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DEPARTMENT OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

Opening Statement

By

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Department of Health and Human Services

and

Chair

Scientific Panel

Interagency Work Group to Study the Possible

Long Term Health Effects of

Phenoxy Herbicides and Contaminants

September 22, 1980

Good morning.

I am John A. Moore, a toxicologist, Deputy Director of the National Toxicology Program and Chair of the Scientific Panel of the Interagency Work Group to Study the Possible Long Term Health Effects of Phenoxy Herbicides and Contaminants. I will be describing several scientific activities that I believe are of relevance to Vietnam veterans.

The activities of the Scientific Panel can be categorized in four broad areas:

1. identification of research activities being conducted or funded by the Federal Government including current status and targeted completion dates;
2. identification of areas in which additional research is required;
3. reviewing proposed research; and
4. review and interpretation of research results for relevance to the concern of Vietnam veterans that they are or may be at increased risk of suffering a variety of health impairments.

Future activities of the Scientific Panel will also include monitoring the progress of these research activities.

In an issue of this type, the preferred course for gathering scientific knowledge is to identify an exposed population and conduct the appropriate medical studies. Attempts to identify a

population from among those ground troops who served in Vietnam have not been successful. This completely frustrates any study whose objective is to define what risk, if any, is associated with Herbicide Orange exposure. Without accurate knowledge as to who was actually exposed, you are likely to misclassify the study population and as a consequence erroneously interpret the study results.

The Air Force Ranch Hand personnel, who applied Herbicide Orange, are the only population whose frequency and duration of exposure are known. The degree of exposure may equal or even exceed that of people involved in the more intensive domestic uses of these types of herbicides. The Interagency Work Group has recommended that studies of the health status of this group be conducted since the detection of adverse health effects would provide an indication as to the type of health effects that may occur in other (ground troop) personnel. I feel obliged to caution that there are definite limitations in the extent to which the results of this will be applicable to the total Vietnam veteran population. Two major limitations are that the small size of the Ranch Hand population restricts the level of confidence that can be placed on a failure to detect an increased incidence of a variety of health effects; second, the detection of a health effect in this study would not permit the establishment of a quantitative health risk for ground troops since the Ranch Hand exposure is estimated to have been much greater.

It remains the opinion of the Scientific Panel that certain health decrements may be present in the veteran population that are a consequence of Vietnam service and are not directly associated with Herbicide Orange exposure. I suspect that any attempt to specifically and accurately identify who might have been exposed to other chemicals (which may include herbicides, insecticides, or drugs) or agents that may be peculiar to the Vietnam environment (such as fungal toxicants) would prove to be a most formidable, if not impossible, task. In view of these circumstances, coupled with the uncertainty of identifying personnel exposed to Herbicide Orange, the Scientific Panel suggests that a prudent approach to determining if Vietnam veterans are suffering health impairment is to design and conduct studies that would indicate if service in Vietnam is the causal factor.

Two possible health effects which are worrying many Vietnam veterans are birth defects and cancer.

Birth Defects

The principal issue is that veterans allege and fear that they are at an increased risk of siring malformed children years after exposure to Herbicide Orange. It is known that exposure of female rats and mice to 2,4,5-T or 2,3,7,8-TCDD (a constituent and contaminant of Herbicide Orange, respectively) can produce malformed offspring, fetal toxicity or fetal death. One cannot predict male effects from results obtained through studies of female exposure. Logic dictates that the ability to sire malformed offspring years after Herbicide Orange exposure could plausibly

occur only if there was permanent genetic damage (mutation) to the spermatogonial cells. Current data on the mutagenicity of the Herbicide Orange components, 2,4-D, 2,4,5-T, and 2,3,7,8-TCDD, are judged to be inadequate. These chemicals are being retested using the best current techniques. The first results are now emerging and more will be forthcoming next year. The Scientific Panel will begin reviewing available data in the next two months.

