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AGENT ORANGE

Persisting Problems With Communication of Ranch Hand Study Data and Results

Statement of Kwai-Cheung Chan, Director,
Special Studies and Evaluations,
National Security and International Affairs Division

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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the findings of our report examining the Air Force's ongoing Ranch Hand study,[1] an expensive and in-depth epidemiological study[2] of Vietnam veterans. The study was designed to investigate whether exposure to herbicides, including Agent Orange,[3] in Vietnam led or would lead to adverse health effects. The study follows the health (morbidity) and mortality rates of the so-called Ranch Hands—the almost 1,300 Air Force personnel who sprayed herbicides from the air in Vietnam.

Since its inception in 1982, the Ranch Hand study has been controversial. Initially, official government and nongovernment reviewers of the study's design expressed concern that the public would not consider the study credible because the Air Force, which conducted the spraying of herbicides in Vietnam, would also conduct the study. Because of these concerns about the appearance of conflict of interest, the design of the study protocol included several safeguards intended to ensure scientific rigor and objectivity. Among these measures was the establishment of a monitoring group, which currently consists of an Advisory Committee (administered by the Food and Drug Administration) responsible for providing independent scientific review.

Our testimony today summarizes the results of our investigation of the Ranch Hand study. We assessed (1) what impact the study has had on veterans' compensation decisions and (2) how the study disseminated results and data, communicated its limitations, and implemented measures to ensure that it was conducted with scientific independence and appropriate outside scientific oversight.

The extent to which most Vietnam veterans were exposed to herbicides is not well known, and one reason the Ranch Hands were selected for the study was that the Air Force believed that they were heavily exposed to herbicides. The study compares the Ranch Hands with a comparison group of Air Force personnel who served in Southeast Asia but who were not involved in the spraying. The comparison group was matched to the Ranch Hands in terms of age, race, and military occupation. Results of the

[1] *Agent Orange: Actions Needed to Improve Communications of Air Force Ranch Hand Study Data and Results* (*GAO/NSIAD-00-31*, Dec. 17, 1999).

[2] A scientific study of the incidences, distribution, or control of diseases in human populations.

[3] Several herbicides, including Agent Orange, contain the chemical 2, 3, 7, 8-tetrachlorodibenzo-p-dioxin. This chemical, often referred to as dioxin, is known to cause a variety of adverse health effects in animals.

study, along with those of other scientific studies of veterans and other populations, are used by the Department of Veterans Affairs to determine whether veterans are eligible to receive disability compensation for conditions believed to be connected to service in Vietnam.

Summary

To date, the Ranch Hand study has had limited impact on decisions affecting veterans' compensation. Its most significant impact so far has been on a decision by the Department of Veterans Affairs to provide compensation to Vietnam veterans' children born with *spina bifida*,[4] but it has not contributed either positively or negatively to decisions to compensate for any other diseases. The study has also led to increased discussion and further study of the association between herbicide exposure and diabetes, an association that was first reported by the Ranch Hand study in 1991. Currently, Vietnam veterans with diabetes are not eligible for compensation. The relatively small size of the Ranch Hand population limits the study's ability to detect increases in risks of rare diseases, including many forms of cancer.

Although the Air Force has conducted many aspects of the study rigorously, we found several past and ongoing problems, including delays in the dissemination of some results, limited public access to detailed data, inadequate communication of the study's limitations, failure to implement some measures to ensure rigor and independence, and insufficient outreach to veterans. Though many of these problems have been resolved, they have led some critics to question the openness and credibility of the study.

In our December 1999 report, we recommended several actions to improve the communication of study results and data. Both the Air Force and the Food and Drug Administration agreed with our recommendations and indicated they were taking steps to address them.

Background

The Ranch Hand study is one of the few ongoing studies of the health effects of herbicides on human populations. This is of particular importance because when it makes compensation decisions, the Department of Veterans Affairs places primary importance on evidence of an association between herbicide exposure and adverse health in humans, not on evidence of adverse health from animal or laboratory studies. The Ranch Hand study is also important because relatively high exposure to a

[4] *Spina bifida* is a birth defect in which the vertebral column (backbone) fails to close, possibly allowing herniation of the spinal cord.

substance may be necessary in order for a scientific study to detect adverse health effects. The 25-year Ranch Hand study, which began in 1982 and is scheduled to end in fiscal year 2006, has cost over $100 million so far and is projected to cost a total of over $140 million. To date, the Air Force has conducted all scheduled phases of the Ranch Hand study, including up to five full physical examinations of each participating member of the Ranch Hand and comparison groups. It has periodically reported study results in official Air Force reports.

