

## Oncologic Drugs Advisory Committee Meeting

September 7, 2006

NDA 21-660 Abraxane (paclitaxel protein-bound particles for injectible suspension)

Abraxis Bioscience, Inc.

Hilton Washington DC/Silver Spring

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### Committee Members in Attendance

#### *Acting Chair*

**Maha H. A. Hussain, M.D., FACP**

Professor of Medicine and Urology  
Department of Internal Medicine and  
Urology

Division of Hematology/Oncology  
University of Michigan  
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**Ronald M. Bukowski, M.D.**

Director  
Experimental Therapeutics Program  
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**\*\*Antonio J. Grillo-Lopez, M.D.**

Retired  
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**David Harrington, Ph.D.**

Department of Biostatistics and  
Computational Biology  
Dana-Farber Cancer Institute  
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**\*Pamela J. Haylock, RN**

Oncology Consultant  
18954 State Highway 16 N.  
Medina, TX 78055

**Alexandra M. Levine, M.D.**

Medical Director  
USC/ Norris Cancer Hospital  
Division of Hematology  
1441 Eastlake Avenue  
Los Angeles, CA 90033

**Michael C. Perry, M.D.**

Director  
Division of Hematology/Medical Oncology  
University of Missouri  
Ellis Fischel Cancer Center  
115 Business Loop 70 West  
Columbia, MO 65203

**Maria Rodriguez, M.D.**

Chairman, Ad-Interim  
M.D. Anderson Cancer Center  
Department of Lymphoma/Myeloma  
1515 Holcombe, Box 429  
Houston, TX 77030

\* *Consumer Representative*

\*\* *Industry Representative (non-voting)*

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**Consultants for Abraxane**

**John Carpenter, M.D.**

Professor of Medicine  
Division of Hematology and Oncology  
University of Alabama at Birmingham  
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Birmingham, AL 35294

**Nancy Davidson, M.D.**

Professor of Oncology & Breast Cancer  
Research  
Chair in Oncology  
The Johns Hopkins University School of  
Medicine  
Johns Hopkins Oncology Center  
The Bunting/Blaustein Cancer Research  
Center  
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**Michael Link, M.D.**

The Lydia J. Lee Professor of Medicine  
Chief, Division of Hematology/Oncology  
Stanford University School of Medicine  
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**Gary Lyman, M.D.**

Professor of Medicine and Oncology  
University of Rochester School of  
Medicine and Dentistry  
Director, Health Services & Outcomes  
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**Richard Simon, D.Sc.**

Chief  
Biometric Research Branch  
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**Sandra Swain, M.D.**

Senior Investigator  
Medical Oncology Branch and Affiliates  
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**Jurgen Venitz, Ph.D.**

Associate Professor  
Virginia Commonwealth University School  
of Pharmacy  
Department of Pharmaceutics  
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**Patient Representative (voting):**

Natalie Compagni Portis, Oakland, CA

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**FDA Center for Drug Evaluation and Research Participants (non-voting)**

Richard Pazdur, M.D., Director, Office of Oncology Drug Products, CDER, FDA

Robert Justice, M.D., Deputy Director, Division of Drug Oncology Products, OODP, CDER,  
FDA

John R. Johnson, M.D., Medical Officer, Division of Drug Oncology Products, OODP, CDER,  
FDA

Patricia Cortazar, M.D., Medical Officer, Division of Drug Oncology Products, OODP, CDER,  
FDA

Brian Booth, Ph.D., Clinical pHarmacology Acting Team Leader for Oncology Drugs, Division  
of Clinical Pharmacology 5, Office of Clinical Pharmacology, CDER, FDA

Rajeshwari Sridhara, Ph.D., Statistical Team Leader for Oncology Drugs, Division of Biometrics  
V, Office of Biostatistics, CDER, FDA