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Memorandum

Date: July 29, 1982

From: Director, Agent Orange Research
and Education Office (OOLE)

To: Administrator

Subject: Agent Orange Research
Predecisional Memorandum

1. The Agent Orange epidemiology research protocol has been reviewed and approved, in general terms, by the White House Agent Orange Working Group (AOWG) Science Panel, the Congressional Office of Technology Assessment (OTA), and the VA Advisory Committee on Health-Related Effects of Herbicides. Although some differences remain among the recommendations made by these committees, all three of these review groups support the idea of including a third cohort to evaluate the effect of the "Vietnam experience" on the health of veterans.

2. The AOWG strongly endorses the three cohort research design as an effective means of evaluating the health effects of both the Vietnam experience and of exposure to Agent Orange.

3. The three cohort research design may have far reaching implications:

- a) A third cohort will increase the cost of the study by nearly 50%;
- b) A three cohort study design will increase the total number of hypotheses to be tested and, therefore, will increase the probability of finding both real and chance effects;
- c) Specific risk factors or exposures will be impossible to identify in the "Vietnam experience" portion of the study. Health problems found to be associated with Vietnam service may require further research to identify causation and establish the relative increase in risk for each health problem;
- d) For the purpose of compensation, the assumption of exposure to a general health risk factor by anyone who served in Vietnam, without requiring documentation of a specific exposure, may include very large numbers of veterans. This also applies to the process of compensation based upon Agent Orange results;
- e) If common health problems are found to be weakly associated with Agent Orange or service in Vietnam (i.e. only a slight increase in relative risk) then the VA may want to consider an "attributed risk" formulation for compensating veterans.

4. It is your decision whether or not the VA will conduct a study of three or only of two cohorts. Public Law 97-72 states that you "may" broaden the scope of the study to look at the general health effects of service in Vietnam. You may also limit the focus of the study to the Agent Orange issue.

5. There are a number of options available to you:

- a) Broaden the scope of the study by including a third cohort as the AOWG recommends. This option appears to be consistent with the wishes of the veterans' service organizations and the Congress;
- b) Limit the scope of the study to the health effects of Agent Orange exposure and study only two cohorts. The U.C.L.A. authors of the research protocol recommend this option on scientific grounds, but do not present a strong argument for their position;
- c) Proceed with plans for a pilot study contract based upon three cohorts. If the National Academy of Sciences (NAS) review group recommends against the three cohort design drop the third group and re-negotiate the pilot study contract;
- d) Proceed as in c) above. If NAS agrees that a three cohort study is appropriate, then the pilot study can be used to evaluate the feasibility of the three cohort design. Participation rates may be lowest for the third, non-Vietnam, cohort. If fewer than 70% of the potential subjects in that group participate in the pilot study, the third group may have to be dropped from the final design for statistical reasons;
- e) Ask the VA Advisory Committee on Health-Related Effects of Herbicides and the VA Policy Coordinating Committee (PCC) to consider the three cohort design issue and provide you with their independent recommendations.

MAURICE E. LEVOIS
Director, Agent Orange Research
and Education Office