



Drug and Medical Device

For the Defense: Litigation Across the Drug and Device Spectrum

Hear Judge Posner speak on ethics in class action settlements

Navigate the emerging landscape of biosimilars

Plan for the future: regulation and litigation surrounding 3-D printing

Learn from the deans of the defense bar in TED Talks-style presentations

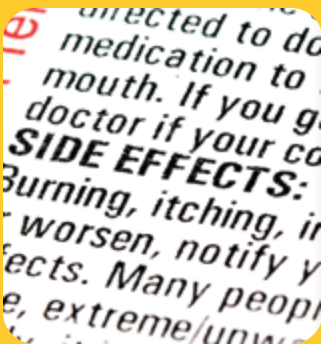
Observe three styles of closing arguments tailored to the locale

May 19-20, 2016

Chicago Marriott Downtown

Chicago, Illinois

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Attend the 2016 DRI Drug and Medical Device Seminar and hear presentations by over 10 in-house counsel, Honorable Richard A. Posner of the Seventh Circuit Court of Appeals, and the deans of the drug and medical device defense bar. This seminar is the leading educational and networking opportunity for drug and medical device practitioners. Connect with clients and colleagues and hear cutting-edge presentations. We hope that you will join us in Chicago!



Gail Rodgers
Program Chair



Sheila S. Boston
Program Vice Chair



J. Carter Thompson, Jr.
Committee Chair



Sara J. Gourley
Committee Vice Chair



Ted J. McDonald III
Law Institute



See what others have to say about DRI seminars

PRESENTED BY **DRI's Drug and Medical Device Committee**

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








What You Will Learn

- The future of drug warnings
- 3-D printing: implications for regulation and litigation
- The First Amendment and off-label promotion
- Closing arguments from around the country
- What you need to know about biosimilars




Get Started

- 1 Review the brochure and identify sessions of interest to you
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- 4 **Add the program** to your calendar
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- 6 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** 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 registrants and speakers.

PROGRAM SCHEDULE

WEDNESDAY, MAY 18, 2016

- 5:30 p.m. **First-Time Attendees Reception**
- 6:00 p.m. **Registration**
- 6:00 p.m. **Networking Reception**
SPONSORED BY **Barnes & Thornburg LLP**

THURSDAY, MAY 19, 2016

- Boarding Pass Kiosk**
SPONSORED BY **King & Spalding**
- Mobile Device Charging Kiosk**
SPONSORED BY **Greenberg Traurig LLP**
- 7:00 a.m. **Registration**
- 7:00 a.m. **Continental Breakfast**
SPONSORED BY **MRC**
Shook Hardy & Bacon LLP
- 8:10 a.m. **Welcome and Introduction**
Ted J. McDonald III, *Adam & McDonald PA*,
Overland Park, Kansas
Gail Rodgers, *DLA Piper LLP (US)*,
New York, New York
- 8:15 a.m. **The Future of Drug Warnings: REMS, Medication Guides, and the (Potential) Erosion of the Learned Intermediary Doctrine**
In response to a recent report suggesting that patients might not fully understand primary risks of medications, FDA made groundbreaking changes to warnings in patient brochures, including pictures of significant adverse events associated with the drug. Hear about the impact these recent changes by FDA may have on the continued viability of the learned intermediary doctrine.
Randall L. Christian, *Bowman and Brooke LLP*,
Austin, Texas
 **Marc Fishman**, *Novo Nordisk Inc.*,
Plainsboro, New Jersey
- 9:10 a.m. **Lies, Damn Lies, and Statistics: The Use and Limitations of Meta-Analyses in Litigation**
Sponsored by the Complex Medicine/Experts SLG. Meta-analyses combine data from multiple studies and are intended to achieve higher statistical power than individual studies and improve estimates of effect size. The panel will discuss *Daubert/Frye* challenges and trial tactics to neutralize expert opinions based on meta-analyses, including real-world examples of the misuse of

Click on any speaker name to view bio.

