The Legal, Regulatory and Compliance Forum on

Over the Counter Drugs

A comprehensive guide to the latest developments affecting non-prescription drug products

October 18 – 19, 2012 | The Carlton Hotel | New York, NY

Distinguished Co-Chairs

Eugene I. Lambert
Senior Counsel
Covington & Burling LLP
(Washington, DC)

Diane C. McEnroe
Partner
Sidley Austin LLP
(New York, NY)

Industry Insights from

GlaxoSmithKline Consumer Healthcare

Merck & Co., Inc.

Novartis Consumer Health, Inc.

Perrigo Company

Pfizer

Key Agency Spotlight

Hear from the FDA on:
The FDA's Proposed New Paradigm for OTC Drugs with Conditions of Safe Use
***Nicholas E. Beshara,* Associate Chief Counsel**
Office of the Chief Counsel
United States Food & Drug Administration

Trends in Recent OTC Enforcement Actions
***Eric Blumberg,* Litigation Deputy**
Office of the Chief Counsel
United States Food & Drug Administration

Hear from the USP on:
Modernizing the Monograph System and the OTC Drug Review Process
Matthew Van Hook
Assistant General Counsel
Compendial Sciences
The United States Pharmacopeial Convention

Preeminent food and drug lawyers, industry counsel, and regulatory experts representing the OTC pharmaceutical industry together with FDA and USP officials will discuss and share insights on the latest legal and regulatory developments affecting non-prescription pharmaceutical products. They will help you:

- **DECIPHER** the complexities and schematic of **the FDA's proposed new paradigm for 'OTC drugs with conditions of safe use'** and its potential repercussions for **Rx to OTC switches**
- **UNDERSTAND** how **monograph modernization** will affect the status of the **OTC Review Process**
- **EVALUATE** the **scope of claims** that can legitimately be made on the **product label** and **AVOID** allegations of **misbranding**
- **DISTIGUISH** reportable from non-reportable **AERs** in the OTC space
- **APPRECIATE** the relationship between **trademarks, trade names** and **line extensions**
- **COMPREHEND** the **respective roles** and **authority of FDA** and **FTC** in OTC advertising
- **DEVELOP** a system of **cGMP 'checks and balances'** as an integral part of your compliance program
- **FORMULATE** effective and efficient **recall execution** and **remediation strategies**
- **AVOID behaviors** which have lead to **enforcement actions,** including **Park doctrine** invocation

Interactive Working Group and Strategy Sessions

October 17, 2012 – Working Group **on OTCs and Consumer Health Care Products 101:** Defining, Establishing and Perfecting OTC-Ness

October 19, 2012 – ***Rx to OTC Switch Master Class:*** In-Depth Analysis and Legal and Business Strategies for Bringing Your Product Over the Counter

Media Partners:
biosimilarlicensing.com
PM360

Earn CLE Credits

AMERICAN CONFERENCE INSTITUTE

Register Now • 888–224–2480 • AmericanConference.com/OTCDrugs

Distinguished Faculty

Co-Chairs

Eugene I. Lambert
Senior Counsel
Covington & Burling LLP
(Washington, DC)

Diane C. McEnroe
Partner
Sidley Austin LLP
(New York, NY)

Speakers

Bryant Aaron
Vice President & Associate General Counsel
Novartis Consumer Health, Inc.
(Parsippany, NJ)

David G. Adams
Partner
Venable LLP (Washington, DC)

Nicholas E. Beshara
Associate Chief Counsel
Office of the Chief Counsel
United States Food & Drug Administration
Food & Drug Division, OGC/HHS
(Silver Spring, MD)

Sharon A. Blinkoff
Of Counsel
Venable LLP (New York, NY)

Eric Blumberg
Litigation Deputy
Office of the Chief Counsel
United States Food & Drug Administration
(Silver Spring, MD)

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

Dickerson M. Downing
Partner
Crowell & Moring, LLP
(New York, NY)

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

Stacy Ehrlich
Partner
Kleinfeld, Kaplan and Becker, LLP
(Washington, DC)

Christopher G. FitzPatrick
Counsel
Smith, Gambrell & Russell, LLP
(New York, NY)

Edward F. Glynn Jr.
Partner
Manatt, Phelps & Phillips, LLP
(Washington, DC)

Matthew J. Golden
Legal Director, Patents
Merck & Co., Inc. (Rahway, N.J.)

