

DEPARTMENT OF HEALTH AND HUMAN SERVICES

and

**FOOD AND DRUG ADMINISTRATION
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH**

convene the

RANCH HAND ADVISORY COMMITTEE MEETING

***Rockville, Maryland
June 10, 2005***

RECORD OF THE PROCEEDINGS

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June 10, 2005
*Rockville, Maryland***

Meeting Minutes

The Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) National Center for Toxicological Research convened a meeting of the Ranch Hand Advisory Committee (RHAC). The proceedings were held on June 10, 2005 at 5630 Fishers Lane in Rockville, Maryland.

Opening Session

Dr. Michael Stoto, the RHAC Chair, called the meeting to order at 8:46 a.m. and welcomed the attendees to the proceedings. Dr. Leonard Schechtman, the RHAC Executive Secretary, read a statement into the record to confirm that no RHAC members had any financial or other conflicts of interests with any of the topics listed on the June 10, 2005 meeting agenda. Dr. Stoto opened the floor for introductions; the list of participants is appended to the minutes as Attachment 1.

Approval of Previous Meeting Minutes. Dr. Stoto announced that the previous meeting minutes were distributed to RHAC for review and comment. The draft minutes were revised based on changes he submitted to FDA prior to the meeting and comments made by Dr. Joel Michalek, the Air Force Health Study (AFHS) Principal Investigator, for scientific accuracy. Dr. Trewyn noted three additional changes for the record. On page 7, the first bullet should end with “significant cancer results” and the remainder of the text should be deleted. On page 7, the fourth bullet should be changed to “... and other herbicides used in Vietnam.” On page 8, “invented” should be changed to “developed” in the fifth bullet.

Dr. Stoto entertained a motion to approve the minutes as modified; a motion was properly made and seconded by Drs. Trewyn and Camacho, respectively. With no further discussion, the November 19, 2004 RHAC Meeting Minutes were unanimously approved with the changes submitted into and noted for the record.

Update on the AFHS Disposition Study

Dr. David Butler, of the National Academy of Sciences (NAS), provided RHAC with a status report of this effort. The Department of Veterans Affairs (VA) was mandated by Congress to conduct the study and allocated funds to NAS to address five primary elements:

1. The scientific merit of retaining and maintaining medical records, other data and laboratory specimens collected during the course of AFHS should be evaluated.
2. The existence of privacy concerns or other ethical and logistical obstacles to retaining and maintaining AFHS materials, data and laboratory specimens should be identified.
3. Advice should be given on providing independent oversight of AFHS medical records, other materials and further study of the records, data and specimens. The mechanism for providing such oversight should also be outlined if further studies are conducted.
4. Recommendations should be made on the potential value and cost of extending the study and the most appropriate federal or non-federal entity to continue the study.
5. Guidance should be given on making laboratory specimens that have been collected available for independent research. This advice should include the value, relevance and potential cost of the research.

To address the five elements, NAS formed an expert committee with extensive knowledge in environmental and occupational medicine, health effects related to Agent Orange, epidemiology, biostatistics, bioethics, privacy issues and SAS database management. A subcommittee was also established to conduct a site visit of the AFHS research facilities. The NAS committee held a meeting in February 2005 and a workshop in April 2005 to obtain its formal charge from the VA, review the process to gather data, and discuss the five elements of the study. Speakers at the April 2005

workshop represented diverse groups, including federal agencies and the veteran's community.

The NAS committee will convene its final meeting and workshop in June 2005 to gather additional information from experts on issues related to privacy concerns and the use of data by outside researchers. Representatives of federal agencies with experience in these areas will describe lessons learned to ensure efforts are not duplicated. NAS expects to release the report of the AFHS disposition study in the fall of 2005, but more information can be obtained in the interim at www.national-academies.org or www.veterans.iom.edu.

Prior to its release, the report of the AFHS disposition study will be reviewed by several persons whose identities will be unknown to the NAS committee. The reviewers' comments will be addressed and a coordinator will examine responses by the NAS committee for accuracy. Dr. Butler confirmed that RHAC will be given copies of presentations from the April 2005 workshop and will also be notified about the release of the report of the AFHS disposition study.

