AdvaMed
Advanced Medical Technology Association
Events & Education

8th Annual MedTech Advertising and Promotion Conference

November 14-15, 2017
The Westin
Washington, DC
AdvaMed.org/Events

About AdvaMed

The Advanced Medical Technology Association (AdvaMed) is a trade association that leads the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world. Visit AdvaMed.org for more information.

Sponsorship

Interested in becoming a sponsor for this event? Visit events.AdvaMed.org/Sponsorship for more information

Other AdvaMed Event and Education Opportunities

- **Cybersecurity Summit,** November 2, 2017, Washington, DC
- **Combination Products: Regulations, Guidances & Rules**, November 28-29, 2017, Washington, DC

Advertising and Promotion

Join us in Washington, DC, where you'll learn from FDA and industry experts how to communicate the value of your medical device without overstepping legal and regulatory boundaries.

From products to consumers to regulation and new media—we're gathering industry practitioners to take a deep dive on the opportunities and challenges of product advertising during this annual conference.

FDA staff, medical technology company leaders, legal experts and public affairs professionals will lead discussions on topics including:

- Key concepts for device promotion
- Regulations relevant to advertising and promotion
- FTC Advertising Substantiation Principles
- Marketing in other countries

This event is open to both AdvaMed members and non-members. *Visit AdvaMed.org/Events to learn more.*

Agenda topics to be covered

- Overview of the Regulation of Medical Device Advertising and Promotion
- Straight from the CDRH Office of Compliance and Medical Device Advertising
- FTC's Authority Applied to the Regulation of Medical Devices
- Friend or Foe: Working with Health Care Professionals Discussion
- Mock Promotional Review Group Panel Discussion
- Enforcement and Compliance
- Labeling: General vs Specific
- Regulatory and Legal Considerations and Criteria when using Social Media to Promote Medical Devices
- Going Global: Global Review Considerations

Agenda - Tuesday, November 14

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8:30 am	**Registration, Check-In and Continental Breakfast** 8:30 - 9:00 am
9:00 am	**Welcome and Introduction** 9:00 - 9:05 pm
9:05 am	**Opening Keynote with FDA** 9:05 - 9:30 am • Related Guidances • What May be Ahead
9:30 am	**Overview of the Regulation of Medical Device Advertising and Promotion** 9:30 - 10:15 am *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 am	**Break** 10:15 - 10:30 am
10:30 am	**Straight from the CDRH Office of Compliance and Medical Device Advertising** 10:30 - 11:30 am *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

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Agenda - Tuesday, November 14 - Wednesday, November 15

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11:30 am	**FTC's Authority Applied to the Regulation of Medical Devices** 11:30 am - 12:15 pm • 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 pm	**Networking Lunch** 12:15 - 1:30 pm
1:30 pm	**FDA Guidances and What Changes Are In Store for MedTech Panel Discussion** 1:30 - 2:30 pm *Greg Levine, Ropes & Gray* *Danielle Humphrey, Partner, Hogan Lovells* • Impact on the future • Q&A from audience participants
2:30 pm	**Break** 2:30 - 2:45 pm
2:45 pm	**Friend or Foe: Working with Health Care Professionals Discussion** 2:45 - 3:40 pm • How does this affect device companies practically as an industry and in the day-to-day? • What is changing?
3:30 pm	**Co-Marketing Between Medical Device Companies & HCPs** 3:30 - 5:00 pm • 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 pm	**Networking Reception** 5:00 - 6:00 pm

Wednesday, November 15

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

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Agenda - Wednesday November 15

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9:00 am	**1st Amendment Considerations and Off Label Communications** 9:00 - 9:45 am • 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 am	**Intended Use Rule and What Changes May be in Store** 9:45 - 10:30 am • Overview and status of general/specific policy • Implications of the policy for 510(k) interactions and labeling • Impact of recent jurisprudence
10:30 am	**Break** 10:30 - 10:45 am
10:45 am	**Regulatory and Legal Considerations and Criteria when using Social Media to Promote Medical Devices** 10:45 - 11:30 am *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 am	**Going Global: Global Review Considerations** 11:30 am - 12:30 pm • 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** 12:30 pm