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Drug and Medical Device

20/20 Insights for Defense of Pharmaceutical and Medical Device Litigation

- Win your case with genomics
- Look to the future with clear vision: modernization of the 510k process
- Hear emerging views on diversity and inclusion from your clients, judges, and law firms
- Collaborate with colleagues to improve MDL and mass tort proceedings
- Hone your expert witness skills through a demonstration by cutting-edge litigators

May 6–8, 2020

Boston Marriott Copley Place

Boston, MA

Join us in historic Boston for the 2020 Drug and Medical Device Seminar! The 20/20 seminar will provide countless opportunities to network with clients, potential clients, colleagues, and friends in the pharmaceutical and medical device industry. You will also hear from a panel of judges about their approaches to key MDL and mass tort litigation issues, and you won't want to miss presentations about data analytics, emerging technologies in patient care, and ethical challenges with social media. This seminar continues to be the "go-to" event year after year for in-house and outside counsel to the pharmaceutical and medical device industry. Register today!

Erik W. **Snapp**
Program Chair

Gail **Rodgers**
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Jennifer Snyder **Heis**
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Sheila S. **Boston**
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Ted J. **McDonald** III
Law Institute

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

THIS SEMINAR BROCHURE IS SPONSORED BY NELSON MULLINS

Register online now at **dri.org** or **complete the form** in the back.

What You Will Learn

- Judicial perspectives on MDL and mass tort litigation
- The impact of technology on patient care, and its effects on product liability defense
- How to avoid ethical landmines when dealing with social media
- How data analytics change the practice of law

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- Access to LegalPoint™ at **dri.org**: Committee newsletters, seminar course materials, and other publications.
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PROGRAM SCHEDULE

Click on any speaker name to view bio.

WEDNESDAY, MAY 6

2:00 p.m. **Registration** for In-House Breakout Session attendees

IN-HOUSE BREAKOUT

2:30–5:30 p.m.

(Seminar registration required; attendance strictly limited to pharmaceutical/medical device company in-house counsel. No CLE available for this session.)

Join your in-house peers for a unique opportunity to discuss topics of importance to in-house counsel. Exchange ideas while networking with colleagues in a forum designed for in-house counsel by in-house counsel. For more information, email Gail Rodgers at **gail.rodgers@dlapiper.com**.

5:00 p.m. **Registration**

5:30 p.m. **First-Time Attendees Reception**
SPONSORED BY **Borden Ladner Gervais LLP**

6:00 p.m. **Networking Reception**
SPONSORED BY **Dechert LLP**
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7:30 p.m. **Dine-Arounds** | Join colleagues and friends at selected restaurants for dinner, including a dinner cruise as an option. Electronic sign-up information will be sent in advance of the seminar.

THURSDAY, MAY 7

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DRI for Life Activity

6:30 a.m. | Contact Shannon Beamer at **sebeamer@venable.com** for information.

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

7:00 a.m. **Continental Breakfast**
SPONSORED BY **Arnold & Porter Kaye Scholer LLP**
Nilan Johnson Lewis PA
Reed Smith LLP
Sidley Austin LLP

8:15 a.m. **Welcome and Introductions**
Ted J. McDonald III, *McDonald Veon PA*, Overland Park, KS
Gail Rodgers, *DLA Piper LLP (US)*, New York, NY
Erik W. Snapp, *Dechert LLP*, Chicago, IL

8:20 a.m. **Hot Topics**
Learn about the latest issues, cases, and trends in drug and device litigation.
Bradley A. Matta, *Mylan Inc.*, Cannonsburg, PA
Michelle A. Ramirez, *Sidley Austin LLP*, Chicago, IL

9:20 a.m. **Genetics and Genomics:** New Answers in Drug and Medical Device Litigation
The Human Genome Project laid the foundation for new discoveries and technologies previously unknown. As genetics and genomics continue to evolve, new and better answers to scientific questions will affect drug and device litigation. Learn how genetics and genomics will change our approach to liability and causation.
E. Paige Sensenbrenner, *Adams and Reese LLP*, New Orleans, LA
Leonel M. (Len) van Zyl, PhD, *ArrayXpress Inc.*, Raleigh-Durham, NC

> *"The content is always quite good. But where DRI excels is creating networking opportunities and events beyond the conference."*

10:10 a.m. **Refreshment Break**
SPONSORED BY **Norton Rose Fulbright US LLP**

10:25 a.m. **TED-Style Talk:** Diversity and Inclusion in the Legal Profession
Sheila S. Boston, *Arnold & Porter Kaye Scholer LLP*, New York, NY
SPONSORED BY **DLA Piper LLP (US)**

10:45 a.m. **An Expert Take on Expert Witnesses**
Witness top trial lawyers conduct live cross-examination of an experienced expert. This panel will focus on the skills necessary to successfully depose your opponent's expert witnesses. It will tie in recent decisions regarding *Daubert*/state equivalent, and will demonstrate techniques to combat plaintiffs' reptile theory tactics.

