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2-day In-person Seminar:

Ensuring Compliance with Advertising and Promotional Requirements for Drugs and Medical Devices

By: **Michael A Swit, Esq.**, FDA Lawyer

Location: San Francisco, CA | March 22-23, 2018



SPEAKER

Michael A Swit, Esq, FDA Lawyer

Michael A. Swit focuses on solving the legal challenges confronted by the pharmaceutical, medical device, and other life sciences industries in tackling the myriad of legal mandates enforced by the U.S. Food & Drug Administration. Mr. Swit has extensive experience counseling life sciences firms on the demands of compliance with FDA's statutory and regulatory requirements to develop and market safe and effective drugs, biologics, medical devices, IVDs and other products. He also has advised regulated firms on a wide range of FDA regulatory matters, including drug and device approvals and marketing/promotional claims, dietary supplement health claims and regulatory issues in corporate acquisitions. His experience includes FDA development strategies, compliance and enforcement initiatives, recalls and crisis management, submissions and related traditional FDA regulatory activities, labeling and advertising, and clinical research efforts.

Mr. Swit has been addressing critical FDA legal and regulatory issues since 1984. Before joining Duane Morris LLP, Mr. Swit served for seven years as vice president at a preeminent scientific and FDA regulatory consulting firm, where he developed and ensured execution of a broad array of regulatory and other services to clients, both directly and through outside counsel.

His multi-faceted experience includes serving for three and a half years as corporate vice president, general counsel and secretary of Par Pharmaceutical, a prominent, publicly-traded, generic drug company and, thus, he brings an industry and commercial perspective to his work with FDA-regulated companies. While at Par, he spearheaded Par's successful response to multiple federal and state criminal and civil investigations arising out of the actions of prior management. Mr. Swit then served for over four years as CEO of FDAnews.com, a premier publisher of FDA regulatory newsletters and other specialty information products for the FDA-regulated community. His private FDA regulatory law practice also has included service as counsel in the FDA practices of three international law firms, as well as a solo FDA practitioner.

Mr. Swit has taught and written on a wide variety of subjects relating to FDA law, regulation and related commercial activities, including, since 1989, co-directing a three-day intensive course on the generic drug approval process and editing a guide to the generic drug approval process, Getting Your Generic Drug Approved. A former member of the Food & Drug Law Journal Editorial Board, Mr. Swit also has been a prominent speaker at numerous conferences sponsored by such organizations as the Food & Drug Law Institute (FDLI), the Regulatory Affairs Professionals Society (RAPS), and the Drug Information Association (DIA).

Mr. Swit is a 1982 graduate of Emory School of Law and a magna cum laude graduate of Bowdoin College (1979), with high honors in history.

LEARNING OBJECTIVES

Key goals of the conference will include learning:

- The basics of FDA law and regulations governing advertising and promotion, as well as sister agencies such as the Federal Trade Commission, which shares jurisdiction with FDA on certain regulated products (e.g., OTC drugs).
- The distinctions between labels, labeling and advertising and how that impacts FDA's powers, and
- How to properly position Direct-to-Consumer (DTC) promotions
- The Dos and Don'ts of promoting products on the internet, including social media sites such as Facebook and Twitter
- The perils of off-label promotion, including criminal and civil actions that have led to multi-billion dollar settlements by regulated drug companies
- Whether the First Amendment provides any insulation for truthful statements regarding regulated products;
- When disseminating medical educational materials crosses the line into improper promotion; and
- Key considerations on how to implement appropriate procedures and controls in your company to minimize the potential for regulatory action by the FDA or the FTC relative to promotion and advertising.

COURSE DESCRIPTION

Federal regulation of the advertising and promotion of pharmaceuticals and medical devices reflects an aggressive attitude on the part of the regulators that demands, in turn, that industry be keenly aware of the legal and regulatory duties, as well as key recent trends in enforcement activities by the Federal Government. This course will explore in detail what FDA requires of drug and device firms as well as recent current hot buttons in FDA enforcement activity for the advertising arena.