Andrew N. Goldfarb
Partner
Zuckerman Spaeder LLP
(Washington, DC)

Todd Halpern
Assistant General Counsel
Regulatory Law
Pfizer (Madison, NJ)

Kurt R. Karst
Director
Hyman, Phelps & McNamara, P.C.
(Washington, DC)

Greer O. Lautrup
Partner
Sidley Austin LLP
(Washington, DC)

Mary Leheny
Chief Trademark Counsel & Assoc. General Counsel
Novartis Consumer Health, Inc.
(Parsippany, NJ)

Lauren Quinn
Head of US Regulatory Affairs
Novartis Consumer Health, Inc.
(Parsippany, NJ)

Kathleen A. Rheintgen
Partner
Husch Blackwell LLP
(Chicago, IL)

Linda F. Schneider
Assistant General Counsel
GlaxoSmithKline Consumer Healthcare (Moon Township, PA)

Frederick A. Stearns
Partner
Keller and Heckman LLP
(Washington, DC)

Richard J. Stec Jr., Ph.D.
Vice President
Global Regulatory Affairs
Perrigo Company (Allegan, MI)

Matthew Van Hook
Assistant General Counsel
Compendial Sciences
The United States Pharmacopeial Convention (Rockville, MD)

Gary L. Yingling
Partner
K & L Gates LLP
(Washington, DC)

Jennifer Zachary
FDA Attorney
Covington & Burling LLP
(Washington, DC)
(formerly Associate Chief Counsel for Enforcement, FDA's Office of Chief Counsel)

Who You Will Meet

OTC or Non-Prescription Drug Industry

- ✓ In-House Counsel, including generalists and those having responsibility for FDA regulatory matters; IP, Patents and Trademarks; Licensing and Business Development
- ✓ Officers, Directors and Executives for Regulatory Affairs; Business Development, and Rx to OTC switches

Prescription Drug Industry

- ✓ In-House Counsel having responsibility for Rx to OTC switches, FDA regulatory matters and patents
- ✓ Officers, Directors and Executives for Regulatory Affairs and Business Development

Law Firm Attorneys for the OTC and Prescription Drug Industry whose practices focus on:

- ✓ FDA and food and drug law
- ✓ IP, patents, and Hatch-Waxman matters
- ✓ Trademarks

Global Sponsorship Opportunities

With more than 500 conferences in the United States, Europe, Asia Pacific, and Latin America, American Conference Institute (ACI) provides a diverse portfolio devoted to providing business intelligence to senior decision makers who need to respond to challenges spanning various industries in the US and around the world.

As a member of our sponsorship faculty, your organization will be deemed as a partner. We will work closely with your organization to create the perfect business development solution catered exclusively to the needs of your practice group, business line or corporation.

For more information about this program or our global portfolio of events, please contact:

Wendy Tyler
Head of Sales, American Conference Institute

Tel: 212-352-3220 x5242 | **Fax:** 212-220-4281
w.tyler@AmericanConference.com

Continuing Legal Education Credits

CLE Credits

Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education requirements. This course is identified as nontransitional 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 in the amount of 13.0 hours. An additional 4.0 credit hours will apply to each workshop.

ACI certifies that this activity has been approved for CLE credit by the State Bar of California in the amount of 11.0 hours. An additional 3.5 credit hours will apply to each workshop.

You are required to bring your state bar number to complete the appropriate state forms during the conference. CLE credits are processed in 4-8 weeks after a conference is held.

ACI has a dedicated team which processes requests for state approval. Please note that event accreditation varies by state and ACI will make every effort to process your request.

