
If you are in
ADVERTISING, PROMOTIONAL MED ED, or PUBLIC RELATIONS
and don't understand...

REMS IN THE NEW ERA OF FDA

...then this teleconference is for you!

Presented through an alliance between



Marketing communication professionals face an increasingly turbulent regulatory terrain with new FDA laws and policies, such as the **Risk Evaluation and Mitigation Strategy (REMS)** requirements. However, with careful planning, this new era presents invaluable opportunities – whether you are on the client-side or within an advertising, promotional medical education, or PR agency. Learn how can you provide more valuable counsel to stakeholders and customers.

Companies Currently with Approved REMS:

Abbott
Amgen
AstraZeneca
Bayer
Biovail Labs
Boehringer Ingelheim
Eisai
Eli Lilly
GlaxoSmithKline
Hoffman-La Roche
Johnson & Johnson
Merck & Co.
Novartis
NovaDel Pharma
Oscient
Otsuka
Pfizer
Schering Corp.
Solvay

Botox[®], Opioids, ...

Which Products Are Next & What's Your Role?

A REMS must be submitted to the FDA for any drug product deemed to have serious risks – either prior to the product's approval or even after the product is marketed. Further, the FDA can delay approval if it deems the submitted REMS to be insufficient. FDA is also authorized to declare the product misbranded (and thus ineligible for marketing) if the company fails to follow the approved REMS.

More and more products are being required to submit a **REMS** – just last month Botox[®] (Botulinum Toxin Type A) made the list. A public meeting on REMS for a class of opioids took place on May 27-28. What products will be next?

The new legislation increases the responsibility of marketing and PR professionals to ensure that risk information is communicated effectively and proactively – both internally and externally.

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3-Part Live One-Way Teleconference (1 hour) – Archived for Future Access

- ◆ **Part I: Overview of REMS – 20 minutes**
 - What is REMS?
 - Why are REMS being enforced?
 - How is a class-wide REMS different?
 - What are the components of a REMS?
 - How do REMS fit into the larger risk management picture?
 - What are REMS best practices: two case studies
- ◆ **Part II: Implications for Communication Professionals – 20 minutes**
 - Role of the Advertising, Promotional Med Ed, and PR professional
 - Importance of Internal Communications
 - Shaping the Market with External Communications
 - Keeping abreast of the changing landscape
- ◆ **Part III: Experts Answer Your Questions – 20 minutes**
 - Exchange between the experts to answer pre-submitted questions

Course Instructors

Wayne Pines – *Chair of the CCC Advisory Board.* Wayne is a nationally recognized expert on regulatory aspects of healthcare advertising and promotion. Wayne served at the FDA for 10 years as chief of consumer education and information, chief of press relations, and associate commissioner for public affairs. He is a nationally recognized expert on crisis management and media strategies.

Andrew Gilman – President and CEO of CommCore Consulting Group, Andrew has been a communications strategist, crisis counselor, and keynote speaker for more than twenty-five years. Co-author of the best-selling book, *Get to the Point*, he is also a lawyer and award-winning journalist. Most recently, *PR News* selected him as Educator/Trainer of the Year. Gilman and CommCore were also selected as public relations counsel for the visit of Pope Benedict XVI to Washington, DC.

Ilyssa Levins, Moderator – Ilyssa Levins has 30 years of healthcare communications experience. Prior to founding CCC, Ilyssa was with Grey Global Group, one of the world's foremost communications firms, for two decades. Her entrepreneurial accomplishments there include launching the BrandEdge marketing consultancy, catapulting Grey's healthcare PR practice to a top 10 global ranking, and leading a PR boutique, GTFH, to be named #1 in healthcare two years in a row.

Price: *Unlimited staff access* – \$395 for archived teleconference audio –available to all staff, including new hires

For more information:

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