



20<sup>th</sup>  
ANNIVERSARY

Register Now • 888-224-2480  
www.DrugandMed.com

Packed with practical and sophisticated content  
see page 4 for new sessions

Earn  
CLE  
ETHICS  
Credits

# DRUG AND MEDICAL DEVICE LITIGATION

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

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

More in-house participation than any year to date, featuring more than 30 companies on the faculty and Advisory Board:

Abbvie	Cook Group Incorporated	Eli Lilly and Company	Medtronic	Shire Pharmaceuticals
Allergan plc	C.R. Bard, Inc.	Fresenius Kabi USA	Merck & Co., Inc.	St. Jude Medical, Inc.
Baxter International Inc.	CryoLife, Inc.	GE Healthcare	Novo Nordisk Inc.	Stryker Corporation
Bayer Corporation	Daiichi Sankyo, Inc.	Genentech	Pfizer Inc.	Turing Pharmaceuticals
Baylor Scott & White Health	Eisai Inc.	GlaxoSmithKline	Purdue Pharma L.P.	W.L. Gore
Bracco Diagnostics Inc.	Endo Pharmaceuticals	McKesson	Sanofi US	Zimmer Biomet

## View From the Bench:



*The Honorable  
Ruben Castillo*  
Chief Judge, United States District Court, Northern District of Illinois



*The Honorable  
Joy Flowers Conti*  
Chief Judge, United States District Court, Western District of Pennsylvania



*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



*The Honorable  
Ed Kinkeade*  
United States District Judge, Northern District of Texas



*The Honorable  
Leslie E. Kobayashi*  
United States District Judge, District of Hawaii



*The Honorable  
Richard A. Kramer*  
Judge, San Francisco County Superior Court



*The Honorable  
J. Frederick Motz*  
Senior Judge, United States District Court, District of Maryland



*The Honorable  
Arnold L. New*  
Supervising Judge, Court of Common Pleas, Trial Division – Civil



*The Honorable  
Christopher A. Nuechterlein*  
United States Magistrate Judge, Northern District of Indiana

## Prepare For Criminal and Civil Enforcement Stemming From Products Liability:



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



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



*Carmen M. Ortiz*  
United States Attorney, District of Massachusetts

Lead Sponsors:

**GT** GreenbergTraurig

KING & SPALDING

Morgan Lewis

Sponsored by:

*Blakes*  
CANADIAN LAWYERS

**B** Bowman and Brooke LLP

BUTLER | SNOW

**DLA** PIPER

DrinkerBiddle

FAEGRE BAKER DANIELS

FOX GALVIN LLC  
ATTORNEYS AT LAW

GOLKOW  
GLOBAL LITIGATION SERVICES

Lighthouse  
eDiscovery\*

MAYER • BROWN

NORTON ROSE FULBRIGHT

**Nutter**  
Nutter McClennen & Fish LLP  
ATTORNEYS AT LAW

Patterson Belknap Webb & Tyler LLP

RECORDEXPRESS

ReedSmith

Segal McCambridge  
Segal McCambridge Singer & Ivahoney

SHOOK  
HARDY & BACON

**MCS**

THOMPSON  
HINE

# ADVISORY BOARD AND DISTINGUISHED FACULTY

Drawn from the best that the bar, the bench, and the industry have to offer

## ACI Drug and Med Advisory Board for 2015:

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

*Mary-Alice Barrett*  
Assistant General Counsel, Senior Counsel Specialist – Litigation  
Genentech (Little Falls, NJ)

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

*Debra L. Burns*  
Senior Counsel Litigation/Investigations  
GE Healthcare (Wauwatosa, WI)

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

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

*Jill Harrison*  
Counsel  
W.L. Gore (Flagstaff, AZ)

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

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

## Co-Chairs:

*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)

## Speaker Faculty:

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

*Jason Baranski*  
Senior Vice President,  
Associate General Counsel  
Shire Pharmaceuticals (Wayne, PA)

