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D/A o.

Veterans Administration

Memorandum

Date: June 10, 1982

To: Members, Science Panel, Agent Orange Working Group

Subj: VA Agent Orange Epidemiologic

1. In a recent meeting between VA and the Army Agent Orange Task Force (AAOTF) personnel the following issues were raised that will influence the conduct of the VA "Epidemiologic Study of Ground Troops Exposed to Agent Orange."

a. Delay in Establishing Agent Orange Data System - Because of contractual delays, the proposed Agent Orange Data System, a computerized system for processing records data on tactical/static troop locations, incidents, personnel information, and locations of all herbicide missions, dumps and perimeter spraying will not be in place until Feburary 1983. In the interim a semi-automated system will be used to generate the names of personnel to be used in the conduct of the pilot phase of the VA Epidemiologic Study. What is the consequence of using two methods, albeit very similar, in the generation of individuals for the study cohorts?

b. Selection of Cohort Based on Branch of Service - Mr. Christian emphasized that the manning of the Agent Orange task force team will consist of representatives from each of the services. He emphasized that the basic reason for such action was that those individuals would be in a better position to select the appropriate individuals for each cohort to participate in the Epidemiologic Study. When asked to clarify that cohort selection criteria, he pointed out that for every 600 individuals selected within a particular cohort, 300 would be Army, 150 Marines, 75 Air Force, and 75 Navy. This selection criteria is not in the protocol. Furthermore, it would seem that such a mutli-service selection would significantly complicate the exposure index.

c. The Use of a Non-Vietnam Cohort - The Veterans Administration has received from a congressional source questions as to the value and justification for the use of a non-Vietnam cohort. Arguments from a previous AOWG discussion stressed that the non-Vietnam Cohort might permit an evaluatin of the Vietnam Experience. Since the present plan is to select the third cohort on the basis of no Agent Orange exposure, as well as no Vietnam service how would the data be interpreted if differences occurred only between the Vietnam versus non-Vietnam cohorts? Would not a study of the Vietnam experience involve an entirely different selction criteria? Deleting a third cohort would impact the scope of the study and perhaps reduce the time to complete the study.

d. Misclassification and Replacement - Mr. Christian noted that misclassification in the exposure index could occur if an individual changed services (e.g., Army to Navy) between tours to Vietnam. They have found that such an individual might have two sets of records and that one set could be overlooked in the records review process. Other situations could occur where an individual was selected for a cohort but later found to be unacceptable for that cohort. In such a situation is the individual replaced?

e. Record Review Bias - During the past several months the AAOTF has made tremendous gains in finding and reviewing records of the Vietnam Conflict. In the course of these reviews they have uncovered events related to insecticide applications, melioidosis, parasitic disease, drugs, and other factors that may have impacted the health and welfare of our troops in Vietnam. More recently they have completed a list of 900 men who served with the Chemical Units. It is recognized that this information is important. However, it is our concern that the finding of this information may bias the cohort selection process. For example, when the researchers identify a combat unit that suffered significant loss of personnel to melioidosis, will they consciously or unconsciously "exclude" that unit from being considered in the cohort selection?

2. It is requested that members of the AOWG Science Panel review and comment on these five issues in the context of their impact on the protocol, pilot study, and the tasks of the AAOTF.

BARCLAY M. SHEPARD, M.D.
Special Assistant to the CMD
for Environmental Medicine

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta, Georgia 30333

VETERANS ADMINISTRATION EDPIDEMIOLOGY STUDY PROTOCOL
Dated April 28, 1982

The following is a concensus review by the Science Panel of the latest revision of the "VA Epidemiology Study Protocol" dated April 28, 1982.

The revised document shows major effort in some areas in response to reviewers' comments; however, the task of providing a revised protocol has not been completed. This leaves the problem of getting the revised protocol written and, more importantly, leaves numerous critical decisions up in the air. The revised document responded to many comments of the reviewers that several methods "could" be used to deal with the problems raised, but did not choose one solution for each problem, defend it, and incorporate the appropriate methodology in a revised protocol. This must be done by another party and will require another round of review.

