Drug and Medical Device

For the Defense: Litigation Across the Drug and Device Spectrum

May 19–20, 2016
Chicago Marriott Downtown
Chicago, Illinois

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

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

1. Review the brochure and identify sessions of interest to you
2. Share this brochure with colleagues
3. Register online at [http://dri.org/Event/20160070](http://dri.org/Event/20160070) or complete the form in the back
4. Add the program to your calendar
5. Download the DRI App [Apple](https://apps.apple.com/us/app/dri-digital-risk-insurance/id1420933153) [Google Play](https://play.google.com/store/apps/details?id=com.dri.android) and make use of its features to get the most out of this program
6. Share on social media

Get Started

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](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 registrants and speakers.
## PROGRAM SCHEDULE

### WEDNESDAY, MAY 18, 2016

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>5:30 p.m.</td>
<td>First-Time Attendees Reception</td>
</tr>
<tr>
<td>6:00 p.m.</td>
<td>Registration</td>
</tr>
<tr>
<td>6:00 p.m.</td>
<td>Networking Reception SPONSORED BY Barnes &amp; Thornburg LLP</td>
</tr>
</tbody>
</table>

### THURSDAY, MAY 19, 2016

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 a.m.</td>
<td>Registration</td>
</tr>
<tr>
<td>7:00 a.m.</td>
<td>Continental Breakfast SPONSORED BY MRC Shook Hardy &amp; Bacon LLP</td>
</tr>
<tr>
<td>8:10 a.m.</td>
<td>Welcome and Introduction</td>
</tr>
<tr>
<td></td>
<td>Ted J. McDonald III, Adam &amp; McDonald PA, Overland Park, Kansas</td>
</tr>
<tr>
<td></td>
<td>Gail Rodgers, DLA Piper LLP (US), New York, New York</td>
</tr>
<tr>
<td>8:15 a.m.</td>
<td>Lies, Damn Lies, and Statistics: The Use and Limitations of Meta-Analyses in Litigation</td>
</tr>
<tr>
<td></td>
<td>Spons...</td>
</tr>
<tr>
<td>9:10 a.m.</td>
<td>Diversity Luncheon</td>
</tr>
<tr>
<td></td>
<td>Andrea Zopp, Candidate for the United States Senate, Chicago, Illinois</td>
</tr>
</tbody>
</table>

### Program Notes

- Denotes THE DRI CLIENT CONNECTION: In-house speakers
- 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
- Lisa M. Baird, Reed Smith LLP, Los Angeles, California
- Rita A. McConnell, Medtronic Inc., Minneapolis, Minnesota

### Additional Information

- **8:10 a.m.** The Future of Drug Warnings: REMS, Medication Guides, and the (Potential) Erosion of the Learned Intermediary Doctrine
- Randall L. Christian, Bowman and Brooke LLP, Austin, Texas
- Marc Fishman, Novo Nordisk Inc., Plainsboro, New Jersey
- **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 Fullbright, 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 & Baun LLP, Chicago, Illinois
Robert L. Johnson III, Attorney at Law, Natchez, Mississippi
Diane P. Sullivan, Weil Gotshal & Manges LLP, New York, New York

3:30 p.m.  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.
Howard M. Cyr III, Teva Pharmaceuticals, Horsham, Pennsylvania

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 Rails-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

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.
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 $585, 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.

Hotel Accommodations

A limited number of discounted hotel rooms have been made available at the Chicago Marriott Downtown, 540 North Michigan, Chicago, IL 60611.

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

1) Reserve online: 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.
FACULTY

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

Howard M. Cyr III, Teva Pharmaceuticals, Horsham, Pennsylvania

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

Denotes THE DRI CLIENT CONNECTION: In-house speakers

Malini Moorthy, Bayer Corp., Pittsburgh, Pennsylvania
Bruce R. Parker, Venable LLP, Baltimore, Maryland

Jessica L. Parker-Battle, Biogen, Weston, Massachusetts
Jeffrey F. Peck, Ulmer & Berne LLP, Cincinnati, Ohio

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

Desiree Rails-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

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.

