AdvaMed
Advanced Medical Technology Association
Events & Education

8th Annual MedTech Advertising and Promotion Conference

The Westin Washington, DC | 1400 M Street NW, Washington, DC
November 14-15, 2017

November 14, 2017

8:30 – 9:00 am **Registration Check-In and Continental Breakfast**

9:00 – 9:05 am **Welcome and Introductions**

9:05 – 9:30 am **Opening Keynote with the FDA**

- Related Guidances
- What May be Ahead

9:30 – 10:15 am **Overview of the Regulation of Medical Device Advertising and Promotion**

- Key concepts in device promotion – intended use, labeling, advertising, false or misleading claims, adequate directions for use, and comparative claims
- The scope of FDA regulation over labeling and advertising
- Limitations in device promotion (unapproved devices, unapproved uses, investigational devices)
- Different promotional considerations for different kinds of devices – 510(k), PMA, restricted devices
- Potential consequences of inadequate disclosure of risk or safety information
- Direct-to-consumer (DTC) advertising and overview of AdvaMed's Guiding Principles
- New risks from communications with healthcare professionals
- Who is establishing national policy in the promotion of medical products?

10:15 – 10:30 am **Break**

10:30 – 11:30 am **Straight from the CDRH Office of Compliance and Medical Device Advertising**
FDA (Invited)

- Office of Compliance organization and authority over advertising and promotion
- Regulations relevant to promotion and advertising
- How does the agency monitor and review advertising?
- What happens to complaints?
- Recent actions by FDA and key areas of interest Guidance documents and resources
- Q&A with FDA

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11:30 – 12:15 pm **FTC's Authority Applied to the Regulation of Medical Devices**

- The FTC's jurisdiction
- The FTC-FDA Liaison Agreement
- FTC Advertising Substantiation Principles – the competent and reliable scientific evidence standard
- Qualified claims and disclosures
- FTC's current trends, priorities, and enforcement actions as they do and may pertain to the medical technology industry

12:15 – 1:30 pm **Networking Lunch**

1:30 – 2:30 pm **FDA Guidances and What Changes Are In Store for MedTech Panel Discussion**

Panelists:
Greg Levine, Ropes & Gray

- Impact on the future
- Q&A from audience participants

2:30 – 2:45 pm **Break**

2:45 – 3:30 pm **Friend or Foe: Working with Health Care Professionals Discussion**

- How does this affect device companies practically as an industry and in the day-to-day?
- What is changing?

3:30 – 5:00 pm **Mock Promotional Review Group Panel Discussion**

- How to effectively do your reviews, logistics of the process
- Interactive case study discussion
- Covering social media, first amendment issues, perspectives from regulatory, legal, and marketing

5:00 – 6:00 pm **Networking Reception**

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8:30 – 9:00 am **Continental Breakfast**

9:00 – 9:30 am **Enforcement and Compliance**

- Enforcement history and priorities
- What we're seeing from the enforcement perspective and how it could have an impact on the medical device industry

9:30 – 10:15 am **Labeling: General vs Specific**

- Overview and status of general/specific policy
- Implications of the policy for 510(k) interactions and labeling
- Impact of recent off-label cases

10:15 – 10:30 am **Break**

10:30 – 11:45 am **Regulatory and Legal Considerations and Criteria when using Social Media to Promote Medical Devices**

- What do you need to consider when establishing policies for social media promotion?
- What factors do you need to be aware of in your decisions?
- Best practice (and worst practice) examples

11:45 – 12:30 pm **Going Global: Global Review Considerations**

- Marketing in other countries
- Challenges of global promotions and the organization of doing so, covering the role of regulatory vs legal

12:30 pm **Adjournment**