Current Issues in Pharmaceutical and Medical Device Litigation

Thursday, November 17, 2011
Hosted by GlaxoSmithKline
Philadelphia, PA

Sponsored by the Pharmaceuticals and Medical Device Subcommittees of the Products Liability Committee of the ABA Section of Litigation
Drug and device companies have been targeted by the government with fraud-based claims in recent years under the False Claims Act and/or state consumer protection statutes. These broad claims often address a company’s alleged off-label marketing, failure to disclose negative test results or adverse events, kickbacks to healthcare providers and/or poor manufacturing practices. Under federal law, the government’s triple threat of exclusion from federally funded programs such as Medicare, enhanced statutory damages and prolonged negative publicity force most companies to settle these claims for enormous sums based on untested legal theories. In many of the state cases, depending on the statute at issue, a low burden of proof exists because causation, reliance and/or injury need not be proven. Since damages are often sought on a per-claim or per-product basis, the potential recoveries are enormous with mass-marketed drugs and devices. Compounding the risk of parallel federal and state civil proceedings is the threat of crim-
inal proceedings based on the same conduct. This Panel consists of members of the judiciary, leading industry manufacturers and defense counsel involved in these claims who will share their insights on this trend in litigation against drug and device manufacturers. Their comments will assist with litigation strategies and help bolster corporate compliance programs to minimize the risk of such claims.

10:25 - 11:35 a.m.  International Issues that Arise in Litigation of Pharmaceutical and Medical Device Cases

Moderator:

Brian A. Troyer
Thompson Hine LLP
Cleveland, OH

Panel:

Caroline M. Tinsley, Baker Sterchi Cowden & Rice, St. Louis, MO
Mark Chalos, Lieff Cabraser Heimann & Bernstein, Nashville, TN
Hon. Dan Aaron Polster, United States District Judge, Cleveland, OH
Samuel L. Felker, Bass Berry & Sims, PLC, Nashville, TN

This panel will discuss international jurisdiction and discovery issues. Our discussion of jurisdiction will focus on the United State Supreme Court’s Nicastro and Goodyear Dunlop decisions and their likely impact in drug and medical device litigation involving multinational business organizations and foreign corporations. While courts and litigants have wrestled with determining the scope of in personam jurisdiction over foreign companies based on their products’ sales in the United States, the Supreme Court’s recent decisions provided some clarification of the Constitutional limits of such jurisdiction. Our discussion of discovery issues will address issues arising from efforts to obtain discovery crossing international boundaries, such as depositions of foreign personnel and discovery of foreign labeling, regulatory, scientific, and corporate documents. We will discuss types of information typically sought in drug and medical device litigation, why they are sought, legal principles applying to such discovery, and ways in which courts and parties have attempted to resolve disputes over such discovery.

11:35 - 11:50 a.m.  Break

11:50 - 1:00 p.m.  Representation of Sales Reps in Pharmaceutical and Medical Device Litigation

Moderator:

Daniel S. Wittenberg
Snell & Wilmer
Denver, CO
Panel:

Abigail M. Butler, Baker & Daniels, Ft. Wayne, IN
Denise Houghton, Synthes, Inc., West Chester, PA
Alex Alvarez, The Alvarez Law Firm, Coral Gables, FL
Brian Hirsch, Cephalon, Inc., Frazer, PA

This panel will discuss how sales representatives create potential liability for manufacturers, including with respect to dilution of warnings, over-promotion and off-label use. In addition, the panel will address issues raised by the presence of sales representatives in the operating room during surgery, including patient privacy concerns and the unauthorized practice of medicine. As a part of these discussions, the panel will also discuss current trends in case law and best practices for avoiding liability.

1:00 - 2:15 p.m.  Lunch

2:15 - 3:25 p.m.  Hot Topics and Recent Developments in Pharmaceutical and Medical Device Litigation

Moderator:

Michael Healy
Sedgwick LLP
San Francisco, CA

Panel:

James M. Beck, Dechert LLP, Philadelphia, PA
Donald Migliori, Motley Rice, Providence, RI
Howard Dorfman, Ferring Pharmaceuticals, Parsippany, NJ
Ann T. Greeley, Ph.D., Senior Director, DecisionQuest, State College, PA

Three years after the Supreme Court’s Riegel decision, manufacturers continue to face product liability claims. This panel, which includes in-house counsel with significant device experience and renowned product liability litigators, will discuss the hot-button issues surrounding the defense and prosecution of these types of claims and share their insights into achieving favorable results in an efficient and cost-effective manner. Particular topics of discussion will include: preemption after Riegel; managing MDL challenges while maneuvering to obtain desirable forums and favorable case results; best practices for evaluating the science and use of experts in cases involving complex scientific issues; handling claims relating to off-label use; and trends in jury research.

