NIH SCIENTIFIC MANAGEMENT REVIEW BOARD

Conference Room 6, C Wing, 6th Floor
Building 31, NIH Campus

September 14-15, 2010

DRAFT AGENDA AT A GLANCE

DAY 1	8:00-8:15	• *Opening Remarks, Agenda Overview, and Approval of May Meeting Minutes* • *Review of NIH Conflict of Interest Policy*
	NIH INTRAMURAL RESEARCH PROGRAM	
	8:15-9:40	• *Presentation of Recommendations* • *Discussion* • *Public Comments* • *SMRB Vote on Recommendations and Report*
	TRANSLATIONAL MEDICINE AND THERAPEUTICS	
	Session I 9:40-12:30	• *Overview of TMAT Working Group Charge* • *New Paradigm Opportunities for Translational Medicine and Therapeutics Discovery: Establishing a Role for NIH* • *Panel Discussion*
	Session II 1:00-4:45	• *Bridging the Gap: Defining and Understanding the Necessary NIH Capabilities and Infrastructure* • *Panel Discussion* • *Public Comments*
DAY 2	8:00-8:05	• *Opening Remarks and Agenda Overview*
	Session III 8:05-9:45	• *Cultivating Partnerships: Setting Goals and Defining Success* • *Panel Discussion*
	Session IV 10:00-11:30	• *Engaging in a Dialogue With the Public* • *Panel Discussion*
	SUBSTANCE USE, ABUSE, AND ADDICTION	
	12:15-2:00	• *Presentation of Recommendations* • *Discussion* • *Public Comments* • *SMRB Vote on Recommendations and Report*

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DRAFT AGENDA — DAY 1

8:00 AM **Opening Remarks, Agenda Overview, and Approval of the May 18-19, 2010, Meeting Minutes**
Norman R. Augustine
Chair, Scientific Management Review Board

8:10 AM **Review of NIH Conflict of Interest Policy**
Amy P. Patterson, M.D.
Executive Secretary, Scientific Management Review Board

NIH INTRAMURAL RESEARCH PROGRAM

8:15 AM **Presentation of the IRP Working Group's Recommendations on the Fiscal Sustainability and Utilization of the NIH Clinical Center**
Arthur H. Rubenstein, M.B.B.Ch.
Chair, NIH Intramural Research Program Working Group

8:35 AM **Discussion**
SMRB Members

9:05 AM **Public Comments**

9:20 AM **SMRB Vote on IRP Working Group Recommendations and Report**

- Arthur H. Rubenstein, M.B.B.Ch.
  Chair, NIH Intramural Research Program Working Group
- Norman R. Augustine
  Chair, Scientific Management Review Board

TRANSLATIONAL MEDICINE AND THERAPEUTICS

9:40 AM **Overview of Translational Medicine and Therapeutics (TMAT) Working Group Charge**
Arthur H. Rubenstein, M.B.B.Ch.
Chair, Translational Medicine and Therapeutics Working Group

SESSION I

New Paradigm Opportunities for Translational Medicine and Therapeutics Discovery: Establishing a Role for NIH

This session explores the evolving landscape of translational medicine and therapeutics development. Particular attention will be paid to potential opportunities for creating new paradigms to enable a faster pace of discovery. Plenary presentations will discuss current trends and future directions in therapeutics development. Further discussion will focus on a potential role for NIH in re-engineering the translational medicine enterprise, with perspectives from both the public and private sectors.

9:50 AM **Current Landscape of Drug Discovery and Opportunities for New Paradigms**
Charles Baum, M.D., Ph.D.
Senior Vice President for Clinical Programs, Pfizer Inc.

10:20 AM **Regulatory Perspectives on the Changing Landscape in Therapeutics Development**
TBD
U.S. Food and Drug Administration

10:50 AM ***Break***

11:05 AM **Panel Discussion**

- **Moderators:**
  - Stephen I. Katz, M.D., Ph.D., *SMRB Member*
  - William R. Brody, M.D., Ph.D., *SMRB Member*
- **Panelists:**
  - Franklin M. Berger, C.F.A., *FMB Research*
  - Ken Duncan, Ph.D., *Bill and Melinda Gates Foundation*
  - Garrett A. FitzGerald, M.D., *University of Pennsylvania School of Medicine*
  - Eric D. Perakslis, Ph.D., *Johnson & Johnson*
  - Mary Woolley, *Research!America*

