FDLI

THE FOOD AND DRUG LAW INSTITUTE'S

ADVERTISING & PROMOTION CONFERENCE

for the Pharmaceutical, Medical Device, Biologic and Veterinary Medicine Industries

AGENDA

(Updated 8/23)

September 26

7:00 a.m.
Registration and Continental Breakfast

8:15-8:30 a.m.
Welcome and Opening Remarks
Susan C. Winckler, RPh, Esq, President & CEO, FDLI

8:30-10:30 a.m.
Policy Updates and Enforcement Developments from FDA's Medical Products Centers

Representatives from FDA's Medical Products Centers will provide updates on policy developments related to advertising and promotion activities of drug, biologic, medical device, and veterinary medicine products. This session lays the foundation for the conference by presenting an overview of the current issues, regulations, enforcement actions, recent developments, perspective on comments received, and insights on the future of FDA's advertising and promotion oversight.

In addition to the question and answer portion of this session, the program concludes with a 45 minute question and answer session on the afternoon of September 27. Attendees may submit questions anytime during the conference.

Speakers:

CBER:
Lisa L. Stockbridge, PhD, Branch Chief, Advertising and Promotional Labeling Branch (APLB), Division of Case Management (DCM), Office of Compliance and Biologics Quality (OCBQ)

CDER:
Thomas W. Abrams, RPh, MBA, Director, Division of Drug Marketing, Advertising, and Communications (DDMAC), Office of Medical Policy (OMP)

CDRH:
Toni M. Stifano, Consumer Safety Officer, Office of Compliance

CVM:
Dorothy R. McAdams, VMD, Team Leader, Post-Approval Review Team, Division of Surveillance, Office of Surveillance and Compliance (OSC)

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

10:30-10:50 a.m.
Refreshment and Networking Break

10:50 a.m.-12:30 p.m.
Trends and Priorities in Enforcement – A Review by the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG), the U.S. Department of Justice (DOJ) and the States

What can be learned from recent enforcement actions involving medical product advertising and promotion? Speakers from the HHS OIG, the DOJ and states will present a summary of recent settlements, Corporate Integrity Agreements, whistleblower rule changes, and provide updates on other issues such as "online pharmacy advertising" (Google Inc.), Sorrell v. IMS Health, and the increase in the number of states that are imposing marketing restrictions on medical device manufacturers.

Speakers:
Jill Furman, Office of Consumer Litigation, Civil Division, U.S. Department of Justice

Mary E. Riordan, Senior Counsel, Administrative & Civil Remedies Branch, Office of the Inspector General, U.S. Department of Health & Human Services

State Government Representative (TBA) (Invited)

Moderator:
Alan R. Bennett, Partner, Ropes & Gray, LLP

12:30-2:00 p.m.
Lunch with Presentation

1:15-1:45 p.m.
A Review of Recent Legal Decisions and the Citizens Petition

Richard M. Cooper, Partner, Williams & Connolly LLP

2:00-3:15 p.m.
FDA's Emerging Guidances, Proposed Studies, Research, and Direct-to-Consumer Updates

An FDA panel will discuss recent and emerging guidances, proposed studies, and findings from social science research. Several guidances are pending release, and may be ready to be addressed during the conference. The social science research investigates applied and theoretical issues in the communication of risk and benefit information in direct-to-consumer (DTC) and professional promotional prescription drug materials. A summary of Agency findings will be presented.

Speakers:
Amie C. O'Donoghue, PhD, Social Science Analyst, Direct-to-Consumer Review Groups I and II, DDMAC, OMP, CDER, FDA

Michael A. Sauers, Group Leader, Direct-to-Consumer Review Group I, DDMAC, OMP, CDER, FDA

Lisa L. Stockbridge, PhD, Branch Chief, APLB, DCM, OCBQ, CBER, FDA

Moderator:
Marci C. Kiester, PharmD, Associate Director of Operations, DDMAC, OMP, CDER, FDA, and Commander, U.S. Public Health Service

3:15-3:30 p.m.

