22nd Annual Conference on
Marketing Pharmaceuticals

Integrated Marketing, Emerging Media Trends, and New Regulations

Tutorials

February 22, 2010

Conference

February 23-24, 2010

New York Marriott Marquis
New York, NY, USA

DIA®
www.diahome.org

22nd Annual Conference on Marketing Pharmaceuticals
Integrated Marketing, Emerging Media Trends, and New Regulations

Tutorials: February 22 Conference: February 23-24, 2010
New York Marriott Marquis, New York, NY, USA

Analyze the Latest FDA Enforcement Actions and Learn Practical Strategies for Marketing Your Products Most Effectively.

This annual must-attend conference will provide valuable insight into the evolution of the regulatory and legal environment and how this new environment impacts the marketing of biopharmaceuticals and related products.

Featured Topics

- Enforcement by the three centers within FDA that regulate drugs, biological products and veterinary drugs
- Direct-to-consumer advertising
- State regulations
- Oversight of off-label issues by the Office of Inspector General and Department of Justice
- Latest innovations in the use of the internet for product communication

Who Should Attend

Professionals who are new to pharmaceutical advertising and promotion as well as those who have been involved in this area for some time, including professionals from:

- Marketing
- Legal/Regulatory affairs
- Public relations/Advertising
- Marketing communications
- Compliance and management in pharmaceutical, veterinary medicine, biologics and medical device companies and organizations

TUTORIALS
TUESDAY, FEBRUARY 22
DDMAC and Compliance 101: A Primer
Social Media Marketing Accelerator
1:30-5:00 PM

Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

DIA®
www.diahome.org

CONTINUING EDUCATION

Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Drug Information Association designates this educational activity for 11.50 contact hours or 1.15 CEUs. 286-000-10-001-L04-P

Type of Activity: Knowledge

Tutorials:
DDMAC: 3.25 contact hours or .325 CEUs; 286-000-10-002-L04-P

Social Medial Marketing Accelerator: 3.25 contact hours or .325 CEUs; 286-000-10-003-L04-P

To receive a statement of credit, please visit www.diahome.org. Detailed instructions on how to complete your credit request and download your certificate will be provided onsite.

Disclosure Policy: It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

LEARNING OBJECTIVES At the conclusion of this meeting, participants should be able to:

- Identify the trends reflected in the latest enforcement actions and policies by the FDA
- Summarize best practices by other companies in implementing regulatory policies
- Describe how companies can best navigate the regulatory review process at FDA
- Outline the policies and actions being taken by others, such as OIG, DOJ and trade and professional associations

TUTORIAL DAY | MONDAY, FEBRUARY 22

12:30-1:30 PM TUTORIAL REGISTRATION

1:30-5:00 PM HALF-DAY TUTORIAL #1

DDMAC and Compliance 101: A Primer

INSTRUCTORS

Lucy Rose, MBA
President
Lucy Rose and Associates, LLC

JoAnn Metzler, PharmD, RPh
Sr. Director, Global Regulatory Affairs
Schering-Plough Corporation

Kelly B. Freeman, MSc, PhD
Director, US Affiliate, Compliance and Ethics
Eli Lilly and Company

Paul James Savidge, JD
Vice President and Associate General Counsel
US Law and Promotion Compliance
Bristol-Myers Squibb Company

If you are new, or relatively new, to DDMAC 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!

Tutorial Learning Objectives

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

- Discuss the latest regulations, enforcement actions, guidelines, and trends affecting the advertising and promotion of medical devices, drugs, and biologics
- Describe how companies can best navigate the FDA regulatory review process
- Provide an overview of the current direct-to-consumer advertising/promotion environment
- Outline the latest policies and actions being taken by the Office of Inspector General (OIG) and Department of Justice (DOJ)
- Summarize the FDA's claim support and fair balance regulatory requirements
- Facilitate proper promotional practices at medical meetings
- Comply with interactive communications regulations on the Internet
- Present best practices in sales force and speakers' bureau monitoring
- Recognize regulatory/compliance challenges associated with public relations and disease state programs

Tutorial Target Audience

This program is designed for individuals involved in marketing, legal, regulatory, public affairs, and advertising executives 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 conference learning!

1:30-5:00 PM HALF-DAY TUTORIAL #2

Social Media Marketing Accelerator

INSTRUCTOR

Jonathan Richman, MBA
Director of Strategic Planning
Bridge Worldwide

Tutorial Learning Objectives

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

- Describe the most and least effective social media marketing programs from multiple industries
- Summarize the current social media platforms used by patients and physicians
- Understand the marketing opportunities and challenges for social media
- Know both the accepted "etiquette" for participating in social media and applicable DDMAC regulations
- Analyze the current social media efforts of multiple pharma and healthcare companies
- Create a "best practice" process for creating and approving social media programs within your organization

Tutorial Target Audience

This program is designed for individuals involved in marketing, legal, regulatory, public affairs, and advertising executives in the pharmaceutical and biologics industries, plus their consultants and agencies. If you find yourself talking more

about social media and its application to your business, you should attend this tutorial.

