HARVARD UNIVERSITY
DEPARTMENT OF STATISTICS

Tel. 617-495-5496
Fax. 617-496-8057
statdept@stat.harvard.edu
http://www.stat.harvard.edu/

Science Center 7th Fl.
One Oxford Street
Cambridge, MA 02138

STATISTICS COLLOQUIUM

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TALK: 5:30 PM — SCIENCE CENTER LECTURE HALL D
RECEPTION: 6:30 PM — SCIENCE CENTER, 7TH FLOOR

"Trends in Premarket Regulation and Postmarket Surveillance of Drugs and Medical Devices: The Intersection of Regulatory Reform and Applied Statistics"

Mark McClellan
Senior Fellow and Director
Health Care Innovation and Value Initiative
Engelberg Center for Health Care Reform
Brookings Institution

ABSTRACT

Two major trends in FDA regulation of medical products in recent years are steps to accelerate the development and approval process for promising drugs and devices, and the emergence of systems for active surveillance of medical products. This is a shift from traditional regulatory approaches, which have relied primarily on randomized controlled trials and other premarket evidence before approval, with only limited capacity for postmarket data collection and analysis. It also reflects a shift in the development of evidence, with the growing availability of large and increasingly sophisticated electronic health care databases to complement premarket studies. While the emerging surveillance systems hold considerable promise for better understanding the real-world utilization of medical products, they also raise challenging statistical issues in terms of addressing causality and bias. This lecture will present an overview of some of the major policy trends in premarket regulation and postmarket surveillance, with an emphasis on the emerging, very large postmarket surveillance systems and the issues they present for policy-relevant statistical inference.