American Conference Institute's 26th

FDA BOOT CAMP

Basic training in core regulatory concepts for life sciences lawyers, business executives, scientists, and policy analysts

September 30 – October 1, 2015 ⟩⟩ Hilton Boston Back Bay ⟩⟩ Boston, MA

Our prior delegates say it best:

"Comprehensive overviews; invaluable resource; anticipate referencing slides often; good information."

- Heather S. Brown, Corporate Counsel
Pfizer Inc. (prior delegate)

"Very efficient, effective speakers."

- Jon Richards, Product Manager
MBL International, Inc. (prior delegate)

"Presentations were relevant & on topic."

- Rebecca Miller-Larson, Counsel
Sunovion Pharmaceuticals, Inc. (prior delegate)

"This was an excellent CLE. Highly informative!"

- Matthew Molloy, Attorney
Dinsmore & Shohl LLP (prior delegate)

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

Earn CLE ETHICS Credits

- ☆ MASTER the basics of the **application and approval processes** for drugs, biologics and devices
- ☆ COMPREHEND the structure of the **FDA** and the roles of the three major agency centers: **CDER**, **CBER**, and **CDRH**
- ☆ 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
- ☆ APPRECIATE 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
- ☆ SEE the importance of **cGMPs** to the post-approval regulatory process
- ☆ NAVIGATE the protocols of **adverse events** monitoring, signal detection, product withdrawals, and **recalls**

Pre-Conference Workshop	Interactive Post-Conference Master Classes: In depth Hatch-Waxman, BPCIA, and Post-Approval Concerns	
Workshop A:	**Master Class B:**	**Master Class C:**
Fundamentals of FDA Regulatory Law	**Hatch-Waxman and BPCIA: Overview of Biosimilars and Life Cycle Planning for Drugs and Biologics**	**Post-Approval Marketing Guidance and Preemption Protocols**

Now in its 26th iteration, FDA Boot Camp is the premier event that will provide you with the ultimate roadmap to the complicated landscape of FDA regulatory law

ACI's FDA Boot Camp has been designed by leading regulatory attorneys to give professionals that work in conjunction with the pharmaceutical, biologics, and medical devices industries — such as products or patent litigators, as well as patent prosecutors, industry in-house counsel, and life sciences investment and securities experts — a strong working knowledge of core FDA 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
  - 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 biologics approval process
- cGMPs and other manufacturing concerns relative to products liability
- Proactive adverse events monitoring and signal detection
- Recalls, product withdrawals, and FDA oversight authority

Attend the pre-conference workshop or post-conference master classes to get the background and/or the in-depth information you need to maximize your learning and networking experience at this event!

Workshop A: Fundamentals of FDA Regulatory Law will address topics to set the stage for the main conference by helping you thoroughly comprehend the structure of the FDA and the essentials of the pre-approval, approval, and post-approval process. Get the background you need to flow seamlessly into the conversations at FDA Boot Camp.

Master Class B: Hatch-Waxman and BPCIA: Overview of Biosimilars and Life Cycle Planning for Drugs and Biologics will provide an in-depth overview of biosimilars as well as analyses of bioequivalency and exclusivities and their role in patent and product life cycle management.

Master Class C: Post-Approval Marketing Guidance and Preemption Protocols will address issues that arise post-approval, including advertising, promotion, and off-label promotion and enforcement, as well as preemption fundamentals.

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 prior iterations of ACI's FDA Boot Camp sold out.* Don't delay — register now by calling 1-888-224-2480, faxing your registration form to 1-877-927-1563, or registering online at www.AmericanConference.com/FDABootCampBos.

I look forward to seeing you in Boston this September!

Very truly yours,

Christopher J. Soverow, Esq.
Conference Director & Legal Analyst

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Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education requirements. This course is identified as transitional as well as non-transitional for the purposes of CLE accreditation.

