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BOSTON EDITION

FDA BOOT CAMP

Basic Training for Products Liability and Patent Lawyers

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Scott M. Lassman
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Partner
Covington & Burling 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
DTC Advertising
Off-Label Use

A "WHO'S WHO OF THE FDA BAR":

The conference is led by the nation's top food & drug lawyers who previously served at:

FDA as
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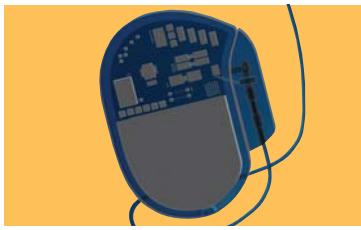
Associate Chief Counsel for Drugs
Associate Chief Counsel for Enforcement
Associate Chief Counsel for Radiological Health

PhRMA as
Senior Assistant General Counsel
Assistant General Counsel



The **FDA Amendments Act of 2007 (FDAAA)** is one of the most comprehensive revisions of the FFDCA in decades and Congress is pushing new safety initiatives and import reforms. Preeminent members of the nation's Food and Drug bar will **drill you in the basics of current FDA law and regulation — including the nuances of FDAAA** – as they help you:

- MASTER the basics of the **application and approval processes** for drugs, biologics, and devices
- COMPREHEND the structure of **FDA** and the roles of **CDER, CBER, & CDRH**
- DEVELOP a practical working knowledge of **clinical trials** for drugs and biologics and the **clearance process** for devices
- APPRECIATE the regulatory balance **between brand** name and **generic** products
- UNDERSTAND the complexities of the **patent and IP** landscape, including Hatch-Waxman, Orange Book, 180-day exclusivity, 30-month stay, **Paragraph IV**, NDA, ANDA and 505(b)(2)
- RECOGNIZE the role of **labeling** in the drug/biological product approval process
- SEE the importance of **cGMPs** to the post-approval regulatory process
- NAVIGATE the protocols of **adverse events** monitoring, pharmacovigilance, and Risk Evaluation and Minimization Strategies (**REMS**)
- LEARN how **devices** are classified, monitored, and regulated
- EXPLORE FDA's expectations and guidance for **recalls**

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FDA BOOT CAMP

Learn how to navigate the regulatory maze that is crucial to your cases and practice areas so you can:

- **Be a Better Products Litigator or Patent/IP Attorney**
- **Develop Greater Business and Investment Expertise in Your Field**

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. Plus, the **FDA Amendments Act of 2007 (FDAAA)** is one of the most comprehensive revisions of FDA law in decades and Congress is pushing new safety initiatives/import reforms. And recent court cases and high-profile trials concerning FDA-regulated products send a clear signal that attorneys who do not have regulatory practices – but who do deal with FDA-regulated products – must understand these concepts. The same demands fall on securities experts and business executives in the life sciences arena.

Products liability and patent litigation concerning these products often hinges on what happened during the pre-approval, approval, or post-approval periods.

However, many products liability lawyers, patent counsel, and business and investment experts — despite their tenure in working with FDA-regulated products — are not well-versed in the essentials of the approval process and the regulatory hurdles of the post-approval period.

Boost your FDA regulatory IQ.
Learn about the FDA approval process and the ins and outs of post-approval challenges.

ACI's FDA Boot Camp 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 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
  - OTC approval
  - 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.

Attend this conference and learn to navigate your way through the regulatory maze that plays such a crucial role to your cases and practice areas. *Seats at the March 2008 New York FDA Boot Camp sold out weeks before the conference*. 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

A "Who's Who of the FDA Bar":

Co-Chairs:

Scott M. Lassman
Partner
WilmerHale

Grail Walsh Sipes
Partner
Covington & Burling LLP

Speakers:

Aaron F. Barkoff, Ph.D
Partner
McDonnell Boehnen Hulbert & Berghoff LLP

Sheldon T. Bradshaw
Partner
Hunton & Williams LLP

Laurie A. Clarke
Partner
King & Spalding LLP

Patrick J. Concannon
Counsel
Edwards Angell Palmer & Dodge LLP

Robert A. Dormer
Director
Hyman, Phelps & McNamara, P.C.

