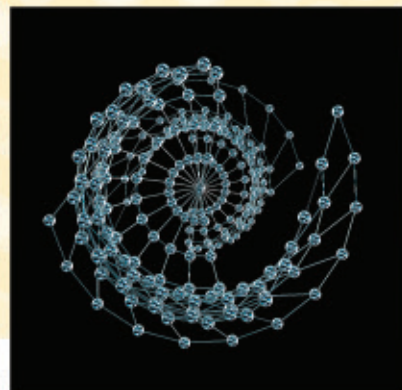


Forum on Drug Discovery, Development, and Translation

2012 Annual Report



INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Advising the nation • Improving health

Message from the Co-Chairs

Jeffrey Drazen and Steven Galson

The Institute of Medicine's (IOM's) Forum on Drug Discovery, Development, and Translation was created in 2005 by the IOM's Board on Health Sciences Policy to foster dialogue among stakeholders and provide ongoing opportunities to discuss issues of mutual interest in a neutral setting. The Forum provides a venue for dialogue and collaboration among its membership, which includes leaders from the pharmaceutical and biotech industries, academia, federal agencies, foundations, and patient groups. The Forum brings ongoing attention and visibility to important issues in drug development; explores new approaches for resolving problem areas; helps define the scope of the field and thus sets the stage for future policy action; provides a catalyst for collaboration on topics where there is synergy among potential partners; and elevates the general understanding of drug discovery, development, and translation among the research, public policy, and broader communities. The Forum is self-governing, with Forum members convening several times each year to identify and prioritize the topics they wish to address.

Reducing risk and uncertainty in the drug development enterprise constituted an underlying theme in the activities of the Forum in 2012. Although breakthroughs in biomedical research have led to an increased understanding of human disease, the translation of these discoveries into therapies for patients has not kept pace with medical need. Patients, industry, federal agencies, academia, and foundations are bringing a broad array of new tools and approaches in response to this challenge with the understanding that thoughtful partnership and collaboration can create results that would be impossible alone. As a neutral convening venue for stakeholders and collaborators, the Forum provides a unique setting in which complex issues of health science policy can be tackled collegially, and in which partnerships may be formed and nurtured.

This is a pivotal time of enormous change and opportunity in the “drug development ecosystem.” New authorities and strategies to improve the approach to drug discovery and development and the scientific basis of drug regulation are under way. The Food and Drug Administration (FDA) has continued to implement critical aspects of its commitment to advancing regulatory science, in partnership with external experts, to serve the agency and public health. In support of this goal, Congress recently funded the Reagan-Udall Foundation to support the mission of FDA by helping to advance regulatory science and technology. The Cures Acceleration Network (CAN), a component of the newly established National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH), was implemented to accelerate the development of high-need cures.

CAN received input from a variety of stakeholders convened by the Forum to consider options and opportunities to maximize the program's usefulness and impact. Forum members who are also leaders of these agencies and organizations have provided key contributions and direction to Forum initiatives throughout the year. Public-private partnerships, consortia, and other collaborative and catalyzing initiatives are making headway but require continued energy, dialogue, and coordination as they pursue advances in the approach to drug discovery and development.

In addition to leveraging opportunities to work with federal agencies, the Forum contributed to broad conversations on biomedical research and policy, including examining the benefits and barriers to sharing clinical research data to facilitate scientific and public health advances. The Forum membership continued its focused effort to address challenges in the U.S. clinical trials enterprise (CTE), facilitating a public dialogue on opportunities to accelerate the use of large simple trials (LSTs) in medical product development and providing a venue to foster collaborative action to advance development of a national certification system for clinical trial sites. Another Forum activity examined current problems in the global drug supply chain for medicines to treat neglected diseases such as multidrug-resistant (MDR) tuberculosis (TB).

We look forward to another groundbreaking and productive year for the Forum in 2013.



A handwritten signature in black ink, appearing to read "Jeff M. Drazen MD".

Jeffrey Drazen
Co-Chair



A handwritten signature in black ink, appearing to read "Steven Galson".

Steven Galson
Co-Chair

Reflecting Back

Forum Activities in 2012

Forum Meetings

The Forum membership met three times in 2012. Discussions at these meetings focused on diverse topics relating to the Forum's priorities, including innovation in the approach to drug discovery, development, and translation; advances in regulatory science; opportunities to improve the efficiency and effectiveness of the CTE in the United States; application of informatics to drug development; and policy developments related to the drug development ecosystem. In addition, the Forum convened public workshops, described and grouped according to Forum priority topics below.

