Current Issues in Pharmaceutical and Medical Device Litigation

Thursday, October 9, 2014
Norton Rose Fulbright
Austin, TX

Sponsored by the ABA Section of Litigation
Products Liability Committee
Medical Device and Pharmaceutical Subcommittees
### CURRENT ISSUES IN PHARMACEUTICAL AND MEDICAL DEVICE LITIGATION

**Thursday, October 9, 2014**  
Norton Rose Fulbright  
98 San Jacinto Blvd., Ste. 1100  
Austin, Texas 78701-4255

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 – 8:45 a.m.</td>
<td>Registration/Continental Breakfast</td>
</tr>
<tr>
<td>8:45 – 9:00 a.m.</td>
<td>Welcome &amp; Introduction</td>
</tr>
</tbody>
</table>
| **Program Co-Chairs:** | Tamar B. Kelber  
                   Sidley Austin LLP, Chicago, IL  
                   Caroline Tinsley  
                   Baker Sterchi Cowden & Rice, LLC, St. Louis, MO |
| 9:00 – 10:10 a.m. | A Diabetes Primer: What Product Liability Trial Attorneys Need to Know |
| **Moderator:** | Karen Fox  
                   MRN, Lake Oswego, OR |
| **Panel:**     | Scott Elder  
                   Alston & Bird, Atlanta, GA  
                   Samuel Dagogo-Jack, M.D.  
                   University of Tennessee Health Science Center  
                   Memphis, TN  
                   Mike Cobo  
                   DecisionQuest, Torrance, CA |

Clinical experts will share information on the pathophysiology of diabetes. The newest approaches and treatments and their risks and benefits will be discussed. Recent clinical studies that shed light on current litigation will be discussed. An experienced trial attorney will share insights regarding cases involving diabetes, and a jury consultant will contribute thoughts on the best ways to educate juries on complex medical information.
Regulation of Molecular Diagnostics and Potential Litigation Issues

Moderator: Krista Cosner
Medivation, Inc., San Francisco, CA

Panel:
Wendy R. Sanhai, Ph.D., MBA
Exponent, Cary, NC

Debra Dunne
Shook Hardy & Bacon, Philadelphia, PA

Allyson Mullen
Hyman, Phelps & McNamara, P.C., Washington, D.C.

Melinda Griffith
CardioDX, Redwood City, CA

This panel will discuss the current bifurcated regulatory pathway for molecular diagnostic tests, including laboratory developed tests (LDTs), and the FDA’s new draft guidance documents intended to streamline the process into a risk-based approval process. These tests are changing the practice of medicine and are integral to advancing personalized medicine. The biotech revolution has caused a dramatic shift in the number and complexity of molecular diagnostics being offered over the last decade. After years of exercising enforcement discretion over LDTs, the FDA has announced its intent to exercise regulatory authority over all molecular diagnostics and to “simplify” the approval process into one similar to medical devices. Any litigator who represents medical device manufacturers will need to understand the complex regulatory history of these products in order to advise their clients on litigation risks, defend them in products liability cases or represent them in regulatory proceedings.

Break

Clinical Trial Issues

Moderator: E. Paige Sensenbrenner
Adams & Reese LLP, New Orleans, LA

Panel:
Cari Wint
Debevoise & Plimpton LLP, New York, NY

Izi Bruker, Ph.D., M.P.H.
Exponent, Natick, MA

James Mizgala
Sidley Austin LLP, Chicago, IL

In recent years, clinical trials have played an increasingly prominent role in litigation in the United States. As a result, to foster public trust and industry accountability, various enforcement agencies are paying closer attention to clinical trials. Such efforts include enhanced scrutiny of informed consent and reporting responsibilities. Counsel representing various pharmaceutical and medical device manufacturers must understand regulatory compliance and the impact this may have in litigation. Our panel of attorneys and experts will discuss best practices for complying with various regulations, including informed consent, and will also discuss current trends and best practices in clinical research to date.
### Navigating Through Potential Landmines While Managing Litigation Concerning Live Products

**Moderator:** Marcos Barbosa  
Baker Sterchi Cowden & Rice, LLC  
Kansas City, MO  

**Panel:**  
Stephen Huffaker  
Norton Rose Fulbright, Austin, TX  

David Brose  
Lengdon and Emison, N. Kansas City, MO  

Michael R. Klatt  
Gordon & Rees, Austin, TX  

Shayna Cook  
Goldman Ismail Tomaselli Brennan & Baum, LLP  
Chicago, IL

This panel is designed to address strategies to surmount new litigation challenges. Faced with ever-evolving tactics from plaintiff and defense bar, and amplified scrutiny by the public and government, there is no room for error. The panelists will discuss, among other things, (1) The Proposed Amendments to Rule 26 and whether they will Provide any Meaningful Relief; (2) What impact will the New FDA Off-Label Guidance have and whether they will Provide a Safe Harbor for manufacturers; and (3) How Will the FDA Guidance Address Generics?

