American Conference Institute's **Second Annual Legal, Regulatory and Compliance Forum** on

Over the Counter Drugs

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

October 29-30, 2013 | The Carlton Hotel | New York, NY

Distinguished Co-Chairs

Melinda Friend
Chief Regulatory Counsel
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(Geneva, Switzerland)

Diane C. McEnroe
Partner
Sidley Austin LLP
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Industry Insights from

Colgate Palmolive
GlaxoSmithKline Consumer Healthcare
McNeil Consumer Healthcare (invited)
Novartis Consumer Health, Inc.
Pfizer Consumer Health
Reckitt Benckiser
Similasan Corporation

Spotlights from Key Agencies

Hear from the FDA on:
The NSURE Initiative and the Agency's Continued Exploration of a New Paradigm for "OTC Drugs With Conditions of Safe Use"

- *Rikin Mehta, PharmD, JD, LLM*
  Deputy Director
  Division of Medical Policy Programs
  United States Food and Drug Administration
  Center for Drug Evaluation and Research
  Office of Medical Policy
  Office of Medical Policy Initiatives

Hear from FTC and NAD on:
Social Media in the OTC Space: Advertising and Promotion vs. Labeling

- *Laura Brett*, Staff Attorney
  National Advertising Division
  Council of Better Business Bureaus, Inc.
- *Nur-ul-Haq*, Attorney
  Federal Trade Commission
  Northeast Region

OTC Enforcement Actions and Private and Public Litigation

- *David G. Mallen*
  Deputy Director for Legal Affairs
  National Advertising Division
  Council of Better Business Bureaus, Inc.

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

- COMPREHEND **FDA's authority, goals** and **objectives** relative to its **NSURE Initiative** for a proposed new paradigm for **'OTC drugs with conditions of safe use'**
- UNDERSTAND how the **Plan B** decision may ultimately influence the future of **Rx-to-OTC switches**
- EXPLORE legal and regulatory **hindrances** for the inclusion of **new technologies** and **dosage forms** into the current **monograph system** and **OTC Review**
- DEVISE strategies for **uniform international launches** of OTC products
- EVALUATE how **new technologies to enhance label sets** may **change the essentials** of **labeling requirements** for OTC drug products
- ESTABLISH best practices to **distinguish reportable** from **non-reportable AERs** for OTC drugs
- ENSURE proper use of **umbrella branding** and **AVOID** associated **name confusion controversies**
- APPRECIATE **patent/IP protections** afforded to OTC drug products
- NAVIGATE the **gray area** between **advertising and promotion** and **labeling** vis-a-vis the use of **social media** in the **OTC space**
- EXAMINE the expanding **role** and unsettled **regulation** of **homeopathic OTCs**
- INCORPORATE integral **'cGMP 'checks and balances'** into your compliance program
- FORMULATE effective and productive **recall execution** and **remediation strategies**
- PREVENT **behaviors** which have led to **government enforcement actions** and **private consumer class action lawsuits**

Interactive Working Group and Master Classes

October 28, 2013: International and Domestic OTC and Consumer Health Care Products 101: Understanding and Re -Evaluating the Essentials of OTC-Ness for An Evolving U.S. and Ex-U.S. Health Care Marketplace

October 30, 2013: Rx-to-OTC Switch Master Class: In-Depth Analysis of Legal, Regulatory and Business Strategies for Bringing Your Prescription Drug Product Over the Counter

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(Washington, DC)
(former Associate Chief Counsel for Enforcement in the 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 regulatory; 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, regulatory 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

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FDA representatives emphasized that the NSURE paradigm is not intended to create a "third class" of drugs, but will work within the existing two-class system of prescription and nonprescription drug classes … nonprescription drug status could be granted through the existing regulatory approval processes, with each Condition of Safe Use tested as part of a comprehensive approach that ensures that the drug will be safe and effective in the nonprescription setting… FDA representatives also emphasized that the main objective of the program is to reach patients who are currently undertreated or without regular access to physicians… [and] that the conceptual framework for NSURE is still being developed.

