DIA VIRTUAL CONFERENCE

Advertising and Promotion Regulatory Affairs Conference

Primer: May 17 | Conference: May 18-20

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Lucy Rose, MBA
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Overview

DIA's *Advertising and Promotion Regulatory Affairs Conference* explores the current state of compliance for marketing both biopharmaceuticals and medical devices. Join thought leaders from industry, legal, public affairs, and government for interactive and compelling discussions that will shape policy and define strategic priorities within the advertising and promotion regulatory space. Representatives from across FDA's Medical Product Offices will provide the latest information on guidance policies, enforcement actions, and future directions of industry hot topics such as pre-approval activities, labeling strategies, and social media tactics.

This conference is geared towards both early and late-career professionals with content that advances the understanding of current regulatory policies, details the latest strategies for effective patient engagement, and discusses the trends in advertising for biopharmaceuticals, combo products and companion diagnostics. Attendees will have the opportunity to network with key thought leaders from the FDA, industry, and other regulatory practitioners, while simultaneously discussing the challenges and opportunities of marketing pharmaceuticals and medical devices today.

Who Should Attend

Professionals involved in:

- Regulatory Affairs
- Marketing
- Communications
- Compliance
- Medical Information and Affairs
- Legal
- Senior Management

Schedule At-A-Glance

PRIMER | SUNDAY, MAY 17	
1:00-5:00PM	Drug and Medical Device Ad Promo Primer

DAY ONE | MONDAY, MAY 18	
10:00-10:30AM	**Opening Remarks and Welcome from the DIA Ad Promo Working Group**
10:30-11:00AM	**Session 1:** Keynote Address: The Patient Voice: Message and Impact on Healthcare
11:00-11:05AM	Break
11:05AM-12:05PM	**Session 2:** FDA Update
12:05-12:30PM	Break
12:30-1:30PM	**Session 3:** OPDP Research Update
1:30-2:30PM	**Session 4:** Adding Value to Ad Promo Review, Tips and Best Practices: Panel Discussion
2:30-2:45PM	Break
2:45-3:45PM	**Session 5:** Engaging with Patients to Diversify Advertising and Promotional Activities
3:45-4:15PM	Relevant and Recent: 2019 Learnings from DIA Ad Promo Working Group RA Community

DAY TWO | TUESDAY, MAY 19	
11:00-11:15AM	**Welcome to Day Two**
11:15AM-12:15PM	**Session 6:** Enforcement Insights to Navigate Decision-Making
12:15-1:15PM	**Session 7:** What Goes into a Successful Promotional Communication Strategy? Panel and Examples
1:15-1:45PM	Break
1:45-2:45PM	**Session 8:** Communications and Pricing Disclosures: From State/Federal Transparency Requirements to Formulary Placement and Value-Based Contracting Communications
2:45-3:45PM	**Session 9: Track B:** Strategies to Address Labeling Changes: The Impact on Promotional Materials
3:45-4:45PM	**Session 9: Track A:** Labeling Changes and the Impact on Medical Devices

DAY THREE | WEDNESDAY, MAY 20	
11:00-11:15AM	**Welcome to Day Three**
11:15AM-12:15PM	**Session 10: Track B:** Promotion and What Rules Apply to Generic Drugs and Biosimilars
12:15-1:15PM	**Session 10: Track A:** Considering the Implications of International Differences in Regulation on Life Science Advertising and Promotions Regulatory Affairs
1:15-1:45PM	Break
1:45-2:45PM	**Session 11: Track B:** eCTD Use and Ad Promo Materials
2:45-3:15PM	Closing Remarks and Live Q&A
3:15PM	Conference Adjourns

Learning Objectives

At the end of this conference participants should be able to:

- Discuss the latest FDA policies, guidances and how they apply on a practical basis to day to day oversight of advertising and promotional materials for pharmaceuticals, biologics, generics, biosimilars, and medical devices
- Describe how other companies are interpreting policies and applying them to their current marketing strategies
- Recognize the differences between US FDA and other international regulatory policies regarding the promotion and advertising of medical devices
- Apply the latest policies to better communicate with all audiences, including payers
- Select and implement effective digital and social media strategies to meet the challenges of ensuring compliance with FDA regulatory requirements

May 18-20 Continuing Education Credit

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, JULY 3, 2020

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This session is designated for up to 15.25 contact hours or 1.525 continuing education units (CEU's).