What's at stake if your advertising and promotional efforts violate the law? Colossal fines – the latest was $3 Billion; criminal liability, including even prison time; and huge disruption in operations while dealing with federal probes into illegal marketing.

AGENDA

DAY ONE (8.30AM – 4.30PM)

Registration Process: 8:30 AM – 9:00 AM
Session Start Time: 9:00 AM

I. Understanding the Basics

A. Who Has Jurisdiction
   1. Drugs & Biologics
      a. Rx Drug Advertising
      b. Nutrient Content Claims
   2. Devices
      a. Restricted
      b. all other
B. Labeling vs. Advertising
C. Basic drug rules
   1. Fair balance
D. Device rules
   1. Intended use deviations
E. DTC advertising
   1. Print
   2. TV
F. Comparative Claims
   1. Standard to support
   2. Push to pursue CER
G. Detailing and Sampling
   1. is there still a future?
   2. what can be said?
   3. danger of "custom" pieces
G. How FDA learns of violations
   1. Keep your house clean or your competitors will rat you out

II. Scientific Exchange

A. Guidances on Dissemination of Scientific Information
B. Risks involved in Off-Label Statements
C. Procedural Requirements and Unsolicited Requests for Information

III. First Amendment

A. Understanding "Commercial Speech" Doctrine
B. FDA and the Regulation of Advertising

IV. Websites & Social Media

A. FDA Policies on the Internet
B. Recent FDA Enforcement Activities
B. How to Handle at the Company Levels

DAY TWO: (8.30AM – 4.30PM)

V. Enforcement Trends

A. FDA Hot Buttons
   1. Understating risk
   2. Overstating effectiveness
B. FTC
   1. POM Wonderful and substantiation
C. Private Litigation – Understanding
   1. Lanham Act
   2. State Unfair Competition

VI. False Claims Act and Criminal Liability

A. Review of Key Settlements
B. "Responsible Corporate Official" Liability

VII. Handling at the Company Level

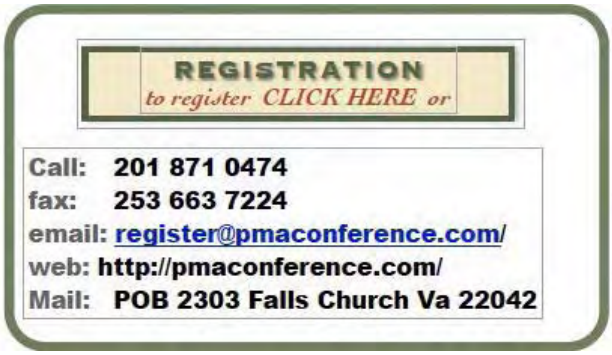
A. Compliance Programs
B. Internal processes

WHO WILL BENEFIT

Senior executives, directors, managers and those who have responsibility for implementing advertising and promotional activities, as well as those that have key collateral roles in reviewing advertising for drug and device firms, including officials from these areas within regulated companies:

- ✔ Sales
- ✔ Marketing
- ✔ Medical Affairs
- ✔ Legal
- ✔ Regulatory
- ✔ Compliance

Click Here for Venue and Fee Information



Cancellations and Substitutions

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $300 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($300) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Seminar Topic: Ensuring Compliance with Advertising and Promotional Requirements for Drugs and Medical Devices

Date & Location: .....

Attendee Details:

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

Company Information

Organization .....

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Address .....

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City .....

State ..... Zip.....

Country .....

Phone ..... Fax .....

Payment Options

☐ Check enclosed

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. .....

Expiration date .....

Total amount $ .....

Signature .....
(Signature required on credit card and bill-me orders.)

Print name.....

☐ Bill me/my company $ .....

Purchase order # .....
(Payment is required by the date of the conference.)

Please fill this form with attendee details and payment details and fax it to 253 663 7224