September 15-16, 2009 | Omni Parker Hotel

BOSTON EDITION

FDA BOOT CAMP

Basic Training for Products Liability and Patent Lawyers

Distinguished Co-Chairs:

Robert B. Nicholas
Partner
McDermott Will & Emery LLP

William W. Vodra
Senior Counsel
Arnold & Porter LLP

SPECIAL TRACKS:

Patent Track

Advanced Life Cycle Considerations:

Non-Patent Exclusivity

Bioequivalency

Follow-On Biologics

Products Litigator Track

Post-Approval Marketing Guidance:

Advertising and Promotion

Off-Label Use

A Who's Who of the nation's Food and Drug bar will provide you with a **comprehensive understanding of the basics of FDA law** as they help you:

- MASTER the complexities of pharmaceutical IP and the regulatory balance between brand name and generic products
- RECOGNIZE the pivotal role of labeling in the drug and biologics approval process
- COMPREHEND the structure of the FDA and the roles of the three major agency centers: CDER, CBER, and CDHR
- UNDERSTAND the basics of the approval processes for drugs, biologics and devices, including in-depth discussion of the application, pre-approval and post-approval requirements
- DEVELOP a practical working knowledge of clinical trials for drugs and biologics and the clearance process for devices
- LEARN how devices are classified, monitored, and regulated
- SEE the importance of cGMPs to the post-approval regulatory process
- NAVIGATE the protocols of adverse events reporting, product withdrawals, and recalls
- ANALYZE the future of follow-on biologics
- ASSESS what marketing activities may constitute off-label promotion

Post-Conference Workshop:

Spotlight on Nanotechnology

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Increase your FDA regulatory knowledge to become a better life sciences products litigator or patent attorney

The approval process…pre-approval concerns…product labeling…clinical trials…adverse events reports…patent concerns…exclusivity. FDA law and regulations govern these critical aspects in the commercialization process for drugs, biologics, and devices. And with the ever-evolving regulations, new preemption case law, and pending legislation concerning FDA-regulated products on the horizon, it is essential for attorneys who do not have regulatory practices – but who deal with FDA-regulated products – to understand the rules and regulations that impact the life sciences arena.

The outcome of products liability and patent litigation concerning these products often hinges on what happened during the pre-approval, approval, or post-approval periods. Becoming well-versed in the essentials of the approval process and post-approval hurdles will enable you to much more effectively navigate the regulatory maze that plays a critical role in your cases and practice.

Boot your FDA regulatory IQ.

Develop greater expertise in your field.

ACI's FDA Boot Camp, the industry standard in providing non-regulatory professionals with a regulatory background, has been designed to give products or patent litigators, as well as patent prosecutors and life sciences investment and securities experts, a strong working knowledge of core FDA regulatory competencies, **including the nuances of the FDAAA**.

A distinguished faculty of top FDA regulatory experts – a "*Who's Who of the FDA Bar*" – will share their knowledge and give you critical insights on:

- The organization, jurisdiction, functions, and operations of the FDA
- The essentials of the approval process for drugs, biologics, and devices, including:
  - NDAs
  - INDs
  - BLAs
  - ANDA applications
  - 505b2s
  - 510 K submissions
  - PMA process
- Clinical trials for drugs and biologics and the clearance process for devices
- The classification of devices and the concept of "risk-based" classification
- The role of the Hatch-Waxman Act in the patenting of drugs and biologics
- Labeling in the drug and biological products approval process
- cGMPs and other manufacturing concerns relative to products liability
- Proactive adverse events monitoring
- Recalls, product withdrawals, and FDA oversight authority

Other program highlights include special tracks for Patent Attorneys and Products Litigators.

Also, expand your expertise by attending the special **Spotlight on Nanotechnology** Workshop on September 16, to learn how nano products are being evaluated and how this emerging area fits into the FDA regulatory scheme.