3:25 - 3:40 p.m.  Break
3:40 - 4:50 p.m.  The Art of Pleading in a Post-Twombly/Iqbal World: Parallel Claims and More

Moderator:

David Graham
Oppenheimer Wolff & Donnelly LLP
Minneapolis, MN

Panel:

James Herschlein, Kaye Scholer LLP, New York, NY
Richard Barnes, Goodell DeVries Leech & Dann, LLP, Baltimore, MD
Tara Sutton, Robins, Kaplan, Miller & Ciresi, LLP, Minneapolis, MN

This panel will explore pleading issues related to the interplay between the Twombly and Iqbal decisions and affirmative defenses, in particular preemption. Panelists will discuss parallel claims to defeat preemption asserting a violation of federal law and claims arguably not imposed by state law, such as breach of warranty, to determine how the concepts work together to defeat or sustain cases where preemption is a defense.

4:50 p.m.  Closing Remarks
5:00 p.m.  Reception at GlaxoSmithKline
Sponsored by

The Pharmaceuticals and Medical Device Subcommittees of the Products Liability Committee of the ABA Section of Litigation

Program Co-Chairs:

Stephanie M. Rippee  
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Jackson, MS

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D. Alan Rudlin  
Hunton & Williams LLP  
Richmond, VA
GENERAL INFORMATION

GlaxoSmithKline:

Please note that there are two different lobbies at GlaxoSmithKline’s Franklin Plaza location. The conference will be held in Conference Room 24-1. Please use the South Lobby entrance to the building to get to Conference Room 24-1.

Accommodations:

We recommend attendees stay at the Sheraton Philadelphia Downtown Hotel, 201 North 17th Street, Philadelphia, PA 19103, due to its close proximity to GlaxoSmithKline. There are, however, a number of other hotels within a few blocks of GlaxoSmithKline as well.

Driving Directions to the Sheraton:

From East

Take the New Jersey Turnpike to Exit 4.
Proceed on Highway 73 North to Highway 38 West.
Continue to Highway 30 West over the Benjamin Franklin Bridge.
After crossing the bridge, continue on Vine Street and turn left onto 17th Street.
The hotel is located 1 block further on the left.

From Interstate 95 South (North/South)

Take Interstate 95 South to Exit 22.
Proceed on Highway 676 West to the Broad Street Exit, this will take you to 15th Street.
Continue 0.5 blocks to Spring Street and turn right.
Proceed 1 block and turn right onto 16th Street
The hotel is 0.25 blocks further on the left.

From West

Take the Pennsylvania Turnpike to Exit 24.
Proceed on Highway 76 East to Exit 344 which is 676 East/Central Philadelphia Exit.
Continue to the Broad Street/Central Philadelphia Exit.
Turn right onto 15th Street and proceed one block to Spring Street and turn right.
Continue 1 block to 16th Street and turn right.
The hotel is located 0.25 blocks down on the left.

Additional Transportation Information:

Both the Sheraton and GlaxoSmithKline are approximately 1 mile from Philadelphia’s 30th Street Station, the main downtown Philadelphia train station and a major Amtrak stop. Philadelphia International Airport is located approximately 7 miles southwest of downtown Philadelphia. The ground transportation system at the airport offers an extensive network of taxi, car rental, shuttle-bus, limousine and van operations. In addition, SEPTA bus and regional rail service run from the airport to downtown Philadelphia on a continuous basis.
Registration:

Visit http://www.abanet.org/litigation/programs/programs_future.html to register online or return the Registration Form on the following page with your payment (checks only) to Stephanie M. Rippee, Watkins & Eager PLLC, The Emporium Building, 400 Capitol Street, Jackson, MS 39201.

Requests for refunds must be made in writing and received no later than November 4th, in the ABA Section of Litigation office. Please email your request to Matthew Thurman, at thurmanm@staff.abanet.org. There will be a $10 administrative fee deducted from the refund. Cancellations received after November 4th will not be refunded; however, the Section will gladly accept substitutions for those unable to attend.

MCLE Credit:

Accreditation has been requested for this program from every state with mandatory continuing legal education requirements for attorneys. Please be aware that each state has its own rules and regulations, including its definition of CLE as well as ‘Ethics’. Therefore, certain programs may not receive credit in some states. Please check with your state agency for confirmation of general as well as ethics approval for any program. You may contact Matthew Thurman at the ABA at matthew.thurman@americanbar.org for confirmation of the number of credits approved by any particular state.

Attendance List:

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**REGISTRATION FORM**

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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**

$140.00 (Section of Litigation members and Government attorneys)

$200.00 (Non-Section members)

**Pre-registration deadline is November 4, 2010.** 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.

Please send your Registration Form and check to: Stephanie M. Rippee, Watkins & Eager PLLC, The Emporium Building, 400 Capitol Street, Jackson, MS 39201

For additional information about the program, please contact:
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*For credit card payment, please visit [http://www.americanbar.org/groups/litigation/events_cle.html](http://www.americanbar.org/groups/litigation/events_cle.html)*