25th Annual

Marketing Pharmaceuticals 2014: Regulating Drug Marketing in the Ever-Changing Regulatory/Legal/ Health Care Environment

Tutorial: February 26 | Workshop: February 27-28 | Washington, DC

PROGRAM COMMITTEE

Thomas W. Abrams, MBA, RPh
Director
Office of Prescription Drug Promotion
CDER, FDA

Glenn N. Byrd, MBA, RAC
Senior Director
Promotional Regulatory Affairs
MedImmune Specialty Care

Dale A. Cooke
Vice President/Group Director
Regulatory Review
Digitas Health

Mark Gaydos
Vice President
US Regulatory Affairs Marketed Products
Sanofi U.S. Inc

Michele Hardy
Vice President
Regulatory Advertising and Promotion Policy
GlaxoSmithKline

John T. Murray
President
Grayscale Compliance LLC

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

Lucy Rose, MBA
President
Lucy Rose and Associates, LLC

Kristina Vlaovic, MPH
Global Regulatory Franchise Head
Ophthalmology & Respiratory
Genentech, A Member of the Roche Group

DIA GLOBAL CENTER
21 Dupont Circle, NW, Suite 300
Washington, DC 20036

WORLDWIDE OFFICES
Basel, Switzerland | Beijing, China | Horsham, PA, USA
Mumbai, India | Tokyo, Japan

OVERVIEW:

This year marks the 25th Anniversary of the DIA Annual Marketing Pharmaceuticals Workshop. This workshop, conducted annually since 1989, continues to be a must-attend event for anyone involved with the. marketing and promotion of pharmaceuticals, over-the-counter (OTC) drugs, biologics, and medical devices. This is a workshop that should be attended by every company's entire promotional team, including not just the regulatory team but also marketing, medical information and affairs, legal and communications. Understanding the complexity of marketing and promoting these products has never been as important as it is now.

SESSION TOPICS:

- FDA Update: Recent Enforcement Actions
- Disease Awareness - Education or Promotion?
- Marketing Prescription Products in the Age of Obama
- Q&A Session with FDA
- Leveraging Innovative Technology Compliantly
- Compliance Update
- Communicating During the Pre-Approval Stages
- Substantial Evidence
- Supporting Successful Product Launches
- Plus More

TUTORIAL:

OPDP/APLB and Compliance 101: A Primer

LEARNING OBJECTIVES:

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

- Identify the trends reflected in the latest enforcement actions and policies issued by the FDA
- Discuss how companies are complying with government regulatory requirements
- Describe how to market products while complying with the FDA and other policies and regulations

Register at **diahome.org/MarketingPharma2014**

FIFTY YEARS 1964-2014 DIA
www.diahome.org

CONTINUING EDUCATION

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 15 contact hours or 1.5 continuing education units (CEU's).

Type of Activity: Knowledge

ACPE Credit Request UpdateDIA 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. 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 has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102; +1.703.506.3275.

As an IACET Authorized Provider, Drug Information Association offers CEUs for its programs that qualify under the ANSI/IACET Standard. Drug Information Association is authorized by IACET to offer up to 1.6 CEUs for the program. Participants must attend the entire workshop and tutorial in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit, you must attend the program and tutorial, if applicable, sign in at the DIA registration desk each day of the program as well as for Sessions 7 and 8, and complete the online credit request process through My Transcript. To access My Transcript, please go to diahome.org select "Login to My DIA" and you will be prompted for your user ID and password. Select "My Transcript" (left side bar) and "Credit Request" to process your credit request. 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 **Friday, March 14, 2014**.