5:00-7:00 PM GENERAL SESSION REGISTRATION

CONFERENCE DAY 1 | TUESDAY, FEBRUARY 23

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

8:30-8:35 AM WELCOME AND OPENING REMARKS

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

8:35-10:00 AM SESSION 1

FDA Update: Recent Enforcement Actions

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

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

CDER Update
Thomas W. Abrams, MBA, RPh
Director, Division of Drug, Advertising, Marketing and Communications (DDMAC)
CDER, FDA

CBER Update
Elenita Ibarra Pratt, RN, MPH
Branch Chief, Advertising and Promotional Labeling Branch,
Division of Case Management, Office of Compliance and Biologics Quality,
CBER, FDA

CVM Update
Dorothy McAdams, VMD
Supervisory Veterinary Medical Officer, Division of Surveillance
CVM, FDA

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM SESSION 2

How Did We Get Here & How Can We Avoid Being Here Again: The Anatomy of a Government Investigation

SESSION CHAIRPERSON

Minnie Baylor-Henry, JD
Regulatory & Capital Markets Consulting
Deloitte & Touche, LLP

Many companies are facing countless investigations by the government. The Department of Justice, Office of the Inspector General, State Attorneys General are actively pursuing actions against pharmaceutical, biotechnology, and device companies. This panel will investigate some of the recent settlements, recent trends (including criminal actions against company employees), and the warning signs along the way.

PANELISTS:

John Brownlee, JD
Partner
Holland & Knight

Patrick C. O'Brien, JD
Partner, O'Brien Gould PLLC

Wendy C. Goldstein, JD
Member of the Firm, Health Care and Life Sciences Practice
Epstein Becker & Green, P.C.

12:00-1:30 PM LUNCHEON

1:30-3:00 PM SESSION 3

DTC Update from DDMAC

Kristin I. Davis, JD
Deputy Director, Division of Drug Marketing, Advertising and Communications (DDMAC)
CDER, FDA

DTC promotion continues to be one of the most visible and politically charged issues for the pharmaceutical industry. This panel will examine DTC television ads, FDA policies and research, and provide practical advice on how to interact with the FDA with its review program.

Direct-to-Consumer FDAAA Update
Kristin I. Davis, JD
Deputy Director, Division of Drug Marketing, Advertising and Communications (DDMAC)
CDER, FDA

DTC Submissions Process
Marci Kiester
Leader, DTC Review Group, Division of Drug, Advertising, Marketing and Communications (DDMAC)
CDER, FDA

Review of Research
Kathryn Aikin, PhD
Social Science Analyst, DTC Review Group Research Team, Division of Drug Marketing, Advertising and Communications (DDMAC)
CDER, FDA

3:00-3:30 PM REFRESHMENT BREAK

3:30-5:00 PM SESSION 4

State and Legislative Updates

SESSION CHAIRPERSON

Lucy Rose, MBA
President
Lucy Rose and Associates, LLC

This session will focus on trends in state and federal enforcement and the changes inside the industry in response to them. Several states have developed new laws regulating drug company marketing, including use of prescriber data, limits on interactions with doctors and formulary groups, and new reporting requirements. Meanwhile, both state and private actions have increased.

PANELISTS:

John Patrick Oroho
Principal
Porzio, Bromberg & Newman, P.C.

John Krayniak
Assistant Attorney General
State of New Jersey

Dan Miller
Former Deputy Attorney General, State of Delaware
Former President, national Association of Medicaid Fraud Units

5:00-6:00 PM RECEPTION

CONFERENCE DAY 2 | **WEDNESDAY, FEBRUARY 24**

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

8:30-9:00 AM KEYNOTE PRESENTATION

Office of Medical Policy: A Strategic Look Forward

Rachel E. Behrman, MD, MPH
Deputy Director, Office of Medical Policy
Associate Commissioner for Clinical Programs

9:00-10:00 AM SESSION 5

FDA Part 15: Promotion of Food and Drug Administration—Regulated Medical Products Using the Internet and Social Media Tools

Jean-Ah Kang, PharmD
Special Assistant to the Director, DDMAC, OMP
CDER, FDA

On November 12-13, 2009, the Food and Drug Administration (FDA) held a public hearing on "Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools." This session provides a brief overview of the 77 presentations that were made and a preliminary synopsis of the promotion-related comments currently submitted to this docket, whoch closes on February 28, 2010. These presentations and comments may help guide FDA in making future policy decisions on the promotion of medical products using the Internet and social media tools.

