









Drug and Medical Device

Defending the Pharmaceutical and Medical Device Industry

Hear reflections on the practice of law in TEDstyle talks by the deans of the defense bar

Strategize regarding best practices in defending against litigation tourism

Learn the lessons of 30 years of defense practice

Hear how to deal with past client transgressions and defend against punitive damages

Learn practical tips on the use of technology such as your iPad in the courtroom

May 11-12, 2017 Sheraton New Orleans New Orleans, Louisiana

DRI
delivers
resources
to build
your practice

Attend the 2017 DRI Drug and Medical Device Seminar and learn from presentations by in-house and outside counsel, a federal judge, deans of the drug and device defense bar, and the US Chamber Litigation Center. This seminar is the foremost educational and networking opportunity for practitioners in the pharmaceutical and medical device defense space. Connect with clients and colleagues and learn from cutting-edge presentations. We hope you join us in New Orleans!



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Sheila S. **Boston** Program Vice Chair



Sara J. **Gourley** Committee Vice Chair



Ted J. **McDonald** III Law Institute



See what others have to say about DRI seminars

http://www.youtube.com/user/DefenseBar

PRESENTED BY DRI'S Drug and Medical Device Committee

THIS SEMINAR BROCHURE IS SPONSORED BY Nelson Mullins Riley & Scarborough LLP



What You Will Learn

- Strategic approaches to proportionality under the federal rules
- How to conduct a successful Science Day
- Implications of the Yates memo on internal investigations
- Strategic approaches to the use of FDA 510K clearance in discovery and trial



Get Started

- **1** Review the brochure and identify sessions of interest to you
- 2 Share this brochure with colleagues
- **3** Register online or complete the form in the back
- Download the DRI App App Store Google play and make use of its features to get the most out of this program
- 5 Share on social media







Maximize Your DRI Seminar Experience No one gets you connected like DRI.

- Use the DRI App to customize your schedule, view course materials, and communicate with fellow attendees and speakers.
- Access the DRI Drug and Medical Device Committee Community at http://community.dri.org/home to network with individual members. Share articles, post blogs, and connect with others on the latest trends in your area of practice.
- Discover the DRI Client Connection—meet in-house and claims professional registrants and speakers.

PROGRAM SCHEDULE

WEDNESDAY, MAY 10

5:30 p.m. First-Time Attendees Reception

6:00 p.m. **Registration**

6:00 p.m. **Networking Reception**

THURSDAY, MAY 11

Mobile Device Charging Kiosk

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7:00 a.m. **Registration**

7:00 a.m. Continental Breakfast

8:00 a.m. Welcome and Introduction

Ted J. McDonald III, *McDonald Davidson PA*, Overland Park, KS

Gail Rodgers, DLA Piper LLP (US), New York, NY

8:05 a.m. Lessons Learned from Mass Torts over the Past 30 Years

Mass torts have evolved significantly and many important lessons should guide your current practice. Hear from experienced defense litigators regarding practical application of lessons learned over a career.

MODERATOR | **Kim E. Moore**, *Irwin Fritchie Urguhart & Moore LLC*, New Orleans, LA

John F. Brenner, C.R. Bard Inc., Murray Hill, NJ

Chilton Davis Varner, *King & Spalding LLP*, Atlanta, GA

8:55 a.m. Plaintiffs Playbook Reprised: How to Best Deal with Past Transgressions and Other Accusations

Hear the latest themes deployed by plaintiffs' counsel against the industry in litigation and learn strategies for dealing with issues ranging

Denotes **THE DRI CLIENT CONNECTION**: In-house and claims professional speakers

from attacks on corporate witnesses to questioning the integrity of the corporation itself.

Rebecca Weinstein Bacon, Bartlit Beck Herman

Palenchar & Scott LLP, Chicago, IL

Paul W. Schmidt, Covington & Burling LLP,

Washington, DC

9:45 a.m. Refreshment Break

SPONSORED BY Baker Donelson Bearman

Cadlwell & Berkowitz PC

10:00 a.m. Litigation Tourists and Multi-Plaintiff
Cases in All the Wrong Places

Hear practical advice about what to do, what motions to file, and how to make the best record when faced with litigation by dozens of plaintiffs in multi-plaintiff cases filed far from the homes of most of those plaintiffs.