— Discussion Guide for Technologies and Nonprescription Medications:
Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care,
Engelberg Center for Health Care Reform at Brookings, May 9, 2013

Understand how the FDA's NSURE Initiative Will Reshape the Tenants of the Current OTC Paradigm of Self Diagnosis and Self Care

FDA's NSURE (Nonprescription Safe Use Regulatory Expansion) Initiative which seeks to establish a new paradigm for **'OTC drugs with conditions of safe use'** will undoubtedly alter existing legal and regulatory protocols and product commercialization in the OTC space. Pharmacist assistance coupled with the use of new technologies and rapid diagnostic testing would in certain instances supplement the current OTC paradigm of self-diagnosis and self-care, thus leading to a multitude of controversies ranging from scope of FDA authority to potential liabilities. Additionally, the granting of OTC status to non-traditional switch candidates such as Oxytrol and the controversy over levonorgestrel also known as Plan B have led to new questions concerning how the NSURE Initiative may also impact the Rx-to- OTC switch mechanism.

Prepare to meet the challenges of the rapidly evolving legal and regulatory landscape of the non-prescription drug industry.

To help you make sense of the NSURE Initiative and in furthering the objectives of our inaugural OTC conference, ACI's Second Annual **Legal, Regulatory and Compliance Forum on Over the Counter Drugs** will help you thoroughly comprehend the continuing evolution of the OTC landscape. By attending this event, you will understand how these latest developments will impact the existing legal and regulatory structures which frame the OTC environment.

A distinguished faculty of over two dozen leading legal and regulatory OTC experts — including current and former FDA 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 umbrella branding; and the modernization of the monograph system.** They will provide you with the critical information that you now need to:

- Understand how the NSURE Initiative may accelerate the approval of novel candidates for Rx-to-OTC switches
- Examine how new technologies may cause new controversies in OTC labeling
- Analyze how the use of social media in the OTC space has blurred the boundaries between advertising and promotion and labeling
- Comprehend why OTC patent protection has implications beyond IP
- Appreciate the unique legal and regulatory challenges associated with natural OTCs and the homeopathic pharmacopeia
- Assess product classifications for international OTC launches
- Overcome regulatory challenges associated with umbrella branding for monograph and NDA OTCs

Prevent and Enforcement Actions and Civil Litigation 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 and FTC enforcers, NAD representatives and industry experts will help you:

- Understand how recent FDA and DOJ — as well as FTC — enforcement in the OTC space will influence future trends and compliance obligations
- Devise effective recall execution strategies
- Implement stringent GMP protocols that will help your company avoid fines, violations and enforcement activity
- Establish compliant protocols for adverse events in the OTC space pursuant to 21 USC §379aa, *i.e.*, Serious Adverse Event Reporting for Nonprescription Drugs

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:

- **Domestic and International OTCs and Consumer Health Care Products 101: Understanding and Re -Evaluating the Essentials of OTC-Ness for An Evolving U.S. and Ex-U.S. Health Care Marketplace** will provide an essential overview of the law and regulations governing over the counter pharmaceutical products in the U.S. as well as in other established markets and the developing world; 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.**

(Registration opens at 1:15)

A Pre–Conference Working Group

Domestic and International OTC and Consumer Health Care Products 101: Understanding and Re–Evaluating the Essentials of OTC–Ness for An Evolving U.S. and Ex–U.S. Health Care Marketplace

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

OTCs and consumer health care products have been a long time economic staple of both U.S. and international health care markets. However, in this age of health care reformation which calls for both cost savings and efficiencies world wide, OTC drug products may take on an even greater role in the global health care marketplace. This hands-on working group will provide you with an essential overview of the laws and regulations covering OTC products both in the U.S, and abroad. It will also set the stage for the main conference by helping you thoroughly comprehend the complexities of and challenges associated with this class of drug product.

