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NEW!
Executive Boardroom Meeting: Engage with the most sophisticated minds in the industry during this intensive and exclusive 3-hour in-house only brainstorming session!

November 28 – 30, 2018 | New York Marriott Marquis, New York, NY

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23RD ANNUAL CONFERENCE ON

DRUG & MED DEVICE LITIGATION

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

Distinguished Co-Chairs:

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Senior Counsel
Cardinal Health

Carolyn M. Hazard
Senior Vice President, Associate General Counsel – Litigation
Endo Pharmaceuticals

Featured Speakers:

Adam C. Bassing
Associate General Counsel
UCB

Ragan E. Cheney
Sr. Vice President, General Counsel Corporate Secretary
Titan Spine

Greg A. Dadika
Associate General Counsel, Litigation
Becton, Dickinson

Rachel Gallagher
Director, Legal Counsel
Teva Pharmaceuticals USA

Gina Gencarelli
Senior Director, Intellectual Property
Par Pharmaceutical

Christopher Guth
Senior Counsel
Bayer U.S.

Elizabeth Howard
Executive VP and General Counsel
Arbutus Biopharma

Wendy Hufford
Chief Operating Officer, Legal Department & Vice President, US Litigation, Risk Management & Human Resources
Boehringer Ingelheim USA

Lisa LeCointe-Cephas
Executive Director, Head of Global Investigations
Merck & Co.

Amanda T. Perez
Assistant General Counsel
Pfizer Inc.

Maureen A. Ruane
Vice President & Head of U.S. Litigation
Novartis

Munjot Sahu
Counsel – Litigation and Legal Compliance
Eli Lilly

Highlighted Judges:

Hon. Ann D. Montgomery
Senior Judge
U.S. District Court, D. Minn.

Hon. Arnold L. New
Coordinating Judge/Complex Litigation Center
Philadelphia Court of Common Pleas

Hon. Patti B. Saris
Chief Judge
U.S. District Court, D. Mass. (Boston, MA)

Hon. Leda Dunn Wettre
Magistrate Judge
U.S. District Court, D.N.J.

Hon. Susan D. Wigenton
Judge
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a C5 Group Company
Business Information in a Global Context

What's New for 2018?

- Extended Networking Breaks
- 18 Ground Breaking Sessions with the Introduction of 7 Thought Provoking Discussions on the Most Pressing Products Liability Challenges of 2018
- 2 Panels of Judges Involved in MDLs and Drug & Device Cases
- Insights on the Future of Drug and Medical Device Litigation from over 2 Dozen In-House Counsel

400+ ATTENDEES

70+ SPEAKERS *including* **24+** IN-HOUSE SPEAKERS

18+ SESSIONS

Special Features for In-House Counsel

Designed with the needs of in-house counsel in mind!

› Highlighted features:

- NEW **Executive Boardroom Meeting:** Engage with the most sophisticated in-house minds in the industry during an intensive and exclusive 3-hour brainstorming session!*
- **In-House Think Tank Lunch *(by Invite Only)*** — Discuss the state of the industry candidly with your peers on how members of the defense bar can coordinate their advocacy efforts for 2019.*
- NEW *Limited **complimentary passes** available this year for qualified in-house counsel. *See page 15 for details.*

› Featured sessions on:

- More than just products liability — the latest on pricing transparency initiatives, regulatory updates and patent litigation impacting the industry
- Diversity: Practical ways for incorporating diversity and inclusion into the trial team and litigation strategy
- Enforcement Initiatives and Priorities straight from the enforcers themselves

Defense Counsel Only War Room

Back by Popular Demand

Open to defense counsel only, join your peers to participate in this unique, interactive networking session 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.

See details on page 6

Participating Companies Include:

Daiichi Sankyo, Inc.
Endo Pharmaceuticals
Medtronic, Inc.
Bayer U.S.
Purdue Pharma L.P.
UCB, Inc.
Eli Lilly
Titan Spine
Becton, Dickinson and Company
Teva Pharmaceuticals USA, Inc.
Cardinal Health
Arbutus Biopharma
Boehringer Ingelheim USA Corporation
Merck & Co., Inc.
Pfizer Inc.
Novartis
GSK
Stryker Corporation
Bristol-Myers Squibb Company
and more...

About Us:

ACI American Conference Institute

The C5 Group, comprising American Conference Institute, The Canadian Institute and C5 in Europe, is a leading global events and business intelligence company.

For over 30 years, C5 Group has provided the opportunities that bring together business leaders, professionals and international experts from around the world to learn, meet, network and make the contacts that create the opportunities.

Our conferences and related products connect the power of people with the power of information, a powerful combination for business growth and success.

