Understanding How the Public Perceives and Values Pharmaceutical Quality

National Press Club • Washington, DC
February 3, 2020

**Breakout Sessions**

12:30 p.m.  Session 3a: Current Understandings of Pharmaceutical Quality – Patient and Provider Perspectives

*Discussion Questions:*

- How do patients and providers define pharmaceutical quality?
- How do stakeholders differentiate between pharmaceutical quality issues and drug side effects?
- How do stakeholders perceive FDA’s role in regulating pharmaceutical quality?
- In what ways do providers (physicians, nurses, NPs, PAs) and pharmacists influence and address patient perceptions of pharmaceutical quality?
- To what extent does media coverage of pharmaceutical quality concerns and drug recalls influence stakeholder perceptions of pharmaceutical quality?
- In what ways does the location of drug manufacturing influence stakeholder perceptions of quality?

*Moderator: Mark McClellan*, Duke-Margolis Center for Health Policy

*Opening Discussants: (15m)*

- John Whyte, WebMD
- Joe Graedon, The People’s Pharmacy
- Steven Kozlowski, U.S. Food & Drug Administration

*Moderated Discussion (45m)*

Session 3b: Current Understandings of Pharmaceutical Quality – Buyer and Payer Perspectives

*Discussion Questions:*

- How do buyers and payers define pharmaceutical quality?
- How do stakeholders perceive FDA’s role in regulating pharmaceutical quality?
- What information do buyers and payers use to inform their understanding of pharmaceutical quality?
- In what ways does the location of drug manufacturing influence stakeholder perceptions of quality?
Moderator: Marta Wosińska, Duke-Margolis Center for Health Policy

Opening Discussants: (15m)
- Michael Ganio, American Society of Health-System Pharmacists
- Paula Gurz, Premier Healthcare Alliance
- Cindy Buhse, U.S. Food & Drug Administration

Moderated Discussion (45m)

1:30 p.m. Session 4a: Medical Decisions and Pharmaceutical Quality

Discussion Questions:
- How do patients factor pharmaceutical quality into their decisions to request brand name versions of drugs, take expired drugs, or not take?
- What decisions do healthcare providers, including pharmacists, make surrounding pharmaceutical quality? How do those decisions impact patient care?
- How much do patient preferences or quality concerns influence provider decisions to prescribe certain drugs or certain versions of a drug (e.g. brand name vs. generic, or particular generic manufacturers)?
- In regulating pharmaceutical quality, FDA must balance drug quality and availability; understanding that there is not a perfect balance, how do stakeholders weigh these considerations? Do they feel that FDA is currently over-valuing safety or availability?

Moderator: Mark McClellan, Duke-Margolis Center for Health Policy

Opening Discussants: (15m)
- Harry Lever, Cleveland Clinic
- Douglas Throckmorton, U.S. Food & Drug Administration

Moderated Discussion (1h)

Session 4b: Purchasing Decisions and Pharmaceutical Quality

Discussion Questions:
- How do healthcare organizations, institutions, and GPOs factor pharmaceutical quality into drug purchasing decisions?
  - From what companies, organizations, or regulators do stakeholders obtain information on pharmaceutical quality?
  - What barriers do stakeholders face in obtaining data on pharmaceutical quality?
When looking at drugs with narrow therapeutic indexes, some institutions and health systems choose to purchase brand name drugs over generics. How do considerations around pharmaceutical quality influence these decisions and what supporting data exist?

In regulating pharmaceutical quality, FDA must balance drug quality and availability; understanding that there is not a perfect balance, how do stakeholders weigh these considerations when purchasing drugs? Do they feel that FDA is currently over-valuing safety or availability?

**Moderator:** Marta Wosińska, Duke-Margolis Center for Health Policy

**Opening Discussants:** (15m)
- Janine Burkett, Express Scripts
- Steven Loborec, The Ohio State University Wexner Medical Center
- Ashley Boam, U.S. Food & Drug Administration

**Moderated Discussion (1h)**

2:45 p.m.  Break

3:00 p.m.  Session 5: Steps to Support Better Understandings of Pharmaceutical Quality

**Discussion Questions:**
- What are some key messages that FDA and stakeholders should be sharing about pharmaceutical quality?
- What useful, actionable data could FDA or others provide that would address stakeholders’ questions and informational needs concerning pharmaceutical quality?
- How can pharmaceutical quality metrics support stakeholder understanding of pharmaceutical quality?
- What actions can stakeholders take to promote pharmaceutical quality?

**Moderator Reports from Breakout Sessions:**
- Mark McClellan, Duke-Margolis Center for Health Policy
- Marta Wosińska, Duke-Margolis Center for Health Policy

**Opening Discussants:** (15m)
- David Light, Valisure
- Daniel Kistner, Vizient
- Ashley Boam, U.S. Food & Drug Administration

**Moderated Discussion (30m)**
3:55 p.m.  Session 6: Synthesis and Next Steps

Discussion Questions:
- What next steps were identified during the day that might promote and facilitate greater understandings of pharmaceutical quality?
- What takeaways exist from the breakout sessions and how can these takeaways assist in understanding the similarities and differences between these different groups of stakeholders?

Moderator: Mark McClellan, Duke-Margolis Center for Health Policy

Moderated Discussion (35m)

4:30 p.m.  Closing Remarks and Adjournment