Hope S. Freiwald, *Dechert LLP*, Philadelphia, PA

Stephen J. McConnell, *Reed Smith LLP*, Philadelphia, PA

◆› **Kevin L. Ong, PhD, PE**, *Exponent*, Philadelphia, PA

12:00 p.m. **Lunch-Arounds** | Join colleagues and friends at selected restaurants for lunch (*on your own*). Sign-up information will be sent in advance of the seminar.

2:00 p.m. **Young Lawyers Blockbuster** (see page 4)

2:00 p.m. **FDA 510(k) Modernization:** Oxymoron or Reality?
The FDA recently announced plans to "modernize" the regulatory clearance pathway for 510(k) medical devices. This presentation will address the current 510(k) process, criticism of the process, the FDA's proposed changes to the process, and the effect of the changes on defending medical device product liability claims.

➤ **Martin Gomez**, *Dexcom Inc.*, San Diego, CA

W. Kennedy Simpson, *Thompson Miller & Simpson PLC*, Louisville, KY

3:00 p.m. **TED-Style Talk:** Diversity and Inclusion in the Legal Profession
The Honorable Jane Triche Milazzo, *US District Court, Eastern District of Louisiana*, New Orleans, LA

3:20 p.m. **Refreshment Break**
SPONSORED BY **Venable LLP**

3:40 p.m. **Beyond the Doctor's Office:** When Technology Expands the Reach of Patient Care
This panel will discuss the effect of cutting-edge technology on patient care and its legal implications, including challenges and opportunities presented by patient-directed apps and tools, FDA guidance on mobile medical apps and their failure, and the effect of telehealth on product liability concepts.

➤ **Michele S. Adeleye**, *Pfizer Inc.*, New York, NY

Mahnu V. Davar, *Arnold & Porter Kaye Scholer LLP*, Washington, DC

Tamar B. Kelber, *Gass Weber Mullins*, Milwaukee, WI

4:40 p.m. **Adjourn**

4:45 p.m. **DRI Drug and Medical Device Committee Meeting** (*open to all*)

5:15 p.m. **Meetings of DRI Specialized Litigation Groups (SLGs)** (*open to all*):
- Class Action/Multi-Party Litigation
- Complex Medicine/Experts
- Defense of Government Actions

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

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◆› Denotes expert

"This was my first attendance at this event in a new practice area for me. Both the education and networking were great."

YOUNG LAWYERS BLOCKBUSTER

THURSDAY, MAY 7 2:00 p.m.–4:50 p.m.

2:00 p.m. **Opening Remarks and Introductions**

Jennifer A. Eppensteiner, *Reed Smith LLP*, Princeton, NJ

Anne A. Gruner, *Duane Morris LLP*, Philadelphia, PA

2:10 p.m. **510(k) Versus PMA:** Regulatory Distinctions with a Difference

Understanding the differences between 510(k) and PMA regulatory pathways is critical to defending medical device cases. Learn whether Comment k, preemption, and punitive damages statutes may be available to defend your cases based on the regulatory clearances involved, and how regulatory experts can shape strategies.

Ryan J. O'Neil, *Campbell Conroy & O'Neil PC*, Berwyn, PA

Jae Yeon Kim, *DLA Piper LLP (US)*, Philadelphia, PA

2:30 p.m. **Learn from the Experts!** How to Leverage Scientific Experts to Develop Case Strategies

Learn how associates can add value by working with experts at both the initial investigation and later report/testimony stages to develop case themes and rebut product defect theories. The presenters will provide insight from both the associate's and expert's perspective on key scientific expert success strategies.