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Agenda At-A-Glance

✹ New This Year

	DAY ONE WEDNESDAY, NOVEMBER 28, 2018	DAY TWO THURSDAY, NOVEMBER 29, 2018	DAY THREE FRIDAY, NOVEMBER 30, 2018
7 am		7:00 **Registration and Welcoming Breakfast** — HOSTED BY: VENABLE LLP	7:15 **Registration and Continental Breakfast**
8 am	8:30 **Drug and Med Cross-Exam 101 Registration and Continental Breakfast**	8:00 **Co-Chairs' Opening Remarks** 8:15 **GC and CLO Roundtable**	8:00 **Co-Chairs' Opening Remarks** 8:15 **A View from the Bench**
9 am	9:00 **Drug and Med Cross-Exam 101**	9:30 ✹ **MDLs: Examining Their Original Purpose and Attempted Ways at Improving the MDL System**	9:30 **Enforcers' Roundtable**
10 am		10:15 **Morning Coffee Break** 10:45 **A View from the Bench**	10:30 **Morning Coffee Break** 10:45 ✹ **Hiring the Right Regional Counsel**
11 am			11:30 ✹ **What Does It Mean to Be an Innovative Thinker as an Outside Counsel**
12 pm	12:30 **In-House Only Think-Tank Lunch**	12:00 **Networking Luncheon** — HOSTED BY: GT Greenberg Traurig	12:15 **Networking Lunch**
1 pm	1:45 **Registration for Afternoon Sessions**	1:00 ✹ **Diversity and Inclusion** 1:45 **Afternoon Breakout Sessions** (CHOOSE A OR B) A. The Future of Personal Jurisdiction B. Gaining Control Over Third-Party Financing of Litigation	1:15 ✹ **Lay of the Land with Respect to Pricing Transparency, Patent Litigation, and Regulatory Trends**
2 pm	2:00 ✹ **Executive Boardroom Meeting** (IN-HOUSE COUNSEL BY INVITATION ONLY) 2:30 **Defense Counsel Only War Room**	2:30 **Afternoon Networking Break** — HOSTED BY: DrinkerBiddle	2:00 **Opioid Enforcement and Litigation Landscape** 2:45 **Conference Ends**
3 pm		3:00 **Afternoon Breakout Sessions** (CHOOSE A OR B) A. How to Move Forward When Faced with a Multi-Plaintiff Trial B. Scope of Discovery 3:45 **Afternoon Breakout Sessions** (CHOOSE A OR B) A. State of the Union on Preemption B. Strategies for Minimizing the Effects of Innovator Liability	
4 pm		4:30 **Afternoon Breakout Sessions** (CHOOSE A OR B) ✹ A. Training the Future Generations of Life Sciences Attorneys ✹ B. Examining the Intersection of Traditional Principles of Product Liability Laws with Digital Health and 3D Printing	
5 pm	5:00 **Pre-Registration and Welcoming Cocktail Reception** — HOSTED BY: McDermott Will & Emery	5:15 **Conference Adjourns to Cocktail Party** — HOSTED BY: KING & SPALDING	

DAY ONE
WEDNESDAY, NOVEMBER 28, 2018

Workshop:
Drug and Med Cross-Examination 101

9:00 – 12:00 (Registration and Continental Breakfast at 8:30)

Sean K. Burke
Partner
Duane Morris (Washington, DC)

Because a drug or device trial often hinges on the expert witness testimony, knowing how to conduct an effective cross-examination of an expert is crucial in determining the direction of the litigation.

Designed for those who are new to this type of litigation, this intensive 3-hour class will arm you with strategies on how to effectively use key case milestones, such as Daubert/Frye motions, as well as how to cross-examine a science and a regulatory/FDA expert. Points of discussion will include:

- Conveying easy to understand scientific concepts to the jury
- Exacting jury-friendly concessions from the opposing expert
- Highlighting the expert's misuse of statistical data and methodology
- How to undercut attempts to confuse principles of burden of proof with principles of statistical significance
- Using the expert to establish the expertise of the FDA and pervasiveness of FDA review and oversight
- Successfully showing — through cross — that the regulatory/FDA expert lacks sufficient qualifications in the area of proposed testimony
- Using prior reports and testimony to demonstrate that the expert's opinions are boilerplate and full of biases
- Following the money: Using the total dollar figures the expert has made providing testimony against him/her

LIMITED COMPLIMENTARY PASSES FOR IN-HOUSE COUNSEL

12:30
In-House Think-Tank Lunch*

2:00 – 5:00 (Registration begins at 1:45)
NEW In-House Executive Boardroom Meeting*

Top drug and device in-house minds will come together for this exclusive invite-only boardroom meeting to discuss their most difficult challenges and top priorities as they navigate and together think through the future of the healthcare industry.

**Open to In-House Counsel and Senior Executives from Drug, Device and Biotech Companies. All interested parties will be pre-qualified before registering for the program.*

Workshop:
Defense Counsel Only War Room

2:30 – 5:00 (Registration begins at 1:45)

Patricia A. Barbieri
SVP, General Counsel and Secretary
Daiichi Sankyo, Inc. (Parsippany, NJ)

Max Heerman
Principal Litigation Counsel
Medtronic (Washington, DC)

Open to defense counsel only — Join your peers for a state-of-the-industry analysis and candid discussion about the latest and greatest in plaintiffs' tactics. In-house and law firm defense counsel are encouraged to participate in this unique, interactive networking session 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. Discussion will include:

- Jurisdictional issues
- Discovery, including cross-border discovery
- Successful motions to dismiss and other dispositive motions
- Litigation tactics in aggregated cases: multiple plaintiff trials
- Defending against junk science and using good science/literature to bolster your defense
- Punitive damages: to bifurcate or not bifurcate?
- In-house counsel: how can your clients better serve you? Outside counsel: how can your clients be better partners?
- Analysis of the recent wave of cases in device litigation where courts have been excluding evidence of the 510k clearance process
- A survey of the less known but important decisions impacting the drug and device space

5:00 – 6:00
Pre-Registration and Welcoming Cocktail Reception

HOSTED BY: McDermott Will & Emery

MAIN CONFERENCE DAY TWO
THURSDAY, NOVEMBER 29, 2018

7:00

Registration and Welcoming Breakfast | HOSTED BY: VENABLE LLP

8:00

Co-Chairs' Opening Remarks

Kailee Goold
Senior Counsel
Cardinal Health (Columbus, OH)

Carolyn M. Hazard
Senior Vice President, Associate General Counsel – Litigation
Endo Pharmaceuticals Inc. (Malvern, PA)

8:15

GC and CLO Roundtable: What Keeps Them Up at Night

Ragan E. Cheney
Sr. Vice President, General Counsel
Corporate Secretary
Titan Spine (Mequon, WI)

Elizabeth Howard
Executive VP and General Counsel
Arbutus Biopharma (Warminster, PA)

