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DRUG & MEDICAL DEVICE LITIGATION

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The Honorable Claire C. Cecchi
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The Honorable Michael J. Davis
Senior Judge, U.S. District Court, D. Minn.


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The Honorable John R. Tunheim
Chief Judge, U.S. District Court, D. Minn.

PLUS, the Enforcers' Spotlight:

Kenneth M. Abell
Chief, Civil Health Care Fraud
United States Attorney's Office for the Eastern District of New York

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

Christopher Harwood
Co-Chief, Civil Frauds Unit
United States Attorney's Office for the Southern District of New York

Margaret (Peg) Hutchinson
Chief, Civil Division
Assistant United States Attorney for the Eastern District of Pennsylvania

Cristy Irvin Phillips
Deputy Chief, Civil Frauds Unit
United States Attorney's Office for the Southern District of New York

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Vice President, US Litigation, Risk
Management & Human Resources
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(Ridgefield, CT)

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Assistant United States Attorney for the Eastern District of Pennsylvania
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Head US Litigation and Investigations
Sandoz Inc. (Princeton, NJ)

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(Cleveland, OH)

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Novo Nordisk (Plainsboro, NJ)

Widely regarded as the go to annual conference for the pharmaceutical and medical device products liability community, ACI's Drug and Med event is the only truly forward-looking think tank event that brings together the judges, government enforcers, in-house counsel, and outside counsel to discuss not only the most pressing issues affecting pharma and device industries today but also where they see these industries heading!

Why our 22nd iteration is a must-attend for you and your team:

- ✓ BRAINSTORM WITH THE BEST IN THE INDUSTRY: Our faculty of trial-tested advocates will share the methods that have worked for them in recent battles and provide specific advice for litigating effectively and efficiently.
- ✓ JOIN THE CONVERSATION with government enforcers from the **US Attorney Offices of New York, New Jersey, Pennsylvania, and Massachusetts** as well as in-house counsel from **Endo, Medtronic, GSK, Novo Nordisk, Advanced Accelerator Applications, Olympus Corporation of the Americas, Boehringer Ingelheim, Stryker, Pfizer, Teva, Bard, Purdue Pharma,** and more.
- ✓ GET INNOVATIVE FORWARD-THINKING CONTENT: High-level content designed to offer thought- provoking perspectives to the industry with sessions that explore the **future of the MDL** as a vehicle for the resolution of the multi-district claims, examining issues with respect to **potential hacking of software in connected medical devices,** addressing concerns involving **trials with multiple plaintiffs,** shining the light on **third-party litigation funding** and more.
- ✓ NETWORKING OPPORTUNITIES: Business development opportunities abound through pre-conference functions, cocktail parties, networking lunches and breaks!
- ✓ CELEBRATE THE ACHIEVEMENTS OF LEADERS IN YOUR COMMUNITY – Participate in the **3rd Annual Champions of the Products Liability Defense Bar Awards!**
- ✓ **PLUS, Our thoughtful working group classes offer intensive learning and intimate networking!**
  - PRE-CONFERENCE WORKSHOP: **Training the Next Generation of Life Sciences Attorneys to Become an Asset**
  - PRE-CONFERENCE **Defense Counsel Only War Room**
  - POST-CONFERENCE WORKSHOP: I**ncorporating Diversity and Inclusion into Your Trial Team Development and Litigation Strategy** ETHICS CREDITS

WHO YOU WILL MEET:

In-house counsel for:

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

Attorneys practicing in:

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

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AGENDA-AT-A-GLANCE

Morning

PRE-CONFERENCE
MONDAY, DECEMBER 4, 2017

8:30 Workshop Registration and Continental Breakfast

9:00 Pre-Conference Workshop: Training the Next Generation of Life Sciences Attorneys to Become an Asset

DAY ONE
TUESDAY, DECEMBER 5, 2017

7:15 Registration and Welcoming Breakfast Hosted by VENABLE LLP

8:15 ACI Opening Remarks and Award Presentation

8:30 Co-Chairs' Opening Remarks

8:45 GC and CLO Roundtable: What Keeps Them Up at Night When Faced with a Products Liability Action

10:15 Morning Coffee Break Sponsored by DTI | epiq

10:30 Shining the Light on the Third-Party Litigation Funding

11:30 Containing Litigation Tourism and the Practical Impact of the BMS Decision Thus Far

DAY TWO
WEDNESDAY, DECEMBER 6, 2017

7:15 Registration and Continental Breakfast

8:00 Co-Chairs' Remarks

8:15 NEW Analysis of the Recent Largest Verdicts and What It Means for the Industry

9:00 NEW Weighing the Pros and Cons of MDLs: Have MDLs Run Their Course?