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. If ACPE credit is not requested by Friday, July 3, 2020, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit **www.cpemonitor.net**.

If you are claiming credit for this virtual meeting you must:

1. Complete a CE Verification of Attendance Form
2. Return it to **NAEvents@diaglobal.org** by May 27, 2020
3. Access your DIA account and select My Transcript to claim your credit, available on June 3, 2020

Drug Information Association (DIA) is accredited by the International Association for Continuing Education and Training (IACET) and is authorized to issue the IACET CEU.

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer **1.6** CEUs for this conference.

Participants must complete the entire conference in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

Continuing Legal Education

For attorneys who would like to receive continuing legal education credits for attending the 2020 Advertising and Promotion Regulatory Affairs Conference, please complete your state's application for credit and submit accordingly. If you require additional information, please contact **CE@DIAglobal.org**.

Continuing Education Credit Allocation

Drug and Medical Device Ad Promo Primer: UAN 0286-0000-20-078-L04-P, Application, 3.5 Contact Hours, .35 CEUs

Day One: Advertising and Promotion Regulatory Affairs Conference: UAN 0286-0000-20-079-L04-P, Knowledge, 3.5 Contact Hours, .35 CEUs

Day Two: Advertising and Promotion Regulatory Affairs Conference: UAN 0286-0000-20-080-L04-P, Knowledge, 5 Contact Hours, .5 CEUs

Day Three: Advertising and Promotion Regulatory Affairs Conference: UAN 0286-0000-20-081-L04-P, Knowledge, 3.25 Contact Hours, .325 CEUs

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On Demand Meeting - Continuing Education

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, JULY 3, 2020

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This session is designated for up to 16.25 contact hours or 1.625 continuing education units (CEU's).

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. If ACPE credit is not requested by Friday, July 3, 2020, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit **www.cpemonitor.net**.

Drug Information Association (DIA) is accredited by the International Association for Continuing Education and Training (IACET) and is authorized to issue the IACET CEU.

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer 1.7 CEUs for this conference.

Participants must complete the entire conference in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

Statement of Credit

If you would like to receive a statement of credit, you must complete all On Demand Sessions within the desired day, complete the post-assessment and evaluation for each day that you wish to receive credit. CE credit must be claimed via the online credit request process through DIA at My Transcript.

Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on Wednesday, June 3, 2020.

On Demand Sessions

Attendee must complete ALL On Demand sessions within the desired day to earn the applicable CE credits. Attendee can complete all four days for a maximum number of 16.25 credit hours.

Drug and Medical Device Ad Promo Primer

UAN: 0286-0000-20-078-H04-P, Knowledge, 3.5 Contact Hours, .35 CEUs; .4 IACET CEUs

- Concurrent Breakout Session: Medical Device Promotion and Drug Promotion
- Introduction and Fundamentals Overview
- Medical Device Promotion and Drug Promotion Case Study Workshops Non-FDA Considerations for Pharmaceutical and Medical Device Promotion

Day 1 - Advertising and Promotion Regulatory Affairs Conference

UAN: 0286-0000-20-092-H04-P, Knowledge, 4.5 Contact Hours, .45 CEUs; .5 IACET CEUs

- Keynote Address: The Patient Voice: Message and Impact on Healthcare
- FDA Update
- OPDP Research Update
- Adding Value to Ad Promo Review, Tips and Best Practices: Panel Discussion
- Engaging with Patients to Diversify Advertising and Promotional Activities
- Relevant and Recent: 2019 Learnings from DIA Ad Promo Working Group RA Community