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Kleinfeld, Kaplan & Becker, LLP

Ralph F. Hall
Counsel
Baker & Daniels LLP

William D. Hare
Legal Director
Concentrx Biosciences, Inc.

Chad A. Landmon
Partner
Axinn, Veltrop & Harkrider LLP

Joseph J. Leghorn
Partner
Nixon Peabody LLP

Erika Lietzan
Partner
Covington & Burling LLP

Alan G. Minsk
Partner
Arnall Golden Gregory LLP

Robert B. Nicholas
Partner
McDermott Will & Emery LLP

Neil F. O'Flaherty
Principal
Olsson Frank Weeda Terman Bode Matz PC

Carmen Shepard
Partner
Buc & Beardsley

William W. Vodra
Senior Counsel
Arnold & Porter LLP

Donald R. Ware
Partner
Foley Hoag LLP

Day One – Monday, September 22, 2008

7:45 Registration and Continental Breakfast

8:45 Co-Chairs' Opening Remarks

Scott M. Lassman
Partner
WilmerHale
(Washington, DC)

Grail Walsh Sipes
Partner
Covington & Burling LLP
(Washington, DC)

9:00 The Basics: Understanding and Working with the FDA — Jurisdiction, Functions, Organization, and Operations

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

- FDA Overview
- How the FDA is 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
  - Food Drug & Cosmetic Act and FDA Amendments Act of 2007
  - Prescription Drug Marketing Act
  - Public Health Services Act
  - Hatch-Waxman Act
  - other applicable laws
- Defining drugs, biologics, and medical devices
- Labeling: when is a drug a drug and not a medical device or cosmetic, and the consequences
- Defining combination products
- Working with the FDA
  - Administrative Procedures Act
  - formal and informal dispute resolution mechanisms
- FDA's policies and procedures

10:00 Morning Coffee Break

Preapproval and Approval

10:15 The Nature of the Approval Process

Erika Lietzan
Partner
Covington & Burling LLP
(Washington, DC)

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)

Biological Products

- What are biological products?
- What does it mean to say that they are also "drugs"?
  - which "new drugs" require BLAs instead of NDAs?
- 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

OTC Products

- The concept of "OTC" (OTC-ness)
- The OTC Review
  - which drugs are covered?
  - what is a "monograph"?
  - what does a monograph contain?
  - what if you want to deviate from the monograph (innovate)?
- When is a new drug suitable for OTC?
  - when must a drug be Rx only?
  - how do you switch a new drug from Rx to OTC?
  - can a new drug be Rx in some forms/dosages/etc., and OTC in others?
- Overview of how an OTC drug comes to market
  - if it's a new drug
  - if it's not a new drug

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11:15 Understanding the Clinical Trial Process for Drugs and Biologics

Scott M. Lassman
Partner
WilmerHale
(Washington, DC)

- Overview of the clinical trial process
  - phases of testing (I-IV)
  - which are mandatory?
  - what happens in each phase?
  - who conducts the testing?
  - special considerations for Phase IV testing
- Regulatory requirements
  - informed consent
  - IRBs
  - sponsor obligations
  - investigator obligations
- FDA authority
- Other issues
  - CROs
  - 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

12:15 Networking Luncheon

1:25 Patent and IP Overview: Hatch-Waxman, Trade Dress, and More

Carmen Shepard
Partner
Buc & Beardsley
(Washington, DC)

William D. Hare
Legal Director
Concentrx Biosciences, Inc.
(Princeton, NJ)

Patrick J. Concannon
Counsel
Edwards Angell Palmer & Dodge LLP
(Boston, MA)

