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DIFFICULT QUESTIONS LIST

Briefing to Gen  
Chesney \*

1. Q. Why did the Air Force make the commitment to study the RANCH HAND population?

A. The AF Surgeon General has made a commitment to Congress and to the Domestic Policy Council of the White House to conduct this epidemiological study of AF personnel who were exposed to herbicides in Vietnam from 1962 to 1970 (RANCH HAND). This pledge was made because of the growing national concern over whether exposure to herbicides caused attributable adverse health effects in those exposed. The AF continues to honor this pledge to do an epidemiological study and will formally initiate the study in the very near future. We feel that the Air Force adage of "caring for our own" is truly applicable to the 1,200 enlisted and officer personnel who performed these RANCH HAND missions. If there are indeed adverse health effects following exposure to Herbicide Orange, then these brave people need to know what the facts are and what the risks are.

\* Briefing at SAM/ER to Maj Gen Chesney / Ag USAF/SG / 10-11 Feb 80, in preparation for congressional testimony 21 Feb 80, Wash. D.C.

## DIFFICULT QUESTIONS LIST

2. Q. What are the reasons for delaying the Air Force study? (Why don't you care enough about these veterans to get moving?)

A. The Air Force originally made a commitment to begin the epidemiological study in October 1979. That start date was subsequently slipped to January 1980 because of the inability of our Peer Review groups to meet our scheduling requirements. These delays in no way reflect Air Force intent to slow down our effort; rather, we have used this time profitably to additionally refine our study protocol and to coordinate it extensively with other federal agencies actively involved in herbicide issues. The task of accounting for every last Air Force person assigned to the Air Force herbicide squadrons and appropriately matched control groups has proved to be a formidable one which we had underestimated in the beginning of our planning efforts. Absolute total population identification is an exceptionally important requirement from the scientific point of view, in that every person on our list must be properly accounted for so that we have not overlooked any possible attributable health effect. Further, we are still awaiting the formal peer review report from the National Academy of Science; we will carefully review and assess their comments before the study is formally initiated. There are several complexities remaining with our study planning that will require careful consideration and discussion with at least three other federal agencies (particularly the Internal Revenue Service to obtain current addresses) before the effort can be formally started. We are now projecting a start date for the study, consisting of the first comprehensive telephone interviews, for June 1980. While we are not pleased with any further delay, the additional time will constitute an investment toward a more comprehensive and valid scientific study.

## DIFFICULT QUESTIONS LIST

3. Q. Why is the Air Force conducting this investigation inhouse, as opposed to allowing another Federal agency or civilian university to conduct the study?

A. The Air Force is conducting an inhouse epidemiological investigation because of its considerable expertise in the herbicide arena. Our epidemiologists are skilled and well-trained in locating and communicating with former military personnel in an appropriate and relevant manner. Our experts designed the Herbicide Orange protocol over a period of nine months, and have subjected their scientific approach to an unprecedented 4-stage Peer Review. We believe that we are in a far better position to implement this project with equal validity and faster than any other federal agency or independent university. We have contracted out minor portions of the study design to outside university agencies, but the bulk of activity remains inhouse because of the congressional and veteran mandates to accomplish this study as quickly as possible. By virtue of the scope and comprehensiveness of our epidemiological effort, including the enumeration of our RANCH HAND personnel and appropriate study group, we are at least 10 months ahead of what any other federal or university team might come up with.

## DIFFICULT QUESTIONS LIST

4. Q. Why do you think the Air Force study will be credible?

A. We believe that the Air Force epidemiological study will indeed be a credible scientific work and will withstand any scientific or lay criticism. Our study design incorporates all appropriate time elements: we will go back in time to determine if there have been any adverse health effects; we will look at these exposed personnel now by means of an exceptionally detailed physical examination; and we will observe this population over a minimum of 5 years to determine if adverse health effects emerge in the future. Our study design has been subjected, at our request, to an unprecedented 4-stage peer review. Our protocol has been reviewed by the University of Texas School of Public Health, the Air Force Scientific Advisory Board, Armed Forces Epidemiological Board, and the National Academy of Science. For the first three Peer Reviews we gratefully accepted the genuinely helpful advice of those review boards, and we incorporated their best suggestions into the body of our protocol. We are now awaiting the last peer review report from the National Academy of Sciences. In addition, the actual implementation of the Air Force epidemiological study will be monitored start to finish by an outside, non-DOD agency, and we are confident that the scientific effort will readily survive the final acid test of its credibility: publication in the open scientific literature.

