2ND ANNUAL

Rx TO OTC Switch

Navigate the Lifecycle of an OTC Switch by Minimizing Regulatory, Clinical Safety and Market Risks

APRIL 20-21, 2016 • DOUBLETREE BY HILTON PRINCETON • PRINCETON, NJ

Specialized Information and Networking Devoted to Advancing Your Strategy:

- Compare and contrast the strategies involved in successful and failed switches
- Create a full proof dossier (clinical sections) to optimize current or future switch plans
- Consider a shelf strategy for an Rx-to-OTC switch that utilizes colors, shapes and unexpected symbols to connect with consumers’ brand recall while shopping
- Establish a road map to identify brands that have accomplished secure levels of protection
- Differentiate packaging while satisfying technical and supply chain requirements
- Learn about recent innovative package successes
- Hear examples of prescription medications that should be considered as switch candidates
- Determine when and how to partner with an OTC company
- Gain best practices for conducting consumer studies for Rx to OTC switch
- Work collaboratively with manufacturers and retailers to ensure that the most relevant strategies and tactics are employed
- Benefit from legal, regulatory, consumer and shopper insights necessary to secure approval and prepare for launch

Expert Speaking Faculty Paves the Way for Success!

Terri Goldstein, Chief Executive Officer, The Goldstein Group
Nancy Limback, Principal, Packaging Strategies & Solutions, LLC
Alankar Gupta, M.D., MS, MBA, E-MBA, Global Medical Leader, Diversified Brands, Merck, Sharp & Dohme Corp.
Daniel A. Hussar, Ph.D., Remington Professor of Pharmacy, Philadelphia College of Pharmacy
Susan B. Levy, Founder and Principal, Susan B. Levy Consulting, LLC.
Joseph P. Reo, DPh, Ph.D., R&D Director, Rx-to-OTC Switch Science, Bayer Consumer Healthcare
Tamar Yarkoni, Senior Manager, Medical Information, Sanofi
Marty Baum, Principal, Edgewood Consulting Group
Alison B. Kessler, Assistant General Counsel, Patents, GSK Consumer Healthcare

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The Pressing Issues Surrounding OTC Switching Activity

Consumer Health: Update – OTC Switches

Stricter regulation on OTC drugs
Financial benefits of OTC switches and the rise of generics
Increasing demand for improved safety and efficacy studies
Consumer self-care initiatives
Fewer novel active ingredient OTC candidates
Retailing trends to include more channels and increased supervision

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Who Should Attend:

You will benefit from attending this event if you are from the pharmaceutical industry with responsibilities or involvement in the following areas:

- Rx to OTC Switch
- Drug Safety
- Labeling
- Regulatory
- Brand Marketing
- Product Lifecycle
- Clinical and Medical Affairs

This conference will also benefit technology providers and companies providing research, legal and consulting services to the above audience.

A Great Place to Meet Your Market!

Take advantage of the best opportunity to meet potential clients face-to-face. Build relationships while demonstrating thought leadership and sharing expertise. For more information on how to position your company as a sponsor or exhibitor, contact Lauren Moras at 339-298-2172 or email lauren.moras@cbinet.com.
DAY ONE
Wednesday, April 20, 2016

7:15 Continental Breakfast and Conference Registration

8:15 Chairman’s Welcome and Opening Remarks
Joseph P. Reo, DPh, PhD, R&D Director, Rx-to-OTC Switch Science, Bayer Consumer Healthcare

8:30 Key Techniques for Successful Brand Establishment with Cognitive Strategies

Benefit from a fun and energizing informational session which demonstrates successful brand establishment.

• Target consumer emotions with visuals to capture the wants, needs, aspirations and rituals that turn into an intuitive yet powerfully emotive “visual vocabulary” for brand packaging
• Create a shelf strategy for an Rx-to-OTC Switch that utilizes colors, shapes and unexpected symbols to connect with consumers’ brand recall through the mind’s Sequence of Cognition while shopping, as well as their impulsive purchase behaviors and patterns
• Identify other brands that have accomplished secure levels of protection and establish a road map to do the same

Terri Goldstein, Chief Executive Officer, The Goldstein Group
Ms. Goldstein is the CEO and founder of The Goldstein Group, and a global creative strategist, who for two decades has created protectable brand images for RX/OTC switches searching for a category of medications that are available without a prescription from a pharmacist.