Refreshment and Networking Break

3:30-5:30 p.m.

Whose Job Is It? Best Practices for Effective Interdisciplinary Promotional Review

Advance review of promotional materials serves as a key control in FDA-regulated manufacturers' enterprise risk management systems. Done properly, copy review assesses and minimizes regulatory, litigation, and reputational exposure across brands, franchises, and the entire company. The Food and Drug Administration Amendments Act of 2007 (FDAAA) civil money penalty provisions make clear that effective copy review must be interdisciplinary, but there is no "playbook" on the best way to achieve that objective. This session will explore best practices in building an effective team of internal and external experts and clearly defining areas of responsibility. Panelists will address key issues such as whether marketing or regulatory (or someone else) should "own" the process; how medical affairs can provide effective input on claims substantiation according to relevant regulatory standards; and effective management of outside vendors to help assure that proposed messages and marketing execution are consistent with business needs and regulatory standards.

Dale Cooke, Vice President/Group Director, Regulatory Review, Digitas Health

Sandra C. Kalter, Vice President and Chief Regulatory Counsel, Medtronic, Inc.

Preeti I. Pinto, President, Preeti Pinto and Associates, LLC

Joi C. True, Senior Corporate Counsel, Genentech, Inc.

Other Industry Speakers (Invited)

Moderator:
Coleen Klasmeier, Partner, Sidley Austin LLP

5:30 p.m.
Adjournment for the Day

5:30-6:30 p.m.

Networking Reception

All conference attendees are invited to the networking reception. Reconnect with colleagues and meet other members of the food and drug law and regulation community.

September 27

7:30 a.m.
Continental Breakfast

8:30-10:30 a.m.
Concurrent Breakout Sessions

Each breakout session will explore product specific examples and obligations of complying with advertising and promotion oversight. Attend one of the breakouts to gain practical information through interactive exercises and discussion.

Following the breakout sessions, all conference attendees will gather in the main meeting room at 10:45 a.m.

1. Animal Health and Veterinary Medicine

   Daniel C. Coyle, Section Leader, Compliance, Inspection and Compliance, Center for Veterinary Biologics, Animal and Plant Health Inspection Service, U.S. Department of Agriculture

   Dorothy R. McAdams, VMD, Team Leader, Post-Approval Review Team, Division of Surveillance, Office of Surveillance and Compliance (OSC), Center for Veterinary Medicine (CVM), FDA

   Kathy McKeen, Senior Regulatory Associate, Surveillance & Compliance, Elanco Animal Health

2. Drugs and Biologics — Getting Things Right: Agency and Industry Promotional Hot Buttons

   Moderator:
   Lisa M. Hubbard, RPh, Professional Review Group III Leader, Division of Drug Marketing, Advertising, and Communications (DDMAC), Office of Medical Policy (OMP), Center for Drug Evaluation and Research (CDER), FDA, and Captain, U.S. Public Health Service

   Panelists:
   Michael Brony, PharmD, Regulatory Review Officer, Advertising and Promotional Labeling Branch (APLB), Division of Case Management (DCM), Office of Compliance and Biologics Quality (OCBQ), CBER, FDA

   Al D'Alonzo, PhD, Senior Director, Pharmaceutical Development and Commercialization, Otsuka America Pharmaceutical, Inc.

   Catherine B. Gray, PharmD, Management Advisor, DDMAC, OMP, CDER, FDA

   Michele M. Hardy, Executive Director, Regulatory Advertising and Promotion Policy, GlaxoSmithKline

   Sangeeta V. Chatterjee, PharmD, Regulatory Counsel Team Leader, DDMAC, OMP, CDER, FDA

3. Medical Devices and Diagnostics

   Terri T. Garvin, Regulatory Counsel, Office of Compliance, Center for Device Evaluation and Radiological Health (CDRH), FDA
   Deborah A. Wolf, Regulatory Counsel, Office of Compliance, CDRH, FDA

   Edward M. Basile, Senior Partner, King & Spalding LLP

   Casper E. Uldriks, Counsel, Olsson Frank Weeda Terman Bode PC

10:30-10:45 a.m.

