



Introduction to Advertising & Promotion for Medical Products

October 12, 2021
Virtual Event

Agenda

12:00–12:15 PM Welcome and Course Overview

Laura Brown, Director, Educational Programs, FDLI
Khara L. Minter, Assistant Director, Training Programs, FDLI

12:15–1:30 PM I. Applicable FDA Offices, Essential Principles, & Key Definitions

Matthew Hegreiness, Special Counsel, Covington & Burling LLP

In this session, we will discuss the relevant FDA offices that regulate advertising and promotional labeling of medical products, including drugs and medical devices for both human and veterinary use. We will also explore essential definitions and principles of medical product advertising and promotion.

A. Why it Matters

B. FDA Offices

1. CDER Office of Prescription Drug Promotion (OPDP) and CBER Advertising and Promotional Labeling Branch (APLB)
2. CDRH Division of Premarket and Labeling Compliance (DPLC)
 - a. Submission Requirements
 - b. Approval Pathways
 - c. Reporting Requirements

C. FDA Enforcement

1. Warning and Untitled Letters
2. FDA's Bad Ad Program
3. Corrective Actions

D. Key Definitions and Essential Principles of Advertising and Promotional Labeling

1. Intended Use and the New Drug Approval Requirement
2. What Are the Differences Between Advertising and Promotional Labeling?
3. Adequate Directions for Use
4. False or Misleading
5. Substantial Evidence
6. Fair Balance
7. Omissions/Minimizations (Material Fact/Risk)

- 8. Disease Awareness (Unbranded) and Scientific Exchange
- E. Types of Claims**
 - 1. Product Claim
 - 2. Comparative
 - 3. Implied
 - 4. Express
- F. Traditional and Other Forums**
 - 1. Direct to Consumer (DTC) Broadcast Advertisements
 - 2. Trade Shows
 - 3. Internet/Social Media
- G. Preapproval Communications**
- H. Submissions**
 - 1. Requesting Advisory Comments
 - 2. Promotional Submission Requirements
 - 3. Special Pre-Submission Requirements Under Subparts E and H

1:30–1:45 PM

Break

1:45–3:00 PM

II. Dissemination of Non-Promotional Information

Heather Banuelos, Counsel, King & Spalding LLP

During this session, we will explore crucial aspects of topics such as unapproved use and intended use, and the First Amendment legal decisions underlying these concepts. We will also discuss guidance documents FDA has issued on this topic, as well as special circumstances regarding dissemination of use information.

- A. Why It Matters and What It Means**
- B. First Amendment Jurisprudence: *Central Hudson*, *Washington Legal Foundation v. Henney*, *Caronia*, and Other Key Decisions**
- C. Key Concepts: Intended Use, Unapproved Use, and Practice of Medicine**
- D. FDA Final Guidance: Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – Questions and Answers**
- E. FDA Final Guidance: Medical Product Communications That Are Consistent with the FDA-Required Labeling – Questions and Answers**
 - 1. Substantiation
 - 2. Data: Patient Reported Outcomes / Patient Preference Information / Real World Evidence
 - 3. Conformance with Approved Labeling
 - 4. General vs. Specific Claims
- F. Good Reprint Practices**
- G. Scientific and Educational Activities, Including Continuing Education**
- H. Role of Medical Science Liaisons (MSLs); Unsolicited Requests for Information by Medical Professionals**

3:00–3:15 PM **Break**

3:15–4:00 PM **III. Other Agencies and Considerations**

August Horvath, Partner, Foley Hoag LLP
Michael Smith, Managing Member, Michael F. Smith Law, PLLC

This session will cover the other agencies and entities that govern and impact advertising and promotion of medical products.

- A. Federal Trade Commission (FTC) Authority**
 - 1. FTC Regulation of Advertising for OTC Drugs and Devices
 - 2. Substantiation
- B. National Advertising Division (NAD)**
 - 1. Case Examples: OTC and Restricted Devices
- C. Lanham Act**
- D. State Actions and Consumer Class Actions**
- E. Interactions with SEC**
- F. False Claims Act, Qui tam Actions, and Anti-Kickback Statute**
- G. PhRMA Code on Interactions with Healthcare Professionals**
- H. AdvaMed Code of Ethics**
- I. Sunshine Act**

4:00–4:15 PM **Break**

4:15–5:15 PM **IV. Case Studies/Hypotheticals**

Madhavi Bellamkonda, Director, Regulatory Intelligence & Integration Management, Intuitive Surgical Inc.

Lynn Deutsch, Founder, President, Regulatory Promo, LLC

During this session, attendees will have the opportunity to apply the advertising and promotion knowledge they have learned over the course of the day through interactive, real-life, and hypothetical examples. This interesting and engaging session will tie together concepts, authorities, and agencies that have been discussed during the course.

5:15 PM **Course Adjournment**

FDLI would like to thank the Curriculum Advisors for planning this Introductory Course:

Rebecca Burnett, Executive Director Framework Solutions
Matthew Hegreness, Special Counsel, Covington & Burling LLP
Thomas Miller, Sr. Counsel, Life Science Lead, Nixon GWILT Law