

SIXTEENTH EDITION

# Handbook of Nonprescription Drugs

An Interactive Approach to Self-Care

Rosemary R. Berardi Stefanie P. Ferreri

Anne L. Hume

Lisa A. Kroon

Gail D. Newton

Nicholas G. Popovich

Tami L. Remington

Carol J. Rollins

Leslie A. Shimp

Karen J. Tietze

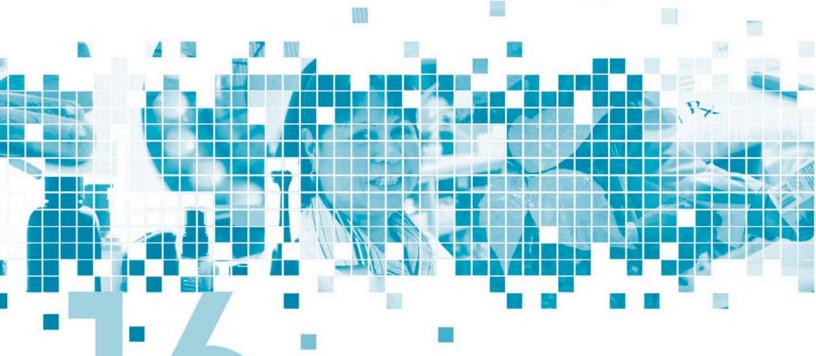


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Carol J. Rollins

Leslie A. Shimp

Karen J. Tietze



### MANAGING EDITOR

Linda L. Young

### **EDITORIAL SERVICES**

DataMasters Professional Editing Services, Eileen Kramer, Linda Young, Potomac Indexing, LLC

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Scott Neitzke, APhA Creative Services

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Aaron Hilmers, Gray Matter Studio, Walter Hilmers, Jr.

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# **Foreword**

The publication of the sixteenth edition of the American Pharmacists Association's Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care could not be more timely. The Consumer Healthcare Products Association indicates that "retail sales of nonprescription medications in the United States in 2007 exceeded \$16.1 billion (excluding sales at Wal-Mart), reflecting an increase from \$3.1 billion in 1972 (http:// www.chpa-info.org/OTC\_Retail\_Sales\_1964\_2007\_.aspx?pid =77&cc=6; last accessed November 20, 2008). Other similar surveys confirm the increased use of nonprescription medications. Sales may also be boosted by the Internal Revenue Service Ruling 2003-102, which went into effect October 1, 2003. This ruling allows employers to reimburse properly substantiated nonprescription medication expenses, but not dietary supplements, from flexible health care spending accounts. (http://www.irs.gov/pub/irs-drop/rr-03-102.pdf; last accessed November 20, 2008). The anticipated increase in the number of prescription medications that will be reclassified as nonprescription will further confound the patient's dilemma in selecting appropriate self-treatment.

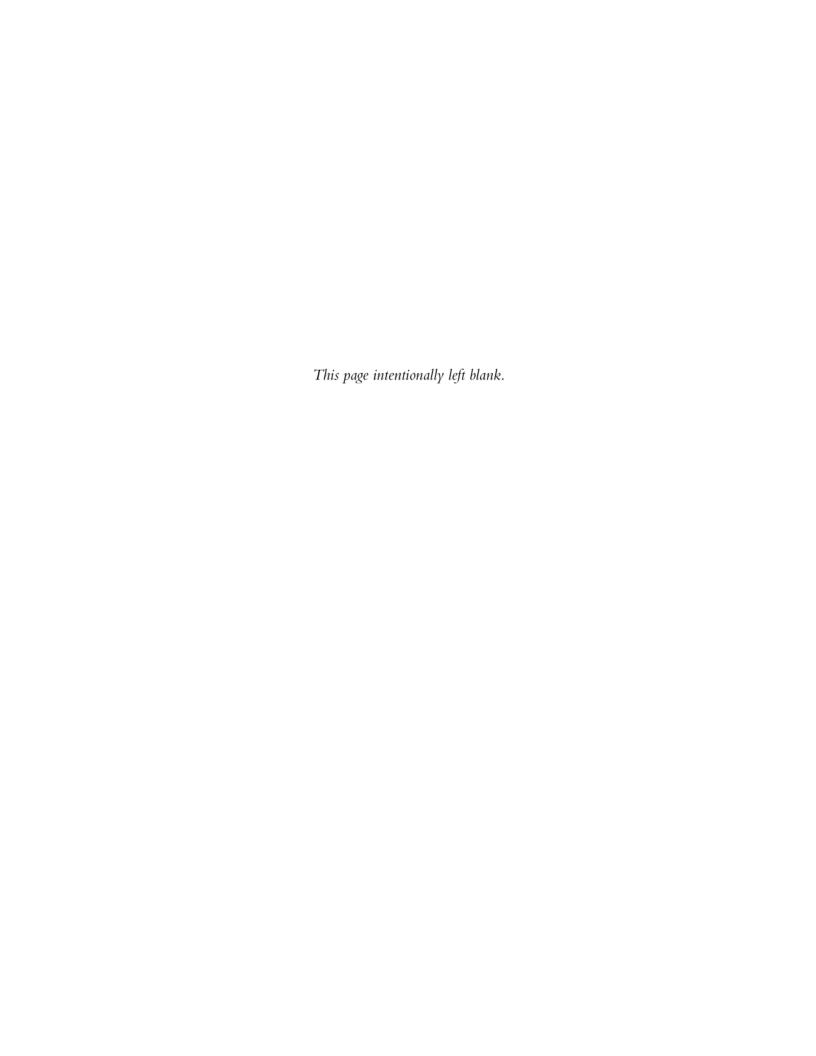
The use of complementary and alternative therapies, dietary supplements, nondrug measures, diagnostic tests, and medical devices is also an integral part of self-care. The paucity of clinical evidence as to their safety and effectiveness and the potential for serious adverse events when these products are combined with nonprescription or prescription medications demand that health care practitioners be knowledgeable about alternatives to traditional medications and be able to provide therapeutic information and guidance to the consumer. Unlike nonprescription medications, no federal regulatory agency evaluates the safety and effectiveness of complementary and alternative therapies.

Numerous other factors have contributed to the growing self-care movement in the United States, including an increase in direct-to-consumer advertising of prescription and nonprescription medications. Information obtained from television commercials, newspaper and magazine advertisements, the Internet, and health-related articles serves to empower the consumer to make decisions about their own health care. However, individuals who wish to self-treat minor health disorders are faced with a staggering number of single-entity and combination nonprescription products and may not have adequate information to determine if their medical condition is amenable to self-treatment and if the self-selected treatment is appropriate for the condition.

All health care practitioners should be able to assist individuals in the management of their own self-care. However, pharmacists, because of their accessibility and expertise with respect to nonprescription and prescription medications, are in a unique position to fulfill the self-care needs of most individuals with minor health ailments. Thus, designing a self-care curriculum for pharmacy students with learning outcomes that ensure appropriate knowledge and skills is now more important than ever. The importance of this objective is reflected in the most recent Accreditation Council for Pharmacy Education's Accreditation Guidelines (http://www.acpe-accredit.org/ deans/standards.asp; last accessed November 20, 2008) and the Competency Statements of the North American Pharmacist Licensure Examination (NAPLEX) taken by all United States pharmacy graduates prior to licensure (http://www.nabp.net/ ftpfiles/NABP01/updatednaplexblueprint.pdf; last accessed November 20, 2008).

The sixteenth edition of the American Pharmacists Association's Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care is an excellent and up-to-date resource for all health care educators, students, and practitioners engaged in self-care.

JOHN A. GANS, PHARMD Executive Vice President & CEO American Pharmacists Association



# **Preface**

The newly revised and updated sixteenth edition of the *Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care* is a comprehensive and authoritative textbook on self-care and nonprescription medications. The goal for this edition was to produce an up-to-date reference that is not only helpful to all health care professionals and students—but is also user-friendly. This edition remains true to the sprit of previous editions, namely to assist practitioners and students in developing knowledge and problem-solving skills needed to:

- Assess a patient's health status, medical problems, and current practice of self-treatment including nonprescription and prescription mediations, dietary supplements, and other self-care measures.
- Determine whether self-care and/or self-testing and monitoring are appropriate
- If appropriate, recommend safe and effective self-care measures, taking into account the patient's treatment preferences.

Written and reviewed by experts, this edition of the *Hand-book* continues to serve as an authoritative source for students and practitioners who guide and care for individuals undertaking self-treatment.

# Highlights of New Features and Revisions

Considerable time and effort have been invested in improving this edition. We are hopeful that the following changes continue to improve the quality and usability of the book, and to provide increased clarity and convenience for students and practitioners.

