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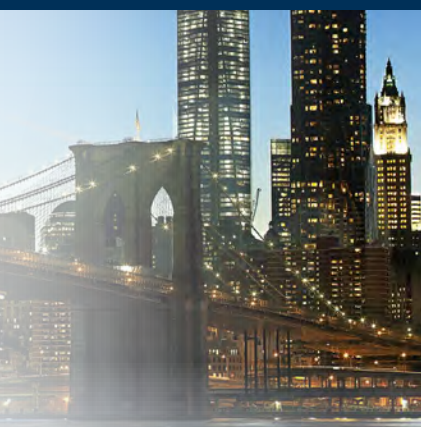

Expert Strategies for Leading Products Liability Litigators & In-House Counsel

DECEMBER 2–4, 2015 | MILLENNIUM BROADWAY HOTEL | NEW YORK, NY

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The Honorable Michael J. Davis
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Eisai Inc. (Woodcliff Lake, NJ)

Frank C. Woodside, III, M.D., J.D.
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Advocacy. Coordination. Innovation.

Faced with potentially exorbitant damages and fighting against creative gamesmanship, members of the defense bar must coordinate their advocacy efforts on behalf of the companies bringing safe and effective therapies to the market for the patients who rely on them.

Be part of the community of high-stakes drug and medical device products liability litigators at the **20th anniversary edition of ACI's flagship Drug and Med conference**, a forum designed to facilitate discussion of the opportunities before defense litigators to better advocate on behalf of life-saving and life-improving drug and device companies. By attending this conference, you will walk away with practical advice on crafting the most effective defenses in mass tort litigation in response to the latest legal challenges.

Why the 20th anniversary event is a must-attend for you and your team:

- ✓ **Network and brainstorm with the Who's Who of the products liability defense bar.** This year's In-House Advisory Board and faculty includes over 35 attorneys representing over 30 different companies including **Medtronic, Pfizer, Eli Lilly, C.R. Bard and dozens more**. Our faculty of trial-tested defense advocates will share the methods that have worked for them in recent battles and provide specific advice for litigating effectively and efficiently. Plus, in-house counsel are invited to participate in a networking luncheon, designed to promote candid discussion about the state of the industry in a less formal setting.
- ✓ **Get a balanced, 360 degree view of products liability litigation from key stakeholders.** This is the only event which brings together not only an exceptional in-house presence on the faculty but also features the top defense firms representing biopharmaceutical and medical device companies, 12 experienced federal and state jurists from around the country, and top DOJ enforcers who will share their perspective.
- ✓ **Participate in sophisticated and practical sessions tailored to appeal to masters in the field.** This year's agenda features new forward-thinking sessions on the topics sure to make headlines in 2016: torts premised on discovery violations, the future of off-label promotion, CAFA and personal jurisdiction, plaintiffs' advertising, international products liability litigation, and more.
- ✓ **Partake in the vibrant cultural resources that only New York City in December can offer, while mingling with hundreds of like-minded peers.**

Plus, new for the 20th Anniversary Edition, nominate a peer for ACI's 1st Annual **Champions of the Products Liability Defense Bar Award**, created to recognize and celebrate the successes and achievements of leaders in the community.

Register early to ensure best pricing. Group discounts are available. Call 1-888-224-2480, fax your registration to 1-877-927-1563, or visit us online at www.drugandmed.com. Additionally, please join the ACI: Drug and Medical Device Litigation group on LinkedIn to 'meet' your peers prior to the start of the conference, and follow us on Twitter @DrugandMed for industry news and exclusive discounts.

Very truly yours,

Nicole M. Cutuffello-Turner

Nicole M. Turner, J.D.
Legal Analyst and Senior Conference Director

When making your travel arrangements, plan on attending three new sessions designed to maximize networking between colleagues:

- Pre-Conference Workshop: **Preparing the Next Generation of Leaders of the Defense Bar- Strategy and Trial Advocacy Deep-Dive**
- Pre-Conference Group Meet-Ups: **Defense Counsel War Room: Deconstructing the Latest and Greatest in Plaintiffs' Tactics** and **Judicial, Special Master, and Healthcare Perspectives**
- Post-Conference Business Development Master Class: **In-House and Law Firm Perspectives on Selection and Evaluation of National and Regional Counsel**

Conference-at-a-glance

NEW! *denotes new session this year*

PRE-CONFERENCE
WEDNESDAY, DECEMBER 2, 2015

Morning

8:30
Workshop Registration and Continental Breakfast

9:00 NEW!
Pre-Conference Workshop:
Preparing the Next Generation of Leaders of the Defense Bar — Strategy and Trial Advocacy Deep-Dive

Afternoon

12:00 NEW!
In-House Think Tank Lunch *(by Invite Only)*

1:15
Pre-Conference Group Meet-Ups Registration
[INCLUDED IN MAIN CONFERENCE TUITION]

2:00
Defense Counsel War Room: Deconstructing the Latest and Greatest in Plaintiffs' Tactics (Facilitated by In-House Counsel)

4:30 NEW!
Judicial, Special Master, and Healthcare Perspectives on Products Liability Litigation

Evening

5:30
Pre-Registration and Welcoming Cocktail Reception

DAY ONE
THURSDAY, DECEMBER 3, 2015

Morning

7:00
Registration and Welcome Breakfast

7:45
American Conference Institute Opening Remarks

8:00
Co-Chairs' Opening Remarks

8:15 NEW!
General Counsel and Chief Litigation Counsel Roundtable: Factoring in the Attendant Consequences of a Products Liability Action When Making Business and Settlement Decisions

