



AdvaMed

Advanced Medical Technology Association

Advertising and Promotion of Medical Devices in an Age of DTC and Social Media Marketing

**Washington, DC
November 5 - 6, 2009**

Thursday, November 5

8:30 – 9:00 REGISTRATION AND CONTINENTAL BREAKFAST

9:00 – 9:05 Welcome: Tom Maeder, Executive Director of AdvaMed's MTLI

9:05 – 10:00 Overview of the Regulation of Medical Device Advertising and Promotion

Marlene Tandy, MD, JD, Senior 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
- New risks from communications with healthcare professionals
- Who is establishing national policy in the promotion of medical products?

10:00 – 10:45 CDRH Office of Compliance and Medical Device Advertising

Deborah Wolf, Acting Director, Promotion & Advertising Staff, 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 concern
- Guidance documents and resources

10:45– 11:00 BREAK

11:00 – 11:45 The Federal Trade Commission and the Regulation of Medical Devices

Andrew Strenio, Partner, Sidley Austin, former Commissioner, Federal Trade Commission

- 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

11:45 – 12:30 Presenting Risk Information in Promotional Materials

Mark Heller, Partner and Chair of FDA Group, Goodwin & Proctor

- FDA's draft guidance on "Presenting Risk Information in Prescription Drug and Medical Device Promotion"

12:30 – 1:30 LUNCH

1:30 – 2:15 Good Reprint Practices and the Dissemination of Clinical Information

Rebecca Wood, Partner, Sidley Austin

- Good practices for the distribution of journal articles and other scientific reference materials on off-label uses of approved or cleared devices
- Provisions of the guidance document
- Congressional criticism

2:15 – 3:00 Data Disclosure and Allowable Claims

Tony Blank, Vice President, Cardiovascular Regulatory Affairs, Boston Scientific

- Breaking newsworthy trial information
- Determining the range of allowable claims – scope of 510(k) clearance vs that of PMA approval
- The migration from clinical/scientific evidence to labeling to advertising and promotion

3:00 – 3:15 BREAK

3:15 – 4:00 Practical Considerations in Developing Promotional Materials

Tony Blank, Vice President, Cardiovascular Regulatory Affairs, Boston Scientific

- General and Special labeling requirements
- Defining and navigating claims issues (e.g., substantiation, comparisons, inclusion in premarket submissions, etc.)
- Internal approval procedures and processes
- Investigational and unapproved devices

4:00 – 4:45 The View from the Drug Side

Marissa Chaet Brykman, Regulatory Counsel, Division of Drug Marketing, Advertising, and Communications, CDER, FDA

- Observations, trends, and concerns from the pharmaceutical side
- How the role of DDMAC has evolved in recent years

4:45 – 5:30 How Current DOJ, OIG, and Whistleblower Suits Affect Promotional Activities – an Update and Forecast

Kathleen McDermott, Partner, Morgan Lewis

John Rah, Partner, Morgan Lewis

- Recent relevant device and drug cases and CIAs, and what they foretell about current government concerns and enforcement trends

5:30 – 6:30 RECEPTION

Friday, November 6

8:00 – 8:30 CONTINENTAL BREAKFAST

8:30 – 9:15 AdvaMed's Guiding Principles for DTC Advertising

Marlene Tandy, MD, JD, Senior Counsel, Johnson & Johnson

- An overview and discussion of best practices for medical device manufacturers

9:30 – 10:15 DTC Advertising Case Study

Sandy Kalter, Senior Legal Director and FDA Counsel, Medtronic

- An example of AdvaMed DTC principles implementation

10:15 – 10:30 BREAK

10:30 – 11:00 Regulatory and Legal Considerations on the Use of New Social Media – Twittering on Legal Trends

Kathleen Sanzo, Partner, Morgan Lewis

- FDA enforcement methods to date on the use of new social media
- FDA efforts to develop new policies on the use of new social media
- Analysis of statutory and constitutional issues concerning the use of new and yet to be created media

11:00 – 12:30 New Social Media, Marketing, and Health Information Dissemination

Moderator: Robin Strongin, President, Amplify Public Affairs

Panelists: Joel Selzer, Co-Founder & CEO, Ozmosis, Inc.

Julie Loughran, Vice President, iConecto

Lars Merk, Product Director, McNeil Pediatrics Ortho-McNeil Janssen Pharmaceuticals, Inc.

- What are social media?

- How are social media being used for marketing and education in the health and medical technology fields?
- Opportunities and caveats for medical technology manufacturers

12:30

ADJOURNMENT