

Understanding How the Public Perceives and Values Pharmaceutical Quality

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Ensuring the quality of pharmaceutical products is essential and is part of the mission of the U.S. Food and Drug Administration (FDA). When pharmaceutical products do not meet quality standards, patients can be harmed or drug shortages can arise. Stakeholders, including patients, providers, pharmacists, drug purchasers, and payers, may each consider quality when making decisions about pharmaceuticals; however, very little research explores the role of quality in stakeholder decision-making.

This half-day public meeting, convened under a cooperative agreement between the Robert J. Margolis, MD, Center for Health Policy at Duke University in partnership with the FDA, will provide an opportunity to explore and better understand how stakeholders perceive and value the quality of pharmaceutical products. Key FDA leadership and staff will provide comments on the Agency's current thinking and there will be opportunities for attendees to ask questions and engage with panelists. Topics for discussion include:

- The importance of pharmaceutical quality;
- The current state of pharmaceutical quality;
- FDA's role in regulating quality; and,
- Stakeholder perceptions of pharmaceutical quality.

9:30 a.m. Welcome and Overview

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

9:35 a.m. Opening Comments from FDA

- **Keagan Lenihan**, U.S. Food & Drug Administration

9:45 a.m. Session 1: Introduction to Pharmaceutical Quality

Objectives:

- Discuss the definition and the importance of pharmaceutical quality.
- Describe the role of FDA's Office of Pharmaceutical Quality (OPQ) in regulating pharmaceutical quality.

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

Presentations:

- **Patrizia Cavazzoni**, U.S. Food & Drug Administration
- **Michael Kopcha**, U.S. Food & Drug Administration

Question & Answer

10:30 a.m. Session 2: The State of Pharmaceutical Quality

Objectives:

- Assess and describe the state of pharmaceutical quality (including discussion of OPQ's quality surveillance program).
- Present and discuss the results of surveys assessing patient and provider perceptions of pharmaceutical quality.

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

Presentations:

- **Cindy Buhse**, U.S. Food & Drug Administration
- **Adam Fisher**, U.S. Food & Drug Administration

Reactant Panel:

- **Michael Ganio**, American Society of Health-System Pharmacists
- **Martin VanTrieste**, Civica Rx

Question & Answer

11:30 a.m. Closing Remarks and Meeting Adjournment