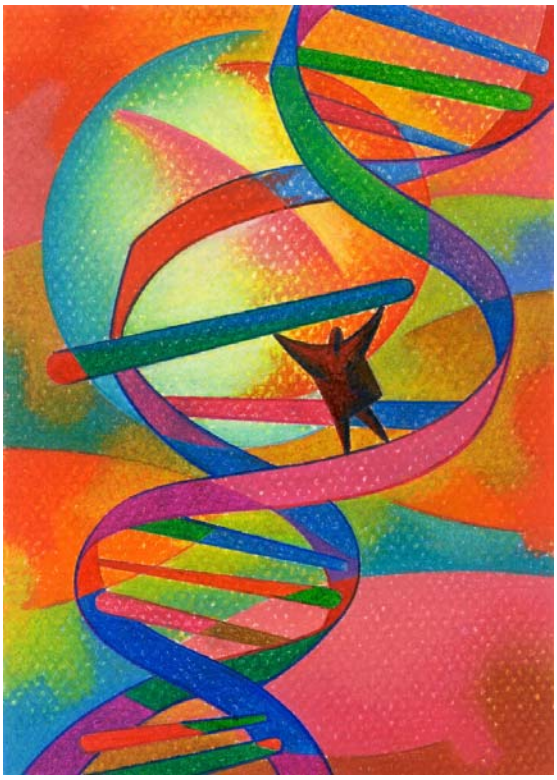
SECTION of LITIGATION

AMERICAN BAR ASSOCIATION

Third Annual

Biotech Institute and Regional CLE Workshop



Sponsored by the ABA Section Of Litigation Products Liability Committee
Subcommittee on Biotech

Wednesday, October 8, 2008
Human Genome Sciences, Inc.
14200 Shady Grove Road
Rockville, MD

Defending Liberty
Pursuing Justice

BIOTECH INSTITUTE AND REGIONAL CLE WORKSHOP

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Agenda and Topics:

8:00-8:45
Continental Breakfast

8:45-9:00
Welcome from Chairs

9:00-10:00
Compliance, FDAAA and Other Concerns

- Robert P. Brady, Partner, Hogan & Hartson
- Kirk Ogrosky, Deputy Chief, Fraud Section, Criminal Division, US Department of Justice
- James H. Davis, Ph.D., Executive Vice-President and General Counsel, Human Genome Sciences, Inc.

Compliance with laws and regulations is always of great concern for Biotechnology and Pharmaceutical companies. On November 28, 2005, the Office of Inspector General (OIG) issued a draft of guiding principles for a compliance program for Public Health Service grant award recipients for biomedical and behavioral research at 70 Fed. Reg. 71,312 (Nov. 28, 2005). These "Guidelines" were withdrawn based on a White House decision that the OIG's principals for research should be made applicable to all government grants and funded activities-not just health care research. Although the broad government-wide funded activity guidelines have not been issued to date, the broad guidance in the OIG's withdrawn draft guidelines is worth considering when creating or implementing a compliance program. Similarly, on September 27, 2007 President Bush signed into law H.R. 3580, the Food and Drug Administration Amendments Act of 2007 (FDAAA). FDAAA is the most comprehensive reform of prescription drug regulation in forty years. Panel members will discuss the FDAAA in the context of the Compliance Guidelines with suggestions for how to establish, implement and update compliance activity in your company.

10:00-11:15
Intellectual Property Case Law Update and Resulting Litigation Issues

- Harold Fox, Partner, Steptoe and Johnson
- Peter E. Strand, Partner, Shook, Hardy & Bacon, L.L.P.
- Michele Wales, VP, Intellectual Property, Human Genome Sciences, Inc.

Intellectual property is essential to the success of innovator biotechnology companies. For established companies, the market exclusivity offered by patent protection is a critical component to justify the tremendous investment in the research and development of products. For start-up companies, strong patents are essential to generate financing, and to advance research. Intellectual property laws and the US patent system are monitored closely by the biotechnology industry. This panel will present an overview of recent intellectual property case law developments and discuss the impact those decisions have on biotechnology.