It was suggested in the document that many problems raised by the reviewers be tested. It is of concern that detailed methodology for such testing and criteria for decision making were not provided. Each problem to be tested in the pilot study requires detailed design and a final protocol for the pilot study must reflect these specific situations in its methodology including clear criteria for the decision making.

Questionnaire and medical examination portions of the document have been improved (but not shortened) by reorganization and the inclusion of many detailed modifications. Table 1 assists in recognizing the expected medical outcomes based on animal and human data. Table 2 provides a good topical breakdown of the questionnaire items. They do not provide, however, a suggested list of abnormal conditions to be measured, the items in the questionnaire and medical exam to be used in their assessment, nor the estimated incidence of the various conditions needed as background for the data analysis. It is still unclear whether or how each of the many items will be used in the final analysis, and since the items to be collected are so numerous, nonessential and nonusable items still require identification and removal.

Specifically, the physical examination, questionnaire, and laboratory tests appear to be fishing expeditions. The response to our previous review that data collected for this study be only that necessary for the study and that are subject to careful standardization and analysis is inadequately addressed.

The questionnaire, in addition to being too diffuse, has many open ended questions and questions that suggest a specific response. The reproductive questionnaire is incomplete. It is the universal experience that incriminating questions (with identifiers) about illicit drug use are not honestly answered, are harmful, and probably would not be cleared by a panel reviewing appropriateness of the questionnaire.

There is vagueness in some of the responses to the reviewers' comments on epidemiologic concerns. Probably because a revised detailed protocol was not produced, it is still unclear what methodologies or criteria will be employed to meet the following problems:

1. A method of recruitment which will ensure comparable response rates from cohorts.

2. Compensation for the participating veterans.

3. Criteria for comparability of laboratory tests from various centers.

4. Methods of notification and followup of medical abnormalities.

5. Methods for "blinding" investigators.

The decision on the choice of exposure index has already been made by the Science Panel to reflect the proposal made by Dr. Bricker and Mr. Christian. The decision on inclusion of the third cohort is recommended by the Science Panel to be left open at this time and that DOD proceed with establishing such a cohort.

Several new suggestions are made in the revised document. Obtaining the assistance of a public relations officer seems desirable. However, the suggestion (page 51) that routine credit checks might be run on participating veterans seems without merit and likely to invite public outcry.

In summary, the present document has provided a much better organization for the demographic and medical assessments and further insights into many problems raised by the reviewers. However, no final protocol was produced, thus leaving many critical questions unanswered.

Vernon N. Houk, M.D.
Chair, Science Panel
Agent Orange Working Group

6/25/82

MINUTES OF THE SCIENCE PANEL

AGENT ORANGE WORKING GROUP

The Science Panel met at 12 Noon on May 7, 1982 in the Humphrey Building in Washington, D.C. Tab A is a list of those in attendance.

Exposure Index

The Chair appointed as a subcommittee to provide epidemiologic support and advice to the Department of Defense (DOD) on the development of cohorts and to determine an individual's exposure to Agent Orange: Dr. Carl Keller, Chairman; Dr. Philip Landrigan; and Lt. Col. Phillip Brown. The Veterans Administration (VA) will also provide an individual for this effort.

The DOD presented a plan for an Alternate Herbicide Exposure Screening Technique (Tab B) to be used for identifying exposure to individuals required for studies other than the VA Epidemiologic Study. This plan is less expensive but may be somewhat less precise than the previous plan for the development of an exposure index to be used for cohort selection for the VA Epidemiologic Study. The following items were agreed upon.

- The previous plan for cohort selection for the VA Epidemioloic Study will be used for that purpose. The names will be provided to the VA and its contractor(s) without any information on the individuals' exposure index. This information will remain blind until the analysis of the study begins.

- The proposed aternate plan will be used for all other studies that relate to individuals. The names, etc., of individuals in question will be provided to DOD without any information of whether they are controls or study group or outcome of the study.

- DOD will precisely define the difference, if any, between the two systems. In this regard a 5 percent sample of those selected in the pilot group and overall group of the cohort selection for the VA Epidemiologic Study will be tested with the alternate method to ascertain differences, if any, that may occur.