CONTINUING EDUCATION CREDIT ALLOCATION

Tutorial, OPDP/APLB and Compliance 101: A Primer: IACET: .3 CEUs; 3.25 contact hours or .325 CEUs, 0286-0000-14-038-L03-P

Workshop:
IACET: 1.3 CEUs

Pharmacy:

Sessions 1, 2, 3, and 4: 6.25 contact hours or .625 CEUs; 0286-0000-14-013-L04-P

Sessions 5 and 6: 3 contact hours or .3 CEUs; 0286-0000-14-014-L04-P

Session 7:
Breakout Session 1: 1.25 contact hour or .125 CEU, 0286-0000-14-015-L04-P
Breakout Session 2: 1.25 contact hour or .125 CEU, 0286-0000-14-016-L04-P

Session 8:
Breakout Session 1: 1.25 contact hour or .125 CEU, 0286-0000-14-017-L04-P
Breakout Session 2: 1.25 contact hour or .125 CEU, 0286-0000-14-018-L04-P

It is Drug Information Association policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers, agenda, and CE information are subject to change without notice. Recording of any DIA educational material in any type of media, is prohibited without prior written consent from DIA.

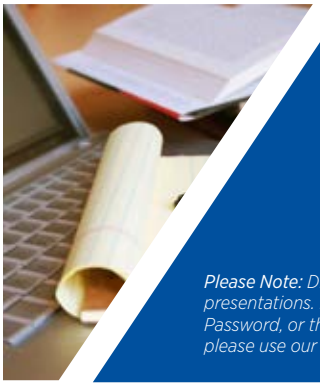
View DIA's Grievance Policy at **diahome.org/CE**

DIA'S CERTIFICATE PROGRAM

This program is part of DIA's Certificate Program and is awarded the following:

- Regulatory Affairs Certificate Program: 8 Elective Units

For more information go to ***diahome.org/certificateprograms***



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TUTORIAL | WEDNESDAY, FEBRUARY 26

12:30–1:30PM TUTORIAL REGISTRATION

1:30-5:00PM TUTORIAL

OPDP/APLB and Compliance 101: A Primer

INSTRUCTORS:

Lucy Rose, MBA
President
Lucy Rose and Associates, LLC

Paul J. Savidge, JD, MBA
Senior Vice President and Deputy General Counsel
Bristol-Myers Squibb Company

Michele L. Sharp, PharmD
Senior Director
Global Regulatory Affairs - US
Eli Lilly and Company

If you are new, or relatively new, to OPDP and/or advertising/promotional compliance, this tutorial is for you!! The leaders will provide a strong introductory foundation for anyone working in our new regulatory environment. Whether you are a regulatory, legal, medical, or marketing professional, the information will be interesting, practical, and vital!

LEARNING OBJECTIVES:

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

- Discuss the current regulatory/compliance environment pertaining to prescription drugs, biologics and medical devices, both from an FDA and OIG/DOJ perspective
- Describe the FDA advertising and promotional requirements, including such topics as: claim support requirements, fair balance expectations, internet challenges, product booths at medical conventions, disease state programs, and public relations challenges

TARGET AUDIENCE:

This tutorial is designed for individuals involved in marketing, legal, regulatory, public affairs, and advertising in the pharmaceutical and biologics industries, plus their consultants and agencies. If you are relatively new to this area, please join our experienced experts to gain the important information you need to maximize your workshop learning!

THURSDAY, FEBRUARY 27

7:30-8:30AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30-8:45AM WELCOME AND OPENING REMARKS

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

Barbara Lopez Kunz
Global Chief Executive
DIA

8:45-10:30AM SESSION 1

FDA Update: Recent Enforcement Actions

Session Chair:

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

This session provides an overview of current issues, laws and guidances relevant to the promotion of prescription drugs, biologics and medical devices. Learn the latest on policy development, enforcement and FDA's future initiatives.

Speakers:

CDER Update

Thomas W. Abrams, MBA, RPh
Director
Office of Prescription Drug Promotion
CDER, FDA

Barbara Chong, PharmD
Office of Prescription Drug Promotion
CDER, FDA

CBER Update

Lisa L. Stockbridge, PhD
Branch Chief
Advertising and Promotional Labeling Branch
CBER, FDA

10:30-11:00AM REFRESHMENT BREAK

11:00AM-12:30PM SESSION 2

Disease Awareness – Education or Promotion?

