

***Pediatric Advisory Subcommittee***  
***A Subcommittee of the Anti-Infective Drugs Advisory Committee***  
***Food and Drug Administration***  
*Hyatt Hotel, SSSS Wisconsin Ave., Bethesda, MD*  
***September 11 and 12, 2000***

**DRAFT AGENDA**  
**September 11, 2000**

**Ethical and Neuropharm. Issues**

- 8:00 a.m. Call to Order/Introductions**  
P. Joan Chesney, M.D., Pediatric Advisory Subcommittee Chair
- Conflict of Interest Statement**  
Jayne E. Peterson, R.Ph., J.D., Executive Secretary
- 8:10 a.m. Welcome and Review of Meeting Agenda**
- Background Information and Overview**  
Dianne Murphy, M.D., Associate Director of Pediatrics, Center for Drug Evaluation and Research (CDER), FDA
- 8:25 a.m. Presentations/Discussion:**  
**Part I: The Ethics of Placebo-Controlled Clinical Trials in Children**
- (To be finalized closer to meeting dates)**
- 12:00 p.m. Lunch**
- 1:00 p.m. Open Public Hearing**  
(\*\*30 minutes allocated unless public participation does not last that long.)
- 1:30 p.m. Continuation of Ethics Discussion**
- 2:45 p.m. Break**
- 3:00 p.m. Part 2: A Proposed Approach to the Development of Psychotropic Drug Therapies for Pediatrics**
- (To be finalized closer to meeting dates)**
- 5:25 p.m. Closing Remarks**  
Dianne Murphy, M.D.
- 5:30 p.m. Adjourn**

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**September 12, 2000**

**Oncologic and Lactation Issues**

- 8:00 a.m. Call to Order/Introductions**  
P. Joan Chesney, M.D., Subcommittee Chair
- 8:05 a.m. Part 1: Oncology**
- 8:10 a.m. Introduction to the Food and Drug Administration Modernization Act (FDAMA)**
- 9:00 a.m. Pediatric Cancer Drug Development Issues**
- 10:00 a.m. Break**
- 10:15 a.m. Applicability of FDAMA to Pediatric Cancer Applications**
- 11:00 a.m. Overview of Pediatric Cancer Studies and Breakout**
- 12:30 a.m. Lunch**
- 1:30 p.m. Open Public Hearing**  
(\*\*30 minutes allocated unless public participation does not last that long.)
- 2:00 p.m. Pregnancy/Lactation Issues**
- 5:30 p.m. Adjourn**