Questions about CLE credits for your state? Visit our online CLE Help Center at www.americanconference.com/CLE

"OTC drugs have had great success in providing consumers with excellent self-care options. But our concept of self-care is limited to conditions that can be self-diagnosed and self-treated based on the information in the drug facts box, combined with common knowledge [.] ["]

["]What we are asking is, should there be more flexibility in the concept of nonprescription drugs?["]

["]Can we broaden the assistance a consumers gets and increase the types of medicines that might be available over-the-counter [?]"

— *Janet Woodcock,* M.D., Director, Center for Drug Evaluation and Research, FDA, March 2012

Prepare to Meet the Challenges of the Rapidly Evolving Legal and Regulatory Landscape of the Non-Prescription Drug Industry.

FDA's proposed introduction of a new paradigm for **'OTC drugs with conditions of safe use'** (which some industry observers have referred to as a third class of drug product or **'behind the counter'/ 'BTC' products**) will put a new twist on existing legal and regulatory protocols and product commercialization in the OTC space. Under this new proposal, self-diagnosis and self-care, two basic tenants of the current OTC paradigm, may be supplemented with the assistance of a pharmacist and rapid diagnosis testing; thus leading to a multitude of questions ranging from scope of FDA authority to potential liabilities.

To help you make sense of this new proposal and its potential impact on existing legal and regulatory structures in the OTC environment, ACI has developed **The Legal, Regulatory and Compliance Forum on Over the Counter Drugs.** A distinguished faculty of over two dozen leading legal and regulatory OTC experts — including FDA and USP representatives — will address the intricacies of this new proposal as well as existing challenges affecting such core OTC functions as **advertising and promotion; labeling; trademarks, trade names and line extensions;** and **the modernization of the monograph system.** They will provide you with the critical information that you now need to:

- Understand the interplay between OTC drugs introduced under this proposed new paradigm and those introduced through traditional Rx to OTC switch mechanisms
- Identify prescription products that are appropriate candidates for an Rx to OTC switch and proposed OTC drugs with conditions of safe use
- Examine the label as a means of advertising and promotion
- Analyze the use of social media in OTC advertising
- Overcome challenges with line extensions for monograph and NDA OTCs

Learn to Prevent and Defend Enforcement Actions in the OTC Space by Mastering Critical AER, GMP and Recall Competencies.

This is the only legal and regulatory gathering specifically designed for the OTC drug industry which will address enforcement activity and preventative measures based on real world examples impacting non-prescription pharmaceutical products. Present and former FDA enforcers and industry experts will help you:

- Understand the scope of FDA and DOJ – as well as FTC – enforcement in the OTC space
- Overcome challenges in forming effective recall execution strategies
- Explore the link between recent GMP violations and enforcement activity in the OTC space
- Establish internal AER review protocols and record keeping systems in accordance with inspection requirements

Benefit from Special Training and Strategy Sessions that will Address the Legal and Regulatory Essentials of OTCs and Intricacies of Commercialization.

To enhance and complete your conference and networking experience, attend one or both of the following strategy sessions:

- **Working Group on OTCs and Consumer Health Care Products 101 — Defining, Establishing and Perfecting OTC-Ness** will provide an essential overview of the law and regulations governing over the counter pharmaceutical products and set the stage for the OTC complexities and challenges addressed during the main conference; and

- **Rx to OTC Switch Master Class: In-Depth Analysis and Legal and Business Strategies for Bringing Your Product Over the Counter** will provide in-depth analysis of one of the most critical legal in regulatory mechanisms in the commercialization of OTC products.

Register Now.

Register today for the industry's premier and most comprehensive legal and regulatory forum on OTC pharmaceutical products by calling **1-888-224-2480,** faxing your registration form to **1-877-927-1563,** or logging on to **www.AmericanConference.com/OTCDrugs.**

Wednesday, October 17, 2012
2:00 pm – 5:30 pm

(Registration opens at 1:15 pm)

Pre-Conference Working Group

OTCs and Consumer Health Care Products 101: Defining, Establishing and Perfecting OTC–Ness

Eugene I. Lambert
Senior Counsel, **Covington & Burling LLP** (Washington, DC)

Diane C. McEnroe
Partner, **Sidley Austin LLP** (New York, NY)

This hands-on working group will provide an essential overview of the law and regulations governing over the counter pharmaceutical products. Topics addressed during this workshop will set the stage for the main conference by helping you thoroughly comprehend the complexities of and challenges associated with this class of drug product.

