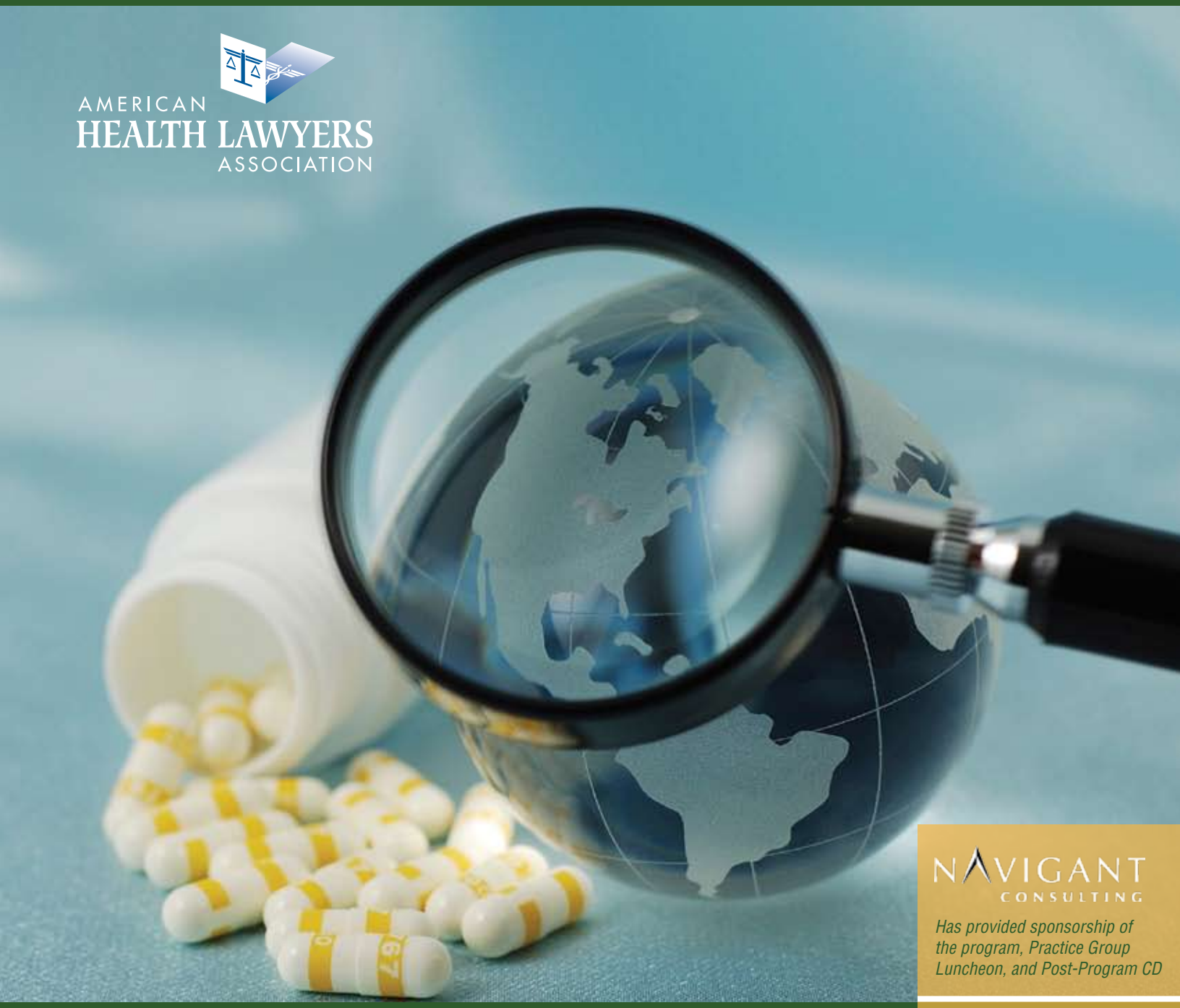
Life Sciences Law Institute

May 7–9, 2008 • Bethesda North Marriott Hotel & Convention Center • Bethesda, MD

AMERICAN HEALTH LAWYERS ASSOCIATION



NAVIGANT CONSULTING

Has provided sponsorship of the program, Practice Group Luncheon, and Post-Program CD

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Robert F. Leibenluft, Esq.
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Mary Riordan, Esq.
Lynn Shapiro Snyder, Esq.
Christopher L. White, Esq.

