INSIDER UPDATE

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

Tutorial: February 26 | Workshop: February 27-28

Washington Marriott Wardman Park | Washington, DC

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Insider Update

This edition of *Insider Update* provides insights from key thought leaders about the marketing and promotion of pharmaceuticals, over-the-counter (OTC) drugs, biologics, and medical devices.

Understanding the complexity of marketing and promoting these products has never been as important as it is now. All of the experts interviewed will speak at this year's Marketing Pharmaceuticals.

"The use of social media by the pharmaceutical and medical device industries continues to increase even while the FDA is formulating its draft guidance."

"Claims are critical to a product's success and what on-label information can be harnessed in support of an advisory comments request."

Are YOU Ready to Get the Insider Scoop?

#1

Wayne L. Pines

President, Regulatory Services and Healthcare
APCO Worldwide, Inc.

Q: What are the hot topics that are affecting marketing of pharmaceuticals, biologics, and OTC drugs, and medical devices that will be discussed at this workshop?

A: "Certainly social media issues remain one of the hot topics that we are all very conscious of. The use of social media by the pharmaceutical and medical device industries continues to increase even while the FDA is formulating its draft guidance. We also will be discussing the latest enforcement actions taken by the agency and their implications. We continue to see evolution of the nuances of FDA policies and this conference will focus on how they affect the marketing of medical products. This workshop always has been essential for those who want to keep up with the latest changes and who want an opportunity to discuss them with their counterparts from other companies and with the FDA directly."

#2

Kristina Vlaovic, MPH

Global Regulatory Franchise Head - Ophthalmology & Respiratory
Genentech, A Member of the Roche Company

Q: Can you please explain which of the following describe the requirements for scientific evidence of promotional claims?

A) Evidence consisting of adequate and well-controlled investigations, which support the conclusion that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling. Data from a single adequate and well-controlled clinical investigation and confirmatory evidence may be considered substantial evidence.

B) Promotional claims must be reliable, accurate, truthful, informative, balanced, up-to-date, and capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks.

C) Promotional information should be clear, legible, accrete, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned.

D) A & B Only

E) All of the Above

A: "Standards of evidence differ across the world. In the US, substantial evidence is the golden standard (Answer A), internationally, WHO Ethical Criteria (1988) and IFPMA Code (2007) sets the standard for promotion (Answers B & C, respectively)."

#3

Mark Gaydos, BA

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

Q: Given the importance of a successful product launch, how can companies balance the need to promptly provide their sales forces with detailed supporting materials upon approval while at the same time ensuring the most effective messaging is delivered without triggering FDA enforcement?

A: "It is critical that a company evaluate what a product's approved labeling permits it to objectively claim in the absence of advisory comments. At the same time, it must carefully consider whether additional, perhaps stronger, claims are critical to a product's success and what on-label information can be harnessed in support of an advisory comments request."

#4

Dale Cooke

Vice President/Group Director, Regulatory Review
Digitas Health

Q: What are the key changes in marketing prescription products that have come into effect recently in the age of Obama?

A: "The past three years have seen a series of new laws including the stimulus act, Obamacare (the Affordable Care Act), and FDASIA. Each has had a measurable impact on pharmaceutical marketers. Combined, they have changed the landscape significantly, and those changes really come to the fore beginning January 1, 2014. Sunshine provisions require the determination, tracking, and reporting of all transfers of value. New EHR systems are transforming the patient-physician dialogue at point of care and the landscape for marketers, and the advent of new reimbursement criteria mean that marketers are being challenged to devise communications strategies in a very different environment."

Q: With Health Care Professionals (HCPs) and consumers adopting digital channels en masse and FDA guidance on social media not yet released, what is the most important lesson for regulatory professionals faced with evaluating these communication channels for compliance?

A: "FDA has provided a significant amount of information about what it considers appropriate and inappropriate communication, and has also made clear, via enforcement actions, how it will apply existing regulations to these new channels. The most important thing for marketers and regulatory professionals responsible for ensuring that communications are compliant is for them to fully understand the underlying technology platform. Whether it's YouTube, Twitter, Facebook, or some other platform, there's always a way to engage compliantly, but that doesn't mean that you can do everything in every channel. For example, you simply can't force a 16-page detail aid into a 144-character tweet, but you can use Twitter compliantly if you take the time to understand the platform, its characteristics and its limitations."

Are YOU Eager to Know More?

- What are the trends reflected in the latest enforcement actions and policies issued by the FDA?
- How are companies complying with government regulatory requirements?
- How has the regulatory and legal environment evolved and affected the marketing and promotion of pharmaceuticals, biologics, OTC, and medical devices?
- How do you market products while complying with the FDA and other policies and regulations?
- What is the impact of the Affordable Care Act and the Sunshine Act on promotional activities?

Where else can YOU ask the FDA your pressing questions in person?