- meta-analyses by experts and how to expose the flaws in their methodologies.
Dominik D. Alexander, PhD, MSPH,
EpidStat Institute, Ann Arbor, Michigan
Bruce R. Parker, *Venable LLP*, Baltimore, Maryland
- 10:00 a.m. **Refreshment Break**
SPONSORED BY **Baker Donelson Bearman Caldwell & Berkowitz PC**
- 10:15 a.m. **Crisis Management for Drug and Medical Device Companies in the New Age**
Drug and medical device in-house and external counsel need decisive and coordinated responses to crises that can otherwise shake the c-suite to its core. Our panel will address hypothetical scenarios to demonstrate how to prepare for and respond to crises effectively.
MODERATOR | **Steven F. Rosenhek**, *Fasken Martineau DuMoulin LLP*, Toronto, Ontario, Canada
Christy D. Jones, *Butler Snow*,
Ridgeland, Mississippi
 **Brennan J. Torregrossa**,
GlaxoSmithKline plc,
Philadelphia, Pennsylvania
- 11:10 a.m. **Free Speech: *Amarin* and First Amendment Challenges**
Amarin Pharma v. FDA has now joined *United States v. Caronia* in recognizing that truthful off-label promotion is protected by the First Amendment and in restricting FDA enforcement activities as a result. This presentation will analyze the implications of this evolving regulatory landscape and what it means for product liability litigation involving off-label use.
Lisa M. Baird, *Reed Smith LLP*,
Los Angeles, California
 **Rita A. McConnell**, *Medtronic Inc.*,
Minneapolis, Minnesota
- 12:00 p.m. **Diversity Luncheon**
Andrea Zopp, *Candidate for the United States Senate*, Chicago, Illinois
SPONSORED BY **DLA Piper LLP (US)**
Gordon & Rees LLP
Kaye Scholer LLP
Norton Rose Fulbright
McDowell Knight
Sidley Austin LLP

- 1:15 p.m. **Daubert: General and Specific Causation Revisited**
This presentation on *Daubert/Frye* will discuss the practical aspects of presenting and defending *Daubert/Frye* challenges, including novel pre-motion discovery and expert background research. The discussion will include trends in filing these motions as well as strategic and tactical considerations regarding whether and when to file your *Daubert/Frye* motion.
Christopher G. Campbell, *DLA Piper LLP (US)*, New York, New York
Michelle M. Fujimoto, *Shook Hardy & Bacon LLP*, Irvine, California
- 1:30 p.m. **Young Lawyers Blockbuster** (see below)
- 2:00 p.m. **TED-Style Talks: Looking Back to Move Forward**
The deans of the drug and device bar discuss what they have learned practicing law, how to make lemons out of lemonade, and the things they wish they had known when they started.
Christy D. Jones, *Butler Snow*, Ridgeland, Mississippi
▶ **Timothy A. Pratt**, *Boston Scientific Corp.*, Marlborough, Massachusetts
▶ **Malini Moorthy**, *Bayer Corp.*, Pittsburgh, Pennsylvania
Jack B. (Skip) McCowan Jr., *Gordon & Rees LLP*, San Francisco, California
- 3:00 p.m. **Refreshment Break**
SPONSORED BY **Venable LLP**
- 3:15 p.m. **When in Rome (or Mississippi or New York or Cook County): Local Approaches to Closing Arguments**
Observe nationally known trial lawyers present dynamic closing arguments in different ways, depending on the place of trial.
Tarek Ismail, *Goldman Ismail Tomaselli Brennan & Baum LLP*, Chicago, Illinois
Robert L. Johnson III, *Attorney at Law*, Natchez, Mississippi
Diane P. Sullivan, *Weil Gotshal & Manges LLP*, New York, New York
- 4:30 p.m. **In-House Counsel Breakout Session** (*In-house counsel only*)
- 4:30 p.m. **Meetings of the Specialized Litigation Groups**
● Defense of Government Actions
● Plaintiffs' Regulatory Experts
● Complex Medicine/Experts
● Defense of Generic Manufacturers
● Class Actions and Multi-Party Litigation
- 5:15 p.m. **Drug and Medical Device Committee Meeting** (*open to all*)
- 6:00 p.m. **Networking Reception**
SPONSORED BY **Morgan, Lewis & Bockius LLP**

YOUNG LAWYERS BLOCKBUSTER

THURSDAY, MAY 19 1:30 P.M.–4:30 P.M.

- 1:30 p.m. **Welcome and Announcements**
- 1:40 p.m. **Guess Who's Coming to Trial: Identifying the Representative Plaintiff for MDL Bellwether Selection**
Jennifer A. Eppensteiner, *Reed Smith LLP*, Philadelphia, Pennsylvania
- 2:00 p.m. **Successfully Challenging Expert Testimony: It Begins with the Deposition**
Sara Deskins Tucker, *Greenberg Traurig LLP*, Atlanta, Georgia
- 2:20 p.m. **Significant Developments in Personal Jurisdiction: Bauman and Subsequent Developments**
Corena G. Larimer, *Tucker Ellis LLP*, San Francisco, California
- 2:40 p.m. **Cyber Security Vulnerabilities with Medical Devices**
Mary R. Topfer, *Harris Beach PLLC*, New York, New York
- 3:00 p.m. **Break**
- 3:15 p.m. **How to Become Indispensable: An Interactive In-House Panel**
▶ **David L. Kleinman**, *Sandoz Inc.*, Princeton, New Jersey
▶ **Ryan Edward Lindsey**, *Edwards Lifesciences Corp.*, Irvine, California
▶ **Jessica L. Parker-Battle**, *Biogen*, Weston, Massachusetts
▶ **Gregory Charles Sicilian**, *Gilead Sciences Inc.*, Foster City, California