Program Supporters:

AdvaMed
Advanced Medical Technology As

Bio

Program Agenda

Wednesday, May 7, 2008

12:00 noon-5:00 pm
Registration and Information

CONCURRENT SESSIONS

1:00-2:30 pm Extended Sessions

A. Coverage, Reimbursement and Fraud and Abuse Basics for FDA (and New) Lawyers (not repeated)
Barry D. Alexander
Michael D. Bell

- Complexities of coverage for drugs and devices
- Coding systems for drugs and devices
- Implications of multiple payment mechanisms
- Fraud and abuse fundamentals

B. FDA Basics for Healthcare (and New) Lawyers (not repeated)
Virginia Behr
Suzanne M. O'Shea

2:45-3:45 pm

C. Patent Issues for Life Science Lawyers (not repeated)
Seth D. Levy
Hans Sauer

- The impact of patent law in drug and device regulation
- The Hatch-Waxman Act Pending biosimilars legislation and patent issues with follow-on biologics
- How clinical trials may amount to a "public use" in a manner that undermines patent rights
- Pending patent reform legislation

D. Compliance Issues in Operating Patient Assistance Programs
Michelle Fried
Andrew D. Ruskin

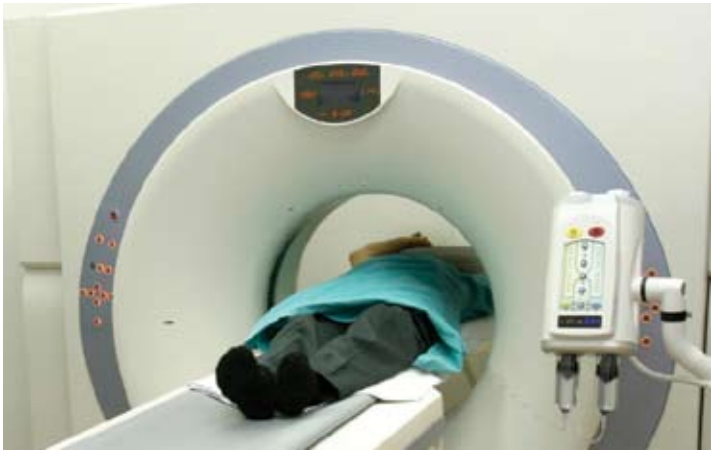
- Anti-Kickback Statute and the Beneficiary Inducement Statute
- OIG pronouncements on structuring patient assistance programs for drugs covered under Medicare Part D or Part B
- Recent regulatory changes to the Medicaid drug rebate program relating to patient assistance programs
- HIPAA rules regarding covered entities and their potential implications for patient assistance programs
- Hypotheticals that indicate how all these rules work in practice

4:00-5:00 pm

E. Stem Cell Policies – Ethics in Research (not repeated)
Story C. Landis

F. Fair Market Value in the Device and Pharma Industry: Is it Relevant?
Robert A. Wade

- Recent settlements involving fair market value in the device/pharma industry
- What is fair market value and how does it apply to the life sciences area?



- Relevant statutes involving fair market value
- Monitoring compensation arrangements with physician consultants to ensure compliance

Thursday, May 8, 2008

7:00 am-5:45 pm
Registration and Information

7:00-8:00 am
Continental Breakfast sponsored by Navigant Consulting
(attendees, speakers, children, registered spouses and guests welcome)

7:00-8:00 am
Life Sciences Affinity Group Networking Breakfast
(attendees and speakers are welcome)

GENERAL SESSION

8:00-8:15 am
Welcome and Introduction
Elizabeth Carder-Thompson, Program Chair
Joel M. Hamme, AHLA President-Elect

8:15-9:45 am
Trends in Federal Enforcement
Mark A. Grider
Mary E. Riordan
Eugene Thirolf

9:45-10:30 am
Clinical Trials: FDA and CMS Regulation
Sheldon Bradshaw
Kathleen H. McGuan
Barry M. Straube

- FDA and the 2007 legislation impact on clinical trials
  – FDAAA expanded the existing NIH clinical trial registry and created a clinical trials results databank

Program Agenda

  - Examination of the expanded registry databank and expanded registry submission content requirements
  - Review of the submission requirements under results databank, including timetables and deadlines
- Medicare and clinical trials — historical overview and current policy
- 2007 reopening of the Clinical Research NCD — CMS' intent
- Policy considerations — towards parallel FDA approval and CMS coverage tracks?
- The roles of FDA, CMS and NIH in future federal regulation of clinical trials

CONCURRENT SESSIONS

10:45 am-12:15 pm Extended Sessions

G. Pharma Datamining (not repeated)
John Kamp
Kevin Outterson
Daniel C. Walden

- State legislation regulating pharmaceutical marketing
- State legislation restricting datamining
- Proposed federal legislation
- Commercial speech
- Ignorance as health policy
- State and Federal proposals

H. Conflicts of Interest in Research Strategies for Managing Compliance and Liability Risks without Stifling Innovation
Bernadette M. Broccolo
Guy M. Chisolm
Haripriya Mannan

- Sources and nature of conflicts of interest in research sponsored or funded by life sciences companies, the applicable legal and regulatory framework and emerging industry standards and best practices
- Relative risks of the various participants in the life cycle of a clinical trial, including industry sponsors, investigators and research team members universities and provider sites