Birth Defects Study

The pilot phase of the Birth Defects Study has been completed. The results (Tab C) indicate that the main study can be successful though it will probably be more costly than anticipated. The response rate and the proportion of fathers having served in Vietnam are within the limits determining the protocol is necessary to address the question.

Fat Biopsies

The Subcommittee examining the issue of fat biopsies and dioxins submitted its final report. The Science Panel accepted it with gratitude. It was agreed that the Chair would transmit it to the Chair, Agent Orange Working Group (AOWG), with the following recommendations.

- That the Science Panel and the AOWG recommend against any fat biopsy procedure until such time that analytic procedures are documented and appropriate segments of the United States population are evaluated for background body burdens.

- That the AOWG approves the listed sequential studies and that they be referred to the Executive Committee of the Committee to Coordinate Environmental and Related Programs (CCERP) for consideration and implementation.

VA Mortality Stuly

The final report of the Subcommittee to review the VA Mortality Study has been submitted to the VA. In addition, the Science Panel believes that a working group to help the VA and to review the progress needs to be established. The Chair will communicate these thoughts to the VA.

It was also deemed essential that the VA or someone select a panel of pathologists to review the tissues being reported for "soft tissue sarcomas."

Wisconsin State Agent Orange Identification and Assistance Program

The Chair, AOWG, referred a request from Senator Cranston that the Science Panel review the Wisconsin proposal in addition to our review of the proposal of the HERBS Tapes Maping previously done (Tab E). Responses were requested from the Science Panel members by May 21. The Chair will consolidate and prepare a concensus document for returning to the Chair, AOWG.

AOWG Charter

The issue of the breath of the AOWG charter was discussed. There appears to be some confusion as to whether the Science Panel should develop an overall research agenda and priority for all research on herbicides and dioxins in the Federal establishment, or if activities should be related only to those issues that specifically address the effect of Agent Orange on Vietnam veterans. The Chair asked Legal Counsel to provide guidance.

Potential of Agent Orange Health Hazard Assessment in the Vietnam Population

The Chair recently sent a memorandum (Tab E) to the Chair, AOWG, on this matter. This position was developed after discussion in December 1981 and subsequent discussion with members of the Science Panel. The position specifically states that U.S. Government scientists should not become involved and questions whether sufficient potential exists for such studies to be successful.

The Chair, Science Panel, received a request for an opinion on this matter from an attorney representing some Vietnam veteran groups (Tab G). A copy of the memordandum discussed above will be sent to the originator of the request.

Vernon N. Houk, M.D.
Chair, Science Panel
Agent Orange Working Group

SCIENCE PANEL MEETING

ATTENDEES

May 7, 1982

Vernon N. Houk	HHS/CDC	236-4111 (404)452-4111
Jerome G. Bricker	OASDCHA, DOD	697-8973
Douglas L. Clark	AAOTF	325-6227
Carlton T. Chapman	AAOTF	325-6227
CDR Hugh Hyland	NAVYAOTF	325-6227
Dick Christian	AAOTF	325-6227
Carl Keller	NIEHS	496-3511
Don Barnes	EPA/OPTS	382-2897
Renate Kimbrough	HHS/CDC	236-4113
Phil Brown	HQUSAF/SGES	767-5078
Dave Erickson	CDC/HHS	236-4055
Michael Gough	OTA	226-2070
Helen Gelband	OTA	226-2070
Lawrence B. Hobson	VA	389-5411
Alfred M. Rivas	USDA/FS	447-2714
Alvin L. Young	VA(102)	389-5534/5411
Barclay M. Shepard	VA(102)	389-5411

CABINET COUNCIL ON HUMAN RESOURCES

AGENT ORANGE WORKING GROUP
(AOWG)

FACT SHEET
ON SCIENTIFIC RESEARCH
OF THE FEDERAL GOVERNMENT

Membership:

