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5/22/86

Don Barnes

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## SCIENTIFIC FEASIBILITY OF AO GROUND TROOPS STUDY

In order to conduct a study which would address the concerns of Congress, ideally, the following elements should be present:

1. A scientifically reasonable hypothesis which can be tested.
2. Sufficient assurance that confounding factors and the possibility of spurious associations have been taken into account, so that the results will be interpretable in terms of the hypothesis being tested.
3. An identifiable population at risk; i.e., an exposed cohort:
  - a. Of sufficient number
  - b. Conceivably exposed to such an extent (magnitude, frequency and duration) that manifest toxic responses could be logically linked to AO/2,3,7,8-TCDD; i.e., are the exposures likely to be toxicologically significant?
  - c. With sufficient assurance that misclassification will not jeopardize the interpretation of the results
4. An identifiable population not at risk; i.e., an unexposed cohort :  
Of sufficient number

As I understand it, the proposed study measures up as follows:

### 1. Hypothesis

The proposed study is investigating an association between exposure to AO and a long list of possible deleterious health effects. While some areas have been identified for special attention (e.g., soft tissue sarcomas and immunological endpoints), the protocol calls for the examination of many additional endpoints as well.

In sum, the hypothesis is ill-defined.

### 2. Confounding factors and spurious associations

Ground troops in Vietnam were exposed to a variety of chemical substances. Relatively little work appears to have been done on confounding factors; e.g., insecticides used in different parts of the Vietnam and differences in drug/alcohol use patterns in different parts of the country. It appears that these potential confounders will be assumed to be equal for all individuals within the study. The basis for such an assumption is not clear.

The large number of potential endpoints will result in some positive finding(s), simply as a matter of chance, if nothing else. If the positive findings happen to be in endpoints already identified as being of concern, the study will add strength to the hypothesis. If an association is very strong, the hypothesis could become very compelling. If associations are found in areas not

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previously suspected of being linked to AO, a sharper hypothesis could be framed; however, it is not likely that it could be examined in a subsequent, more powerful study.

Alternatively, unexpected associations could be argued away on the basis of statistical happenstance and/or biological implausibility, either of which -- while scientifically defensible -- could be politically unpopular.

Lack of a correlation will not definitively settle the issue; you can't prove a negative.

In sum, positive associations between AO exposure opportunities and suspect endpoints would be very helpful findings. However, any other findings will raise new questions and/or fail to resolve old questions.

### 3. Identification of a population at risk

#### a. Of sufficient numbers

The question of sufficient numbers resides in the netherworld of statistics and willingness to extend the time and geographic "windows". It is not clear from the results of the pilot study that sufficient numbers can be easily obtained or that it would be appropriate to include those in the outer portions of the "windows" (e.g., 5 km away).

In sum, it looks as if it will be difficult to obtain a population of plausibly exposed individuals of sufficient size that the study will have high statistical power.

#### b. With probable biologically significant exposures

The exposures postulated for exposure to 2,4-D, 2,4,5-T, and 2,3,7,8-TCDD through the "re-entry" route (non-"wet" encounters) -- which is the type that will capture the greatest number of participants in the study -- are generally small; i.e., less than 1 pg/kg-d for 2,3,7,8-TCDD. Since this is the level of daily exposure for a lifetime which is calculated to lead to the background levels of 2,3,7,8-TCDD seen in the human population (5 - 10 ppt) (Schlatter, 1985), it is unlikely that the bulk of the ground troops would have encountered biologically significant levels of 2,3,7,8-TCDD from their encounter with AO. The likelihood of toxicologically significant exposures to the herbicides is similarly small.

In sum, it is probable that the 2,3,7,8-TCDD exposures experienced by the "exposed" and "unexposed" ground troops in Vietnam are comparable to the exposures they have shared since the conflict, which are exposures of arguable biological relevance. In any event, a distinction between the two groups would be difficult to make.

#### c. With an assurance against misclassification

Apparently, the records will not permit identification of

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individuals with sufficient clarity that "high opportunity for exposure" individuals can be distinguished unequivocally from "low opportunity for exposure" individuals.

Only if there were some independent validation of the exposure opportunity approach would there be scientific support for its use. In the absence of a records-based verification, at present, the only candidate for an verification procedure is analysis of 2,3,7,8-TCDD in human tissue. This approach is currently under development. Even its use has some limitations; e.g., questionable half life of 2,3,7,8-TCDD in the body, alternative sources to exposure to 2,3,7,8-TCDD (additional sources are coming to light yearly; e.g., the pulp and paper industry, municipal waste combustion, and automobile exhaust), and absence of an agreed upon analytical protocol.

In sum, misclassification is likely to be a problem, even if the procedures for analyzing tissues levels of 2,3,7,8-TCDD are developed.

#### 4. Identification of non-exposed population

Our discussions here were a bit unclear. It seems that there was a considerable amount of spraying which took place around base camps that was inadequately documented. Therefore, the records cannot give a clear indication of exposed vs. unexposed. However, it is plausible that certain camps were not likely to have been sprayed, based simply on geographical grounds; e.g., Cam Rahn Bay.

In sum, it is not clear that a sufficient number of documented "low exposure probability" individuals can be easily found who are also comparable to those "high exposure probability" individuals in such important factors as geographic environment and combat stress.

In sum, it appears at this point that there is little likelihood of a ground troops study's successfully addressing the concerns raised by Congress. While there are avenues which could be and are being pursued, ~~there~~ is not likely that they will bear fruit in the near term. To the degree that the approaches under development do yield promising results, however, a decision to re-consider the feasibility of a ground troops study would be warranted.