REGISTRATION FEES

Nonmember:
Charitable Nonprofit/Academia $1010

Government $855

Industry $1795

Member:
Charitable Nonprofit/Academia $785

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Industry $1420

Industry (As of 02/06/14) $1570

Tutorial: $405

Register by February 5 to Save $150!

Bring your entire promotional review team and save! Group Discounts Available: Register 3, get the 4th FREE!

25th Annual

Your Special Invitation to the 25th Anniversary of the Annual Workshop!

We would like to invite you to this year's Marketing Pharmaceuticals Workshop, which will be held **February 27-28** in **Washington, DC**, and is where you'll get answers to all your questions and ensure you stay compliant in 2014!

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

Who Should Attend?

Professionals in pharmaceutical, biologics, OTC, and medical device companies involved in:

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

Interested in Exhibiting?

Showcase your products and services to key decision makers. Submit your application to exhibits@diahome.org today!

Workshop Highlights:

Networking & Exhibits

- Networking Reception: February 27 at 5:00-6:00PM
- Tabletop Exhibits: February 27-28

Half Day Tutorial | February 26

- OPDP/APLB and Compliance 101: A Primer

Featured Speakers:

- Thomas W. Abrams, RPh, MBA, Director, Office of Prescription Drug Promotion, CDER, FDA
- Michelle D. Axelrod, JD, Principal, Porzio, Bromberg & Newman, PC
- Sara Miron Bloom, JD, Assistant United States Attorney, District of Massachusetts
- Glenn N. Byrd, MBA, RAC, Senior Director, Promotional Regulatory Affairs, Medimmune Specialty Care
- Sue Duvall, RN, MPA, Senior Director International Regulatory Advertising and Promotion, Abbvie
- Barri Falk, MS, Director, Life Sciences and Healthcare Strategy, Deloitte Consulting LLP
- Kim Hasili, BA, MBA, Primary Review Director, Promotional Regulatory Affairs, AstraZeneca Pharmaceuticals LP
- Lynette Hopkinson, PharmD, Senior. Director Commercial Regulatory Affairs, Global Regulatory Affairs, Eisai, Inc
- Coleen Klasmeier, JD, Global Coordinator, Food, Drug and Medical Device Regulatory Practice Sidley Austin LLP
- Joy Liu, Esq, Partner, Ropes and Gray
- Frank J. Lock, Director, Information Center, Global Commercial Excellence/Global Channel Solutions AstraZeneca Pharmaceuticals LP
- Katie Lyons, PharmD, Director, Medical Content Consulting Services
- Mukesh Mehta, PharmD, MBA, RPh, Vice President, Clinical and Regulatory Solutions, PDR Network, LLC
- Mark Meltz, JD, Associate General Counsel, Corporate, Biogen Idec
- Trish Nettleship, Director, Social Media & Influence, UCB, Inc.
- Ryan Olohan, National Industry Director, Healthcare, Google
- Leah Palmer, PharmD, Executive Director, Regulatory Promotion, Amgen, Inc
- Lisa L. Stockbridge, PhD, Branch Chief, Advertising and Promotional Labeling Branch, CBER, FDA
- Mary Sullivan, Executive Director, Regulatory Affairs, Advertising and Promotion Compliance Boehringer Ingelheim Pharmaceuticals, Inc
- Gina Vestea, PharmD, Director, US Regulatory Affairs Marketed Products, Sanofi US Inc.

We look forward to seeing you in Washington, DC!

REGISTER ONLINE

You Might Also be Interested in:

Meetings:

- Benefit-Risk Assessment from Inception to Maturation: Aligning Regulatory and Industry Goals
  Tutorial: February 9 | Meeting: 10-11 | Bethesda, MD | *Register by January 21 to Save!*
- Medical and Scientific Communications 2014 Annual Forum
  Core Curriculum: March 9 | Tutorials (AM): March 10 | Forum: March 10-12 | Orlando, FL
  Register by February 17 to Save!
- Global Labeling 2014: Compliance in a Changing Regulatory Environment
  Tutorial: April 8 | Meeting: April 9-10 | Bethesda, MD
  Register by March 18 to Save!
- A Model of Patient, Payer, and Product Developer Collaboration to Support Innovating for Value
  April 2014 | Washington, DC
  Co-sponsored with the Engelberg Center for Health Care Reform at the Brookings Institution

Training Courses:

- Regulatory Affairs for Biologics
  March 3-4 | Horsham, PA | *Register by February 10 to Save!*
- Regulatory Affairs: The IND, NDA, and Postmarketing
  March 16-19 | Irvine, CA | *Register by February 23 to Save!*
- Key Considerations for the Development and Marketing of Biosimilar Products
  April 24-25 | Horsham, PA | *Register by April 3 to Save!*

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DIA 2014
50th Annual Meeting
June 15-19 | San Diego, CA
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