



LITIGATION
CONFERENCES presents



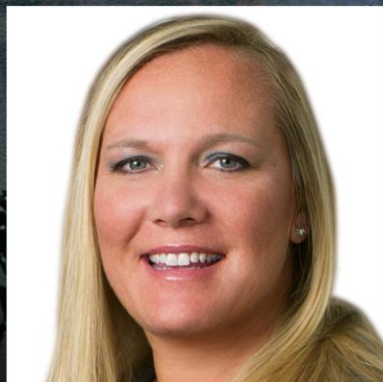
Defense Only!



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	REGISTRATION & BREAKFAST	
8:15	<p>WELCOME!</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>Tom Hagy <i>Managing Director, HB Litigation Conferences</i></p> <p>Megan Grossman <i>Shareholder, Segal, McCambridge, Singer & Mahoney Ltd.</i></p> <p>Michelle Hart Yeary <i>Counsel, Dechert LLP</i></p>
8:30	<p>DOES YOUR CORPORATE COUNSEL RELATIONSHIP NEED COUNSELING?</p> <ul style="list-style-type: none"> •The importance of client/counsel communication •Litigation guidelines - compliance is key •How to foster the long-lasting relationship - duration over decades is the ultimate goal •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? •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 •Excessive billings and other examples of how the relationship can be jeopardized •When things unravel - how to handle the termination of the relationship 	<p>Lori Cohen <i>Shareholder, Greenberg Traurig LLP</i></p> <p>Alice Marshall <i>Assistant Counsel, Merck</i></p> <p>Jeffrey Singer <i>Shareholder, Segal, McCambridge, Singer & Mahoney Ltd.</i></p>
9:15	<p>OUTLOOK FOR 2016 & BEYOND</p> <p>Hot topics to watch in drug and device litigation</p> <ul style="list-style-type: none"> • Looking into the crystal ball: Understanding plaintiffs-side advertising to forecast litigation trends, mitigate risk and defend product reputation •On-Patent and In-Litigation: Counseling on a product that is on the market while subject to litigation •Trends away from off-label: Focus on anti-kickback litigation in special situations 	<p>Kate Harr <i>Senior Counsel, Bristol-Myers Squibb</i></p> <p>Andrew K. Solow <i>Partner, Kaye Scholer LLP</i></p> <p>Rustin Silverstein <i>President & Founder, X Ante</i></p> <p>Jobina Jones-McDonnell <i>Senior Litigation Attorney, Endo Pharmaceuticals</i></p>



Time	Topic	Speakers
10:15	BREAK	
10:30	MASS TORT LITIGATION HAPPENINGS <ul style="list-style-type: none"> •Federal/State coordination •Litigations on the horizon •Selection of Bellwether cases 	Denise Houghton <i>Litigation Counsel, Johnson & Johnson</i> Don LeGower <i>Senior Counsel, Litigation, Bristol-Myers Squibb</i> Will Sachse <i>Litigation Partner, Dechert LLP</i>
11:15	TIPS FOR TOEING THE LINE ON FDA COMPLIANCE <ul style="list-style-type: none"> •Consent decrees •Civil penalties •Accelerated approval and breakthrough designation •Recent FDA product recalls and warnings 	Carl Fischer <i>Director, Division of International Compliance Operations, Office of Compliance, Food & Drug Administration's Center for Devices and Radiological Health</i>
12:00	LUNCH	
1:00	CREATING VALUE THROUGH CORPORATE ETHICS & COMPLIANCE <ul style="list-style-type: none"> •Ethics & Compliance Best Practices: why you need them, what they look like and the benefits of a world-class ethics & compliance program •Cross-roads between compliance and litigation 	Susan Frank Divers, moderator <i>Senior Advisor, LRN</i> Melissa Stapleton Barnes <i>Senior Vice President, Enterprise Risk Management and Chief Ethics and Compliance Officer, Eli Lilly & Co.</i> Prof. Edward Queen III <i>Director, Ethics & Servant Leadership and Coordinator of Undergraduate Studies at Emory University's Center for Ethics</i> Karen McDonnell <i>Chief Compliance Counsel, GE Healthcare</i>
2:00	GETTING THE WORD OUT--LABELING & PROMOTION FOR BRANDS/GENERIC <ul style="list-style-type: none"> •Coronia/Solis and other First Amendment cases regarding off-label marketing •Regulatory update for generic manufacturers •Post-Mensing case developments •Report on failure-to-update claims •Status of proposed FDA regulations 	Henninger "Hank" S. Bullock <i>Partner, Mayer Brown</i> Beth S. Rose <i>Member, Sills Cummis</i>



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

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