9:45
Morning Coffee Break Hosted by:
Patterson Belknap Webb & Tyler LLP

10:00
Efficiently and Effectively Managing Large Scale Discovery: Best Practices for Preservation and Production and How to Avoid Discovery Being Used as a Blunt Tool Against the Defense

11:30 NEW!
Getting Out Of Dodge — A Strategic Checklist For Getting Out of Unfriendly Jurisdictions and Practical Tips For Using Personal Jurisdiction, Forum Non Conveniens, Severance Motions, And CAFA And Other Removal Arguments

Afternoon

12:30
Networking Luncheon for Speakers and Delegates
Hosted by: GT GreenbergTraurig

1:30 NEW!
Plaintiffs' Lawyer Advertising and Lead Generation: Neutralizing the Efforts of Increasingly Aggressive Plaintiffs' Tactics

2:30
AFTERNOON BREAKOUT SESSIONS – Choose A or B

A. FDA's Generic Drug Labeling Proposed Rule: Best Practices for Generic, Innovator, and Biosimilars Manufacturers to Combat Anticipated Plaintiffs' Tactics

B. Preserving the Medical Device Preemption Defense in Light of Contrary Court Decisions and a Resurgence of Off-Label Attacks

3:30
Afternoon Networking Break
Hosted by: DrinkerBiddle

3:45
AFTERNOON BREAKOUT SESSIONS – Choose C or D

C. Enforcers' Spotlight: Understanding Government's Enforcement Priorities vis-à-vis Drug and Device Products Liability Matters

D. Controlling the Effects of Social Media on Products Liability Litigation: Practical Tips for Drug and Device Manufacturers

4:45
Continue to Next Session

5:00
AFTERNOON BREAKOUT SESSIONS – Choose E or F

E. What Drug and Defense Counsel Need to Know About the Rapidly Evolving Off-Label Promotion Landscape Post-*Amarin v. FDA* NEW!

F. Recent Developments and Strategies for Strengthening Your Class Action Defense NEW!

Evening

6:00
Conference Adjourns to Cocktail Party
Hosted by: KING & SPALDING

DAY TWO
FRIDAY, DECEMBER 4, 2015

Morning

7:30
Registration and Continental Breakfast

8:00
Co-Chairs' Opening Remarks and Recap of Day 1

8:15
Revisiting Bellwether Trials as the Go-To Choice for Mass Tort Litigation: A Close Look at the Benefits and Effectiveness of the Process

9:15
A View from the Bench: Judicial Insights into Drug and Medical Device Products Liability Litigation

10:45
Morning Coffee and Networking Break

11:00 NEW!
The Globalization of Drug and Med Products Liability: A Checklist for Creating a Cost-Effective Approach to International Mass Tort Litigation

Afternoon

12:00
Networking Luncheon Hosted by: Lighthouse eDiscovery

1:00 NEW!
Successfully Defending the Corporate Deposition: Concrete Examples of How to Prepare Witnesses for Reptile Questions

2:00
Afternoon Networking Coffee Break

2:15
Earn CLE ETHICS Credits
Hot Topics in Legal Ethics: Civility, Discovery, Privilege, Diversity, and More

3:15
Main Conference Concludes

3:30 – 5:30
Post-Conference Business Development Master Class: In-House and Law Firm Perspectives on Selection and Evaluation of National and Regional Counsel

PRE-CONFERENCE WORKSHOP • WEDNESDAY, DECEMBER 2, 2015
9:00 A.M. – 12:00 P.M. (REGISTRATION AND CONTINENTAL BREAKFAST AT 8:30 A.M.)

Preparing the Next Generation of Leaders of the Defense Bar — Strategy and Trial Advocacy Deep-Dive

March D. Coleman
Director, Legal
Merck & Co., Inc. (North Wales, PA)

Colleen M. Hennessey
Partner
Peabody & Arnold LLP (Boston, MA)

Frank C. Woodside, III, M.D., J.D.
Of Counsel
Dinsmore & Shohl LLP (Cincinnati, OH)

In this session designed for up-and-coming drug and medical device products liability attorneys, leading members of the defense bar will share the insights that they have gained in the trenches of litigation and will give attendees the nuanced information they need to stand out in this competitive field. More than just a primer of defending mass torts, this session will teach the rising stars of the defense products liability bar what they need to know to try a case and will increase their value to pharmaceutical and medical device clients. Topics to be discussed include:

- Setting the framework and demystifying what litigators need to know about the FDA's role in products liability: approval, labeling, adverse event reporting, off label promotion, clinical trials, social media regulations and more
- Fighting discovery battles
  - Working with the client to get the best info to prepare a strategy: what are the right questions to ask?
  - Avoiding discovery pitfalls and landmines
  - Getting key documents early on in a case
  - Making meaningful objections and taking concrete positions on what you want produced
  - Heading off any attempts to assert a spoliation of evidence claim
- Taking depositions: plaintiffs, treating and prescribing physicians, experts
  - Analyzing the applicable case law regarding the requirements for the admission of testimony by treating/prescribing physicians and expert witnesses
  - Conducting discovery with the goal of filing Daubert motions to preclude the admission of plaintiffs' treating physicians and expert witnesses
- Trial hacks: tips and best practices for those who are new to products liability litigation from those at the top of the game
  - Case analysis for potential mass torts
  - Choosing trial themes that resonate and will mitigate any bad facts in your case
  - Openings and closings
  - Direct and cross examination

12:00 **In-House Think Tank Lunch *(by Invite Only)***

Only for in-house counsel, this working lunch will provide a forum to discuss the state of the industry candidly with your peers and to focus on how members of the defense bar can coordinate their advocacy efforts to match those of a highly organized and well-funded plaintiffs' bar.