Maureen A. Ruane
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Purdue Pharma L.P. (Stamford, CT)

Jonathan Wasserman
Vice President and Associate General Counsel,
Litigation & Government Investigations
Bristol-Myers Squibb Company (Lawrenceville, NJ)

Moderator

Lori G. Cohen
Co-Chair, Global Litigation; Chair, Pharmaceutical, Medical Device & Health Care Litigation Group; Chair, Trial Practice Group
Greenberg Traurig, LLP (Atlanta, GA)

In this exclusive session, attendees will have the unique opportunity to hear directly from leading counsel at pharmaceutical and device companies about their greatest products liability challenges. Gain critical insights into the thinking and mindset of key legal decision makers on such topics as:

- Conducting litigation and compliance audits to determine key areas of risk
  - » Factoring in litigation trends and recent product liability law suits and enforcement activity against life sciences companies
  - » Analyzing areas of risk for your company based on internal audits and forecasting the likelihood of a potential lawsuit or enforcement action
  - » Assessing costs of potential litigation
- Communicating areas of potential risk to company's senior executives
- Weighing options to manage an MDL when settlement is not feasible
- Exploring the latest fee arrangement and alternate payment structures with outside counsel
- Balancing the litigation environment with business demands/realities
- How to best address/respond to media scrutiny and attack as well as other public relations issues

9:30

NEW MDLs: Their Intended Purpose, What Attempts Have Been Made at Improving the MDL System, and Effective Ways for Wrapping Them Up

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

Malini Moorthy
Vice President & Associate General Counsel; Head of Global Litigation
Bayer U.S. (Pittsburgh, PA)

Lana K. Varney
Partner
King & Spalding (Austin, TX)

- What is the intended purpose behind MDLs and has that purpose been obscured by practicalities of courts' needing to manage the case dockets?
- What attempts have been made at improving the MDL system?
- Early judicial analysis of inventories in MDLs: Looking at the issue of meritless cases hiding within the MDLs, can any strategies be suggested to the courts as to how to address it?

Getting closure: How to wrap up an MDL?

- » Ideas and strategies as to how to manage whatever is left after the settlement (e.g., unpaid claims)
- » How to negotiate and convince Plaintiff's counsel?
- » How to manage client's expectations?
- » What kind of assurances can be had?

10:15

Morning Coffee Break

10:45

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

Hon. Michael J. Davis
Senior Judge
U.S. District Court, D. Minn. (Minneapolis, MN)

Hon. David R. Herndon
Judge
U.S. District Court, S.D. Ill. (East St. Louis, IL)

Hon. Loretta A. Preska
Senior Judge
U.S. District Court, S.D.N.Y. (New York, NY)

Hon. Nancy J. Rosenstengel
Judge
U.S. District Court, S.D. Ill. (East St. Louis, IL)

Moderator:

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

12:00

Networking Luncheon

HOSTED BY: Greenberg Traurig

1:00

NEW **Practical Ways for Incorporating Diversity and Inclusion into Your Trial Team and Litigation Strategy**

Sonia Chen Arnold
Assistant General Counsel
Lilly Diabetes
Eli Lilly and Company (Indianapolis, IN)

Rachel Gallagher
Director, Legal Counsel
Teva Pharmaceuticals USA, Inc (Horsham, PA)

Kim M. Schmid
Firm Vice Chair and Executive Managing Partner
Bowman and Brooke LLP (Minneapolis, MN)

Robert Simpson
Partner
Shipman & Goodwin LLP

Having a diverse group of attorneys comprised of individuals of different races, genders, sexual orientations, and generations, which is reflective of the community in which cases are tried, makes for a stronger litigation team with a wealth of perspectives and personal experience. In addition to this common sense rationale for diversity, in-house counsel have espoused a commitment to diversity within their law departments and have made it clear that diversity matters to them when vetting and choosing law firms to represent them. In this session, points of discussion will include:

- Making sure all understand why it makes good business sense to have a diverse litigation team within both companies and law firms
- Moving from an intellectual understanding of the need for diversity to measurable efforts showing recruitment, retention, and advancement
  - » Discussing what diversity initiatives are working and designing sustainable diversity program for life sciences companies and outside law firms representing them
- How law firms and companies can best implement policies that will truly effect change and promote a diverse workforce
  - » What specific evidence of diversity are companies seeking from outside counsel
    - Firm composition overall
    - Partners
    - Breakdowns within teams
- Evaluating a firm's efforts in promoting diversity
  - » Having a written plan and timeline in place to measure diversity efforts
  - » Targeting specific deficiencies within the firm's composition
  - » Putting together a leadership team to develop and mentor diverse talent

"I enjoy attending ACI's Drug and Med because of the quality presentations, and the interaction with the lawyers and clients that I've had the opportunity to work with for so many years."

Goodell DeVries Leech & Dann LLP

AFTERNOON BREAKOUT SESSIONS

THURSDAY, NOVEMBER 29, 2018

(CHOOSE A OR B)

A

1:45

The Future of Personal Jurisdiction: Decisions of Note and Interpretations Around the Country

Halli D. Cohn
Partner
Troutman Sanders LLP (Atlanta, GA)

Sarah Heineman
Senior Counsel
Bayer U.S. (Pittsburgh, PA)

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

In the aftermath of the *BMS* decision, the discussion will focus on how the decision has been applied by the courts around the country as well as what the next stages are and how Plaintiffs' attorneys have looked to circumvent the decision.

OR

B

1:45

Gaining Control Over Third-Party Financing of Litigation: How are Third-Party Funding Deals Structured and What Efforts Have Been Made to Combat the Trend

John H. Beisner
Partner
Skadden, Arps, Slate, Meagher & Flom LLP (Washington, D.C.)