10:15 Morning Coffee Break

10:30 A View from the Bench: Judicial Insights into Drug and Medical Device Products Liability Litigation

12:00 Networking Lunch

Afternoon

12:30 In-House Think Tank Lunch (by Invite Only)

1:45 Defense Counsel Only War Room Registration

2:30 Pre-Conference Defense Counsel Only War Room

Attendance at the War Room is exclusively for qualified defense counsel applicants only.

12:30 Networking Luncheon Hosted by GT Greenberg Traurig

1:45 The ESI Discovery Conundrum and Scrutinizing the Effectiveness of Using Proportionality in Minimizing E-Discovery Burdens and Costs

2:45 Afternoon Breakout Sessions: Choose A or B

A Dealing Effectively with the Rise in Plaintiffs' Advertising

B NEW Trial by Juror: Overcoming Challenges with Jury Selection, Communicating with Multigenerational Jurors, and Practical Guidance on Diffusing Juror Bias

3:45 Afternoon Networking Break Hosted by DrinkerBiddle

4:00 Afternoon Breakout Sessions: Choose C or D

C NEW Opioid Crisis and Its Impact: Enforcement Trends and Latest Developments in Litigation

D NEW Anticipating the Next Wave of Cyber Attacks in the Medical Device Industry: Examining the Issues Surrounding the Potential Hacking of Software in Connected Medical Devices

5:00 Afternoon Breakout Sessions: Choose E or F

E Latest Developments on the Status of Preemption Law: Emerging Theories, Express Preemption, and Innovator Liability

F NEW Strategies for Opposing Trials with Multiple Plaintiffs

1:00 Enforcers' Spotlight: Government's Enforcement Priorities vis-à-vis Drug and Device Products Liability Matters

2:15 NEW Disrupting the Mass Tort Industry

3:15 Main Conference Concludes

3:30-5:30 Post-Conference Workshop: Incorporating Diversity and Inclusion into Your Trial Team Development and Litigation Strategy

ETHICS CREDITS

Evening

5:00 Pre-Registration and Welcoming Cocktail Reception Hosted by ankura

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

PRE-CONFERENCE WORKSHOPS
MONDAY, DECEMBER 4, 2017

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

A Training the Next Generation of Life Sciences Attorneys to Become an Asset

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

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

Gregory Jackson
Senior Director, Legal Affairs & Litigation
NuVasive, Inc.
(San Diego, CA)

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

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 become the best they can be. More than just a primer on defending mass torts, this session will teach the next generation of the defense products liability bar what they need to know to try a case in order to increase value to their clients and become an asset.

- 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 regulation, and more
- Discovery
  - » Working with clients to get the best information 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
- 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
- Tips and best practices for those who are new to products liability litigation

12:30

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 on how members of the defense bar can coordinate their advocacy efforts for 2018 to match those of a highly organized and well-funded plaintiffs' bar.

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

B Defense Counsel Only War Room

Molly M. Joyce
Senior Counsel, Commercial Litigation
AbbVie Inc.
(North Chicago, IL)

Steve Phillips
Special Counsel
Medtronic, Inc.

Franklin T. Pyle III
Assistant General Counsel
Olympus Corporation of the Americas
(Center Valley, PA)

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.*

Please come prepared to discuss the following:

- Updates on select mass torts, bellwether trials, and key state court proceedings from around the country: what tactics and themes are plaintiffs' attorneys using?
- Overview of key plaintiffs' firms and third party players: who is driving the litigation?
- Motions to dismiss: on what grounds have you seen success?
- Good science and bad science: sharing literature that is relevant to the defense perspective regarding causation
- Expert witnesses: who are the frequent testifiers?
- Deconstructing recent noteworthy jury verdicts: what language and themes are resonating with juries?
- Analysis of active and unfriendly jurisdictions
- Keeping up with tort reform initiatives: peering behind the curtain on where the plaintiffs' bar is focusing its lobbying efforts and identifying defense advocacy issues to focus on for 2018