ACI certifies that the activity has been approved for CLE credit by the New York State Continuing Legal Education Board. Additional credit hours (including ethics) will apply to participation in workshop A. Additional credit hours will apply to participation in Master Class B or C.

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PRE-CONFERENCE WORKSHOP
Tuesday, September 29, 2015 ⟩⟩ 1:00 p.m.

A

FDA Regulatory Fundamentals 101 with Ethics Session

Daniel A. Kracov
Partner
Arnold & Porter LLP

1:00

Fundamentals of FDA Regulatory Law

Aimed at providing a primer to professionals who have limited or no experience working with FDA on regulatory matters, this workshop will provide you with a basic overview of FDA regulations and will prepare you for the more in-depth discussions that will take place throughout the conference. Topics addressed during this workshop will set the stage for the main conference by helping you thoroughly comprehend the structure of the FDA and walk you through the pre-approval, approval, and post-approval process. Get the background you need to flow seamlessly into the conversations at FDA Boot Camp.

Topics to include:

- FDA Mission
- FDA Organization
- History of FDA Laws
- Acronyms and Terminology
- Clinical Trials Process
- Types of New Drug Applications
- The Review Process
- The Hatch Waxman Act
- Legal Barriers to Approval
- Biological Products
- The Basics of Device classification and approval
- Post-marketing issues and enforcement, including recalls

4:00

Resolving Ethical Challenges Encountered During the Drug Approval Process

This one hour program will explore ethical issues that may arise in the context of communications with FDA on behalf of clients. The program is based on scenarios involving situations in which FDA requires full disclosure of adverse information and authority. For example:

(1) In the context of citizen petitions FDA requires certification that the petition includes all information and views on which the petition relies as well as data and information known to the petitioner which is unfavorable to the petitioner. 21 CFR 10.30. The discussion will cover the implications of that certification upon an attorney in light of Rules 1.6, 1.7 and 1.8 of the Rules of Professional Responsibility.

(2) In the context of an Advisory Committee meeting at which counsel is present, Committee members ask whether all data regarding adverse events have been reported to FDA. The discussion will cover the implications of the lawyer's participation in light of the requirements of Rules 1.3, 3.4, and 4.1.

(3) Your client has retained a former FDA official and tells you that he will be contacting FDA to discuss a pending NDA. The discussion will cover the implications of Rule 1.11.

MAIN CONFERENCE DAY 1
Wednesday, September 30, 2015

8:00 **Registration and Continental Breakfast**

8:30

Co-Chairs' Opening Remarks and Brief Overview of FDA Practice

Kurt R. Karst
Director
Hyman, Phelps & McNamara, P.C.

Scott M. Lassman
Partner
Kleinfeld Kaplan & Becker LLP

Preapproval and Approval

8:45

The Nature of the Approval Process

David G. Adams
Partner
Venable LLP

Seth A. Mailhot
Partner
Michael Best & Friedrich LLP

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
  - what you need to report when researching a drug in terms of adverse events
- 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)
- Different uses of the REMS process in new drug approvals

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

10:00 **Understanding the Clinical Trial Process for Drugs and Biologics**

Daniel A. Kracov
Partner
Arnold & Porter LLP

- 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
  - inspections
  - refusal to accept data
  - clinical hold
  - disqualification of irb and/or investigator
- Other issues
  - CROs
  - SMOs
  - 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

11:15 **Morning Coffee Break**

11:30 **Drugs and Biologics: Labeling**

Alan G. Minsk
Partner
Arnall Golden Gregory LLP

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?
- When can punitive damages may be rewarded with respect to labeling
- Assessing the impact of labeling on reimbursement

12:30 **Networking Luncheon**

Patent and IP Overview for Drugs and Biologics: Understanding The Connection Between FDA Regulation and IP and Related Mechanisms Under Hatch-Waxman and BPCIA

1:45 **Part 1 — Patents, Trademarks and Other IP Protections and Mechanisms**

Jill K. MacAlpine, Ph.D.
Partner
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Donna M. Meuth
Associate General Counsel Intellectual Property
Eisai Inc.

