

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



American Pharmacists Association[®]
Improving medication use. Advancing patient care.

APhA

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Nonprescription Drugs
An Interactive Approach to Self-Care

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16

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MANAGING EDITOR

Linda L. Young

EDITORIAL SERVICES

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

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Circle Graphics Inc.

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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, PHARM.D.
Executive Vice President & CEO
American Pharmacists Association

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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 spirit 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 medications, 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 *Handbook* 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 problem-solving 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 self-treatments, 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 nonprescription 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

February 2009

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

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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 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. Hagemeyer, 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, Iowa

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 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, Massachusetts 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

Daniel E. Baker, PharmD, FASHP, FASCP (2)

Associate Dean for Clinical 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

**Hildegard 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 University 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, Illinois; 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. Emswiler 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. Hagemeyer, 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 Pediatrics, The University of Alabama at Birmingham

Erika Kleppinger, PharmD, BCPS, CDE (29)
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 (8, 9)
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, Cincinnati, 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 Northern 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 Hospital & 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 Osteopathic 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 Wongwiwatthanakut, 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

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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 self-treatment. 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 possi-

ble 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.

SECTION



The Practitioner's Role in Self-Care



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Self-Care and Nonprescription Pharmacotherapy

Lawrence W. Davidow

Self-Care

Self-care is the independent act of preventing, diagnosing, and treating one's own illnesses without seeking professional advice. Preventive self-care involves maintaining well-being and appearance through exercise and a healthy lifestyle. For many individuals, a healthy lifestyle includes controlling their diet; taking vitamins, minerals, and herbal supplements; and maintaining their appearance by using dental, skin, and hair-care products. However, sickness self-care for individuals involves diagnosing their conditions, and obtaining products for the goal of mitigating illness and relieving symptoms. Examples of sickness self-care include dietary options (e.g., feeding warm soup for a cold), using devices for both disease assessment (e.g., home blood glucose meters and pregnancy tests) and treatment (e.g., ice packs, first-aid bandages, vaporizers, and nasal strips), as well as taking nonprescription medications. The use of sickness self-care products is limited to mild illness or short-term management of illness, and most products warn users to contact a health care provider if conditions do not improve within a short period of time.

For the provision of sickness self-care, a single individual from each household usually plays a leading role in adopting a course of action. This individual must determine whether to consult a health care provider or whether the use of home remedies and self-care will suffice. Furthermore, the number of individuals involved in choosing the most appropriate self-care option is increasing, owing to the growth of the U.S. geriatric population and the decreasing number of persons per household.¹

Individuals responsible for providing self-care to themselves or family members rely on knowledge and experience to guide their decisions. For better or worse, there is no shortage of information, given the wealth of health-related self-help books, newspaper feature articles, television advertisements, magazine and radio programs, instructional audio- and videotapes, and Internet sites, all of which provide self-care advice. The abundance of health-related information available, especially from the Internet, helps consumers become more "self-empowered" to address their own health care issues and leads to an aggressive use of self-care alternatives. Nevertheless, although it is more accepted today for people to attempt to manage their own health-related issues rather than to consult a health care provider, the concern is whether they are making appropriate and informed judgments. Furthermore, all this health information can become overwhelming, driving some individuals to seek advice from family and friends. This well-intentioned advice can be prob-

lematic, because it is often biased, and most people are not sufficiently informed to consider another's health conditions or medications before making a recommendation. They simply state what has worked best for them and fail to consider how their approach might apply to someone else.

Commercial products used for preventive or sickness self-care are often classified together as health and beauty care (HBC) products. Staggering numbers of HBC products are available. For example, Figure 1-1 illustrates the number of commercial products available in 2006 for various categories of preventive and sickness self-care.² Although access to quality HBC products is crucial to the goal of self-care, the vast number of similar, competing products makes appropriate selection difficult. Yet, in one consumer poll in which 66% of adults believed that the wide range of competing products made selection difficult, less than half (43%) said they consulted a pharmacist before making a purchase.³ The pharmacist plays a crucial role in assisting patients who are seeking both types of self-care products. The practicing pharmacist has the expertise to screen patient health information and apply his or her knowledge and training to select products according to individual health care needs. Therefore, for pharmacies to provide pharmacist-assisted self-care, only quality HBC products should be stocked, and access to a pharmacist for assistance should be readily available for patients who request it.

Self-Medication

Self-medication is often the most sought-after first level of self-care. As self-care has increased, so has the practice of self-medication with vitamins (i.e., nutritional dietary supplements), natural products (i.e., herbal/botanical and nonherbal dietary supplements [e.g., glucosamine]), and nonprescription medications. Factors that help drive reliance on self-medication include (1) the increase in size of the aging population, (2) restricted access to prescribers through health management organizations, (3) the increasing costs of health care, and (4) the high proportion of underinsured or uninsured people in the U.S. population. It is the easy access and cost-effectiveness of self-medication products that ensure their essential role in the U.S. health care system.

The results of a survey conducted for the National Council on Patient Information and Education (NCPPIE)⁴ illustrate how ubiquitous the use of nonprescription medications has become. According to the survey, 59% of Americans had taken at least

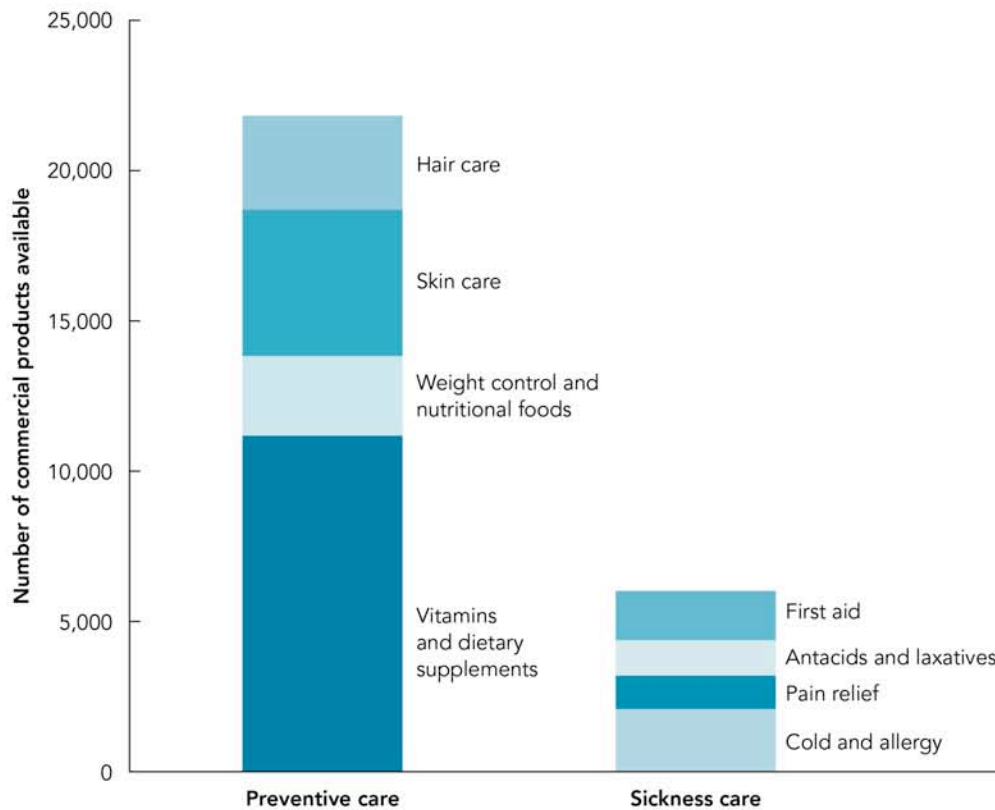


FIGURE 1-1 Number of HBC products for selected departments in 2006. (Source: Reference 2.)

one nonprescription medication in the last 6 months. Conditions commonly treated with nonprescription medications included:

- Pain (78%)
- Cough/cold/flu/sore throat (52%)
- Allergy/sinus problems (45%)
- Heartburn, indigestion (37%)
- Constipation/diarrhea/gas (21%)
- Minor infections (12%)
- Skin problems (10%)

Approximately 20% of Americans believe that they are consuming more nonprescription medications and taking them more frequently than they did 5 years ago.⁴ This increase in nonprescription drug use may reflect a consumer belief that self-medication can be accomplished safely. A survey published by Roper Starch Worldwide “Self-Care in the New Millennium” supports the view that American consumers are confident in their use of nonprescription medications.⁵ Survey results show that:

- 73% would rather try and treat their own condition than go to a physician.
- More than 80% stated that they were satisfied with the nonprescription medications they used to treat their most recent health problems.
- 87% believe that nonprescription medications are safe when used as directed.
- 90% or more stated that the first time they took a nonprescription medication, they took time to read package labels regarding the correct choice, directions for use, and side effects and drug interactions.

In addition, self-medication plays an increasing role as adjunctive therapy for chronic diseases that are managed by physicians with prescription medications. Examples include low-dose aspirin for reducing heart attack risk, fish oil (omega-3 fatty acids) to help treat certain dyslipidemias, and glucosamine with chondroitin to help reverse osteoarthritis. However, the benefits of using nonprescription products as adjunctive therapy come with a risk of harm resulting from incorrect selection of products. For example, many patients who require daily low-dose aspirin do not fully understand the difference between the many different aspirin products. There are different strengths (low-dose, regular, and extra-strength) and products (chewable, buffered, and enteric-coated). Selection of the wrong product by a patient could result in adverse reactions (e.g., gastritis or ulcer) or drug-drug interactions (e.g., warfarin, blood pressure medications). The pharmacist plays an important role in helping these patients select the correct products for their condition.

Options for Self-Medication

Three general categories of products are available to consumers for self-medication: (1) nonprescription medications, (2) nutritional dietary supplements, and (3) natural products and homeopathic remedies.

Nonprescription Medications

Nonprescription medications are regulated by the Center for Drug Evaluation and Research, a division of the U.S. Food and Drug Administration (FDA)—the same agency that regulates prescription drug products. As such, nonprescription medica-

tions are held to the same standards of drug product formulation (e.g., purity and stability), labeling, and safety (benefits outweigh risks) as those for prescription medications. It is worth noting that, although nonprescription medications are regulated in a manner equivalent to that of prescription medications, the sales of nonprescription medications are not limited to pharmacies; they are commonly sold at discount stores and supermarkets.

The provisions of the 1951 Durham-Humphrey Amendment to the Food, Drug, and Cosmetic Act (FDCA) of 1938 gives FDA the final authority to categorize a medication as prescription or nonprescription. Nonprescription medications are judged by FDA as safe and effective when used without a prescriber's directive and oversight. In 2000, more than 100,000 FDA-approved nonprescription drug products, including more than 800 active ingredients that covered more than 100 therapeutic categories, were available.⁶ Table 1-1 illustrates some of the conditions that are self-treatable with nonprescription medications.

Sales of nonprescription medications were estimated in 2003 at \$17.5 billion dollars. Sales of the top 15 therapeutic categories of nonprescription medications for the years 2003–2006 are shown in Figure 1-2.⁷ Not surprisingly, the dollars spent, as shown in Figure 1-2, correspond to what consumer surveys have reported as the most common conditions. For example, in a survey in which consumers were asked what health problems they had experienced in the preceding 6 months, the most frequent response was muscle/back/joint pain and cough/cold/flu/sore throat, both categories at 48%, with headache and heartburn/indigestion trailing at 43% and 32%, respectively.⁵ The correlation between common types of illnesses and dollars spent implies that most Americans provide self-care for these conditions using nonprescription medications.

