

National Cancer Policy Forum Workshop
Institute of Medicine
July 12–13, 2010

The Liaison Capitol Hill Hotel
"The Hill" Conference Room
415 New Jersey Avenue NW
Washington, DC 20001

DAY 1 - July 12

8:30 am Breakfast Available

9:00 am Welcome
Edward Benz, planning committee chair, *Dana Farber Cancer Institute*

Session 1 – Introduction to Nanotechnology and Nanomedicine

Moderator: Edward Benz, Dana Farber Cancer Institute

9:15 am **Historical View of Nanotechnology and Nanomedicine**
Mauro Ferrari, *University of Texas Health Science Center – Houston*

9:45 am **The NCI Nanotechnology Alliance for Cancer:
Making Personalized Cancer Medicine a Reality**
Anna Barker, *National Cancer Institute*

10:15 am BREAK

10:30 am **Cancer Nanotechnology Beyond the NCI**
Steven Curley, *M.D. Anderson Cancer Center*

Session 2 – Clinical Research and Translational Science – Accommodating and Enabling
Nanotechnology

Moderator: Steven Curley, M.D. Anderson Cancer Center

Each speaker is asked to comment on the flow of translational research:

- What does a clinical investigator planning trials incorporating nanotechnology need to know?
- What will it take to get there?

Clinical Research Perspective

Speakers are asked to address the following questions:

- What do clinical researchers need to know about nanotechnology?
- What tests must nano-materials themselves undergo?
- What are potential and known risks with use of nanotechnology and how are unknowns being addressed?
- Are there real advantages to nanotechnology (as diagnostics, screening tools, therapeutics, etc.)?

11:00 am **Nanoparticles as Therapeutic Platforms**
Steve Libutti, *Albert Einstein School of Medicine*

11:30 am **Biologic Barriers to In Vivo Nanomedicine Delivery: Major Hurdles for Clinical
Translation**

King Li, *The Methodist Hospital Research Institute*

12:00 pm LUNCH

Industry Perspective

Speakers are asked to address the following questions:

- How are companies thinking about moving nanotechnology products through the pipeline from proof of concept to development for clinical trials?
- What is the current state of preclinical studies in testing efficacy and toxicity?
- What are the long-term effects of these incredibly stable products?
- Is it known what happens in degradation processes?

1:00 pm **The nab-Platform: From Bench to the Clinic and Beyond**

Neil Desai, Abraxis Biosciences

Preventive Medicine Perspective

Speakers are asked to address the following questions:

- What issues, opportunities, and known efforts exist within this domain?
- What challenges and unique enhancements does nanotechnology provide in this area?
- How can nanotechnology be used to improve health (i.e., through environmental remediation or to make safer foods, etc.)?

1:30 pm **Nanotechnology and Cancer Prevention**

Ernie Hawk, M.D. Anderson Cancer Institute

Diagnostics and Therapeutics Discovery and Development Perspective

Speakers are asked to address the following questions:

- What issues, opportunities, and known efforts exist within this domain?
- What challenges and unique enhancements does nanotechnology provide in this area?

2:00 pm **Opportunities for Reproducibility and Uniformity of Therapeutics and Vaccines Using
Templated Nanomanufacturing Methods**

Joseph DeSimone, University of North Carolina

2:30 pm **Jim Heath, California Institute of Technology**

3:00 pm BREAK

Radiology and Laboratory Medicine Perspective

Speakers are asked to address the following questions:

- What issues, opportunities, and known efforts exist within this domain?
- What challenges and unique enhancements does nanotechnology provide in this area?

3:15 pm **Microfluidic Approaches for Single Cell Analysis**

Scott Manalis, Massachusetts Institute of Technology

3:45 pm **Magnetic Nanoparticles & MR: From Contrast Agents to Assays to Sensors**

Lee Josephson, Harvard University

4:15 pm **Panel Discussion – Ideas for making progress in the next 2, 10, and 20 years**
All session speakers

4:45 pm Adjourn until Tuesday

DAY 2, July 13:

8:00 am Breakfast Available

8:20 am Welcome Back

Session 3 – Government Research Initiatives, Regulation, and International Standards

Moderator: Mauro Ferrari, University of Texas Health Science Center – Houston

Government Research Initiatives

Speaker is asked to address the following questions:

- Describe the role of the NCL and how it may evolve over the next 10 years
- Describe some challenges overcome and current challenges facing the laboratory
- How do these lessons extend to other government research initiatives?

8:30 am **NCI's Nanotechnology Characterization Lab: Lessons Learned and Future**

Directions

Scott McNeil, Nanotechnology Characterization Laboratory

9:00 am **Discussion** with Scott McNeil, Piotr Grodzinski, Mauro Ferrari, and Anna Barker

International Standards: Cooperative Research and Regulation: Lessons and Challenges

Speakers are asked to address the following questions:

- What lessons can US regulators learn from regulation of nanotechnology in other countries?
- What policies support cooperative research internationally?
- What policies support product development and regulation internationally?

9:30 am **Crossroad of Nanomedicine: Nanosafety and Policy**

Yuliang Zhao, Chinese Academy of Sciences, and Research Center for Cancer Nanotechnology

10:00 am **BREAK**

10:15 am Successful Transfer of Innovative Technologies from Lab-Patient-Routine Use: Lessons Learnt and Global Opportunities

Ruth Duncan, Cardiff, UK

10:45 am Nanomedicines Challenges and Opportunities in a Global Development Environment

Rogerio Gaspar, Research Institute for Medicines and Pharmaceutical Sciences

11:15 am **Discussion**

11:30 am **WORKING LUNCH (boxed lunches available)**

Regulatory Challenges and Safety

Speakers are asked to address the following questions:

- What are regulators looking for?
- How is nanotechnology being handled?
- What concerns do the public have and how are they best addressed?

11:45 am **Kristen Kulinowski, Rice University**

12:15 pm **Jonathan Sackner-Bernstein**, *Food and Drug Administration*

12:45 pm Discussion

Workshop Wrap-up

1:00 pm *Moderator: Mauro Ferrari, University of Texas Health Science Center - Houston*

1:15 pm Adjourn