PRE-CONFERENCE GROUP MEET-UPS: 2:00 P.M. – 5:30 P.M. (REGISTRATION BEGINS AT 1:15 P.M.)

2:00 **Defense Counsel War Room: Deconstructing the Latest and Greatest in Plaintiffs' Tactics** *(Facilitated by In-House Counsel)*

Jennifer E. Dubas
Senior Vice President,
Associate General Counsel
Endo Pharmaceuticals (Malvern, PA)

Connie Matteo
Assistant General Counsel
Pfizer Inc. (New York, NY)

Sarah M. Padgitt
Senior Counsel
Baxter International Inc.
(Deerfield, IL)

Steve Phillips
Special Counsel
Medtronic, Inc.

Included in your registration, join your peers for a state-of-the-industry analysis and candid discussion about what is happening in the trenches of drug and medical device products liability litigation. In-house and law firm defense counsel are encouraged to participate in this unique networking session featuring interactive polling that will set the stage for the topics discussed in-depth throughout the event and provide you with valuable takeaways about what your peers from around the country are seeing from the plaintiffs' bar.

Topics of discussion will include:

- Examining the theories of liability plaintiffs are using in products liability cases against drug and device manufacturers around the country
- Status of select mass torts and bellwether trials from around the country: what are the new mass torts and MDLS, and where is the plaintiffs' bar headed in these cases?
- Proactively identifying drugs or devices which may be ripe for mass tort litigation in light of adverse event reports, social media postings, and attorney advertising
- Deconstructing recent noteworthy jury verdicts and coming up with a drug and med defense playbook of what themes resonate with juries
- Analysis of active and unfriendly jurisdictions
- Overview of plaintiffs' firms: who are the key players driving this litigation?
- Expert witnesses: who are the frequent testifiers?
- Good science and bad science: sharing literature that is relevant to the defense perspective in select mass torts
- Update on third party funding of products liability claims
- Getting the message of people over profits out there: successfully telling the public the real story of the efforts and costs inherent in the development of a drug or device to promote health and well-being
- Developing a good reputation and fostering positive public relations to increase favorable public perception pre-suit
- Combating public perception against corporations generally and preventing trials from turning into an indictment of "Big Pharma" or "Big Device" in particular
- Peeling back the lid on where the plaintiffs' bar focusing its lobbying efforts
- Keeping up with tort reform initiatives: moving forward with concerted tort reform efforts for 2016

4:30 **Judicial, Special Master, and Healthcare Perspectives on Products Liability Litigation**

The Honorable Ed Kinkeade
District Judge, United States District Court, Northern District of Texas
(Dallas, TX)

Wm. Stephen Boyd
Chief Legal Officer
Baylor Health Care System and Baylor Scott & White Health (Dallas, TX)

The Honorable James M. Stanton
Former State District Judge
Stanton Law Firm, PC
(Dallas, TX)

5:30 **Pre-Registration and Welcoming Cocktail Reception**

7:00 **Registration and Welcome Breakfast**

7:45 **American Conference Institute Opening Remarks**

8:00 **Co-Chairs' Opening Remarks**

Sonia Chen Arnold
Assistant General Counsel – Litigation and Legal Compliance
Eli Lilly and Company (Indianapolis, IN)

Max C. Heerman
Principal Litigation Counsel
Medtronic (Minneapolis, MN)

Sarah Heineman
Senior Counsel
Bayer Corporation (Pittsburgh, PA)

8:15 **General Counsel and Chief Litigation Counsel Roundtable: Factoring in the Attendant Consequences of a Products Liability Action When Making Business and Settlement Decisions**

Jean F. Holloway
Vice President, General Counsel & Secretary
CryoLife, Inc. (Kennesaw, GA)

Rita A. McConnell
Vice President and Chief Litigation Counsel
Medtronic, Inc. (Minneapolis, MN)

Richard W. Silbert
V.P., Assoc. General Counsel
Purdue Pharma L.P. (Stamford, CT)

Jack C. Silhavy
Executive Vice President & General Counsel
Fresenius Kabi USA (Lake Zurich, IL)

Anthony P. Tinari
Vice President and General Counsel
Bracco Diagnostics Inc. (Monroe Township, NJ)

Megan Westerberg
Senior Counsel, Litigation
Eisai Inc. (Woodcliff Lake, NJ)

Moderated by:

Lori G. Cohen
Shareholder and Chair, Pharmaceutical, Medical Device & Health Care Litigation Practice and Trial Practice Group
Greenberg Traurig, LLP (Atlanta, GA)

- What keeps in-house products liability counsel up at night when faced with a potential products liability issue?
- Creative management and resolution of mass tort scenarios before the cases are filed
- Considerations for putting systems in place before products liability litigation happens based on a clear understanding of how these ancillary consequences drive and trigger each other
- Tools for coordinating strategies with different in-house constituencies to cover the collateral consequences and form a bulletproof defense
- Determining when to bring in law firm counsel
- Early case evaluation and various approaches to settlement
  - Exploring the troubling steady increase in the size of drug and medical device products liability settlements and verdicts
  - Understanding the challenges inherent in executing a trial/settlement strategy in the face of an increasingly aggressive plaintiffs' bar and ever-rising litigation costs
  - Positioning yourself from the outset to drive down the costs of settlement decision
  - Anticipating the consequences of settlement decisions: how do you resolve one side of a potential products liability issue without creating a monster on the other side?