Dietary Supplements

The Dietary Supplement Health and Education Act of 1994 amended the 1983 FDC Act to establish standards with respect to dietary supplements. This new act defined dietary supplements as products that are intended to supplement the diet and bear or contain one or more of the following dietary ingredients: (1) a vitamin, (2) a mineral, (3) an herb, or (4) an amino acid. A 1999–2000 survey indicated that 52% of consumers had taken a dietary supplement in the previous month.⁸ The most common supplements taken in this survey were multivitamin/multimineral formulations (35%), vitamin E (13%), vitamin C (12%), and calcium (10%). High demand has created a huge dietary supplement industry, with yearly sales in 2003 totaling nearly \$18.8 billion dollars.⁸

CAM and Homeopathic Remedies

Because of factors such as high health care costs and restricted access to conventional practitioners, many consumers seek treatment from providers of complementary and alternative medicine (CAM). The National Center for Complementary and Alternative Medicine and the National Center for Health Statistics reported survey results on the use of CAM by Americans.⁹ Between 36% and 74% of the people surveyed reported having used some form of CAM therapy. Some of the most common forms of CAM therapy were prayer, natural and vitamin products, deep breathing, chiropractic care, and yoga.⁹

Self-medication is a component of many CAM therapies. In 2005, total estimated sales of natural products were \$4.41 billion, the top-selling supplements being garlic, echinacea, saw palmetto, and *Ginkgo biloba*.¹⁰ A 2002 National Health Survey indicated that

TABLE 1-1 Selected Medical Disorders Amenable to Nonprescription Drug Therapy^a

Abrasions	Colds (viral upper respiratory infection)	Gastritis	Ostomy care
Aches and pains (general, mild-to-moderate)	Congestion (chest, nasal)	Gingivitis	Ovulation prediction
Acidity	Constipation	Hair loss	Periodontal disease
Acne	Contact lens care	Halitosis	Pharyngitis
Albumin testing	Contraception	Morning hangover relief	Pinworm infestation
Allergic reactions	Corns	Head lice	Pregnancy (diagnostic)
Allergic rhinitis	Cough	Headache	Premenstrual syndrome
Anemia	Cuts (superficial)	Heartburn	Prickly heat
Arthralgia	Dandruff	Hemorrhoids	Psoriasis
Asthma	Decongestant, nasal	Herpes	Ringworm
Athlete's foot	Dental care	Impetigo	Seborrhea
Bacterial infection	Dermatitis (contact)	Indigestion	Sinusitis
Blisters	Diabetes mellitus (insulin, monitoring equipment, supplies)	Ingrown toenails	Smoking cessation
Blood pressure monitoring	Diaper rash	Insect bites and stings	Sprains
Boils	Diarrhea	Insomnia	Strains
Bowel preparation (diagnostic)	Dry skin	Jet lag	Stye (hordeolum)
Burns (minor, thermal)	Dyslipidemia	Jock itch	Sunburn
Calluses	Dysmenorrhea	Migraine	Teething
Candidal vaginitis	Dyspepsia	Motion sickness	Thrush
Canker sores	Fever	Myalgia	Toothache
Carbuncles	Flatulence	Nausea	Vomiting
Chapped skin		Nutrition (infant)	Warts (common and plantar)
Cold sores		Obesity	Xerostomia
		Occult blood, fecal (detection)	Wound care

^a The pertinent nonprescription medication(s) for a particular disorder may serve as primary or major adjunctive therapy.

Source: Rulemaking History for Nonprescription Products: Drug Category List. Available at: http://www.fda.gov/cder/otcmonographs/rulemaking_index.htm. Last accessed July 28, 2008.

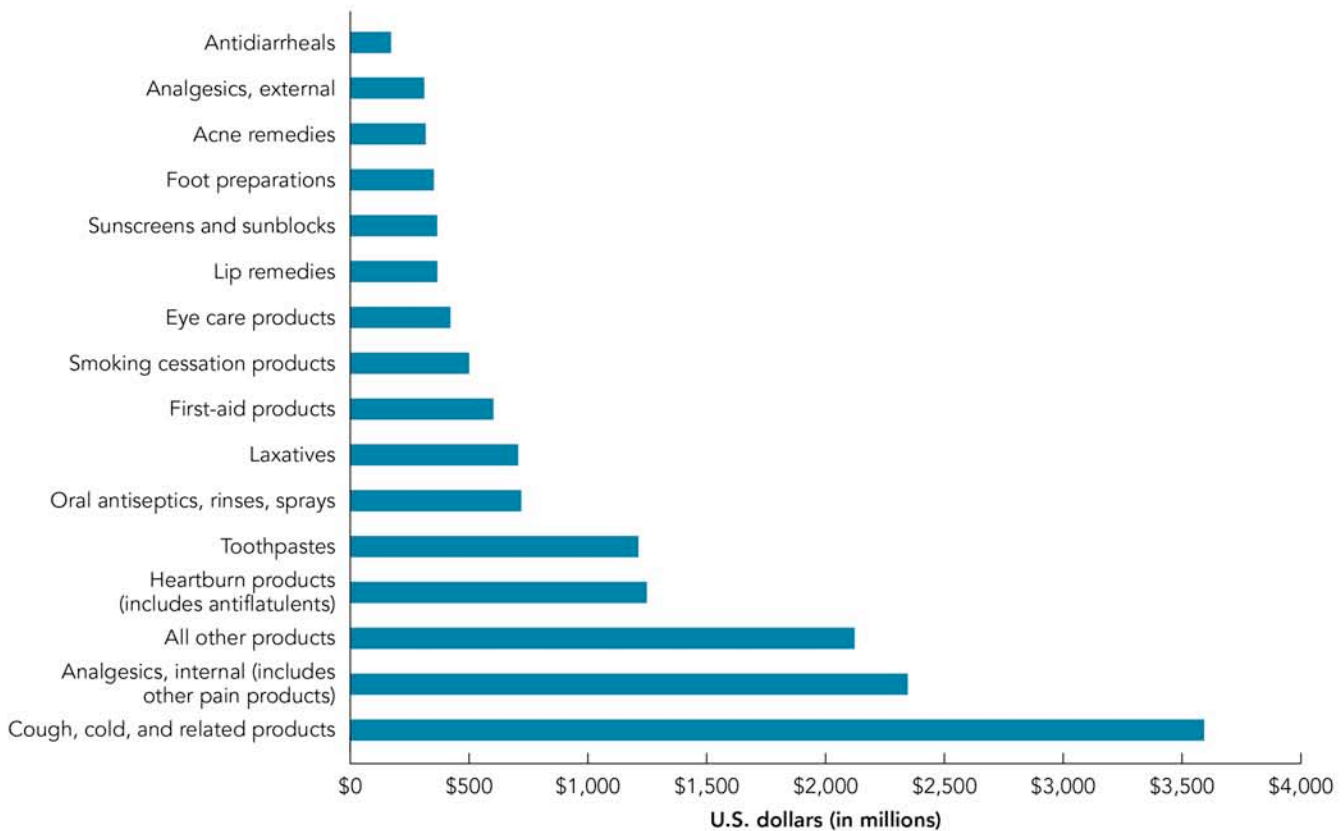


FIGURE 1-2 2006 sales of U.S. nonprescription drugs. (Source: Reference 7.)

about 13% of elderly patients had used an herbal supplement during the preceding year.¹¹ The use of combined herbal and conventional therapy raises safety concerns, because 51% of patients failed to inform their health care provider about their herbal therapy.¹¹ These safety concerns include the potential for herbal supplement–drug interactions. *Facts & Comparisons: Drug Interaction Facts* (St. Louis: Wolters Kluwer Health; 2007) lists approximately 150 herb–drug interactions, with St. John’s wort and *Ginkgo biloba* having 59 and 20 interactions, respectively. Therefore, individuals who take prescription or nonprescription medications should consult with a pharmacist or other health care provider before self-medicating with herbal supplements.

Influences on Self-Medication

Costs

Individuals can save money by purchasing nonprescription medications using money from a flexible spending account (FSA). These accounts were established when the Internal Revenue Service began allowing reimbursement of medically substantiated nonprescription medications with pretax dollars.¹² Reimbursable expenses include “nonprescription drugs” defined in the 1938 FDC Act as “alleviating or treating” personal injuries/illness, but only those that make such therapeutic claims on their labels are eligible. Also qualified for pretax reimbursements of health care dollars are dietary supplements if the patient’s physician has suggested their use for the treatment/mitigation of an illness, such as iron for iron-deficiency anemia. Dietary supplements such as vita-

mins, minerals, and natural products, which are “merely beneficial to the general health,” are not eligible as pretax expenses.

In 2006, approximately 10% of Americans used FSAs to pay for health care expenses.¹³ The disadvantage of using FSAs is that the money must be allocated in advance and is either used within a plan year or lost. This “use-it-or-lose-it” feature encourages people to limit their FSA contributions.¹⁴ Furthermore, consumers are confused about what purchases are FSA-eligible. For example, it has been reported that less than half of the money spent from FSA accounts is for eligible purchases.¹³ Pharmacists play a role in educating patients about what purchases are FSA-eligible and in encouraging FSA use by reminding patients to use their FSA debit card when purchasing nonprescription medications.

In 2003, the Medicare Modernization Act established Health Savings Accounts (HSAs), whereby individuals who are enrolled in a High Deductible Health Plan may contribute pretax dollars that can be used to pay for health-related expenses. These accounts function as normal savings accounts with accruable and interest-bearing balances that grow over time. However, with HSAs, both contributions and disbursements are tax-free as long as they are spent on health care.¹⁴ Unlike FSAs, purchases for nonprescription medications from HSAs have no time limit; the HSA balance will roll over to the next tax year.

Whether from FSA or HSA accounts, the medical expense “pretax” deduction is becoming increasingly popular as Americans pay more for “out-of-pocket” health care costs. In 2004, 5.02% of taxpayers claimed medical expense deductions, up from 4.3% in 1997.¹⁵ Consumers have an economic incentive to use low-cost nonprescription medications rather than expensive

prescription medications (with high insurance copayments), which in turn gives pharmacists greater opportunity for therapeutic counseling.

The Medicare Modernization Act of 2003 also established Medicare Part D prescription coverage. When the plan was first introduced, it did not pay for nonprescription medications, even when their use was directed by a physician.¹⁶ However, beginning in 2007, the Centers for Medicare & Medicaid Services began loosening restrictions on coverage of nonprescription medications that are less expensive than prescription alternatives in a Medicare Part D plan's formulary. It is expected that many Medicare drug plans will likely pay for nonprescription medications to drive utilization and reduce costs for medications such as proton pump inhibitors, nonsteroidal anti-inflammatory drugs, and antihistamines, which all have low-cost nonprescription alternatives.¹⁶

Aging Population

New projections illustrate the magnitude of the still-to-come elderly boom. The average life expectancy for Americans has increased, with individuals reaching age 65 expected to live an additional 12.4 years.¹⁷ The percentage of older Americans started to increase sharply as the baby boom generation approached the 65 and older age group.¹⁸ By 2030, an estimated 20% (70 million) of the U.S. population will be 65 years or older, up from 12.6% (35 million) in 2000.¹⁹ The fastest-growing segment of the elderly are those older than 85 years.¹⁸ Because these patients tend to be in poorer health and require more services than patients between 65 and 85 years, they will have a bigger impact on the future of the U.S. health care system.