## DIFFICULT QUESTIONS LIST

5. Q. Don't you think the Air Force study will duplicate other larger proposed Federal and civilian studies?

A. We do not believe that the AF study of RANCH HAND personnel will be duplicative of other studies, either in the planning stage or completed and published in the scientific literature. The more we study the RANCH HAND population and the more we talk with the RANCH HAND Association members, the clearer it becomes that the AF population was uniquely exposed to high doses of Herbicide Orange over a sustained period of time. Further, we believe that the detailed nature of our mortality analysis which is strongly linked to our followup study, as well as our comprehensive baseline physical examination, will yield more complete data than has been reported to date. For reasons previously described, we believe that each epidemiological study based on its own different exposed population will make significant contributions to answering the overall question.

## DIFFICULT QUESTIONS LIST

6. Q. Why will the Air Force study of RANCH HAND personnel be more valid than the previously conducted civilian studies?

A. Many of the civilian studies reported in the scientific literature were limited by problems of methodology, small study group size, and/or inadequate time intervals to assess truly long term effects. The Alsea Oregon study has been sharply criticized for deficiencies in data - gathering methods, and statistical analysis. Only 3 1/2 years have elapsed since the industrial accident in Seveso, Italy and despite the large size of the study population, sufficient time has not elapsed to form conclusions as to the presence or absence of long term effects of health. Most studies of groups exposed to phenolic compounds and TCDD in an industrial setting have involved groups of fewer than 300 exposed individuals, and thus, these small numbers severely limit the ability to draw statistically valid conclusions for or against health effects arising from these exposures. The proposed Air Force study has attempted to overcome these limiting factors by submitting the study design to an extensive peer review process, by selecting a population for study which had exposure 9-17 years ago, and by attempting to maximize the group size (approximately 1200). This approach should make the Air Force study as or more valid than previously conducted studies of civilian populations.

## DIFFICULT QUESTIONS LIST

7. Q. Since your study population has small numbers, how will you reconcile the criticism of a weak or inadequate study?

A. I wish to point out to the Committee that all epidemiological studies found in the medical literature suffer, in one way or another, from the disturbing problem of small numbers. The Air Force RANCH HAND study is no exception, and we recognize the statistical limitations of our effort. There are a variety of scientific methods and techniques that can be used to partially compensate for a small number problem and we have done so. The ability of the Air Force study to define a cause and effect relationship between exposure and illness is relatively weak for the rarer diseases, but is relatively good for the more common diseases (for example, heart disease). In the final analysis, the strength of our study will depend on the degree of participation from both the RANCH HAND population and the designated control population. If participation is over 90%, the overall strength of our study will be relatively good. If herbicide exposure does cause substantial disease or death, our study will clearly detect it, particularly if our participation rates are high.