Christopher Guth
Senior Counsel
Bayer U.S. (Pittsburgh, PA)

Kelley S. Olah
Partner
Barnes & Thornburg LLP (Los Angeles, CA)

- Who gets funded?
- How are these deals structured?
- Potential issues with these deals and ways of addressing them
- Status of the current bill introduced in Congress by Senators Grassley, Tillis, and Cornyn that would require disclosure of third-party litigation financing agreements in civil lawsuits

2:30

Afternoon Networking Break

HOSTED BY: DrinkerBiddle

AFTERNOON BREAKOUT SESSIONS

THURSDAY, NOVEMBER 29, 2018

(CHOOSE A OR B)

A

3:00

Best Strategies for Moving Forward When Faced with an Actual Multi-Plaintiff Trial

Amanda T. Perez
Assistant General Counsel
Pfizer Inc. (New York, NY)

Hildy Sastre
Partner
Shook Hardy & Bacon L.L.P. (Miami, FL)

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

- Best strategies for arguing against multi-plaintiff trials
- Once faced with this type of a trial, what are the best safeguards that can be put in place?
  - » How to structure limines to preserve the record?

OR

B

3:00

Has Proportionality Changed Anything? Impact of Recent Decisions and New Technologies on the Scope of Discovery

Julie Y. Park
Partner
Morrison & Foerster LLP (San Diego, CA)

Patrick H. Reilly
Partner
Faegre Baker Daniels LLP (Indianapolis, IN)

Munjot Sahu
Counsel – Litigation and Legal Compliance
Eli Lilly and Company (Indianapolis IN)

- Latest arguments on discovery
  - » How have the FRCP amendments affected the scope of discovery?
  - » What are the prevailing arguments on plaintiffs' side? Defense side?
- Has proportionality affected discovery in state courts?
  - » How can defendants protect themselves in state courts that don't have the proportionality standard?
- Putting machine learning to work in discovery
  - » What needs to change to make machine learning accepted in discovery?
  - » How comfortable is the industry with machines making distinctions between responsive and privileged documents?

A

3:45

State of the Union on Preemption

Paul J. Cosgrove
Partner
Ulmer & Berne LLP (Cincinnati, OH)

David W. O'Quinn
Member
Irwin Fritchie Urquhart & Moore LLC (New Orleans, LA)

Erica Valenti Visokey
Legal Counsel
Stryker Corporation (Stamford, CT)

Moderator

Terrence J. Dee
Partner
McDermott Will & Emery (Chicago, IL)

- Medical device preemption: what is a parallel claim?
- Implied preemption: recent case law
- Examples of successful defense arguments

OR

B

3:45

Strategies for Minimizing the Effects of Innovator Liability

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

Sean Fahey
Partner
Pepper Hamilton LLP (Philadelphia, PA)

Janet H. Kwuon
Partner
Reed Smith LLP (Los Angeles, CA)

Moderator:

Brennan Torregrossa
Vice President and Associate General Counsel
Head of Global External Legal Relations Team (GELRT)
GSK (Philadelphia, PA)

- In light of the California Novartis decision, what attempts have been made to combat the effects of innovator liability?
- Given the different decisions in different jurisdictions, how should companies best position themselves?

AFTERNOON BREAKOUT SESSIONS

THURSDAY, NOVEMBER 29, 2018

(CHOOSE A OR B)

A

4:30

Training the Future Generations of Life Sciences Attorneys to Become the Next Deans of the Products Liability Bar

Wendy Hufford
Chief Operating Officer & Vice President, US Litigation, Risk Management & Human Resources
Boehringer Ingelheim (Ridgefield, CT)

Heidi Levine
Partner
Sidley Austin LLP (New York, NY)

Sara K. Thompson
Shareholder
Greenberg Traurig LLP (Atlanta, GA)

- What do clients seek in an associate?
- Recognizing that clients are the ones who are driving the change, what can clients do to help train young attorneys to become the next generation of go to counsel for these types of cases?
  - » Bringing young attorneys to the discussion table with clients
  - » Encouraging candid conversations between clients and their outside counsel as to what is needed to institute the change

B

4:30

Predicting Risk and Examining the Intersection of Traditional Principles of Product Liability Laws with Digital Health and 3D Printing

James M. Beck
Senior Life Sciences Policy Analyst
Reed Smith LLP (Philadelphia, PA)

Erin M. Bosman
Partner
Morrison & Foerster LLP (San Diego, CA)

Michelle M. Bufano
Partner
Patterson Belknap Webb and Tyler LLP (New York, NY)

Vernessa T. Pollard
Partner
McDermott Will & Emery (Washington, DC)

IoT

- What is the reasonable standard of care in creating a secure IoT device?
- Is hackability a design defect?
- What is an adequate warning?
- For how long must device manufacturers provide security monitoring and software updates after selling a product?
- Does user failure to download corrective updates act as superseding cause or failure to mitigate?
- Who is liable when a manufacturer cedes control to a third party?