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

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

*Heminger S. Bullock*  
Partner, Mayer Brown LLP (New York, NY)

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

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

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

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

*Mark Cheffo*  
Global Co-Head of Products Liability and  
Mass Torts, Quinn Emanuel Urquhart &  
Sullivan, LLP (New York, NY)

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

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

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

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

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

*The Honorable Michael J. Davis*  
United States District Judge,  
District of Minnesota (Minneapolis, MN)

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

*Howard L. Dorfman*  
Founder  
H.L. Dorfman Consulting  
(West Orange, NJ)  
(Former Senior Vice President and General  
Counsel, Turing Pharmaceuticals)

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

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

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

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

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

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

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

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

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

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

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

*Michael B. Hewes*  
Member  
Butler Snow LLP (Gulfport, MS)

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

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

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

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

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

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

*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)

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

*James W. A. Ladner*  
Deputy General Counsel –  
Litigation & Investigations  
St. Jude Medical, Inc. (St. Paul, MN)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*Steve Phillips*  
Special Counsel  
Medtronic

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

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

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

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

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

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

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

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

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

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

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

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

# 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](http://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. 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





## PRE-CONFERENCE WEDNESDAY, DECEMBER 2, 2015

## DAY ONE THURSDAY, DECEMBER 3, 2015

## DAY TWO FRIDAY, DECEMBER 4, 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

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

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 **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

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  
**NEW!** Post-*Amarin v. FDA*

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

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  
 **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

Evening

5:30  
Pre-Registration and Welcoming Cocktail Reception

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

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. Padgett**  
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



### **Howard L. Dorfman**

Founder  
H.L. Dorfman Consulting (West Orange, NJ)  
(Former Senior Vice President and General Counsel,  
Turing Pharmaceuticals)



### **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?



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



**Henninger S. Bullock**  
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**

### Global Sponsorship Opportunities

With more than 300 conferences in the United States, Europe, Asia Pacific, and Latin America, **American Conference Institute (ACI)** provides a diverse portfolio devoted to providing business intelligence to senior decision makers who need to respond to challenges spanning various industries in the US and around the world.

As a member of our sponsorship faculty, your organization will be deemed as a partner. We will work closely with your organization to create the perfect business development solution catered exclusively to the needs of your practice group, business line or corporation.

For more information about this program or our global portfolio of events, please contact:

**Wendy Tyler**, Director of Sales, American Conference Institute

Tel: 212-352-3220 x5242 | [w.tyler@AmericanConference.com](mailto:w.tyler@AmericanConference.com)





**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



**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**

**Continuing Legal Education Credits**



Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education requirements. This course is identified as nontransitional for the purposes of CLE accreditation.

ACI certifies that the activity has been approved for CLE credit by the New York State Continuing Legal Education Board.

ACI certifies that this activity has been approved for CLE credit by the State Bar of California.

You are required to bring your state bar number to complete the appropriate state forms during the conference. CLE credits are processed in 4–8 weeks after a conference is held.

ACI has a dedicated team which processes requests for state approval. Please note that event accreditation varies by state and ACI will make every effort to process your request.

Questions about CLE credits for your state? Visit our online CLE Help Center at [www.AmericanConference.com/CLE](http://www.AmericanConference.com/CLE)



**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**

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

**James W. A. Ladner**  
Deputy General Counsel – Litigation & Investigations  
St. Jude Medical, Inc. (St. Paul, MN)



**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**  
Senior Vice President, Associate General Counsel  
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)



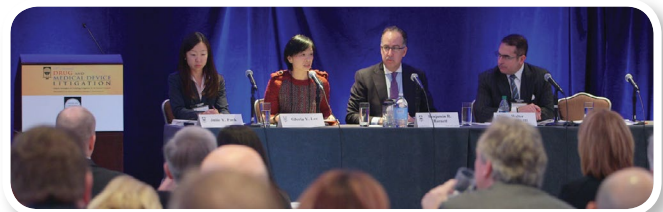
**Mary R. Pawelek**  
Executive Managing Partner  
Bowman & Brooke LLP (Austin, TX)