Complementary and Alternative Medicine (CAM) Chapters: The CAM section consists of three chapters that have been significantly revised and reorganized. A new introductory chapter provides a foundation for understanding current issues with regard to natural products. This chapter also addresses quackery and provides tips to educate consumers on how to spot fraudulent claims. The botanical and nonbotanical CAM chapters in the previous edition have been combined into a single chapter and organized according to an organ system approach. In previous editions, the third CAM chapter focused solely on homeopathy. Although the home-

- opathy chapter possessed valuable information, it has been revised to address key points related to six different types of CAM health systems/healing practices, including naturopathy and massage. The intent of these changes was to provide the reader with a broad overview of the different health systems/healing practices that a consumer may be using.
- Standardization of CAM Discussions in Disease-Specific Chapters: In addition to revising the CAM section, the discussions of natural products in the individual disease-specific chapters have been carefully evaluated and standardized to ensure greater consistency in the assessment of the evidence supporting or refuting the use of natural products.
- Prevention of Pregnancy and Sexually Transmitted Infections Chapter: This chapter has been updated to include new and expanded information on the emergency contraceptive Plan B that is now available as a nonprescription product for women 18 years of age and older.
- Primary Drug/Therapy Chapters: Selected chapters have been designated as the primary chapter to discuss the basic information about a drug or other therapy (such as fiber, nutrition, dietary supplements) when these agents are used to treat multiple disorders. Other chapters that discuss the use of these drugs or therapies will focus on information relevant to the specific disorder and will cross-reference the primary chapter for basic information.
- Case Assessment Model: New cases were developed for each disease-related chapter.

### **Chapter Content**

All disease-oriented chapters in this edition include the following features and information:

- Up-to-date information on nonprescription medications including indications, dosages, interactions, supportive evidence for efficacy and safety, medical conditions or symptoms amenable to self-treatment, prescription-to-nonprescription reclassifications, and nonprescription drug withdrawals from the market.
- Treatment algorithms that outline triage and treatment.
- Controversies in self-care therapeutics.
- Self-care treatment or prevention guidelines.
- Product tables with examples of specific nonprescription products.

New nonprescription medications and dietary supplements. Nutrition-related dietary supplements, such as vitamins and minerals, continue to be discussed in the nutrition section of the book.

### **Chapter Features**

Most chapter features remain unchanged and are intended to promote an interactive approach to self-care. Students and practitioners can use these features to develop or improve problemsolving and critical thinking skills.

- Disease-oriented chapters are grouped primarily according to body systems. These chapters begin with a discussion of the epidemiologic, etiologic, and pathophysiologic characteristics and the clinical manifestations of the disorder. These discussions are followed by a comprehensive discussion of self-care options. The inclusion of dietary supplements, as well as nonpharmacologic and preventive measures, completes the discussion of self-care options.
- Case studies, treatment algorithms, comparisons of selftreatments, patient education boxes, and product selection guidelines foster an interactive therapeutic approach to learning.
- Sections on the evaluation of patient outcomes reinforce follow-up of patients who are self-treating. This section defines the parameters for confirming successful self-treatment and those that indicate the need for medical referral.
- Chapters include tables that list interactions (drug-drug, drug-supplement, drug-nutrient), as well as dosage and administration guidelines.
- Authors provide comparisons of agents based on clinical studies of safety and efficacy, as well as product selection guidelines based on patient factors and preferences.
- Authors discuss the role of nonprescription therapies among the available treatment options for a specific disorder and describe other options in the event that nonprescription therapy fails or is not appropriate.
- The book's organization and content allow students and practitioners to quickly identify the information needed

to make a treatment recommendation and to counsel patients.

### Acknowledgments

We would like to acknowledge the many individuals who contributed to the new edition of this textbook. We are grateful to the 77 authors and coauthors and 131 reviewers who contributed to this comprehensive and authoritative textbook. These individuals were selected from many practice settings and health professions throughout the country. Their scholarship and clinical experience reflect a broad perspective and interdisciplinary approach to patient care. The dedication of the authors and reviewers in ensuring that chapters were accurate, comprehensive, balanced, and relevant to practice and of the highest quality is deeply appreciated.

The editors acknowledge the work of Celtina K. Reinert, PharmD, in standardizing the discussion of natural products in the disease chapters in this edition. At that time, she was a Natural Product Information and Research Fellow, University of Missouri-Kansas City School of Pharmacy Drug Information Center

The authors of Chapter 55 also respectfully acknowledge the work of members of the Natural Standard Research Collaboration for their support in the development of the chapter, especially the efforts of Dr. Wendy Chao, Dawn Costa, Wendy Weissner, and Jen Woods.

We would like to convey a special thanks to Linda Young, our managing editor. Ms. Young provided invaluable guidance and support to the editors and authors in all aspects related to the publication of this edition of the textbook. She contributed to the copyediting of chapters, and managed the design, editorial, and composition stages of the book. Without her experience and attention to detail, the improvements in this edition would not have been possible.

We are confident that the combined efforts of these individuals will ensure that the *Handbook of Nonprescription Drugs:* An Interactive Approach to Self-Care continues to serve as the worldwide practice and teaching resource on self-care and non-prescription products.

ROSEMARY R. BERARDI STEFANIE P. FERRERI ANNE L. HUME LISA A. KROON GAIL D. NEWTON NICHOLAS G. POPOVICH TAMI REMINGTON CAROL J. ROLLINS LESLIE A. SHIMP KAREN J. TIETZE

# **Editors**

### Editor in Chief and Section Editor

### Rosemary R. Berardi, PharmD, FCCP, FASHP

Professor of Pharmacy, Department of Clinical Sciences, The University of Michigan College of Pharmacy, Ann Arbor

### Section Editors

### Stefanie P. Ferreri, PharmD, CDE

Clinical Assistant Professor and Director, Community Pharmacy Residency Program, University of North Carolina Eshelman School of Pharmacy, Chapel Hill

### Anne Lamont Hume, PharmD, FCCP, BCPS

Professor of Pharmacy, Department of Pharmacy Practice, University of Rhode Island College of Pharmacy, Kingston; Adjunct Professor of Family Medicine, Brown University/Memorial Hospital of Rhode Island, Providence

### Lisa A. Kroon, PharmD, CDE

Associate Professor of Clinical Pharmacy, Department of Clinical Pharmacy, University of California at San Francisco School of Pharmacy

### Gail D. Newton, PhD, RPh

Associate Professor, Department of Pharmacy Practice, Purdue University School of Pharmacy and Pharmaceutical Sciences, West Lafayette, Indiana

### Nicholas G. Popovich, PhD

Professor and Head, Department of Pharmacy Administration, University of Illinois at Chicago College of Pharmacy

### Tami L. Remington, PharmD

Clinical Pharmacist, Department of Pharmacy, The University of Michigan Hospitals and Health System; Clinical Associate Professor, Department of Clinical Sciences, The University of Michigan College of Pharmacy, Ann Arbor

### Carol J. Rollins, MS, RD, PharmD, BCNSP

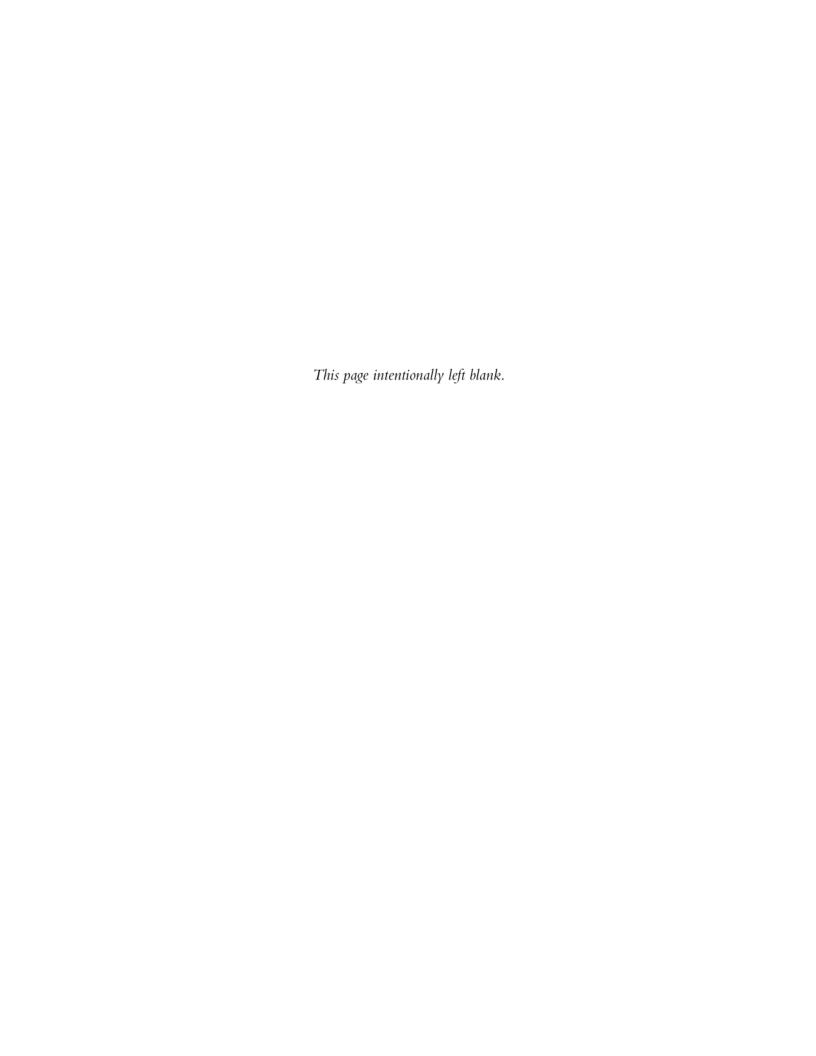
Coordinator, Nutrition Support Pharmacy, University Medical Center, Tucson; Associate Clinical Professor, Department of Pharmacy Practice and Science, University of Arizona College of Pharmacy, Tucson

### Leslie A. Shimp, PharmD, MS

Professor of Pharmacy, The University of Michigan College of Pharmacy, Ann Arbor

### Karen J. Tietze, PharmD

Professor of Clinical Pharmacy, Department of Pharmacy Practice and Pharmacy Administration, Philadelphia College of Pharmacy, University of the Sciences in Philadelphia, Philadelphia, Pennsylvania



# Contributors

### Authors

Note: Numbers in parentheses denote the chapter(s) authored or co-authored.

