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Agent Orange Status Report

Status report on the management of the VA Agent Orange Epidemiology study, and the matter of whether to include a third cohort in the design of the study:

I. Research Management:

No final decision has been reached on the question of in-house -vs- out-house conduct of the VA Agent Orange epidemiology study. We are exploring options and evaluating the level of interest, and capability, of potential scientific contractors and other government offices the VA might engage to conduct this study.

Due to the lengthy scientific review process, there remain conflicting views about some aspects of the protocol. These differences must be reconciled before we can proceed to a final decision about who will actually direct the scientific investigation.

Our next step is to hire a small VACO scientific staff and, with the aid of consultants if needed, to begin the final integration and completion of the UCLA protocol. This will be done more quickly if we also involve the scientific review committees in this process and if we identify the scientific oversight panel which will follow the progress of the actual research.

At the same time the protocol is being completed, we will seek to identify potential investigators for the pilot study. We are currently developing a Request For Proposals (RFP), and a contract statement of work, so that we will be able to begin the pilot study as soon as possible after the protocol is finished and approved. We hope to commit FY 82 funds to the pilot study and to begin data collection early in 1983.

II. Third Cohort:

The AO/G Science Panel has recommended that the VA's epidemiology study include a third cohort in order to look at the broader issue of possible health effects resulting from service in Vietnam. Selecting appropriate health outcomes to adequately represent possible health effects of the "Vietnam experience", rather than only Agent Orange effects, has been mentioned by OTA as a potential problem. It is not too difficult to address this issue. The range of health data included in the UCLA protocol is already very broad. The authors note that their choice of outcomes to be examined relied as much on press reports of Vietnam veteran's health problems as it did on the limited scientific literature on the effects of exposure to phenoxy herbicides (Appendix G of the UCLA protocol). If the VA is prepared to conduct an expanded health evaluation, then health outcomes of interest representing the entire "Vietnam experience" could be built into the study.

Representative sampling is a problem not so easily addressed. There are really two related problems in this area.

1) The UCLA authors have pointed out that Vietnam veterans who did not go to Vietnem may differ in important ways from those who did serve in Vietnam and survived. How they might differ is not explained. It is reasonalbe to suppose that military training, physical fitness, willingness to take risks and the proven ability to survive a war, are four dimensions which could contribute to very different health profiles for the Vietnam and non-Vietnam groups, having nothing to do with exposure to Agent Orange. This problem, of finding a perfectly comparable third cohort, can never be totally solved. It will be important to identify and evaluate the potential size and direction of health differences thought to exist in these groups before we proceed with a third cohort.

2) Another sampling problem arises when we atempt to conduct both a "Vietnam experience" study, and an Agent Orange study, using three cohorts. The high and low Agent Orange exposure-likelihood cohorts must be as similar as possible on all other factors which cannot be objectively measured. Combat stress is one example of an important potential confounding factor which is difficult to measure

at the level of the individual soldier. Combat stress should be controlled by selecting both Agent Orange exposure cohorts from combat units thought to be equivalent in terms of exposure to stress. Idally, the high and low exposure cohorts should be equivalent in every way except exposure to Agent Orange. Unfortunately, this approach reduces the generalizability of the study. If only combat veterans are sampled,just a fraction of all the troops who served in Vietnam will be represented.

Do the high and low Agent Orange exposure cohorts, as presently defined in the protocol, adequately represent the "Vietnam experience" (i.e. all of the health risks encountered by Vietnam veterans)? I don't think so. However, with careful cohort selection, and very clear cohort definition, the "Vietnam experience" represented by subjects in the two Vietnam cohorts could represent the most salient aspects of that experience.

The AOWG Science Panel has recommended a balanced emphasis on both the broader issue of evaluating all health risks associated with service in Vietnam, and the narrower question of the effects of Agent Orange. This will ultimately require some compromise in the design of both studies. This will also require further delay while these issues are debated, encorporated into the protocol, reviewed and approved.