

5TH RX -TO- OTC SWITCH SUMMIT



Develop Business and Marketing Strategies to Implement Best Practices to Ensure a Successful Switch

December 6–7, | Sonesta Philadelphia Rittenhouse Square | Philadelphia, PA



Paul Wardle,
Vice President, U.S. Women's Health,
HRA PHARMA



Susan Levy,
Founder and Principal,
SUSAN B. LEVY CONSULTING



Terri Goldstein,
CEO,
THE GOLDSTEIN GROUP



Dr. Juby Jacob-Nara,
Former CMO, and Vice President,
Global Clinical Development and
Global Medical Affairs,
PFIZER



Amy Replogle,
Director, Rx-to-OTC Switch Science,
BAYER



Randall Thornton,
Clinical Pharmacist,
EMORY HEALTHCARE



Susan Lavine Coleman,
President,
NCI CONSULTING, INC



Allie Wollum, MPH,
Senior Project Manager,
IBIS REPRODUCTIVE HEALTH

KEY EVENT TAKEAWAYS

- ✓ Discuss key research on branding with respect to the OTC consumer shopping and choice experience
- ✓ Use new technologies, new ways of thinking, and new regulatory developments to advance consumer self-care
- ✓ Analyze evolving legislation and the changing laws and regulations impacting OTC products
- ✓ Learn how key indication, safety and dosing messages from Rx labeling get translated to “consumer-friendly” Drug Facts Label (DFL) language
- ✓ Design intuitive, effective comprehension alternate models to expand consumer access



CASE STUDY: Review Best Practices and Insight from Galderma for a Successful Rx-to-OTC Switch From Launch to Year Two

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WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical and biotechnology companies with responsibilities in the following areas:

- › Rx-to-OTC Switch
- › Marketing/Branding/Commercialization
- › Research/Drug Development
- › Regulatory/Medical/Scientific Affairs
- › Consumer Healthcare Products
- › Drug Developers/Pharmaceutical Companies
- › Clinical Development
- › Clinical Trials
- › Research and Development
- › Business Strategy and Marketing Consultants
- › Product Development
- › Labeling/Packaging
- › Product Development
- › Scientists
- › Corporate Development
- › Consumer Insight

This conference is also of interest to:

- › Regulatory Consultants
- › Clinical Research Labs
- › CROs/CMOs
- › Drug After-Market Manufacturers/Suppliers
- › Advisors
- › Statistical Service Providers
- › Marketing/Media Organization

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DEAR COLLEAGUE,

Switching drugs from prescription (Rx) to over-the-counter (OTC) status is a commercial strategy that has been growing in popularity. Successful Switches are as much an art as a science, and it has become increasingly apparent that for Switch teams to effectively collaborate, they must revise their best practices in strategy, marketing, sales, clinical research, regulatory affairs, medical writing, labeling, and packaging, among other areas.

Now in its fifth year, ExL's **Rx-to-OTC Switch Summit** is the most advanced thought leadership event that experts can attend to discuss all aspects of a Switch, from the NDA process to the final over-the-counter product; analyze current trends, and prepare for future Switches. This Summit brings industry leaders together to discuss the changing Rx-to-OTC Switch landscape from quality, testing, regulatory, strategy and marketing standpoints.

Attendees will learn how to:

- › Discuss key research on branding with respect to the OTC consumer shopping and choice experience
- › Explore how to use new technologies, new ways of thinking, and new regulatory developments to advance consumer self-care
- › Analyze the changing laws and regulations impacting OTC products
- › Learn how key indication, safety and dosing messages from Rx labeling get translated to "consumer-friendly" Drug Facts label (DFL) language
- › Design effective comprehension alternate models to expand consumer access

I look forward to welcoming you to Philadelphia this December!

Sincerely,

Aimee Gutzler

Aimee Gutzler
Conference Production Director
ExL Events, a division of Questex, LLC

VENUE INFORMATION

Sonesta Philadelphia
Rittenhouse Square
1800 Market Street
Philadelphia, PA 19103

To make reservations, please call **1.800.SONESTA** and request the negotiated rate for **ExL 15th Metrics, 5th RX-to-OTC, GDRP Update**. You may also make reservations online using the following weblink: bit.ly/2KD9b4U. The group rate is available until **November 15, 2018**. Please book your room early, as rooms available at this rate are limited.