3D Printing

- Digital heath information and cyber-privacy — pitfalls that lead to litigation
- Preventive strategies to cyber-privacy issues involving digital health information, and defenses to litigation
- Liability should connected medical devices be compromised
- FDA initiatives in digital health information and regulation of 3D printing
- Potential defendants in product liability litigation over 3D printed prescription medical products
- Electronic information as a "product" in litigation over 3D printed prescription medical products
- Crossing the service/product line — hospital/physician's office product liability over point-of-care 3D printing
- Non-traditional applications of traditional negligence and warranty causes of action in 3D printing cases

5:30

Conference Adjourns to Cocktail Party

HOSTED BY: King & Spalding

MAIN CONFERENCE DAY THREE
FRIDAY, NOVEMBER 30, 2018

7:15

Registration and Continental Breakfast

8:00

Co-Chairs' Opening Remarks

8:15

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

Hon. Ann D. Montgomery
Senior Judge
U.S. District Court, D. Minn. (Minneapolis, MN)

Hon. Arnold L. New
Coordinating Judge/Complex Litigation Center
Philadelphia Court of Common Pleas (Philadelphia, PA)

Hon. Patti B. Saris
Chief Judge
U.S. District Court, D. Mass. (Boston, MA)

Hon. Leda Dunn Wettre
Magistrate Judge
U.S. District Court, D.N.J. (Newark, NJ)

Hon. Susan D. Wigenton
Judge
U.S. District Court, D.N.J. (Newark, NJ)

Moderator

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

9:30

Enforcers' Roundtable: Priorities with Respect to Consumer Fraud, False Claims, Anti-Kick-Back, and Off-Label

David M. Eskew
Chief, Health Care & Government Fraud Unit
U.S. Attorney's Office, District of New Jersey (Newark, NJ)

Lisa D. Kutlin
U.S. Attorney's Office, Assistant U.S. Attorney
Eastern District of New York (Brooklyn, NY)

Gregg Shapiro
Chief, Affirmative Civil Enforcement
U.S. Attorney's Office, District of Massachusetts (Boston, MA)

Pat Stein
Senior Asst. Attorney General for Health Fraud
Consumer Protection Division
The Attorney General's Office for the State of Texas (Dallas, TX)

Moderators:

Carolyn M. Hazard
Senior Vice President, Associate General Counsel – Litigation
Endo (Malvern, PA)

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

- The government's perspective on when and why to prosecute: how do enforcers identify companies for investigations?
  - » What techniques are enforcers using these days to investigate manufacturers?
  - » What specific information are enforcers focusing on?
- Practical considerations for in-house and law firm counsel when faced with DOJ or AG action: best practices for responding to a government investigation

10:30

Morning Coffee Break

10:45

NEW **Hiring the Right Regional Counsel**

Adam C. Bassing
Associate General Counsel
UCB, Inc. (Smyrna, GA)

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

Andrew D. Kaplan
Partner
Crowell & Moring (Washington, DC)

It is critically important for lead counsel as well as their in-house clients to ensure that they are working with the best regional counsel. At the same time, as a regional counsel, it is important to ensure that you know how to communicate to the lead as well as in-house counsel your skill-set and what you can contribute to the litigation. In this session, attendees will have an opportunity to develop best strategies for evaluating regional counsel, including what questions to ask and what to look for to make sure that any particular regional counsel is the best fit. The session will also include a discussion of what regional counsel can do to make sure they are answering the needs of their potential clients.

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Questions about CLE credits for your state? Visit our online CLE Help Center at www.americanconference.com/CLE

11:30

NEW

Engaging the Courts in the Right Way: What Does It Mean to Be an Innovative Thinker as an Outside Counsel

Greg A. Dadika
Associate General Counsel, Litigation
Becton, Dickinson and Company (Murray Hill, NJ)

Jan Dodd
Partner
Norton Rose Fulbright US LLP (Los Angeles, CA)

Kailee Goold
Senior Counsel
Cardinal Health (Columbus, OH)

Stephen E. Marshall
Partner
Venable LLP (Baltimore, MD)

Drug and device companies are changing the face of healthcare in a challenging environment every day. Sharing these companies' values around creativity and advancement is going to become critical in order for outside counsel to distinguish themselves. This session will look to illuminate what lawyers/law firms/in-house counsel can do differently to really add value. Among topics to be discussed are:

- Fostering an environment of creativity
  - » How to think about things differently
  - » Questions to ask yourself/client/team
  - » Rewarding and not punishing outside the box thinking
  - » How to advance these ideas with the business
- Improving communication skills
- Candid feedback during and after the matter
  - » Practical tips for doing this

12:30

Networking Lunch

1:30

NEW

Lay of the Land with Respect to Regulatory Trends, Pricing Transparency, and Patent Litigation

Gina Gencarelli
Senior Director, Intellectual Property
Par Pharmaceutical (Chestnut Ridge, NY)

Lisa LeCointe-Cephas
Executive Director, Head of Global Investigations
Merck & Co., Inc. (Kenilworth, NJ)

Julia Post
Attorney
Covington & Burling LLP (Washington, DC)

As an in-house counsel, staying abreast of the key rulings and positions government takes as well as what government enforcers plan to do is crucial when looking to assess the risk for a company. In this session, we will look to extrapolate biggest trends and developments with respect to pricing transparency, patent litigation, and most recent regulation within the past year.

2:30

Opioid Enforcement and Litigation Landscape

Patricia A. Barbieri
SVP, General Counsel and Secretary
Daiichi Sankyo, Inc. (Parsippany, NJ)

Terry M. Henry
Partner
Blank Rome LLP (Philadelphia, PA)

Wendy West Feinstein
Partner
Morgan Lewis & Bockius LLP (Pittsburgh, PA)

- Enforcement and litigation update
- How is opioid MDL different from a typical MDL?
- Interplay of state consumer protection laws with product liability actions
- New theories of tort liability being advanced and how these expansions of traditional confines of tort law may impact other areas of products tort litigation

3:30

Conference Ends

"ACI's Drug and Med conference is informative and attracts top professionals year after year, giving you the opportunity to develop lasting professional and personal relationships."

Danaher Lagnese PC

"I attend ACI's Drug and Med because it's an opportunity to meet and reconnect with colleagues who are both my peers at other law firms and clients. I found the presentation on attorney advertising to be very helpful."