Kelly A. Evans, *Snell & Wilmer LLP*,

Las Vegas, NV

Kate Comerford Todd, *US Chamber Litigation Center*, Washington, DC

10:50 a.m. Staffing the Mass Tort and Jury Trial Team: Stereotypes and Ethical Considerations

This provocative and interactive hypotheticaldriven session will explore stereotypes, biases, assumptions, and ethical considerations that go into choosing the lawyers who will staff and lead a mass tort over its lifetime.

Rick R. Fuentes, PhD, R&D Strategic Solutions LLC, Atlanta, GA

Bradley (Brad) E. Lerman, Medtronic Inc., Minneapolis. MN

Heidi L. Levine. Sidlev Austin LLP. New York, NY

Elpidio (PD) Villarreal, GlaxoSmithKline, Philadelphia. PA

11:50a.m. **Diversity and Inclusion Luncheon (\$40**

fee, check box on registration form)

Justin I. Woods, *Louisiana Court of Appeal, Fourth Circuit*, New Orleans, LA

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1:05 p.m. Young Lawyer Blockbuster (see below)

1:05 p.m. The Yates Memo: Practical Implications for In-house and Defense Counsel

> In the wake of the Yates memo and an increased focus on individual liability for corporate misconduct, investigators and company lawyers need strategic guidance about potential conflicts of interest, unintended consequences, and best practices for internal investigations.

> Michael K. Loucks, Skadden Arps Slate Meagher & Flom LLP, Boston, MA

Proportionality Under the Federal 1:55 p.m. Rules: A Strategic Approach

> Hear from a federal judge and defense practitioner about proportionality under the revised federal rules, the application of the rules, and strategic methods to explore and develop case law on proportionality.

Brandee J. Kowalzyk, Nelson Mullins Riley & Scarborough LLP, Atlanta, GA

The Honorable Loretta A. Preska.

US District Court, Southern District of New York, New York, NY

2:45 p.m. **Refreshment Break** SPONSORED BY Venable LLP

3:00 p.m. **TED-Style Talks: Reflections** on the Practice of Law

> Hear from renowned in-house counsel and trial lawyers about their personal experiences and reflections on the practice of law.

Sandra Leung, Bristol-Myers Squibb Co., New York, NY

Chilton Davis Varner, *King & Spalding LLP*, Atlanta, GA

Elpidio (PD) Villarreal, *GlaxoSmithKline*, Philadelphia, PA

4:00 p.m. In-House Counsel Breakout Session (in-house counsel only)

YOUNG LAWYER BLOCKBUSTER

THURSDAY, MAY 11 1:05 P.M.-4:00 P.M.

Opening Remarks and Introductions 1:05 p.m.

Evan C. Holden. *Greenberg Trauria LLP*.

Atlanta, GA

Heather M. Howard, King & Spalding LLP,

Atlanta, GA

1:15 p.m. Successfully Challenging Expert Testimony: It Starts with the Deposition

Sara Deskins Tucker, Greenberg Traurig LLP,

Atlanta, GA

1:35 p.m. Strategies for Combating Off-Label Marketing Claims with the **Learned Intermediary Doctrine**

> **Thomas P. Kurland**, *Patterson Belknap Webb &* Tyler LLP, New York, NY

Plaintiff Challenges to Company Document 1:55 p.m. Confidentiality: Are You Protected?

Christopher J. Kaufman. Shook Hardv &

Bacon LLP, Kansas City, MO

2:15 p.m. **Refreshment Break**

2:25 p.m. **Blurred Lines: The Growing Question of** Sales Rep Liability in Medical Device Cases

> **Katy O. Meszaros**. *Nutter McClennen & Fish LLP.* Boston, MA

2:45 p.m. I Want You: What In-House Counsel **Want from Young Lawyers**

> **Danielle J. Diviaio**, *Boehringer Ingelheim* USA Corp., Ridgefield, CT

Larissa A. Eustice, Bayer Corporation, Whippany, NJ

Ashley Garry, *Eli Lilly and Company*, Indianapolis, IN

Bradley A. Matta, Mylan Laboratories Inc., Canonsburg, PA

4:00 p.m. Young Lawver Drug and Medical **Device Committee Meeting and Networking Reception** (open to all)

