



LITIGATION  
CONFERENCES presents



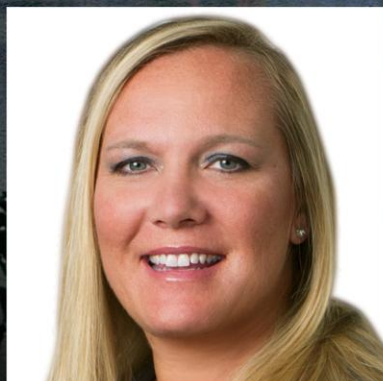
Defense Only!



# Drug & Device Defense

EMERGING LITIGATION & REGULATORY DEVELOPMENTS

CHAIRD BY



MEGAN GROSSMAN  
Segal McCambridge  
Singer & Mahoney LLP



MICHELLE HART YEARY  
Dechert LLP

Philadelphia • October 20, 2015




| Time | Topic  |   |
|------|--|---|
| 7:00 | <b>REGISTRATION &amp; BREAKFAST</b>  |   |
| 8:15 | <p><b>WELCOME!</b></p> <p>The conference producer and co-chairs describe the format for the day and provide an overview of what you will learn.</p>  | <p><b>Tom Hagy</b><br/><i>Managing Director, HB Litigation Conferences</i></p> <p><b>Megan Grossman</b><br/><i>Shareholder, Segal, McCambridge, Singer &amp; Mahoney Ltd.</i></p> <p><b>Michelle Hart Yeary</b><br/><i>Counsel, Dechert LLP</i></p>   |
| 8:30 | <p><b>DOES YOUR CORPORATE COUNSEL RELATIONSHIP NEED COUNSELING?</b></p> <ul style="list-style-type: none"> <li>•The importance of client/counsel communication</li> <li>•Litigation guidelines - compliance is key</li> <li>•How to foster the long-lasting relationship - duration over decades is the ultimate goal</li> <li>•How involved should the client be in the relationship, staffing and compensation decisions of the firm? When does supporting of diversity go too far? Or does it?</li> <li>•Fostering a stronger relationship: value-added contributions to the relationship; a team approach to developing a litigation strategy on national and one-off litigation; and other strategies</li> <li>•Excessive billings and other examples of how the relationship can be jeopardized</li> <li>•When things unravel - how to handle the termination of the relationship</li> </ul> | <p><b>Lori Cohen</b><br/><i>Shareholder, Greenberg Traurig LLP</i></p> <p><b>Alice Marshall</b><br/><i>Assistant Counsel, Merck</i></p> <p><b>Jeffrey Singer</b><br/><i>Shareholder, Segal, McCambridge, Singer &amp; Mahoney Ltd.</i></p>  |
| 9:15 | <p><b>OUTLOOK FOR 2016 &amp; BEYOND</b></p> <p>Hot topics to watch in drug and device litigation</p> <ul style="list-style-type: none"> <li>• Looking into the crystal ball: Understanding plaintiffs-side advertising to forecast litigation trends, mitigate risk and defend product reputation</li> <li>•On-Patent and In-Litigation: Counseling on a product that is on the market while subject to litigation</li> <li>•Trends away from off-label: Focus on anti-kickback litigation in special situations</li> </ul>  | <p><b>Kate Harr</b><br/><i>Senior Counsel, Bristol-Myers Squibb</i></p> <p><b>Andrew K. Solow</b><br/><i>Partner, Kaye Scholer LLP</i></p> <p><b>Rustin Silverstein</b><br/><i>President &amp; Founder, X Ante</i></p> <p><b>Jobina Jones-McDonnell</b><br/><i>Senior Litigation Attorney, Endo Pharmaceuticals</i></p> |