- Understanding how OTCs fit into the future of health care delivery both in the US and abroad
  - in developing markets?
- Defining OTC drug products
  - in the U.S.
    - drugs vs. cosmetics vs. supplements
    - cosmeticeuticals; nutraceuticals
    - when can a vitamin or cosmetic be considered a drug?
  - in the EU and other European countries
  - in the developing world
    - China
- Exploring the criteria for OTC drug products
  - safety, efficacy, self-diagnosis, self- treatment
  - how does the U.S criteria compare with that of ex-U.S. and developing markets?
- OTC drugs vs. Rx drug products
  - domestic and international perspectives
- The role and authority of FDA in the U.S. 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
- Survey of international regulatory bodies having responsibility for OTC oversight
- Laws and regulations governing OTCs
- Overview of how an OTC drug comes to market
  - in the U.S
    - if it's a new drug
    - if it's not a new drug
    - Rx to OTC switch
  - outside the U.S.
    - switch concepts in Europe and elsewhere
- 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)?
  - review of international systems comparable to U.S. monograph system
- When is a new drug suitable for OTC usage?
  - U.S, vs., international criteria relative to:
    - 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 in the U.S. as compared to other jurisdictions?
- OTC advertising and promotion
  - the role of the FTC in the U.S.
  - comparable international regulatory bodies

7:15 Registration and Continental Breakfast

8:00 **Co–Chairs Opening Remarks**

Melinda Friend
Chief Regulatory Counsel
Colgate Palmolive
(Geneva, Switzerland)

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

8:15 **The FDA's NSURE Initiative Update: Delving into the Agency's Continued Exploration of a New Paradigm for "OTC Drugs With Conditions of Safe Use" and Its Potential Impact on the Future of Rx–to–OTC Switches**

William A. McConagha
Partner
Sidley Austin LLP
(Washington, DC)
(former Assistant Commissioner and Senior Counsel, Office of Chief Counsel, U.S. Food and Drug Administration)

Rikin Mehta, PharmD, JD, LLM
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United States Food and Drug Administration
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Office of Medical Policy Initiatives
(Silver Spring, MD)

Larry Miller
Chief Counsel
Pfizer Consumer Healthcare
(Madison, NJ)

The FDA's NSURE (Nonprescription Safe Use Regulatory Expansion) Initiative has been incorrectly perceived by many as an initiative for the creation of a third class of drug product or a behind the counter (BTC) class of drugs. However, NSURE's goal is instead to bring certain Rx drugs to OTC status with the proviso for 'conditions of safe use.' While the Rx-to-OTC switch mechanism has long been used as means to take certain prescription drug products (meeting established criteria) to non-prescription status, the NSURE initiative would take this accepted concept a bit further through the creation of certain monitoring mechanisms which have yet to be set. FDA, together with the Engelberg Center for Health Care Reform at the Brookings Institute and certain OTC industry stakeholders have held several workshops exploring means by which certain products outside the realm of a 'traditional' switch candidate can be brought to market.

This session will explore these findings; the future of Rx-to-OTC switches; the use of technology; and physician and pharmacist assistance in the furtherance of NSURE's goals. Points of discussion will include:

<u>NSURE update</u>

- Summary of findings of NSURE's focus groups
- How NSURE's goals coincide with the greater goals of health care reform in the U.S. – cost savings, preventative care, and efficiencies
  - remedy for under treatment of disease and certain chronic conditions
  - comparison of NSURE's objectives with international OTC paradigms
- Examining FDA's authority, goal, objectives and strategy to approve and monitor OTC drugs with 'conditions of safe use'
- Defining conditions of 'safe use'
- Ensuring safe use
  - label comprehension studies
  - self-selection
  - actual use tests
- Use of pharmacists and physicians in the NSURE initiative
  - is the use of such a learned intermediary counterintuitive to the OTC concept?
  - does the product under such circumstances become something akin to the European category of behind the counter product?
- Utilization of new technologies to ensure conditions of safe use
  - can technology replace the learned intermediary?
  - would use of certain technologies remove the OTC product status from that of a drug to that of an OTC device of combination product?

