-2801 or Scott, at 5-2861 to cosponsor or for additional information.

Sincerely,

Tom Daschle

Leon Panetta

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Office of the
Exec. Assist. to the CMD

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DR. YOUNG

concepts of health care delivery in the medical field.

Franklin General's second decade under community sponsorship was a dynamic period. During that time, the hospital had completed a new 16-bed emergency department, an urgently needed 99-bed addition, and a 300-car parking field. Included in the additions to the facility were an eight-bed coronary care unit and an eight-bed intensive care unit, which is considered one of the finest in the area. Also included was a 21-bed short-term psychiatric unit.

The hospital is looking forward to a third decade of service to its surrounding communities. Franklin General now has a total of 305 beds, including a new set of initiatives geared toward teaching programs, home care and long-term care services and other outreach programs geared for the elderly.

As a member of the hospital's advisory committee, I believe the future holds many promises for Franklin General. Despite changes and innovations in the hospital field, one thing remains constant: Franklin General is continuing its commitment to providing quality health care to all.●

ALL-AMERICAN CITY AWARDED TO SANTA ANA

HON. JERRY M. PATTERSON

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Tuesday, April 19, 1983

● Mr. PATTERSON. Mr. Speaker, the city of Santa Ana was recently chosen as a recipient of the All-American City Award, a national honor bestowed by the National Municipal League. Because the award recognizes citizen involvement by community residents, it is also a direct reflection on the mayor of Santa Ana, Gordon Bricken.

Having served as mayor of Santa Ana since April 14, 1981, Mr. Bricken is now stepping down from that post.

Gordon Bricken has been an outstanding leader in contributing to the general welfare and prosperity of the city of Santa Ana, and has been a central force in the growth of the community. Mr. Bricken has been instrumental in creating a new image for the city of Santa Ana through community activities such as the Golden City Days, the Community Christmas Tree and Christmas Parade, and the Ambassador's Ball. He has also encouraged open communications between citizens and local government through community programs such as the Mayor's Roundtables and the Santa Ana Tomorrow Conferences.

During Mr. Bricken's term as mayor, many projects came to fruition in the city of Santa Ana, including the awarding of a cable television franchise, the opening of the Downtown Parking Structure, the initial development of Sasser Park, and the opening of the Orange County World Trade Center.

Gordon Bricken has taken part in various programs that have had a beneficial impact on the city of Santa Ana. Mayor Bricken led the Orange County delegation to the "Invest in America's Cities" Conference in Hong Kong and served on the board of directors of the Santa Ana Economic Development Corp.

In addition, as chairman of the urban rail subcommittee of the U.S. Conference of Mayors, Mr. Bricken has supported local rail transportation through active participation in local and national conferences.

In recognition of his distinguished and unselfish contribution toward civic betterment, it is with pleasure that I invite my colleagues to join me in recognizing Gordon Bricken for his dedicated work as mayor of Santa Ana, Calif. The citizens of Santa Ana and I appreciate the mayor's hard work and accomplishments and will miss his outstanding leadership.●

SHEILA PETERSEN: VOLUNTEER OF THE YEAR

HON. RICHARD L. OTTINGER

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Tuesday, April 19, 1983

● Mr. OTTINGER. Mr. Speaker, I would like to extend my congratulations to Sheila Petersen, of North Salem, N.Y., who is being named Westchester County Volunteer of the Year, 1983, by the Volunteer Service Bureau of Westchester County.

Her dedication to improving the quality of life for terminally ill children has made her truly deserving of this award and I would like to share some of her achievements with my colleagues. In 1978 Ms. Petersen pioneered the fund "Friends of Karen" to raise money for Karen MacInnes, a terminally ill patient who wished to die at home. Ms. Petersen's fund raising drive made this possible. The money was used so that Karen could receive proper medical care yet remain at home surrounded by those that loved her.

This was just the beginning of Ms. Petersen's work with terminally ill children. Because of her complete dedication the "Friends of Karen" fund continues to thrive, increasing public awareness of terminally ill children's desire to be able to die at home, while raising the funds to make this possible.

Ms. Petersen's work does not stop with this fund. She provides much more than financial assistance to families with terminally ill children. Instead she gives all of her resources and makes herself available at all times to bring emotional support to these families during a most difficult time. I must truly commend Sheila Petersen, once again, and wish her continued success as she makes it possible both financially and emotionally for terminally ill children to live their last days at home.

I would also like to commend three other volunteer groups that will be honored by the Westchester County Volunteer Bureau. The Westchester Nature Helpers are a group of volunteers who provide, at any time of day or night, emotional support for their neighbors. Although informally organized, this group has provided crucial preventive mental health intervention.

Roger C. Paulmeno will be receiving the student volunteer award. His work, though, has extended far beyond his student project. Mr. Paulmeno volunteers at the Geriatric Continuing Treatment Program of Central Westchester Mental Health Service. He is extensively involved in all aspects of patient care and has become an integral part of the staff.

Finally, I would like to congratulate the workers at Reader's Digest for their involvement in Project LIVE. This program, provides a one-to-one tutoring experience for middle school children who have fallen behind the required reading level. The employees at Reader's Digest who have volunteered their time, tutor the children at work, thus providing them both with help in basic skills, yet also added vocational exposure. This program has been most instrumental in increasing the children's academic and emotional growth.●

DOW CHEMICAL CO., AND DIOXIN

HON. THOMAS A. DASCHLE

OF SOUTH DAKOTA

IN THE HOUSE OF REPRESENTATIVES

Tuesday, April 19, 1983

● Mr. DASCHLE. Mr. Speaker, in today's New York Times, April 19, 1983, a front page article appeared revealing what many of us have been saying for some time: that the Dow Chemical Co. was aware of the health hazards and toxicity of dioxin, the contaminant found in agent orange and other herbicides, before extensive use of agent orange and these other herbicides occurred both in Southeast Asia and in the United States. Dow of course, made no effort to notify the USDA, DOD, or any other major governmental purchaser of dioxin contaminated herbicides of their concerns.

Dow's track record on dioxin has been far from exemplary and the information revealed in the Times article today further damages the claims of Dow, the Veterans' Administration and others that dioxin is relatively safe and that veterans in Vietnam are unlikely to be suffering unusual health effects as a result of their exposure to dioxin contaminated chemicals. I submit this article for the RECORD and hope that all Members and staff will take the time to read it.

Al, Be ready for questions on this — since it so recently in the record Daschle is bound to bring up. 3-6

The article follows:

[From the New York Times, Apr. 19, 1983]

1965 MEMOS SHOW DOW'S ANXIETY ON DIOXIN

(By David Burnham)

WASHINGTON, April 18—Almost 20 years ago, scientists from four rival chemical companies attended a closed meeting at the Dow Chemical Company's headquarters. The subject was the health hazards of dioxon, a toxic contaminant found in a widely used herbicide that the companies manufactured.

Shortly after the meeting in Midland, Mich., on March 24, 1965, one of those attending wrote in a memorandum that Dow did not want its findings about dioxin made public because the situation might "explode" and generate a new wave of government regulation for the chemical industry. Another scientist noted that Dow officials had disclosed at the meeting a study which showed that dioxin caused "severe" liver damage in rabbits.

Dioxin, which has also been linked to birth defects and skin disorders in laboratory animals, is believed to be the deadliest chemical made by man, but its effects on humans have been difficult to prove conclusively. Since the Midland session, various studies have yielded conflicting evidence on whether dioxin increases the risk of cancer in humans.

Although it has been known for many years that Dow held the 1965 meeting with its competitors, excerpts from corporate memorandums about the session are only now beginning to emerge as a result of a lawsuit filed in 1979 against Dow and several other chemical companies. The memorandums raise the possibility that Dow scientists have been saying one thing in private about dioxin while the company's management has said something else in public.

"There is absolutely no evidence of dioxin doing any damage to humans except for something called chloracne," Paul F. Oreffice, the president of Dow, said last month on NBC's "Today" show. "It's a rash." Dow has performed medical tests on individuals suffering from chloracne for "over 20 years," he added, "and there is no evidence of any damage other than this rash which went away soon after."

Dow's critics challenge the accuracy of Mr. Oreffice's flat assertion that there is no evidence that dioxin causes human damage other than chloracne and also charge that Dow has failed to publish all the information it has collected in its own dioxin research. Furthermore, they say, Dow has systematically resisted Federal and state efforts to learn about and regulate dioxin.

According to a pretrial motion filed by Yannacone & Associates, the legal organization created to represent the Vietnam veterans in the Agent Orange case, the 1965 meeting on dioxin was attended by eight of Dow's senior scientists and six officials of Hooker Chemical; the Diamond Alkali Company, which later became part of Diamond Shamrock, and the Hercules Powder Company. A representative of the Monsanto Chemical Company was invited but did not attend.

Donald R. Frayer, a spokesman for Dow, confirmed in an interview April 5 that the giant chemical company had called the meeting to discuss the health hazards of dioxin. "We feel the meeting was pretty darn straightforward and proper," he said. "I think on the balance that the record shows we discovered a problem, sought out our competitors and tried to give them information and a means to control the problem."

INVITATION TO MEETING

The pretrial motion filed by Yannacone & Associates quoted a number of documents. V. K. Rowe, then director of Dow's Biochemical Research Laboratory, said in his invitation to the meeting that Dow had been researching "toxicological problems caused by the presence of certain highly toxic impurities in certain samples" of the herbicide 2,4,5-T and wished to share its findings. The Dow laboratory was and is recognized as one of the world's finest privately owned toxicology labs.

Two days after the meeting, C. L. Dunn, a chemist who was manager for regulatory affairs for Hercules, summarized in writing what he had been told.

"Dow says that their examination of their own and competitors' 2,4,5-T products contain what they call 'surprisingly high' amounts of the toxic impurities," he wrote.

"In addition to the skin effect," he wrote, describing the results of tests on rabbits, "liver damage is severe, and a no-effect level based on liver response has not yet been established. Even vigorous washing of the skin 15 minutes after application will not prevent damage and may possibly enhance the absorption of the material. There is some evidence it is systemic."

FEAR ON SITUATION

Dr. John Frawley, the chief toxicologist for Hercules, who had also attended the March meeting, got a follow-up telephone call four months later from Earl Farnum, a Dow executive. Dr. Frawley immediately wrote a confidential memorandum to the file.

Mr. Farnum, he wrote, said he was calling on behalf of a Dow vice president, Donald Baldwin, and "stated that Dow was extremely frightened that this situation might explode."

"They are aware that their competitors are marketing 2,4,5-T which contains 'alarming amounts' of acnegen," Dr. Frawley continued, referring to dioxin, "and if the Government learns about this the whole industry will suffer. They are particularly fearful of a Congressional investigation and excessive restrictive legislation on the manufacture of pesticides which might result."

A second memorandum written by Dr. Frawley, and quoted in part by lawyers for the veterans, said he had just received new information about health effects of dioxin from Monsanto, which did not sent a representative to the meeting. "From the data provided, a sample which contained 5 parts per million would be acutely toxic," he wrote. "Whether this refers to death or liver damage is not clear."

Daniel Bishop, a Monsanto spokesman, said in an interview that his company "didn't do any testing, period, not then and not now." He said that a fair reading of Dr. Frawley's full statement would make it clear that he had not received the toxicity information from Monsanto, but was not able to identify the information's source because the material in the Agent Orange case had been sealed by the judge. The documents were sealed at the chemical companies' request.

GROUP OF 75 COMPOUNDS

Dioxin is the name given to any of a family of 75 compounds, called dibenzo-para-dioxins, composed of benzene molecules and oxygen atoms. The compounds are an unwanted byproduct of several chemical processes, including the manufacture of 2,4,5-T under certain circumstances; 2,4,5-T is one of the two major components of Agent Orange.

Proving the specific effects of toxic chemicals on humans is extremely difficult; human experiments are generally prohibited by medical ethics. Animal tests, which are universally accepted by scientists as providing essential guidance on appropriate exposure levels for humans, are not a perfect guide because various species react differently.

In laboratory rats, concentrations as small as five parts per 1,000 million have caused statistically significant increases of cancer in rats.

Two studies, conducted on a group of forestry workers in northern Sweden and on a group of agriculture workers in southern Sweden, point to a possible association between exposure to herbicides contaminated with dioxin and an increased risk of soft-tissue cancers. Other studies, however, including one in New Zealand, show no higher risk of cancers for a group of farmers, foresters and fisherman exposed to dioxin than in men in other occupations.

WARNING ON DIOXIN STUDIES

Dr. Samuel S. Epstein, a physician who is professor of occupational and environmental medicine at the University of Illinois Medical Center in Chicago, cites the Swedish studies and other research on such questions as reproductive abnormalities to challenge the statement of Dow's president that there is no evidence that dioxin causes any more damage than a skin rash. "For Mr. Oreffice to make that statement is absurd," he said in a recent interview.

On March 23, Dr. Perry J. Gehrig, Dow's vice president for agricultural research and development and director of health and environmental science, cautioned the House Subcommittee on Natural Resources, Agriculture Research and Environment against "overinterpreting" the Swedish studies. The reports, he argued, "are too incomplete, both individually and in aggregate, to currently formulate a clear picture of the possible associations between TCDD and soft-tissue sarcomas." TCDD is a form of dioxin.

In 1982, Dow scientists published a report of a company survey on the occurrence of spontaneous abortions, stillbirths, infant deaths and several categories of birth defects among the wives of Dow workers who had been directly exposed to dioxin. The study concluded there were few differences in the number and kind of birth abnormalities found in these women compared with the wives of Dow workers not exposed to dioxin, and the report has been used frequently to support the theory that dioxin is not as dangerous as generally believed.

But Dr. Marvin S. Legator, professor and director of environmental toxicology at the University of Texas in Galveston, questions the study.

"Initially," Dr. Legator went on, "Dow planned on comparing the birth defects among the wives of Dow dioxin workers with two controls. First, a group of wives of Dow workers in Midland who had not been directly exposed to dioxin, and second, some wives of workmen who lived outside the Midland area. This second control group was important because the Midland area is quite polluted and the general population has a relatively high level of congenital abnormalities. But when they published the study the second control group was not included."

A "SAMPLING PROBLEM"

Mr. Frayer, the Dow spokesman, said the second group had been deleted because of "sampling problems."

"The women could not be compared with those in the first two groups, and they were questioned in a different way," Mr. Frayer said.

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Information compiled by Dr. Alvin Young, an expert at the Veterans Administration, indicates that from 1961 to 69 American companies made a total of 154.5 million pounds of 2,4,5-T.

Of that total, 44 million pounds were applied to the jungles of Vietnam, 23.4 million pounds were exported to other countries and 78.1 million pounds were used domestically. The balance, 10 million pounds, was destroyed by the Government after it was decided to halt the Vietnam defoliation program.

Dr. Young estimates that 1,700 pounds of dioxin a year were produced in the United States from the mid-1950's to about 1975, when steps were taken to limit it through changing the manufacturing process.

There is broad agreement that a substantial portion of dioxin-contaminated wastes are buried in thousands of dumps around the country. The Environmental Protection Agency recently said there were 12,000 of these dumps. Other experts have estimated the number may be closer to 50,000.

SUITS AGAINST COMPANIES

Billions of dollars are at stake in the answer to the question of what the chemical companies knew and when they knew it. In addition to the tens of thousands of veterans who have sued the chemical companies because of their exposure to Agent Orange in Vietnam, thousands of other Americans living near toxic dumps, such as the one in the Love Canal area of Niagara Falls, N.Y., are seeking damages on the grounds that dioxin and chemical poisons left there have shortened their lives and caused cancer, birth defects and genetic damage.

In January 1979, a group of veterans brought a Federal suit in New York, charging that the dioxin contained in the 2,4,5-T sprayed in Vietnam was a cause of cancer and other diseases among their members and had resulted in genetic damage and the birth of severely deformed children.

Victor John Yannacone, Jr., a principal organizer of the association of lawyers handling the class-action suit, said in a recent interview that the group now represents 20,000 Vietnam veterans, widows and children of veterans who are seeking damages against the chemical companies that provided the Government with Agent Orange.

The suit against Dow and the other major manufacturers of 2,4,5-T is scheduled to go to trial in the Uniondale, L.I., court of Federal District Judge George C. Pratt Jr. in June.

In an annual report filed with the Securities and Exchange Commission in Washington called a 10-K, Dow said it was one of six chemical companies who were defendants in the suit. "Dow believes it has not been scientifically demonstrated that the injuries claimed by the plaintiffs were caused or could have been caused by exposure to Agent Orange," the report said.

The Dow report also noted that the chemical company was opposing a move by the Environmental Protection Agency initiated during the Carter Administration that would totally ban the use of 2,4,5-T in the United States. The herbicide therefore is still being used on rice fields, on range lands and in industrial areas such as refineries, to control weeds.

The company's repeated public statements about the comparative safety of dioxin, including testimony to Congressional committees, press releases and scientific papers, have been accompanied by efforts on its part, particularly in the Reagan Administration, to block the Government from collecting information about the contaminant.

Evidence of the repeated contacts between Dow and E.P.A. officials in Washington, if not of the subject of the meetings, is contained in the calendars and travel records of these officials that have been obtained by the House subcommittees investigating the agency.

LINKS TO GOVERNMENT

Anne McGill Burford, for example, made at least two trips to Midland, Mich., in her 22 months as the head of the Environmental Protection Agency. Rita M. Lavelle, the former head of the Government program to clean up toxic waste dumps, met at least 14 times with Dow officials in the 11 months she held office.

Mrs. Burford, Miss Lavelle and 11 other political appointees recently resigned or were dismissed amid Congressional inquiries on allegations that the agency's toxic waste program had been mishandled.

According to the public testimony of some officials of the agency, Dow used its connections with the top echelon of the agency's Washington officials to get its way on several important matters relating to the regulation of dioxin.

Three weeks ago, for example, agency officials in Chicago told the Investigations Subcommittee of the House Committee on Energy and Commerce that their superiors in Washington ordered them to change an important report on dioxin to comply with the wishes of Dow.

The key deletion from the report was the following central conclusion about Dow's Midland plant: "Dow's discharge represented the major source, if not the only source, of TCDD contamination found in the Tittabawasse and Saginaw Rivers and Saginaw Bay in Michighan."●

PULITZER PRIZE TO THE BOSTON GLOBE

HON. EDWARD J. MARKEY

OF MASSACHUSETTS

IN THE HOUSE OF REPRESENTATIVES

Tuesday, April 19, 1983

● Mr. MARKEY. Mr. Speaker, yesterday, the Pulitzer Prize Board made known its selections for the recipients of the 67th annual Pulitzer Prize Awards for outstanding journalism. Selected as one of the winners from among more than 1,200 entries was a unique and brilliantly crafted feature produced by the Boston Globe. Entitled, "War and Peace in the Nuclear Age," this special supplement to the Sunday, October 17, 1982, issue of the Boston Globe was chosen for this prestigious honor in the category of national affairs reporting.

I can think of no piece of journalism yet produced on the urgent topic of the nuclear age more deserving of the recognition it has now received. Special credit should be given to the superb editing work of Michael C. Janeway and Harry K. King who directed the impressive assemblage of an excellent series of articles and illustrations on this topic.

The people of Massachusetts are truly among the most politically sophisticated citizens of the Nation. They have been at the forefront of important political issues repeatedly throughout the history of our Nation. Indeed, the recent reawakening of the people of America to the peril of the nuclear arms race had its roots in the minds and actions of the people of the Commonwealth of Massachusetts.

The preeminent newspaper of the Northeast and one of the truly outstanding newspapers in the country, the Boston Globe, deserves a great deal of credit for providing to its readers consistently excellent journalism which enables them to become responsible and effective citizens. The Pulitzer Prize truly redeems credit well deserved.

In introducing its special supplement, the editors left this message with the reader:

We offer in the pages that follow some introductions to the nuclear arms debate. Each piece of the nuclear-arms jigsaw puzzle requires its own short guide, or handle. We have tried to make key parts of the discussion plain, and also to point where the discussion is heading. The effort is not to be encyclopedic, or to preach or prescribe. It is to encourage the fresh, cleansing process of public education and debate about a matter of life and death for mankind.

"War and Peace in the Nuclear Age" is surely one of the most significant contributions any journalistic entity has made in recent years toward educating Americans about the urgent threat of nuclear war. I sincerely hope that by receiving this well-deserved award bestowed by the most prestigious organization in professional journalism that many more Americans will now have the opportunity to read and learn from the Boston Globe's excellent work. I congratulate the Boston Globe for earning this honor and for its attention to so important a topic.●

GOVERNMENT MUST BE A PARTNER IN OUR NATION'S RESEARCH EFFORT

HON. TIMOTHY E. WIRTH

OF COLORADO

IN THE HOUSE OF REPRESENTATIVES

Tuesday, April 19, 1983

● Mr. WIRTH. Mr. Speaker, I have long been concerned about declines in our national investments in research and development, and have worked for years to reverse this dangerous trend. At a time when more than ever before in our history, the future economic health of the United States relies on our ability to maintain our traditional distinction as the ideal capital of the world, we need a new concerted national effort to continue to lead the way in high technology and information industries. In this increasingly international economy these fields offer us hope for developing a healthier balance of trade. They also have enormous job potential for our own economy.

Maintaining our lead in high technology industries like electronics, photovoltaics, telecommunications, and many others will require a greatly improved national research base. Gov-

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Office of the
Administrator
of Veterans Affairs

Washington, D.C. 20420

DRAFT AT OMB
~~4/20~~ 4/21/83
~~4/19~~

Veterans
Administration

Honorable G. V. Montgomery
Chairman, Committee on
Veterans' Affairs
House of Representatives
Washington, D.C. 20515

Dear Mr Chairman:

I am pleased to present the views of the Veterans Administration on H.R. 1961, 98th Congress, the proposed "Vietnam Veterans Agent Orange Relief Act." I share with you and other members of Congress the desire for a meaningful Federal response to the fears of veterans who served in Vietnam that their exposure to Agent Orange may have long-term adverse effects on their health. However, we consider the approach taken in H.R. 1961 inadvisable given the present state of scientific knowledge.

The controversies arising from the Government's use of Agent Orange in Vietnam are a long way from resolution. Some of them may never be resolved. Before turning to the Veterans Administration's observations concerning the several issues raised by H.R. 1961, I would like to emphasize that the potential cost of paying compensation based on any Agent-Orange-caused disabilities played no part in our deliberations on this measure. The Federal Government, since its beginning, has fulfilled its sacred obligation to veterans disabled in the line of duty and will continue to do so.

The devastating wars of this century, and the need to maintain peacetime forces in order to assure the defense of our Nation, have been accompanied by legislative and programmatic developments intended to assure that no veteran's reasonable claim to compensation is denied. This is true whether the disability results from a combat wound, service-incurred disease, in-service accident, psychological trauma resulting from combat or other conditions of military service, or exposure to a substance known or later discovered to have adverse health effects.

We are immensely proud of our Agency's record of achievement. It can safely be maintained that our compensation program is the finest in the world, both in terms of the number of

Mr. Chairman

veterans we serve and in the amount of benefits paid. Moreover, the American people--who fund this program with their taxes--have given it overwhelming support, as has the Congress of the United States.

The preservation and integrity of the compensation program are among the highest priorities of the Veterans Administration.

There are certainly many veterans suffering from illnesses they ascribe to exposure to that herbicide, especially its contaminant dioxin. There are persons in the medical and scientific communities who contend that exposure may lead to a host of disorders that appear long after the exposure has ceased. There are also organizations and individuals who believe very sincerely that the Veterans Administration has not responded adequately to the issues involved.

As guardians of the public trust, Congress and the Administration share, I believe, a commonality of aims respecting these issues. The compensation program must be attuned to justifiable conclusions about the connection between Agent Orange exposure and disorders possibly arising from that exposure. At the same time we must do our best to avoid taking steps that have the potential for undermining the program's credibility and legitimacy. I know that you and other Members will give careful and thorough consideration to the bill, keeping in mind the commonality of aims to which I have previously alluded.

H.R. 1961 is intended to assist veterans who served in Southeast Asia during the Vietnam era establish entitlement to service-connected disability compensation if they are currently suffering from one of the disorders specified in the bill. It would do this by amending section 312 of title 38, United States Code, in order to provide for a special presumption of service connection applicable only to these veterans.

The bill is based on the premise that each of the specified disorders, no matter how long after military service symptoms appear, can be attributed to exposure to a phenoxy herbicide

in service. During the period 1962 to 1971, phenoxy herbicides, including Agent Orange, were used in Vietnam. As I have noted, H.R. 1961 is an effort to respond to the widespread concern that exposure to Agent Orange, especially its contaminant dioxin, may have long-term adverse effects on veterans' health.

Authority to award compensation on the basis of the presumption provided for in the bill would terminate one year after submission to Congress of the comprehensive epidemiological study mandated by Pub. L. No. 96-151. This "sunset" provision is analogous to the sunset provision applicable to VA health care for certain disorders possibly associated with phenoxy herbicide exposure, authorized by Pub. L. No. 97-72. Both sunset provisions recognize the current uncertainties as to the long-term adverse effects of exposure.

The Agent Orange controversy, as it relates to individual veterans' compensation claims, involves two basic questions: (1) whether the veteran was exposed, and (2) whether the veteran's disability results from the exposure. H.R. 1961, it should be noted, does not require any evidence of exposure; it would afford the presumption to any veteran who served in Southeast Asia during the Vietnam era (1964-1975). We have previously made public our decision to resolve the issue of exposure in a manner favorable to veterans; unless there is affirmative evidence to the contrary, we are prepared to presume exposure if a veteran served in Vietnam during the relevant period. This policy, prompted by the lack of a definitive method for identifying exposed individuals, is consistent with our longstanding policy of giving veterans the benefit of the doubt.

There may be, however, some cases in which affirmative evidence refutes even the possibility of exposure, and, therefore, our policy is necessarily qualified. The lack of any similar qualification in H.R. 1961, in our view, is unjustifiable. We observe also that affording the presumption to veterans who served in Southeast Asia--a far broader region than Vietnam, embracing areas where no phenoxy herbicides were used--inappropriately expands the category of veterans intended to be benefited.

Our principal concerns, however, relate to the concept of an open-ended presumption that would be established by the bill and to the conclusions it embodies as to the specific disorders chloracne, porphyria cutanea tarda (PCT), and the several malignancies grouped as soft-tissue sarcoma. The bill would also authorize presumptive service connection for additional disorders, provided for by regulation, that medical research has shown may be attributable to chemical exposure or environmental hazards or conditions.

Mr. Chairman

The post-service presumption periods provided for in section 312(a) of title 38 are appropriate for chronic diseases whose inception in service may not be recorded because the development of pathology is gradual and insidious. They are justifiable when reasonably supported by medical knowledge as to the pathological courses of the particular diseases.

Congress has wisely set time limits on these presumptive provisions; unless symptoms of the disease appear within a specified period of time after service, the presumption is not available. The section 312(a) presumption, together with the time limits, assures that no veteran's reasonable claim is overlooked but also does not dictate grants of service connection when there is no evidence of service incurrence and it is not reasonable to infer service origin.

Reputable studies have concluded that dioxin exposure may result, within a relatively short period, in chloracne. PCT resulting from exposure also appears within a few weeks. On the other hand, no studies have shown that exposure results in the initial appearance of these disorders after lengthy delays. Our current authorities are adequate, without the need of a presumption, to award service connection and compensation, if appropriate, in cases of chloracne or PCT appearing within expected time limits after the exposure. Requiring us to award service connection for initial occurrence of these disorders long after the exposure incidents is, we believe, unjustifiable in the absence of any evidence indicating they are latent effects of exposure.

As I have noted, individuals in whom these relatively rare disorders appear begin to suffer symptoms soon after exposure, ordinarily within days or weeks. Chloracne is a skin disorder caused by exposure to certain chlorine-containing chemicals, including dioxin. In its more serious manifestations, it causes discomfort and disfigurement. Most cases clear up within a year or two after the exposure ceases, but in a few, the disorder persists. The Veterans Administration acknowledges that chloracne can result from exposure to Agent Orange during service in Vietnam and has established procedures to assure careful and liberal consideration of all claims based on this disorder.

Since 1978, we have awarded service connection in 1,225 skin-disorder cases involving veterans who served in Vietnam. We have scrutinized more than 3,000 claims for service-connected benefits to determine whether there are indications of chloracne. Those cases in which it was believed this diagnosis was at least possible were further reviewed by a VA dermatologist, and 13 have been examined in person by dermatologists at prestigious private clinics.

Mr. Chairman

Although all of these cases involve skin disorders of various types and all involve veterans who served in Vietnam, only one case of possible chloracne has been identified. We will, of course, continue our investigations of this issue.

H.R. 1961 would also extend presumption of service connection for "chloracneform lesions." This is a term not found in medical or scientific literature, but can be taken to mean "lesions resembling chloracne." As certain common skin disorders may resemble chloracne, this term is overly broad and would, we believe, cause unnecessary confusion.

PCT, an uncommon liver disorder, can be triggered by exposure to various chemicals including alcohol. There is no evidence that PCT is a latent effect of exposure. Each attack ordinarily subsides in about a year after contact with the chemical ceases, but prolonged exposure, as in chronic alcoholism, may cause permanent damage to the liver. An attack of PCT induced by Agent Orange or exposure to any other chemical during service in Vietnam years ago would not be expected to impair a veteran's health today. As is the case with chloracne, we regard our current authorities as fully adequate to assure proper consideration of PCT claims based on exposures during military service. As a technical matter, the proper application of section 313 of title 38, United States Code, making section 312 presumptions rebuttable if there is evidence of an intercurrent cause, would reduce the likelihood of awards of service connection based on the PCT presumption, if enacted.

The issue as to whether the malignancies grouped as "soft-tissue sarcomas" result from phenoxy herbicide exposure presents a problem of far greater complexity. There is considerable uncertainty in the scientific community on this issue. Advocates of the belief that exposure "causes" soft-tissue sarcoma generally cite studies involving cancer victims believed to have been exposed to phenoxy herbicides whose first symptoms appeared long after the exposure. Because it is well established that exposure to radiation and other agents like asbestos and benzene may result in the latent development of malignancy, these advocates reason by analogy that phenoxy herbicide exposure "causes" soft-tissue sarcoma. The vital question is, therefore, the weight that should be given to the studies they cite.

"Soft tissue sarcomas" are a group of malignant tumors, or cancers. Any sarcoma arises in a body cell that does not cover a body surface, form glandular tissue, or line certain body cavities. "Soft tissue" excludes sarcomas in "hard tissues" such as bone or cartilage. Hence, soft tissue sarcomas arise from such body tissues as muscles, tendons, blood vessels, fat, and connective tissues.

Mr. Chairman

Certain cancers share some characteristics of soft-tissue sarcomas but are not placed in that group. These include most brain tumors and the so-called blood cancers, chiefly the leukemias. Some authorities include tumors of the lymph nodes--the lymphomas--with the soft-tissue sarcomas. The World Health Organization "International Classification of Tumors, No. 3, Histological Typing of Soft Tissue Tumors," however, excludes lymphomas and appears to be adequate for purposes of defining the malignancies in this category.

There is no evidence that all soft-tissue sarcomas have a common etiology or cause. These malignancies differ from one another as to how rapidly they grow and spread, how they are treated, and the results that treatment achieves. However, all are considered lethal if not successfully treated.

These malignancies are rare. According to the National Cancer Institute, they comprise 2.76 percent of all cancer cases in men aged 25 to 29 and 0.58 percent of all cancer cases in men aged 55 to 59; the percentage declines because other types of cancers become increasingly common with age. Lymphomas, sometimes included with soft-tissue sarcomas, contribute another 5.21 percent at ages 25 to 29 and 2.40 percent at ages 55 to 59.

Although there is no evidence establishing a common cause for these sarcomas, some malignancies in the group are known to be associated with exposure to environmental hazards. For example, malignant mesothelioma is known to be caused by asbestos exposure, and angiosarcoma of the liver by exposure to vinyl chloride.

Because these malignancies are rare, it is difficult to devise adequate techniques to investigate their causes. A series of studies in Sweden using the "case/control" method grouped the soft-tissue sarcomas together in order to investigate whether Swedish foresters and farmers exposed to herbicides and a chemical known as chlorophenol in their work, suffered latent malignancies of this type. These studies have been carefully reviewed by Richard D. Remington, Dean of the School of Public Health, University of Michigan, at the request of the Office of Technology Assessment and determined to have been carefully conducted and well reported with results that <u>suggest</u> a relationship between herbicide exposure and soft-tissue sarcomas. Significantly, Dr. Remington pointed out the limitations of the case/control methodology and found the Swedish studies inadequate to permit definite conclusions.

Investigations in the United States based on studies of industrial workers have also suggested a phenoxy-compound connection with soft-tissue sarcomas. In addition, an East German investigation of malignant neoplasms among pesticide

sprayers and agricultural technicians tends to support the Swedish studies by finding a single case of soft-tissue "malignancy," which probably was a soft-tissue sarcoma.

Other studies, in Finland, New Zealand, Great Britain, the Netherlands, and Italy have not confirmed the Swedish studies. In addition, a separate investigation of Swedish forestry workers casts some doubt on the Swedish studies.

We do not disagree with Dr. Remington's conclusions as to the credibility and limitations of the Swedish studies. They lay a predicate for further investigation and do not rule out the possibility of a causal link. They do not, however, provide a reasonable basis upon which to favorably decide VA compensation claims.

We recognize the importance of careful scientific analysis in matters of this kind, and have appended to this report detailed background papers concerning these diseases.

The comprehensive epidemiological study mandated by Pub. L. No. 96-151, together with other ongoing studies including some devoted specifically to the soft-tissue sarcoma issue, may resolve many of the controversial questions raised by the use of Agent Orange in Vietnam. As I stated at the outset of this report, we must work toward the dual objectives of fair compensation for any Agent-Orange-caused disabilities and avoidance of steps that would compromise the integrity of the program. At this point, there is no evidence that either chloracne or PCT is a delayed effect of exposure, and we believe the provisions of H.R. 1961 respecting these disorders are not justified. We do not believe it has been satisfactorily demonstrated that exposure can cause soft-tissue sarcoma.

Accordingly, we oppose the enactment of H.R. 1961. In view of the current state of scientific findings, enactment would compromise the integrity of the compensation program and engender unfounded fears among Vietnam veterans that lethal illnesses may yet befall them as a result of having answered duty's call. Our biding moral obligation to veterans who have given so much demands that we act responsibly in all matters affecting the compensation program.

If the soft-tissue sarcoma presumption in H.R. 1961 were to be enacted, we estimate compensation benefit costs in fiscal

year-1984 ranging from $2 million to $11 million, with the range for DIC benefits $3.5 million to $18.7 million. Benefit costs for future fiscal years would be comparable. A range of estimates is necessary because of uncertainty as to which malignancies are to be covered. Administrative costs would be sizeable in the first fiscal year and are anticipated to be $6.2 million, but would level off during subsequent fiscal years to less than $600,000 in fiscal year 1988.

Costs relating to chloracne are estimated as insignificant. We can only speculate with regard to costs resulting from the inclusion of "chloracneform lesions."

As PCT is a relatively uncommon disorder, we would not anticipate benefit costs exceeding $1 million in any fiscal year from the PCT presumption.

CHRONOLOGY OF SIGNIFICANT EVENTS PERTAINING TO THE AGENT ORANGE ISSUE

Oct 1977	A non-medical VA employee became convinced that Agent Orange caused wide variety of disabilities among Vietnam veterans, prompting them to file claims for compensation in late 1977.
March 1978	Chicago TV program on adverse effects of Agent Orange featured supposed cases of such effects supplied by the employee and suggesting the filing of claims.
April 1978	First meeting of herbicide consultants with prior experience that related to Agent Orange matters. Subsequent meetings were held in July and September to evaluate the current state of knowledge about phenoxy herbicides and their contaminants.
	DVB issued "Rating Practices and Procedures: Disability, Vietnam Defoliant Exposure" PG 21-1, Change 259, Section 0-18, to guide VA ROs in processing claims for disabilities resulting from chemical defoliants in Vietnam. All rating claims were to be reviewed in VACO.
May 1978	Telephone "Hotline" discussion of Agent Orange situation between Hospital Directors, Chiefs of Staff and VACO.
	DM&S distributed to all medical facilities a teletyped release "Potential Exposure of Veterans to Chemical Defoliants During the Vietnam War." This release established the basis for the "Agent Orange Registry" and the examination of concerned veterans. It also began the process of providing information to VA personnel dealing with defoliant problems.
June 1978	First meeting of the VACO Steering Committee on Herbicides that met until July 1980, to coordinate the activities of the various VACO components involved in the Agent Orange problem.

July 1978	DM&S prepared brief brochure, "Biological Actions of Herbicides Used During the Vietnam War" for guidance of medical staff and directors.
Aug 1978	DM&S concluded agreement with Armed Forces Institute of Pathology (AFIP) to establish a Special Registry to collect and examine all types of biopsy and autopsy material from veterans claiming exposure to Agent Orange.
Sept 1978	Circular 10-78-219, "Possible Exposure to Veterans to Herbicides During the Vietnam War," directed VAMCs to establish a registry of Vietnam veterans receiving Agent Orange-related physical examinations. The registry established on card file on concerned Vietnam veterans and a medical record of the pertinent history and examination results.
	VACO staff briefed the Washington staffs of veterans organizations on herbicides used in Vietnam and VA's work on the Agent Orange problem.
	DM&S issued Circular 10-78-234, "Special Registry" directing VAMC's to provide specimens to AFIP for study.
	Decision made to request approval for the establishment of an advisory committee.
Oct 1978	Congressional Hearing. DM&S reported current information and activities to the Subcommittee on Medical Facilities and Benefits of the House Veterans' Affairs Committee.
Feb 1979	Announcement that a surgical method for checking whether some Vietnam veterans carry after-effects of Agent Orange in their body fat will be tested by the VA. The test is part of a VA search for a simple way to find whether any Vietnam veterans might have after-effects from exposure to herbicides in Vietnam.
April 1979	Charter issued authorizing establishment of the VA Advisory Committee on Health-Related Effects of Herbicides, in accordance with Public Law 94-463.

VACO staff met with Professor Ton That Tung of Vietnam, who has conducted research on effects of Agent Orange on Vietnamese.

Circular 21-79-6, "Assistance to Agent Orange Exposure Claimants," established DVB procedures for providing assistance to veterans claiming disabilities resulting from exposure to herbicide orange.

May 1979

VA, in a news release, lauded a DOD decision to do an in-depth follow-up on 1,200 Vietnam veterans who were heavily exposed to Agent Orange while involved in spraying operations in Vietnam. The 1,200 people handled and sprayed Agent Orange during air missions known as "Operation Ranch Hand." Data on their health will be matched to a larger group not exposed.

June 1979

The establishment of a Veterans Administration Advisory Committee on Health-Related Effects of Herbicides was announced. The Committee, which included representatives nominated by government, veteran organizations, and academic sources, monitors VA's continuing inquiry into the possible health effects of Agent Orange on veterans who served in Vietnam. The Advisory Committee first met in June 1979. Subsequent meetings have been held on a quarterly basis.

Congressional Hearings. Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce held hearings on "Involuntary Exposure to Agent Orange and other Toxic Spraying." VA was not requested to appear.

Sept 1979

First Educational Conference held for physicians in each VA facility who are in charge of examining veterans claiming possible exposure to Agent Orange.

Dec 1979

Congress, in section 307 of Public Law 96-151, directed the VA 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. A comprehensive review and scientific analysis of world literature covering studies relating to long-term adverse health effects in human from exposure to dioxins was also mandated by this legislation.

The White House announced the establishment of an Interagency Work Group to Study the Possible Long-term Health Effects of Phenoxy Herbicides and Contaminants. The group included representatives from VA, HHS, and DOD, and observers from several other agencies.

Feb 1980 — Initial meeting of Interagency Work Group held.

Administrator testified on Agent Orange before the Senate Committee on Veterans' Affairs and the Subcommittee on Medical Facilities and Benefits of the House Committee on Veterans' Affairs.

A news release was issued which outlined the Administrator's testimony of results obtained in a VA study of the levels of dioxin in the fat of veterans known to have been exposed to Agent Orange as compared to a control group of unexposed veterans.

March 1980 — The VA issued an RFP requesting firm fixed-price offers for the required protocol design.

Spring 1980 — VACO officials visited a series of major cities (Chicago, New York, Los Angeles, Boston) to brief VAMC and VARO personnel on Agent Orange activities.

April 1980

The Interagency Work Group agreed that Centers for Disease Control (CDC) conduct a retrospective case control study to determine whether Vietnam veterans may have a higher risk of producing children with birth defects. Costs are to be borne by HHS, DOD, and VA.

Office of Special Assistant to Chief Medical Director for Environmental Medicine (102) established to coordinate DM&S Agent Orange program and related matters.

May 1980

The Policy Coordinating Committee (PCC) was established by the Administrator, under the chairmanship of the General Counsel, to serve as a central focal point within the agency to review all aspects of Agent Orange activities within the VA and to recommend, develop and establish new policy initiatives.

Second Continuing Education Conference on Herbicide Orange was held in Washington, D.C. Attendees included 180 VA environmental physicians and 58 adjudication officers who were updated on VA Agent Orange-related activities and provided an overview of significant scientific and medical information concerning this defoliant.

National Veterans Law Center sought court order prohibiting VA from opening bids received for the epidemiological study design contract. Court denied the request. VA reviews bid received.

VACO DM&S spokesman testified before committee of New York State Legislature regarding Agent Orange. Subsequent testimony was given before state legislative committees in Minnesota and California.

June 1980

In recognition of the concern expressed by veterans regarding chloracne, a skin condition resulting from exposure to Agent Orange, a special Chloracne Task Force (CTF) was established by the Chief Medical Director. The activities of the CTF are monitored by the Office of Environmental Medicine (102). Responsibilities assigned to the CTF include the ongoing review of skin conditions reported by

Vietnam veterans which may be chloracne and to make recommendations on questionable cases for further examinations.

District Court referred National Veterans Law Center bid protest to GAO for review.

A Special Data Analysis Task Force was established to review activities of the VA's Agent Orange Registry and to recommend and implement the streamlining of statistical reporting procedures. The Task Force meets twice monthly to improve the registry process and the quality of retrieved data obtained from the examination of concerned Vietnam veterans.

VA pamphlet, "Worried about Agent Orange?" published and forwarded to all field stations for mass distribution to Vietnam veterans, their families, and others concerned about possible effects of exposure to Agent Orange.

VACO Office of Planning and Program Evaluation completed report on the Minnesota Agent Orange Outreach Program. (Minnesota had implemented most extensive AO outreach program in the nation).

July 1980 — Congressional Hearing. Subcommittee on Medical Facilities and Benefits of House Committee on Veterans' Affairs held an oversight hearing on Agent Orange. No VA testimony.

Sept 1980 — Hearings of the Senate Committee on Veterans' Affairs; the Subcommittee on Medical Facilities and Benefits of the House Committee on Veterans' Affairs; and the Subcommittee on Oversight and Investigation of the House Committee on Interstate and Foreign Commerce. The VA testified before all three committees. The Administrator delivered the testimony before the Committee on Interstate and Foreign Commerce.

VA signed interagency agreement with HHS and DOD to provide total of $338,400 in FY 1981/1982 (1/3 of total cost) for CDC birth defects study.

	Workshop on "Impact of Chlorinated Dioxins and Related Compounds on the Environment", held in Rome, Italy with participation of Office of Environmental Medicine.
Dec 1980	The Office of Environmental Medicine conducted a nationwide conference call with key field station officials regarding Agent Orange.
	The VA awarded contract to JRB Associates, Inc. of McLean, VA, to conduct a review and analysis of world literature on herbicides used in Vietnam. Effort was mandated by Public Law 96-151.
	Initial issue of Agent Orange Bulletin. Publication established to advise VA physicians and medical staff responsible for Agent Orange activities at VAMC's with information regarding recent developments.
Jan 1981	VA film, titled "Agent Orange -- A Search for Answers," was distributed to VAMCs, clinics and regional offices as part of a nationwide VA program to bring to concerned Vietnam veterans the latest scientific information on Agent Orange. The program was produced by the South Central Regional Medical Center in St. Louis, with technical assistance from the Office of Environmental Medicine (102). The production has earned an "Emmy" and several other awards.
	GAO denied National Veterans Law Center protest concerning epidemiological study design contract award procedure. Decision allowed VA to proceed on contract award.
March 1981	The Office of Environmental Medicine conducted first of a series of regularly scheduled nationwide conference calls with key field station officials on the subject of Agent Orange. Subsequent calls have been held on a bimonthly basis.

April 1981	Charter of VA Advisory Committee on Health-Related Effects of Herbicides renewed. Committee extended for two years. First of series of mailouts sent to all environmental physicians to ensure that they have updated information on Agent Orange-related matters.
April/May 1981	Hearings of the Subcommittee on Hospitals and Health Care of the House Committee on Veterans' Affairs; the Senate Committee on Veterans' Affairs; and the Subcommittee on Oversight and Investigations of House Committee on Veterans' Affairs. VA testified before all three groups.
May 1981	VA announced the award of a $114,288 contract under which Drs. Gary Spivey and Roger Detels of UCLA's School of Public Health would design an epidemiological study. The study was mandated by Congress in December of 1979 and VA issued a request for proposals to design it in March of 1980. Legal objections raised by the National Veterans Law Center delayed award of the design contract until this time.
July 1981	The Agent Orange Working Group was established at the Cabinet Council level. This reconstituted committee was formerly designated as the Interagency Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (IWG). The lead agency for the working group is DHHS. Major Alvin L. Young, USAF, an expert in herbicides, was detailed to VACO for two years to assist Office of Environmental Medicine.
Aug 1981	The Administrator formalized the ad hoc Agent Orange Policy Coordinating Committee established in May, 1980. Under this arrangement, the committee was elevated and the Deputy Administrator appointed Chairman. The Committee is currently composed of representative

from DM&S, DVB, Office of General Counsel, Office of Information Services and Office of Planning and Program Evaluation.