SESSION I — Discussion Questions

- *What are the desirable attributes of a new paradigm for drug discovery? In what way do these differ from the status quo?*
- *What functions should a new paradigm enable to best capitalize on current opportunities? What functions would be necessary to surmount current obstacles?*
- *What is needed to catalyze, implement, and sustain a new paradigm?*
- *What role should NIH serve in incentivizing participation in a new paradigm?*
- *How can NIH most effectively contribute to the success of this new paradigm? How can the Agency accelerate progress while minimizing redundancy?*

12:30 PM ***Break for Working Lunch***

SESSION II

Bridging the Gap: Defining and Understanding the Necessary NIH Capabilities and Infrastructure

This session explores, in more detail, the role NIH should serve in catalyzing, incentivizing, and sustaining a new paradigm for accelerating translational medicine and therapeutics development. Initial discussion will focus on lessons learned from Academic Health Centers and extant Agency efforts in this arena, including perspectives from both the intra- and extramural communities regarding lessons learned and future needs. Further discussion will explore the necessary activities and functional capabilities of a federal program designed to accelerate therapeutics discovery — including the relevant infrastructure required for supporting this new paradigm.

1:00 PM **Identifying a Role for NIH: Lessons Learned From Academic Health Centers**

- Garret A. FitzGerald, M.D.
  McNeil Professor in Translational Medicine and Therapeutics; Associate Dean for Translational Research; Chair, Department of Pharmacology; Director, Institute for Translational Medicine and Therapeutics, University of Pennsylvania
- Mary L. Disis, M.D., F.A.C.P.
  Co-chair of T1 Translational Research Strategic Goal Committee, Clinical and Translational Science Awards, University of Washington

1:40 PM **NIH Resources and Programs for a New Paradigm**

- James H. Doroshow, M.D.
  Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, NIH
- Susan E. Old, Ph.D.
  Deputy Director, Therapeutics for Rare and Neglected Diseases Program, NIH
- Thomas Miller, Ph.D., M.B.A.
  Program Director, Office of Translational Research, National Institute of Neurological Disorders and Stroke, NIH
- Michael G. Kurilla, M.D., Ph.D.
  Director, Office of BioDefense Research Affairs, National Institute of Allergy and Infectious Diseases, NIH
- John I. Gallin, M.D.
  Director, NIH Clinical Center

2:40 PM ***Break***

2:55 PM **Panel Discussion**

- **Moderators:**

- Griffin P. Rodgers, M.D., M.A.C.P., *SMRB Member*
- William L. Roper, M.D., M.P.H., *SMRB Member*

- **Panelists:**
  - Raymond C. Bergan, M.D., *Northwestern University*
  - Robert M. Califf, M.D., *Duke University Medical Center*
  - Brian K. Halak, Ph.D., *Domain Associates*
  - Thomas R. Insel, M.D., *National Institute of Mental Health*
  - William Matthew, Ph.D., *National Institute for Neurological Disorders and Stroke*

SESSION II — Discussion Questions

- *What lessons learned from academic drug discovery units can be extrapolated to improve Agency efforts in this arena?*
- *What does NIH need to accomplish to both facilitate and engage a new paradigm for therapeutics development? On which activities should NIH focus? What current NIH activities (both intramural and extramural) are best leveraged for advancing therapeutics development?*
- *What are the specific resources that the Agency should develop and/or support to maximize external participation in a new paradigm? In particular, what can NIH develop and/or support in order to facilitate success of academic health centers?*
- *What resources, tools, and infrastructure does NIH need to develop internally to enable and maximize the Agency's participation in the therapeutics development enterprise?*

4:15 PM **Public Comments**

4:45 PM **Closing Remarks**
Norman R. Augustine
Chair, Scientific Management Review Board

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DRAFT AGENDA — DAY 2

8:00 AM **Opening Remarks and Agenda Overview**
Norman R. Augustine
Chair, Scientific Management Review Board

TRANSLATIONAL MEDICINE AND THERAPEUTICS

SESSION III

Cultivating Partnerships: Setting Goals and Defining Success

This session will explore the defining features of a successful partnership, with a particular emphasis on establishing metrics and defining goals. Initial discussion will focus on lessons learned from existing partnerships between the public and private sectors regarding priority-setting, decision-making, and intellectual property agreements.