Elderly patients consume a disproportionately larger share of nonprescription medications; patients older than 65 years purchase 40% of all nonprescription medications, although they represent only 12% of the population.²⁰ One study in elderly nursing home patients showed that use of nonprescription medications (93.9%) was only slightly less than that of prescription medications (98.2%).²¹ This study noted that, on average, nursing home residents used 8.8 unique medications per month, one-third (2.8) of which were nonprescription medications. Increased use

of nonprescription medications in the elderly can be attributed to the following:

- Conditions for which nonprescription medications are used, such as arthritis pain, insomnia, and constipation, become more prevalent with advancing age.
- Nonprescription medications provide low-cost alternatives to more expensive primary care visits and prescription medications.
- Accessibility to pharmacists in the community setting makes nonprescription medications an acceptable alternative to scheduling visits with primary care providers.

There are heightened safety concerns for elderly patients who use nonprescription medications because of the likelihood for multiple disease states and concurrent use of prescription medications. For example, one study documented the use of nonprescription medications and dietary supplements in 45 elderly patients (average age: 85 years) residing in assisted-living facilities.²² The results showed that elderly residents used an average of 3.4 nonprescription products, the most common being nutritional dietary supplements (32%), gastrointestinal products (17%), pain relievers (16.3%), and herbal products (14.4%). Potential safety concerns of drug duplication (70%) and potential drug/disease/food interactions (20.8%) were identified in more than one-half of these patients.

Gender Differences

As is true worldwide, there are more women than men in the United States. The gender gap widens dramatically with age. For example, in 2000, comparison of the number of all males to females, regardless of age, showed a ratio of 95.5 males/100 females.¹⁹ This ratio decreased to 68.9 males/100 females at age 65 years or older and plummeted to 40.5 males/100 females in the 85 years or older age group.

The preponderance of elderly women has a considerable influence on self-medication. In the "Self-Care in the New Millennium" survey, women consistently reported having a variety of health problems more frequently than men.⁵ Figure 1-3 shows

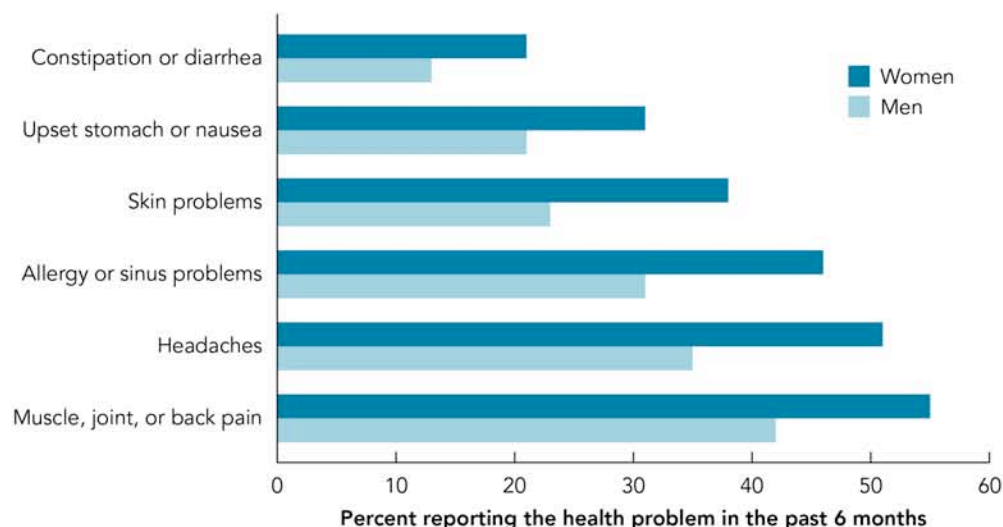


FIGURE 1-3 Selected ailments self-treated by men and women. (Source: Reference 5.)

that, across the board, more women than men (in the range of 31%–65%) report having each of six ailments. Women in this survey were also more likely to report using nonprescription medications (82%) than were men (71%). This gender difference was also observed in dietary supplement use, which was reported by 30% of women but only 23% of men.⁵ Therefore, the increasing population of older women will increase demand for nonprescription products in the future.

There are also gender-specific self-medication concerns such as the use of nonprescription medications during pregnancy. More than 80% of pregnant women reported taking at least one medication, with about 30% using more than four.²³ This same study reported that 6 of the top 10 medications used were nonprescription medications. However, the ability of pregnant women to self-medicate safely is limited by the fact that most products state “if pregnant or breast-feeding, ask a health care professional before use.” Pharmacists are trained to assess whether a nonprescription medication is safe for use during pregnancy.

Breast-feeding mothers are also faced with difficult choices when selecting nonprescription medications. All three main active ingredients in nonprescription pain relievers (i.e., aspirin, acetaminophen, and ibuprofen) have the potential to enter breast milk. The following are recommendations a pharmacist can make to help avoid problems in women who are breast-feeding²⁴:

- Use nonpharmacologic therapy if possible.
- Take medications immediately after nursing or before the infant's longest sleep period.
- Avoid recommending any medications that are extra-strength, maximum-strength, or long-acting.
- Avoid recommending combination products.
- Counsel about potential side effects that could occur in the child.

Nonprescription status of an emergency contraception (Plan B) is another example for which female patients will need direct access to the pharmacist. The pharmacist plays an important role in screening the patient's age and ensuring timely access to the medication. In some states pharmacists need to become certified and trained to provide Plan B directly to patients.

Accessibility to Nonprescription Drug Products for Self-Medication

Internet Pharmacies and Drug Information

As people live longer, work longer, and take on a more active role in their own health care, they need to become better informed about self-care options and how to safely self-medicate. Health care-related information is available on the Internet with resources that are easily and rapidly accessed in the privacy and comfort of a patient's home. According to a 2006 Pew Internet & American Life Project report, 80% of American Internet users, or some 113 million adults, have searched for information on at least one of 17 health topics.²⁵ Individuals who were most likely to search for health information online were women, those younger than 65 years of age, college graduates, and those with broadband access at home. Drug information (both prescription and nonprescription) was sought by 37% of Internet users seeking health information.²⁵

Dependence on the Internet for self-care information can be problematic, given the lack of quality control, which in many instances compromises patients' welfare.²⁶ No single organiza-

tion is accountable for the quality or accuracy of health-related information available on Web sites.²⁷ The sheer number and diversity of Internet sources increase the likelihood that patients unknowingly view biased or outdated information. The Pew report concluded that “most internet users start at a search engine when looking for health information online and very few check the source and date of the information they find.”²⁵ Because many sites contain inadequate, outdated, or incomplete information, it is not safe to simply “surf” and self-medicate.²⁸ For example, one study that evaluated the suitability of written supplemental materials available on the Internet for nonprescription medications determined that most manufacturer-sponsored Web sites intended for consumers had information that scored poorly in the areas of reading level and use of uncommon words.²⁹

In response to public-safety concerns, the National Association of Boards of Pharmacy (NABP) has started to evaluate the credentials of online pharmacies (also known as e-pharmacies) through the Verified Internet Pharmacy Practice Sites (VIPPS) program.³⁰ The VIPPS program is voluntary, and an e-pharmacy must agree to strict conditions including NABP inspections to be certified under its auspices. Use of the VIPPS logo on Web pages confers credibility to each e-pharmacy that meets the NABP standards. As of December 2007, there were 15 VIPPS-approved Web site addresses in the United States.³¹ Although prescription medications are dispensed at all of these sites, some also sell nonprescription medications, nutritional dietary supplements, herbal products, and medical devices, in addition to providing “on site” medical/pharmaceutical information for patients.

Rx-to-OTC Switch

An Rx-to-OTC switch is defined as over-the-counter (OTC) marketing of a drug product that was once a prescription (Rx) drug for the same indication, with the same strength, dose, duration of use, dosage form, and route of administration.³² Pharmaceutical companies can benefit financially by requesting that FDA switch from prescription to nonprescription status a medication that is about to lose market share because of patent expiration and subsequent generic drug competition. The much longer period of sales generated as a nonprescription medication can offset the decreased revenue associated with the agent being a prescription medication in competition with generic entities. However, FDA has the final word in reclassifying a drug from prescription to nonprescription status. The Agency considers a medication for Rx-to-OTC switch if the following types of questions can be answered in the affirmative:

1. Can the patient adequately self-diagnose the clinical abnormality?
2. Can the clinically abnormal condition be successfully self-treated?
3. Is the self-treatment product safe and effective for consumer use, under conditions of actual use?

Since 1976 more than 80 ingredients, indications, or dosage strengths have been switched from prescription to nonprescription status, resulting in more than 700 nonprescription products on the market.³³ Table 1–2 shows examples of pharmaceuticals switched from prescription to nonprescription status between 2000 and 2007.³⁴

Consumers benefit from Rx-to-OTC switches because they broaden access to important medications. In addition, the nonprescription versions are more cost-effective for consumers

TABLE 1-2 Examples of Prescription-to-Nonprescription Switches, 2000–2007

Year of Approval	Ingredient	Brand Name	Use
2000	Ibuprofen	Motrin Migraine Pain	Migraine
2000	Ibuprofen	Advil Migraine Liqui-Gels	Migraine
2000	Famotidine, calcium carbonate, magnesium hydroxide	Pepcid Complete	Heartburn, acid indigestion
2001	Butenafine hydrochloride	Lotrimin Ultra	Athlete's foot, jock itch, ringworm
2002	Ibuprofen, pseudoephedrine	Children's Advil Cold	Cold symptoms
2002	Guaifenesin extended-release tablet	Mucinex	Loosens mucus
2002	Nicotine polacrilex	Commit	Smoking cessation
2002	Loratadine	Claritin	Allergy symptoms
2002	Loratadine, pseudoephedrine	Claritin-D	Allergy symptoms
2003	Omeprazole	Prilosec OTC	Acid reducer, heartburn
2003	Loratadine	Claritin	Hives relief
2005	Diphenhydramine, ibuprofen	Advil PM	Pain relief, sleep aid
2006	Ecamsule (combined with avobenzone and octocrylene)	Anthelios SX	Sunscreen
2006	Levonorgestrel	Plan B	Contraception
2006	Polyethylene glycol 3350	MiraLAX	Constipation
2006	Ketotifen	Zaditor	Itchy eyes
2007	Orlistat	alli	Weight loss aid
2007	Cetirizine	Zyrtec	Allergy symptoms
2007	Cetirizine, pseudoephedrine	Zyrtec-D	Allergy symptoms

Source: Reference 34.

and third-party insurers. One study estimated Rx-to-OTC switches have saved consumers \$13 billion and managed care organizations \$20 million.³⁵ Additional examples of the cost benefits of Rx-to-OTC switches include the following:

- A female patient can save as much as \$80 by using switched nonprescription vaginal antifungal products for recurring yeast infections, according to the American Pharmacists Association. A nonprescription drug can be obtained for less than \$20; however, a physician's visit and prescription-only vaginal antifungal drug can cost almost \$100. Savings can be even greater when indirect (e.g., travel, lost time from work) costs are considered.³⁶
- A survey found that consumers save up to \$750 million a year as a result of using nonprescription cough/cold medications that once were available only by prescription. The same study demonstrated that physician visits for the common cold dropped by 110,000 a year between 1976 and 1989.³⁶

The pharmacist is ideally situated to advise patients on appropriate choices of recently switched nonprescription medications. For example, in 1996 an entirely new nonprescription drug category called "smoking cessation aids" was created when Nicorette chewing gum, NicoDerm CQ transdermal patch, and Nicotrol transdermal patch were switched from prescription to nonprescription status. A 10-year review of the effect of nonprescription

nicotine replacement therapy (NRT) concluded "Studies over the decade of OTC nicotine replacement therapy (NRT) availability demonstrate that OTC availability increased access and utilization of treatment, while also demonstrating that the projected adverse effects of OTC switch have not materialized: OTC NRT is being used safely and effectively, without substantial misuse or abuse. . . ."³⁷

Behind-the-Counter (BTC) Medications

FDA is exploring whether to expand the use of a third drug class, which would be kept behind the pharmacy counter and require a pharmacist to dispense but without the need of a prescription. These behind-the-counter (BTC) medications are also sometimes referred to as "pharmacist only" or "Schedule 3" medications. This class of medications could provide patients greater access to medications that require safeguards for their use. Pharmacists could ensure appropriate drug selection while screening for potential drug-disease or drug-drug interactions. Examples of BTC medications already used in countries such as Canada and the United Kingdom include emergency contraception and simvastatin, a "statin" used to lower cholesterol.