Attend this conference and become the best life sciences products litigator or patent attorney you can be. Don't delay – register today by calling **1-888-224-2480**, faxing your registration form to **1-877-927-1563**, or going online at: **www.AmericanConference.com/FDABootCampBOS**

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> –Azim Chowdhury, Associate, Duane Morris LLP

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SPEAKERS:

Aaron F. Barkoff, Ph.D.
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Partner
Wiley Rein LLP

Donald R. Ware
Partner
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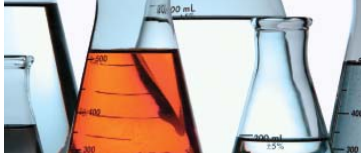

DAY ONE
Tuesday, September 15, 2009

8:00 **Registration and Continental Breakfast**

8:45 **Co-Chairs' Opening Remarks**

Robert B. Nicholas
Partner
McDermott Will & Emery LLP

William W. Vodra
Senior Counsel
Arnold & Porter LLP

9:00 **The Basics: Understanding and Working with the FDA and the New Administration – Jurisdiction, Functions, Organizations, & Operations**

Robert B. Nicholas
Partner
McDermott Will & Emery LLP (Washington, D.C.)

- FDA Overview: How it's organized
  - Department of Health and Human Services and the Commissioner
  - The 5 FDA Centers and the Office of Regulatory Affairs and their functions
- The 3 major centers and their roles
  - CDER (Drug)
  - CBER (Biologic)
  - CDRH (Device)
- Understanding how CDER and CBER intersect
  - Intersection with CDRH
- Defining the scope of the FDA's jurisdiction
- Examining how the FDA exercises its jurisdiction
  - Rule making
  - Product decisions
  - Enforcement
  - Informal mechanisms
- Reviewing the laws that the FDA enforces
- Defining drugs, biologics, and medical devices
- Emerging & expanding technologies
  - human cell and tissue-based products
  - nanotechnology
- Labeling: when is a drug a drug and not a medical device or cosmetic, and the consequences
- Defining combination products
- The FDAAA and current FDA policies and procedures
- Working with the FDA, the new administration, and Congress
  - Administrative Procedures Act
  - Formal and informal dispute resolution mechanisms
  - The new players – who's who and what you need to know
- Looking forward – anticipated legislative change

10:00 **Morning Coffee Break**

PRE-APPROVAL AND APPROVAL

10:15 **The Nature of the Approval Process**

Mark A. Heller
Partner
Goodwin Procter LLP (Washington, D.C.)

Erika Lietzan
Partner
Covington & Burling LLP (Washington, D.C.)

Rx Drugs

- Understanding the difference between "new drugs" and other drugs
- Overview of the research, development, and approval process for new drugs
- The investigational new drug application (IND)
  - When you need to file one
  - What it needs to contain
  - What it entitles you to do
- The new drug application (NDA)
  - When you need to file one
  - What it needs to contain
  - FDA review process and timing
  - Advisory committees
- Accelerated approval (fast track)
- FD&C 505b2 (an alternative pathway to an ANDA)

Biological Products

- What are biological products?
- What does it mean to say that they are also "drugs"?
  - Which "new drugs" require BLA's instead of NDA's?
- How does the research, development, and approval process for biological products differ from the process for new drugs?
- The biologics license application (BLA)
  - When you need to file one
  - What it needs to contain
  - FDA review process and timing
  - Advisory committees
- Key similarities and differences between the drug and biological product schemes

Medical Devices

- Overview of how a medical device comes to market
- Understanding the FDA's risk-based classification scheme for medical devices
- Three main classes of medical devices
  - Class I – "low risk"
  - Class II – "moderate risk"
  - Class III – "high risk"
- Device reclassification
- 510(k) exemptions for low risk devices
- Premarket notification (510(k)) process
- Premarket approval process (PMA)
- The role of Investigational Device Exemption (IDE)

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11:15 **Essential Requirements of the Clinical Trials Processes**

