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The attached was provided to me by Vern Houk of CDC.

Don Barnes

LABORATORY PROJECTS RELATED TO AGENT ORANGE

Body Burden Measurements of Polychlorinated Dibenzyl Dioxins (PCDD's) and Furans (PCDF's)

VA-EPA Collaborative Study of Dioxin Levels in Human Adipose Tissues (stored specimens 1970 to present).

In September 1984, the Environmental Protection Agency submitted for technical review their protocol for the proposed VA-EPA Collaborative Study of Dioxin Levels in Human Adipose Tissues. The proposal is a retrospective designed study, consisting of identifying Vietnam veteran-related adipose tissue specimens procured through the National Human Adipose Tissue Survey (NHATS) and comparing the PCDD and PCDF levels observed in these specimens to levels found in a carefully selected control group obtained from the same cohort of stored specimens. The protocol and supporting documentation were carefully reviewed by several staff members and several areas of scientific concern relative to the validity and feasibility of the proposed study have been identified.

The procedures used to select specimens to be included in the NHATS program represent a good statistical design and are scientifically sound in terms of the program goal to monitor human adipose tissue concentration of selected chemicals in broad groups of the U. S. population. Although EPA

has collected over 21,000 adipose specimens since 1970, it is estimated that only 50 to 60 of these specimens will be related to Vietnam veterans. Because of this small number of applicable specimens, factors not considered in the original survey selection process, i.e. occupational exposure, and urban/rural distribution, will become increasingly important to the study and must be carefully considered. Two other variables that could drastically affect the decision-making power of the proposed study and, therefore, must be taken into consideration are: 1) the high variability of the possible PCDD exposure received while serving in Vietnam; 2) variability in the time delay between exposure in Vietnam and specimen procurement.

Another area of concern is the possible inconsistency of compliance to sample procurement and storage protocols. More than 40 hospitals and medical examiners were involved in specimen procurement and no information is currently available to document that these procurement centers routinely followed the described procedures in obtaining the requested specimens. Some of the specimens were stored in freezers that were not always operational; and furthermore, the storage temperature was approximately $-20^{\circ}C$ which is inadequate for storing specimens of this type over long periods of time. The effect of this storage on the PCDD/PCDF levels within these tissues is unknown and cannot be completely defined.

Study limitations arising from the above problems and the extremely high cost of PCDD/PCDF analysis of adipose specimens, have resulted in the staff

consensous that the proposed retrospective study comparing the PCDD/PCDF levels in stored specimens obtained from Vietnam veterans to the levels seen in the general population should not be undertaken.

VA-EPA Study of PCDD/PCDF in Human Adipose Tissue (currently procured specimens).

As a result of the many scientific concerns relative to the validity of the stored specimens, a study has been proposed in which specimens currently being obtained from deceased Vietnam veterans would be identified and analyzed for PCDD/PCDF levels. For comparison, a carefully selected control group would be identified and the PCDD/PCDF levels determined. The main concern with this study would be the extensive period of time between possible exposure to PCDD in Vietnam and the sample procurement. Since completion of military service in Vietnam, the individuals could have experienced exposure to a wide spectrum of PCDD's/PCDF's from a variety of sources, all of which could drastically affect thier body burdren of these compounds at the time of death. The inability to fully define the extent and routes of exposure, coupled with the relatively low number of available specimens, would greatly decrease the decision-making power of this proposed study and move us to recommend against its being done. Additionally, the question of developing an isomeric fingerprint of dioxin and furan congeners in order to attribute the source of the exposure greatly raises the complexity and cost of such a study to the point that any consideration should be on strong scientific grounds.

CEH Assistance

As will be discussed in the next section, CEH is currently developing protocols for several epidemiological and laboratory studies related to PCDD/PCDF body burdens and the possible human health effects these toxicants may have on the human body. Because it is essential that data bases generated by the various studies be compatible and statistically definable, CEH is very interested in a cooperative effort, assisting EPA in their undertaking of any valid study to define human body burdens of PCDD's and PCDF's.

Extensive expertise has developed within CEH in the areas of study design and analytical technology and these resources are available to assist the VA and EPA in preparing study protocols. CEH has a comprehensive program in the analysis of biological specimens for dioxins and furans and can assist EPA in the development and evaluation of methods to be used by participating laboratories. Additionally, the CEH laboratory staff has diversified experience in quality assurance and control techniques; and can assist in designing and establishing QA/QC programs which are critically important in developing total analytical systems that will generate valid applicable data.

CEH Body Burden Measurement Program

The primary purpose of two currrently proposed CEH studies is to establish a national survey of PCDD/PCDF levels in adipose tissue to be used in establishing national and sectional reference value ranges for assessing exposure to and body burden of these toxicants. In the first of these

studies, adipose tissue samples will be obtained from elective surgical cases in predesignated hospitals in various regions of the United States. Stratification of participants will be on sex, age, area of residence, occupation, and socioeconomic status. Cooperative participation of EPA in this study is currently under discussion. The second study will be a cooperative effort between EPA and CEH in which EPA will provide to CEH an adipose tissue specimen for PCDD/PCDF analysis from each of the individuals that are selected for inclusion in the NHATS. As indicated, these two studies have a common purpose; however, by simultaneously undertaking both, with their different schemes for specimen selection and procurement, the available PCDD/PCDF body burden data file should develop more rapidly and be more diversified in its stratification. Data from these two studies will be carefully evaluated and used to establish reference PCDD/PCDF levels for various segments of the U. S. population, and will serve as a comparison cohort for future PCDD/PCDF studies.