Session Chair:

Carla E. Brooks
Regulatory Affairs Associate Director
MedImmune, LLC

Proper education of consumers and health care professionals about diseases is an important component of ensuring promotion and protection of the Public Health. But often, the lines get blurred between disease education and product promotion. Join us in examining the current trends in disease awareness/education as well as the trends in FDA enforcement and how to keep each activity — disease awareness and product promotion compliant.

Speakers:

Carla E. Brooks
Regulatory Affairs Associate Director
MedImmune, LLC

William McConagha, JD
Partner
Sidley Austin LLP

Sheetal Patel, PharmD
Director
Regulatory Advertising and Promotion
Johnson & Johnson US Pharmaceuticals Group HCC

12:30-1:30PM LUNCHEON

1:30-3:00PM SESSION 3

Marketing Prescription Products in the Age of Obama

Session Chair:

Dale Cooke
Vice President/Group Director
Regulatory Review
Digitas Health

The passage of the 2009 stimulus, Patient Protection and Affordable Care Act (Obamacare) in 2010, and FDASIA in 2012, have made significant changes in the landscape of marketing prescription products. This session highlights the impact of those changes on marketing opportunities, such as the expanded role of electronic health records (EHRs) and how the Sunshine Rule affects the review and approval of promotional tactics.

Speakers:

Mukesh Mehta, PharmD, MBA, RPh
Vice President
Clinical and Regulatory Solutions
PDR Network, LLC

Christine N. Bradshaw, JD
Director of Regulatory and Compliance Services
Porzio Life Sciences, LLC

Representative Invited

3:00-3:30PM REFRESHMENT BREAK

3:30-5:00PM SESSION 4

Question and Answer Session with FDA

Session Chair:

Lucy Rose, MBA
President
Lucy Rose and Associates, LLC

Use this unique opportunity to bring your pressing questions for FDA to address in person. This session will attempt to answer any remaining questions from earlier sessions and to allow the audience to ask new questions to our FDA speakers.

Panelists:

Thomas W. Abrams, MBA, RPh
Director
Office of Prescription Drug Promotion
CDER, FDA

Lisa L. Stockbridge, PhD
Branch Chief
Advertising and Promotional Labeling
CBER, FDA

Deborah Wolf, JD
Branch Chief
Regulatory Counsel Office of Compliance
CDRH, FDA

5:00-6:00PM RECEPTION

FRIDAY, FEBRUARY 28

7:30-8:00AM REGISTRATION AND CONTINENTAL BREAKFAST

8:00-9:30AM SESSION 5

Leveraging Innovative Technology Compliantly

SESSION CHAIR:

Dale Cooke
Vice President/Group Director
Regulatory Review
Digitas Health

Consumers and health care professionals rely on the Internet and their digital communications devices as essential tools for finding information about health care, medicine, and other treatment options. Lots of companies have leapt into this space providing information about health care, but makers of prescription products have been lagging behind in the uptake of these tools. This session looks at YouTube, Twitter, and Facebook and examines how marketers are using them to provided needed information and overcoming the regulatory hurdles they entail.

SPEAKERS:

Ryan Olohan
National Industry Director
Healthcare
Google

Frank J. Lock
Director
Information Center
Global Commercial Excellence/Global Channel Solutions
AstraZeneca

Trish Nettleship
Director
Social Media & Influence
UCB, Inc.

9:30-10:00AM REFRESHMENT BREAK

10:00-11:30AM SESSION 6

Compliance Update

SESSION CHAIR:

John T. Murray
President
Grayscale Compliance

Learn from industry and government experts on recent misbranding settlements and corporate integrity agreements. Panelists will discuss current and emerging trends in the government's enforcement focus and compliance program management.

