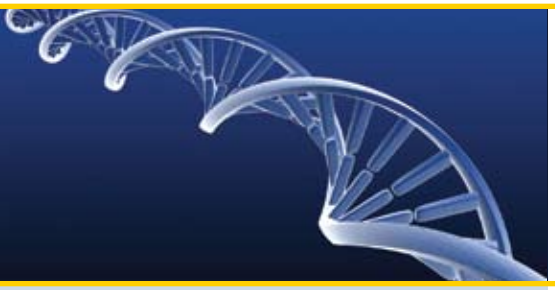
August 25-26, 2010 | Sheraton Fisherman's Wharf, San Francisco, CA

# FDA BOOT CAMP

## Basic Training for Products Liability and Patent Lawyers



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*Brian J. Malkin*
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(New York, NY)

### SPECIAL TRACKS:

**Patent Track**

- Non-Patent Exclusivity
- Bioequivalency

**Products Litigator Track**

- Off-Label Use
- Examination of Regulatory Experts

A Who's Who of the nation's Food and Drug bar will drill you in **the basics of FDA law** and regulation as they help you:

- MASTER the complexities of **pharmaceutical IP** and the regulatory balance between brand name and generic products
- ANALYZE the future of **follow-on biologics** following recent health care reform legislation
- 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
- EVALUATE when **preemption** arguments may offer protection for life sciences companies
- ASSESS what marketing activities may constitute **off-label promotion**
- NAVIGATE the protocols of **adverse events** reporting
- DEVELOP a practical working knowledge of **clinical trials** for drugs and biologics and the clearance process for devices

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American Conference Institute

# FDA BOOT CAMP



## 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. Recent court cases and high-profile litigation concerning FDA-regulated products have made it clear that 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.

**Products liability and patent litigation concerning FDA-regulated 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.

### Boost your FDA regulatory IQ.

### Understand the FDA approval process and the ins and outs of post-approval challenges.

**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.

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
- Preemption arguments currently being debated by the courts
- Proactive adverse events monitoring
- Regulation of advertising and particular concerns relating to off-label promotion

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

Attend this conference and learn to navigate the regulatory concepts that play such a crucial role in your practice area. **This program has sold out twice recently in New York** and is rarely offered on the West Coast. Register today by calling **1-888-224-2480**, faxing your registration form to **1-877-927-1563**, or going online at: **www.AmericanConference.com/FDABootCampSF**

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Foley & Lardner LLP (San Francisco, CA)

***Stephen A. Wood***
Partner
Kelley Drye & Warren LLP (Chicago, IL)



## Day One: Wednesday, August 25, 2010

8:15 **Registration and Continental Breakfast**

9:00 **Chair's Opening Remarks**

*Brian J. Malkin*
Partner
Frommer Lawrence & Haug LLP (New York, NY)

9:15 **The Basics: Understanding and Working with the FDA — Jurisdiction, Functions, Organization, and Operations**

*Natasha Lekovsek*
Partner
Cooley Godward Kronish 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
- Defining drugs, biologics, and medical devices
- Emerging and expanding technologies
  - 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
- Working with the FDA
  - Administrative Procedures Act
  - formal and informal dispute resolution mechanisms
- FDA's policies and procedures

10:20 **Morning Coffee Break**

## Preapproval and Approval

10:30 **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 do 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

11:30 **Understanding the Clinical Trial Process for Drugs and Biologics**

*Ben Haas*
Partner
Latham & Watkins LLP (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
- Global clinical trials: overview of FDA regulation for trials conducted overseas

12:30 **Networking Luncheon**

## 1:45 Patent and IP Overview: Hatch-Waxman, Trade Dress, and More

***Lisa A. Haile, Ph.D.***
Partner and Co-Chair, Global Life Sciences Sector
DLA Piper LLP (San Diego, CA)

***Jonathan A. Harris***
Partner
Axinn Veltrop Harkrider LLP (Hartford, CT)

***Robin M. Silva***
Partner
Morgan, Lewis & Bockius LLP (San Francisco, CA)

IP Protection for Drugs and Biologics
- 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)

Biologics
- Identifying biologics that fall within the purview of Hatch-Waxman
  - understanding why other biologics fall outside of the Hatch-Waxman rubric
- Examining the FDA's current position on an abbreviated application process for generic biologics

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

3:00 **Afternoon Refreshment Break**

## 3:15 Spotlight on Follow-On (Comparable or Biosimilar) Biologics and the 2010 Health Care Reform Legislation

***Madison C. Jellins***
Partner
Alston & Bird LLP (Palo Alto, CA)

- 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?
- Review of the Omnitrope approval–what does it say about FDA's views on follow-ons?
- Detailed analysis of the provision in the Health Care Reform Bill creating a pathway to enable the FDA to approve biosimilars
  - approval pathway
  - clinical standards
  - safety
  - interchangeability and substitutions
  - postmarket requirements
  - public process
  - exclusivity provisions

## 4:00 Drugs and Biologics: Labeling

***Julie A. Dykstra***
Of Counsel
Barnes and Thornburg LLP (Grand Rapids, MI)

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?