Refreshment and Networking Break

10:45 a.m.-11:30 a.m.

The Impact of Safety, Risk Communications, and Product Liability on Advertising and Promotion Strategies

FDAAA gave FDA new powers and responsibilities in the areas of safety, risk communications, and risk management. These powers include the authority to require new safety labeling information, post marketing studies, and Risk Evaluation and Mitigation Strategies (REMS) – powers that the Agency has used vigorously and, some would say, aggressively. What effect have these developments had on advertising and promotional strategies? What mechanisms have companies put in place to assure that their advertising and promotion adequately reflects changes in product information resulting from these measures? What, if any, implications are there for product liability exposure?

Speakers:

Industry Representative (Invited)

James N. Czaban, Chair, FDA Practice Group, Wiley Rein LLP

Michael McCaughan, Editor, The RPM Report and Founding Member, Prevision Policy LLC

Moderator:
Geoffrey M. Levitt, Senior Vice President & Associate General Counsel, Regulatory & Policy, Pfizer, Inc., and Vice Chair, FDLI Board

11:30-1:00 p.m.
Lunch with Presentation

1:00-2:00 p.m.
A Historical Look at Enforcement and Warning Letters and Hot Button Issues: What do we Know from FDA Actions that Can Help Companies Navigate Internal Debates and Challenges?

This interactive session will review FDA and Federal Trade Commission Enforcement and Warning Letters and explain the accompanying advertising and promotion challenges faced by companies. The panelists, with input by the audience, will discuss:

- Hot button topics/main challenges in medical product advertising and promotion activities
- Steps to increase compliance within marketing teams and vendors
- Reprint Distribution
- Pipeline Presentations
- Economic Claims

Industry Speaker (Invited)

Tracy L. Acker, PharmD, President, The Acker Group LLC
Anne V. Maher, Partner, Kleinfeld, Kaplan & Becker, LLP

Moderator:
Patrick C. O'Brien, Partner, Holland & Knight, LLP

2:00-2:45 p.m.
The Global Market Place: Key Regulatory Issues in Worldwide Markets

As the world consumption of medical products continues to grow, with an expectation of further growth in emerging markets, this session will provide an overview of the advertising and promotion matters facing the medical products industry. What are the key advertising and promotion issues multi-national companies are considering when launching products outside of the United States? How are product claims harmonized? What approaches are companies taking to maintain consistent messaging? What role does corporate social responsibility have in the global marketplace?

Sharon A. Tonetta, PhD, Vice President, Global Regulatory Affairs, Bausch & Lomb, Incorporated

Industry Speaker (invited)

Moderator:
Minnie V. Baylor-Henry, Worldwide Vice President -Regulatory Affairs, Medical Devices & Diagnostics, Johnson & Johnson, and FDLI Board Chair

2:45-3:00 p.m.
Refreshment and Networking Break

3:00-4:00 p.m.
Questions and Answers with FDA's Medical Products

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

Dorothy R. McAdams, VMD, Team Leader, Post-Approval Review Team, Division of Surveillance, Office of Surveillance and Compliance (OSC), Center for Veterinary Medicine (CVM), FDA

Lisa L. Stockbridge, PhD, Branch Chief, Advertising and Promotional Labeling Branch (APLB), Division of Case Management (DCM), Office of Compliance and Biologics Quality (OCBQ), CBER, FDA

Deborah A. Wolf, Regulatory Counsel, Office of Compliance, CDRH, FDA

Moderator:
Janet Lucy Rose, President, Lucy Rose & Associates, LLC

4:15 p.m.
Conference Summary/Take-Aways; Adjournment