



CME and Consultants Conference Roundtable

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CME: The Enforcement Risk

- Government increasingly focused on off-label promotion
- “Parke-Davis” theory: Off-label promotion actionable under the False Claims Act
 - Driven by whistleblowers

CME: The Enforcement Risk

- Company involvement in CME on unapproved uses may be viewed as evidence of off-label promotion

“Parke-Davis also used its control over continuing medical education programs that were ostensibly, but not in fact, independent, as part of its strategy to promote off-label uses of Neurontin.”

CME: The Enforcement Risk

- Company involvement in CME on unapproved uses may be viewed as evidence of off-label promotion

“The evidence demonstrates that Parke-Davis influenced the content of purportedly independent medical education, while the programs explicitly disclaimed any such influence, and concealed and made false statements about the payments that it had made to doctors who acted as speakers and faculty for such education.”

CME: The Enforcement Risk

- Particularly troubling public policy issues in oncology
 - Significant physician experimentation
 - Dependence on new data
 - Appetite for latest information
 - Pressure on companies to disseminate data
- Similar issues for neuroscience drugs

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