A direct method of securing relevant toxicology data is through the administration of the constituents of Herbicide Orange to male laboratory animals and examining their sperm, ability to fertilize untreated females, as well as examination of their offspring for viability and malformations. The National Toxicology Program performed such a study in mice and reported its results in August. The study reported that there was no evidence of germ cell toxicity or adverse effects in the development and survival of offspring as a consequence of paternal exposure to simulated mixtures of Herbicide Orange. This report is now being reviewed by the Scientific Panel.

A third approach is to study and evaluate human birth records data. The Scientific Panel evaluated the potential utility of a birth defects registry that has been maintained since 1968 in the metropolitan Atlanta area. The Panel recommended that a case control epidemiological study be conducted using this registry. The Panel felt that such a study would have a good probability of determining if Vietnam veterans are siring children with an increased incidence of specific malformations.

Detailed planning of this study is underway at the Center for Disease Control. A detailed protocol for this study was recently submitted to the Scientific Panel, and will be reviewed September 25. While it will be useful as a means of determining if service in Vietnam resulted in an adverse health consequence, the study is unlikely to be able to indicate that Herbicide Orange was the factor responsible for increased incidence of malformations, should such a phenomenon exist.

Cancer

Veterans are concerned that cancer death, illness, or increased risk is associated with Herbicide Orange exposure.

Previously published studies had reported 2,3,7,8-TCDD (the contaminant in Herbicide Orange) to be a carcinogen in rats. Two additional animal cancer bioassays were recently completed by the National Cancer Institute and National Toxicology Program (NTP). The draft reports were reviewed for the National Toxicology Program by a group of independent scientists in June. This group of scientists concurred in the reports' findings that TCDD was carcinogenic in rats and mice. The recent study in rats confirmed the previously published reports; the mouse study extends the observation that 2,3,7,8-TCDD is a carcinogen to a second animal species.

The Scientific Panel also reviewed several case control epidemiology studies that were conducted by Swedish scientists. The Panel concluded that in spite of the reservations associated

with case control epidemiology studies, the studies show a correlation between exposure to phenoxy acid herbicides and an increased risk of some forms of cancer. They also were of the opinion that independent verification would further validate these studies.

While these studies do establish a cancer risk from TCDD and possible phenoxy acid exposure, the data do not lend themselves to the establishment of a quantitative risk for veterans exposed to Herbicide Orange. To determine if "risk" is resulting in tumor occurrence, the veteran population should be studied directly. A valid scientific criticism of such a study conducted at this time is that the study may be premature and prone to a false negative result given that the time elapsed since exposure in Vietnam is less than the 15-20 years that is typically required for excess cancer incidence to become manifest. However, the perception of cancer risk is a current concern, and in some instances, excess cancer may appear in a population 10 years after exposure. Therefore, such a study should be initiated. The rationale for this recommendation is:

1. A negative finding would allay the current and possibly increasing fear that Herbicide Orange exposure or Vietnam service already is resulting in excess cancer deaths.
2. A positive finding would establish service connection and permit appropriate policy decisions with respect to service connected disability and

right to compensation.

3. A positive finding would identify the types of cancer for which there is increased risk and the medical community could focus attention on specific surveillance for early detection of tumors with a possible attendant increase in successful treatment.
4. An appropriate cohort will have been registered that can and must be resurveyed at appropriate time periods to detect changes in major morbidity or cancer incidence.

Such a study could easily be included as part of the Congressionally mandated Veterans Administration epidemiology study. Since results from this study are not expected for several years, other mechanisms will continue to be explored. The proposed Air Force Ranch Hand Study will study cancer incidence; however, the limitation of study size dictates that a larger study also be planned.

In conclusion, I am not optimistic that scientific studies will provide unequivocal data as to the significance of Herbicide Orange exposure to the health of Vietnam veterans. It is plausible that studies can determine if various health effects are associated with Vietnam service. The principal studies needed to provide such data may require several years to complete.