4:00 p.m. Specialized Litigation Group Meetings

- Class Action and Multi-Party Litigation
- Complex Medicine/Experts
- Defense of Generic and OTC Manufacturers
- Defense of Governmental Actions
- Plaintiffs' Regulatory Experts

5:30 p.m. **Drug and Medical Device Committee Meeting** (open to all)

6:00 p.m. Networking Reception
SPONSORED BY Barnes & Thornburg LLP

FRIDAY, MAY 12

Mobile Device Charging Kiosk SPONSORED BY Greenberg Traurig LLP

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7:00 a.m. **Registration**

7:00 a.m. Continental Breakfast

SPONSORED BY Reed Smith LLP

8:00 a.m. Welcome and Introduction

Sara J. Gourley, Sidley Austin LLP, Chicago, IL

Sheila S. Boston, *Arnold & Porter Kaye Scholer LLP*. New York. NY

8:05 a.m. Not Your Average Science Fair

Learn best practices for conducting Science Days in the courtroom and how to keep the judge engaged during the presentation of complex scientific concepts, including epidemiology, the Bradford-Hill criteria, and use of expert witnesses, as well as how to showcase your themes through the science without advocating.

Mark S. Cheffo, Quinn Emanuel Urquhart & Sullivan LLP, New York, NY

8:55 a.m. Defending the Medical Device Claim: Strategically Approaching Your Defense

This session will discuss several common defense issues, including FDA 510(k) clearance evidence, causation in failure-to-report claims, and responding to manufacturing defect arguments, as well as when no FDA evidence is allowed, when FDA clearance is contained only

in the judge's instructions, and when all evidence is admissible, allowing for "fraud-on-the-FDA" arguments.

Amy R. Fiterman, *Faegre Baker Daniels LLP*, Minneapolis, MN

Marc A. Polk, Stryker Corporation, Allendale, NJ

9:45 a.m. **Refreshment Break**

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Quattlebaum Grooms & Tull PLLC

10:00 a.m. Bet You Can't Take Just One Byte: Using an iPad to Improve Your Litigation Practice

This session will provide tips and tricks for using your iPad to work with email, pleadings, exhibits, and deposition transcripts more effectively, and it will also provide advice for effective use of an iPad during hearings on motions, trials, and appellate arguments.

Jeffrey E. Richardson, *Adams and Reese LLP*, New Orleans, LA

10:50 a.m. **Defending Against Punitives:** When History Comes Back to Bite

Prior facts such as corporate integrity agreements and FDA Form 483 letters are frequently used by plaintiffs in their quests for large punitive damage awards. Learn strategic methods for dealing with prior "bad acts" and company conduct during discovery and at trial.

Kelly A. Evans, Snell & Wilmer LLP,

Las Vegas, NV

Reiko Hasuike, PhD, *R&D Strategic Solutions LLC*, Manhattan Beach, CA

11:40 a.m. Hot Topics: Strategic Approaches to Dealing with Trends in Discovery and Trial

Hear from in-house and outside counsel who are on the front lines dealing with these issues, including litigation under the threat of individual sanctions and the absence of a corporate witness at trial.

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

Mariam Koohdary, AstraZeneca Pharmaceuticals LP, Wilmington, DE

12:40 p.m. **Adjourn**

3:00 p.m. **Community Service** (see page 6)

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GENERAL INFORMATION

In-House Counsel

In-house counsel are eligible for free registration to DRI seminars. In-house counsel are defined as licensed attorneys, who are employed exclusively by a corporation or other private sector organization for the purpose of providing legal representation and counsel only to that corporation, its affiliates and subsidiaries. In order to qualify for free registration, the individual must also be a DRI member and a member of DRI's Corporate Counsel Committee. Offer excludes the DRI Annual Meeting.

Claims Executives

Any member of DRI employed as a claims professional by a corporation or insurance company, who spends a substantial portion of his or her professional time hiring or supervising outside counsel in the representation of business, insurance companies or their insureds, associations or governmental entities in civil litigation, will be entitled to free attendance at any DRI program. **Limited to one seminar per calendar year.** Offer excludes DRI Annual Meeting.