9:45 **Morning Coffee Break Hosted by:**

Patterson Belknap Webb & Tyler LLP

10:00 **Efficiently and Effectively Managing Large Scale Discovery: Best Practices for Preservation and Production and How to Avoid Discovery Being Used as a Blunt Tool Against the Defense**

Candace Camarata
Assistant General Counsel, Litigation & Investigations
C.R. Bard, Inc. (New Providence, NJ)

Courtney Camp Enloe
Lead Counsel, Litigation
McKesson (San Francisco, CA)

Joanne R. Lane
Associate Director
Merck & Co., Inc. (Rahway, NJ)

Christopher D. Liwski
Senior Corporate Counsel, NA Litigation & Investigations
Sanofi US (Bridgewater, NJ)

Michael P. Panagrossi
Associate General Counsel
Purdue Pharma L.P. (Stamford, CT)

Patrick L. Oot
Partner
Shook, Hardy & Bacon L.L.P. (Washington, DC)

- Reexamining company policies for document preservation in light of current e-discovery standards and expectations of U.S. Courts
  - What best practices and procedures should prudent companies have in place surrounding ESI to prevent million dollar mistakes?
  - Formulating internal policies and educating employees about the consequences of failure to comply with discovery and litigation holds to mitigate risk stemming from employees' actions and email usage

- Survey of the quickly evolving case law surrounding ESI protocols: updates on key federal and state decisions
- Considerations for international companies: managing cumbersome global discovery demands in light of differing privacy rules internationally
- Practical considerations: what is the projected growth of stored data and are the costs feasible given the exponentially large volume?
- Acquiring and using the contents of private cell phones and text messages in litigation: considerations vis-à-vis company employees' privacy rights and plaintiffs

- Complying with litigation holds: Understanding what is expected in terms of deadlines and production and the consequences for failing to comply
  - Arguing for limited jury instructions and against adverse jury instructions regarding litigation holds in light of the risk of exorbitant punitive verdicts disproportionate to the actual harm
  - Analyzing where an attorney's duty ethically begins and ends in light of recent strict case law about spoliation: law firm and in-house considerations
- Understanding how the December 2015 implementation of the changes to Rule 37(e) of the Federal Rules of Civil Procedure in December will impact litigation strategy going forward
  - Practical implications: will the new good faith standard bring proportionality to discovery?
  - Examining whether *Actos* has created a feeding frenzy and emboldened the plaintiffs' bar to pursue "discovery torts"
  - Anticipating ways some plaintiffs' attorneys will still find ways to use discovery to drive up costs and force settlements and gain a tactical advantage
  - Exploring other approaches to discovery: how to get more and better information from plaintiffs

11:30 Getting Out Of Dodge — A Strategic Checklist For Getting Out of Unfriendly Jurisdictions and Practical Tips For Using Personal Jurisdiction, Forum Non Conveniens, Severance Motions, And CAFA And Other Removal Arguments

Sarah Heineman
Senior Counsel
Bayer Corporation (Pittsburgh, PA)

Alan S. Modlinger
Counsel
Merck & Co., Inc. (Kenilworth, NJ)

Eric L. Alexander
Partner
Reed Smith LLP (Washington, DC)

Sean P. Fahey
Partner
Pepper Hamilton LLP (Philadelphia, PA)

- Examining the disparate procedural mechanisms in your arsenal and considerations for using them in the knock-down drag-out battle for removal to federal court
  - CAFA removal provisions — diversity and mass actions
  - Federal question arguments and specific versus general jurisdiction post-*Bristol-Myers Squibb Co. v. Superior Court of San Francisco County*
  - Severing claims that fall short of removal pursuant to CAFA numbers based on personal jurisdiction in the wake of *Daimler AG v. Bauman* and *Walden v. Fiore*
  - Understanding how *Mylan v. Astra Zeneca* will affect the personal jurisdiction analysis
  - Transfers under 1404
  - Growing case law surrounding forum non conveniens: will this kill mass proceedings in certain states?
  - Fraudulent joinder/misjoinder
- Update on plaintiffs' efforts to manipulate venue and jurisdiction
  - Anticipating more cases in which plaintiffs attempt to defeat the CAFA removal provisions by filing no more than a hundred actions per complaint in state court
  - Multi-plaintiff filings with spoiler plaintiffs and defendants
  - Overview of some of the recent cases regarding removal between state and federal court: what is the defense scorecard?
- Best practices for litigating in plaintiff friendly jurisdictions when manufacturers are unable to defeat remand to state court
  - How to improve your chances in unfriendly jurisdictions
  - Conducting discovery in full-discovery states
  - Litigating in multi-plaintiff cases

12:30 Networking Luncheon for Speakers and Delegates

Hosted by: GT GreenbergTraurig

1:30 Plaintiffs' Lawyer Advertising and Lead Generation: Neutralizing the Efforts of Increasingly Aggressive Plaintiffs' Tactics

Blaine R. Dart
Senior Corporate Counsel, Litigation, Investigations & Risk Management
Zimmer Biomet (Warsaw, IN)

Michael W. King
Corporate Counsel
Novo Nordisk Inc. (Plainsboro, NJ)

Abigail M. Butler
Partner
Faegre Baker Daniels (Fort Wayne, IN)

Brooke Killian Kim
Partner
DLA Piper (San Diego, CA)

- What can defense attorneys do to counterbalance the frustrating volume of plaintiffs' lawyer advertising to create claims?
  - Creating a defense message focused on safety and desire to promote health and well-being
  - Getting the word out there about victories for pharma and medical device companies in products liability actions to counteract reputational risk when lawsuits are publically filed
- Striking back: case studies of manufacturers who have taken an aggressive stance against false or misleading statements by law firms and 3rd party funding groups
  - Cease and desist letters
  - Countering free speech and lawsuits against public policy arguments
  - Factoring in relevant ethical rules surrounding attorney advertising
  - Understanding the business impact of going this route
- Using plaintiffs' advertising offensively
  - Monitoring new trends in plaintiffs' advertising and gauging what's coming down the pike in terms of exposure and liability
  - Focusing defense claims based on this analysis
  - Statute of limitations arguments: when does this begin to toll based on when ads are run?