8:05 AM **Setting Goals and Defining Success: Lessons Learned From Public-Private Partnerships**
Stephen L. Eck, M.D., Ph.D.
Vice President, Translational Medicine and Pharmacogenomics, Eli Lilly and Co.

8:35 AM **Panel Discussion**

- **Moderators**:
  - Richard J. Hodes, M.D., *SMRB Member*
  - A. Eugene Washington, M.D., M.Sc., *SMRB Member*
- **Panelists:**
  - Charles Baum, M.D., Ph.D., *Pfizer Inc.*
  - Ken Duncan, Ph.D., *Bill and Melinda Gates Foundation*
  - Brian K. Halak, Ph.D., *Domain Associates*
  - Thomas R. Insel, M.D., *National Institute of Mental Health*
  - Jean-Pierre Paccaud, Ph.D., *Drugs for Neglected Diseases Initiative*
  - Eric D. Perakslis, Ph.D., *Johnson & Johnson*

SESSION III — Discussion Questions

- *What attributes are key to the formation and sustention of a successful partnership?*
- *In reference to existing partnerships:*
  - *How was success for each partner defined?*
  - *How were the expectations and responsibilities of each partner negotiated?*
  - *How were appropriate benchmarks for each partner determined?*
- *In reference to NIH, what are appropriate metrics for success?*
- *How should decisions be made in selecting and prioritizing projects? What factors need to be taken into consideration?*
- *What have been the successes of public-private partnerships? What hurdles have been encountered in realizing the potential of these partnerships?*

9:45 AM ***Break***

SESSION IV

Engaging in a Dialogue With the Public

This session will explore the opportunities and needs for public engagement in reshaping and sustaining the translational medicine enterprise. Discussion will address potential strategies for soliciting and incorporating public input in decision-making and priority-setting processes, methods for communicating with the public regarding research in this area (including communicating about progress as well as the inherent high-risk nature of the research), and the important elements of public expectations and transparency.

10:00 AM **Soliciting Input and Facilitating Outreach**
Jeff Allen, M.D.
Executive Director, Friends of Cancer Research

10:20 AM **Panel Discussion**

- **Moderators:**
  - Norman R. Augustine, *SMRB Chair*
  - Anthony S. Fauci, M.D., *SMRB Member*
- **Panelists:**
  - Margaret A. Anderson, *FasterCures*
  - Ken Duncan, Ph.D., *Bill and Melinda Gates Foundation*
  - Jean-Pierre Paccaud, Ph.D., *Drugs for Neglected Diseases Initiative*
  - Amy Comstock Rick, J.D., *Parkinson's Action Network*
  - Steven M. Rowe, M.D., M.S.P.H., *University of Alabama at Birmingham; Cystic Fibrosis Foundation*
  - Gregory C. Simon, J.D., *Pfizer Inc.*

SESSION IV — Discussion Questions

Recent scientific discoveries and technological innovations have generated an unprecedented window of opportunity for accelerating the development of new therapeutics.

- *How will patients, the public, and Congress interpret and respond to a focused, agencywide effort to accelerate the discovery of new therapeutics?*
- *How can the Agency enhance communication with diverse stakeholders to convey both the risk and opportunity?*
- *How can NIH effectively solicit and incorporate public input to establish tangible goals and obtainable priorities?*
- *Will increasing government participation alter patient and consumer perceptions regarding timeliness, access, and/or cost?If so, how could such expectations be addressed?*
- *How can the Agency convey the importance and necessity of participating in novel partnerships between, for example, the public and private sectors to advance therapeutics development?*

11:30 AM ***Break for Lunch***

SUBSTANCE USE, ABUSE, AND ADDICTION

12:15 PM **Presentation of the SUAA Working Group's Recommendations on the Optimal Organization of SUAA Research at NIH**
William L. Roper, M.D., M.P.H.
Chair, Substance Use, Abuse, and Addiction Working Group

12:35 PM **Discussion**
SMRB Members

1:15 PM **Public Comments**

1:45 PM **SMRB Vote on SUAA Working Group Recommendations and Report**

- William L. Roper, M.D., M.P.H.
  Chair, Substance Use, Abuse, and Addiction Working Group
- Norman R. Augustine
  Chair, Scientific Management Review Board

2:00 PM **Closing Remarks and Adjournment**
Norman R. Augustine
Chair, Scientific Management Review Board