First meeting of the newly constituted Agent Orange Working Group.

DHHS Secretary Schweiker unexpectedly announced that Agent Orange was jettisoned during aborted spraying missions in Vietnam. The information provided some additional detail to that already in public domain, but produced increased anxiety among many Vietnam veterans and their families.

VACO officials met with hunger strikers at VAMC Wadsworth.

VACO announced solicitation of research proposals dealing with the effects of animal and human exposure to Agent Orange and Agent Blue with emphasis on delayed effects. Solicitation limited to VA researchers.

Preliminary epidemiological study design submitted by UCLA.

Sept 1981

Contract to conduct the questionnaire for CDC birth defects study took effect. (Contract was signed in August). The pilot study is scheduled for completion by March 1982, with the main study scheduled for completion by April 1983.

Air Force contract awarded to Louis Harris and Associates to administer questionnaire for Ranch Hand epidemiological study. The study will assist in determining whether a causal relationship exists between exposure to Agent Orange and changes in the long-term health status of Air Force personnel known to have been extensively and repeatedly exposed to this herbicide as part of spraying mission in Vietnam.

Oct 1981

International Dioxin Symposium held in Arlington, VA. Office of Environmental Medicine aided in organization of this scientific meeting. Many environmental physicians participated in the symposium.

Oct/Nov 1981	Agent Orange Work Group Science Panel, Office of Technological Assessment, and VA Advisory Committee on Health-Related Effects of Herbicides completed review of epidemiological submission. Responses sent to UCLA.
Nov 1981	Public Law 97-72 provided for medical treatment for disabilities that may be related to exposure to Agent Orange. Law amended P.L. 96-151 to allow expansion of scope of epidemiological study and literature review.
	Circular 10-81-249, issued providing interim guidelines for implementation of Agent Orange medical care provisions.
	Administrator testified before the Senate Committee on Veterans' Affairs concerning agency Agent Orange-related activities.
	VA began distribution to researchers throughout government and the scientific community, a compilation of world scientific literature on Agent Orange and other herbicides used in Vietnam.
Dec 1981	The Federal Register published interim guidelines (Circular 10-81-249) pertaining to treatment of veterans exposed to Agent Orange. Comments, suggestions, and objections were welcomed.
	The Kelsey-Seybold Clinic in Houston was awarded contract to conduct physical examination in Air Force Ranch Hand Study.
Jan 1982	Physical examination began for Air Force Ranch Hand Study.
	Revised protocol for epidemiological study submitted, to VA by UCLA.
Feb 1982	Expiration of comment period for guidelines (Circular 10-81-249) published in the Federal Register. Initiation of effort by Office of Environmental Medicine to revise circular in light of consumer recommendations.

Feb 1982	Agent Orange Research and Education Office established, in Office of Deputy Administrator, to serve as a focal point for all VA Agent Orange matters.
March 1982	Agent Orange Working Group's Science Panel, Office of Technology Assessment, and VA Advisory Committee on Health-Related Effects of Herbicides completed review of second submission of epidemiological study draft protocol. Comments provided to UCLA.
	First of several Agent Orange pamphlets published by Office of Public and Consumer Affairs.
April 1982	Third and final draft epidemiological study submission received from UCLA.
May 1982	Epidemiological Study submission provided to Agent Orange Working Group and Office of Technology Assessment for review. VA Advisory Committee reviewed and discussed document in closed session. Contract signed with National Academy of Sciences for review of protocol.
	Deputy Administrator letter sent to all participants of VA Agent Orange registry enclosing recently published pamphlets.
June 1982	Administrator approved first comprehensive Agent Orange budget.
June-Sept 1982	Discussions and correspondence among Federal agencies attempted to define epidemiological study cohorts.
Aug 1982	Circular 10-82-154 issued to provide for update of names and address in VA Agent Orange registry.

Sept 1982	Congressional Hearing. Subcommittee on Oversight and Investigations of House Committee on Veterans' Affairs held a hearing on the Federal Agent Orange activities.
	Correspondence began between VA & HHS concerning possibility of transfer of epidemiological study.
	OTA complained that future progress on epidemiological study could not be made without decisions on basic design of the study.
	Letter from leadership of House Veterans' Affairs Committee recommends that VA contract with Centers for Disease Control (CDC) to conduct epidemiological study.
	Chloracne Task Force reestablished with Dr. A. Betty Fischmann, Chief, Dermatology Service, VAMC Washington, D.C., as chairperson.
	Final guidelines issued implementing Agent Orange medical care provisions of Public Law 97-72.
Oct 1982	Third International Symposium on Chlorinated Dioxins and Related Compounds held in Salzburg, Austria. VA participated.
	General Accounting Office report issued on VA Agent Orange Examination Program.
	100 members of Congress signed letter urging transfer of epidemiology study to CDC. HHS and VA agreed in principle that study should be transferred.
	National Academy of Sciences provided comments on proposed protocol.
Nov 1982	Total number of initial Agent Orange registry examinations exceeded 100,000.
	Air Force Health Study (of Ranch Hand personnel) interim report issued.

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Nov 1982	Establishment of DM&S Agent Orange Projects Office announced.
	First issue of Agent Orange Review, a periodical with updated information concerning the VA Agent Orange program, sent to all VA field installations.
Jan 1983	Interagency agreement betwen VA and HHS signed transferring epidemiology study to CDC.

EPIDEMIOLOGICAL STUDY - CHRONOLOGY

December 1979	- Congress passes the "Veterans Health Programs Extension and Improvement Act of 1979." PL 96-151, Section 307 of the Act directs the Administrator to design a protocol for and conduct an epidemiological study of Vietnam veterans who were exposed to dioxins contained in herbicides (Agent Orange).
December 20, 1979	- President signs the Act into law.
January 8, 1980	- Decision made to use the competitive procurement method to obtain the required services for the design of the protocol.
January 10, 1980	- President directs the Administrator to forward protocol to Director, Office of Technology Assessment (OTA) for information purposes only.
February 4, 1980	- Announcement of intent to let contract for the design of the protocol published in Commerce Business Daily.
February 6, 1980	- Administrator advises OTA of President's directive and offers to cooperate to the extent that the Constitution permits.
February 21, 1980	- Chairman, Senate Veterans Affairs Committee, advised by Administrator of President's directive and assures him that VA would not proceed with a protocol to which OTA had serious objection.
March 19, 1980	Request for proposals issued.
April 11, 1980	- Pre-bid conference conducted by VA at VACO.

May 6, 1980	- National Veterans Law Center initiates legal action attempting to obtain a temporary restraining order to preclude VA from opening any proposals received for the contract for the design of the study.
May 7, 1980	- Court denies motion for temporary restraining order but retains jurisdiction.
May 8, 1980	- Last day for receipt of bids.
May 1980	- A selection panel of government epidemiologists (including one from OTA) reviews bids received and makes tentative ranking. On advice of U.S. attorney no further action is taken because of litigation and pending referral of bid protest to GAO.
June 13, 1980	At the request of the National Veterans Law Center, Judge Green refers matter to GAO to rule on bid protest.
June 1980	- VA General Counsel, with concurrence of Department of Justice, advises against award of contract prior to resolution of pre-award protest.
February 2, 1981	- GAO rules entirely in favor of VA.
February/March 1981	- VA contacts bidders and allows updating of submission if still interested in and capable of designing study protocol.
April 1981	- Panel of experts reconvened to review revised bids.
May 1, 1981	- School of Public Health, U.C.L.A., selected to design study protocol.
May 1, 1981	- U.C.L.A. receives notice of award. (contracted for $114,288). Has 60 days to submit draft of study protocol.
June 1981	- U.C.L.A. granted 30 day extension for submission due to difficulty experienced in working with DoD records.

August 6, 1981	- Preliminary design submitted by U.C.L.A.
August 1981	- VA submits design to Agent Orange Working Group, VA's Advisory Committee and OTA for review and comment.
October 8, 1981	- Response received from OTA and provided to U.C.L.A.
October 21, 1981	- Response from Science Panel, Agent Orange Working Group received.
November 3, 1981	- PL 97-72 signed, allowing Administrator to expand study to include other factors in Vietnam experience.
November 6, 1981	- Response received from VA's Advisory Committee.
November 9, 1981	- Responses from review groups sent to UCLA.
November 18, 1981	- Senate Committee on Veterans Affairs hearing on Agent Orange.
November 25, 1981	- VA notified UCLA that submission, as received and reviewed, was inadequate and allowed UCLA 35 days to resubmit.
December 14, 1981	- UCLA requested additional 35 days (to January 25, 1982) because of Principal Investigator's illness.
January 22, 1982	- Revised protocol for epidemiological study submitted to VA by UCLA with recommendation for two cohort effort.
February 1982	- Revised protocol provided to Agent Orange Working Group (AOWG), VA's Advisory Committee, and OTA.

March 24, 1982	- AOWG completed review of protocol and endorsed the design with certain recommendations.
March 1982	- OTA completed review with findings similar to those of the AOWG. VA's Advisory Committee members submit views. Comments sent to UCLA.
April 29, 1982	- Third and final protocol submission received from UCLA.
May 1982	- Revised protocol provided to Agent Orange Working Group and OTA.
May 13, 1982	- During special closed session, VA's Advisory Committee reviewed third submission.
May 20, 1982	- Contract signed with National Academy of Sciences (NAS) for review of proposed protocol.
June 10, 1982	- VA requested AOWG views on a number of issues, including selection and use of cohorts.
July 2, 1982	- Letter from DoD to AOWG argued for three cohort study.
July 6-8, 1982	- NAS review began.
July 15, 1982	- Science Panel of AOWG discussed cohort selection and established subcommittee to recommend how cohorts should be identified.
August 23, 1982	- NAS requests extension of time until October 31 to complete review of protocol.
September 3, 1982	- Cohort selection sub-committee sent status report to AOWG suggesting method of cohort identification to be tried in pilot test.
September 7, 1982	- VA requests additional justification from NAS to substantiate time extension.

September 15, 1982 - Subcommittee on Oversight and Investigations of House Committee on Veterans' Affairs held hearings on Federal Agent Orange activities. Witness from Centers for Disease Control (CDC) suggested that CDC could have designed and initiated the study more expeditiously than VA.

September 27, 1982 - Letter fron Congressman G.V. (Sonny) Montgomery (Chairman, House Committee on Veterans' Affairs), John Paul Hammerschmidt (Ranking Minority Member, House Committee on Veterans' Affairs and Ranking Minority Member, Subcommittee on Hospitals and Health Care), and Ronald M. Mohl (Chairman, Subcommittee on Hospitals and Health Care) recommended that VA contract with CDC to "conduct all phases of the Agent Orange Study."

September 30, 1982 - Letter from Administrator to Secretary of Health and Human Services (HHS) concerning possibility of transfer of study to CDC.

- Letter from Office of Technology Assessment concerning progress on the study and the need to make decisions about the basic design of the study.

October 6, 1982 - Letter from Congressman Tom Daschle and 99 other members of Congress proposed that CDC "assume responsibility over the remaining segments" of the study.

October 14, 1982 - Letter from Administrator to Secretary of HHS requesting information on CDC's interest in performing the study.

- Letter from Administrator to Chairman Montgomery stating "that it would be prudent to enter into an agreement with a non-VA scientific body" to perform study. Letter noted contact with HHS in effort to transfer study to CDC.

October 22, 1982	- Letter from Secretary of HHS to Administrator acknowledging letters of September 30 and October 14. He agrees in principle to the transfer of the study to CDC provided adequate resources are made available and requests that copies of all pertinent documents be forwarded to CDC.
	- Meeting between Chief Medical Director, VA, and Assistant Secretary for Health, Human Services (HHS). Agreement in principle to transfer study to CDC.
October 28, 1982	- NAS comments on proposed protocol received by VA.
November 23, 1982	- VA draft of interagency agency agreement submitted to CDC for review and comment.
November 31, 1982	- Chief Medical Director (CMD) discussed transfer of study at open meeting of VA Advisory Committee on Health-Related Effects of Herbicides. CMD indicated desire for expeditious finalization of interagency agreement.
December 6, 1982	- Letter from Assistant Secretary for Health, HHS, concerning transfer of study enclosed CDC's version of proposed interagency agreement and CDC's proposed protocol outline and tentative timetable for conduct of the study.
December 23, 1982	- Letter from CDC outlining requirements for conduct of epidemiology study

January 13, 1983 - Letter from CMD to Dr. Brandt, Assistant Secretary for Health, DHHS, transmitting interagency agreement signed by VA for review and signature by CDC.

January 14, 1983 - Interagency agreement between VA and HHS signed transferring epidemiology study to CDC.

February 2, 1983 - OTA receives copy of CDC's proposed study protocol. Copies forwarded to members of OTA Agent Orange Advisory Panel.

March 3, 1983 - Letter from John Gibbons, OTA, to Administrator commenting on CDC's "Outline" (protocol). Advised in letter that CDC expects to complete drafting of protocol into April or early May. Protocol outline and tentative timetable for study transmitted by letter.

March 4, 1983 - Letter from Assistant Secretary for Health, DHHS, to CMD briefly outlining CDC's FY 1983 resource requirements and suggested FTEE requirements for FY 1984. Request made by DHHS that VA take expeditious action to obtain OMB approval for transfer of resources. Draft letter from DHHS to OMB outlining resource justification provided to CMD.

March 11, 1983 - Meeting at VACO between Dr. David Erickson, CDC, Agent Orange Projects Staff, Comptroller's Office and Supply Service to discuss CDC's justification package for 28 FTEE requested by CDC in FY 1983. Participants advised by Dr. Barclay M. Shepard that a stronger justification is required. A conference call at this time with Annette Rooney, OMB, resulted in CDC agreement to prepare a stronger justification package and to participate in a March 18 meeting at OMB on CDC's request for FTEE.

- Dr. Barclay M. Shepard advised by Mr. Claude Picklesheimer, Finance Office, CDC, that CDC was under impression that $3 million was FY 83/84 money. Advised by Dr. Shepard that resources would be lost at close of fiscal year. Dr. Shepard urged that CDC request funds as soon as staff are on board for study and funds can be obligated.

March 15, 1983	- Administrator directs DM&S to continue to provide all necessary support and to expedite the transfer of resources to CDC in order to assist CDC in initiating the epidemiology study in the immediate future.
	- Contact made with Dr. David Erickson, CDC, requesting CDC participation in March 18 meeting at OMB to justify to OMB the resources requested by CDC.
March 17, 1983	- Letter transmitted from Assistant Deputy Administrator, Budget and Finance to OMB forwarding proposed study outline and request for personnel resources as submitted to VA by CDC.
March 18, 1983	- Meeting between VA/CDC/OMB at OMB on justification of resources requested by CDC.
March 25, 1983	- Letter from Administrator to Sam Clarkson, OMB, requesting 28 positions (14.0 FTEE) and notification that CDC is to provide VA with complete budget estimates and justification for FY 84 and beyond.
April 15, 1983	- Meeting with OMB representative and VA staff on need to request further justification for CDC's FY 1984 budget requirements.

6.

Department of Medicine and Surgery
Washington D.C. 20420

Veterans Administration

JAN 13 1983

In Reply Refer To: 10A7

Edward N. Brandt, Jr., M.D.
Assistant Secretary for Health
Department of Health and
Human Services
Washington, D.C. 20201

Dear Dr. Brandt:

Enclosed is the proposed Interagency Agreement to effect the transfer of the epidemiological study from the VA to the CDC. The present language of the agreement is the culmination of a number of previous efforts and informal contacts between staff members of our respective offices. In the interest of expediting the completion of protocol development and implementation of the study, I am hopeful that you will find the language of the agreement satisfactory and suitable for signing within the next few days.

The VA is prepared at this time to make an advanced payment to CDC of the $3,000,000 identified in the VA's FY 1983 budget for initiation of the study. In addition, we will work with you in obtaining OMB clearance for providing to CDC the requisite 28 FTEE for this fiscal year.

In your letter of December 23,1982, you propose that resource requirements beyond the $3,000,000 and 28 FTEE be included as a multi-year appropriation in FY 1984. We will be pleased to join you in exploring the feasibility of this suggestion with OMB and the appropriate Congressional committees. On the matter of the periodic mortality follow-up effort, I believe this should be included in the CDC study, and as such be made a part of the budget proposal in support of the full study.

I have reviewed with interest the outline for the conduct of the study as proposed by CDC. The concept of two concurrent studies, one to examine the effects of exposure to Agent Orange and the other the impact of the Vietnam experience has

considerable merit and provides the advantages of two complimentary efforts. I do have great concern, however, over the suggestion that the VA conduct the physical examinations and laboratory studies for the 4,000 veterans, in each of the five cohorts, who will not be examined by CDC as part of the study. If two-thirds of the individuals answering the questionnaire are to be examined in VA medical centers, I believe that it would be very difficult to convince the majority of Vietnam veterans that the VA is not actually involved in the conduct of the study. I therefore have taken the position that if it is the recommendation of CDC that all study subjects receive a physical examination and laboratory work-up, CDC should include this as part of the budget proposal and justification for OMB and Congressional action.

I hope that we have reached sufficient consensus on these issues so that we can now finalize the interagency agreement.

Sincerely,

DONALD L. CUSTIS, M.D.
Chief Medical Director

Enclosure

6-2

JAN 11 1983

IGA V101(91)P-83002

INTERAGENCY AGREEMENT
BETWEEN
VETERANS ADMINISTRATION
AND
CENTERS FOR DISEASE CONTROL
PUBLIC HEALTH SERVICE

I. Background.

Public Law 96-151, Section 307, mandates that the Veterans Administration (VA) design a protocol and conduct an epidemiological study to determine if veterans of the Vietnam conflict suffer long-term adverse health effects from exposure to dioxins produced in the manufacture of phenoxy herbicides including Agent Orange. Public Law 97-72 permitted the expansion of the protocol design and study to include an evaluation of any long-term adverse health effects in humans which may result from other factors involved in service in Vietnam including exposure to other herbicides, chemicals, medications, or environmental hazards or conditions.

Members of Congress recently urged that the VA "contract with the Centers for Disease Control (CDC), Atlanta, Georgia, to conduct all phases of the Agent Orange Study." As a result of subsequent meetings and correspondence between VA and CDC, an agreement in principle has been reached for the transfer of the study from VA to CDC. The details relating to the respective responsibilities of the two agencies are outlined below.

II. Purpose.

This Interagency Agreement is for the purpose of transferring from the VA to the CDC the resources and authority for the design, implementation, analysis, and scientific interpretation of a valid epidemiological study in accordance with Section 307 of Public Law 96-151, as amended.

III. VA Responsibilities.

A. For the purpose of assisting CDC in developing its recommended study design, the VA has provided CDC with a preliminary study design developed by the School of Public Health, University of California at Los Angeles, along with extensive reviews from the Science Panel, Agent Orange Working Group; the Office of Technology Assessment; the VA Advisory Committee on the Health Related Effects of Herbicides; and the National Academy of Sciences, National Research Council. Also provided were: certain suggested modifications of the study design (insofar as these have been developed), a statistical consultant's report on the study design, and a draft statement of work for inclusion in a Request for Proposal for the conduct of a pilot phase of the study. Upon request from CDC, the VA will provide other documents in its possession as are necessary for the further design and conduct of the study.

B. The VA will submit to the Office of Management and Budget (OMB) and the appropriate committees of Congress specific requests for fiscal and personnel resources to support the conduct of the study. In so doing, the VA will depend on information and justification provided by CDC as outlined in Sections IV.H. and VI.C. of this agreement.

C. The VA will forward the final report of the findings of the study to the Congress as it is received in finished form from CDC.

D. The VA will submit to OMB the CDC's information collection budget proposal for approval under the Paperwork Reduction Act. Accordingly, any information collection hours associated with the study will be assigned to the VA's information collection budget for use by CDC in the conduct of the epidemiological study.

E. The VA will provide a point of contact to act as liaison with the CDC project officer as noted in Section IV.I. of this agreement. The VA's point of contact is:

Title: Director, Agent Orange Projects Office (10A7)
Address: Room 848, VA Central Office
810 Vermont Avenue
Washington, D.C. 20420
Telephone: FTS 389-5411; Commercial (202) 389-5411

IV. CDC Responsibilities.

A. The CDC will complete the epidemiological study as expeditiously as possible, but not later than September 30, 1987.

B. All decisions related to the design, conduct, analysis, and scientific interpretation of the results of the study, as well as analysis of the data obtained during the course of the study, shall be the sole responsibility of the CDC. The CDC will submit the study protocol to the office of Technology Assessment for its review and comments. Reports of results of the study will be authored by the CDC.

C. To the extent permitted by law, the CDC agrees to maintain the confidentiality of any documents provided by the VA as outlined in Section III.A. of this agreement and designated by the VA as confidential. Also to the extent permitted by law, the CDC agrees that all documents provided by the VA to the CDC pursuant to this agreement, whether designated by the VA as confidential or not, shall be used solely for the purpose of the study and for no other purpose unless mutually agreed upon by VA and CDC.

D. The CDC will prepare the necessary information collection budget proposal for OMB approval under the Paperwork Reduction Act. This proposal will be submitted by the CDC to the VA for formal submission by the VA to OMB.

E. The CDC will furnish reports of information necessary for the VA to comply with the Report to Congress required by Public Law 96-151, Section 307(b)(2), as amended by Public Law 97-72, Section 401(b)(1).

F. Findings resulting from the epidemiological study and an evaluation of those findings will be incorporated into a final report from CDC to VA as expeditiously as possible.

G. The CDC agrees to provide quarterly progress reports to the VA.

H. The CDC will, at the VA's request, assist the VA in providing testimony at any and all congressional hearings, including appropriation hearings, regarding the epidemiological study until such time as the study is complete.

I. The CDC project officer is:

Name:	Dr. J. David Erickson
Title:	Epidemiologist, Center for Environmental Health
Address:	Centers for Disease Control Atlanta, Georgia 30333
Telephone:	FTS 236-4035; Commercial (404) 452-4035

V. Authority.

A. The CDC has legislative authority under Section 301(a) of the Public Health Service Act to conduct research into the health effects of a broad range of environmental hazards and to cooperate with other appropriate authorities in the conduct of such research.

B. As previously indicated, the VA has authority under Section 307 of Public Law 96-151 to design and conduct an epidemiological study relating to exposure to Agent Orange and to expand the scope of the study as provided in Public Law 97-72.

C. The VA has authority to enter into this agreement under the Economy Act, as amended (31 U.S.C. Section 1535) and 38 U.S.C. Section 213.

VI. Resources.

A. The VA will initiate appropriate action to obtain OMB approval of the CDC request for 28 full-time equivalent employment (FTEE) for FY 1983.

B. Upon request from the CDC for advance payment, the VA will pay CDC up to $3,000,000 for goods and services required under this agreement during FY 1983. Subsequent fiscal year funding requests may also be paid in advance as agreed to by the VA from time to time. Any amount paid in advance is subject to adjustment for actual costs incurred, as required in 31 U.S.C., Section 1535 (1982).

C. The CDC will identify and fully justify all fiscal and FTEE requirements for use by the VA in submitting specific funding requests to OMB and Congress for the conduct of the study in FY 1984 and beyond. These requirements will be submitted in a timely and appropriate manner so as to be included and specifically identified in the VA's budget and planning efforts. Only those resources specifically approved by OMB and appropriated by Congress for the conduct of the study will be made available to CDC by the VA for this purpose.

D. CDC agrees to utilize the resources provided by the VA solely for purposes that CDC deems to be related to the epidemiological study. CDC will provide VA with a quarterly statement of the costs incurred in the performance of this agreement. The cost statement shall be made in conformance with standard government budget and accounting requirements.

VII. Amendments.

This agreement or any of its specific provisions may be revised by signature approval of both the parties signatory hereto, or their respective successors.

VIII. Effective Date.

This agreement is effective as of October 16, 1982, and shall continue in effect unless modified in writing by mutual agreement.

IX. Termination.

A. The period of this agreement is through September 30, 1984, to be renewed annually thereafter for the duration of the study.

B. In the event that the necessary fiscal and personnel resources are not provided to the CDC as specified in Section VI.A., B., and C. of this agreement, the CDC will be under no obligation to undertake or complete this epidemiological study.

C. In the event that OMB fails to approve the necessary information collection budget hours in accordance with the Paperwork Reduction Act of 1980, the CDC will be under no obligation to undertake this epidemiological study.

VETERANS ADMINISTRATION

By _____

Title Chief Medical Director

Date 13 Jan '83

U. S. PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH AND
HUMAN SERVICES

By _____

Title Assistant Secretary for Health

Date 14 Jan '83

DELEGATION OF AUTHORITY

The Chief Medical Director is hereby delegated the authority to enter into an agreement with the United States Public Health Service, Department of Health and Human Services, for the transfer of the responsibility for the design, implementation, analysis and interpretation of the epidemiological study mandated by Pub. L. No. 96-151, as amended by Pub. L. No. 97-72.

Any modification, revision, or termination of this agreement may be accomplished only with the concurrence of the Administrator of Veterans Affairs.

Harry N. Walters

HARRY N. WALTERS
Administrator

Date: 1/12/83

6-8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

DEC 6 1982

Donald Custis, M.D. (10)
Chief Medical Director
Veterans Administration
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Dear Dr. Custis:

Enclosed is the Centers for Disease Control (CDC) protocol outline for epidemiologic studies related to the possible health effects of military service in Vietnam and exposure to Agent Orange. Two separate but parallel historical cohort studies are proposed. The first will compare three cohorts of Vietnam veterans which will differ in their presumed levels of exposure to Agent Orange. The second will compare a cohort of Vietnam veterans with a cohort of Vietnam-era veterans who did not serve in Vietnam ("Vietnam Experience" study).

This protocol outline is the result of intensive work during the past several weeks by a committee of CDC scientists. The outline requires substantial effort to bring it to a full and complete protocol. This effort will require the assembly of a sizeable CDC team, extensive use of consultants, intensive scrutiny and review by non-Federal scientists, and comment by veterans groups. Before proceeding with this considerable effort, a formal interagency agreement must be reached in the near future between the Veterans Administration (VA) and CDC for transfer of a total of $3 million and 28 full-time equivalent (FTE) positions for Fiscal Year 1983. For Fiscal Year 1984, in addition to monies, an additional 22 FTE's will be required, bringing the total FTE's to 50 for the duration of the study. Also enclosed is a revised copy of proposed interagency agreement which we need to finalize as quickly as possible so that further development of the protocol can proceed.

We also need for the VA to agree to transfer further fiscal resources to CDC to support the conduct of the study. Depending on the details of the final study design, which will emerge only after the vigorous debate which no doubt will take place during protocol development, up to a maximum of 50 FTE's annually and a total of $150 million may be required (a detailed budget is being prepared). The FTE's and any unexpended funds would revert to the VA upon completion of the studies. We also need agreement that the VA will provide the required number of information collection budget hours. Without these commitments from the VA, CDC cannot accept responsibility for designing and conducting the requisite studies.

Our estimated costs for the design and conduct of these studies range between $70 and $150 million. This wide range derives from 2 factors. First, the protocol outline calls for each cohort to comprise 6,000 veterans. It is proposed that each of the 6,000 veterans be included in a mortality study and invited to complete a health/exposure questionnaire. It is further proposed that (at most) 2,000 from each cohort be given a physical examination and laboratory workup. The exact specifications for the physical examination and laboratory analyses can only be determined during the process of full protocol development. Thus, we have taken the approach of estimating examination and laboratory costs by assuming very comprehensive workups like those being done in the Air Force's Ranch Hand study. Further, the CDC committee which drew up the protocol outline believes that it is possible that the final protocol might call for fewer than 2,000 examination/laboratory participants per cohort. However, since this cannot be decided without considerable further effort, we have based our estimated lowest costs on 2,000 per cohort.

The second major factor which has led us to present a broad range of possible costs involves an uncertainty about what expectations study participants might have concerning the examination/laboratory phase. Whatever scientific decision is reached about the numbers required for this phase, veterans who participate in the questionnaire phase may expect to receive an examination and laboratory analysis. Some mechanism may need to be developed whereby those who participate in the questionnaire phase, but who are not chosen for the examination phase, can have a thorough and sympathetic (nonstudy) examination done at no cost, if desired. The highest of our budget projections, therefore, reflects payment for comprehensive (Ranch Hand-like) examinations for 6,000 men per cohort. These costs would be markedly reduced if the VA decided to provide in its facilities the physical examinations and laboratory test for the remaining 4,000 men per cohort.

I would like you to know the background which formed the basis of our recommendation for conducting the Agent Orange and Vietnam Experience studies concurrently.

First, it is possible that Vietnam veterans do suffer poorer health than their counterparts who did not serve in Vietnam; however, such poor health could be due to a variety of causes other than Agent Orange exposure. An Agent Orange study alone will not test other causative factors. If the Agent Orange study alone is done and no health differences are found between exposed and nonexposed veterans, it would be reasonable for Vietnam veterans to ask if their self-perceived poorer health is due to causes other than Agent Orange. Also, once protocol development is complete, an Agent Orange study will take about 4 1/2 years to produce results.

If a Vietnam Experience study is found necessary after the completion of the Agent Orange study, an additional 5 or more years will be required for new protocol development and data collection and analysis. Thus, beginning both

studies in parallel will avoid unnecessary delays in providing information which veterans anxiously await. Moreover, the total costs will be less if the studies are done in tandem, because there will be less duplication of effort and because of economies of scale.

Second, the development of criteria defining exposure and nonexposure to Agent Orange will be difficult. Even though considerable thought has been given to this issue over the past 3 years by several groups, no general consensus has emerged. Obtaining a consensus on the acceptability and validity of exposure criteria from all interested parties (including veterans groups, as suggested by the National Academy of Sciences review panel) will be time-consuming, and indeed may not be possible. As you know, it was uncertainty about the definition of Agent Orange exposure in Vietnam which led to the passage of the section of PL 97-72 which permitted the expansion of the mandated Agent Orange study (PL 96-151) to include an assessment of the Vietnam experience. Public and congressional expectations are that a scientifically sound study can be done and that this study will be done quickly. Limiting attention only to an Agent Orange study may prove to be shortsighted. Concurrent development and early implementation of a Vietnam Experience study will provide the best opportunity to be responsive to public and congressional expectations and to assure that a feasible and scientifically sound health effects study will be conducted even if consensus cannot be reached regarding Agent Orange exposure.

Two other issues merit discussion. First, in addition to ongoing and proposed Federal research activities, there may be other opportunities for clarifying Vietnam-related health issues. A concerted effort should be made to explore ways in which currently available data can be used. For example, the VA's Patient Treatment File might provide a mechanism for investigating the health of Vietnam veterans. CDC is available to consult with the VA on ways in which these and other data might be used, but CDC is not seeking an active role in such studies.

The second issue is the suggestion in CDC's protocol outline that the study cohorts should be assessed for mortality every 5 years for the "foreseeable future." This extended followup has not been included in CDC's budget estimate, since it is not clear which agency would have responsibility.

In summary, we propose:

(1) That a Vietnam Experience study, as well as an Agent Orange study, be conducted;

(2) That the VA commit to provide to CDC the necessary positions and funds, up to 50 FTE's annually and a cumulative total up to $150 million; and

(3) That the VA approve the enclosed interagency agreement to provide immediately $3 million and 28 FTE's to CDC so that protocol development may proceed expeditiously.

I look forward to your review and early response to these proposals.

Sincerely yours,

Edward N. Brandt, Jr., M.D.
Assistant Secretary for Health

Enclosures

Protocol Outline
Tentative Timetable
Epidemiological Studies of the Health of Vietnam-Era Veterans (Agent Orange)

Overall Design

The Centers for Disease Control (CDC) recommends two complementary historical or retrospective cohort studies. One study will compare the health of a group of U.S. veterans of the Vietnam conflict with the health of a group of Vietnam-era veterans who did not serve in Vietnam; it may include individuals from all four branches of the military. The purpose of this study will be to make an assessment of the possible health effects of the general Vietnam service experience. The other study, which is designed to evaluate the health effects of possible exposure to herbicide Agent Orange, will compare the health of three groups or cohorts of Vietnam veterans who differ in their probable level of exposure to Agent Orange. This second study will focus primarily on veterans of the Army but will probably include veterans of the Marine Corps.

Each of these two studies will have three major components: 1) a mortality assessment (mortality followup will be repeated every 5 years for the foreseeable future); 2) a health and exposure questionnaire; and 3) a clinical and laboratory assessment. The studies will have several other features in common. However, the sampling plans and some of the health outcomes measured in the questionnaire and clinical assessments will differ between the two studies. Moreover, they will follow different timetables. They are designed to answer related but distinct questions of importance to Vietnam veterans and their families.

These two studies should be sufficient to meet the directive of Congress which instructed the Veterans Administration to conduct an "epidemiological study"; in addition, they are responsive to current veterans' and congressional concern. However, these studies are but a part of the Federal effort to provide answers about the possible health effects of herbicides and their contaminants, and about the effects of military service in Vietnam. Other major Federal activities include: 1) CDC's ongoing study which is designed to determine if Vietnam veterans are at increased risk of fathering babies with birth defects; 2) CDC's NIOSH Dioxin Registry, which will assess the health effects of occupational exposure to dioxin during the manufacture of herbicides and related chemicals; 3) the U.S. Air Force's comprehensive health study of veterans who applied herbicides in Vietnam from fixed-wing aircraft ("Ranch Hand" study); 4) the Veterans Administration's (VA) proportionate mortality study of Vietnam veterans; the VA is also supporting protocol development for a study of twins, one of whom went to Vietnam and one of whom did not.

Composition of Cohorts and Sampling Plans

The choice of individuals for inclusion in the various study cohorts will derive from review of military records from the Vietnam era. Considerable

thought about and work with records from Vietnam has been done by the Department of Defense (primarily staff of the Army Agent Orange Task Force--AAOTF), the Veterans Administration, and the White House Agent Orange Working Group. A consensus seems to have been reached that the choice of individual veterans for an Agent Orange study will involve the use of personnel records and company level action records and a variety of herbicide usage records. More thought needs to given to the specific organization and analyses of records which might be used for a Vietnam Experience study, but it is recommended that company level records also be used for this study.

a) Agent Orange Study

A good design for a historical cohort study of the possible health effects of Agent Orange would involve the use of 2 groups of men who were as similar as possible in all respects except for their exposure to the herbicide. One group would ideally be free from all exposure while the others would have been subjected to "meaningful" exposure. (Other attractive designs might include subdivisions of those exposed based on levels and/or duration of exposure, or even continuous measures of exposure for individual veterans.)

It appears that such an ideal is not attainable. Obstacles include: 1) the military records which must be used were made during a war and, therefore, of uneven quality; 2) an inability to define objectively "meaningful" exposure; 3) the difficulty in ensuring that veterans who were possibly or likely exposed (by whatever measure) are comparable (with respect to all things which might influence health) to veterans who were not exposed. Under ordinary circumstances, such obstacles would probably prevent the initiation of an Agent Orange study. It is, therefore, mandatory that advance advice and consent be obtained from veterans' groups with respect to study policies and procedures, especially those directed at defining Agent Orange exposure.

The important company records which give information about troops are the morning reports and the journal files. The morning reports can be used to document the presence or absence of individual servicemen on a daily basis while the daily journal files will indicate the locations of companies in time and space. The major herbicide records are those which document the time and location of fixed-wing aircraft applications of herbicide (Ranch Hand missions--contained on the "Herbs" tape), base perimeter applications records, and information about Ranch Hand mission aborts (dumps). The choice of an individual for inclusion in the "likely-exposed" cohort will be based on a measure of company proximity in time and space to herbicide applications as documented by these records. Members of the "non-exposed" cohort will likewise be chosen because of a measure of their company's distance in time and space from any herbicide applications.

The company records may contain gaps (i.e., whole periods of time missing) and are probably quite variable in terms of quality and detail, because they were created during the war. The herbicide usage records are known to contain errors with respect to the time and location of applications and the degree of their completeness is unknown. They are far from ideal as the starting point for an historical cohort study. There may be opportunities to assess the accuracy and completeness of the herbicide usage records, and every effort will be made to pursue these opportunities. However, there are no possiblities for similar checking of the company troop records. Thus, the categorization of individuals with respect to their potential for herbicide exposure will be uncertain and will forever remain so.

The desire to ensure that troops classified as "exposed" to Agent Orange are comparable to "non-exposed" troops with respect to other factors which might influence health is another issue which makes it difficult to design an "ideal" study. The underlying problem is that the use of herbicide was not equally distributed in Vietnam. Areas where it was heavily used were generally combat areas and differed in terrain and flora from those areas where it was little used. These areas may also have differed in other important respects, such as, indigenous diseases, level of combat intensity, and type of personnel deployed. It is for these reasons that much of the recent thinking about the subdivision of troops into "exposed" and "non-exposed" groups has been directed at choosing the cohorts from the same area of Vietnam. Unfortunately, because of the inherent limitations of the records, this approach may have the effect of increasing exposure misclassification (especially the categorization of those who are truly "exposed" into the "non-exposed" group). These two competing forces, the desires for comparability and for maximum exposure separation, have drawn CDC to recommend a three-cohort design. Two of the three cohorts will be from the same area of Vietnam (and time during the war) but will differ in regard to their exposure likelihood. These two cohorts will be comparable but suffer from imprecision of exposure separation. The third cohort will be drawn from another area of Vietnam (but from the same time period), an area where there is good evidence of little or no herbicide usage. This cohort will give maximum exposure separation from the "exposed" cohort but may suffer from a lack of comparability in respect of other health-influencing factors. This design is incomplete, as is illustrated in the following 2 x 2 table which cross-classifies exposure by a measure of general experience, which will be called "combat."

		Agent Orange Exposure	
		Yes	No
"Combat"	Yes	Cohort 1	Cohort 2
	No		Cohort 3

The empty cell, representing the combination of Agent Orange exposure with no "combat," cannot be filled, because it is our understanding from the military that Agent Orange use was inextricably entwined with a certain "combat" experience. Because of its incompleteness, this design will present problems in analysis and interpretation. Moreover, the comparison of the first and third cohorts, which will ensure maximum exposure separation, may be subject to respondent bias; respondent bias should not be a problem in a comparison of cohorts 1 and 2, because individual respondents will probably be uncertain about their (study) exposure status. Despite these problems, we believe that this design is better than either of the other alternatives based on an approach which uses only two cohorts--either decreasing exposure misclassification by decreasing comparability or increasing exposure misclassification by increasing comparability. The results of the Ranch Hand study, currently being conducted by the U.S. Air Force, may help in the interpretation of this incomplete design. The Ranch Hand study will compare the health of crews who flew the herbicide spray missions with air crews who did not fly spray missions. Thus, it will provide information about Agent Orange exposure in the absence of the general experience of ground troops.

b) Vietnam Experience Study

The idea of studying ill-health effects which might derive from the "general experience" of having been in Vietnam is at once attractive and unappealing. It is attractive because there may have been many factors which could have adversely affected those who served in Vietnam, in contrast to their counterparts who served elsewhere. And it is also plausible that Vietnam veterans who did not see active combat in Vietnam were subjected to health-influencing events that were not part of the experience of those who served elsewhere. Any study which focuses on Agent Orange alone will obviously not test such a plausible multifactorial hypothesis.

However, the multifactorial nature of this hypothesis makes the study of the "Vietnam experience" unappealing from the scientific point of view. The "experience" comprises many factors, many of which are unknown, poorly defined, or not quantifiable. Nevertheless, it is our opinion that this is an important question to the Vietnam veteran, and one which deserves as much attention as the issue of the possible effects of Agent Orange.

Viewed in the broadest terms, the Vietnam "experience" could have influenced anyone who served there. It is, therefore, suggested that consideration be given to the inclusion of veterans of the Army, Navy, Marines, and, if possible, the Air Force (the records systems of the Air Force might make inclusion of that service's veterans very difficult).

A major concern about the validity of making a comparison of Vietnam and non-Vietnam veterans derives from an undocumented suspicion that there may have been preexisting differences between the two groups in terms of health-influencing factors and behaviors. If such differences existed and if they applied to all veterans, then a valid study of the Vietnam "experience" would not be possible. However, military personnel with whom we have consulted do not feel that such factors would have existed for all Vietnam veterans. Specifically, it is their belief that being sent to Vietnam was a matter of the "luck of the draw" for those who were drafted or who were short-term enlistees. Serving in Vietnam, the U.S., in Europe, or elsewhere was, in their opinion, a matter which depended on occupational specialty and the operational needs of the various commands. Thus, any given serviceman was at risk of serving anywhere where there was a need for his occupational specialty.

Choice of individuals for the two cohorts of this study should be made after a review of company and personnel files in much the same manner as will be done for the Agent Orange study. A simple random sample or a stratified random sample of Vietnam veterans and non-Vietnam veterans would probably be the method of choice but the filing of the available records probably makes this infeasible. Therefore, we recommend a cluster sampling of military units (much as will be done for the Agent Orange study) and a random sampling within clusters as the method for selecting members of each cohort.

Sample Sizes

It is recommended that each of the 5 cohorts (3 Agent Orange study and 2 Vietnam Experience) be composed of 6,000 servicemen. All of these individuals will be included in the mortality studies, and it is hoped that up to 90% of the surviving cohort members will be included in the questionnaire phase of the studies. (The results of the Ranch Hand study, better than 95% interview completion, give reason to set such an optimistic goal. If, however, the questionnaire pilot studies give indications of completion rates much under 70 or 75%, careful consideration should be given to not proceeding with the main studies.) The number of 6,000 for each cohort was chosen because comparisons between 2 groups of between 5,000 and 6,000 each will be able to detect (alpha = beta = 0.05, 1-tail) 2-fold increases in the relative risk for health outcomes which ordinarily occur at the rate of 0.5%, for example, all cancers (detecting associations for specific cancers would require truly massive cohorts--this problem is probably best approached through specific case-control studies).

For the clinical and laboratory phases, it is suggested that random samples of 2,000 from each cohort be chosen. It is hoped that as many as 80% of those chosen will participate and, as with the questionnaire phases, if the pilot study shows rates much below the 70% level, it will be necessary to question the wisdom of proceeding with the main study phases. The number 2,000 was chosen because samples between 1,500 and 2,000 will give good power (alpha = beta = 0.05, 1-tail) to detect 2.5-fold increases in the risk of outcomes which usually occur at the rate of 1.0%.

(The major health outcome categories from which the questionnaire and clinical laboratory phases will be developed during protocol design and review are listed in a later section of this outline.)

Study Sequences

Three phases are planned for each of the 2 studies and each phase will culminate in a separate report. The 3 reports will concern 1) mortality experience of the cohort members; this phase of the study will also give an indication of the proportion institutionalized, 2) the results of the health questionnaire, and 3) the results of the clinical and laboratory tests. It is anticipated that work will proceed first on the Vietnam Experience study because there will be less work involved in selecting the cohort members than there will be for the Agent Orange study. Within each study, ascertainment of vital status will be a part of the process of locating cohort members for the health questionnaire and clinical/laboratory phases. Thus, mortality analysis will be completed first; reports on the health questionnaire and clinical/laboratory analyses will follow later. Even though these studies are subdivided into phases, it is expected that at some point in time work will be proceeding simultaneously on both studies (see schedule, later in this outline).

The major steps which will be required to complete the two studies are (after full protocol design and approval and after pilot testing of procedures):

1) Selection of individual cohort members by the Army Agent Orange Task Force (AAOTF)

   For the Vietnam Experience study, identifying information about the cohort members will be transmitted to CDC immediately after selection. For the Agent Orange study much more work will be required of AAOTF personnel because of the need to review exposure information. Identifying information about cohort members for each study will arrive at CDC in small batches, possibly on a monthly basis, as they are selected. Therefore, the selection will be done in such a way that an appropriate balance of "exposed" and "non-exposed" for the Agent Orange study and of Vietnam and non-Vietnam veterans for the Vietnam Experience study are included in each batch.

2) Vital Status Determination and Location of Cohort Members

   As soon as a batch of information for study individuals is received, a check will be made against the Beneficiaries Identification and Records Location System (BIRLS) files and the National Death Index to try to ascertain those individuals who are deceased. For those who are found to be dead, collection of death certificates, pathology reports and other relevant material will ensue. Procedures to determine the location of those currently alive will begin simultaneous with the checks against the BIRLS and National Death

Index--the first step will be to check against Internal Revenue Service (IRS) files, which is a rapid and inexpensive method to obtain relatively current addresses for taxpayers. For those individuals who are not found on the BIRLS file or National Death Index and who are also not found on the IRS files, more expensive and time consuming methods of location will be used. The goal for both studies will be a location rate of 95% for those who are presumed alive.

3) Health Questionnaire

Interviews of about 45 minutes in length will be conducted by telephone where possible. For potential respondents without telephones, personal interviews will be conducted at a place convenient for the respondent; for potential respondents who are institutionalized, personal interviews will be conducted at the place of institutionalization. The major outcomes from which questionnaire items will be chosen during the stage of full protocol development are listed later in this outline. The goal for both studies will be an interview completion rate of better than 90% of those located.

4) Clinical and Laboratory Examinations

Clinical examinations of the 2,000 individuals from each of the 5 cohorts will take place at 1 or 2 examining facilities, much like that used by the Ranch Hand study. The physical examination will include a standard, good quality review of systems. Multiple laboratories may be used for the various laboratory tests, but each particular test will be performed in a single laboratory. Special emphasis will be given to the clinical and laboratory outcomes which will be chosen during protocol development from among those which are listed later in this outline.

Vietnam Experience Study
Tentative Timetable

This tentative timetable is divided into 2 phases - protocol development and study implementation. However, some tasks which are formally a part of the implementation phase are scheduled to begin during the development phase. This approach is proposed so that there will be no unnecessary delays in the event that the protocol review goes smoothly and according to schedule. Month number 1 for each study phase begins at the time resources are made available to CDC by the VA.