Harry M. Byrne, *Duane Morris LLP*, Philadelphia, PA

Angela Cai, *Wilkinson Walsh LLP*, New York, NY

Richard Underwood, PhD, *Exponent*, Philadelphia, PA

2:50 p.m. **Looking Ahead:** Obtaining Optimal Deposition Testimony for Pretrial Motions Briefing and Beyond

Set yourself up for success at the summary judgment stage with practical tips on developing your dispositive arguments early through thoughtful depositions. The presenters will address commonly briefed issues, analyzing testimony that attorneys should seek to elicit for a winning motion.

Devin J. Griffin, *Reed Smith LLP*, Princeton, NJ

Sarah A. Westby, *Shipman & Goodwin LLP*, Hartford, CT

3:10 p.m. **Autonomous Robotic Surgery:** Liability for Medical Device Manufacturers

Autonomous surgical robots challenge traditional legal rubrics that have been central to product liability defense. Evolving legal issues include the potential effect on the learned intermediary doctrine; responsibilities and liabilities of co-manufacturers; and how to determine the "product" for purposes of a strict liability action.

Melanie Woodward, *Nutter McClennon & Fish LLP*, Boston, MA

3:30 p.m. **Refreshment Break**

SPONSORED BY **Venable LLP**

3:40 p.m. **Invaluable:** Client Service from an In-House Perspective

- **Jonathan Amar**, *Sanofi-Aventis US*, Princeton Junction, NJ
- **Adam C. Bassing**, *UCB Inc.*, Atlanta, GA
- **Sandra M. Di Iorio**, *Endo Pharmaceuticals Inc.*, Malvern, PA
- **Elizabeth M. Mitchell**, *Smith & Nephew Inc.*, Andover, MA
- **Munjot Sahu**, *Eli Lilly and Company*, Indianapolis, IN

4:40 p.m. **Adjourn**

"Excellent opportunity to learn about trends in the field and meet other attorneys. Very valuable experience for young lawyers."

7:00 p.m. **Dine-Arounds** | Join colleagues and friends at selected restaurants for dinner. Sign-up information will be sent in advance of the seminar.

FRIDAY, MAY 8

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7:30 a.m. **Registration**

7:30 a.m. **Continental Breakfast**
SPONSORED BY **Arnold & Porter Kaye Scholer LLP**
Baker Donelson Bearman Caldwell & Berkowitz PC
Bennett Jones LLP
Reed Smith LLP

8:15 a.m. **Opening Remarks and Introductions**
Sheila S. Boston, *Arnold & Porter Kaye Scholer LLP*, New York, NY
Jennifer Snyder Heis, *Ulmer & Berne LLP*, Cincinnati, OH

8:20 a.m. **Data Analytics:** Transforming the Way Law Firms and Corporate Legal Departments Handle Litigation

Litigants now have the ability to use data analytics to tailor arguments and strategies to particular courts and judges and use detailed financial analytics to evaluate the costs of potential strategies. This panel will explore this transformation and what it means for law firms and legal departments.

Eric M. Falkenberry, *DLA Piper LLP (US)*, New York, NY
Daniel W. Linna, Jr., *Northwestern University Pritzker School of Law*, Chicago, IL
Connie A. Matteo, *Pfizer Inc.*, Peapack, NJ

9:20 a.m. **The Ever-Changing MDL:** Judges' Perspectives

As MDL cases increasingly fill federal court dockets, judges and defense counsel continue to adapt their practices. Hear federal judges discuss how they manage MDLs, what they expect from lawyers appearing before them, and where they see room for improvement in MDL practice.

MODERATOR | **Jaime L. Dodge**, *Emory University School of Law*, Atlanta, GA
The Honorable Karen K. Caldwell, *US District Court, Eastern District of Kentucky*, Frankfort, KY
The Honorable Jane Triche Milazzo, *US District Court, Eastern District of Louisiana*, New Orleans, LA

10:20 a.m. **TED-Style Talk:** Diversity and Inclusion in the Legal Profession
Desiree Ralls-Morrison, *Boston Scientific Corporation*, Boston, MA

10:40 a.m. **Refreshment Break**
SPONSORED BY **Butler Snow LLP**
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- *For The Defense*
- *In-House Defense Quarterly*
- Committee Newsletters
- Defense Library Series (DLS)
- Seminar Materials
- DRI Defense Wins Reporter

Go to dri.org and click on Legal Resources.