Day 2 - Advertising and Promotion Regulatory Affairs Conference

UAN: 0286-0000-20-093-H04-P, Knowledge, 5 Contact Hours, .5 CEUs; .5 IACET CEUs

- Enforcement Insights to Navigate Decision-Making
- What Goes into a Successful Promotional Communication Strategy? Panel and Examples
- Communications and Pricing Disclosures: From State/Federal Transparency Requirements to Formulary Placement and Value-Based Contracting Communications
- Strategies to Address Labeling Changes: The Impact on Promotional Materials
- Labeling Changes and the Impact on Medical Devices

Day 3 - Advertising and Promotion Regulatory Affairs Conference

UAN: 0286-0000-20-094-H04-P, Knowledge, 3.25 Contact Hours, .325 CEUs; .3 IACET CEUs

- Promotion and What Rules Apply to Generic Drugs and Biosimilars
- Considering the Implications of International Differences in Regulation on Life Science Advertising and Promotions Regulatory Affairs
- eCTD Use and Ad Promo Materials

1:00-5:00PM

Drug and Medical Device Ad Promo Primer

*This course requires and additional fee.

DIA's extremely popular Ad Promo Primer returns this year with a new track dedicated to medical device promotion. Participants in the primer will be able to choose a drug/biologic or medical device track and may even switch between tracks throughout the day. This flexibility and expanded offering is designed to allow for more nuanced discussions about promotional standards, tactics, execution, and enforcement. The primer will be interesting, practical, and vital for those new to the field as well as experienced professionals who are seeking a refresher. The primer is designed for regulatory, legal, medical, compliance, or marketing professionals, their advisers and consultants, or for anyone else in the field of prescription drugs and medical device product promotion. Instructors will provide clear and practical background and insights to field your most difficult questions.

Instructors

Kevin Madagan, JD, Partner, Reed Smith, LLP

Dale Cooke, JD, MA, President, PhillyCooke Consulting

Darshan Kulkarni, PharmD, JD, MS, Esq., Principal Attorney, Kulkarni Law Firm

Julia Lake, Associate, ReedSmith, LLP

Dolores Shank-Samiec, MS, Executive Director, Office of Promotion and Advertising Review, Merck

Wayne Pines, President, Regulatory Services and Healthcare, APCO Worldwide Inc.

Medical Device Promotion Track Highlights

This track will provide the professionals responsible for the advertising and promotion of medical devices with the background to get the most out of the main conference and know how to ensure that medical device communications comply with all relevant standards.

At the conclusion of this track, the participant should be able to:

- Describe the scope of the FDA's authority over medical device promotion
- Apply the relevant FDA standards to promotional messages about medical devices
- Identify when to look to other agencies (especially FTC) for promotional standards

Drug Promotion Track Highlights

This course is designed to provide background information for you to better understand the conference content. The leaders will provide an introductory foundation for anyone working in our current regulatory environment. Whether you are a regulatory, legal, medical, compliance, or marketing professional, the information will be interesting, practical, and vital.

At the conclusion of this track, participants should be able to:

- Discuss the current regulatory/compliance environment pertaining to the advertising and promotion of prescription drugs, vaccines, and biologics
- Describe FDA advertising and promotional requirements, including claim support requirements, fair balance expectations, internet and social media challenges, product booths at medical conventions, adherence and preference programs, patient involvement and outreach, disease state programs, and public relations challenges
- Assess the importance of the promotional review process, and be equipped to serve as a leading member of a promotional review committee

1:00-1:45PM

Introduction and Fundamentals Overview

1:45-2:00PM

Break One

2:00-3:15PM

Breakout Session

Track A: Medical Device Promotion

Track B: Drug Promotion

3:15-3:30PM	**Break Two**
3:30-4:15PM	**Case Study Workshop** **Track A:** Medical Device Promotion **Track B:** Drug Promotion
4:15-5:00PM	**Non-FDA Considerations for Pharmaceutical and Medical Device Promotion**

DAY ONE | MONDAY, MAY 18

10:00-10:30AM

Opening Remarksand Welcome from the DIA Ad Promo Working Group

Session Chair
Micheline Awad, MBA, Director Regulatory Affairs, Advertising and Promotion, Neurocrine Biosciences, Inc.