Study Phase	Month Number		Major Milestones
Protocol Development	1	o	recruit new personnel and short-term consultants for protocol development
	2		
	3	o	complete development of protocol
	4	o	complete peer review of protocol
		o	complete preliminary work with military files for sample selection
		o	begin developmental work for contracts for questionnaire administration, clinical and laboratory work
	6	o	complete OMB review
		o	complete selection of pilot study samples
Study Implementation	1	o	begin selection of main study samples
		o	begin final formatting of questionnaires and clinical instruments
	2	o	begin data collection for main study mortality analysis
	6	o	award contract for questionnaire administration

Vietnam Experience Study
Tentative Timetable (continued)

Study Phase	Month Number		Major Milestones
	7	o	begin questionnaire pilot study
	10	o	award contract for clinical and laboratory studies
	11	o	begin clinical and laboratory pilot study
		o	evaluate questionnaire pilot study
	12	o	obtain OMB approval for any revisions to main study
	13	o	begin questionnaire main study
	16	o	evaluate clinical and laboratory pilot study
	17	o	begin clinical and laboratory main study
	23	o	complete study sample selection
	32	o	complete mortality study data collection
	35	o	REPORT mortality study analysis
	36	o	complete questionnaire data collection
	41	o	complete clinical and laboratory data collection
	42	o	REPORT questionnaire analysis
	47	o	REPORT clinical and laboratory data collection

Agent Orange Study
Tentative Timetable

Timetable for this study will parallel the Vietnam experience study timetable in the early phases (i.e., protocol development and review). Because of the extra time required to review military records for determination of Agent Orange exposure, data collection for the 3 study phases (mortality, questionnaire, clinical) will begin approximately 6 months after the comparable phase of the Vietnam experience study. Accordingly, the reports will appear 6 months later:

Study Phase	Month Number	Major Milestones
Study Implementation	41	o REPORT mortality study analysis
	48	o REPORT questionnaire analysis
	53	o REPORT clinical and laboratory data collection

8.

Congress of the United States
OFFICE OF TECHNOLOGY ASSESSMENT
WASHINGTON, D.C. 20510

JOHN H. GIBBONS
DIRECTOR

March 3, 1983

Honorable Harry N. Walters
Administrator
Veterans Administration
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Dear Mr. Walters:

A little more than three years ago, in December 1979, Congress mandated that the Veterans Administration (VA) conduct a study of possible long-term health effects associated with exposure to herbicides, specifically "Agent Orange," during the Vietnam War. The same Public Law (PL 96-151) also directed the Office of Technology Assessment (OTA) to approve the design of and monitor the conduct of the study. Following passage of the law, VA contracted with the University of California at Los Angeles (UCLA) to design the study protocol. As required by PL 96-151, OTA reviewed each draft of the UCLA design and reported its comments to the Veterans Affairs Committees and the Appropriations Subcommittees on HUD and Independent Agencies in both the House and the Senate. In June of 1982, OTA approved the UCLA protocol and urged that the VA test several aspects of the protocol in preparation for the full-scale study.

In September and October of 1982, criticisms of VA's handling of the study reached a crescendo, and VA began negotiating an agreement with the Centers for Disease Control (CDC). According to that agreement, signed in January 1983, CDC is responsible for designing and executing the study. By mid-January, CDC had prepared an outline of the proposed study.

OTA received a copy of CDC's outline on February 2, 1983. Copies were forwarded to the members of the OTA Agent Orange Review Advisory Panel (membership roster appears at the end of the enclosed review), and the members mailed or phoned in their comments to OTA staff.

As a result of the CDC involvement in the study, this OTA review is being sent also to the Congressional Committees with jurisdiction over the Department of Health and Human Services. Those Committees, the Senate Committee on Labor and Human Resources, the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, the House Appropriations Subcommittee on Labor - Health and Human Services - Education, and the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will be included in all mailings and reports from OTA concerning Agent Orange.

OTA is pleased with CDC's outline. In a few pages, it presents convincing information that they have grasped the complexities of the problem and devised or soon will devise methods to carry out the study. CDC has tackled the problem of whether to study Agent Orange or the broader "Vietnam experience" by proposing two studies. The option of studying the Vietnam experience is provided by PL 97-72, passed in November 1981, which gives the VA Administrator discretion to expand the scope of the study from a focus solely on Agent Orange to the broader question. The two studies together address the questions of greatest concern to veterans and their families: What, if any, are the health effects of 1) exposure to Agent Orange, and 2) service in Vietnam, which may have included exposures to Agent Orange, other chemicals, drugs, and other factors in an exotic environment? OTA is in full concurrence with the proposed studies as they have been outlined.

CDC expects to complete the drafting of a protocol in late April or early May. That date now appears realistic to CDC, but some concern has been expressed that completion of the protocol may be delayed unless personnel positions promised to CDC in connection with these studies are indeed made available. OTA will, as required by PL 96-151, review that protocol within 30 days and final approval of the protocol will be considered at that time.

For your information, I am enclosing a copy of a paper that was presented at the 1982 Annual Meeting of the American Public Health Association by Michael Gough and Hellen Gelband. The paper provides a review of events since the passage of PL 96-151. If Committee Members or staff desire further information about Agent Orange or OTA's role in the Congressionally-mandated study, please call me (224-3695) or Dr. Gough, director of the OTA review, or Ms. Gelband (both at 226-2070).

Sincerely,

John H. Gibbons

Enclosure

Office of Technology Assessment

Review of the Centers for Disease Control

"Protocol Outline and Tentative Timetable for

Epidemiological Studies of the Health of Vietnam-Era Veterans (Agent Orange)"

March 1983

Brief Description of the Proposed Studies

The Centers for Disease Control's (CDC) outline lays out a plan for two concurrent studies: an Agent Orange Study and a Vietnam Experience Study. The former will concentrate on the health effects of exposure to Agent Orange. The latter will assess health effects of service in Vietnam.

The basic design -- an historical cohort study -- will be the same for both studies, but the studies will differ in the details of cohort selection and data collection. The health outcomes to be investigated in the two studies were not specified in the CDC outline, but there is expected to be some overlapping of the outcomes between the two studies.

The Agent Orange Study will compare three cohorts of 6,000 men each: 1) troops defined as "exposed" to Agent Orange, who served in combat areas; 2) troops defined as "non-exposed" to Agent Orange, who served in combat areas; and 3) troops defined as "non-exposed" to Agent Orange, who served in non-combat areas. Veterans of the Army and probably the Marine Corps will be included in the Agent Orange Study.

The Vietnam Experience Study will compare two cohorts of 6,000 men each: 1) veterans who served in Vietnam; and 2) veterans who served during the Vietnam era but did not go to Vietnam. Veterans of the Army, Navy, and

Marines and, if records permit, the Air Force, will be included in the Vietnam Experience Study.

CDC describes three basic components for each study:

1. A mortality assessment (mortality followup will be repeated every 5 years for the foreseeable future).
2. A health and exposure questionnaire, which will differ somewhat for the two studies, to be administered by telephone when possible. The goal is to secure the participation of more than 90 percent of those located. Participation rates much under 70-75 percent will be cause to consider not proceeding with the studies.
3. Clinical and laboratory examinations, to be conducted on a random sample of 2,000 from each cohort. Examinations will take place at one or two facilities. The goal for participation for this phase is 80 percent; less than 70 percent would be cause for concern.

CDC's strategy is well thought out and sound. They clearly and concisely describe the basic structure for the Agent Orange and Vietnam Experience Studies. CDC has, in a very short time, become aware of the many difficulties of doing these studies. The imperfect knowledge of exposure to Agent Orange, which, in CDC's words, "will forever remain so," has driven the design of the Agent Orange Study. Together, the studies fulfill the Congressional mandates of both PL 96-151 (that called for a study of possible health effects associated with exposure to Agent Orange) and PL 97-72 (that authorized the VA to expand the scope of the study to investigate possible health effects associated with service in Vietnam).

The studies proposed in the outline address the questions of greatest concern to veterans and their families: What, if any, are the health effects of 1) exposure to Agent Orange, and 2) service in Vietnam, which may have included exposures to Agent Orange, other chemicals, drugs, and other factors in an exotic environment? OTA is in general concurrence with the proposed studies as they have been outlined. Final approval will be considered when the detailed protocol is reviewed.

CDC's efforts to secure the advice and support of the veterans' organizations is applauded. The current outline has been discussed with the major organizations and their comments solicited. CDC mentions its desire for "mandatory...advance advice and consent" (p. 2, para. 3) from veterans' groups. While unanimous agreement is the ideal, what course would CDC take in the absence of unaminity?

At this point, it remains for CDC to complete full-scale protocols for the studies. OTA understands that protocol development is proceeding and expected to be complete by about May 1983. Progress is hampered to the extent that CDC does not yet have the required personnel slots described as necessary to plan and execute these studies. Getting fully under way depends upon the Office of Management and Budget's completing transfer of the necessary positions to CDC.

OTA is prepared to review the full protocol as soon as it is available. A meeting of the Agent Orange Advisory Panel will be convened and a report written within 30 days after receipt of the protocol as is required by PL 96-151.

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General Comments

CDC has made an impressive and laudable start toward planning and executing perhaps the most difficult and certainly the most controversial epidemiologic studies of our time. OTA, because of its Congressional mandate, feels no less responsible in assuring that the studies are the best possible. With that in mind, and in a spirit of cooperation, some general and specific comments and concerns are offered in the following pages. OTA has provided a copy of this review to CDC.

Timetable

CDC has presented a very optimistic timetable. The physical examination schedule would require completing examinations on an average of 20 individuals per day, an enormous task for any institution. In addition, the time left between completing data collection and reporting results is quite short, considering that as many as 30,000 questionnaires and 10,000 physical examinations may be conducted. As the details of the studies are worked out, changes in the timetable might be necessary.

Specification of Outcomes

CDC has not yet specified any health outcomes that are of interest for either study. To some extent, data collection instruments and clinical examinations depend upon looking for specified conditions and symptoms. Significant health effects for the two studies may differ considerably. For exposure to Agent Orange, there are suggestions, from both animal studies and epidemiology, that some health effects are more likely than others.

Hypotheses about effects of the Vietnam experience have been aired to a much lesser extent. For health effects more plausibly associated with exposure to either Agent Orange or Vietnam in general, the studies can be seen as "hypothesis testing." For other possible, but unexpected and biologically less plausible effects, the studies will be "hypothesis generating." In the full protocol, some distinction should be made between the more and less likely outcomes, allowing also for entirely unexpected findings. Tests of specific hypotheses should state, to the degree possible the number of events that are expected, the confounding variables and the potential methods of analysis.

The authors of the outline mentioned the expected usefulness of the ongoing CDC birth defects study and the Ranch Hand study in developing the protocols. Although we are certain that CDC is aware of the Australian Agent Orange study, we mention it here because it may contain important lessons for the design of the CDC studies.

Conditions for Participation

No mention is made in the outline of possible incentives for participation in the studies. This is particularly important for the 10,000 veterans selected for clinical examinations. With only one or two examination centers, a significant amount of time will be needed to complete the examinations. Furthermore, veterans selected for examination will be inconvenienced by having to travel to an examination center. This is an area where the veterans' organizations will likely be extremely helpful, both in suggesting fair and equitable solutions and in helping to obtain cooperation from veterans. This aspect will affect the participation rate and therefore the integrity of the study and should be brought into consideration early on.

The Agent Orange Study

The outline properly acknowledges the difficulties of assigning veterans to "exposed" or "non-exposed" cohorts in the Agent Orange Study. However, several specific comments made in the outline deserve elaboration in the protocol. The extent to which choosing "exposed" and "non-exposed" cohorts from the same area of Vietnam will increase the chance of misclassification (p. 3, para. 2) deserves exposition. If the "areas" are very small, chances of misclassification might be very high; if they are larger, the chances should be smaller.

The arguments advanced for including Cohort 3 in the study stem from the problems of misclassifying veterans between "exposed" and "non-exposed." Addition of that cohort will increase the size and cost of the study. Attention should be given to estimating the magnitude of the misclassification problem in order to justify inclusion of the third cohort. The protocol designers, if they choose to include the third cohort, should discuss possible interpretations if health outcomes differ between Cohort 2 and Cohort 3, both of which are "control groups." The protocol designers might also reserve a final decision about the third cohort until the pilot study is complete. The pilot study may shed a great deal of light on the magnitude of possible misclassification.

The characterization of the study design as "incomplete" (bottom of p. 3) because one cell ("no combat"-"Agent Orange exposure") of a 2 X 2 table cannot be filled seems inappropriate. The fact that logically a cohort of veterans does not exist in the cell of a hypothetical table does not make the design incomplete. Rather the absence of those veterans dictates the type of study that can be done.

The Vietnam Experience Study

Description of the Vietnam Experience Study is rather sketchy. OTA is concerned that the groundwork for the Vietnam Experience Study may need to be laid more fully before the study can begin. CDC foresees being able to begin this study before the Agent Orange study gets under way. Since the passage of PL 96-151 in December 1979 and even before, attention has focused on Agent Orange and its possible effects. CDC is breaking new ground in studying the Vietnam experience. The outline states that the Vietnam experience comprises many factors which are "unknown, poorly defined or not quantifiable." OTA expects that the protocol will contain some discussion of these and the better known factors. This task should not be underestimated. The existing literature about the effects of war must be consulted, but that will not be sufficient. In addition to the stresses and exposures common to all wars, Vietnam presented new and varied conditions which, to the extent possible, should be made explicit.

The method of cohort selection for the Vietnam Experience Study has not yet been worked out. Again, a great deal of effort has gone into developing a cohort selection method for the Agent Orange Study. After three years of steady progress, that system may be nearly ready. While the conceptual problems for the Vietnam Experience Study cohort selection are fewer, CDC is pioneering this effort, and its plans and expectations need to be described fully.

The truth of the "luck of the draw" (p. 5, para.1) — random allocation of soliders to Vietnam or to other theaters — requires further examination before the full study begins. A small scale comparison of randomly selected

representatives of the Vietnam and non-Vietnam cohorts on baseline variables could be considered to find out if, in fact, the two groups are similar. Standard epidemiologic techniques to improve comparability of the cohorts will undoubtedly be employed by CDC.

The outline mentions a "cluster sampling of military units," but no details are presented. Will full companies be the sampling units for both the Agent Orange and Vietnam study? The full protocol should present the arguments for the chosen sampling method. It is not immediately apparent that the same sampling technique should be used for both studies.

The practical need to limit participation in the Agent Orange Study to males has been argued and largely accepted during the past three years. The same arguments may or may not apply to the Vietnam Experience Study. OTA is suggesting neither that women be included nor excluded, but that the question be considered by CDC.

Specific Comments

Sample Sizes

The outline states that a random sample of 2,000 from each 6,000-man cohort will be chosen for clinical examination. Is a random sample the best approach? The alternative is to use information from the questionnaire interviews to select a proportion of the 2,000. A scoring system based on a combination of responses might be used to target high risk individuals, which in turn could increase the power of the examination sample. Targetting only a portion, say half of the 2,000, would allow for unexpected findings from the randomly selected group, and would allow the examinations to begin before the interviews are completed.

The outline is properly cautionary (p. 5, para. 3) in stating that the proposed studies will not reveal associations between Agent Orange or Vietnam service and relatively uncommon health outcomes, speicific cancers, for instance. Examination of such associations, which may be suggested during the course of the outlined studies, may require case-control studies.

The outline provides a brief description of the statistical power of the studies. When the protocol is developed, the power of the studies to detect increases of specified magnitudes for each outcome should be included.

Health Questionnaire

The tentative list of items for the health questionnaire is seriously deficient in reproductive outcomes. Questions about infertility, birth defects and miscarriages should be included. These questions can, of course, be related to information now available and soon to be available from the Ranchhand study and CDC's birth defects study.

General anesthesias as well as surgical procedures should be queried.

Sensitivity to bisulfites should be considered in allergy section.

A question about excessive salivation or drooling, and speech slurring should be asked.

In the neuropsychiatric section, questions about hallucinations, flashbacks, phobias and fears might be considered.

The protocol whould descuss how the study designers will interpret or employ possible contradictions between exposure classifications based on the exposure index and those based on individual recall at the interview.

Physical Examination

Retina should be included in eye examinations.

Peripheral pulses should be included in cardiovascular examination.

The neurological portion of the physical examination does not specify the particular attributes that will be assessed except for "motor systems." The components are all standard for neurologic testing except for "emotional responses," which needs clarification. Also, it may not be necessary to include mental status when extensive psychological testing is also being done. As much as possible, sensory tests should be quantified and objective, rather than subjective measurements. This is particularly important given the fact that polyneuritis is one of the most plausible health effects of Agent Orange, based on animal and human evidence from studies of 2,4-D and 2,4,5-T.

Psychological Testing

As noted in the outline, the psychological testing section requires additional consultative advice. In general, it appears that some selection of subtests from the instruments listed will be necessary and desirable. A slant more toward detecting emotional and affective disorders, and less emphasis than currently on cognitive disorders should be considered. The Diagnostic Interview Schedule (DIS), for example, might be an appropriate addition. Another component of psychological testing that should be considered is a measure of an individual's perception of control of his environment (referred to as "desired health locus of control"), for which standardized tests are available.

Laboratory Tests

Consider adding a battery of endocrinology tests related to fertility.

Office of Technology Assessment

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December 1982

CONGRESSIONALLY MANDATED REVIEW OF AN AGENT ORANGE EPIDEMIOLOGY STUDY

Michael Gough and Hellen Gelband
Office of Technology Assessment
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Agent Orange and Phenoxyacid Herbicides

Agent Orange, a 50:50 mixture of n-butyl esters of 2,4-dichlorophenoxyacetic acid (2,4-D) and 2,4,5-trichlorophenoxyacetic acid (2,4,5-T), was the herbicide most widely used during the Vietnam war. The mixture contained a number of contaminants, including varying amounts of the class of chemicals known as "dioxins," which are by-products of the synthesis of 2,4,5-T. 2,3,7,8-Tetrachlorodibenzo-para-dioxin (TCDD), one of the most toxic chemicals known, was the most common dioxin. As much as 170 kg of TCDD may have been disseminated in Vietnam before 1970, when the use of Agent Orange was drastically curtailed because of studies done in the United States that showed 2,4,5-T caused birth defects in laboratory animals.

Estimated amounts of TCDD sprayed in Vietnam, which are based on concentrations of TCDD measured in small number of archived samples of herbicide, are little more than guesses. For one thing, there is no way of knowing how representative the stored samples are. It is generally assumed

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that the herbicide sprayed in the early years, when few U.S. troops were in Vietnam, contained much higher levels of TCDD than did the herbicide used in the peak spraying years of 1967-69.

Health Effects of Agent Orange and Its Contaminants

The components and contaminants of Agent Orange have been tested for toxicity in a number of animal systems. They have been found to be teratogenic and carcinogenic in animals, and, in fact, are toxic to essentially every organ system in one or another experimental animal.

At the present, there is no evidence from epidemiologic studies that Agent Orange, as used in Vietnam, has caused any adverse long-term health effects. However, studies in other settings have produced evidence of associations between exposures to phenoxyacid herbicides and certain cancers.

The most convincing evidence of human carcinogenicity is from studies that showed an association between phenoxyacid exposure and soft-tissue sarcomas. The first published evidence was two case-control studies from areas in Sweden where herbicides were extensively used in forestry and agriculture. Corroborating evidence comes from a number of studies of exposed workers in this country which showed an association between soft-tissue sarcomas and phenoxy acids. A number of studies done elsewhere in the world, however, have not detected an increased risk of soft-tissue sarcomas. Coggon and Acheson, who reviewed the evidence linking phenoxy herbicides and cancer in man, judged the evidence strong enough to warrant further study of this rather diverse group of tumors (The Lancet, May 8, 1982, pp. 1057-1059). Most

of the health effects that have been suggested as sequelae of Agent Orange exposure have not been studied in human beings at all.

A Congressionally Mandated Study of Possible Health Effects Resulting from Exposure to Agent Orange

Since the end of the Vietnam conflict, attention has been drawn to adverse health effects being suffered by veterans. To a major extent, complaints centered on Agent Orange as a possible cause, and in December 1979 the U.S. Congress responded to the concern and complaints. Public Law 96-151, passed at that time mandates that the Veterans Administration (VA):

> 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.

In the same law, Congress directed that the study be "conducted in accordance with a protocol approved by the Director of the Office of Technology Assessment [OTA]," and further that the OTA Director monitor the conduct of the study.

The task of approving and monitoring an executive branch study is an unusual one for OTA. As one of the four Congressional support agencies -- the others being the Congressional Research Service (CRS), the General Accounting Office (GAO), and the Congressional Budget Office (CBO) -- OTA is charged with providing unbiased information about technical matters to assist Congressional decisionmaking. The Office is organized into nine programs, including the Health Program, where the Agent Orange project is located, and it prepares

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reports, upon request from Congressional committees, about the applications, implications, impacts, and possibilities of technologies. As will be seen in this paper, CRS and GAO, as well as OTA, have been involved in the attempts tp resolve the controversies around Agent Orange.

The Constitutional Issue of Separation of Powers

The President signed the law mandating the VA study and OTA's role in it in late December 1979. A few days later, on January 2, 1980, he vetoed a bill that required the Department of Health, Education and Welfare (HEW) to undertake a study of the possible long-term health effects resulting from occupational exposures to dioxins. The HEW bill, like the VA bill, mandated that the OTA approve the study plan and monitor the conduct of the study. In his review of the HEW bill, President Carter decided that the requirement that OTA, a Congressional agency, was to approve an Executive Branch study was a violation of the separation of powers between the Legislative and Executive branches of government. The law was, in his view, unconstitutional.

In his veto message, the President stated that although he had signed the VA Law, he had instructed the VA Administrator to ignore the provision that OTA was to approve the study plan. His reason for so instructing the Administrator was the same as for vetoing the HEW bill; he saw the OTA approval role in the study as a violation of the separation of powers.

The question of the constitutionality of OTA acting to approve Executive Branch studies was referred by the Senate to the American Law Section of the CRS. In the opinion of CRS, which works for Congress, OTA's role was constitutional, and the President's veto was without merit. Of course, the

Executive Branch has lawyers too, and it turned to the Justice Department and asked for an executive branch opinion. Not unexpectedly, the Justice Department agreed with the President's veto. Congress then went back to CRS and asked them to comment on the Justice Department opinion. As you might expect, CRS reaffirmed its earlier conclusion that the OTA role was constitutional and that the veto was not justified. Since neither branch of government has elected to go to court to resolve the constitutionality of the bill requiring OTA approval of the HEW study, there is no answer to the questions raised by the HEW bill and its veto.

So far as we know, there has been no request for legal opinions about the President's instructing the VA to ignore the Congressionally-mandated requirement for OTA approval of the VA study. Soon after President Carter issued his instruction, Senator Cranston, who at that time was Chairman of the Senate Veterans' Affairs Committee, wrote to the VA Administrator and suggested that ignoring the law of the land was not a wise course of action. He pointed out that Congress must approve funds for the study and that Congress will require OTA approval of the study plan.

The working relationship between OTA and VA, and, indeed, between OTA and all the executive branch agencies involved in Agent Orange, has been generally cordial and cooperative. For instance, OTA was named as an observer and has been an active participant in Executive Branch working groups concerned with Agent Orange.

Changes in Opinion About the Possibility of Executing an Agent Orange Study

Two types of information are necessary to determine who was likely to

have been exposed to Agent Orange. The first is knowledge about where and how much of the herbicide was used; the second is where troops were relative to the herbicide.

Before late 1979, there seemed to be no reason to try to determine who might have been exposed because the Department of Defense claimed that ground troops did not enter areas that had been sprayed until four to six weeks after spraying. By that time, it was thought that most of the Agent Orange would have been degraded. That opinion was discredited by the results of a GAO study published late in 1979 (U.S. Ground Troops in South Vietnam Were In Areas Sprayed With Herbicide Orange. United States General Accounting Office, Washington, D.C., November 16, 1979). GAO showed that relatively large numbers of Marines (about 5900 in I Corps, the northern section of South Vietnam) were within 0.5 kilometers of areas sprayed with Agent Orange on the day of spraying. In fact, some units were directly in the path of spray missions.

Equally important, the methods used by GAO showed that the movement of troops, at least at the battalion level, could be tracked over the course of time, and their movements and positions matched with the locations and times of Ranch Hand spray missions.

At the time of the GAO study, the only information available about Agent Orange use was Air Force records of spraying from fixed wing aircraft, C-123's, during Operation Ranch Hand. During the last two and a half years, a group of Army records experts has wrung more and more information from the existing records. Now information is also available about spraying from helicopters, around base perimeters, and accidental exposures following jettisoning of large amounts of herbicides in emergencies.

During the period when it seemed impossible to study the effects of Agent Orange, Congress wrote a law that allows the VA Administrator, if he deems it appropriate, to:

> expand the scope [of the study]...to include long-term adverse health effects...[from] other herbicides, chemicals, medications, or environmental hazards or conditions...

As more information about exposures became available, opinions changed, and in November of 1981, OTA and officials from the Executive Branch testified before the Senate that a study of Agent Orange appeared possible. However, development of additional exposure information did not dampen all enthusiasm for studying the Vietnam experience, either by itself or as part of the same study that focuses on Agent Orange.

Development of a Protocol for the Study of Ground Troops Exposed to Agent Orange

The VA acted quickly to develop a protocol after the enactment of PL 96-151 in December 1979. In February 1980, the VA published its intention to have the study protocol prepared by a outside contractor, and in March, issued a Request for Proposal (RFP). Four proposals were received and were reviewed by the VA's selection board composed of government experts. In May, a legal challenge to the validity of the contracting process, brought by the National Veterans Law Center, stopped the contracting process. Resolution of the challenge was not complete until February 1981, and no work was done on development of the protocol during the time May 1980 through February 1981.

During that time, another provision of the law requiring the Agent Orange study was activated:

> In the event that the Director [of OTA] has not approved

> such protocol during the one hundred and eighty days following the date of the enactment of ths Act, the Director shall (I) submit to the appropriate commitees of the Congress a report descibing the reasons why the Director has not given such approval, and (II) submit an update report on such initial report each sixty days thereafter until such protocol is approved.

The 180 days was up at the end of May 1980, which meant that from that time forward, the OTA director wrote to six Congressional committees every two months to let them know that he had not approved a protocol because, in fact, there was no protocol to consider for approval. This condition did not change until August 1981.

After resolution of the conflict about contracting procedure, the VA solicited and received revised proposals from the original bidders on the RFP. In early May 1981 a contract, calling for delivery of the study protocol in 60 days, was awarded to the University of California at Los Angeles (UCLA) School of Public Health. UCLA was granted an additional 30 days to revise the draft protocol after review comments were received from the OTA and other groups. After an initial visit to the Pentagon by the UCLA investigators revealed previously unknown records which were of great potential value for the study, UCLA requested and was granted a 30-day extension of the contract. The 90 days was a short time for preparing a protocol, and effectively UCLA had less time for certain tasks, because the VA had not arranged appropriate clearances for the investigators to examine Department of Defense documents needed to develop ideas about exposure.

OTA Review

Each major OTA project has an advisory panel, composed of technical

experts and representatives of all major stakeholders in whatever the topic may be. The OTA Agent Orange advisory panel includes four academic epidemiologists and biostatisticians; three industry representatives (a corporate medical director, a vice president for environmental policy, and an epidemiologist), two of whom work for chemical companies named in a class action lawsuit brought by a group of veterans against the manufacturers of Agent Orange; representatives of three veterans organizations; two additional medical specialists (a neurologist and a specialist in birth defects); an academic pharmaceutical chemist; a lawyer, and a public representative who is a chemical engineer and who was a state toxic substances commissioner.

The OTA advisory panel met in early September 1981 and produced a very critical review of the first protocol that VA received from UCLA. We reported to Congress and the VA that the protocol was so general and vague that it was impossible for OTA to consider approval. In part, the lack of detail was a consequence of the relatively short time UCLA had to prepare the protocol. But the expressed intention of the investigators to withhold details to protect the integrity of the study also contributed to the lack of detail. While we agreed that it might be preferable to withhold certain details of the protocol from the public until the study is completed, it is impossible to review such a protocol for the purpose of approving it.

The UCLA draft protocol proposed a large cohort study of exposed and non-exposed veterans and five smaller studies to produce more immediate results. OTA recommended that UCLA drop the five preliminary studies of mortality and morbidity and concentrate on the proposed long-term cohort study.

The VA decided that the first document was not acceptable even as a draft protocol, which meant that UCLA would have two opportunities for revision.

The protocol writers received a 90 day period to produce what would be considered as the draft protocol, and a 30-day revision period to respond to reviewers' comments.

After some delays, the VA received the new draft protocol in late January 1982. The OTA advisory panel met in mid-February to consider the new document, which was a vast improvement over the original. The protocol included a proposed questionnaire and physical examination for the study, generally described a well-considered study, and dropped the five preliminary studies that OTA had criticized. It was not a finished protocol that could be put to immediate use, but it did provide enough information for OTA to identify the items that needed further attention and to make suggestions for improvements.

An interesting feature of the January protocol was that it contained a proposed exposure index that had been developed by Department of Defense (DoD) representatives to the Executive Branch Agent Orange Working Group. The DoD document, which was an Appendix to the protocol, emphasized the possibility of expanding the study to include a third cohort. The third cohort would be made up of Vietnam-era veterans who had not served in Vietnam and would provide a comparison group to study the total effect of the "Vietnam experience." Neither UCLA as authors of the protocol nor OTA as reviewers endorsed the expansion of the study. Subsequently, in the fall of 1982, the National Academy of Sciences reviewed the protocol, and they, too, opposed expansion of the study. However, another review group, the Executive Branch's Agent Orange Working Group, recommended expansion of the study to include the Vietnam experience as a risk factor.

UCLA's final document, which was accepted as meeting the terms of the

contract by the VA, did not contain plans for a third cohort. As it turned out, VA never decided whether the study was to concern only Agent Orange or to be expanded to study the Vietnam experience.

In March, OTA sent its review to Congress and the VA, along with a letter conditionally approving the protocol, pending further improvements. The UCLA investigators accepted most of OTA's suggestions and produced a revised questionnaire and physical examination. OTA reviewed the revised protocol internally, and sent a letter to Congress and the VA approving the protocol in June of this year.

Events Subsequent to OTA's Approval of the UCLA Protocol

In September 1982, almost three years after passage of the law requiring the Agent Orange study, a series of events began which resulted in VA's relinguishing control of the study to another government agency. Charges repeatedly made that the VA was moving too slowly were voiced again at a House of Representatives Veterans' Affairs Committee hearing on September 15, 1982. Many of the issues discussed there and some additional ones raised in a "60-day" letter from OTA Director Gibbons to Congress on September 30th focused criticism on VA. For instance, VA had employed neither an epidemiologist nor a statistician in its Agent Orange office, and it had still not decided between an Agent Orange only study and some other kind of study. Congressman at the hearing threatened legislation to take the study away from VA. A week later, 101 Congressmen signed a critical leter to VA, the Senate Veterans' Affairs Committee wrote a letter of general dissatisifaction, and, perhaps most important, no Representative or Senator came forward on behalf of VA.

8-24

A letter from Representative Montgomery, Chairman of the House Veteran's Affairs Committee, suggested that VA hand over conduct of the study to the Centers for Disease Control (CDC) in the Department of Health and Human Services (HHS). VA responded by writing to Secretary Schweiker of HHS to ask about CDC's takiing on the study. It is now a foregone conclusion that CDC will do the study through some contractual arrangement with VA, which will probably be signed in January 1983. The study will likely include 2 parts: one a study of Agent Orange; the second a study of the Vietnam experience. If so, the two parts will be conducted separately and each have its own control group.

Summary

From its conception, this study of the possible long-term health effects of Agent Orange has been anything but a purely scientific investigation of a possible cause and effect relationship. Congress mandating a study is somewhat unusual, and Congress's mandating the OTA review is unique. The organization responsible for carrying out the study, the VA, suffers from a lack of credibility, whether deservedly so or not, among the people it serves, the same people who would stand to benefit from the results of the study. The exact importance of the lack of credibility in the decision to hand the conduct of the study to CDC cannot be measured, but it must have played a role. That action demonstrates that acceptance or rejection of the study depends not only on the integrity of the study design and execution, but to some extent on the general credibility of the organizations and individuals who eventually carry out the study and interpret the results.

Evaluation of OTA's role in the Agent Orange study is difficult.

However, Congressional Committee staff have expressed praise and appreciation for the OTA reviews, which have aided them in making sense of a complex technical issue. Furthermore, we have been thanked for keeping Congress informed of developments that have not been directly related to the protocol.

The Agent Orange study will surely go ahead and will probably be completed. However, as important as it is to establish whether Agent Orange has caused long-term health effects, the study will leave some policy issues unresolved. Consider the outcome if the study is negative: Veterans have real complaints. A study showing that either Agent Orange or the Vietnam experience is not the cause will not likely lead the veterans to stop pressing their cases and claims. Instead, they may ask for additional studies or for compensation as more just and, perhaps, less costly than additional studies. Consider that the study is positive: If relatively common diseases are associated with exposure to Agent Orange or service in Vietnam, someone will have to apportion the impacts of the exposure or service in making compensation payments. Such problems will remain after the study is complete, and the government will be left with even more difficult decisions.

Updated January 1983

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

MAR 4 1983

Donald L. Custis, M.D.
Chief Medical Director
Department of Medicine and Surgery
Veterans Administration
Washington, D.C. 20420

Dear Dr. Custis:

Thank you for your letter of January 13 regarding the interagency agreement related to the Agent Orange/Vietnam Experience Study which you signed on that date. I co-signed and returned the interagency agreement on January 14.

As you suggested, we will include the periodic mortality followup effort as part of the Centers for Disease Control study and will include it in the budget proposal in support of the full study. Also as you suggested, we will not recommend that the Veterans Administration Medical Centers participate in or conduct examinations of veterans involved in the study. If it is decided that all study subjects receive a physical examination and laboratory workup, we will include that as part of the budget proposal. We are currently developing and will send you in the very near future a Fiscal Year 1984 budget proposal which will be our best estimate subject to change upon final approval of a protocol.

As a final matter, I am pleased that the VA is willing to make an advanced payment of $3 million from its FY 1983 budget to initiate the study. Equally important, however, are the 28 positions and the 14 FTEs which are required this year. You should note however, that the personnel resources required in FY 1984 may be at least 55 depending on the outcome of the protocol development. Consistent with Sections III(B) and VI(A) of the memorandum of understanding, I am requesting that VA expeditiously take the action necessary to obtain OMB approval to transfer these resources. For your convenience, I have enclosed a draft letter to the Office of Management and Budget. If further justification is needed for this request, please let me know.

Sincerely yours,

Edward N. Brandt, Jr., M.D.
Assistant Secretary for Health

Enclosure

Dr. Kenneth W. Clarkson
Associate Director
Human Resources, Veterans and Labor
Office of Management and Budget
Old Executive Office Building, Room 262
Washington, D.C. 20503

Dear Dr. Clarkson:

The purpose of this letter is to request your assistance to transfer FTEs from the Veterans Administration (VA) to the Centers for Disease Control (CDC). As you know, the VA has been working closely with the CDC to develop a comprehensive Agent Orange/Vietnam Veterans Exposure Study. The enclosed material, which has been provided to your staff, provides a justification of the resources required to undertake this study. At the present time, we estimate that CDC will require 28 people to undertake this activity.

The VA has already concurred by interagency agreement to transfer $3 million to CDC to design a protocol for the study. The VA has also agreed to allocate 28 positions and 14 FTEs in FY 1983. Personnel resources required in FY 1984 may be as many as 55 depending on the results of the protocol.

As stated in the interagency agreement, CDC will be able to proceed with development of the protocol and preparations for study implementation only when full resources, including the requested positions and FTEs, are available. I am therefore requesting that you take the action necessary to transfer these positions and FTEs to CDC so that this study can be initiated.

Sincerely yours,

Conrad Hoffman
Assistant Deputy Administrator for
Budget & Finance
Veterans Administration

9-2

AGENT ORANGE-VIETNAM EXPERIENCE STUDY
PROTOCOL DEVELOPMENT STAGE--FY 83

I. Program Objective

To design a protocol for and conduct an epidemiological study to detect any long-term adverse health effects in veterans of military service in Vietnam and of exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced as contaminants in the manufacture of such herbicides.

II. Program Mandate

Public Law 96-151, Section 307, mandates that the Veterans Administration (VA) design a protocol and conduct an epidemiologic study to determine if veterans of the Vietnam conflict suffer long-term adverse health effects from exposure to dioxins produced in the manufacture of phenoxy herbicides including Agent Orange. Public Law 97-72 permitted the expansion of the protocol design and study to include exposure to other herbicides, chemicals, medications, or environmental hazards or conditions. Members of Congress recently urged the VA to "contract with the Centers for Disease Control (CDC), Atlanta, Georgia, to conduct all phases of the Agent Orange Study." The Administrator of Veterans Affairs, in a letter dated October 4, 1982, to the Secretary of the Department of Health and Human Services (HHS), agreed to have CDC conduct the study.

An Interagency Agreement transferring from the VA to CDC the responsibility for the design, implementation, analyses, and interpretation of the epidemiologic study in accordance with Section 307(a)(1) of Public Law 96-151 as amended was signed by the VA on January 13 and by HHS on January 14, 1983. The agreement stipulates that CDC is not obligated to undertake the study unless adequate resources are provided.

The Secretary of HHS, the Assistant Secretary for Health, and the Director of CDC have assigned a high priority to this complex epidemiologic study. The positions requested represent a positive response to this priority and are necessary in order to undertake and expedite this study.

III. Workload

Over the past few years an increasing number of Vietnam veterans have expressed concern that they have experienced an abnormally high frequency of certain illnesses. Much of their concern has been centered on their presumed exposure to Agent Orange, a herbicide that was widely used for military purposes in Vietnam. Agent Orange was contaminated with a highly toxic substance, dioxin, which is carcinogenic and teratogenic in experimental animals. It is possible that Vietnam veterans do suffer poorer health than their counterparts who did not serve in Vietnam; however, such poor health could be due to a variety of causes other than Agent Orange exposure. To answer these questions about the possible health effects of military service in Vietnam and exposure to Agent Orange, it has been agreed that CDC would design a protocol for and conduct an epidemiologic study.

In preparation for undertaking this task, CDC assembled a committee to consider options for study design. The outline of the study plan proposed by this committee, which was submitted to the VA prior to the signing of an Interagency Agreement, calls for two separate but parallel studies. One study will compare the health of three groups of Vietnam veterans who differ in their presumed level of exposure to Agent Orange. The second study will compare the health of a group of Vietnam veterans with a group of Vietnam-era veterans who did not serve in Vietnam (the likelihood of Agent Orange exposure in Vietnam veterans will not be a factor in the selection of subjects for this second study). Individual veterans will be selected for study on the basis of information contained in existing Department of Defense records. The first phase of each of the studies will be a mortality followup of group members. The second phase of the studies will involve a health interview with each of the surviving veterans who can be located and who is willing to participate. The third phase of the studies will consist of physical and laboratory examinations. Each of the two studies will be preceded by a pilot study, the purpose of which will be to test all proposed study instruments and procedures.

CDC will undertake to assemble a team of workers to: 1) develop a complete study protocol, including interview instruments, clinical and laboratory procedures, and study clearances including necessary information collection budget clearance packages; 2) have the protocol reviewed extensively by CDC staff and by outside consultants, including representatives of veterans groups; 3) work extensively with Department of Defense personnel to develop methods for choosing study subjects from personnel records, company-level action records, and a variety of herbicide-usage records; 4) develop contracts to obtain private sector assistance in locating, interviewing, and examining study subjects; 5) establish procedures and staffing responsibilities for maintaining close and strict monitoring of the performance of selected contractors; and 6) develop the data collection system including data collection instruments, system design, data output formatting, programming analysis and interpretation schema and methods, and format for reporting findings and recommendations.

It should be noted that CDC, in conducting studies where much of the necessary labor is obtained from outside sources, requires close and strict monitoring of all contractors' performance. These studies, because of their highly visible nature, will require special oversight efforts. Moreover, because of the magnitude of the studies and because they are each composed of several phases which will require differing contractor capabilities, CDC expects that a number of contracts will be awarded.

The 28 personnel requested will concentrate on the following areas/activities:

Project Director - Direct and supervise all aspects of the Agent Orange-Vietnam Experience Study. Provide epidemiological and other scientific guidance and coordination for protocol development and validation. Oversee development of scientific aspects of contracting instruments. Ensure that contractors follow protocol and ensure high quality data collection. Provide guidance on data analysis. Oversee report writing. Serve as focal point for issues and concerns related to Agent Orange - Vietnam Experience Study.

Project Manager - Responsible for all management and administrative activities related to the Agent Orange-Vietnam Experience Study. Provides and coordinates project activities relating to staffing, training, budgeting, procurement, interagency communication, and data systems.

Epidemiologist (4, including one senior epidemiologist serving as team leader) - Design epidemiologic protocol for the Agent Orange and Vietnam Experience Study. Epidemiology group to be organized into two subgroups: one for health interview related activities, the other for physical examination activities. Conduct an ongoing review of related literature. Maintain ongoing liaison and dialogue with other related studies (Ranch Hand, Australian, NIOSH, etc.) and concerned Federal agencies and veterans organizations. Participate in peer review of protocol and incorporate accepted modifications. Participate in design of data base system and statistical analysis of these data. Participate in design of Request for Contract (RFC) and selection of contractors. Monitor contractors' performance for adherence to protocol. Assist in epidemiological analysis and report writing.

Public Health Advisors (4) - Participate in the design and development of the study protocol, including definition of data bases and statistical analysis methods to be used. Two to be assigned to the health interview epidemiology subgroup, two to be assigned to the physical examination epidemiology subgroup. Serve as liaison to interested agencies, organizations, and individuals. Identify and evaluate other studies, related data, and information sources. Procure appropriate data and information. Provide programmatic consultation, oversight review to contractors and conduct performance audits.

Program Analyst - Participate with project management in the design and evaluation of the study protocol and data gathering instruments (questionnaires) to ensure that data required at all points of analysis are valid and able to be input readily to the project's computer programs. Is involved in designing data output formats and analysing their usefulness in meeting project goals.

Computer System Analysts (2) - Initiate, maintain, and update automated information management system to incorporate input data and produce desired output information in the desired format. Participate in identifying and procuring hardware and software needs. Participate in defining related personnel needs and provide appropriate training.

Computer Programmer - Program computer to accept study input data and produce desired output documents. Maintain and review computer programs as required.

Clerk-Typists (4) - Provide secretarial and clerical support for 16 professional staff. Maintain administrative files, answer telephones, make travel, conference, and meeting arrangements.

Laboratory Chemists (3) - Design and coordinate laboratory aspects of studies, including internal and external quality control of laboratory functions. Develop and validate appropriate reference materials. Develop protocol for specimen collection and treatment, laboratory data processing coordination and collection. Advise project director in selection of outside laboratories and serve on laboratory surveillance and patient data review committees.

Statisticians (3, including one senior to serve as team leader for statistical and all data processing requirements) - Participate in statistical design and development of the protocols by providing appropriate statistical models to meet the study's objectives. Determine sample sizes required to achieve desired precision. Determine when data collection procedures and mechanisms are appropriate for creation of computerized data files for the purposes of the study.

Information/Communications Specialist - Serve as primary project contact for veterans and for public information inquiries, and as liaison with counterpart functions at DOD, VA, and veterans organizations. Originate periodic public reports on project progress. Advise on interpersonal and interorganizational communications aspects of the project.

Questionnaire Design Expert - In participation with project scientific staff: design, evaluate, and validate a behaviorally practical and scientifically sound questionnaire (instrument) for use by contracted interviewers. Participate in training interviewers in use of the instrument.

Public Health Advisor - Provide an immediate contact for agencies and organizations located in the Washington, D.C., area. Function as liaison to DOD in selection of cohorts. Establish and maintain working relationships with other Federal agencies (IRS, VA, SSA, etc.) to obtain additional identifying and locating information on selected individuals.

Contract Management Specialist - Participate in the design and development of RFC's for the location, questionnaire administration, and medical examination of selected study participants. Participate in the review of contract proposal and selection of contractors. Participate in the negotiation, administration, and termination of related contracts.

TOTAL 28 positions.

IV. Relationship to Base Positions

This project will be conducted by the new organizational entity known as the Agent Orange Activity of the Chronic Diseases Division (CDD), Center for Environmental Health, Centers for Disease Control. Organizationally the project director will relate directly to the Director, CDD, who will serve as his immediate supervisor.

V. Staffing Strategy

The CDD is the organizational entity within the Centers for Disease Control charged with conducting epidemiologic investigation of potential adverse health effects related to environmental exposure. The dramatically increased concern related to toxic chemical and hazardous substance exposure has already taxed to capacity the CDD to fulfill its mission.

Due to the complexities of the operational and technical problems involved and the scope of this study, other alternatives would not provide the capacity and linkage necessary to make the type of response appropriate to this priority. CDC needs these personnel resources to undertake this study.

VI. Impact on Other Federal Programs

The proposed study is only one part of the Federal effort to provide answers about the possible health effects of herbicides and their contaminants, and about the effects of military service in Vietnam. Other major Federal activities include: 1) CDC's ongoing study designed to determine if Vietnam veterans are at increased risk of fathering babies with birth defects; 2) CDC's NIOSH Dioxin Registry, which will assess the health effects of occupational exposure to dioxin during the manufacture of herbicides and related chemicals; 3) the U.S. Air Force's comprehensive health study of veterans who applied herbicides in Vietnam from fixed-wing aircraft ("Ranch Hand Study"); 4) the Veterans Administration's (VA) proportionate mortality study of Vietnam veterans; and 5) the VA supported protocol development for a study of twins, one of whom went to Vietnam and one of whom did not.