Report on the AFHS Disposition Study Workshop

Dr. Stoto clarified that his presentation during the April 2005 NAS workshop reflected his personal opinions and not the respective positions of the U.S. Air Force (USAF), RHAC, NAS or his employer. His remarks focused on the purpose, design and endpoints of AFHS; the relatively high exposure to dioxin among AFHS subjects; currently available data; AFHS research results; the impact of continuing the AFHS; and consent to use AFHS records and materials. Dr. Stoto's position about the disposition of AFHS is as follows.

Research that is underway should be completed and relatively inexpensive efforts to monitor mortality of the subjects should be continued. Retaining and maintaining AFHS data and materials and providing researchers with access to these data will be extremely valuable. However, due to the age of the subjects and the amount of information previously gathered, it is unlikely that much will be learned from performing additional physical examinations.

Although designed for a narrow purpose, the wealth of data and materials that have already been gathered by the APHS means that future research with these data materials could address the health effects of herbicides and dioxin in veterans; environmental and occupational exposures and other aspects of military health; more

general chronic disease risks; the normal aging process, and other issues. It is likely that if they knew about the existence of these data and materials, researchers with expertise in these and other fields could obtain funding through the regular processes at the National Institutes of Health and other public and private institutions, and conduct creative and innovative studies using the AFHS data and materials.

The NAS study is intended to identify the potential benefits of this material to future researchers, as well as the costs and logistical issues involved with maintaining access to them. One specific issue that will have to be addressed is informed consent. During the last round of examinations, ~96% of subjects were willing to give their consent for records and materials to be used in “Agent Orange and military health studies” and 3% for “Agent Orange only.” Only 1% of subjects were not willing to give their consent. The subjects were not asked about other uses of the data.

The RHAC agreed that despite the 25-year history of AFHS, new findings are still being discovered and this issue should be strongly emphasized to the NAS committee. Other comments by RHAC on the AFHS disposition study are outlined below.

- Identify specific elements of the AFHS disposition study for RHAC to collectively endorse. For example, RHAC could develop and submit a formal statement to the NAS committee on the importance of maintaining valuable AFHS data for future studies and the benefits of re-analyzing existing data with new information or different methodologies. RHAC’s previous letters to NAS or Dr. Stoto’s presentation during the April 2005 NAS workshop could be used as the basis for RHAC’s formal position statement on the AFHS disposition study.
- Outline a specific process if the NAS committee recommends that AFHS laboratory specimens be made available to independent researchers. For example, specimens should not be examined as individual submissions. Instead, materials should be accessible in a batch mode with applications considered during an appropriate time period. This approach will provide material handlers with better knowledge of the strengths and limitations of AFHS data.
- Explore the possibility of establishing a fair and independent oversight body to systematically examine different methodologies that have been applied in other research projects. Use this approach to increase credibility of the AFHS disposition study. For example, different levels of access or restrictions could be placed on specific data components rather than the entire data set because some studies will not require samples or identification of personal information. Data can also be protected by

- running statistical analyses from the database rather than releasing raw data/information to researchers.
- Ensure that the Census Bureau and National Center for Health Statistics are actively engaged in discussions about the disposition study due to the experience of these agencies in this area.

Dr. Butler confirmed that he would provide the NAS committee with RHAC's June 2005 meeting minutes or its formal position statement on the AFHS disposition study if the members decided to develop this document. He encouraged RHAC to contact him at afhs_study@nas.edu.

AFHS Comprehensive Report

Dr. Stoto, Col. Karen Fox of USAF, and Dr. William Grubbs of Science Applications International Corporation (SAIC) led RHAC in a discussion of the AFHS summary report and the process to review the document. USAF awarded a contract to SAIC to summarize key findings, collected data, reports published in the scientific literature and other relevant research related to AFHS. The summary report will be organized into three major categories of an introduction, historical measures of exposure, and results. SAIC will deliver the first draft of the summary report to USAF by September 23, 2005 and will then revise the document based on two USAF reviews. USAF will distribute the summary report to RHAC at least two weeks prior to the November 2005 meeting for review and comment before finalizing the document.

With respect to other reports, USAF awarded a contract to SAIC to develop a paper on the overall history of AFHS. A statement of work is now being written for the longitudinal study that is expected to be completed before AFHS is concluded on September 30, 2006. The draft longitudinal study and its time-line will be shared with RHAC for review and comment.

Dr. Stoto will assign each RHAC member specific sections of the summary report to review prior to the November 2005 meeting. An outline and description of the document were distributed to RHAC; comments from the members are outlined below.

