

**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  
November 19, 2004*

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**RECORD OF THE PROCEEDINGS**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
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**RANCH HAND ADVISORY COMMITTEE MEETING  
*November 19, 2004*  
*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 November 19, 2004 at 5630 Fishers Lane, Rockville, MD.

***Opening Session***

Dr. Michael Stoto, the RHAC Chair, called the meeting to order at 8:08 a.m. and welcomed the participants to the meeting. 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 November 19, 2004 meeting agenda. Dr. Stoto opened the floor for introductions; the following individuals were present for the deliberations.

**RHAC Members**

Dr. Michael Stoto, Chair  
Dr. Paul Camacho  
Dr. Ezdihar Hassoun  
Dr. David Johnson  
Dr. Robert Sills  
Dr. Ronald Trewyn

**FDA/NCTR Representatives**

Dr. Leonard Schechtman  
RHAC Executive Secretary

Ms. Kimberly Campbell  
Committee Management Specialist

**U.S. Air Force Representatives**

Dr. Joel Michalek  
2<sup>nd</sup> Lt. Margaret Montgomery  
Lt. Col. Julie Robinson

**U.S. Air Force Contractors**

Mr. Manuel Blancas  
UD Tech

Dr. William Grubbs  
Science Applications International  
Corporation  
Dr. Judson Miner, Operational  
Technologies Corporation

Mr. Maurice Owens  
Science Applications International  
Corporation

Ms. Meagan Yeager  
Science Applications International  
Corporation

**Guests**

Dr. David Butler  
National Academy of Sciences

Dr. Gary Kayajanian  
Public

Ms. Jaclyn Petrello  
Exponent

Mr. Rick Weidman  
Vietnam Veterans of America

Approval of Previous Meeting Minutes. Dr. Stoto announced that the previous meeting minutes were distributed to RHAC for review and comment. He submitted changes to the office of the RHAC Executive Secretary prior to the meeting and opened the floor for other members to propose revisions as well. He entertained a motion to approve the minutes as modified; a motion was properly made and seconded by Drs. Trewyn and Johnson, respectively. With no further discussion, the September 22, 2004 RHAC Meeting Minutes were unanimously approved as modified. Dr. Stoto requested that in the future, he receive changes to the minutes submitted by the U.S. Air Force (USAF) to ensure the comments are appropriate from a technical perspective.

***Update on the Air Force Health Study (AFHS) Disposition Study***

Dr. David Butler, of the National Academy of Sciences (NAS), explained that the Veterans Benefits Act of 2003 contained a Congressional mandate to conduct the AFHS disposition study. The law was signed in December 2003 and directed NAS to address several elements in conducting the study. First, the scientific merit of retaining and maintaining medical records, other data and laboratory specimens collected during the course of AFHS should be evaluated. Second, the existence of privacy concerns or other ethical and logistical obstacles to retaining and maintaining AFHS materials, data and laboratory specimens should be identified. Third, 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. Fourth, recommendations should be made on the potential value and cost of extending the AFHS and the most appropriate federal or non-federal entity to continue the AFHS. Fifth, guidance should be given on making laboratory specimens that have been collected during the course of

the AFHS available for independent research. This advice should include the value, relevance and potential cost of the research.

At this point, NAS has signed a contract with the Department of Veterans Affairs (DVA) and has received ~\$850,000 to conduct the AFHS disposition study. NAS is now soliciting input from a variety of sources in three key areas. First, potential members to serve on a committee for the study are being identified. Government employees cannot be selected as committee members since the study is sponsored by a federal agency. Areas of expertise the committee should have are being assessed, such as environmental medicine; veteran's health or aging and military populations; longitudinal epidemiologic studies; analysis of biologic samples; long-term maintenance of records; sample size and other biostatistical issues; and informed consent and other bioethical issues.

Second, appropriate materials for the committee to consider are being evaluated since all NAS studies, recommendations and conclusions are science-based. Third, potential topics and speakers are being identified for a workshop NAS will convene in March or April 2005 in Washington, DC. The purpose of the meeting will be to gather additional information for the committee to consider. The workshop will be open to the public, posted on the NAS web site and also broadly announced to the public. NAS expects to produce a report on the AFHS disposition study by November 2005.

Dr. Butler encouraged RHAC members to e-mail him at [afhs\\_study@nas.edu](mailto:afhs_study@nas.edu) to provide input on potential committee members, areas of expertise and any other aspect of the AFHS disposition study or the 2005 workshop. He committed to providing Dr. Schechtman with more details about the workshop for distribution to RHAC.

#### **Update by the AFHS Principal Investigator**

Dr. Joel Michalek covered the following items in his status report. First, USAF will discontinue research on January 1, 2006 in accordance with its directive to terminate all AFHS activities on October 1, 2006. If NAS makes a recommendation in November 2005 to continue AFHS, proactive measures will need to be taken to revise USAF's time-line. However, the USAF shutdown plan is sufficiently flexible to address the NAS recommendations on disposition of AFHS.

Second, USAF has revised and resubmitted its paper on cancer in the control group to the *Journal of Occupational and Environmental Medicine*. The data show associations in the control group between cancer and dioxin as well as cancer and years in the Southeast Asia (SEA) region. The paper states that the reasons for these associations are unknown. USAF is also evaluating cancer in the Ranch Hand cohort due to the

findings in the control group and expects to complete this paper prior to the next RHAC meeting.

Third, USAF is summarizing its research that demonstrated participation in the AFHS did not statistically prolong the life or measurably improve the health of any subject. Fourth, USAF is conducting a case-by-case review of Ranch Hand enlisted ground crew who died of cardiovascular disease to better understand these patterns. Fifth, the Centers for Disease Control and Prevention (CDC) completed 500 randomly selected assays of the TEQ that provided measurements on 36 dioxin congeners, furans and PCBs for the first time. USAF and CDC are compiling these findings for a manuscript.

### *Review of Chapter 18: Endocrine*

Dr. Leffingwell was charged with the review of Chapter 18. He was absent from the meeting, but submitted his comments in writing for RHAC to review and discuss. In general, both RHAC and USAF found Dr. Leffingwell's comments to be well written, thorough and helpful in strengthening the chapter. USAF confirmed that the majority of the comments could be addressed with minor editorial changes. In particular, USAF agreed to add language to respond to two specific points raised by Dr. Leffingwell.

First, text from USAF's published insulin paper will be included to clarify lines 163-165. A review of the paper pointed out that in the process of developing diabetes, an individual maintains glucose levels, but only through very high levels of insulin until the point is reached when insulin production fails and diabetes results. Second, language will be added to lines 311-314 to place the relative concentrations of dioxin levels in Ranch Hands in context with other cohorts. A member of the public suggested that USAF analyze the comparison group by assessing endocrine effects as a function of length of duty tour to determine whether a longer stay resulted in more harm. Dr. Leffingwell's comments are appended to the minutes as Attachment 1.

### *Review of Chapter 20: Pulmonary*

Dr. Johnson was charged with the review of Chapter 20. In general, he found the chapter to be well written and agreed with the conclusions and summary. In particular, his comments and those of other RHAC members are outlined below.

- Revise line 166 to clarify whether the reduction in all examinations is "slight" or "significant."