Food and Drug Administration
Center for Drug Evaluation and Research

Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee (AIDAC)
in joint session with the
Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (ODAC)

Hyatt Regency, One Metro Center, Bethesda, Maryland

Agenda — September 12, 2000

8:00	Call to Order and Opening Remarks	P. Joan Chesney, M.D. Chair Pediatric Subcommittee of AIDAC
	Introduction of the Meeting Participants	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
8:15	Introduction to the Issues	Dianne Murphy, M.D. Associate Director of Pediatrics CDER, FDA
8:30	The Application of Evidence Based Medicine to Achieve Progress in Pediatric Oncology	Malcolm Smith, M.D., Ph.D. National Cancer Institute
9:10	Lessons and Challenges of Participation in Clinical Trials – A Family Perspective	Susan L. Weiner, Ph.D. The Children's Cause, Inc.
9:50	FDA Initiatives in Pediatric Oncology - Adaptation of the General Case to Special Circumstances	Richard Pazdur, M.D. Director Division of Oncology Drug Products CDER, FDA
10:05	Break	
10:15	Open Public Hearing (*60 minutes allocated unless public participation does not take that long*)	
11:15	Discussion	
12:00	Adjourn	

Question to the Committee

Special characteristics of pediatric oncology necessitated a more general drug development plan to qualify for the FDAMA pediatric exclusivity incentive. These characteristics are rarity of the diseases, life threatening natural history of the diseases, biological differences between adult and pediatric tumors, the existence of established cooperative groups, and research protocols as the standard of care. Are there other areas of pediatrics that have similar characteristics that may benefit from a similar approach?