

**NATIONAL CANCER INSTITUTE-INDUSTRY FORUM
ON BIOMEDICAL IMAGING IN ONCOLOGY
The Madison Hotel -- Washington, DC
September 1, 1999**

- 8:30 AM - 8:45 AM **Opening Welcome, Purpose of Forum**
Dr. Ellen Feigal, Deputy Director, Division of Cancer Treatment and
Diagnosis (DCTD), National Cancer Institute (NCI)
Mr. Morgan Nields, Chairman and CEO, Fischer Imaging Corporation
- 8:45 AM - 9:15 AM **Vision of Cancer, From a Molecular, Cell Biology Perspective:
Integration With Imaging**
Dr. Richard Klausner, Director, NCI
- 9:15 AM - 9:45 AM **Clinical Overview: Types of Scientific Questions, Opportunities and
Challenges That Might Benefit From Interaction With
Non-Invasive Imaging**
Dr. Robert Wittes, Deputy Director, Extramural Sciences and Director,
DCTD, NCI
- 9:45 AM - 10:00 AM **Break**
- 10:00 AM - 10:10 AM **NCI Initiatives in Imaging**
Dr. Daniel Sullivan, Associate Director, Diagnostic Imaging Program, NCI
- 10:10 AM - 12:40 AM **TECHNOLOGY ADVANCES AND FUTURE DIRECTIONS**
Moderator: Dr. James Anderson, Director of Radiology Research, Johns
Hopkins School of Medicine
- 10:10 AM - 10:35 AM **Therapy: Challenges for Imaging Sciences**
Dr. Thomas Brady, Professor of Radiology, Massachusetts
General Hospital
- 10:35 AM - 11:00 AM **Functional Imaging**
Dr. Thomas Budinger, Chairman of Bioengineering,
University of California at Berkeley and Head, Center for
Functional Imaging, Lawrence Berkeley National Laboratory
- 11:00 AM - 11:25 AM **Imaging at the Molecular-cellular Level**
Dr. Thomas Meade, Director, Program for Bioinorganic
Drug Design and Discovery, California Institute of

Technology

11:25 AM - 11:50 AM **PET Imaging in Oncology**
Dr. R. Edward Coleman, Director of Nuclear Medicine and
Vice Chairman, Department of Radiology, Duke University

11:50 AM - 12:15 PM **Biomedical Imaging**
Dr. Michael Phelps, Chair of Molecular and Medical
Pharmacology, and Director, Crump Institute for Biological
Imaging and Associate Director, Laboratory of Structural
Biology and Molecular Medicine, University of California,
Los Angeles

12:15 PM - 12:40 PM **Image Guided Diagnosis and Therapy: Future
Directions**
Dr. James Anderson, Director of Radiology Research,
Johns Hopkins School of Medicine

12:40 PM -2:00 PM **Lunch** (on your own)

2:00 PM - 5:15 PM **CASE STUDIES**

Case Studies will address either a critical medical problem, or a technology-oriented challenge. After each case presentation, panelists representing expertise from imaging, clinical oncology, FDA, HCFA, and NEMA will discuss their approaches and perspectives, and what they see as the critical issues in imaging, regulatory, reimbursement/coverage.

2:00 PM - 3:30 PM **Case Study #1: Pre-Invasive and Invasive Prostate Cancer**

Moderator: Dr. Peter Scardino, Chief, Urology Service and
Head, Prostate Cancer Program, Memorial Sloan-Kettering
Cancer Center

Panelists: Dr. Susan Alpert, Director of Device Evaluation,
Center for Devices and Radiological Health, FDA; Dr. Grant
Bagley, Director of Coverage and Analysis Group, Office of
Clinical Standards and Quality, HCFA; Dr. Anthony D'Amico,
Assistant Professor of Radiation Oncology, Harvard Medical
School; Dr. Bruce Hillman, Professor and Chair of Radiology,

University of Virginia; Dr. Patrick Loehrer, Professor of Medicine, University of Indiana; Dr. Patricia Love, Director, Division of Medical Imaging and Radiopharmaceuticals Drug Products, Center for Drug Evaluation and Research, FDA; Mr. Thomas Miller, President and CEO, Carl Zeiss, Inc.; Dr. Sarah Nelson, Associate Professor of Radiology and Engineering, University of California, San Francisco; Dr. Derek Raghavan, Professor of Medicine, University of Southern California

This disease-oriented case study will be a multidisciplinary presentation, with major emphases addressing key staging issues surrounding selection of patients for initial therapy, e.g., how to identify which types of patients might benefit from surgery for early invasive disease, or which patients might be appropriate for a therapeutic intervention trial for non-invasive disease; identify physiologic and molecular characteristics that could be integrated with staging; use of sophisticated non-invasive technologies for assaying surrogates of response, or drug uptake and targeting. Subsequent panel discussion will primarily focus on scientific issues and technology development.

3:30 PM - 3:45 PM **Break**

3:45 PM - 5:15 PM **Case Study #2: Positron Emission Tomography in the Staging of Cancer**

Session Moderator: Dr. E. James Potchen, Chairperson, Department of Radiology, Michigan State University

Panelists: Dr. Susan Alpert, Director of Device Evaluation, Center for Devices and Radiological Health, FDA; Dr. Jane Axelrad, Associate Director for Policy, Center for Drugs, FDA; Dr. R. Edward Coleman, Director of Nuclear Medicine and Vice Chairman, Department of Radiology, Duke University; Dr. Jeffrey Kang, Director of Clinical Standards and Quality, HCFA; Dr. Patricia Love, Director of Medical Imaging, FDA; Dr. W. Fred Lucas, President, Lucas Medical Associates, Inc.; Dr. Michael Phelps, Chair of Molecular and Medical Pharmacology, and Director, Crump Institute for Biological Imaging and Associate Director, Laboratory of Structural Biology and Molecular Medicine, University of California, Los Angeles; Dr. Barry Siegel, Director of Nuclear Medicine, Mallinckrodt Institute of Radiology

This technology-oriented case study presentation's major objective is to determine how to assess the value of a new imaging approach. The study will illustrate with a real device the different issues that come into play, e.g., biomedical opportunities and challenges, technology issues, regulatory and reimbursement and coverage issues. PET data in several cancers will be presented, and the subsequent panel discussion will have a major focus on regulatory and reimbursement/coverage issues. For example, how do they value PET? Issues for the clinician: is it clinically relevant? Does this technology solve a problem (s)? Does this technology allow for "one stop shopping" or does it add to other methods? For the health care provider, issues might include: is it better? Cheaper? Faster? For the FDA, is the evidence sufficient to show safety and efficacy?

5:15 PM **Summary/Discussion of Forum Issues**

Dr. Michael Vannier, Professor and Chair, Radiology, University of Iowa

Dr. R. Edward Coleman, Director of Nuclear Medicine and Vice Chairman,
Department of Radiology, Duke University

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