### Mitra Assemi, PharmD (47)

Director, UCSF Fresno Pharmacy Education Program, Fresno, California; Associate Professor of Clinical Pharmacy, Department of Clinical Pharmacy, University of California at San Francisco School of Pharmacy

### Cathy L. Bartels, PharmD, FAAIM (27)

Associate Professor, Department of Pharmacy Practice, Creighton University School of Pharmacy and Health Professions, Omaha, Nebraska

# Rosemary R. Berardi, PharmD, FCCP, FASHP (14, 18)

Professor of Pharmacy, Department of Clinical Sciences, The University of Michigan College of Pharmacy, Ann Arbor

### Daphne B. Bernard, PharmD, CACP (42)

Associate Professor, Department of Pharmacy Practice, Howard University College of Pharmacy, Nursing, and Allied Health Sciences, Washington, DC

### Ilisa B. G. Bernstein, PharmD, JD (4)

Senior Advisor for Regulatory Policy, Office of Policy, Food and Drug Administration, Rockville, Maryland

# Suzanne G. Bollmeier, PharmD, BCPS, AE-C (13)

Associate Professor of Pharmacy Practice, St. Louis College of Pharmacy, St. Louis, Missouri

### Geneva Clark Briggs, PharmD, BCPS (51)

Clinical Associate, MedOutcomes, Inc., Richmond, Virginia

### Lawrence M. Brown, PharmD, PhD (2)

Assistant Professor, Department of Pharmaceutical Sciences, College of Pharmacy; Assistant Professor, Department of Preventive Medicine, College of Medicine, University of Tennessee Health Sciences Center, Memphis

### Wayne Buff, PharmD (37)

Associate Dean and Clinical Associate Professor, Department of Pharmacy Practice and Outcomes Sciences, South Carolina College of Pharmacy, University of South Carolina Campus, Columbia

### Demetris M. Butler, PharmD (16)

Director of Clinical Pharmacy Programs, Clinical Pharmacy Associates, Inc., Laurel, Maryland

### Juliana Chan, PharmD (18)

Clinical Assistant Professor, Department of Pharmacy Practice, College of Pharmacy; Department of Medicine, Sections of Digestive Diseases & Nutrition and Section of Hepatology, University of Illinois at Chicago

# Katherine H. Chessman, PharmD, FCCP, BCNSP, BCPS (26)

Associate Professor, Department of Pharmacy Practice and Clinical Sciences, Clinical Pharmacy Specialist, Pediatrics/Pediatric Surgery, and Residency Program Director, Pediatric Pharmacy Practice, South Carolina College of Pharmacy, Medical University of South Carolina Campus, Charleston

### Cynthia W. Coffey, PharmD (45)

Clinical Pharmacist, Pride Medical Pharmacy, Atlanta, Georgia

### Robin L. Corelli, PharmD (50)

Professor of Clinical Pharmacy, Department of of Clinical Pharmacy, University of California at San Francisco School of Pharmacy

# Kimberly M. Crosby, PharmD, BCPS (39, 40)

Clinical Assistant Professor, Department of Clinical and Administrative Sciences, The University of Oklahoma College of Pharmacy–Tulsa; Clinical Pharmacist, USA Drug, Tulsa

### Barbara Insley Crouch, PharmD, MSPH (21)

Director, Utah Poison Control Center and Professor (Clinical) and Vice Chair, Department of Pharmacotherapy, University of Utah College of Pharmacy, Salt Lake City

### Clarence E. Curry, Jr., PharmD (16)

Associate Professor of Pharmacy Practice, Department of Clinical and Administrative Pharmacy Sciences, Howard University College of Pharmacy, Nursing and Allied Health Sciences, Washington, DC

### Patricia L. Darbishire, PharmD (35)

Clinical Assistant Professor, Department of Pharmacy Practice, Purdue University School of Pharmacy and Pharmaceutical Sciences, West Lafayette, Indiana

### Lawrence W. Davidow, PhD (1)

Director, Pharmacy Skills Laboratory, Clinical Assistant Professor, Department of Pharmacy Practice, and Director, Integrated Laboratory, Kansas University School of Pharmacy, Lawrence

### Cathi Dennehy, PharmD (53)

Department of Clinical Pharmacy, University of California at San Francisco School of Pharmacy

### Janet P. Engle, PharmD, RPh, FAPhA (29)

Associate Dean for Academic Affairs and Clinical Professor of Pharmacy Practice, University of Illinois at Chicago College of Pharmacy

### Brett Feret, PharmD (6)

Clinical Associate Professor, University of Rhode Island College of Pharmacy, Kingston

### Richard G. Fiscella, RPh, MPH (28)

Clinical Professor, Department of Pharmacy Practice, College of Pharmacy; Adjunctive Assistant Professor, Department of Ophthalmology, University of Illinois at Chicago

### Karla T. Foster, PharmD (38, 45)

Clinical Assistant Professor, Department of Clinical and Administrative Sciences, Mercer University Southern School of Pharmacy, Atlanta, Georgia

### Cliff Fuhrman, PhD (37)

Clinical Associate Professor, Department of Pharmaceutics and Biomedical Sciences, South Carolina College of Pharmacy, University of South Carolina Campus, Columbia

### Jeffery A. Goad, PharmD, MPH (19)

Associate Professor of Clinical Pharmacy, Coordinator, Community Pharmacy Program, and Director, Community Pharmacy Practice Residence, University of Southern California School of Pharmacy; Travel Health Consultant, University of Southern California Pharmacy, Student Health and Family Medicine, Los Angeles

### Nicholas E. Hagemeier, PharmD, MS (36)

Pharmacist, Cowan Drugs, Inc., Lebanon, Indiana

### Jennifer L. Hardman, PharmD (10)

Clinical Pharmacist and Clinical Assistant Professor, Department of Pharmacy Practice, University of Illinois at Chicago College of Pharmacy (1999-2007)

### Michael D. Hogue, PharmD (46)

Assistant Professor, Department of Pharmacy Practice, Samford University McWhorter School of Pharmacy, Birmingham, Alabama

### Yvonne Huckleberry, RD, PharmD (23)

Clinical Staff Pharmacist, Department of Pharmacy, University Medical Center, Tucson; Clinical Assistant Professor, College of Pharmacy, University of Arizona, Tucson

### Karen Suchanek Hudmon, DrPH, MS, RPh (50)

Associate Professor, Department of Pharmacy Practice, Purdue University School of Pharmacy and Pharmaceutical Sciences, Indianapolis, Indiana

### Holly Hurley, PharmD (51)

Assistant Professor of Pharmacy Practice, University of Appalachia College of Pharmacy, Grundy, Virginia

### Brian J. Isetts, PhD, BCPS, FAPhA (2)

Associate Professor, Peters Institute of Pharmaceutical Care, Department of Pharmaceutical Care and Health Systems, University of Minnesota College of Pharmacy, Minneapolis

### Michael Kirk Jensen, RPh, MS (28)

Clinical Associate Professor of Pharmacy Practice, University of Utah College of Pharmacy; Clinical Ophthalmic Pharmacy Specialist, John A. Moran Eye Center, Salt Lake City, Utah

### Cynthia K. Kirkwood, PharmD, BCPP (48)

Vice Chair for Education and Associate Professor of Pharmacy, Virginia Commonwealth University, Richmond

### Wendy Klein-Schwartz, PharmD, MPH (21)

Coordinator of Research and Education, Maryland Poison Center and Associate Professor. Department of Pharmacy Practice and Science, University of Maryland School of Pharmacy, Baltimore

### Lisa A. Kroon, PharmD, CDE (50)

Associate Professor of Clinical Pharmacy, Department of Clinical Pharmacy, University of California at San Francisco School of Pharmacy

### Linda Krypel, PharmD, FAPhA (30)

Professor of Pharmacy Practice, Department of Pharmacy Practice, Drake University College of Pharmacy and Health Sciences, Des Moines,