Patent Protection for Drugs and Biologics

- Summarizing the patenting process for drugs and biologics
- Strategies for building patent protection drugs and biologics
- Seeking extension of patent term for time spent in the drug approval process (Patent Term Extension, Supplemental Protection Certificates), and/or time spent obtaining a patent at the United States Patent Office (Patent Term Adjustment)
- 271(e)(1) "safe harbor"
- Identifying the respective roles of the FDA and the PTO in the patenting of drugs and biological products

Trademarks, Trade Names, and Trade Dress

- The art and science of selecting a brand name for a proposed drug product
  - how does the branding process work for your product?
- Understanding the respective roles of the USPTO and FDA in the drug naming process
- Identifying the PTO and FDA clearances necessary for trade name/trademark approval on your product
- Appreciating the use of trade dress as a means of IP protection for drug products

3:00 **Afternoon Refreshment Break**

3:15 **Part 2 — Hatch-Waxman and BPCIA Overview**

Kurt R. Karst
Director
Hyman, Phelps & McNamara, P.C.

Scott M. Lassman
Partner
Kleinfeld Kaplan & Becker LLP

Drugs

- Comparing the NDA, 505(b)(2) and ANDA (Abbreviated New Drug Application) drug approval routes
- ANDA filing: what does the FDA require?
- Showing bioequivalence in an ANDA
- ANDA Paragraph IV Certification, and response to Notice Letters
- The role of the Orange Book in the drug approval process: what is it and why is it Orange?
  - listings and de-listings
  - use codes

- importance of Orange Book listing
- Regulatory Exclusivity (FDA)
  - regulatory (data) exclusivity
    - NCE (new chemical entity)
      - 5 years marketing exclusivity
      - 5 years data exclusivity
    - indication (new indication or use)
      - 3 years marketing exclusivity
    - NDF (new dosage formulation)
    - ODE (orphan drug exclusivity)
    - PED (pediatric exclusivity)
  - overview of Hatch-Waxman and reforms under MMA
  - the role of Orange Book under Hatch-Waxman vis-à-vis the MMA
    - 30-month stay
    - patent extensions
    - ANDA-filer exclusivity (180 day)

Biologics

- Identifying products approved/regulated as biologics
- Overview of biosimilar (FOB) legislation and regulations
  - Title VII of the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148), i.e., Biologics Price Competition and Innovation Act of 2009 (BPCIA)
- The rationale for safety and efficacy concerns surrounding second generation biologics

Exclusivity for Combination Products

- Status and review of Combination Drug Development Incentive Act of 2013 (H.R. 2985)
- Exploring exclusivities for combination products comprised of two new Orange Book listed drugs
  - review of necessary criteria for each of the component drugs to receive 5 year NCE exclusivity
  - Gilead (Stribild) Ferring (Prepopik) and Bayer (Natazia) Citizens Petitions
- What are the available exclusivities for a combination product comprised of two old Orange Book listed drugs?
- What exclusivity protections are afforded to a combination product comprised of a new and old Orange Book listed drug?
- What of available exclusivities for combination products comprised of:
  - an Orange Book listed drug and device?
  - an Orange Book listed drug and biological product?

4:45 **Using FDA's Citizen Petition Process and Litigation to Achieve Market Success**

James A. Boiani
Member
Epstein Becker & Green

- Overview of FDA's Citizen Petition process
- Market exclusivities and other issues that can be addressed in a petition
- Maximizing your chance of success before FDA
- To sue or not to sue FDA
- Strategies for prevailing in Court against FDA
- Recent court decisions involving FDA issues
- Taking the pulse of the FTC and being mindful of anti-trust litigation

5:30 **Conference Adjourns to Day Two**

Day Two: Thursday, October 1, 2015

7:30 **Registration and Continental Breakfast**

8:00 **Co-Chairs' Opening Remarks and Recap of Day One**

Post-Approval

8:15 **cGMPs: Drugs and Biologics (current Good Manufacturing Practices)**

Carol A. Poindexter
Partner
Norton Rose Fulbright

- Examining cGMPs (current Good Manufacturing Practices) 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
- How are laboratory investigations in relation to cGMPs conducted?
- Defining the term "quality systems"
- How are cGMPs factoring into products litigation?
- Evaluating the cost of enforcement actions: what happens to company stock when there is an announcement of an enforcement action?