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8:15 REGISTRATION AND CONTINENTAL BREAKFAST

9:15 CHAIRPERSON'S OPENING REMARKS

Edwin Hemwall, Ph.D., *Principal*, EDWIN HEMWALL LLC, REGULATORY AND SCIENTIFIC CONSULTING SERVICES

NAVIGATE THE CURRENT RX-TO-OTC MARKET

9:30 CONFERENCE WORKSHOP

RX-TO-OTC 101 – SWITCH BASICS

- Obtain a step-by-step best practices guide for conducting an Rx-to-OTC Switch
- Understand FDA's mindset with regard to Rx-to-OTC Switch
- Review case studies for successful (and failed) Rx-to-OTC Switches (from a regulatory perspective)
- Learn about the top ten factors that determine whether an Rx-to-OTC Switch will be commercially successful
- Examine case studies for successful (and failed) Rx-to-OTC Switches (from a commercial perspective)
- Explore how to evaluate Rx-to-OTC switch opportunities

Susan Levy, *Founder and Principal*, SUSAN B. LEVY CONSULTING

There will be a half-hour networking break at 10:45.



12:00 INVESTIGATE SWITCH SUCCESS FACTORS

- Define the product's drug class and review its current market position
- Define whether the switch will create a new OTC class or move into an existing class
- Prepare for the internal marketing challenges of Switch and how to address them
- Explore a case study on the evolution of Switch
- Review success and failures of Pepcid, Mevacor and Oxytrol

Amy Replogle, *Director Rx-to-OTC Switch Science*, BAYER

12:45 LUNCHEON

1:45 HOW TO DESIGN AND OWN YOUR RX/OTC SWITCH FOR AN OMNICHANNEL WORLD

- Ensure you adhere to the FDA monograph or NDA compliance, attach informative imagery that does not over-promise and always design with consumer safety top of mind.
- Understand the desire for in-store promotion vehicles and unique shelf strategies and structures that will command attention.
- Uncover the consumer sequence of cognition when selecting one brand over another, both on-shelf and online.

Terri Goldstein, *Chief Executive Officer*, THE GOLDSTEIN GROUP

2:30 DEVELOP A CONSUMER BRAND

- Educate on the importance of marketing
- Understand which prescription brand to Switch and when
- Discuss the exclusivity period
- Avoid missing market opportunities by formulating a strategy before patent expiration
- Research the potential consumer and evaluate the brand's OTC attractiveness
- Consider the regulatory perspective of commercial and growth potential

Paul Wardle, *Vice President*, U.S. Women's Health, HRA PHARMA

3:15 NETWORKING BREAK

3:45 LEAD A PRODUCT CATEGORIES IN THE OTC DRUGS MARKET

- Review the fastest-growing segments according to the industry and hone in on which treatment segments are most likely to experience future Rx-to OTC Switches, such as statins and erectile dysfunction drugs
- Describe which indications are most likely to experience future Rx-to-OTC Switches and discuss the possibility of a BTC drug class and uncover candidates for BTC status
- Educate on public health value and the need to empower self-care

Dr. Juby Jacob-Nara, *Former CMO, and Vice President*, Global Clinical Development and Global Medical Affairs, PFIZER

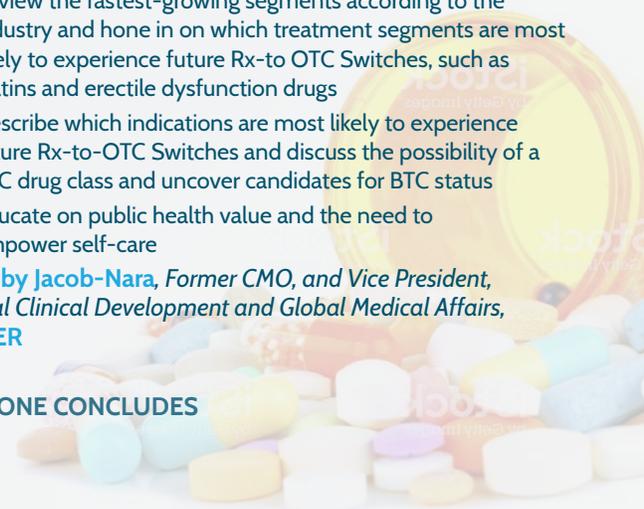
4:30 DAY ONE CONCLUDES

"Excellent Insight!"

—*Director, R&D*
BAYER CONSUMER CARE

"Brought up some new points that i did not think of previously."