One current example of a BTC medication in the United States is pseudoephedrine (PSE). Nonprescription pseudoephedrine is used to manufacture methamphetamine illicitly and has become a major public health concern. PSE-containing

products were moved behind the counter on the recommendation of the Drug Enforcement Administration to combat shoplifting and the sale of bulk quantities needed to manufacture methamphetamine. Consumers must show pharmacy staff photograph identification and sign a logbook when purchasing PSE-containing products. Quantities of PSE-containing products available for purchase are also limited. One report suggests that the BTC status of PSE-containing products is reducing their sales.³⁸ However, the report noted that it is unclear whether the decreased sales are related to the burden of having to request the BTC drug or to the reformulation of many products with phenylephrine, a decongestant that does not require BTC status.³⁸

Another example of making a nonprescription medication BTC is Plan B, an emergency contraceptive. In this instance, FDA wanted to ensure that Plan B was dispensed only to women 18 years or older so they placed it BTC. A pharmacist must verify the patient's age before this product can be sold. However, this requirement also places the pharmacist in the perfect situation to be able to counsel a patient about the proper use and potential side effects of the drug.

Despite the potential advantages, several strong lobbying groups oppose the expansion of BTC medications. Manufacturers of nonprescription medications oppose the creation of BTC medications, because it would reduce the number of retail outlets for their products and thereby reduce sales. Some grocery stores and other mass retailers without pharmacies that have traditionally sold nonprescription medications would be unable to sell BTC medications. The pharmaceutical manufacturers have stated that they can work with FDA and design the appropriate tools to address any challenges to a particular nonprescription medication without having to make it BTC.³³

Other groups opposed to BTC medications cite a 1995 U.S. Government Accounting Office (GAO) report "Nonprescription Drugs, Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated."³⁹ The GAO report gave several observations to support its conclusion, including: (1) while a pharmacy or pharmacist class is assumed by some to improve safeguards against drug misuse and abuse, in the 10 countries studied these safeguards were easily circumvented, and studies showed that pharmacist counseling was infrequent and incomplete; and (2) experience in Florida with a class of drugs similar to a BTC class had not been successful, because pharmacists did not regularly prescribe the drugs and record-keeping requirements were frequently not followed.

Self-Medication and the Safe Use of Nonprescription Drug Products

Informed, appropriate, and responsible use of nonprescription medications is crucial for effective self-medication. Casual or inappropriate use of nonprescription medications can lead to serious adverse effects (e.g., liver toxicity with prolonged intake of high doses of acetaminophen), drug-drug interactions, and indirect effects (e.g., from delay in seeking appropriate medical attention). Pharmacists can combat misuse of nonprescription medications through the following measures:

- Ensure that patients are able to read and understand product labeling.
- Help patients avoid drug interactions.
- Warn about potential allergic reactions and side effects.
- Discuss appropriate drug storage and handling.

Nonprescription Drug Labeling

The Omnibus Budget Reconciliation Act of 1990 mandates pharmacists to "offer to counsel" on the prescription medications they dispense. However, nonprescription medications are exempted from this provision. Therefore, it is also up to the consumer to seek information from the pharmacist when they have a question. In the absence of this verbal consultation, the consumer must understand what is written on the product label to ensure proper use.

To assist consumers with reading of product labels, FDA has mandated use of a standard label format for each of the product categories, namely, herbals, dietary supplements, and nonprescription medications.⁴⁰ The standard product label for nonprescription medications, titled "Drug Facts," has specific sections for active ingredients, uses, warnings, when to use the product, directions, and inactive ingredients (see Chapter 4). The new label was designed to be easy to read, with all relevant information about taking the drug appearing in the same sequence on all package labels. This consistency in labeling enables patients to find information in a familiar spot on the label regardless of the use for the product (e.g., pain, cough/cold, and diarrhea). Initiated in 2002, the "Drug Facts" label has been on all nonprescription medications since May 15, 2005.

NCPIE commissioned a survey to determine if the "Drug Facts" label has helped to promote the message that nonprescription medications must be taken with care.³ Results of this survey include the following:

- As for reading the label: 44% looked for the active ingredient, 20% read about possible side effects, and 8% read nothing on the label.
- As for following the dosing recommendations: 48% of respondents confided that, if needed to increase product effectiveness, they would take more than the recommended dose by either taking the next dose sooner than directed (35%), taking more than the recommended amount at a single time (32%), or taking the medication more times during the day than recommended (18%).
- Practitioners cited nonprescription medications being used incorrectly in the following ways: combining nonprescription and prescription medications (51%), chronic use of a nonprescription medication (44%), using a nonprescription drug for a prescription indication (32%), and taking more than one nonprescription product with the same active ingredient (27%).

The likelihood of inappropriate nonprescription drug use resulting from misreading of product labels increases when patients have limited reading skills or language barriers. The National Adult Literacy Survey found that nearly 44 million Americans cannot read and write, and 90 million adults have difficulty understanding information related to health care.⁴¹ Effects of health illiteracy are particularly profound for Medicaid recipients, 90% of whom have reading skills at the fifth-grade level. Such a low level of literacy could be expected to adversely affect health care in patients using nonprescription medications, because a ninth-grade reading level is required to comprehend most nonprescription drug labels.⁴² Other factors that can impair a consumer's ability to read nonprescription drug labeling include the size of type and price or antitheft tags improperly placed over critical information.^{43,44}

Despite literacy concerns many studies have concluded that nonprescription medications are being used safely. For example, appropriate use of nonprescription medications such as topical steroids (hydrocortisone),⁴⁵ proton pump inhibitors (omeprazole),⁴⁶ and NRT³⁷ has been documented. Nevertheless, in January 2008 FDA began warning consumers to avoid treating children younger than 2 years with nonprescription cough and cold products because of an increased risk of overdose requiring emergency medical treatment. FDA cited studies that estimated that during a 2-year period, 1519 children younger than 2 years were admitted to emergency departments (EDs) for evaluation after known or possible exposure to cough/cold products. Of these incidents, it was noted that a large percentage of ED visits were related to inappropriate dosing and inappropriate use of the drug based on its labeling. Pharmacists can take a prominent role in ensuring the safe use of cough/cold medications in children by counseling parents to (1) carefully determine their child's dose according to weight not age, (2) avoid mistakenly duplicating ingredients if giving multi-ingredient products (e.g., adding a dose of Tylenol after administering a cough/cold medication that contains acetaminophen), and (3) use the provided dosing device correctly to measure the amount needed.

Nonprescription Drug Product Reformulation

Reformulation of nonprescription drug products is sometimes initiated by FDA because of safety or efficacy concerns. For example, Kaopectate is a brand-name antidiarrheal product that has been on the market for many years and has strong name recognition. The name "Kaopectate" was originally derived from its active ingredients kaolin and pectin. However, in 1992 it was reformulated with attapulgite, because FDA banned the use of pectin in nonprescription products because of insufficient data about its safety and efficacy. The product was reformulated again in 2003 to contain bismuth subsalicylate given that all attapulgite-containing medications were discontinued.

Confusion and misuse can occur when a nonprescription drug product is reformulated to contain different active ingredient(s) but does not change its brand name. Although reformulated products may be labeled as being "new and improved," there may be no indication that the active ingredient in a product is entirely different. Again using Kaopectate as an example, the product prior to its reformulation in 2003 could be used in children and had pediatric dosing instructions on the label. However, in 2004, the FDA ruled that antidiarrheals containing bismuth subsalicylate could be labeled for use by only adults and children 12 years and older. Therefore, the most recent version of the Kaopectate label does not include pediatric dosing information. As a result of all these formulation changes, there was a time in 2004 when consumers were faced with three different bottles labeled "Kaopectate": one containing attapulgite, one with bismuth subsalicylate and pediatric dosing information, and a third with bismuth subsalicylate and no pediatric dosing information. In addition, patients with aspirin or salicylate allergies who may have previously taken the old formulation of Kaopectate should not take the new version because it contains bismuth subsalicylate. A potentially serious adverse reaction could occur in a patient who does not carefully recheck the label of a "new and improved" product that they have used safely in the past.

It is also important to note that drug manufacturers can reformulate products for their own reasons. Changes to PSE-containing products are an example of a drug manufacturer-driven product reformulation. When the government restricted the sale of PSE-containing products to BTC status, many large pharmaceutical companies rushed to reformulate their brand-name products to contain a different decongestant, phenylephrine, which was not restricted. In most cases the brand names of these products did not change. This therapeutic switch was not because of safety or efficacy concerns but because of fears that BTC restrictions would decrease sales. In fact, phenylephrine prior to the reformulation was not used widely because of its limited effectiveness. Moreover, there have been recent reports questioning phenylephrine's efficacy at its FDA-approved adult dose of 10 mg, including a letter published in the *Journal of Allergy and Clinical Immunology*, which concluded that there is "virtually no evidence to show that phenylephrine oral nasal decongestants at the FDA-sanctioned dose of 10 mg are effective."⁴⁷ FDA has been subsequently petitioned to review dosing guidelines toward establishing a more effective 25 mg dose (FDA Docket #2007P-0047; www.fda.gov/ohrms/dockets).

Drug Interactions

The risk for drug interactions increases as consumers use more nonprescription medications, many of which have active ingredients that interact with the human body in different ways in a few individuals. In addition, diet and lifestyle can have a considerable effect on a medication's ability to work in the body. Certain foods, beverages (e.g., grapefruit juice), alcohol, caffeine, and even cigarette smoking can interact with medications. These interactions may make the medications less effective or may cause dangerous side effects or other therapeutic problems. For example, one study concluded that older adults were unaware of the adverse risks associated with concurrent use of nonprescription pain medications, alcohol, high blood pressure medications, and regular caffeine use, and that health care practitioners need to increase their educational efforts.⁴⁸ To avoid drug interactions, patients should consult pharmacists when first selecting herbal products, nutritional dietary supplements, or nonprescription medications. Table 1-3 lists some commonly used nonprescription medications and their interactions with food, alcohol, certain disease conditions, and other nonprescription medications.