<u>Evolution of Rx-to-OTC Switch in light of NSURE Initiative</u>

- Understanding how the NSURE Initiative may determine the future course of Rx products eligible for an OTC switch
- How NSURE may alter the basic tenants of OTC eligibility, *i.e.*, self-diagnosis and self care
- Exploring switches in the last year which are indicative of the evolution of OTC classification and switch eligibility
  - Oxytrol
  - Plan B
- How the NSURE initiative may influence filings of citizen petitions and other third party challenges to force switches of Rx products which have been traditionally outside of the OTC sphere

9:30 Plan B Case Study: Understanding the Political, Administrative and Regulatory Controversies and Their Collective Impact on the Future of the OTC Landscape

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

Michael S. Labson
Partner
Covington & Burling LLP
(Washington, DC)

In April of this year, U.S. District Court Judge Edward Korman ruled that the emergency contraceptive pill, Plan B should be sold over the counter to woman of all ages and effectively overruled HHS Secretary's Kathleen Sebelius's mandate that the product be sold only from behind the counter to women 17 years or older with proof of age. This ruling set off a firestorm of controversy not only with respect to women's contraceptive rights, but also as to FDA and HHS authority; abuse of agency discretion; and political motivation. In June, the FDA, in line with Judge Korman's ruling finally approved the over the counter sale of Plan B to all women of child-bearing age. This panel will explore the points of contention which this matter raised, in addition to how the Plan B controversy will impact the future OTC landscape. Points of discussion will include:

- FDA's original findings with respect to the safety and efficacy of plan B within the traditional criteria for OTC classification, *i.e.*, self-diagnosis and self-care
- FDA's subsequent approval of the over the counter sale of Plan B to all women of child-bearing age
  - FDA's determination on age restriction on Plan B through a subsequent application brought by the drug's manufacturer
- Question of age restrictions within OTC schematic
- Evaluation of over the counter vs. behind the counter restrictions on this product
- HHS mandate vs. scientific findings
  - politics vs. science
- How may the Plan B decision ultimately influence the future of OTC product approvals and switches

10:15 Morning Coffee Break

10:30 Exploring Continuing Legal and Regulatory Conundrums Associated with the Monograph System and the OTC Drug Review Process: A Call and Case for Modernization

David Fox
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(Washington, DC)

Paul M. Hyman
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(Washington, DC)

Marcy L. Sussman, RAC
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GlaxoSmithKline Consumer Healthcare
(Rockville, MD)

Moderator:

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

For over a decade, the OTC drug industry has been patiently awaiting the modernization of the FDA Monograph and OTC Review. In the interim, the industry has tried to devise work arounds in the absence of definitive guidance and often finds itself at the impasse of legal and regulatory uncertainties. This panel will explore current industry challenges and possible solutions in the void of definitive guidance.

- Monograph Modernization update
  - status and progress of the USP Monograph Modernization initiative
    - role of USP and FDA in monograph modernization
    - re-examining safety and efficacy by modern standards
- Differentiating between final monographs and tentative final monographs
  - if a monograph is not final, then how us it abided?
  - Time and Extent Applications
- Understanding the linkage between monograph modernization and the status of the OTC Review Process
- Exploring legal and regulatory hindrances to OTC Review completion
  - FDA rulemaking
- Assessing legal and regulatory concerns and consequences associated with antiquated quality standards in monographed products
  - impurities
  - comparison of quality standards for OTC monographed drugs vs. OTC and Rx NDA drugs
  - international challenges
- Exploring potential legal and regulatory hindrances for inclusions of new technologies and dosage forms into the current monograph system
  - how can these technologies and dosage forms be utilized in the absence of guidance from the monograph?
  - evaluating liability for use and incorporation of these new technologies
- Pros and cons of expansion of OTC Review

11:30 Global Planning For the International Commercialization of Your OTC Drug Product

Melinda Friend
Chief Regulatory Counsel
Colgate Palmolive
(Geneva, Switzerland)