### Nicole M. Lodise, PharmD (8)

Assistant Professor of Pharmacy Practice-Women's Health/Tobacco Cessation, Union University Albany College of Pharmacy; Clinical Pharmacy Specialist, Albany Medical Center, Albany, New York

### Joycelyn Mallari, PharmD (19)

Assistant Professor, Department of Pharmacotherapy and Outcome Sciences, Loma Linda University School of Pharmacy, Loma Linda, California

### Macary Weck Marciniak, PharmD, BCPS (32)

Clinical Associate Professor, University of North Carolina Eshelman School of Pharmacy, Chapel Hill

### Cydney E. McQueen, PharmD (54)

Assistant Director, Natural Product Information and Assistant Clinical Professor, Pharmacy Practice, University of Missouri-Kansas City Drug Information Center

### Patrick D. Meek, PharmD, MS (15)

Assistant Professor, Department of Pharmacy Practice, Union University Albany College of Pharmacy, Albany, New York

### Sarah T. Melton, PharmD, BCPP, CGP (48)

Associate Professor of Pharmacy Practice, University of Appalachia College of Pharmacy, Oakwood, Virginia

### Sarah J. Miller, PharmD (27)

Professor of Clinical Pharmacy, Department of Pharmacy Practice, University of Montana Skaggs School of Pharmacy, Missoula

### Candis M. Morello, PharmD, CDE (47)

Assistant Professor of Clinical Pharmacy, Skaggs School of Pharmacy and Pharmaceutical Sciences, University of California San Diego; Clinical Pharmacist, Veterans Affairs San Diego Healthcare System, La Jolla, California

### Mark Newnham, PharmD, BCPS, BCNSP (25)

Clinical Affiliate Assistant Professor, College of Pharmacy, NOVA Southeastern University, Fort Lauderdale, Florida; Clinical Coordinator, Lawnwood Regional Medical Center, Fort Pierce, Florida

### Gail D. Newton, PhD, RPh (43, 44)

Associate Professor, Department of Pharmacy Practice, Purdue University School of Pharmacy and Pharmaceutical Sciences, West Lafayette, Indiana

### Gloria J. Nichols-English, BSP, MED, PhD (3)

Associate Professor and Senior Fellow, Center for Minority Health Services Research, Department of Clinical and Administrative Pharmacy Sciences, Howard University College of Pharmacy, Nursing, and Allied Health Sciences, Washington, DC

### Lynda Oderda, PharmD (20)

Clinical Assistant Professor, Department of Pharmacy Practice, University of Utah College of Pharmacy, Salt Lake City

### Christine K. O'Neil, PharmD, BCPS, FCCP, CGP (52)

Professor of Clinical Pharmacy, Department of Pharmacy Practice, Duquesne University Mylan School of Pharmacy, Pittsburgh, Pennsylvania

### Katherine Kelly Orr, PharmD (54)

Clinical Assistant Professor, University of Rhode Island College of Pharmacy, Kingston

### Louise Parent-Stevens, PharmD, BCPS (10)

Clinical Assistant Professor, Department of Pharmacy Practice and Clinical Pharmacist, Family Medicine Center; University of Illinois at Chicago College of Pharmacy

### Kimberly S. Plake, PhD (35)

Assistant Professor, Department of Pharmacy Practice, Purdue University School of Pharmacy and Pharmaceutical Sciences, West Lafayette, Indiana

### Nicholas G. Popovich, PhD (43, 44)

Professor and Head, Department of Pharmacy Administration, University of Illinois at Chicago College of Pharmacy, University of Illinois at Chicago

### Valerie T. Prince, PharmD, FAPhA, BCPS (41)

Assistant Professor of Pharmacy Practice, Samford University McWhorter School of Pharmacy; Family Practice Pharmacist, Medical Center East Family Practice Residency Program, Birmingham, Alabama

### Theresa R. Prosser, PharmD, FCCP, BCPS, AE-C (13)

Professor of Pharmacy Practice, St. Louis College of Pharmacy, St. Louis, Missouri

### Kristi Quairoli, PharmD (38)

Primary Care Clinical Pharmacist, Grady Health System, Atlanta, Georgia; At the time of writing: Clinical Assistant Professor and Director, Community Practice Residency, Department of Pharmacy Practice, Mercer University College of Pharmacy and Health Sciences, Atlanta, Georgia

### Tami L. Remington, PharmD (5)

Clinical Pharmacist, Department of Pharmacy, The University of Michigan Hospitals and Health System; Clinical Associate Professor, Department of Clinical Sciences, The University of Michigan College of Pharmacy, Ann Arbor

### Edward D. Rickert, JD, RPh (4)

Partner, Smith, Rickert, and Smith, Downers Grove, Illinois; Instructor, Adjunct Professor, Pharmacy Law, Department of Pharmacy Administration, University of Illinois at Chicago College of Pharmacy

# Magaly Rodriguez de Bittner, PharmD, BCPS, CDE (3)

Chair and Professor, Department of Pharmacy Practice and Science, University of Maryland School of Pharmacy, Baltimore

# Carol J. Rollins, MS, RD, PharmD, BCNSP (23, 24)

Coordinator, Nutrition Support Pharmacy, University Medical Center, Tucson; Associate Clinical Professor, Department of Pharmacy Practice and Science, University of Arizona College of Pharmacy, Tucson

### Erica Rusie-Seamon, PharmD (55)

Clinical Research Associate, Natural Standard, Washington, DC

### Kelly L. Scolaro, PharmD (11)

Clinical Assistant Professor and Director of Pharmaceutical Care Laboratory, Division of Pharmacy Practice and Experiential Education, The University of North Carolina Eshelman School of Pharmacy, Chapel Hill

### Steven A. Scott, PharmD (33, 34)

Associate Professor of Clinical Pharmacy and Associate Head, Department of Pharmacy Practice, Purdue University School of Pharmacy and Pharmaceutical Sciences, West Lafayette, Indiana

### Joan Lerner Selekof, BSN, RN, CWOCN (22)

Certified Wound Ostomy Continence Nurse, University of Maryland Medical Center, Baltimore

# Laura Shane-McWhorter, PharmD, BCPS, FASCP, CDE, BC-ADM (20)

Professor (Clinical), Department of Pharmacotherapy, University of Utah College of Pharmacy, Salt Lake City

### Leslie A. Shimp, PharmD, MS (8, 9)

Professor of Pharmacy, The University of Michigan College of Pharmacy, Ann Arbor

### Karen J. Tietze, PharmD (12)

Professor of Clinical Pharmacy, Department of Pharmacy Practice and Pharmacy Administration, Philadelphia College of Pharmacy, University of the Sciences in Philadelphia, Philadelphia, Pennsylvania

### Candy Tsourounis, PharmD (53)

Associate Professor of Clinical Pharmacy, Department of of Clinical Pharmacy, University of California at San Francisco School of Pharmacy

### Catherine Ulbricht, PharmD, MBA [c] (55)

Founder, Natural Standard, Editor-in-Chief, Journal of Herbal Pharmacotherapy, and Senior Attending Pharmacist, Massachussetts General Hospital, Cambridge

### Paul C. Walker, PharmD (17)

Clinical Associate Professor, College of Pharmacy, Department of Clinical Sciences, The University of Michigan College of Pharmacy; Manager of Clinical Services, Department of Pharmacy, The University of Michigan Health System, Ann Arbor

### Amy L. Whitaker, PharmD (31)

Assistant Professor, Department of Pharmacy, Virginia Commonwealth University School of Pharmacy, Richmond

### Sharon Wilson, PharmD (22)

Clinical Specialist-Surgery/Transplantation, University of Maryland Medical Center; Clinical Assistant Professor, Department of Pharmacy Services, University of Maryland School of Pharmacy, Baltimore

### Michael Z. Wincor, PharmD, BCPP (49)

Director of External Programs and Associate Professor of Clinical Pharmacy, Psychiatry, and the Behavioral Sciences, Schools of Pharmacy and Medicine, University of Southern California, Los Angeles

### Eric Wright, PharmD, BCPS (7)

Associate Professor, Department of Pharmacy Practice, Wilkes University Nesbitt School of Pharmacy, Wilkes-Barre, Pennsylvania

### Ann Zweber, B. Pharm (14)

Senior Instructor, Department of Pharmacy Practice, Oregon State University College of Pharmacy, Corvallis

### Reviewers

Note: Numbers in parentheses denote the chapter(s) reviewed.

