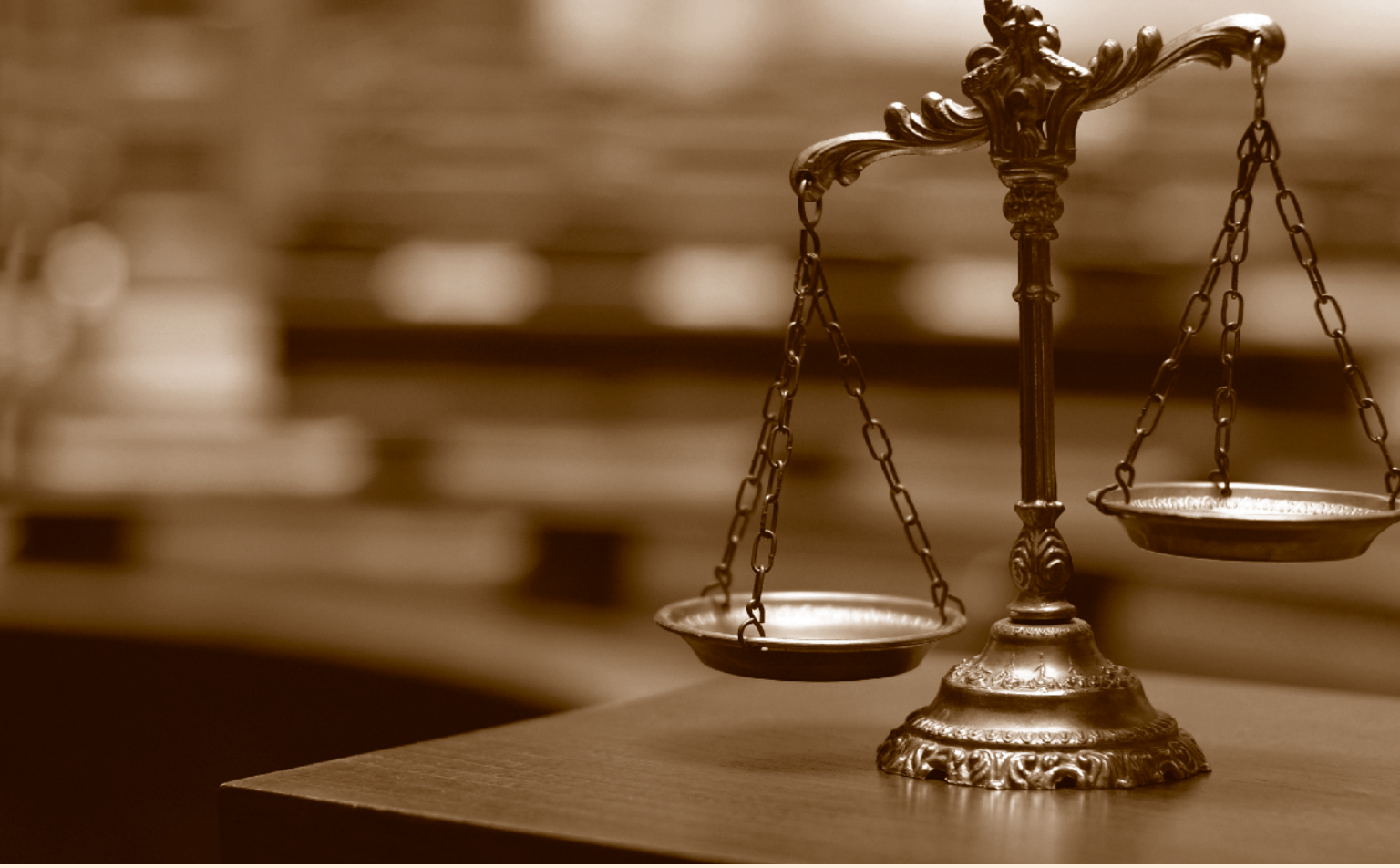

Pharmacy Practice and the Law

Eighth Edition

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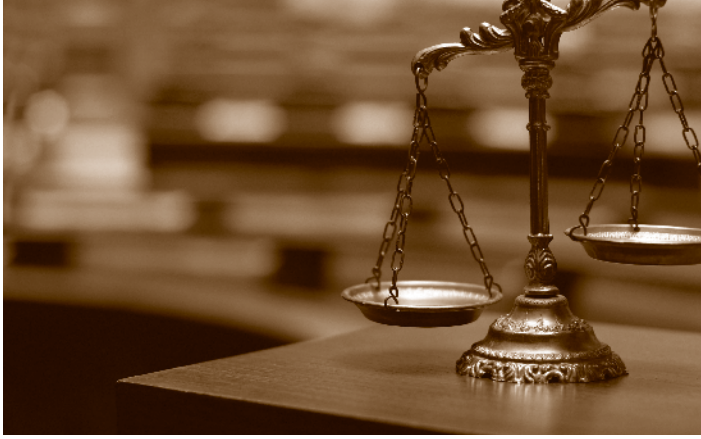
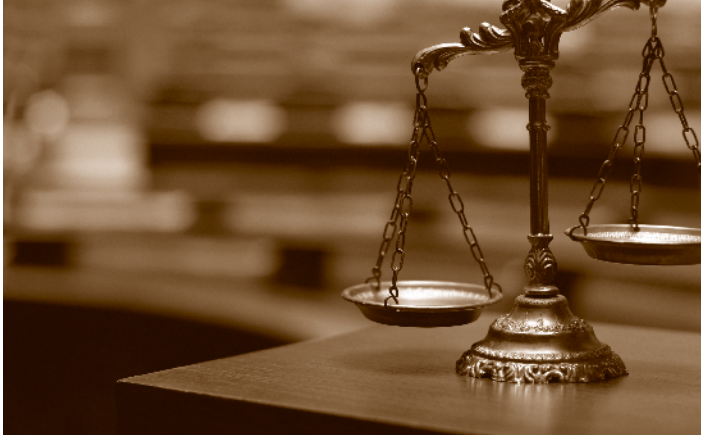


To Jeri, Aaron, and Meredith
RRA

To Pete, Cassidy, and Karalynn
KAB



BRIEF CONTENTS

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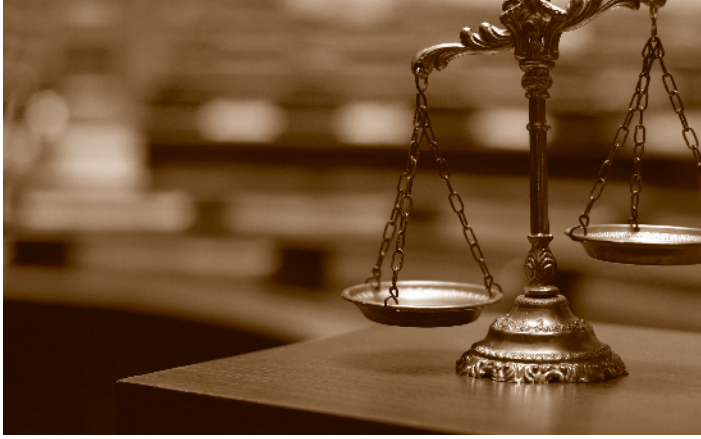

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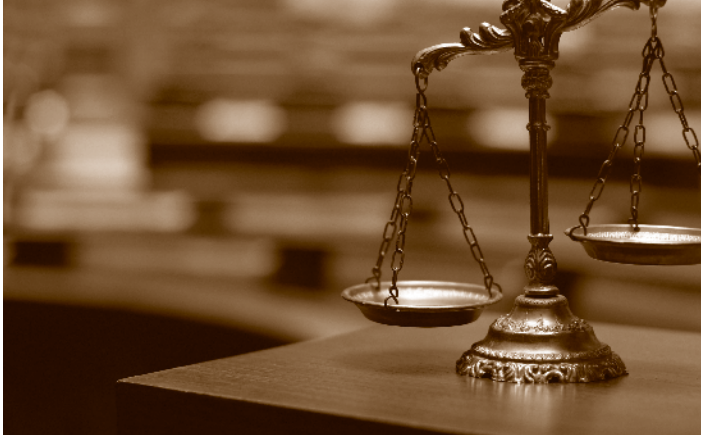


PREFACE

I am very pleased that Kim Burns agreed to be my coauthor for the eighth edition of *Pharmacy Practice and the Law*. In this edition, we have continued the effort of previous editions: to provide a resource that is useful for teaching the facts of pharmacy law, providing a degree of depth to support those facts, and stimulating critical thinking about issues in the field. The *Eighth Edition* retains the format of the *Seventh Edition* while incorporating several of the relevant changes that have recently occurred in pharmacy law. Please refer to "New to the *Eighth Edition*" for a more detailed description of the changes between the previous edition and this updated *Eighth Edition*.