Allergies to Active or Inactive/Inert Ingredients

Although the likelihood is low, any medicine can cause an allergic reaction. For example, allergic reactions have occurred in patients taking common nonprescription pain relievers such as aspirin, ibuprofen, naproxen, and ketoprofen. Patients should always be counseled about the signs and symptoms of an allergic reaction (itching, hives, and trouble breathing) and instructed to seek medical care immediately. Allergic reactions and side effects are caused by active ingredients and can also involve inactive ingredients. Inactive ingredients in nonprescription medications—such as binders, disintegrants, fillers, and preservatives—can cause reactions in a few individuals. Therefore, for safety reasons, FDA requires inactive ingredients to also be listed on the label. Table 1-4 lists some of the common inactive ingredients used in drug formulations and their known adverse effects.

TABLE 1-3 Potential Interactions with Selected Nonprescription Drugs

Drug–Drug Interactions

Drug	Drug	Potential Adverse Effect
Aluminum-containing antacids	Ascorbic acid	Decreased aluminum absorption
Aspirin	Products containing aluminum, calcium, or magnesium	Decreased blood aspirin concentration by increasing aspirin elimination
Iron	Products containing aluminum, calcium, or magnesium	Decreased iron absorption
Mineral oil	Docusate	Increased mineral oil absorption
Psyllium	Antidiabetic agents (metformin)	Decreased metformin absorption

Drug–Food/Beverage Interaction

OTC Drug	Food/Beverage	Potential Adverse Effect
Acetaminophen	Garlic	Delayed acetaminophen absorption
Aspirin	Garlic	Increased risk of bleeding
Calcium	Oxalic acid foods (spinach, rhubarb); phytic acid foods (bran/whole-grain cereal)	Altered calcium absorption
Zinc	Caffeine; dairy products (milk)	Decreased zinc absorption

Drug–Disease Interactions

OTC Drug	Condition	Mechanism
Aspirin	Hyperuricemia	Decreased renal excretion of uric acid
Doxylamine succinate, phenylephrine HCl	Glaucoma	Obstructed aqueous outflow
Naproxen, ketoprofen	Peptic ulcer disease	Altered gastric mucosal barrier
Pheniramine maleate, naphazoline HCl, nicotine	Hypertension	Increased vascular resistance

Drug–Alcohol Interactions

OTC Drug	Potential Adverse Effect	Mechanism
Aspirin	Increased gastrointestinal blood loss	Prolongs bleeding time
Diphenhydramine HCl	Increased sedation	Depresses central nervous system
Insulin	Increased hypoglycemia	Decreases hepatic gluconeogenesis
Ketoconazole (topical)	Vomiting, tachycardia	Causes disulfiram-like reaction
Yohimbine	Increased blood pressure	Increases norepinephrine level

Source: Wolters Kluwer Health. *Facts & Comparisons 4.0*. Available at: <http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&q=->. Last accessed July 28, 2008.

Handling and Storage of Nonprescription Medications

For a consumer to benefit from using a nonprescription medication, it must have the potency stated on its label. Consumers reasonably assume that, because nonprescription drug products are under the aegis of the FDA, they are pure and have their stated potency. Although this is usually the case, recalls of nonprescription medications because of impurity, contamination, or incorrect potency can occur. Some “out of the ordinary” clues that should arouse suspicion before one uses a nonprescription prod-

uct include abnormal odors, color changes, texture differences, and abnormal shape of a solid dosage form. Consumers should avoid taking any drug product they suspect is bad. Pharmacists should also actively remove any recalled drug product from their shelves and post notices informing patients of the recall and what action they should take.

Before any product is used, consumers should check the expiration date that appears on the product label. However, health care providers should be aware that there is a lot of conflicting information for consumers about the real meaning of a drug prod-

TABLE 1-4 Adverse Effects of Some Inactive Ingredients Used in Drug Preparations

Inactive Ingredient	Use	Where Found	Adverse Events
Aspartame	Sweetener	Liquid sucrose-free preparations	Headaches, hallucinations, panic attacks
Benzalkonium chloride	Preservative	Anti-asthmatic drugs, nasal decongestants	Airway constriction
Benzyl alcohol	Preservative	Liquid preparations	Neonatal deaths, severe respiratory and metabolic complications
Lactose	Filler	Capsules and tablets	Diarrhea, dehydration, cramping
Propylene glycol	Solubilizes drugs	Liquid preparations	Respiratory problems, irregular heartbeat, low blood pressure, seizure, skin rashes
Saccharin	Sweetener	Liquid preparations	Cross-sensitivity with sulfonamides, dermatologic reactions, pruritus
Sulfites	Antioxidant	Anti-asthmatic drugs; anti-inflammatories	Wheezing, breathing difficulties
Yellow tartrazine	Coloring agent	Solid/liquid preparations	Allergic reaction similar to that of aspirin

Source: Wolters Kluwer Health. *Facts & Comparisons 4.0*. Available at: <http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&q=>. Last accessed July 28, 2008.

uct expiration date. Many publications including *Consumer Reports* and the *Wall Street Journal* have published articles stating that many drug products are still potent for a long time after their expiration date.⁴⁹ These articles suggest that expiration dates may be shortened by drug manufacturers for the purpose of increasing sales. Pharmacists should help patients understand that after the expiration date, the product is no longer under the manufacturer's "warranty" and that the product "may" no longer work.

To retain its potency, a drug must be stored properly. Prescription and nonprescription medications are often mistakenly stored in bathroom cabinets, usually above the sink. Humidity and heat from the shower and sink are easily trapped in the cabinet, accelerating the degradation of the medications, even if they are in a prescription vial or bottle. Consumers need to be aware that all medications should be stored away from high humidity in a cool, dark place to ensure that they retain their potency and effectiveness. Furthermore, all medications should be stored a sufficient distance from the ground to ensure that they are kept out of a child's reach. This precaution is especially important for the many nonprescription medications that are not packaged in child-resistant containers. Examples of nonprescription product packaging that is not childproof include blister packs, lozenges, topical creams or ointments, spray canisters, and bulk powder containers (e.g., laxatives). Table 1-5 lists some nonprescription medications and health care products, with storage recommendations, generally kept on hand to treat minor ailments or injuries. It is a good practice to encourage patients to check product expiration dates and purge medicine cabinets at least once every 6 months.

Pharmacists' Role in Nonprescription Drug Therapy

The public's ability to discern critical information about the condition being treated and the clinical risk–benefit of a nonprescription drug is highly variable. The array of product choices; line extensions; and overstated, vague, or misleading marketing messages lead to consumer confusion. Generally package labeling is limited in the breadth and depth of the message it communicates;

it can never address the informational needs of all patients. Therefore, the pharmacist–patient interaction is vital for ensuring optimal nonprescription drug therapy. In 2007, *U.S. Pharmacist* published survey results of pharmacists (41.4% chain store, 34.4% independent retail) about their roles in counseling on nonprescription medications.⁵⁰ More than 90% of pharmacists surveyed stated that they have an active role in counseling patients on nonprescription medications, with more than 40% recommending 6 to 10 products per day. Table 1-6 shows how pharmacists ranked the importance of various counseling topics. Pharmacists clearly feel

TABLE 1-5 Recommended Storage Places of Selected Nonprescription Health Care Products

Closet/Kitchen Cabinet or Shelf	Bathroom Medicine Cabinet
Analgesics (relieve pain)	Adhesive bandages
Antacids (relieve upset stomach)	Adhesive tape
Antibiotic ointments (reduce risk of infection)	Alcohol wipes
Antihistamines (relieve allergy symptoms)	Calibrated measuring spoon
Antipyretics (reduce fever; adult and child formulations)	Dental floss
Antiseptics (help prevent infection)	Disinfectant
Decongestants (relieve stuffy nose and cold)	Gauze pads
Hydrocortisone (relieves itching and inflammation)	Thermometer

Source: Adapted from Lewis C. Your medicine cabinet needs an annual checkup, too. *FDA Consum.* 2000;34(2):25–8.

TABLE 1-6 Pharmacist Ranking of Nonprescription Drug Counseling Topics**Survey Question**

"Which of the following counseling topics are most important when discussing OTC-related products with patients?"

**Average Rank
(1 = highest importance;
5 = lowest importance)**

Selection of right product	1.5
Rx-to-OTC drug interactions	2.5
Side effects/adverse reactions	3.0
Directions/instructions	3.0
Cost	4.4

Source: Reference 50.

that their main service is to help patients select the most appropriate drug for their condition while avoiding drug interactions.

The underlying goal of pharmacists' counseling is to ensure that the patient gets correct, practical information and understands it in the context of the ailment being treated. Validation of the patient's understanding is also critically important. The pharmacist should always encourage the patient to ask questions and learn more. In the initial encounter with a patient who is seeking assistance with nonprescription medications, the pharmacist should:

- Assess, by interview and observation, the patient's physical complaint/symptoms and medical condition (see Chapter 2).
- Differentiate self-treatable conditions from those requiring a primary care provider's intervention.
- Advise and counsel the patient on the proper course of action (i.e., no drug treatment, self-treatment with nonprescription medications, or referral to a primary care provider or other health care provider).
- Advise the patient on the outcome of the selected course of action.
- Assure the patient that the desired therapeutic outcome can be achieved if nonprescription medications are taken as directed on the label and/or recommended by the physician/pharmacist.
- Reinforce the concept that the pharmacist and physician are qualified to perform follow-up assessment of the treatment.

If self-care with nonprescription medications is in the best interest of the patient, then pharmacists can help in the following ways:

- Assist in product selection.
- Assess patient risk factors (e.g., contraindications, warnings, precautions, comorbidities, age, and organ function).
- Counsel the patient about proper drug use (e.g., dosage, administration technique, monitoring parameters, and duration of self-therapy).
- Maintain an accurate patient drug profile that includes prescription, nonprescription, and herbal/dietary supplement products.

- Assess the potential of nonprescription medications to mask symptoms of a more serious condition.
- Prevent delays in seeking appropriate medical attention.

Key Points for Self-Care and Nonprescription Pharmacotherapy

- Self-care will play an increasingly important role in health care, and self-medication represents a significant element in the self-care process.
- Nonprescription medications are used by millions of Americans each year, because they offer safe and effective relief for a variety of common health care ailments.
- Health care professionals and FDA agree that nonprescription medications, although safe and effective, bear some risks associated with patients not reading and closely following the label instructions when taking the medications.
- Patients, manufacturers, governmental agencies, and, particularly, pharmacists should become even more intent on recognizing that each group fulfills essential functions in ensuring the safe, appropriate, effective, and economical use of nonprescription medications.

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Patient Assessment and Consultation

Lawrence M. Brown and Brian J. Isetts

The development of viable pharmaceutical care business models is helping pharmacists to respond more effectively to the drug-related needs of patients. One important development relates to the use of a clearly defined patient care process to fulfill a patient's self-care needs. In addition, decisions made by pharmacists, who function to identify, resolve, and prevent drug therapy problems, are valid, or clinically credible, as judged by panels of physicians and pharmaceutical care practitioners. This chapter describes the consistent and systematic process used to meet the drug-related needs of patients with self-care concerns.