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

**ETHICS**

**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)



**Mark Cheffo**  
Global Co-Head of Products  
Liability and Mass Torts  
Quinn Emanuel Urquhart &  
Sullivan, LLP (New York, NY)

**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



### American Conference Institute:

**The leading networking and information resource for counsel and senior executives.**

Each year more than 15,000 in-house counsel, attorneys in private practice and other senior executives participate in ACI events — and the numbers keep growing.

#### Guaranteed Value Based on Comprehensive Research

ACI’s highly trained team of attorney-producers are dedicated, full-time, to developing the content and scope of our conferences based on comprehensive research with you and others facing similar challenges. We speak your language, ensuring that our programs provide strategic, cutting edge guidance on practical issues.

#### Unparalleled Learning and Networking

ACI understands that gaining perspectives from — and building relationships with — your fellow delegates during the breaks can be just as valuable as the structured conference sessions. ACI strives to make both the formal and informal aspects of your conference as productive as possible.

© American Conference Institute, 2015

# THE 20<sup>TH</sup> ANNUAL DRUG & MEDICAL DEVICE LITIGATION CONFERENCE

## APPRECIATES THE SUPPORT OF THE FOLLOWING ORGANIZATIONS

### Lead Sponsors:

#### **GT** GreenbergTraurig

Greenberg Traurig LLP is an international, multi-practice law firm with approximately 1,800 attorneys serving clients from 37 offices in the United States, Latin America, Europe, Asia, and the Middle East. The firm's Pharmaceutical, Medical Device & Health Care Litigation Practice is an integral part of the 600-plus member national Litigation Practice. The team is nationally recognized for its dynamic courtroom presence, responsiveness to clients and deep subject matter knowledge. Recent recognitions include national rankings for 2015 "Products Liability & Mass Torts" from *Chambers USA Guide*; national rankings for 2014 "Practice Liability & Mass Torts Defense: Pharmaceuticals and Medical Devices" from The Legal 500 United States; and a first-tier national ranking for "Litigation – Mass Tort Litigation and Class Actions – Defendants" from *U.S. News – Best Lawyers*® 2015 Best Law Firms. In addition, Greenberg Traurig is recognized as a "Product Liability Litigation Standout" in the *BTI Litigation Outlook* 2015 published by BTI Consulting Group. For more information, please visit [www.gtlaw.com](http://www.gtlaw.com).

#### **KING & SPALDING**

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](http://www.kslaw.com)

#### **Morgan Lewis**

Morgan Lewis is a global law firm with more than 2,000 legal professionals in 28 offices worldwide. Our comprehensive life sciences practice includes more than 200 lawyers, scientists and other technical specialists, many with advanced degrees, who have the experience and capability to represent the full life cycle of FDA-regulated products. Our strength is our ability to work collaboratively across several practice areas, such as products liability, consumer fraud, government investigations and FDA regulatory counseling and compliance, to provide strategic solutions for the multi-faceted challenges our clients face. Morgan Lewis offers extensive capabilities and decades of experience coordinating complex national litigation, in addition to providing efficient, powerful solutions for the increasingly demanding discovery environment. We are nationally recognized for our leadership and innovation in developing alternative fee structures. For more information, please visit [www.morganlewis.com](http://www.morganlewis.com).

### Sponsored by:



Blakes is one of Canada's leading and largest law firms with offices in Montréal, Ottawa, Toronto, Calgary and Vancouver as well as several key international locations. Internationally recognized for our life sciences expertise, we combine our dispute resolution, class action, product liability, regulatory, intellectual property and other expertise to meet the needs of our clients operating in the sector. These clients include multinational pharmaceutical, biotech, medical device and diagnostic product manufacturers as well as health-related service providers, research institutions and investors. Blakes' strength and coordination across offices and practice areas ensures high quality service, whether an issue is local or multi-jurisdictional.