4:45 **Conference Adjourns to Day Two**



## Day Two: Thursday, August 26, 2010

8:15 **Continental Breakfast**

8:45 **Opening Remarks**

## Post-Approval

9:00 **Marketing and Promotion**

***Caryn McDowell***
Senior Corporate Counsel
Genentech, Inc (South San Francisco, CA)

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

Advertising and Promotion Overview

- 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
  - SEC?
- 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
- What constitutes a launch?
- What defines an advertisement?
  - what information must a drug advertisement include?
- Exploring the role of the label in advertising

Special Concerns for DTC Advertising

- 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?
- FDA's DTC Television User Fee Program
- Advertising and new media
  - how is Internet and e-mail advertising regulated?
  - application of FDA guidance to evolving social networking sites

10:00 **Morning Coffee Break**

10:15 **Preemption Fundamentals**

***Stephen A. Wood***
Partner
Kelley Drye & Warren LLP (Chicago, IL)

- Defining express and implied preemption
- Recognizing the basis for drug and device preemption
- Uncovering how the presumption against preemption has been applied in drug and device litigation
- Recognizing the interplay between preemption and the FDA regulatory process
- Emerging precedents: *Riegel v. Medtronic* and *Wyeth v. Levine*
- Understanding the "parallel requirements" exception to preemption

## Bifurcated Tracks – Choose One

### Patent Track

11:00 **Non-Patent Exclusivity**

***Brian J. Malkin***
Partner
Frommer Lawrence & Haug LLP (New York, NY)

- 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

12:00 **Bioequivalence: What Patent Lawyers Need to Know**

***Emily A. Evans***
Partner
Morrison & Foerster LLP (Palo Alto, CA)

- Defining bioequivalence in drugs and biologics
  - drugs v. 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 v. Doctrine of Equivalents – what is the difference?
  - arguments about bioequivalence raised in Paragraph IV patent litigation
    - infringement, copying (non-obviousness)

### Products Litigator Track

11:00 **Regulation and Dissemination of Off-Label Information**

***Judith A. Waltz***
Partner
Foley & Lardner LLP (San Francisco, CA)



- 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
- How allegations of improper off-label activity can become the bases of personal injury actions

11:45 **Examination of Regulatory/FDA Experts**

***Genese K. Dopson***
Partner
Wilson Elser Moskowitz Edelman & Dicker LLP
(San Francisco, CA)

Direct Examination

- Making the most of the direct of the FDA expert: getting him/her to explain the extensive regulatory process and the agency's extensive authority
- Utilizing the expert to set forth the label review and approval processes
- Handling problematic FDA evidence

Cross-Examination

- Using the plaintiff's regulatory/FDA expert to:
  - establish the credibility of the FDA
  - establish the pervasiveness of FDA review/oversight
  - establish yourself as knowledgeable
- Showing that the expert's direct testimony lacks focus with respect to the issues in the case
- Exploring the basis of the expert's opinions

12:45 **Networking Luncheon**

2:00 **Adverse Events Monitoring, Pharmacovigilance and Risk Management**

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

***C. Stephen Lawrence***
Partner
Hogan & Hartson LLP (Irvine, CA)

- 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

3:00 **Afternoon Refreshment Break**

## Medical Devices

3:15 **Medical Device Essentials: Premarket and Post-Market Requirements**

***Elaine H. Tseng***
Partner
King & Spalding LLP (San Francisco, CA)

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"
  - Class II: "moderate risk"
  - Class III: "high risk"
- 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)

Post-Market Requirements and Concerns

- 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 kinds of field actions must be reported
- What other types of post-market requirements can FDA impose on medical devices, e.g., tracking?

Labeling and Advertising

- What are the differences between labeling and adverting 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 manufacturers convey information about new uses to health care professionals and/or consumers?
- What are the consequences of illegal promotion of a device?

4:30 **Conference Ends**



## Who You Will Meet

- ✓ Attorneys for the pharmaceutical, biotech, and medical device industries whose practices focus on:
  - Products liability litigation
  - Patent litigation
  - Patent prosecution
- ✓ In-house counsel for the pharmaceutical, biotech, and medical device industries with responsibility for:
  - Litigation
  - Patents and IP
- ✓ Securities Attorneys with practices in pharmaceuticals, biotech and device
- ✓ Investment Bankers and Venture Capitalists with practices in pharmaceuticals, biotech and device

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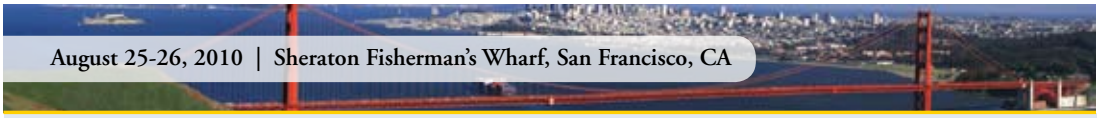

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## SPECIAL TRACKS:

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### Products Litigator Track

- Off-Label Use
- Examination of Regulatory Experts

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