**Attendance is exclusively for qualified defense counsel applicants only.*

5:00 – 6:00

Pre-Registration and Welcoming Cocktail Reception Hosted by

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COLLABORATION DRIVES RESULTS

MAIN CONFERENCE DAY ONE
TUESDAY, DECEMBER 5, 2017

7:15

Registration and Welcoming Breakfast Hosted by

VENABLE LLP

8:15

ACI Opening Remarks and Award Presentation

8:30

Co-Chairs' Opening Remarks

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

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

8:45

GC and CLO Roundtable: What Keeps Them Up at Night When Faced with a Products Liability Action

Marc E. Fishman
Vice President, Associate General Counsel
Litigation and Risk Management
Novo Nordisk Inc.
(Plainsboro, NJ)

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

Mariam Koohdary
Deputy General Counsel
AstraZeneca
(Wilmington, DE)

Edward A. Sturchio
Global General Counsel
Advanced Accelerator Applications
(New York, NY)

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

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

Moderated by:

Lori G. Cohen
Shareholder; 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 insights from leaders at biopharmaceutical and medical device companies about their greatest products liability challenges, including gamesmanship from an increasingly aggressive plaintiffs' bar, controlling ever-rising litigation costs, and preparing for collateral consequences and follow-on actions stemming from products liability.

- What are the options to manage an MDL when settlement is not feasible? What can be done to resolve a mass tort without immediately jumping into settlement?
- Handling E-discovery costs and burdens
  - » What are companies doing with new data sources whether internal instant messaging, texting between employees, social media accounts, etc.?
- How are in-house attorneys managing costs?
  - » Latest fee arrangements with outside counsel
- Strategic moves to fight personal jurisdiction/litigation tourism
- Splitting responsibilities among a number of outside counsel firms: what are the pros and cons?
  - » Has it been successful or are in-house counsel considering other approaches to handling mass tort cases?
  - » How do in-house counsel select their teams? Should trial counsel or settlement counsel be separate from national counsel managing the litigation?

10:15

Morning Coffee Break
Sponsored by

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10:30

Shining the Light on the Third-Party Litigation Funding

Michelle W. Cohen
Partner
Patterson Belknap Webb and Tyler LLP
(New York, NY)

Ashley A. Garry
Counsel – Litigation and Legal Compliance
Eli Lilly and Company
(Indianapolis IN)

Tarifa B. Laddon
Partner
Faegre Baker Daniels LLP
(Los Angeles, CA)

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

- Understanding the rise of third-party litigation funding
  - » Latest developments and how this phenomenon is changing the balance of power in litigation
  - » How is this fueling drug and medical device products liability litigation?
- How common is this and how are cases being funded?
- Best practices for maintaining control when the third-party funder is driving the litigation
- Considerations for resolution and settlement in this increasingly complicated arena

11:30

Containing Litigation Tourism and the Practical Impact of the BMS Decision Thus Far

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

G. Brian Jackson
Partner
Butler Snow LLP
(Nashville, TN)

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

Donald LeGower
Senior Counsel, Litigation
Bristol-Myers Squibb
(Lawrenceville, NJ)

- How will the below decisions shape the way defendants will handle this litigation going forward?
  - » *State ex rel. Norfolk Southern Railway Company v. the Hon. Colleen Dolan*
  - » *BNSF Railway Co. v. Tyrell*
  - » *Bristol-Myers Squibb Co. v. Superior Court of California*
- What impact has been seen thus far?
- Implementation strategies to ensure that the BMS decision is used in your practice
  - » Educating practitioners on how to protect their companies
  - » Understanding how this decision is going to impact company's risk management
  - » Where can companies expect to be sued post-BMS?
  - » Where can they expect to avoid being sued?
- Have any defenses based on the BMS case been tried and if so, what are they?
- Have any shifts in plaintiffs' strategies been evident at this time? What does the defense anticipate plaintiffs will attempt to argue?