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM SESSION 6

Furthering the Pharmaceutical Industry's Engagement in Electronic Social Media: A Regulatory Roadmap

SESSION CHAIRPERSON

Mark Gaydos
Senior Director, US Regulatory Affairs Marketed Products
sanofi-aventis

A panel od Regulatory Affairs professionals will provide industry perspectives on the November 12-13, 2009 FDA public hearing on "Promotion of FDA-Regulated Medical Products Using the Internet and Social Medial Tools." In addition to discussing some of the insights and key takeaways from the public hearing presentations, the panel members will provide their perspectives on practical approaches for engaging in the online space, specifically addressing the challenges posed by social media. The panel session will conclude with a Q&A session.

PANELISTS:

Mark Gaydos
Senior Director, US Regulatory Affairs Marketed Products
sanofi-aventis

Craig M. Audet
Vice President, US Regulatory
sanofi-aventis

Preeti Pinto
Executive Director, Promotional Regulatory Affairs
AstraZeneca LP

Paul James Savidge, JD
Vice President and Associate General Counsel
US Law & Promotion Compliance
Bristol-Myers Squibb Company

12:00-1:30 PM LUNCHEON

1:30-3:00 PM SESSION 7

Healthcare Reform and Comparative Effectiveness in the Age of Obama

SESSION CHAIRPERSON

John F. Kamp, JD, PhD
Executive Director
Coalition of Healthcare Communication

- Review the funding for Comparative Effectiveness(CE) in the 2009 economic stimulus bill and the research priorities by NIH
- Analysis of how this research might be used by government policy makers, including possible formulary and marketing decisions
- Review of the most significant provisions of health care reform bill, especially those related to marketing

PANELISTS:

Robert E. Ratner, MD
Robert Wood Johnson Health Policy Fellow
Health Division, Office of Management and Budget

Tammara M. Lewis, JD
Director, Advertising Promotion and Labeling
Genzyme Corporation

Jennifer L Butler, JD
Partner
Alston + Bird LLP

3:00-3:30 PM REFRESHMENT BREAK

3:30-4:30 PM SESSION 8

Question and Answer with FDA

SESSION CHAIRPERSON

Glenn Byrd, MBA, RAC
Director, Regulatory Affairs
MedImmune, Inc.

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.

4:30 PM CONFERENCE ADJOURN

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

22nd Annual Conference on Marketing Pharmaceuticals: Integrated Marketing, Emerging Media Trends, and New Regulations

Event #10007 • Tutorials: February 22 • Workshop: February 23-24, 2010
New York Marriott Marquis Hotel, New York, NY, USA

Registration Fees If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

Member Fee US $1630 ❑

Join DIA now to take advantage of all the benefits of membership!
www.diahome.org/Membership
MEMBERSHIP
US $140 ❑

Nonmember Fee US $1770 ❑

A one-year membership to DIA is available to those paying a NONMEMBER registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ❑ I do NOT want to be a DIA member ❑

Discount Fees	MEMBER	NONMEMBER
Government (Full-time)	US $650 ❑	US $790 ❑
Charitable Nonprofit/Academia (Full-time)	US $815 ❑	US $955 ❑

**If paying a nonmember fee, please check one box above, indicating whether you want membership.*

TUTORIALS: FEBRUARY 22, 2010 1:30-5:00 PM

DDMAC and Compliance 101: A Primer US $405 ❑

Social Media Marketing Accelerator US $405 ❑

GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must register and prepay at the same time – no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.** To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

❑ **Please indicate that this form is part of a group registration by checking this box and list below the names of the other three registrants from your company.**

1. _____

2. _____

3. _____

PAYMENT OPTIONS: Register online at **www.diahome.org** or check payment method.

❑ **CREDIT CARD** number may be faxed to: +1.215.442.6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

☐ **Visa** ☐ **MC** ☐ **AMEX** Exp Date _____

Card # _____

Name (printed) _____

Signature _____

❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

❑ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

TRAVEL AND HOTEL The most convenient airport is JFK International Airport and attendees should make airline reservations as early as possible. The New York Marriott Marquis Hotel is holding a block of rooms at the reduced rate below until January 24, 2010, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $229 **Double $229**

Attendees must make their own hotel reservations. Contact the New York Marriott Marquis Hotel by telephone at +1.800.843.4898 or +1.212.398.1900 and mention the DIA event. The hotel is located at 1535 Broadway, New York, NY 10036, USA.

CANCELLATION POLICY: On or before FEBRUARY 15, 2010
Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

Participants with Disabilities: DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

EVENT INFORMATION
Contact **Ellen Diegel, Program Manager,** Phone **+1.215.442.6158**
Fax **+1.215.442.6199,** email **Ellen.Diegel@diahome.org**

Please check the applicable category:

❑ Academia ❑ Government ❑ Industry ❑ CSO ❑ Student
(Call for registration information)

Last Name _____

First Name _____ M.I.

Degrees _____ ❑ Dr. ❑ Mr. ❑ Ms.

Job Title _____

Company _____

Address (As required for postal delivery to your location) _____ Mail Stop

City _____ State _____ Zip/Postal _____ Country _____

email **Required for confirmation** _____

Phone Number _____ Fax Number **Required for confirmation** _____