The patient care process pertaining to medication therapy management includes assessment, care planning, and evaluation and follow-up. Assessment represents the first set of clinical judgments made by a practitioner when caring for a patient. The purpose of assessment is to determine, describe, and define the patient's drug-related needs, including the goals of therapy and identification of drug therapy problems that the patient may be experiencing. Assessment provides the practitioner with a basis for consulting with a patient to decide which of the patient's drug therapy problems the practitioner will help resolve. A care plan is a detailed schedule of responsibilities for achieving treatment goals and for resolving and preventing drug therapy problems, whereas follow-up evaluation represents an accounting of actual patient outcomes.

Patients expect pharmacists to assist them with many health care concerns and to help them interpret treatment options within the health care delivery system. This chapter is divided into six sections:

1. A brief review of the demands for self-care.
2. An introduction to the consistent and systematic patient care process used by practitioners when assuming responsibility for a patient's drug-related needs.
3. A description of the rational and ordered process for conducting an assessment, developing a care plan, and completing a follow-up evaluation of a patient's drug-related needs.
4. A discussion of the skills required by pharmacists to care for patients with self-care needs.
5. A summary of special considerations when caring for selected high-risk and special patient populations (infants and children, persons of advanced age, and pregnant and breast-feeding women).
6. Key points for integrating these principles into pharmacy practice.

Because the federal government and the medical profession have helped to clarify the relationship of "medication therapy management services" (MTMS) provided within the practice of pharmaceutical care, there is commonality in the use of these terms in this chapter. The term MTMS first appeared in federal legislation introduced, but not passed, in the late 1990s, proposing to compensate pharmacists for pharmaceutical care services. Throughout this chapter a case-based format is used to demonstrate how a pharmacist can apply this information to the care of patients with self-care needs.

Demand for Self-Care

The U.S. health care system is dynamic and marked by rapid change. Access, cost, and quality of health care are debated extensively at a public policy level. Our complicated, diverse, and fractionated health care system can leave consumers frustrated when confronted with personal health care concerns. Fortunately, patients have come to trust and depend on their pharmacists when faced with their own personal health care needs.

Pharmacists, who are often on the front line of the health care delivery system, are called on to help patients evaluate therapeutic options. In most cases, the pharmacist can help patients by (1) recommending no treatment at all, (2) recommending self-care therapy, or (3) referring patients to other health care providers. Several chapters in this book contain information and tables on exclusions for self-care treatment that pharmacists may find helpful in deciding when to refer patients to other health care providers. In addition, issues relating to special populations such as infants and young children, persons of advanced age, and pregnant or breast-feeding women are also addressed in this text.

Self-care, self-diagnosis, and self-medication are important components of the health care system in the United States. Instead of seeking the advice of a medical care provider, many people self-diagnose and treat their symptoms using a vast array of self-care options, ranging from nonprescription medications, herbal products, and home remedies to yoga, meditation, and spiritual healing, among others. Survey data show that about 80% of Americans who have conditions that can be treated with nonprescription medications use self-care for those conditions.¹ Nonprescription medications allow individuals to manage their many medical problems rapidly, economically, and conveniently, and may prevent unnecessary visits to a primary care provider or specialist. Patients often believe that products that move from

prescription to nonprescription status are more effective than other nonprescription medications, and 87% of Americans believe that nonprescription medications are safe when used as directed.² The demand for and shift toward self-medication are further described and documented in Chapter 1.

The appropriate use of a nonprescription product, like the use of any other medication, requires attention to the intended use, effectiveness, safety, and convenience of administration. Although warnings are required on the labels of such products, labeling alone may be inadequate, and the patient may need assistance in selecting and properly using nonprescription medications. Inappropriate use and misuse of nonprescription medications can increase the risk of drug misadventures,³ resulting in increased health care costs and more serious illness. Therefore, the pharmacist's role is crucial in assessing a patient's need for nonprescription medications.

The magnitude of drug misadventures, or drug therapy problems, has been described in terms of drug-related morbidity and mortality.^{4,5} In addition, one category of drug therapy problems, referred to as medication safety, has received extensive national attention in reports such as those issued through the Institute of Medicine and the work of organizations such as the Institute for Safe Medication Practices. From 1995 to 2000, the cost of drug therapy problems more than doubled.⁵ Drug therapy problems are defined as any aspect of a patient's drug therapy that is interfering with a desired, positive therapeutic outcome.⁶ A patient who requires a nonprescription medication pursuant to a self-care consultation with a pharmacist is experiencing a drug therapy problem, because he or she has an untreated medical condition and requires the intervention of a pharmacist. A pharmacist's interpretation that use of a nonprescription product can help the patient achieve a desired therapeutic outcome is an intervention intended to resolve the patient's drug therapy problem (i.e., the patient needs additional drug therapy). In addition, it is noted that 23% of all drug therapy problems involve one or more nonprescription drug products, either as the cause of the drug therapy problem or in its resolution.⁶

Many patients do not appreciate, or are not aware of, the need for professional assistance in selecting nonprescription medications. The presence of a pharmacist differentiates the nonprescription drug department in a pharmacy from a similar department in a nonpharmacy outlet. To better serve patients, pharmacists need to maximize the personal service they offer. Patient inquiries should be referred to pharmacists, who must actively promote the value of their guidance in selecting and monitoring treatment with a nonprescription medication. It is essential to increase a patient's awareness of the importance of consulting a pharmacist, not only when considering a medication for the first time but also when making subsequent purchases.

A patient's primary patronage motive, or choice of pharmacy, is convenience, followed by price and service.⁷ A random-sample telephone interview survey of 1009 adults found that 80% of Americans purchase specific OTC products on the basis of what their pharmacist recommends. Nevertheless, only 43% of those interviewed seek information from a pharmacist about treatment before they buy an OTC product.¹

The principles of pharmaceutical care are available to help practitioners more effectively address the self-care needs of patients. A consistent and systematic patient care process helps practitioners to be complete and concise when assuming responsibility for a patient's self-care needs. In addition, the use of the systematic patient care process is important in obtaining compensation for the pharmacist's care.

Introduction to MTMS Provided within the Practice of Pharmaceutical Care

The profession of pharmacy has recently achieved two important goals: recognition of pharmacists as health care practitioners, and inclusion of pharmacists' services within the authoritative health care reporting and billing system. The two federal laws significantly affecting pharmacist practitioner classification are HIPAA⁸ and the Medicare Modernization Act.⁹ These two laws helped the profession of pharmacy work with the American Medical Association (AMA) and the Centers for Medicare & Medicaid Services (CMS) to establish pharmacists' professional service billing codes described in *Current Procedural Terminology* (i.e., CPT codes) and to include pharmacies as a "Place of Service" in the *CPT Manual*.¹⁰ The significance of these new developments to the care delivered by pharmacists is highlighted throughout this chapter.

Evidence of the effectiveness and safety of MTMS contained in the original CPT code proposal was derived from literature on the practice of pharmaceutical care. The detailed CPT reference guide description of MTMS reflects this literature by describing the service as face-to-face patient assessment and intervention to identify and resolve drug therapy problems; formulating a medication treatment plan to optimize the response to medications and achieve patients' goals of therapy, and monitoring and evaluating patient outcomes of therapy.¹¹ The relationship of MTMS as a distinct procedure provided within the practice of pharmaceutical care was included in this body of evidence.^{12,13}

The practice of pharmaceutical care has fulfilled an unmet need in the health care delivery system by providing a systematic approach for consistently achieving intended drug therapy treatment goals while avoiding adverse, unintended, and ineffective medication consequences. In addition, pharmaceutical care has clarified the responsibilities of pharmacists as health care practitioners, and defined the relationship between the profession and society.¹⁴ Now that pharmacists are officially classified as health care practitioners eligible for patient care compensation, the principles of pharmaceutical care will be important to the growing number of pharmacists who are building and expanding patient care practices.

The established characteristics of a pharmaceutical care practice were based on the rules governing the conduct of other professional practices. A practice may be viewed as the application of knowledge—guided by a commonly held social purpose—to the resolution of specific problems in a standard manner accepted and recognized by society. The definition of a pharmaceutical care practice, developed through analysis of other professional practices, is "a practice in which the practitioner takes responsibility for all of a patient's drug-related needs and is held accountable for this commitment."⁶ The clinical and economic outcomes of MTMS provided within the practice of pharmaceutical care have been summarized previously.¹⁵

The goal when assuming responsibility for a patient's drug-related needs is to help the patient achieve the intended therapeutic goals and ensure a positive outcome. A standard problem-solving process, originally termed the "Pharmacist's Workup of Drug Therapy" and now referred to as the "Pharmacotherapy Workup," was developed to help pharmacists systematically address all of a patient's drug-related needs.⁶ This standard problem-solving process is designed to move the pharmacist through an ordered sequence of decisions related to the intended use, effectiveness, safety, and convenience of use of

the patient's drug therapies. The purpose of defining a common patient care process is to accomplish positive patient care objectives, not to constrain the freedoms or decisions of individual practitioners.¹⁶

Pharmacists must use a systematic, comprehensive, and efficient process to take responsibility for a patient's drug-related needs. To meet this objective, the patient care process involves the following three major steps⁶:

1. Assess, or systematically review, the patient's drug-related needs, including identifying any and all drug therapy problems.
2. Create a care plan or detailed schedule that outlines both the practitioner's and the patient's activities and responsibilities, and that is designed to resolve any drug therapy problems and achieve treatment goals, and to prevent any potential drug therapy problems.
3. Evaluate the patient's outcome and current status at planned follow-up intervals.

The care plan and evaluation provide the accountability and results that are often lacking in the health care delivery system. The following section focuses on conducting an assessment of a patient's drug-related needs, with an emphasis on assessing the drug-related needs of patients who present with self-care concerns.

Assessment of a Patient's Drug-Related Needs

Identifying drug therapy problems is a primary clinical decision made by the practitioner. From a consumer perspective, pharmaceutical care is a new and emerging concept. Patients are now seeking the personal attention of a trusted professional to help them achieve drug therapy treatment goals, while avoiding or minimizing the adverse consequences of taking medications. The rational and ordered process for conducting an assessment helps the pharmacist—functioning as a health care practitioner—maintain a disciplined approach when confronted with this changing societal demand. Assessing all of a patient's drug-related needs comprises a variety of actions including taking a history, obtaining information, and collecting data.

Before presenting specific examples of how to use the information presented in this chapter, it is important to discuss the realities of providing self-care consultations during the course of a typical day for a pharmacist working in the dispensing business of a pharmacy, compared with consulting with a patient in a practice that receives reimbursement through the patient care business of a pharmacy. Obviously, pharmacists who are asked to conduct a self-care consultation while fulfilling prescription dispensing responsibilities will have less time to devote to working with the patient than pharmacists who are working in the patient care business. For those pharmacists who have not yet worked in the patient care business of a pharmacy, it is important to point out that there are a number of proven strategies and approaches for starting a patient care business in relationship to a pharmacy's traditional prescription-dispensing business. Payment for the provision of MTMS provided within the practice of pharmaceutical care is a reality, and pharmacists who desire a future focused on working in a pharmacy's patient care business can now seek out these employment opportunities.

