

# CONTENTS

<b>Frances M. Jagla</b> <i>Partner, Lane Powell PC</i> NAVIGATING TRADEMARK ISSUES IN THE PHARMACEUTICAL FIELD	7
<b>Barry J. Siegel, <i>Partner,</i> and William A. Garvin, <i>Counsel,</i> Buchanan Ingersoll &amp; Rooney PC</b> MAJOR EXISTING AND FUTURE CHALLENGES TO THE MANUFACTURING, PROMOTION, AND SALE OF DRUG AND DEVICE PRODUCTS	19
<b>Peter A. Arhangel'sky</b> <i>Principal, Emord &amp; Associates PC</i> KEY CONCERNS AND CHALLENGES FOR MEDICAL DEVICE INDUSTRY CLIENTS	35
<b>Seth A. Mailhot</b> <i>Partner, Michael Best &amp; Friedrich LLP</i> THE CHALLENGE OF SOFTWARE	65
<b>Amy S. Tingley</b> <i>Shareholder, Stovash Case &amp; Tingley PA</i> IMPACTS OF FEDERAL LEGISLATIVE CHANGES AND INVESTIGATORY TRENDS ON THE DRUG AND PHARMACEUTICAL INDUSTRY	79
<b>M. Gabrielle Hils</b> <i>Partner, Dinsmore &amp; Shohl LLP</i> DEFENDING AGAINST THE ONSLAUGHT OF STATE ATTORNEYS GENERAL ACTIONS AGAINST DRUG MANUFACTURERS: LESSONS LEARNED FROM RECENT CASES	95

**Jeffrey R. Lilly** 123  
*Partner, Gordon & Rees LLP*  
*FRAUD ON THE MARKET*

**James A. Robertson and Walter F. Timpone** 135  
*Partners, McElroy Deutsch Mulvaney*  
*& Carpenter LLP, and*  
**Matt Allegrucci, V**  
*ice President of Ethics & Compliance Officer,*  
**Daiichi Sankyo, Inc.**  
*COMPLIANCE ISSUES FOR PHARMACEUTICAL AND*  
*MEDICAL DEVICE MANUFACTURERS*