BOARD ON HEALTH SCIENCES POLICY

Forum on Neuroscience and Nervous System Disorders

2010 Annual Report







INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

Advising the nation • Improving health

About the Neuroscience Forum

The IOM in 2006 established the Forum on Neuroscience and Nervous System Disorders. The Forum is designed to provide its members with a neutral venue for exchanging information, sharing individual views, and allowing a structured opportunity for dialogue and discussion while scrutinizing critical and possibly contentious scientific and policy issues. Representatives from government, industry, academia, patient advocacy organizations, and other interested parties serve as Forum members. It convenes three times a year to confer on subject areas of mutual interest and concern. At its meetings, the Forum identifies and discusses emerging scientific and policy issues related to basic neuroscience and nervous system disorders, as well as effective clinical interventions and policy options. The Forum also sponsors workshops (symposia) as an additional mechanism for informing the membership of the Forum, other relevant stakeholders, and the public. Information about past or upcoming meetings is available at the Forum's website, www.iom.edu/neuroforum.

About the Institute of Medicine

The Institute of Medicine serves as adviser to the nation to improve health. Established in 1970 under the charter of the National Academy of Sciences, the Institute of Medicine provides independent, objective, evidence-based advice to policymakers, health professionals, the private sector, and the public. The mission of the Institute of Medicine embraces the health of people everywhere.



Message from the Chair

The Institute of Medicine (IOM) established the Forum on Neuroscience and Nervous System Disorders to provide a venue through which neuroscience leaders from private sector sponsors and users of biomedical and clinical research, federal agencies sponsoring and regulating research, private foundations, the academic community, and other consumers could consider critical issues and how they might be dealt with.

Discussions in 2010 have focused on a diverse array of topics, including the implications of recent cutbacks by top pharmaceutical companies in drug development for central nervous system disorders, and great opportunities for the field, including Patrick Kennedy's "Moon shot" effort to increase the funding and coordination of neuroscience research.

With an agenda set by the members, the Forum undertook a variety of initiatives to address these challenges and opportunities. Looking ahead to 2011, the Forum plans to host an array of activities, including workshops examining such topics as:

- Public-Private Partnerships in CNS Research and Development
- US and European Animal-research Regulations: Impact on Neuroscience Research
- Follow-up to the 2009 Sub-Saharan Africa Quality of Care Workshop
- Animal Models of Nervous System Disorders

We look forward to another productive and interesting year for the Forum.

Alan Leshner

Chair

Reflecting Back

Forum Activities in 2010

Sex Differences and Implications for Translational Neuroscience Research

The Forum hosted a workshop to explore the key principles and strategies used by basic translational researchers and industry in studying sex differences in the neurosciences for the therapy development pathway. Basic research that involves delineating meaningful drug effects and behavioral and physiological responses that differ between the sexes can be costly and time consuming because they require additional experiment groups and protocols. However, epidemiological and clinical studies indicate substantial sex differences in response to drugs. The sex differences cut across other parameters such as socioeconomic factors, race, age, etc. In the current era of translational research and personalized medicine, it is increasingly important to take sex differences into account, so that these drug effects can be more accurately understood. Report available for download.

Glutamate-related Biomarkers for Disorders of the Nervous System

In June, the Forum hosted a workshop that explored current and emerging technologies with potential as reliable glutamate biomarkers to advance drug development for nervous system disorders. Present medications, while advanced over initial compounds, nevertheless provide unsatisfactory treatment for individuals with a range of central nervous system disorders with persistent negative symptoms, significant cognitive deficits, and poor function. Biomarkers that specifically measure glutamate signaling and related circuitry are a promising means to accelerate drug development by providing quantitative measures for diagnosis, patient stratification, and assessment of drug efficacy. The workshop also outlined strategies to accelerate development, validation, and implementation of these biomarkers. Report available for download.

Future Opportunities to Leverage the Alzheimer's Disease Neuroimaging Initiative

In July, the Forum hosted a public workshop at the 2010 International Conference on Alzheimer's Disease (ICAD), which was designed to explore future opportunities to leverage the Alzheimer's Disease Neuroimaging Initiative (ADNI), with particular focus on the second phase of the ADNI project, ADNI 2. Panelists from industry, academia, and government examined the key elements of success of the research partnerships established as a result of ADNI. Included in the workshop were presentations outlining current efforts by the Japanese, European, and Australian ADNI projects. Discussions focused on the establishment of future multi-sector efforts to explore central nervous system developmental and neurodegenerative disorders. Report available for download.