Speakers
Kimberly Belsky, MS, Executive Director, Regulatory Policy and Intelligence, Regulatory Affairs, Mallinckrodt Pharmaceuticals

Dolores Marie Shank-Samiec, MS, Executive Director, Office of Promotion and Advertising Review, Merck and Co., Inc.

10:30-11:00AM

Session 1: Keynote Address: The Patient Voice: Message and Impact on Healthcare

Session Chair
Micheline Awad, MBA, Director Regulatory Affairs, Advertising and Promotion, Neurocrine Biosciences, Inc.

FDA recognizes that the patient perspective on new drug benefits and risks, and whether the disease burdens that matter most are addressed, is critically informative to regulatory decision-making. Drug development programs have often failed to explicitly account for the disease burdens and treatment burdens that would matter most to patients and fail to reliably measure these effects in clinical trials. FDA expects drug sponsors to incorporate the patient's perspective starting early in development to ensure that the investigational product profile and development program incorporate clinical outcomes and endpoints that reflect what matters to patients. This session describes the background and content of a new FDA guidance series to foster patient focused drug development and sponsor use of such outcomes and endpoints. Reliable measures of what matters to patients and evidence of meaningful improvement will not only inform FDA decision making but may also better inform the decisions of other health authorities (e.g., HTA and payors).

Keynote Speaker
Theresa Mullin, PhD, Associate Director for Strategic Initiatives, CDER, FDA

11:00-11:05AM **Break**

11:05AM-12:05PM

Session 2: FDA Update

Session Chair
Wayne Pines, President, Regulatory Services and Healthcare, APCO Worldwide Inc.

This session, organized by senior representatives from the three FDA medical centers, will provide a summary of recent enforcement and actions taken in the ad promo area. This session will also present a perspective on the enforcement priorities and concerns of the FDA centers, recent guidance issued, and the guidance's being developed.

Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products-Questions and Answers: Draft Guidance
Elizabeth Pepinsky, JD, Health Science Policy Analyst, FDA

FDA Update on Oversight of Prescription Drug Promotion
Thomas Abrams, MBA, RPh, Director, Office of Prescription Drug Promotion, OMP, CDER, FDA

CBER APLB
Lisa Stockbridge, PhD, Branch Chief, Advertising and Promotional Labeling Branch, OCBQ, CBER, FDA

Introduction to Combination Products
Melissa Burns, MS, MSc, Senior Program Manager, Office of Combination Products, FDA

12:05-12:30PM **Break**

12:30-1:30PM **Session 3:** OPDP Research Update

Session Chair
Kathryn Aikin, PhD, Senior Social Science Analyst, Research Team Lead, OPDP, CDER, FDA

Individual FDA/OPDP researchers will present findings from OPDP research studies. Attendees will gain a better understanding of the FDA/OPDP Research program and how it may contribute to knowledge, guidance, and policy development. This session is designed to educate attendees on the regulatory research FDA has done to help inform policy and guidance development.

Introduction to the OPDP Research Program
Kathryn Aikin, PhD, Senior Social Science Analyst, Research Team Lead, OPDP, CDER, FDA

Animation in Direct-to-Consumer Prescription Drug Television Advertising
Amie O'Donoghue, PhD, Social Science Analyst, OPDP, CDER, FDA

Physician and Consumer Capability to Detect and Inclination to Report Deceptive Prescription Drug Promotion
Kevin Betts, PhD, Social Science Analyst, FDA

Consumers' Understanding of Oncology Clinical Endpoints: Focus Group Findings
Helen Sullivan, PhD, MPH, Social Science Analyst, OPDP, CDER, FDA

Consumers' Experience with and Attitudes toward Direct-to-Consumer Prescription Drug Promotion: A Nationally Representative: Survey Selected Findings
Kathryn Aikin, PhD, Senior Social Science Analyst, Research Team Lead, OPDP, CDER, FDA