- Department of Health & Human Services (Lead Agency)
- Department of State
- Department of Defense
- Department of Agriculture
- Department of Labor
- Office of Management & Budget, Executive Office of the President
- White House Office of Policy Development
- Council of Economic Advisors
- ACTION
- Environmental Protection Agency
- Veterans Administration
- White House Office of Science & Technology Policy

Observer:

- Congressional Office of Technology Assessment

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Mr. Maurice LeVois,
Veterans Administration
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Dr. Peter Flynn
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Dr. Philip Kearney
Department of Agriculture
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Dr. Donald Barnes
Environmental Protection Agency
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This Fact Sheet of Agent Orange Research was compiled by the Agent Orange Working Group to inform the interested public about current U.S. Federal Government research on phenoxy herbicides and their contaminants. The list describes ongoing research and demonstrates the breadth of research efforts. Interested persons may obtain further information on these studies by contacting the representative, as listed in the Fact Sheet, from each Federal agency conducting research.

This Fact Sheet, describing the forty-six federal studies and research projects completed and underway, is a clear illustration of the time and effort and funding that has been expended in the Federal arena and demonstrates the government's positive effort to seek answers to the Agent Orange question.

The Agent Orange Working Group has the responsibility for overseeing such research and disseminating information to the public as it becomes available. In light of this mandate, the Working Group has compiled this list. The Working Group will also assure that research findings are promptly made available to the public as data are gathered and analyses are completed.

DEPARTMENT OF HEALTH AND HUMAN SERVICES (24 studies):

Title : Bioassy of Octachlorodibenzo-p-dioxin

Results : Terminated due to unavailability of purified chemical.

Title : Carcinogenesis Bioassy of 2,3,7,8-Tetrachlorodibenzo-p-dioxin in Swiss Webster Mice

Results : This compound found carcinogenic for B6C3P-1 mice and Osborne-Mendel rats producing liver and thyroid tumors.

Title : Carcinogenesis Bioassy of 2,3,7,8-Tetrachlorodibenzo-p-dioxin in Osborne-Mendel Rats and B6C3F1 Mice

Results : This compound found carcinogenic for Swiss-Webster female mice producing tumors of the integument.

Title : Bioassy of a Mixture of 1,2,3,6,7,8- and a Mixture of 1,2,3,6,7,8- Hexachlorodibenzo-p-dioxins for Possible Carcinogenicity

Results : Under the conditions of this bioassy, HCDD was not considered carcinogenic for Swiss-Webster mice.

HCDD administered by gavage was carcinogenic for Osborne-Mendel rats and B6C3F1 mice producing tumors of the liver.

Title : Comparative Species Evaluation of Chemical Disposition and Metabolism of 2,3,7,8-Tetrachlorodibenzofuran (TCDF) in Rat, Monkey, Guinea Pig and Two Strains of Mice

Results : The speed of metabolism and excretion correlated inversely with the observed acute toxicity of TCDF in these species.

Title : Neurotoxicity of 2,4-D in Rodents

Results : Single oral doses of 2,4-D indicate a persisting effect (4-8 weeks) on fore- and hindlimb grip strength in male Fisher rats. Other neurobehavorial tests to measure the effects on sensory and motor functioning, affective behavior, learning, and memory have been undertaken.

Title : Studies of the Chemical Disposition and Metabolism of Octachloridibenzodoxin (OCDD)

Results : Discontinued because chemical could not be purified.

Title : Effects of Agent Orange Components on Male Fertility and Reproduction

Objective : Sperm number and morphology, mating frequency, fertility efficiency, dominant lethal mutation, incidence of congenital malformations, viability of offspring and sisterchromatid exchanges are being measured in male mice fed large doses of the constituents of "Agent Orange" and will be published soon.

Title : Mutagenicity Studies of TCDD, 2,4-D, 2,4,5-T and Esters of 2,4-D and 2,4,5-T

Objective : The Ames test for point mutations, Drosophila tests for six-linked recessive mutations and mammalian cell tissue culture tests for chromosomal aberrations are almost complete and have yielded negative results so far.