Skills Necessary to Care for Patients with Self-Care Needs

Advising patients on self-treatment is an important part of a pharmacist's professional responsibilities. When pharmacists use a standard care process to address a patient's self-care needs, they serve in the role of a primary care practitioner. Often the pharmacist is a patient's first contact with the health care system, and the pharmacist can evaluate the situation and recommend a course of action. This role may include recommending a nonprescription medication, dissuading patients from buying a medication when drug therapy is not indicated, recommending a nondrug treatment, or referring patients to another health care practitioner. If the pharmacist deters healthy people from using more costly health care services or products and refers more seriously ill patients to other primary care providers, health care delivery in the United States can be improved and health care resources can be conserved.

The following case study, presented in five parts, illustrates a few important pharmacotherapy assessment skills necessary to care for patients with self-care needs.

PATIENT-PHARMACIST CONSULTATION

General Patient Presentation

Mrs. E.J. is a 66-year-old female patient in good medical condition taking three prescription medications (lisinopril, atenolol, and lovastatin) to manage two chronic medical conditions (hypertension and dyslipidemia). Mrs. E.J.'s primary concern relates to the fact that she has been finding it a little more difficult to initiate a bowel movement.

Regardless of whether a pharmacist is working in a busy dispensing pharmacy or caring for patients during scheduled appointments, working with patients to identify their drug-related needs is at the center of the pharmacist's communication process during interaction with patients. Drug-related needs are defined as those health care needs of a patient that have some relationship to drug therapy and for which the practitioner is able to offer professional assistance.⁶ Patients will tell their story or present a picture (e.g., "When I urinate, I feel as though I am going to pass out") in a random fashion. It is the pharmacist's job to interpret a patient's explicit and implicit drug-related needs. This skill is somewhat analogous to throwing a deck of cards into the air and reassembling the deck according to suits.

In the case of Mrs. E.J., the pharmacist will listen to the patient's concerns to ascertain the nature and extent of her problem. The pharmacist will also want to know the patient's current medications to determine whether the condition may be caused by a medication and to select a product appropriate for the patient. The pharmacist will then move forward to assess all of the patient's current medications, supplements, and remedies for indication, effectiveness, safety, and convenience of use. Proceeding systematically in this order is critical to avoid missing an important piece of information or jumping to an erroneous conclusion. Patients express their drug-related needs as understanding (or sometimes as a lack of understanding), expectations, concerns, and behavior (nonadherence). The pharmacist translates a patient's expression of drug-related needs into an assessment of drug therapy problems.

PATIENT-PHARMACIST CONSULTATION

Translation of Patient Concerns into an Assessment of Drug Therapy Problems

Mrs. E.J.'s primary concern relates to the fact that she has been finding it a little more difficult to initiate a bowel movement. She informs you that she doesn't want anything too strong because a friend of hers became, "dependent on laxatives." The pharmacist also finds out that the patient has not started any new medications within the last 6 months and has not had any changes in her diet. A decision is made to start Mrs. E.J. on the stool softener docusate 100 mg once daily for 1 week. This patient's primary concern has been translated into a need for additional drug therapy.

A final determination of drug therapy problems is conducted in consultation and agreement with the patient. Pharmacists cannot force their will on patients. A therapeutic relationship is a partnership between the practitioner and the patient, formed for the purpose of identifying the patient's drug-related needs.⁶ When pharmacists care for patients using this systematic process, physicians and pharmaceutical care practitioners have been found to agree with 94.2% of all the pharmacists' clinical decisions made to identify, resolve, and prevent drug therapy problems, and to achieve intended drug therapy treatment goals.¹²

Communication

Interactions by pharmacists through consultation and effective assessment strategies can enhance patient outcomes. Patients' expression of their drug-related needs is one of the most important sources of information pharmacists need to provide pharmaceutical care services related to nonprescription medications. Each step of the patient care process involves communicating with the patient, gathering information from the patient, and transmitting information back to the patient. This process is particularly important during the assessment step, because these data form the basis for the care plan and subsequent follow-up evaluation.

Interaction between the pharmacist and the patient establishes a therapeutic relationship, or an alliance, needed to identify the patient's drug-related needs. It is characterized by trust, empathy, respect, authenticity, and responsiveness. This relationship allows the pharmacist to gather detailed, sometimes intimate, information from patients. In return, patients rely on the pharmacist to use knowledge, skills, and experience to ensure safe and effective drug therapy. Scheduled patient follow-up and reassessment are vital components of this therapeutic relationship and are used to determine actual patient outcomes and progress toward meeting therapeutic objectives. These components allow a pharmacist to reassess whether a patient is experiencing drug therapy problems. In the case of Mrs. E.J., the goal of therapy is a return to the patient's normal bowel movement pattern within 1 week.

The patient-pharmacist relationship is dynamically affected by numerous variables. A positive interaction one day could be followed by a negative interaction a few days later for reasons unrelated to the pharmacist's care. The pharmacist must become adept at interpreting nonverbal cues (e.g., facial expression or body position), as well as at responding to voice tones, inflection, and mood.¹⁷ If a patient has a drug-related need but does

not have the time or inclination to discuss it during a particular encounter, the pharmacist should schedule an alternative time to gather additional information to assess the patient's drug-related needs and determine an appropriate intervention. The potential severity of a drug therapy problem will dictate the timetable for these actions.

General Principles of Communication

To establish an effective therapeutic relationship with the patient, the pharmacist must be capable of demonstrating empathy to objectively identify with the patient's affective state.¹⁸ Because the pharmacist's underlying attitude toward the patient will influence the quality of communication, the pharmacist must eliminate barriers by avoiding biases toward a patient's level of education, socioeconomic or cultural background, interests, or attitudes. In addition, the pharmacist must assure patients that any information they discuss will be kept in strict confidence.

A first step in a patient encounter is to assess what the patient already knows and determine where gaps in knowledge exist. This step is important because patients may resent being told what they already know and may be confused if the pharmacist wrongly assumes that they understand more than they do. When interacting with patients, the pharmacist should use words that a layperson can understand.

Effective communication occurs when the receiver of a message hears and understands exactly what the sender wants to communicate. One way to ensure understanding is through active listening, a process in which the receiver repeats the information to the sender. As information is exchanged, the participants change roles as receivers and senders of information. The message received is influenced by its content and context, as well as by how it is sent. Communications can be improved by paying attention to the interaction between sender and receiver.

Effective Questioning

Skillful questioning is a mark of a good communicator. Patients should feel that the pharmacist's questions convey a genuine interest in them and a desire to help. Because a patient may be uncooperative if the questions suggest only superficial curiosity, the pharmacist should explain the reason for asking personal questions (e.g., "I want to obtain additional information so I can determine if a nonprescription medication will help treat your specific problem"). It is important to avoid interrupting, or cutting off the patient in the middle of a response, which can occur when thinking ahead to the next question without adequately processing the current response.

When the pharmacist is unfamiliar with the patient, he or she should start the patient encounter by stating, "My name is _____, and I'm the pharmacist." The pharmacist should begin the exchange with an open-ended query such as, "How may I help you?" or "Would you please tell me more about the symptoms/problems you have?" Such valuable open-ended queries allow for increased flexibility and provide greater information than will questions that can be answered with only a yes or no response. Such open-ended queries enable a good practitioner to collect information efficiently and to establish better communications. If a patient's response wanders, however, the pharmacist must keep the interaction focused. To be sure that a patient understands dosage instructions, the pharmacist could ask, "So I know that I haven't forgotten to tell you anything, would you please tell me how you plan to take this medicine?"

Summarizing the important points or redirecting the interaction with a closed-ended question is useful. A question such as “How long have you had this pain?” may help the pharmacist gather specific information or clarify information obtained through earlier open-ended questions. It is important to ask one question at a time; asking two questions in rapid succession or multiple-choice questions will cause confusion and restrict communication. It is also important to avoid leading questions or judgmental questions such as “You don’t smoke, do you?”

Effective Listening

Effective listening is a vital component of communication. When the pharmacist really listens, patients are free to state their problem completely and are assured of receiving the pharmacist’s undivided attention. The pharmacist must focus on the patient and exclude distractions such as a telephone or a computer screen. The pharmacist may need to clarify the details of a patient’s problem and should be receptive to a patient’s response to questions. The pharmacist should respond with empathy, perhaps by paraphrasing a patient’s words or by reflecting on what was said in terms of the patient’s own experience. For instance, after listening to a complaint of pain, the pharmacist could say, “You have a sharp, stabbing pain in your wrist; is that right?” and end with a statement such as “That must be very uncomfortable.” Interrupting or demonstrating lack of interest or disapproval may inhibit a patient’s discussion of problems and concerns. Encouraging a patient to talk, exploring a patient’s comments, and expressing understanding all facilitate communication. The pharmacist should reinforce wise decisions that a patient has made while reserving judgment about potentially unhealthy behaviors.

Nonverbal Communication

Nonverbal communication skills are important when conducting an assessment. A pharmacist’s body language, such as posture and facial expression, communicates strong, direct messages.¹⁷ Pharmacists should be aware of their own nonverbal behavior as well as that of the patient. An open body posture—facing the patient with arms and legs uncrossed—indicates openness, honesty, and a willingness to communicate and listen. Maintaining an appropriate distance from a patient will facilitate confidential communication without making patients uncomfortable. If a patient backs away or moves closer, the pharmacist should maintain the new distance the patient has established. Pharmacists should maintain eye contact with a patient and control their facial expressions to avoid showing negative emotions such as disapproval or shock.

The patient’s nonverbal communication is equally important. If a patient has a closed body posture—arms crossed, legs crossed, body turned away—the pharmacist may need to find out why the patient is uncomfortable and then try to allay any concerns. The pharmacist should watch a patient’s facial expressions for signs of anxiety, nervousness, and physical symptoms such as pain.

Physical Barriers to Communication

High counters, glass separators, cluttered aisles, and elevated platforms inhibit communication and provide physical barriers. Pharmacists should try to be at eye level with the patient. A tall pharmacist may need to sit on a stool or lower his or her body position to avoid “hovering over” the patient. Discussions

between patient and pharmacist should be as private and uninterrupted as possible. If the pharmacist expects or perceives that a patient is uncomfortable discussing the problem, a quiet semiprivate or private consultation area should be sought and used. Ideally, a specific, private area should be designated for patient consultations.

Communication Techniques for Special Populations

Special communication techniques may be required with some patients.¹⁹ Writing or printing out the information to provide a quality copy may be necessary if the patient is deaf or hearing-impaired. If a patient who is hearing-impaired reads lips, the pharmacist should be physically close to, and directly in front of, the patient and maintain eye contact while speaking. The pharmacist should speak slowly and distinctly in a low-pitched, moderate tone, because yelling further distorts the sound and might embarrass the patient. A quiet, well-lit environment is essential, because background noise and dimness can markedly diminish a hearing-impaired individual’s ability to communicate. Using written or printed information alone can create misunderstandings with language that confuses the patient and requires further explanation. However, using printed information in conjunction with patient discussions has been found to be more effective than using written information alone.¹⁹

When interacting with a patient who is blind or visually impaired, the pharmacist should first state, “I am the pharmacist.” Because a blind patient cannot perceive most nonverbal communication, the pharmacist should depend on tone of voice and verbal feedback to convey empathy and interest in the patient’s problem. If the pharmacist needs to touch the patient to obtain additional information about the patient’s condition, such as might be the case with a sprained ankle or to obtain a fingerstick blood glucose measurement, permission should first be obtained.