1:30-2:30PM **Session 4:** Adding Value to Ad Promo Review, Tips and Best Practices: Panel Discussion

Session Chair
Victoria Tamarkin, MS, Founder and Principal, Regulatory Compliance, Advertising and Promotion, Victoria Tamarkin Consulting LLC

Join a mock Medical/Legal/Regulatory (MLR) panel as they walk participants through their strategies for Ad Promo review. Panelists will explore case studies and discuss best practices for reviewing materials for different audiences and settings such as in social media and in convention booths at scientific congresses. Participants will learn how the panel views complex topics such as evaluating and applying the appropriate evidentiary standards that guide the review of different types of materials. Lastly, the panel will share best practices for effectively managing conflicting points of view and in this way furthering the contribution of each review discipline as part of a well-functioning promotional review committee.

Speakers
Danielle Asuncion Carreon, MPH, **RAC,** Director, Regulatory Affairs, Bristol-Myers Squibb

William Aprea, JD, Executive Director, Senior Franchise and Compliance Counsel (former) Bristol-Myers Squibb

Richard Gersh, MD, PhD, Executive Director, Global Medical Affairs, Merck

2:30-2:45PM **Break**

2:45-3:45PM **Session 5:** Engaging with Patients to Diversify Advertising and Promotional Activities

Session Chair
Joanne Hawana, JD, MS, Member, Mintz, Levin, Cohn, Ferris, Glovsky & Popeo P.C.

Medical product developers are interacting with patients and caregivers more than ever before in unique and diverse ways, from recruiting clinical trial subjects through social media outlets to providing educational information about complex therapies or diseases. This area of focus has accelerated in recent years as FDA and other regulators encourage "patient-focused" drug and medical device product development. Patients are also more likely to be involved in their healthcare plans today than ever before, and they seek out medical

knowledge from a variety of sources, including pharmaceutical and medical device companies developing products for their specific disease or condition but also patient organizations, government sources, and elsewhere.

Although there are numerous opportunities for companies to engage directly with patients and caregivers, there also are legal and regulatory risks and barriers to certain activities and limitations on what companies can communicate to consumers as part of these activities. This session will explore the opportunities and challenges associated with companies' outreach to patients and caregivers. We will also discuss ways to ensure such activities do not run afoul of regulatory requirements and provide tips to ensure promotional efforts that incorporate patient-derived information remain in compliance with applicable laws.

Panelists
Pamela Goldberg, MBA, President and CEO, Medical Device Innovation Consortium (MDIC)

Minerva Hughes, JD, PhD, Regulatory Counsel, Office of Clinical Evidence and Analysis, CDRH, FDA

Lisa Pieretti, MBA, Executive Director, Co-Founder International Hyperhidrosis Society

3:45-4:15PM

Relevant and Recent: 2019 Learnings from DIA Ad Promo Working Group RA Community

Session Chair
Kimberly Belsky, MS, Executive Director, Regulatory Policy and Intelligence, Regulatory Affairs, Mallinckrodt Pharmaceuticals

Session Co-Chair
Dolores Marie Shank-Samiec, MS, Executive Director, Office of Promotion and Advertising Review, Merck and Co., Inc.

Learn and engage! This session will provide an overview of recent hot topics and learnings discussed by DIA's Advertising and Promotion Working Group. Topics will include: "You received an enforcement letter, now what?", accelerated approval 'how to', notables from recent enforcement letters, the role of patient influencers, and ex-US happenings. You will also learn how you can enhance your expertise throughout the year by becoming involved in the Working Group.

DAY TWO | TUESDAY, MAY 19

11:00-11:15AM

Welcome to Day Two

11:15AM-12:15PM

Session 6: Enforcement Insights to Navigate Decision-Making

Session Chair
Kimberly Belsky, MS, Executive Director, Regulatory Policy and Intelligence, Regulatory Affairs, Mallinckrodt Pharmaceuticals

While the advertising and promotion regulations have not changed, areas of enforcement can evolve. Understanding current enforcement actions can help to navigate the complexities of risk-based decision-making. This session will provide insights and key learnings into recent FDA enforcement and potential impact beyond FDA (e.g., FTC, State AG's, Lanham Act, private litigants).

