

Joint Meeting of the Pediatric and Oncologic Drugs Advisory Committees

Topic: Scientific and ethical issues involved in developing drug treatments for children with diffuse pontine gliomas.

Location: Hilton Washington DC North/Gaithersburg
620 Perry Parkway, Gaithersburg, Maryland 20877

Draft Agenda for Monday, April 27, 2009
8:00 a.m. to 6:00 p.m.

8:00 a.m.	Call to Order, Introductions Meeting Statement	Marsha D. Rappley, MD, Chair Carlos Peña, PhD, MS Executive Secretary
8:20 a.m.	Welcome, Introduction to the Meeting, and Questions (20 min)	Robert M. Nelson, MD, PhD Pediatric Ethicist, Office of Pediatric Therapeutics, FDA
8:40 a.m.	Introduction to Presentations (5 min)	Marsha D. Rappley, MD, Chair
8:45 a.m.	Clinical Presentation (15 min)	Kenneth J. Cohen, MD, MBA
9:00 a.m.	Science Presentation (45 min)	Nicholas Foreman, MD
9:45 a.m.	Science Presentation (15 min)	Lisa M. McShane, PhD
10:00 a.m.	Clarifying Questions (15 min)	Advisory Committee Members
10:15 a.m.	Neurosurgical Risks (20 min)	Michael Handler, MD
10:35 a.m.	Clarifying Questions (10 min)	Advisory Committee Members
10:45 a.m.	Break (15 min)	
11:00 a.m.	Ethical Issues (40 min)	Steven Joffe, MD, MPH
11:40 a.m.	Parent Response (20 min)	Loice Anne Swisher, MD
12:00 p.m.	Clarifying Questions (15 min)	Advisory Committee Members
12:15 p.m.	Lunch (1 hr)	
1:15 p.m.	Open Public Hearing and Summary of Submitted Public Comments (1 hr)	Marsha D. Rappley, MD, Chair
2:15 p.m.	Presentation of Questions (5 min)	Robert M. Nelson, MD, PhD Pediatric Ethicist, Office of Pediatric Therapeutics, FDA
2:20 pm	Panel Discussion (1 hr)	Advisory Committee Members
3:20 p.m.	Break (15 min)	
3:35 p.m.	Panel Discussion (2 hrs)	Advisory Committee Members
5:30 p.m.	Summary of Advisory Committee Deliberations (30 min)	Marsha D. Rappley, MD, Chair
6:00 p.m.	Close	