## DIFFICULT QUESTIONS LIST

8. Q. Since your study population is small, why don't you add it to other federal studies to increase the numbers?

A. Certainly there are a variety of other studies, federal and civilian, that could be proposed as adjunct or fold-in epidemiological studies to our effort. For example, some have suggested that we add the RANCH HAND study to the Veterans' Administration study of Army and Marine personnel who were exposed as a result of the aerial application of Herbicide Orange; others have suggested that we might add our study to the proposed HEW and USDA study of agriculturally exposed applicators. Other proponents of larger studies have suggested that we add other exposed military groups, such as herbicide drum handlers, US Army helicopter crews, etc. While there is almost instant appeal to the notion of adding groups or additional studies, there are negative scientific considerations for these procedures that are somewhat complex and difficult to perceive. Basically, there are two considerations which should prohibit the proposal for adding studies: (1) From the estimated exposure point of view, mixing study groups is like mixing apples and oranges. Basically the concept is a statistical one: that is, if we mix high exposure and low exposure groups of individuals, then in all probability we will dilute or mask a herbicide health effect, particularly if that effect is not strong. Secondly, it is critical to the validity and accuracy of the study that the total study population at risk be very accurately defined. That requirement is easily met in the RANCH HAND study as we will define the population at risk to well within 1%. This may not be true of the VA or HEW studies. If we add ancillary study groups to the RANCH HAND study for the simple sake of numbers, we may well create a significant bias by virtue of adding these underdefined groups. That bias would most likely cause a positive attribution to adverse health effects when, in fact, it might not exist. I hope this explanation of the complex statistical difficulties will aid in convincing the Committee that from the estimated exposure point of view, these epidemiological studies are not additive. Rather, these studies should each stand alone on its own merits to add pieces to the total puzzle.

## DIFFICULT QUESTIONS LIST

9. Q. What are the objectives (goals) of the Air Force study?

A. The purpose of the Air Force epidemiological investigation is to determine whether long term health effects exist and can be attributable to occupational exposure to Herbicide Orange. Our study basically has three goals:

a. Health

(1) To identify veteran and active duty individuals with adverse health effects (physical and psychological) if any, which are attributable to herbicide exposure, and

(2) To identify other individuals at risk of developing future adverse health effects, if such exist.

b. Political

To satisfy the social concern for proper investigation voiced by lay and scientific communities, both national and international.

c. Legal

To clarify the question of compensation awards to the VA claimants.

d. moral - humanitarian

## DIFFICULT QUESTIONS LIST

10. Q. When will the Air Force study be completed? We need answers now.

A. The Air Force study will be conducted for a minimum of five years. Please understand that this is not a long period of time for the completion of a comprehensive epidemiological study. During this period of time, the study population will be under intense medical surveillance. The complexity of the herbicide health effects issue requires a comprehensive approach. The first report on the mortality portion of our study will be completed approximately 18 months after the starting date, the morbidity portion will be completed at year four, and the followup report will conclude the study at year five.

# TOTAL  
FIVE Million

DIFFICULT QUESTIONS LIST

11. Q. What is the total cost of this study to the American taxpayer?

A. The taxpayer cost in 1980 dollars of the five year study is estimated at 2.5 million dollars. The real cost to the taxpayer would result from not doing this study. The veteran's compensation issue combined with the moral issue of the real long-term health effects of exposure are questions that must be answered not only for the taxpayer, but for the veteran and the entire Air Force community. The health and welfare of "our own people" are vital concerns to those of us in Air Force leadership positions. Cost of this endeavor must be viewed from more than a dollar expenditure perspective.

## DIFFICULT QUESTIONS LIST

12. Q. To what degree are you coordinating your study with other Federal agencies?

A. The Air Force is conducting extensive coordination with other Federal agencies in the planning of this study. We have, of course, presented the study and resource requirements extensively to the DoD for their consideration; and a member of my staff serves as a backup DoD representative to the VA Coordination Committee. Over the past six months, members of our study design team have made eight presentations to the VA in assisting them to launch their study effort. Other coordination includes extensive telephone coordination/conversations with the IRS, NIOSH, USDA, GSA, HEW and EPA. In addition, basic elements of our complex study design and scheduling projections have been presented to staff members of the White House Domestic Policy Council. Our scientists have conducted extensive coordination and site visits with civilian investigators who are conducting ongoing epidemiological studies concerning phenolic compounds and TCDD. We look forward in the future to working even closer with the VA in assisting them with the design of their study.