Speaker
Kimberly Belsky, MS, Executive Director, Regulatory Policy and Intelligence, Regulatory Affairs, Mallinckrodt Pharmaceuticals

OPDP Enforcement Insights-Select Learnings
Francis Nguyen, PharmD, Assistant Director, Regulatory Advertising and Promotion, Bayer Healthcare Pharmaceuticals

Is Private Enforcement the Answer: Lanham Act and Other Private Actions
Heather Rennie, JD, Executive Director, Managing Counsel, US Commercial Legal, Merck & Co., Inc.

12:15-1:15PM

Session 7: What Goes into a Successful Promotional Communication Strategy? Panel and Examples

Session Chair
Mary Raber Johnson, PhD, RAC, Assistant Professor, Clinical, The Ohio State University College of Pharmacy

A communication strategy is complex, with a foundation built from extensive research on the patient and

other key stakeholders. During this research phase, regulatory affairs and other disciplines (e.g., medical affairs, payers) can provide valuable feedback with the end goal of both compliant and effective messaging. This session will describe behind-the-scenes marketing activities, as well as uncover real-world examples illustrating effective collaborations with regulatory affairs to deliver a successful promotional communication strategy.

How to Create a More Collaborative Approach to Communications Strategy
Mark Stinson, Founder and Principal Consultant at Bioscience Bridge, LLC

Speakers
Carlotta Dillon, MA, MBA, Principal, Dillon Consulting, LLC

George Wan, PhD, MPH, VP Health Economics & Outcomes Research, Mallinckrodt Pharmaceuticals

"Ask Me Anything" – What Really Goes into Developing a Communication Strategy?
Panel Discussion, All Session Speakers

1:15-1:45PM **Break**

1:45-2:45PM **Session 8:** Communications and Pricing Disclosures: From State/Federal Transparency Requirements to Formulary Placement and Value-Based Contracting Communications

Session Chair
Kevin Madagan, JD, Partner, Reed Smith, LLP

Advertising and promotional regulatory affairs professionals are increasingly confronted with promotional communication issues involving cost and pricing data. These communications can be voluntary company initiatives or triggered by government-mandated transparency laws. Although many professionals historically relied on their legal and compliance colleagues to oversee these communications, regulatory affairs professionals are increasingly being asked to play a role in ensuring the accuracy of the data and underlying message in these communications. Importantly, these professionals must also account for new state laws, which are now being enacted around the country in different forms, that demand certain price disclosures when engaging in certain types of promotional activity.

Consequently, to operate effectively in 2020, advertising and promotional regulatory affairs professionals must remain well-informed of current industry standards and state/federal requirements governing cost and price disclosures in promotional communications.

Speaker
Kevin Madagan, JD, Partner, Reed Smith, LLP

Speaker
Darshan Kulkarni, PharmD, JD, MS, Esq., Principal Attorney, Kulkarni Law Firm

Communications and Pricing Landscape: Federal Developments
Jonathan Bigelow, Executive Director, Coalition for Healthcare Communication

Speaker
Donald May, MPA, Executive Vice President, Payment and Health Care Delivery, AdvaMed

2:45-3:45PM **Session 9: Track B:** Strategies to Address Labeling Changes: The Impact on Promotional Materials

Session Chair
Mark Gaydos, Vice President NA General Medicines/US Advertising and Promotion, Sanofi

This session will focus on the impact of prescription drug and biologic labeling changes on product promotion. Specifically, the panel will consider the timing associated with ensuring promotional materials reflect, and are accompanied by, current prescribing information or, for advertising, a brief summary of prescribing information. Criteria and timelines for updating important risk/safety information related to labeling changes will also be addressed.

The Intersection of Rx Drug Labeling and Promotion
Mark Gaydos, Vice President NA General Medicines/US Advertising and Promotion, Global Regulatory Affairs, Sanofi

Types of Labeling Changes and Planning Strategies and Implementation, Timing, and Other Considerations
Virginia Foley, Principal Consultant, Opus Regulatory, Inc.