Title : Implications of Low Level Exposure to Dioxins

Objective : Two year dietary exposure to 5 and 50 parts-per-trillion TCDD will include clinical and behavorial evaluation of toxicity and fat biopsies to measure TCDD bioaccumulation in rhesus monkeys.

Title : Mechanisms of Toxicity of the Chlorinated-p-dioxins

Objective : In viro and in vitro metabolism of TCDD and examinations for the presence of receptor sites in different rodent species is in progress.

Title : Research Toward Understanding the Molecular Level Mechanism of Toxicity of TCDD and Related Compounds.

Objective : An ongoing activity to determine the structure and electronic properties of the dioxin receptor in order to understand the mechanisms of toxicity.

Title : Synthesis of Selected Tetrachlorodibenzo-p-dioxins and Related Compounds as Analytical Standards

Objective : It is anticipated that another year will be necessary to have a minimum set of standards in hand before analytical method development can truly begin.

Title : Dioxin Registry

Objective : To establish a registry of all workers in the United States who have been associated with the synthesis of 2,4,5-T. The registry will include work and exposure histories for all registrants. The registry will be utilized initially for a retrospective cohort mortality study, and the workers will be followed prospectively. In the future, an evaluation will be made of the registry to determine if the cohorts can be utilized for studies of morbidity and reproductive outcome.

Title : Soft Tissue Sarcoma Investigation

Objective : To determine the association between occupational exposure to herbicides such as 2,4,5-T and the development of a malignant tumor known as soft tissue sarcoma.

Title : Investigation of Leukemia Cluster in Madison County, Kentucky Allegedly Associated with Pentachlorophenal-Treated Ammunition Boxes

Objective : Effect on human contact.

Title : Matrix Effect and Sub Parts-per-billion Quantitative Analysis of TCDD by Mass Spectrometry - With Special Reference to Milk

Objective : This project is designed to validate the determination step for TCDD at low parts-per-trillion levels in environmental/biological samples by high resolution gas chromatography and high resolution mass spectrometry.

Title : Toxin Actions of Tetrachloroazobenzene and Dioxins

Objective : This project is designed to examine the pharmacokinetics and toxicologic, pathologic and biochemical changes with chronic exposure to TCAOB and TCCD using <u>in viro</u> and <u>in vitro</u> methods.

Title : Xenobiotic Induction of Pleiotropic Responses in Liver

Objective : This project is an attempt to identify potentially toxic substances by their ability to induce certain hepatic enzymes before overt toxic effects are manifest.

Title : Molecular, Biochemical Actions of Chlorinated-p-dioxins

OBJECTIVE: This project is designed to investigate biochemical mechanisms of TCDD toxicity in mammals via alterations in fatty acid metabolism.

Title : Molecular Basis of Dioxin Toxicity to Keratinocytes

Objective: This project is designed to characterize the effects of TCDD on growth and differentiation of human skin cells in tissue culture.

Title : Mechanism(s) for Toxicity of Chlorinated Dibenzo-dioxins

Objective: This project is designed to measure interspecies variation in toxic metabolic and neural response to TCDD.

Title : Establishment and Maintenance of an International Register of Persons Exposed to Phenoxy Acid Herbicides and Contaminants

Objective: An ongoing and long-term project which has begun only recently. Preliminary contacts have been made with key individuals in Nordic countries and Italy and an international meeting will be held in the summer of 1982 to plan further efforts.

Title : Birth defects and Military Service in Vietnam (in conjunction with the VA and DoD)

Objective: To determine whether an unusually high proportion of fathers of babies born with defects served in Vietnam. This comparison will yield an estimate of the risks of siring a child with a defect for Vietnam Veterans relative to the risks for non-Veterans. If they are to be found to be at increased risk, it may be desirable to try to determine if the increase is associated with Agent Orange exposure or with some other factor(s).

<u>DEPARTMENT OF DEFENSE (one study and support for CDC Birth Defects Study)</u>

Title : Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to "Herbicide Orange"

Objective: To determine whether there are or will be long term health effects attributable to occupational exposure to Herbicide Orange and its contaminant TCDD.