- Defining OTC drug products
  - drugs vs. cosmetics vs. supplements
  - nutraceuticals; cosmeceuticals
  - when can a vitamin or cosmetic be considered a drug?
- Exploring the criteria for OTC drug products
  - safety, efficacy, self-diagnosis, self- treatment
- OTC drugs vs. Rx drug products
- The role and authority of FDA in the OTC market
  - CDER's Office of Nonprescription Drug Products
  - The Office of Drug Evaluation IV (ODE IV)
  - Office of New Drugs
  - Nonprescription Drug Advisory Committee
- Laws and regulations governing OTCs
- Overview of how an OTC drug comes to market
  - if it's a new drug
  - if it's not a new drug
  - Rx to OTC switch
- The OTC Review
  - which drugs are covered?
  - the "monograph" system
    - monographs v. NDAs
    - when is an NDA or ANDA used in the OTC process?
  - what information 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?
- The significance of the label
  - what information must an OTC label contain?
- Branding
- OTC advertising and promotion
  - the role of the FTC

Main Conference – Day 1
Thursday, October 18, 2012

7:15 Registration and Continental Breakfast

8:15 Co–Chairs' Opening Remarks

Eugene I. Lambert
Senior Counsel, **Covington & Burling LLP** (Washington, DC)

Diane C. McEnroe
Partner, **Sidley Austin LLP** (New York, NY)

8:30 Understanding the Ramifications of FDA's Proposed New Paradigm for OTC Drugs with Conditions of Safe Use

David G. Adams
Partner, **Venable LLP** (Washington, DC)

Nicholas E. Beshara
Associate Chief Counsel, Office of the Chief Counsel
United States Food & Drug Administration
Food & Drug Division, OGC/HHS (Silver Spring, MD)

The FDA is seriously considering approving OTC drugs with conditions of safe use. Such drugs would essentially be comprised of products that might have previously been available only by prescription. One potential example under this new paradigm could involve non-prescription access to a drug after an initial prescribed dose in order to treat chronic conditions such as high blood pressure or high cholesterol. However, the proposed paradigm is not without controversy or perceived regulatory hindrance.

Our panel will discuss the legal and regulatory challenges that this proposed paradigm would create. Points of discussion will include:

- The authority of FDA to approve and regulate OTC drugs with conditions of safe use
- Anticipated role of proposed new paradigm in curbing health care costs
- Defining conditions of 'safe use' in allowing non-prescription access to Rx drug products in certain circumstances
- The role of the pharmacist in selling or dispensing OTC drugs with conditions of safe use
  - related potential liabilities
  - pharmacist v. physician
- The use of rapid diagnosis test and computer program in self-diagnosis as potential conditions of safe use
- Lessons learned from analogous switches
  - Plan B
  - vaginal yeast treatments
  - pseudoephedrine

9:45 Morning Coffee Break

10:00 Best Practices for Evaluating an Rx to OTC Switch: Critical Legal and Regulatory Considerations

Andrew N. Goldfarb
Partner, **Zuckerman Spaeder LLP**, (Washington, DC)

Kurt R. Karst
Director, **Hyman, Phelps & McNamara, P.C.** (Washington, DC)

Richard J. Stec Jr., Ph.D.
Vice President, Global Regulatory Affairs
Perrigo Company (Allegan, MI)

- Identifying prescription products that are appropriate candidates for an Rx to OTC switch

  - is the Rx product used for a therapeutic area that is appropriate for self-diagnosis?
    - safety
    - efficacy
- Assessing switch drivers relative to the FDA push for a third class of drug
  - how will this impact current OTC switch candidate criteria and evaluation
  - quasi-switched products
- Evaluating key considerations in risk benefits analysis for switch
  - duration of patent
  - anticipated generic challenge to Rx product
  - formulary placement
  - public and private payor payment and reimbursement
- Examining Orange Book listing status for switched products
- Exploring exclusivity eligibility criteria and requirements for switched products
  - research studies relative to exclusivity
- Understanding the use of citizens petitions in the switch process
  - third party challenges to Rx status
  - exploring scenarios in which a switch may be forced
  - FDA authority to switch