Legal Considerations
Dara Katcher Levy, JD, Attorney, Hyman, Phelps & McNamara, P.C.

3:45-4:45PM

Session 9: Track A: Labeling Changes and the Impact on Medical Devices

Session Chair
Madhavi Bellamkonda, MSc, Director Regulatory Affairs, Advertising and Promotion, Abbott Vascular

This session will be an engaging and interactive session that will focus on the impact of labeling changes in the medical device industry. Specifically, the panel will delve into three aspects:

- Clinical trial data updates within labeling / not within labeling and impact on promotional claims
- Labeling changes and impact on Important Safety Information for Class III combination medical
- Planning and market implementation of a labeling change for a successful product launch

Labeling for Devices Panel
Gerrit Nijveldt, MSc, Labeling Consultant, EASi

Speaker
Madhavi Bellamkonda, MSc, Director Regulatory Affairs, Advertising and Promotion, Abbott Vascular

DAY THREE | WEDNESDAY, MAY 20

11:00-11:15AM

Welcome to Day Three

Session Chair
Micheline Awad, MBA, Director, Regulatory Affairs, Advertising and Promotion, Neurocrine Biosciences, Inc.

11:15AM-12:15PM

Session 10: Track B: Promotion and What Rules Apply to Generic Drugs and Biosimilars

Session Chair
Cheryl Roberts, JD, MS, Senior Director Regulatory Affairs Lead, Mylan Pharmaceuticals

As generic and biosimilar drug promotion becomes more prolific, this session will cover the rules of the road for promotional review committees charged with overseeing promotional materials and media for generic drugs and biosimilars. This session will review the regulatory landscape, new guidances, do's and don'ts, common pitfalls, and the enforcement landscape surrounding generic and biosimilar drug promotion. Attendees will gain insights into key regulatory considerations and factors that should guide their review of generic and biosimilar drug promotional materials, across a range of media.

Promoting a Biosimilar Product: Explore the Nuts and Bolts
Marci Schentzel, Director, Regulatory Affairs, Mylan

Avoiding the Pitfalls of Generic Drug Promotion
Julie Tibbets, JD, Partner, Goodwin Procter LLP

12:15-1:15PM

Session 10: Track A: Considering the Implications of International Differences in Regulation on Life Science Advertising and Promotions Regulatory Affairs

Session Chair
Ratinder Dhami, MS, RAC, Director, Regulatory Affairs, Network Partners

Industry creates global marketing strategies for healthcare products but navigating the different adverting and promotional requirements across regions can be difficult. This session will discuss the similarities and differences in the regulations that govern Direct to Consumer Advertising (DTCA) for medical devices in Canada, EU, and US. Presenters will describe key principles for advertising strategies in a global market and provide an overview of the process and procedures that affect international reviews.

Optimizing Product Launch in Canada
John Wong, MPharm, Director, Regulatory Drug Advertising & Promotion, TPIreg/Innomar Strategies

Navigating International Waters for Social Media and DTCA
Madhavi Bellamkonda, MSc, Director Regulatory Affairs, Advertising and Promotion, Abbott

1:15-1:45PM

Break

1:45-2:45PM **Session 11: Track B:** eCTD Use and Ad Promo Materials

Session Chair
Jason Cober, Lead Project Manager, OPDP, CDER, FDA

This session will provide an overview of the binding requirements and non-binding recommendations provided in FDA's Final Guidance titled "Providing Regulatory Submissions in Electronic and Non-Electronic Format – Promotional Labeling and Advertising Materials for Human Prescription Drugs." The presentation will discuss the Promotional submission types that will be required in eCTD format beginning in June 2021. Additionally, the presenters will discuss common questions and topics raised by Industry related to promotional eCTD Submissions and provide the FDA's perspective along with real world solutions.

