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Corporate Author

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WHITE PAPER

STATUS OF VA EPIDEMIOLOGIC STUDY OF AGENT ORANGE

The epidemiology protocol originally submitted to the VA by the U.C.L.A. School of Public Health on April 29, 1982, has now been reviewed by the VA Advisory Committee on Health-Related Effects of Herbicides, the White House established Agent Orange Working Group (AOWG) and the Office of Technology Assessment. All of these review groups have noted that further development of the research protocol is needed in certain areas. For example, each of the following topics has been mentioned by one or more of the protocol review groups as needing additional attention: a clear statement of specific hypotheses to be tested; the data reduction and analytic methods to be employed; the rationale for a third cohort; and more exact statistical power calculations associated with these refinements of the protocol.

The protocol is currently being reviewed by a committee of the National Academy of Sciences (NAS). The VA has been advised that NAS is now in the final stages of this review process. It is expected that the report will be completed and forwarded to the Veterans Administration by the third week of September. Further refinement of the protocol is underway and should be completed during the month of October. Barring unforeseen complications, a contract for the conduct of a pilot study of approximately 900 veterans (or 300 per cohort) should be awarded in the January-February 1983 time frame.

A critical component of the pilot study will be to evaluate the cohort selection procedures and the feasibility of developing cohorts for the full scale study which will be twenty times larger than the pilot study cohorts. This aspect of the protocol was not developed by U.C.L.A. and has become the focal point of recent activity by the VA, the Army Agent Orange Task Force (AAOTF) and the AOWG. The basic issue is whether the military records are sufficiently complete and detailed so as to provide a reliable indicator of

"likelihood of exposure" to herbicides. The present assessment of the records suggest that identifying the cohort with a high likelihood of exposure will be easier than identifying the cohort with low likelihood of exposure. The reason for this is that the present records of herbicide missions, the HERBS Tape, provide a reference point for estimating likelihood of exposure because tracking a company in an area known to have been sprayed with herbicides on a given day can be objectively determined by the records. When looking for units considered "not likely exposed" the record searchers can only assume selected units were not near herbicide targets; a subjective evaluation; thus, they cannot document the absence of exposure to herbicides. It is important therefore to note that misclassifying an individual as to likelihood of exposure can result in "diluting-out" any health effect that may be present and associated with exposure.

The AOWG has appointed a subcommittee of its Science Panel to establish procedures for cohort selection for the epidemiology pilot study. The VA has brought in biostatistical consultants to work with this subcommittee and with the AAOTF. The subcommittee is now in the process of preparing its final report to the Science Panel. When this report is forwarded to the VA, a recommendation will be made by the Chief Medical Director to the Administrator as to whether the pilot study will focus only on Agent Orange or whether it will center on the total Vietnam experience with Agent Orange as a major emphasis.

The pilot study itself is expected to be a major factor in the final decision to broaden or limit the scope of the full scale epidemiology study. That decision may not be made until the results of the pilot study are available in late 1984 or early 1985.