Office of Budget
and Finance

Washington DC 20420

Veterans
Administration

MAR 17 1983

In Reply Refer To: 04

Mr. John W. Merck
Chief, Veterans Affairs Branch
Office of Management & Budget
Room 2013
Washington, D.C. 20503

Dear Mr. Merck:

Enclosed for your consideration is the proposed outline and request for personnel resources as submitted to VA by the Centers for Disease Control, DHSS, for the conduct of the epidemiological study mandated by Public Law 96-151. Also enclosed is a copy of the Interagency Agreement between Veterans Administration and Centers for Disease Control.

It is my understanding that further justification for the FTE is being prepared by CDC and that a meeting of the principals involved is scheduled at OMB on March 18 to further discuss this matter.

Sincerely,

CONRAD R. HOFFMAN
Assistant Deputy Administrator
Budget & Finance

Enclosure

9-8

RETURN TO 10A7

MAR 15 1983

10A7

Edward N. Brandt, Jr., M.D.
Assistant Secretary for Health
Department of Health & Human Services
Washington, D.C. 20201

Dear Dr. Brandt:

Thank you for your letter of March 4, 1983, in response to my letter of January 13. I am pleased to learn that you will complete, in the near future, the Fiscal Year 1984 budget proposal for the conduct of the epidemiological study. It is my understanding that OMB and the cognizant Congressional Committees will need budget figure estimates by fiscal year for the duration of the study.

My staff is working closely with the CDC administrative personnel to finalize the details for disbursing funds from VA to CDC using the $3 million currently available in the FY 83 budget for Agent Orange-related research. It is important to understand that the authority for obligation of these funds expires at the end of the current fiscal year. This fact adds to the urgency for finalizing CDC's FY 84 resource requirements.

We are also working with CDC and OMB to expeditiously achieve a resolution of the matter of personnel resources necessary to complete the protocol and initiate the actual study. To that end, a meeting has been scheduled at OMB on March 18 at which time CDC staff will discuss the proposed study methodology and the justification for OMB approval for the 23 position in FY 83 and the additional FTE for FY 84 and beyond.

The Veterans Administration will continue to support, in every way possible, CDC's efforts to initiate the epidemiologic study at the earliest date.

Sincerely,

DONALD L. CUSTIS, M.D.
Chief Medical Director

cc: 02C
101B11(2)

10A7:BSHEPARD:BAB:3-15-83

10A7

per Dr. Brandt release!

RETURN TO 10A7

9-9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date March 17, 1983

From Chief. Cancer Branch, CEH/CDD

Subject Duties related to 28 Requested Agent Orange Projects Positions

To Daniel VanderMeer
Associate Director, CEH

The following information is intended to be helpful to you in explaining Agent Orange Projects personnel needs to OMB.

In describing a matrix management system such as that which we plan to apply to these large and complex investigations, it is virtually impossible to state with any specicifity what duties individual staff members will execute at given points of time during the duration of the projects. Concise answers to a few germane questions will aid in understanding our personnel plans.

Question: What is the difference between the project director and the project manager?

Answer: The project director will have overall responsibility for the planning and execution of CDC's studies. The director will be a scientist (epidemiologist) and concentrate on providing scientific direction. The project manager will also have major overall responsibility for the planning and execution of the studies, but will concentrate on the numerous administrative matters which inevitably arise in the conduct of such studies.

Question: What is a Public Health Advisor?

Answer: A Public Health Advisor is a lay public health worker. Most of CDC's top administrative officers (in the non-scientific, non-medical categories) have risen through the Public Health Advisor ranks. The Agent Orange Projects Program Manager will be a Public Health Advisor.

Question: What Parts of CDC's studies will be done "in-house" and what parts will be done under contract?

Answer:

In summary, CDC staff will:

a) Design the full study protocols, including;
   1) specification of all items to be included in interview, examination and laboratory phases of the studies;
   2) design of interview instruments;
   3) design sampling methods and criteria for the eligibility of potential study subjects, and methods for locating study subjects;
   4) design data analytical methods;
   5) define criteria and methods for ensuring quality collection of interview, examination and laboratory data.

b) Assist the Department of Defense in the selection of study subjects.

c) Perform the first steps of locating study subjects (primarily in conjunction with the Internal Revenue Service).

d) Develop contracting instruments, review proposals and select contractors. Separate contracts will be awarded for the following areas:
   1) location of study subjects and interviewing;
   2) clinical examinations (more than one contract likely); and
   3) laboratory tests (more than one contract likely).

e) Monitor contractors' performance. This will likely include CDC-performed quality-control checks of interviews, clinical examinations, and laboratory tests. Full-time on-site monitors will likely be required for interview and clinical examination contractors.

f) Perform highly specialized laboratory tests for which no qualified private contractors are available.

g) Set up and monitor systems for data base management.

h) Develop and test data analytic methods and procedures; test methods on simulated data.

i) Perform data analysis.

j) Write reports on study findings.

CDC's contractors will be responsible for:

a) finalizing the format of the interview, examination, and some laboratory procedures;
b) locating and interviewing study subjects;
c) performing clinical examinations;
d) performing standard laboratory tests; and
e) editing raw data to provide CDC with "clean" data for analytic purposes.

Question: Why are several statisticians, epidemiologists, and public health advisors needed? Why are they needed for the duration of the studies?

Answer: The studies will require a matrix management system. The tasks to be undertaken by the various specialists will vary with the stage of the project. In the developmental phases, a team comprised of an epidemiologist, a behavioral scientist, a statistician, and public health advisor will concentrate on the health interview, another similar team will work on the clinical examination, while another team (including laboratory scientists) will work on development of appropriate laboratory protocols. A separate team of computer scientists will work on assessing the data processing needs of the projects; computer scientists will also devise specifications for contracts and handle early data manipulation tasks required for protocol development and pilot testing.

As the studies progress beyond the development stage, the teams will be reconstituted so as to comprise a team which will include all specialists for the Agent Orange study and another team for the Vietnam Experience study.

The various specialists are needed for the duration of the study to ensure that the data which will be developed by contractors will be of the best quality obtainable. The importance of close monitoring of contractors by both scientific and administrative staff cannot be overemphasized. In large measure, this derives from the fact that CDC will be contracting for data collection only--little or no design or analytic services will be purchased. If CDC were to be provided with the substantial numbers of additional positions which would be required to do the labor of data collection "in-house," a more extensive management operation would be required.

Moreover, it will be important to provide for continuity in the management of the studies, particularly from the standpoint of scientific management. The design of studies by a scientific team assembled now, followed by analysis of data several years hence by another team would violate important principles of good study conduct--evaluation of data collection requires intimate knowledge of the scientific aspects of study protocols and sound data analysis requires extensive knowledge of potential weaknesses and errors in the data. These principles can only be followed if a continuity of personnel is maintained for the whole course of the studies.

As mentioned earlier, the projects will utilize a matrix management system, shifting personnel to meet needs as they present over the duration of the studies. Simultaneous with the phasing out of some front end activities in early FY 84, personnel will be shifted to other activities and reorganized to initiate the following activities:

1. Develop RFP's for questionnaire administration (30,000 participants) and medical examinations (10,000 participants). Solicit contractor proposals.

2. Review and select contractors, orientate and consult with contractors. Put in place a logistical system (travel, etc.) for participants in medical examinations.

3. Select pilot sample of 1,500 (5% of 30,000) and conduct demonstration studies.

4. Monitor contractor's performance and evaluate data provided by them. Make necessary or appropriate adjustments to the systems/protocols.

5. Recruit and orientate additional staff to monitor/oversee contractor's performance and process data.

6. Initiate full scale studies at the rate of approximately 1,000 participants per month.

7. Monitor and provide consultation to contractors and evaluate incoming data for efficacy and flow of participants through studies system.

J. David Erickson, D.D.S., Ph.D.

Director
Centers for Disease Control

Agent Orange Epidemiologic Study Budget Options - ACTION

The Assistant Secretary for Health
Through: ES/PHS_____

BACKGROUND

The Veterans Administration (VA) and the Centers for Disease Control (CDC) have entered into an Interagency Reimbursable Agreement under which CDC will carry out the epidemiological studies authorized by Public Laws 96-151 (Section 307) and 97-72. The Agreement proposes that two related but separate epidemiological studies be conducted to determine whether Vietnam-era military veterans as a group, including those particularly most likely to have had significant exposure to the dioxin-contaminated herbicide "Agent Orange," suffer long-term adverse health effects. Funds and positions to design and conduct the studies are to be provided from monies appropriated to the VA.

The CDC intends that these studies:

1. Will be designed to resolve the issue of long-term health effects resulting from military service in Vietnam (especially in areas where Agent Orange was used) as compared to service outside of Vietnam during the same period.

2. Will be scientifically credible and compatible with one another so as to allow whatever interchange of data may be appropriate over time.

3. Will result in significant savings by a Vietnam Experience study being conducted simultaneously with one directed primarily to Agent Orange exposure. VA and CDC officials agree that both veterans and Congress are determined that both studies of the possible effects of Agent Orange exposure and the effects of military service in Vietnam be carried out.

The Interagency Reimbursable Agreement provides:

1. Financial support by the VA to the CDC in FY 83 for the developmental stages of the studies.

2. A mechanism ensuring continued support in FY's 84-87 for execution of the studies, contingent upon availability of funds and positions for implementation of the agreement, and for insuring that the necessary approvals for the study design are obtained.

9-14

The Agreement satisfies the financial requirements for the developmental stage of the studies, but as of this date personnel positions have not been made available. CDC has developed an outline for the protocol for the studies. However, before CDC begins development of a detailed protocol for the studies, approval of the general approach is sought from executive branch management and budget policy offices.

To that end, CDC program staff have prepared this options paper, including the best preliminary costs estimates of several alternatives, including the one strongly recommended by CDC on the basis that it represents the best possible scientific approach to the issues. Final costs of any option are surely to change, depending on the recommendations of review groups and other factors.

This paper presents six options: CDC Recommendation, Full Service, Mid-Range, Low Budget, Soft Tissue Sarcoma (cancer) Surveillance, and Zero Cost. Each option except the Soft Tissue Sarcoma Surveillance and the Zero Cost options will involve a participant base of 30,000 veterans (five cohorts of 6,000, including one cohort of Vietnam-era veterans who did not serve in Vietnam). This number was selected because it provides the minimum necessary participants to make statistically valid statements of correlation between service in Vietnam and health outcomes expected to be associated with dioxin exposure.

Several studies have indicated that a relationship may exist between exposure to dioxin-contaminated herbicides and the incidence of soft tissue sarcoma. An epidemiologic surveillance system will be established as a component of the CDC Recommendation, Full Service, Mid-Range, Low Budget and Soft Tissue Sarcoma Surveillance options. The systems will identify persons with soft tissue sarcoma and provide the basis for case-control studies to determine if Vietnam veterans are at increased risk of developing this cancer. The question of cancer incidence is one of keen interest among veterans and CDC is convinced that this subject must be investigated. Design implementation and management of the sarcoma surveillance will require $1,000,000 and 5 FTE's each year between 1984 and 1987.

Each of the options (with the exception of the Soft Tissue Sarcoma Surveillance and the Zero Cost options) call for collection of questionnaire data on living veterans among the 30,000 identified as participants and postmortem data on those who are deceased. The data analysis phase and the phase during which subsequent recommendations are defined are roughly comparable among each of the five options which involve studies. Thus, the major differences relate to the quantity and types of medical examinations called for by each option.

Since the period under study occurred approximately 15 years ago, locating these participants will be difficult and certainly costly. The most costly component of the studies, however, will be administration of comprehensive, "study quality," medical examinations (including laboratory work), and related expenses.

CDC will be entirely responsible for the study design, data analysis, and the conclusions of the studies. CDC does not intend to use its staff to locate, interview, or examine the participants, but it is critical that the work of the contractors conducting these activities be under the oversight and management of CDC scientists.

The following sections briefly describe the methodological and budget differences among all six options and contain the arguments for and against the characteristics of each.

1. CDC RECOMMENDATION

A comprehensive interview questionnaire would be administered to all living participants or postmortem data collected for the deceased from a group of 30,000 persons selected for the studies. Comprehensive, "study quality," medical examinations would be performed for a statistically valid sample of 10,000 participants (2,000 from each of five cohorts). Medical exams would not be offered or be provided under this study for the remaining 20,000 participants. Those not selected for the clinical examinations and laboratory tests would still be eligible for the usual medical services provided by the VA to Vietnam veterans.

Cost estimates: FY 84-87 $72,400,000 55 FTE/YR

PROS:

Requires administration of significantly fewer yet an adequate number of "study quality" physical examinations and laboratory tests, without sacrificing statistical validity and scientific acceptability.

Data collection and management costs are considerably less than for the Full Service and Mid-Range options.

Requires fewer resources (personnel, space, computer time, contractors' services, etc.) than Full Service or Mid-Range options.

CONS:

Reduced number of medical exams may invite (unwarranted) criticism of the studies' validity.

Groups and individuals who want all study participants to receive equally exhaustive "study quality" physical exams and tests may be concerned by a decision to withhold exams and tests from some.

The government could be criticized by veterans groups and others for failure to provide equal treatment and health services (physicals and tests) to all participating veterans.

2. FULL SERVICE OPTION

A specialized questionnaire will be administered to all living participants or specialized postmortem data would be collected from 30,000 persons. Comprehensive, "study quality" medical examinations will be performed for all willing participants (potential maximum of 30,000).

Cost Estimates: FY 84-87 $158,750,000 92 FTE/YR

PROS:

More veterans are likely to benefit by learning of illness or other conditions which might otherwise go undetected without the physical exams and laboratory tests received during these studies.

Larger numbers of "study quality" physical exams and lab tests will yield larger (and potentially more useful) data bases for future analyses.

Larger sample sizes are more impressive to nonprofessional critics of the study protocol and may stem their criticism.

The government is less likely to be criticized by veterans groups and individuals for apparent failure to provide equal treatment and health services (physicals and tests) to all participating veterans.

CONS:

The number of persons to be examined exceeds the sample sizes required to achieve statistically valid and scientifically acceptable results, and the resulting costs are significantly greater than options 1 and 3.

Requires more resources (personnel, space, computer time, contractors' services, etc.) than any other option and would cost twice as much as the CDC recommended option.

"How much is enough?" Even 30,000 thoroughly examined and tested participants may be too few to convince a small minority of the studies' validity.

3. MID-RANGE OPTION

Questionnaire or postmortem data would be collected from 30,000 participants. Comprehensive, "study quality" medical examinations would be performed for a statistically valid sample base of 10,000 participants (2,000 from each of five cohorts). Less expensive, or "routine," "life insurance quality" medical examinations would be provided on request to participants who are not selected to receive the comprehensive examinations necessary for the epidemiologic study.

For budget estimate purposes it is assumed that 50% of the 20,000 participants who would not receive "study quality" medical examinations will request routine examinations. None of the data from the routine physical examinations would be collected or analyzed by CDC or used in any other way for study purposes.

Cost Estimates: FY 84-87 $84,000,000 79 FTE/YR

PROS:

Requires administration of significantly fewer "study quality" physical examinations and laboratory tests than the Full Service option without sacrificing statistical validity and scientific acceptability.

Provides a means for participants who do not receive "study quality" medical examinations and who are concerned for their personal health to receive potentially helpful physical examinations.

Data collection and management costs are less than for the Full Service option.

Requires fewer resources (personnel, space, computer time, contractors' services, etc.) than the Full Service option.

Reduces risk of criticism for failure to provide "study quality" physical exams for all participating veterans.

CONS:

Smaller sample sizes may invite (unwarranted) criticism of the studies' validity.

Funds will be spent to provide physicals which will not contribute to studies' outcome.

Veterans' health problems which might have been identified during exhaustive "study quality" physical exams and lab tests may remain undiscovered in study participants who receive less thorough or no physical exams.

Groups and individuals who want <u>all</u> study participants to receive "study quality" physical exams and tests may be concerned by a decision to provide less thorough exams for some.

The government is likely to be criticized by veterans groups and individuals for apparent failure to provide equal treatment to all participating veterans.

4. LOW BUDGET OPTION

The questionnaire or postmortem data would be collected on 30,000 participants. No medical examinations conducted.

Cost Estimates: FY 84-87 $27,100,000 40 FTE/YR

PROS:

Requires fewer resources (personnel, space, computer time, contractors' services, etc.) than Full Service, Mid-Range and CDC Recommendation options.

Will take less time to complete the studies.

CONS:

There will be no medical exam data to confirm/validate responses to questionnaire.

An integral component of the studies' protocol will be eliminated.

Lack of physical exams and laboratory work will invite strong criticism of the studies' validity.

Participating veterans' health problems, which might have been identified during physical exams and lab tests, may remain undiscovered.

Groups and individuals who want all study participants to receive "study quality" physical exams and tests may be angered by a decision to withhold exams and tests.

The government is likely to be criticized by veterans groups and individuals for failure to provide necessary health examinations (physicals and tests) to all participating veterans.

5. SOFT TISSUE SARCOMA AND LYMPHOMA SURVEILLANCE OPTION*

Under this option only the retrospective soft tissue sarcoma and lymphoma surveillance system referred to in the general description of all other options which involve studies would be conducted.

Cost Estimates FY 84-87 $7,000,000 33 FTE/YR

PROS:

Requires fewer resources (personnel, space, computer time, contractors' services, etc.) than any option other than Zero Cost.

CONS:

Fails to meet Congressional mandate.

Fails to fully respond to Congressional and veterans' calls for investigation of perceived health problems other than sarcomas.

Non-responsive to interagency agreement with VA.

6. ZERO COST OPTION*

No epidemiological studies will be carried out after feasibility of doing the studies is fully explored.

May not reflect now but may emerge for consideration.

Costs Estimate: FY 84 $3,000,000 28 FTE

PROS:

Involves no resources beyond those expended to attempt to reach a valid protocol.

This option is presented only because it is recognized that it may not be possible to develop a protocol which is satisfactory or acceptable to the various scientific and policy review panels with review and approval authority.

CONS:

Fails to meet Congressional mandate.

There will be severe criticism for failure to respond to Congressional and veterans' calls for investigation of perceived health problems.

*Under these options it is anticipated that protocol development, review, and refinement will continue into FY 1984. FTE requirements would decrease to 5 for sarcoma option, and to 0 for Zero Cost option, for FY 85 and beyond.

RECOMMENDATION

I recommend approval of Option 1, which we believe to be both scientifically acceptable and cost effective.

Approved_____ Disapproved_____ Date_____

If you concur, please sign the transmittal letter to Dr. Custis of the VA and forward with it the budget submission prepared in their requested format.

William H. Foege, M.D.
Assistant Surgeon General

cc:
ES/PHS
CDC/W
OD
CEH

CDC:CEH:DVanderMeer/JGallagher:ms 3-30-83
Doc. #0318R

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

Donald Custis, M.D. (10)
Chief Medical Director
Veterans Administration
810 Vermont Avenue, NW.
Washington, D.C. 20420

Dear Dr. Custis:

Enclosed is the budget proposal for the CDC recommended option to conduct the Agent Orange Epidemiology Study for the period FY 1984 - FY 1987. A proposal for the soft tissue sarcoma case-control study, as discussed with your staff, is included at a cost of $4,000,000 and five FTE's for the four-year period.

Your expeditious review and submission of this request to the Office of Management and Budget will be necessary to ensure that it is amended to the Veterans Administration FY 1984 budget. Failure to obtain the necessary funds and personnel resources may result in a one-year delay in initiating the studies.

Sincerely yours,

Edward N. Brandt, Jr., M.D.
Assistant Secretary for Health

Enclosure

9-22

"AGENT ORANGE" EPIDEMIOLOGICAL STUDIES

PROGRAM DESCRIPTION

Public Law 96-151, Section 307, mandated the Administration to design a protocol and conduct an epidemiologic study to determine the possible long-term adverse health effects resulting from exposure of Vietnam veterans to chemical contaminants found in the herbicide "Agent Orange." Public Law 97-72 permitted the expansion of the protocol design and study to include exposure to other herbicides, chemicals, medications, or environmental hazards or conditions. An Interagency Agreement between the Administration and the Department of Health and Human Services (HHS) was signed on January 14, 1983, transferring from the Veterans Administration (VA) to the Centers for Disease Control (CDC), HHS, the responsibility for the design, implementation, analyses, and interpretation of the Agent Orange epidemiologic study in accordance with Section 307(a)(1) of Public Law 96-151, as amended. Resources to conduct the studies are to be provided by the Administration and transferred by Interagency Agreement to CDC. The CDC ceiling for positions and FTE will be increased to 55 for the duration of the studies.

The CDC protocol outline calls for two complementary retrospective cohort studies of Vietnam era veterans, and a parallel case-control study of soft tissue sarcomas and lymphomas. One veterans' study, which is designed to evaluate the health effects of possible exposure to the herbicide Agent Orange, will compare the health of three cohorts of Vietnam veterans who differ in their probable level of exposure to Agent Orange. This study will focus primarily on veterans of the Army but could include veterans of the Marine Corps. The other veterans' study will compare the health of a group of U.S. veterans of the Vietnam conflict with the health of a group of Vietnam-era veterans who did not serve in Vietnam; it may include individuals from all four branches of the military. The purpose of the second study is to make an assessment of the possible health effects of the general Vietnam service experience.

Each of these two veterans' studies will have three major components: 1) a mortality assessment (mortality followup will be repeated every 5 years); 2) a health and exposure questionnaire; and 3) a clinical and laboratory assessment. Although the studies will have several other features in common, the sampling plan timetables and some of the health outcomes measured in the questionnaire and clinical assessments will differ between the two studies. They are designed to answer related but distinct questions of importance to Vietnam veterans and their families.

The choice of veterans for inclusion in the various study cohorts will derive from review of military records from the Vietnam era. Considerable work with records from Vietnam has already been done in consultation and cooperation with the Department of Defense (DoD) (primarily staff of the Army Agent Orange Task Force--AAOTF) and the White House Agent Orange Working Group. DoD will assist in identifying and locating study participants in accordance with the Agent Orange study protocols developed by CDC.

The parallel case-control study will identify male patients between the ages of 30 and 49 years who have presented with soft tissue sarcomas or lymphomas. DoD records and personal interviews will establish the probability of these individuals' exposure to Agent Orange during service in Vietnam. A control group of men will be identified, with similar demographic characteristics but not known to have soft tissue sarcomas or lymphomas. DoD records will be used to establish the likelihood of exposure to Agent Orange of members of the control group who also served in Vietnam. The study results will be based upon analysis and interpretation of differences between the case and control groups.

JUSTIFICATION OF ESTIMATES

The VA funding obligation for FY 84 is estimated to be $56,500,000, and supports 55 FTE. This estimate incorporates funds for most of the contracted activities through FY 87. These activities include: locating and interviewing study participants, conducting medical examinations and laboratory analyses, and surveillance of sarcoma and lymphoma cases and controls. A multi-discipline matrix management system approach will be used to: 1) complete development of final, detailed, scientific protocols for the studies; 2) conduct pilot tests to validate participant locating, data collection and processing methods; 3) establish committments with contracted organizations that will conduct the main body of participant interviews and examinations and arrange for participant travel; and 4) set up logistical support and contract monitoring for the studies, and initiate the Agent Orange and Vietnam Experience studies. [redacted]

Beginning in FY 84 and continuing through FY 87, the Administration's funding obligation is expanded to support an additional 27 FTE, bringing the total CDC Agent Orange Projects staff to 55 FTE. These additional positions will be utilized in an expanded matrix management system, and are required for conduct of the actual edpidemiological studies; i.e., contracts monitoring, data systems development and anaylsis, statistical model development, data collection and interpretation, laboratory quality control, preparation of reports, etc.

Doc. No. 3301N
3/30/83

AGENT ORANGE PROJECTS, CEH:CDD
OBLIGATIONS BY OBJECT
(dollars in thousands)

		1982 Actual	1983 Budget Estimate	1983 Current Estimate	1984 Estimate	1985 Estimate	1986 Estimate	1987 Estimate	1988 Estimate
10	Personal Services	$ 0	$ 900	$ 614	$ 3000	$ 3150	$ 3300	$ 3040	$ 0
21	Travel and Transport of persons:								
	Employee Travel		55	39	300	315	330	275	
	All Other		138	99	60	20	15	10	
	Subtotal		193	138	360	335	345	285	
22	Transportation of things		42	30	30	30	10	10	
23	Communications, utilities and other rent		49	35	50	60	60	50	
24	Printing and reproductions		13	10	25	50	50	30	
25	Other Services (Contracts)		117	111	53000	5000	20	20	
26	Supplies and Materials		9	6	10	10	10	10	
31	Equipment		1677	1200	25	15	5	5	
32	Lands and structures		0	0	0	0	0	0	
	Total Obligations	$0	$3000	$2144	$56500	$8650	$3800	$3450	$ 0

Doc. No. 3301N
3/30/83

3,000
- 2,144
+ $856

12-6

Agent Orange Studies Budget
Justification by Object Class
FY 1984

10 Personal Services - Salary, fringe benefits, and indirect cost for 55 FTE's. The increase of 27 FTE's in FY 1984 will be required to carry out the implementation activities of promotion, consultation, contract administration and monitoring, data collection and analysis, and laboratory work.

21 Travel and Transport - Temporary duty travel for information dissemination, program consultation and promotion, liaison activities with veterans organizations, contract monitoring and management, and changes of duty station. Advisory committee travel.

22 Transportation of Things - Relocation of household goods related to change of duty station and equipment and records shipments.

23 Communications, Utilities, and Other Rent - Telephone, electric, mail and rental charges related to the studies.

24 Printing and Reproductions - Preparing and printing materials (including protocol) for staff orientation and use in response to professional, public, and congressional inquiries. Development and printing of promotional materials.

25 Other Services - The contract mechanism will be utilized for locating, interviewing, and providing medical examinations for study participants and for supporting consultant services. The estimated cost of the contracts for the duration of the study, $55,000,000, will be required to locate and interview 30,000 study participants ($500 each) and to provide quality medical examinations to 10,000 ($4,000 each). $2,000,000 in contracts will support information collection and analysis related to a soft tissue sarcoma case-control study. An additional $5,000,000 is budgeted in FY 1985 to assure continuity and completion of contract activities.

26 Supplies and Materials - Purchase of general office and laboratory supplies. The purchase of laboratory supplies, including reference materials and analytically certified controls for multiple analyses to develop external quality assurance systems for contract laboratories, and storage facilities, containers and racks for maintaining quality control materials under stable conditions.

31 Equipment - Maintenance and upgrading of data processing and word processing equipment for conduct of studies. Acquisition of equipment necessary to assure the security of data.

Doc. No. 3299N
3/30/83

APR 8 1983

Mr. Dale Sopper
Assistant Secretary for
Management and Budget
Department of Health and Human Services
Washington, D.C. 20201

Dear Mr. Sopper:

This is in response to your March 21, 1983 letter to adjust the Department of Health and Human Services full time equivalent (FTE) ceiling.

The request to transfer responsibility for conducting all phases of an Agent Orange study from the Veterans Administration to HHS's Centers for Disease Control including 14 FTE in FY83 is approved. Since this study will be for a limited duration, associated increases in your employment ceiling will be provided only until the study is completed. Therefore, it is assumed that new employees associated with this increase will be appointed on a nonpermanent basis.

The transfer to the Department of Justice's Community Relations Service of 13 FTE in FY83, effective March 7, 1983, is approved. These are resources necessary for the Department of Justice to carry out responsibilities for Cuban and Haitian entrant reception and processing activities (transferred from HHS to Justice in FY82).

Adjustments in your FY84 FTE ceiling will be made upon agreement with VA on the number of FTE to be transferred; and upon agreement between HHS and the Department of Justice on the number of FTE to be transferred.

Accordingly, the employment ceilings for the Department are revised as follows:

Full-time Equivalent (FTE) Employment	1983
FROM	
Total Employment	142,000
TO	
Total Employment	142,001

Sincerely,

Joseph R. Wright, Jr.
Deputy Director

cc: Official file -- IM Branch
DO Records
Director's Chron
Mr. Wright
Mr. Moran
Mr. Clarkson
Mr. Strauss
Mr. Modlin
Mr. Kleinberg (2)
office chron

HIMD/IM -- Jwong: dlb -- 3/29/83

9-28

VA Chron

APR 6 1983

Honorable Harry N. Walters
Administrator of Veterans' Affairs
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Dear Harry:

This is in response to your request for additional employment for fiscal year 1983 to conduct the Agent Orange epidemiological study transferred to the Centers for Disease Control, Department of Health and Human Services (DHHS). Since the staffing for this study had not been included in the employment ceiling for your agency, the required 14 full-time equivalent (FTE) workyears are being provided to the Veterans Administration (VA) for use by CDC in the conduct of this study for fiscal year 1983. The net effect of this action is no change in your 1983 employment ceiling of 217,113, with your additional 14 FTE provided to the DHHS.

Sincerely,

JOE

Joseph R. Wright, Jr.
Deputy Director

cc:
Official File-VA Branch
DO Chron
Mr. Wright
Mr. Moran
Mr. Clarkson
Mr. Strauss
Mr. Modlin
Mr. Martin (2)
Mr. Kleinberg
Mr. Zafra
VA Chron

Rooney #7 "3/30/Walters"

LVED:ARooney:jk 3/30/83

15425

9-29

Veterans Administration
Department of Medicine and Surgery
Washington, DC 20420

CIRCULAR 10-82-185

September 16, 1982

TO: Directors, Medical Centers, Medical and Regional Office Centers, Regional Offices, Regional Offices with Outpatient Clinics, Domiciliary, and Outpatient Clinics

SUBJ: Guidelines for Implementation of Legislation Related to the Provision of Health Care Services to Veterans Exposed to Dioxins

1. The "Veterans' Health Care, Training, and Small Business Loan Act of 1981" was signed into law on November 3, 1981. The Act, Public Law 97-72, authorizes the Veterans Administration to provide certain health care services, as described in paragraph 3, to any veteran of the Vietnam era (August 5, 1964 - May 7, 1975) who while serving in Vietnam may have been exposed to dioxin or was exposed to a toxic substance in a herbicide or defoliant used for military purposes. Verification of service in Vietnam during the Vietnam era (August 5, 1964 - May 7, 1975) will be required. In the absence of affirmative evidence to the contrary, a Vietnam veteran's contention of exposure will be accepted.

2. Health care services may not be provided under this law, for the care of conditions which are found to have resulted from a cause other than the specified exposures.

3. Health care services authorized under this provision are limited to hospital and nursing home care in VA facilities and outpatient care in VA facilities on a pre- or post-hospitalization basis or to obviate a need for hospitalization. Such health care services will be provided without regard to the veteran's age, service-connected status or the inability of the veteran to defray the expenses of such care. Veterans furnished outpatient care under this authority will be accorded priority ahead of other nonservice-connected veterans and equal to former Prisoners of War who are receiving care for nonservice-connected conditions. Congress made it clear that this law provides for health care only, and that a determination that the veteran is eligible for such care does not constitute a basis for service-connection or in any way affect determinations regarding service-connection.

THIS CIRCULAR EXPIRES ON SETPEMBER 15, 1983

4. Each veteran who served in the Republic of Vietnam and who requests VA medical care will be provided a physical examination and appropriate diagnostic studies as prescribed by DM&S Circular 10-81-54, "Possible Exposure of Veterans to Herbicides During the Vietnam War." The examination and studies with a complete medical history will be documented in the medical record. If such an examination has been completed within the prior six months, only those procedures which are medically indicated by the current circumstances need be repeated. Where the findings reveal a condition requiring treatment, the responsible staff physician shall make a determination as to whether the condition resulted from a cause other than the specified exposure. In making this determination, the physician should consider that the following types of conditions are not ordinarily considered to be due to such exposure:

a. Congenital or developmental conditions, e.g., spina bifida; scoliosis.

b. Conditions which are known to have pre-existed military service.

c. Conditions resulting from trauma, e.g., deformity or limitation of motion of an extremity.

d. Conditions having a specific and well established etiology, e.g., tuberculosis; gout.

e. Common conditions having a well recognized clinical course, e.g., inguinal hernia; acute appendicitis.

5. On occasion, the responsible staff physician may find that a veteran requires care for one or more of the conditions listed in paragraph 4, but that the case presents complicating circumstances that make the provision of care under this authority appropriate. In such instances, the physician should seek guidance from the Chief of Staff and the Environmental Physician regarding authorization for treatment. If treatment is so authorized, the reasons will be clearly documented in the medical record. Veterans who are not provided needed medical care under this circular may be furnished care if they are eligible under any other statutory authority.

6. In the event the responsible staff physician finds that a veteran has a condition not ordinarily considered to be due to the specified exposure and there are no complicating circumstances warranting the provision of care under this authority, the decision and its basis will be clearly documented in the medical record.

7. The provisions of this circular will not exclude any veteran who served in the Republic of Vietnam from being included in the VA's Agent Orange Registry Program as outlined in DM&S Circular 10-81-54, dated March 19, 1981.

8. These guidelines will be effective upon receipt. A copy of the pertinent guidelines should be made available to any veteran seeking care under this authority.

9. This circular rescinds DM&S Circular 10-81-249 dated November 18, 1981.

W. J. JACOBY, JR., M.D.
Deputy Chief Medical Director

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SS (102) FLD: MA-300 each and DO, OC & OCRO-100 each and RO-200 each plus 200-8
EX: Box 44-6, Boxes 60, 54, 52-1 each & 63-5

10-2

Veterans Administration
Department of Medicine and Surgery
Washington, DC 20420

CIRCULAR 10-82-185

September 16, 1982

TO: Directors, Medical Centers, Medical and Regional Office Centers, Regional Offices, Regional Offices with Outpatient Clinics, Domiciliary, and Outpatient Clinics

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2. Health care services may not be provided under this law, for the care of conditions which are found to have resulted from a cause other than the specified exposures.

3. Health care services authorized under this provision are limited to hospital and nursing home care in VA facilities and outpatient care in VA facilities on a pre- or post-hospitalization basis or to obviate a need for hospitalization. Such health care services will be provided without regard to the veteran's age, service-connected status or the inability of the veteran to defray the expenses of such care. Veterans furnished outpatient care under this authority will be accorded priority ahead of other nonservice-connected veterans and equal to former Prisoners of War who are receiving care for nonservice-connected conditions. Congress made it clear that this law provides for health care only, and that a determination that the veteran is eligible for such care does not constitute a basis for service-connection or in any way affect determinations regarding service-connection.

THIS CIRCULAR EXPIRES ON SETPEMBER 15, 1983

10-4

4. Each veteran who served in the Republic of Vietnam and who requests VA medical care will be provided a physical examination and appropriate diagnostic studies as prescribed by DM&S Circular 10-81-54, "Possible Exposure of Veterans to Herbicides During the Vietnam War." The examination and studies with a complete medical history will be documented in the medical record. If such an examination has been completed within the prior six months, only those procedures which are medically indicated by the current circumstances need be repeated. Where the findings reveal a condition requiring treatment, the responsible staff physician shall make a determination as to whether the condition resulted from a cause other than the specified exposure. In making this determination, the physician should consider that the following types of conditions are not ordinarily considered to be due to such exposure:

a. Congenital or developmental conditions, e.g., spina bifida; scoliosis.

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d. Conditions having a specific and well established etiology, e.g., tuberculosis; gout.

e. Common conditions having a well recognized clinical course, e.g., inguinal hernia; acute appendicitis.

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6. In the event the responsible staff physician finds that a veteran has a condition not ordinarily considered to be due to the specified exposure and there are no complicating circumstances warranting the provision of care under this authority, the decision and its basis will be clearly documented in the medical record.

7. The provisions of this circular will not exclude any veteran who served in the Republic of Vietnam from being included in the VA's Agent Orange Registry Program as outlined in DM&S Circular 10-81-54, dated March 19, 1981.

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W. J. JACOBY, JR., M.D.
Deputy Chief Medical Director

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EX: Box 44-6, Boxes 60, 54, 52-1 each & 63-5

10-B

VIETNAM VETERAN TWIN STUDY

The Vietnam Veteran Identical Twin Study involves a study of identical twin veterans where one twin served in Vietnam during the period of Herbicide Orange spraying and the twin sibling did not serve in Southeast Asia. Approximately 400 pairs of twins would be examined at the St. Louis VAMC, using a battery of psychologic, physiologic, and biochemical tests. The difference in test and measure scores within the twin pairs will be examined as function of both service in Vietnam and herbicide exposure.

PROJECT MILESTONES (Twin Study)

ACTIVITY	TARGET DATE	STATUS
Organization of Planning Committee and Plans for Protocol Design	January 1983	Completed
Planning Committee's Initial Protocol Review for Full Study	April 1983	Protocol is in Preparation
Initial Review of Protocol for Twin Find	February 1983	Completed
Award Twin Find Contract	June 1983	Pending
Study Protocol Finalized	September 1983	
Participant Examination Begins	April 1984	
Examinations Completed	August 1985	
Study Completed	February 1986	

Note: Examination and study completion dates dependent upon success of Twin Find and recruitment efforts.

VIETNAM VETERAN MORTALITY STUDY

In the conduct of any large scale health survey which examines the effects of chemical or other environmental agents, an essential element is an examination of mortality data including the cause and rate of death in comparable groups of individuals. A carefully designed and well executed mortality analysis of Vietnam veterans would provide answers to many questions raised by the Agent Orange exposure issue in particular and the possible health effects of service in Vietnam in general.

PROJECT MILESTONES

ACTIVITY	TARGET DATE	STATUS
Protocol Development		Completed
Let Contracts for Data Collection		Completed
Negotiate Interagency Support Agreement with GSA		Completed
Develop Statistical Methodology for Data Analysis	December 1983	Underway
Complete Collection of Data on Military Service and Cause of Death	March 1984	Data Collection Underway
Complete Data Analysis	July 1984	
Final Review	November 1984	

DIOXIN/FURAN ADIPOSE TISSUE STUDY

In a limited study conducted in 1979-1980, the VA found that 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) could be detected and quantified in adipose tissue removed from Vietnam-era veterans. Although there was no clear relationship between levels of 2,3,7,8-TCDD and Vietnam service, exposure to Agent Orange, or current health status, the study indicated the need for further investigation.

Since 1970, the Environmental Protection Agency has been collecting human adipose tissue from a statistically representative segment of the general population to be analyzed for residues of selected pesticide-related chemicals and polychlorinated biphenyls (PCBs). Within the bank of approximately 4,000 tissue specimens available for further chemical analysis there are specimens from 555 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 hopefully will determine if service in Vietnam has had an effect on the levels of TCDD in adipose tissue.

The study will be conducted in three phases. In phase I the names and social security numbers of the approximately 555 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 dioxins (especially the 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, e.g., 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 calendar year 1983, and the report from Phase III should be available in early 1985.

PROJECT MILESTONES

ACTIVITY	TARGET DATE	STATUS
Interagency Agreement with the Environmental Protection Agency		Completed
Survey of EPA's National Adipose Tissue Bank for Tissues Meeting VA Selection Criteria	January 1983	Completed
Initiate Pilot Study	February 1983	Initiated

DIOXIN/FURAN ADIPOSE TISSUE STUDY

ACTIVITY	TARGET DATE	STATUS
Contact Hospital Pathologists for Social Security Number and Names of Tissue Donors	April 1983	Letters Prepared for Distribution March 1983
Selected Analytical Chemists from U.S. and Canada to Meet to Review Analytical Protocol Draft	April 1983	Meeting in Kansas City, Missouri on April 27, 28, 1983, to review draft from Mid-west Research Institute (MRI) published March 11, 1983
Finalize Analytical Protocol for Analysis of Tissue	June 1983	
Develop Statistically-based Sampling Protocol of Tissue Donors	June 1983	
Validation Tests for Analytic Method	January 1984	
Initiate Analysis of Adipose Tissue	January 1984	
Complete the Analysis of Adipose Tissue	January 1985	
Submit Study to a Scientific Journal for Publication	March 1986	

LITERATURE REVIEW UPDATE

The goal of this project is the preparation of an updated comprehensive review and scientific analysis of the literature covering human studies and related biomedical research efforts on the herbicides 2, 4-D, cacodylic acid, picloram, and 2,4,5-T (and its associated dioxin contaminant) which were used as defoliants during the Vietnam War. The review will focus on the potential for adverse health effects of humans for exposure to these herbicides and related compounds, e.g., dioxins. This updated review and analysis will be based on an exhaustive search of the world's literature on this subject and will augment the previous two-volume, 1981, literature review titled Review of Literature on Herbicides, Including Pehnoxy Herbicides and Associated Dioxins.

PROJECT MILESTONES

ACTIVITY	TARGET DATE	STATUS
Award of Contract	April 1983	Evaluation of Proposals completed. Award Process in Progress.
First Monthly Progress Report	June 1983	
Final Report	January 1984	
Submission for Review and Comment	January 1984	
Publish and Distribute	January 1984	

VA MONOGRAPH SERIES

The VA Monograph Series is designed to provide useful scientific information on environmental and occupational factors that have or may have impacted the health of military personnel serving in Vietnam. The monographs will be authored by internationally recognized experts and will be a source of invaluable scientific information on selected topics to VA Environmental Physicians, researchers and other members of the scientific community.

PROJECT MILESTONES

ACTIVITY	TARGET DATE	STATUS
Chloracne		
Selection and Appointment of Authors	June 1983	Underway
Completion of Draft	November 1983	
Publish and Distribute	June 1984	
Human Exposure to Phenoxy Herbicides		
Completion of Draft	September 1983	Underway
Publish and Distribute	April 1984	
Birth Defects, Genetic Screening and Counseling		
Completion of Draft	September 1983	Underway
Publish and Distribute	April 1984	
Cacodylic Acid (Agent Blue)		
Completion of Draft	June 1983	Underway
Publish and Distribute	December 1983	

VIETNAM SERVICE INDICATOR IN PATIENT TREATMENT FILE (PTF)

The Patient Treatment File (PTF) maintained by the Department of Medicine and Surgery has great potential for epidemiologic research related to Vietnam veterans. A major problem with this file is that at present there is no automated capacity to identify Vietnam era veterans who actually served in Vietnam. The establishment of such an indicator, in most instances, would require a hand search of the individual veteran's service record.

PROJECT MILESTONES

ACTIVITY	TARGET DATE	STATUS
Let Contract		Completed
Interagency Agreement with GSA		Completed
Complete Collection of Data on Vietnam Service	August 1983	Underway
Final Report	December 1983	

VA SPECIALLY SOLICITED RESEARCH PROJECTS

Research and Development Letter IL-15-81-12, August 13, 1981 solicited Veterans Administration scientists to submit research proposals on the biochemical, physiological, or toxicological aspects of herbicide and TCDD exposure. In keeping with the recommendations in the first chapter of the 1981 VA Literature Review on Herbicides, the emphasis for the proposed research studies will focus on mechanisms of toxicity and delayed effects of exposure to herbicides and TCDD. These solicited projects will provide data important to the conduct of the Epidemiologic Study.

PROJECT MILESTONES

ACTIVITY	METHOD OF ACCOMPLISHMENT	ESTIMATED COMPLETION DATE
Selection of Research Projects	Merit Review Panel	July 1982
1983 Funding of Projects	Research Service	August 1982
One 2-year Project		1984
Six 3-year Projects		1985
One 4-year Project		1986
Two 5-year Projects		1987

MONTHLY STATUS REPORT
OF
AGENT ORANGE ACTIVITIES
FOR
MARCH 1983

Prepared by:

Agent Orange Projects Office (10A7)
Department of Medicine and Surgery
Veterans Administration Central Office
Washington, D.C. 20420

Agent Orange Registry

A revised Agent Orange Registry code sheet was distributed to all VA health care facilities in March 1983. The revised registry code sheet will assist the Veterans Administration in obtaining and computerizing data obtained as a result of Agent Orange-related examinations provided within the Agent Orange Registry program of physical examinations. The new code sheet will serve to obtain the veteran participant's name, address, sex, specific diagnosis for the veterans' health problems and other related information. This information was not obtained in a computerized form previously. It is anticipated that the new registry code sheet will greatly facilitate the information gathering/coding process.

As of January 31, 1983, the Veterans Administration computerized Agent Orange Registry data base indicates that 106,149 Vietnam veterans have received an initial registry examination. The data base also reveals that 24,544 veterans have received a follow-up examination since the initiation of the registry in May 1978. During the month of January 1983, 2,231 veterans reported for an initial ("first-time") examination and 747 veterans reported for a follow-up examination during that same period. During this same month, 940 veterans who were scheduled for the examination failed to keep their appointments.

Chloracne Monograph

In addition to three other monographs currently being prepared by consultants on behalf of the Veterans Administration (Agent Blue; Birth Defects, Genetic Screening and Counselling; Human Exposure to Herbicides), a monograph on the skin condition chloracne has been initiated. Dr. Donald L. Birmingham, Clinical Professor of Dermatology, Wayne State Health Center, Detroit, Michigan, has agreed to serve as senior editor for the monograph. The ultimate preparation of the chloracne monograph will involve seven other authors and will encompass major aspects of the subject of chloracne. This monograph, like the other three monographs now underway, is designed to provide useful scientific information on environmental factors that may have affected the health of military personnel who served in Vietnam. The four monographs will be widely distributed, when completed, to professional health care staff located at major VA health care facilities throughout the nation. It is anticipated that the chloracne monograph and the other three monographs will be published and available for distribution in late 1984.

Vietnam Experience Twin Study (VETS)

During January 1983, the Vietnam Experience Twin Study (VETS) was placed into the Veterans Administration's (VA) Cooperative Studies Program. This action will enhance the conduct of the study, assuring the full support and assistance of the VA research community. The proposed study will eventually involve some 400-450 identical twin veterans where one twin served in Vietnam during the period of herbicide orange spraying and the other did not serve in Southeast Asia. Additionally, the study will encompass the question of whether the current psychological and physical health of Vietnam veterans was adversely affected by the Vietnam Experience. The twin study will include a pilot effort to validate the proposed physical and psychological tests and measures on a series of identical and fraternal twins who will not be a part of the main study. It is anticipated that a satisfactory protocol will be finalized by October 1983.