P. Terrence Gaffney
Partner
Duane Morris LLP (Baltimore, MD)

- Overview of the clinical trials process
  - Phases of testing (I-IV)
  - Which phases are mandatory for drugs, biologics, & medical devices?
  - What happens in each phase?
  - Who conducts the testing?
  - Special considerations for Phase IV testing
- Regulatory requirements
  - IRB's
  - Sponsor obligations
  - Investigator obligations
- Good Clinical Practice and ethical integrity
  - Human subject protection mechanisms
  - What constitutes informed consent?
- FDA authority
- Other considerations
  - CRO's
  - Who reviews the data?
  - How do clinical trials for drugs differ from clinical trials for biologics?
- Disclosure of clinical trial information
  - FDA Amendments Act of 2007
  - FDAMA § 113
  - Clinicaltrials.gov
  - PhRMA policies
- Global Clinical Trials: overview of FDA regulation and approval for trials conducted overseas

12:15 **Networking Lunch**

1:30 **Patent & IP Spotlight: Hatch-Waxman, the Patenting Process, and More**

Michael H. Hinckle
Partner
K&L Gates LLP (Research Triangle Park, NC)

Eric J. Marandett
Partner and Chair, Intellectual Property Litigation Group
Choate Hall & Stewart LLP (Boston, MA)

- Seeking and obtaining patent protection during the pre-approval process
- Making up for lost time in the patent life cycle during the pre-approval process
- Distinguishing the patenting process for drugs from that of biologics: which biologics are treated as drugs and why?
- Identifying the respective roles of the FDA and the PTO in the patenting of drugs and biological products
- NDA vs. ANDA (Abbreviated New Drug Application)
  - How do they differ?
  - What does an ANDA require?
- Paragraph IV Certifications and Notice Letters
- Bioequivalence defined
- The Orange Book: what is it and why is it orange?
  - Listings
  - De-listings
- Hatch Waxman Overview – the patent end game
  - Hatch Waxman and reforms under MMA
  - The Orange Book
  - Exclusivity (180 day)
  - Forfeiture provisions
  - 30-month stay
  - Patent extensions
  - The safe harbor
- Citizen's petitions

2:45 **Afternoon Coffee Break**

3:00 **Drugs, Biological, and Medical Device Products: Labeling**

William A. McGrath
Partner
Wiley Rein LLP (Washington, DC)

The labeling of drug, biological, and medical device products is the final stage of the approval process. The labeling affects what you can do post-approval. It is the point of transition between the approval process and post-approval world.

- Labeling overview: key regulatory requirements, information, and contents
- Review process for labeling
- How does the final labeling control the scope of post-market activities?
- When should the labeling be amended post-market?
  - What is the process for doing so?
- What claims can device manufacturers make regarding cleared/approved devices, devices with pending 510(k) notices, and investigational devices?
- How is labeling a defense in products litigation?

POST-APPROVAL

3:45 **Current Good Manufacturing Practices (cGMPs) and Quality System Regulation (QSR)**

Robert Dormer
Director
Hyman, Phelps & McNamara P.C. (Washington, D.C.)

- Examining cGMPs and the scope of their importance in pharmaceutical/biological product commercialization
- Looking at how cGMPs factor into the scope of the FDA's authority and history
- Exploring the scope of the FDA's cGMP Initiative and how the concept of "risk-based" cGMPs is defined
- Defining the concept of validation

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- How are laboratory investigations in relation to cGMPs conducted?
- How are cGMPs factoring into products litigation?
- What types of post-market requirements can FDA impose on medical devices, e.g., tracking?
- What is the scope of the Quality System Regulation (QSR)?
- Defining the term "quality systems"
- What types of facilities must comply with FDA's establishment registration and device listing requirements?