- Devising strategies to plan for the international launch of an OTC drug product
- Understanding potential differences in product classifications in different global markets
  - OTC drug status in U.S. vs. OTC device status abroad
  - OTC drug status in U.S. vs. cosmetic status abroad
  - OTC drug status in U.S. vs. OTC combination product abroad
- Evaluating whether a product can be reformulated to meet the requirements of a single classification in desired global markets
- Assessing how differences in classifications in international and developing markets will affect approval and commercialization strategies

12:15 Networking Luncheon

1:30 Evolving Challenges in OTC Labeling: How the Use of New Technologies May Impact Claims and Compliance

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

- How use of new technologies to enhance label sets may change the essentials of labeling requirements for OTC drug products
  - QR codes
  - apps and software
  - information kiosks
- Would the incorporation of these technologies be ultimately classified by FDA as an element of the label?
  - would these technologies need to be monitored like OTC devices by FDA?
  - would such monitoring change drug classification of product to a device or combination product if use of new technology was necessary to label comprehension?
- Evaluating label comprehension studies and remedying label failures
- Exploring labeling challenges relative to Rx-to-OTC switches
- Understanding how labeling may need to evolve in view of proposed new OTC paradigm under NSURE initiative
- Exploring gray areas in labeling
  - are websites part of the label?
    - displays?
    - package design?
- Status of possible harmonized label requirements
  - for OTC and Rx versions of drugs
  - for domestic and international markets
- Assessing the necessity of label changes
  - when is it absolutely necessary?
  - what does the label change process entail?
- Understanding the scope of legitimate claims which can be made on the label
  - claims for monographed products
    - controversies over terms such as "fast acting"
      - necessity of testing and studies
  - claims for OTC as opposed to Rx versions of the same drug
  - borderline claims
  - how may new technologies considered as labeling affect claims?
- Recognizing labeling errors which may be associated with misbranding
  - potential liabilities for findings of misbranding
  - assessing whether new technologies may lead to labeling errors or new misbranding concerns
- Label requirements relative to the reporting of adverse events
  - Dietary Supplement and Nonprescription Drug Consumer Protection Act
  - how may new technologies used in conjunction with AER requirements on the label enhance the objectives of Dietary Supplement and Nonprescription Drug Consumer Protection Act?

2:15 Define, Distinguish & Differentiate: Best Practice Protocols for Adverse Event Reporting of Non–Prescription Drug Products

Sarah Roller, J.D., R.D., M.P.H.,
Partner
Kelley Drye & Warren LLP
(Washington, DC)

- Establishing compliant protocols for adverse events in the OTC space pursuant to 21 USC §379aa, *i.e.*, Serious Adverse Event Reporting for Nonprescription Drugs
  - 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

- Best practices for cataloguing reportable and non-reportable adverse events
  - serious adverse event
- Review of record keeping requirements for adverse events
- Establishing internal review protocols and record keeping systems in accordance with inspection requirements
- Understanding how new technologies may enhance AER reporting by the consumer
  - social media risks/controversies

3:00 Afternoon Refreshment Break

3:15 Umbrella Branding for OTCs: Strategies for Maximizing the Value of Trade Names and Trademarks While Avoiding Legal and Regulatory Liabilities

Mark Brian Levine
Associate General Counsel
Reckitt Benckiser
(Parsippany, NJ)

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

Renuka Singh
Senior Counsel
Reckitt Benckiser
(Parsippany, NJ)

Moderator:

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

- Exploring the value of umbrella branding and how it is viewed as a locomotive which powers the branded OTC industry
  - FDA regulation of OTC umbrella branding and line extensions for monographed products
  - regulations and protocols for international umbrella branding
  - established vs. developing markets
- Examining the relationship between trade names, trademarks and umbrella branding
- What's in a name?: The art of choosing wisely
  - consumer recognition
  - FDA approval
  - international recognition and applicability
  - what does the product name convey?
    - is there a chance for confusion or misunderstanding?
- Trade name/trademark review for monographed and NDA OTCs
  - comparison to Rx OTC trademark/trade name review
  - PTO registration
- Understanding the FDA's contention that the product name is a claim and how this contention applies to the concept of umbrella branding
- Recent FDA scrutiny of umbrella branding of monograph and NDA OTCs
  - avoiding name confusion controversies associated with umbrella branding
    - *e.g.*, brand name extension given to a product with completely different ingredients