## DIFFICULT QUESTIONS LIST

13. Q. Will you provide a copy of the AF Scientific Protocol for review to the Committee?

A. I respectfully propose to the Committee at this time that a copy of the Air Force scientific protocol not be provided for review in as much as we do not view it as a final product. As previously mentioned, we are awaiting the National Academy of Sciences to provide us a copy of their formal review. Following the receipt of that document we may wish to make final modifications before initiating the program. While we have provided working drafts of our scientific approach to four review committees and to staffers of the White House Domestic Policy Council, we continue to view the scientific protocol, the contents of the telephone questionnaire, and the specific items of the physical examination to be highly confidential in nature. Premature leak of these items to either the press or to the concerned veterans groups might well create additional pre-conditioned responses -- that is, positive bias -- from which no epidemiological study could properly recover. If members of this committee wish to review the scope and comprehensiveness of our approach, we would propose a presentation by our study designers to you rather than release the protocol at this time. We believe that these restrictions will work to the best interest of this committee and to our concerned veteran groups. We intend to be totally open on the study design elements once the baseline questionnaire and physical examination have been completed. Indeed, it is our intent to formally publish the entire study design, questionnaire and physical examination protocol in the open scientific literature.

## DIFFICULT QUESTIONS LIST

14. Q. The NAS has informally told us that the Air Force scientific study is well designed. How do you respond?

A. Give those assholes a raise!

## DIFFICULT QUESTIONS LIST

15. Q. The National Academy of Sciences has informally told us that the Air Force scientific study is not up to par: How do you respond.

A. I am indeed sorry to learn for the first time of a suboptimal report coming from the National Academy of Sciences. Since I have not seen that document I cannot respond informatively to specific items. We will be pleased to respond more in depth to the National Academy of Sciences' critique at a later subcommittee hearing after we have had an opportunity to review their critique.



## DIFFICULT QUESTIONS LIST

16. Q. Will you accept the National Academy of Sciences critique and incorporate their suggestions into your study protocol?

A. The Air Force ground rules for peer reviews prior to the National Academy of Sciences presentation have included providing the peer groups with a copy of our working draft protocol, complete literature review package, and a detailed briefing to discuss these complexities with the review groups. Following our receipt of a formal critique, detailed reviews were conducted by the Air Force study design team. Written comments were then provided from our team back to the review group expressing acceptance, rejection, or modification of specific recommendations. Thus far, we have accepted and incorporated into our study design protocol almost all the helpful comments of the first three reviews. Overall the acceptance of our protocol by the three peer review groups has been excellent and all peer review groups have expressed genuine admiration and respect for the depth, comprehension, and approach developed by our team. We propose to respond to the National Academy of Sciences critique as we have to other peer reviews. If they have helpful suggestions to make in terms of increasing scientific accuracy and validity of our study, we will accept them.

## DIFFICULT QUESTIONS LIST

17. Q. Is this an Air Force or DoD-sponsored study? (Definitive answer requires HQ USAF staffing prior to the Hearings.)

A. As of today, the RANCH HAND epidemiological study remains an Air Force product, designed, developed, and funded by the Air Force; to be sure, we have extensively coordinated our plans with a variety of offices in the Department of Defense. There are current sustained discussions that indicate that the Department of Defense may play a more central role in the conduct of this study, and in fact, may underwrite the resource requirements for it.

## DIFFICULT QUESTIONS LIST

18. Q. In light of the GAO report, why did not the DoD previously identify Marines as a possible exposure group: (Definitive answer required HQ USAF staffing prior to the Hearings.)

A. The Air Force has selected for study a military population, the RANCH HAND group, as a population known to have been exposed to herbicides. This is an ideal group to study since it may be possible to develop an exposure index, or even to possibly reconstruct actual exposure scenarios using simulants. The GAO document, as presented, neither permits an assessment of the validity of the methodology nor does it consider pertinent biologically significant factors. The method identifies a potential exposed population, apparently to primarily counter the DoD position that ground troops were rarely exposed to Herbicide Orange. Verification of exposure will be complex if not impossible. Distance from the spray line and elapsed time after spraying as provided by their method ignores the environmental fate of herbicide and its associated dioxin. Their time-distance exposure concept, if adopted as a primary study methodology, may suffer significant errors of misclassification which could either dilute a true health affect or produce a biased attribution of cause and effect.