11:00 a.m. **Mass Torts Gone Wild:** Taming the Beast

As mass torts become more massive, the drum beat to examine our MDL system grows louder. This interactive panel will bring ideas to help defense counsel become thought leaders and save clients time and money as MDL rules are discussed.

MODERATOR | **Mary Terese Novacheck**, *Bowman & Brooke LLP*, Minneapolis, MN

- **A. Elizabeth Balakhani**, *GlaxoSmithKline*, Philadelphia, PA
- **Christopher P. Gramling**, *Eli Lilly and Co.*, Indianapolis, IN

Mary Massaron, *Plunkett Cooney PC*, Bloomfield Hills, MI

12:00 p.m. **Ethically Walking the Social Media Tightrope**

This panel will address the current social media environment and how defense counsel's ethical obligations intersect with our own social media use and that of our clients, our firms, and our opposing counsel, particularly as they apply to drug and medical device defense counsel.

John Browning, *Spencer Fane LLP*, Plano, TX

- **Larissa A. Eustice**, *Bayer Corporation*, Whippany, NJ
- **Allison Oliver**, *Smith & Carson Investigations*, Austin, TX

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

Community Service Project: St. Francis House 2:00 p.m.

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In the heart of downtown Boston, St. Francis House (not religiously affiliated) is the largest day shelter in Massachusetts and supports as many as 600 people daily. Its "Fresh Threads" program provides not only everyday clothing, but also professional attire for people getting back on their feet. Please join us at St. Francis House to help sort Fresh Threads donations. Please also bring new or gently used clothing to the collection bins at the seminar for donation to Fresh Threads. Please contact David Walz at **dwalz@carltonfields.com** for more information

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"I've gone to this seminar almost every year for the past 20+ years. It provides excellent networking opportunities as many of my clients and national counsel firms attend annually."

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, or its subsidiaries. To qualify for free registration, in-house counsel must be a DRI member and a member of the DRI Corporate Counsel Committee *or* be sponsored by a DRI member who is both registered and has paid for the seminar. **Nonmember in-house counsel may utilize this offer only once. This offer excludes the DRI Annual Meeting and the DRI Business Management Principles for Lawyers Seminar.**

Claims Executives

Claims professionals are eligible for free registration to DRI seminars. Claims professionals are defined as any individuals employed by a corporation or insurance company, who spend a substantial portion of their professional time hiring or supervising outside counsel in the representation of businesses, insurance companies or their insureds, associations, or governmental entities in civil litigation. To qualify for free registration, the claims professional must be a DRI member under a corporate membership *or* be sponsored by a DRI member who is both registered and has paid for the seminar. **Nonmember claims professionals may utilize this offer once per calendar year. This offer excludes the DRI Annual Meeting.**

CLE Accreditation

This seminar has been approved for MCLE credit by the State Bar of California for up to **10** 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. 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 6, 2020. (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 13, 2020** (*please allow 10 days for processing*). Registrations received after **April 13, 2020**, will be processed onsite.

Refund Policy

The registration fee is fully refundable for cancellations received on or before **April 13, 2020**. Cancellations received after **April 13** and on or before **April 20, 2020** will receive a refund, less a $100 processing fee. Cancellations made after **April 20** 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 6, 2020**. After **April 6**, 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 **Boston Marriott Copley Place, 110 Huntington Avenue, Boston, MA 02116** (**click here** to view hotel photos).

Take advantage of the group rate of **$319 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" button.

2) Or **contact the hotel directly at 617.236.5800** 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 6, 2020**, to be eligible for the group rate. Requests for reservations made after **April 6** are subject to room and rate availability.

FACULTY *Click on any name to view bio.*

Michele S. Adeleye, Pfizer Inc., New York, NY

Jonathan Amar, Sanofi-Aventis US, Princeton Junction, NJ

A. Elizabeth Balakhani, GlaxoSmithKline, Philadelphia, PA

Adam C. Bassing, UCB Inc., Atlanta, GA

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The Honorable Karen K. Caldwell, US District Court, Eastern District of Kentucky, Frankfort, KY

Mahnu V. Davar, Arnold & Porter Kaye Scholer LLP, Washington, DC

Sandra M. Di Iorio, Endo Pharmaceuticals Inc., Malvern, PA

Jaime L. Dodge, Emory University School of Law, Atlanta, GA

Jennifer A. Eppensteiner, Reed Smith LLP, Princeton, NJ

Larissa A. Eustice, Bayer Corporation, Whippany, NJ

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Jae Yeon Kim, DLA Piper LLP (US), Philadelphia, PA