- Effective compliance program design and implementation strategies from the various participants' perspectives
- Prospects for coordination and cooperation that will appropriately and effectively manage and allocate conflict of interest risk and enhance rather than disrupt the research process

J. Trends in Corporate Integrity: Investigations and Obligations
Vickie L. McCormick
Heidi A. Sorensen

- Recent enforcement trends including deferred prosecution agreements, FCA settlements, OIG CMPL cases, and issues under the Foreign Corrupt Practices Act
- Lessons learned from the OIG's corporate integrity agreements, including understanding the OIG's expectations and goals
- Issues to consider in implementing and making operational a voluntary compliance program for a life sciences company
- Top do's and don'ts for companies contemplating an OIG CIA

K. Update on FDA Regulatory/Legislative Issues Impacting Drugs, Biologicals and Medical Devices
Sandra J.P. Dennis
Gerald Masoudi
Phoebe Mounts

- FDA Amendments Act (FDAAA)of 2007, follow-on biologics and 2008 legislative proposals
- Key provisions of FDAAA and impact on stakeholders
- Status of FDA's implementation of FDAAA and future initiatives

12:15-1:30 pm

Life Sciences Practice Group Luncheon sponsored by Navigant Consulting (all attendees and speakers welcome)

Personalized Healthcare: Opportunities and Challenges for a New Era in Science and Health
Sheila D. Walcoff, Esq.
Former Counselor to the HHS Secretary Michael O. Leavitt
Former Senior Advisor to U.S. Presidential Candidate Fred Thompson, Washington, DC

CONCURRENT SESSIONS

1:45-2:45 pm

L. Secondary Use of Electronic Health Information (not repeated)
Brent L. Henry
Kristen B. Rosati

- What are new developments in using EHRs and health information exchanges for post-marketing drug safety surveillance?
- How is electronic health information appropriately used to identify potential research participants and investigators?
- What are appropriate—and inappropriate—uses of electronic health information for commercial purposes?
- What are special concerns related to secondary uses of genetic information in the EHR?

Program Agenda

M. Medicaid Reimbursement
Seth H. Lundy

N. Global Compliance
Bernard J. Ford
Laura C. O'Donnell
- Building and sustaining a "burning platform" outside of the US
- Transforming the business model to reinforce ethical conduct
- Finding and nurturing new internal compliance advocates
- Identifying and conceptually addressing regulatory gaps/ overlaps (i.e. FCPA, Local Anti-Corruption laws, regional/local codes, hospital/third party approval processes)
- Developing global compliance infrastructure plan (i.e. systems, recruiting compliance talent, documentation, SOPs, COBC, hotline, etc.)

F. Fair Market Value in the Device and Pharma Industry: Is it Relevant? (repeat)

3:00-4:30 pm Extended Sessions

O. Legal Ethics and Professional Responsibility in Life Sciences: A Timely Update *(not repeated)*
Alan S. Goldberg
- Bar and other codes
- HIPAA Administrative Simplification, IRS Circular 230, USPTO Rules, Sarbanes-Oxley and more
- Clients and beyond: Engagement when and how, or not
- Competence without compromise
- Privilege, work product, confidentiality and criminal prosecutions
- Obligations to disclose versus clients and careers
- Time, bills and money: Avoiding headaches
- eDiscovery and technology: 12/01/06 and electronically stored information

H. Conflicts of Interest in Research Strategies for Managing Compliance and Liability Risks without Stifling Innovation (repeat)

J. Trends in Corporate Integrity: Investigations and Obligations (repeat)

K. Update on FDA Regulatory/ Legislative Issues Impacting Drugs, Biologicals and Medical Devices (repeat)

4:45-5:45 pm

P. Secondary Research – Opportunities and Strategies (not repeated)
Jennifer S. Geetter
- Strategic importance of tissue and data banking to providers and industry
- Regulatory landscape pertaining to research on secondary research materials
- Regulatory landscape pertaining to privacy on secondary research
- Attendant IP considerations

Q. Research Misconduct–Integrity in Research: What has been going on since 2005?
Susan J. Garfinkel
Holley Thames Lutz
- Scientific misconduct regulations - overview of key changes
- Key requirements and institutional obligations
- How have institutions/investigators/sites embraced these changes
- Practical tips on conducting inquiries/investigations
- Recent enforcement and settlement activity

D. Compliance Issues in Operating Patient Assistance Programs (repeat)

N. Global Compliance (repeat)

5:45-6:45 pm
Reception sponsored by Navigant Consulting
(attendees, speakers, children, registered spouses and guests welcome)

Friday, May 9, 2008

7:30 am-3:30 pm
Registration and Information

7:30-8:30 am
Breakfast sponsored by Navigant Consulting
(attendees, speakers, children, registered spouses and guests welcome)

GENERAL SESSION

8:30-9:45 am
State Law Enforcement Initiatives
John Guthrie
Cheryl L. Johnson
James D. Kole