12:30

Networking Luncheon
Hosted by

GT Greenberg Traurig

1:45

The ESI Discovery Conundrum and Scrutinizing the Effectiveness of Using Proportionality in Minimizing E-Discovery Burdens and Costs

Jeffrey Nass
Senior Counsel – eDiscovery
Boehringer Ingelheim USA Corp.
(Ridgefield, CT)

Lynn Reilly
Senior Director, Hosted Solutions
Lighthouse eDiscovery
(Seattle, WA)

Bart C. Sullivan
Partner
Fox Galvin, LLC
(St. Louis, MO)

- How to manage ESI discovery? How to cost-shift? How is law evolving with respect to all the devices that are used for corporate communications?
- Survey of the quickly evolving case law surrounding ESI protocols: updates on key federal and state decisions
- Using favorable court opinions limiting the scope of document preservation and e-discovery in the past year: analysis by jurisdiction
- Considerations for international companies: managing cumbersome global discovery demands in light of differing privacy rules internationally
- What have been the practical effects in terms of improving proportionality, efficiency, and costs?
  - » Has the new emphasis on proportionality made the difference in terms of limiting the costs?
  - » Status of enforcement by the courts
- Opportunities under the new rules to prevent discovery from being used as a blunt weapon to leverage claims against the defense
- Making meaningful objections to burdensome disproportionate preservation and discovery requests

2:45

AFTERNOON BREAKOUT SESSIONS
CHOOSE A OR B

A

Dealing Effectively with the Rise in Plaintiffs' Advertising

Candace Camarata
Assistant General Counsel
C.R. Bard, Inc.
(Murray Hill, NJ)

Peter A. Meyer
Partner
Faegre Baker Daniels LLP
(Fort Wayne, IN)

- Developing concrete strategies to neutralize the effects of increasingly aggressive plaintiffs' advertising
  - » What are some of the specific things companies can do?
  - » Have there been any successful strategies thus far?
- Limiting plaintiff advertising: taking an aggressive stance against false or misleading messages to the public
  - » Creating a defense message focused on safety and desire to promote health and well-being
  - » Getting the word out about victories for pharma and medical device companies in products liability actions to counteract reputational risk when lawsuits are publicly filed
- Acquiring data regarding plaintiff attorney advertising spend into discovery
- Ethical issues associated with non-lawyers doing legal advertising to collect cases and then selling that information to legal firms across the country

B

Trial by Juror: Overcoming Challenges with Jury Selection, Communicating with Multigenerational Jurors, and Practical Guidance on Diffusing Juror Bias

Celeste M. Brecht
Partner
Venable LLP
(Los Angeles, CA)

William V. Essig
Partner
Drinker Biddle & Reath LLP
(Chicago, IL)

Lisa M. Dunkin
Senior Litigation Counsel
Zimmer Biomet
(Warsaw, IN)

Craig A. Thompson
Partner
Venable LLP
(Baltimore, MD)

- Addressing the considerable amount of mistrust expressed by the public toward pharmaceutical and medical device manufacturers
- Additional challenges posed by millennials who are exhibiting unprecedented levels of skepticism
- Extrapolating specific ways for the defense bar to start to regain the trust and dispel current notions prevalent among the potential jurors
- Knowing how to best position a case before reaching the opening statement phase
  - » Necessity of the defense trial team to research and know the community they are trying a case in is becoming exceedingly important given that the plaintiffs' bar has been strategic with how, where, and when it chooses to focus its very targeted advertising, which results in a tainted jury pool.
  - » Looking at the need to understand how juries think about advancements and developments in science and medicine (i.e., jury questionnaire, mini opening statements before voir dire, etc.)

3:45

Afternoon Networking Break Hosted by

DrinkerBiddle

4:00

AFTERNOON BREAKOUT SESSIONS
CHOOSE C OR D

C

Opioid Crisis and Its Impact: Enforcement Trends and Latest Developments in Litigation

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

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

Carolyn M. Hazard
Vice President, Assistant General Counsel, Litigation
Endo Pharmaceuticals
(Malvern, PA)

Richard W. Silbert
Vice President and Chief Litigation Counsel
Purdue Pharma L.P.
(Stamford, CT)

In the wake of recent attorney generals' suits against opioid manufacturers and a trend involving the hiring of plaintiffs' law firms to pursue these cases on behalf of states, the questions as to potential liability abound. Additionally, there are questions as to the precedent that is being created for the pharmaceutical industry as a whole by the use of statutes not meant to deal with this issue and thus, effecting opinions not in line with what those statutes were designed to address in the first place. The session will look at the potential enforcement and litigation consequences for the industry down the road.