### Litigating Product Liability Cases During and After a Recall

**Moderator:** Bonnie Lau  
Dentons, San Francisco, CA  

**Panel:**  
Tariq Naeem  
Tucker Ellis LLP, Cleveland, OH  

Rand Nolen  
Fleming Nolen & Jez LLP, Houston, TX  

Marilyn Jager  
Morris Polich & Purdy LLP, Los Angeles, CA  

Jane Bockus  
Cox Smith, San Antonio, TX

The manner in which a product recall is conducted is likely to have a significant impact on whether the recall will strengthen or hamper product liability litigation. This panel will discuss current and evolving legal trends in managing recalls in connection with litigation, including best practices for managing and defending recalls, carefully drafting and controlling internal and external communications, working with the FDA, remediation efforts, evidentiary and admissibility concerns in litigation, and strategies to defend the product after a recall has occurred.

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**Closing Remarks**

**Reception**
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The Pharmaceutical and Medical Device Subcommittees
of the Products Liability Committee of the ABA Section of Litigation

Program Co-Chairs:
Tamar B. Kelber, Sidley Austin LLP, Chicago, IL
Caroline M. Tinsley, Baker Sterchi Cowden & Rice, LLC, St. Louis, MO

Products Liability Pharmaceutical Subcommittee Chairs:
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Caroline M. Tinsley, Baker Sterchi Cowden & Rice, LLC, St. Louis, MO

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Lara E. White, Adams & Reese LLP, New Orleans, LA
GENERAL INFORMATION

Accommodations:

Discounted hotel rooms are available in Austin.

Please reference Norton Rose Fulbright to take advantage of the discounted rates.

The following hotels are located close to Norton Rose Fulbright:

- **Hyatt Place Downtown Austin** – 211 E. Third Street
  512.476.4440
- **Four Seasons Hotel Austin** – 98 San Jacinto Blvd.
  512.478.4500

Rooms and rates are available on a first-come, first-served basis and are subject to room and rate availability.
Registration:

Visit [http://www.americanbar.org/groups/litigation/events_cle.html](http://www.americanbar.org/groups/litigation/events_cle.html) to register online or return the Registration Form on the following page with your payment (checks only) to:

Katie Peternell  
American Bar Association  
321 N. Clark St  
Chicago, IL 60610

Requests for refunds must be made in writing and received no later than October 7th, in the ABA Section of Litigation office. Please email your request to Katie Peternell, at katie.peternell@americanbar.org. There will be a $10 administrative fee deducted from the refund. Cancellations received after October 7th will not be refunded; however, the Section will gladly accept substitutions for those unable to attend.

MCLE Credit:

The ABA directly applies for and ordinarily receives CLE credit for ABA programs in AK, AL, AR, AZ, CA, CO, DE, GA, GU, HI, IA, IL, IN, KS, KY, LA, MN, MS, MO, MT, NM, NV, NY, NC, ND, OH, OK, OR, PA, SC, TN, TX, UT, VT, VA, VI, WA, WI, and WV. These states sometimes do not approve a program for credit before the program occurs. This course is expected to qualify for 6.25 CLE credit hours in 60-minute states, and 7.5 credit hours in 50-minute states. This transitional program is approved for both newly admitted and experienced attorneys in NY. For more information about CLE accreditation in your state, visit [http://www.americanbar.org/cle/mandatory_cle.html](http://www.americanbar.org/cle/mandatory_cle.html) or contact Katie Peternell at katie.peternell@americanbar.org or 312.988.6714.

Attendance List:

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Name ____________________________________________
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City _____________________________________________ State ________________ Zip Code
Telephone ______________________________ Fax __________________________
E-mail ____________________________________________
ABA Member No. __________________________________

The information submitted on this registration form will be used only to create an attendance list for the Current Issues in Pharmaceuticals and Medical Device Litigation CLE Workshop.

Registration Information

$175.00 (Section of Litigation members and Government attorneys)
$235.00 (Non-Section members)

Pre-registration deadline is October 7, 2014.

Checks for attendance and course materials should be made payable to the AMERICAN BAR ASSOCIATION (Credit cards for on-line registration only).

☐ I will attend the meeting and my check for $ ______.00 is enclosed.
☐ I would like to join the Section of Litigation for $60.00 and attend the meeting for the section rate of $175.00.
☐ I am unable to attend the meeting, but please send the course materials to the above address, at a cost of $35.00, a check for which is enclosed.

A limited amount of scholarships are available for this program. For more information, please contact: Katie Peternell at (312) 988-6714.

Please send your Registration Form and check to: Katie Peternell
American Bar Association
321 N. Clark St.
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For additional information about the program, please contact:
Tamar B. Kelber 312-853-7770/tkelber@sidley.com
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