4:45 **Conference Adjourns**

DAY TWO
Wednesday, September 16, 2009

8:00 **Continental Breakfast**

8:30 **Co-Chairs Opening Remarks**

8:45 **Import/Export Guidelines & Emerging International Regulatory Concerns**

Jill A. Deal
Partner
Venable LLP (Washington, DC)

- Overview of international harmonization efforts
- Importation of drugs and biologics
  - FDA's foreign drug inspection program and oversight initiatives
  - How regulated products are entered into the U.S.
  - Registration requirements
  - Special considerations: API's and OTC's
- Exportation under FDA's Export Reform and Enhancement Act of 1996
  - Exportation Certificates
  - Exportation of imported products
- FDA enforcement and civil penalties

9:45 **Morning Coffee Break**

Bifurcated Tracks: Choose ONE
Patent or Products Liability

PATENT TRACK

Advanced Life Cycle Considerations

10:00 **Non-Patent Exclusivity**

Aaron F. Barkoff, Ph.D.
Partner
McDonnell Boehnen Hulbert & Berghoff LLP
(Chicago, IL)

- The different modes and methods of exclusivity (non-patent)
  - Data
  - Orphan drug
  - Pediatric
  - New product
- What role does the FDA play in regulating these modes of exclusivity?
- When are each of these methods sought?
- Exploring the relation and intersection of each of these methods to 180-day exclusivity

10:45 **Bioequivalence: What Patent Lawyers Need to Know**

Chad A. Landmon
Partner
Axinn Veltrop & Harkrider LLP
(Hartford, CT and Washington, DC)

- Defining bioequivalence in drugs and biologics
  - Drugs vs. biologics
- What an ANDA filer must demonstrate for bioequivalence
  - Bioequivalence and dosage form – oral tablet/capsule, injection, nasal sprays, topical
- How does bioequivalence relate to patents?
  - Patenting of bioequivalence characteristics – extended-release drug products
  - Bioequivalence vs. Doctrine of Equivalents – what is the difference?
  - Arguments about bioequivalence raised in Paragraph IV patent litigation
    - o Infringement, copying (non-obviousness)

11:30 **Follow-On (Comparable or Biosimilar) Biologics**

Donald R. Ware
Partner
Foley Hoag LLP (Boston, MA)

- What are biologic drugs and why are they different for purposes of generic competition?
- When can FDA approve a follow-on biologic under current law?
- What kind of abbreviated approval route for biologics is being considered in Congress?
- The Pathway for Biosimilars Act
- Will follow-on biologics ever be interchangeable with innovators they copy?

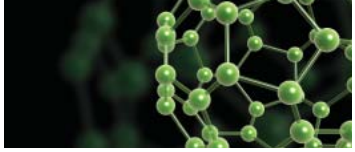
PRODUCTS LITIGATOR TRACK

Post-Approval Marketing Guidance

10:00 **Advertising & Promotion**

William H. Kitchens
Partner
Arnall Golden Gregory LLP (Atlanta, GA)

- Overview of the laws and regulations controlling the advertising, marketing, and promotion of prescription drugs and biologics


- 21 CFR §§202.1, 352(n), 314.81(b)(3); §352(n) of FD&C
- Guidance documents

DDMAC (Division of Drug Marketing, Advertising and Communications)

- What duties and responsibilities is DDMAC charged with?
- What are the enforcement capabilities and jurisdiction?
- Identifying the role of the FTC in the advertising and promotion of drugs
- Advertising requirements for prescription vs. nonprescription products
- Reviewing the steps which DDMAC takes for the review of launch campaigns and promotion materials
  - Overview of the promotional materials submission and review process
- What constitutes a launch?
- What defines an advertisement? What information must be included?
- Exploring the role of labeling in advertising

Special Concerns for DTC Advertising

- What FDAAA regulations impact DTC program provisions?
- How is direct-to-consumer advertising regulated and monitored? How is it different from other pharmaceutical advertising?
- What information must every DTC contain?
- The FDA's DTC Television User Fee Program
- Internet and e-mail advertising regulation

Medical Devices

- What claims can device manufacturers make regarding cleared/approved devices, devices with pending 510(k) notices, and investigational devices?
- How can device manufacturers convey information about new uses to health care professionals and/or consumers?
- What are the consequences of illegal promotion of a device?