Some of the changes and updates are the result of suggestions from faculty who use this book as an assigned text in their pharmacy law courses. We greatly appreciate the valuable feedback from those using this book, and we hope that we continue to receive this feedback. Our thanks to Professor Rajul Patel, PharmD, PhD, for reviewing and editing the Medicare Part D section in Chapter 6. Although we acknowledge with gratitude the input from many trusted colleagues, we accept full responsibility for any omissions or deficiencies anyone might find in this *Eighth Edition*.

This text generally appeals to faculty who believe that a pharmacy law course should be much more than preparation for the board examination. The book reflects our position that a pharmacy law course should not be just about memorizing laws and regulations and learning the "rules of the game." Rather, the course should prepare students to understand and critically analyze the law that governs both the profession and the products they distribute. Understanding requires that students know some history behind the laws, why they exist, how they affect pharmacy practice, and subsequently how to apply the law and how to analyze whether there is a better approach. Understanding pharmacy law is critical to understanding the profession. Pharmacy law reflects the history, social policy, and standards of practice that have created and shaped the profession into its current form. Our hope is that this book helps students to understand pharmacy law and, in the process, to develop an awareness and appreciation of the profession they otherwise might not have.

This book contains a great deal of information. Faculty should use their judgment as to how much they expect students to learn. Some might even wish to supplement this text with current articles or additional cases on the various legal topics. The text contains several cites to the *Federal Register*, *Code of Federal Regulations*, statutes, public laws, and websites for those wishing to delve deeper into the many topics presented.

Cases are included at the end of each chapter because they lead to challenging discussions, stimulate critical thinking, help students learn legal rules better and in greater depth, and kindle student interest. Each case starts with an overview designed to provide a brief explanation of the case and to generally cue the students as to what issues to think

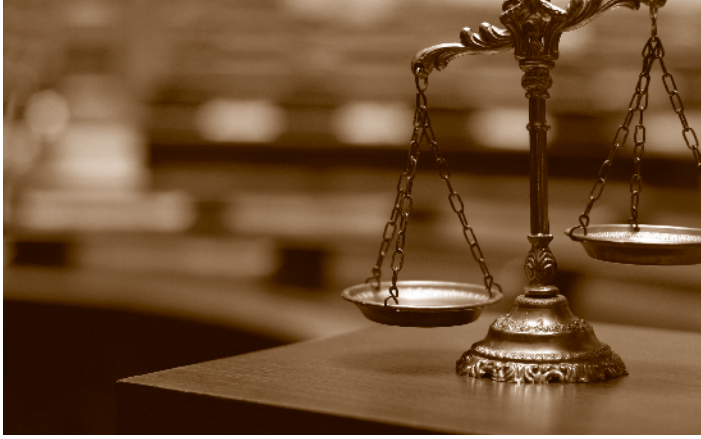
about as they read the case. As much as possible, the court's own language has been retained. By doing so, students learn that law is seldom "black and white" but rather requires a considerable measure of reasoning and analysis to reach a decision. Faculty should recognize that the questions raised in the overview are designed to stimulate discussion. A specific correct answer might not always exist; rather, there could be several answers to some of the questions. The notes following each case serve to address the questions arising from the case and to clarify certain points about the case.

The structure of all eight chapters remains essentially the same as that of the previous edition except, of course, for the updates. As in the *Seventh Edition*, this edition includes study scenarios and study questions after various chapter sections. The instructor can use these to lead class discussions. Additional study scenarios and study questions can be found in the Instructor Manual.

CHAPTER BREAKDOWN

- **Chapter 1** provides an overview of law and the legal system.
- **Chapters 2 and 3** cover the federal regulation of medications, with Chapter 2 describing the basic regulatory framework of food and drug law and Chapter 3 applying that framework to pharmacy practice.
- **Chapters 4 and 5** discuss relevant provisions of the federal Controlled Substances Act (CSA). Chapter 4 provides an overview of the framework of the CSA, while Chapter 5 applies that framework more specifically to pharmacy practice.
- The main focus of **Chapter 6** is the significant influence of the federal government on the state-regulated practice of pharmacy and on business and financial issues related to the profession. From the standards established in the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) to the Medicare and Medicaid laws and the federal antitrust laws, federal requirements for drugs have a profound effect on the professionals who dispense and monitor drugs. This chapter also discusses some very important recent developments involving privacy, electronic records, and pharmacy reimbursement.
- **Chapter 7** describes some of the basic principles of state regulation of pharmacy practice, including licensure and standards setting. Chapter 7 is intended to provide only a general overview of state law issues and contains a discussion of some important recent regulatory trends occurring among the states and discussions of the similarities and differences among state pharmacy practice acts.
- Finally, **Chapter 8** provides an overview of malpractice and product liability for order processing and pharmaceutical care activities, with specific tips on liability avoidance through risk management programs. Chapter 8 is important, not just to understand legal risk but also to understand the conflicting judicial opinions of the societal expectations of pharmacists, why those expectations exist, and whether they are changing. Courts mirror societal values and sometimes provide us with both flattering and unflattering perspectives of our profession.

