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June 11, 1984

Dear Al,

This is the paper that I mentioned to you. As we discussed on the phone, I am a little uncomfortable attempting to scuttle the CDC study so long as OTA is mandated a role in it, but I don't think that we will gain enough from the study to justify doing it. I also have some pride of authorship about the paper. If you or anyone else finds it convincing or useful, I'd like someday to get credit for it, but that's not uppermost on my mind.

Please feel free to duplicate the paper as you want. If you have any suggestions for additions or corrections to it, please call me.

Sincerely,

Mike

The CDC Epidemiologic Study of Vietnam Veterans
Will Cost Much, Buy Little,
and Cancelling It Does Not Leave Us Without Information

In December 1979, Congress passed Public Law 96-151 directing the Veterans Administration (VA) to study possible long-term health effects in Vietnam veterans exposed to dioxin-containing herbicides. Now, four and a half years later, the responsibility for the study has been transferred to the Centers for Disease Control (CDC), and work has begun on a study that is expected to produce its first results in about three years and to cost \$70,000,000 and perhaps much more. The CDC study is to examine three possibilities: (1) that exposure to dioxin present in Agent Orange is associated with adverse health effects among Vietnam veterans, (2) that service in Vietnam is associated with adverse health effects, and (3) that an elevated risk of developing certain cancers is associated with service in Vietnam and/or exposure to Agent Orange.

The first possibility will be examined by comparing the health status of three cohorts (groups): combat soldiers likely to have been exposed to Agent Orange, combat soldiers not likely to have been exposed, and soldiers of any sort who were not likely to have been exposed. The second possibility will be examined by comparing the health of a cohort of Vietnam veterans with the health of veterans of service in other areas. Each cohort will consist of 6,000 men; all cohort members will answer a detailed questionnaire, and 2,000 of each cohort will undergo a detailed medical and psychological examination. By any measure, the CDC study will be among the largest cohort studies ever undertaken. The third possibility will be examined by a case-control study. "Cases," men who have the types of tumors being studied, will be identified from cancer registries. The

frequency of Vietnam service among that group will be compared to the frequency among a group of "controls," men who live in the same geographical areas but who do not have the cancers. Military records will be used to estimate veterans' exposure to Agent Orange.

Comparison of the levels of dioxin exposure in Vietnam to levels of exposure in other situations convinces many (certainly most, and perhaps almost all) experts familiar with dioxin's effects that the CDC study will find no health detriment associated with Agent Orange. Some veterans, however, claim that the wartime nature of their exposures in Vietnam accentuated the effects of dioxin, and that possibility is the strongest argument for doing the CDC study. Nevertheless, veterans have not developed chloracne, a disease associated with relatively high dioxin exposure. There were no cases of chloracne among Ranch Handers, the veterans who were exposed to the highest levels of dioxin, and only one possible case among the veterans who have enrolled in the VA's Agent Orange registry. Therefore, the conditions in Vietnam were not sufficient to cause the one visible manifestation of dioxin exposure.

Veterans correctly point out that there is a possibility that exposures to dioxin at levels too low to cause chloracne might cause cancer or other effects. There is no denying that argument on scientific grounds; it could be. However, there is now no convincing evidence for health effects other than chloracne and some liver and biochemical abnormalities that have been seen in exposed chemical workers. Those symptoms did not appear in chemical workers who were employed in non-contaminated areas of plants. It is reasonable to think that those workers were exposed to levels of dioxin too low to cause chloracne, but still much greater than

levels most people are exposed to. Neither populations of workers who developed chloracne nor others probably exposed to lesser levels of dioxin have suffered from unusually high rates of cancer or reproductive health effects. These observations argue against manifestation of any health effects other than chloracne and the symptoms seen in chemical workers and against manifestation of any other diseases in the absence of chloracne. (The last statement is not made in ignorance of the higher than expected rate of stomach cancer in one exposed occupational population or the reported excess of soft tissue sarcomas in another exposed population. However, those specific suggestions of associations are better investigated in a case-control study such as described below.)

The possible results of the Vietnam service study are more uncertain; there may be significant effects on health. Nevertheless, the power of the study to detect excess health deterrents is sufficiently limited that it will provide little information for making decisions about compensating individual veterans who claim adverse health effects.

The cohort studies have a good chance of detecting any 2-fold increases in diseases that occur with a normal frequency of 0.5 to 2.0 percent. In males of the age of Vietnam veterans, the only diseases that occur that frequently are common allergies and mild respiratory infections. The likelihood of detecting rarer diseases is smaller.

Unfortunately, the absence of finding any effects cannot be presented as a finding that there is no effect. Instead, the study will only be able to say that Agent Orange-exposed veterans or Vietnam veterans are not experiencing particular diseases at rates two or more times those seen in other veterans.

The case-control study of some cancers, according to CDC, has a 95 percent chance of detecting a two-fold increase in soft-tissue sarcomas if the excess is present. According to at least one review of the CDC study plan, the study will be unable to detect an increase smaller than four or five-fold. In any case, the study will be unable to detect excesses smaller than two fold; neither will it be able to rule them out even if there is no excess. Nevertheless, the case-control study has the virtue of testing a hypothesis--that dioxin causes specific cancers. Although other (National Cancer Institute) studies are examining the same question, they are concentrated in non-industrial areas of the country and have less chance of examining the possible effects of industrial exposures to dioxin. Therefore, the case-control study might go ahead as an effort to settle outstanding questions about soft tissue sarcomas and lymphomas.

As the recently negotiated settlement of the veterans' case against the chemical companies showed, science is not necessary to make policy judgments (or tradeoffs). Although some spokesmen for the veterans claim that the companies settled because the companies knew that they were at fault, other interpretations are possible. Had the nine cases representing the veterans' class action gone to trial, the veterans would probably have won some, the companies some. The losers in both cases would have appealed. The cases could have wound on across the years and been resolved who knows when. By settling, the companies eliminated uncertainties about future litigation and liabilities. Each company's stock rose on Wall Street the day the suit was settled. Furthermore, the settlement stipulates that no causal link was shown between herbicides and the veterans' illnesses.

A 1983 court case in Nova Scotia did consider what is known about dioxin's health effects in a dispute between timber companies and citizens of nearby areas. The judge who heard the case decided for the companies, saying that the citizens had not shown that spraying with dioxin-containing herbicides would result in a risk to human health.

Either ignoring scientific information or making use of what is available, it is possible to make policy about dioxins at the present time. Given that the CDC study is likely to find no adverse health effects but be unable to show that some small elevated risk does not exist, it will not materially assist policymaking or making compensation decisions.

The possibility that there might be "something really there," that there are now-undetected disastrous health effects among veterans, makes it difficult to consider cancelling the CDC study. In fact, there is little risk of missing something that is really there. The CDC study of birth defects (results expected in mid-summer) will provide much more information about possible birth defects than will the cohort studies. The Air Force Ranch Hand study is underway and will continue for 20 years with periodic reports on the morbidity and mortality of those men. If excess adverse health effects appear in the Ranch Handers, veterans of the ground forces in Vietnam could be examined for that particular condition or the appearance of the disease in the Ranch Handers could be taken as presumptive evidence that other veterans are suffering the same diseases.