D

Anticipating the Next Wave of Cyber Attacks in the Medical Device Industry: Examining the Issues Surrounding the Potential Hacking of Software in Connected Medical Devices

Max Heerman
Principal Litigation Counsel
Medtronic, Inc.
(Washington, D.C.)

Victoria Davis Lockard
Shareholder
Greenberg Traurig LLP
(Atlanta, GA)

- What is the medical device industry doing now to build up protections?
  - » In what ways are other players in the industry proactively helping: FDA, IT and cyber experts, federal agencies, national institutes of health, etc.?
- The question of liability in case of an event – who can be held liable?
- What, if any, has been the impact thus far of the Health Care Industry Cybersecurity Task Force's final report to Congress titled: "Report on Improving Cybersecurity in the Health Care Industry"?

> *The content at ACI's Drug and Med is outstanding. This event has a great assortment of speakers and the information is top-notch. For someone like me who's just been in the industry for the past 3 years, particularly the pharmaceutical, it's very helpful, clear and well-organized.*
>
> **Christopher Fowlkes, Barnes & Thornburg LLP**

> *I think ACI's Drug and Med is the perfect combination of substantive information and great networking opportunities. I enjoy everything about this conference.*
>
> **Maureen Witt, Holland & Hart LLP**

5:00

AFTERNOON BREAKOUT SESSIONS
CHOOSE E OR F

E

Latest Developments on the Status of Preemption Law: Emerging Theories, Express Preemption, and Innovator Liability

Howard Cyr
Associate General Counsel
Teva Pharmaceuticals
(North Wales, PA)

Daniel Healey
Corporate Counsel
Pfizer Inc.
(New York, NY)

Matt Holian
Partner
DLA Piper LLP (US)
(Boston, MA)

Daniel L. Ring
Partner
Mayer Brown LLP
(Chicago, IL)

Kacy Wiggum
Senior Attorney
Novo Nordisk
(Plainsboro, NJ)

- What survives express preemption?
- Emerging theories of parallel claims as plaintiffs look to avoid preemption
  - » What are some examples of new theories coming from the plaintiffs' bar as to what constitutes a parallel claim?
  - » What do parallel claims mean to companies' record keeping? What paper trail/records are needed to show that a company is in compliance with the federal regulations?
- What has been the plaintiffs' bar success in looking to avoid preemption defense?
  - » What to watch out for?
  - » Which defense arguments work and which don't?
- Innovator Liability: The state of law vis-à-vis the extension of a brand manufacturer liability
  - » Latest legal developments with respect to branded manufacturers' responsibility for the generic drugs
  - » What strategies can an innovator employ to protect itself in these situations?
  - » Strategies for defending branded products with the preemption defense
  - » Are there strategies for using FDA reviews of different safety issues to establish what would permit a preemption defense when there is clear evidence that the FDA would have rejected a change in label proposed by plaintiffs?
  - » Biosimilars: Will biologic originator have liability for either development or labeling with respect to a biosimilar?

F

Strategies for Opposing Trials with Multiple Plaintiffs

Timothy F. Daniels
Member
Irwin Fritchie Urquhart & Moore
(New Orleans, LA)

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

Matthew D. Keenan
Partner
Shook Hardy & Bacon L.L.P.
(Kansas City, MO)

Jobina Jones-McDonnell
Senior Counsel, Litigation and Risk
Endo Pharmaceuticals
(Malvern, PA)

Moderated by:

Mary-Alice Barrett
Associate Director, Assistant General Counsel
Genentech
(Little Falls, NJ)

In the wake of recent phenomenon involving multi-plaintiff trials where the courts are allowing multiple trials to be tried within one MDL case and where jury is hearing multiple sets of facts at one time, what strategies can the defense bar employ to minimize the prejudicial effect of these situations and limit its use by courts?

- What is the current state of law on multi-plaintiff trials: overview of the latest decisions
- How are courts approaching this issue?
- Have there been any successful arguments with respect to defeating this phenomenon? If so, what are they?