11:15-11:30
Coffee Break

11:30-12:30
The FDA and Preemption

- Steve Scheve, Partner, Baker Botts
- Jeffrey Senger, Deputy General Counsel, FDA
- Perry Goldman, VP, Legal Affairs, Actelion

Levine v. Wyeth is set for oral argument before the United States Supreme Court on Monday, November 3, 2008. The critical question to be answered by the Court is whether a statute that is silent on its face can nonetheless implicitly preempt state common law claims in a prescription drug case. *Levine* was preceded at the Court this year by decisions in *Riegel v. Medtronic* and *Warner-Lambert Co. v. Kent.* In *Riegel*, the U.S. Supreme Court held that a federal statute governing regulation of medical devices expressly preempts, or displaces, state tort law claims when a device has received FDA pre-market approval. *Kent* was expected to resolve a federal circuit split on whether fraud-on-the-FDA-based exceptions in state tort reform states survived federal preemption. But, eleven days after its decision in *Riegel*, the Court, in a *per curiam* order in the *Kent* case, affirmed the Second Circuit's decision in a 4-4 split. Our panel that includes the Deputy Chief Counsel of the FDA and several experienced pharmaceutical and biotechnology practitioners who will discuss the three cited cases, FDA regulations that conceivably preempt state tort law claims and how to handle the issue in your cases.

12:30-1:30
Networking Lunch on site

1:45-3:00
The Value of Active Risk Evaluation and Mitigation Strategies for Products Liability Exposures: Could Enterprise Risk Management Processes Meet the New FDA Standards for Greater Product Scrutiny & Protocols?

- Laura Langone, Moderator, Marsh, San Francisco, SVP Life Sciences Practice and formerly Director of Risk Management at Genentech, Inc.
- John Marron, Risk Manager, CSL
- Michael Chagares, Partner, Oliver Wyman
- Paul Hinton, Vice President, NERA Economic Consulting

This panel discussion will highlight significant mass tort product liability litigation, insurance capacity erosion and the changes to FDA requirements for company compliance and oversight. Through an Enterprise Risk Management process, panelists will present processes companies like CSL are undertaking to understand their exposure and mitigate the impact of potential product liability litigation and continued FDA oversight and scrutiny required of life science companies. Panelists will discuss some passive and active approaches to meeting the heightened scrutiny.

3:00-3:15
Coffee Break

3:30-4:45
Negotiating an Effective Clinical Trial Agreement and Limiting Litigation Exposure

- Diane Lifton, Partner, Hughes Hubbard
- Frederick M. Frankhauser, J.D., R.Ph., Director, Clinical Research Contracting, Tufts Medical Center
- Teresia Bost, Counsel, Celgene Corp.
- Lee W. Farrow, SVP, ACE Medical Risk

Clinical Research is the lifeblood of the biotechnology industry, and clinical trial agreements dictate the terms and conditions among the sponsor, institution and investigator. The agreements must be entered into knowingly, effectively and efficiently. From publishing rights and intellectual property, to indemnification and insurance, many issues can lead to significant delays, or even an impasse in negotiating these agreements. This panel will draw from differing and diverse perspectives to discuss how clinical trial agreements can be negotiated, and what potential obstacles to be aware of.

5:00-6:30
Cocktail Reception on site

Sponsored by
The ABA Section of Litigation, Products Liability Committee,
Subcommittee on Biotech

Hosted by
Human Genome Sciences, Inc.

Program Steering Committee:

Harold J. Decker	Linda Chang	Lee W. Farrow
Miller, Canfield	Human Genome	ACE Medical Risk
Kalamazoo, MI	Rockville, MD	New York, NY

Products Liability Committee Chairs:

Daniel Wittenberg	Jerry Bradford
Snell & Wilmer	Alcon Laboratories
Denver, CO	Fort Worth, TX

Biotech Subcommittee Chairs:

Harold J. Decker	Lee W. Farrow
Miller, Canfield	ACE Medical Risk
Kalamazoo, MI	New York, NY

Travel and Hotel Information:

Attendees are responsible for making their own travel and hotel arrangements. A block of rooms has been reserved at the Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, Maryland 20878. The number is 301-590-0044 (fax is 301-212-6155) and to get the special rate of $179 (plus 13% tax), please mention the ABA Biotech Seminar.

