FOR IMMEDIATE RELEASE
Contact: Michelle Shaljian, 202-797-6465, mshaljian@brookings.edu

New Planning Board Will Support Design of National Medical Device Tracking System to Improve Patient Safety and Outcomes

May 1, 2014 - (Washington, DC) – Brookings’ Engelberg Center for Health Care Reform announced the members of its National Medical Device Postmarket Surveillance System Planning Board, originally outlined in a 2012 U.S. Food and Drug Administration’s (FDA) report titled, Strengthening Our National System for Medical Device Postmarket Surveillance. The board’s goal is to develop a set of strategies and priorities that will inform the creation of a robust tracking system, ensure the safety and effectiveness of millions of medical devices, and enhance the quality of patient outcomes. The 22-member group is composed of a broad range of medical device, industry and regulatory experts, 16 of whom are from the private sector, along with five representatives from federal agencies.

“We’re grateful that these distinguished individuals have agreed to help build this very important system to ensure the safety of medical devices and patient outcomes,” said Brookings Senior Fellow Mark McClellan, and director of the Health Care Innovation and Value Initiative. “The Planning Board covers a broad range of skills and perspectives, including representation from the device industry, academia, payers, medical practices, patient and consumer groups, and federal agencies.”

The group will focus on three areas of architecting the integrated system: governance; practices, policies, and procedures; and business models. Key considerations include system design, legal and privacy policies, infrastructure stability and flexibility, mechanisms to support the use and sharing of patient data, communication policies, and system financing.

Planning Board Members include:
- Kathleen Blake, American Medical Association
- Mike Crompton, ReVision Optics
- Nancy Dreyer, Quintiles
- Joseph Drozda, Mercy
- David Flum, University of Washington
- Leslie Kelly Hall, Healthwise
- Jo Carol Hiatt, Kaiser Permanente
- Harlan Krumholz, Yale University
- Michael Mack, Baylor Health Care System
- Dale Nordenberg, Novasano Health and Science
- J. Marc Overhage, Siemens
- Edmund Pezalla, Aetna, Inc.
- Alan Rosenberg, WellPoint, Inc.
- Patricia Shrader, Medtronic, Inc.
- Carol Walton, The Parkinson Alliance
- Natalia Wilson, Arizona State University
- Tamara Syrek Jensen, Centers for Medicare and Medicaid Services (CMS)
- Rachael Fleurence, Patient-Centered Outcomes Research Institute (PCORI)
- Anne Trontell, Agency for Healthcare Research and Quality (AHRQ)
“We’ve made significant progress toward developing new regulatory requirements for unique device identifiers (UDI), providing us an unprecedented opportunity to enhance surveillance of not only medical device safety, but to track their performance once they are in use,” said Gregory W. Daniel, managing director for evidence development & innovation at the Center. “Once designed and implemented, this system will improve the lives of the tens of millions of individuals with simple glucose meters, pacemakers, heart valves, artificial joints, and the like.”

Members were selected by an independent committee convened by the Engelberg Center, and applied via a public call for nominations in January 2014. The Planning Board will be convened for a one year period. More information about the Planning Board, including selection criteria and the nomination process can be found here.