Chloracne Task Force Activities

At a VA Herbicide Advisory Committee meeting in late 1982, a member of VA's newly reorganized Chloracne Task Force recommended a major effort to locate Vietnam veterans who may be suffering from chloracne - a skin disease believed caused by exposure to dioxin, a contaminant found in Agent Orange.

Dr. A. Betty Fischmann, chairpersonof the Task Force, said that the major focus of the Task Force is to resolve the chloracne health-care issue in the near future.

The reorganized Task Force, which consists of five members and a program analyst based at the Washington, D.C., VA Medical Center, held its first meeting in December 1982 during the annual meeting of the American Academy of Dermatology.

Dr. Fischmann reported on the status of Task Force activities at VA's Herbicide Advisory Committee meeting in February 1983. In this regard, Dr. Fischmann stated that the Task Force has:

- Organized a nationwide network of dermatological consultants;
- Developed a standard questionnaire for dermatologic Agent Orange examinations, which is now being reviewed;
- Developed criteria for diagnosing chloracne, which also are being reviewed; and
- Organized special examinations at private clinics for veterans with possible cases of chloracne.

The chloracne examinations at private clinics had been completed by January 1983. Of the 3,200 claims filed by Vietnam veterans for disability compensation for skin conditions, 13 of the 14 possible chloracne cases have been examined.

One veteran has not been located. Of the 13 veterans examined, 11 were found to have acne but none could be diagnosed as chloracne. One man may have had chloracne in Vietnam and another had an increase in acne when he worked as a civilian with halogenated hydrocarbons.

The Task Force also has completed a pilot analysis of Agent Orange examinations at the Washington VA Medical Center to identify dermatologic diseases that might be chloracne. The Task Force has proposed an ongoing review of current Agent Orange Registry examinations.

The Task Force also serves as a resource in the development of a monograph on chloracne.

Soft-Tissue Sarcomas

VA's Agent Orange Projects Office is now in the process of researching data on the number of Vietnam-era veterans who have been diagnosed as having soft-tissue sarcomas (malignant tumors). The VA's Data Processing Center in Austin and the patient treatment records have provided a count and a list of names of veterans who were diagnosed as having such sarcomas.

Several epidemiological studies conducted by Swedish scientists report evidence of a relationship between soft-tissue sarcomas and exposure to phenoxy herbicides. Similar studies in New Zealand and Finland, however, show no such relationship.

The Swedish studies consisted of two investigations by the same investigators. The first involved 52 soft-tissue sarcoma patients who were matched with 208 controls without such tumors. Results indicated a five-fold increase in the risk of soft-tissue sarcomas in those workers exposed to phenoxy herbicides. In the second study, using the same technique as the first, 110 patients with soft-tissue sarcomas and 219 controls were matched. Forestry and agricultural workers had a risk five-times greater than that of the other workers.

New Zealand scientists conducted a study involving 102 males with soft-tissue sarcomas who appeared on the New Zealand Cancer Registry between 1976 and 1980 and 306 controls chosen from patients with other forms of cancer. The two groups were matched by age, year and occupation when added to the Cancer Registry. In spite of the fact that phenoxy herbicides have been used extensively for many years in New Zealand in agriculture and forestry, the study findings do not show an excess of soft-tissue sarcomas for workers involved in these occupations.

In Finland, mortality data on 1,926 workers involved in dioxin-contained-herbicide spraying during 1955-1971 were studied from 1972 to 1980. although exposure was rather low and of a short duration (but similar to that reported in the Swedish studies), no cases of death from soft-tissue sarcomas were found. Mortality figures (including deaths from natural causes and from all types of cancers) also were studied separately for subgroups of workers who were more heavily exposed. Results did not show an increased mortality rate for these workers.

Mortality Studies

The Veterans Administration Mortality Studies, initiated in mid 1982, are designed to analyze and compare death rates and cause-of-death of profiles between veterans with service in Vietnam and comparable veterans with no service in Vietnam. The studies use existing VA computer records (BIRLS) to identify a group of approximately 60,000 deceased veterans. Cause-of-death data will be obtained from death certificates and histories of military service will be obtained from military records. As part of the mortality studies, an independent validation of BIRLS will be undertaken by the National Academy of Sciences.

As of November 10, 1982, WESTAT has been under contract to abstract tly Military Personnel Records (MPR). An Interagency Agreement (IGA) with the General Services Administration (GSA) was formalized on January 4, 1983, to locate and pull MPRs and provide them to WESTAT for des (such abstraction. An agreement was reached with the Department of Veterans Benefits to provide working space for WESTAT personnel at the Military Personnel Center, St. Louis. In early March WESTAT provided a draft report of a pilot study based upon a sampling of 200 cases reviewed to date. Moschmann Associates Inc., received a contract in December 1982, for the coding of death certificates. In conjunction with this action, another IGA was initiated. A pilot study of coding has been initiated involving about 2,000 of these records. all.

Thus, the gathering of data for the Mortality Studies is well underway and completion of data collection is anticipated by March 1984. The results should be published in a report by December 1984. Approximately $1.13 million have been allocated by the Department of Medicine and Surgery for these studies.

Dioxin Literature

A new book has been released by Plenum on "Human and Environmental Risks of the Chlorinated Dioxins and Related Compounds." Dr. Alvin L. Young of the Agent Orange Projects Office is a co-editor. The book is a compilation of the 53 original manuscripts and the Blue Ribbon Panel Reports of the 2nd International Symposium on Chlorinated Dioxins and Related Compounds held October 25-29, 1981 in Arlington, Virginia.

The book is organized into the following sections: A Definition of the Problem, Analytical Chemistry, Environmental Chemistry, Environmental Toxicology, Biochemistry and Metabolism, Environmental Toxicology, Human Observations, Risk Assessment, Laboratory Safety and Waste Management, and Panel Reports.

This volume will be invaluable to scientists, public health agencies, natural resources managers, and others concerned with the presence of dioxins in the environment.

The book may be obtained from:

Plenum Publishing Corporation
233 Spring Street
New York, New York 10013

Price: $95.00

Retrospective Study of Dioxins and Furans in Adipose Tissue

The Adipose Tissue Study is designed to provide analytical data on the levels of dioxins (especially the 2,3,7,8-TCDD) on the United States Vietnam Era-aged male population. Additionally, it may determine whether service in the military and especially Vietnam has had an effect on the levels of TCDD in adipose tissue. A draft of the analytical method for the study will be discussed and reviewed by authorities meeting in Kansas City, Missouri, on April 27-28, 1983. Based upon comments received, the draft will be revised for further review prior to finalization of the methodology. Twenty-nine representatives of the scientific community (government, academic and private sector) are expected to attend the meeting. It is felt that this approach will insure the development of a valid analytical method. Analyses of tissues should begin in January 1984 and a report prepared for distribution in early 1985.

Literature Review

A project has been initiated within the Agent Orange Projects Office (AOPO) to prepare an updated comprehensive review and scientific analysis of the literature covering human studies and directly related biomedical subjects. The review will be based on an exhaustive compilation of the world's literature on the subject and will update the previous two-volume set entitled "Review of Literature on Herbicides, Including Phenoxy Herbicides and Associated Dioxins" which was published in 1981. The literature update and assessment will be useful to a broad audience and illustrates the VA's continued efforts to provide Congress and all concerned with the most current information available dealing with the question of Agent Orange and dioxins. The review is expected to be published in January 1984.

Australia Releases Two Reports on Australian Vietnam Vets

Two reports on Australian forces who served in Vietnam have been issued. The first examines the possible effects of pesticides on their health and the second covers whether they are at an increased risk of having children and birth defects.

After evaluating evidence and reviewing claims made by the Vietnam Veterans Association of Australia, the Australian Senate's Standing Committee on Science and the Environment released its first report on the possible effects of pesticides on Australian Vietnam veterans.

The committee reached these conclusions:

- It is unlikely that the majority of Australian troops were directly or indirectly exposed to herbicides used by U.S. forces, namely Agent Orange and other compounds containing the phenoxy herbicides, 2,4-D and 2,4,5-T. However, direct exposure to insecticides (such as malathion) used to control malaria was probable in the majority of cases.

- It is accepted that all Vietnam veterans would have been exposed to harmful chemicals outside of Vietnam. The report suggests that the additional burden of exposure to potential cancer-causing substances associated with a one-year-period of service in Vietnam is likely to have been relatively small.

- There is no convincing evidence, at present, that the rates of birth abnormalities, psychiatric disorders and mortality are excessive among Vietnam veterans. The committee does not rule out the possibility that excessive rates may appear in the future.

- There is insufficient evidence to support allegations that there is an increased mortality rate among Vietnam veterans because of cancer. Other causes of death (suicides and accidents resulting from psychiatric disorders) in Vietnam veterans may be excessive and, therefore, may justify further monitoring.

In a separate study, a team from the Commonwealth Institute of Health, University of Sydney, attempted to determine whether Vietnam-era Australian veterans were at an increased risk of fathering a malformed child.

In February 1983, the Australian government issued a report on the results of this study entitled "Case-Control Study of Congenital Anomalies and Vietnam Service (Birth Defects Study)." It is the first scientific study on the subject ever completed.

The study found that Australian veterans of the Vietnam conflict were not at increased risk of fathering a malformed child.

Three groups were included in the study: Vietnam veterans, contemporary Army personnel who did not serve in Vietnam and community members who did not serve in the Army at that time.

The analysis also showed that the risk of fathering a malformed child was no higher for either Vietnam veteran or Army non-Vietnam veteran fathers than for other Australian males and the risk was not different for National Service and Australian Regular Army Vietnam veterans.

State Agent Orange Groups Hold First National Meeting

Seventeen states have begun their own programs relating to the Agent Orange issue.

VA's Agent Orange Projects Office maintains an ongoing relationship with each state program, providing Agent Orange informational materials and other assistance.

Representatives from seven of the official state Agent Orange programs held the first national meeting on Agent Orange in the fall of 1982. Representatives agreed to share medical, scientific and outreach information to promote action on resolving the Agent Orange issue.

Representatives also attended the VA Advisory Committee on Health-Related Effects of Herbicides in February 1983 and a special meeting with Administrator Harry Walters.

Veterans Administration
Department of Medicine and Surgery
Washington, D.C. 20420

Circular 10-83-38

March 1, 1983

TO: Regional Directors; Directors, VA Medical Center Activities, Domiciliary, Outpatient Clinics, and Regional Offices with Outpatient Clinics (136)

SUBJ: Possible Exposure of Veterans to Herbicides During the Vietnam War, RCS 11-49

1. This represents a revision of Circular 10-81-54, dated March 19, 1981. The following circular is referenced: 10-82-37 dated March 15, 1982.

2. The issue of Agent Orange continues to be a genuine concern to a large number of veterans, the scientific community and the chemical industry, and as a result, continues to receive extensive media attention. The VA remains in the forefront of this issue and continues to play a leading role in supporting scientific and educational initiatives in an effort to provide all concerned veterans with the information and guidance they need, as well as any medical care for which they are eligible.

3. The Agent Orange Projects Office (10A7) has the responsibility to coordinate and monitor all DM&S activities relating to the Agent Orange issue including the registry. All policy and clinical questions relating to the potential effects of herbicides should be referred to this office (FTS: 389-5412). Questions relating to eligibility of veterans or treatment of active duty personnel should be referred to Medical Administration Service (136) VACO (FTS: 389-2598/2849).

4. The maintenance of the Agent Orange Registry remains an important function of the VA and is managed centrally by the Agent Orange Projects Office (10A7). The Agent Orange Registry remains our most effective means of identifying concerned Vietnam veterans. The importance of the role of each VA employee, beginning with the initial contact, in providing physical examinations and necessary treatment and advising the veteran of the results of the examination cannot be over-stressed. Any eligible Vietnam veteran expressing a concern relating to exposure to herbicides is encouraged to participate in the registry which includes a thorough medical examination. In addition, any eligible Vietnam veteran currently receiving treatment in VA medical centers and outpatient clinics will be identified and provided with the opportunity to participate in the Agent Orange Registry. Follow-up of the veterans entered into the registry will be conducted over a period of years in an effort to obtain further information regarding any long-term health effects resulting from these chemicals.

THIS CIRCULAR EXPIRES ON FEBRUARY 29, 1984

5. VA Environmental Physicians play a most significant role in determining the perceptions Vietnam veterans have concerning the quality of VA health care services and of their individual treatment by VA health care providers. The Environmental Physician will review the records of every Vietnam veteran examined to assure that a complete physical examination was performed and documented. It is important that each veteran be fully advised of the limitations of an Agent Orange related examination, that is, what the examination can or cannot reveal as regards the presence of dioxin in the body system and/or the relationship to adverse health effects or potential health defects or illnesses which may or may not be related to a veterans exposure to Agent Orange. I wish to strongly encourage your consideration of the best way to accomplish this communication process. The following alternatives might be considered.

(1) Provide each Vietnam veteran reporting to the Outpatient Admissions area with a handout describing the purpose of the examination and its limitations. This can be further clarified by the examining physician during the course of the physical examination, preferably prior to beginning the physical examination process.

(2) Provide each veteran with the opportunity to view the audiovisual "Agent Orange: A Search for Answers." Veterans and/or visitors to VA health care facilities should be informed concerning the film and when and where it can be viewed.

(3) Make all Agent Orange pamphlets and other informational materials available to Vietnam veterans and the public - keeping them displayed in prominent areas and ensuring that sufficient copies are available for distribution. It should be standard operating procedure to provide copies of VA Agent Orange pamphlets to all telephone callers requesting Agent Orange information.

6. It is essential that a complete medical history and physical examination be performed and documented. The medical history should be documented on SF 50 4 and SF 505 and the physical examination should be documented on SF 506 or VAF 10-7978e. The Agent Orange Registry code sheet (VAF 10-9009) does not replace any medical record. In eliciting the medical history and performing the physical examination (which should be conducted by/or under the direct supervision of the Environmental Physician), special attention will be given to those organ systems alleged to be most frequently

affected by exposure to herbicides containing TCDD. These include the liver, kidneys, skin and the reproductive, endocrine, immunologic and nervous systems. Particular attention will be paid to the detection of chloracne, a skin condition which has been associated with acute exposure to TCDD and other dioxins. Evidence will also be sought concerning the following potentially relevant symptoms or conditions: altered sex drive; sterility; congenital deformities among children; repeated infections; neoplasia; and for female veterans, difficulties in carrying pregnancies to term. In gathering these data, it is important to determine and record the time of onset of the symptoms or conditions; their intensity; the degree of physical incapacitation; and the details of any treatment received. The person actually performing the physical exam should be identified with the signature and title (M.D., P.A., etc.). If the examiner is other than a physician, a physician's countersignature is required, preferably the Environmental Physician. When an Agent Orange examination is done as part of a compensation and pension examination, the physical examination will be done by/or under the direct supervision of the Environmental Physician.

7. All veterans participating in the Agent Orange Registry will be given the following baseline laboratory studies: complete blood count, urinalysis, SMA-6, SMA-12, and a chest x-ray if one has not been done within the past 6 months. Appropriate additional diagnostic studies should be performed and consultations obtained as indicated by the patient's symptoms and physical and laboratory findings. Non-routine diagnostic studies, such as sperm counts, should be performed only if medically indicated.

8. The Environmental Physician will personally discuss with each veteran examined the results of the examination and the laboratory studies which are available at the time the physical examination is completed. This personal interview will be conducted in such a way as to encourage the veteran to discuss his/her own health concerns as well as those of his /her family as they relate to exposure to herbicides. In the absence of the Environmental Physician, the interview will be provided by a designated physician familiar with the Agent Orange program. The interviewing physician will document this action in a progress note in the veteran's medical record. In addition to the personal interview, a follow-up letter will be sent to each veteran explaining the results of the examination and laboratory studies. A copy of this letter will be filed in the veteran's administrative medical record. Recommended sample letters are provided in attachments A and B.

9. Particular attention is directed to the Special Registry at the Armed Forces Institute of Pathology (see DM&S Circular, dated 10-82-37 March 15, 1982). All pathological material (autopsy, surgical, cytologic, or other similar tissue) obtained from any Vietnam veteran will be processed in accordance with DM&S Circular 10-82-37 for inclusion in this special registry.

10. It has been determined that the analytical technology for measuring minute levels (parts per trillion) of TCDD in human fat does exist. The results of this study, however, are inconclusive as regards exposure to herbicides in Vietnam. Therefore, no VA medical center will perform any surgical or other procedure for the purpose of obtaining tissue for measuring TCDD in patients without prior approval by VACO (10A7).

11. When a Vietnam veteran requests an Agent Orange examination at a VA medical center, the center's Medical Administration Service will be notified and will initiate the procedures listed below:

a. Prepare a 3x5 card with the following typewritten information:

(1) Veteran's full name
(2) Veteran's address and telephone number
(3) Date of birth
(4) Social Security Number
(5) Date of initial examination
(6) Dates of follow-up examinations

b. The card will be filed alphabetically in a special file, labeled "Agent Orange Registry." This registry card will be maintained until further notice. Every effort should be made to maintain the veteran's current address and telephone number.

c. VA Form 10-10M contains a statement regarding "Possible Exposure." This item should be completed for all veterans applying for the Agent Orange examination.

12. The original records of all examinations performed on Vietnam veterans for possible herbicide toxicity are to be retained in the veteran's Consolidated Health Record (CHR). If a CHR does not already exist for a veteran examined for herbicide toxicity, one will be established, and the results of the examination for herbicide toxicity is to be enclosed in the CHR. A locator card will be created with the establishment of CHR.

13. The following procedures pertain to active duty personnel according to the site of the Agent Orange examination:

a. When active duty members of the uniformed services apply to VA facilities for an Agent Orange examination, the requirements of M-1, Part 1, Chapter 15 regarding the authorization from the

appropriate branch of service and the billing of the appropriate branch of service will apply. The procedures of establishing a 3x5 card, of processing and completing the code sheet for active duty personnel will be the same as those followed for a veteran participating in the Agent Orange registry.

b. However, a military facility may perform the Agent Orange examination according to VA instructions. Military facilities have been informed to obtain a copy of the pertinent VA directive and samples of appropriate forms from the nearest VA facility. The completed physical examination, laboratory tests, and questionnaire will be forwarded to the nearest VA medical center or outpatient clinic. For these individuals the Medical Administration Service personnel at the medical center will:

(1) Prepare a colored 3x5 card with similar data as prepared for a veteran clearly label card as "Active Duty." Insert card in Agent Orange Registry file.
(2) Abstract the data from the medical record documents to the code sheet.
(3) Submit original code sheet to the VA Data Processing Center, Austin, TX as indicated in paragraph 18.
(4) Forward copies of the medical record documents with a copy of the code sheet to VA Central Office (10A7A).
(5) Place the original medical record documents in a plain folder properly identified with the name and social security number and a notation "Active Duty - Agent Orange Exam at _____ military facility." These folders should be maintained in a special location in the file room.
(6) While the medical documents are not placed in the CHR (Type I or II folders), these special folders are subject to the same retention and disposition policies of the CHR.
(7) If an active-duty military person becomes discharged and reports for treatment as a veteran, the Agent Orange examination will be filed in the CHR.

14. There is a high priority concern for prompt handling and scheduling Agent Orange examinations. Facilities should make every effort not to have 50 or more Agent Orange examinations pending at the end of the month. Facilities having 50 or more examinations pending will be contacted by Agent Orange Projects Office Staff to ascertain the plan of action to be implemented in reducing the backlog and to determine how many examinations are pending beyond 30 days.

15. A monthly submission of medical record documents and code sheets will be sent to VACO, Agent Orange Projects Office (10A7A, Rm B-67) according to the mailing schedule listed in paragraph 17. The monthly submission will contain the following:

a. One legible copy of all the medical record documents relating to the Agent Orange examination. These documents should be placed in alphabetical order with the code sheets stapled on top of the medical record documentation for submission to 10A7A. Pertinent laboratory data and consultations obtained as part of these examinations will be held pending arrival of these data. Only copies of completed examinations should be submitted.

b. Follow-up examinations will be reported in the same manner.

c. The Agent Orange Registry Code Sheet (VAF 10-9009) will be prepared in three copies. One copy will be filed in the veteran's CHR with the documentation from the Agent Orange examination. One copy will be stapled to the corresponding medical record documents that are sent to VACO (10A7A). The original code sheet will be sent to the Austin Data Processing Center in (DPC). See paragraph 18 for instructions for mailing the code sheets to the DPC.

16. Instructions for completing the code sheets (VAF 10-9009) are listed in Attachment C. Effective with the issuance of this circular, the new code sheets (VAF 10-9009) must now be used. The Agent Orange Registry code sheet has been revised. DO NOT USE the VAF 10-9009 with November 1980 and September 1981 dates, they will no longer be accepted. The VAF 10-9009 with the 1982 date will be used. Old stocks of 1980 and 1981 VAF 10-9009 may be destroyed. The VAF 10-20681 (NR) Initial Data Base will no longer be used.

17. The following mailing schedule should be used for mailing the monthly submission to VACO (10A7A) and the Austin DPC.

Region Number	Mailing Date
1	6th of Month
2	10th of Month
3	14th of Month
4	18th of Month
5	22nd of Month
6	26th of Month

18. The following instructions should be followed for the mailing of the original code sheet (VAF 10-9009) to the DPC. These code sheets will be mailed monthly. Code sheets must be received at the DPC according to the mailing schedule listed in paragraph 17.

a. Batching of input documents:

(1) Code sheets should be scanned to ensure all required fields have been completed.

(2) Completed code sheets will be batched in groups of no more than 25 code sheets. Each batch will include code sheets for only one facility as indicated by identical entries in all six positions of the code sheet field one. Different facilities must be batched separately (i.e. VAMC one batch, OPC one batch). Batches of less than 25 code sheets are acceptable.

(3) Attach a transmittal form to each batch of documents. Record the six position facility number and the number of documents on the transmittal.

(4) Using the batch control log (see 18c below) assign the next sequential batch number and record it on the transmittal form. NOTE: Begin batching with batch number 001 in January of each year and continue with sequential numbers throughout the year.

(5) Code sheets should be stapled together in the upper left-hand corner. No medical record documentation should be attached to these code sheets.

(6) Corrected code sheets do not have to be batched separately or handled separately. They can be mailed with the regular code sheets as long as they are for the same facility number.

b. Transmittal form:

(1) Two copies of VA Form 30-7252, "Transmittal Form for the Use in Shipment of Tabulating Data," will accompany each batch of code sheets. One copy will be retained at

the Austin DPC and the other copy will be returned to the transmitting facility with the code sheets and edit analysis lists prepared at the DPC.

(2) The transmittal form will be completed as follows:

Item 2: Name and address of transmitting facility
Item 3: Facility number of transmitting facility and correspondence symbol
Item 6: Date of dispatch
Item 7: Name and telephone number (FTS) of responsible individual at facility
Item 8: Facility Number: The three (3) to six (6) position PTF facility number used on the code sheets of this batch (code sheet field #1)
Batch number: The batch number assigned by the transmitting facility (see below --control log).
Code Sheet Count: The number of code sheets in this batch (25 or less).

(3) The following is an example of the completed transmittal form.

TRANSMITTAL FORM FOR USE IN SHIPMENT OF TABULATING DATA

1. ADDRESSEE
VA Data Processing Center (200/392A)
1615 East Woodward Street
Austin, TX. 78772
ATTN: Agent Orange Clerk

2. STATION NAME AND ADDRESS
VA Medical Center
50 Irving Street, N.W.
Washington, D.C. 20422

3. REPLY REFERENCE (Sta. no./symbol): 688/136B

4. EFFECTIVE DATE OF DATA:

5. NO. OF PACKAGES:

6. DISPATCH DATE:

6A. FINAL BATCH (Check):

7. OFFICIAL RESPONSIBLE FOR SHIPMENT (Name, title and signature)
Jane Smith 389-5412

8. TABULATING DATA

REPORTS CONTROL SYMBOL (A)	JOB NUMBER (B)		DESCRIPTION (C)	NO. OF COPIES OF REPORTS (D)	CARD COUNT (E)
	10	20A1	AGENT ORANGE		
			Facility number 688		
			Batch number ØØ2		
			Code sheet count Ø25		

9. REMARKS

VA FORM MAR 1972 **30-7252**

EXISTING STOCK OF VA FORM 30-7252, MAR 1966, WILL BE USED.

(4) The encircled area on the copy of the transmittal sheet (the address of the DPC, address of the transmitting facility, station number, and mail symbol, job number, "Agent Orange," facility number, batch number, and code sheet count) should be overprinted on the VA Form 30-7252 at each facility. The facility number entered has to be the PTF or OPC number that is coded on the code sheet.

c. Control log:

As batches are prepared for submission to the DPC an entry should be made on the control log. Instructions for the use of the control log and an example of the control log follows:

FACILITY (1) AGENT ORANGE CONTROL LOG

(2) Batch Number	(3) # Code Sheets	(4) Date Sent	(5) Date Returned			
002	25	10-6-81	10-26-81			

(1) An Agent Orange address control log should be maintained for each facility (Facility Code Number).

(2) The batch number will be assigned sequentially by facility. The batch number will be recorded on the log and on the transmittal sheet (Item 8).

(3) The number of code sheets in the batch will be recorded on the log and on the transmittal sheet (Item 8).

(4) Date the batch was mailed to the DPC.

(5) Date the batch and associated edit output was returned from the DPC.

d. Mailing:

(1) The facilities will establish their own control over the mailing of code sheets to the DPC. In order to ensure that the computer files are current, each facility should submit input at least once each month.

(2) The mailing address for the DPC is:

VA DATA PROCESSING CENTER (200/392A)
1615 East Woodward Street
Austin, TX 78772
ATTN: AGENT ORANGE CLERK

(3) Contact the Agent Orange Clerk at the DPC regarding questions about submitting code sheets, batch control, etc., The telephone number is FTS 770-7281. It is not appropriate to call the DPC in regard to questions on code sheet completion or correction of rejections. These questions should be referred to Nancy Howard, VACO, FTS 389-5412.

e. Processing:

(1) The DPC will keypunch the data from the code sheets and the records twice each month (10th and 25th). Subsequent to editing, the DPC will return all batches and the edit lists to the transmitting facility.

(2) While all code sheets will be returned to the transmitting facility, computer listings will reflect only rejected records. For correction of the rejected records, refer to the coding instructions in Attachment C. There will be no published edit list of how to correct errors; carefully following the instructions and double checking the information coded is absolutely essential! Corrections are to be made on the returned code sheet with RED pen or RED felt-tipped pen or a new code sheet can be made with the corrections in the appropriate field(s). If a new code sheet is prepared for the return of a correction, do not just complete the corrected field(s)—all of the fields must be completed as if it were an initial input. DO NOT leave any blank fields.

(3) All returned code sheets should be disposed of only after all information input is verified as correct. Refer to the RCS 10-1 schedule under Medical Administration Service section for the disposition schedule.

(4) There has been a programming change in the editing process for the Agent Orange Registry. Several new error messages are appearing. Examples of the new messages and the corrective action needed are listed below:

(a) ****** - means an error is in a field.
ACTION - correct error and resubmit.

(b) Duplicate Initial Exam - means there already appears on the file an initial Agent Orange examination for this veteran. It may be for the same reporting facility or a different VA facility.
ACTION - No action is necessary.

(c) Warning - No Initial Exam - means the file does not contain an Initial Exam record for this veteran, but the registry has accepted the follow-up record that was previously submitted.
ACTION - Reconstruct the initial exam record and submit to the DPC. DO NOT resubmit the follow-up exam.

19. A monthly statistical report will be sent to VACO, Agent Orange Projects Office, Attn: Nancy L. Howard, RRA (10A7A, Rm, 848). Do not enclose this letter with the medical record documentation and code sheets sent to 10A7, Rm. B-67. This statistical report will be prepared on a monthly basis and should arrive in VACO (10A7) by the tenth workday following the end of the month. Negative reports are required. Please assure that accurate statistics are reported. For Satellite OPC's performing Agent Orange examinations do not submit the statistical report separately. The totals should be combined with the parent facility totals. Do not use the mailing schedule described in paragraph 17 for submission of this statistical report. This transmittal letter should contain:

a. The number of initial examinations performed during the month;

b. The cumulative total of initial examinations performed;

c. The number of follow-up examinations performed during the month;

d. The cumulative total of follow-up examinations performed;

e. The number of initial examinations pending beyond the end of the month;

f. The number of veterans failing to keep an initial examination appointment.

See definitions in Attachment D for an explanation of the monthly report terminology. A copy of the format for the statistical report is illustrated in Attachment E.

It should be noted that the pending examination total (e) and the number of veterans failing to keep an initial examination appointment (f) are not cumulative totals. These apply to the report month only.

20. Special care should be addressed to the completion of the examination code sheets. A black ball-point pen or a black felt-tipped pen should be used. No pencils or blue ink pens should be used as these markings do not reproduce clearly. Carefully follow the instructions for completing the code sheets to assure that all data fields are completed. It is recommended that the Chief, Medical Information Section, be given the responsibility for the coding, completing, mailing of the code sheets to the DPC and the correcting of the code sheets to assure all areas are completed accurately.

21. This circular rescinds DM&S circulars:

10-80-203, dated September 12, 1980;
10-81-12, dated January 15, 1981;
10-81-54, dated March 19, 1981;
10-81-82, dated April 28, 1981;
10-81-115, dated June 4, 1981;
10-81-263, dated December 1, 1981;
10-82-5, dated January 18, 1982; and
10-82-110, dated June 28, 1982.

W. J. JACOBY, JR., M.D.
Deputy Chief Medical Director

DISTRIBUTION: COB: (10) only plus (10A7) 500
SS (10A7) FLD: MA-5 each and RD, DO, OC & OCRO-2 each plus 200-8
EX: Box 44-6, Boxes 60, 54, 52-1 ea. & 63-5

14-12

ATTACHMENT A

Circular 10-83-38
March 1, 198^

(FACILITY LETTERHEAD)

Positive Findings -- Recommended Format

Dear Veteran:

We sincerely appreciate your recent participation in the Veterans Administration's Agent Orange Registry. This effort should prove to be very helpful in assisting us to better serve veterans, such as yourself, who are concerned about the possible adverse health effects of exposure to Agent Orange.

A review of the results of your examination indicates that _____
(Use this space to briefly describe any positive findings.)_____
_____

In view of the above findings, we suggest that you contact the Outpatient Admissions Office at extension _____ to schedule a follow-up examination. This will provide us with an opportunity to personally discuss these findings with you and to suggest or provide any essential medical treatment.

Again, your participation in the registry is appreciated.

Sincerely,

(NAME)
Environmental Physician

14-13

ATTACHMENT B

Circular 10-83-38
March 1, 1983

(FACILITY LETTERHEAD)

Negative Findings -- Recommended Format

Dear Veteran:

We sincerely appreciate your recent participation in the Veterans Administration's Agent Orange Registry. This effort should prove to be very helpful in assisting us to better serve you and your fellow veterans who are concerned about the possible adverse health effects of exposure to Agent Orange.

The results of your examination and laboratory tests suggest that you are presently in good health and that you have no reason at this time to be concerned about possible adverse health effects resulting from exposure to Agent Orange. However, if in the future you have a medical condition about which you are concerned, I would encourage you to seek the help and advice of your nearest Veterans Administration Medical Center.

The results of your examination will be maintained by the Veterans Administration and will be available for future use as needed.

Again, your participation in the registry is appreciated.

Sincerely,

(NAME)
Environmental Physician

Attachment C

INSTRUCTIONS FOR ITEMS 1-20 for the Agent Orange Registry Codesheet. (VAF 10-9009).

Item 1 - Facility Number - Suffix - Enter PTF facility code. Use the AMIS Suffix (BY, BZ etc) to indicate your satellite facility. DO NOT USE Q,R,S,

Item 2 - Veteran's Name

Beginning in block 8, enter veteran's last name (please print) using one letter per block. Apostrophes and hyphens in the name should not be used and empty blocks must not be left between the letters of the last name. Do not skip a space or use a comma if the last name is followed with JR, SR, I, II or III, etc.

Beginning in block 34, print the first name, one letter per block. If there is a middle name, enter the middle name beginning in block 49 - otherwise leave this block blank.

Item 5 - Type of Exam - Enter A = initial; C = follow-up. To delete an entire initial examination with a noted error after it has been accepted into the registry, resubmit the original code sheet with a "B" coded in block 59 and submit a code sheet with the correct information with an "A coded in block 59. All fields must be completed on a resubmission. The code sheets can be shipped in the same batch. An example for this usage will be for incorrect spelling of the name, incorrect social security number, changing of address etc.

To delete an entire follow-up examination with a noted error after it has been accepted into the registry, resubmit the original code sheet with a "D" coded in block 59 and submit a code sheet with the correct information with a "C" coded in block 59.

Item 6 - Social Security Number

Block 60 should be left blank. Enter the SSN in blocks 61 through 69. If the veteran does not have a social security number, place the letter "P" in block 60 and assign a pseudo SSN. (See PTF instructions for pseudo SSN). Numerical zeros must be slashed (Ø).

Item 7 - Service Serial Number

Enter the Service Serial Number beginning in block 70, unused blocks remain blank. Numerical zeros must be slashed (Ø).

If the serial number begins with US, blocks 72-79 must contain a number(s).

Fill unused block(s) with zero(s) for this instance only.

If the serial number is unknown, enter a U in block 70. Unused blocks remain blank.

14-15

Example:

70	71	72	73	74	75	76	77	78	79
7	Ø	8	Ø	Ø	Ø				

Service Serial Number
708000

70	71	72	73	74	75	76	77	78	79
U	S	6	6	7	Ø	Ø	Ø	Ø	Ø

Service Serial Number:
US 66700000

70	71	72	73	74	75	76	77	78	79
U									

Veteran does not know serial number

Item 8 - Date of Birth

Enter the numerical equivalent for the month (blocks 80-81) and day (blocks 82-83). Enter the last two digits of the year of birth in blocks 84 and 85. Numerical zeros must be slashed (Ø).

Example:

MO.		DAY		YR.	
80	81	82	83	84	85
Ø	5	Ø	9	4	7

May 9, 1947

Item 9 - Current Address

Print the veteran's current address in the spaces provided. Use of one block per letter or number. Leave one blank space between street number and name. Print street address in blocks 86-111. Print city or town in blocks 112-137. Print zip code in blocks 138-142. Blocks 143-146 will be blank. Using the PTF codes, assign the proper country and state codes in block 147-151.

Item 10 - Race/ Ethnicity

Enter the appropriate code in block 152.

Item 11-13 - Sex, Martial Status & Current Status of Veteran

Enter appropriate codes.

Item 14 - Branch of Service

Enter appropriate codes in block 156.

If veteran was in more than one branch of service (item 14), code the latest Vietnam service.

Item 15 - Enter the appropriate code for Vietnam service in block 157. If the veteran did not serve in Vietnam, blocks 158-173 should be left blank.

Item 15A - Code the numerical equivalent of the month and code the last two digits of the year of last period of service in Vietnam. Numerical zeros must be slashed (Ø).

Item 15B - If veteran had two or more periods of service in Vietnam, the next to last period of service should be coded in the blocks provided.If only one period of service in Vietnam code this in 17(a) and leave 17(b) blank. Numerical zeros must be slashed (Ø).

Item 16 - Corps or Area Served

Enter the appropriate code (in block 174) for the corps or area in which veteran served. If he served in more than one, use code 6.

Item 17 - Military Unit

Enter the military unit in which the veteran served. Please specify complete unabbreviated title. (Company, battalion, corps, ship, division).

Item 18 - Last Two Periods of Service

Code the month and year of the last two periods of service in 18(a) and (b) regardless of whether or not they were in Vietnam. If veteran did not have more than one period of service, leave (b) blank.

Item 19(a) - (e) Exposure to Agent Orange

Place the most appropriate code that describes veterans exposure to Agent Orange in the block provided. Do not leave any block blank.

Item 20 - Veteran's Health

Enter the code that most appropriately describes veterans health.

INSTRUCTIONS FOR ITEMS 21-34 (THE ITEMS TO BE COMPLETED BY THE EXAMINING PHYSICIAN OR THE DESIGNATED PHYSICIAN)

Item 21 - Date of Exam

Enter the numerical equivalent of the month, day, and year in the appropriate blocks.

Item 22 - Veteran's Complaint(s)

Print the veteran's complaint(s) in the blanks provided. MAS personnel will fill in the blocks for 22(a), (b) and (c), utilizing the ICD-9-CM coding systems. Use the symptoms and signs categories (780-789) for this coding. The "78" has been preprinted for you. For uncodable symptoms, use 78999. For no known complaints use 78ØØØ.

Item 23 - Chief Complaint

Enter appropriate code (1 or 2) in the block.

Item 24 - Number of Complaints

Enter the number of complaints the veteran has in the block provided. If the veteran has 5 or more complaints, enter 5 in the block.

Item 25 - Evidence of Birth Defects in Veteran's Children?

Enter the appropriate code for item 25.

Item 26 - Diagnostic Work-up and/or Consultation

If no work-up and no consultation has been done, enter code 1 in the blocks provided. If a work-up and/or consultation has been done, enter the appropriate code (2,3,4) in the blocks provided. All blocks must have one entry.

Item 27 - Additional Workups/Consultations

Specify any additional workups/consultations performed but not listed in item 26.

Item 28 - Diagnosis

Print the veteran's major medical diagnosis(es) in the spaces provided (a,b,c). For each diagnosis listed, MAS will utilize the ICD-9-CM coding system.

Any diagnosis relating to a neoplasm should be documented in item 29.

Item 29 - Evidence of Neoplasia

Block 240 of ths section must be completed with the appropriate response. If the veteran has a neoplasm or has a known history of a neoplasm, document the appropriate diagnosis and the specific ICD-9-CM diagnostic code must be listed in blocks 241 to 245. If no neoplasm is recorded, leave blank.

Item 30 - No Disease Found

If no disease is found, put a 1 in block 246. Otherwise, leave this block blank.

Item 31 - Years of Onset

For each listed diagnosis in item 28, code the last two digits of the year of onset; leave blank if year of onset is unknown.

Item 32 - Disposition

Place a code (1 or 2) in each block provided. Do not leave any of the blocks blank.

For section d in item 32, if the veteran was referred for VA outpatient care, indicate the two digit code for the clinic in the designated blocks (257-266). Refer to the Outpatient Routing List (VAF 10-2875-1) for the clinic codes to be utilized to code this section.

Item 33 - Remarks

Utilize this space for additional information.

Item 34-36 - Name and Title of Examiner

The name and title of the examiner should be printed in the space provided. The examiner should also sign his/her name.

Information to be abstracted for a follow-up examination:

Items 1 through 13 - must be completed
Items 14 through 20 - no entry
Item 21 - must be completed
Items 22 through 33 - may be blank unless you have follow-up data to report in in any of these items.
Items 34 through 36 - must be completed

PLEASE NOTE: The first time a follow-up visit is recorded on the revised code sheet for a veteran who previously received an initial exam recorded on the old code sheet, every attempt should be made to obtain and record the information to complete Items 14-20.

14-19

DEFINITIONS FOR THE MONTHLY REPORT TERMINOLOGY

1. Initial Examination: First time Agent Orange examination given for the purpose of entering a Vietnam veteran into the Agent Orange Registry. The total of initial examinations given during the period of the current report (i.e., 30 initial exams given during January).

2. Cumulative Initial Examination: Includes the total number of "first-time" examinations performed by the medical facility since the beginning of the registry in 1978. Examinations performed by satellite outpatient clinics should be included in the total cumulative figure for the VA medical center of jurisdiction. Independent outpatient clinics should report in a manner similar to the VA medical centers.

3. Follow-up Examination: Any Agent Orange-related examination/visit subsequent to the initial examination.

4. Cumulative Follow-up Examination: Includes the total number of follow-up examinations performed by the medical facility since the beginning of the registry in 1978.

5. Pending Examinations: Initial Agent Orange examinations for which appointments have been scheduled beyond the end of the month.

6. Number of veterans failing to keep an initial examination appointment: number of veterans who failed to keep a scheduled appointment during the month.

EXAMPLE
(FACILITY LETTERHEAD)

Agent Orange Projects Office (10A7)
ATTN: Nancy L. Howard, RRA
VA Central Office, Rm. 848
810 Vermont Avenue, N.W.
Washington, D.C. 20420

SUBJECT: Monthly Report on Possible Exposure of Veterans to Herbicides During the Vietnam War, RCS 11-49

1. The following information is submitted for the month ending _____ _____; facility number_____.

   a. Total number of initial examinations performed _____

   b. Cumulative total of initial examinations performed _____

   c. Total number of follow-up examinations performed _____

   d. Cumulative total of follow-up examinations performed_____

   e. Number of pending initial examinations at the end of the month _____

   f. Number of veterans failing to keep an initial examination appointment _____

2. Comments/problems regarding pending exams:

3. The name and FTS number of the person preparing the report:

_____

(Name)
MEDICAL CENTER DIRECTOR

630491

March 1, 1983

AGENT ORANGE CLAIMS

		Number	Percent
A.	Total Number of Claims	16821	100.0%
	Claims with Diagnosis Confirmed	8341	49.6%
	Claims with Diagnosis not Confirmed	4456	26.5%
	Claims with No Disability Alleged	4024	23.9%
B.	Claims with Diagnosis Confirmed	8341	100.0%
	Allowed for Reason Other than Agent Orange	1300*	15.6%
	Denied	7041[a]	84.4%

a. These 7041 claims having more than one claimed diagnosis fall into the following categories:

Skin condition (acne, alopecia, eczema, keloids and urticaria)	4303
Nervousness, headaches and fatigue (claimed)	2453
Paralysis or numbness and other symptoms of extremities	911
GI and GU conditions	796
Malignancies (leukemia, lymphoma, melanoma, Hodgkin's, etc.)	508
Impaired sexual activity (alleged)	360
EENT pathology	466
Lung condition	293
Cardiovascular and hypertension	252
Misc.	146

* Approximately 94 or 1225 of the total 1300 claims allowed are service connected for skin condition. Balance of 6% or 68 claims were allowed for cancer, psychiatric and neurological conditions and various other miscellaneous disabilities.

such program shall submit a written application to the Administrator. Such application shall contain a certification—

"(A) of the training objectives to be pursued, the total number of hours of training to be provided, and the schedule for the training program;

"(B) that the wages and benefits to be paid to an eligible veteran participating in such training program are not less than the wages and benefits normally paid by the employer to employees participating in such program;

"(C) that the employer has planned for the employment of the veteran in a position for which the veteran is to be trained and that the employer has no reason to expect that that position will not be available to such veteran at the end of the training period;

"(D) that no currently employed worker will be displaced (including partially displaced, such as through a reduction in nonovertime work hours, wages, or benefits), or laid-off workers prevented from recall, as a result of either the establishment of the training program and the participation of such veteran in such program or the subsequent employment of such veteran;

"(E) that the training content of the program is adequate to qualify an eligible veteran participating in such program generally for a job in the field for which training is to be provided and specifically for the position for which the veteran is being trained;

"(F) that the field or job for which training is to be provided customarily requires full-time training for a period of not less than six months;

"(G) that the length of the training period under the program is not longer than the length of programs that employers in the community customarily require new employees to complete in order to be competent in such field or job; and

"(H) that records needed to determine compliance with the requirements of this chapter will be maintained by the employer and will be available at reasonable times for examination by authorized representatives of the Federal Government.

"(2) For the purposes of this subsection, approval of a program of apprenticeship or other on-job training for the purposes of section 1787 of this title shall meet all requirements for approval of such program under this chapter.

"§ 1951. Training establishments

"Any employer may enter into an arrangement or agreement with an educational institution that has been approved for the enrollment of veterans under chapter 34 of this title in order that such institution may provide the training program (or a portion thereof) under this chapter. When such an arrangement or agreement has been entered into, the application of the employer shall so state and set forth a description of the training to be so provided.

"§ 1952. Nonqualifying programs of training

"No assistance under this chapter may be paid on behalf of a veteran participating in a program of training—

"(1) for employment in a seasonal, intermittent, or temporary job;

"(2) for employment under which commissions are the primary source of income;

"(3) for employment which involves political or religious activities; or

"(4) if the training program will not be carried out in the United States.

"§ 1953. Relationship to other programs of assistance

"(a) No assistance under this chapter may be paid on behalf of an eligible veteran if—

"(1) such veteran is receiving a monthly training assistance allowance pursuant to section 1787 of this title; or

"(2) the employer is receiving any other form of assistance (including a tax credit) from the Federal Government on account of the training or employment of such veteran.

"(b) In the case of an eligible veteran participating in both a training program under this chapter and a vocational rehabilitation program under chapter 31 of this title, the provisions of section 1508(c)(1) of this title shall apply to the employer to which retraining assistance is payable under this chapter, and the wages and benefits paid to such veterans by such employer shall be considered income paid to the veteran for purposes of such provisions.

"(c) Assistance under chapter 34 or 38 of this title may not be paid to a veteran in connection with such veteran's participation in a training program under this chapter.

"§ 1954. Suspension of payments

"If the Administrator finds that a program of training approved under this chapter fails to meet any of the requirements of this chapter, the Administrator may immediately suspend the payment of retraining assistance on behalf of an eligible veteran participating in such program. The employer and any educational institution conducting, and each eligible veteran participating in, such program shall each be notified immediately of such suspension by a certified or registered letter (return receipt requested).

"§ 1955. Recovery of overpayments

"(a) Whenever the Administrator finds that an overpayment of retraining assistance under this chapter has been made to an employer on behalf of an eligible veteran as a result of the willful or negligent false certification by an employer, the amount of such overpayment shall constitute a liability of the employer to the United States.