Because the overall structure of the text remains the same, faculty who have used this text in the past should not have to make major adjustments in the way they use this new edition.



NEW TO THE *EIGHTH EDITION*

There have been several legal/regulatory developments that have occurred since the publication of the *Seventh Edition* in 2012. This *Eighth Edition* includes those developments most relevant to the pharmacy profession. An additional change from the *Seventh Edition* is the inclusion of "Take-Away Points" after each major section in each chapter. A brief chapter-by-chapter description of substantive changes includes:

Chapter 1

Chapter 1 remains largely unchanged. The section "Distinguishing Criminal, Civil and Administrative Law" was moved and placed under the "Sources of U.S. Law" section and a Rhode Island case, *Blais v. Rhode Island Department of Health,* is now mentioned.

Chapter 2

In the "Historical Overview" section, new statistics for the Orphan Drug Act of 1983 and a brief description of the Drug Quality and Security Act of 2013 are added. This law is extensively discussed later in Chapter 3.

Other changes in the chapter include new or updated discussions of the following topics:

- The Food and Drug Administration organizational structure
- Regulation of e-cigarettes
- Medical foods
- Nutraceuticals and functional foods
- Health claims for foods and dietary supplements
- The Dietary Supplement and Nonprescription Drug Consumer Protection Act
- Dietary supplement product investigation by the New York Attorney General's office
- Clarification of FDA authority over drug product recalls
- Adulteration examples in pharmacies
- Misbranding example in pharmacies regarding drug name on the label
- Unit dose labeling requirements for prescription drugs
- Proposed electronic distribution of package inserts
- Pregnancy warning requirements in labeling
- National Drug Code Number
- Prescription Drug User Fee Act's effect on NDA review time
- FDA's Drug Rating and Classification System
- FDA's adverse event reporting system database

- FDA's REMS program
- Postmarket drug safety information for patients and providers
- Exclusion payments by drug manufacturers (pay-for-delay agreements)
- Generic drug labeling controversies created by the courts
- Section 505(b)(2) NDAs
- Individual patient access to investigational drugs for serious diseases, including state "right to try" laws
- Expedited approval of drugs intended to treat serious or life-threatening illnesses
- Biologics and biosimilars
- Medical devices for general wellness, including computer software and mobile applications
- Unique device identifier requirement for devices
- Medical device expedited approval process
- Physician Payment Sunshine Act
- FDA regulation regarding the promotion of prescription drugs and devices through social media
- FDA regulatory authority over "off-label" use
- Replacement of *WLF v. Friedman* with *United States. v. Caronia* in the case studies section

Chapter 3

Chapter 3 changes from the previous edition include new or updated discussions of:

- Expiration or beyond-use dating, including USP and FDA guidelines
- Emergency contraception and Plan B
- Medication Guides
- Medication Guides and REMS
- The pharmacy compounding provisions under Section 503A
- The Drug Quality and Security Act of 2013, including FDA compliance and draft compliance guides
- USP compounding requirements
- Pedigrees, counterfeit drugs, and drug supply chain security
- The Drug Supply Chain Security Act of 2013
- Importation of prescription drugs for personal use
- FDA inspection authority of pharmacies

Chapter 4

Changes in Chapter 4 include new or updated discussions of the following items:

- State versus federal authority
- Medical and recreational use of marijuana
- Hydrocodone combination products rescheduled to a schedule II substance
- Tramadol as a schedule IV substance
- DEA reference available to identify controlled substances authority for mid-level practitioners by discipline and state
- Distributing versus dispensing (constructive delivery)
- Treatment of addicts outside of OTPs (DATA)
- The Combat Methamphetamine Epidemic Act of 2005 and the Methamphetamine Production Prevention Act of 2008
- Deletion of the *Seeley v. State of Washington* case in the "Case Studies" section

Chapter 5

Changes in Chapter 5 include new or updated discussions of the following items:

