



2015 OHE ANNUAL LECTURE

Regulation, Reimbursement, and Evidence on New Medical Technologies: Experiences and Future Directions in the United States

Mark McClellan, MD PhD, Brookings Institution

To be held at 6:00 pm, Monday 6 July 2015
at The Royal College of Physicians
11 St Andrews Place, Regent's Park, London
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This lecture will review some of the issues and trends in the evaluation and payment for new medical technologies based on experiences in the United States, emphasizing promising new directions for more efficient regulation and reimbursement. It will draw on practical experiences with efforts to make policies used by the US Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) process more efficient, including initiatives for parallel review, coverage with evidence development, and payments based on results.

These issues are most salient for “breakthrough treatments,” which have received considerable attention as a result of progress in the development of targeted medicines and bipartisan Congressional initiatives to accelerate their availability to patients. Some evidence suggests that breakthrough initiatives are shortening review times, but they are also associated with significant coverage limitations by payers and questions about the adequacy of evidence. In response, some new pricing models and systems for developing postmarket evidence are emerging that may significantly alter the incentives for developing and using these treatments in the future. The policy developments are also driven by the shift of many US health care provider payment systems from fee-for-service payments to payments that involve accountability for overall patient costs and outcomes. Further progress on regulatory and payment policies to support both high-value innovation and affordable health care programs in the US will require greater alignment of medical technology regulation and reimbursement with the new payment models for health care providers, and more robust postmarket evidence systems.

Mark McClellan, MD, PhD, is a Senior Fellow and Director of the Initiatives on Value and Innovation in Health Care at the Brookings Institution. His work focuses on strategies and policy reforms to improve health care, including such areas as accountable care, better evidence from real-world practice, and more effective drug

and device innovation. A doctor and economist by training, he also has a highly distinguished record in public service and in academic research. Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, Medicare and Medicaid payment reforms, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan is the founding chair and a current board member of the Reagan-Udall Foundation for the FDA, is co-chair of the Quality Alliance Steering Committee, chairs the National Quality Forum's partnership on clinician quality measurement, is a member of the Institute of Medicine, and is a research associate at the National Bureau of Economic Research. He has also served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House, and as Deputy Assistant Secretary for Economic Policy at the Department of the Treasury. He was previously an associate professor of economics and medicine with tenure at Stanford University, and has twice received the Kenneth Arrow Award for Outstanding Research in Health Economics.

If you would like to attend or have any questions, please contact:

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