"(b) Whenever the Administrator finds that an overpayment of retraining assistance under this chapter has been made to an employer on behalf of an eligible veteran as a result of the willful or negligent false certification by a veteran, the amount of such overpayment shall constitute a liability of the veteran to the United States.

"(c)(1) Any overpayment referred to in subsection (a) or (b) of this section may be recovered in the same manner as any other debt due the United States.

"(2) Nothing in this section or any other provision of this title shall be construed as precluding the imposition of any civil or criminal liability under this title or any other law with respect to such an overpayment.

"SUBCHAPTER V—COORDINATION WITH OTHER AGENCIES

"§ 1960. Coordination with the Department of Labor

"(a) Except as otherwise permitted in section 1932(a) of this title, the Secretary shall carry out the Secretary's responsibilities under this chapter through the Assistant Secretary.

"(b) The Administrator shall carry out the provisions of this chapter in consultation and coordination with the Secretary, and the Administrator and the Secretary shall jointly conduct an outreach and public information program designed to—

"(1) inform eligible veterans about opportunities for training under this chapter; and

"(2) inform private industry and business concerns (including small business concerns), educational institutions, trade associations, and labor unions of opportunities under this chapter, and to encourage employers and unions to make training programs available for eligible veterans.

"(c) The Secretary, in consultation and cooperation with the Administrator, shall assist veterans and employers desiring to participate under this chapter in making application and completing necessary certifications. In carrying out this responsibility, the Secretary shall use the services of State and Assistant State Directors for Veterans' Employment, disabled veterans' outreach program specialists, and employees of local offices appointed pursuant to sections 2203, 2003A, and 2004 of this title. The Secretary shall also use such resources as are available under title IV-C of the Job Training Partnership Act.

"§ 1961. Coordination with the Small Business Administration

"The Administrator shall request and obtain from the Administrator of the Small Business Administration a listing of small business concerns, particularly new small business concerns in sectors of the economy which have a high potential for sustained demand or growth, and, on a regular basis, update such listings. Such listings shall be used to identify and promote possible training and employment opportunities for eligible veterans.

"§ 1962. Coordination with the Department of Education

"The Administrator, in consultation and cooperation with the Secretary of Education, shall take appropriate actions to advise educational institutions of the opportunities made available to veterans under this chapter and the opportunity for such institutions to enter into agreements or arrangements with employers pursuant to section 1961 of this title.".

(b) The table of chapters at the beginning of such title and at the beginning of part III of such title are each amended by inserting after the item relating to chapter 39 the following new item:

"40. Emergency Retraining Assistance..... 1920".

SEC. 3. The amendments made by this Act shall take effect on October 1, 1983.

[Circular 10-83-61, Apr. 5, 1983]

VETERANS ADMINISTRATION,
Department of Medicine and Surgery,
Washington, D.C.

To: Regional Directors; Directors, VA Medical Center Activities, Domiciliary, Outpatient Clinics, and Regional Offices with Outpatient Clinics.

Information: Directors, Regional Offices; District Counsels.

Subject: Guidelines for Implementation of Legislation Related to the Provision of Health Services to Veterans Exposed to Ionizing Radiation As a Result of Detonation of Nuclear Devices.

1. The "Veterans Health Care, Training, and Small Business Loan Act of 1981" was signed into law on November 3, 1981. The Act, Public Law 97-72, authorizes the Veterans Administration to provide certain health care services, as described in paragraph 3, to veterans who, while serving on active military duty, were exposed to ionizing radiation from the detonation of nuclear device as a result of participation in either the testing of such a device between 1945 and 1962, or the American occupation of Hiroshima or Nagasaki, Japan, between September 11, 1945, and July 1, 1946. Verification of service at a site during the testing of nuclear devices, or in Hiroshima/Nagasaki during the occupation of Japan, during the times specified will be required. In the absence of affirmative evidence to the contrary, a veteran's contention of exposure at

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a nuclear device testing site, or in Hiroshima/Nagasaki will be accepted.

2. Health care services may not be provided under this law for the care of conditions which are found to have resulted from a cause other than the specified exposures.

3. Health care services authorized under this provision are limited to hospital and nursing home care in VA facilities and outpatient care in VA facilities on a pre- or post-hospitalization basis or to obviate a need for hospitalization. Such health care services will be provided without regard to the veteran's age, service connected status or the inability of the veteran to defray the expenses of such care. Veterans furnished outpatient care under this authority will be accorded priority ahead of other nonservice-connected veterans and equal to former Prisoners of War who are receiving care for nonservice-connected conditions. Congress made it clear that this law provides for health care only, and that a determination that the veteran is eligible for such care does not constitute a basis for service connection or in any way affect determinations regarding service connection.

4. Each veteran who participated in the testing of a nuclear device or who participated in the occupation of Hiroshima or Nagasaki, Japan, between September 11, 1945, and July 1, 1946, and who requests VA medical care will be provided a physical examination and appropriate diagnostic studies in accordance with DM&S Circular 10-83-12. The examination and studies will be documented in the medical record. If such an examination has been completed within the prior six months, only those procedures which are medically indicated by the current circumstances need be repeated. Where the findings reveal a condition requiring treatment, the responsible staff physician shall made a determination as to whether that condition resulted from a cause other than the veteran's exposure to ionizing radiation.

Veterans who meet the criteria of this circular may be treated under this authority. In making this determination, the physician should consider that the following types of conditions are not ordinarily considered to be due to such exposure:

(a) Congenital or developmental conditions, e.g., spina bifida; scoliosis.

(b) Conditions which are known to have pre-existed military service.

(c) Conditions resulting from trauma, e.g., deformity or limitation of motion of an extremity.

(d) Conditions having a specific and well established etiology, e.g., tuberculosis; gout.

(e) Common conditions having a well recognized clinical course, e.g., inguinal hernia; acute appendicitis.

5. On occasion, the responsible staff physician may find that a veteran requires care for one or more of the conditions listed in paragrah 4, but that the case presents complicating circumstances that make the provision of care under this authority appropriate. In such instances, the physician should seek guidance from the Chief of Staff and the Environmental Physician regarding authorization for treatment. If treatment is so authorized, the reasons will be clearly documented in the medical record. Veterans who are not provided needed medical care under this circular may be furnished care if they are eligible under any other statutory authority.

6. In the event the responsible staff physician finds that a veteran has a condition not ordinarily considered to be due to the specified exposure and there are not complicating circumstances warranting the provision of care under this authority, the decision and its basis will be clearly documented in the medical record.

7. The provisions of this circular will not exclude any veteran who alleges exposure to ionizing radiation as described in paragraph 1 of this circular from being included in a VA Radiation Exposure Registry Program, under development.

8. These guidelines will be effective upon receipt. A copy of the pertinent guidelines should be made available to any veteran seeking care under this authority.

9. This circular rescinds DM&S Circular 10-82-246 dated December 21, 1982.

W. J. JACOBY, JR., M.D.,
Deputy Chief Medical Director.

COMMITTEE ON VETERANS' AFFAIRS,
Washington, D.C., March 22, 1983.

Hon. HARRY N. WALTERS,
Administrator of Veterans' Affairs, Washington, D.C.

DEAR HARRY: I was very pleased to receive your responsive and forthcoming letter of February 18 regarding new initiatives you plan to take with respect to certain ionizing-radiation issues. As you know, I have long been deeply concerned about questions relating to the long-term health effects in veterans of their active-duty exposure to radiation from the detonation of nuclear devices, as well as the difficulties that some of them have had in obtaining VA health care for disabilities which may be related to their exposure. Likewise, I have been concerned about the difficulties faced by some of these veterans in pursuing claims for compensation and by the survivors of such veterans in pursuing claims for disability and indemnity compensation.

I have several follow-up thoughts to share with you arising out of your letter.

1. As the author of S. 11, which contains a provision to mandate a morbidity study of these veterans, I am particularly encouraged by your plan to explore with the Interagency Radiation Research Committee the feasibility of conducting such a study. I urge that you also consult with National Academy of Sciences staff members, such as Seymour Jablon and Dennis Robinette, on the feasibility of the study. As a result of NAS' long-standing involvement with various radiation-related efforts—including the U.S. participation in evaluating the experience of the Japanese survivors of Hiroshima and Nagasaki, the work of the Committee on the Biological Effects of Ionizing Radiation, and NAS' ongoing mortality study of some 55,000 veterans who participated in the atmospheric nuclear testing serious—NAS has developed perspectives and expertise that could be of substantial value to you in your consideration of undertaking such a study. In addition, some NAS staff members have given thought to possible means of studying birth defects in the offspring of exposed veterans, an issue that should constitute a crucial part of any morbidity study.

2. Your proposal to call upon experts in the field of nuclear effects to evaluate the National Library of Medicine's reports on the radiation literature and to consider the epidemiological recommendations of the IRRC is a useful step forward. However, I believe that such a collection of experts could, as an ongoing committee where views could be exchanged directly on a variety of issues, lend valuable expertise to the VA in more than these two limited areas. Such a committee could, for example, stimulate the development of and help to evaluate proposals for other radiation-related research relevant to veterans' concerns and provide ongoing advice on any morbidity study that is developed. I also believe that such a committee could serve as a valuable resource for the Board of Veterans' Appeals, the Chief Benefits Director, and the Chief Medical Director and would generally be a worthwhile, continuing supplement to the VA's admittedly small Central Office staff in this area. Thus, I urge that you reconsider your present position as stated in your earlier, February 4 letter to me and take steps to establish such an entity on a formal basis.

3. Having previously written the Chief Medical Director and the former Administrator regarding health-care eligibility under section 102 of Public Law 97-72 for veterans exposed to ionizing radiation on three occasions, I very much support the steps you are taking to ensure that the implementation of this provision does not reflect differing interpretations of the law for veterans exposed to Agent Orange and for those exposed to ionizing radiation. Under section 102, veterans who experienced certain exposure to Agent Orange or ionizing radiation are eligible for care for disabilities that cannot be determined to result from causes other than their exposure to Agent Organge or ionizing radiation.

As the Senate author of this provision of law, I have been concerned that the implementing guidelines issued by the VA treat the two groups of veterans differently. The Agent Orange guidelines reflect the proper approach of specifying the particular categories of disabilities that the VA has determined are not caused by Agent Orange exposure and which thus do not provide a basis for eligibility. The VA guidelines afford VA health-care eligibility for all other disabilities of Agent Orange-exposed Vietnam veterans. By contrast, the guidelines provide access to care for veterans who have been exposed to radiation only if they have certain specified types of disabilities, apparently those that the VA considers are likely to be caused by radiation. Thus, I am pleased that you have directed that the circulars pertaining to this authority be revised to "have comparable expression of policy"—apparently to bring the radiation policy into line with the Agent Orange policy—and I look forward to the issuance of the revisions.

As I have already indicated, Harry, I believe the initiatives you outlined in your February 18 letter are very positive, and I congratulate you on them. I look forward to learning your thoughts on the suggestions set forth above and to your carrying out efforts to address the important concerns of veterans exposed to ionizing radiation as a result of nuclear detonations.

With warm regards,
Cordially,

ALAN CRANSTON,
Ranking Minority Member.

VETERANS ADMINISTRATION, OFFICE OF THE ADMINISTRATOR OF VETERANS AFFAIRS,
Washington D.C., February 18, 1983.

Hon. ALAN CRANSTON,
Ranking Minority Member, Committee on Veterans' Affairs, U.S. Senate, Washington, D.C.

DEAR SENATOR CRANSTON: Regarding our programs concerning veterans exposed to ionizing radiation as a result of detonation of nuclear devices I am pleased to advise you of several new initiatives.

First, the Veterans Administration has requested the Interagency Radiation Research Committee to provide its advice on the feasibility of conducting a morbidity study of veterans exposed to radiation during active military duty.

Secondly, we have requested the National Library of Medicine to make available to the Veterans Administration their extensive literature reviews on the health effects of ex-

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posure to nuclear radiation. The Director of the National Library of Medicine, Dr. Martin M. Cummings, has charged his staff epidemiologist, Dr. Clifford Bachrach, and researcher, Miss Charlotte Kenton, with the responsibility of making available to the Veterans Administration their past extensive literature searches on the health effects of nuclear radiation and, beginning March 1, 1983, of supplying the Veterans Administration with monthly reports of worldwide radiation research.

We also will call upon experts in the field of nuclear effects to evaluate the National Library of Medicine's reports, and to consider the epidemiological recommendations of the Interagency Radiation Research Committee. There will also be a periodically updated manual for the use of Veterans Administration physicians in the examining and treating of veterans exposed to ionizing radiation while in military service.

Finally, we have undertaken to revise the instructions to the various VA medical centers concerning the implementation of Public Law 97-72 relating to the provision of health care services to veterans exposed to ionizing radiation as a result of a detonation of nuclear devices. The revision is being made so as to have comparable expression of policy regarding radiation as now exists with respect to veterans exposed to dioxin.

Regarding the issue of the relationship between exposure to dioxin and the subsequent development of soft tissue sarcomas, the Veterans Administration is unable at present to find scientific proof that Agent Orange or its ingredients are causes of one or more of the group of diseases called soft-tissue sarcomas. We are continuing the undertaking of a detailed literature search, and data review on illnesses and death among Vietnam veterans, including the files of the Armed Forces Institute of Pathology.

I will, of course, keep you advised of further developments in this matter.

Sincerely,

HARRY N. WALTERS,
Administrator.

VETERANS' ADMINISTRATION,
Washington, D.C., February 3, 1983.

Hon. ALAN CRANSTON,
Ranking Minority Member, Committee on Veterans' Affairs, U.S. Senate, Washington, D.C.

DEAR SENATOR CRANSTON: A letter regarding ionizing radiation was forwarded to your office on January 12, 1983. The prudence of establishing a VA Committee on Ionizing Radiation was discussed in that letter.

It has come to my attention that the reference to that committee was misleading. Permit me to rectify the situation. In 1978 the agency developed an informal task group which functioned as a quasi committee. Consideration was given to establishing a formal advisory committee; however, it was decided not to do so at that time. It was the judgment of the agency that a less formal approach would be both responsive and cost-effective in meeting agency needs in the area of ionizing radiation. It is acknowledged that this approach, albeit satisfactory in meeting the Veterans Administration's needs, does not address the broader concern about the need for a statutory committee raised in your October 15, 1982 letter. However, Dr. Curtis and I believe that the practice of using eminently qualified scientists and professionals as a consultant group does meet our program needs. A list of those individuals is included in Attachment A for your information.

Certainly we agree with the notion that ionizing radiation is a subject which holds a broad national concern. The broader national concern seems to cut across a more universal societal interest than the mission and constituency of the Veterans Administration. Therefore, we do not believe that a statutory or otherwise formally chartered committee on ionizing radiation for the Veterans Administration is indicated. Rather, the universality of the issue suggests that the establishment of a statutory committee within an agency having a more universal and primary mission associated with national health issues and problems would be more appropriate. We have highly skilled professionals who could contribute to such a committee should one be established; and, we would be pleased to participate together with other federal agencies, as a member of such a committee.

Again, I assure you of our concern with the adverse effects—real and perceived—of both agent orange and ionizing radiation. We remain fully committed to forthrightly addressing these issues as they relate to veteran health care concerns and serving America's veterans openly, honestly, and compassionately consistent with the intent of the Congress.

Sincerely,

HARRY N. WALTERS,
Administrator.

CONSULTANT GROUP ON NUCLEAR DEVICE TESTING AND RADIATION EFFECTS

Dr. John A. Auxier, Division Director, Industrial Safety and Applied Health Physics, Oak Ridge National Laboratories.

Dr. Gilbert W. Beebe, Clinical Epidemiology Branch, National Cancer Institute, NIH.

Dr. Eugene P. Cronkite, Chairman, Medical Department, Brookhaven National Laboratory.

Dr. Karl F. Hubner, Medical and Health Sciences Division, Oak Ridge Associated Universities, Oak Ridge, Tennessee.

Dr. John S. Laughlin, Chairman, Department of Medical Physics, Memorial Sloan Kettering Cancer Institute.

Dr. Takashi Makinodan, Director, GRECC, West Los Angeles, VAMC.

Dr. Klaus Mayer, Chief, Hematology, Memorial Sloan Kettering Cancer Institute.

Dr. Thomas G. Mitchell, Associate Professor of Radiology (Nuclear Medicine), Associate Professor of Environmental Health Sciences (Radiation Health Sciences), Johns Hopkins Medical Institutions.

Dr. William C. Moloney, Professor, Emeritus of Medicine, Harvard Medical School; Chief, Emeritus, Hematology Service, Peter Bent Brigham Hospital.

Dr. Robert C. Ricks, Medical and Health Sciences Division, Oak Ridge Associated Universities, Oak Ridge, Tennessee.

Dr. Henry N. Wagner, Jr., Professor of Medicine, Radiology, and Environmental Health Sciences; Director of Divisions of Nuclear Medicine and Radiation Health, Johns Hopkins Medical Institutions.

Dr. Rosalyn S. Yalow, Senior Medical Investigator, Bronx VAMC, N.Y., N.Y.; Chairman, Department of Clinical Sciences, Montefiore Hospital, Bronx, N.Y.; Distinguished Professor at Large, Albert Einstein College of Medicine, N.Y., N.Y.

VETERANS ADMINISTRATION,
Washington, D.C, Jan. 12, 1983.

Hon. ALAN CRANSTON,
Ranking Minority Member, Committee on Veterans' Affairs, U.S. Senate, Washington, D.C.

DEAR SENATOR CRANSTON: I am pleased to respond to your October 15, 1982, letter to then Administrator Robert P. Nimmo on the subject of ionizing radiation.

Let me first state that as Administrator of Veterans Affairs I will be equally concerned with the adverse effects—real and perceived—of both Agent Orange and ionizing radiation on America's veterans. In that regard, I have directed my people to ensure that unexplainable inconsistencies in our handling of Agent Orange and ionizing radiation are removed so as to conform to the needs of our veterans and the intent of Congress.

The issue of ionizing radiation is a continuing one which has been discussed and researched for years. Agent Orange, on the other hand, is a more contemporary issue. Because less is known about its effects, the vast number of personnel exposed to the substance are fearful, and rightfully so. The VA has a long established Committee on Nuclear Device Testing and Radiation Effects, and participates in numerous meetings of other committees in the field of ionizing radiation. I cannot see, at this point, where the establishment of another VA Committee would be particularly beneficial. However, if you believe that a government-sponsored committee to examine the effects of radiation on humans—probably under the auspices of the Department of Health and Human Services—would be of value, the VA would be pleased to serve.

Discussions regarding a literature search and epidemiological studies are enclosed. I hope you find these helpful. Additionally, with regard to your question about DM&S Circular 10-81-250, it will be published in the near future.

Sincerely,

HARRY N. WALTERS,
Administrator.

LITERATURE SEARCH

The vast literature on the biological effects of ionizing radiation has been meticulously searched, evaluated, and summarized by qualified professionals in the earlier publications, Biological Effects of Ionizing Radiation (BEIR) United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), as well as in such others as the 1981 report, Federal Research on the Biological and Health Effects of Ionizing Radiation (FREIR), which is the work of a 29-member committee aided by 123 outstanding consultants in the field of the biological effects of ionizing radiation.

The 1977 UNSCEAR report is about to be superseded by a new UNSCEAR report. In addition, the reports of the Intergency Radiation Research Committee (IRRC), together with those of the National Council on Radiation Protection (NCRP), and the International Commission on Radiological Protection (ICRP), are continually published and read by experts, including our VA scientists.

Beyond this, the VA maintains a current search of the literature on the biological effects of ionizing radiation through computer utilization of the National Library of Medicine and the monthly Cumulative Index of Medicine.

The literature on ionizing radiation has been, and continues to be, as thoroughly explored as any literature on any scientific topic in the world. It is the consensus of experts in the matter of ionizing radiation that the literature on this subject has been so thoroughly searched and researched that still another review would not only be redundant, but also would divert scientific effort and money from more profitable new directions such as investigations of the effect of low-level ionizing radiation at cellular and molecular levels.

EPIDEMIOLOGY

Because there may not be general awareness of the extensive epidemiological and

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human effects of ionizing radiation, the most comprehensive total figures currently available, those in the 1981 FREIR report follow.

In Fiscal Year 1979, 17 Federal agencies, employing 601 investigators, spent $111,045,595 on studies of the bioeffects of ionizing radiation.

Of that total, $79,667,997 (72%) was devoted to epidemiological studies by 413 investigators.

The Veterans Administration, in matters of veteran health and radiation effects, correlates information obtained from pertinent literature, the opinions of its consultant group on radiation effects, the attendance of its experts at germane scientific and interagency meetings, data from the Defense Nuclear Agency and the Nuclear Test Personnel Review, and from opinions expressed at meetings with various veterans' groups and representatives of service organizations.

COMMITTEE ON VETERANS' AFFAIRS,
Washington, D.C., October 15, 1982.

Hon. ROBERT P. NIMMO,
Administrator of Veterans' Affairs, Washington, D.C.

DEAR BOB: Last February I wrote Don Custis with specific comments on the Veterans' Administration's published guidelines—DM&S Circular 10-81-250, Interim Guidelines for Implementation of Legislation Related to the Provision of Health Care Services to Veterans Exposed to Ionizing Radiation as a Result of Detonation of Nuclear Devices"—issued on November 18, 1981, in implementation of section 102 of Public Law 97-72. In that letter, I stressed that the Guidelines as they pertained to radiation-related conditions were overly restrictive in two respects: First, they would exclude conditions which could not be shown to have resulted from a "cause other than exposure to radiation", the criterion in section 610(a)(1)(B) as added by section 102 of Public Law 97-72; and, second, they also might exclude conditions, such as thyroid disorders, as to which there is scientific evidence linking them to exposure to radiation.

In Dr. Custis' response of April 6, 1982, he indicated that the final Guidelines would include thyroid nodules as an addition to the class of disorders—otherwise limited to cancers—that would be considered as not having resulted from a cause other than exposure to radiation for purposes of establishing health-care eligibility under the new law.

Although I welcome this addition, I remain troubled by the agency's interpretation of Public Law 97-72 as it relates to veterans exposed to radiation. The approach adopted thus far suggests a fundamental inconsistency between the Guidelines applicable to those veterans exposed to Agent Orange and those exposed to radiation. In light of the paucity of knowledge on the health of each of these two populations and considering the ongoing controversy in the literature on the effects of radiation and of Agent Orange exposure on humans, I believe that, as a minimum, equal latitude for access to VA health care should be provided in the Guidelines for those exposed to radiation and those exposed to Agent Orange. To do otherwise on the basis of the current state of knowledge would be, in my view, unjust and not in conformity with the underlying intent of Congress.

On this point, a story (copy enclosed) carried on September 20, 1982, by United Press International relating to a press conference held that day by members of the National Association of Atomic Veterans, noted that Don Hickman, speaking for the agency, had said that "anyone who believes he was exposed to radiation is getting free treatment at agency hospitals". Such a result, which comes much closer to the implementation of section 102 of Public Law 97-72 with respect to Agent Orange exposure, is not consistent with the approach in the interim Guidelines. I urge that this matter be clarified in the Guidelines; alternatively, but far less satisfactorily, the information provided by those representing the agency in public statements should be conformed to the Guidelines.

The differences in the Guidelines for implementing Public Law 97-72 are only one example of the differences in the way the VA responds to issues associated with veterans potentially exposed to herbicides in Vietnam and those exposed to low-level ionizing radiation. In general, the agency is devoting significant resources and attention to Agent Orange-related issues; a comparable level of activity is not present regarding radiation-related issues. I believe that this lack of attention to the radiation issue is not justified.

I have in the past urged greater attention to this issue and am writing to you today to recommend that, in order to help remedy this deficiency, the VA take the following concrete steps:

(1) Establish entities relating to radiation exposure analagous to the Agent Orange Policy Coordinating Committee—so that internal agency efforts to address these matters may be examined, compared, and coordinated, which should promote greater awareness within the VA—and the VA Advisory Committee on Health Related Effects of Herbicides—so that outside expertise, veterans organizations, and public interest groups can be brought together in a public forum.

(2) Conduct, directly or by contract, a comprehensive review of the scientific literature on the health effects of exposure to ionizing radiation.

(3) Give serious consideration to conducting or providing for the conduct of an epidemiological study, relating to morbidity and genetic damage, of veterans exposed to radiation resulting from nuclear detonations.

I have long believed that a literature review would be a worthwhile undertaking. The version of S. 971 passed by the Senate on July 24, 1981—a measure ultimately enacted as Public Law 97-66—contained a provision I authored that would have required the VA to conduct a review and analysis of literature relating to the long-term adverse health effects of human exposure to radiation and to consult with and actively coordinate with other Federal Government entities involved in radiation exposure-related activities. Although this provision was not accepted by the House, I have continued to urge that such a review be carried out, with or without a legislative mandate.

Such a review would serve to ensure that the VA is more fully informed regarding radiation exposure and would pull together available relevant scientific information on this issue. I believe that it would enhance the VA's ability to resolve fairly and consistently the very complex issues involved in radiation-related VA compensation and DIC claims.

The VA, in dealing with radiation-related claims, has relied heavily on comprehensive reviews, such as the 1972 and the 1980 reports of the Committee on Biological Effects of Ionizing Radiation (BEIR) of the National Academy of Sciences and the 1977 report of the United Nations Scientific Committee on the Effects of Atomic Radiation. Because these reviews were concerned primarily with determining minimum exposure levels that might be considered safe, because of the time that has elapsed and the studies that have been completed since these reviews were published, and because many individuals, including researchers and veterans' representatives, have advised me that the analagous Agent Orange literature review has been very useful, I believe that a literature review is warranted to update and consolidate information from the BEIR, UN, and other reports. Hence, I urge that you reconsider your decision not to conduct a literature review, as outlined in your August 13, 1981, letter to me.

Regarding an epidemiological study, I am aware that limited consideration of such a study has already been given by various governmental and non-governmental entities, including the National Academy of Sciences. The Academy is currently engaged in conducting a mortality study but not a morbidity study of veterans exposed at test sites. Its August 1981 report on the feasibility of an epidemiological study of those veterans who were present at Hiroshima and Nagasaki concluded that a morbidity study was not feasible and that a mortality study would not be cost effective. Because our troops' exposure levels in Hiroshima and Nagasaki are considered generally to have been lower than those received at the Pacific or U.S. test sites, the NAS' 1981 analysis and conclusion (which is not free from controversy) relating to a study of veterans exposed at Hiroshima or Nagasaki does not suggest that the same conclusions should be reached with respect to an epidemiological study of the morbidity of veterans exposed to radiation at the test sites. Thus, I believe that the subject of conducting a morbidity and a birth defects study to complement the NAS mortality study in progress merits further consideration by the VA.

I would appreciate your views on these most important matters as well as information on the current timetable for the issuance of the final Gudelines. I know that you share my concern that our Nation's veterans be treated fairly.

With warm regards,
Cordially,

ALAN CRANSTON,
Ranking Minority Member.

WASHINGTON.—Angry and scarred veterans who claim their problems are due to exposure to atomic test blasts in the 1950's won a pledge from Congress to hold hearings on the subject next year.

The National Association of Atomic Veterans; representing 250,000 men who were exposed to 235 above-ground atomic tests from 1945 to 1963 or who served in Hiroshima and Nagasaki after the Japanese cities were destroyed by atomic bombs, successfully lobbied Monday with chairmen of the House and Senate Veterans Committees.

At an earlier news conference, they expressed anger—in some cases they were near tears—at the Defense Department's and Veterans' Administration's refusal to certify the men as having service-connected disabilities.

"Our people are dying at an alarming rate from cancer and other diseases and Government agencies refuse to help," said John Smitherman of Fayetteville, Tenn., a legless veteran whose left hand is deformed by deterioration of his lymphatic system.

But VA spokesman John Hickman called the veterans' charges of a coverup "utter nonsense" and said anyone who believes he was exposed to radiation is getting free

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treatment at agency hospitals. He said 2,882 veterans have asked for treatment.

VETERANS ADMINISTRATION,
Washington, D.C., April 6, 1982.

Hon. ALAN CRANSTON,
Committee on Veterans' Affairs,
U.S. Senate,
Washington, D.C.

DEAR SENATOR CRANSTON: Thank you for your letter of February 23, 1982, commenting on DM&S Circular 10-81-250 "Interim Guidelines for Implementation of Legislation Related to the Provision of Health Care Services to Veterans Exposed to Ionizing Radiation as a Result of Detonation of Nuclear Devices." As you know, the "Guidelines" were published in the Federal Register of December 2, 1981 (Vol. 46, No. 231, page 58637) for the purpose of soliciting comments on the proposal.

Among the comments received was the suggestion that thyroid dysfunction be included with cancer in paragraph 4 as a consequence of exposure to ionizing radiation. My staff gave careful consideration to the matter and we are in the process of adding thyroid nodules as a consequence of exposure.

Hypothyroidism was considered with other dysfunctions and was not included because it seems extremely unlikely to result from the type of exposure sustained by military personnel at atmospheric or submarine nuclear tests. Hypothyroidism results from intense ionizing radiation to the neck or, as in the Marshallese, from ingestion of considerable amounts of iodine made radioactive by ionizing radiation. Veterans were not exposed to either hazard.

Much consideration has been given to disorders that might be considered late effects of low-level radiation. The "Report of the Interagency Task Force on the Health Effects of Ionizing Radiation" discussed the issue in the summary volume (pages 31 to 38) and in the "Report of the Work Group on Science" (pages 7 to 20). The "Federal Research on the Biological and Health Effects of Ionizing Radiation" (BEIR) report of 1981 (Chapter 4) discusses the entire question.

Further consideration is contained in the 1977 report of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), "Sources and Effects of Ionizing Radiation" (pages 4 to 9).

The National Research Council convened a panel of experts which met in May 1981, with participants from various veterans organizations including the National Association of Atomic Veterans. Its report on "Feasibility and Desirability of Performing Epidemiological Studies on U.S. Veterans of Hiroshima and Nagasaki" deals less directly with the question of possible disorders. The report does conclude that it would be impossible to detect any disorders attributable to the radiation exposure.

The reported results indicate that some forms of cancer are the only treatable conditions likely to appear years after exposure to radiation and then usually after much larger doses. Inclusion of all cancers as possible treatable consequences of the veterans' experience reflects a liberal interpretation of the law, as you have urged.

The publications, excerpts from which are enclosed, confirm the conclusions arrived at during less formal contacts with experts from the National Academy of Sciences, the Centers for Disease Control and the National Cancer Institute. There is general agreement that the treatable late effects of low-level ionizing radiation are limited to carcinogenesis which includes the production of "blood cancers", chiefly leukemias. Thyroid nodules are included because they must be diagnosed further as to their possible malignancy.

As always, I appreciate your interest.

Sincerely,

DONALD L. CUSTIS, M.D.,
Chief Medical Director.

COMMITTEE ON VETERANS' AFFAIRS,
Washington, D.C., February 23, 1982.

DR. DONALD L. CUSTIS,
Veterans' Administration,
Washington, D.C.

DEAR DON: I am writing to express certain concerns that I have about the radiation exposure part of the guidelines—DM&S Circular 10-81-250, "Interim Guidelines for Implementation of Legislation Related to the Provision of Health Care Services to Veterans Exposed to Ionizing Radiation as a Result of Detonation of Nuclear Devices"—issued on November 18, 1981, in implementation of section 102 of Public Law 97-72.

Section 102 provides certain VA health-care eligibility to veterans who were exposed to ionizing radiation from nuclear detonations during their active-duty service. With the exception of a disability found, in accordance with guidelines issued by you, "to have resulted from a cause other than such exposure", Congress expressly provided that this new eligibility is for health care for any disability from which the veteran is suffering even though "there is insufficient medical evidence to conclude that such disability may be associated with . . . exposure [to such radiation]". Specifically, my concern is that the statement in paragraph four of the guidelines that "conditions other than cancer are usually considered to be due to causes other than exposure to radiation" may be overly restrictive in seeming to exclude treatment, pursuant to the new eligibility, for disabilities that may be, and in some cases disabilities that have been determined by apparently credible professionals to have been scientifically shown to be, related to exposure to ionizing radiation.

As discussed in the explanatory statement that was inserted in the record of the debates on final passage of this measure in both Houses (*Congressional Record* H6813, October 2, 1981, and S11573, October 16, 1981, (daily ed.)), the Veterans' Affairs Committees intended that the authority to issue guidelines providing for the exclusion of certain disabilities be used "so as to provide a basis for examining physicians to reach a medical judgment that the cause of the claimed disability is *clearly* something other than the exposure in question" (emphasis added). Thus, I believe that when there is conflicting evidence, or even merely suggestive evidence, of a relationship between a health disorder and exposure to ionizing radiation, you should exercise great caution in excluding that disorder from the category of disabilities for which treatment would consistently be made available under the new eligibility.

I recognize that paragraph five of the guidelines provides for individual case determinations, in situations of doubt, by the attending physician and the Chief of Staff of the facility concerned, and thereby allows for some degree of flexibility. However, I believe that too many disorders may have been relegated to this category, for which uniform guidance is not provided. Certain thyroid disorders other than cancer are a good example of such. The *Review of Medical Findings in a Marshallese Population Twenty-Six Years After Accidental Exposure to Radioactive Fallout* by Robert A. Conrad, M.D., *et al.*, of Brookhaven National Laboratory, states on page 53:

"It has been clearly demonstrated that the most serious effects of accidental exposure to fallout in the Marshallese residing on Rongelap and Utirik Atolls on March 1, 1954, has been related to radiation injury to the thyroid, as evidenced by development of nodularities and hypofunction of the gland."

That report further states that the principal effects of thyroid exposure in the Marshallese were development of nodules (benign and malignant) and hypofunction. Although malignant nodules in veterans exposed to radiation would be covered by paragraph four of the current guidelines, treatment of thyroid hypofunction and benign nodules would not.

In a similar vein, I note that Public Law 95-134, which authorized appropriations for compensation of Marshallese exposed to radiation as a result of the nuclear test program, clearly recognized the association between such exposure and thyroid disorders. That law required the Secretary of the Interior to "pay $25,000 to each such individual from whom the thyroid gland or a neurofibroma in the neck was surgically removed, or who has developed hypothyroidism, or who develops a radiation related malignancy, such as leukemia." Although the basic purposes of Public Law 95-134 and Public Law 97-72 differ, each recognizes the possibility of health effects in humans of exposure to ionizing radiation, and it seems inappropriate to me that VA health care would not be authorized under Public Law 97-72 for the same conditions for which exposed Marshallese are being compensated under Public Law 95-134. On this point, I realize that there is some controversy in the literature on radiation-related thyroid disorders regarding the relationship of both sex and age to increased risk of radiation-related thyroid disorders; however, Public Law 95-134 makes no distinction for the purposes of compensation between male and female or between persons exposed as adults and those exposed as children.

I am also concerned that paragraph four of the guidelines may exclude, or may impede appropriate recognition of, other possible health effects of ionizing radiation in veterans requesting health care under the new eligibility. Thus, I urge that in addition to the publication of guidelines in the Federal Register you specifically consult with a wide range of specialists and other interested and knowledgeable parties, such as the Centers for Disease Control, the National Academy of Sciences, Brookhaven National Laboratory, and the National Association of Atomic Veterans, on the possible adverse health effects of exposure to ionizing radiation. I would appreciate receiving a report on any such consultations that you have and any previous consultations that were had in formulating the interim guidelines, including the recommendations offered by each party consulted.

Don, I appreciate your continuing cooperation.

With warm regards,

Cordially,

ALAN CRANSTON,
Ranking Minority Member.

By Mr. DURENBERGER:

S. 993. A bill to provide a program of emergency unemployment compensation for areas experiencing high rates of unemployment; to the Committee on Finance.

EMERGENCY UNEMPLOYMENT COMPENSATION ACT OF 1983

● Mr. DURENBERGER. Mr. President, Congress has an obligation to do everything it can to produce a rapid and sustained economic recovery. But

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while we work for that recovery, we have an equally important obligation to protect the millions of Americans who are out of work through no fault of their own. Last month in the jobs bill and the social security bill Congress took important steps toward putting people back to work and providing additional relief through the supplemental compensation program to those unable to find jobs.

Those actions, however, fail to address a major problem in the extended benefit part of our current unemployment compensation law. Current law treats a State as a single entity when determining eligibility for extended benefits. This ignores the fact that areas within a State—such as Minnesota's Iron Range—may suffer extremely high and prolonged unemployment, despite the fact that the State's overall unemployment rate may be below the "trigger rate" for extended benefits. I am introducing legislation today to correct this problem by permitting States to designate areas within a State as eligible for extended benefits if they meet certain criteria.

My bill would modify the requirements that trigger eligibility for extended unemployment compensation benefits. It would permit States to make high unemployment areas eligible for extended benefits even though the State as a whole does not qualify. To be eligible, an area would have to have an insured unemployment rate (IUR) of 6 percent or higher.

The Secretary of Labor would designate the areas, which generally would have a minimum population of 50,000. A person living or previously working in an area with a 6-percent IUR would be eligible to receive these extended benefits after his or her regular and supplemental benefits are exhausted. As with the present extended benefit program, the cost would be shared equally by the Federal Government and the State.

Minnesota's unemployment situation in the past 9 months dramatically illustrates the need for an area trigger. The State's February total unemployment level, the most recent data available, was 10.4 percent. The IUR was under 5 percent—below the trigger level for extended benefits.

Yet, the unemployment levels in a number of Minnesota counties are staggering. In Lake County the unemployment rate is 25.9 percent—2½ times the national average. In St. Louis County it is 23 percent, and in Itasca County 22.5 percent. Nor is the Iron Range the only part of the State with high unemployment. Elsewhere, the counties of Clearwater, Morrision, Red Lake, Marshall, Roseau, and Koochiching also have high jobless levels.

When I introduced this same bill last year the unemployment rates in these counties were nearly as high but the IUR was only 3.77 percent. Tragically, since that time the unemployment rate in the rest of the State has risen to the point where Minnesota has reached the 5-percent IUR rate for statewide extended benefits. But the simple fact that Minnesotans are now eligible for extended benefits does not obviate the need for this legislation. Areas of the country such as the Iron Range that are undergoing fundamental economic changes will still need protection when other areas are participating more fully in the burgeoning economic revival.

Mr. President, I am not asking the Federal Government to be the sole savior of the unemployed in Minnesota. This must be a concerted effort by all levels of government and the private sector as well. In fact, the State of Minnesota and the private sector have taken steps and are developing more programs to help deal with the Iron Range's crushing unemployment. A number of these programs are long term, designed to solve the problem of the displaced worker. But relocation, retraining, and economic recovery take time. Unless we help—these people will not have the time.

Chronic long-term unemployment is like the stone dropped into a calm pond. The ramifications of long-term unemployment expand like the ripples on the pond, and the cumulative effects are devastating—increased infant mortality, families going hungry, vital medical care foregone, increased child abuse, and battered spouses. These are only some of the ramifications of long-term unemployment.

Mr. President, the supplemental compensation program is providing essential temporary relief, but our system of unemployment compensation will never address the problem of high unemployment pockets without fundamental reform. The people of the Iron Range need it. The people in other high unemployment areas need it. This bill is a first step in the process, and I urge its consideration in the near future.

I ask unanimous consent that the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 893

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

SHORT TITLE

SECTION 1. This Act may be cited as the "Emergency Unemployment Compensation Act of 1983".

FEDERAL-STATE AGREEMENTS

SEC. 2. (a) Any State, the State unemployment compensation law of which is approved by the Secretary of Labor (hereinafter in this Act referred to as the "Secretary") under section 3304 of the Internal Revenue Code of 1954, may enter into and participate in an agreement with the Secretary under this Act, if such State law contains (as of the date such agreement is entered into) a requirement that extended compensation be payable thereunder as provided by the Federal-State Extended Unemployment Compensation Act of 1970. Any State which is a party to an agreement under this Act may, upon providing thirty days' written notice to the Secretary, terminate such agreement.

(b) Any such agreement shall provide that the State agency of the State will make payments of emergency compensation—

(1) to individuals who—

(A) have exhausted all rights to regular compensation under the State law and to Federal supplemental compensation under the Federal Supplemental Compensation Act of 1982;

(B) have no rights to compensation (including regular compensation, extending compensation, and Federal supplemental compensation) with respect to a week under such laws or any other State unemployment compensation law or under any other Federal law; and

(C) are not receiving compensation with respect to such week under the unemployment compensation law of Canada,

(2) for any week of unemployment which begins in—

(A) an emergency benefit period (as defined in subsection (c)(2)), and

(B) the individual's period of eligibility (as defined in section 5(a)(2));

except that no payment of emergency compensation shall be made to any individual for any week of unemployment which begins more than two years after the end of the benefit year for which he exhausted his rights to regular compensation.

(c)(1) For purposes of subsection (b)(1)(A), an individual shall be deemed to have exhausted his rights to regular compensation under a State law when—

(A) no payments of regular compensation can be made under such law because such individual has received all regular compensation available to him based on employment or wages during his base period; or

(B) his rights to such compensation have been terminated by reason of the expiration of the benefit year with respect to which such rights existed.

(2) For purposes of subsection (b)(1)(A), an individual shall be deemed to have exhausted his rights to Federal supplemental compensation under the Federal Supplemental Compensation Act of 1982 when—

(A) no payments can be made under such Act because such individual has received all the compensation available in his account established under section 602(c) of such Act;

(B) such individual's period of eligibility under such Act has expired; or

(C) compensation may not be paid under such Act because of the termination date set forth in section 602(f)(2) of such Act.

(3)(A)(i) For purposes of subsection (b)(2)(A), in the case of any area of a State, an emergency benefit period—

(I) shall begin with the third week after a week for which there is an area "emergency on" indicator; and

(II) shall end with the third week after the first week for which there is an area "emergency off" indicator.

(ii) In the case of any area of a State, no emergency benefit period shall last for a period of less than 13 consecutive weeks.

(iii) When a determination has been made that an emergency benefit period is beginning or ending with respect to any area of a State, the Secretary shall cause notice of such determination to be published in the Federal Register.

(B)(i) For purposes of subparagraph (A), there is an area "emergency on" indicator for a week if the rate of insured unemployment in such area for the period consisting of such week and the immediately preceding 13 weeks equaled or exceeded 6 percent.

(ii) For purposes of subparagraph (A), there is an area "emergency off" indicator for a week if the rate of insured unemploy-

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Veterans Administration
Department of Medicine and Surgery
Washington, DC 20420

CIRCULAR 10-82-185

September 16, 1982

TO: Directors, Medical Centers, Medical and Regional Office Centers, Regional Offices, Regional Offices with Outpatient Clinics, Domiciliary, and Outpatient Clinics

SUBJ: Guidelines for Implementation of Legislation Related to the Provision of Health Care Services to Veterans Exposed to Dioxins

1. The "Veterans' Health Care, Training, and Small Business Loan Act of 1981" was signed into law on November 3, 1981. The Act, Public Law 97-72, authorizes the Veterans Administration to provide certain health care services, as described in paragraph 3, to any veteran of the Vietnam era (August 5, 1964 - May 7, 1975) who while serving in Vietnam may have been exposed to dioxin or was exposed to a toxic substance in a herbicide or defoliant used for military purposes. Verification of service in Vietnam during the Vietnam era (August 5, 1964 - May 7, 1975) will be required. In the absence of affirmative evidence to the contrary, a Vietnam veteran's contention of exposure will be accepted.

2. Health care services may not be provided under this law, for the care of conditions which are found to have resulted from a cause other than the specified exposures.

3. Health care services authorized under this provision are limited to hospital and nursing home care in VA facilities and outpatient care in VA facilities on a pre- or post-hospitalization basis or to obviate a need for hospitalization. Such health care services will be provided without regard to the veteran's age, service-connected status or the inability of the veteran to defray the expenses of such care. Veterans furnished outpatient care under this authority will be accorded priority ahead of other nonservice-connected veterans and equal to former Prisoners of War who are receiving care for nonservice-connected conditions. Congress made it clear that this law provides for health care only, and that a determination that the veteran is eligible for such care does not constitute a basis for service-connection or in any way affect determinations regarding service-connection.

THIS CIRCULAR EXPIRES ON SETPEMBER 15, 1983

6. In the event the responsible staff physician finds that a veteran has a condition not ordinarily considered to be due to the specified exposure and there are no complicating circumstances warranting the provision of care under this authority, the decision and its basis will be clearly documented in the medical record.

7. The provisions of this circular will not exclude any veteran who served in the Republic of Vietnam from being included in the VA's Agent Orange Registry Program as outlined in DM&S Circular 10-81-54, dated March 19, 1981.

8. These guidelines will be effective upon receipt. A copy of the pertinent guidelines should be made available to any veteran seeking care under this authority.

9. This circular rescinds DM&S Circular 10-81-249 dated November 18, 1981.

W. J. JACOBY, JR., M.D.
Deputy Chief Medical Director

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REVIEW OF CHLORACNE CLAIMS

The Department of Medicine and Surgery reviewed the Rating Decision Sheets of more than 3000 veterans who had filed claims for compensation with the Department of Veterans Benefits. From them, some 300 cases were selected as having descriptions of conditions that might suggest chloracne.

A VA dermatologist then reviewed the medical records of the 300 claimants and identified 14 veterans who could have chloracne. Thus far, 13 of these 14 men have received a medical examination with emphasis on the skin problems; the remaining man has been unavailable.

Each of the 13 examinations has been performed by a prestigious private clinic. No case could be diagnosed as chloracne although one man gave a history of exposure that suggests that he has or has had chloracne. His condition is being investigated further.

Eleven of the 13 veterans, including the one still being investigated, were diagnosed as having common acne. Although 10 of the 14 veterans have one or more service-connected disabilities, none has been service-connected for chloracne.

