



The A to Z of Off-Label Issues

March 30, 2010
National Harbor, MD

Tuesday, March 30th

- 8:15 – 8:45** **REGISTRATION AND CONTINENTAL BREAKFAST**
- 8:45 – 9:00** **Opening Remarks:**
Thomas Crane, Partner, Mintz Levin & Program Chair
- 9:00 – 10:15** **FDA's Regulation of Off-Label Medical Devices**
Deb Wolf, Associate Director for Regulatory Guidance Government Affairs, CDRH, FDA
- Key concepts and definitions
 - What is "off-label" use?
 - Limitations on promotion of unapproved devices, approved devices for unapproved uses, and investigational devices
 - Custom devices
 - FDA penalties
 - Clinical evidence on off-label uses
 - The practice of medicine and off-label use
- 10:15 – 10:30** **BREAK**
- 10:30 – 11:15** **CMS Reimbursement for Unapproved Devices and Off-Label Use**
Elizabeth Jungman, Associate, Covington & Burling
- Category A and B devices
 - Local and national coverage policies
 - What is paid for and what is not
 - The Medicare clinical research policy
 - Investigational cardiac device litigation
- 11:15 – 12:30** **Fraud and Abuse Issues in Off-Label Marketing**
Virginia Gibson, First Assistant U.S. Attorney, Eastern District of Pennsylvania
Tom Crane, Partner, Mintz Levin
- Qui tam and False Claims Act
 - Kickback issues
 - Enforcement priorities
 - *Caputo* and other recent
- 12:30 – 2:00** **LUNCH**
Lunch Speaker: Hank Walther, Assistant Chief, Fraud Section, Criminal Section, U.S. Department of Justice

2:00 – 3:00

How to Create an Effective Off-Label Compliance Program

Retta Riordan, President, Riordan Consulting, LLC

- Billing policies and procedures
- Data systems to capture necessary information
- How to handle promotion of off-label uses by affiliated physicians
- Training
- Auditing
- Informed consent
- Integrating compliance into the company culture

3:00 – 3:15

BREAK

3:15 – 4:00

Good Reprint Practices

Coleen Klasmeier, 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

4:00 – 4:45

Product Liability and Off-Label Use

Thomas Sullivan, Partner, Morgan Lewis

- What product liability risks might be associated with off-label use?

4:45 – 5:30

Panel Discussion – Interdisciplinary Issues in Off-Label Marketing

Panel of previous speakers

- The balance of free speech – truthful advertising – regulatory constraints – communication of useful clinical information
- The CMS clinical research policy
- Department of Justice jurisdiction over regulatory violations

ADJOURNMENT

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