INSTITUTE OF MEDICINE

Building a National Framework for the Establishment of Regulatory Science for Drug Development

February 26, 2010
National Academy of Sciences Building
Lecture Room
2100 C Street NW
Washington, DC

> *"Our nation has invested billions of dollars in biomedical research – an effort that is indispensable for medical progress – but this research will not result in cures unless it is married to a robust investment in regulatory science."*
>
> Dr. Margaret Hamburg
> FDA Commissioner
> October 26, 2009

The IOM's 2007 report, The Future of Drug Safety: Promoting and Protecting the Health of the Public, identified the need for an improved science base for drug evaluation, including both internal resources and extramural funding for collaboration with academia. A 2008 IOM Drug Forum meeting examined this question in a public workshop that explored the science of drug regulation, focusing on the gap between leading edge technologies of drug development and the capacity of the FDA to adapt the process of regulatory evaluation to these technologies. A subsequent report by the FDA Science Board examined in depth the need for an enhanced science base, including infrastructure development, multi-sectoral collaboration, and the expansion of a workforce capable of addressing the rapidly evolving science of drug discovery and development. Together these meetings and reports suggest a widening gap between the scientific developments in areas that are relevant to FDA and its ability to meet each innovation and simultaneously regulate products that make up 25% of the U.S. economy. Despite the importance and urgency to the nation of developing a sound science for regulatory decisions, there also exists a gap in understanding between the public, policymakers, and the agency on what is required to carry out such a task.

To address these concerns, the IOM Drug Forum will convene a public workshop to examine the state of the science of drug regulation and consider approaches for enhancing the scientific basis of regulatory decision making. This workshop will provide an opportunity to fully explore the concept of regulatory science, examine how it can be used to improve regulatory decision making, and consider alternative mechanisms and institutional frameworks for its development and application in regulatory decision making. It will feature experts on the science of drug regulation, as well as stakeholders in drug development and the regulatory process, including representatives of patient groups, academia, government, and industry.

A range of approaches and innovative mechanisms will be considered, which may include: fostering the scientific discipline of regulatory science; promoting closer collaboration between of regulatory and academic researchers; and developing a solid infrastructure to support regulatory science. Specific models to be considered may include: regulatory science centers of excellence; innovative federal grant-making mechanisms; and medical education and professional development programs.

The meeting will be available via webcast, and participants will be able to remotely submit questions to the panelists. Immediately following the workshop, presentation slides and other supporting materials will be available on the Drug Forum website. A summary of the proceedings will be subsequently published and made available free of charge through the website.

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AGENDA

8:00 – 8:15	**Opening Remarks**

DRUG FORUM CO-CHAIRS:
Gail Cassell, Eli Lilly
Jeff Drazen, New England Journal of Medicine

8:15 – 8:45	**Regulatory Science: Overview**

Moderator: Jeff Drazen, New England Journal of Medicine

Garret FitzGerald, Institute for the Translational Medicine and Therapeutics, University of Pennsylvania

8:45 – 9:15	**Keynote Speaker**

Congresswoman Rosa DeLauro (D-CT)

9:15 – 10:00	**FDA Initiatives on Regulatory Science**

Margaret Hamburg, FDA Commissioner

10:00 – 10:15	**Break**

10:15 – 11:30	**Session 1: Opportunities for Enhancing Regulatory Science**

Moderator: Mark McClellan, The Brookings Institution

THE IOM AND FDA SCIENCE BOARD RECOMMENDATIONS
Gail Cassell, Eli Lilly

ACADEMIC PERSPECTIVE
Phil Pizzo, Dean, Stanford University School of Medicine, Chair, Council of Deans American Association of Medical Colleges

A BLUEPRINT FROM THE PATIENT'S PERSPECTIVE
Ellen Sigal, Friends of Cancer Research

11:30 – 11:45	**Break and Working Lunch**

Guests are asked to pick up lunch and return to their seats.

11:45 – 1:15	**Session 2: Opportunities for Enhancing Regulatory Science (cont'd)**

Moderator: Barbara Alving, National Center for Research Resources, NIH

TRANSLATIONAL APPROACHES TO UNDERSTAND AND PREDICT RARE ADVERSE REACTIONS TO DRUGS
Paul Watkins, Hamner—University of North Carolina Institute for Drug Safety Sciences

A ROLE FOR REGULATORY SCIENCE IN EMERGING TECHNOLOGIES: GENOMICS
Allen Roses, Deane Drug Discovery Institute, Duke University

OPPORTUNITIES IN STATISTICAL DESIGN, ANALYSIS, AND MODELING
Susan Ellenberg, University of Pennsylvania School of Medicine

IT INFRASTRUCTURE, INFORMATICS AND SCIENTIFIC COMPUTING IN REGULATORY SCIENCE
Sangtae Kim, Morgridge Institute for Research

1:15 – 2:15	**Panel 1: A Comparison of Existing and Potential Mechanisms for Promoting Regulatory Science**

Moderator: Peter Honig, FDA and Merck (ret.)

PANELISTS:

- Jesse Goodman, FDA
- Dale Nordenberg, formerly CDC
- Judith Kramer, Clinical Trials Transformation Initiative, Duke University
- Margaret Anderson, FasterCures
- Harry Greenberg, Associate Dean for Research, Stanford University School of Medicine

2:15 - 2:30	**Break**

2:30 – 3:15	**Panel 2: Energizing Public Policy to Advance the Science**

Moderator: Janet Tobias, Ikana Media

PANELISTS:

- Steven Grossman, HSP Group and Alliance for a Stronger FDA
- Michael Manganiello, HCM Strategists
- Mary Woolley, Research! America

3:15 – 3:45	**An HHS Perspective**

PROTECTING THE PUBLIC THROUGH REGULATORY SCIENCE—A NATIONAL PRIORITY

Bill Corr, Deputy Secretary, HHS

3:45 – 4:00	**Summary and Next Steps**

Gail Cassell, Eli Lilly

4:00	**Adjourn**