Addressing the Approach to Drug Development

Maximizing the Goals of the Cures Acceleration Network to Accelerate the Development of New Drugs and Diagnostics—Workshop (June 2012)

Recent years have seen both extraordinary opportunity and complex challenges in pharmaceutical innovation. New biomedical technology platforms are creating novel avenues for research and new opportunities for the discovery and clinical development of innovative diagnostics and therapies. Yet, despite these advances, the pathway from basic science to new therapeutics faces challenges on many fronts. The translational divide results in only a small fraction of investigational new drugs achieving FDA approval and reaching the patients who need them. New paradigms for discovering and developing drugs are being sought to bridge the ever-widening gap between scientific discoveries and the translation of those discoveries into life-changing medications. New collaborative approaches within federal agencies, academia, and industry are directing focused attention to the advancement of the drug development enterprise. In response to a request from NCATS, the Forum convened a public workshop to explore ways to maximize the usefulness and impact of CAN in order to advance translational sciences. The

FORUM ACTIVITIES TIMELINE

2000-2004

2005

Clinical Research Roundtable,
predecessor to the Drug Forum

workshop included consideration of the effective use of CAN's grants and contracting authorities for the development of new tools and methods to enhance the development and testing of therapies and diagnostics for patients. In addition to providing suggestions to NCATS, the workshop was, in part, a response to congressional interest in CAN expressed in the FY 2012 appropriations act conference report. The workshop summary report, released in August 2012, has informed NIH/NCATS and the CAN Board in its efforts to implement CAN and advance translational sciences. The report serves as a resource for the public, policy communities, and other stakeholders to enhance the development and testing of therapies and diagnostics.



Maximizing the Goals of CAN Workshop co-chairs Louis DeGennaro and Carolyn Compton

Transforming Research and Fostering Collaborative Research

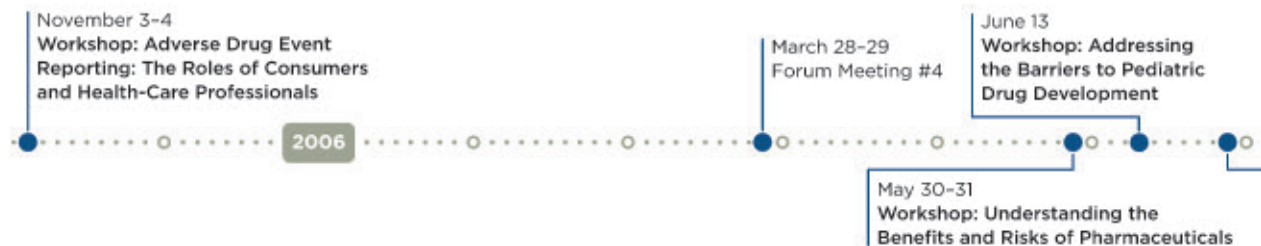
Sharing Clinical Research Data—Workshop (October 2012)

Pharmaceutical companies, academics, government agencies such as FDA and NIH, and patient-centered organizations have large quantities of clinical research data. Data sharing within each sector and across sectors could facilitate scientific and public health advances as well as enhance analysis of safety and efficacy. Many of these data, however, are never published or shared. This workshop explored benefits of and barriers to the sharing of

clinical research data, specifically clinical trial data, and strategies for enhancing sharing to facilitate research and development of effective, safe, and needed products. Workshop presentations and discussions centered around four core themes: (1) identification of the benefits of sharing clinical research data; (2) consideration of the design, best practices, and lessons learned from different data sharing models; (3) exploration of the opportunities and limitations of data standardization and governance; and (4) evaluation of opportunities to incentivize changes in culture and policy to enhance data sharing. The workshop was jointly hosted by the IOM's Forum on Drug Discovery, Development, and Translation, Forum on Neuroscience and Nervous System Disorders, National Cancer Policy Forum, and Roundtable on Translating Genomic-Based Research for Health. The



Sharing Clinical Research Data Workshop panelists from left to right: Andrew Vickers, Hans-Georg Eichler, Robert Harrington, and chair Sharon Terry



workshop highlighted challenges and opportunities across the spectrum of clinical research data sharing. In follow-up to the workshop, a cross-Forum/Roundtable working group is being formed to consider how the IOM can catalyze, encourage, and foster collaborative efforts to help clear the way for productive and effective clinical trial data sharing while not compromising important principles, including the need to be sure that public data are used and interpreted responsibly.