2:30 Afternoon Breakout Sessions – Choose A or B

A FDA's Generic Drug Labeling Proposed Rule: Best Practices for Generic, Innovator, and Biosimilars Manufacturers to Combat Anticipated Plaintiffs' Tactics

Andrew J. Calica
Partner
Mayer Brown LLP
(New York, NY)

José A. Isasi, II
Partner
Jones Day (Chicago, IL)

Kevin C. Newsom
Partner
Bradley Arant Boult Cummings LLC (Birmingham, AL)

- Updates on the status of FDA's proposed generic labeling and preemption rule: deep-dive into the practical implications for both branded, generics, and biosimilars
  - Branded liability based on their ability to unilaterally change the label: which state Courts are rejecting and accepting *Conte?*
  - Utilizing an innovator liability theory when arguing for generic preemption
- Survey of the new preemption landscape: Overview of the new Federal Court and lower Court decisions and pending significant appeals
  - Dissecting plaintiffs' best arguments for pleading around preemption
  - Overview of successful defense strategies in recent cases regarding parallel claims
  - Forecasting the resurgence of the impossibility preemption defense in light of recent case law
  - Update on the status of the infamous "Footnote 4" exception cases winding their way through the Courts

B Preserving the Medical Device Preemption Defense in Light of Contrary Court Decisions and a Resurgence of Off-Label Attacks

Max C. Heerman
Principal Litigation Counsel
Medtronic
(Minneapolis, MN)

John P. Lavelle, Jr.
Partner
Morgan Lewis & Bockius LLP
(Philadelphia, PA)

James F. Murdica
Partner
Patterson Belknap Webb & Tyler LLP (New York, NY)

- Putting a defense strategy in place in spite of the current subtle contradiction in case law surrounding state-law parallel claims: what is the state of play with the Circuit splits?
  - Understanding the significance of the Supreme Court's denial of Cert in *Stengel* with respect to parallel state failure-to-warn claims
  - Avoiding express and implied preemption in cases regarding Class III medical devices
  - What are plaintiffs pleading to state their claims around preemption?
  - Which Courts are adopting or accepting the Solicitor General's opinion?
- Insights into recent allegations of off-label promotion on medical device manufacturers
  - Understanding how expressed and implied preemption will be affected
  - Special considerations surrounding preemption for PMA devices with combination or multiple parts including bone and hip grafts and infused products: what is the scope of pre-market approval?
  - Exploring the rise of FDA's use of human factors experts and analysis
- Insights from real arguments to best respond to the concerns on Judges' minds surrounding preemption going forward

3:30 Afternoon Networking Break Hosted by: Drinker Biddle

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C Enforcers' Spotlight: Understanding Government's Enforcement Priorities vis-à-vis Drug and Device Products Liability Matters

Jacob T. Elberg
Chief, Health Care & Government Fraud Unit
United States Attorney's Office, District of New Jersey
(Newark, NJ)

Charlene Keller Fullmer
Assistant United States Attorney and Deputy Chief, Affirmative Litigation, United States Attorney's Office, Eastern District of Pennsylvania (Philadelphia, PA)

Carmen M. Ortiz
United States Attorney
District of Massachusetts
(Boston, MA)

Sarah M. Padgitt
Senior Counsel
Baxter International Inc.
(Deerfield, IL)

Moderator:

John J. Pease
Partner
Morgan Lewis & Bockius LLP
(Philadelphia, PA)

- Preparing for increased criminal and civil enforcement actions stemming from drug and med device products liability
  - Off-label
  - Consumer Fraud
  - False Claims
  - Anti-kickback statute
  - FCPA for products distributed abroad
- Is a billion the new million? Analyzing the steady trend of staggering penalties and fines for drug and device makers in these cases
- The government's perspective on when and why to prosecute: how do enforcers identify companies for investigations?
  - Recognizing behaviors which may raise a red flag for enforcers and cause an enforcement and products liability action to go hand-in-hand: alleged false statements and misleading statements to watch out for
  - Addressing the increased threat of individual liability for responsible corporate officers and in-house counsel stemming from alleged products liability
  - Examining the level of interaction between federal and state governments in investigations stemming from the same alleged misconduct
  - What is the nature of the state's burden of proof in establishing harm?
  - What does the government expect and appreciate in how companies conduct discovery during an investigation?
- Practical considerations for in-house and law firm counsel when faced with DOJ or AG action
  - Best practices for responding to a government investigation
  - Properly conducting and documenting internal investigations
  - Making the difficult choice to voluntarily disclose the results of internal investigation in return for cooperation credit
  - Factoring the effect of follow-on civil litigation into the decision to settle with the DOJ
  - Analyzing the best arguments for and against AG's contingency fee arrangements with plaintiffs' counsel

D Controlling the Effects of Social Media on Products Liability Litigation: Practical Tips for Drug and Device Manufacturers

David M. Layfer
Counsel
Abbvie (North Chicago, IL)

Erica L. Visokey
Legal Counsel
Stryker Corporation
(Allendale, NJ)

Tariq M. Naeem
Partner
Tucker Ellis LLP (Cleveland, OH)

