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Off-Label Use of Medical Devices: Promotion and Compliance

Wednesday, November 18, 2009
8:00-9:00am

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Virginia Gibson
US Attorney's Office

Mark C. Levy
Saul Ewing

Drugs, biologics, and devices are widely used to treat patients in ways that were not specifically approved or cleared by FDA. While FDA does not regulate the practice of medicine or off-label use, it does heavily regulate off-label promotion. Most recently, FDA has put together a draft guidance that could permit companies to use certain types of materials such as peer-reviewed articles to promote products off-label.

In addition to FDA, the U.S. Department of Justice has firmly taken control of off-label use allegations against pharmaceutical, biotechnology, and medical device manufacturers through the Food, Drug and Cosmetic Act (FDCA), the Anti-Kickback Statute, and the False Claims Act.

This tension between patient benefit and government enforcement puts companies in a difficult position. Should they remain silent when data is developed that may benefit patients, or risk prosecution and litigation related to off-label promotion by disseminating scientific information that may indicate important therapeutic options for patients?

In this seminar, the panel will discuss problems arising from off-label use and promotion, while providing practical instruction on how to deal with them.

Topics will include:

- Training and monitoring sales and marketing representatives
- Product liability litigation and other civil actions including Allergan vs. United States of America, et al.
- Government enforcement of off-label sales and marketing compliance

Please join us for this panel presentation. A continental breakfast will be served at 7:30am.

Fuller Conference Room
University City Science Center
3711 Market Street, Suite 800

Continental Breakfast at 7:30 am

Seminar is FREE!
1.0 hours of MCLE credit approved
Questions?

Please call (215) 594-8800
or email mcle@exponent.com

Virginia Gibson is the First Assistant United States Attorney for the Eastern District of Pennsylvania. Ms. Gibson served as Chief of the Civil Division in both that office and the District of Delaware. She has represented the United States and its agencies at trial in defense of all varieties of civil litigation. She has brought and supervised a wide range of civil actions on behalf of the United States, seeking remedies for environmental violations and government and consumer fraud. Under her leadership, both offices obtained record-breaking recoveries in pharmaceutical fraud prosecutions.

Ms. Gibson is a graduate of Boston University School of Law where she served on Law Review, and prior to her career in government service she was associated with the firm Drinker, Biddle & Reath. Ms. Gibson served as Board Member and President of the Support Center for Child Advocates. She teaches Health Care Fraud as an adjunct professor at both Temple and Widener Law Schools.

Mark C. Levy is a litigator and trial attorney at Saul Ewing. He has represented Fortune 500 companies in complex commercial litigation in state and federal forums across the country. Mr. Levy regularly provides risk-management advice to businesses that manufacture and sell products for consumer use and has also represented corporations charged with violations of federal criminal law. He has handled investigations into alleged government procurement fraud, healthcare fraud, and environmental crimes. He has counseled pharmaceutical companies and medical device manufacturers on product recalls as well as the effects of government inquiries on business relations such as co-marketing agreements and joint venture partnerships and distributor agreements. He has also developed compliance programs for various clients in different highly regulated environments. Mr. Levy is an author in and the editor of the book, "[Off-Label Communications: A Guide to Sales and Marketing Compliance](#)," now in its second edition. He also serves as a board member of the Food and Drug Law Institute Journal.

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