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Off-Label Communication in 2016: Meeting Information Needs through New Policy Options

Marriott Marquis · Washington, DC
February 18, 2016

Agenda

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

9:00 a.m. **Welcome**
Mark McClellan, Duke-Margolis Center for Health Policy

9:15 a.m. **Off-Label Communication in a Changing Health Care Landscape**
The ready availability of scientific information on medical products – both on- and off-label – is an important part of patient and provider decision-making, routine care delivery, and coverage and reimbursement decisions. The information needs of stakeholders in these various settings and the means through which they access such information continue to evolve alongside a changing landscape of available treatments and an increasing focus on the value and outcomes of care. How does current regulation of off-label communication fall short of fully enabling stakeholder decision-making in this environment, and what information needs may continue to go unmet? What do patients, providers, and payers need from an improved scientific communication process? Speakers will address these questions from their unique stakeholder perspective and discuss their views on the gaps and challenges in adequate scientific communication.

- Richard Schilsky, American Society of Clinical Oncology
- Eleanor Perfetto, National Health Council
- Ed Pezalla, Aetna Inc.

10:00 a.m. **Audience Q&A**

10:20 a.m. **Break**

10:30 a.m. **Potential Policy Solutions for an Improved Communication Process**
In order to meet stakeholder information needs, safeguard the U.S. Food and Drug Administration's regulatory authority, and move beyond the current cycle of litigation, a range of potential policy options are likely necessary for improving off-label communication. In this session, speakers will discuss the guiding principles that such policy proposals should address in order to be considered effective, and highlight near- and long-term policy options as laid out in the Duke-Margolis white paper to which they contributed.

- Coleen Klasmeier, Sidley Austin LLP
- Marc Scheineson, Alston & Bird LLP
- Peter Pitts, Center for Medicine in the Public Interest

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11: 00 a.m. **Stakeholder Reactions and Panel Discussion**

Invited experts will join the working group members and provide their reactions to the guiding principles and policy recommendations put forward in the white paper. After each speaker has a chance to share their views, the entire group will engage in a moderated panel discussion about how best to make progress in 2016 and beyond.

- Joshua Sharfstein, Johns Hopkins Bloomberg School of Public Health
- Michael Listgarten, Genentech Inc.

11:40 a.m. **Audience Q&A**

12:00 p.m. **Closing Remarks**

Mark McClellan