Large Simple Trials and Knowledge Generation in a Learning Health System—Workshop (November 2012)

Randomized clinical trials have traditionally been conducted in narrowly selected populations and involve the implementation of complex clinical trial protocols. NIH, academia, and industry recognize that significant opportunities exist to streamline clinical trials to reduce cost and time spent while increasing applicability of research results to broader, more representative, patient populations. In November 2012, the Forum collaborated with the IOM's Roundtable on Value and Science-Driven Health Care to convene a workshop to explore accelerating the use of LSTs to improve the speed and practicality of knowledge generation for medical decision making and medical product development. Workshop participants considered the concepts of LST design, the infrastructure needed to build LST capacity, and the structural, cultural, and regulatory barriers hindering the development of an enhanced LST capacity.

Developing a National Certification System to Improve Clinical Trial Performance—Innovation Collaborative (December 2012)

Also in 2012, the Forum initiated an ad hoc Innovation Collaborative activity to foster development of a national certification system for clinical trial sites. The Innovation Collaborative is a convening activity under the auspices of the Forum, which will provide a venue for joint and collaborative activities among participants to advance development of a national system to improve clinical trial site performance through certification of clinical trial sites. Participants are drawn from multiple sectors and disciplines and convened themselves for the first time in December 2012 to discuss opportunities for collaboration and advancement in the area of clinical trial site certification.



Innovation Collaborative co-chairs Freda Lewis-Hell and Clay Johnston with Harvey Fineberg, IOM President

Developing Drugs for Rare and Neglected Diseases and Addressing Urgent Global Health Problems

Developing and Strengthening the Global Supply Chain for Second-Line Drugs for Multidrug-Resistant Tuberculosis—Workshop (July/August 2012)

The Forum has convened a multiyear international initiative on MDR TB, which began with a foundational workshop in Washington, DC, in 2008, and when completed will have included international workshops in the high-burden countries of





Forum member Gail Cassell

South Africa (2010), Russia (2010), India (2011), and China (forthcoming, 2013). To effectively treat patients diagnosed with MDR TB and protect the population from further transmission of this disease, an uninterrupted supply of quality-assured second-line anti-TB drugs (SLDs) is necessary. The first four workshops each identified issues related to the global drug supply chain for quality-assured SLDs for MDR TB as major barriers to access to treatment. Ensuring a reliable and affordable supply of

high-quality SLDs is a complex public health intervention that, thus far, has not been organized or implemented in a way that allows all providers and patients to access SLDs when they are needed. To address this specific aspect of the global problem of MDR TB, the Forum convened a workshop in July/August 2012. Workshop participants included a diverse group of international supply chain experts, TB program managers, policy makers, donors and funders, nongovernmental organizations, and global health leaders. The workshop explored innovative solutions to the problem of how to get the right SLDs for MDR TB to people who critically need them. Discussions focused on strategies to improve logistics, supply and demand, quality of SLDs, and financing arrangements for the global supply chain for SLDs.

November 30
Discussion Series: A Conversation
with Tony Fauci

2008

February 20–21
Discussion Series: Comparative
Effectiveness (Forum Meeting #9)

April 21
Discussion Series:
Science at FDA: Challenges
and Opportunities

June 23
Workshop: Breakthrough
Business Models: Drug
Development for Rare
and Neglected Diseases

June 23–24
Symposium: Diseases and Individualized
Therapies (Forum Meeting #10)

Looking Forward

Forum Activities in 2013

Forum Meetings

The Forum membership will meet in February, June, and October 2013 to continue its discussions of key problems and strategies in the discovery, development, and translation of drugs. Forum working groups are convening to discuss and explore potential workshop topics in the areas of informatics in drug development, benefit-risk assessment, and biomarker validation and qualification. In addition, the Forum is convening the public workshops described below.

