

**FOR IMMEDIATE RELEASE**  
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**FDLI Publishes Comprehensive Handbook on Pharmaceutical Risk Management**

*300-Page Book, with Foreword by FDA's Janet Woodcock, MD,  
Provides Practical Guidance on New REMS Requirements*

Now that the Food and Drug Administration (FDA) has new authority to improve the safe use of pharmaceuticals, drug manufacturers can be required to develop comprehensive risk assessment evaluations and restrict their marketing on existing pharmaceuticals.

To help pharmaceutical companies, consultants and other drug industry stakeholders prepare and comply with the new rules on risk evaluation and mitigation strategy (REMS) mandated under the Food and Drug Administrations Act Amendments of 2007, FDLI has issued the most complete handbook on risk evaluation and management published to date: *Pharmaceutical Risk Management: Practical Applications*.

This comprehensive, 300-page book, which includes a foreword by Janet Woodcock, MD, Director of the Center for Drug Evaluation and Research at FDA, provides practical guidance to enable drug companies to effectively negotiate the REMS pre- and post-marketing surveillance maze, including:

- > What actions to take to determine if the benefits of a drug outweigh its risks; and
- > What to do if FDA decides new safety information requires companies to make changes in the marketing of existing drugs.

The nuts-and-bolts book also includes instructive chapters on:

- > The environmental and historical context for risk management;
- > Proven strategies for designing and measuring REMS effectiveness;
- > Practical examples and case studies of successful risk management strategies; and
- > Crisis management considerations.

The book also contains invaluable appendices, including FDA's guidance for industry on pre-marketing risk assessment.

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“Knowing how to design, execute and evaluate a risk management and communications program can spell the difference between drug approval and approval delay,” says co-editor Wayne L. Pines, President, Regulatory Services and Healthcare, APCO Worldwide, and former Associate Commissioner at FDA. The other two editors of the book are Jeffrey E. Fetterman, president and CEO of ParagonRx, a healthcare consulting firm and Gary H. Slatko, M.D., the firm’s Chief Medical Officer.

For more information on the book, *Pharmaceutical Risk Management: Practical Applications*, visit [www.fdpi.org](http://www.fdpi.org) or call (202) 371-1420.

*Media:* To request a review copy, contact Michael Levin-Epstein, Editor-in-Chief, FDLI at (202) 222-0897 or [mdl@fdli.org](mailto:mdl@fdli.org)

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Founded in 1949, FDLI publishes the award-winning, peer-reviewed *Food and Drug Law Journal*; the bimonthly magazine *Update; FDA Directory*; and dozens of books and publications for attorneys, regulatory affairs practitioners, scientists, health care professionals, government employees and marketers in the food and drug field. For more information, visit [www.fdpi.org](http://www.fdpi.org)