11:15 Modernizing the Monograph System and the OTC Drug Review Process in Light of New OTC Drivers and Technologies

Eugene I. Lambert
Senior Counsel, **Covington & Burling LLP** (Washington, DC)

Matthew Van Hook
Assistant General Counsel, Compendial Sciences
The United States Pharmacopeial Convention (Rockville, MD)

- Re-examining the current FDA monograph system and OTC Drug Review Process
  - exploring new OTC drivers and technologies
  - USP Monograph Modernization initiative
    - distinguishing FDA's OTC Monograph system, from USP drug quality compendial monographs
  - role of USP and FDA in monograph modernization
    - the respective roles of USP and FDA in modernizing the various related aspects of the OTC Monograph space
  - re-examining safety and efficacy by modern standards
- Understanding how monograph modernization will affect the status of the OTC Review Process
  - when will the OTC Review be complete?
    - FDA rulemaking
  - exploring legal and regulatory hindrances to OTC Review completion
  - final monographs vs. tentative final monographs
  - Time and Extent Applications
- Addressing legal and regulatory concerns relative to antiquated quality standards in monographed products
  - impurities
  - global harmonization
  - comparison of quality standards for OTC monographed drugs vs. OTC and Rx NDA drugs
- Exploring legal and regulatory challenges surrounding the inclusions of new technologies and dosage forms into the current monograph system
- Weighing arguments for expanding drugs covered by OTC Review
  - should certain drugs be removed from NDA status?
    - third class of drug

12:00 Networking Luncheon

1:15 OTC Labeling: Claims, Compliance and Avoiding Product Misbranding

Sharon A. Blinkoff
Of Counsel, **Venable LLP** (New York, NY)

Stacy Ehrlich
Partner, **Kleinfeld, Kaplan and Becker, LLP** (Washington, DC)

Linda F. Schneider
Assistant General Counsel
GlaxoSmithKline Consumer Healthcare (Moon Township, PA)

- Overview of essential labeling requirements for OTC drug products
  - label comprehension studies
- Exploring the concept of uniform labeling for domestic and international markets
- Harmonizing label standards for OTC and Rx versions of drugs
- Evaluating label changes
  - when is it necessary and when is it worth the trouble?
  - the label change process
- Exploring the scope of legitimate claims which can be made on the label
  - claims for OTC as opposed to Rx versions of the same drug
  - narrow vs. broad
  - borderline claims, *e.g.,* drug and cosmetic; drug and supplement
- Avoiding labeling errors which may lead to misbranding allegations
- What information is required under the label relative to the reporting of adverse events
  - Dietary Supplement and Nonprescription Drug Consumer Protection Act
- Examining liabilities relative to labeling errors and findings of misbranding

2:15 Define, Distinguish and Differentiate: Best Practices for Adverse Event Reporting of Non Prescription Drug Products

Diane C. McEnroe
Partner, **Sidley Austin LLP** (New York, NY)

- Defining adverse events in the OTC space
  - Serious Adverse Event Reporting for Nonprescription Drugs, 21 USC §379aa
- Distinguishing reportable from non-reportable adverse events
  - serious adverse event
- Differentiating between adverse event reporting requirements and protocols relative to OTC monograph and OTC NDA products
  - regulations governing adverse event reporting for monograph and NDA OTC products
  - electronic reporting system, *i.e.,* Medwatch
  - link between reporting requirements and OTC labeling
- Review of record keeping requirements for adverse events
- Establishing internal review protocols and record keeping systems in accordance with inspection requirements
  - ensuring compliance with applicable laws and regulations
- Benchmarking your reporting and record keeping policies against competitors

3:15 Afternoon Refreshment Break

3:30 **Making and Maintaining Your Mark: Mitigating Legal and Regulatory Risks Relative to Trademarks, Trade Names and Brand Name Product Line Extensions in the OTC Space**