VETERANS ADMINISTRATION (eight studies)

Title : Review and Analysis of Literature on Phenoxy Herbicides and Dioxin

Objective : To comply with the provision of Public Law 96-151, mandating the VA to conduct "...a comprehensive review and analysis of the worldwide literature on Agent Orange and other phenoxy herbicides."

Title : Epidemiology of Agent Orange in Vietnam Veterans

Objective : To comply with the mandated provisions of Public Law 96-151, Section 307, which directs the Administrator of Veterans Affairs to design a protocol for, and conduct an epidemiological study of, Vietnam Veterans who may have been exposed to dioxins contained in herbicides particularly Agent Orange sprayed in Vietnam.

Title : TCDD Assay of Human Fat

Objective : To determine whether TCDD could be measured in human fat and whether its presence could be used to determine exposure to Agent Orange.

Title : Birth Defects and Military Service in Vietnam (in conjunction with the Centers for Disease Control)

Objective : To determine whether an unusually high proportion of fathers of babies born with defects served in Vietnam. This comparison will yield an estimate of the risk of siring a child with a defect for Vietnam veterans relative to the risk for non-veterans. If they are found to be at increased risk, it may be desirable to try to determine if the increase if associated with Agent Orange exposure or with some other factor(s).

Title : Vietnam Veterans' Mortality Studies

Objective : To analyze and compare death rates and cause of death profiles of veterans with service in Vietnam and comparable veterans with no service in Vietnam.

Title : Urinary 6-Hydroxy Cortisol: Physiologic and Pharmacologic Studies (including Agent Orange)

Objective : To determine the effects of dioxin on hepatic microsomal enzymes and determine whether altered steroid metabolism can be helpful in assessing any continuing effects of herbicides and TCDD in exposed humans.

Title : Effect of TCDD on Lipid Metabolism

Objective : To study acute and chronic effects of TCDD on plasma lipids and adipose tissues in animals.

Title : Mechanisms of Dioxin Induced Toxicity Using the Chloracne Model

Objective : To develop an animal model for dioxin induced chloracne.

DEPARTMENT OF AGRICULTURE (eight studies)

Title : Exposure Survey on Herbicides Including Phenoxys

Objective : To determine the amount of exposure to 2,4-D and 2,4,5-T in farm and forestry workers under normal use conditions.

Title : Use Survey on Herbicides Including Phenoxys

Objective : To estimate on a state-by-state basis the use of phenoxy herbicides in crop protection programs.

Title : Survey of Phenoxy Herbicide Literature

Objective : To maintain an up-to-date bibliography on all literature published on phenoxy herbicides.

Title : Photolysis of 2,4,5-T

Objective : To measure the rate and products of 2,4,5-T photolysis in water.

Title : Biological and Economic Assessment of 2,4,5-T and Silvex

Objective : To provide a current biological and economic impact statement on the possible loss of 2,4,5-T and Silvex from American agriculture.

Title : TCDD Residue Monitoring in Deer

Objective : To determine the levels of TCDD in deer from forest spray programs.

Title : 2,4-D Human Exposure Study

Objective : To measure the concentration of 2,4-D in two sets of farm workers in the States of Washington and North Dakota.

Title : Participation in Study of Herbicides and Spontaneous Abortions being Conducted by SRI International

Objective : To assist in the funding of the SRI study aimed primarily at farm and forestry workers.

ENVIRONMENTAL PROTECTION AGENCY (five studies):

Title : Evaluation of Large Scale Combustion Sources

Objective: To analyze emissions for PCDDs and PCDFs.

Title : Evaluation of Municipal Waste Combustors

Objective: To analyze emissions for polychlorinated dibenzo-p-dioxins and dibensofurans.

Title : Bacterial Decomposition of TCDD

Objective: To search to discover bacterial genes which code for the capability to degrade TCDD.

Title : Investigation of Bioavailability to Fresh Water Fish of TCDDs in Fly Ash

Objective: To determine the bioavailability to fresh water fish of TCDDs in fly ash.

Title : Analysis of Environmental Samples for PCDDs and PCDFs

Objective: To respond to requests for an analysis of environmental samples from Regional Offices.