David B. Sudzus
Partner
Drinker Biddle & Reath LLP
(Chicago, IL)

- Update on FDA's social media guidelines for pharmaceutical and medical device manufacturers
  - Developing appropriate, risk-based protocols for social media presence to promote your products, in the absence of final guidance
  - Insights from recent warning letters of behavior that companies should avoid
  - Preparing and training employees about appropriate social media use
  - Alerting employees of the potential risks of tweets, blogs, and social media posts during litigation
  - Establishing a corporate record retention policy regarding social media
- Examining how social media might become a catalyst to products liability action
  - Overview of the ways FDA is using social media to detect and monitor adverse effects of drugs
  - Understanding the scope manufacturer liability for posted comments involving alleged adverse events and off-label product use
  - What is a company's duty to monitor the internet, beyond its own sponsored sites?
  - Beyond that, what is the duty to follow up?
- Making successful objections to keep out damaging posts and messages

4:45 Continue to Next Session

5:00 Afternoon Breakout Sessions – Choose E or F

E What Drug and Defense Counsel Need to Know About the Rapidly Evolving Off-Label Promotion Landscape Post-*Amarin v. FDA*

Patrick L. Gibson
Director, Government Investigations
Merck & Co., Inc.
(North Wales, PA)

Michael J. Hulka
General Counsel and Senior Director, Strategy and Operations, Lilly Oncology
Eli Lilly and Company
(Indianapolis, IN)

Mark Crane
Shareholder
Segal McCambridge Singer & Mahoney, Ltd. (Chicago, IL)

Sean P. Wajert
Managing Partner – Philadelphia Office
Shook, Hardy & Bacon L.L.P.
(Philadelphia, PA)

- Going through the year's biggest developments in the Legislatures and the Courts signaling that clarity surrounding permissible off-label usage might be on the horizon
- Examining the import of the First Amendment ruling in *Amarin v. FDA:* how to interpret the rights of sales to promote in a truthful and non-misleading method for an off-label indication?
- Status of the 21st Century Cures Act: will FDA be mandated to issue guidance?
- Update on recent drug and device Court battles surrounding off-label: what are the new trends vis-à-vis off-label marketing and products liability?
- Communicating to judges and juries that off-label does not necessarily equate unsafe

F Recent Developments and Strategies for Strengthening Your Class Action Defense

Blaine R. Dart
Senior Corporate Counsel, Litigation, Investigations & Risk Management
Zimmer Biomet (Warsaw, IN)

Donald R. Frederico
Partner
Pierce Atwood LLP(Boston, MA)

Brian A. Troyer
Partner
Thompson Hine LLP
(Cleveland, OH)

- Survey of recent case law: strategies for success in defending against class actions against drug and device manufacturers
- Rule 23(c)(4): understanding and defeating certification of issue classes
- Using Daubert challenges in opposition to class certification
- Developments and strategic considerations regarding overbreadth and ascertainability challenges
- Understanding key issues in the use of statistics and econometrics in class actions
- Developments in American Pipe tolling and mootness based on offers of judgment

6:00 Conference Adjourns to Cocktail Party Hosted by: KING & SPALDING

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7:30 **Registration and Continental Breakfast**

8:00 **Co-Chairs' Opening Remarks and Recap of Day 1**

8:15 **Revisiting Bellwether Trials as the Go-To Choice for Mass Tort Litigation: A Close Look at the Benefits and Effectiveness of the Process**

Cynthia J. Kretz
Vice President, General Counsel
Cook Group Incorporated (Bloomington, IN)

Christopher P. Gramling
Assistant General Counsel – Litigation and Legal Compliance
Eli Lilly and Company (Indianapolis, IN)

Alexander G. Calfo
Partner
King & Spalding (Los Angeles, CA)

John E. Galvin
Partner
Fox Galvin, LLC (St. Louis, MO)

Andrea Roberts Pierson
Partner
Faegre Baker Daniels (Indianapolis, IN)

- Examining the benefits and drawbacks of going the bellwether trial route knowing that the case has the potential to shape the entire litigation
  - Lessons learned from the year's biggest bellwether trials with a focus on both challenging rulings for the defense as well victories
  - Is it dangerous for corporate to defendants to put all their eggs in one basket or do that cost savings make it worthwhile?
- Best practices when electing to go the bellwether route: Implementing smart front-end strategies and setting precedents to streamline future trials and minimize litigation risks going forward
  - Effectively using screening orders and Lone Pine orders in mass torts to narrow the claims before the bellwether trials: setting up the case and implementing the order
  - Strategically selecting issues which have the best chance of eliminating future claims
  - Lobbying for favorable forums
  - Securing desirable timing and case sequences
- Overview of viable alternatives to the bellwether process: what are the relative strengths and weaknesses of each?
  - Allowing cases to go forward in state court
  - Groups of cases worked up in an MDL but tried in different District Courts
  - Sets of cases tried in front of a transferee judge

9:15 **A View from the Bench: Judicial Insights into Drug and Medical Device Products Liability Litigation**

The Honorable Ruben Castillo
Chief Judge, United States District Court,
Northern District of Illinois (Chicago, IL)

The Honorable Joy Flowers Conti
Chief Judge, United States District Court,
Western District of Pennsylvania (Pittsburgh, PA)

The Honorable Michael J. Davis
United States District Judge, District of Minnesota

The Honorable David R. Herndon
United States District Judge, Southern District of Illinois
(East St. Louis, IL)

The Honorable Leslie E. Kobayashi
United States District Judge, District of Hawaii
(Honolulu, HI)