### Stephen R. Abel, PharmD (28, 29)

Assistant Dean for Clinical Programs, and Bucke Professor and Head, Department of Pharmacy Practice, Purdue University School of Pharmacy and Pharmaceutical Sciences, Indianapolis, Indiana

### Renee Ahrens, PharmD, MBA (12, 18)

Associate Professor, Shenandoah University Bernard J. Dunn School of Pharmacy, Winchester, Virginia

### Nicole Paolini Albanese, PharmD (31, 32)

Clinical Assistant Professor, Department of Pharmacy Practice, The State University of New York at Buffalo School of Pharmacy and Pharmaceutical Sciences; Director, Buffalo Medical Group–PGY1: Primary Care; Director, Lifetime Health - PGY1: Managed Care, Buffalo

### Emily M. Ambizas, PharmD (30)

Assistant Clinical Professor, St. John's University College of Pharmacy and Allied Health Professions, Jamaica, New York; Clinical Specialist, Brooks Eckerd Pharmacy, Whitestone, New York

### Kenneth A. Bachmann, PhD, FCP (49)

Distinguished University Professor (Emeritus), Department of Pharmacology, The University of Toledo College of Pharmacy; Interim Chief Executive Officer, CeutiCare, LLC, Toledo, Ohio

### Becky K. Baer, BS, PharmD (40)

Associate Professor, South Dakota State University College of Pharmacy, Brookings

# Danial E. Baker, PharmD, FASHP, FASCP (2)

Associate Dean for Clincial Programs, Professor of Pharmacotherapy, Department of Pharmacotherapy, Washington State University Spokane College of Pharmacy

### Erin Ballard, PharmD, BCNSP (27)

University of Arizona College of Pharmacy, Tucson

### Veronica T. Bandy, PharmD (30)

Clinical Assistant Professor, Pharmacy Practice Department, University of the Pacific Thomas J. Long School of Pharmacy and Health Sciences, Stockton, California

### Jeffrey L. Barnett, MD (18)

Private Practitioner, Huron Gastroenterology Associates, Ypsilanti, Michigan

### Cathy L. Bartels, PharmD, FAAIM (53)

Associate Professor of Pharmacy Practice, Creighton University School of Pharmacy and Health Professions, Omaha, Nebraska

# Hildegarde J. Berdine, BS, PharmD, BCPS (7)

Assistant Professor of Pharmacy Practice, Department of Clinical, Social, and Administrative Sciences, Duquesne University Mylan School of Pharmacy, Pittsburgh, Pennsylvania

### Tricia M. Berry, PharmD, BCPS (43, 46)

Associate Professor, Division of Pharmacy Practice, St. Louis College of Pharmacy, St. Louis, Missouri

# Elizabeth Ewing Betchick, PharmD, BCPS, BCNSP (23)

Assistant Professor, Department of Pharmacy, University of Tennessee College of Pharmacy, Memphis; Clinical Pharmacy Specialist, Methodist LeBonheur Healthcare–Germantown, Germantown, Tennessee

### Missy L. Blue, RPh, JD (4)

Staff Pharmacist, Walgreens, Lebanon, Indiana

### Karen Beth Bohan, PharmD, BCPS (45)

Assistant Professor, Wilkes University Nesbitt College of Pharmacy and Nursing, Wilkes-Barre, Pennsylvania

### Donald J. Brideau Jr., MD, MMM (50)

Family Physician, Springfield Family Medicine, Alexandria, Virginia; Assistant Clinical Professor, Georgetown Unviversity and George Washington University Schools of Medicine, Washington, DC

### Tina Penick Brock, RPh, MS, EdD (50)

Management Sciences for Health, Arlington, Virginia

### Wayne Buff, PharmD (1)

Associate Dean, and Clinical Associate Professor, Department of Pharmacy Practice and Outcomes Sciences, South Carolina College of Pharmacy, University of South Carolina Campus, Columbia

### Stephen M. Caiola, MS, FRSH (15, 51)

Associate Professor and Director, Postgraduate/Continuing Education Program, University of North Carolina Eshelman School of Pharmacy, Chapel Hill

# Lingtak-Neander Chan, PharmD, BCNSP (24)

Associate Professor, School of Pharmacy and Graduate Program in Nutritional Sciences, University of Washington, Seattle

### Hae Mi Choe, PharmD, CDE (12)

Clinical Assistant Professor, Department of Pharmacy Practice, The University of Michigan College of Pharmacy, Ann Arbor

### Peter A. Chyka, PharmD (21)

Professor and Associate Dean, University of Tennessee College of Pharmacy, Knoxville Campus

### Martha D. Cobb, MS, MEd, CWOCN (22)

Clinical Associate Professor (Emeritus), University of Arizona College of Nursing, Tucson

### Mary Petrea Cober, PharmD (6)

Clinical Pharmacist–Pediatric Surgery/Intestinal Failure Program, University of Michigan CS Mott Children's Hospital; Clinical Adjunct Assistant Professor, University of Michigan College of Pharmacy, Ann Arbor

# Andrea D. Collaro, PharmD, CDM, RPh (47)

Category Manager-Diagnostics, Walgreens Company, Deerfield, Illlinois; Adjunctive Faculty, Clinical Assistant Professor, Department of Pharmacy Practice, University of Illinois at Chicago

## Janice C. Colwell, MS, RN, CWOCN (22)

University of Chicago Medical Center, Chicago, Illinois

### Susan Cornell, PharmD, CDE, CDM (47)

Assistant Director of Experiential Education and Assistant Professor of Pharmacy Practice, Midwestern University Chicago College of Pharmacy, Downers Grove, Illinois

# Catherine M. Crill, PharmD, BCPS, BCNSP (26)

Associate Professor, Department of Clinical Pharmacy, The University of Tennessee Health Science Center, Memphis

### Lourdes M. Cuellar, MS, RPH, FASHP (3)

Director, Pharmacy Department and Patient Safety Officer, Memorial Hermann–TIRR, Houston, Texas

# Jeffrey C. Delafuente, MS, FCCP, FASCP (11)

Associate Dean for Professional Education, Professor of Pharmacy and Director of Geriatric Programs, Virginia Commonwealth University School of Pharmacy, Richmond

### Thomas Scott Devetski, OD (29)

Associate Optometrist, Alamance Eye Center, Burlington/Chapel Hill; Clinical Assistant Professor, Department of Ophthalmology, University of North Carolina, Chapel Hill

### Joseph T. DiPiro, PharmD (17)

Executive Dean, South Carolina College of Pharmacy, The Medical University of South Carolina Campus, Charleston, and The University of South Carolina Campus, Columbia

### Michael B. Doherty, PharmD (47)

Director of Experiential Training and Assistant Professor of Clinical Pharmacy Practice, University of Cincinnati College of Pharmacy, Cincinnati, Ohio

### Janell Norris Downing, PharmD (32)

Community Pharmacist and Medication Therapy Management Coordinator, Bear Drug, Kitty Hawk, North Carolina; Pharmacy Student Preceptor, University of North Carolina Eshelman School of Pharmacy, Chapel Hill

### Jeremiah Duby, PharmD, BCPS (25)

Critical Care Clinical Pharmacist, Department of Pharmacy, U.C. Davis Medical Center, Sacramento, California; Clinical Associate Professor, College of Pharmacy, Touro University, Mare Island, Vallejo, California

### B. DeeAnn Dugan, PharmD (6)

Assistant Professor of Community Pharmacy Practice, Lloyd L. Gregory School of Pharmacy, Palm Beach Atlantic University, West Palm Beach, Florida

### Kaelen C. Dunican, PharmD, RPh (43)

Assistant Professor, Pharmacy Practice, Massachusetts College of Pharmacy and Health Sciences School of Pharmacy, Worcester, Massachusetts

### Herbert L. DuPont, MD (17)

Chief, Internal Medicine Service, St. Luke's Episcopal Hospital; Director, Center for Infectious Diseases, University of Texas School of Public Health; Clinical Professor and Vice-Chairman of the Department of Medicine, Baylor College of Medicine, Houston, Texas

### Marilyn S. Edwards, PhD, RD (25)

Professor, Department of Internal Medicine, Division of Gastroenterology, Hepatology, and Nutrition, The University of Texas Medical School at Houston

### Patricia M. Elsner, PharmD (42, 43)

Staff Pharmacist, Walgreens 10974, Lafayette, Indiana

# Carl F. Emswiller Jr, BS Pharmacy, FACA (30)

Pharmacist (Retired), Leesburg, Virginia

### Linda M. Farho, PharmD (16)

Assistant Professor, Pharmacy Practice, University of Nebraska Medical Center College of Pharmacy, Omaha

### Stefanie P. Ferreri, PharmD, CDE (16)

Clinical Assistant Professor and Director, Community Pharmacy Residency Program, University of North Carolina Eshelman School of Pharmacy, Chapel Hill

### Richard Finkel, PharmD (48)

Assistant Professor, Department of Pharmaceutical and Administrative Sciences, College of Pharmacy, Nova Southeastern University, Fort Lauderdale, Florida

### Daniel Forrister, PharmD (31)

Clinical Assistant Professor, Department of Clinical and Administrative Pharmacy, The University of Georgia College of Pharmacy, Athens

### Karla T. Foster, PharmD (20, 33)

Clinical Assistant Professor, Department of Clinical and Administrative Sciences, Mercer University Southern School of Pharmacy, Atlanta, Georgia