- Change the title from "longitudinal summary" because the document will serve as a summary report rather than a longitudinal study.
- Do not use "statistically significant" because this term will not be understandable to a broad audience. Provide clear details in the

“description of the writing strategy” section on items the reader should expect to review in the summary report.

- Include a paragraph that specifically focuses on the strengths and weaknesses of the AFHS. Use this text to strengthen credibility of the AFHS, particularly in the veteran’s community. For example, insignificant results for cancer and other health outcomes may become much more important when existing data are assessed, grouped or re-analyzed with different or new methodologies.
- Expand on existing efforts to ensure the history, controversy and other issues related to the AFHS are transparent and accurately captured. For example, engage political scientists or sociologists while developing the summary report. Contact Dr. Camacho to obtain information on a previous literature review of the political and social aspects of the AFHS.
- Establish a clear process to identify statistical and clinical significance. For example, many potential problems can be avoided by analyzing inconsistencies among or between officers, enlisted personnel, and other AFHS subgroups.
- Explore the possibility of including unpublished data in the summary report as well as recently released papers which may contain important new findings.
- Include text to clarify that additional efforts will be undertaken and new data related to the AFHS will be released in the future.

Molecular Epidemiology Study

Dr. Fumio Matsumura, of the University of California-Davis, presented results from a new field of epidemiological science that is designed to increase the sensitivity of detecting biological effects and provide a logical basis for empirically observed correlations. A molecular epidemiology study was conducted in the AFHS cohort. A total of 313 volunteers *Ranch Hands (RHs) and carefully matched comparisons) donated adipose samples for the study. The molecular markers selected included glucose transporter 4 (GLUT4), an adiposity index, an inflammation marker (NFκB), a signal messenger for toxic action of dioxin, and a housekeeping gene used as a normalization standard.

The molecular epidemiology study was designed with several strategies. The statistical power was increased by dividing each service group into four quartiles according to the level of dioxin residues. Statistically significant correlations between molecular marker expressions and dioxin residues were identified. Positive correlations between dioxin

and combinations of all marker ratios were located. Relationships between the ratio of GLUT4 and NFκB (G:N ratio) and dioxin were analyzed. Subgroups that were most affected by dioxin were identified. The hypothesis of the similarity between the diabetogenic effect of TCDD and obesity was tested. The relationship between the G:N ratio and recent changes in body fat was studied. Fasting glucose was used as a diabetes marker. Relationships among G:N ratio, percent of body fat and dioxin residue levels were identified.

The following conclusions were reached in the molecular epidemiology study. The G:N ratio was found to be the best marker to detect diabetogenic effects of obesity and genetic risk factors. Some subgroups were found to affect the pattern of correlations. The use of the quartile approach was found to be justifiable because the same results could be obtained through other methods. Obese and lean subgroups were shown to respond differently to dioxin.

Dioxin exposure was found to make non-diabetic RHs more susceptible to diabetogenic influences of obesity. The G:N ratio among non-diabetic subjects was found to be negatively correlated to obesity, but an opposite trend was seen among diabetic subjects. The G:N ratio was found to be a reliable marker of diabetes because of its high correlation to fasting glucose levels. Fasting glucose levels were found to be directly affected by dioxin and a sensitive marker in detecting diabetogenic effects of obesity.

Dioxin was found to act as a diabetogenic risk factor among Vietnam veterans even after a long period of time from low-level exposure. The diabetogenic effect of dioxin was found in comparisons whose serum levels of dioxin overlapped with the medium to high end of the general public. Overall, environmental health scientists should be concerned about potential diabetes-related health effects to the general public from even low levels of dioxin exposure, particularly to persons with known risk factors. The manuscript of the study was recently submitted for publication.

Dr. Michalek described three unique aspects of the molecular epidemiology study. First, the study is the only body of research in the world in which a contaminant was measured in both the control and index groups. Second, ~98% of both the control and exposed groups were measured for dioxin by the same laboratory. Third, the study is the only body of research that exists on adipose markers in humans related to dioxin.

Public Comment Period

The Chair opened the floor for public comments; no attendees responded.

Update on AFHS Research Activities

Dr. Michalek conveyed that the AFHS is most likely the best epidemiologic study ever conducted and is based on some of the most solid data ever collected in humans. The government launched the AFHS in 1979 and is continuing to commit resources to ~30 years of effective follow-up. The AFHS was designed with an unprecedented scope, quality and consistency to answer sensitive questions, but the study contains several limitations. The AFHS is an extremely complex research effort due to the lack of dosimetry data to determine when service personnel were exposed to chemicals in Vietnam. The government mandate to apply a standard epidemiologic template to a study with unprecedented complications was also problematic. Nevertheless, the AFHS represents decades of diligent efforts and dedication from a wealth of individuals to collect data and fill gaps. Dr. Michalek's summary of AFHS is outlined below.