IP Protection

- Analyzing the patenting process
- Seeking patent protection during the pre-approval process
- Making up for time lost in the patent life cycle during the pre-approval process
  - IP and regulatory redress for lost time
- 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

Drugs

- NDA v. ANDA (Abbreviated New Drug Application)
  - how do they differ?
- ANDA
  - 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
- The patent end game (Hatch-Waxman Overview)
  - overview of Hatch-Waxman and reforms under MMA
  - the Orange Book
  - exclusivity (180 day)
  - 30-month stay
  - patent extensions
  - the safe harbor
- FD&C 505b2 (an alternate pathway to an ANDA)

Trademark Issues

- Identifying the PTO and FDA clearances necessary for trade name/trademark approval on your product

2:45 Afternoon Refreshment Break

3:00 Drugs and Biological Products: Labeling

Sheldon T. Bradshaw
Partner
Hunton & Williams LLP
(Washington, DC)

The labeling of the drug/biological product 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?
- How is the labeling a defense in products litigation?

POST-APPROVAL

4:00 cGMPs: Drugs and Biologics (current Good Manufacturing Practices)

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

- The elements of cGMPs and the importance of cGMPs in pharmaceutical/biological product commercialization
- Examining the FDA's authority to inspect for cGMP compliance

- How companies handle cGMP inspections
- What you need to know about inspection of drug manufacturing facilities outside of the U.S.
- Examining 483s and their aftermath
- How are cGMPs factoring into products litigation?

5:00 **Conference Adjourns**

Day Two – Tuesday, September 23, 2008

7:30 **Continental Breakfast**

8:00 **Co-Chairs' Opening Remarks**

Post-Approval Bifurcated Tracks Choose One

Patent Track

Advanced Life Cycle Considerations

8:10 **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
- FD&C 505b2 (alternate pathway to ANDA)
- 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

9:10 **Bioequivalence: What Patent Lawyers Need to Know**

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

- Defining bioequivalence
- What an ANDA-filer must demonstrate for bioequivalence
- Challenging bioequivalence standards and determinations
- How does bioequivalence relate to patents?
  - patenting of bioequivalence characteristics – extended-release drug products
  - impact of FDA's bioequivalence rules on claim construction
  - bioequivalence and infringement
  - invalidating bioequivalence claims in Paragraph IV patent litigation
    - anticipation, obviousness and written description arguments

9:55 **Morning Coffee Break**

10:10 **Follow-On (Comparable or Biosimilar) Biologics**

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

- How are biologic drugs different for purposes of generic competition?
- When can FDA approve a follow-on biologic under current law?
- What does the Omnitrope approval say about FDA's views on follow-ons?
- What kind of abbreviated approval route for biologics is being considered in Congress?
- Will follow-on biologics ever be interchangeable with the innovators they copy?
- What data exclusivity provisions will apply to innovators under the proposed legislation?
- What will be the process for patent challenges by follow-on applicants?

Products Litigator Track

Post-Approval Marketing Guidance

8:10 **Advertising and Promotion**

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

- Overview of laws and regulations controlling the advertising, marketing, and promotion of prescription drugs and biologics
  - 21 CFR Sections 202.1, 352(n), 314.81(b)(3); Section 352(n) of FD&CA
  - guidance documents
- DDMAC (Division of Drug Marketing, Advertising and Communications)
  - what duties and responsibilities is DDMAC charged with?
  - what are its enforcement capabilities and jurisdiction?
- Identifying the role of the FTC in the advertising and promotion of drugs
- Advertising requirements for prescription v. nonprescription products
- Reviewing the steps which DDMAC takes for the review of launch campaigns and promotional materials
  - overview of the promotional materials submission and review process
  - FDAAA provisions concerning review of electronic media advertisements
- What constitutes a launch?
- What defines an advertisement and any elements that it must include?
- Exploring the role of the label in advertising

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9:10 Special Concerns for DTC Advertising

Daniel R. Dwyer
Partner
Kleinfeld, Kaplan & Becker, LLP
(Washington, DC)

- How is direct-to-consumer advertising regulated and monitored?
  - how is it different from other pharmaceutical advertising?
- What information must every DTC ad contain?
- How do the PhRMA DTC guidelines interplay with current FDA regulation?
- Advertising and new media
  - how is Internet and e-mail advertising regulated?

