

CCC Webinars and Podcasts

CCC understands the importance of communicating information about regulatory developments and related marketplace trends to internal stakeholders. To support your organization's ongoing education and training objectives, CCC provides expert-developed webinars and podcasts on job-relevant topics. CCC's webinars and podcasts quickly integrate content for any size audience while providing routinely updated information on specific topics.

Delivery

Unlimited 24/7 access to archived webinars and podcasts is provided via the [CCC website](#) at a flat rate of \$695 each.

Topics

Please select the webinar/podcast that your organization would be interested in ordering. They are organized as follows:

- **U.S. Regulatory Environment**
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- **U.S. Promotional Tools**
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 - Mobile Device Marketing
 - Disease Awareness
 - Alliance Management
 - Medical Editing & Writing in a Regulated Environment
 - Public Relations: Tools of the Trade
 - CME: Independent Vs. Promotional Education
 - Promotion of Drugs with Black Box Warnings
 - Promotion of Drugs Under Accelerated Approval

The U.S. Regulatory Environment: National Focus

FOOD & DRUG ADMINISTRATION AMENDMENTS ACT (FDAAA): IMPLICATIONS FOR DRUG DEVELOPMENT AND MARKETING

Learn best practices for complying with the rapidly evolving regulation of drug development. The implementation of the 2007 Food and Drug Administration Amendments Act (FDAAA) brought significant changes to the review process. For example, Risk Evaluation and Mitigation Strategies (REMS) are now required, and CDER appears to have raised the drug approval bar, seeking more comparative effectiveness data and more thorough risk assessment.

REMS IN THE NEW ERA OF FDA

Healthcare professionals in all company functions and staff at promotional agencies face an increasingly turbulent regulatory terrain with [Risk Evaluation and Mitigation Strategy \(REMS\)](#) requirements. However, with careful planning this requirement actually presents invaluable opportunities. What is needed is an understanding of: the risk assessment process, effective scenario planning, product positioning, and proper implementation of the communications features of REMS programs.

COMPARATIVE EFFECTIVENESS: IMPACTS ON INDUSTRY AND HEALTH OUTCOMES

It's critical to keep abreast of discussions underway about comparative effectiveness as this requirement, included in the healthcare reform legislation, will affect every company and all functions, including R&D, clinical, regulatory, legal, and marketing and communications. Comparative effectiveness remains a significant challenge and its implementation is going to be done gradually by various government agencies. Get the basics on the current thinking.

The U.S. Regulatory Environment: State Focus

STATE REGULATIONS FOR PHYSICIAN PAYMENTS: AN OVERVIEW

State regulation of pharmaceutical drug and device promotion can be complex and confusing. It is critical for regulatory, legal, and marketing professionals, and their promotional agencies involved in direct-to-physician outreach, to be aware of the different state laws affecting compensation to physicians in all forms.

STATE REGULATIONS FOR PHYSICIAN PAYMENTS: IN-DEPTH SINGLE STATE ANALYSIS

Laws and their implications for promotional programs are reviewed for any of the following eight States: California, District of Columbia, Maine, Massachusetts, Minnesota, Nevada, Vermont, and West Virginia.

Government Guidance

DRAFT GUIDANCE ON PRESENTATION OF RISK INFORMATION IN PHARMACEUTICAL/DEVICE PROMOTION: MACRO-PERSPECTIVE

If you, like so many others, haven't had an opportunity to read and fully digest the FDA's 27-page *Draft Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion*, then you will benefit from this expert recap. FDA regulatory and legal experts review the key points from this critical Draft Guidance, including what can be expected to remain in the Final Guidance.

U.S. Promotional Tools

SOCIAL MEDIA: A LOOK INTO THE CRYSTAL BALL

Regulatory, legal, communication, and compliance experts share their multiple perspectives on the future of social media in the pharmaceutical drug and medical device promotional space.

MARKETING ON MOBILE DEVICES: COMPLIANCE HOW-TO

Mobile communication is being transformed and is expanding rapidly, so healthcare marketers must understand the regulatory implications of sharing information wirelessly. Mobile device marketing must take into consideration such topics as: HIPAA requirements and restrictions, FDA/DDMAC concerns (e.g., fair balance), and other relevant legal and regulatory considerations.

DISEASE AWARENESS: WHAT YOU NEED TO KNOW ABOUT THE REGULATORY PITFALLS

Regulatory snafus are possible even when promotional programs do not mention specific marketed drugs or devices. Learn how promotional laws and policies are applied to promotional disease awareness/educational programs. Examples of troublesome areas and best practices are shared, along with a summary of the FDA guidance document on this subject.

ALLIANCE MANAGEMENT: ADVOCACY GROUP RELATIONS AND REGULATORY CONSIDERATIONS

Relationships with third-party groups are critical for furthering patient and public education around disease states. However, with intense scrutiny by Congress around these relationships, there currently appear to be more questions than answers in terms of how to establish and manage alliances. Learn what the experts consider to be best practices in this dynamic area.

MEDICAL EDITING & WRITING IN A REGULATED ENVIRONMENT

Marketing, communications, regulatory, and legal professionals who write, edit, review, or final proof promotional copy must serve two masters at the same time: the rules of good medical writing, and the guidelines set forth by government regulations. This webinar explains how to avoid common pitfalls that can trip up both seasoned and less experienced professionals when they create or review promotional copy. Topics covered include the wording of indications and disease states, FDA's multiple "implementation factors," the relation between message and graphic elements, and maintaining consistency of Brand Identity in the regulatory context.

PUBLIC RELATIONS: TOOLS OF THE TRADE

Public relations (PR) is growing in importance within the drug and medical device industries because there are several advantages, including cost efficiency and timely delivery of breaking news. However, to make the most of PR investments, organizations must ensure all stakeholders are educated about how to use PR tactics within the boundaries of an organization's culture of compliance.

CME: INDEPENDENT VS. PROMOTIONAL EDUCATION

Independent and Promotional Medical Education are quite different, being governed by separate guidelines. This webinar thoroughly addresses key differences (and some similarities), from a regulatory perspective. Topics include sponsorship guidelines, what each type of education is permitted to discuss, rules governing speaker training and speaker bureaus, standards for independence, CME credit, accreditation of providers, and the selection of audience and content.

PROMOTION OF DRUGS WITH BLACK BOX WARNINGS

This webinar, featuring former FDA officials, addresses all key aspects of the marketing and promotion of drugs that require black box warnings, including the special requirements and

restrictions mandated by FDA guidelines. The promotional and regulatory impact of an already-approved product being given a black box warning will also be addressed.

PROMOTION OF DRUGS UNDER THE ACCELERATED APPROVAL PROCESS

Former FDA officials will explain the various requirements placed on manufacturers who seek to bring their products to market quickly under the FDA's Accelerated Approval Process (Subpart H), including: what products are eligible, what documents must be pre-cleared and when, and what post-approval activities are mandated by law.