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September 15, 1982

AGENT ORANGE EPIDEMIOLOGIC STUDY

DECISION PAPER

The U.C.L.A.-submitted epidemiology protocol for the study mandated by Public law 96-151, has undergone extensive review and revisions. Many of the reviewers, especially members of the White House Agent Orange Working Group (ACWG), have recommended widening the focus of the study. Although U.C.L.A. has prepared a protocol for strictly an Agent Orange study (high and low likelihood of exposure cohorts of Vietnam veterans) it has been suggested that a third cohort consisting of Vietnam era veterans (no Vietnam service) be included to assess the Vietnam experience. Some reviewers (e.g., members of the VA Committee on Health Related Effects of Herbicides) have proposed that the VA conduct a study of the Vietnam experience only. If the results are positive, further efforts to elucidate a cause and effect would be possible but not required.

It is apparent that at least three courses of action are available to the Agency.

1. Conduct an Agent Orange study based on the current version of the U.C.L.A. protocol. This study would compare the health outcomes of two groups of Vietnam veterans, those having a high or low likelihood of exposure to herbicides.
2. Conduct an Agent Orange study but add a cohort of veterans that did not serve in Vietnam. This study would involve a modified version of the present protocol and would compare health outcomes between two cohorts that served in Vietnam and one that did not serve in Vietnam.
3. Conduct a study of the Vietnam experience. This study would compare the health of veterans that served in Vietnam with veterans that served in other parts of the world during the same period.

The options and major arguments for selecting or rejecting each are as follows:

OPTION I. SHOULD THE VETERANS ADMINISTRATION CONDUCT A PURELY AGENT ORANGE STUDY (TWO COHORTS IN VIETNAM)?

PRO VIEW

- o An Agent Orange study was mandated by Public Law 96-151.
- o The U.C.L.A. protocol has been designed around a two cohort study of Vietnam veterans (high and low likelihood of exposure).
- o A purely Agent Orange Study provides a single issue focus for the VA since the perception is that this is the major concern of Vietnam veterans.
- o The AOWG Science Panel Chairman on November 18, 1981, testified before the Senate Veterans Affairs Committee that an Agent Orange study can be conducted.
- o An AOWG Science Panel Subcommittee on "Cohort Selection and Exposure to Herbicides" indicates that cohorts for an Agent Orange Study can likely, and objectively, be found by using DOD records.
- o Many scientists are genuinely concerned over potential low dose effects of dioxin and Agent Orange.
- o A two cohort study may be conducted more rapidly and at less cost than a three cohort study.
- o A pilot study can be conducted rapidly because fewer changes in the present protocol will be needed and fewer subjects need to be recruited and examined.

ANTI VIEW

- o Public Law 97-72 permits the VA to expand the focus of study.
- o There are scientific problems associated with conducting a purely Agent Orange study involving two cohorts:

- there are no clearly defined long-term health outcomes attributable to TCDD and Agent Orange exposure (the Air Force Health Study consisted of a very extensive health examination because of this).
- the military records necessary to determine objective assessment of exposure in Vietnam were never designed for use in an epidemiologic study; thus, there is a significant potential for misclassifying individuals as to whether they were or were not truly exposed to herbicides.
- there is no scientific way to equate modes of exposure in Vietnam (e.g., how many perimeter exposures equal a RANCH HAND exposure?)
- o Errors resulting from misclassification of individuals within the high and low exposure cohorts will seriously impair the useability of data.
- o DOD and selected members of AOWG are against conducting only an Agent Orange study. They believe that the scope of the study is too limited.
- o A pure Agent Orange study may resolve the concerns raised by some Vietnam veterans. However, if the study shows no effect attributable to Agent Orange, many veterans will say it was something else in Vietnam that impacted their health.

OPTION II. SHOULD THE VETERANS ADMINISTRATION CONDUCT AN AGENT ORANGE STUDY WITH AN ADDITIONAL COHORT TO ASSESS VIETNAM EXPERIENCE (THREE COHORT STUDY)?

PRO VIEW

- o This study may permit some answers as to the impact of the Vietnam experience on the health of Vietnam veterans.

- o Some government agencies (e.g., DOD) and some Congressmen favor a broader study.
- o Many veteran groups may favor a broader study so long as the VA adequately addresses Agent Orange.
- o The Air Force Health Study adequately addresses the health issues associated with heavy exposure to herbicides including Agent Orange, but it does not address the impact of the Vietnam experience.
- o DOD believes that a non-Vietnam cohort can be selected without great difficulty.

#### ANTI VIEW

- o The protocol for an Agent Orange Study may not be suitable for a Vietnam experience study. Hence, to study both issues with the same protocol may compromise the quality of both studies.
- o The present U.C.L.A. protocol would require significant modification in order to incorporate selection criteria for a third cohort. Moreover, such modifications of the present protocol may have public as well as scientific repercussions.
- o The identification of a third cohort will require an expanded records search effort by DOD. This will require additional time and resources.
- o To conduct a study of 18,000 individuals (three cohorts @ 6,000) will require significantly more resources than will be required for the study of two cohorts.

### OPTION III. SHOULD THE VETERANS ADMINISTRATION CONDUCT A SEPARATE EPIDEMIOLOGIC STUDY TO ASSESS THE VIETNAM EXPERIENCE?

#### PRO VIEW

- o If the Veterans Administration is concerned with the broader issue of the health of the Vietnam veteran, it must then be equally concerned over the effects of infectious diseases, illicit drugs, combat stress, herbicides, insecticides, etc.

- o This study may provide the Agency with significant information to aid in the development of a compensation policy.

ANTI VIEW

- o This Option will require the preparation of an entirely new protocol. It will require time for protocol preparation and scientific review.
- o Because this study must be "something for all", i.e., it must be widely focused in terms of the potential health outcomes, it will require indepth physical, biochemical, and psychological studies of the subjects and by necessity may be more costly and take longer to conduct.

RECOMMENDATIONS:

1. It is recommended that the VA conduct an Agent Orange Study as designed by the U.C.L.A. Protocol. This study will focus on the health of two cohorts of veterans who served in Vietnam. The issue is whether there is a long-term health effect as a consequence of exposure to Agent Orange. The impact of the total Vietnam experience must be viewed as a separate issue. The U.C.L.A. protocol has received extensive review, and needs only to be slightly revised (Sections on Cohort Selection and Biostatistical Methods expanded) prior to the award of a contract for the conduct of a pilot study. The present protocol can be completed within the next 6 weeks and Request For Proposals (RFPs) for the conduct of a pilot study can be initiated within 60 days.

APPROVE/DISAPPROVE

APPROVE/DISAPPROVE

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

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ROBERT P. NIMMO  
Administrator

2. In order to address the issue of the Vietnam experience, the Agency will conduct the Vietnam Veteran Mortality Studies and the Vietnam Veteran Identical Twin Study. These studies, in association with the CDC Birth Defects Study and Australian Studies will bear on the issue of the Vietnam experience. However, the Agency should explore the feasibility of a separate epidemiologic study to address the impact of the Vietnam experience.

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