Summary of the 2002 Air Force Health Study Follow-up Physical Examination Report. Of 1,951 persons given physical examinations in 2002, 777 were RHs and 1,174 were comparisons. Statistical models were used to address uncertainties in AFHS. Model 1 focused on differences between RHs and controls on any measure of health. Model 2 focused on connections between health and initial doses estimated in RHs while serving in Vietnam. Model 3 focused on increased risks to RHs with high dioxin levels compared to controls. Model 4 focused on the relationship between health and dioxin as measured in 1987. Laboratory results, questionnaires, physical examinations and external medical records were used as data sources.

Findings were:

- Body mass index (BMI) increased with dioxin.
- No remarkable results were found to relate dioxin or herbicide exposure to cancer.
- A mixed pattern of associations did not indicate an overall relationship between adverse neurological health and herbicide or dioxin exposure.
- No psychological outcome measures were found to be associated with herbicide or dioxin exposure.

- The risk of abnormally high triglycerides was increased in RH enlisted ground crew in the high dioxin category.

The frequency and occurrence of reported acne after service in Southeast Asia (SEA) were increased in RH enlisted ground crew in the high dioxin category. No association was seen between dioxin and skin lesions indicated by dermatologists during the physical examination. An inconsistent pattern of associations was seen between different measures of cardiovascular health and dioxin or herbicide exposure. The risk of death from cardiovascular disease was found to be significantly increased among RH enlisted ground crew. A corresponding association was not seen in the analysis of veterans with dioxin assay to support the mortality outcome.

- Associations were not found to indicate adverse relationships between hematological health or renal function and dioxin or herbicide exposure.
- An association was seen between adult onset diabetes and dioxin or herbicide exposure.
 - o The risk of acquiring type 2 diabetes and taking insulin was increased among RHs with high dioxin levels.
 - o The risk of abnormally high hemoglobin A1c increased with dioxin.
- No consistent or interpretable association was seen between any measure of immune function and dioxin or herbicide exposure in the cohort.
- Similar results of no consistent or interpretable association between dioxin or herbicide exposure and pulmonary function were seen.

The AFHS is a unique study due to adjustments made for diabetes and cancer risk factors, including age, BMI, family history, occupational exposure outside of USAF, exposures to metals and chemicals, skin reaction to sunlight, eye and hair color, and smoking history in pack years. Overall, no significant group differences between RHs and controls were seen for any disease outcome in the AFHS.

Publication: Diabetes. The diabetes results were published in *Epidemiology* in 1997. The risk of adult onset type-2 diabetes increased with dioxin among RHs. The time to diabetes onset decreased and diabetes severity increased with dioxin. However, no difference was seen between RHs and controls in the overall prevalence of dioxin. This contradictory result produced a “check mark” pattern in which RHs with high dioxin levels had a greater risk than controls and RHs with low dioxin levels had a lesser risk than controls. Attempts were made to statistically model the check mark pattern, but these efforts were not published.

Current Research:

Diabetes. New analyses of dioxin and diabetes were performed in both Cycles 5 and 6 with adjustments for risk factors of days of spraying, calendar period of spraying, and last year of service from 1962-1970. The total number of individuals in the data set who were available for analysis was 3,049. However, the actual sample size was 2,469 because individuals were excluded based on a diagnosis of diabetes prior to service in Vietnam or SEA, non-compliance with at least one physical examination and no dioxin levels.

Persons who served in Vietnam with <90 days of spraying were also excluded from the new analyses because the median was ~300 days of spraying. The time to diabetes onset was measured from the end of the qualifying tour. NAS's review of the 1997 *Epidemiology* paper and subsequent conclusion that a plausible association existed between dioxin and type-2 diabetes led the VA to compensate Vietnam veterans for this disease.

The diabetes analysis showed that persons who served in SEA prior to 1969 had higher dioxin levels than those whose last year of service was after 1969. This finding supports the hypothesis that herbicides were more contaminated with dioxin earlier rather than later in the war. The risk factor of calendar year of service led to a fairly remarkable outcome of reversing the pharmacokinetics of dioxin. These data were the only body of evidence in the world that could be used to make this assessment in humans because RHs are the only cohort with extensive measurements of dioxin and other risk factors related to service in Vietnam.