Providing Regulatory Submissions in Electronic and Non-Electronic Format
Jason Cober, Lead Project Manager, OPDP, CDER, FDA

Promotional Labeling and Advertising Materials for Human Prescription Drugs
Josephine Secnik, MBA, MS, Director, Ad Promo Regulatory Affairs, Eli Lilly and Company

2:45-3:15PM **Closing Remarks and Live Q&A**

Session Chair
Micheline Awad, MBA, Director Regulatory Affairs, Advertising and Promotion, Neurocrine Biosciences, Inc

Session Co-Chair
Kimberly Belsky, MS, Executive Director, Regulatory Policy and Intelligence, Regulatory Affairs, Mallinckrodt Pharmaceuticals

3:15PM **Conference Adjourns**

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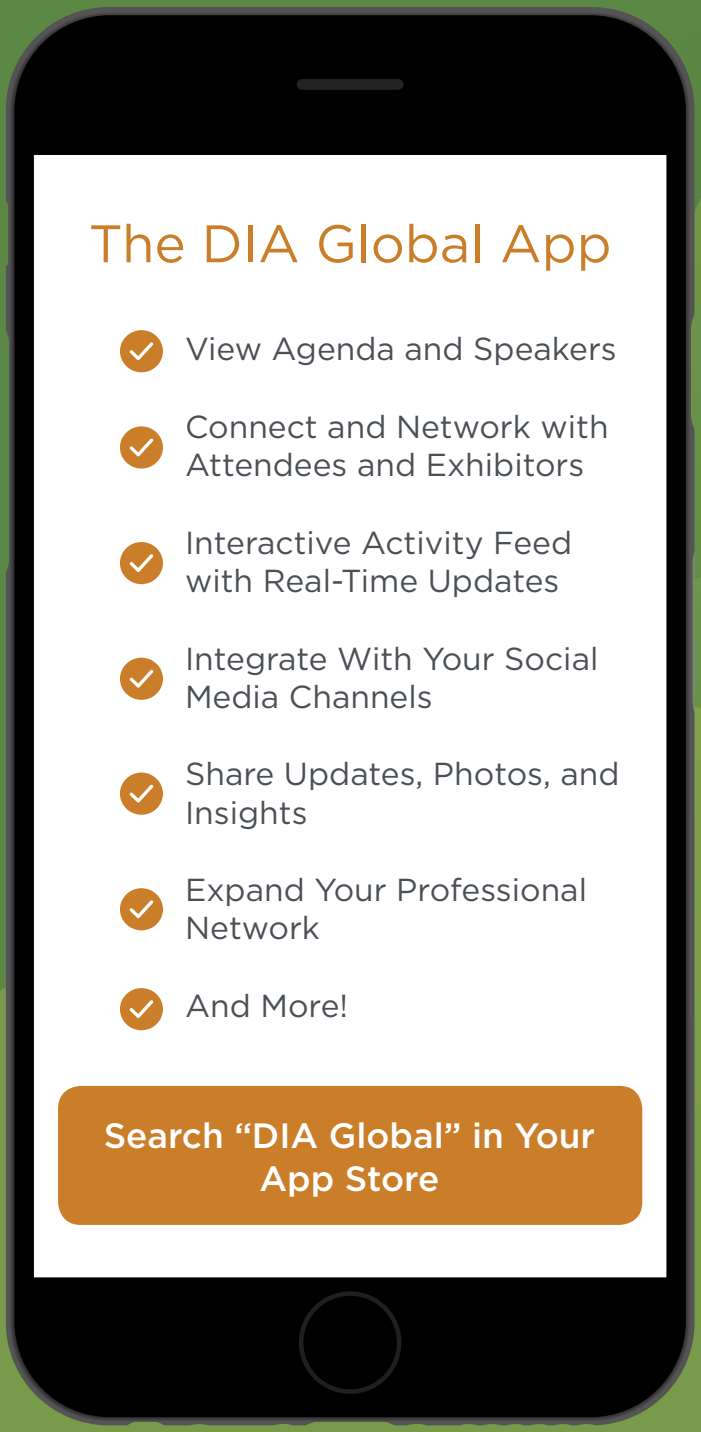

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