9:55 Morning Coffee Break

10:10 Regulation and Dissemination of Off-Label Information

Alan G. Minsk
Partner
Arnall Golden Gregory LLP
(Atlanta, GA)

- 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 v. ghost-writing
  - MSLs v. 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

POST-APPROVAL (CONT'D)

10:55 Adverse Events Monitoring, Pharmacovigilance and Risk Management

William W. Vodra
Senior Counsel
Arnold & Porter LLP
(Washington, DC)

- What is pharmacovigilance?
- How pharmacovigilance uses adverse event reports
  - how ADE reports come to a company
    - solicited direct reports
    - unsolicited direct reports
    - indirect reports
  - how companies investigate, analyze and use ADE reports
    - causality assessments
    - labeling changes
  - requirements for reporting ADEs to regulatory agencies
    - premarket stage
    - post-market stage
  - how regulatory agencies use ADE reports
- 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

11:55 Networking Luncheon

MEDICAL DEVICES

1:05 Medical Devices: Classification and the Essentials of the Device Premarket Review Process

Grail Walsh Sipes
Partner
Covington & Burling LLP
(Washington, DC)

FDA's Risk-Based Classification Scheme for Medical Devices

- Understanding the concept of risk-based classification
- Three main classes of medical devices
  - Class I: "low risk" devices, e.g., orthopedic blade, tongue depressor
  - Class II: "moderate risk" devices, e.g., powered wheelchair, endoscope
  - Class III: "high risk" devices, e.g., cardiac ablation catheters, drug eluting stents
- Device reclassification

The Premarket Review Process for Medical Devices

- 510(k) exemptions for low risk devices
- Premarket notification (510(k)) process
  - understanding the selection of "predicate" devices when 510(k) submissions are made and the consequences of choosing the wrong predicate
- Premarket approval (PMA) process
- The role of the Investigational Device Exemption (IDE)

2:05 Post-Market Requirements and Concerns for Medical Devices

Ralph F. Hall
Counsel, Baker & Daniels LLP (Indianapolis, IN)
Distinguished Visiting Practitioner and Professor, University of Minnesota Law School (Minneapolis, MN)

- What types of facilities must comply with FDA's establishment registration and device listing requirements?
- What is the scope of the Quality System Regulation (QSR)?
- What types of adverse events must be reported under the Medical Device Reporting (MDR) regulation?
- What kinds of field actions must be reported under the Reports of Corrections and Removals regulation?
- What other types of postmarket requirements can FDA impose on medical devices, e.g., tracking?

3:05 Afternoon Refreshment Break

3:20 Medical Device Labeling and Advertising

Laurie A. Clarke
Partner
King & Spalding LLP
(Washington, DC)

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

Recalls and Withdrawals

4:05 Recall Guidance for Drugs, Biologics, and Medical Devices: What You Need To Know

Neil F. O'Flaherty
Principal
Olsson Frank Weeda Terman Bode Matz PC
(Washington, DC)

- 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 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 preventive action
- What are the consequences of not instituting a recall?
- FDA seizure and injunction power
- When can product be reintroduced to the market?

5:05 Conference Ends

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Attorneys for the pharmaceutical, biotech, and medical device industries whose practices focus on:

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- Patent litigation
- Patent prosecution

In-house counsel for the pharmaceutical, biotech, and medical device industries with responsibility for:

- Litigation
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FDAAA is one of the most comprehensive revisions of the FFDCA in decades and Congress is pushing new safety initiatives and import reforms. The nation's top Food and Drug attorneys will **drill you in the basics of FDA law and regulation – including the nuances of FDAAA at:**

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