A relationship was seen between number of days of spraying and body burden of dioxin. No significant increased risk of type-2 adult onset diabetes was seen without adjusting for calendar year of service and number of days of spraying because these risk factors change the relationship between dioxin and diabetes. Other unknown factors may also be important, particularly by incorporating information from daily spray records to further refine the diabetes analysis.

- **Cancer.** The cancer results were published in the *Journal of Occupational and Environmental Medicine* in 2005. Associations between cancer and dioxin were not evident in simple main effects models. Years of service in SEA were found to be a risk factor for cancer in comparisons. Associations between cancer and dioxin were seen after stratification by years of service in SEA and the proportion of time spent in Vietnam. The calendar period of service and days of spraying were considered. Cancer was determined through September 30, 2004. Onset

to the first diagnosis of Surveillance, Epidemiology and End Results (SEER) cancer was measured from baseline to January 1, 1982.

The time to onset for veterans without cancer was the date of the last physical examination plus two years or the date of death. Cancer was determined by a review of medical records of death certificates. All analyses were performed with proportional hazards models adjusted for known risk factors. Individuals who were compliant to at least one physical examination were included in the analysis. The total number of individuals who were available for analysis was 3,049, but the actual sample size was 2,583. Persons were excluded based on cancer prior to service in Vietnam or SEA, non-compliance with at least one physical examination and no dioxin levels. Individuals who served in Vietnam with <30 days of spraying were also excluded.

The stratified analysis for cancer had several limitations. The entire cohort was not examined and the last year of service in the RH unit was stratified as 1968 or prior. The relative risk became stronger in earlier years and suggested an exposure effect on dioxin in cancer, but the number of subjects became smaller due to fewer persons in SEA during the early years of the war. Years of service in SEA was found to be a risk factor for all-site SEER cancer in the control group and required an adjustment for the length of time comparisons were in SEA. Different types of cancer were combined. However, the stratified analysis was strengthened with the inclusion of operational information outside of p values, such as days of spraying and last year of service.

The results showed that individuals who served in SEA earlier rather than later in the war had higher dioxin levels. This finding supported the hypothesis that herbicides were indeed more heavily contaminated during this time period. A relationship was seen between days of spraying and body burden of dioxin among RHs. No association was seen between all-site SEER cancer and dioxin without adjusting for days of spraying or last year of service in SEA because these risk factors served as effect modifiers. A significant trend of an increased risk of cancer was seen in the entire cohort of 788 persons when adjustments were made for days of spraying, service during or prior to 1968 and whites only. No significant results were seen in the high-dioxin category with the model 3 analysis and inclusion of dioxin.

Relative risks increased in RHs when comparisons with a long duration of time in SEA were excluded. A significant trend of an increased risk of cancer was seen when the factors of days of spraying, service during or prior to 1968, and less than two years of service in SEA were combined. The risk factor of days of spraying

alone was not found to relate to cancer in the control group or provide sufficient information to detect an exposure effect on cancer in RHs. A significant group difference in cancer was not seen after these adjustments, but a significant increase in the risk of cancer in RHs was detected. Overall, a significant association was found between cancer and dioxin and an unexpected relationship was seen between cancer and years of service in SEA in the control group.

- Sleep Disorders. The sleep disorder analysis was submitted to *Environmental Health Perspectives* and is currently being considered for publication. The analysis serves as the first effort to measure sleep disorders and dioxin in the same subjects. Sleep questionnaires were administered to AFHS participants in 1987 and 1992. The analysis was restricted to individuals who were compliant to the 1987 or 1992 physical examinations; used the model 3 dioxin category analysis; and applied “insomnia” and “para-insomnia” as defined in the literature. Risk factors used in the analysis were consistent with other components of AFHS research.

The results showed adverse health effects related to dioxin exposure and sleep disorders. Significant increases in sleep complaints, disabling daytime fatigue, daytime sleepiness and insomnia were reported among veterans in low- and high-dioxin categories compared to controls after adjusting for risk factors. Overall, dioxin was found to target arousal regulation and interfere with sleep.

