BOSTON EDITION

September 17 – 18, 2013 | Omni Parker House | Boston, MA

FDA BOOT CAMP

Basic training in core regulatory concepts for life sciences lawyers

Our prior delegates say it best:

"A wealth of information presented by knowledgeable individuals, providing numerous take aways that will be put to practical use."
– Jonathan Cutty, Contract Specialist, Novo Nordisk, Inc. (2012 delegate)

"I thought it was very informative and relevant to my practice."
– Iciar P. Garcia, Corporate Counsel, Forest Laboratories, Inc. (2012 delegate)

"Wide and sufficient coverage of relevant topics."
– David Hutchinson, General Counsel, EMD Millipore (2012 delegate)

"GREAT! Nice balance between general overview and a couple of specifics without getting bogged down in details."
– Stephen Kim, Corporate Counsel, Celgene Corporation (2012 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:

- **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: Fundamentals of FDA Regulatory Law	MASTER CLASS B: Hatch-Waxman and BPCIA: Overview of Biosimilars and Life Cycle Planning for Drugs and Biologics	MASTER CLASS C: Post-Approval Marketing Guidance and Preemption Protocols

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Get the ultimate roadmap to the complicated landscape of FDA regulatory law

The approval process…pre-approval concerns…product labeling… clinical trials…adverse events reports… patent concerns… exclusivity – all are critical aspects in the commercialization process for drugs, biologics, and devices which are governed by FDA law and regulation. Recent court cases, and high-profile trials concerning FDA-regulated products have made it clear that it is essential for attorneys who do not have regulatory practices — but who do deal with FDA-regulated products — to have a familiarity with these concepts. The changing business dynamics of the life sciences industry have also made it critical for business executives, policy analysts and securities experts who work in this field to have a clear understanding of the dynamics of the FDA.

Law-suits * Business Development and Investment Strategies* Compliance Protocols* Policy Matters* Pricing and Reimbursement Decisions * Patent and Product Life Cycle Management

Litigation as well as numerous other legal, business, and policy decisions concerning FDA-regulated products often hinge on what happened during the pre-approval, approval, or post-approval periods.

Many products liability lawyers, patent counsel, business and investment experts, medical and regulatory affairs professionals, and those involved in pricing and reimbursement — 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. Whether you are a products liability or patent litigator, in-house counsel, in-house business development or federal affairs professional, FDA Boot Camp will provide you the insights you need.

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, 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 analysis 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**

DISTINGUISHED FACULTY

Co-Chairs

Anne K. Walsh
Partner, Hyman, Phelps & McNamara, P.C
(Washington, DC)

Karen Weaver, J.D., R.Ph.
VP, Associate General Counsel, Regulatory
CareFusion (San Diego, CA)

Speakers

Alan Bennett
Partner, Ropes & Gray LLP (Washington, DC)

James M. Beck
Partner, Reed Smith LLP (Philadelphia, PA)

Nicholas M. Boivin
Director, IP Counsel, Cubist Pharmaceuticals
(Lexington, MA)

Cathy Burgess
Partner, Alston & Bird (Washington, DC)

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

Dale Cooke
Vice President/Group Director, Regulatory Review
Digitas Health (Philadelphia, PA)

Sarah Cooleybeck
Partner, Foley Hoag, L.L.P. (Boston, MA)

Sonali P. Gunawardhana
Of Counsel, FDA Practice Group
Wiley Rein LLP (Washington, DC)

Naomi Halpern
Sr. Regulatory Compliance Attorney
Arent Fox, L.L.P. (Washington, DC)

Scott Lassman
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Gary L. Yingling
Partner, Morgan, Lewis & Bockius LLP
(Washington, DC)

PRE-CONFERENCE WORKSHOP: Monday, September 16, 2013 | 1:00 p.m. – 5:00 p.m. (Registration starts at 12:00 p.m.)

A

1:00 Fundamentals of FDA Regulatory Law

Sonali P. Gunawardhana
Of Counsel, FDA Practice Group
Wiley Rein LLP (Washington, DC)

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

ETHICS

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.

DAY 1: Tuesday, September 17, 2013

7:45 Registration and Continental Breakfast

8:45 Co-Chairs' Opening Remarks

Anne K. Walsh
Partner, Hyman, Phelps & McNamara, P.C (Washington, DC)

Karen Weaver, J.D., R.Ph.
VP, Associate General Counsel, Regulatory
CareFusion (San Diego, CA)

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

Gary L. Yingling
Partner
Morgan, Lewis & Bockius 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
  - Prescription Drug Marketing Act
  - Public Health Services Act
  - Hatch-Waxman Act
  - Follow-On Biologics
  - Recalls
  - 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
- Interrelationships with OIG and DOJ
- Recent developments at the FDA
  - regulations and guidance
  - enforcement initiatives
  - personnel
  - safety related actions at FDA

10:15 Morning Coffee Break

Preapproval and Approval

10:30 The Nature of the Approval Process

Naomi Halpern
Sr. Regulatory Compliance Attorney
Arent Fox, L.L.P. (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
  - 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

11:45 Understanding the Clinical Trial Process for Drugs and Biologics

Laurie A. Clarke
Partner, King & Spalding 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
  - 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

12:45 Networking Luncheon

Obtaining and Challenging Market Exclusivity for Drug Products and Biologic Products: IP protection, Data Exclusivity, Trademark and Brand Protection, Hatch-Waxman, BPCIA, and More

2:00 Part 1 – Overview of Patent and Trademark Issues

Nicholas M. Boivin
Director, IP Counsel, Cubist Pharmaceuticals (Lexington, MA)

Sarah Cooleybeck
Partner, Foley Hoag, L.L.P. (Boston, MA)

IP 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

Trademark Issues

- Overview of selecting a brand name for a proposed drug product
- 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
- How does the branding process work for your product?