**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](http://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.

#### **DrinkerBiddle**

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](http://www.drinkerbiddle.com).

#### **FAEGRE BAKER DANIELS**

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](http://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.



Lighthouse eDiscovery guides clients through every aspect of ediscovery. Our experienced client teams deliver with high velocity, unparalleled quality, and a pragmatic focus on lowering costs. We develop highly innovative applications built on leading third-party technology and custom-engineer solutions to specific client requirements. Our client-aligned approach enables us to form long-term relationships with many of the world's leading corporations and top law firms who rely on us for their ediscovery needs."

#### **MAYER • BROWN**

Mayer Brown is a global legal services provider advising clients in the full array of product liability and mass tort actions with extensive experience defending medical device and pharmaceutical manufacturers. Our nationally recognized practice draws upon a deep bench of trial lawyers, a wealth of multi-district and complex litigation experience and a leading Supreme Court and appellate practice to provide clients with an holistic approach to protecting their interests. Our global capabilities offer clients a cohesive multi-jurisdictional, multi-disciplinary product liability practice that avoids duplication of effort, enhances consistency and maximizes cost effectiveness. Please visit [www.mayerbrown.com](http://www.mayerbrown.com) for more information.

#### **NORTON ROSE FULBRIGHT**

Norton Rose Fulbright is a nationally recognized partner to industry in managing high-stakes litigation involving pharmaceuticals and medical devices. Our lawyers devote their practice to the defense of clients in contentious proceedings before courts and regulatory authorities across the US and the world. While focusing on efficient and strategic solutions to complex litigation, our lawyers have successfully tried cases in the toughest venues against the most formidable opponents. With over 3800 lawyers in over 50 cities across the globe, we can provide integrated advice on both domestic and cross-border matters. For more information, please visit [www.nortonrosefulbright.com](http://www.nortonrosefulbright.com).



Nutter McClennen & Fish LLP is a premier Boston law firm that provides high level legal counsel to clients across the country and around the world. For decades, one of the backbones of Nutter's civil litigation practice has been product liability defense. Our attorneys have years of real-world experience defending companies through trial and appeal in all types of product liability litigation, with a particular emphasis in drug and medical device claims and toxic torts.

#### **Patterson Belknap Webb & Tyler** LLP

Patterson Belknap delivers legal services across more than 20 practice groups. We frequently serve as national and regional litigation counsel for major pharmaceutical companies and other manufacturers. Our lawyers have handled all levels of trials and appeals and are skilled in making complex science understandable to juries and judges. For more information, please visit [www.pbwt.com](http://www.pbwt.com).





## ReedSmith

Reed Smith's Life Sciences Health Industry Group is dedicated to serving clients who help save patients' lives and health, through biotechnology, pharmaceuticals, medical devices, or the delivery of health care. Our full-service litigation practice is home to a deep bench of seasoned trial lawyers and appellate specialists, and consistently recognized for its successes in high-profile product liability and mass tort litigations. For more than 40 years, Reed Smith has served as national, strategic, trial, and science counsel to the top global pharmaceutical and medical device manufacturers in single plaintiff and complex litigation matters.

## SegalMcCambridge

Segal McCambridge Singer & Mahoney has served as National Coordinating Counsel, regional trial counsel and special counsel for pharmaceutical and medical device companies since the Firm was founded in 1986. Our success in handling these matters is predicated upon our vast experience in the various FDA regulatory schemes which govern the product at issue and our extensive experience in product liability litigation. The Firm has received repeated recognition for successfully defending complex drug and medical device claims demonstrating our familiarity with the industry, the challenges of the regulatory process and a deep understanding of the issues our clients face in this highly specialized area of litigation.

