

## PDUFA and the Expansion of FDA User Fees: Lessons from Negotiators

Edited by Nancy Bradish Myers and Anne Petruska McNickle

### Contributing Authors

Tim Franson

Keith Flanagan

Alan Goldhammer

Suzanne Junod

Nancy Bradish Myers

Stephen J. Northrup

Lawrence Susskind

Vince Ventimiglia

Janet Woodcock

Since passage of the first Prescription Drug User Fee Act almost 20 years ago, user fee negotiations and the legislative vehicles that authorize them have significantly changed the scope of FDA's responsibilities. After PDUFA paved the way to the acceptance of user fees, programs were created for other FDA-regulated industries, such as medical devices, animal drugs, generic animal drugs and tobacco. Several additional user fee programs are on the horizon, such as those for generic human drugs and biosimilars. Are you and your organization ready to engage in a smart, educated manner?

There are many issues that reach across user fee programs. This book addresses: What approaches have been taken by FDA and the regulated industries to the various user fee programs? What can the history of prescription drug and medical device user fee negotiations tell us about future negotiations? What strategies worked in the past? What are the lessons learned that can be applied across all stakeholders?

Chapters explore the history leading to the first user fee program (PDUFA), the biopharmaceutical industry perspective on negotiating user fees, a first-of-its-kind view of negotiations from the FDA lens, a clear explanation of Congress' role in enacting user fees, insight into how user fees expanded to medical devices, advice from professional negotiators on how to bring new tools to the negotiation table and overall lessons learned for all stakeholders.

This book serves as a guide to stakeholders preparing for any user fee negotiation, whether it's for a new program, or reauthorization of an existing one. The book draws on the institutional knowledge of many of the most experienced user fee negotiators, affording a unique 360-degree view of the evolving nature of such negotiations; it offers practical insights not only for those at the negotiating table, but for anyone involved in helping to shape, analyze, monitor or understand user fee programs.

### Authors Clients Receive a 10% discount

Use promo code: PDUFA11A

### Introductory Price Expires: 4/15/2011

\$99 Members | \$129 Non-Members | \$79 Government Rate

### Standard Price

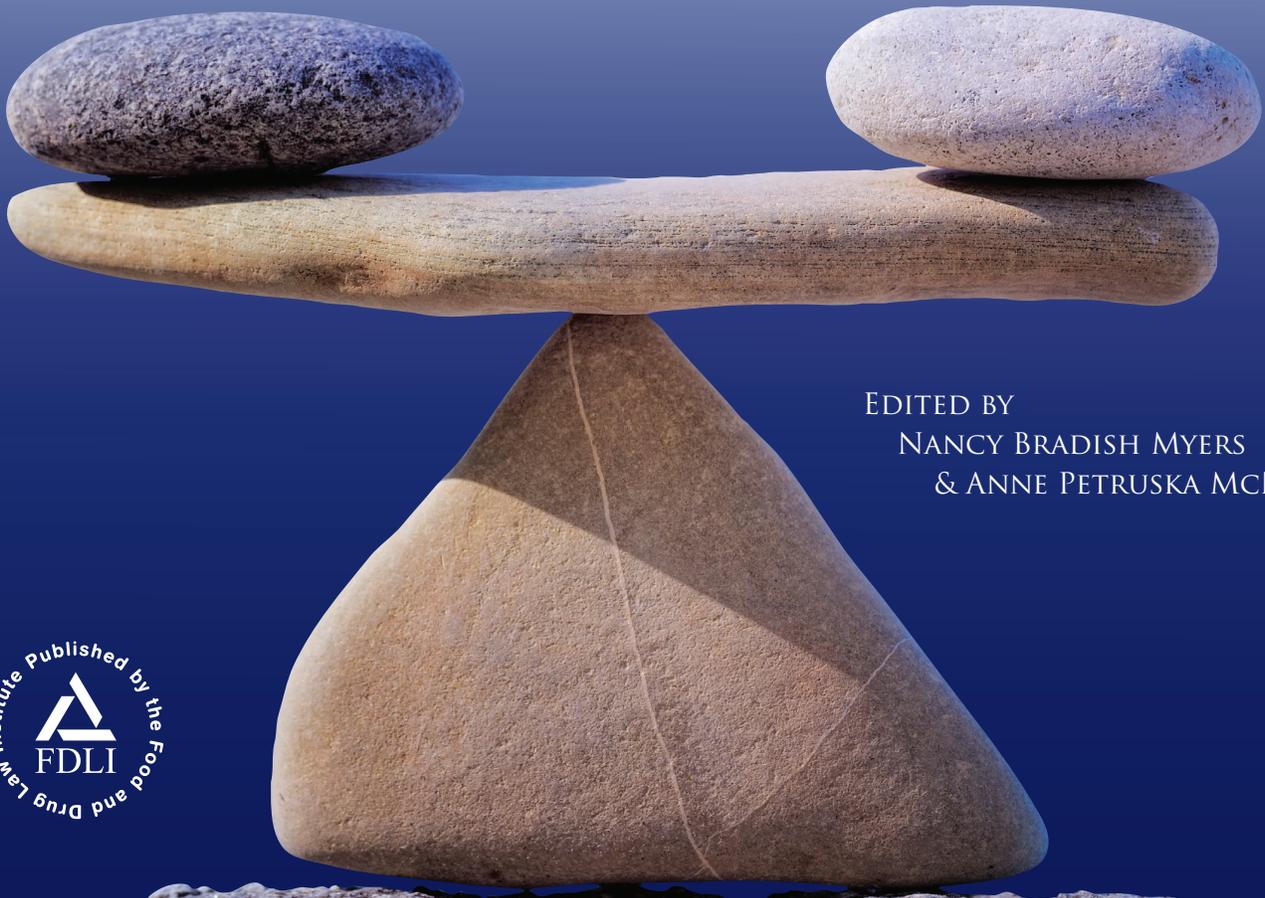
\$149 Members | \$179 Non-Members

*\*For academic pricing and bulk discounts, contact Customer Service, (202) 371-1420.*

[www.fdpi.org](http://www.fdpi.org)

# PDUFA & THE EXPANSION OF FDA USER FEES:

LESSONS FROM NEGOTIATORS



EDITED BY  
NANCY BRADISH MYERS  
& ANNE PETRUSKA MCNICKLE