2:45 Part 2 – Hatch-Waxman and BPCIA Overview

Scott Lassman
Partner, Kleinfeld, Kaplan & Becker LLP (Washington, DC)

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)
- Analysis of overview information as applied to OxyContin decision

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

4:00 Afternoon Refreshment Break

4:15 **Drugs and Biologics: Labeling**

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

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

5:15 Conference Adjourns to Day Two

DAY TWO: Wednesday, September 18, 2013

7:40 Continental Breakfast

8:20 **Co-Chairs' Opening Remarks**

Post-Approval

8:30 **cGMPs: Drugs and Biologics (current Good Manufacturing Practices)**

Cathy Burgess
Partner, Alston & Bird (Washington, DC)

- 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?
- Recent cGMP developments: Increased statutory authority under FDASIA and new trends in cGMP enforcement litigation

9:00 **Adverse Events Monitoring, Pharmacovigilance and Risk Management**

Anne K. Walsh
Partner, Hyman, Phelps & McNamara, P.C (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

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**

Seth Mailhot
Special Counsel
Sheppard, Mullin, Richter & Hampton LLP (Washington, DC)

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

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

- 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
- 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
- De novo process
- Premarket approval (PMA) process

Other Pre- and Post-Market Requirements and Concerns

- Establishment registration and listing
- Labeling requirements
- What is the scope of the Quality System Regulation (QSR)?
- What are the reporting requirements under the Medical Device Reporting (MDR)?
- Reports of Corrections and Removals
- 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?

Recalls and Withdrawals

11:30 **Recall Guidance for Drugs, Biologics, and Medical Devices: What You Need to Know**

Karen Weaver, J.D., R.Ph.
VP, Associate General Counsel, Regulatory
CareFusion (San Diego, CA)

- 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?

12:15 Conference Concludes
Networking Luncheon for Attendees of Master Class B and C

POST-CONFERENCE MASTER CLASSES: Wednesday, September 18, 2013 | 1:15 p.m. – 4:45 p.m.

In depth 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**

Joseph A. Mahoney
Partner, Mayer Brown (Chicago, IL)

- 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
  - addition of the word "protein" to the PHSA definition of biologics
  - identifying the "reference" product and proving biosimilarity
    - analytical data requirements
    - when will clinical data submission be necessary?
- Exploring interchangeability requirements
- Understanding the significance of the methods of making claims in this legislation
  - query: if a protein is made by a completely different process than the reference product, is the patent infringed?
- Examining the effect of this abbreviated approval pathway on innovation
  - how will this impact brand name and generic companies
- 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**

Lance L. Shea, M.S., J.D.
Partner, BakerHostetler (Washington, DC)

- 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, nasal sprays
- Exploring bioeq uivalency 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**

Peter Safir
Partner, Covington & Burling (Washington, DC)

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)
- Antibiotic Exclusivity (5 and 3 years)
- New Clinical Study Exclusivity (3 years)
- Pediatric Exclusivity (6 months)
- First Generic Applicant Exclusivity (180 days)
- Antibiotic Exclusivity (+5 years)
- Exclusivity and Patent Settlements

4:45 Master Class B Concludes

C Post-Approval Marketing Guidance and Preemption Protocols

1:15 **Off-Label Promotion: A case study of Civil Penalties, Criminal Enforcement and Tort Claims**

Michael Walsh
Partner, Strasburger & Price (Dallas, TX)

Joseph G. Poluka
Partner, Blank Rome LLP (Philadelphia, PA)

- A "case study" compilation of facts and promotional conduct from recent off-label promotion cases
- What went right and what went wrong and how the outcome might have been different
- In depth application of the "rules" governing off-label promotion
- How the OIG, U.S. Attorney's Office, and states monitor and prosecute off-label promotion cases
- Evolving civil litigation and theories
- Including the PPACA and healthcare offenses that might factor in to promotional claims

2:30 **Preemption Fundamentals**

James M. Beck
Partner
Reed Smith LLP (Philadelphia, PA)

- 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

3:30 Afternoon Refreshment Break

3:45 **Advertising and Promotion**

Alan Bennett
Partner, Ropes & Gray LLP (Washington, DC)

Dale Cooke
Vice President/Group Director, Regulatory Review
Digitas Health (Philadelphia, PA)

<u>Advertising and Promotion Overview</u>

- 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 are DDMAC charged with?
  - what are its enforcement capabilities and jurisdiction?
  - DDMAC 2010: a year in review
    - forthcoming guidance on internet promotions
    - what is happening with FDA regulation of social media and other internet-related activities?
- Consumer fraud class action litigation
- Off label cases
- 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
- What constitutes a launch?
- What defines an advertisement?
  - what information must a drug advertisement include?
- Exploring the role of the label in advertising

<u>Special Concerns for DTC Advertising</u>

- 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?

4:45 Master Class C Concludes

CONTINUING LEGAL EDUCATION CREDITS

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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 nontransitional for the purposes of CLE accreditation.

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Basic training in core regulatory concepts for life sciences lawyers

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Fundamentals of FDA Regulatory Law

Wednesday, September 18, 2013
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Interactive Post-Conference Master Classes: In depth Hatch-Waxman, BPCIA, and Post-Approval Concerns

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

Master Class C:
Post-Approval Marketing Guidance and Preemption Protocols

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