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Report/Article Title Cover Letter, List of Addresses, and Memorandum sent to Congressional Committees after a meeting of the Office of Technology Assessment Advisory Panel, February 28, 1985.

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Description NOTBS Memorandum is a Report on the Progress of the Centers For Disease Control's Studies of the Health of Vietnam Veterans.

Congress of the United fttate*
OFFICE OF TECHNOLOGY ASSESSMENT
WASHINGTON, D.C. 205 10

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JOHN H. GIBBONS

I am enclosing a copy of the cover letter, a list of addressees, and the memorandum that was sent to the appropriate Congressional Committees after a meeting of the OTA advisory panel on February 28, 1985.

Michael Gough
April 11, 1985

William

Congress of the United States

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JOHN H. GIBBONS

OTA's Agent Orange Advisory Panel met on February 28, 1985, to discuss progress in the Centers for Disease **Control's** (CDC) studies of the health of Vietnam veterans. As discussed in the enclosed memorandum, CDC is making good progress in the conduct of the studies, but OTA draws attention to two areas that deserve some additional attention:

(1.) A study done in Massachusetts reports a significant excess of deaths from soft tissue sarcomas among Vietnam veterans. Those cancers are the ones most frequently associated with exposure to dioxin, although studies done in different populations and parts of the world have produced conflicting results. CDC's current plans are to publish the results of a study of soft tissue sarcomas among veterans in 1990. Because of the interest in those cancers, OTA suggests that CDC try to increase the number of cancer registries participating in the soft tissue sarcoma study so that the study can be completed sooner.

(2.) The major part of the advisory panel meeting and of the enclosed memo focused on the subject of estimating exposure to Agent Orange. The basic idea behind estimating exposure is to determine what military units a veteran served with while in Vietnam, locate the positions (and times) where the units were stationed in Vietnam, and compare those locations to known uses of Agent Orange. At the time OTA approved the CDC study plan, it was expected that it would be possible to locate Army **companies**. According to a report presented to OTA by CDC, that had proved impossible. Instead, it was possible only to locate battalions, which were spread out over areas of scores of kilometers in Vietnam. As is detailed in our report, OTA questions the usefulness of exposures estimated with that kind of data. We expect to **hold** another meeting in about six months to see if improvements can be made.

Following the advisory panel meeting, OTA staff visited the Army records experts who have information about unit locations in Vietnam and were told that the Army thought that it is possible to provide data at the company level. OTA urged that a meeting take place between the Army and CDC to discuss that possibility. After the meeting was held, OTA received a letter from CDC stating that efforts are now being made to locate companies. CDC expects to know by early summer if those efforts are successful.

Sincerely,

John H. Gibbons

Enclosure

The Honorable Patrick J. Leahy
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Senator Leahy

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Mr. Chairman

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Congressman Broyhill

Staff Memorandum

Prepared by the

Office of Special Projects and
Health Program

April 1985

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

This OTA Staff Memorandum has
neither been reviewed nor approved
by the Technology Assessment Board.

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 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 determining 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 assumptions 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.

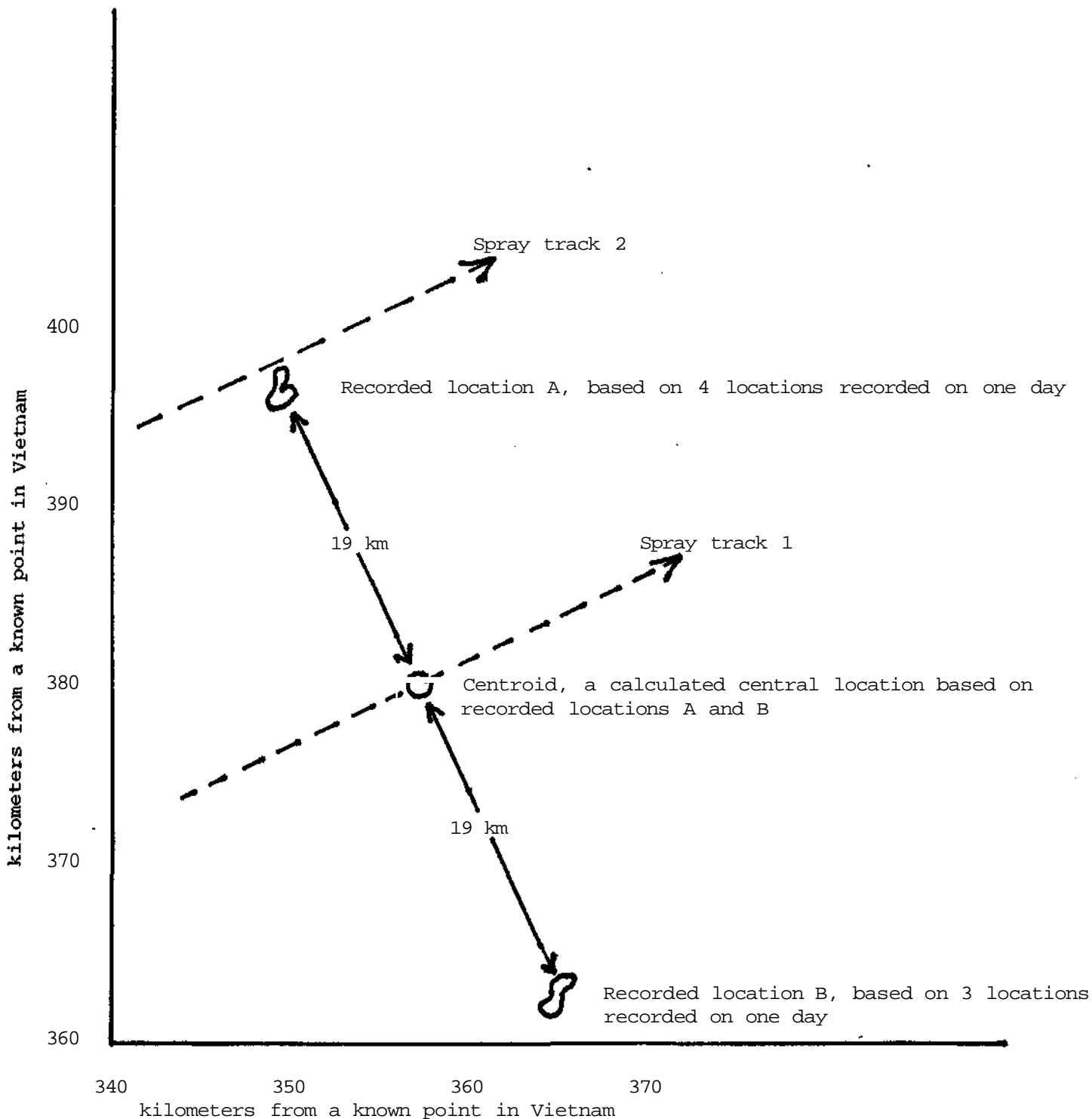
In the eyes of several OTA advisory panel members, inability to locate companies significantly changes the study from the one that was approved, seriously and perhaps fatally compromising the Agent Orange study. As an example, consider the locations and centroid on the diagram (the data are taken from 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.