9:45-10:45 am
Keynote Speaker
Harvey V. Fineberg

Program Agenda

CONCURRENT SESSIONS
11:00 am-12:00 noon

R. Conducting Due Diligence of a Company in the Life Sciences Industry (not repeated)
Julia Kahr
David E. Matyas

As Wall Street's enthusiasm for investing in healthcare organizations, and in particular companies in the life sciences, does not appear to be declining and as recent state and federal laws and investigations have raised the stakes associated with these organizations, this session will address:

- The due diligence process
- How the results are otherwise incorporated into the transaction documents
- The top 10 health regulatory topics that financial institutions are actively examining when considering whether to invest in or lend money to a company that is involved in the manufacturing of pharmaceuticals, medical devices or biotechnology
- How outside counsel can provide practical advice to a financial institution in the midst of considering a transaction

S. Make Clinical Trial Agreements Safe and Effective for the Research Institutions and Sponsors
Barbara M. Longmire
Phillip D. Porter
Sheila Prindiville

- Efforts of the National Cancer Institute and the CEO Roundtable on Cancer's Life Sciences Consortium to standardize the most heavily negotiated provisions in clinical trial agreements
- Ownership of inventions that might arise during clinical trials in the context of the needs of research sponsors and research institutions
- Categories of data that are created during clinical trials and use of the categories to resolve ownership issues and access, usage and disclosure limitations
- Risks that are inevitably associated with clinical trial agreements among the parties to those agreements
- How to deal with claims by the parties that information exchanged or created during the trial should be treated as confidential and for how long
- Roles, rights and obligations of the parties to a clinical trial agreement in publication of the results of the trial
- Ownership of, and rights to use, biological samples

T. Drug Price Reporting
Joseph W. Metro
Richard L. Zimmerer

- Update on NACDS/use of amp and bp in reimbursement
- Overview of final rule and CMS FAQs
- Bundling
- AGs

U. Commercial Issues for Drug and Device Manufacturers
Paul M. Campbell
Howard M. Tag

- Product positioning, coverage and evidence
  – Implications of FDA approval on product positioning
  – Role of evidence in coverage, coding and payment
  – Trends in national coverage determinations
  – Impact of Medicare contracting reform on local coverage determinations
  – Future of least costly alternative policy; a coverage decision with payment implications
- Issues for pricing and payment planning
  – Shift in priority from quality to value
  – Changes in payment methodologies
  – Using health economic and quality of life data
  – Impact of patient cost sharing

12:00 noon-1:00 pm
Lunch on your own

CONCURRENT SESSION
1:15-2:15 pm

V. Antitrust Issues for Life Science Companies (not repeated)
Robert F. Leibenluft
Mark Woodward

- Antitrust framework for non-antitrust lawyers
- Merger review of pharmaceutical and device manufacturer mergers
- Antitrust challenges to conduct to delay generic entry under the Hatch-Waxman Act
- Antitrust issues raised by joint research, marketing and selling arrangements
- Bundling, exclusivity and loyalty discounts

T. Drug Price Reporting (repeat)

U. Commercial Issues for Drug and Device Manufacturers (repeat)

2:30-3:30 pm
M. Medicaid Reimbursement (repeat)

Q. Research Misconduct–Integrity in Research: What has been going on since 2005?(repeat)

S. Make Clinical Trial Agreements Safe and Effective for the Research Institutions and Sponsors (repeat)

Adjournment

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Program at a Glance

Wednesday, May 7, 2008

12:00 noon– 5:00 pm	**Registration and Information**	
1:00– 2:30 pm Extended Sessions	**A. Coverage, Reimbursement and Fraud and Abuse Basics for FDA (and New) Lawyers** *(not repeated)* *Alexander* *Bell*	**B. FDA Basics for Healthcare (and New) Lawyers** *(not repeated)* *Behr* *O'Shea*
2:45– 3:45 pm	**C. Patent Issues for Life Science Lawyers** *(not repeated)* *Levy* *Sauer*	**D. Compliance Issues in Operating Patient Assistance Programs** *Fried* *Ruskin*
4:00– 5:00 pm	**E. Stem Cell Policies – Ethics in Research** *(not repeated)* *Landis*	**F. Fair Market Value in the Device and Pharma Industry: Is it Relevant?** *Wade*

Thursday, May 8, 2008

7:00 am– 5:45 pm	**Registration and Information**
7:00– 8:00 am	**Continental Breakfast sponsored by Navigant Consulting** *(attendees, speakers, children, registered spouses and guests welcome)* 7:00–8:00 am **Life Sciences Affinity Group Networking Breakfast** *(attendees and speakers welcome)*
8:00– 10:30 am	**GENERAL SESSION** 8:00–8:15 am **Welcome and Introduction** *Carder-Thompson, Hamme* 8:15–9:45 am **Trends in Federal Enforcement** *Grider, Riordan, Thirolf* 9:45–10:30 am **Clinical Trials: FDA and CMS Regulation** *Bradshaw, McGuan, Straube*
10:30– 10:45 am	**Break**