CLE/Claims Adjusters Accreditation

This seminar has been approved for MCLE credit by the State Bar of California for up to 10.50 hours, including 1.0 hour of ethics credit. Accreditation has been requested from every state with mandatory continuing legal education (CLE) requirements. Certificates of attendance will be provided to each attendee. Attendees are responsible for obtaining CLE credits from their respective states. Application has been made for continuing education for claims adjusters. Credit availability and requirements vary from state to state; please check the DRI website at dri.org for the latest information for your state.



Registration Policy

Save \$100 when you register by April 11, 2017. (See the registration form for pricing.) The registration fee includes course materials, continental breakfasts, refreshment breaks, networking receptions, and access to the DRI App. If you wish to have your name appear on the registration list distributed at the conference and receive the course materials in advance, DRI must receive your registration by **April 18, 2017** (*please allow 10 days for processing*). Registrations received after **April 18, 2017**, will be processed on-site.

Refund Policy

The registration fee is fully refundable for cancellations received on or before **April 18**, **2017**. Cancellations received after **April 18** and on or before **April 25**, **2017**, will receive a refund, less a \$100 processing fee. Cancellations made after **April 25** will not receive a refund, but a \$100 certificate good for any DRI seminar within the next 12 months will be issued. All cancellations and requests for refunds must be made in writing. Fax (312.795.0747) or email (**seminars@dri.org**) to DRI's Accounting Department. Processing of refunds will occur within four weeks after the date of the seminar. All refunds will be processed in the same method that the payment was received. Substitutions may be made at any time without charge and must be submitted in writing.

Discounts

Group Discount The first and second registrations from the same firm or company are subject to the fees outlined previously. The registration fee for additional registrants from the same firm or company is **\$895**, regardless of membership status if received on or before **April 11**, **2017**. After **April 11**, the group rate is **\$995**. All registrations must be received at the same time to receive the discount.

Travel Discounts DRI offers discounted meeting fares on various major air carriers for **DRI Drug and Medical Device Seminar** attendees. To receive these discounts, please contact Direct Travel, DRI's official travel provider, at 800.840.0908. As always, to obtain the lowest available fares, early booking is recommended.

- The taping or recording of DRI seminars is prohibited without the written permission of DRI.
- Speakers and times may be subject to last-minute changes.
- A small portion of your room rate offsets the costs of the seminar.
- DRI policy provides there will be no group functions sponsored by others in connection with its seminars.

Hotel Accommodations

A limited number of discounted hotel rooms have been made available at the **Sheraton New Orleans, 500 Canal Street, New Orleans, LA 70130**.

Take advantage of the group rate of **\$239 Single/Double** in one of two ways:

- Reserve online: Visit dri.org and go to the DRI Drug and Medical Device Seminar page and click on the "Book hotel" button
- 2) Or contact the hotel directly at 504.525.2500 and mention the DRI Drug and Medical Device Seminar

The hotel block is limited and rooms and rates are available on a first-come, first-served basis. You must make reservations by **April 11, 2017**, to be eligible for the group rate. Requests for reservations made after **April 11, 2017** are subject to room and rate availability.

FACULTY

Rebecca Weinstein Bacon, Bartlit Beck Herman Palenchar & Scott LLP, Chicago, IL

Sheila S. Boston, Arnold & Porter Kaye Scholer LLP, New York, NY

John F. Brenner, C.R. Bard Inc., Murray Hill, NJ

Mark S. Cheffo, Quinn Emanuel Urquhart & Sullivan LLP, New York, NY

D'Lesli M. Davis, Norton Rose Fulbright US LLP, Dallas, TX **Sara Deskins Tucker**, Greenberg Traurig LLP, Atlanta, GA

Danielle J. Diviaio, Boehringer Ingelheim USA Corp., Ridgefield, CT

Larissa A. Eustice, Bayer Corporation, Whippany, NJ

Kelly A. Evans, Snell & Wilmer LLP, Las Vegas, NV

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Heather M. Howard, King & Spalding LLP, Atlanta, GA

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Brandee J. Kowalzyk, Nelson Mullins Riley & Scarborough LLP, Atlanta, GA