6:00

Conference Adjourns to Cocktail Party Hosted by KING & SPALDING

MAIN CONFERENCE DAY TWO
WEDNESDAY, DECEMBER 6, 2017

7:15

Registration and Continental Breakfast

8:00

Co-Chairs' Remarks

8:15

Analysis of the Recent Largest Verdicts and What It Means for the Industry

John P. Hooper
Partner
King & Spalding
(New York, NY)

Gregory Jackson
Senior Director, Legal Affairs & Litigation
NuVasive, Inc.
(San Diego, CA)

Sarah E. Johnston
Partner
Barnes & Thornburg LLP
(Los Angeles, CA)

Given the slew of cases involving proton pump inhibitor, blood-thinning drugs, pelvic mesh, hip-replacement implant, and talc, to name a few, this session will look at the impact of the recent large verdicts on the way pharmaceutical and medical devices manufacturers will be approaching this type of litigation going forward. In this session, speakers will deconstruct these lines of cases and discuss the specific theories behind the plaintiffs' arguments and what led to these extreme results.

9:00

Weighing the Pros and Cons of MDLs: Have MDLs Run Their Course?

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

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

Stacey A. Martinez
Partner-in-Charge
Norton Rose Fulbright US LLP
(Austin, TX)

Moderated By:

Edward J. Bell
Senior Managing Director
Ankura Consulting Group, LLC
(Washington, DC)

- Does an MDL as a vehicle need to be modified or substituted? Is there a better way to resolve multi-district claims?
- When should an MDL be considered?
  - When there is over a certain number of plaintiffs?
  - What damages?
- Update on a recent trend involving a slow-down in creation of new MDLs
- If it is better not to use an MDL, what strategies can be employed to resist them?
- Bell weather trials and ways of making them truly reflective of the majority of the claims as opposed to the best cases for one side or the other
- How does an MDL impact settlement considerations?

10:15

Morning Coffee Break

10:30

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

The Honorable Rex M. Burlison
Circuit Judge
22nd Judicial Circuit
(St. Louis City, MO)

The Honorable Claire C. Cecchi
Judge
U.S. District Court, D.N.J.
(Newark, NJ)

The Honorable Kenneth M. Hoyt
Senior Judge
U.S. District Court, S.D. Tex.
(Houston, TX)

The Honorable Dan A. Polster
Judge
U.S. District Court, N.D. Ohio
(Cleveland, OH)

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

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

The Honorable John R. Tunheim
Chief Judge
U.S. District Court, D. Minn.
(Minneapolis, MN)

Moderated by:

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

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

12:00

Networking Lunch

1:00

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

Kenneth M. Abell
Chief, Civil Health Care Fraud
United States Attorney's Office for the Eastern District of New York
(New York, NY)

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

Christopher Harwood
Co-Chief, Civil Frauds Unit
United States Attorney's Office for the Southern District of New York
(New York, NY)

Margaret (Peg) Hutchinson
Chief, Civil Division
Assistant United States Attorney for the Eastern District of Pennsylvania
(Philadelphia, PA)

Cristy Irvin Phillips
Deputy Chief, Civil Frauds Unit
United States Attorney's Office for the Southern District of New York
(New York, NY)

Gregg Shapiro
Chief, Affirmative Civil Enforcement
United States Attorney's Office for the District of Massachusetts
(Boston, MA)

Moderated by:

Zane David Memeger
Partner
Morgan, Lewis & Bockius LLP
(Philadelphia, PA)

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

- Preparing for increased criminal and civil enforcement actions stemming from drug and medical device products liability
  - » Antitrust
  - » Consumer Fraud
  - » False Claims
  - » Anti-kickback statute
  - » Off-label
- The government's perspective on when and why to prosecute: how do enforcers identify companies for investigations?
- Analyzing the steady trend of staggering penalties and fines for drug and device makers in these cases
- Practical considerations for in-house and law firm counsel when faced with DOJ or AG action: best practices for responding to a government investigation
- Exploring the practical implications of AG's contingency-fee arrangements with plaintiffs' counsel in consumer protection actions

2:15

Disrupting the Mass Tort Industry

Matthew J. Maletta
Executive Vice President, Chief Legal Officer
Endo Pharmaceuticals
(Malvern, PA)

Buffy J. Mims
Partner
Shook Hardy & Bacon L.L.P.
(Washington, DC)

PD Villarreal
Senior Vice President – Global Litigation
GlaxoSmithKline
(Philadelphia, PA)

Sonja S. Weissman
Partner
Reed Smith LLP
(San Francisco, CA)