## DIFFICULT QUESTIONS LIST

19. Q. What is the DoD position on the results of the Veterans' Administration fat biopsy study? (Definitive answer required HQ USAF staffing prior to the Hearings.)

A. The Veterans' Administration fat biopsy study was conducted to answer the limited question of whether a biopsy and analysis for TCDD would be of value as a diagnostic procedure in the evaluation of Vietnam veterans. Their results show that with the available technology, positive results are found in unexposed as well as exposed individuals, and that a positive value for TCDD does not correlate with the presence or absence of symptoms. The biopsy and analysis procedure could be useful in a diagnostic sense if future technological developments will permit the differentiation of 2,3,7,8 TCDD from other isomers not found in the herbicides. At the present time, the presence of a positive biopsy result is not predictive of present or future herbicide related disease and conversely, a negative result does not imply that disease will not occur in the future.

## DIFFICULT QUESTIONS LIST

20. Q. Why will study of the RANCH HAND population provide any better clues to herbicide health effects than studies of Army and Marine personnel?

A. The epidemiological study of the Air Force RANCH HAND population certainly has better potential of uncovering and perhaps quantitating adverse health effects than an epidemiological study of Army and Marine personnel. We believe that the operational setting for certain Air Force personnel in Vietnam provided the most sustained exposure to Herbicide Orange. The extent of probable exposure alone makes the study of these Air Force personnel more attractive from the scientific point of view. It is the best scientific prediction at this time that the higher the exposure and the longer the opportunity for exposure, the higher will be the chances of illness and perhaps death, consistent with a classic dose response curve. We feel that, on the average, RANCH HAND personnel were probably exposed more severely and over a longer period of time than other service personnel. Consequently, they should manifest more signs and symptoms of illness, and develop them sooner than other service personnel. Additionally, we believe that our scientific estimates of exposure will be more accurate and more workable from the statistical point of view than those exposure estimates which could be developed for Army, Navy, or Marine personnel. For our study populations there will be very little change to misclassify people based on whether or not they were exposed to Herbicide Orange; the degree of misclassification between exposed and non-exposed for other service personnel will always remain as a strong point of scientific critique. Therefore, from the "pure" exposure aspect, the Air Force RANCH HAND population represents the most promising study population within the Veterans group.

## DIFFICULT QUESTIONS LIST

21. Q. What other chemicals/pesticides were troops potentially exposed to in Vietnam?

A. In addition to the herbicides, numerous other chemicals were shipped to South Vietnam in 55-gallon drums. These included selected fuel additives, cleaning solvents, cooking oils and a variety of other pesticides. The insecticide malathion was widely used for control of mosquitoes and at least 400,000 gallons were aeriaily-sprayed from 1966 through 1970. In addition, much smaller quantities of the insecticides lindane and DDT were used in ground operations throughout the war in Southeast Asia. Two other chemicals should be mentioned. The military widely used the drug Dapsone for the treatment and prophylaxis of malaria in high risk personnel. In addition, the insect repellent DEET was standard issue in personal protection kits issued to all combat military personnel.

## DIFFICULT QUESTIONS LIST

22. Q. Where else was Herbicide Orange used other than in Vietnam?

A. As was the practice with all commonly used herbicides during the Vietnam era, Herbicide Orange was assigned a Federal Stock Number. It was possible and likely that many military installations requested small quantities (e.g., a few drums) of the herbicide to be used in approved brush and weed control programs. Records verifying distribution of the herbicide to these installations are apparently no longer available. Herbicide Orange was extensively used in test programs during the development of aerial spray equipment. A large spray equipment program occurred at Eglin AFB FL from 1962 through 1969, and in Thailand from 1963 through 1965. Some RANCH HAND missions involved spraying the border regions between Cambodia, Laos, and Vietnam. Thus, these three countries may have received a limited amount of herbicide during the war years.