Driving Directions to Human Genome Sciences:

Directions from Dulles:

Take the Dulles Access Road to I-495, follow Exit to I-495 north towards Rockville, Maryland. Continue on I-495 to I-270 north. From I-270 north, take Exit 8, Shady Grove Road and head West (left). Cross over Research Blvd., Key West Avenue, and Darnestown Road. The entrance is on the right side, shortly after you cross the light at Traville Gateway Drive. Take an immediate right for visitor parking.

Directions from Baltimore/BWI Airport:

Take 195 to I-95. Take I-95 south to I-495 west, Silver Spring. Follow I-495 west nine miles to I-270. Follow I-270 to Exit 8, Shady Grove Road and head West (left). Cross over Research Blvd., Key West Avenue, and Darnestown Road. The entrance is on the right side, shortly after you cross the light at Traville Gateway Drive. Take an immediate right for visitor parking.

Directions from Washington/National Airport:

Take the GW Parkway to I-495. Take I-495 towards Baltimore. Travel North 8 miles to Exit 38, I-270 North to Frederick. Follow I-270 to Exit 8, Shady Grove Road and head West (left). Cross over Research Blvd., Key West Avenue, and Darnestown Road. The entrance is on the right side, shortly after you cross the light at Traville Gateway Drive. Take an immediate right for visitor parking.

Directions from Frederick:

Take I-270 south to Exit 8, Shady Grove Road and head West (right). Cross over Research Blvd., Key West Avenue, and Darnestown Road. The entrance is on the right side, shortly after you cross the light at Traville Gateway Drive. Take an immediate right for visitor parking.

Directions from the Gaithersburg Marriott

Depart the Gaithersburg Marriott by going left. At the light make a left onto Fields Road. Continue on Fields Road until you reach Key West Avenue (this is the first intersection/light you reach), at Key West Avenue make a left. Continue on Key West Avenue until you reach Shady Grove Road (this will again be the first intersection you reach), at Shady Grove Road make a right and continue through three intersections. After the third light you will make your next available right turn. The blue glass building on your right is your destination.

After turning right you can proceed to your next available right, and then another immediate right off of the entrance circle. This leads to the visitor parking.

In the event that the visitor parking area is full return to the circle and access road and make a right. Continue down and enter the garage at your next available right. The exit from the garage is located on the right side of the garage on the first floor. Signs will direct you to the entrance.

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Registration Information

$100.00 (Section of Litigation members and Government attorneys)
$155.00 (Non-Section members)

Register online by visiting: http://www.abanet.org/litigation/programs/cle_100808.html
Or

Register by Mail by completing the below form and sending check payable to the American Bar Assoc., to:

Lee Farrow, ACE Medical Risk, 140 Broadway, 41st Floor, NY, NY 10005

Name _____

Affiliation _____

Address _____

City _____ State _____ Zip Code _____

Telephone _____ E-mail _____

ABA Member No_____

The information submitted on this registration form will be used only to create an attendance list for the Second Annual Biotech Institute & Regional CLE Workshop.

Registration deadline is October 3, 2008. Checks for attendance and course materials should be made payable to the American Bar Association (sorry-no credit cards unless registering online).

☐ I will attend the meeting and my check for $_____.00 is enclosed.
☐ 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.

For additional information about the program, please contact:
Lee W. Farrow, (646) 458-6969, lee.farrow@ace-ina.com

MCLE Credit

Required sponsor documentation has been forwarded to and credit requested from MCLE states with general requirements for all lawyers. Lawyers seeking credit in Pennsylvania must pay a fee of $1.50 per credit hour directly to the PA CLE Board. The ABA pays applicable fees in other states where the sponsor is required to do so. In states where a late fee may become applicable, the ABA pays this fee as well. 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 Esther Brewer at the ABA at (312) 988-5499 for confirmation of the number of credits approved by any particular state.