DLA Piper LLP

THE 23RD ANNUAL

DRUG & MED DEVICE

LITIGATION CONFERENCE

Appreciates The Support Of The Following Organizations

Greenberg Traurig, LLP (GTLaw) has more than 2,000 attorneys in 38 offices in the United States, Latin America, Europe, Asia and the Middle East and is celebrating its 50th anniversary. The firm's Pharmaceutical, Medical Device & Health Care Litigation Group is comprised of more than 90 attorneys, in addition to a team of paralegals, nurse paralegals, and trial consultants across the country. The group is an integral part of Greenberg Traurig's National Litigation Practice, encompassing 600+ attorneys in offices across the United States. Recent recognitions include national rankings for 2017 "Products Liability & Mass Torts" from Chambers USA Guide and national rankings for 2017 "Practice Liability & Mass Torts Defense: Pharmaceuticals and Medical Devices" from The Legal 500 United States, among others.

King & Spalding is an international law firm with more than 1,000 lawyers in 20 offices globally. Our Pharmaceutical & Medical Device Litigation Team helps manufacturers navigate the litigation life cycle, from risk assessments through trial and appeal. Working with more than 300 lawyers and professionals who devote all or a substantial portion of their practices to life-sciences clients, we know the industry and governing laws better than anyone. With over 175 lawyers across the world, our Product Liability team, which Law360 named in 2017 as Group of the Year for the fifth consecutive year, leverages knowledge of the complex science and technology behind today's products to deliver litigation victories. We handle the most significant individual, multidistrict, mass tort and class action lawsuits for pharmaceutical and medical device companies. We offer our clients a depth of trial experience that is increasingly unusual in firms of our size. While many firms can "litigate" cases, we try product cases each year in some of the most challenging jurisdictions for corporate clients. For more information, please visit **www.kslaw.com.**

Barnes & Thornburg's extensive drug and medical device practice has been addressing clients' needs in an efficient and results-driven manner for more than 30 years. As national trial counsel in high-stakes pharmaceutical and medical device litigation for Fortune 500 companies, we have the resources and expertise to help you address the evolving challenges you face.

Bowman and Brooke LLP is a nationally recognized trial firm with one of the largest product liability practices in the country. The firm's Pharmaceutical and Medical Device Litigation practice is comprised of experienced, nationally recognized trial lawyers serving as national, regional and local counsel in high-profile individual and mass tort litigation. Whether we are preparing and defending company witnesses in the areas of regulatory, drug safety, clinical trials, medical affairs and marketing, assisting our clients in assessing their product warnings and package inserts to meet FDA compliance, or navigating complex legal challenges, we aggressively defend our clients based on the unique requirements of each case. 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-effective and complementary to our clients' core business objectives. The firm's attorneys defend a variety of corporate clients, including many Global 500 companies, in widely publicized catastrophic injury and wrongful death matters, and other complex litigation throughout all 50 states. For more information, please visit **www.bowmanandbrooke.com.**

With over 1,400 lawyers in 32 offices across North America, Europe, the Middle East and Asia, **Bryan Cave Leighton Paisner LLP** is a fully integrated global law firm that provides clients with connected legal advice, wherever and whenever they need it. The firm is known for its relationship-driven, collaborative culture, diverse legal experience and industry-shaping innovation and offers clients one of the most active M&A, real estate, financial services, litigation and corporate risk practices in the world. **www.bclplaw.com**

Butler Snow LLP is a full-service law firm with more than 350 attorneys and advisors collaborating across a network of 25 offices in the United States, Europe and Asia. Ranked as a leading firm for client relations and one of America's Top 100 law firms in the BTI Power Rankings, Butler Snow is recognized as one of the nation's top law firms for client service. The firm was recently ranked 48th out of 650 firms in the BTI Client Relationship Scorecard for understanding our client's business, anticipating client's needs, unprompted communication, legal skills, quality and keeping clients informed. For more information, visit **www.butlersnow.com** or follow Butler Snow on Twitter **@Butler_Snow.**

Drinker Biddle & Reath LLP is a national law firm with more than 600 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. With a nationwide ranking in Chambers USA 2018, our product liability litigation team has 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 consultants from our advisory and advocacy division based in Washington, D.C., Faegre Baker Daniels 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.

Founded in 2006, **Golkow Litigation Services** is a global leader in court reporting, litigation support and trial consulting services. Specializing in highly technical real-time transcription for the pharmaceutical and medical device industry, Golkow has provided deposition and video services in all 50 states and over 25 countries. As a preferred provider of court reporting services for hundreds of national MDLs and other consolidated matters, Golkow services law firms across the country on a daily basis providing a web-based repository, streaming internet depositions and a proprietary Picture-in-Picture trial ready work product. With offices across the country, Golkow has expertise handling complex and multi-party litigation. Our dedicated case management team is committed to delivering personalized client services around the clock and across the globe.

Based in New Orleans, **Irwin Fritchie Urquhart & Moore LLC** has a diverse, nationwide practice in pharmaceutical and medical-device litigation. Clients have trusted Irwin Fritchie to serve as national coordinating counsel, national trial counsel, and national and international science counsel in a variety of mass torts, often working together in litigation teams with other premier law firms. Irwin Fritchie provides the highest quality work at a tremendous value to its clients. For more information, please visit **www.irwinllc.com.**

Mayer Brown is a global legal services provider defending clients in the full array of product liability and mass tort actions with extensive experience advising 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, a robust regulatory team 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** for more information.

McDermott Will & Emery is helping the most progressive leaders transform health care and protect their hard-earned innovations. From today's regulatory developments and industry trends to litigating the tools of tomorrow, our global team takes a forward-looking approach to product defense in the health care space. We have represented defendants in large-exposure product liability cases, and possess the collective experience, knowledge and resources necessary to provide our clients with exceptional service. Our legal experience spans the world's foremost health and life sciences companies to its most innovative startups. With a bolstered international presence, we meet you where you need us most. How can we help you?