In 1984, and again in 1991, Congress revised the process used by the Department of Veterans Affairs to determine whether Vietnam veterans are eligible to receive compensation for health effects from exposure to herbicides.[5] Since 1991, the Department has been required to contract with the National Academy of Sciences to perform reviews of scientific literature, including published reports from the Ranch Hand study, on the association between diseases and herbicide exposure. Largely on the basis of these reviews, the Department determines which diseases show a positive association between herbicide exposure and the disease. Vietnam veterans with such diseases are then eligible for disability compensation.

Study Has Had Limited Impact on Compensation Decisions

The most significant impact of the Ranch Hand study to date has been on the Department of Veterans Affairs' decision to provide compensation to Vietnam veterans' children with the birth defect *spina bifida*. On the basis of Ranch Hand birth defects findings, released in a report in 1992 and published in a scientific journal in 1995, the National Academy of Sciences decided in 1996 to upgrade its evaluation of evidence for association between herbicide exposure and *spina bifida* in Vietnam veterans' children. Subsequently, the Department of Veterans Affairs requested, and Congress approved, legislation allowing the Department to provide compensation to Vietnam veterans' children with the disease.

In part because of its statistical limitations, the study has not contributed either positively or negatively to the Department's decisions concerning compensation for any other disease, including nine (in addition to *spina bifida*) for which Vietnam veterans are currently eligible to receive compensation.[6] The study's relatively small sample size provides limited

[5] P.L. 98-542 (1984) and P.L. 102-4 (1991).

[6] The 10 diseases for which veterans are currently eligible for compensation benefits are: chloracne, Hodgkin's disease, multiple myeloma, non-Hodgkin's lymphoma, prophyria cutanea tarda, respiratory cancers (lung, bronchus, larynx, and trachea), soft-tissue sarcoma, acute and subacute peripheral neuropathy, prostate cancer, and *spina bifida* in offspring.

potential for addressing possible links between herbicide exposure and many forms of cancer. For instance, in order to detect a statistically significant increase in the risk of non-Hodgkins lymphoma (for which veterans can receive compensation), the study would have to find an incidence of the disease among Ranch Hands more than twice as high as among members of the comparison group. A finding of a possible association between herbicide exposure and diabetes was first reported by the Ranch Hand study in 1991. This finding led to further review of the issue by the National Academy of Sciences and further scientific investigation by the Air Force and others.[7] However, the Department of Veterans Affairs has not yet determined whether Vietnam veterans with the disease are eligible for compensation, though in 1999 it did request that the Academy issue an interim report on diabetes, currently due in March or April 2000.

Problems Have Led Critics to Question the Study's Credibility

The Air Force has conducted many parts of the Ranch Hand study in a rigorous manner. But we found that a number of problems experienced early on damaged the study's credibility. Many of these initial problems have been corrected, although some persist. Past problems included delays in and limits on dissemination of study results, limited public access to detailed study data, inadequate communication of study limitations, failure to implement measures to ensure that the study was conducted rigorously and independently, and insufficient outreach to veterans' organizations. Communication of the study's data and limitations and outreach to veterans remain problem areas.

Publication of Study Results and Update of Birth Defects Report Were Delayed

Delays occurred in the publication of morbidity and mortality findings in scientific journals during the study's early years. No journal articles on these findings were published until 1990, even though the first mortality and morbidity reports were issued in 1983 and 1984, respectively, and even though the Advisory Committee had repeatedly recommended that such articles be published in peer-reviewed journals as soon as possible. The importance of publishing journal articles is illustrated by the fact that even though the Air Force's report on reproductive outcomes was released 1992, compensation for veterans' children with *spina bifida* was instituted only in 1996, after a journal article was published in 1995. The pace of journal article publication has increased in recent years.

[7] For instance, the Academy stated in its 1994 report that additional information on characteristics of dioxin metabolism, particularly with regard to total body fat, was necessary to interpret the observed association.

A detailed report on reproductive outcomes was also delayed. Although it reported preliminary findings in 1984, the Air Force did not release the more detailed update until 8 years later, in 1992. The delay was caused by the Air Force's decision to verify birth defects data extensively and to perform additional data analyses without releasing any interim findings. The amount of data verification was highly unusual and virtually unprecedented for a study of this size. Although these additional efforts ultimately strengthened the scientific basis of this portion of the study, the length of the delay and the decision not to release an interim report led to concerns by some veterans and scientists that the study was being purposely delayed to suppress information. One scientist told us that preliminary findings could have been useful for making decisions affecting veterans' family planning or prenatal care. Others stated that earlier reporting might have led to an earlier decision to compensate for *spina bifida*.

Public Access to Study Data Remains Limited

Although the number of published reports has increased in recent years, some scientists and veterans' groups want full and ready access to all the study's data so they can verify the findings and perform additional analyses. However, only a relatively small amount of data is currently available, and its storage format (magnetic tape) is difficult to use. Currently, the public can access only data the Air Force analyzed in 1987 and released in 1995. Air Force officials have told us that they intend to make all other data available by the end of 2000. This should help increase the credibility of the study's results.