Drug-Resistant Tuberculosis in China—Workshop (January 2013)

The final workshop in the Forum's international workshop series on MDR TB will be held in Beijing, China, in January 2013 in collaboration with the Institute of Microbiology, Chinese Academy of Sciences. This workshop will address the current status of drug-resistant (DR) TB in China and across the globe; highlight key challenges to controlling the spread of DR strains; and discuss innovative strategies to advance and harmonize local and international efforts to prevent and treat DR TB. The meeting will focus on various aspects of DR TB, including epidemiology, diagnostics and preventive therapies, treatment, transmission and infection control, pediatric TB, innovative approaches to TB control, and drug procurement and supply issues. A summary of this workshop will be prepared and made available on the Forum website.



International Regulatory Harmonization Amid Globalization of Biomedical Research and Medical Product Development—Workshop (February 2013)

The last several decades have seen a rapid globalization of commerce, including within the medical product and technology sectors. Investigational studies for products intended for use in U.S. populations are increasingly being conducted outside the United States, often in countries with limited regulatory capacity. Moreover, biopharmaceutical companies seeking global markets for a single product face requirements for regulatory submissions in numerous international jurisdictions that could introduce scientific requirements that are discordant with U.S. standards. Discordant data requirements could result in additional clinical trials and animal studies, exposing more patients to experimental drugs and increasing the use of laboratory animals. There is a need for globally harmonized, science-based standards for the development and evaluation of safety, quality, and efficacy of medical products—both to enhance the efficiency and clarity of the drug development and evaluation process and ultimately to promote and enhance product quality and the public's health. There is also need for harmonization of standards for ongoing safety and quality surveillance of marketed biomedical products. This public workshop will address needs for international harmonization of regulatory standards to support the development, evaluation, and surveillance of biomedical products. A summary of this workshop will be prepared and made available on the Forum website.

April 27
**Workshop: Streamlining
Clinical Trial and Material
Transfer Negotiations**

April 27–28
Forum Meeting #12

September 2
**Discussion Series: FDA
Community Update on
Post-Market Drug Safety**

July 10
**Symposium: Drug Regulation with
FDA Commissioner Peggy Hamburg
(Forum Meeting #13)**

October 15–16
Forum Meeting #14

October 7–8
**Workshop: Transforming Clinical
Research in the United States**

Forum Initiatives

Addressing the Approach to Drug Development

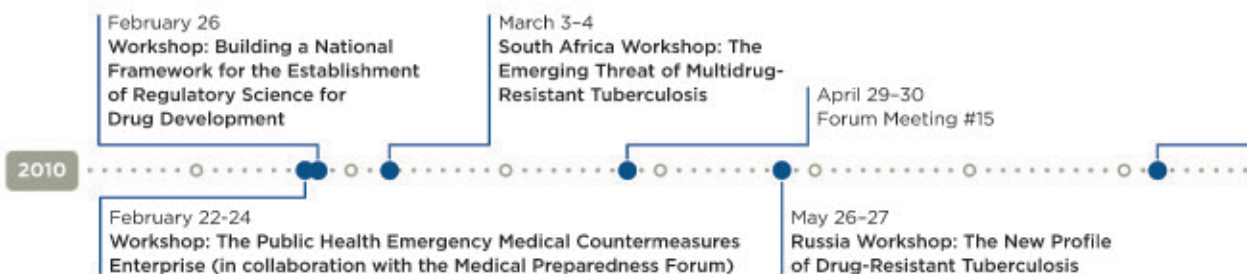
Despite exciting scientific advances, the pathway from basic science to new therapeutics faces challenges on many fronts. New paradigms for discovering and developing drugs are being sought to bridge the ever-widening gap between scientific discoveries and translation of those discoveries into life-changing medications. The Forum has explored these issues from many perspectives—emerging technology platforms, regulatory efficiency, intellectual property concerns, the potential for pre-competitive collaboration, and innovative business models that address the “valley of death.” Activities undertaken by the Forum have included a focus on how new federal initiatives, such as CAN, can facilitate acceleration of new therapies.