L. B. Hobson 4/19/83

Chloracne and the Agent Orange Examination

Veterans who served in Vietnam from 1962 through 1971 may have been exposed to Agent Orange, an herbicide widely used to destroy crops or protective cover. Other herbicides and several insecticides were extensively sprayed but Agent Orange contained, as a contaminant, TCDD or dioxin. This substance is highly toxic to some animal species, much less so to others, and toxic doses of it cause birth defects if given to pregnant rodents. It may be a carcinogen or may potentiate carcinogens in experimental animals. The immediate effects of TCDD on men have not been so severe as on animals and only chloracne is well established as a prolonged consequence.

Chloracne characteristically appears within a few weeks of exposure to a chlorinated hydrocarbon such as TCDD. It closely resembles acne vulgaris and is associated with numerous large comedones and straw-colored cysts a millimeter to a centimeter in diameter. The acneiform lesions are most common over the malar area, other facial areas, behind the ears, and along the arms, although they may occur on other skin surfaces as well. In most cases, chloracne disappears within a few months or years; cases have persisted for a decade or more without known continued contact with the causative agent.

Veterans have claimed that Agent Orange causes a variety of ill effects that appear or persist over years after exposure. These include many skin conditions, infertility and birth defects, cancer, liver disease, gastrointestinal complaints, neuropathy, fatigability, nervousness, and general debility. None of the varied complaints, except chloracne, has been linked to Agent Orange by conclusive medical or scientific studies.

Veterans who served in Vietnam and who express concern about possible exposure to Agent Orange should receive the Agent Orange Registry examination. They should be referred to the Environmental Physician at the appropriate VAMC or clinic if they have not had this examination. If this is not practical, for example, in the case of a prisoner, the Environmental Physician should supply the questionnaire, directions for the physical and laboratory examinations, and the proper reporting forms.

The registry examination contains no test unique to Agent Orange. It is essentially an evaluation of the veteran's health status. It will not determine whether a person was exposed to the herbicide or whether the veteran's body contains TCDD or the ingredients of Agent Orange. The results cannot be used per se to determine whether a given condition results from herbicide exposure. The Registry does allow the VA to provide later information to the veteran and is one means of identifying possible common consequences of service in Vietnam.

If the veteran is referred for a claimant's examination, the usual tests relevant to the complaint will be used. In addition, attention should be paid to examination of the skin, nervous system, muscular function, liver, kidneys, and mental status even when the claim is not directed to them. Questioning should attempt to uncover details of exposure to Agent Orange, to any adverse effects that are reported to have followed immediately after the exposure, and the time relation between later effects and exposure. When birth defect is claimed in an offspring, the obstetrical history of the spouse, including other births, should be elicited as well as familial histories of birth defects of both parents as should details including birth date and defects of the child in question. Confirmatory information from the obstitrician, pediatrician or other medical attendant should be sought.

L. B. HOBSON 1/14/83

EPIDEMIOLOGY OF SOFT-TISSUE SARCOMA AND RELATED HUMAN RESEARCH

Initiation of Swedish Studies of Herbicides and Cancer

In 1972 Swedish newspapers published rumors that railroad workers were dying from lung cancer as a result of exposure to herbicides used in their work. The National Board of Occupational Safety, as a result, requested Professor Olav Axelson, a specialist in occupational medicine, to undertake an epidemiological investigation of the matter.

The results of this investigation have been reported in a series of four papers, 1-4. Another series, 5-7, was prompted by criticism of the epidemiological and statistical methods employed in this and related studies. Attention in the United States has focussed on the pre-publication manuscript of the 1980 paper by Axelson, Sundell, Andersson, Edling, Hogstedt, and Kling, 4.

This paper dealt with two aspects of the study of railroad workers. The initial phase was a cohort study of 348 men who had been exposed, individually rather than as a group, to herbicides for more than 45 days during 1957 to 1972 and who were followed through October 1978. Exposure information was incomplete but the workers were divided into subcohorts with exposure to phenoxy acids (which include the ingredients of Agent Orange), amitrol, or to both herbicides. The mortality rates for these exposed subcohorts were compared to the age-specific national death rates for Swedish men, the latter serving as the control cohort.

Overall 49 deaths were expected in the exposed cohort; 45 occurred, a result attributed to the "healthy worker effect." There were, however, 17 tumors found where 11.85 were expected. Among the deaths occurring at least ten years after the first exposure, 6 cancers were found although only 1.78 were expected. Dr. Axelson, 8, later increased this to 7 tumor cases. Each subcohort had an excessive number of tumor deaths, the greatest being in the group exposed to both phenoxy herbicides and amitrol.

Although initially, 2, amitrol was associated with an increased tumor mortality, somewhat different results were found in a second phase of the examination, described as a case-referent study (identical to a case-control study). The data indicated a "statistical association" of phenoxy herbicides and excess tumor mortality, 3. Suspicion was increased by finding that workers exposed to phenoxy acids

alone had a "statistically significant excess of stomach cancer", specifically 2 cases compared to 0.33 expected when this type of herbicide was used alone and 3 cases as compared to 5.1 expected (increased from 4.1, 8) for all workers exposed to phenoxy herbicides, alone or with amitrol.

The series of papers on railroad workers has been criticized on several methodological grounds, 9, and Axelson has replied to these criticisms, 6. Richard D. Remington, Dean of the School of Public Health, University of Michigan, reviewed this and other Swedish studies for the Office of Technology Assessment. His evaluation, 10, was that the Axelson investigations had been "carefully conducted" and "well reported." He pointed out the limitations of the statistical methods used and found that "the numbers available ... are inadequate to permit definite conclusions" although "the results ... are suggestive."

Of interest in connection with the question of soft-tissue sarcomas and phenoxy herbicides is the type of tumors found by Axelson's group, 4. One case of Hodgkin's lymphoma occurred among the eight tumors in men exposed to phenoxy herbicides alone and no soft-tissue sarcomas or non-Hodgkin's lymphomas was diagnosed among the eight tumors appearing in workers exposed to both amitrol and phenoxy herbicides. In other words, no sarcomas were reported for the total of 207 men exposed to phenoxy compounds, 2. A reticulum cell sarcoma and a Hodgkin's lymphoma were found among the 7 tumors of workers exposed to amitrol alone. Thus, there was one soft-tissue sarcoma reported for 152 men exposed to amitrol, 2. Another 28 persons described as exposed to "other herbicides and combinations" cannot be identified as to exposure to specific herbicides but apparently none developed a tumor.

Axelson's work is directly related to the later work on soft-tissue sarcomas and lymphomas by Lennart Hardell. Indeed, Axelson suggested to Hardell in 1976, that he conduct a case-control study of soft-tissue sarcomas and has actively assisted in Hardell's work since then.

Swedish Investigation of Soft-Tissue Sarcoma

That work began when Hardell admitted for treatment 3 patients in the autumn of 1976, each with a soft-tissue sarcoma, and a history of exposure to phenoxy herbicides. He then found a total of 7 patients with "malignant mesenchymal tumors" (soft-tissue sarcomas) who gave a history of having worked with phenoxy herbicides 10 to 20 years earlier. The cases were among 87 patients with soft-tissue sarcomas, 55 of

whom were men. Of these men, 9 were forestry workers, 6 worked in forestry and on farms, and 6 were employed in saw mills or pulp plants. Another two tumors appeared in men whose connection with forestry was less direct. The malignancies found were two leiomyosarcomas, two rhabdomyosarcomas, two neurofibrosarcomas, with one each of fibroid liposarcoma, myxofibrosarcoma, and polymorphocellular sarcoma, 12.

Following Axelson's advice, Hardell began a case-control study that was published in two journals, 13, 14, a common practice of reporting in Swedish with an almost identical paper in English. The second paper in English aroused much interest in the United States.

Hardell and Sandstrom found 21 living and 31 dead men who were diagnosed as having soft-tissue sarcomas in Hardell's oncology department in northern Sweden. They were matched for age and place of residence, as well as date of death for the deceased, with other men selected from the Swedish National Population Registry or from the National Registry for Causes of Death. Each living patient had 4 living controls; each dead man had 4 deceased controls. Exposure information was sought by the use of a mailed questionnaire that has never been published. It contained 130 questions, including 16 about the use of organic solvents, 4 about plastics, 3 about glues, 4 about drugs, "several" about smoking habits and an unstated number about exposure to phenoxy herbicides and chlorophenol as used in the lumber and paper mills. This questionnaire was mailed to the patient or to his next of kin if he were dead, 15.

When the answers to the questionnaire were less than clear, a supplementary interview was obtained, usually by telephone, with the interviewer unaware of the health status of the person in question. Employers, neighbors, and others were consulted "if necessary to verify and monitor the accuracy of the exposure information," 15.

Using the criteria for exposure established for the study, 36.5% of the 52 patients and 9.2% of the 208 controls had been exposed to phenoxy herbicides and/or chlorophenols. The "relative risk" of developing soft-tissue sarcomas was calculated as 5.7, i.e. men exposed to the chemicals had almost six times as great a change of developing a sarcoma as did those who were not exposed. The relative risk was 5.3 for the 46 men exposed to phenoxy herbicides alone, and 6.6 for the 40 men exposed only to chlorophenols. It was thought that confounding factors had an insignificant effect.

The authors concluded that "the investigation showed an increased risk for soft-tissue sarcomas" but "a specific evaluation of the effect of separate chemical substances was not possible," 14.

The study's methods have been criticized and doubts have been expressed about the 100% response rate to the questionnaire approach, 9. (Actually, 2 of 208 controls did not answer, 14.) The statistical approach was described as slightly misrepresented and a major criticism was leveled because of the possibility of "selective recall," the greater tendency for an ill person to remember a supposed "cause" for the illness than a well person would have to remember the same "causal" event.

The criticisms evoked several replies. Axelson defended the case-control design, the objectivity of obtaining exposure data retrospectively, and the statistical techniques, 6. He concluded that the use of interviews for determining exposure is justified, 7, and defended in principle the treatment of confounding factors, 16. Hardell recalculated the 1979 results and his subsequent papers to substantiate his earlier findings and performed a separate investigation in support of his confidence that "no substantial observational bias could exist in the studies," 15.

Remington, 10, expressed the view that "the findings of this particular investigation are suggestive" and that "a relative risk of 5.3 for exposure to phenoxyacetic acids must be taken seriously." However, "case-control studies are uniquely susceptible to hidden sources of bias" even when the investigators are "unusually careful" as they are in this "excellent investigation."

Hardell's group also undertook a second case-control study of identical design in southern Sweden which is more devoted to agriculture than to forestry, 17, 18. In this investigation each of 72 living and 38 dead patients was matched with two controls. Among the 110 cases, 22.7% reported exposure to phenoxy herbicides or chlorophenols and, among the 219 controls, 5.9% were so exposed. This gave a relative risk of 5.1 with matching and 4.7 when the matching was dissolved, i.e. when sorting by age was ignored during statistical calculations. The relative risk from exposure to phenoxy herbicides was calculated to be 6.8, and that from chlorophenols to be 3.3. Exposure to more than a dozen other noxious materials, e.g. asbestos, smoking, DDT, and lindane, were considered as possible confounding factors although none was found to be clearly associated with an increased risk by itself.

The reports list the diagnoses of all 110 cases of soft-tissue sarcoma as: leiomyosarcoma, 33; malignant fibrous histiocytoma, 19; liposarcoma, 15; neurogenic sarcoma, 11; angiosarcoma, 9; myxofibrosarcoma, 7; fibrosarcoma, 5; dermatofibrosarcoma, 3; atypical fibroxanthoma, synovial sarcoma, sarcoma NOS, 2 each; Ewings's sarcoma (extraskeletal) and rhabdomyosarcoma, 1 each. No statement is made as to which of these tumors was found in the 25 cases with identified exposures and no histological diagnoses are reported for the northern Swedish series, 13, 14.

The authors of the southern Swedish study conclude that "exposure to phenoxy acids and chlorophenols might constitute a risk factor in the development of soft tissue sarcomas," 18. The investigation has been the subject of the same criticisms and refutations as the earlier study.

Remington concludes that "the results are consistent with the hypothesis that phenoxy acid exposure increases the risk of tumors of this type" but adds that "case-control methodology is intrinsically susceptible to subtle and unmeasurable biases."

Swedish Investigation of Lymphoma

In May, 1978, Hardell was prompted to a new study by a patient with a malignant histiocytic lymphoma and a history of "massive exposure to phenoxyacetic acids." All men admitted to the oncology department with this type of tumor during the first nine months of 1978 were asked about their occupation and possible chemical exposure. Of 17 patients, 14 reported an occupation consistent with exposure and 11 of them had had contact with phenoxy herbicides or chlorophenols ten or more years earlier, 19.

These observations led to a case-control study, the report of which in 1981, 21, differs considerably from that in 1980, 20. The earlier report was commented upon in manuscript form by various experts but the later version will be used here.

The investigation, in collaboration with Axelson, 20, included both Hodgkin's disease and non-Hodgkin lymphomas. The 169 cases consisted of 60 Hodgkin's disease patients (lymphocyte predominance, 20; nodular sclerosis, 3; mixed cellularity, 27; lymphocyte depletion, 10), 105 men with non-Hodgkin's lymphomas (follicular center cell (FCC) type, 53; non-FCC type, 52), and 4 individuals with unclassifiable lymphomas. Each case had two matched controls, 338 in all. Of the cases, 62 had died as had 124 of the controls.

Questionnaires and interviews were used to determine exposure to phenoxy herbicides, chlorophenols, organic solvents, or medicines and to characterize jobs, hobbies, and smoking as they were determined in the soft-tissue sarcoma investigations, 20. All cases and controls were from northern Sweden.

Cases in which exposure was reported to chlorophenol, or to "mutagenic" solvents (benzene, trichloroethylene, perchloroethylene and styrene) were divided into high-grade and low-grade exposure groups. Continuous exposure for a week or less or repeated exposures totaling less than a month were considered low-grade. Analyses also divided cases into two groups depending on whether 5 years had elapsed as a latency period between the first exposure to the chemical and the tumor diagnosis.

Of the cases, 36.1% had been exposed to phenoxy herbicides or chlorophenols; 9.6% of the controls had been so exposed. The relative risk for these exposures was 6.0 with matching and 5.3 without it. Phenoxy herbicides gave a relative risk of 4.8 although it was greater if exposure was for 90 days or more. Chlorophenols gave relative risks of 8.4 for high-grade exposure, 2.9 for low-grade. High- and low-grade exposure to organic solvents gave relative risks of 2.8 and 1.2 respectively. On the other hand the few cases with both phenoxy herbicide and high-grade organic solvent exposure was calculated to have a relative risk of 11.2 and some other combinations also gave large relative risks. The length of the latency period, however, seemed to have no effect.

The authors conclude that "this investigation suggests that exposure to organic solvents, chlorophenols, and/or phenoxy acids constitutes a risk factor for malignant lymphoma," 21. Dr. Remington commented that "a substantial and statistically significant relative risk is found for this group of tumors. And again, pnenoxy acid exposure is specifically incriminated." He continues, however, that the limitations of case-control methods have to be considered as well.

Swedish Investigation of Carcinoma of the Colon

Hardell undertook to answer doubts that his questionnaire and interview methods allowed observational bias in assessing exposure by conducting a case-control study of "colon cancer." The condition is not suspected of having any association with phenoxy herbicides or chlorophenols. In consequence, if the previously used exposure determination

resulted in a relative risk of 1.0 or near it, there had been no observational bias in the questionnaire-interview procedure used in the earlier studies of soft-tissue sarcomas and lymphomas.

Of the 157 men with colon cancer all but 3 answered the questionnaire. The controls consisted of the control groups from the soft-tissue sarcoma study (206 men) and the malignant lymphoma study (335 men). In all, 41% of the cases and 45% of the controls were dead. Of the cases and controls, 11.0 and 10.4% respectively had been exposed to phenoxy herbicides or chlorophenols. For phenoxy herbicides, the relative risk was calculated to be 1.3 and for chlorophenol it was 1.8. Neither was significantly above 1.0. The conclusion was that "the previously reported associations between exposure to phenoxy acids or chlorophenols and soft-tissue sarcoma and malignant lymphoma cannot to any essential degree be explained by observational bias," 15.

Later Criticism of Swedish Studies

There remain, however, doubts about the practical significance of the Swedish epidemiological studies stemming from several of their characteristics. The main criticism is the reliance on recall of the men or their relatives, employers and associates for undramatic events years earlier as well as the possibility of unconscious bias on the part of the interviewer, the "observational bias" discussed above. Coggan and Acheson point out that the positive association between exposure to phenoxy herbicides and the development of several or many soft-tissue sarcomas, Hodgkin's disease and non-Hodgkin's lymphoma may indicate "a serious undetected bias" even though the explanation has been offered that all these tumors are embryologically related, 22. These authors conclude that "it is as yet impossible to estimate with any precision the risk of soft-tissue sarcoma due to phenoxy herbicides" but add that "there is suggestive evidence of a biological association between phenoxy herbicides (or their contaminants) and soft-tissue sarcomas." They feel that there is weaker evidence for an association between herbicides and lymphomas.

Hardell and Axelson reject the idea of observational bias, citing the colon cancer study as evidence, 23. They also defend the aggregation of tumors because of the "so-called addition theorum for chi-square and Poisson distributions" as well as the embryological relationship of the neoplastic tissues.

American Support for Swedish Conclusions

Support for the connection between soft-tissue sarcomas and exposure to phenoxy compounds has been reported in several papers from outside Sweden. The data most often cited as favoring the relationship are derived from observations in the American chemical industry.* The first was a note by Honchar and Halperin in which they pointed out that of 105 deaths in four exposed industrial "cohorts" 3 (2.9%) were due to soft-tissue sarcoma, whereas only 0.07% of deaths among adult American men are so caused. The three cases were malignant fibrous histiocytoma, fibrosarcoma, and liposarcoma. The authors felt that these "suggest a common pattern," 24. Cook added a fourth case, another malignant fibrous histiocytoma and noted that all four were smokers and two had chloracne, 25.

Moses and Selikoff reported a fifth case, a non-smoker, with neurogenic sarcoma (malignant schwannoma). They give the total annual incidence of soft-tissue sarcomas as 4500 (less than 1% of newly diagnosed cancers) in the U.S. and quote 4.9% of soft-tissue sarcomas as malignant schwannoma, 26.

Johnson and his co-workers briefly described a young man who died of fibrosarcomatous mesothelioma some four years after first being exposed to phenol. His father had a liposarcoma after "prolonged exposure" in a plant manufacturing chlorinated phenols among other chemicals, 27.

Hardell and Ericksson accepted the two additional cases to total 7 deaths from soft-tissue sarcoma among 105 deaths among American industrial workers, the expected number being 0.07%. This would "fit in with" the Swedish investigations, they believe, 28.

To date no critical review has been made of the cases and the industrial population in which they were detected. The reports have been brief "Letters to the Editor" and each discusses one to three cases. The total of 105 deaths used as the number of dead workers has not been kept current as new soft-tissue sarcoma cases were added and the total number

*Data given by Honchar and Halperin, Cook, Moses and Selikoff, and Johnson et al pertain to workers at Monsanto Company and Dow Chmical Company. For details of studies of these workers see 24a and 25a.

of exposed workers has not been given. No use has been made of controls, even in the form of a retrospective cohort comparison.

A case report without statistical data briefly described three soft-tissue sarcomas among Vietnam veterans who reported exposure to phenoxy herbicides in that country. One man had an inflammatory histiocytoma, another suffered from a fibrosarcoma, and the third had a leiomyosarcoma, 29.

European Support for Swedish Conclusions

Barthel determined the frequency of malignant neoplasms among 1791 pesticide sprayers and agricultural technicians in East Germany during 1976 to 1979. He states the retrospective cohort study used police as controls but gives no data for them. After eliminating "on statistical grounds" 133 cases who died before 1970, he compared the mortality rate and cancer incidence with corresponding figures from the death statistics and the cancer registry of the Health and Social Welfare. The "case" group had multiple exposures over the years to fungicides, insecticides, and herbicides including phenocyacetic acids. Among 169 malignant neoplasms in 1658 exposed men were 1 lymphosarcoma, 3 plasmacytomas, 1 described as a malignancy of lymphoid tissue, and 1 of soft-tissue, not otherwise characterized. Bronchogenic carcinoma was the most common malignancy with 59 cases, double the expected occurrence, although the cases had smoking habits like those of the general population, 30. A brief report describes a case of non-Hodgkin's lymphoma and a second of malignant lymphoma among 158 workers with pentachlorophenol. This type of neoplasm would have an expected occurance of 0.28, 31.

Studies Not Supporting Swedish Conclusions

In contrast to the reports of an association between phenoxy herbicides or related compounds and soft-tissue sarcomas and malignant lymphomas, some investigators have found no association. Some of these investigated a possible relation, others were "follow-up" studies of industrial workers in whom no sarcomas or lymphomas were found.

Dr. Riikimaki and his collaborators have completed nine years of mortality study following 1,926 persons who worked with phenoxy herbicides in Finland during the 1955-1971 period. All had at least two weeks of exposure and a quarter of the men totalled eight weeks or more as of 1971. The mortality rates among the workers were compared with the national death rates. As of 1980, there had been 82 deaths

of exposed men as compared to 91 expected and, of these, 17 were cancer deaths with 18.4 expected. There were no cases of soft-tissue sarcoma nor of lymphomas although 0.1 and 0.8 would have been expected. The authors believe that "the ... investigation cannot be regarded as a conclusive negative study" but point out that the "results do not confirm the ... association between mixed herbicide exposures" and cancer risk, 32.

Hogstedt and Westerlund compared the mortality rate of Swedish supervisors and workers in forestry. The supervisors were fewer in number (142) than the workers (244) but the former were judged to have been more heavily exposed. The relative risk of death was about the expected but, after a 10-year latent period, the relative risk for cancer was about 4 for the supervisors and only about 0.4 for the workers. The fatal tumors were of various types but there was no soft-tissue sarcoma or lymphoma, 33.

Two case-control studies in New Zealand have been initiated by Smith et al to examine the association suggested by Swedish studies of phenoxy herbicides with soft-tissue sarcomas and malignant lymphomas. In the first investigation, 102 cases of soft-tissue sarcoma have been identified in men from the New Zealand Cancer Registry between 1976 and 1980. An equal number of matched controls with other forms of cancer were selected for comparison. The sarcomas are fibrosarcomas, 25; liposarcomas, 20; rhabdomyosarcomas, 9; leiomyosarcomas, 7; malignant histiocytomas, 6; other types, 22; and unspecified, 13. The preliminary report compares cases and controls as to the occupation shown on the Registry enrollment. There was no significant difference betwen the groups as to the number of men working in agriculture, forestry, and fishing, the occupations with the greatest likelihood of exposure to phenoxy herbicides and chlorophenols. The only occupations associated with soft-tissue sarcomas exclusively are blacksmiths, machine tool operators, electrical fitters, and electrical workers. The investigators are now obtaining work histories for cases and controls by telephone interviews and warn that later results may change their conclusions. The data at present "do not give evidence for a relationship (of soft-tissue sarcoma) with occupational exposure to phenoxy herbicides and chlorophenols" but "should not be taken as substantive evidence against the hypothesis", 34.

A second report by Smith et al includes the results of the telephone interviews regarding 80 cases and 92 controls already completed. Probable or definite exposure to phenoxy herbicides for more than one day earlier than five years before cancer registration was found in 17 cases and 13 con-

trols, giving an odds ratio of 1.6. This would be expected to increase when the exposure criteria were more stringent, but, when exposure was at least five days and more than ten years before registration, there were 13 cases and 12 controls included reducing odds ratio of 1.3. Neither ratio is statistically significant and there have been no soft-tissue sarcomas reported among the most highly exposed group of 2000 aerial and ground sprayers. The results, the authors believe, "do not generally support the hypothesis that exposure to phenoxy acid herbicides cause soft-tissue sarcoma," 35.

A brief initial report by Edling and Granstam compared the causes of death for 375 Swedish forestry workers, aged 25 to 69 years, who died during 1968 to 1977, with the mortality figures from the Swedish national statistics. There were 75 deaths from all malignant tumors, as compared to 86 expected. Renal tumors killed 8 with 3.84 expected and "tumors of lymphatic and hematopoetic systems" were responsible for 14 deaths with 7.5 expected. No deaths were attributed to soft-tissue sarcoma, 36.

In addition to these studies, several small industrial groups have been followed well into the latent period for solid tumors. None has been reported to include cases of soft-tissue sarcoma or malignant lymphoma. May examined 41 of 79 workers who developed chloracne following accidental exposure to trichlorophenol in 1968 at the Coalite Company in Great Britain. Another 54 employees were possibly exposed. None of the workers had significant changes ten years after the accident and neither death from nor evidence of neoplasm was found, 37. Jirasek's group has closely followed 55 men who were intensely exposed during the manufacture of 2,4,5-trichlorophenoxyacetate from 1965 to 1968 in Spolana, Czechoslovakia, and who developed evidence of acute intoxication. Two workers died of bronchogenic carcinoma 5 to 5.5 years after the first exposure. There was no other evidence of malignant neoplasms during a ten-year follow-up, 38.

In 1963 an explosion at Philips-Duphar, Amsterdam, exposed 106 workers involved in manufacturing 2,4,5-tetrachlorophenyoxy acewtate. Among the 93 workers followed to 1977, only one death 14 months after the accident was due to cancer and the pancreatic carcinoma involved was apparently symtomatic before the explosion. No case of soft-tissue sarcoma or malignant lymphoma was reported, 39.

One study is often cited with the Swedish studies although it did not deal with soft-tissue sarcomas and malignant lymphomas, 40. A more recent review by Thiess et al reports that all 74 exposed persons are still being followed

after 26 years. There have been 21 deaths, about equal to the 18 to 20 deaths expected from major comparative populations and 18 and 19 deaths expected among matched unexposed controls. Cancer was responsible for 7 deaths as compared to 4.1 expected from the comparative populations and 5 in each internal control group. Gastric carcinoma in 3 exposed persons exceeds the expected 0.61 to 0.70 expected cases. There were, however, no soft-tissue sarcomas or malignant lymphomas among these chemical workers at BASF, 41.

A number of other industrial exposures to phenoxy herbicides, their precursors or contaminants were reported before 1973, 42. The populations were small but generally heavily exposed. Unfortunately it has not been possible to locate late reports on the exposed populations although ten years or more have elapsed since exposure.

The accident at the ICMESA factory in Seveso, Italy, in July 1976 exposed many people to trichlorphenol; more than 5400 adults and children of both sexes are known to have been in contact with the chemicals for several days, 43. Although only about six years have elapsed since the exposure, the population has been under surveillance and the rate and causes of death are being followed. To date no soft-tissue sarcomas or malignant lymphomas have been reported.

Another less systematic observation bears on the situation. The phenoxy herbicides have been used frequently and extensively in agriculture and forestry in the United States since the late 1940's. They were used on lawns in cities, as well, for most of that period. If the relative risk of developing so distinctive a group of tumors as the soft-tissue sarcomas and the malignant lymphomas had increased by 5 of 6 fold over that before 1945 as the Swedish studies would predict, it almost certainly would have been evident to clinicians and pathologists, especially in the rural areas, even without systematic studies. No such increase was noted.

Critical Evaluations

The Swedish investigators have been cautious in interpreting their results. In his medical dissertation based on his epidemiological studies, Hardell judges that the similar results in the two case-control investigations (12, 13, 14, 16) "seem to increase the confidence that the observed association of exposure to phenoxy acids and soft-tissue sarcoma was not spurious" and did not believe that confounding factors "could account for the observed relation." In summary, he concluded that "it is suggested that exposure to phenoxy

acids should be looked upon as an occupational cancer hazard," 44.

Other reviewers have been more skeptical as to the significance of the work. Remington's overall opinion was that "in toto, the Swedish work is credible if not fully conclusive. Certainly this work would seem to justify further investigation," 10. Coggan and Acheson, after reviewing other work as well as the Swedish studies, state that "on the present evidence it seems possible that soft-tissue sarcomas have arisen in association with exposure to phenoxy herbicides" but continue that "it is as yet impossible to estimate with any precision the risk of soft-tissue sarcoma due to phenoxy herbicides." They conclude that "there is suggestive evidence of a biological association between phenoxy herbicides (or their contaminants) and soft-tissue sarcoma. The evidence relating these products to the occurance of lymphoma is weaker," 22. An unsigned editorial in Lancet commenting on the opinions of Coggan and Acheson seems to agree with their conclusions with regard to soft-tissue sarcomas, 45.

Hardell and Axelson disagreed with both the Coggan and Acheson's opinions and the Lancet editorial, 23. They have been at some pains to counter charges of "observational bias," 15, but have not convinced everyone that faulty memories do not result in significant errors in evaluating exposure, 45.

The causal connection between phenoxy herbicides and soft-tissue sarcomas would be much more likely if there were a unique preponderance of one type or even of a few types in the exposed men. The Swedish reports never compare the morphological types or location of the malignant tumors in cases with those in controls, 45. Their only justification for aggregating the types, and presumably for omitting the data from their reports is "the uncertainty of relations between the various histological groups in terms of causal mechanisms" and "the so-called addition theorem for chi-square and Poisson distribution," 23. The uncertainty of causal relations is precisely the reason for reporting the groups and the addition theorem cannot justify the aggregation of unlike

*2,3,7,8-tetrachlorodibenzo-p-dioxin has been suggested as the principal carcinogen in the phenoxy herbicide 2,4,5-T and trichlorophenols but this has been disputed. See 22, 23, 45, 46. The controversy is not considered in this discussion.

entities unless significant common factors have been demonstrated.

Scientific results are strengthened greatly when independent investigators substantiate them. The Swedish studies have been said to be independent and confirmatory. The two soft-tissue sarcoma investigations do support one another (12, 13, 14, 16) but they are the work of the same group of investigators. The investigation of malignant histiocytic lymphoma was also conducted by the same group but was a case-control study of a separate entity, (19-21). Axelson's work on herbicide exposure and cancer (1-4) was not truly independent from Hardell's efforts since Hardell has recognized his indebtedness to Axelson for his assistance in the first case-control study, (13, 14). More important Axelson did not associate phenoxy herbicides or chlorophenolic compounds with soft-tissue sarcomas nor with malignant lymphomas among railroad workers, 1-4.

The reports of soft-tissue sarcomas among chlorphenol workers in the United States (24-27) have been cited as supporting Hardell's conclusions, 24, 28, 44, 46. The data have been reported piecemeal without a clearly enumerated total population from which they were drawn. The comparison was made to mortality data for the general population of the appropriate age and sex. The type of soft-tissue sarcoma is known for each case; among the 7 men were 2 malignant fibrous histiocytomas, 2 liposarcomas, as well as one each of fibrosarcoma, malignant schwannoma, and fibrosarcomatous mesothelioma. As before, the tumors are not of a uniform type.

Coggan and Acheson comment that the Swedish studies and the American reports taken separately do not "provide convincing evidence that the incidence of soft-tissue sarcomas is increased after exposure to phenoxy acids and chlorophenols, -- Considered together the whole becomes more persuasive." They add that "it is surprising that the association should apply to tumors of such a variety of tissues," 22. The Lancet editorial finds only that "the number of deaths due to soft-tissue sarcomas [in the American data] is disturbing," 45.

In addition to the American experience, the British (37), European (30, 32, 33, 36, 38-41) and New Zealand (34, 35) medical and scientific writers have studied populations five years or longer after exposure to phenoxy herbicides and/or chlorophenols in a variety of situations, some intense and acute, others prolonged. Only one observer (30) reported a case described as a soft-tissue malignant neoplasm without

further characterization. The same report included a lymphosarcoma, a malignant neoplasm of lymphoid tissue and 3 plasmocytomas. No other study found a soft-tissue tumor.

In summary, the Swedish studies of soft-tissue sarcomas cannot be considered to have proved that exposure to phenoxy herbicides is the cause of one or more types of this varied group of malignant tumors. There are no fully reported systematic studies to confirm what the Swedish investigators describe as an association. There are an epidemiological study (32) and observations of exposed populations that do not support the finding as opposed to uncorrelated American observations and an East German study (30) that do strengthen the case for such an association.

At best, the Scottish verdict of "Not proven" seems most realistic at this time. The Advisory Panel on Toxic Substances of the American Medical Association says that "while 2,4,5-T and 2,4-D pesticides (phenoxy herbicides in Agent Orange) have been used in agriculture, forest management and residential landscaping for over 30 years, there is still no conclusive evidence that they and/or TCDD (a contaminant of Agent Orange) are mutagenic, carcinogenic, or teratogenic in man, nor that they have caused reproductive difficulties in the human," 47.

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PORPHYRIA CUTANEA TARDA

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PORPHYRIA CUTANEA TARDA

Definition: Porphyria cutanea tarda (PCT) is the most frequent of a group of uncommon diseases, the porphyrias, that comprise disturbances in the body's formation of hemoglobin, the red chemical in blood. A specific pattern of chemicals called porphyrins, excreted in the urine and stool, characterizes PCT and reflects a deficiency of one of the liver's enzymes involved in hemoglobin formation. The disease manifests itself in the skin where small and large blisters form on the exposed parts of the body, probably as a slow response to sunlight. The skin becomes very fragile and easily rubs off to produce sores that scab over and sometimes leave scars. PCT appears to be inherited, at least in some cases, but exposure to some chemical or other external factor is required before it becomes manifest. (1-4)

Clinical Manifestations: PCT is usually first noticed when small or large blisters appear on the face, the back of the hands, and the arms usually following exposure to sunlight many hours or days earlier. This contrasts with the prompt reaction to sunlight in other porphyrias. The skin slowly becomes so fragile that even slight rubbing strips off the top layer leaving an open shallow sore that scabs over and heals slowly. The thin skin that forms in the area gradually returns to normal over months. It may instead scar permanently or, in severe cases, may progressively stiffen and thicken until it resembles another skin disease, scleroderma. (5, 6) In a few very severe cases, the skin changes have resulted in the loss of parts of the nose, ears or fingers. (2)

Hair, especially around the temples and upper cheeks, may grow dark and prominent. (7) The skin may darken or may lighten abnormally in the affected areas. (8) Small "white heads" sometimes appear before or after blistering.

The porphyrins in the urine often give it a pink, dark red or brown color. They fluoresce red in ultra-violet light, a phenomenon that assists in diagnosing PCT. (3)

Several methods of treating PCT are available, the most frequently used being repeated bleeding, and the disease is more successfully treated than are other porphyrias. The most important measure, however, is the avoidance of any chemical or other factor that precipitated the attack. (1, 2)

The time it takes the patient to recover seems to depend upon how severely the body was damaged. The skin changes disappear first, usually within 6 months when even severe cases are treated. (9, 10) The disturbance of the body's chemistry clears up in

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about a year. In less severe cases, simply avoiding contact with the causative chemical or other external factor is followed by complete recovery within a year. (11) Children who developed PCT after prolonged and intensive exposure when they ate seed grain treated with a chemical were very ill and had scarring, hairiness, arthritis and stunted growth even 20 years later. (12)

PCT is usually accompanied by some liver damage and in 4 percent or more of the patients a particular form of liver cancer develops. (1) It is difficult to determine whether the liver is damaged by PCT or by alcoholism which often precipitates the porphyria.

Causes: At present, PCT is thought to have two causes: heredity and external factors. There is little agreement on the relative role of these two or on exactly how they interact.

Heredity: There is good evidence that some cases of PCT have a hereditary basis. This has been demonstrated by finding, in healthy blood relatives, the same chemical defects as appear in patients although the changes are less severe in the well relatives. (13 - 16) The few available studies (16, 17) indicate that 6 to 10 percent of the general population have the hereditary defect; most never develop obvious PCT.

The various family studies show that PCT is inherited as what geneticists call an "autosomal dominant gene." (13 - 16) This gene decreases the liver's ability to produce an enzyme called "uroporphyrinogen decarboxylase" that is essential for the normal production of hemoglobin. A deficiency of this enzyme can result in the appearance in the urine of unusually large amounts of substances called "uroporphyrins" as well as related changes in the body's chemistry. (1 - 4)

The situation is more complicated, however, than this suggests. Not all persons who have the hereditary defect develop PCT and not all persons with PCT have evidence of the hereditary defect. It apparently requires exposure to some other factor, generally an environmental one, to produce the disease prophyria cutanea tarda even in the presence of the hereditary defect.

External Factors: A wide variety of chemicals, diseases, and even bodily states can disturb the liver's ability to bring about normal chemical reactions in the formation of hemoglobin and so produce one or another type of prophyria. (18) Some of these changes are relatively slight and transient; others are more serious and longer lasting.

The chemicals that produce PCT have been divided by some investigators into two catagories: those that trigger attacks in

people with the hereditary enzyme defect and those that produce the disease in people without the defect. The chemical hexachlorobenzene is most often given as an example of a substance that produces PCT in anyone. This is largely because 4000 people in rural Turkey who ate, over several winters, seed grain treated with the chemical developed attacks of PCT that were often severe and protracted. (12) Relatively large doses of the female hormone estrogen is said to produce PCT only when the hereditary defect is present. (2) The interaction of hereditary and external factors is still not understood but it is important in several situations, two of which are alcoholism and exposure to TCDD or dioxin.

Chronic alcoholism is unquestionably the most common precipitating factor producing PCT among the populations of North America and Europe where about 68 percent of PCT patients are alcoholic. (19) The alcoholic patients who develop PCT, however, have often not been so impaired by their drinking that they could not hold jobs.

Alcohol abuse has many deleterious effects, of course. Among them are the storage of an excessive amount of iron in the liver and the production of various liver changes culminating in hepatic cirrhosis. Both of these changes are associated with PCT but exactly how they are related to it is not clear. (1) While alcoholism is common among PCT patients only about 2 percent of alcoholic patients with cirrhosis develop uroporphyrinogen decarboxylase deficiency and PCT. (20) This suggests that a hereditary defect probably plays a part in the appearance of PCT in alcoholics.

TCDD or dioxin (2,3,7,8-tetrachlorodibenzo-p-dioxin) has been implicated as the cause of PCT in only two industrial episodes, both involving prolonged contact with large amounts of the chemical. In both instances, the workers were exposed to other chemicals as well.

At the Diamond Chemical plant in New Jersey that manufactured chemicals containing TCDD, 55 men were examined in 1963 when 3 workers were found to have had the skin and hair changes of PCT and to pass urine containing uroporphyrin. When no longer in contact with TCDD, one man recovered completely within a year and another had recovered during a two-year period. The third had only some scars a year after being removed from contact with TCDD. Another 11 men had uroporphyrin in their urine without skin changes. Of the 55 men, 17 had the other skin disease, chloracne, indicating exposure to TCDD or a related chemical but there was no relationship between the occurrence of PCT and of chloracne. (21)

Six years after the initial examination, a second group of doctors examined 73 men working at the same New Jersey plant which

had taken steps to protect its employees from exposure to TCDD after the earlier episode. No PCT was found and only one worker continued to pass uroporphyrin. Some men still had slight to moderate chloracne, however, (22)

The second industrial episode involved intense exposure to similar chemicals, including TCDD, between 1965 and 1968 in a manufacturing plant in Czechoslovakia. In all, 80 of 400 workers became ill. (23) A total of 78 developed chloracne as evidence of contact with TCDD or pentachlorophenol both of which were present. Twelve workers, more than half of them over 40 years of age, were diagnosed as having PCT. One man is said to have been exposed to the chemicals for only two and a half weeks before he developed PCT and in one patient porphyria is reported to have progressed rapidly into hardening of his brain's arteries. (24) Neither the rapid onset nor the progression to arterial hardening is known to occur in PCT.

Among 55 workers examined repeatedly, 11 persistently had large amounts of uroporphyrin in the urine; 12 others intermittently passed large amounts. These values gradually decreased during a four-year period. Of the 11 workers with a heavy output of porphyrin, 10 had the usual skin changes of PCT. (25)

The patients knew of no porphyria in members of their families and the researchers were unable to determine whether any of the men drank excessively. (26) In 1974, the doctors reported that the amount of uroporphyrin in the urine had been greatest in 1969 but had returned to normal as the skin changes improved. After 9 years of observation excessive excretion of uroporphyrin and skin manifestations were "exceptional" occurrences. (27) A year later such abnormalities were said to be "very rare." (23)

In addition to these two incidents of PCT as a consequence of exposure to high concentrations of TCDD, other researchers have described a less severe and completely non-symptomatic change in the liver's enzyme performance following the industrial accident at Seveso, Italy in 1976. Two years after the accident the amount of porphyrins in the urine was normal but the types excreted showed minimal changes in 84% of the people examined. This may indicate that TCDD has an effect but it did not indicate that the people had any disease. (28)

To make matters more complicated two related persons who lived near Seveso were found to have PCT. Examination of 66 family members demonstrated, however, that the two were suffering from the hereditary form of PCT. (29) It raises the possibility that TCDD as an environmental factor may have enabled the hereditary enzyme defect to exert its adverse effect.

Treatment: The most important therapeutic and preventive measure for PCT patients is the avoidance so far as possible of further contact with the external factor or factors that precipitate the attacks. This is critical whether alcohol, estrogen, polychlorinated biphenyls (PCBs), hexachlorobenzene, certain drugs, TCDD, or other factors are involved.

The usual active treatment is repeated bleeding. In most patients with severe PCT there are excessive iron stores, especially in the liver. Judicious bleedings, as in blood donations, remove this iron and improve the patient's condition. There are medications that can be used to reduce the body's iron stores although generally they are not as safe as bleeding.

Untreated, the disease grows worse year by year if the external factors are not removed. Eventually the liver becomes seriously damaged. Removal of the external cause, however, expecially after a single or a few relatively brief contacts, is followed by slow but progressive improvement with apparent recovery. (30)

Agent Orange as External Factor: Since one component of Agent Orange contained small amounts of TCDD, it has been suggested that the herbicide acted as an external factor to cause porphyria cutanea tarda, with persistence of the condition to produce continuing trouble at the present time. This seems unlikely for several reasons.

PCT is a skin problem with a dramatic appearance and under conditions of combat in Vietnam would probably have been incapacitating, unlike chloracne which would have been relatively inconspicuous in most cases. In New Jersey and Czechoslovakia, the only two episodes where TCDD is known to have produced PCT, the skin changes were readily noticed.

The industrial exposures to TCDD causing PCT were intense and prolonged, lasting several years for most of the workers. Troops in Vietnam were exposed to much less TCDD.

Recovery from PCT usually follows removal from contact with the external cause within five years. The last contact with Agent Orange in Vietnam was ten years ago.

There are current external factors much more likely than Agent Orange exposure a decade or more ago to cause attacks of PCT at present. Among them are various medications, PCBs and alcoholism, none of them rare in America today. They should be eliminated from consideration as the precipitating factor before Agent Orange is accepted as a cause of PCT in any individual.

L. B. Hobson April 11, 1983

21-6

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Office of the
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Washington DC 20420

Veterans
Administration

Editor
The Wall Street Journal
22 Cortlandt Street
New York, NY 10007

Dear Sir:

The regrettable article on Agent Orange by Joan Maiman in the Wall Street Journal of April 13 repeats a persistent misunderstanding of the different cases represented by Times Beach and the Vietnam veterans.

The differences, if not understood, lead to what appears to be a logical question as to why the government compensates one group of citizens and not another. The differences are real and the question can be answered by setting the record straight.

The situations in Vietnam and in Times Beach are dissimilar in virtually every respect, notwithstanding that dioxin was involved in both instances. On the average, dioxin was present in concentrations of 2 parts per million in Agent Orange. For the most part it was sprayed from aircraft onto dense jungle vegetation where much of the dioxin was rapidly degraded by sunlight. In Times Beach a mixture of waste oils containing approximately 350 parts per million was applied directly to the ground resulting in soil concentrations of dioxin in the range of 300 parts per billion. In Vietnam, the average concentration of dioxin in the soil would not have exceeded 0.016 parts per billion, even if Agent Orange were applied directly on the ground and no degrading of the dioxin by sunlight occurred.

The government acted in Times Beach to remove a continuing potential hazard by buying contaminated property. No person in Times Beach has been compensated for adverse health effects due to dioxin. Exposure of Americans in Vietnam ended ten years ago, and veterans have not been exposed to Agent Orange since then. The Vietnam veterans are asking for compensation for what they believe to be adverse health effects due to their prior Agent Orange exposure.

Some 2,500,000 American military personnel served in Vietnam. It can be anticipated that among such a large group of veterans some will develop serious illnesses, suffer other adversities, and even father children with birth defects, a situation which tragically occurs in about 4 percent of all live births in the United States and most countries around the world. There is as yet, however, no scientific evidence that any single disease or characteristic group of illnesses have appeared as a result of service in Vietnam.

22-11

From the very beginning of the Agent Orange issue the Veterans Administration has maintained an open mind on the subject of potential health hazards resulting from exposure to herbicides in Vietnam. We have worked very closely with other federal agencies, veterans service organizations, the U.S. Congress and state organizations to address the many questions of concern to Vietnam veterans. A tremendous amount of research, both in this country and abroad, is being conducted to attempt to answer the many puzzling questions surrounding the whole dioxin dilemma. Much of this research is being funded by the Veterans Administration.

In the meantime, the VA continues to provide health care to a large number of Vietnam veterans who believe they have health problems resulting from herbicide exposure, notwithstanding the lack of scientific evidence to support a cause-and-effect relationship. In addition, we have always encouraged any veterans who feel that they have been treated in a discourteous or unsatisfactory manner to call this to our attention. Such reports are investigated and corrective action is taken when justified.

The General Accounting Office report on the Agent Orange program had, we believe, a number of flaws. Corrective measures were taken where the criticisms were justified. This is the appropriate response to such reviews.

I want to stress that we remain sympathetic to Agent Orange claimants in the Vietnam veteran population. We have repeatedly encouraged them to seek care in the Veterans Administration health care system when they require it, without prejudice to their claims. We continue to carry out and support research and studies into the possible health effects of exposure to Agent Orange. We do not yet have all the answers. Nobody does.