Program at a Glance

Thursday, May 8, 2008 (continued)

10:45 am– 12:15 pm Extended Sessions	**G. Pharma Datamining** *(not repeated)* *Kamp* *Outterson* *Walden*	**H. Conflicts of Interest in Research Strategies for Managing Compliance and Liability Risks without Stifling Innovation** *Broccolo* *Chilsolm* *Mannan*	**J. Trends in Corporate Integrity: Investigations and Obligations** *McCormick* *Sorensen*	**K. Update on FDA Regulatory/Legislative Issues Impacting Drugs, Biologicals and Medical Devices** *Dennis* *Masoudi* *Mounts*
12:15– 1:30 pm	**Life Sciences Practice Group Luncheon sponsored by Navigant Consulting** *(all attendees and speakers welcome)*			
1:45– 2:45 pm	**L. Secondary Use of Electronic Health Information** *(not repeated)* *Henry* *Rosati*	**M. Medicaid Reimbursement** *Lundy*	**N. Global Compliance** *Ford* *O'Donnell*	**F. Fair Market Value in the Device and Pharma Industry: Is it Relevant?** *(repeat)* *Wade*
3:00– 4:30 pm Extended Sessions	**O. Legal Ethics and Professional Responsibility in Life Sciences: A Timely Update** *(not repeated)* *Goldberg*	**H. Conflicts of Interest in Research Strategies for Managing Compliance and Liability Risks without Stifling Innovation** *(repeat)* *Broccolo* *Chisolm* *Mannan*	**J. Trends in Corporate Integrity: Investigations and Obligations** *(repeat)* *McCormick* *Sorensen*	**K. Update on FDA Regulatory/ Legislative Issues Impacting Drugs, Biologicals and Medical Devices** *(repeat)* *Dennis* *Masoudi* *Mounts*
4:45– 5:45 pm	**P. Secondary Research – Opportunities and Strategies** *(not repeated)* *Geetter*	**Q. Research Misconduct–Integrity in Research: What has been going on since 2005?** *Garfinkel* *Lutz*	**D. Compliance Issues in Operating Patient Assistance Programs** *(repeat)* *Fried* *Ruskin*	**N. Global Compliance** *(repeat)* *Ford* *O'Donnell*
5:45– 6:45 pm	**Reception sponsored by Navigant Consulting** *(attendees, speakers, children, registered spouses and guests welcome)*			

Program at a Glance

Friday, May 9, 2008

7:30 am– 3:30 pm	**Registration and Information**			
7:30– 8:30 am	**Breakfast sponsored by Navigant Consulting** *(attendees, speakers, children, registered spouses and guests welcome)*			
8:30– 10:45 am	**General Session** 8:30–9:45 am **State Law** *Guthrie, Johnson, Kole* 9:45–10:45 am **Keynote Speaker** *Fineberg*			
10:45– 11:00 am	**Break**			
11:00 am– 12:00 noon	**R. Conducting Due Diligence of a Company in the Life Sciences Industry** *(not repeated)* *Kahr* *Matyas*	**S. Make Clinical Trial Agreements Safe and Effective for the Research Institutions and Sponsors** *Longmire* *Porter* *Prindiville*	**T. Drug Price Reporting** *Metro* *Zimmerer*	**U. Commercial Issues for Drug and Device Manufacturers** *Campbell* *Tag*
12:00 noon– 1:00 pm	**Lunch on your own**			
1:15– 2:15 pm	**V. Antitrust Issues for Life Science Companies** *(not repeated)* *Leibenluft* *Woodward*	**T. Drug Price Reporting** *(repeat)* *Metro* *Zimmerer*	**U. Commercial Issues for Drug and Device Manufacturers** *(repeat)* *Campbell* *Tag*	
2:30– 3:30 pm	**M. Medicaid Reimbursement** *(repeat)* *Lundy*	**Q. Research Misconduct-Integrity in Research: What has been going on since 2005?** *(repeat)* *Garfinkel* *Lutz*	**S. Make Clinical Trial Agreements Safe and Effective for the Research Institutions and Sponsors** *(repeat)* *Longmire* *Porter* *Prindiville*	

Life Sciences Practice Group

The Life Sciences Practice Group (LSPG) provides educational and informational services and resources to in-house attorneys; outside counsel; government attorneys; compliance officers; finance and reimbursement executives; FDA, research, clinical trials and regulatory affairs professionals; and consultants who practice in the traditional life sciences field with respect to issues involving pharmaceutical manufacturers, medical device manufacturers, biotechnology companies, research and site management organizations, manufacturing and supplier vendors, prescription drug plans, wholesale distributors, retail and specialty pharmacies, pharmacy benefit managers, and the financial services firms that invest in these entities.