Some RHAC members expressed concern that significant results were seen with a small sample size in the stratified cancer analysis. A suggestion was made to further stratify to identify variables or attributes that were not previously considered when the experimental protocol was initially designed. RHAC agreed with Dr. Michalek that the risk factors of days of spraying and last year of service in SEA are extremely important variables and indicates the need to consider other endpoints. RHAC also noted the importance of releasing data from the new diabetes, cancer and sleep disorder analyses to the public as soon as possible. RHAC’s specific comments on the AFHS research activities are outlined below.

- Use other published findings in addition to the AFHS to make the Cycle 6 report more valuable, beneficial and sensitive to the Vietnam veteran’s community. Undertake this effort because only a few clinically significant results were found outside of diabetes.
- Analyze AFHS data in the future with different methodologies to identify important associations between dioxin and other adverse health effects, such as birth defects, heart disease and hypertension.

- Examine Agent Blue with cacodylic acid and other non-dioxin compounds to detect additional adverse health effects.
- Refine the specificity of the analyses by incorporating other molecular markers.
- Delay publication of the AFHS summary report to include data from the new cancer, diabetes and sleep disorder analyses.
- Design the AFHS summary report to be open and transparent by explicitly stating that positive results were found in non-AFHS research and valuable information other than the history of the AFHS can be obtained from these data.
- Clearly outline the strengths and limitations of the AFHS in the summary report.

Dr. Michalek and Col. Fox made several follow-up remarks to RHAC's discussion. USAF extensively reviewed all comments on the Cycle 6 report that RHAC made during meetings or submitted in writing. All of the suggested revisions could not be incorporated, but the current version reflects most of the changes. Most notably, a preface was included that explains other findings in the published literature may not agree with the Cycle 6 report. The document has been submitted for public release clearance. A press release should be forthcoming.

The Centers for Disease Control and Prevention (CDC) is currently analyzing AFHS sera for dioxin-like chemicals in ~700 samples to strengthen the overall exposure assessment and clarify existing patterns. The new analysis may also lead to inaccurate exposure classifications of AFHS participants in terms of being comparisons or having background, low or high dioxin levels. . . .

Longitudinal Report (Summary Report). Publication of the AFHS summary report may not be able to be delayed to incorporate data from the new cancer, diabetes and sleep disorder analyses. However, the document could perhaps be revised to emphasize that these data have been collected. Moreover, the new diabetes analysis will soon be submitted to a journal and may be published prior to the November 2005 RHAC meeting. Dr. Michalek compiled data from the new diabetes, cancer and sleep disorder analyses into a manuscript and submitted a proposal for USAF to allocate funding to complete the paper. The USAF is in negotiation with SAIC on publication support and Dr Michalek's two proposals are under review.

RHAC Business

Dr. Schechtman announced that the next two RHAC meetings will be held on September 19, 2005 and in November 2005 based on the availability of the members and USAF. He and Col. Fox listed potential items for RHAC to review and discuss during the meetings.

- The Cycle 6 follow-up physical examination report, update on its release.
- Dr. Michalek's draft diabetes paper.
- The AFHS summary report.
- Report of the IOM AFHS disposition study.
- The SAIC paper on the history of AFHS.
- Update on the CDC analysis of all dioxin-like chemicals and congeners.
- Overview of USAF's methodology to unfreeze portions of samples from all six cycles, perform analyses for ~100 chemistry values, and determine if the samples are viable from 1982 and thereafter.

Based on preliminary time-lines for these agenda items according to input from NAS, SAIC and USAF, RHAC agreed that no meeting should be held in September 2005 and the November 2005 meeting should perhaps be extended to 1.5 days. Dr. Schechtman noted that based on FDA's availability, the meeting should be convened on November 18, 10 or 3, 2005 in this order of preference. RHAC indicated that its first choice would be a meeting on November 18, 2005, but agreement was reached to poll the members and USAF to confirm availability.

Closing Session

Dr. Stoto thanked the speakers for their informative presentations, RHAC for its valuable input, USAF, and FDA for making logistical arrangements for the meeting.

With no further discussion or business brought before RHAC, Dr. Stoto adjourned the meeting at 2:15 p.m.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

Date

Michael A. Stoto, Ph.D.
Chair, Ranch Hand Advisory Committee

Date

Leonard M. Schechtman, Ph.D.
Executive Secretary,
Ranch Hand Advisory Committee

ATTACHMENT 1

List of Participants

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Dr. David Johnson
Dr. Sanford Leffingwell
Dr. Ronald Trewyn

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RHAC Executive Secretary

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