Dickerson M. Downing
Partner, **Crowell & Moring, LLP** (New York, NY)

Mary Leheny
Chief Trademark Counsel & Assoc. General Counsel
Novartis Consumer Health, Inc. (Parsippany, NJ)

Lauren Quinn
Head of US Regulatory Affairs
Novartis Consumer Health, Inc. (Parsippany, NJ)

Kathleen A. Rheintgen
Partner, **Husch Blackwell LLP** (Chicago, IL)

- Comparing and contrasting FDA's view of trade names and trademarks against views supported by IP law
  - FDA/PTO interplay
- Understanding the FDA's contention that the product name is a claim
  - what does the product name convey?
  - is there room for confusion or misunderstanding?
- Trade name/trademark review for monograph vs. NDA OTCs
  - comparison to Rx OTC trademark/trade name review
- Exploring the relationship between trade name and line extensions
  - FDA regulation regarding OTC line extension for monographed products
- Addressing name confusion controversies relative to line extensions
  - *e.g.,* brand name extension given to a product with completely different ingredients
- Overcoming challenges with line extensions for monograph and NDA OTCs
  - recent FDA scrutiny of line extensions

4:30 **Staking Your Claim: Balancing Competitive Advantage and Legal Exposure in The Advertising and Promotion of OTC Products**

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

Christopher G. FitzPatrick
Counsel, **Smith, Gambrell & Russell, LLP** (New York, NY)

Edward F. Glynn Jr.
Partner, **Manatt, Phelps & Phillips, LLP** (Washington, DC)

- Distinguishing between advertising and promotion regulations for OTC monograph products and OTC NDA products
- Examining the label as a means of advertising and promotion
- Analyzing the use of social media in OTC advertising
- Substantiating product claims
  - clinical studies
  - monograph claims
  - what you can say vs. what you cannot
- FDA vs. FTC authority in OTC advertising and promotion
  - regulation of product claims for monograph vs. NDA OTCs
  - role of DDMAC
- Exploring Lanham Act challenges relative to false and misleading claims for competitor products
- Monitoring of OTC advertising by National Advertising Department of Better Business Bureau (NAD)

5:45 **Conference Adjourns to Day Two**

Main Conference – Day Two
Friday, October 19, 2012

7:15 **Continental Breakfast**

8:30 **Co–Chairs' Opening Remarks and Recap of Day One**

8:45 **Mastering Good Manufacturing Practices in The World of Non–Prescription Drugs**

Greer O. Lautrup
Partner, **Sidley Austin LLP** (Washington, DC)

- Examining cGMPs (current Good Manufacturing Practices) and their critical importance in OTC drug product commercialization
- Overview of recent GMP violations and enforcement activity in the OTC space
- Exploring the scope of the FDA's cGMP Initiative and how the concept of "risk-based" cGMPs is defined
  - understanding the scope of the FDA's authority Relative to GMPs
  - application of these concepts and authorities to OTC/Consumer Health Product space
- Defining the concept of validation
- How are laboratory investigations in relation to cGMPs conducted?
- Defining the term "quality systems"
- Understanding the importance of incorporating cGMP checks and balances into your compliance program
- How do cGMPs factor into products liability and consumer products litigation in the OTC?

9:45 **Morning Coffee Break**

10:00 **Anatomy of an OTC Recall: Causes, Consequences and Corrective Actions**

Bryant Aaron
Vice President & Associate General Counsel
Novartis Consumer Health, Inc. (Parsippany, NJ)

Todd Halpern
Assistant General Counsel, Regulatory Law, **Pfizer** (Madison, NJ)

Gary L. Yingling
Partner, **K & L Gates LLP** (Washington, DC)

- Examining recent recall activity relating to OTC products
  - what were the nature of these recalls
  - what corrective actions were taken?
  - what are the lessons learned?
- Overview of the FDA's recall and oversight authority with respect to OTC and other drug products
  - 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
- Challenges in forming effective recall execution strategies
- Weighing your recall options
  - working with the FDA versus working alone
  - what are the risks and benefits in each course of action?
- Assessing the impact of divergent post-marketing reporting requirements for OTC drugs
- Comparing FDA's recall expectations for prescription drugs to OTC products

