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The 21st Century Cures Act and Real World Evidence: What the Trial Lawyer Needs to Know

Wednesday, November 13, 2019
12:00 - 1:00 p.m. CST

Dear IADC Member:

Please join us for a complimentary Webinar (Web-based seminar produced through Adobe Connect) sponsored by the IADC Drug, Device and Biotechnology Committee, Medical Defense and Health Law Committee, and Product Liability Committee on Wednesday, November 13, 2019 for (1) hour beginning at:

10:00 AM PST / 11:00 AM MST / 12:00 PM Noon CST / 1:00 PM EST.

HOW TO REGISTER:

ONLINE REGISTRATION! Although there is no fee to attend, you must register so that the IADC can plan accordingly for the number of interested participants. Click here to register online. You must be logged in with your IADC username and password in order to register. If you are registering multiple participants from the same firm, please register each participant individually.

We hope that you will join us for this exciting and informative program. If you have any questions, please contact **Melisa Maisel Vanis, Director of Professional Development**, at mmaisel@iadclaw.org or by telephone at 312.368.1494.

THE PRESENTATION:

The 21st Century Cures Act and Real World Evidence: What the Trial Lawyer Needs to Know

The 21st Century Cures Act (Cures Act) was designed to accelerate the discovery, development, and delivery of new medical products. One key feature of the Cures Act is that patients' perspectives are to be further incorporated in the FDA's decision-making process. The Cures Act also includes a framework for evaluating the use of real world evidence and data to support the FDA's regulatory decisions. The Cures Act was widely supported by the pharmaceutical and medical device industry and could bring great benefit to patients and to the advancement of medical products. At the same time, the acceleration in approval of medical products, the use of patients' perspectives in the approval process, and the use of non-clinical trial data in regulatory decision-making will bring some of plaintiffs' favorite trial themes to the forefront. Join us for a discussion on what this might mean for trial strategy and how to effectively address these themes at trial.

THE PRESENTERS:

Claudia V. Garcia (claudia.garcia@dbr.com)
Drinker Biddle & Reath LLP, San Francisco, CA

Claudia V. Garcia represents major pharmaceutical and medical device companies in products liability cases involving prescription and over-the-counter medications, medical devices and consumer products. She has experience handling cases at the state and federal court levels, including multidistrict litigation and state coordinated proceedings.

Sean Kennedy (sean.kennedy1@bms.com)
Bristol Myers Squibb, New York, NY

Sean Kennedy is a Counsel in the U.S. Commercial Law & Compliance Department at Bristol-Myers Squibb. Sean provides legal, regulatory, and compliance advice for promotional material, scientific exchange, commercial strategy, business planning, and corporate giving pieces related to Bristol-Myer's oncology portfolio. Sean was previously an associate at Drinker Biddle & Reath LLP where he defended pharmaceutical and medical device companies in large mast tort litigations. Sean clerked for the Honorable Angela White Dalton, J.S.C., and was a senior intern for the Honorable Michael A. Shipp, D.N.J. Sean graduated from the Seton Hall University School of Law where he was a proud member of the school's nationally ranked Interscholastic Moot Court Competition team.

Chanda A. Miller (chanda.miller@dbr.com)
Drinker Biddle & Reath LLP, Philadelphia, PA

Chanda A. Miller handles complex commercial litigation, including products liability, antitrust, and appellate litigation. Chanda defends major pharmaceutical and medical device companies in multidistrict litigation, coordinated state proceedings, and individual cases involving claims of personal injury, price-fixing claims, alleged false claims act violations, and consumer protection claims. Her appellate experience includes work on successful appeals in state and federal courts across the country.

Michael C. Zogby (michael.zogby@dbr.com)
Drinker Biddle & Reath LLP, Florham Park, NJ

Michael C. Zogby is co-chair of the Products Liability & Mass Tort department at Drinker Biddle, and he is co-chair of the firm's Pharma and Life Sciences Industry Group. His products liability trial practice includes the defense of major pharmaceutical and medical device companies in products liability, negligence, failure to warn, strict liability design and manufacturing defect, and wrongful death actions that involve prescription medications and orthopaedic implants before state and federal courts and in mass tort, class action, and multidistrict proceedings. He has been appointed liaison counsel, discovery counsel, and trial counsel in pharmaceutical, medical device, and mass tort litigations throughout the United States. Mike's commercial litigation trial and appellate experience includes representing pharmaceutical companies in patent infringement, Robinson-Patman Act, false marking, intellectual property, and antitrust actions, as well as defending large law and accounting firms in professional liability actions, defending hospitals and health care organizations in tortious interference, unfair competition, civil conspiracy, and ERISA matters, and representing a variety of other corporate clients in commercial, employment, insurance coverage and real estate litigation matters. Mike has significant experience coordinating cross-border discovery and data collections involving Asian and European companies in United States mass tort litigations.

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