11:15 Session: Regulation and Dissemination of Off-Label Information

Joseph J. Leghorn
Partner
Nixon Peabody LLP (Boston, MA)

- Overview of the FDA's regulation of off-label promotion
- How can information on off-label or unapproved uses of drugs and biologics be disseminated?
  - Peer review articles vs. ghost writing
  - MSLs vs. sales reps
- What are the consequences of inappropriate off-label promotion?
  - The role of the OIG, U.S. Attorney's Office, and states in monitoring off-label promotion
  - DOJ settlements and corporate integrity agreements

END SEPARATE TRACKS

12:15 Lunch

1:30 Adverse Events Monitoring, Pharmacovigilance, and Risk Management

Howard L. Dorfman
Counsel
Ropes & Gray (New York, NY)

- What is pharmacovigilance?
- How pharmacovigilance uses adverse event reports
  - How ADE reports come to a company
    - o Solicited direct reports
    - o Unsolicited direct reports
    - o Indirect reports
  - How companies investigate, analyze and use ADE reports
    - o Causality assessments
    - o Labeling changes
  - Requirements for reporting ADEs to regulatory agencies
- Examining other tools for pharmacovigilance
- What is risk management?
  - The new Risk Evaluation and Minimization Strategies (REMS) law
  - Risk evaluation in the approval process
  - Risk minimization tools
  - REMS assessments
- Enforcement of ADE reporting and REMS requirements
- Examining the relevance to product liability risks
- Uncovering what types of adverse events must be reported under the Medical Device Reporting (MDR) regulation.
- Mandatory post-market reporting for medical devices under the FDAAA
- What kinds of field actions must be reported under the Reports of Corrections and Removals regulation?

2:15 Recalls and Withdrawals

Cathy L. Burgess
Counsel
Crowell & Moring, LLP (Washington, D.C.)

- What is the FDA's recall and oversight authority?
  - From where does this authority derive?
  - Overview of 21 CFR Part 7
  - Guidance versus regulation
  - Voluntary recalls versus mandatory recalls
  - Market withdrawals and stock recoveries
- What medical device recalls need to be reported to the FDA?
- When should a company institute a recall?
  - Can new labeling or a new product warning constitute a recall?
- When should the decision be made to work with the FDA?
  - Working with the FDA versus working alone?
  - What are the risks and benefits in each course of action?
- Interaction between recalls and corrective and preventative action
- FDA seizure and injunction power
- When can the product be reintroduced to the market?

3:00 Conference Concludes



POST-CONFERENCE WORKSHOP

Wednesday, September 16, 2009

3:15 – 5:30 pm (Registration opens 3:00 pm)

Spotlight on Nanotechnology

Ricardo Carvajal
Of Counsel
Hyman, Phelps & McNamara, P.C. (Washington, D.C.)

Nanotechnology represents one of the most sought-after and fastest growing new legal disciplines. There are currently over 50 nano products being tested by the FDA. How are they being evaluated? Is the current regulatory structure adequate to accommodate the emerging technology? Proactive measures are currently in place to introduce nanotechnology products into the FDA regulatory scheme for approval. This timely workshop will provide an opportunity to be at the forefront of this emerging area. It will walk you through:

- A comprehensive overview of current and proposed FDA policies on nanotechnology regulation
- National Nanotechnology Initiative
- Potential legislation to regulate nano products
- Classifying nano products for FDA approval

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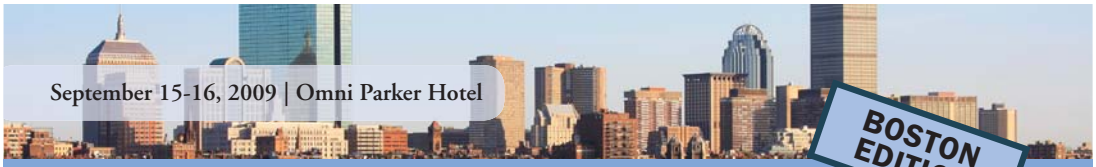

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Follow-On Biologics

Products Litigator Track

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