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Author Gough, Michael

Corporate Author

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CHAPTER 9

"THE IMPORTANCE OF AGENT ORANGE AND DIOXIN WAS ACKNOWLEDGED WHEN THE HIGHEST LEVELS OF GOVERNMENT BECAME INVOLVED."

THE POLITICAL ASSESSMENT: A CONGRESSIONAL VIEW

MICHAEL GOUGH

In December, 1979, Congress passed and President Carter signed Public Law 96-151, which instructed the Veterans Administration to carry out a study of possible long-term health effects resulting from exposure to dioxin-containing herbicides in Vietnam.

This was not the first time that Congress had considered Agent Orange. Almost a decade earlier, in 1970, Senator Philip Hart of Michigan held hearings about the possibility that spraying with Agent Orange was causing birth defects in Vietnam and that the use of the same herbicides could be harmful for the population of the United States. In response to those hearings, the Department of Health reduced the use of 2,4,5-T in the United States and the Department of Defense stopped Agent Orange spray missions in Vietnam.

The law that was passed in 1979 mandating the Agent Orange study resulted from veterans testifying before Congress that Agent Orange had caused cancer, birth defects, and other health effects. It directed the Veterans Administration to study ground troops who had served in Vietnam to see if any long-term health effects in veterans or their families could be related to the use of Agent Orange. To prod the Veterans Administration along, Congress said that the protocol for the study had to be designed within 180 days or the Congress had to be told the reason why.

The OTA (Office of Technology Assessment), which is a technical support office of Congress, was directed by law to review and approve the plans for the Veterans Administration study and to monitor the conduct of the resulting study. The bulk of my presentation is about OTA's role, but before going into that, I will discuss other major events in the Agent Orange issue.

Some results are now available from the Ranch Hand study, the mortality and morbidity study of the Air Force personnel who flew the spray missions in Vietnam, which was well underway in 1979. The Air Force had responded early to Congressional inquiries and realized that they had an occupational health problem. They moved ahead on their own without the intense prodding Congress put on the Veterans Administration for the ground troop study. George Lathrop has dismissed those studies.

Also in December, 1979, President Carter established the Agent Orange Working Group (AOWG), composed of Executive Branch agencies with programs that touched on possible effects on health of dioxin, Agent Orange, and herbicides. In February, 1980, the Office of Technology Assessment was invited to sit with the Agent Orange Working Group as an observer, and it became an active participant in this group. In August, 1981, President Reagan placed the Agent Orange Working Group into the Cabinet Council on Human Resources, elevating and enlarging the scope of the work group.

The Agent Orange Working Group has had profound effects on Executive Branch efforts to try to better understand dioxin and Agent Orange. Among the several studies coordinated by the Agent Orange Working Group (ten major epidemiological studies scheduled for completion by 1990 and five ongoing health surveillance projects), one is complete. It is the

Birth Defects Study carried out by the Center for Disease Control. This study has two conclusions: the first conclusion was that there is no association between service in Vietnam and birth defects. The second conclusion was that there may be an association between opportunities for exposure to Agent Orange and a handful of birth defects. As soon as the results of that study were released, at least one bill was written in the Senate which was to provide compensation to all veterans who had fathered children with spina bifida, a collection of tumors, and cleft lip with or without cleft palate.

That legislation never left the Senator's office. The people who had done the study at the Center for Disease Control, i.e., Dave Ericson and his colleagues, came to Congress. They talked to congressional staff in great detail about the structure of the study, its strengths and limits, and how to draw conclusions from its results. They also went to the American Legion, the Disabled American Veterans, the Vietnam Veterans of American, and other veterans organizations, where they explained the study and convinced those veterans that the connections that had been shown, although theoretically valid, would not make a great deal of sense biologically. This was a great achievement for solid scientific exposition and convincing people not to be afraid and consequently do something foolish.

Some scientists still argue about the meaning of those possible connections between exposure to Agent Orange and birth defects. The Birth Defects Study, like many of the other Agent Orange studies, was done for political reasons. Politically, it has been examined and tried. The Congress looked at the conclusions and decided no harm had been associated with Agent Orange. So the CDC Birth Defects Study, from the point of view of politics, is over. The Congress will not reopen it.

It is interesting to note in this context that in the Agent Orange lawsuit which was settled in the District Court of New York in May, 1985, Judge Weinstein also considered the CDC Birth Defects Study. He reached the same conclusion as Congress, deciding that the study results were not sufficient to sustain any association between Agent Orange and birth defects. Thus, in the judicial system also, the CDC Birth Defects Study has been weighed and found not to be convincing in demonstrating any association between Agent Orange exposure and birth defects.