9:00 **The Drug Supply Chain Act — Summarizing the Act and Its Effect on FDA Practice**

Michael A. Walsh
Partner
Strasburg & Price LLP

- Overview of the Drug Supply Chain Act (Title II of the Drug Quality and Security Act of 2013)
- Identifying pharmaceuticals that fall within the purview of the act
- Outlining obligations to create a unique product identifier
- Establishing tracing and monitoring systems
- Developing detection and response protocols regarding counterfeit materials
- Understanding notification obligations
- Evaluating the effect of the act on the recall process

10:00 **Morning Coffee Break**

Medical Devices

10:15 **Medical Devices: Classifications, the Essentials of the Premarket Review Process, and Post-Market Requirements and Concerns**

Maya P. Florence
Partner
Skadden, Arps, Slate, Meager & Flom LLP

Gael Diane Tisack
Terumo Cardiovascular Group Vice President of Legal Affairs & Terumo Americas Vice President of Intellectual Property

FDA's Risk-Based Classification Scheme

- Understanding the concept of risk-based classification
- Three main classes of medical devices
- Device reclassification

The Premarket Review Process

- Potential changes to 510(k) process and changes to diagnostics
  - Should Class II medical devices be split in 2 with 510k-heavy and 510k-lite
- 510(k) exemptions for low risk devices and the role of the Investigational Device Exemption (IDE)
- 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

Post-Market Requirements and Concerns

- What is the scope of the Quality System Regulation (QSR)?
- What are the reporting requirements under the Medical Device Reporting (MDR) and Reports of Corrections and Removals regulations?
- What other types of post-market requirements can FDA impose on medical devices, e.g., tracking?
- What claims can device manufacturers make regarding cleared/approved devices, devices with pending 510(k) notices, and investigational devices?
- What are the consequences of illegal promotion of a device?

11:30 **Adverse Events Monitoring, Pharmacovigilance, Risk Management, and Recalls**

Christina M. Markus
Partner
King & Spalding

- What is pharmacovigilance?
- How pharmacovigilance uses adverse event reports
  - direct versus indirect reports
  - causality assessments
  - labeling changes
  - pre- and post-market ADE reporting requirements
  - how regulatory agencies use ADE reports
- Risk Evaluation and Minimization Strategies (REMS)
- Risk evaluation in the approval process
- Risk minimization tools
- Enforcement of ADE reporting and REMS requirements
- Examining the relevance to product liability risks, including innovator and co-promoter liability risks
- What is FDA's recall and oversight authority (overview of 21 CFR Part 7)?
  - guidance versus regulation
  - voluntary versus mandatory recalls
  - market withdrawals and stock recoveries
- Interaction between recalls and corrective and preventive action

12:15 **Conference Concludes***

Post-Conference Master Classes: Thursday, October 1, 2015 ⟩⟩ 1:00 p.m. – 5:00 p.m.

In-Depth Symposia on Hatch-Waxman, BPCIA, and Post-Approval Concerns

These concurrent workshops build on content covered during the main conference relative to Hatch-Waxman, BPCIA, post-approval marketing, and preemption. These detailed master classes will provide enhanced information specific to the intersection of IP and regulatory law, and to litigation and compliance matters, and also help you thoroughly comprehend the complexities and nuances of these areas of regulatory law

- Master Class B: **Hatch-Waxman and BPCIA: Overview of Biosimilars and Life Cycle Planning for Drugs and Biologics** will provide an in-depth overview of biosimilars as well as analyses of bioequivalence and exclusivities and their role in patent and product life cycle management.
- Master Class C: **Post-Approval Marketing Guidance and Preemption Protocols** will address issues that arise post-approval, including advertising, promotion, and off-label promotion and enforcement, as well as preemption fundamentals.