### Andrea R. Franks, PharmD, BCPS (18)

Associate Professor, Departments of Clinical Pharmacy and Family Medicine, University of Tennessee Health Science Center Colleges of Pharmacy and Medicine, Knoxville Campus

### Conchetta White Fulton, PharmD (7)

Clinical Associate Professor, Department of Pharmacy Practice, Xavier University of Louisiana College of Pharmacy, New Orleans

### Candice Garwood, PharmD, BCPS (53)

Clinical Assistant Professor, Department of Pharmaceutics/Pharmacy, Wayne State University Eugene Applebaum College of Pharmacy and Health Sciences; Clinical Pharmacy Specialist, Ambulatory Care, Harper University Hospital, Detroit Medical Center, Detroit, Michigan

### Diane B. Ginsburg, MS, RPh, FASHP (3)

Clinical Professor, Division of Pharmacy Practice, Assistant Dean for Student Affairs, and Regional Director, Internship Program, The University of Texas at Austin College of Pharmacy

### Jeffery A. Goad, PharmD, MPH (17)

Associate Professor of Clinical Pharmacy, Coordinator, Community Pharmacy Program, and Director, Community Pharmacy Practice Residence, University of Southern California School of Pharmacy, Los Angeles; Travel Health Consultant, University of Southern California Pharmacy, Student Health and Family Medicine, Los Angeles

# William C. Gong, PharmD, FASHP, FCSHP (2)

Associate Professor of Clinical Pharmacy, and Director, Residency and Fellowship Training, University of Southern California School of Pharmacy, Los Angeles

### Philip Gregory, PharmD (54)

Assistant Professor, Department of Pharmacy Practice, Creighton University, Omaha

# Nicholas E. Hagemeier, PharmD, MS (39, 41)

Pharmacist, Cowan Drugs, Inc., Lebanon, Indiana

# Judy Sommers Hanson, PharmD, CDM (30)

Manager, Clinical Education and Shared Faculty, Walgreens Health Initiatives, Deerfield, Illinois

### Ila M. Harris, PharmD, FCCP, BCPS (55)

Associate Professor, Department of Pharmaceutical Care and Health Systems, College of Pharmacy; Adjunct Associate Professor, Medical School, Department of Family Medicine and Community Health, University of Minnesota, Minneapolis

### Jan K. Hastings, PharmD (3)

Associate Professor, Department of Pharmacy Practice, University of Arkansas for Medical Services College of Pharmacy, Little Rock

### Katherine Heller, PharmD (7)

Assistant Professor of Pharmacy Practice, Lloyd L. Gregory School of Pharmacy, Palm Beach Atlantic University, West Palm Beach, Florida

### Metta Lou Henderson, RPh, PhD (1)

Professor Emerita of Pharmacy, Raabe College of Pharmacy, Ohio Northern University, Ada, Ohio

### Karl Hess, PharmD (19)

Assistant Professor of Pharmacy Practice, Western University of Health Sciences College of Pharmacy, Pomona, California

### Michelle L. Hilaire, PharmD, CDE (28)

Clinical Assistant Professor, Department of Pharmacy Practice, University of Wyoming School of Pharmacy, Laramie; Clinical Pharmacist, Fort Collins Family Medicine Residency Program, Fort Collins, Colorado

### Thomas J. Holmes Jr, PhD (44)

Associate Dean and Professor, Medicinal/Pharmaceutical Chemistry/Pharmacognosy, Campbell University School of Pharmacy, Buies Creek, North Carolina

### James P. Hoover, DPM (44)

Private Practitioner, Lafayette, Indiana

# Daniel A. Hussar, BS Pharmacy, MS, PhD (2)

Remington Professor of Pharmacy, Philadelphia College of Pharmacy, University of the Sciences in Philadelphia, Philadelphia, Pennsylvania

### Eric Jackson, PharmD, BCPS (54, 55)

Associate Professor of Family Medicine, Family Medicine Center at Asylum Hill, University of Connecticut School of Medicine and Saint Francis Hospital and Medical Center, Hartford

# Pramodini B. Kale-Pradhan, PharmD (12, 20)

Associate Clinical Professor, Department of Pharmacy Practice, Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University; Clinical Specialist–Surgery, Department of Pharmacy Services, St. John Hospital and Medical Center, Detroit, Michigan

### William D. King, RPh, MPH, DrPH (20)

Division Director and Professor of Pediatrics, Department of Pediatarics, The University of Alabama at Birmingham

# Erika Kleppinger, PharmD, BCPS,

Assistant Clinical Professor, Department of Pharmacy Practice, Auburn University Harrison School of Pharmacy, Auburn, Alabama

### Teresa B. Klepser, PharmD, BCPS (35)

Associate Professor, Department of Pharmacy Practice, Ferris State University College of Pharmacy, Kalamazoo, Michigan; Clinical Pharmacist, Borgess at Woodbridge Hills, ProMed Family Practice, Portage, Michigan

### Erin Koopman, PharmD, BCNSP (23)

Clinical Pharmacy Specialist in Nutrition Support, Saint Marys Hospital, Mayo Clinic, Rochester, Minnesota

### Jeffrey Kreitman, PharmD (6)

Regional Clinical Pharmacist, AmeriHealth Mercy Health Plan, Harrisburg, Pennsylvania

### Thomas E. Lackner, PharmD (52)

Professor, Experimental and Clinical Pharmacology and Institute for the Study of Geriatric Pharmacotherapy, University of Minnesota College of Pharmacy, Minneapolis

### J. Kyle Lawson, PharmD (35, 37, 38)

Pharmacist, Kroger Pharmacy J-81, Crawfordsville, Indiana

### Cherokee Layson-Wolf, PharmD, CGP (28)

Assistant Professor, Department of Pharmacy Practice and Science, and Director, Community Residency Program, University of Maryland School of Pharmacy; Patient Care Program Coordinator, NeighborCare Professional Pharmacies. Baltimore, Maryland

### Karen W. Lee, PharmD, CDM (11)

Associate Director of Professional Development, Clinical Pharmacy Services of Commonwealth Medicine and University of Massachusetts Medical School, Shrewsbury

### Howard Madsen, RD, PharmD, CNSD (23)

Nutrition Support/Clinical Pharmacist, Samaritan Health Services, Lebanon, Oregon

### Patricia Marshik, PharmD (13)

Director, Pediatric Asthma Outreach Clinics and Associate Professor of Pharmacy, University of New Mexico Health Sciences Center School of Pharmacy, Albuquerque

### Beth A. Martin, PhD, RPh (50)

Assistant Professor (CHS), University of Wisconsin–Madison School of Pharmacy

# Linda Gore Martin, PharmD, MBA, BCPS

Associate Professor, Department of Social and Administrative Pharmacy, University of Wyoming School of Pharmacy, Laramie

# Marsha McFalls-Stringert, RPh, PharmD (41)

Assistant Professor of Pharmacy Practice, and Director, Academic Center for Pharmacy Practice, Department of Clinical, Social, and Administrative Sciences, Duquesne University Mylan School of Pharmacy, Pittsburgh, Pennsylvania

### Emily K. Meuleman, RN, C, MS (8, 9)

Family Nurse Practitioner, Department of Family Medicine, University of Michigan, Chelsea

# Susan M. Meyer, BS Pharmacy, MS, PhD (51)

Associate Dean for Education and Professor, University of Pittsburgh School of Pharmacy, Pittsburgh, Pennsylvania

### Jill E. Michels, PharmD (21)

Managing Director, Palmetto Poison Center and Clinical Assistant Professor, South Carolina College of Pharmacy, University of South Carolina Campus, Columbia

### Janis Miller, RN, PhD (52)

Assistant Professor of Nursing and Associate Research Scientist, Nursing, The University of Michigan School of Nursing; Research Assistant Professor of Obstetrics and Gynecology, The University of Michigan Medical School, Ann Arbor

### Brad A. Miller, PharmD (5)

Clinical Specialist-Emergency Medicine, Pharmacy Department, Spectrum Health System, Grand Rapids, Michigan

### Jane R. Mort, PharmD (16)

Professor of Pharmacy Practice, South Dakota State University College of Pharmacy, Brookings

# David Paquette, DMD, MPH, DMSc (31, 32)

Associate Professor and Graduate Program Director, Department of Periodontology, University of North Carolina School of Dentistry, Chapel Hill

### Jeegisha Patel, PharmD (28)

Clinical Assistant Professor, Department of Pharmacy Practice, Oregon State University College of Pharmacy, Oregon Health & Science University, Portland

# Karen Steinmetz Pater, PharmD, BCPS, CDE (5)

Assistant Professor, University of Pittsburgh School of Pharmacy, Pittsburgh, Pennsylvania

# Roy Alton Pleasants II, PharmD, BCPS (13)

Associate Professor, Campbell University School of Pharmacy, Buies Creek, North Carolina; Clinical Pharmacist in Pulmonary Medicine, Division of Pulmonary, Allergy, and Critical Care Medicine, Department of Medicine, Duke University, Durham, North Carolina

