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Staff Memorandum

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Report on the Progress of the Centers for Disease Control's Studies of the Health of Vietnam Veterans

Report on Progress in the Centers for Disease Control's Studies of the Health of Vietnam Veterans

OTA held a meeting of its Agent Orange Advisory Panel on February 28 and March 1, 1985. February 28 was devoted to discussing CDC's Agent Orange, Vietnam Experience, and Selected Cancers studies. Peter Layde, Project Officer, and Dan McGee, both from CDC, attended the meeting at OTA's invitation. They presented information about the studies, and answered questions from the Advisory Panel, contributing to the efficient use of time at the meeting. [On March 1, the protocol for the Vietnam Experience Twin Study (VETS II) was considered. Our findings about VETS II are contained in the OTA Director's letters of March 20, 1985 to the Chairman and Ranking Minority Member of the House Committee on Veterans' Affairs.]

CDC has made considerable progress in various aspects of all three studies. Among their accomplishments, they have established that more than 90 percent of contacted veterans are willing to answer the questionnaire and participate in the medical examination for the Vietnam Experience Study. In addition, contracts have been placed for administration of the questionnaire and the examinations. In general, CDC is on schedule with a large array of tasks and is to be commended on their efficient management of the studies. Rather than catalogue CDC's accomplishments, however, OTA will use this report to draw attention to

two major areas of concern. The first is the timetable for the Selected Cancers Study, which is scheduled to be completed in 1989. While that scheduling has not, in fact, changed since the protocol was written, we are concerned that those results may not be as timely as they might be. The second issue is the method now proposed to estimate Agent Orange exposure in the Agent Orange study. That has changed significantly since the original protocol, now representing a much less precise measure.

Timetable for the Selected Cancers Study

The Selected Cancers Study is a case-control study of soft tissue sarcoma, lymphoma, primary liver cancer, and nasal and nasopharyngeal cancers. Except for lymphoma, these are all relatively rare tumors. Six cancer registries that maintain records of cancers diagnosed in different areas of the country are currently are under contract to CDC. They are to provide names of men of the age of Vietnam veterans who have or will be diagnosed as having those cancers between December 1, 1984 and November 30, 1988. CDC will then contact those men to learn about service in Vietnam and other factors that might be related to their cancers. Results of the analysis are expected in 1989.

OTA is concerned that a result in 1989 will have considerably less value than one that could be reported sooner. We believe that CDC could considerably shorten the time needed for the study by recruiting additional cancer registries to provide cases. We understand that this may not be possible, but recommend that it be given serious consideration. CDC already finds it necessary to add one registry

because of the large number of AIDS-associated Kaposi's sarcomas (a type of soft tissue sarcoma) in the San Francisco Bay area registry. Inclusion of those tumors, not related to Vietnam service, might bias the results of the study. Solicitation of other registries could go on at the same time to enlarge the sample.

Agent Orange Exposure Assessment

Major changes in the method of determing possible exposure to Agent Orange have been forced on CDC. The best way to describe those changes is to recall the salient features of the method described in the CDC protocol that was approved by OTA. Briefly, the Army's Environmental Support Group (ESG) was expected to track the movements of more than 100 Army companies in Vietnam during the two years of peak Agent Orange use. The locations of the companies then would be compared to locations to known uses of Agent Orange, and the companies divided into three groups, those most and least exposed and an intermediate group. The companies chosen for the study would be those with the highest and lowest cumulative exposures to Agent Orange.

Two assumptions were built into this approach: (1) that many or most soldiers served their entire tours of duty in Vietnam with single companies, and (2) that ESG would be able to specify the locations of companies. In other words, Soldier S served with Company C and Soldier T with Company D, and once we knew the locations of Companies C and D, we would be able to classify the soldiers' exposures. According to a report prepared by CDC, neither of those assuptions is justified.

The CDC report includes the results of a study of combat company records which found that only 16 percent of 3838 men spent as long as 9 months in a particular company. That finding means that many men moved between companies during their year in Vietnam, making it impossible to divide veterans into high or low exposure on the basis of company cumulative exposures. For instance, a soldier who spent 6 months in a highly exposed unit could have been tranfered to a less exposed company. The only way to describe his exposure is by tracking his movements: he has neither the high exposure associated with the first company nor the low exposure of the second. Because individual exposure cannot be equated with company exposure, it is now impossible to pick high and low exposed companies and drop out those in between. That means exposures will fall across a continuum from low to intermediate to high rather than a dichotomous grouping of low versus high. It also means that the amount of work necessary to classify a veteran is increased, but that is not an insurmountable barrier.

Of far more importance is CDC's conclusion that there is too little information to locate companies and that decisions about exposure will have to be based on battalion locations. The number of men in a battalion is roughly five times that in a company, and battalions were spread out over much larger areas. CDC presents data showing multiple reported locations for a single battalion on a single day. The different locations represent the positions of individual companies or other subunits of the battalion, and CDC points out that the records are not sufficient to decide how many of the battalion's 1,000 men might have been present at any of the reported locations. Therefore, they

calculate a "centroid," which is an "average" location of the battalion. Unfortunately, significant distances, approaching 20 kilometers (km), can separate the reported locations and the centroid.