These are events which are very important. It should be kept in mind that here we are not dealing with a purely scientific issue but with very sensitive and complicated political and social issues. The scientific conclusions, therefore, while they are very important to us to understand whether or not dioxin and Agent Orange cause disease, still are less important to society than the decisions that are made in the courtrooms and in the Congressional Hearing Rooms.

To come back to OTA, Congress wrote OTA into the Agent Orange study because of disagreement between the Senate and House Committees on Veterans' Affairs. Sensitive to veterans' complaints that the Veterans Administration was indifferent to their claims of harm from Agent Orange, the Senate wanted the study to be carried out by some other agency. The House Committee, on the other hand, had more faith in the Veterans Administration and acted to preserve Veterans Administration's responsibilities for research on veterans' health. The two committees compromised, giving responsibility for the study to the Veterans Administration and mandating that the Office of Technology Assessment make periodic reports to the committee, keeping Congress informed about progress or lack of it.

This was an entirely new role for the Office of Technology Assessment, and its constitutionality has been questioned. The question arose a month after Congress directed the Veterans Administration to do the Agent Orange study. At that time, Congress passed another law directing the National Institute for Occupational Safety and Health to do a study on dioxin-exposed workers, and, again, Congress required that the Office of Technology Assessment review and approve the protocol and monitor the conduct of the study.

President Carter vetoed that law on the basis that giving a congressional branch agency--the Office of Technology Assessment--veto authority over the execution of an Executive Branch study was a violation of separation of powers doctrine. Executive Branch lawyers concluded after examining the case that the bill was unconstitutional. Legislative Branch lawyers, however, concluded that it was constitutional. Neither branch has taken the case to court, and the issue is unresolved. The veto of the NIOSH bill was successful.

President Carter's veto message also instructed the Administrator of the Veterans Administration to ignore the provisions of Public Law 96-151 which directed the Veterans Administration to submit the study plan to the Office of Technology Assessment for review. However, Senator Alan Cranston, at that time Chairman of the Senate Committee on Veterans' Affairs, wrote the Administrator that ignoring the provision would not be a wise course. He pointed out that Congress must provide funds for the Veterans Administration study and that funding depended on the Office of Technology Assessment reviewing and approving the study plan. The Office of Technology Assessment was part of the process, and it has played an active role in Agent Orange issues ever since.

OTA assembled an Advisory Board to participate in its Agent Orange activities. The panel includes academics--epidemiologists and statisticians, a toxicologist, a neurologist, and a gynecologist. Then there are members who represent stakeholders. There are three representatives from chemical companies that made the Agent Orange components: Monsanto, Dow Chemical, and American Cyanamid. They are neatly balanced by representatives of the American Legion, the Disabled American Veterans, and the Vietnam Veterans of America.

Despite the congressional requirement that a protocol be written in 180 days, the Veterans Administration did not produce one within that time. The Veterans Administration was sued by veterans' groups because of some of its procedures. There was a hearing before the General Accounting Office about the methods used by the Veterans Administration to contract for the protocol design. All of these events contributed to the protocol's being late.

When the Office of Technology Assessment received the first draft of the protocol, we rejected it as inadequate. The basic plan of the protocol was to compare morbidity and mortality rates between two groups of veterans, one which had been exposed to Agent Orange and one which had not been.

In response to OTA's and others' criticisms, the protocol was revised. The revision process just dragged along. It was not until September, 1982, two and a half years after Congress passed the law, that OTA approved the protocol. By that time the Agent Orange Working Group Science Panel had become convinced that it was really impossible to separate exposed from not-exposed veterans, and they were urging that a study be done to compare the health of veterans who had gone to Vietnam with the health of veterans who have not gone to Vietnam. A study of that type would at least provide a

clue as to whether or not Vietnam veterans in general were suffering from ill effects as a result of that experience. The recommendation placed pressure on the Veterans Administration to do a "Vietnam Experience Study" even though the Administration was planning an Agent Orange study.

Rather than making a decision between the two studies on its own, the Veterans Administration asked for another review of their protocol from the National Academy of Sciences. In September, 1982, all the delay came to a head because Congress had exhausted its patience. One hundred and one representatives from the House of Representatives wrote a letter to the Veterans Administration requesting that the study be transferred from the Veterans Administration to some other agency. Dr. Vernon Houk of the Centers for Disease Control, in testifying before the House Veterans' Affairs Committee, said that the Centers for Disease Control was well placed to do the study. The Senate Veterans' Affairs Committee reaffirmed its previously held conviction that the responsibility for the study should be transferred somewhere else. The result was that the execution of the study was taken from the Veterans Administration and given to the Centers for Disease Control. The Centers for Disease Control finally resolved the controversy about whether to do an Agent Orange Study or a Vietnam Experience Study: they are doing both.