Thomas P. Kurland, Patterson Belknap Webb & Tyler LLP, New York, NY

Bradley (Brad) E. Lerman, Medtronic Inc., Minneapolis, MN

Sandra Leung, Bristol-Myers Squibb Co., New York, NY

Heidi L. Levine, Sidley Austin LLP, New York, NY

Michael K. Loucks, Skadden Arps Slate Meagher & Flom LLP, Boston, MA

Bradley A. Matta, Mylan Laboratories Inc., Canonsburg, PA

Ted J. McDonald III, McDonald Davidson PA, Overland Park, KS

Katy O. Meszaros, Nutter McClennen & Fish LLP, Boston, MA

Kim E. Moore, Irwin Fritchie Urquhart & Moore LLC, New Orleans, LA

Marc A. Polk, Stryker Corporation, Allendale, NJ

The Honorable Loretta A. Preska, US District Court, Southern District of New York, New York, NY

Jeffrey E. Richardson, Adams and Reese LLP, New Orleans, LA

Gail Rodgers, DLA Piper LLP (US), New York, NY

Paul W. Schmidt, Covington & Burling LLP, Washington, DC

J. Carter Thompson, Jr., Baker Donelson Bearman Caldwell & Berkowitz PC, Jackson, MS, and Memphis, TN

Kate Comerford Todd, US Chamber Litigation Center, Washington, DC

Chilton Davis Varner, King & Spalding LLP, Atlanta, GA

Elpidio (PD) Villarreal, GlaxoSmithKline, Philadelphia, PA

Justin I. Woods, Louisiana Court of Appeal, Fourth Circuit, New Orleans, LA

View faculty bios on the Drug and Medical Device Seminar webpage; click on "Speaker List" tab.

COMMUNITY SERVICE Friday, May 12, 3:00 p.m.



Join the committee leadership for a transformative experience as we assist the New Orleans Mission Inc. in their daily meals outreach program on Friday afternoon in several New Orleans neighborhoods, including the Lower Ninth Ward. The Mission, one of the largest service providers to the homeless and economically disadvantaged population of New Orleans, serves residents as far as the southern coastal parishes of St. Tammany, lower Jefferson, St. Bernard, Terrebonne, Plaquemines, and Lafourche. The Mission will be picking up participants directly at the hotel at 3:00 pm and dropping us off at 5:00 pm. To reserve your spot, check the "community service project" box on your registration form or email Jim

Craven at **JCraven@wiggin.com**. If you cannot participate, please consider making a tax-deductible financial contribution. On-site volunteers will accept donations.

CLE for Your Practice

View complete list of DRI's Continuing Legal Education offerings at http://dri.org/education-cle

March 2-3

Medical Liability and Health Care Law

The Cosmopolitan of Las Vegas, Las Vegas, NV

March 15-17

Trial Tactics

The Venetian Palazzo Resort, Las Vegas, NV

March 23-24

Toxic Torts and Environmental Law

Sheraton New Orleans, New Orleans, LA

May 4-5

Retail and Hospitality Litigation

Loews Chicago Hotel, Chicago, IL

May 11-12

Appellate Advocacy

Sheraton New Orleans, New Orleans, LA

June 15-16

Diversity for Success

Swissôtel Chicago, Chicago, IL

June 22-23

Young Lawyers

The Westin Austin Downtown, Austin. TX

September 6-8

Data Management and Security

Westin Michigan Avenue, Chicago, IL

Publications for Your Practice

Members can access committee newsletters and seminar course materials via **DRI Online** at **dri.org**. **Newsletter** *Rx For The Defense* (4 times a year)

Visit the **Drug and Medical Device Committee page** on **dri.org** for information about the committee and related resources.

Drug and Medical Device focus in *For The Defense*

September 2017 (upcoming)

September 2016

September 2015

Defense Library Series

FDA Basics for the Drug and Medical Device Lawyer



Diversity and Inclusion in DRI: A Statement of Principle

DRI is the largest international membership organization of attorneys defending the interests of business and individuals in civil litigation.

Diversity Diversity is a core value at DRI. Indeed, diversity, which includes sexual orientation, is fundamental to the success of the organization, and we seek out and embrace the innumerable benefits and contributions that the perspectives, backgrounds, cultures, and life experiences a diverse membership provides.

Inclusiveness is the chief means to increase the diversity of DRI's membership and leadership positions. DRI's members and potential leaders are often also members and leaders of other defense organizations. Accordingly, DRI encourages all national, state, and local defense organizations to promote diversity and inclusion in their membership and leadership.

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