Facilitating Translational Research for Clinical Neuroscience Applications

Throughout 2010, individuals from pharmaceutical and diagnostic industry, academia, and the NIH have joined members of the Forum in meetings on facilitating translational research for clinical neuroscience applications. The meetings stimulated discussion aimed at improving the understanding between what pharmaceutical and diagnostic developers are looking for and how academic researchers can best contribute to the partnership in a meaningful way in order to improve the neuroscience translational research pipeline. Discussions focused on ways to bridge the interface between basic and drug/diagnostic development researchers in the neurosciences.



Looking Forward

Forum Activities in 2011

U.S. and European Animal-research Regulations: Impact on Neuroscience Research

The Forum, in collaboration with the National Research Council's Committee on Science Technology and Law and the Institute for Laboratory Animal Research, will host a workshop that will bring together representatives from the United States and Europe to examine laws, directives, and policies designed to regulate the use of non-human animals in the medical research enterprise, including a particular focus on the neurosciences. Specifically participants will identify and discuss current animal use regulations, examine the implications of current policies on the research enterprise, and discuss activity in the courts that may affect the use of animals in research. The workshop will provide an opportunity for international dialog around public relations and development of core principles and outcomes for animal research.





eg Hood, John Burkardt, and Greg Fo ttsburgh Supercomputing Center

4th meeting

Sackler U.S.A.-U.K. Scientific Forum on Neuroscience and the Law

The National Academy of Sciences and the U.K. Royal Society will host the Second Raymond and Beverly Sackler U.S.A.-U.K. Scientific Forum on *Neuroscience and the Law*. The meeting will be held on March 2–3, 2011 and is being organized through a collaborative effort between the Royal Society; the Committee on Science, Technology and Law; and the Forum. The Raymond and Beverly Sackler Forum was launched in 2008 as a venue where scientific conferences and meetings could be held to "help the scientific leadership of the United Kingdom and the United States forge an enduring and productive partnership on pressing topics of worldwide scientific concern with benefit to all people." The meeting will draw on the convening power of the sponsoring organizations to bring together experts for presentations and moderated discussions in the following topic areas: neuroscience in court; mind reading (to include a discussion of lie detection, pain, and false memory); criminal responsibility and sentencing; moral reasoning and psychopathy; and the developing brain.

Animal Models for Nervous System Diseases and Disorders

The poor predictive power of preclinical studies in animal models of candidate therapeutics has been recognized as a major reason for the high failure rate of candidate CNS drugs in clinical trials. The Forum will plan and host a workshop that will bring together key stakeholders to discuss potential opportunities for maximizing the translation of effective therapies from animal models to clinical practice. Specifically, participants will examine current methods of animal model characterization, preclinical testing design, and data reporting.



Working Groups

Working groups are established and maintained by interested members and are open to all members. The Forum's working groups engage in regular discussions, usually via teleconferences, on topics of interest to that group. Workshop topics often originate from working groups and are organized by an independently appointed workshop planning committee.

Translational Neuroscience

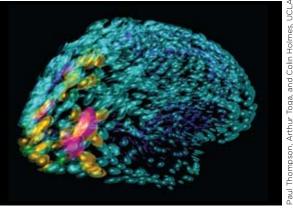
The translational neuroscience working group was established to focus on identifying areas of synergy where public and private sector stakeholders can partner to improve the efficiency and effectiveness of drug discovery and development for neurological and mental disorders. The group is currently developing a workshop aimed at improving the understanding between what pharmaceutical and diagnostic developers are looking for and how academic researchers can best contribute to the partnership in a meaningful way in order to improve the neuroscience translational research pipeline.

Grand Challenges in Neuroscience

This working group continues to follow up on the efforts set out by the Forum's 2008 workshop on grand challenges in neuroscience titled "From Molecules to Mind: Challenges for the 21st Century." The group is currently focusing on aiding former Rhode Island Congressman Patrick Kennedy's initiative "One Mind for Brain Research." The project aims to create a new space for key stakeholders to harness vital knowledge and resources and hasten the development of treatments and cures for neurological disorders. The catalysts to this effort are the 300,000 American veterans suffering from post traumatic stress disorder (PTSD) and traumatic brain injury (TBI). In addition, the working group is helping to develop strategic plans for federal research—engaging the community in identifying and prioritizing opportunities.