- DEA registration number of prescribers to include "G" as a beginning letter
- DEA electronic resource available to help verify active DEA registrations
- Recently released educational video ("Red Flags") for pharmacists to assist in properly exercising their corresponding responsibility
- Dispensing of schedule II controlled substances
- State multiple-copy and security prescription form programs
- Partial filling of schedule III, IV, or V prescriptions
- Return of controlled substances to pharmacy for disposal, including the newly created DEA definitions of "collection" and "collector"
- Long-Term Care (LTC) Pharmacy
- Inventory requirements
- Distribution from a pharmacy to another practitioner
- Disposal or destruction of controlled substances

Chapter 6

Changes in Chapter 6 include new or updated discussions of the following items:

- OBRA '90 flow chart
- Recent updates and modifications to HIPAA
- Expansion of HIPAA to directly apply to business associates
- Updates to the HIPAA notice of privacy provision
- Modifications to HIPAA regarding patients' requests to access and obtain copies of PHI
- Update on the status of the accounting for disclosure rules
- Modifications to breaches of PHI
- New changes to HIPAA regarding marketing, sale of PHI, and patient authorizations
- Expanded penalties and enforcements under HIPAA
- Medicare Part D beneficiary costs
- Medicare Part D covered drugs and plan formularies
- Medicare Part D pharmacy access and "any willing provider"
- Medicare Part D fraud and abuse
- Medicare and provider status for pharmacists
- Medicaid reimbursement for multiple-source drugs
- Medicaid estimated acquisition cost and average wholesale price
- Litigation over state Medicaid cuts
- Medicare/Medicaid fraud and abuse laws
  - The False Claims Act (FCA)
  - The Anti-Kickback Statute (AKS)
- Long term care facility short-cycle dispensing
- Robinson-Patman Act and the Brand-Name Prescription Drugs litigation
- 340B drugs

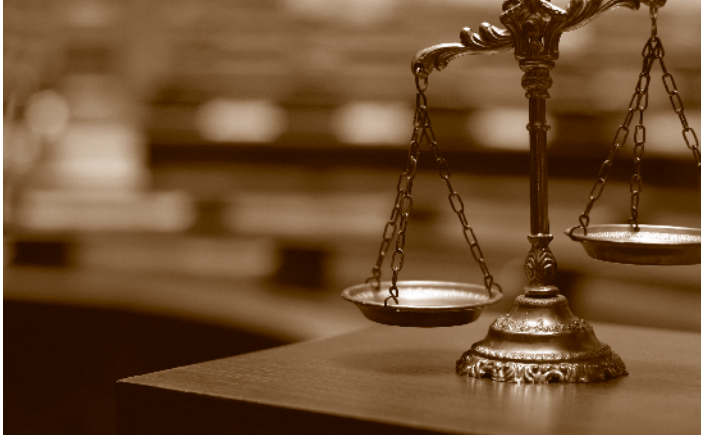
Chapter 7

Few changes were made to Chapter 7 in the *Eighth Edition*. The discussion of licensing of pharmacists was updated. The section discussing the definition of the practice of pharmacy now reflects the term drug therapy management. The section on ancillary pharmacy personnel was updated to reflect recent NABP changes and state trends

regarding pharmacy technicians. The section on continuous quality improvement was also updated to discuss the recent advances in accreditation of outpatient pharmacies.

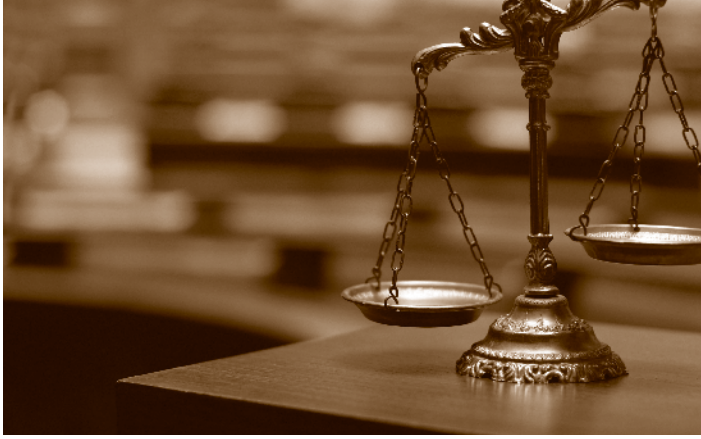
CHAPTER 8

Chapter 8 is essentially unchanged.



A SPECIAL ACKNOWLEDGMENT

I am indebted to David Brushwood, for his friendship and for being my coauthor for the first three editions of this book, and also to those who have used this text in their classrooms and provided valuable suggestions. RRA



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