NCCS CANCER POLICY ROUNDTABLE
Fairmont Hotel, Washington, DC
April 9-10, 2014

WEDNESDAY, APRIL 9

8:00 to 8:45 a.m.
Breakfast

8:45 to 9:00 a.m.
Welcome and Introductions

9:00 to 11:00 a.m.
Affordable Care Act: Enrollment Update and Adequacy of Exchange Plans for Cancer Patients

The enrollment period for the first year of the Affordable Care Act exchange plans will end in March, by which time many individuals will be enrolled in new insurance plans offered through the exchanges. Although newly insured individuals will not by this time have full utilized and tested their insurance coverage, consumer advocates and other parties will have learned more about the adequacy of exchange plans.

This session will feature speakers providing updates on enrollment in Medicaid and exchange plans to date and speakers evaluating problems related to enrollment. This panel will also discuss the available data regarding exchange plan benefits, directing special attention to network scope and adequacy and prescription drug coverage and the impact of exchange plan coverage on cancer patients and their access to quality care.

Tanisha Carino, PhD
Executive Vice President
Avalere Health

Emily Mueller, MD
Child Health Evaluation and Research Unit
University of Michigan

Sophie Stern, MPH
Deputy Director, Best Practices Institute
Enroll America

JoAnn Volk, MA
Senior Research Fellow and Project Director
Center on Health Insurance Reforms
Georgetown University Health Policy Institute

11:00 to 11:30 a.m.
Break

11:30 a.m. to 1:00 p.m.
Targeted Therapies: Encouraging Regulatory and Treatment Strategies that will Ensure Patient Access

FDA has articulated standards for the co-development drugs and diagnostics, and pharmaceutical and device companies have partnered to develop drugs and companion diagnostics. Some now suggest that the utility of tests that identify a single molecular marker may be increasingly limited. Instead, they recommend that "multi-plex" tests to identify multiple molecular markers or next-gen sequencing may be more useful in targeting new cancer treatments and guiding overall treatment options. However, the regulatory pathways for those new diagnostics are unclear.

In addition to challenges related to development and regulatory review of diagnostics, there are some indications that patients who should be evaluated for treatment with targeted therapies are not in fact not undergoing such testing. And even when the appropriate diagnostic is utilized, questions may arise about third-party reimbursement for the test. All of these issues combine to create obstacles to the development and utilization of diagnostics that guide targeted therapies.

This panel will discuss the best diagnostic tools for the delivery of targeted, or personalized, treatment; the appropriate regulatory standards for review of these diagnostic tools; reforms to the cancer care system to ensure patient access to molecular diagnostics and targeted therapies; and changes to the reimbursement system to ensure the use of the appropriate diagnostic for each patient's care.

John Cox, OD, FACP, FASCO
Texas Oncology
Editor, *Journal of Oncology Practice*

Andrew Fish, JD
Executive Director
AdvaMed DX

Alberto Gutierrez, PhD
Director, Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
Food and Drug Administration

Gail H. Vance, MD
Professor of Medical & Molecular Genetics

Director of Indiana Familial Cancer Program
Indiana University

1:00 to 2:30 p.m.
Lunch

2:30 to 4:30 p.m.
Bundles or Episodes of Care: Are These Payment Models Workable for Cancer Care?

Congress may by March 2014 have approved physician payment reform legislation that encourages the development of alternative systems for physician payment that move away from the volume-based fee-for-service system. If Congress approves such legislation, it would not dictate the alternative models but would leave development of such models to physician groups and health care systems. Many cancer care interests are already considering and even implementing alternative systems of care and payment. This session will include speakers who will describe development of models for cancer care bundles and episodes of cancer care and the feasibility of their implementation.

Emily Oshima Lee, MA
Policy Analyst
Center for American Progress

John O'Shea, MD, MPA, FACS
Research Fellow
Engelberg Center for Health Care Reform
Brookings Institution

Steve Spaulding
Senior Vice President of Enterprise Networks
Arkansas BlueCross BlueShield

John Sprandio, MD
Chief of Medical Oncology and Hematology
Consultants in Medical Oncology and Hematology

Peter Yu, MD, FASCO
President-Elect, American Society of Clinical Oncology

4:30 p.m.
Reception

THURSDAY, APRIL 10

8:00 to 8:30 a.m.
Breakfast

8:30 to 9:30 a.m.
Balancing Risk and Benefit in Cancer Drugs

Marketing and sales of a recently approved cancer drug have been suspended as a result of serious adverse events that were not detected in clinical trials. The sponsor agreed to the suspension of sales while it investigated the adverse events further, and that investigation led to a decision to permit access in certain circumstances. Using this recent withdrawal as a point of departure, this panel will consider the challenges of evaluating adverse events of new therapies, assessing benefits compared to risks, and making decisions about permitting access to drugs in the face of risks.

Ann Farrell, MD
Director, Division of Hematology Products
Office of Hematology and Oncology Products
Food and Drug Administration

Beth Galliart
Co-Founder, Iclusig Patient Group

9:30 to 11:30 a.m.
Getting New Medicines to Patients Faster: Innovative Approaches

Cancer researchers in academia, private foundations, and the biopharmaceutical industry are pioneering new approaches to the development of new cancer therapies. These innovators are pursuing strategies to make the drug development process more efficient and to bring promising new medicines to patients faster. This panel will include speakers who will discuss adaptive trial design, innovative public-private research partnerships, development of drugs in the neoadjuvant setting, and other approaches to speed the cancer drug development process.

Peter C. Adamson, MD
Chair, Children's Oncology Group
Chief, Division of Clinical Pharmacology & Therapeutics
The Children's Hospital of Philadelphia

Bob Erwin
Marti Nelson Cancer Foundation

Angela DeMichele, MD, MSCE
Jill and Alan Miller Associate Professor in Breast Cancer Excellence
Abramson Cancer Center
University of Pennsylvania

Gregory Reaman, MD
Office of Hematology and Oncology Products
Food and Drug Administration

Wendy K.D. Selig, MS
President & Chief Executive Officer
Melanoma Research Alliance