FRIDAY, MAY 20, 2016

Boarding Pass Kiosk

SPONSORED BY **King & Spalding**

Mobile Device Charging Kiosk

SPONSORED BY **Greenberg Traurig LLP**

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

7:00 a.m. **Continental Breakfast**

SPONSORED BY **Reed Smith LLP**

8:00 a.m. **Announcements**

Sara J. Gourley, *Sidley Austin LLP*, Chicago, Illinois

Sheila S. Boston, *Kaye Scholer LLP*,
New York, New York

8:05 a.m. **Wild Card Judges: Combating
Cognitive Errors and Bias in Judges**

Dr. Ellis will discuss the conventional wisdom that you are better off with a judge than with a jury in a high-stakes case. Dr. Ellis will use mock hearing examples to describe research about what influences judges and their decisions, the mental shortcuts often used, and cognitive errors made.
Leslie Ellis, PhD, *DecisionQuest*, Washington, D.C.

9:00 a.m. **3-D Printing and Medical Devices: New
Technology and Old Product Liability Claims**

3-D technology is already being used to create products such as orthopedic and dental implants, hearing aids, and prosthetics. This presentation will explore implications for our regulatory framework and the manner in which traditional product liability claims and defenses will be litigated.

Angela R. Vicari, *Kaye Scholer LLP*,
New York, New York

10:00 a.m. **Refreshment Break**

SPONSORED BY **Butler Snow
Quattlebaum Grooms & Tull PLLC**

10:15 a.m. **Generics: The Failure to Timely
Update—Pre-Litigation Counseling,
Preemptive Planning, and Litigation**

Sponsored by the Generics SLG. With plaintiffs searching for every new avenue to sue generic

manufacturers, claims based on a failure to timely update merit careful attention and handling. This presentation will address the regulatory issues involved, the best ways to address these claims before they land on your desk, what happens in litigation, and the potential impact of any final new FDA rule on generic labeling.

Tracey A. Van Dillen, *Actavis plc (now Allergan)*, Parsippany, NJ

Jeffrey F. Peck, *Ulmer & Berne LLP*, Cincinnati, Ohio

11:05 a.m. **Biosimilars: The Emerging Landscape
for Pharmaceutical Companies**

Biosimilars are the new wave of scientific development for many pharmaceutical companies. As science progresses, so do FDA regulations and litigation opportunities for plaintiffs. Hear from in-house counsel regarding new developments and anticipated responses to both the regulatory framework and litigation.

 **Desiree Ralls-Morrison**,
Boehringer Ingelheim USA Corp.,
Ridgefield, Connecticut

12:00 p.m. **From the Bench: Do I Have an
Ethics Lesson for You!**

Class action settlements call for “intense judicial scrutiny,” including of the appropriateness of *cy pres* awards and class counsel fees. This scrutiny grows out of the “built-in conflict of interest” in class action suits between class counsel and their nominal clients. Judge Posner will discuss how those issues arise and what issues defense counsel should consider in negotiating such settlements to facilitate judicial approval.

MODERATOR | **Sara J. Gourley**, *Sidley Austin LLP*,
Chicago, Illinois

Honorable Richard A. Posner, *United States
Court of Appeals for the Seventh Circuit*,
Chicago, Illinois

1:00 p.m. **Adjourn**

3:00 p.m. **Community Service**

SPONSORED BY **Wiggin and
Dana LLP**



Join committee leadership as we assist the world’s largest Ronald McDonald House near Lurie Children’s Hospital in their “Meals from the Heart” volunteer program by preparing and providing a home-cooked dinner to the approximately 80 family members staying at the home. This service gives families time to relax and replenish after spending a long day at their child’s bedside and it is conveniently located just a short walk from the hotel. To participate, 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.

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 **11.75** hours, including **1** 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.



A limited number of discounted hotel rooms have been made available at **Chicago Marriott Downtown, 540 North Michigan, Chicago, IL 60611** ([click here](#) to view hotel photos).

Take advantage of the group rate of **\$289 Single/Double** in one of two ways:

- 1) Reserve online: [Click here](#) or visit dri.org and go to the **DRI Drug and Medical Device Seminar** page and click on the "Book Hotel" tab.
- 2) Or **contact the hotel directly at 312.836.0100** 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 19, 2016**, to be eligible for the group rate. Requests for reservations made after **April 19** are subject to room and rate availability.