Study Limitations Have Not Been Clearly Communicated to the Public

Like all epidemiological studies, the Ranch Hand study has a number of inherent limitations. However, the Air Force has not clearly or effectively communicated these limitations to the public. The study has two major limitations: it has difficulty in detecting low to moderate increases in risks of rare diseases because of the relatively small size of the Ranch Hand population, and its findings cannot be generalized to all Vietnam veterans because Ranch Hands and ground troops were exposed to different levels of herbicides in different ways. Blood measurements of dioxin (a chemical in some herbicides that is known to cause adverse health effects in animals) suggest that the Ranch Hands' exposure levels were significantly higher than those of many ground troops. But ground troops may have been exposed in ways (such as through contaminated food and water) that Ranch Hands were not, and little is known about the potential effects of such differences.

As far back as 1980, a government working group emphasized that the public needed to understand clearly the limitations created by the study's sample size. However, in its first two morbidity reports, the Air Force described the study's lack of findings as "reassuring" because they detected few statistically significant increased risks of disease. The use of such language could have led to the misinterpretation that the study showed herbicides were safe. The Air Force stopped using this type of language in 1990, and while communication of study limitations to the public has improved over the years, additional improvements are possible. The Air Force still reports the study's findings through press releases and executive summaries that do not make the study's limitations clear.

Implementation of Oversight Measures Had Problems

During the study's first several years, two measures intended to ensure that the study was conducted independently and without any appearance of bias were not carried out as planned. The study's protocol (published in 1982) mandated that (1) Air Force scientists, subject to review by an independent scientific monitoring group (the Advisory Committee), have primary responsibility over the scientific aspects of the study and (2) the monitoring group (currently consisting of nine scientists) include scientists nominated by veterans' organizations. These requirements were not fully implemented until 1989. According to documents we reviewed dating from 1984 and 1985, Air Force management and the White House at the time tried to direct certain aspects of the scientists' research. These attempts deviated from the protocol's requirement that Air Force scientists retain primary responsibility over the study's scientific conduct. In addition, the White House's actions bypassed review by the Advisory Committee. Furthermore, the Advisory Committee did not include any veterans' representatives, as required, until 1989.

Problems Remain With Advisory Committee's Outreach to Veterans

Although many early problems were resolved through executive and congressional actions, the Committee's outreach to veterans is still an issue. For example, although the Committee's public meetings are announced in the Federal Register, the Committee has not routinely informed veterans' organizations directly of these meetings. In addition, the Committee's informal process for soliciting nominations has resulted in some interested veterans' organizations not being notified of opportunities to nominate Committee members. Better notification of Committee meetings and vacancies would help ensure that veterans' groups perceive the Committee as fulfilling its role as an independent and unbiased oversight body.

Recommendations

We recommended in our report that the Secretary of Defense direct the Air Force scientists in charge of the Ranch Hand study to establish and publicize a timetable for the release of all study data and release the data through a medium (such as CD-ROM or the Internet) that is easily accessible to the general public. We also recommended that the Air Force include more information on the study's limitations in its press releases and executive summaries of study reports. In particular, we recommended that it provide clear information on the limited applicability of study results to other Vietnam veterans and on the study's limited ability to detect small to moderate increases in risks of rare diseases. The Air Force concurred with our recommendations and indicated that it was taking steps to address them.

In addition, we recommended that the Advisory Committee's Executive Secretary at the Food and Drug Administration provide direct and timely notification to veterans' organizations of scheduled Committee meetings and of opportunities for nominations of Committee members. The Food and Drug Administration concurred with our recommendation and stated that it has begun working to ensure that veterans' organizations are notified of the Committee's activities in a timely manner.

Objectives, Scope, and Methodology

To examine the conduct and findings of the Ranch Hand study, we obtained and reviewed the study protocol, various study memoranda and correspondence, published study reports and peer-reviewed journal articles, executive summaries and Air Force press releases, and other available documents related to the study. In addition, we interviewed Ranch Hand study investigators, Advisory Committee members, Air Force program officials, Department of Veterans Affairs officials, veterans' representatives, and scientists involved in research on the health effects associated with exposure to herbicides and dioxin. We also visited Brooks Air Force Base, San Antonio, Texas, to interview members of the Ranch Hand study team and to review data collection and reporting procedures.

This concludes our formal statement. If you or other members of the committee have any questions, we will be pleased to answer them.

For future contacts regarding this testimony, please contact Kwai-Cheung Chan at (202) 512-3652. Individuals making key contributions to this testimony included Dr. John Oppenheim and Dr. Weihsueh Chiu.

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