Ms. Goldstein is an expert in turning companies’ dreams into reality. She has created packaging for such brands as Tiny Love, Carmex, Aqua Net, Bayer Aspirin, Rolaids, Phillips’ Colon Health, Selsun Blue, Balmex, Gentle Naturals, Little Remedies, Cortizone-10, IcyHot, and One-A-Day to name a few.

11:00 Switches from Prescription to Nonprescription Status — A Pharmacist’s Perspectives and Recommendations
We are not close to the potential that exists for switching medications from prescription to nonprescription status. Pharmaceutical companies, the FDA and associations of pharmacists can do much more to significantly increase the number of switches. There should be formal recognition and support for a category of medications that are available without a prescription from a pharmacist.

• Examples of prescription medications that should be considered as switch candidates
Daniel A. Hussar, Ph.D., Remington Professor of Pharmacy, Philadelphia College of Pharmacy

12:00 Networking Luncheon

1:15 Engaging in Switch Partnership
Rx to OTC switch provides an effective lifecycle management strategy for maximizing the value of pharmaceutical assets. There are increasingly fewer Rx companies with consumer healthcare divisions, however. As a result, pharmaceutical organizations with switchable assets need to determine when and if they want to find a partner to accompany them on their switch journey. In this session, examine:

• The difference between simply switching a drug and driving commercial success of an OTC asset and the implications for pharmaceutical companies
• When and how to find the ideal switch partner
• Recent switch deals and switch deal “watch outs”
Susan B. Levy, Founder and Principal, Susan B. Levy Consulting, LLC.

2:15 Selecting the Ideal Switch Candidate
Just because a patent expires doesn’t mean that your product will be a successful switch. Hear about what should be considered before deciding upon a switch candidate.

• Learn from past switches and implications for future growth initiatives
• Critical considerations in pursuing a launch into a new category
• Determine how to prioritize “where to play”
• Gain insight into "how to win" in validating specific scientific platforms and respective commercial viability
• Assess critical criteria from past OTC switches to better predict future success, and avoid common pitfalls

Robert Molander, Former Senior Director of Marketing, Shionogi Inc.

3:00 Networking and Refreshment Break

3:30 Explore Varying Market Conditions Impacting Switch

This interactive Panel discussion provides an opportunity to analyze the market conditions of a successfully switched drug. Market conditions are major factors in the success of switching a product from prescription to over-the-counter. Explore the different market conditions that have the ability to impact the achievement of the switch — Take the following questions into consideration:
• Was there competition?
• Was the brand losing share?
• What was the impact on managed care — Did plans stop covering certain categories since it went OTC?
• What was the influence the brand could have had on setting retail price?
• What was the financial benefit going OTC?

MODERATOR: Natalia Borinshteyn, M.D., Ph.D., President, Life Science Excellence Inc

PANELISTS:
Joseph P. Reo, DPh, Ph.D., R&D Director, Rx-to-OTC Switch Science, Bayer Consumer Healthcare
Susan B. Levy, Founder and Principal, Susan B. Levy Consulting, LLC.
Monica Feldman, Head of Industry Research – Consumer Health, Euromonitor International

4:30 Develop Tactics and Capabilities to Help Achieve Competitive Advantage

If a patent is expiring in the future, it is important to plan ahead to extend the profitability of the product and achieve competitive advantage. Switching the product from prescription to over the counter is a way in which companies can expand the access of their product to more consumers. During this case study, learn how it is possible to implement an Rx to OTC switch strategy to extend the life of their product.
• Forecast trends early to improve the success of the product
• Expand product access by using a switch process
• Evaluate a global growth strategy based on challenges and evolution of the pharmaceutical industry

Alex Kandybin, Principal, S&, Innovation Strategy, PwC

5:15 Close of Day One

Networking, Wine and Cheese Reception immediately following the final session on day one

