

***Pediatric Subcommittee***  
*of the*  
***Anti-Infective Drugs Advisory Committee***  
***Center for Drug Evaluation and Research, Food and Drug Administration***  
*ACS Conference Room, Room 1066, 5630 Fishers Lane, Rockville, MD*  
***April 24, 2001***

**AGENDA**

**Issue: Clinical Development of Products  
for Drooling in Neurologically Impaired Children**

- 8:00 a.m. Call to Order/Introductions**  
P. Joan Chesney, M.D., Chair, Pediatric Advisory Subcommittee
- Conflict of Interest Statement**  
Jayne E. Peterson, R.Ph., J.D., Subcommittee Executive Secretary
- 8:05 a.m. Welcome/Background Information and Overview**  
Dianne Murphy, M.D., Associate Director of Pediatrics, Center for Drug Evaluation and Research (CDER), FDA
- 8:10 a.m. Review of Meeting Agenda/Introduction to the Issues**  
John V. Kelsey, D.D.S., Clinical Team Leader, Division of Dermatologic and Dental Drug Products (DDDDP), FDA
- 8:20 a.m. Pharmacologic Control of Drooling**  
Lisa Mathis, M.D., Medical Officer, DDDDP, FDA
- 8:35 a.m. Questions from the Subcommittee**
- 8:45 a.m. Ethical Issues in Pediatric Research: Antimuscarinics to Control the Medical and Psychosocial Complications of Drooling**  
Benjamin Wilfond, M.D., Office of Bioethics and Special Populations Research, Department of Clinical Bioethics, National Institutes of Health (NIH)
- 9:00 a.m. The Medical/Surgical Management of Drooling**  
Maria Pena, M.D., Department of Otolaryngology, Children's National Medical Center
- 9:15 a.m. Assessment/Methods for Capturing Information from the Patient**  
Ross Hays, M.D., Children's Hospital, Seattle, Washington
- 9:30 a.m. Questions from the Subcommittee**

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**AGENDA (cont.)**

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- 9:40 a.m. American Academy of Pediatrics (AAP) Perspective**  
Scott Stiefel, M.D., Assistant Professor, Department of  
Pediatrics and Child and Adult Psychiatry, University of Utah
- 9:50 a.m. The Scope of the Problem**  
Murray Goldstein, D.O., Medical Director, United Cerebral Palsy Research and  
Educational Foundation
- 10:00 a.m. Parent/Caregiver Perspective**  
Ms. Belinda Hurlburt
- 10:10 a.m. Questions from the Subcommittee**
- 10:15 a.m. Break**
- 10:30 a.m. Open Public Hearing**  
(\*30 minutes allocated unless public participation does not last that long.)
- 11:00 a.m. Presentation of Issues**  
John V. Kelsey, D.D.S., DDDDP, FDA
- Subcommittee Discussion of Issues/Questions**
- 12:00 noon Lunch**
- 1:00 p.m. Continuation of Subcommittee Discussion of Issues/Questions**
- 2:50 p.m. Closing Remarks**  
Dianne Murphy, M.D.
- 3:00 p.m. Adjournment**