Food and Drug Administration

Center for Drug Evaluation and Research

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Oncologic Drugs Advisory Committee

Quality of Life Subcommittee

Ramada Inn
Bethesda, Maryland

Tentative Agenda — February 10, 2000

8:00	Call to Order and Opening Remarks	David Cella, Ph.D. Chair, Quality of Life Subcommittee
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
8:15	Open Public Hearing	
	(Paula Simper) – Pancreatic Cancer Action Network Katherine Meade – National Prostate Cancer Coalition William Li – Angiogenesis Foundation Georgea Sacher – Colorectal Cancer Network Jan Maryak – American Federation for Urologic Diseases Nancy Roach – Colon Cancer Alliance Margaret Volpe – Clifton, Virginia (letter)	
8:45	ODAC perspective on the need for this subcommittee	Richard Schilsky, M.D. Chair, ODAC
9:00	Definitional issues across the continuum of patient-centered outcomes - Disease symptoms and treatment side effects - Function and well-being - Dimensions of health - Overall health-related quality of life/health status	Carol Moinpour, Ph.D. Presenter Donald Patrick, Ph.D., MSPH Discussant
10:00	Break	
10:15	Clinical significance/clinical interpretation - Meaningful change in group comparisons - Meaningful change in individual measurement - Clinical interpretability of questions and summary scores	Jeff A. Sloan, Ph.D. Presenter Stacy Nerenstone, M.D. Discussant
12:00	Lunch	
1:00	Open Public Hearing	
1:15	Data analysis - Handling missing data - Longitudinal modeling - Data aggregation/multiple comparisons	Diane Fairclough, Dr. P.H. Presenter Nan Laird, Ph.D. Discussant (by telecon)
2:45	Break	
3:00	Future Plans for the Subcommittee - When should one study HRQL?	David Cella, Ph.D.

- Study design
- Questionnaire validity and acceptable modifications
- Post-marketing and ancillary studies
- Reporting and labeling

4:00 Adjourn