The Veterans Administration will continue to remain true to its commitment of service to all veterans and to the American public.

Sincerely,

HARRY N. WALTERS
Administrator

Veterans Administration

March 11, 1983

Department of Medicine and Surgery

Washington D.C. 20420

Comparison of Missouri and Vietnam TCDD Episodes

Recent newspaper and magazines articles on the dioxin contamination in Times Beach, Missouri, have prompted statements comparing that dioxin (TCDD) episode with the dioxin levels in Vietnam that may have resulted from the sparying of Agent Orange. Such a comparison is possible but only if similar components are compared. For example, road surfaces in Times Beach, were sprayed with waste oil that had been contaminated with 350 parts-per-million (ppm) TCDD. Agent Orange contaminated with 2 ppm TCDD was sprayed in Vietnam on jungle vegetation primarily by fixed-wing aircraft flying at an altitude of 150 feet above the ground. Thus, although the dioxin compound is the same between the two episodes, the way it was introduced into the environment was very different. Personnel within the Department of Medicine and Surgery, who are experts on dioxins in the environment, are preparing an in-depth report on the differences between the two episodes. However, they have noted that the concentrations of TCDD in soil between the two episodes would be very different. The 300 parts-per-billion (ppb) level for TCDD found in Times Beach, Missouri would be over 20,000 times greater than the amount resulting from the spraying of Agent Orange directly to the bare soil (a level of 0.016 ppb, calculated). An adequate comparison would also have to include consideration for routes of exposure, length of exposure, and the environmental fate of TCDD. If these factors are all considered, it is apparent that the two situations are not analogues, and any comparisons of the potential for human risks must recognize these differences.

QUESTIONS

1. In a recent article in the Washington Post, VA Administrator Harold Walters was quoted as stating that Vietnam veterans will not have to wait for scientists to prove a direct link between the herbicide Agent Orange and certain kinds of ailments to qualify for disability benefits. The Administrator went on to say that if the government's epidemiological study shows that Vietnam veterans, as a group, are suffering a "statistically significant" rate of health problems that is higher than the rate for non-veterans, the VA will consider those ailments service-connected. Therefore, it is my understanding from these statements that if the epidemiological study comes out positive for certain diseases that it could serve as a basis for compensation. I would like to know specifically if the CDC epidemiological study is going to serve as basis for policy for VA compensation for Agent Orange?

2. What is the anticipated cost of the epidemiological study and is the VA going to reauthorize funding for this study every year?

3. It is general principle in the field of epidemiological studies that rarer conditions can only be determined in large populations. Is the sample size of the CDC epidemiological study large enough to pick up rare conditions?

4. The VA has been monitoring medical treatment being given to veterans claiming ailments related to Agent Orange as directed under P. L. 97-72. In your views are veterans receiving the level of attention laid out in the law?

5. The GAO in its October 1982 report on the Agent Orange Examining Program, criticized the VA's Agent Orange Registry for a number of inadequacies and recommended that the registry be discontinued. What is the status of the registry today?

6. I would like to know how applicable the findings of the Ranch Hand study are to Agent Orange victims as a whole? I believe the Ranch Hand participants had showers following their exposure to Agent Orange, whereas ground troops were unaware of their exposure while it was sprayed from plane above them. In addition it is my understanding that the participants in the Ranch Hand Study have been found to be healthier than the general population. Would this factor influence the results of this study?

7. As you know, there is a Swedish study which links soft tissue sarcoma to exposure to phenoxy herbicides. It is my understanding that the VA contends that the results of the Swedish study are not enough to show a connection. What I would like to know is if this study is not enough, does it mean our epidemiological study is not going to be enough to determine a connection between Agent Orange and certain diseases?

8. How much scientific evidence is necessary to make veterans eligible for Agent Orange compensation?

9. We are all aware of the recent award to the citizens of Times Beach, Missouri, for their exposure to dioxin. I would like to know the difference between exposure to dioxin in Times Beach and the exposure to dioxin of our troops in Southeast Asia? How can we compensate in one case and not in the other? DVB

10. Has the VA or Department of Defense have any way of determining what areas in Southeast Asia were sprayed with phenoxy herbicides and what troops were directly sprayed with it? Have they any numbers on how many American civilians working in Southeast Asia and the U.S. during the Vietnam era were exposed to these herbicides?

BRIEFING OVERVIEW

COMPARISON OF MISSOURI AND VIETNAM
DIOXIN EPISODES
MARCH 1983

- Dioxin (TCDD) as a Contaminant

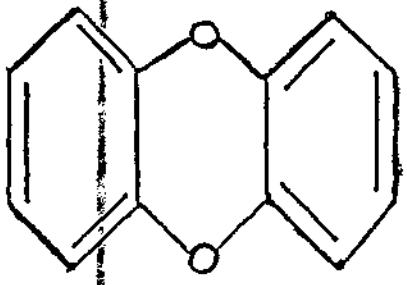
  Sources and Toxicity
  Exposure versus Dose

- Missouri versus Vietnam

- Issues for Resolution

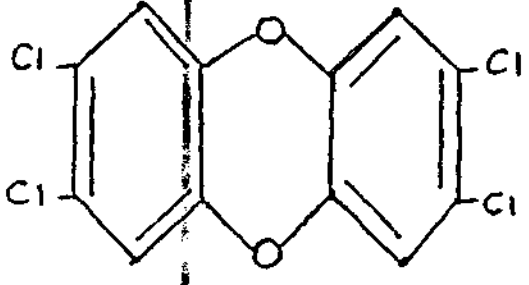
ALVIN L. YOUNG, Major, USAF
Consultant, Environmental Science

A dioxin is any of a family of compounds known chemically as dibenzo-para-dioxins.



There are 75 different chlorinated dioxins.
There are 22 different tetra isomers

Dioxin of Concern = 2,3,7,8-TCDD



TOXICITY OF 2,3,7,8-TCDD

Acute Toxicity:	Single Dose LD_{50} (µg/kg)
Guinea Pig	0.6
Rat	40
Rabbit	115
Monkey	70
Dog	150
Mouse	200
Hamster	3500
Bullfrog	Over 1000
Man	No deaths reported in literature
Teratogenic (Birth Defects)	
Mouse	Cleft palate, kidney abnormality
Other species	Embryo-and Fetotoxic
Mutagenic (Mutation)	Probably not a mutagen in higher animals
Carcinogenic (Cancer)	Liver, lung and oropharynx cancer noted in rats

Significance: Bioavailability on Environmental matrices

EXPOSURE VERSUS DOSE

Exposure	Dose
(Amount of TCDD in Environmental Components)	(Amounts of TCDD in Biological Systems)
Parts-per-billion	Milligrams per kilogram body weight
Part-per-trillion	Microgram per kilogram body weight

SOURCES OF HUMAN EXPOSURE

- Industrial Accidents (Trichlorophenol Production)
- Occupational Exposure (NIOSH Dioxin Registry)
- Contaminated Industrial Wastes (Missouri Episode)
- Herbicide Applications (Vietnam Episode)
- Transportation Accidents
- Food - Contaminated Fish (Great Lakes)
- Low Temperature Combustion
- Hexachlorophene Exposures

Significance: VA Adipose Study

TCDD EPISODE COMPARISON

	Vietnam	Times Beach Missouri
Source of Contamination	Agent Orange	Waste Oil and TCP Residue
Total Quantity of Liquid Dissemination	10.6 million gallons	18,000 gallons
Mean TCDD Concentration of Liquid	2 ppm	356 ppm
Estimated Total Quantity of TCDD	368 pounds	70 pounds
Estimated Number of Acres Treated	3,000,000 acres	5,000 acres

TCDD EPISODE COMPARISON
Continued

	Vietnam	Times Beach Missouri
Pounds TCDD/Acre	0.00013 lb/A (0.06 gms)	0.014 (6.4 gms)
Method Introduced Into the Environment	Aerial Spray onto Vegetation	Ground spray onto soil
Likelihood of Photodegradation	High	Very Low
Soil TCDD Levels	0.016 ppb*	300 ppb
Water Levels	Parts-per-trillion on soil particles	Parts-per-trillion on soil particles

* Assume 3 gal. Agent Orange containing 2 ppm TCDD applied directly to top 1 inch of soil.

TCDD EPISODE COMPARISON

	Vietnam Veterans	Times Beach Missouri Residents
Personnel Likely Exposed	Men (Women)	Men, women, children
Potential Dates of Exposure	1965-1971	1971-1983
Length of Exposure	1 Day - 1 Year	1-11 Years
Major Routes of Contamination	Dermal Contact with Liquid (Probably Rare) Environmental: Soil Water	Dermal Contact with Liquid (Rare); Environmental: Soil, Water
Health Status	Agent Orange Registry Exam (Chloracne under review)	Chloracne reported in 5 people in 1971; Current health apparently normal

ISSUES FOR RESOLUTION

Agencies primarily concerned with TCDD

FDA	CDC	USDA
EPA	OSHA	USDI
VA	DOT	DOD

Issues

- Clarification of Compensatory Policies and Responsibilities
- Level of contamination permitted in Herbicides
- Level of contamination permitted in food and water
- Hazardous waste management criteria

Needs

- Interagency Dioxin Workgroup-science coordination
- Risk assessments and agreements on no-effect-levels
- Determination of bioavailability in environmental substrates

Q. I understand that Cong. Daschle has recently introduced legislation to provide presumptive service-connection for soft-tissue sarcoma, porphyria cutanea tarda, chloracne and chloracneform lesions. What is the VA's position on this proposal?

A. The VA has given careful consideration to Congressman Daschle's Bill (HR 1961) and we find it difficult to determine precisely how to implement the provision for compensating the specified conditions.

Soft-tissue sarcomas are a varied group of cancers that are not always clearly defined. Some authorities include among soft-tissue sarcomas tumors that others do not.

Porphyria cutanea tarda is a single disease, so far as we know, but the disabling phase of the condition follows promptly after exposure to a triggering chemical. The Bill assumes that this exposure occurred in Vietnam ten or more years ago. Alcoholism, however, triggers attacks and eventually the cumulative damage from alcohol can produce more persistent defects. It will not be clear whether the VA is granting continuing compensation for porphyria cutanea tarda in the past or for alcoholism in the present.

"Chloracneform" is a new term, not found in medical language. By analogy it means "resembling chloracne", we believe. If this is true, " chloracneform lesions" include acne vulgaris, the common acne that is experienced by most of us as adolescents and sometimes persists into our adult years. It is unlikely that common acne is caused by military service although it may be made temporarily worse by service in tropical climates.

Q. What is the VA's reaction to the recently released report of the Australian Birth Defects Study?

A. The Australian Veterans Health Studies have issued their report entitled "Case-Control Study of Congenital Anomalies and Vietnam Service (Birth Defects Study)." The investigators determined whether the fathers of 8,517 defective children and an equal number of normal children were military veterans and whether they had served in Vietnam. The fathers of 329 defective children had served in the armed forces and 127 had been in Vietnam. The fathers of 329 normal children also had been in the armed forces and 123 were Vietnam veterans.

There was no evidence that Vietnam service increased the risk of fathering a defective child nor that military service influenced the risk. Length of service in Vietnam was also without effect on the chance of having a malformed child.

The investigators could not establish with statistical certainty that any one defect or group of defects was more common in the children of Vietnam veterans. The Australian study has thus given results similar to those with other exposed groups of men chemical workers and pesticide sprayers. It supports the belief that there is no increase in birth defects as the result of Vietnam service and the exposure to Agent Orange of veterans.

Q. Aren't there scientific studies showing that Agent Orange or the chemicals in it cause soft-tissue sarcomas and prophyria cutanea tarda as well as chloracne?

A. Chloracne has certainly been shown to be caused by dioxin, a chemical contaminant in Agent Orange. The active condition, however, usually persists for less than two years unless there is continuing contact with some chemical that causes it.

In two industrial situations, porphyria cutanea tarda appeared in some individuals who had intense exposure to dioxin, a contaminant of Agent Orange. As usually true for porphyria cutanea, the changes disappeared within five years. The reports saying that the observed liver changes persisted for years do not state whether these individuals are alcoholics nor were they tested for abnormal liver functions before their exposure to the chemical. In our opinion, the evidence for continued porphyria due to exposure to the ingredients of Agent Orange is not scientifically acceptable.

Soft-tissue sarcomas were associated, as you know, with phenoxy herbicides by a single group of Swedish investigators who performed two case-control studies among agricultural and forestry workers. Related studies in Finland and New Zealand did not find any associations. Less scientifically controlled studies have supported the Swedes and other similar studies have not shown any association of soft-tissue sarcomas with herbicides.

The pros and cons of these studies are complex, opinions among experts are not firmly held, and it seems wise to interpret them cautiously. The Advisory panel on Toxic Substances of the American Medical Association has said of the ingredients of Agent Orange "while 2,4,5-T and 2,4-D pesticides have been used in agriculture, forest management and residential landscaping for over 30 years, there is still no conclusive evidence that they and/or TCDD (also called dioxin) are metugenic, carcinogenic or teratogenic in man, nor that they have caused reproductive difficulties in the human", In brief, it cannot be said that there is conclusive evidence that exposure to Agent Orange causes soft-tissue sarcoma.

Q. What is the purpose of the Vietnam Service Indicator?

A. The Vietnam Service Indicator is used to identify a veteran who actually had in-country Vietnam service. This indicator is now placed on the veteran's patient data card which is used to imprint the forms entered into the medical record. This indicator enables the medical center personnel to identify any tissue specimen of a Vietnam veteran which should be forwarded for inclusion in the AFIP Agent Orange tissue registry. More importantly, the indicator is entered into the PTF System and will enable us to report on the number of hospitalizations for Vietnam veterans and allow us to obtain specific diagnostic information. The Vietnam Service Indicator will also allow us to monitor the impact of P.L. 97-72 as it relates to outpatient visits.

The Vietnam Service Indicator was implemented on July 1, 1982 for all hospital discharges entered in the PTF. The veteran's patient data cards will be updated as the veteran comes to the medical center for treatment. The indicator will be placed in the PTF system when the earlier records have been reviewed under the contract with JAYCOR.

Q. Based on the findings in the GAO report, there are considerable deficiencies documented for the Agent Orange Registry. What does the agency plan to do regarding the GAO findings?

A. The GAO report utilized several findings that were outdated; these findings were based on a review of activities which occured in 1980. Significant improvements were made in the interim but were not reflected in the GAO report. GAO was asked to reconsider several criticisms by utilizing the current information and declined the opportunity. The VA has carefully reviewed the recommendations made throughout the report and continues to act forthrightly to implement those with merit and will continue to make improvements in the existing system.

Q. According to the GAO report, 57 percent of the veterans surveyed indicated dissatisfaction with the completeness and thoroughness of the Agent Orange physical examination. How does the agency plan to correct this deficiency and assure that veterans are receiving complete thorough physical examinations?

A. It is extremely difficult for non-health professionals to evaluate the performance of health professionals. Much of what is done during a physical examination is inapparent to the person being examined. A related limitation occurs when a person evaluates the physical examination that occurred months earlier. Many persons will be unable to recall whether specific questions were asked or how complete an examination of body systems was conducted. On many occasions through conference calls, CMD Information letters and circulars, the VA stressed to the physicians the need to assure that a complete physical examination be performed and well documented. This will continue to be our policy. The report of veterans of unsatisfactory physician performance is more valuable as an indicator of the veteran's satisfaction in general than of the quality of the examination. The GAO report indicates some appreciation of this fact and the GAO team examined medical records to evaluate the professional performance of the examiners. The record audits were taken to determine the quality of the examination. These can be important but records are difficult to evaluate as reflecting the quality of professional performance and probably cannot be accomplished by persons who are not qualified health care professionals.

Q. The GAO report recommended that if the Agent Orange Registry was discontinued, a substantial cost could be eliminated or transferred to a program to benefit veterans. But, in the November 30, 1982 Advisory Committee on the Health-Related Effects of Herbicides meeting, it was stated that the costs of the registry may be reduced by planned refinements in the existing system. How can the agency justify the expansion of the Registry when GAO has recommended it be discontinued.

A. The Agent Orange Registry is the only way the VA has to identify any Vietnam veteran who is concerned about the possible adverse health effects due to the exposure to Agent Orange. We are monitoring the Registry to determine what refinements can be made to better utilize the information. In August 1982, we issued DM&S Circular 10-82-154 entitled, " Agent Orange Registry Follow-up Activities." This circular established procedures for obtaining the current address of every veteran who had received an Agent Orange examination and conducted a small health questionnaire of the registry participants. The veteran's current address will be entered into the computerized registry to establish a mailing list for maintaining future contacts.

In December 1982, OMB granted approval for the revision of the Agent Orange Registry code sheet. The revised registry code sheet will obtain the veteran's address, sex, specific diagnosis for the veteran's health problems and other related information. This information was not obtained in a computerizable form previously and there is a demonstrable need to have this information readily available. The new registry code sheet which facilitates the information gathering/coding process in the medical centers, was implemented in March 1983.

Q. When does the VA plan to establish a statutory framework for determining how much and precisely what kind of evidence it will take to compensate Vietnam veterans and their families for the various illnesses and disabilities attributed to Agent Orange exposure?

If the VA does plan to develop such a framework, will it be completed before the Air Force and Center for Disease Control report on the initial findings of their respective studies?

A. The VA already has ample statutory authority to compensate veterans or their survivors for disabilities or death due to injuries and diseases incurred or aggravated in service. 38 U.S.C. Sections 310 et seq., 410 et seq. A new statutory framework is not required. What is lacking is a scientific basis upon which it can be reasonably concluded that long-term adverse health effects (other than chloracne) have resulted from exposure to herbicides in Vietnam. It is deeply hoped that the Air Force and CDC studies will further this scientific inquiry.

Q. After stating for years that animal studies could not be used to correlate dioxin's effects on humans, the VA has recently awarded $4.7 million for Agent Orange research exclusive of the epidemiology study. Does this mean that the VA will accept animal studies as evidence for paying compensation?

A. Various animal species react differently to the same substance. Dioxin or TCDD given by mouth to guinea pigs is at least 500 times as lethal as it is for dogs when the amount given is corrected for the differences in the animals' weights. Cats are stimulated by morphine; dogs are depressed. Such differences make it difficult, if not impossible, to accept the results obtained in one or several species when given dioxin as firm indicators of what dioxin does to humans.

Animals are used to investigate the effects of dioxin, as the most toxic component of Agent Orange, because it is impossible to perform many fundamental experiments on humans. This is particularly true of research that involves exposing the living experimental subject to such a toxic material as dioxin. There is no satisfactory way to determine, for example, how the body can rid itself of the toxic material except to examine this phenomenon in several species. The results obtained from this research are then compared with what is known to occur in man.

A. (continued)

The VA is seeking sources of information about Agent Orange and dioxin that will help detect and treat possible ill effects from contact with them. Any information clarifying the effects of exposure to these chemicals will be used to decide whether to compensate veterans. Because of the differences between various animal species and man, however, the VA does not accept the results of animal studies unsupported by results from studies of humans as satisfactory evidence for paying compensation to veterans claiming exposure to Agent Orange.

Q. Now that the epidemiological study has been transferred to CDC, what is the VA's role in this study? Has the protocol been finalized? Is CDC using all or part of draft protocol designed by UCLA? When will this study actual start and be completed?

A. Under the terms of the interagency agreement, approved January 14, 1983, the VA has very limited responsibilities. We have provided CDC with the preliminary study designed developed by UCLA, along with extensive review comments and other pertinent documents. The VA will not be involved in the actual conduct of this study in any way. We have not yet seen the protocol which the CDC will use for the conduct of the study. The interagency agreement provides that the CDC will complete the epidemiological study as expeditiously as possible, but not later than September 30, 1987.

Q. There is a perception that the VA is not doing a very good job handling veterans concerned about Agent Orange. Many people believe that the VA unnecessarily delayed the epidemiological study (in three years the agency could not even develop a final protocol), is doing a poor job in the examination/registry program (see the GAO report), and is refusing to compensate sick and dying veterans. Is this perception accurate? If not, what is the VA doing to correct this misperception?

A. We feel that this perception is not accurate and will change when veterans learn what the VA has done and is doing to serve them. The epidemiology study, unfortunately, was delayed by factors totally beyond our control. The GAO report was outdated long before its publication and represented problems inherent in any massive nationwide program in its initial stages. The VA does compensate veterans with injuries and illnesses which were incurred in or aggravated by military service. The Office of Public and Consumer Affairs has developed an extensive program to advise Vietnam veterans about our program.

Q. Public Law 96-151, approved in December 1979, required the VA to conduct an epidemiological study of Vietnam veterans exposed to Agent Orange. It was not until February 1983 - one month after the transfer of this study that the VA actually hired an epidemiologist for the Agent Orange program. What does this indicate about the commitment of the agency to the resolution of the Agent Orange controversy? What will the epidemiologist be doing now that the study has been transferred?

A. The VA has long planned to hire an epidemiologist to conduct or monitor the study mandated by P.L. 96-151. This expertise, however, was not required during the early planning stages of this study. We are very pleased that Dr. Han K. Kang, a well qualified epidemiologist, formerly employed as a senior epidemiologist, Occupational Health and Safety Administration (OSHA), has now joined our staff as Chief, Research Section, Agent Orange Projects Office. Dr. Kang will supervise a wide range of vital research activities relative to the Agent Orange controversy.

Q. According to GAO, you could save almost $1 million a year in administrative staff and computer costs by discontinuing the computerized Agent Orange Registry. How much does your budget request include for the registry?

A. The VA does not know how GAO arrived at the costs of $1 million a year for the Agent Orange Registry. The registry activities are not cost accounted but are rather insignificant inclusions in other budget items, e.g. patient care. Because of this, we cannot give specific costs associated with the registry. Costs of operating the registry, in a large part, are being absorbed through existing resources at the national and local level. The VA does have a specific line item in FY 1984 of $45 thousand identified for the registry. As I said, other activities of the registry are covered by other components of the VA but the budget does not identify the portion ascribable to the registry.

Q. What are the VA's plans concerning the expansion of Agent Orange Registry Activities?

A. The computerized record of Agent Orange Registry has been revised. The Office of Managment and Budget (OMB) granted approval for the revision of the Agent Orange Registry code sheet which is utilized by all VA health care facilities to record information obtained through the interview and examination process. As soon as it is printed, the revised Agent Orange Registry code sheet will be used to obtain veteran's name, address, specific diagnosis for the veteran's health problems and other related information. Not all of this information was obtained in a computerizable form previously and there is a demonstrable need to have the data readily available. The Agent Orange Registry address information will be used by the VA's Agent Orange Projects Office to assist in the conduct of periodic health surveys of registry participants. The computerized mailing list will also be used by other VA offices to provide registry participants with updated information on VA policy, health care programs, research, and other significant Agent Orange-related information.

Q. Couldn't money spent on the computerized Agent Orange Registry be better used to insure the quality and thoroughness of examinations?

A. No. The computerized registry is the only way the VA has to identify and uniformaly record information on Vietnam veterans concerned about the adverse health effects from possible exposure to Agent Orange. The environmental physicians have been asked to ensure that each veteran who applies receives a complete and thorough physical examination.

Q. Have any funds been included in VA budget requests to cover the costs of analyzing and releasing Agent Orange Registry data on the types of health problems experienced by Vietnam veterans? If not why?

A. No, but any expense of examining the registry's contents will not be great. The Agent Orange Registry is not designed as a statistical tool to determine the occurrence rate of health problems experienced by Vietnam veterans. Data based on a self-selected population, such as the registry, is misleading and often is misconstrued by people not versed in medical statistics. Health data obtained from such a self-selected population is neither valid nor reliable as an indicator of how often a disease or disability occurs since it almost always over-estimates its frequency. The release of data derived from the registry thus can be alarming to Vietnam veterans without serving a useful purpose. On the other hand, the registry is very useful to identify, examine and establish permanent health care records on concerned Vietnam veterans reporting to our health care facilities. Accordingly, the VA is now in the process of enhancing the possible beneficial aspects of the registry data base.

Q. What will be done to eliminate the errors in the 89,000 locator cards already in the registry?

A. The Agent Orange Registry contains demographic, historical and medical information on all Vietnam veterans participating in the program. The locator cards are maintained by each VA health care facility to identify the Vietnam veterans who have participated in the Agent Orange Registry. The locator card contains the veteran's name, address, social security number, date of birth and dates of examinations (initial and follow-up). Instructions for the preparation and maintenance of the locator cards have been issued through agency circulars. Recently, all Agent Orange Registry participants were mailed a name and address questionnaire for the purpose of obtaining and recording the veteran's current address so that our address files could be updated.

Q. VA recently signed an agreement with CDC for transfer of the Agent Orange epidemiology study to CDC. The agreement calls for transfer of 28 FTEE and $3 million from VA to CDC during FY 83. Are there funds included in the FY 84 VA budget for the CDC study?

A. The interagency agreement between the VA and CDC, which was signed on January 14, 1983, provides that the VA will submit the OMB and the appropriate committees of Congress specific requests from the CDC for fiscal and personnel resources to support the conduct of the study. There is currently available $3 million for CDC to initiate the conduct of the pilot phase of the epidemiological study in FY 83. The availability of these resources will terminate on September 30, 1983. The interagency agreement provides for the VA to assist in obtaining OMB approval of CDC's request for 28 full-time equivalent employees (FTEE). The OMB has approved the requested positions. CDC has provided the VA with justifications for FY 84 resource support of the study and these have been sent to the OMB as resources required during FY 84. They provide the basis for a FY 84 supplemental request.

Q. Has the Centers for Disease Control (CDC) recommended that the registry be maintained by the VA?

A. CDC has made no recommendation for the continuance of discontinuance of the registry. The Agent Orange Registry was developed by the VA to identify all Vietnam veterans who are concerned about the possible ill-effects from exposure to Agent Orange. The registry was never defined as, or intended to be, a statistical tool for a scientific, epidemiological study.

Q. What costs will be incurred by the VA during FY 84 for Agent Orange?

A. Current budget projections include an agency estimate of approximately $95 million associated with the conduct of activities related to Agent Orange. The projected costs are related to the continuance of the VA's Agent Orange Registry, the provision of medical care and treatment to eligible Vietnam veterans as authorized by Public Law 97-72; an update of the literature analysis of worldwide scientific literature originally mandated by Public Law 96-151; the conduct of Agent Orange-related research, including specially solicited research by VA research staff; the maintenance of the VA's Agent Orange Projects Office and information activities of the Office of Public and Consumer Affairs. The projected costs do not include those resources which will be required by CDC's conduct of the pilot phase of the epidemiology study.

Q. What Agent Orange activities will the additional 5 FTEE assigned to the Research Section of the Agent Orange Projects Office be performing in FY 1984 and beyond?

A. The 5.0 FTEE assigned to the Research Section, Agent Orange Projects Office, will continue to carry out in FY 1984 those research activities begun in FY's 1982 and 1983. In addition to following the progress of CDC in conducting the epidemiology study mandated by Public Law 96-151, the 5.0 FTEE will be engaged in the continuing conduct or monitoring of a mortality study on Vietnam veterans. They will continue to oversee and later edit the four scientific monographs on environmental factors that may affect the health of military service personnel serving in Vietnam. Oversight and coordination of the conduct of a Vietnam Experience Twin Study of identical twin veterans, where one veteran served in Vietnam and one did not, will be another of the major responsibilities of this staff. Finally, the staff will be involved in monitoring a retrospective study of chlorinated dioxins and furans in adipose tissue. This latter study will be completed under an interagency agreement between the VA and the Environmental Protection Agency. This study will assist in establishing background levels of 2,3,7,8-TCDD in the U.S. male population and in determining whether service in the military, and especially in Vietnam, has had an effect on the level of TCDD in adipose tissue. In addition to these currently ongoing efforts, it is anticipated that the 5.0 FTEE will be involved in the conduct of other research efforts which may be subsequently identified.

23-24

Q. When do you expect the Centers for Disease Control (CDC) to complete the epidemiology study?

A. The CDC has told us that they expect to complete the study in 1987.

23-25

Q. Are you satisfied that the CDC's projected date for completion of the epidemiology study in 1987 is realistic?

A. The VA would like to have the results of the epidemiological study as soon as possible but it seem to us that 1987 certainly does not represent an unrealistic period of time to allow a completion of the study.

Q. In its report to the Congress concerning the VA's Agent Orange Examination Program, the Comptroller General, last October, noted that although the VA has prepared informational materials on Agent Orange, they were not generally available outside of VA medical facilities, regional offices or outreach centers. What specific efforts have you taken to inform people on this issue of public concern?

A. It is readily evident that the Agent Orange issue centers around one of the most fundamental tenets of our political culture, namely, the care we owe to those disabled in the armed service of our country. The Veterans Administration, as the primary provider of this care, has developed an extensive network for the dissemination of information on all VA benefits and services. Over the last twenty years we have expanded and improved public accessibility to our regional office network by implementing a national system of toll-free telephone service so that anyone may speak with a veterans benefits counselor for no more than the cost of a local call. We have consciously publicized this system so as to make it the source of readily available VA information within the community.

A. (continued)

In light of our development of this system and efforts to channel inquiries into it, we believe that it is only a logical consequence that we have focused our resources and expertise to meet the demand here for information that the public requires. Our veterans benefits counselors have been kept abreast of Agent Orange developments as well as VA-related services and are in the best position in providing accurate information and assistance.

The emotion surrounding much Agent Orange discussion seem, at times, to beg for impulsive reaction such as the unilaterial widespread or even blanket distribution of material on the subject throughout our area. The reality, however, of scientific research at this stage is far short of conclusive and such a distribution runs a serious risk of engendering an unnecessary alarmism. Our approach to dissemination of Agent Orange information has tried to balance the products of a rigorous scientific inquiry and the natural concerns of individuals possibly affected.

A. (continued)

Besides our own efforts in this area we have tried to assist, as far as possible, state and local Agent Orange initiatives. When the California state legislature authorized an Agent Orange outreach effort last year, VA regional office personnel made presentations to their service officers to add to their general knowledge and familiarize them with our resources. We have also worked with the New York State Temporary Commission on Dioxins in making their literature available.

In dealing with Agent Orange, neither a fortress mentality nor a panic reaction is in the best interest of the public we serve. We have and will continue to be true to our primary responsibility, a charge at the heart of our political culture, to care for those who have borne the battle.

Background

BIRTH DEFECTS: AUSTRALIAN GOVERNMENT STATEMENT

24-1

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BIRTH DEFECTS STUDY RESULTS RELEASED

The first scientific study of the subject ever completed has found that Australian veterans of the Vietnam conflict were not at increased risk of fathering a malformed child.

The Minister for Veterans' Affairs, Senator Tony Messner, said that the report provided some of the best news which could be given to anxious veterans and their wives.

The report, entitled "Case-Control Study of Congenital Anomalies and Vietnam Service (Birth Defects Study)", was released by the Minister today. The study was conducted by an expert team assembled by the Commonwealth Insitute of Health, University of Sydney.

In the study, children born with any of a defined set of congenital anomalies were identified from hospital and cytogenetic laboratory records and their fathers were identified as belonging to one of three groups of Australians:

- Vietnam veterans;
- contemporary Army personnel who did not serve in Vietnam; or
- community members who did not serve in the Army at that time.

The most basic finding of the study was that Vietnam service was shown to have had no effect on the risk of fathering a malformed child.

The analysis also showed that:

. The risk of fathering a malformed child was no higher for either Vietnam veteran or Army non-Vietnam veteran fathers than for other Australian males.

. The risk was not different for National Service and Australian Regular Army Vietnam veterans.

The investigating team's analysis demonstrated the high degree of confidence which could be placed in the results, Senator Messner said.

The Minister pointed out that the separate and independent Scientific Advisory Committee, a group of eminent experts in the fields of medical science and statistics, had progressively assessed the methodology as the study proceeded. In endorsing the validity of the findings, the Committee advised that the report was a comprehensive, detailed and well written report of a well conducted study.

Senator Messner paid tribute to the dedicated efforts made by the investigating team to complete this very detailed study. Scientific investigation where feasible was an important element of the government's overall program to bring out the facts on Vietnam service and to assist veterans.

"I am delighted" the Minister said, "that an authoritative

study is now available. The results should reassure those veterans and their wives who were anxious about having children that there is not a birth defects problem peculiar to those fathers who served in Vietnam".

A summary of the study's findings as they appear in the report is provided in the attachment to this release.

SUMMARY - BIRTH DEFECTS STUDY

THIS INVESTIGATION WAS ORIGINALLY DESIGNED AND COMMENCED BY DR ROBERT MACLENNAN, THEN ASSOCIATE PROFESSOR OF EPIDEMIOLOGY, COMMONWEALTH INSTITUTE OF HEALTH, UNIVERSITY OF SYDNEY, AND CONTINUED BY DR JOHN DONOVAN, THE SENIOR ADVISER IN EPIDEMIOLOGY TO THE DEPARTMENT OF HEALTH. DR DONOVAN LATER MODIFIED CERTAIN ASPECTS OF THE ORIGINAL DESIGN IN THE LIGHT OF THE FIELD EXPERIENCES OF HIS TEAM AND WAS RESPONSIBLE FOR CONDUCT OF THE STUDY AND PREPARATION OF THIS REPORT.

THE INVESTIGATION INVOLVED EXAMINATION OF THE HOSPITAL AND CYTOGENETIC LABORATORY RECORDS OF INFANTS BORN WITH ANOMALIES (BIRTH DEFECTS) IN NEW SOUTH WALES, VICTORIA AND THE AUSTRALIAN CAPITAL TERRITORY BETWEEN THE YEARS 1966 AND 1979 INCLUSIVE. IN ALL, 34 HOSPITALS AND 4 CYTOGENETIC LABORATORIES WERE INVOLVED AND COOPERATED FULLY WITH THE INVESTIGATING TEAM. WHENEVER THE BIRTH OF AN INFANT WITH AN ANOMALY WAS DETECTED, IT WAS MATCHED TO A HEALTHY CONTROL INFANT BORN IN THE SAME HOSPITAL, TO A MOTHER OF SIMILAR AGE, AND AS CLOSE AS POSSIBLE IN TIME TO THE BIRTH OF THE CHILD WITH THE ANOMALY.

THE FATHERS OF BOTH CASES AND CONTROLS WERE IDENTIFIED IN 8517 INSTANCES AND THOSE IDENTIFIED WERE COMPARED WITH A LIST OF EVERY MAN WHO SERVED IN THE AUSTRALIAN ARMY BETWEEN 1962 AND 1972, WHICH WAS THE PERIOD OF AUSTRALIAN INVOLVEMENT IN VIETNAM. FATHERS IDENTIFIED AS HAVING SERVED IN THE ARMY DURING THIS PERIOD WERE THEN CLASSIFIED ACCORDING TO WHETHER OR NOT THEY HAD SERVED IN VIETNAM. THE SAMPLE WAS LARGE ENOUGH TO ENABLE THE STUDY TO MEET ITS AIMS. (CHAPTER 1)

THE IMPORTANT FINDING FROM THE STUDY IS THAT 127 OF THE FATHERS OF CHILDREN WITH ANOMALIES WERE VIETNAM VETERANS, WHILST 123 VETERANS WERE AMONGST THE FATHERS OF HEALTHY CHILDREN. THIS INDICATES THAT THERE IS NO EVIDENCE THAT ARMY SERVICE IN VIETNAM RELATES TO THE RISK OF FATHERING A CHILD WITH AN ANOMALY. (CHAPTER 2)

THE FINDING GIVEN ABOVE NEEDS TO BE CONFIRMED BY STATISTICAL ANALYSES. THESE USE THE MOST APPROPRIATE AND UP-TO-DATE METHODS. (CHAPTER 3)

THE FIRST STATISTICAL EXAMINATION CONFIRMS THAT THE MATCHING OF MALFORMED WITH HEALTHY INFANTS WAS GENERALLY ADEQUATE, BUT THAT A SMALL ADDITIONAL STATISTICAL ADJUSTMENT FOR AGE OF MOTHER MAY BE NECESSARY IN LATER ANALYSES. RISK WAS LEAST FOR MOTHERS AGED 25. (CHAPTER 4)

OTHER FACTORS ON WHICH INFORMATION WAS AVAILABLE AND WHICH MIGHT BEAR ON RISK WERE THEN EXAMINED. THE RISK OF MALFORMATION IS HIGHER IN MALE CHILDREN THAN IN FEMALE, AND IN MULTIPLE THAN IN SINGLE BIRTHS. THE NATURE OF BOTH THESE RELATIONSHIPS ALSO VARIES WITH AGE OF THE MOTHER. STATISTICAL TECHNIQUES WERE USED TO ALLOW FOR THESE RELATIONSHIPS IN LATER ANALYSES OF RISK ASSOCIATED WITH VIETNAM SERVICE OF THE FATHER. ANOTHER FACTOR EXAMINED WHICH NEEDED TO BE TAKEN INTO ACCOUNT IN THESE LATER ANALSYES WAS BORTHPLACE OF THE FATHER. FACTORS EXAMINED WHICH PROVED NOT TO NEED TO BE TAKEN INTO ACCOUNT INCLUDED AGE OF THE FATHER, SOCIO-ECONOMIC GROUP OF THE

FATHER, BIRTHPLACE OF THE MOTHER, AND URBAN OR RURAL RESIDENCE OF THE PARENTS. (CHAPTER 5)

THE STUDY GIVES PERSUASIVE EVIDENCE THAT VIETNAM SERVICE HAS NOT BEEN ASSOCIATED WITH ANY IMPORTANT INCREASE IN THE RISK OF BIRTH DEFECTS IN CHILDREN OF VETERANS. ACCORDING TO THE STANDARD STATISTICAL ESTIMATION PROCEDURE, THERE IS A 95 PERCENT CHANCE THAT THE TRUE VALUE OF THE RISK OF A VIETNAM VETERAN FATHERING A MALFORMED CHILD COMPARED WITH THAT OF A NON-VETERAN LIES BETWEEN 0.78 (A 22 PERCENT DECREASE) AND 1.32 (A 33 PERCENT INCREASE). THE MOST LIKELY ESTIMATE OF THE RISK IS 1.02, ONLY 2 PERCENT GREATER THAN NO DIFFERENCE AT ALL IN RISK.

WHEN THE RISKS WERE ESTIMATED SEPARATELY FOR AUSTRALIAN REGULAR ARMY AND FOR NATIONAL SERVICE VETERANS THEY WERE FOUND TO BE SIMILAR. THE SAME APPLIED FOR COMPARISONS OF RISK IN CONTEMPORARY MEMBERS OF THE AUSTRALIAN REGULAR ARMY AND NATIONAL SERVICEMEN WHO DID NOT SERVE IN VIETNAM, COMPARED WITH AUSTRALIAN FATHERS WHO DID NOT SERVE IN THE ARMY.

COMPARISONS OF RISKS WERE ALSO MADE WITH OTHER ASPECTS OF VIETNAM SERVICE WHICH MIGHT HAVE BEEN EXPECTED TO BEAR ON AN INCREASE IN RISK, HAD ONE BEEN FOUND. WHILE THERE WAS A TENDENCY TOWARD LOWER RISK FOR VETERANS WITH LONGER VIETNAM SERVICE, NO EFFECT ON RISK OF THIS, OF TIME BETWEEN DEPLANEMENT AND CONCEPTION, OR CALENDAR YEAR OF VIETNAM SERVICE, WAS DEMONSTRATED.

WHEN VETERANS WERE SUB-DIVIDED ACCORDING TO WHETHER THEY HAD SERVED IN VIETNAM BEFORE CONCEPTION OF THE CHILD, OR ONLY AFTERWARDS, IT WAS FOUND THAT THE RISKS WERE SIMILAR, WITH ESTIMATES SLIGHTLY HIGHER FOR CHILDREN CONCEIVED BEFORE THE FATHER HAD BEEN TO VIETNAM.

EXAMINATION OF THE STUDY PROCEDURES REVEALED SOME LIMITATIONS IN DATA SOURCES AND IN HANDLING. THE ANALYSES WERE REPEATED IN WAYS WHICH DEMONSTRATED THAT THESE COULD NOT HAVE INFLUENCED THE CONCLUSIONS. IT WAS ALSO SHOWN THAT THE WAY IN WHICH THE STATISTICAL ADJUSTMENTS FOR VARIABLES ASSOCIATED WITH RISK WERE MADE DID NOT AFFECT THE CONCLUSIONS.

TO THE EXTENT THAT WAS POSSIBLE IN A STUDY OF THIS SIZE, THE DATA WERE EXAMINED TO SEE WHETHER THERE WAS ANY SINGLE MALFORMATION OR GROUP OF MALFORMATIONS SUFFICIENTLY STRONGLY ASSOCIATED WITH VIETNAM SERVICE TO JUSTIFY FURTHER EXAMINATION. NO FURTHER EXAMINATION WAS WARRANTED. (CHAPTER 6)

THE LIMITATIONS OF THE DATA SOURCES AND THEIR HANDLING WERE FURTHER EVALUATED. THIS EVALUATION INCLUDED THE REWORKING OF THE PROCESSING FOR A 2 PERCENT SAMPLE OF THE DATA. IT WAS CONCLUDED THAT THERE SHOULD BE CONSIDERABLE CONFIDENCE IN THE VALIDITY OF THE FINDINGS. (CHAPTER 7)

THERE IS NO EVIDENCE THAT ARMY SERVICE IN VIETNAM HAS INCREASED THE RISK OF THE BIRTH OF A CHILD WITH AN ANOMALY.

Background

EXTRACT FROM AUSTRALIAN PARLIAMENTARY REPORT

On 15 October 1981, the Senate resolved that the following matter be referred to the Standing Committee on Science and the Environment: The use of pesticides, particularly phenoxy chemicals and chemicals containing dioxin with reference to:

(a) their ecological effects; and

(b) their effects on human and animal health;

and that in considering this matter the Committee deal first with the possible effects on Vietnam veterans of exposure to herbicides.

The Committee agreed that the Inquiry should best proceed in two stages: The first pertaining to the possible effects on Vietnam veterans of exposure to herbicides; and the second to the use of pesticides in Australia with reference to their ecological and health effects. This First Report, therefore, relates to the first stage of the Inquiry. However, the Committee recognises that many of the issues examined in this First Report, e.g. those relating to exposure to potentially harmful chemicals and the mechanisms by which birth defects are caused, are extremely complex.

The Committee regards the response of the Government to this Report as both urgent and crucial. In view of all the circumstances, the Committee expects the Government's response by 31 March 1983.

The Committee will meet again to consider the Government's response and any further information arising from current research and make a further report to the Senate.

The Committee conducted ten public hearings between 8 December 1981 and 22 September 1982 at which 39 witnesses gave evidence. The hearings took place in Canberra (4), Melbourne (2) and Sydney (4).

24-6

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RECOMMENDATIONS

The Committee is unanimous in recommending:

(1) That the Department of Defence impose more stringent measures to ensure that the instructions for the handling and spraying of pesticides are rigidly enforced (p. 57);

(2) that much more attention be paid by the Australian scientific and medical communities to promoting an understanding of the heritable genetic effects that may result from the exposure of humans to mutagenic chemicals (p. 76);

(3) that the Commonwealth Department of Health, in collaboration with appropriate medical and scientific bodies, undertake a public education program on the nature and origin of birth defects and the frequency of their occurrence in the community (p. 95);

(4) that the CIH, with the co-operation of the VVAA, establish a mutually acceptable panel of psychiatrists and neurologists to examine Vietnam veterans who claim to be afflicted by chemically-caused psychiatric conditions in order to provide an independent assessment of the symptom profile commonly reported amongst Vietnam veterans (p. 147);

(5) that in view of the time taken over the morbidity study, a decision be made to proceed with due emphasis being placed on attempting to establish whether psychiatric symptoms in Vietnam veterans are due to a war neurosis or exposure to harmful chemicals (p. 160);

(6) that priority be given to the conduct of the retrospective mortality study because of the likelihood of it producing an answer to the question of whether the rate of deaths among veterans is excessive (p. 160);

(7) that the case-control study be completed as soon as possible (p. 160);

(8) that the review of the repatriation legislation include an examination of the way in which the determining authorities have been applying the evidentiary provisions of the legislation. The review should also examine whether the determining authorities have been relying too heavily on information provided by departmental sources (p. 170);

...3

(9) that the Department of Veterans' Affairs fully investigate all claims made in evidence to the Committee dealing with the alleged rudeness and unco-operative attitudes of its staff towards Vietnam veterans. If these claims are found to have substance, staff training policies should be reviewed as a matter of urgency (p. 177);

(10) that the staff resources of the Department of Veterans' Affairs be increased so that more staff can be allocated to process claims and to personally attend to veterans' inquiries (p. 177);

(11) that the Department of Veterans' Affairs implement a reverse charge telephone service for veterans living outside metropolitan areas to facilitate access to advice from the Department regarding the repatriation system (p. 178);

(12) that the Department of Veterans' Affairs give high priority to improving the knowledge of local medical officers regarding the repatriation system and related matters, particularly the physical conditions of war service (p. 178);

(13) that adequate staffing levels at the Vietnam Veterans Counselling Service be provided to enable the collection and publication of data on: The services provided; the number of clients and the types of problems presenting; and the outcome of the various treatment options available at the centres (p. 181);

(14) that serious consideration be given to extending the Vietnam Veterans Counselling Service beyond 31 December 1983 (p. 181);

(15) that the Department of Veterans' Affairs maintain statistical data relating to veterans serving prison sentences (p. 184);

(16) that the Department of Veterans' Affairs approach the various state prison authorities to secure access to the Vietnam Veterans Counselling Service for Vietnam veterans serving prison sentences (p. 184);

(17) that the proposed remodelling of the repatriation claims system be undertaken as a matter of urgency (p. 186); and

(18) that the Department of Veterans' Affairs review and upgrade its data collection system and also complete the computerisation of its manual indexes (p. 188).

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