Maximizing the Goals of CAN Workshop speaker Thomas Insel

Strengthening the Scientific Basis of Drug Regulation

There has been considerable and increasing attention to the need for robust science to underlay and serve as the basis for regulatory decision making. “Regulatory science” involves the development and application of scientific tools and methodologies to improve the development, review, and oversight of new therapeutics. Recent rapid advances in



innovative drug development science present opportunity for revolutionary developments of new scientific techniques, therapeutic products, and applications. For example, advances in genomic science, systems biology, and cell-based technologies have led to exciting new avenues of biomedical research and drug discovery and have given us glimpses of the “personalized” future of medicine. As FDA has recognized, both science and infrastructure are key components in ensuring that the highest-quality regulatory decisions are made to ensure the safety and public health of the U.S. population while fostering, and not inhibiting, innovation in an increasingly challenging and globalized business environment. The Forum has focused considerable attention on the need to develop, support, and enhance a discipline of regulatory science as an essential component of the drug discovery enterprise and translational sciences. Activities undertaken by the Forum, including symposia and workshops, have contributed to the defining and establishment of regulatory science, and have considered in depth issues such as cutting-edge drug safety science, development of biomarkers for safety, personalized medicine, adverse event reporting and postmarketing safety surveillance, infrastructure and workforce needs, and collaborative approaches to support and sustain regulatory science and drug development.

Transforming Clinical Research and Fostering Collaborative Research

Clinical research is the critical link between bench and bedside in developing new therapeutics. Significant infrastructural, cultural, and regulatory impediments challenge efforts to integrate clinical trials into the health care delivery system. Collaborative, cross-sector approaches can help articulate and address these key challenges and foster systemic responses, such as a comprehensive clinical trials infrastructure and harmonization of



regulatory standards and institutional processes. The Forum has established a multiyear initiative to examine the state of clinical trials in the United States, identify areas of strength and weakness in our current clinical trial enterprise, and consider transformative strategies for enhancing the ways in which clinical trials are organized and conducted. In addition to sponsoring two to three symposia and workshops per year, under this initiative, the Forum is fostering innovative, collaborative efforts to facilitate needed change in areas such as improvement of clinical trial site performance.

Developing Drugs for Rare and Neglected Diseases and Addressing Urgent Global Health Problems

There are a number of diseases for which there is extensive unmet medical need and a lack of therapeutics, for which the population affected by the disease is very small (rare and orphan diseases), or for which the market for the therapeutic product is underdeveloped or inaccessible (neglected diseases). For these diseases, economic markets alone are insufficient to incentivize product development, and financial and regulatory incentives have been sought to stimulate therapeutics development and access to products. The Forum has recognized that the emergence of DR TB is a global threat that warrants focused attention to address the multitude of complex problems in drug development and access to therapeutics for patients affected by this neglected disease. The Forum is sponsoring a series of international collaborative workshops on DR TB, with a focus on drug delivery issues in the four countries with the highest burden of DR TB. The Forum has also held focused meetings and public workshops



considering particular issues impeding the development of orphan drug products and other areas of unmet medical need, such as medical countermeasures.

Promoting Public Understanding of Drug Development

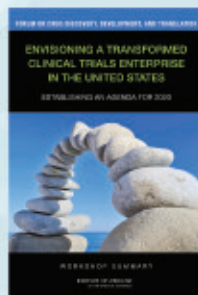
In these increasingly resource-constrained times, it is essential that the public understand both the complexity of and the need for the drug development process. Collaborative efforts to de-risk drug development are reported to be limited in some cases by a lack of public understanding of the need to support innovation and collaboration among the federal government, academia, industry, and other entities such as voluntary health organizations. In addition, successful introduction of new therapeutic entities requires testing in an informed and motivated public. The Forum has spent concerted effort to understand what limits public engagement and how to enhance more widespread acceptance of the importance of advancing therapeutic development through public participation in and support for the drug development process.



Theresa Mullin, Center for Drug Evaluation and Research, FDA



Reports Released in 2012

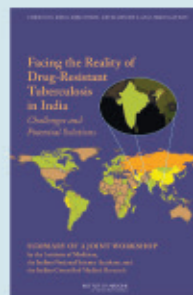


Envisioning a Transformed Clinical Trials Enterprise in the United States: Establishing an Agenda for 2020: Workshop Summary

Released: April 13, 2012

There is growing recognition that the U.S. CTE faces great challenges.

There is a gap between what is desired—medical care based solely on high-quality evidence—and the reality—limited capacity to generate timely and practical evidence for drug development and support medical treatment decisions. With the need for transforming the CTE in the United States becoming more pressing, the IOM's Forum on Drug Discovery, Development, and Translation held a workshop bringing together leaders in research and health care.