## SHOOK

SHOOK HARDY & BACON  
Shook, Hardy & Bacon L.L.P. is a premier international firm with approximately 500 attorneys in 13 offices worldwide. The firm has successfully represented leading pharmaceutical and medical device companies in product liability and other high-stakes litigation matters for over 40 years. In January 2012, *The American Lawyer* magazine named Shook the winner of its Product Liability Litigation Department of the Year contest, which followed the firm's recognition as winner in the same category in 2008 and finalist in 2010. In 2015, the firm was also named Global Product Liability Law Firm of the Year for the 11th consecutive year by *Who's Who Legal* and was named a "standout" in Product Liability Litigation and Class Actions in BTI Consulting Group's Litigation Outlook 2015 report. Shook also received the Association of Corporate Counsel's "Value Champion" Award in 2012, 2013 and 2015, more times than any other law firm. [www.shb.com](http://www.shb.com)

## THOMPSON HINE

Nationally recognized for providing superior client service, Thompson Hine serves premier businesses worldwide. The lawyers in our Pharmaceutical and Medical Device Litigation practice have the knowledge and experience to develop practical, efficient solutions to the challenges pharmaceutical and medical device companies face when confronted with personal injury, commercial, or consumer litigation. For more information, please visit [www.ThompsonHine.com](http://www.ThompsonHine.com)

# REGISTRATION INFORMATION

## 5 Easy Ways to Register

**MAIL**  
American Conference Institute  
45 West 25th Street, 11th Floor  
New York, NY 10010

**PHONE**  
888-224-2480

**FAX**  
877-927-1563

**ONLINE**  
[www.DrugandMed.com](http://www.DrugandMed.com)

**EMAIL**  
[CustomerService@AmericanConference.com](mailto:CustomerService@AmericanConference.com)

CONFERENCE CODE: 801L16-NYC

FEE PER DELEGATE	Advance Pricing On or Before September 25, 2015	Standard Pricing By November 6, 2015	Late Registration After November 6, 2015
<input type="checkbox"/> Conference, Group Meet-Up + Both Workshops	\$3195	\$3395	\$3695
<input type="checkbox"/> Conference, Group Meet-Up + 1 Workshop	\$2795	\$2995	\$3295
<input type="checkbox"/> Conference and Group Meet-Up	\$2195	\$2395	\$2695
<input type="checkbox"/> Please reserve ___ additional copies of the Conference Materials at \$199 per copy.			
Special \$1395 rate for in-house counsel from drug, device and biotechnology companies			

### Hotel Information

American Conference Institute is pleased to offer our delegates a limited number of hotel rooms at a preferential rate. Please contact the hotel directly and mention the "ACI Drug & Med" conference to receive this rate.

Venue: Millennium Broadway Hotel New York  
Address: 145 West 44th Street, New York, NY, 10036, United States  
Reservations: 212-768-4400 or 866-858-9973

### ACH Payment (\$USD)

Please quote the name of the attendee(s) and the event code 801L16 as a reference.

For US registrants:

Bank Name: HSBC USA

Address: 800 6th Avenue, New York, NY 10001

Account Name: American Conference Institute

UPIC Routing and Transit Number: 021-05205-3

UPIC Account Number: 74952405

Non-US residents please contact Customer Service for Wire Payment information

For Payment information and Cancellation Policy, please visit our website [www.DrugandMed.com](http://www.DrugandMed.com)

### Incorrect Mailing Information

If you would like us to change any of your details please fax the label on this brochure to our Database Administrator at 1-877-927-1563, or email [data@AmericanConference.com](mailto:data@AmericanConference.com). **ACI reserves the right to deny admission to anyone, at any time, for any reason.**

### GROUP PRICING

1-2	No Discount
3-4	10% Discount
5-6	15% Discount
7	20% Discount
More than 7	Call 888-224-2480

### Special Discount

We offer special pricing for groups and government employees. Please email or call for details. Promotional discounts may not be combined. ACI offers financial scholarships for government employees, judges, law students, non-profit entities and others. For more information, please email or call customer service.