Daniel W. Linna, Jr., Northwestern University Pritzker School of Law, Chicago, IL

Mary Massaron, Plunkett Cooney PC, Bloomfield Hills, MI

Bradley A. Matta, Mylan Inc., Cannonsburg, PA

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Stephen J. McConnell, Reed Smith LLP, Philadelphia, PA

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The Honorable Jane Triche Milazzo, US District Court, Eastern District of Louisiana, New Orleans, LA

Elizabeth M. Mitchell, Smith & Nephew Inc., Andover, MA

Mary Terese Novacheck, Bowman & Brooke LLP, Minneapolis, MN

Allison Oliver, Smith & Carson Investigations, Austin, TX

Ryan J. O'Neil, Campbell Conroy & O'Neil PC, Berwyn, PA

Kevin L. Ong, PhD, PE, Exponent, Philadelphia, PA

Desiree Ralls-Morrison, Boston Scientific Corporation, Boston, MA

Michelle A. Ramirez, Sidley Austin LLP, Chicago, IL

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

Munjot Sahu, Eli Lilly and Company, Indianapolis, IN

E. Paige Sensenbrenner, Adams and Reese LLP, New Orleans, LA

W. Kennedy Simpson, Thompson Miller & Simpson PLC, Louisville, KY

Erik W. Snapp, Dechert LLP, Chicago, IL

Richard Underwood, PhD, Exponent, Philadelphia, PA

Leonel M. (Len) van Zyl, PhD, ArrayXpress Inc., Raleigh-Durham, NC

Sarah A. Westby, Shipman & Goodwin LLP, Hartford, CT

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April 29–May 1
Life, Health, Disability and ERISA
Sheraton New Orleans, New Orleans, LA

May 6
Cannabis Law
Boston Marriott Copley, Boston, MA

May 14–15
Intellectual Property Litigation
Minneapolis Marriott City Center, Minneapolis, MN

June 11–12
Diversity for Success
Westin Michigan Avenue, Chicago, IL

June 25–26
Young Lawyers
InterContinental Buckhead, Atlanta, GA

September 10–11
Nursing Home/ALF Litigation
Omni Nashville Hotel, Nashville, TN

November 19–20
Asbestos Medicine
Manchester Grand Hyatt, San Diego, CA

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Sheraton New York, New York, NY

December 3–4
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The DRI Drug and Medical Device Committee is the preeminent organization for attorneys who represent the manufacturers of pharmaceuticals, medical devices, biologics, and other products created to provide health benefits to consumers. There are a number of opportunities to become involved for new practitioners and seasoned attorneys, alike—whether they are in a firm, in-house, or in risk management.

- Learn more about the committee and its leadership: **https://www.dri.org/committees/committee-detail/0070**
- Access the **DRI Drug and Medical Device Committee Community** at **http://community.dri.org/home**: Share articles, post blogs, and connect with others on the latest trends in your area of practice.
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  - Publications
  - Young Lawyers
- Publications
  - Newsletter: *Rx For The Defense* (3 times a year)
  - *For The Defense* committee-anchored issues (September)
  - *In-House Defense Quarterly*
  - Defense Library Series
    - *FDA Basics for the Drug and Medical Device Lawyer* (2015)
    - *Science Basics for the Drug and Medical Device Lawyer* (forthcoming)
    - *International Comparative Legal Guide to Drug & Medical Device Litigation* (*contributor*)

dri™ Committed to Diversity

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.

Harassment and Discrimination

DRI is committed to the policy of equal opportunity regardless of race, color, religion, sex, sexual orientation, gender, national origin and disability in all of its programs and activities, as well as maintaining an environment in our programs and activities which is free from all forms of harassment or discrimination of any kind. Pursuant to this policy, if any person who attends our programs or activities experiences unlawful discrimination or harassment, this should be reported to the Executive Director so that appropriate action may be taken.

Drug and Medical Device Seminar

May 6–8, 2020
Boston Marriott Copley Place | Boston, MA

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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? _____

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Registration fee includes seminar attendance, networking receptions, 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. Only members of DRI will have access to the PowerPoint presentations after the seminar.

	On or before Apr. 6, 2020	After Apr. 6, 2020
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