

***** DRAFT AGENDA *****

**4th Meeting of the
Secretary's Advisory Committee on Xenotransplantation**
March 11-12, 2002
Holiday Inn Select, Bethesda, MD

Day 1 – Monday, March 11, 2002

- 8:00 am **Opening Remarks**
Harold Vanderpool, SACX Chair
- 8:10 am **Introduction: Science Symposium on the Immunology and Applications of Xenotransplantation**
Megan Sykes, SACX Member (Moderator for morning session of symposium)
- SYSTEMS PHYSIOLOGY: COMPLEMENT AND COAGULATION SYSTEMS
AND THE ROLE OF SURFACE CARBOHYDRATES
- 8:15 am **Complement Systems** (working title)
Agustin Dalmaso, University of Minnesota
- 8:40 am Q&A (for clarification purposes)
- 8:45 am **Coagulation Systems** (working title)
Simon Robson, Harvard University
- 9:10 am Q&A (for clarification purposes)
- 9:15 am **Role of Surface Carbohydrates** (working title)
James Paulson, Scripps Research Institute
- 9:40 am Q&A (for clarification purposes))
- IMMUNE RESPONSE, TOLERANCE, AND IMMUNOSUPPRESSION
- 9:45 am **Endothelial Cell-host Interactions in Solid Organ Xenotransplantation** (working title)
Jeff Platt, Mayo Clinic
- 10:10 am Q&A (for clarification purposes)
- 10:15 am **Use of Immunosuppressive Drugs in Pig-to-Primate Models of Xenotransplantation**
(working title)
Robert Zhong, University of Western Ontario
- 10:40 am Q&A (for clarification purposes)
- 10:45 am **Immune Rejection and Tolerance** (working title)
Megan Sykes, Harvard Medical School, SACX Member
- 11:10 am Q&A (for clarification purposes)

11:15 am

Break

PANEL DISCUSSION

11:30 am

Panel Discussion with Speakers and SACX Members

Moderator: Megan Sykes, SACX Member

1:00 pm

Lunch

EXTRACORPOREAL AND BIOARTIFICIAL TECHNOLOGIES

2:00 pm

Liver Perfusion, Bioartificial Liver Devices (working title)

Gary Levy, University of Toronto

2:25 pm

Q&A (for clarification purposes)

2:30 pm

Cardiac Devices (working title)

Robert Michler, Ohio State University

2:55 pm

Q&A (for clarification purposes)

3:00 pm

Discussion

TRANSGENIC ENGINEERING AND CLONING OF POTENTIAL SOURCE ANIMALS

3:15 pm

Transgenic Pigs for Biomedicine and Agriculture

Randall Prather, U Missouri-Columbia

3:40 pm

Q&A (for clarification purposes)

3:45 pm

Genetic Modification of Gal Transferase Knockout Pigs (working title)

Julia Greenstein, Immerge BioTherapeutics

4:10 pm

Q&A (for clarification purposes)

4:15 pm

Development and Characterization of Transgenic Pigs for Xenotransplantation

Guerrard Byrne, Nextran

4:40 pm

Q&A (for clarification purposes)

4:45 pm

Break

5:00 pm

Discussion

CELLULAR TRANSPLANTS

5:35 pm

Islets, Neural Cells, Myoblasts, Hepatocytes (working title)

Dan Salomon, The Scripps Research Institute, SACX Member

6:00 pm

Q&A (for clarification purposes)

6:05 pm

Fishing for a Cure: Piscine (Tilapia) Islet Xenotransplantation

James Wright, Dalhousie University

6:30 pm

Q&A (for clarification purposes)

- 6:35 pm **Discussion**
- 6:55 pm **Concluding Remarks for the Symposium**
Megan Sykes, SACX member, Symposium Moderator
Dan Salomon, SACX member, Symposium Moderator
- 7:00 pm Symposium concludes, Adjourn for the day

Day 2 – Tuesday, March 12, 2002

- 8:30-9:15 am **Xenotransplantation: Meeting Updates, News Items, Activity Updates**
- Brief overview of the February 2002 meeting of the European Agency for Evaluation of Medicinal Products
Eda Bloom, FDA/CBER
 - Announcement of PERV Immunoassay Workshop
Carolyn Wilson, FDA/CBER
 - Video of SACX member Jim Finn’s interview with Oprah and/or Dan Rather
 - Highlights of recent article: “Attitudes toward xenotransplantation—patients waiting for transplantation versus the general public” Persson et al., *Transpl Int* (2001) 14:332
- 9:15 am **Public Comment**
- 9:35 am **Breakout Sessions: SACX Working Groups**
- 11:35 am **Plenary Progress Updates on Working Groups**
- 12:20 pm Break
- 12:40 pm **FDA Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and their Intimate Contacts**
Andrew Dayton, FDA/CBER
- 1:00 pm Q&A (for clarification purposes)
- 1:05 pm **Discussion**
- 1:50 pm **Closing Remarks**
Harold Vanderpool, SACX Chair
- 2:00 pm Meeting Closes