Thursday, November 10, 2016

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

9:00 – 9:05 am  Welcome and Introductions

9:05 – 10:00 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?

10:00 – 11:15 am  Straight from the CDRH Office of Compliance and Medical Device Advertising  
Toni Stifano, Division of Premarket and Labeling Compliance, Office of Compliance, CDRH  
Kendra Jones, Division of Premarket and Labeling Compliance, Office of Compliance, CDRH  
- 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

11:15 – 11:30 am  Networking Break
11:30 – 12:15 pm  
**FTC’s Authority Applied to the Regulation of Medical Devices**

*Joanne Hawana, Attorney, 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 – 1:15 pm  
**Networking Lunch**

1:15 – 1:30 pm  
**An Overview of Recent FDA Guidances**

*Katherine Norris, Director, Berkeley Research Group*

- Other Related Guidances
- What May be Ahead

1:30 – 2:15 pm  
**FDA Guidances Panel Discussion**

*Moderator: Joanne Hawana, Attorney, Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, P.C.*

*Panelists:*

- Marlene Tandy, Assistant General Counsel, Johnson & Johnson
- Katherine Norris, Director, Berkeley Research Group
- Rebecca Wood, Partner, Sidley Austin

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

2:15 – 2:45 pm  
**Break**

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

*Tony Blank, Cofounder and Senior Advisor, Barton & Blank LLC*

*Monaya Krause, Senior Legal Director, Medtronic*

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

3:45 – 5:00 pm  
**Mock Promotional Review Group Panel Discussion**

*Moderator: Michelle Axelrod, Vice President, Porzio Life Sciences LLC*

*Panelists:*

- Tony Blank, Cofounder and Senior Advisor, Barton & Blank LLC
- David Bloch, Principal Legal Counsel, Medtronic
- Nina Sherak, W.L. Gore & Associates, Inc.

- 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

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

Friday, November 11, 2016

8:30 – 9:00 am  Continental Breakfast

9:00 – 9:30 am  Enforcement and Compliance  
*John Kelly, Bass, Berry, & Sims*
  - 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  
*Nancy Stade, Partner, Sidley Austin*
  - 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  
*Tony Blank, Cofounder and Senior Advisor, Barton & Blank LLC*
  - 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 – 12:15 pm  Going Global: Global Review Considerations  
*Tony Blank, Cofounder and 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

12:15 – 1:00 pm  Networking Lunch and Adjournment

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