### Missed A Conference — Order The Conference Materials Now!

If you missed the chance to attend an ACI event, you can still benefit from the conference presentation materials. To order the Conference Materials, please call +1-888-224-2480 or visit: [www.americanconference.com/conference\\_papers](http://www.americanconference.com/conference_papers)



American Conference Institute  
45 West 25th Street, 11th Floor  
New York, NY 10010

ATTENTION MAILROOM: If undeliverable to addressee,  
please forward to: COUNSEL, LITIGATION/PRODUCTS  
LIABILITY ATTORNEY

## HERE'S WHAT PRIOR DELEGATES HAD TO SAY

There is no better forum for leading edge thinking on today's most pressing drug and med litigation challenges

**Patrick L. Gibson**  
Director, Government Investigations Merck & Co., Inc.



The ACI Drug and Med conference is a great opportunity to connect with other members of the products liability bar and get real-time and real-world information about mass tort litigation throughout the country.

**Debra L. Burns**  
Senior Counsel Litigation/Investigations, GE Healthcare



### REGISTRATION CODE

S10-801-801L16.S



20<sup>th</sup>  
ANNIVERSARY

# DRUG AND MEDICAL DEVICE LITIGATION

Earn  
CLE  
ETHICS  
Credits

Expert Strategies for Leading Products Liability Litigators & In-House Counsel  
DECEMBER 2-4, 2015 | MILLENNIUM BROADWAY HOTEL | NEW YORK, NY

### Why this event is a must-attend for you and your team:

1

More in-house presence than any year to date — over 30 in-house counsel speakers

3

Mingle with 400 of your peers from around the country

2

Hear from 12 leading federal and state jurists

4

Eligible for CLE and Ethics credits

Register Now • 888-224-2480 • [www.DrugandMed.com](http://www.DrugandMed.com)

More in-house participation than any year to date, featuring more than 30 diverse companies on the faculty and Advisory Board including:

Abbvie	Eisai Inc.	Novo Nordisk Inc.
Allergan plc	Endo Pharmaceuticals	Pfizer Inc.
Baxter International Inc.	Eli Lilly and Company	Purdue Pharma L.P.
Bayer Corporation	Fresenius Kabi USA	Sanofi US
Baylor Scott & White Health	GE Healthcare	Shire Pharmaceuticals
Bracco Diagnostics Inc.	Genentech	St. Jude Medical, Inc.
Cook Group Incorporated	GlaxoSmithKline	Stryker Corporation
C.R. Bard, Inc.	McKesson	Turing Pharmaceuticals
CryoLife, Inc.	Medtronic	W.L. Gore
Daiichi Sankyo, Inc.	Merck & Co., Inc.	Zimmer Biomet

Lead Sponsors:

**GT** GreenbergTraurig

KING & SPALDING

Morgan Lewis

Sponsored by:

**Blakes**  
CANNON LAWYERS

**B** Bowman and Brooke

BUTLER | SNOW

**DLA** PIPER

DrinkerBiddle

**FAEGRE BAKER DANIELS**

**FOX GALVIN**  
ATTORNEYS AT LAW

**GOLKOW**  
GLOBAL LITIGATION SERVICES

**Lighthouse**  
eDiscovery

MAYER · BROWN

**NORTON ROSE FULBRIGHT**

**Patterson Belknap Webb & Tyler** LLP

**Nutter**  
Nutter McClennen & Fish LLP  
ATTORNEYS AT LAW

**RECORDEXPRESS**

**ReedSmith**

**Segal McCambridge**  
Segal McCambridge Singer & Stanton

**SHOOK**  
HARDY & BACON

**MCS**

**THOMPSON**  
LINE