DAY TWO
Thursday, April 21, 2016

8:00 Continental Breakfast

8:30 Chairman’s Review of Day One

Joseph P. Reo, DPh, PhD, R&D Director, Rx-to-OTC Switch Science, Bayer Consumer Healthcare

Methods for Ensuring Safety, Adherence and Consumer Acceptance

8:45 Redefining the Profile of the Consumer in Health — An Opportunity for Rx to OTC Switches

Self-care is seeing yet another big transformation amid the adoption of novel digital technology (smartphones, wearables and mobile medical devices) that will change how consumers empower themselves for better health so as to further Rx to OTC switches. This is just the tip of the iceberg where the concept of health optimization will bring new opportunities for the consumer health industry.
• The status of self-care in relation to switches * measuring value from the U.S. and global perspective
* prevention trends to outpace treatments — What does it mean for switches?
• The role of the retailing environment in the delivery of health * what is working and what is not in the emerging model of retail healthcare delivery at the consumer level
* emerging safety networks in dispensing that will support the case for Rx to OTC switches
• Health optimization — Connecting the dots * proposal of the development of “OTC solutions” for health and wellbeing
* new discoveries based on humble OTC formulations to disrupt the industry by addressing unmet medical demands in the population — An attractive alternative to switches

Monica Feldman, Head of Industry Research – Consumer Health, Euromonitor International

9:30 Delve into the Role of Technology in Improving the Safety Environment for a Switch

With Rx to OTC switches, the medical intermediary is no longer there and consumers are taking on more responsibilities to self-diagnose and self-select. In addition, consumers are becoming more reliant on technology for health information. During this session, evaluate how technology aids the consumer’s ability to self-diagnose and self-select the appropriate drug.

Monica Feldman, Head of Industry Research – Consumer Health, Euromonitor International
• What Drug Facts labels tell (and do not tell) the consumer
• How can patients protect themselves while taking OTC products?
• Examples of technology resources (i.e., apps)
• Future trends and predictions for Rx to OTC switch candidates

Tamar Yarkoni, Senior Manager, Medical Information, Sanofi

10:15 Networking and Refreshment Break

10:45 Understand the Chief Considerations for Patent Protection in Rx to OTC Switches
Benefit from an analysis of patent protection from previously switched products and ideas for protecting product improvements as part of the strategy to expand access.
• Protecting product improvements and innovative packaging
• Evaluate the impact of recent court cases as they may cast some doubt on product selection patents
• Discuss early forecasting of trends and examining protections for prior product switches
• Examine patent protections for products that have switched from prescription to over-the-counter

Alison B. Kessler, Assistant General Counsel, Patents, GSK Consumer Healthcare

11:30 Commercializing the Rx to OTC Switch
Benefit from hearing about how manufacturers and retailers can work more effectively in the area of Rx to OTC switches, including:
• Development of a best practices approach to optimize switch commercialization
• Work collaboratively with manufacturers and retailers to ensure that the most relevant strategies and tactics are employed
• Legal, regulatory and consumer and shopper insights necessary to secure approval and prepare for launch

Marty Baum, Principal, Edgewood Consulting Group
Phil Kantor, Global Marketing Director, GSK Consumer Healthcare

12:30 Close of Conference

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“This conference was great for sharing best practices, hearing about various industry perspectives and for networking. It was very worthwhile. Thank you.”

— Previous Attendee, Senior Manager, Medical Information, Sanofi

“Rx to OTC Switch has a very peculiar scope and science. Although it can bring fantastic value to any firm and patients; due to limited knowledge, skillset and various other barriers, only 1-2 big switches occur in the U.S. every 1-2 years. Hence it is very tough to find expertise and knowledge on how to operationalize these huge projects.”

— Previous Attendee, Global Medical Leader, Diversified Brands, Merck
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ANY QUESTIONS OR TO REGISTER
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Register by March 11, 2016 and SAVE $300. Fee includes continental breakfast, lunch, wine and cheese reception, refreshments and conference documentation. Credit Card (Visa, MC, AMEX) or checks accepted. Please make checks (in U.S. funds drawn on a U.S. bank) payable to: CBI. (No personal checks accepted.) PLEASE NOTE: All advertised discounts are taken from the full, Standard Rate.

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