4:30 The Patenting of Non–Prescription Drug Products: What Every OTC Attorney and Regulatory Affairs Executive Should Know

Diane E. Furman
Senior Patent Counsel
Novartis Consumer Health, Inc.
(Parsippany, NJ)

Robert M. Isackson
Partner
Orrick, Herrington & Sutcliffe LLP
(New York, NY)

- Overview of patent protections afforded to OTC products outside of the FDA Monograph
- Patent protections allowed to products which result from an Rx-to-OTC switch scenario
  - can certain patents carry over from Rx to OTC version of product?
- Identifying instances in which NDA OTC products are afforded patent protections outside of an Rx-to-OTC switch scenario
  - Rx NDA v. OTC NDA
- Patent implications tied to the product label
  - dosage
  - formulation
- Applicability of Hatch-Waxman Act to OTC products
  - Orange Book listings
  - exclusivities
  - 180 day vs. applicable regulatory exclusivities
  - Paragraph IV challenges for OTC products
  - invalidity and non-infringement
    - Delsym patent
    - Mucinex patent
  - 30 month stay

5:30 Conference Adjourns to Day Two

Main Conference – Day Two
Wednesday, October 30, 2013

7:15 Continental Breakfast

8:00 Co–Chairs Opening Remarks and Recap of Day One

8:15 Social Media in the OTC Space: Navigating The Uncharted Territory and Undefined Border Between Advertising and Promotion and Labeling

Laura Brett
Staff Attorney
National Advertising Division
Council of Better Business Bureaus, Inc.
(New York, NY)

Spring C. Potoczak
Associate General Counsel
Novartis Consumer Health, Inc.
(Parsippany, NJ)

Nur-ul-Haq
Attorney
Federal Trade Commission, Northeast Region
(New York, NY)

Moderator:

Sharon A. Blinkoff
Counsel
Edwards Wildman Palmer LLP
(New York, NY)

- Examining the use of social media in the OTC space
  - unanswered questions concerning proper use of social media in the absence of definitive FDA guidance in this area
  - when can social media be viewed as advertising and promotion?
  - when is it viewed as labeling?
  - when is it viewed as both?
- The importance of understanding why and how the use of social media falls in a gray area between advertising and promotion and labeling
  - repercussions and liabilities through use of this unregulated medium
    - misbranding
    - unsubstantiated claims
  - FDA vs. FTC authority in OTC advertising and promotion
    - regulation of product claims for monographed and NDA OTCs
      - FTC's position on social media in advertising of OTC products
  - distinguishing between advertising and promotion regulations for OTC monograph products and OTC NDA products
  - examining the label as a means of advertising and promotion
- Substantiating product claims via social media
  - what can you say vs. what you cannot
  - role of DDMAC
- Exploring Lanham Act challenges relative to false and misleading claims for competitor products in social media
- Monitoring of OTC advertising and use of social media in this space by National Advertising Department of Better Business Bureau (NAD)

9:30 Homeopathic OTCs: Special Legal and Regulatory Considerations for Products Outside of the Realm of Traditional OTC Products

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

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

Kimberly Mills
Director of Regulatory Affairs & Quality Assurance
Similasan Corporation
(Highlands Ranch, CO)

- Defining homeopathic products
  - prescription vs. OTC
  - homeopathy and natural medicine
- Understanding how these products are regulated and classified by FDA
  - in comparison to traditional otcs
  - absence of monograph
  - homeopathic pharmacopeia
- Examining marketing protocols for these products
  - FDA Compliance Policy Guide
- Comparison of homeopathic OTCs to dietary supplements