- recall requirements under the Consumer Product Safety Act
- Interaction between recalls and corrective and preventive action
- What are the consequences of not instituting a recall?
  - FDA seizure and injunction power
- When can a product be reintroduced to the market?
  - a look at recent product reintroductions

11:15 **Trends in Recent OTC Enforcement Actions and Litigation: Lessons Learned for Risk Mitigation and Compliance**

Eric Blumberg
Litigation Deputy, Office of the Chief Counsel
United States Food & Drug Administration (Silver Spring, MD)

Frederick A. Stearns
Partner, **Keller and Heckman LLP** (Washington, DC)

Jennifer Zachary
FDA Attorney, **Covington & Burling LLP** (Washington, DC)
(formerly Associate Chief Counsel for Enforcement, FDA's Office of Chief Counsel)

- Understanding enforcement authority in the OTC space
  - FDA authority v. DOJ authority
  - private enforcement litigation
    - NAD actions
  - application and use of the Park doctrine
- Case studies of recent enforcement actions
  - scope of wrongdoing
  - remediation
- Exploring trends in private litigation relative to OTC products
  - link between private and public OTC suits
- Lessons learned from the J&J consent decree
- Examining FCPA concerns relative to OTCs and Consumer Health Products
- Review of applicability of aggregate spend, sunshine and sampling laws to OTC products
- Evaluating the cost of enforcement actions: what happens to company stock when there is an announcement of an enforcement action?

12:30 **Conference Adjourns**

Friday, October 19, 2012
2:00 PM – 5:30 PM

(Registration opens at 1:15 pm)

Luncheon will be provided for Master Class Attendees beginning at 12:45 PM

Rx to OTC Switch Master Class

In–Depth Analysis and Legal and Business Strategies for Bringing Your Product Over the Counter

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

Matthew J. Golden
Legal Director, **Patents, Merck & Co., Inc.** (Rahway, N.J.)

Rx to OTC switches are a main stay for the non-prescription drug industry. However, the switch concept is coming into greater prominence of late as a result of several factors, including, the loss of patent protection, rising health care costs, consumer demand, FDA amenability to the switch concept – as well as the switch concept's relevance to the creation of a new paradigm for OTC drugs. In this interactive session, our strategy session leaders will address these factors in addition to presenting cases studies on some of the most pressing and complex legal and business challenges concerning the switch concept.

Points of discussion will include:

- Role of Hatch-Waxman litigation in choosing which products to switch
- Analysis of regulatory exclusivity criteria
  - Miralax case study
- Handicapping the OTC launch
  - strategies for obtaining regulatory market exclusivity in the OTC space during launch of generic Rx product
  - tie-in with licensing
  - tie in with launch of new Rx brand line extension
    - case study Prilosec, Nexium
- Patentability of OTC products
- Status hearings for OTC switch candidates
  - completing necessary studies and clinical review necessary for switch
- Exploring scenarios in which a switch may be forced
  - addressing third party challenges to Rx status
    - insurance company challenges: Claritin, Allegra and Zyrtec case studies
  - FDA authority to switch
- The concept of novel switch
  - limited indications
- Licensing the manufacturing of OTC versions

The Legal, Regulatory and Compliance Forum on

Over the Counter Drugs

A comprehensive guide to the latest developments affecting non-prescription drug products

October 18 – 19, 2012 | The Carlton Hotel | New York, NY

REGISTRATION FORM

PRIORITY SERVICE CODE

754L13_INH

ATTENTION MAILROOM: If undeliverable to addressee, please forward to:
General Counsel; OTC Counsel; Director, OTC Regulatory

Can be recycled

CONFERENCE CODE: 754L13-NYC

☐ **YES! Please register the following delegate for** Over the Counter Drugs

CONTACT DETAILS

NAME _____ POSITION _____

APPROVING MANAGER _____ POSITION _____

ORGANIZATION _____

ADDRESS _____

CITY _____ STATE _____ ZIP CODE _____

TELEPHONE _____ FAX _____

EMAIL _____ TYPE OF BUSINESS _____

☐ I would like to receive CLE accreditation for the following states: _____. See CLE details inside.