# Charles D. Ponte, PharmD, BC-ADM, BCPS, CDE, FAPhA, FASHP, FCCP (10, 38)

Professor of Clinical Pharmacy and Family Medicine, Departments of Clinical Pharmacy and Family Medicine, West Virginia University Robert C. Byrd Health Sciences Center Schools of Pharmacy and Medicine, Morgantown

### David R. Potts, MD (42)

Private Practitioner, Unity Healthcare, Lafayette, Indiana

### Pamela Ringor, MBA, RPh (37, 39)

Staff Pharmacist, PayLess Pharmacy, Lafayette, Indiana

### Ronald J. Ruggiero, PharmD (9, 10)

Clinical Professor (Emeritus), Departments of Clinical Pharmacy and Obstetrics, Gynecology, and Reproductive Sciences, Schools of Pharmacy and Medicine, The UCSF National Center of Excellence in Women's Health, The Medical Center at University of California, San Francisco

### Gina J. Ryan, PharmD, BCPS, CDE (3)

Clinical Assistant Professor of Pharmacy Practice, Mercer University College of Pharmacy and Health Sciences, Atlanta, Georgia

### Jasmine K. Sahni, PharmD (26)

Assistant Professor, Department of Clinical Pharmacy, University of Tennessee College of Pharmacy, Memphis

# Elizabeth J. Scharman, PharmD, ABAT, BCPS, FAACT (21)

Director, West Virginia Poison Center; Professor, Department of Clinical Pharmacy, West Virginia University School of Pharmacy, Charleston

### Philip Schneider, PharmD (16, 20)

Director of Pharmacy, Olathe Medical Center, Olathe, Kansas; Adjunct Clinical Assistant Professor, Department of Pharmacy Practice, University of Kansas School of Pharmacy, Lawrence

### Kelly L. Scolaro, PharmD (51)

Clinical Assistant Professor and Director of Pharmaceutical Care Laboratory, Division of Pharmacy Practice and Experiential Education, The University of North Carolina Eshelman School of Pharmacy, Chapel Hill

### Steven A. Scott, PharmD (45)

Associate Professor of Clinical Pharmacy and Associate Head, Department of Pharmacy Practice, Purdue University School of Pharmacy and Pharmaceutical Sciences, West Lafayette, Indiana

### Chad Shedron, PharmD (33, 34)

Owner, Family Pharmacare, Lafayette, Indiana

# Debra Sibbald, BSc Phm, ACPR, MA, PhD [candidate] (36)

Coordinator, Pharmaceutical Care I, University of Toronto Faculty of Pharmacy, Mississauga, Ontario, Canada

# John K. Siepler, PharmD, BCNSP, FCCP (14)

Research Specialist, Nutrishare, Inc., Elk Grove, California; Clinical Professor, University of California at San Francisco School of Pharmacy

# Heather Skillman, MS, RD, CSP, CNSD (26)

Pediatric Critical Care Dietitian, The Children's Hospital, Denver, Colorado

### Susan Claire Smolinske, PharmD (21)

Poison Control Center, Children's Hospital of Michigan, Detroit

### Jenelle L. Sobotka, PharmD (1)

Manager, Professional Relations, The Procter and Gamble Company, Cincinatti, Ohio

### Vanessa A. Stanford, MS, RD, CSCS (25)

Research Specialist, Sr., Department of Nutritional Sciences, University of Arizona College of Agriculture and Life Sciences, Tucson

### Scott K. Stolte, PharmD (17)

Chair, Department of Pharmacy Practice, Shenandoah University Bernard J. Dunn School of Pharmacy, Winchester, Virginia

### Donald L. Sullivan, PhD (51)

Associate Professor of Pharmacy Practice, Department of Pharmacy Practice, Ohio Norhtern University College of Pharmacy, Ada

### Keith A. Swanson, PharmD (48)

Associate Professor, Department of Pharmacy Practice, University of Oklahoma College of Pharmacy, Oklahoma City

### Larry N. Swanson, PharmD, FASHP (34)

Professor and Chairman, Department of Pharmacy Practice, Campbell University School of Pharmacy, Buies Creek, North Carolina

### Sahar Swidan, PharmD (5)

Clinical Associate Professor, Department of Clinical Sciences, The University of Michigan College of Pharmacy; President and CEO, Pharmacy Solutions, Ann Arbor, Michigan

# Jane Takagi, PharmD, FCSHP, FASHP (27)

Adjunct Associate Professor of Pharmacy Practice, University of Southern California School of Pharmacy, Los Angeles; Assistant Clinical Professor, Department of Clinical Pharmacy, University of California at San Francisco School of Pharmacy; Kaiser Permanente Drug Information Services, Downey, California

### Jeff G. Taylor, PhD (11)

Associate Professor of Pharmacy, University of Saskatchewan College of Pharmacy and Nutrition, Saskatoon

### Jeremy Lynn Thomas, PharmD (15)

Assistant Professor, Department of Clinical Pharmacy, University of Tennessee Health Science Center College of Pharmacy, Memphis

### Cynthia Thomson, RD, PhD (24)

Associate Professor, Department of Nutritional Sciences, University of Arizona, Tucson

### Michael S. Torre, MS, RPh, CDE (47)

Clinical Professor of Pharmacy, Department of Clinical Pharmacy Practice, College of Pharmacy and Allied Health Professions, St. John's University, Jamaica, New York

# Dominic P. Trombetta, PharmD, BCPS, CGP (46)

Associate Professor of Pharmacy Practice, Wilkes University Nesbitt School of Pharmacy, Wilkes-Barre, Pennsylvania; Allied Services Rehabilitation Hosptial & Outpatient Centers, Scranton, Pennsylvania

### Candy Tsourounis, PharmD (48, 49)

Associate Professor of Clinical Pharmacy, Department of of Clinical Pharmacy, University of California at San Francisco School of Pharmacy

### Angela R. Vinti, PharmD, BCPS (30)

Assistant Clinical Professor, Department of Pharmacy Practice, Auburn University Harrison School of Pharmacy, Mobile Satellite Campus; Adjunct Assistant Professor, Department of Family Medicine, University of South Alabama College of Medicine, Mobile

### Paul C. Walker, PharmD (19, 36)

Clinical Associate Professor, College of Pharmacy, Department of Clinical Sciences, The University of Michigan; Manager of Clinical Services, Department of Pharmacy, The University of Michigan Health Systems, Ann Arbor

# Geoffrey C. Wall, RPh, PharmD, BCPS, CGP (14)

Associate Professor of Pharmacy Practice,
College of Pharmacy and Health Sciences, Drake
University; Internal Medicine Clinical
Pharmacist and Director, Pharmacy Practice
Residency Program, Iowa Methodist Medical
Center; Clinical Assistant Professor of
Pharmacology/Physiology, Des Moines
University College of Osteopoathic Medicine,
Des Moines, Iowa

### C. Wayne Weart, PharmD (14)

Professor, Department of Pharmacy and Clinical Sciences, South Carolina College of Pharmacy, Medical University of South Carolina Campus; Associate Professor of Family Medicine, Medical University of South Carolina, Charleston

### Kristin Weitzl, PharmD (19)

Assistant Editor, *Pharmacist's Letter* and *Prescriber's Letter*, Stockton, California; Clinical Associate Professor (Adjunct), Department of Pharmacy Practice, University of Florida College of Pharmacy, Gainesville, Florida

### Amy L. Whitaker, PharmD (40)

Assistant Professor, Department of Pharmacy, Virginia Commonwealth University School of Pharmacy, Richmond

### G. Thomas Wilson, BS Pharm, JD (4)

Associate Professor of Pharmacy Practice and Law, Department of Pharmacy Practice, Purdue University School of Pharmacy and Pharmaceutical Sciences, West Lafayette, Indiana

### Kenneth W. Witte, PharmD (24)

Adjunct Clinical Associate Professor, University of Illinois at Chicago College of Pharmacy; President, Clinical Pharmacy Consultants, Inc., LaGrange, Illinois