10:15 Morning Coffee Break

10:30 Best Practices for Good Manufacturing Practice Compliance for Non–Prescription Drug Products

Shane H. Freedman (invited)
Vice President, Law
McNeil Consumer Healthcare
(Fort Washington, PA)

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

- Overview of recent GMP violations and enforcement activity in the OTC space
  - what can we glean from current 483 activity in this space?
- Understanding the scope of the FDA's authority relative to GMPs in the OTC/Consumer Health Product space
- Anticipating and preparing for an FDA inspection
- Responding to a 483 warning letter and/or FDA enforcement action
  - taking voluntary corrective measures and working with FDA
  - entering into a corporate integrity (CIA) or corrective action plan with FDA
- Incorporating cGMP protocols into your company's compliance program
- Developing a system of internal checks and balances
- How do cGMPs factor into products liability and consumer products litigation in the OTC space?

11:15 Lessons Learned in the Aftermath of Notable OTC Recalls: Consequences and Corrective Actions

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

James R. Johnson
Attorney
Hogan Lovells US LLP
(Washington, DC)
(former Associate Chief Counsel in the FDA's Office of the Chief Counsel)

- Examining recall activity relating to OTC products from 2009 to present
  - what were the nature of these recalls
  - what corrective actions were taken?
  - what are the lessons learned?
- Evaluating the risks and benefits of cooperating with FDA in the course of a recall
  - FDA's recall and oversight authority with respect to OTC and other drug products
  - FDA's recall expectations for prescription drugs vs. OTC products
    - recall requirements under the Consumer Product Safety Act
- Voluntary recalls versus mandatory recalls
  - market withdrawals and stock recoveries
- What are the consequences of not instituting a recall?
  - FDA seizure and injunction power
- Best practices for formulating effective recall execution strategies
- Assessing the impact of divergent post-marketing reporting requirements for OTC drugs
- Interaction between recalls and corrective and preventive action
- Strategies for introducing a product back to market
  - recent product reintroductions

12:15 OTC Enforcement Actions and Private and Public Litigation

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

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

David G. Mallen
Deputy Director
for Legal Affairs
National Advertising Division
Council of Better Business
Bureaus, Inc.
(New York, NY)

- Recent OTC enforcement actions: case studies and lessons learned
  - scope of wrongdoing
  - remediation
  - take aways from J&J McNeil
- Exploring trends in private litigation relative to OTC products
  - link between private and public OTC suits
- Evaluating the economic cost of enforcement actions: impact on brand and reputation
- Survey of NAD actions relative to OTC claims
  - connection to consumer class action suits and government enforcement actions

1:15 Conference Adjourns

1:15 Lunch will provided for Attendees of the Post–Conference Workshop

Wednesday, October 30, 2013
2:15 PM – 5:45 PM

(Registration Opens at 1:45)

B Post–Conference Workshop

Rx–to–OTC Switch Master Class: In–Depth Analysis of Legal, Regulatory and Business Strategies for Bringing Your Prescription Drug Product Over the Counter

Thomas Blake, R.Ph.
Regulatory Strategist
(Budd Lake, NJ)

Susan B. Levy
Principal
Susan B. Levy Consulting, LLC
(Westfield, NJ)

Arnold Burstein
Executive Vice President
BioClara Group
(New York, NY)

Erin Oliver, MS, MBA, RAC
Director, Regulatory Affairs
GSK Consumer Healthcare
(Parsippany, NJ)

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 NSURE Initiative. In this interactive session, our Master Class 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:

- 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's NSURE Initiative
  - 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
- 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 manufacture on and OTC versions
- 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

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

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October 28, 2013: **Domestic and International OTC and Consumer Health Care Products 101: Understanding and Re -Evaluating the Essentials of OTC-Ness for An Evolving U.S. and Ex-U.S. Health Care Marketplace**

October 30, 2013: **Rx-to-OTC Switch Master Class: In-Depth Analysis of Legal, Regulatory and Business Strategies for Bringing Your Prescription Drug Product Over the Counter**

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