Reducing the Threat of Counterfeit and Unapproved Drugs in Clinical Settings
The Brookings Institution • Washington, DC
Friday, July 19, 2013

Agenda

8:30 a.m.   **Registration**

9:00 a.m.   **Welcome, Introduction and Meeting Objectives**
Mark McClellan, Health Care Innovation and Value Initiative at Brookings
Greg Daniel, Engelberg Center for Health Care Reform at Brookings

9:15 a.m.   **Introduction**
Janet Woodcock, U.S. Food and Drug Administration

9:30 a.m.   **Session I: Current Approaches to Controlling Counterfeit and Unapproved Drugs, and Remaining Gaps in Knowledge and Enforcement**
Mark McClellan – *Moderator*
Thomas T. Kubic, Pharmaceutical Security Institute
Jeffrey Ebersole, U.S. Food and Drug Administration
Howard Sklamberg, U.S. Food and Drug Administration

Potential Topics
- What efforts have been undertaken to secure the drug supply chain?
- What is the scope of FDA's ability to ensure drugs are safe, effective, and high quality?
- How are counterfeit and unapproved drugs an unresolved problem on the "demand side?" What is known about this problem?
- What are potential legal and regulatory liabilities associated with the purchase of counterfeit or unapproved drugs (*e.g.*, fraud)?
- How have other enforcement mechanisms played a role in combating this issue (*e.g.*, criminal prosecution, loss of professional licensure, reimbursement policies)? How effective are these mechanisms?

10:30 a.m.   **Break**

10:45 a.m.   **Session II: Identifying Strategies to Improve Communication and Awareness between Stakeholders**
Mark McClellan – *Moderator*
Shabbir Imber Safdar, Partnership for Safe Medicines
Carolyn Hendricks, The Center for Breast Health
Ray Bullman, National Council on Patient Information and Education

Potential Topics
- Who are the relevant stakeholders? What are the informational needs of stakeholders?
- Are there mechanisms in place for communicating the public health risks of counterfeit and unapproved drugs to the public?
- Are there mechanisms in place for communicating the professional and legal liability for purchase and use of counterfeit drugs?

- How can communication and education reduce the purchase and use of counterfeits?
- How can communication between stakeholders be improved?
- How have communication initiatives influenced medical practice and purchasing practices?
  - Examples of successful communication campaigns

11:45 p.m.   **Lunch**

1:00 p.m.   **Session III: Identifying Solutions to Improve Compliance and Professional Behavior**
Mark McClellan – *Moderator*
Lisa Robin, Federation of State Medical Boards
Richard Bruzek, HealthPartners
Albert I. Wertheimer, Temple University School of Pharmacy

Potential Topics
- How can stakeholders collaborate to deter purchasing and dispensing of counterfeit and unapproved drugs in clinical settings?
- How can stakeholders incentivize proper purchasing practices and reporting of improper practices?
- What role can medical boards, professional societies, malpractice insurers, and payers play in reducing the threat of counterfeit and unapproved drugs? How can these stakeholders be supported and engaged by FDA?
- What are the issues and consequences related to reimbursement for counterfeit and unapproved drugs used in clinical settings?

2:00 p.m.   **Session IV: Next Steps for Reducing the Threat of Counterfeit and Unapproved Drugs in Clinical Settings**
Mark McClellan – *Moderator*

Potential Topics
- What practical steps can stakeholders take to implement the solutions or strategies that have been identified?
- What are specific ways stakeholders can begin to collaborate to share information about the purchase and use of counterfeit and unapproved drugs by healthcare providers?

2:30 p.m.   **Adjournment**