Use the DRI App to enhance your seminar experience

- View the program schedule and customize your own
- View speaker bios and contact info
- Use the attendees list to communicate with colleagues in attendance
- Keep notes
- Access seminar materials
- Make use of social media within the app to share your seminar experience

Download the New DRI App!
CLE for Your Practice

View complete list of upcoming seminars at http://www.dri.org/Events/Seminars

View complete list of upcoming webcasts at http://dri.org/Events/Webcasts

- 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

Publications for Your Practice

- Newsletter  
  Rx For The Defense (4 times a year)
  Visit the Drug and Medical Device Committee page on dri.org and scroll down to “Latest Newsletter.”

- Drug and Medical Device focus in For The Defense
  September 2016 (upcoming)
  September 2015
  September 2014

- 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.
SeminAr Sponsors
DRI wishes to thank our sponsors for their support at this year’s seminar!

Platinum sponsors

Morgan Lewis

Gold sponsors

Barnes & Thornburg LLP
Greenberg Traurig
Nutter
Bowman and Brooke
King & Spalding
Reed Smith
Exponent
Nelson Mullins Riley & Scarborough LLP
Tucker Ellis LLP

Silver sponsors

Baker Donelson
Kaye Scholer LLP
Quattlebaum Grooms & Tull PLLC
Blake’s
LMI
Shook Hardy & Bacon
Butler Snow
McDowell Knight
Sidley Austin LLP
Campbell Trial Lawyers
Medical Risk Consultant
DLA Piper
Norton Rose Fulbright
Wiggin and Dana
Gordon & Rees

Bronze sponsors

THOMSON REUTERS®
SE.A.
FORMAL NAME

NAME (as you would like it to appear on badge)

COMPANY/FIRM/LAW SCHOOL

ADDRESS

CITY

STATE/PROVINCE

ZIP/POST CODE

TELEPHONE

FAX

EMAIL

Please list any special needs

Are you a first-time attendee at this DRI seminar?  

☐ Yes  ☐ No

How many attorneys are in your firm?  
What is your primary area of practice?

REGISTRATION FEE

Registration fee includes seminar attendance, networking events, course materials, and access to the DRI App. DRI will email a link to download the course materials to all registrants two weeks in advance of the seminar. You can order additional copies of the course materials on CD-ROM by checking the appropriate box below or going online at dri.org.

<table>
<thead>
<tr>
<th></th>
<th>On or before Apr. 21, 2016</th>
<th>After Apr. 21, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Member</td>
<td>$935</td>
<td>$1,035</td>
</tr>
<tr>
<td>Nonmember</td>
<td>$1,165</td>
<td>$1,265</td>
</tr>
<tr>
<td>Government Member</td>
<td>$600</td>
<td></td>
</tr>
<tr>
<td>Law Student Member</td>
<td>FREE</td>
<td></td>
</tr>
<tr>
<td>In-House Counsel Member*</td>
<td>FREE</td>
<td></td>
</tr>
<tr>
<td>Claims Executive Member*</td>
<td>FREE</td>
<td></td>
</tr>
<tr>
<td>Group Discount*</td>
<td>$855 (*as defined on page 5)</td>
<td></td>
</tr>
<tr>
<td>Diversity Luncheon</td>
<td>$40</td>
<td></td>
</tr>
<tr>
<td>Community Service Project**</td>
<td>FREE</td>
<td></td>
</tr>
</tbody>
</table>

For inclusion on the prerogistration list and to receive course materials in advance, register by April 28, 2016.

ADDITIONAL COURSE MATERIALS

☐ Member  $75  ☐ Nonmember  $95  (Illinois residents, please add 9.25% sales tax. Shipping charges for U.S. and Canada only: $6.50)

PAYMENT METHOD

☐ My check for _________ (USD) is enclosed.

☐ Please charge my ☐ VISA  ☐ MasterCard  ☐ American Express.

Card # _______ Exp. Date _______

Signature __________________________

Please remit payment by **MAIL to:**
DRI
72225 Eagle Way, Chicago, IL 60678-7252
PHONE: 312.795.1101  |  FAX: 312.795.0749  |  EMAIL: seminars@dri.org  |  WEB: dri.org
DRI Membership
+ Committee Participation
= DRI Communities

The center of all substantive activity.

- Connect through the discussion list
- Learn through blog posts
- Stay current through the community calendar
- Share resources in the community library
- Network using the member directory
- Learn about volunteer opportunities

Log on now at http://community.dri.org/home