Registration Policy

Save \$100 when you register by April 21, 2016. (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 28, 2016** (*please allow 10 days for processing*). Registrations received after **April 28, 2016**, will be processed on-site.

Refund Policy

The registration fee is fully refundable for cancellations received on or before **April 28, 2016**. Cancellations received after **April 28** and on or before **May 5, 2016**, will receive a refund, less a \$100 processing fee. Cancellations made after **May 5** will not receive a refund, but the course materials on CD-ROM and 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 on the registration form. The registration fee for additional registrants from the same firm or company is **\$855**, regardless of membership status. 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

FACULTY *Click on any name to view bio.*

Dominik D. Alexander, PhD, MSPH, EpidStat Institute, Ann Arbor, Michigan

Lisa M. Baird, Reed Smith LLP, Los Angeles, California

Sheila S. Boston, Kaye Scholer LLP, New York, New York

Christopher G. Campbell, DLA Piper LLP (US), New York, New York

Randall L. Christian, Bowman and Brooke LLP, Austin, Texas

Leslie Ellis, PhD, DecisionQuest, Washington, D.C.

Jennifer A. Eppensteiner, Reed Smith LLP, Philadelphia, Pennsylvania

Marc Fishman, Novo Nordisk Inc., Plainsboro, New Jersey

Michelle M. Fujimoto, Shook Hardy & Bacon LLP, Irvine, California

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

Tarek Ismail, Goldman Ismail Tomaselli Brennan & Baum LLP, Chicago, Illinois

Robert L. Johnson III, Attorney at Law, Natchez, Mississippi

Christy D. Jones, Butler Snow, Ridgeland, Mississippi

David L. Kleinman, Sandoz Inc., Princeton, New Jersey

Corena G. Larimer, Tucker Ellis LLP, San Francisco, California

Ryan Edward Lindsey, Edwards Lifesciences Corp., Irvine, California

Rita A. McConnell, Medtronic Inc., Minneapolis, Minnesota

Jack B. (Skip) McCowan Jr., Gordon & Rees LLP, San Francisco, California

Ted J. McDonald III, Adam & McDonald PA, Overland Park, Kansas

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Bruce R. Parker, Venable LLP, Baltimore, Maryland

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Jessica L. Parker-Battle, Biogen, Weston, Massachusetts

Jeffrey F. Peck, Ulmer & Berne LLP, Cincinnati, Ohio

Honorable Richard A. Posner, United States Court of Appeals for the Seventh Circuit, Chicago, Illinois

Timothy A. Pratt, Boston Scientific Corp., Marlborough, Massachusetts

Desiree Ralls-Morrison, Boehringer Ingelheim USA Corp., Ridgefield, Connecticut

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

Steven F. Rosenhek, Fasken Martineau DuMoulin LLP, Toronto, Ontario, Canada

Gregory Charles Sicilian, Gilead Sciences, Inc., Foster City, California

Diane P. Sullivan, Weil Gotshal & Manges LLP, New York, New York

J. Carter Thompson, Jr., Baker Donelson Bearman Caldwell & Berkowitz PC, Jackson, Mississippi

Mary R. Topfer, Harris Beach PLLC, New York, New York

Brennan J. Torregrossa, GlaxoSmithKline plc, Philadelphia, Pennsylvania

Sara Deskins Tucker, Greenberg Traurig LLP, Atlanta, Georgia

Tracey A. Van Dillen, Actavis plc (now Allergan), Parsippany, NJ

Angela R. Vicari, Kaye Scholer LLP, New York, New York

Andrea Zopp, Candidate for the United States Senate, Chicago, Illinois

View faculty bios online at <http://www.dri.org/Event/20160070> (Drug and Medical Device Seminar webpage); click on "Speaker List" tab.

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May 20

Fidelity and Surety Roundtable

The Gwen, Chicago, Illinois

June 2–3

Hot Topics in International Dispute Resolution

Hilton Vienna Plaza, Vienna, Austria

June 2–3

Construction Law

Sheraton New Orleans,
New Orleans, Louisiana

June 9–10

Diversity for Success

Fairmont Chicago, Chicago, Illinois

June 16–17

Young Lawyers

Encore at the Wynn, Las
Vegas, Nevada

July 21–22

Class Actions

JW Marriott, Washington, DC

September 8–9

Nursing Home/ALF Litigation

Westin Kierland, Phoenix, Arizona

September 22–23

Data Breach and Privacy Law

The Atlanta Marriott Marquis,
Atlanta, Georgia

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Drug and Medical Device focus in *For The Defense*

September 2016 (*upcoming*)

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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 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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<input type="checkbox"/> Diversity Luncheon	\$40	
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