The Honorable Richard A. Kramer
Judge, San Francisco County Superior Court
(San Francisco, CA)

The Honorable J. Frederick Motz
Senior Judge, United States District Court,
District of Maryland (Baltimore, MD)

The Honorable Arnold L. New
Supervising Judge, Court of Common Pleas,
Trial Division – Civil (Philadelphia, PA)

The Honorable Christopher A. Nuechterlein
United States Magistrate Judge,
Northern District of Indiana (South Bend, IN)

Moderator:

Andrew T. Bayman
Partner
King & Spalding LLP (Atlanta, GA)

Hear what arguments and claims Courts find most effective and persuasive when presiding over a drug or medical device products liability case. Formulate your drug and med litigation strategies based upon the insights of renowned jurists experienced in products liability litigation who will share their thoughts on pressing issues within litigation, including discovery, science days, civility, and cooperation between state and federal proceedings.

10:45 **Morning Coffee and Networking Break**

11:00 **The Globalization of Drug and Med Products Liability: A Checklist for Creating a Cost-Effective Approach to International Mass Tort Litigation**

Jobina Jones-McDonnell
Senior Litigation Attorney
Endo Pharmaceuticals (Malvern, PA)

Lisbeth Warren
Assistant General Counsel
Johnson & Johnson (New Brunswick, NJ)

David L. Ferrera
Partner, Chair, Product Liability and
Toxic Tort Litigation Practice Group
Nutter McClennen & Fish LLP (Boston, MA)

Jill M. Lawrie
Partner
Blake, Cassels & Graydon LLP (Toronto, ON)

- Preparing for increased mass torts actions which start in the US and extend overseas: working with the same fact patterns and same witnesses, but operating under the nuances of a different legal framework
- Understanding the interplay between USFDA and foreign regulatory bodies: how can your label, clinical trials etc. conducted under the laws of one jurisdiction come back to impact you in products liability litigation in another jurisdiction?
- Handling the nuances in foreign jurisdictions and mastering logistical coordination challenges
  - Coordinating with foreign law firms and leading trial teams overseas
  - Narrowing the defendant list to exclude affiliates, parents, etc.
  - Attorney client privilege issues across different jurisdictions
  - Conducting discovery under different rules
  - Service of process: exploring the creative ways plaintiffs are serving complaints on foreign manufacturers
  - Preparing witnesses and combating witness fatigue
- Update on key recent ex-US legal developments which may affect products liability litigation outcomes

12:00 **Networking Luncheon Hosted by:** Lighthouse eDiscovery

1:00 Successfully Defending the Corporate Deposition: Concrete Examples of How to Prepare Witnesses for Reptile Questions

Jason Baranski
Head Counsel U.S. Commercial
Shire Pharmaceuticals (Wayne, PA)

D'Lesli M. Davis
Partner
Norton Rose Fulbright US LLP (Dallas, TX)

Michael B. Hewes
Member
Butler Snow LLP (MS)

- Old tricks, new name: familiarizing corporate witnesses with plaintiffs' tactics to demonstrate danger to the community as a whole and tap into jurors' "reptile brains"
- Real life examples of questions that plaintiffs' lawyers have used to rattle even the most experienced corporate witnesses in depositions and create sound bites to use in trial
  - Duty-related questions
  - Questions about safety
  - Regulatory concerns
  - Company policy questions
  - Personal opinions
- Tips to counteract this plaintiffs' technique before it gains traction: how to prepare corporate representatives to respond, diffuse the situation, and recover
  - Creating confident witnesses, armed with the truth and knowledge of the product history
  - Developing themes with the witness to return to in the face of reptile-type attacks

2:00 **Afternoon Networking Coffee Break**

2:15 Hot Topics in Legal Ethics: Civility, Discovery, Privilege, Diversity, and More

Sonia Chen Arnold
Assistant General Counsel – Litigation and Legal Compliance
Eli Lilly and Company (Indianapolis, IN)

Donald P. Bunnin
Senior Litigation Counsel
Allergan plc (Irvine, CA)

Brennan J. Torregrossa
Assistant General Counsel
GlaxoSmithKline (Philadelphia, PA)

Stephen J. McConnell
Partner
Reed Smith LLP (Philadelphia, PA)

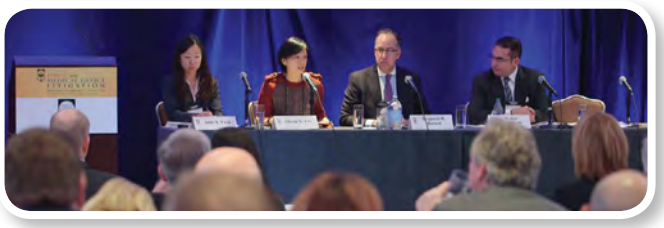
Mary R. Pawelek
Executive Managing Partner
Bowman & Brooke LLP (Austin, TX)

ETHICS

In this CLE Ethics session, leading counsel will go through a series of hypotheticals and examine the relevant ethical rules at play.

- Maintaining civility when litigating against an aggressive opponent
  - When do you cross the line in a spirited products liability defense?
  - Filing Rule 11 motions
  - Balancing zealous advocacy for your client corporation with compliant corporate responsibility based on developments in the responsible corporate officer doctrine: concerns for in-house and outside counsel
- Discovery: Avoiding ethical landmines and spoliation charges in document production
  - Understanding the duties of a life sciences attorney during document production in the digital age
  - Applying traditional ethical analysis under the Model Rules to a previously unimaginable amount of electronic data
- Attorney-client issues: Conducting internal investigations of products liability without fear of breaking attorney client and work product privileges
- Diversity: exploring the challenges and opportunities in attracting and retaining diverse trial counsel
  - How firms and companies can best implement policies that will truly effect change and promote a diverse workforce
  - Moving from an intellectual understanding of the need for diversity to measurable efforts showing recruitment, retention and advancement
  - Putting together a leadership team to develop and mentor diverse talent
  - Drilling down into the criteria that in-house counsel looks for when choosing diverse law firms

3:15 **Main Conference Concludes**



POST-CONFERENCE BUSINESS DEVELOPMENT MASTER CLASS
3:30 P.M. – 5:30 P.M.