# Supakit Wongwiwatthananukit, PharmD, PhD (50)

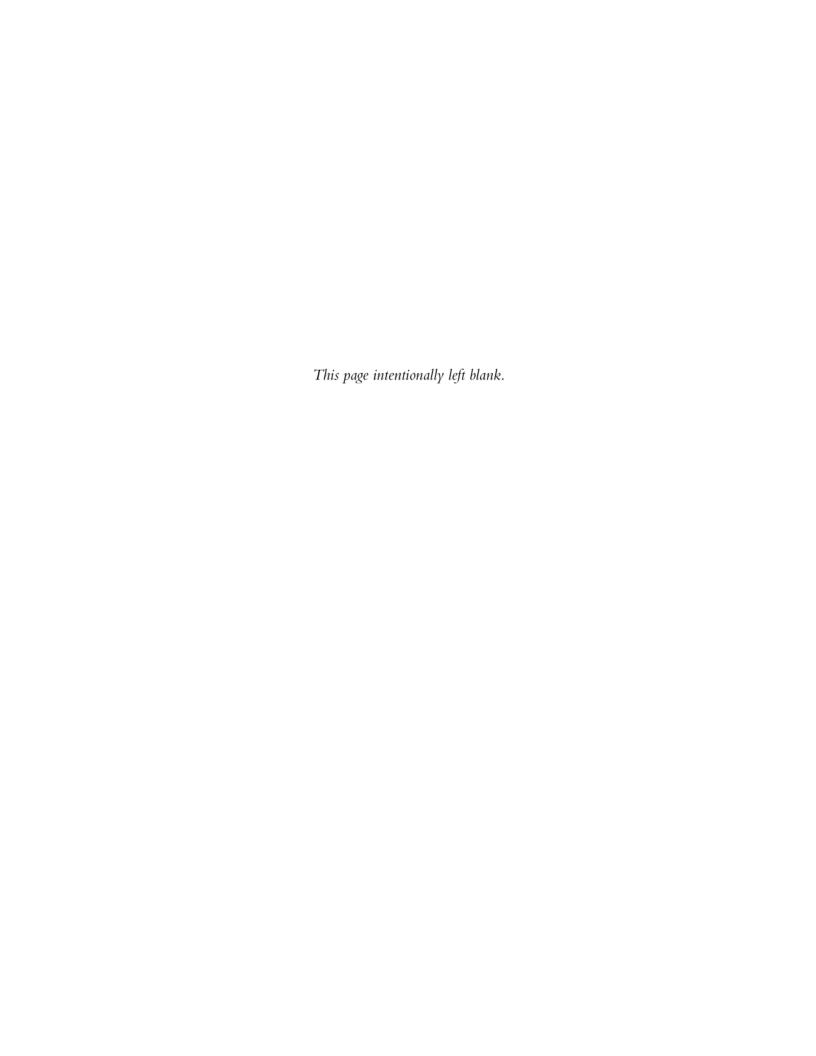
Assistant Professor, Department of Pharmacy Practice, College of Pharmacy, University of Hawaii, Hilo

### John R. Yuen, PharmD, BCNP (28, 29)

Board Certified Nuclear Pharmacist, Oncology Pharmacist Specialist (Hospital and Ambulatory Care), Kaiser Permanente Los Angeles Medical Center; Adjunct Assistant Professor of Pharmacy Practice, University of Southern California School of Pharmacy, Los Angeles

### Ann Zweber, B. Pharm (15)

Senior Instructor, Department of Pharmacy Practice, Oregon State University College of Pharmacy, Corvallis



# How to Use the Case Problem-Solving Model

### Rationale for Case Format

Use of a problem-solving model is one mechanism for developing problem-solving skills. Repeated exposure to the model in a variety of contexts aids students in learning the model and applying it in various circumstances. Use of the model in each diseases-related chapter in this text provides repeated exposure and reinforces learning.

### **Case Format Description**

The case format is based on the guided-design instructional format that models the steps of decision making. This format facilitates student development of a framework for the organization and application of acquired information to the solution of novel problems. The basic steps used in the guided-design decision-making format are as follows.

- Gather information pertinent to the problem and its solution.
- Identify the problem.
- Identify exclusions for self-treatment.
- Perform patient assessment and triage.
- Identify alternative solutions.
- Select an optimal solution.
- Prepare and implement a plan to solve the problem.
- Provide patient education.
- Evaluate patient outcome.
- When outcomes do not achieve the self-treatment goal, start the process again from the beginning.

### Steps 1 and 2: Gather Information

When a patient presents to a practitioner and is in need of self-care advice, the practitioner must collect information about the patient that may be pertinent to solving the patient's problem. This information falls into two general categories: (1) information about the symptoms that prompted the patient to seek assistance and (2) information about the patient's background characteristics (history). The first two steps in the case format direct the student to elicit this type of information.

It may be argued that it is unnecessary to collect all the patient's background characteristics to solve every patient problem. However, it should be remembered that novice problem solvers do not yet have the expertise to selectively elicit the most pertinent information to a specific situation. Thus, the model prompts them to ask about all of the listed characteristics to avoid overlooking information that is critical to the solution of the problem.

### Step 3: Identify the Problem

The third step involves the evaluation of information gathered in the previous steps to identify the patient's problem, its severity, and its most probable cause. Clear articulation of the problem is critical to (1) assist with differentiation among conditions with similar symptoms and (2) determine the goals of selftreatment. A comparison of the patient's symptoms to the usual or typical presentation of symptoms for a particular disease will help to differentiate and determine the most likely primary problem. For example, it is inadequate to conclude that a patient's problem is a common cold. In this instance, the therapeutic goal—to relieve the cold—is too vague to be useful, because there are dozens of symptoms that may or may not be associated with the common cold and there are even more alternatives for symptomatic relief. On the other hand, if the patient's problem is nasal congestion, the goal would be to relieve the congestion: This goal is a much more useful criterion against which to evaluate a more limited set of potential therapeutic options.

### Step 4: Identify Exclusions for Self-Treatment

There are several reasons why it may be inappropriate for an individual to self-treat the symptoms or problems they are experiencing, which include (1) symptoms should not be self-treated because medical referral is necessary (e.g., eye pain); (2) patient is not an appropriate candidate for self-care (e.g., a woman with diabetes who develops a vaginal candidal infection); (3) symptoms are too severe or long-lasting for self-treatment; or (4) effective nonprescription therapy is not available, or nonprescription dosages or duration of treatment is inadequate to treat the disorder.

Assessing the severity and determining the most likely primary problem that a patient is experiencing are essential in making appropriate recommendations for treatment or referral. For example, a patient who complains of a cough associated with a cold is often a candidate for self-care. However, if the cough is significantly hampering the patient's ability to sleep or carry out routine activities, or if the cough produces pain in the chest

area, referral to a primary care provider may be appropriate. In another instance, a patient who complains of a mild cough may not be a candidate for self-care if other information about the condition (e.g., history of tobacco use and emphysema) suggests an etiology that is not amenable to self-management.

### Step 5: Identify Alternative Solutions

The fifth step involves formulation of a list of possible approaches to the patient's problem. At this point, no alternative is prejudged or omitted. Four general options are available to practitioners who are advising patients about self-care: (1) recommend self-care with drug, nondrug, and/or alternative/complementary therapies; (2) refer patient to an appropriate primary care provider for treatment; (3) recommend self-care until an appropriate primary care provider can be consulted; and (4) take no action. In the context of self-treatment, all potentially plausible product categories, dosage forms, and nondrug products and measures should be included in the list. In the context of self-treatment, all potentially plausible product categories, dosage forms, and nondrug products and measures should be included in the list. Similarly, all potentially useful sources of primary care (e.g., urgent care clinic, dentist, or emergency department) should be considered.

Critics of this approach have sometimes indicated that including no action as an option is unconscionable or not in the best interest of patients. In fact, there are situations in which this option may be preferred. For example, consider a situation involving a patient on a limited income who suffers from an asymptomatic, common wart that is in a location where it is neither noticeable nor likely to be spread easily to others. Because most common warts resolve spontaneously without treatment and the patient has limited income to pay for a nonprescription product, taking no action may indeed be an optimal solution in this instance. Furthermore, the crucial point often overlooked by critics is that, at this point in the decision-making process, all ideas are listed and none are prejudged. Thus, it is entirely appropriate to consider no action, even if it turns out to be an inappropriate alternative. Again, this format is targeted at novice problem solvers who have little experience in identifying alternative therapeutic options. Thus, the model prompts them to formulate a list of all possible alternatives to prevent them from prematurely ruling out appropriate options.

### Step 6: Select an Optimal Solution

During the sixth step, each of the plausible solutions is evaluated to determine whether and to what extent each achieves the intended goal and is concordant with the patient's preferences in terms of goals of therapy, cost of therapy, and overall approach (e.g., personal philosophy, health beliefs) to self-care. Next, one of the alternatives that may adequately achieve the goal is selected on the basis of a variety of patient-specific and therapy-specific variables. Therapy-specific variables include dosage forms, ingredients, side effects, adverse reactions, relative effectiveness, and price. Patient-specific variables may include age, sex, medication history, concurrent medical conditions, patient preferences, and economic status.

### Steps 7 and 8: Prepare and Implement a Plan

These steps involve the communication of a therapeutic plan to the patient. The plan should include a summary of the condition and the reasons for treatment. The patient should be made aware of the available treatment options and their relative merits should also be included in the plan. When the recommended solution involves drug therapy, the plan should include monitoring parameters.

### Steps 9-11: Educate Patient

Patient education is designed to provide a clear and concise description of administration of the treatment, side effects and precautions, expected outcome, and guidelines for appropriate use. When appropriate, the plan should also include nondrug measures, lifestyle changes, and additional information resources.

The practitioner should ensure that the patient understands the plan by having the patient repeat it and by correcting any misunderstandings. Finally, after answering any remaining questions from the patient, the practitioner should encourage the patient to call or return if the symptoms fail to resolve. If symptoms are not resolved, the entire decision-making procedure begins anew.