
The rules on drug and device marketing are changing. In the absence of settled policy, safe harbor lies in following the terms of three draft FDA guidances.

Falls Church, VA (PRWEB) July 13, 2017 -- Navigating New Terrain in Advertising and Promotion of Medical Products: A Practical Approach to the New Communications and Off-Label Landscape
**An FDAnews Webinar**
July 27, 2017 — 1:30 p.m. – 3:00 p.m. ET
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In the fast-changing world of drug and device marketing and promotion, manufacturers need safe harbors.

The FDA has provided them, three draft guidances that are the closest thing to FDA policy that exists at the moment.

But manufacturers can’t make use of them unless they understand them. For that, they need lawyers.

Mark the calendar for Thursday, July 27, when two top Washington lawyers deconstruct FDA handiwork into the language manufacturers can understand.

Lisa Dwyer and Heather Bañuelos, the tag team from the top Washington law firm King & Spalding, served in top FDA advisory positions before moving to the private sector. They’re as well qualified as anyone in Washington to guide manufacturers through the triple mazes known as:

- Draft Guidance: Medical Product Communications That Are Consistent With the FDA-Required Labeling
- Draft Guidance: Communications With Payors, Formulary Committees, and Similar Entities
- Draft Guidance: Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products

In just 90 fast-paced minutes, attendees will hear crystal-clear guidance to arcane legal concepts including:

- What “consistent communications” means vs. on-label and off-label communications
- How the FDA interprets the “three factor test” for consistent communications and how to apply it in practice
- How to evaluate consistent communications as “scientifically appropriate and statistically sound”
- The real-life scope of the new safe harbor for pre-approval communications with payors
- The everyday application of the concept “healthcare economic information” to products
- How to consider the context of communications to ensure adequate disclosure of information (e.g., study designs, limitations, disclaimers, etc.)
- And much more!

The rules on marketing drugs and devices, never clear, continue to evolve. Why skate on thin ice when best
practices aren’t that hard to understand and follow? Register today.

Meet Your Presenters:
Lisa M. Dwyer is a partner in King & Spalding’s Washington, DC office and a member of the firm’s FDA & Life Sciences practice group. Lisa has more than 15 years’ of experience working with legal and policy matters involving all FDA-regulated products. From 2010-2015, she served in the Commissioner’s Office at FDA as a Senior Policy Advisor in the Office of Policy, and as the Deputy Chief of Staff to the Commissioner of Food and Drugs. In these roles, Lisa provided strategic counseling to FDA’s Commissioner and other senior leadership on the agency’s most significant and complex issues, including off-label marketing. She routinely counsels clients on promotion and advertising, and off-label communication strategies.

Heather Bañuelos is Counsel in King & Spalding’s Washington, DC office and a member of the firm’s FDA & Life Sciences practice group. Heather’s primary practice is focused on regulatory strategies and initiatives for the development, labeling, promotion and advertising of FDA-regulated products. She has served on over a dozen different promotional review committees and medical and scientific review committees, with a knack for practical advice and recommendations to help clients find a path forward. Heather is a former Associate Chief Counsel in the FDA’s Office of the Chief Counsel, and has also served as senior in-house regulatory counsel for multiple clients, including two large pharmaceutical companies and a leading food company. Her experience in government and in-house give her a unique and valuable perspective as outside counsel.

Who Will Benefit:
- Marketing/Advertising
- Legal Affairs
- Regulatory Affairs
- Research & Development
- Commercial Operations
- Medical Affairs
- Clinical Trial Design

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Contact Information
Michelle Butler
FDANEWS
http://www.fdanews.com
+1 (703) 538-7665

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