FEE PER DELEGATE	Register & Pay by Aug. 20, 2012	Register & Pay by Sept. 24, 2012	Register after Sept. 24, 2012
☐ ELITEPASS*: Conference & Both Workshops	$3195	$3295	$3495
☐ Conference & ☐ Workshop or ☐Master Class	$2595	$2695	$2895
☐ Conference Only	$1995	$2095	$2295
☐ I cannot attend but would like information on accessing the ACI publication library and archive			

**ELITEPASS is recommended for maximum learning and networking value.*

PAYMENT

Please charge my

☐ VISA ☐ MasterCard ☐ AMEX ☐ Discover Card ☐ Please invoice me

NUMBER _____ EXP. DATE _____

CARDHOLDER _____

☐ I have enclosed my check for $_____ made payable to **American Conference Institute** (T.I.N.—98-0116207)

☐ ACH Payment ($USD)

Please quote the name of the attendee(s) and the event code 754L13 as a reference.

For US registrants:
Bank Name: HSBC USA
Address: 800 6th Avenue, New York, NY 10001
Account Name: American Conference Institute
UPIC Routing and Transit Number: 021-05205-3
UPIC Account Number: 74952405

Non–US residents please contact Customer Service for Wire Payment information

Interactive Working Group and Strategy Sessions

October 17, 2012 – ***Working Group*** **on OTCs and Consumer Health Care Products 101:** Defining, Establishing and Perfecting OTC-Ness

October 19, 2012 – ***Rx to OTC Switch Master Class:*** In-Depth Analysis and Legal and Business Strategies for Bringing Your Product Over the Counter

Registration Fee

The fee includes the conference, all program materials, continental breakfasts, lunches and refreshments.

Payment Policy

Payment must be received in full by the conference date. All discounts will be applied to the Conference Only fee (excluding add–ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to individuals employed by the same organization.

Cancellation and Refund Policy

You must notify us by email at least 48 hrs in advance if you wish to send a substitute participant. Delegates may not "share" a pass between multiple attendees without prior authorization. If you are unable to find a substitute, please notify **American Conference Institute (ACI)** in writing up to 10 days prior to the conference date and a credit voucher valid for 1 year will be issued to you for the full amount paid, redeemable against any other **ACI** conference. If you prefer, you may request a refund of fees paid less a 25% service charge. No credits or refunds will be given for cancellations received after 10 days prior to the conference date. **ACI** reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or other costs incurred by registrants. No liability is assumed by **ACI** for changes in program date, content, speakers, or venue.

Hotel Information

American Conference Institute is pleased to offer our delegates a limited number of hotel rooms at a preferential rate. Please contact the hotel directly and mention the "ACI: Over the Counter Drugs" conference to receive this rate:

Venue: The Carlton Hotel
Address: 88 Madison Avenue, New York, NY 10016
Reservations: 1–800–601–8500 or 212–532–4100

Incorrect Mailing Information

If you would like us to change any of your details please fax the label on this brochure to our Database Administrator at 1–877–927–1563, or email data@AmericanConference.com.

5 Easy Ways to Register

MAIL **American Conference Institute**
45 West 25th Street, 11th Floor
New York, NY 10010

PHONE 888–224–2480

FAX 877–927–1563

ONLINE
AmericanConference.com/OTCDrugs

EMAIL
CustomerService
@AmericanConference.com

CONFERENCE PUBLICATIONS

To reserve your copy or to receive a catalog of **ACI** titles go to www.aciresources.com or call 1–888–224–2480.

SPECIAL DISCOUNT

We offer special pricing for groups and government employees. Please email or call for details.
Promotional discounts may not be combined. **ACI** offers financial scholarships for government employees, judges, law students, non–profit entities and others. For more information, please email or call customer service.