—*Senior Director of Regulatory Affairs*,
PERRIGO



8:00 CONTINENTAL BREAKFAST

9:00 **CHAIRPERSON'S RECAP OF DAY ONE**
 Edwin Hemwall, Ph.D., *Principal*, EDWIN HEMWALL LLC,
 REGULATORY AND SCIENTIFIC CONSULTING SERVICES

INVESTIGATE FUTURE TRENDS IN RX-TO-OTC SWITCHES

9:15 **DISCUSS EMERGING STRATEGIES TO WIN
 FDA APPROVAL**

- Discuss the role and limitations of data in Switch
- Review the challenge of polarization
- Dive into emerging stakeholder models
- Highlight new paradigms to expand consumer access

Susan Lavine Coleman, *President*, NCI CONSULTING, INC.

10:00 **EXPLORE OPPORTUNITIES TO CREATE NOVEL SWITCH
 PARADIGMS WITH TECHNOLOGY-BASED TOOLS**

- Expand access to treatments for common medical conditions through innovative conditions of safe use for OTC Switch candidates
- Review the historical context of the FDA's NSURE initiative
- Explore regulatory framework projected to allow for tech-aided Drug Facts Labeling
- Assess the FDA's 2018 Draft Guidance on "Innovative Approaches for Nonprescription Drug Products" and forthcoming rulemaking process
- Provide models of adjunctive tools designed to aid and improve correct self-selection and product use
- Describe system development and evolution from prototype to marketplace
- Discuss critical success factors for a unique tech-enabled Switch program

Edwin Hemwall, Ph.D., *Principal*, EDWIN HEMWALL LLC,
 REGULATORY AND SCIENTIFIC CONSULTING SERVICES

11:00 NETWORKING BREAK

11:30 **LEVERAGE DIGITAL HEALTH TO FACILITATE SWITCH**

- Employ digital tools for patient/consumer engagement, disease management and other applications
- Provide broad perspective on digital health within the industry
- Review the impact of e-commerce, online pharmacies, and Smart Healthcare

12:15 **DISCUSS WHY PHARMACY AND RX-TO-OTC SHOULD
 WORK TOGETHER AND THE IMPACT ON RX AND
 OTC DRUGS**

- Address how state pharmacy boards are moving on pharmacist scope of practice and changing care
- Review the future of oral birth control and why Albuterol inhalers can be moved to OTC status
- Address Rx-to-OTC changes for impacting the opioid crisis
- How the FDA is looking for ways to influence Rx-to-OTC
- Dive into ED drugs: Moving over an overprescribed class
- Uncover who will sponsor the next major Switch product and reasons why major chains support Switch

Randall Thornton, *Clinical Pharmacist*,
 EMORY HEALTHCARE

1:00 LUNCHEON

2:00 **THE ORAL CONTRACEPTIVES (OCS) OVER-THE-
 COUNTER (OTC) WORKING GROUP: MOVEMENT
 BUILDING TO REVOLUTIONIZE CONTRACEPTIVE ACCESS**

- Explain how an OTC Switch for OCs would help women in the U.S. to overcome barriers to birth control access
- Describe the history and role of the OCs OTC Working Group
- Discuss the working group's current priorities and activities in research, supporting the implementation of a regulatory strategy, communications, and advocacy to ensure that a future OTC OC is affordable, covered by insurance, and available to people of all ages

Allie Wollum, MPH, *Senior Project Manager*,
 IBIS REPRODUCTIVE HEALTH

2:45 **CASE STUDY: REVIEW BEST PRACTICES AND INSIGHT
 FROM GALDERMA FOR A SUCCESSFUL RX-TO-OTC
 SWITCH FROM LAUNCH TO YEAR TWO**



- Navigate the marketing, trade and regulatory "nuts and bolts" fundamentals of the most recent first-in-class Switch of Differin Gel from ideation to meeting with FDA and submission content
 - Establish a speed to market launch plan; principles to entering a category that has not had an Rx-to-OTC Switch occur in it in over 30 years
 - Maximize market penetration in year two of launch
 - Discuss the studies required to support a Switch including label comprehension, self-selection and actual use studies and how they are similar, and different, from those typically encountered in the pharmaceutical world
 - Review regulatory activities after approval including surprises and key learnings
 - Deal with the FDA Nonprescription Division
- Sean Griffin, *Senior Director, Regulatory Affairs*, GALDERMA
 Meredith Balderas, *Sr. Brand Manager Differin OTC/Acne, Consumer Business Unit*, GALDERMA
 Katherine Rouse, *Director of Marketing*, GALDERMA

3:45 CHAIRPERSON'S CLOSING REMARKS

4:00 CONFERENCE CONCLUDES

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