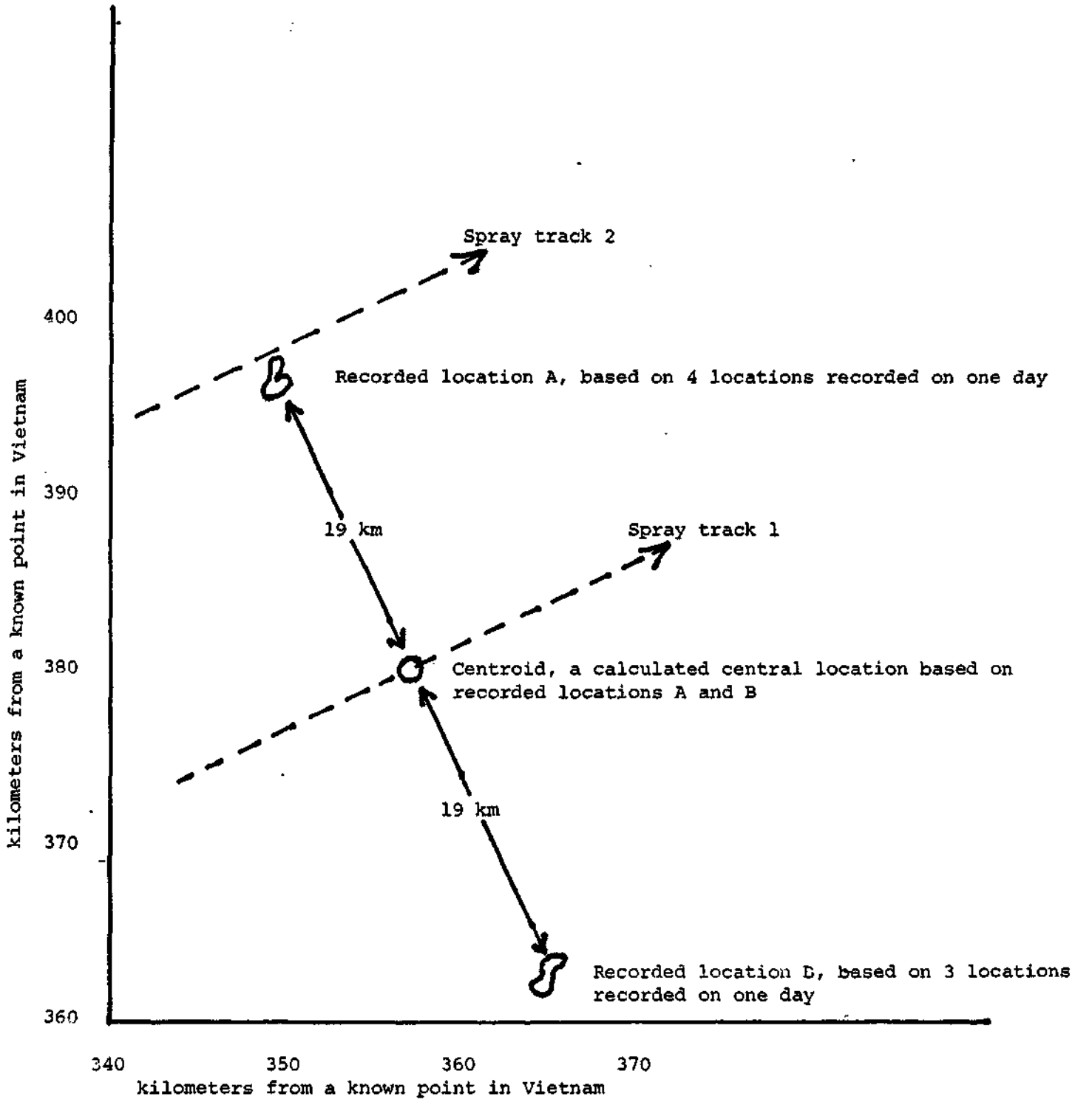
In the eyes of several OTA advisory panel members, inability to locate companies significantly changes the study from the one that was approved, seriously and perhaps fatally compromising the Agent Orange study. As an example, consider the locations and centroid on the diagram (the data are taken from the CDC report). Assume that a Ranch Hand mission passed directly over the centroid as shown by track 1. This would result in the battalion being classified as exposed. However, the members of the battalion were spread over a large area, and those at either of the two Known locations were about 19 km away from the spray mission. Moreover, since the centroid is a calculated position, there may have been no one there at all.

Another possibility is that a spray mission was flown as shown by track 2. In that case, the track would be about 19 Km away from the centroid, and the battalion would be classified as unexposed. Note, however, that any men at the reported location A could have been exposed.

The two examples show the possibilities of misclassification. In the track 1 example, men who were not exposed would be called exposed; in the other, exposed men would be called unexposed.

These are serious problems, but OTA comes to no conclusion about their impact on the study at this time. We expect to hold another meeting in about six months to hear from CDC about any improvements that can be made. If there are no improvements, OTA may decide that the

An Example of Recorded Positions of a Battalion's Subunits and the Calculated "Centroid" of those Locations.



problems of deciding on exposure are so overwhelming that it is impossible to study the possible effects of Agent Orange. OTA made one request and one suggestion to CDC:

1. If CDC continues with an exposure assessment similar to the one described, OTA would like to have an estimate of the chance of misclassification into high or low exposure categories.

2. Every effort should be made to find an external validator of exposure. We realize that this is a difficult task, but an external validator would be of great value.

OTA Followup on the Exposure Question

Following the Advisory Panel meeting, OTA staff contacted Mr. Richard Christian of the ESG and asked if he concurred in the CDC evaluation that companies cannot be located. He said he did not. OTA staff visited him and his colleagues and were convinced that locating companies was still a viable possibility. Following that visit, OTA staff urged that CDC and ESG hold a meeting to discuss the company question. According to both ESG and CDC, the meeting was a success, and efforts are now being made to apply an ESG-developed method for locating companies.

This experience underlines the fact that ESG has information available from no other source and that CDC has to make every effort to understand what ESG can and cannot provide. Clearly, the two organizations must cooperate closely. OTA has not investigated the relationship between ESG and CDC to the point that we know what should be done to improve and maintain good communications between them, but such communication is imperative.