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

To register, visit www.ShopABA.org/mdevice2015

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.

Here’s What Your Colleagues Had to Say About the 2014 Institute:
“Great program!”
“Loved the format and “real-world” approach on day two.”
“Good content and informative speakers ... Looking forward to next year!”

ABA CLE National Institutes bring you face-to-face with nationally recognized experts on substantive topics — often while fulfilling most of your annual CLE requirements.
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For the best value, join an ABA Section.

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Presented by

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


Earn up to 7.5 CLE credits

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All faculty are confirmed or invited. Faculty subject to change without notice.
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<th>Time</th>
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<td>8:00 a.m.</td>
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<td>8:50 a.m.</td>
<td>Introductory Remarks</td>
<td>Welcome comments and conference agenda details.</td>
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| 9:00 a.m. | Hot Topics in Medical Device Law            | Panelists: David K. Elder, Mark C. Levy, 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: Michael E. Burke, Stephanie Fertig, Ali Bebahani  
Moderator: Sheila Hemeon-Heyer  
Exploration of financing medical device innovation and associated regulatory and legal risks. |
| 5:00 | Reception (Sponsored by Collora)            |                                                                                                                                          |
### 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.
Also from the ABA Health Law Section

**Washington Health Law Summit**

**December 7-8, 2015**  
**Washington, DC**

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. To register call *(800) 285-2221*.

**Conference on Emerging Issues in Healthcare Law**

**March 2-5, 2016**  
**San Diego, CA**

As the Section’s flagship program, Emerging Issues in Healthcare Law provides timely, practical presentations on cutting-edge topics that are critical to lawyers in all aspects of health law. Proposals should address the most emergent topics facing the healthcare bar as the healthcare industry undergoes changes and continues to develop with healthcare reform. To register, call *(800) 285-2221*.

**Featured Books from the Health Law Section**

Available @ www.ShopABA.org

- **Physician Law: Evolving Trends & Hot Topics 2015**  
  Product Code: 5630133

- **What Is... Stark Law?**  
  Product Code: 5630122

- **What Is... The Anti-Kickback Statute?**  
  Product Code: 5630129

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  Product Code: 5630132

- **What Are... The Physician Payments Sunshine Act or "Open Payments"?**  
  Product Code: 5630134

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  Product Code: 5630135
ABA CLE Opportunities

Also from the ABA:

NEW CLE VALUE PASS
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FDA Medical Device Law Fundamentals
(Audio CD-ROM)
To order call (800) 285-2221
or
Step 1: Registration Rates

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I qualify for a $50/person group discount. Enter your $50 discount on line 4B.

To qualify for a group discount, three or more people must register together. Please call us to register your group or send all registrations in the same envelope. Not applicable to government rates.

Step 2: Section Membership

- Enroll me in the ABA Health Law Section - $55. Enter your $55 fee on line 4C.
- Enroll me in the ABA Section of Science & Technology Law - $55. Enter your $55 fee on line 4D.

Step 3: Course Materials*

Electronic course materials will be provided via download at least 48 hours prior to the start of the Institute.

Please provide printed course materials on-site for $50. Enter your $50 fee on line 4E.

* If you cannot attend, but would like to order the Course Materials, please visit us at www.ShopABA.org/mdevice2015 or call (800) 285-2221 for pricing and availability. Course materials will be shipped after the event.

Step 4: Your Total Amount Due

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Step 5: Your Information

Name

Law Firm/Organization

Address

Suite/Apt.

City

State

Zip Code

Telephone

Email

ABA Member ID

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Step 6: Payment Information

- ABA Credit Card from Bank of America
- Visa
- American Express
- Check Payable to American Bar Association
- Mastercard

Name as it appears on Card

Account Number

Expiration Date

Signature

Billing Zip Code

*If you cannot attend... please visit www.shopaba.org and search under program title or call (800) 285-2221 for more information.

Step 7: 4 Easy Ways to Register

Visit www.ShopABA.org/mdevice2015

Call (800) 285-2221

Fax this form to (312) 988-5850

Complete and mail this form:

The American Bar Association
Financial Services Dept. CE1510MDM
P.O. Box 109078
Chicago, IL 60654-7598
MCLE
The ABA directly applies for and ordinarily receives CLE credit for ABA programs in AK, AL, AR, AZ, CA, CO, DE, GA, GU, HI, IA, IL, IN, KS, KY, LA, MN, MS, MO, MT, NH, NM, NV, NY, NC, ND, OH, OK, OR, PA, SC, TN, TX, UT, VT, VA, VI, WA, WI, and WV. These states sometimes do not approve a program for credit before the program occurs. This course is expected to qualify for 11.75 CLE credit hours in 60-minute states, including 1.50 ethics credit and 14.10 credit hours, including 1.80 ethics hours) in 50-minute-hour states. This transitional program is approved for both newly admitted and experienced attorneys in NY. Attorneys may be eligible to receive CLE credit through reciprocity or attorney self-submission in other states. For more information about CLE accreditation in your state, visit www.ShopABA.org/mdevice2015.

Scholarships
For more information on scholarships, visit www.americanbar.org/groups/cle/scholarship.

Attire
Business casual attire is appropriate for all activities.

Cancellations
Cancellations received five business days or more before the program will receive a full refund, less a $50 cancellation fee. No refunds will be provided for cancellations after that date; however, substitute registrants are welcome at any time. To cancel your registration or substitute another individual, please call the ABA at (800) 285-2221 or fax your request to (312) 988-5850. Registrants who do not cancel within the allotted time period and who do not attend the program will receive a copy of the course materials after program completion.

Services for Persons with Disabilities
If special arrangements are required, please contact Donna Prather Williams at (312) 988-6210 or donna.williams@americanbar.org. Reasonable advance notice is requested.

In-Person Registration
If you plan to register in person, please call the ABA at least 24 hours in advance to confirm that the program is being held as scheduled and that space is available. Cash payments will not be accepted.

Program Confirmation
Written confirmation of your registration will be sent to you upon receipt. If you do not receive the confirmation notice prior to the program, please call the ABA at (800) 285-2221 at least 24 hours in advance to confirm that your registration was received and that the program is being held as scheduled.

Hotel Information
ABA members should visit www.americanbar.org/travel and click under the Preferred Rate Hotel Program link to check for ABA rates at Washington, DC hotels.

Program Location
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Airline Information
Airline discount codes are available for ABA meetings as follows:

American Airlines: ABA Discount only available at ABA Orbitz for Business.
United Airlines: Call (800) 426-1122 and mention Agreement Code: 414489 / Z Code: ZSZU or go to www.united.com – Online Discount Code: ZSZU414489
Delta Airlines: Call (800) 328-1111 or go to www.delta.com and use Domestic Code: NMKEJ; International Code: NMJHL. Use the same codes for online discounts. More details at www.americanbar.org/travel.

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