Training Translational Neuroscientists

The pace of new therapeutic discovery for central nervous system disorders has noticeably slowed over the last decade. Advancing translational neuroscience, the application of fundamental research to therapeutic development, will be critical in efforts to reverse this trend. There is an increasing need for investigators who are able to bridge the gap between basic and clinical neuroscience. A working group will be established to examine current practices of training scientists and identify opportunities for increasing and strengthening translational neuroscience programs.

Mental Health, Neurological, and Substance Use Disorders in Sub-Saharan Africa

In collaboration with the World Health Organization mental health Gap Action Programme (mhGAP), the Forum is currently exploring potential opportunities for additional efforts to build on the 2009 "Mental Health and Neurological Disorders in Sub-Saharan Africa" workshop. The working group is focused on identifying innovative solutions to enhance care for mental, neurological, and substance use disorders in sub-Saharan Africa. Special attention is being paid to finding solutions to increasing human and financial resources to support current and future efforts.

Nov 9 **Animal Law Workshop** Jun 22 **Glutamate Workshop** Jul 12 ADNI-2 Workshop

Forum Members

(as of December 2010)

Alan Leshner (Chair)

American Association for the Advancement of Science

Huda Akil

University of Michigan

Marc Barlow

GE Healthcare

Mark Bear

Massachusetts Institute of Technology

David Bredt

Eli Lilly and Company

Daniel Burch

CeNeRx Biopharma

Dennis Choi

The Simons Foundation

Timothy Coetzee

FastForward of the National Multiple Sclerosis Society

David Cohen

Columbia University, Society for Neuroscience representative

John Dunlop

Pfizer Inc.

Emmeline Edwards

National Center for Complementary and Alternative Medicine

Richard Frank

GE Healthcare, Inc.

Myron Gutmann

National Science Foundation

Richard Hodes

National Institute on Aging

Katie Hood

The Michael J. Fox Foundation for Parkinson's Research

Steven Hyman

Harvard University

Thomas Insel

National Institute of Mental Health

Daniel Javitt

New York University School of Medicine

Story Landis

National Institute of Neurological Disorders and Stroke

Husseini Manji

Johnson & Johnson Pharmaceuticals

Eve Marder

Brandeis University

David Michelson

Merck & Co., Inc.

Jonathan Moreno

University of Pennsylvania School of Medicine

Kathie Olsen

Association of Public and

Land-grant Universities

Atul Pande

GlaxoSmithKline

Menelas Pangalos

AstraZeneca Pharmaceuticals

Steven Paul

Weill Cornell Medical College

William Potter

Foundation for the National Institutes of Health

Paul Sieving

National Eye Institute

Rae Silver

Columbia University

William Thies

Alzheimer's Association

Nora Volkow

National Institute on Drug Abuse

Kenneth Warren

National Institute on Alcohol Abuse and Alcoholism

Frank Yocca

AstraZeneca Pharmaceuticals

Stevin Zorn

Lundbeck USA

Charles Zorumski

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Diana Pankevich, Ph.D., Associate Program Officer

Lora Taylor, Senior Project Assistant

IOM Board on Health Sciences Policy

Andrew M. Pope, Ph.D.,

Director

Mar 2-3
Sackler Neuroscience and the Law Forum

Dec 10

12th meeting

Feb 2 13th meeting

Forum Sponsorship

Financial support for the Forum is derived from federal agencies, patient advocacy organizations, industry, and a non-profit membership society.

Alzheimer's Association

AstraZeneca Pharmaceuticals

CeNeRx Biopharma

Eli Lilly and Company

GE Healthcare

GlaxoSmithKline

Johnson & Johnson Pharmaceuticals

Lundbeck, USA

Merck Research Laboratories

The Michael J. Fox Foundation for Parkinson's Research

National Eye Institute

National Institute on Aging

National Institute on Alcohol Abuse and Alcoholism

National Institute on Drug Abuse

National Institutes of Health Neuroscience Blueprint

National Institute of Mental Health

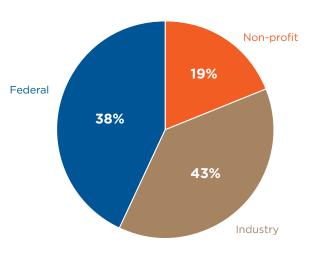
National Institute of Neurological Disorders and Stroke

National Multiple Sclerosis Society

National Science Foundation

Society for Neuroscience

Wyeth Research



Jul 26-27 Animal Regulations Workshop

Jun 28-29 14th meeting Nov 29-30 15th meeting