The LSPG concentrates on issues such as food and drug law regulation, third-party payment and reimbursement (e.g., coverage, coding, and payment methodologies for products), fraud and abuse, government contracts, products liability, intellectual property, clinical trials, and research.

Life Sciences Practice Group Mid-Year Luncheon

Personalized Healthcare: Opportunities and Challenges for a New Era in Science and Health

Description:
Advances in medical, biomedical science, and information technology present opportunities for enabling health practices to be increasingly patient-specific. Pharmaceutical and biotech companies, market analysts, and entrepreneurs are beginning to recognize and understand the significance of personalized healthcare and consumer interest is growing. At the same time, policymakers across the national government have identified personalized medicine as a key objective to optimizing outcomes, controlling healthcare costs and creating true value for each patient. But, is a continuum of transformation that builds on knowledge management to support the integration of discovery, development and delivery in the healthcare enterprise attainable? What are national policymakers doing to accelerate the development of more personalized healthcare? How will healthcare providers, regulators, and industry manage risks and avoid over promising and underestimating the complexity of science of genomics to an increasingly eager consumer base? And, how will these initiatives reshape the development, marketing, and delivery of therapeutics and diagnostics?

Presenter:
Sheila D. Walcoff, Esq.
Former Counselor to the HHS Secretary Michael O. Leavitt
Former Senior Advisor to U.S. Presidential Candidate Fred Thompson
Washington, DC

Get Involved!

The LSPG is very pleased that for 2008, it will be kicking off LSPG Affinity Groups. These Groups are intended to be forums that focus on the interests and issues most relevant to the major subsets of the life sciences practice area. The Affinity Group leaders will be responsible for developing and implementing a plan to launch each Affinity Group and to make it a success for the practitioners who work in their area. The leaders are now working on plans to include strategies for: (a) recruiting members for the Affinity Group; (b) generating discussion of issues relevant to the Affinity Group on the LSPG listserve; (c) generating Affinity Group-specific content for the LSPG newsletter and website; and (d) sponsoring Affinity Group-specific events such as teleconferences.

We know the leaders would welcome assistance as they develop these plans! The co-chairs for each Group are as follows:

Research and Development: Michele K. Russell-Einhorn, Dana-Farber/Harvard Cancer Institute, Boston, MA, and Lori Spencer, Smith Moore LLP, Atlanta, GA.

FDA Regulatory: Erika Lietzen, Covington & Burling LLP, Washington, DC, and Marc B. Wilenzick, Pfizer, New York, NY.

Coverage, Coding, Payment, and Pricing: John McInnes, Arnold & Porter LLP, Washington, DC, and Paul Seltman, Drinker Biddle & Reath LLP, Washington, DC.

State Law: Jeff Layne, Fulbright & Jaworski, Austin, TX, and Brenda Eady Stafford, Drinker Biddle & Reath LLP, Florham Park, NJ.

Intellectual Property: Sergio Garcia, Fenwick & West LLP, San Francisco, CA, and Kelli Watson Francuzenko, McDermott Will & Emery, LLP, Washington, DC.

Join us for our introductory LSPG Affinity Groups networking **breakfast meeting on Thursday, May 8 from 7:00-8:00 am.** Check at AHLA registration desk for location information, no pre-registration is required. We hope to see you there!

Life Sciences Practice Group Benefits

Since its launch in January 2007, the LSPG has provided numerous outstanding resources to its members, including:

- Three Newsletters
- One Member Briefing
- Numerous email alerts
- Two luncheons
- Feature article in *Health Lawyers News*
- Six teleconferences
- Life Sciences Listserve
- And much more…

AMERICAN HEALTH LAWYERS ASSOCIATION

Membership & Practice Groups Application

Mr. Ms. Name: _____
(circle one)

Affiliation (law firm or employer): _____

Address: _____

City: _____ State:_____Zip+4:_____

Mailing Address: ❑ **Home** ❑ **Business (Please print, type,or attach business card.)**

Email:_____

Phone: _____ Fax:_____

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Practice Groups (PGs)

SPECIAL OFFER FOR NEW MEMBERS!

Join AHLA today for a special rate of $200 and receive the Life Sciences Practice Group for free!*

When you join today, you will receive:
- Access to the Life Sciences Practice Group website;
- Life Sciences Practice Group publications, resources, and email alerts;
- Discounts when you register for the Practice Group teleconferences;
- The Health and Life Sciences Law Daily email;
- Subscription to the Life Sciences listserve;
- Reduced registration rates to AHLA programs and to the Life Sciences Practice Group luncheons; and
- Many other AHLA membership benefits!

*This special offer is only available to new members.

