

**5th Meeting of the
Secretary's Advisory Committee on Xenotransplantation**

February 3-4, 2003
Holiday Inn Select, Bethesda, MD

MEETING AGENDA

Day 1 – Monday, February 3, 2003

- 8:30 am **Opening Remarks**
Harold Vanderpool, SACX Chair
- 8:40 am **Xenotransplantation: Meeting Updates, News Items, Activity Updates (Part I)**
- **Follow-up on PRIM&R Workshop on xenotransplantation issues**
Robyn Shapiro and Harold Vanderpool, SACX members
 - **RFA for National Swine Research and Resource Center**
Franziska Grieder, National Center for Research Resources, NIH

INDUSTRY UPDATES ON XENOTRANSPLANTATION STUDIES

- 9:00 am **Pig-to-primate models of heart transplant: Immunological Aspects**
John Logan, Nextran Inc.
- Cardiac Xenotransplantation: Continuing Progress in the Laboratory**
Christopher McGregor, Mayo Clinic
- 9:40 am Q&A
- 9:50 am **Xenotransplantation: Miniature Swine Genetic Engineering and Preclinical Transplantation**
Julia Greenstein, Immerge BioTherapeutics
- 10:10 am Q&A
- 10:20 **Islet Cell Xenotransplantation**
Bernhard Hering, University of Minnesota
- 10:40 Q&A
- 10:50 am Break
- 11:05 am **Genetic Modification of Pigs for Xenotransplantation**
David Ayares, PPL Therapeutics Inc.
- 11:25 am Q&A
- 11:35 am **Committee discussion of presentations and specific questions posed by FDA**

- 12:55 pm Lunch
- OVERVIEWS AND DISCUSSION OF SACX DRAFT REPORTS
- 1:55 pm **Overview of Draft Report on Informed Consent in Clinical Research Involving Xenotransplantation**
Members of SACX Working Group on Informed Consent
- 2:15 pm **Plenary Discussion of Draft Report on Informed Consent in Clinical Research Involving Xenotransplantation**
Moderator: Robyn Shapiro, WG Co-chair
- 4:00 pm **Public Comment**
- 4:10 pm Break
- 4:25 pm **Overview of Draft Report on the State of the Science in Xenotransplantation**
Members of the SACX Working Group on State of the Science
- 4:45 pm **Plenary Discussion of Draft Report on the State of the Science in Xenotransplantation**
Moderator: Jon Allan and Megan Sykes, WG Co-chairs
- 6:30 pm **Public Comment**
- 6:40 pm Adjourn for the day

Day 2 – Tuesday, February 4, 2003

- 8:30 am **Xenotransplantation: Meeting Updates, News Items, Activity Updates (Part II)**
- **DHHS activities regarding xenotourism issues**
Howard Zucker, Office of Public Health and Science, DHHS
 - **Follow-up on FDA PERV Workshop**
Carolyn Wilson, Center for Biologics Evaluation and Research, FDA
- 9:10 am **Public Comments**
- 9:20 am **Breakout Sessions: SACX Working Groups**
- 11:35 am Break
- 11:50 am **Plenary Progress Reports by Working Groups**
Working Group Chairs
- 12:20 pm **Discussion**
- 1:20 pm **Closing Remarks**
Harold Vanderpool, SACX Chair
- 1:30 pm Meeting Closes