The CDC studies are the largest, probably the most complicated, and the most expensive epidemiology studies ever conceived. They will cost at least \$70 million, involve interviews of 30,000 veterans, and 10,000 physical examinations to be carried out at the Lovelace Clinic.

The Vietnam Experience Study is relatively straightforward. Looking at the records easily establishes whether or not a veteran went to Vietnam. The two cohorts can thus

be easily assembled, with the men who went to Vietnam on one side and those who did not on the other; then their health can be examined. The Vietnam Experience Study is underway and on schedule. The same cannot be said about the Agent Orange Study, because it is much harder to say whether or not a veteran was exposed to Agent Orange. In January, 1985, the Centers for Disease Control sent the Office of Technology Assessment a summary of their efforts to resolve the exposure problem. At that time the Centers for Disease Control were able to identify the locations of battalions on the ground in Vietnam.

A battalion is about 1,000 men, four maneuver companies and a headquarters company. The battalion that the Centers for Disease Control provided as an example was spread out along a line of 40 kilometers. It was not possible to know where the 1,000 men actually were. Were 990 at the middle of the line or were they at one end? Were they spread out evenly along the entire line? No one knows. One way to decide that a battalion was exposed is to declare that any Agent Orange spray mission within a fixed distance caused exposure. In practice, AOWG and CDC have accepted that a spray mission at a distance of two kilometers might result in exposure.

Now consider an airplane spraying Agent Orange somewhere within two kilometers of the battalion spread out on the 40 kilometer line. It is very hard to say who of the battalion was exposed and who was not. Even assuming that exposure could be ascertained, it is impossible to know how much exposure took place.

OTA was very critical of the plans to decide a battalion was exposed on the basis of such data. This criticism was expressed in periodic reports sent to the congressional committees.

Right now, I think a majority of the OTA Advisory Board feels that the study on Agent Orange should not go on because of difficulties in deciding who was exposed and who was not. The panel has not voted on this issue, and I could be wrong in my assessment, but I don't think so. If, after seeing more details about exposure, OTA decides the study is impossible, Congress could decide not to do the study. That would involve an act of courage on the part of the Congress because it has made a commitment that this study would be done. The Veterans' Affairs Committees of the Senate and of the House may face the dilemma, having promised the veterans to do the study, that they have changed their mind. I used to think that, no matter what the technical problems, the study would be done. I am no longer so certain.

Congress has considered, over and over again, providing compensation to veterans who claim ill effects from Agent Orange exposure. At one time there was a list of over 20 diseases being considered as compensable. Congress finally passed a law which provides compensation for chloracne and porphyria cutanea tarda (PCT), if they occurred within one year after leaving Vietnam. Although there are very few cases of either disease, the law was not a hollow gesture on the part of the Congress. They wanted to do something to compensate veterans who had been harmed, but, at the same time, they wanted to limit compensation to diseases that might be connected with Agent Orange.

Subsequently, Congress directed the Veterans Administration to set up a special committee to review claims about diseases resulting from Agent Orange exposure. That committee will function only until the studies of the Centers for Disease Control are complete, because at that moment we expect to have the answer to our questions.

Summing up, we can say that Congress is working out the Agent Orange controversy. In 1979, Congress refused to make a decision about whether or not Agent Orange had caused health effects. Instead, Congress directed the Executive Branch to gather information for making a decision. By now, some results have come in. The Air Force's studies on Ranch Hand personnel provide no convincing evidence that Agent Orange has affected human health. The Birth Defects Study, performed by the Centers for Disease Control, also failed to provide convincing evidence of a connection between Agent Orange and human effects. Congress has directed the Veterans Administration to compensate two conditions which have been related to dioxin exposure should they appear in Vietnam veterans. The judge in the Agent Orange class action stated that the veterans had failed to prove their case in court that Agent Orange was the cause of their illnesses. These points are convincing many people that, regardless of all the fears about Agent Orange and the toxicity which might reside in the dioxin molecule, exposure to Agent Orange, if it occurred, has not harmed the veterans.

However, that is not yet the end of the Agent Orange controversy. Intellectually and emotionally the veterans might accept that they have not been able to prove that their diseases were caused by Agent Orange, but they can always contend that no one could prove the contrary.

Probably, Agent Orange will pass away as a political issue. Some veterans will continue to contend they were harmed, but the decisions already made in Congress and in the courtroom will convince many people that no detectable harm was done. As more study results come in, if the results continue to show no health effects, they will reinforce the conclusions already made.