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Morgan Lewis is a global law firm with more than 2,200 legal professionals in 30 offices worldwide. With more than 250 international partners and counsel who focus on the life sciences industry, including more than 60 professionals with advanced scientific degrees, Morgan Lewis has one of the most comprehensive practices in this area. We are unsurpassed in our global understanding of the business, regulatory, intellectual property, litigation, and related issues that our clients face along the product life cycle, from innovation and emerging business issues, through research and development, regulatory approval, product reimbursement, marketing and distribution, to fraud and abuse, product liability and intellectual property litigation, to mergers and acquisitions, collaborations, and outsourcing. 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.**

With approximately 1,000 lawyers in 16 offices, **Morrison & Foerster** is a preeminent global law firm dedicated to delivering business-oriented results to clients across the United States, Europe and Asia. MoFo is recognized throughout the world as a leader in providing cutting-edge legal advice on matters that are redefining practices and industries. Leading consumer product companies, dynamic technology and life science companies, large financial institutions and other market leaders come to MoFo for knowledge, innovation and business aptitude. MoFo also represents investment funds and startup companies, and over the years have supported many in their growth and development as leading industry players and household brands. The firm is a pro bono leader whose work runs the gamut, from class action representation that benefits thousands to individual advocacy for people who otherwise would be shut out from access to justice.

Norton Rose Fulbright is a global law firm. We provide the world's preeminent corporations and financial institutions with a full business law service. We have more than 4000 lawyers and other legal staff based in more than 50 cities across Europe, the United States, Canada, Latin America, Asia, Australia, Africa, the Middle East and Central Asia.

Recognized for our industry focus, we are strong across all the key industry sectors: financial institutions; energy; infrastructure, mining and commodities; transport; technology and innovation; and life sciences and healthcare. Through our global risk advisory group, we leverage our industry experience with our knowledge of legal, regulatory, compliance and governance issues to provide our clients with practical solutions to the legal and regulatory risks facing their businesses.

Wherever we are, we operate in accordance with our global business principles of quality, unity and integrity. We aim to provide the highest possible standard of legal service in each of our offices and to maintain that level of quality at every point of contact.

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Nutter is a Boston-based law firm that provides legal counsel to industry-leading companies, early stage entrepreneurs, institutions, foundations, and families, across the country and around the world. Founded in 1879, Nutter is dedicated to helping companies prosper in today's competitive business environment. For decades, product liability defense has been one of the cornerstones of Nutter's highly successful litigation practice. Leading multinational companies have turned to Nutter to defend cases in courts throughout the United States and around the world involving allegedly defective medical devices, drugs, industrial materials, and automotive products. The firm's lawyers are known for their client-centric approach and extensive experience in litigation, business and finance, intellectual property, real estate and land use, labor and employment, tax, and trusts and estates.

Patterson Belknap Webb & Tyler LLP is based in New York City with approximately 200 lawyers delivering a full range of services across more than 20 practice groups in both litigation and commercial law. More than half of the attorneys at Patterson Belknap are devoted to litigation. Our litigating partners have tried hundreds of cases, including many of the most complex in their fields. We frequently serve as national and regional litigation counsel for the nation's largest pharmaceutical and medical device companies in products liability matters.

Reed Smith's life sciences team is committed to anticipating and solving legal challenges so you can focus on what you do best: improving and saving lives. In addition to our skilled life sciences transactional and regulatory lawyers, our highly-regarded, full-service life sciences litigation practice features a deep bench of seasoned trial lawyers and appellate specialists. 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, and is regularly recognized for its successes in high-profile product liability and mass tort litigations.

A powerful resource in litigation for nearly 50 years, **S-E-A** is a multi-disciplined forensic engineering and visualization company specializing in failure analysis.

S-E-A's Health Sciences group provides comprehensive services in the testing and analysis of medical related procedures and implants. The interdisciplinary team addresses alleged failures of class I, II and III medical devices and can investigate device performance and surgical procedures under clinical conditions. Comprised of biomedical, biomechanical and material engineers, along with medical illustrators and animators, the group is positioned to assist with products and devices ranging from purported wheelchair malfunctions to knee replacements and pedicle screws.

Coupled with S-E-A's team of experts, their new 110,000 square foot testing and research facility incorporates the latest technologies and resources including a scanning electron microscope (SEM), licensed in-vitro anatomic laboratory and FDA approved 3D patient specific reconstruction software for computational modeling.

Shipman & Goodwin LLP is a full-service law firm recognized for its depth of knowledge and experience in a number of industry sectors, including pharmaceuticals and medical devices, financial services, real estate development, information technology, government, petroleum, telecommunications, emerging and middle market companies, franchising, health care, education and retail. With more than 165 attorneys and offices in Connecticut, Washington, D.C. and New York, the firm represents many businesses, institutions, individuals and government entities throughout New England and nationally.

Founded in 1919, we understand that the relationship with outside counsel is key to the structure and delivery of effective legal counsel, ultimately minimizing risk. Shipman & Goodwin is committed to its clients, to understanding their needs and priorities and to utilizing the full breadth of its experience to provide sound cost-efficient legal solutions.

With a well-earned reputation as a litigation powerhouse, **Shook, Hardy & Bacon** is the go-to firm for the world's leading health, science and technology companies. In addition to fielding the largest product liability practice in the world, Shook handles commercial litigation, environmental and toxic tort, and intellectual property disputes for the pharmaceutical and medical device, food and beverage, and consumer goods industries. While its high-stakes, complex litigation expertise is second to none, the firm also has the regulatory compliance and risk management experience upon which companies have come to rely. Established in Kansas City in 1889, Shook has grown to approximately 500 attorneys and 200 research analysts and paraprofessionals, many of whom have advanced scientific and technical degrees. Shook's offices are strategically located in Chicago, Denver, Houston, Kansas City, London, Miami, Orange County, Philadelphia, San Francisco, Seattle, Tampa and Washington, DC.