Facing the Reality of Drug-Resistant Tuberculosis in India: Challenges and Potential Solutions: Summary of a Joint Workshop

Released: April 27, 2012

An estimated 8.8 million people fell ill with TB in 2010, and 1.4 million

died from the disease. Although antibiotics to treat TB were developed in the 1950s and are effective against a large percentage of TB cases, resistance to these antibiotics has emerged over the years, resulting in the growing spread of MDR TB. The IOM's Forum on Drug Discovery, Development, and Translation held a workshop in collaboration with the Indian National Science Academy and the Indian Council of Medical Research to highlight key challenges to controlling the spread of DR strains of TB in India and to discuss strategies for advancing and integrating local and international efforts to prevent and treat DR TB.

November 26–27

Workshop: Large Simple Trials and Knowledge Generation in a Learning Health System (in collaboration with the Roundtable on Value & Science-Driven Health Care)

January 15

Workshop Summary Report
Release: *Developing and Strengthening the Global Supply Chain for Second-Line Drugs for Multidrug-Resistant Tuberculosis*

January 16–18
China Workshop: The Global Crisis of Drug-Resistant Tuberculosis and the Leadership of the BRICS Countries

February 13–14

Workshop: International Regulatory Harmonization Amid Globalization of Biomedical Research & Medical Product Development

October 23–24
Forum Meeting #23

December 19
Innovation Collaborative: Developing a National Certification System to Improve Clinical Trial Performance

February 12
Forum Meeting #24

June 3–4
Forum Meeting #25

2013



Accelerating the Development of New Drugs and Diagnostics: Maximizing the Impact of the Cures Acceleration Network: Workshop Summary

Released: August 22, 2012

Although many scientific opportunities exist for the development of new drugs and diagnostics, only a small fraction of investigational products are successfully developed into cures and therapies that can be accessed by patients. The newly developed CAN—a part of NCATS within NIH—has the potential to catalyze widespread changes in NCATS, NIH, and the drug development ecosystem in general. The IOM's Forum on Drug Discovery, Development, and Translation held a workshop to explore options and opportunities in the implementation of CAN.



Developing and Strengthening the Global Supply Chain for Second-Line Drugs for Multidrug-Resistant Tuberculosis: Workshop Summary

Released: December 14, 2012

Patients diagnosed with MDR TB face lengthy treatment regimens of 2 years or more with daily, directly observed treatment with SLDs that are less potent, more toxic, and more expensive than those used to treat drug-susceptible TB. A strengthened global supply chain for SLDs could save lives by consistently delivering high-quality medicines to more of the people who need them. Ensuring a reliable and affordable supply of high-quality SLDs is a complex public health intervention that, so far, has not been organized or implemented in a way that allows all providers and patients to access SLDs when they are needed. The IOM's Forum on Drug Discovery, Development, and Translation held a workshop to explore options and opportunities to improve the effectiveness of the global SLD supply chain in delivering drugs to patients.

Forum Members

(as of December 31, 2012)

Membership in the Forum includes a diverse range of stakeholders from multiple sectors, including government, the pharmaceutical and biotechnology industries, academic health centers, and patient groups.

Jeffrey Drazen (Co-Chair)
New England Journal of Medicine
Steven Galson (Co-Chair)
 Amgen Inc.

Margaret Anderson
 FasterCures

Hugh Auchincloss
 National Institute of Allergy and Infectious Diseases

Christopher Austin
 National Center for Advancing Translational Sciences

Leslie Benet
 University of California, San Francisco

Ann Bonham
 Association of American Medical Colleges

Linda Brady
 National Institute of Mental Health

Robert Califf
 Duke University Medical Center

C. Thomas Caskey
 Baylor College of Medicine

Gail Cassell
 Harvard Medical School Department of Social and Global Medicine (Visiting)

Peter Corr
 Celtic Therapeutics, LLLP

Andrew Dahlem
 Eli Lilly & Co.