Building on the discussion of the past 2 days, the panelists will be discussing product liability litigation in the U.S. generally, highlighting what some of the key current trends mean for the industry as a whole, where this litigation will likely be in 5 years, and how companies and counsel can adapt and prepare now. ***This interactive Q and A session is specifically designed to attempt to address ways in which the whole system could be transformed into something that more effectively and efficiently administers appropriate justice without all the unnecessary litigation burdens and costs.***

3:15

Main Conference Concludes

POST-CONFERENCE WORKSHOP
WEDNESDAY, DECEMBER 6, 2017

3:30 – 5:30 ETHICS CREDITS

Incorporating Diversity and Inclusion into Your Trial Team Development and Litigation Strategy

Mary-Alice Barrett
Associate Director, Assistant General Counsel
Genentech
(Little Falls, NJ)

Joyce D. Edelman
Partner
Porter Wright
(Columbus, Ohio)

Ashley A. Garry
Counsel – Litigation and Legal Compliance
Eli Lilly and Company
(Indianapolis, IN)

Gordon Hwang
Head US Litigation and Investigations
Sandoz Inc.
(Princeton, NJ)

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 the products liability bar, 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:

- 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

> *ACI's Drug and Med provides cutting-edge information on current topics as well as time to socialize with people in the industry and colleagues who face the same issues that you do day-to-day.*
>
> **Peter Rotolo III, Chaffe McCall LLP**

> *I enjoy the opportunity to get together with hundreds of colleagues in probably the largest group of pharmaceutical and medical device attorneys in the country. I also enjoy the cutting edge programs on such topics as 3D printing and biosimilars.*
>
> **Jeffery Kruse, Baker Sterchi Cowden & Rice LLC**

> *Great attendance at this event combined with a room of people who are interested in the subject matter is what makes speaking at ACI's Drug and Med everything you would hope for.*
>
> **Andrew Tauber, Mayer Brown LLP**

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THE 22nd ANNUAL DRUG & MEDICAL DEVICE LITIGATION CONFERENCE

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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 and awarded 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 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.

Butler Snow LLP is a full-service law firm with more than 330 attorneys representing local, regional, national and international clients from 22 U.S. offices and offices in London and Singapore. Ranked as a Leading Firm for pharmaceutical 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. Butler Snow's practice areas include a full range of business law and litigation services, and the firm's team approach allows it to utilize resources across the firm to match legal experience with client need. As a result, clients benefit from strategic counsel, efficient execution and innovative solutions to complex challenges. For more information, visit www.butlersnow.com or follow Butler Snow on twitter @Butler_Snow.

Bryan Cave LLP offers the best of both worlds: a modern global law firm that values its heritage, combining sophisticated strategic thinking and leading-edge innovation in legal services with a long history of building and maintaining true client partnerships. We take pride in delivering the best value for the highest quality legal services by listening carefully to our clients' needs and concerns and creating thoughtful, customized solutions—whether they be legal, technological, or business-oriented.

In this globalized era of intense competition and exploding litigation regarding medicines and medical devices, we understand that clients need assistance around the world, with the consistent quality and depth to deal with any issues that may arise from investigations, product liability-related litigation, product recalls, or regulatory issues. DLA Piper is unique among law firms in that DLA Piper has broad experience in developing and implementing comprehensive responses to these issues by leveraging the experience of lawyers in dozens of our offices throughout the world, including the Americas, Europe, the Middle East, Africa and Asia Pacific.

Drinker Biddle is a full-service national law firm with more than 653 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.

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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 2017, 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 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.

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.

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Morgan Lewis is a global law firm with more than 2,200 legal professionals in 30 offices worldwide. Our comprehensive life sciences practice includes more than 250 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.

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Nutter McClennen & Fish LLP (Nutter) is a premier Boston law firm that provides high-level, client-centric legal counsel to clients across the country and around the world. For decades, one of the cornerstones 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. To learn more, visit us at www.nutter.com.

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 solving and anticipating legal challenges so you can focus on what you do best: improving and saving lives. In addition to skilled transactional and regulatory lawyers, we offer a highly-regarded, full-service life sciences litigation practice, featuring a deep bench of seasoned trial lawyers and appellate specialists, that has been 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.

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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 LLP

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 Power Rankings for the best client relationships.

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