| Time  | Topic   | Speakers   |
|-------|---|--|
| 10:15 | <b>BREAK</b>  |  |
| 10:30 | <b>MASS TORT LITIGATION HAPPENINGS</b> <ul style="list-style-type: none"> <li>•Federal/State coordination</li> <li>•Litigations on the horizon</li> <li>•Selection of Bellwether cases</li> </ul>   | <b>Denise Houghton</b><br><i>Litigation Counsel, Johnson &amp; Johnson</i><br><br><b>Don LeGower</b><br><i>Senior Counsel, Litigation, Bristol-Myers Squibb</i><br><br><b>Will Sachse</b><br><i>Litigation Partner, Dechert LLP</i>  |
| 11:15 | <b>THE INTERSECTION OF FDA MEDICAL-DEVICE ENFORCEMENT AND PRODUCT-LIABILITY LITIGATION</b> <ul style="list-style-type: none"> <li>•Voluntary compliance: how to avoid actions</li> <li>•Costs of non-compliance</li> <li>•GMP-based warning letters and consent decrees</li> <li>•Corporate-wide compliance</li> <li>•Defending against private plaintiffs' use of alleged FDCA violations</li> </ul> | <b>Carl Fischer</b><br><i>Director, Division of International Compliance Operations, Office of Compliance, Food &amp; Drug Administration's Center for Devices and Radiological Health</i><br><br><b>Andrew Tauber</b><br><i>Partner, Mayer Brown</i>  |
| 12:00 | <b>LUNCH</b>  |  |
| 1:00  | <b>CREATING VALUE THROUGH CORPORATE ETHICS &amp; COMPLIANCE</b> <ul style="list-style-type: none"> <li>•Ethics &amp; Compliance Best Practices: why you need them, what they look like and the benefits of a world-class ethics &amp; compliance program</li> <li>•Cross-roads between compliance and litigation</li> </ul>   | <b>Susan Frank Divers, moderator</b><br><i>Senior Advisor, LRN</i><br><br><b>Melissa Stapleton Barnes</b><br><i>Senior Vice President, Enterprise Risk Management and Chief Ethics and Compliance Officer, Eli Lilly &amp; Co.</i><br><br><b>Prof. Edward Queen III</b><br><i>Director, Ethics &amp; Servant Leadership and Coordinator of Undergraduate Studies at Emory University's Center for Ethics</i><br><br><b>Karen McDonnell</b><br><i>Chief Compliance Counsel, GE Healthcare</i> |
| 2:00  | <b>GETTING THE WORD OUT--LABELING &amp; PROMOTION FOR BRANDS/GENERIC</b> <ul style="list-style-type: none"> <li>•Coronia/Solis and other First Amendment cases regarding off-label marketing</li> <li>•Regulatory update for generic manufacturers</li> <li>•Post-Mensing case developments</li> <li>•Report on failure-to-update claims</li> <li>•Status of proposed FDA regulations</li> </ul>      | <b>Henninger "Hank" S. Bullock</b><br><i>Partner, Mayer Brown</i><br><br><b>Beth S. Rose</b><br><i>Member, Sills Cummis</i>  |



| Time | Topic   |  |
|------|---|--|
| 2:45 | <b>EDUCATING THE JURY: TRIAL GRAPHICS AND ANIMATIONS FOR PHARMACEUTICAL AND MEDICAL DEVICE CASES</b>  | <b>Christina Marinakis, J.D., Psy.D.</b><br><i>Senior Consultant, Litigation Insights</i>  |
| 3:00 | <b>BREAK</b>  |  |
| 3:15 | <b>STAYING AHEAD OF EVER-INCREASING GOVERNMENT INVESTIGATIONS</b> <ul style="list-style-type: none"> <li>• Policies available to cover the substantial costs involved with responding to government investigations and related litigation</li> <li>• Three major coverage issues under D&amp;O policies                             <ul style="list-style-type: none"> <li>• Notice of claim</li> <li>• Advancement of defense costs</li> <li>• Key exclusions</li> </ul> </li> <li>• Best practices for securing coverage for investigations and related litigation</li> </ul>   | <b>Brian G. Friel</b><br><i>Partner, Miller Friel PLLC</i><br><br><b>Jay Desjardins</b><br><i>Managing Director, Aon Risk Services</i>                           |
| 4:00 | <b>3D PRINTING</b> <ul style="list-style-type: none"> <li>• How is 3D printing being used to create medical devices? What about pharmaceuticals?</li> <li>• What does the FDA say about this new technology?</li> <li>• What are the risks to companies and individuals?</li> <li>• What legal issues does this technology present?</li> </ul>  | <b>Sara E. Dyson</b><br><i>Assistant Vice President, Loss Control, Medmarc</i><br><br><b>Michael P. Bruyere</b><br><i>Partner, Freeman Mathis &amp; Gary LLP</i> |
| 4:45 | <b>THE DUTY OF CONFIDENTIALITY V. THE DUTY OF CANDOR – WHY IT MAKES A DIFFERENCE ... OR DOES IT?</b> <ul style="list-style-type: none"> <li>• Duty of confidentiality                             <ul style="list-style-type: none"> <li>• Common law duties</li> <li>• Codification by ethical rules                                     <ul style="list-style-type: none"> <li>• The canons, code &amp; rules</li> </ul> </li> <li>• Attorney-client privilege                                     <ul style="list-style-type: none"> <li>• Statutory &amp; common law</li> <li>• The Nationwide saga</li> </ul> </li> </ul> </li> <li>• Duty of candor                             <ul style="list-style-type: none"> <li>• Rules of professional conduct</li> <li>• Federal regulation (e.g. SOX)</li> </ul> </li> <li>• The consequences                             <ul style="list-style-type: none"> <li>• Sanctions                                     <ul style="list-style-type: none"> <li>• The Qualcomm and its progeny</li> <li>• Federal /legislation rules</li> </ul> </li> </ul> </li> </ul> | <b>Abraham Reich</b><br><i>Co-Chair, Fox Rothschild</i><br><br>              |
| 5:30 | <b>COCKTAIL RECEPTION</b>   |  |

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