In-House and Law Firm Perspectives on Selection and Evaluation of National and Regional Counsel

Patricia A. Barbieri
Deputy General Counsel, Legal Affairs
Daiichi Sankyo, Inc. (Parsippany, NJ)

David N. Royster
Vice President,
Deputy General Counsel
Zimmer Biomet Holdings, Inc.
(Warsaw, IN)

Back by popular demand: Designed to provide inside insights from both in-house and national trial counsel, this intimate networking group will leave attendees armed with the knowledge of what top companies and firms expect from their "go-to" team members.

- Comparing the various models for counsel roles — national, regional, local or by areas of expertise (e.g., evidence, discovery, appellate, *Daubert* and related scientific issues)
- Demystifying the selection process: what criteria are companies using to select national law firm counsel to represent them
  - What is the process for becoming a manufacturer's preferred provider?
  - How do the smaller firms get in the game?
  - Referral resources and decision making
  - Underlying partner relationships and engagement of outside counsel
  - How does the selection processes differ for high-stakes work?
- Tips for regional and liaison counsel: how can you most benefit and be a resource to your trial team?
  - Explaining local mores during jury selection
  - Ensuring local court practices and filings are appropriately adhered to
  - Questioning witnesses and providing additional support
- Dealing with the tremendous pressure to reduce costs and slash budgets in light of increased costs to life sciences companies in drug development, government regulations and requirements arising from healthcare reform
- Increasing outside counsel's performance while decreasing costs
  - Assessing outside counsel's performance: metrics for effectiveness and efficiency
  - Monitoring billing practices
  - What kinds of alternate and fixed fee arrangements with law firms are working to lower the cost of litigating products liability cases, to in-house counsel's satisfaction?
- Examining in-house and law firm counsels' "pet peeves" with regards to their outside counsel — what behavior/activities/style should be avoided?

Who You Will Meet

✓ In-house counsel for:

- pharmaceutical companies
- medical device companies
- biotech companies
- health care organizations

✓ Attorneys practicing in:

- pharmaceuticals
- drug and medical devices
- products liability
- mass tort
- complex and multidistrict litigation
- healthcare

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King & Spalding is an international law firm with more than 800 lawyers in 18 offices across the United States, Europe, the Middle East and Asia. More than 250 of our lawyers, scientists and consultants are dedicated to representing life sciences companies, with specialized experience at every stage of the product life cycle. We add to this a range of trial experience that is increasingly unusual in large firms. The firm's healthcare, life sciences and food and beverage practices are all named leading national practices by Chambers USA. King & Spalding is ranked a tier one firm for Healthcare Law, FDA Law and Mass Tort Litigation/Class Actions – Defendants by US News & World Report. For more information, please visit **www.kslaw.com**

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Bowman and Brooke LLP is a nationally recognized trial firm with one of the largest product liability practices in the country. The firm's Drug and Medical Device Litigation practice is comprised of experienced trial lawyers serving as national, regional and local counsel in some of today's most high profile individual and mass tort litigation. With a passion and drive for mastering complex medical, scientific, epidemiological, engineering and regulatory issues, Bowman and Brooke's lawyers deliver legal representation that is innovative, cost conscious and complements our clients' core business objectives. The firm's attorneys defend a variety of corporate clients, including many Global 500 and internationally based companies, in widely publicized catastrophic injury and wrongful death matters, and in other complex litigation throughout all 50 states. For more information, please visit **www.bowmanandbrooke.com**.

DLA Piper is a global law firm with a drug & medical device litigation team that advises clients on risk, compliance and business management at every stage of the product life cycle. We are positioned to efficiently defend claims of any scope, around the globe.

Drinker Biddle is a full-service national law firm with nearly 650 lawyers. We handle all types and aspects of products liability litigation and frequently serve as trial counsel and national coordinating counsel in suits defending prescription drugs, over-the-counter drugs and medical devices including orthopedic implants, antibiotics, contraceptives and antipsychotics. For more information, please visit **www.drinkerbiddle.com**.

Faegre Baker Daniels' product liability lawyers represent pharmaceutical and medical device manufacturers in all 50 states, Canada and Europe. With 750 lawyers and consultants in the U.S., U.K. and China, our firm offers integrated services to help achieve the goals of life science companies ranging from emerging startups to multinational corporations. We have served as national, regional and local defense counsel in major pharmaceutical and medical device product liability litigation. Our professionals aggressively defend claims in complex mass tort, toxic tort, multidistrict and class action litigation. In addition, we counsel clients on product liability risk management, regulatory compliance, reimbursement and more. Our practice is supported by our national health and life sciences industry team that includes our advisory and advocacy division based in Washington, D.C., FaegreBD Consulting. For more information, please visit **FaegreBD.com**.

Comfortable before a jury or arguing a complex MDL motion, **Fox Galvin** attorneys serve in a variety of roles on drug and medical device litigation. From our central St. Louis location, we have experience bringing great results and value as lead trial counsel, on discovery teams and as local/liaison counsel.

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