Tamara Darsow
 American Diabetes Association

James Doroshow
 National Cancer Institute

Gary Filerman
 Atlas Health Foundation

Garret FitzGerald
 University of Pennsylvania School of Medicine

Mark Goldberger
 Abbott Pharmaceuticals

Harry Greenberg
 Stanford University School of Medicine

Stephen Groft
 NIH Office of Rare Diseases Research

Lynn Hudson
 Critical Path Institute

Michael Katz
 March of Dimes Foundation

Petra Kaufmann
 National Institute of Neurological Disorders and Stroke

Jack Keene
 Duke University Medical Center

Ronald Krall
 University of Pennsylvania

Freda Lewis-Hall
 Pfizer Inc.

Mark McClellan
 The Brookings Institution

Carol Mimura
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Elizabeth (Betsy) Myers
 Doris Duke Charitable Foundation

John Orloff
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Amy Patterson
 NIH Office of the Director

Michael Rosenblatt
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Janet Shoemaker
 American Society for Microbiology

Ellen Sigal
 Friends of Cancer Research

Elliott Sigal
 Bristol-Myers Squibb

Ellen Strahman
 GlaxoSmithKline

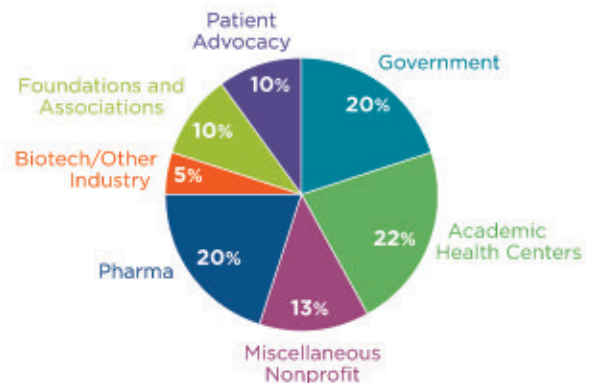
Nancy Sung
 Burroughs Wellcome Fund

Janet Tobias
 Ikana Health

Joanne Waldstreicher
 Janssen Research & Development, LLC

Janet Woodcock
 FDA Center for Drug Evaluation and Research

Membership



Forum Sponsorship

(as of December 31, 2012)

Financial support for the Forum is derived from private foundations, government agencies, industry sponsors, and nonprofit associations.

Private Foundations

Burroughs Wellcome Fund
Doris Duke Charitable Foundation
Eli Lilly & Co. Foundation

Other Nonprofit Organizations

American Diabetes Association
American Society for Microbiology
Association of American Medical Colleges
Critical Path Institute
FasterCures
Foundation for the National Institutes of Health
Friends of Cancer Research
March of Dimes Foundation

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National Institute of Allergy and Infectious Diseases (NIH)
National Institute of Mental Health (NIH)
National Institute of Neurological Disorders and Stroke (NIH)

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Novartis Pharmaceuticals Corporation
Pfizer Inc.

About the Forum on Drug Discovery, Development, and Translation

The IOM's Forum on Drug Discovery, Development, and Translation was created in 2005 by the IOM's Board on Health Sciences Policy to provide a unique platform for dialogue and collaboration among thought leaders and stakeholders in government, academia, industry, foundations, and patient advocacy. The Forum brings together leaders from private-sector sponsors of biomedical and clinical research, federal agencies sponsoring and regulating biomedical and clinical research, the academic community, and consumers, and in doing so serves to educate the policy community about issues where science and policy intersect.

The Forum convenes several times each year to identify and discuss key problems and strategies in the discovery, development, and translation of drugs. To supplement the perspectives and expertise of its members, the Forum also holds public workshops to engage a wide range of experts, members of the public, and the policy community in discussing areas of concern in the science and policy of drug development. The Forum's public meetings focus substantial public attention on critical areas of drug development. Proceedings and speaker presentations are disseminated to the public through published summaries and the Forum website. For more information about the Forum on Drug Discovery, Development, and Translation, please visit our website at: www.iom.edu/drug.

About the Institute of Medicine

The Institute of Medicine was established in 1970 by the National Academy of Sciences to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public. The Institute acts under the responsibility assigned to the National Academy of Sciences by its congressional charter to serve as an adviser to the federal government and, upon its own initiative, to identify issues needing attention in the areas of medical care, research, and education.

Forum Staff

Anne B. Claiborne, J.D., M.P.H.
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Senior Program Assistant

Board on Health Sciences Policy

Andrew M. Pope, Ph.D.
Director



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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.