PANELISTS:

Sara Miron Bloom, JD
Assistant United States Attorney
District of Massachusetts

Kristin Koehler, JD
Partner
Sidley Austin LLP

Seth B. Whitelaw, JD, LLM, SJD
Director
Deloitte & Touche LLP

William R. Mitchelson, Jr.
Partner
Alston & Bird LLP

11:30AM-12:30PM LUNCHEON

12:30-1:45PM SESSION 7

TRACK 1

Substantial Evidence

Session Chair:

Kristina Vlaovic, MPH
Global Regulatory Franchise Head
Ophthalmology & Respiratory
Genentech, A Member of the
Roche Group

Substantial evidence serves as the cornerstone of promotional claims. This interactive session will provide an overview of the considerations which companies must take into account when developing promotional claims, and breakout groups for you to evaluate and discuss several relevant scenarios with peers and a group of industry experts.

Panelists:

Sue Duvall, RN, MPA
Senior Director
International Regulatory Advertising and Promotion
Abbvie

Lynette Hopkinson, PharmD
Senior. Director Commercial
Regulatory Affairs
Global Regulatory Affairs
Eisai, Inc

Leah Palmer, PharmD
Executive Director
Regulatory Promotion
Amgen, Inc

TRACK 2

Supporting Successful Product Launches

Session Chair:

Mark Gaydos
Vice President
US Regulatory Affairs Marketed Products
Sanofi U.S. Inc

A new product launch sets the tone and trajectory for that product's future commercial success. This session will examine permissible and prudent communications a company can engage in prior to approval, while examining the strategic and operational aspects of soliciting advisory comments, as well as mandatory Subpart E & H preclearance, for core launch promotional materials. The session will also address how companies can move forward with an immediate product launch using key materials while awaiting receipt of FDA comments on core launch materials.

Speakers:

Gina Vestea, PharmD
Director
US Regulatory Affairs Marketed Products
Sanofi U.S. Inc

Barri Falk, MS
Director
Life Sciences and Healthcare Strategy
Deloitte Consulting LLP

Mark Meltz, JD
Associate General Counsel Corporate
Biogen Idec

TRACK 3

Communicating During the Pre-Approval Stages

Session Chair:

Michael Misocky, JD, RPh
President
Misocky Consulting Group LLC

This session will examine what can be done, and what poses risks, during the investigational/pre-approval stage of a new product. What precautions are needed in reaching out to patient groups and insurers/formulary committees? Are there any truly safe harbors?

Speakers:

Medical Perspective

Katie Lyons, PharmD, MS
Director
Medical Content Consulting Services

Regulatory Perspective

Mary Sullivan
Executive Director
Regulatory Affairs, Advertising and Promotion Compliance
Boehringer Ingelheim Pharmaceuticals, Inc

Legal Perspective

Kellie B. Combs, JD
Counsel
Ropes & Gray LLP

1:45-2:00PM REFRESHMENT BREAK

2:00-3:15PM **SESSION 8**

TRACK 1

Substantial Evidence

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Kristina Vlaovic, MPH
Global Regulatory Franchise Head
Ophthalmology & Respiratory
Genentech, A Member of the Roche Group

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Eisai, Inc

Leah Palmer, PharmD
Executive Director
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Amgen, Inc

TRACK 2

Supporting Successful Product Launches

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Vice President
US Regulatory Affairs Marketed Products
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Biogen Idec

TRACK 3

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Regulatory Perspective

Mary Sullivan
Executive Director
Regulatory Affairs, Advertising and Promotion Compliance
Boehringer Ingelheim Pharmaceuticals, Inc

Legal Perspective

Kellie B. Combs, JD
Counsel
Ropes & Gray LLP

3:15-3:30PM **REFRESHMENT BREAK**

3:30-4:30PM **SESSION 9**

Hot Topics

Session Chair:

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

This session will address the latest and "hottest" topics affecting the advertising and promotion of pharmaceuticals and medical devices. The session will describe what has occurred and ask experts to discuss the impact or potential impact on the regulation of marketing materials.

Panelists:

Alan R. Bennett, JD
Senior Counsel, Ropes & Gray. LLP

Freddy A. Jimenez, JD
Assistant General Counsel, Johnson & Johnson

4:30PM **WORKSHOP ADJOURNED**