B Hatch-Waxman and BPCIA: Overview of Biosimilars and Life Cycle Planning for Drugs and Biologics

1:15 **Biosimilars**

Scott M. Lassman
Partner
Kleinfeld Kaplan & Becker LLP

- Overview of Title VII of the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148), i.e., Biologics Price Competition and Innovation Act of 2009 (BPCIA)
- Biosimilar pathway vs. 505(b)(2) and BLAs
- Defining "biological" and "biosimilars" under BPCIA
- Exploring interchangeability requirements
- Understanding the significance of the methods of making claims in this legislation
- Examining the effect of this abbreviated approval pathway on innovation

C Post-Approval Marketing Guidance and Preemption Protocols

1:15 **Advertising and Promotion**

Edward F. Glynn, Jr.
Partner
Locke Lord LLP

Advertising and Promotion Overview

- Overview of laws and regulations controlling the advertising, marketing, and promotion of prescription drugs and biologics
- Office of Prescription Drug Promotion (OPDP) — duties, responsibilities, and enforcement authority
- Evaluating the new guidance on internet promotions and use of social media
- Consumer fraud class action litigation
- Identifying the role of the FTC in the advertising and promotion of drugs

- A look at FDA Rule making and guidance relative to biosimilars
- How will biosimilars fit in with life cycle strategies?
  - targeting R&D efforts
  - re-examining prosecution efforts
  - anticipating vulnerable patents and litigation

2:30 **Bioequivalence and the "Same Active Ingredient" vis-à-vis Patentability**

Donna M. Meuth
Associate General Counsel Intellectual Property
Eisai Inc.

- Defining bioequivalence in drugs and biologics
- What must an ANDA-filer demonstrate for bioequivalence?
- Exploring bioequivalency under a biosimilar pathway pursuant to BPCIA
- 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)

3:30 **Afternoon Refreshment Break**

3:45 **Marketing Exclusivities (Non-Patent): Challenges, Opportunities, and Current Controversies**

Kurt R. Karst
Director
Hyman, Phelps & McNamara, P.C.

There are a number of different modes and methods of exclusivity (non-patent). This session will outline what they are and what challenges, opportunities, and current controversies arise in relation to them, including the role that the FDA plays in regulating these modes of exclusivity. Modes and methods of exclusivity to be discussed include:

- Orphan Drug Exclusivity (7 years)
- New Chemical Entity Exclusivity (5 years)
- New Clinical Study Exclusivity (3 years)
- Pediatric Exclusivity (6 months)
- First Generic Applicant Exclusivity (180 days)
- New Antibiotic Exclusivity

5:00 **Master Class B Concludes**

- Advertising requirements for prescription versus nonprescription products
- Overview of the promotional materials submission and review process
- What constitutes a launch?
- What information must a drug advertisement include?
- Exploring the role of the label in advertising and the perils of off-label promotion

Special Concerns for DTC Advertising

- How is direct-to-consumer advertising regulated and monitored?
- 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?

2:30 **Regulation and Dissemination of Off-Label Information**

Carol A. Poindexter
Partner
Norton Rose Fulbright

Michael A. Walsh
Partner
Strasburg & Price LLP

- 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?
- What are the consequences of inappropriate off-label promotion?
- Survey of recent investigations, penalties, and settlements

3:30 **Afternoon Refreshment Break**

3:45 **Preemption Fundamentals**

James M. Beck
Partner
Reed Smith LLP

- 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

5:00 **Master Class C Concludes**

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