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 Remarks with the FDA
Deborah Wolf, Regulatory Counsel, Division of Premarket & Labeling Compliance, CDRH

9:30 – 10:15 am  Overview of the Regulation of Medical Device Advertising and Promotion
Marlene Tandy, Assistant General Counsel, Johnson & Johnson
- 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
Cesar Perez, Regulatory Officer, Center for Devices and Radiological Health, FDA
- 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

Important Notice
The information provided in this course represents the personal opinions of the instructors and does not necessarily represent the opinions of AdvaMed staff. Companies relying on the information do so at their own risk and assume the risk of any subsequent liability that results from relying on the information. The information does not constitute legal advice.
11:30 – 12:15 pm  FTC’s Authority Applied to the Regulation of Medical Devices  
Joanne Hawana, Of Counsel, Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, P.C.  
- 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 – 2:00 pm  FDA Guidances and What Changes Are In Store for MedTech  
Jennifer Henderson, Partner, Hogan Lovells

2:00 – 2:30 pm  Enforcement and Compliance  
Danielle Humphrey, Senior Associate, Hogan Lovells

2:30 – 2:45 pm  Break

2:45 – 3:30 pm  Friend or Foe: Working with Health Care Professionals Discussion  
Tony Blank, Co-Founder & Senior Advisor, Barton & Blank, LLC  
- 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 – 9:45 am  1st Amendment Considerations and Off Label Communications
Moderator: Sandy Kalter, Vice President & Chief Regulatory Counsel, Medtronic
Kellie Combs, Partner, Ropes & Gray
Tony Blank, Co-Founder & Senior Advisor, Barton & Blank, LLC
• Overview and status of final tobacco rule
• Challenges to the rule
• Impact of recent off label cases
• Recent guidances: payer communication, consistent with labeling and others

9:45 – 10:30 am  Intended Use Rule and What Changes May be in Store
Jennifer Bragg, Partner, Skadden
• Overview and status of general/specific policy
• Implications of the policy for 510(k) interactions and labeling
• Impact of recent jurisprudence

10:30 – 10:45 am  Break

10:45 – 11:30 am  Regulatory and Legal Considerations and Criteria when using Social Media to Promote Medical Devices
Jen Romanski, Life Sciences Compliance and Regulatory Counseling Department, Porzio
• 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

11:30 – 12:30 pm  Going Global: Global Review Considerations
Tony Blank, Co-Founder & Senior Advisor, Barton & Blank, LLC
• 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

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