Pharmaceutical and Medical Device Litigation Practice
Troutman Sanders has a long-standing record of successfully defending clients in pharmaceutical and medical device litigation. We have handled high-stakes pharmaceutical and medical device litigation for over 30 years. We defend major pharmaceutical and medical device manufacturers in claims involving surgical devices, orthopedic implants, cosmetic devices and prescription drugs. We have extensive expertise in handling mass tort litigation for our clients, who are among the largest and most well-known pharmaceutical and medical device companies in the world.

Our attorneys have extensive first-chair trial experience and regularly serve as national counsel and regional counsel. Our defense strategies involve an in-depth understanding of our clients' products, processes and markets, and exceptional knowledge of the science and technologies underlying these systems. In addition to our strong litigation experience, we provide liability counseling to promote product safety and minimize future liability exposure. We analyze design and manufacturing processes; test protocols and quality assurance programs; advise on insurance coverage; draft product warnings and instructions; review warranty, disclaimer and indemnity language in vendor and customer agreements; develop programs for proper document retention and post-sale product retrofits or recalls; and ensure regulatory compliance.

We are established leaders in the bar. Several of our attorneys hold leadership positions in organizations including the American College of Trial Lawyers, Product Liability Advisory Council (PLAC), Defense Research Institute (DRI), American Bar Association Committee on Products Liability

At **Ulmer**, the focus is on exceeding client expectations and delivering superior, customized legal solutions for an exceptional value. The firm is a leader in defending class-action, multidistrict, and mass tort litigation concerning drugs, medical devices, and dietary supplements. Ulmer attorneys serve as lead national defense counsel in high-impact litigation involving antidepressants, contraceptives, testosterone replacement therapy, pain medications, oncology drugs, gastrointestinal products, ADHD medications, pelvic mesh products, weight management products, and performance training supplements. They also counsel pharmaceutical, medical device, and dietary supplement companies on regulatory and risk management matters. The practice is strengthened by its many attorneys with degrees in various scientific disciplines. **Ulmer.com**

Venable has one of the most active and respected product liability practices in the United States. We are particularly well-known for our defense of pharmaceutical and medical device manufacturers in jurisdictions across the country. In the past five years, Venable has served as lead or second-chair trial counsel for pharmaceutical manufacturers in 12 trials within federal MDLs and state-wide coordinated proceedings. In addition to serving as trial counsel, we have experience in all aspects of pharmaceutical mass tort litigation including leading expert witness teams, developing company witnesses, managing briefing teams, and handling eDiscovery. The group is the recipient of the 2017 Chambers USA Client Service Award for Products Liability and Mass Torts and was on BTI Consulting's 2017 and 2018 Power Rankings for the best client relationships.

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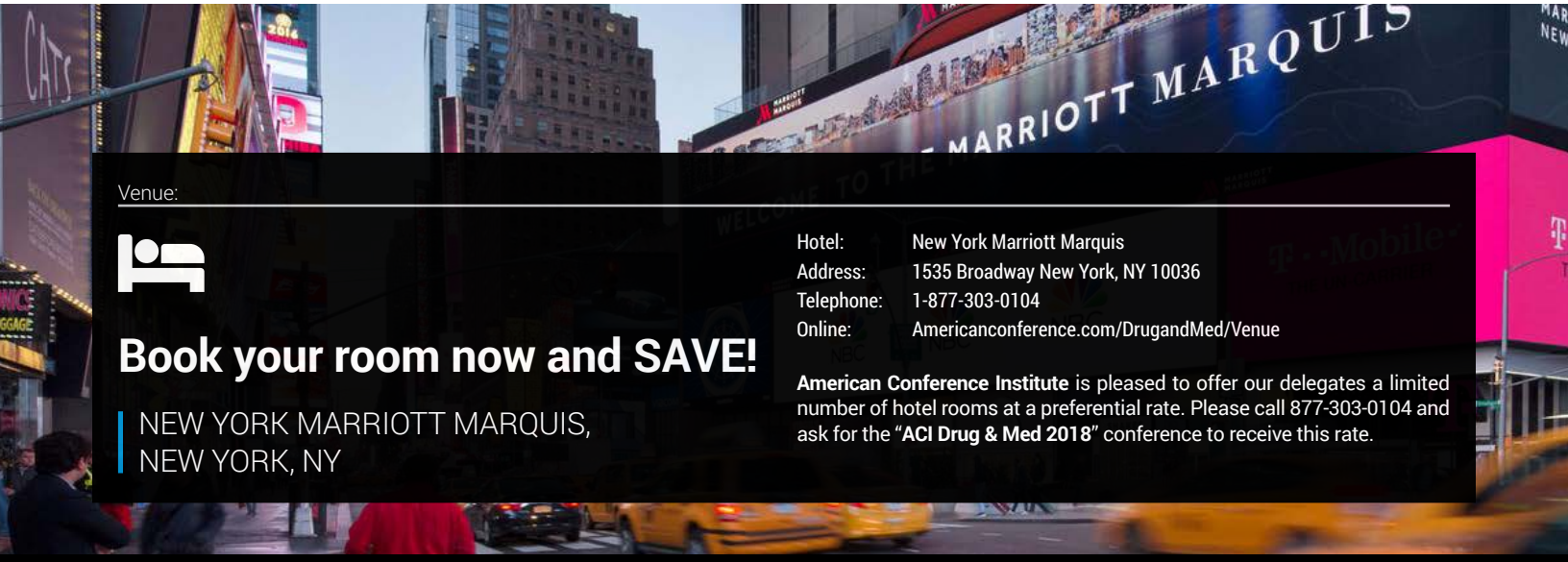

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