

## **Defining and Measuring Innovation in a Changing Biomedical Landscape**

Washington Plaza Hotel • Washington, DC

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The biomedical innovation ecosystem continues to evolve and enhance the processes by which treatments are developed and delivered to patients. Unprecedented scientific advancements are laying the foundation for more targeted, curative treatments. Older drugs continue to evolve through discoveries of new uses and new formulations that improve health outcomes. An increasingly nimble and collaborative regulatory review process is expediting access to innovative medical products while staying true to the safety and efficacy standards that protect patients. Bipartisan legislation and public policy efforts are seeking new ways forward to further improve both development and review. All the while, overarching health reforms are refocusing health care payment and delivery on outcomes and value.

Given this changing biomedical innovation landscape, it is imperative that all stakeholders work to ensure that development programs, regulatory practices, and the policies that enable them are aligned on and achieving a common set of goals. This will require a thorough reexamination of our understanding of biomedical innovation – and the subsequent ways in which we seek to incentivize it – in order to more effectively bridge research and analysis of the process itself with the science and policy underpinning it.

Traditional research into the efficiency and effectiveness of drug development programs has tended to focus on the “inputs” and process trends in product development, quantifying the innovation as discrete units. The number of annual medical product approvals, for example, or aggregate R&D spending by sector or therapeutic area are commonly cited as being indicative of the health of the innovation enterprise. These process measures have been further supported by proxies meant to assess some aspect of approved products’ “innovativeness” – the number of products approved that represent a true advancement in their therapeutic class, for example, or trends in the use of FDA designations and pathways used to expedite development. These measures are useful but increasingly do not provide a complete picture.

At the opposite end of the research spectrum are potential measures that could be categorized as “value” or “outcomes” metrics. How is a new product truly changing treatment within a patient population? What outcomes are realized, and how might we value different outcomes over others in various disease areas? How can the patient perspective be better integrated into what is considered a meaningful step forward in treatment? How are market access, uptake, and price considerations affecting what should truly be considered “innovative?”

Identifying the appropriate measures across this spectrum – from inputs and technological progress through outcomes and value – and how such metrics can be in conversation with each other to improve the innovation process will be the focus of this Brookings-FDA expert workshop. The day-long roundtable will engage key stakeholders from throughout the innovation ecosystem to explore the factors and characteristics that could improve our understanding of what constitutes modern “innovation” and how best to track progress.

## Agenda

- 8:30 a.m. Registration**
- 9:00 a.m. Welcome**  
**Mark McClellan**, Senior Fellow and Director, Health Care Innovation and Value Initiative, The Brookings Institution
- 9:05 a.m. Defining ‘Innovation:’ Traditional Approaches and a Framework for Improvement**  
**Moderator: Mark McClellan**
- Presentations:**
- Opportunities for Creating a More Robust Definition of ‘Innovation’ - **Gregory Daniel**, Managing Director for Evidence Development & Innovation, Center for Health Policy and Fellow, Economic Studies, The Brookings Institution
  - FDA’s Perspective - **Janet Woodcock**, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- 9:50 a.m. Open Discussion**
- 10:20 a.m. Break**
- 10:30 a.m. Bridging Metrics Gaps: Comprehensive Measures for Improving Analysis**  
**Moderator: Mark McClellan**
- In this session, an introductory panel will highlight current metrics, gaps in available data, and opportunities for incorporating broader or more detailed measures in innovation analysis. Open discussion on metrics and measures will immediately follow.
- Panelists:**
- **Murray Aitken**, Senior Vice President, IMS Health and Executive Director, IMS Institute for Healthcare Informatics
  - **Ken Kaitin**, Director, Tufts Center for the Study of Drug Development and Professor, Tufts University School of Medicine
  - **Marta Wosinska**, Director, Economics Staff, Office of Program and Strategic Analysis, Office of Strategic Programs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
  - **Paul Kluetz**, Acting Deputy Director, Office of Hematology and Oncology Products, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
  - **Peter Neumann**, Director, Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy Studies, Tufts University and Professor of Medicine, Tufts University School of Medicine
- 11:30 a.m. Open Discussion**

**12:00 p.m.      Lunch**

**1:00 p.m.      Establishing a Common Understanding of the Dimensions of Innovation: Implications  
for Policy, Research, and Development**  
***Moderator: Mark McClellan***

Following lunch, workshop participants will build on morning sessions through roundtable discussion on the key questions and challenges outlined below. This session is intended to be interactive and an opportunity to lay out actionable next steps for collaboratively improving research on and measurement of biomedical innovation.

**Discussion Questions:**

- How can stakeholders move toward consensus definitions on the dimensions of innovation?
- How might common definitions impact or reframe new and ongoing policy efforts?
- What immediate next steps are needed to further such common definitions?
- How could stakeholders improve analysis and reporting on medical product innovation in line with such definitions?
- What tools and data are immediately available to begin improving measurement and analysis of biomedical innovation? Where are the data or research methods gaps?
- What are key research questions stakeholders are interested in answering?
- What opportunities exist for better *prospective* data gathering and analysis?

**2:30 p.m.      Adjourn**