Payment

❑ Check/Money Order (U.S. Dollars, payable to AHLA)
or Credit Card: ❑ Visa ❑ MasterCard ❑ American Express

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Special Offer	
Membership and Life Sciences PG	❑ $200
Date Admitted to First Bar or if non-lawyer date of college graduation (month, day, year):_____	
Admitted to the Bar/College less than four years ago	
In-House Counsel	❑
Solo practitioner or attorney at law firm	❑
Health Professional/Non-lawyer	❑
Admitted to the Bar/College between four and eight years ago	
In-House Counsel	❑
Solo practitioner or attorney at law firm	❑
Health Professional/Non-lawyer	❑
Admitted to the Bar/College eight or more years ago	
In-House Counsel	❑
Solo practitioner or attorney at law firm	❑
Health Professional/Non-lawyer	❑
Other Membership Choices Available (Life Sciences PG not included)	
Government Attorney	
Regular Government membership	❑ Dues $150
Electronic (E-GOV) Government membership	❑ Dues $75
Academician	
Regular Academic membership	❑ Dues $150
Electronic (E-ACD) Academic membership	❑ Dues $75
Public Interest Attorney	❑ Dues $100
Paralegal (E-PLG)	❑ Dues $75
Student (law/graduate)	❑ Dues $25
Practice Group Enrollments	
Add the Life Sciences Practice Group for just $45	$ _____
Total Payment Enclosed	$ _____

FOUR Convenient Ways to Join!

By Mail — Complete/return form with payment information to AHLA, PO Box 79340, Baltimore, MD 21279-0340

By Fax — Complete/return form with payment information to (202) 775-2482

By Internet — Log onto www.healthlawyers.org/join_renew to enter our secure Website area

By Phone — Call the Member Service Center (202) 833-0766

❑ Occasionally AHLA makes its member list available to organizations that offer products deemed to be of professional interest to members. Check if you wish to have your name excluded.

❑ Do not list me in the electronic or online *Membership Directory.*

Membership App 08

Life Sciences Resources

Special deal on our Fundamentals publications:

Purchase the *Fundamentals of Health Law, Fourth Edition* and receive **20% off** the *Fundamentals of Life Sciences.* These bestsellers provide new and seasoned attorneys with a thorough grounding in the basics of Health and Life Sciences Law.

Also available:

The American Health Lawyers Association is pleased to bring you the next CD in the Complete "Connected" Series—*The Complete "Connected" Pharmaceutical and Medical Devices Law and Regulations CD.* With the assistance of our editors **Elizabeth Carder-Thompson, Esquire**, and **Pamela J. Furman, Esquire** we have compiled the critical information you need to understand the regulation and pharmaceuticals, medical devices, and biologics. **SAVE BIG NOW!** Purchase the Complete Connected when you register and receive a discount on the CD and the Program.

To order, call 1-800-533-1637, or visit our online bookstore at www.healthlawyers.org/bookstore.

Special Offer to All Program Attendees!

While at the program, all attendees can sign up to receive free copy of the Post-Program CD. CDs include all the audio recordings and materials with an electronic index and link to each of the topics, practical tools, exhibits, checklists and forms in each presentation. Please stop by the Navigant Consulting exhibit booth to get your coupon for the free CD. All CDs will be mailed 4-6 weeks after the program.

Public Interest

Coming Soon...

A new guidebook will be added to AHLA's Public Information Series: *Medical Research: A Consumer's Guide for Participation.* The guidebook will explain the difference between basic, translational, and clinical research. In addition, the resource will inform the reader about the protective measures that are in place to protect the medical research volunteer, the volunteer's rights and responsibilities, payment issues, and guidance on what questions to ask regarding various phases of research treatment. Visit www.healthlawyers/org/publicinterest to check out other Public Interest resources.

Program Information

Dates: May 7-9, 2008
Place: Bethesda North Marriott Hotel & Conference Center
5701 Marinelli Road
Bethesda, MD 20852
Phone: (301) 822-9200
Toll-free: (800) 859-8033
Fax: (301) 822-9201

Registration Fees:
$735 AHLA, BIO, and AdvaMed Members
$660 Member Group
$935 Non-Members

If you have indicated an incorrect amount due to errors in addition or not being eligible for a specific rate, AHLA will charge the correct amount to the credit card you have supplied.

Discounted Registration Fees: Government employees, in-house counsel, academicians, solo practitioners and students: please call (202) 833-0766 for special discounted registration fees.

Spouse/Guest Fee: For an additional $30 spouses and adult guests can register to attend the reception on Thursday evening and the breakfasts on Thursday and Friday mornings. Please sign up on the registration form. (Children are welcome to attend these events at no additional charge.)

Continuing Education: Participants will be given continuing education forms at the program. Forms must be completed and returned to AHLA staff to receive credit. AHLA is an approved sponsor of continuing legal education credits in most states. This seminar will be worth approximately 15.75 continuing education credits (including 1.25 ethics credit) based on a 60-minute hour and 18.9 credits (including 1.5 ethics credits) based on a 50-minute hour.

AHLA is registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National Registry of CPE Sponsors. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be addressed to the National Registry of CPE Sponsors, 150 Fourth Avenue North, Suite 700, Nashville, TN 37219-2417. Web site: www.nasba.org. This seminar will be worth approximately 18.0 CPE credits.

