

Medical Device Law: Compliance Issues, Best Practices and Trends

October 15-16, 2015
Gibson Dunn
1050 Connecticut Avenue, NW
Washington, DC



Medical Device Law: Compliance Issues, Best Practices and Trends

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Program Description

The program brings together an all-star faculty of private lawyers, general counsel, compliance and regulatory affairs professionals, medical device executives and key regulators to discuss the latest topics and issues affecting the medical device industry.

The agenda includes sessions on:

- Overview of medical device law
- Recently issued FDA guidances
- Regulation of novel technologies
- HIPAA, privacy and cyber-security
- Financing medical device innovation
- Effective compliance programs
- Managing False Claims Act and FCPA liability

This program will particularly focus on the security of medical devices in light of their continued expansion into the broader consumer health market.

This is a must program for those who want to interact with medical device executives; those responsible for managing compliance programs; or those who wish to increase their competency in effectively managing medical device regulatory risk. The program will satisfy the interests of those newly involved in the medical device industry and industry veterans. This program will assist medical device professionals to better face the many significant threats of today and tomorrow.

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“Loved the format and “real-world” approach on day two.”

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Presented by

- ABA Health Law Section
- ABA Section of Science & Technology Law
- The Food and Drug Law Institute
- Federal Bar Association
- Medical Device Manufacturers Association



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Rakes & Moore*
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Agenda

Day 1 *State of the Nation*: Thursday, October 15, 2015

8:00 a.m. — Registration

8:50 a.m. — Introductory Remarks

Welcome comments and conference agenda details.

9:00 a.m. — Hot Topics in Medical Device Law

Panelists: David K. Elder, Nancy Singer
Moderator: Gail Hannah Javitt

Overview of current FDA regulatory compliance issues affecting medical device companies.

10:15 a.m. — Networking Break

10:30 a.m. — Advanced Issues in Medical Device Law

Panelists: Maura Norden, John Manthei, Philip Phillips
Moderator: Sonali Gunawardhana

Advanced discussion of FDA regulatory compliance issues affecting medical device companies and evolving regulatory trends.

12:30 p.m. — Luncheon Keynote Speaker

Julie Taitsman, MD, JD, Chief Medical Officer, Office of Inspector General,
U.S. Department of Health and Human Services, Washington DC

Discussion of government perspective on medical device enforcement trends and cooperation between industry and government.

1:30 p.m. — Industry Perspective on Past Years' FDA Compliance Guidance

Panelists: Michael Carvin, Joy Liu, Timothy M. Moore
Moderator: Colleen M. Heisey

In-depth discussion of FDA guidance developments and effect upon medical device companies.

3:00 p.m. — Networking Break

3:15 p.m.-5:00 p.m. — Financing Medical Devices through Conventional and Unconventional Means

Panelists: Stephanie Fertig, Ali Behbahani
Moderator: Sheila Hemeon-Heyer

Exploration of financing medical device innovation and associated regulatory and legal risks.

5:00 — Reception (Sponsored by Collora)

Agenda (continued)

Day 2 *New Frontier*: Friday, October 16, 2015

8:00 a.m. — Breakfast

8:15 a.m. — Keynote Address

Yogesh Bahl, Managing Director, Financial Advisory Services, *AlixPartners*, New York, NY

9:00 a.m. — Compliance Issues for Emerging and Novel Technologies

Panelists: Lisa Clark, Hemant Pathak, Randy Sabett
Moderator: Andrew Gantt

Focus on compliance and regulatory risks of novel medical technologies.

10:15 a.m. — Networking Break

10:30 a.m. — Evolving HIPAA and Privacy Issues for the Medical Device Industry

Panelists: Matthew R. Fisher, Clinton Royce Mikel, Mauricio F. Paez,
Gregory F. Noonan
Moderator: Philip S. Brewster

Overview of HIPAA and privacy concerns for medical device companies and legal risk mitigation strategies.

11:45 a.m. — Lunch (On your Own)

12:30 p.m. — Practical Cyber Security for the Device Industry

Panelists: Mauricio F. Paez, Justin P. O'Brien, John L. Robertson,
Mary K. Logan
Moderator: Michael E. Clark

Summary of current risks in cyber security for medical device companies and discussion of solutions.

1:45 p.m. — Networking Break

2:00 p.m. — Regulatory Risk Management and Mitigation (Ethics CLE):

Panelists: Joel Androphy, David L. Douglass, John Reed Thomas, Jr.,
Jennifer Short
Moderator: Robert T. Rhoad

Practical discussion of approaches to manage, assess and mitigate medical device regulatory risk and associated FCA/*qui tam* exposure with emphasis on ethical considerations.



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The Washington Health Law Summit, held in Washington, DC, serves to bring attendees up to date on the latest legislative and policy developments. Proposals should address new legislation, policy developments, or the implementation of significant healthcare initiatives emanating from HHS, CMS, IRS, DOJ, and other key government agencies.

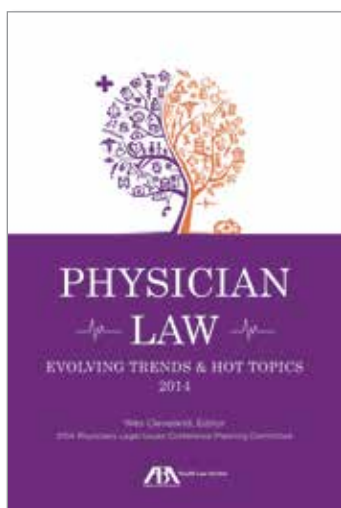
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Business casual attire is appropriate for all activities.

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