## DIFFICULT QUESTIONS LIST

23. Q. Has the DoD determined exposure levels for the personnel that participated in either the PACER HO or RANCH HAND Projects?

A. An extensive industrial hygiene air monitoring program was conducted during the PACER HO operation. "Breathing Zone" samples of air from personnel working in all phases of the dedrumming operation revealed that under the worst case noted, the levels of 2,4-D and 2,4,5-T vapors were well below the Time-weighted Threshold Values for each of these materials. The noted levels were at least two and in most cases three orders of magnitude below the TLVs. TCDD was not detected in any air sample when examined with the state-of-the-art analytical technique. No industrial hygiene program was used in Vietnam during the RANCH HAND Project. However, personnel charged with the supervisory responsibilities of handling the herbicides were indoctrinated in appropriate safety precautions including the use of gloves and face shields as needed. Personnel handling the chemicals were encouraged to "take normal sanitary precautions and to maintain personal cleanliness and to avoid skin and eye contact with the material. Contaminated clothing was to be washed before re-use. Spillage on the skin or in the eyes was to be rinsed copiously with clear water."



## DIFFICULT QUESTIONS LIST

24. Q. Was there an Occupational Health Program established for PACER HO?

A. Personnel assigned to Project PACER HO were given pre- and post-exposure physical examinations. In addition, during all dedrumming and other handling operations, all workers were provided daily changes of freshly laundered work clothes. They were also provided with protective clothing consisting of cartridge respirators, face shields, rubber aprons and rubber gloves and boots. An assessment of the occupational medicine program concluded that no apparent physical or medical effects were attributed to these activities.

## DIFFICULT QUESTIONS LIST

25. Q. Why do you not have on-going surveillance programs for all personnel exposed to herbicides?

A. It is not logistically feasible to identify and follow each and every individual exposed to herbicide or any other chemical or physical agent. However, key groups of individuals can be identified and placed under medical surveillance programs. All individuals who participated in the Herbicide Orange disposal project (PACER HO) received pre- and post-exposure physical examinations, were closely monitored during the project, and can be re-evaluated in the future. Since environmental/industrial hygiene monitoring studies during the project revealed negligible exposure levels, post-exposure physical examinations were normal, and only 2 1/2 years have elapsed since the operation, further followup studies are not currently planned. However, such studies will be considered if the results of the RANCH HAND II study indicate that a potential health risk exists for PACER HO workers.

## DIFFICULT QUESTIONS LIST

26. Q. How do you propose to assist the VA in clarifying the compensation issue?

A. It is apparent that data and conclusions arising from this study, positive or negative or indeterminate, can be used to better assess the issue of long term health effects and resulting compensation. If the study shows significant attributable health effects, it will be our objective to define these health effects as clearly as possible so that the Veterans Administration can identify veterans who demonstrate these health effects. We wish to point out to the Committee at the outset that no single epidemiological study will yield unquestionable conclusions. The most optimistic outlook is that if there are significant health effects from exposure, several epidemiological studies using different population groups and different scientific approaches will produce consistent and reproducible results. Only in this fashion can the issue of compensation be approached in a scientific manner.

## DIFFICULT QUESTIONS LIST

27. Q. What is being done as followup on Vietnamese civilians exposed to the herbicides?

A. Vietnamese civilians were potentially exposed to the herbicides in two ways: (1) by contact with herbicides after dissemination and (2) by handling the herbicide in storage depots. Valid scientific studies of these groups are currently impossible since identification of exposed individuals and documentation of exposures do not exist. While a partial listing of some individuals alleging exposure can be developed, a valid study must include an assessment of all individuals in the population at risk; those who are well or not motivated to identify themselves and those who may have died in the intervening years. A cooperative effort with the Government of Vietnam to attempt identification and evaluation of these individuals has been suggested.

# Question Key

WHY COMMITMENT	#1
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WHY STUDY CREDIBLE	4
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