There are no prerequisites or advanced preparations required to register for this group live program. Sessions are intermediate unless otherwise indicated.

Hotel Reservations: All reservations should be made through the hotel's toll-free number (800)859-8003. When making your reservation please mention you would like to reserve a room under the American Health Lawyers Association room block.

Reservations can also be made online at www.bethesdanorthmarriott.com and the online group code for AHLA is HEAHEAA. Check-in time is 4:00 pm. The entire hotel is non-smoking. The room rate of $209 is exclusive of room tax of 13%. All reservations should be made no later than **April 15th**.

Membership: Special Offer for New Members! Pay the member registration fee for the program plus $200 and become a member of AHLA and the Life Sciences Practice Group (*see* page 11) for one year. Submit the membership application (p. 12) and applicable fee with your registration form and take advantage of the special offer.

Regular dues are $180 for those admitted to the Bar/graduated from college within the last four years; $295 for those admitted/ graduated more than four but less than eight years ago; and $340 for those admitted/graduated eight or more years ago. Dues are $150 (or $75 for electronic benefits) for government employees and full-time academicians; and $25 for full-time law school students to receive benefits electronically.

Cancellations/Substitutions: Cancellations must be received in writing no later than April 30, 2008. Refunds will not be issued for cancellations received after this date. Registration fees, less a $125 administrative fee, will be refunded approximately 3-4 weeks following the program. If you wish to send a substitute or need more information regarding refund, complaint and program cancellation policies, please call (202) 833-1100. Please note that registration fees are based on the membership status of the individual who actually attends the program.

Special Needs: If you need any of the auxiliary aids or services identified in the Americans with Disabilities Act, please call the Member Service Center at (202) 833-0766.

Travel: Association Travel Concepts (ATC) has negotiated discounts with United, American, Enterprise and Avis Rental Car to bring you special airfares and car rental rates lower than those available to the public. Discounts apply for travel May 4-12, 2008. For tickets purchased less than 30 days prior, the discounts will be 5% to 15% off of the lowest available fares. Some restrictions may apply and a service fee may apply.

ATC will also search for the lowest available fare on any airline.

ASSOCIATION TRAVEL CONCEPTS
1-800-458-9383
email: reservations@atcmeetings.com
www.atcmeetings.com
(follow the Member Travel links)
Fax: (858) 362-3153
ATC is available for reservations from 9:00 am until 7:30 pm Eastern, Monday through Friday.

Life Sciences Law Institute Registration ③

To register: Remit payment and completed registration form by mail to the American Health Lawyers Association • P.O. Box 79340 • Baltimore, MD 21279-0340 or fax with credit card information to (202) 775-2482. To register by phone call (202) 833-0766. If any program is over-subscribed, only Health Lawyers members will be placed on a waiting list. On-site registrations will be accepted on a space-available basis only.

Name: _____ Member ID #:_____

First Name for Badge (if different than above): _____ Title: _____

Organization: _____

Address: _____

City: _____ State: _____ ZIP+ 4: _____

Telephone: (_____) _____ Fax: (_____) _____

E-Mail: _____

Spouse/Guest Name: _____

Registration Fees:

☐ **$735 AHLA, BIO, AdvaMed Members** ☐ **$935 Non-Members**

☐ $660 each additional member registering from the same organization at the same time on the same check or credit card payment.

☐ **Please add the Complete Connected Pharma/Medical Device CD to my order.**

PAYMENT INFORMATION

Please fill in applicable amount: (Sorry! Registrations cannot be processed unless accompanied by payment.)

$_____ Registration Fee

$_____ Complete Connected Pharma/Medical Device CD ($285)

$_____ Spouse/Guest Fee ($30)

$_____ Discount: Subtract $200 if you register and purchase the CD

$_____ Total Enclosed

☐ Check enclosed (Make checks payable to American Health Lawyers Association)

Bill my credit card: ☐ VISA ☐ MasterCard ☐

Number: _____ Exp. Date: ☐☐ /☐☐

Name of Cardholder: _____

Signature of Cardholder: _____

ZIP Code of Cardholder's Billing Address _____

Please Note: Should your credit card total be miscalculated, AHLA will charge your credit card for the correct amount.
To receive a refund of the registration fee paid minus $125, cancellation notice must be received in writing by April 30, 2008. Please see p. 14 of this brochure for AHLA's full refund policy.

**All orders will be fulfilled within 2 weeks after the program. (5.75% tax will be added for DC residents)*

AMERICAN
HEALTH LAWYERS
ASSOCIATION

1025 Connecticut Avenue, NW
Suite 600
Washington, DC 20036-5405

Life Sciences Law Institute

May 7–9, 2008
Bethesda North Marriott Hotel & Conference Center
Bethesda, MD

Presorted
First-Class Mail
U.S. Postage Paid
Suburban, MD
Permit No. 4841