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June 2014

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Item ID Number	04939 ☐ **Not Scanned**
Author	
Corporate Author	
Report/Article Title	Typescript: Brief History of the Veterans Administration Agent Orange Study and OTA's Involvement
Journal/Book Title	
Year	1981
Month/Day	July 9
Color	☐
Number of Images	2
Descripton Notes	

BRIEF HISTORY OF THE VETERANS ADMINISTRATION AGENT ORANGE STUDY AND OTA'S INVOLVEMENT

"Agent Orange" is the herbicide that was used most extensively to defoliate vegetation during the Viet Nam conflict. Identified by orange-colored stripes on the drums which contained it, Agent Orange, or Herbicide Orange, was a mixture of the herbicides 2,4-D and 2,4,5-T. The mixture also contained a number of contaminants, the most important being TCDD or "dioxin," an unavoidable byproduct in the synthesis of 2,4,5-T. Because of concern among veterans about possible adverse health effects associated with exposure to herbicides, and scientific evidence about the toxicity of dioxins, Congress directed the Veterans Administration (VA) to design a protocol for and to conduct an epidemiologic study of Viet Nam veterans to determine the possible long-term adverse health effects from exposures to dioxin-containing herbicides. In response to similar concerns, the Air Force is carrying out a separate study of its "Ranch Hand" personnel -- the pilots, aircrew, and groundcrew most directly involved in spraying Agent Orange.

The VA epidemiologic study is mandated by the Veterans Health Programs Extension and Improvement Act of 1979 (Public Law 96-151). The same Act also mandates that the Office of Technology Assessment (OTA), an office of the Congress, approve a protocol for the study within 180 days of passage of the law (the 180 days were up in mid-June 1980) or provide Congress with reasons for disapproval of the study plan. The Act further mandates that OTA monitor the study to assure that it is carried out in accordance with the protocol.

In February 1980, the VA published its intention to have the study protocol prepared by an outside contractor, and in March, issued a Request for Proposal. Proposals were received and were reviewed by the VA's selection board of government experts. A legal challenge to the validity of the contract process, brought in May by the National Veterans Law Center, halted progress.

To resolve the conflict, Judge Harold H. Green of the District of Columbia District Federal Court asked the General Accounting Office (GAO), in June 1980, to rule on the issues raised in the bid protest. GAO completed its review in February 1981, finding that the VA had acted properly, and the VA then proceeded.

After soliciting and receiving revised proposals from the bidders, the VA reactivated its selection board. In early May, a contract, calling for delivery of the study protocol in 60 days, was awarded to the University of California (UCLA) School of Public Health, Dr. Gary Spivey, Principal Investigator. After an initial visit to the Army records group at the Pentagon revealed previously unknown records which were of great potential value for the study, Dr. Spivey requested and was granted a 30-day extension of the contract. The VA now expects to receive the protocol in early August.

OTA has been working toward assembling an advisory panel to assist in its review of the protocol. The panel will include one or more representatives of veterans' organizations, public interest groups, and industry, and experts in epidemiology, statistics, and other biomedical and medical specialties. Panel members will be asked to review the protocol before attending a meeting in early September where they will discuss their findings. OTA staff will prepare a written report including reviewers' comments and suggestions for improvements.

The VA will forward OTA's report, and those of three other review bodies -- the National Academy of Sciences, the Interagency Work Group to Study Possible Long-Term Effects of Phenoxy Herbicides and Contaminants, and the VA Committee on Health-Related Effects of Herbicides -- to UCLA for consideration. Approximately 30 days will be allowed for modifications to be made by UCLA, and a revised protocol will then be submitted to the VA. If deemed necessary, an additional review by the four groups mentioned above will be conducted.

After completion of the study plan, the VA will decide about what group will carry out the study. As called for in the law, OTA will monitor the conduct of the study.