An estimated 13% to 40% of Americans are illiterate, and another 20% are considered marginally literate.¹⁹ For these patients, written information or directions on a label are barriers, and the pharmacist cannot rely on them to reinforce information provided orally. Patients with reading impairments may be less inclined to ask questions or express their concerns. Although some common characteristics of illiteracy are related to age, education, and employment status,¹⁹ an understanding of the patient’s literacy status may take time to determine through the development of a therapeutic relationship.

The pharmacist must build a caring relationship to provide effective communication and consultation. The pharmacist can facilitate communication by using simple language and pictorial labels. Language and cultural barriers to communication may occur when interacting with patients of unfamiliar ethnic backgrounds.²⁰ Interpreters are also available as a resource in some communities and medical care facilities, and pharmacists may ask questions related to cultural beliefs to assess how these beliefs influence the patient’s use of medications (see Chapter 3). Similarly, cultural behaviors may result in failure to make eye contact and should not be interpreted as a lack of interest or understanding.

Patient Consultation

Interacting with a patient regarding self-treatment is a primary care activity that carries a great professional responsibility. Patients with self-care needs present differently from those

who have already received a treatment decision from a health care provider. To ensure that a particular drug product is appropriate for a patient, the pharmacist needs to perform an assessment by eliciting information from the patient, integrating these data to determine if any drug therapy problems exist, and then develop a patient care plan. As mentioned previously, pharmacists functioning in the dispensing business of a pharmacy, as well as pharmacists being reimbursed for providing pharmaceutical care, both start from the same point in interacting with a patient with self-care concerns (i.e., nature and extent of the patient's problem, current medications, and other medical conditions).

The self-care encounter in a pharmacy can be initiated by either the patient or the pharmacist (Figure 2-1). Although patients often initiate the consultation, an increasing number of pharmacists greet patients who are entering the self-care section of the premises and initiate an assessment of the patient's self-care concerns and drug-related needs.

Information-Gathering Process

Before formulating a plan for self-treatment or medical referral, the pharmacist must obtain enough information to identify and assess the patient's medical condition and drug therapy problem(s). Important data include the patient's perceived needs and concerns, demographics (i.e., patient-related variables), diseases, and medications. With experience, the pharmacist will be able to gather the necessary information to assess a particular condition within a relatively short period of time.

In a pharmaceutical care practice, the pharmacist will also conduct a general review of systems. A verbal review of the patient's physiologic systems, from head to toe, can help account for all of a patient's drug-related needs. The Pharmacotherapy Workup provides pharmacists with a complete listing of all

body organ systems needed to conduct this review of systems: neurologic, psychological, eye-ear-nose-throat, endocrine, vital signs, cardiovascular, hematologic, pulmonary, musculoskeletal, gastrointestinal (GI), fluid/electrolyte status, renal, hepatic, genitourinary/reproductive, and skin.

Other important information gathering is an accurate accounting of each medication a patient is using to treat all medical conditions. This list includes prescription, nonprescription, and herbal products, and vitamins and dietary supplements. Thorough questioning is important given that patients tend to underreport use of nonprescription medications and dietary supplements.²¹ If possible, the pharmacist may find it helpful to have the patient's medication history available at the start of the patient consultation.

The pharmacist can explain the need to review all medications by saying, "I would like to review each of the medications you are currently taking so that the drug product we might select for you fits with your current therapy. Here is a list of medications you have received at our pharmacy. Let's take a minute to see which ones you are currently taking, as well as what other medications you may be using." It may also be helpful for the pharmacist to have patients describe their daily activities and medication schedule in case they have difficulty recalling the names of all the medications they are taking.

When an accurate picture of the patient's active medication list has been obtained, the pharmacist in a pharmaceutical care practice will tie all active medications to each of the patient's medical conditions. A patient's drug allergies and medical history may be obtained at this point. The assessment process is dictated by the patient's knowledge level, as well as by the amount of time available to continue the interaction. Therefore, to obtain the needed information quickly and efficiently, the pharmacist should approach the problem logically and keep the questioning direct and to the point.

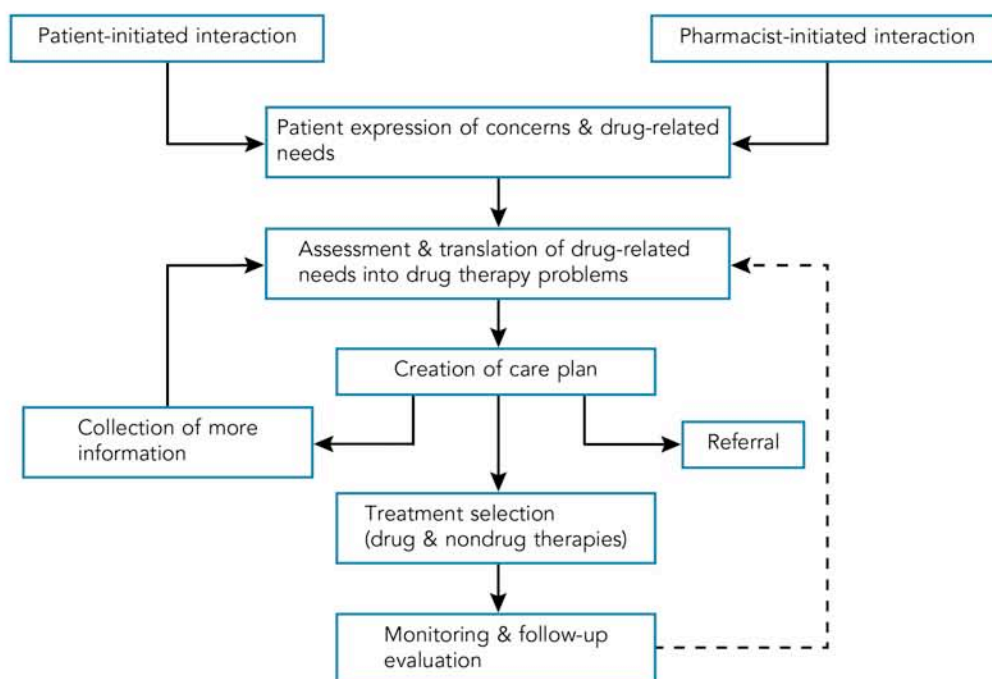


FIGURE 2-1 Patient-pharmacist consultation process.

Fortunately, within the context of providing MTMS within the practice of pharmaceutical care, the pharmacist need not try to obtain all relevant information in one encounter. The planned follow-up evaluation extends the initial assessment process and allows the pharmacist to obtain additional information. With continual practice, the pharmacist will learn to use every patient encounter to gather important additional information. The pharmacist will develop a sense, based on the patient's expression of needs, as to when to bring the initial assessment to a close and, in a pharmaceutical care practice, how to establish appropriate follow-up.

Patient History

After the pharmacist has accounted for the patient's other medications and drug-related needs, it is time to return to the patient's initial presentation of his or her self-care concerns. If the patient is not using any medications, supplements, or other remedies, the pharmacist commences the self-care encounter with a broad overview of the patient's health to determine the nature and extent of the problem. This overview of the patient's health enables the pharmacist to understand the patient's condition and make the most appropriate recommendation, regardless of whether a medication is included. Pharmacists should start by determining a patient's needs with an open-ended question such as "How may I help you?" Patients may initially present incomplete and vague information. To determine the specific symptoms and whether they are amenable to self-treatment, the pharmacist can pose the following open-ended queries or requests:

- Describe your problem.
- Describe to me how your problem has changed over time.
- How does the problem limit your daily activities (e.g., sleeping, eating, working, or walking)?
- Tell me about any foods, medications, and/or physical activities that make the problem worse.
- What have you done to relieve this problem in the past?
- What have you been doing so far to treat the problem?

The next step is to gather patient-specific data, including demographic information and medical history. The pharmacist should selectively elicit the following information:

- Who is the patient? Is the patient the person in the pharmacy or someone else?
- How old is the patient?
- Is the patient male or female? If the patient is female, is she pregnant or breast-feeding?
- Does the patient have any other medical problems that may alter the expected effects of a nonprescription medication or be aggravated by the medication's effects? Is the complaint related to a chronic illness?
- Does the patient have any allergies?
- Is the patient using any prescription, nonprescription, or social drugs (e.g., vitamins or food supplements, caffeine, nicotine, alcohol, or marijuana)?
- Has the patient experienced adverse drug reactions in the past?

Throughout the encounter, the pharmacist is formulating a clinical decision-making hypothesis based on identifying drug therapy problems. The pharmacist should determine whether the patient has misinterpreted the condition, done any harm by waiting to seek advice, or caused the condition to worsen by previous attempts at self-treatment.

Observed Physical Data

In addition to the historical data, physical data are helpful in determining the patient's self-care needs. Physical data include pulse rate, heart sounds, respiration rate, age, and weight. Depending on training and skills, the pharmacist can collect physical data by all or some of the following techniques: observation or inspection, palpation or manipulation, percussion, and auscultation. The importance of each technique in the process of data collection depends on the body system involved. For example, the skin is easily assessed by inspection and palpation, the lungs require percussion and auscultation, and all four skills are essential in examining the abdomen. However, most pharmacists obtain physical data primarily through observation.

Many clues to a patient's general health and the seriousness of a condition can come from simple observation. The degree of discomfort caused by pain may be judged from a patient's facial expressions or lack of use of a limb. Manifestations of an infection may include lethargy and pallor. The practitioner needs to inspect the patient's skin before offering advice about a skin rash, which may result from a simple contact phenomenon or be suggestive of systemic disease. It is recommended that nonlatex examination gloves be available for use when physical contact with the patient is required.

Patient Assessment

Assessment of a patient's drug-related needs during a self-care consultation involves evaluating data collected from the patient to determine the etiology and severity of the medical condition. This assessment is essential for reaching appropriate conclusions about treatment or the need for referral. Methods of assessing severity will vary, depending on the problem. Pharmacists and students of pharmacy who are learning how to conduct an assessment have found it useful to view the initial patient interaction as having a flow consisting of three broad, general phases: (1) establishing a therapeutic relationship, including determining the patient's primary concerns about his or her health; (2) reviewing all of the patient's active medications to assess indication, effectiveness, safety, and convenience of use; and (3) conducting a verbal review of systems to ensure that no drug-related needs have been overlooked.²²

Assessing the severity of the patient's condition is an important component of deciding on treatment or referral. Many times, however, the etiology and severity of a condition cannot be conclusively determined because data are not accessible. Referral may be required when available information suggests that a certain etiology is responsible or a condition may be particularly severe. In general, the more severe the problem, the greater is the potential for referral.

Patients of advanced age, infants, children, patients with multiple chronic diseases, recently hospitalized patients, and patients who are receiving treatment from several health care providers are at greater risk for complications and require more careful evaluation.

Care Plan Development

After collecting all available information, evaluating the patient's condition, and assessing the patient's drug-related needs, the pharmacist formulates a care plan. A care plan is simply an understanding of the intended goals of therapy with an accompanying time

frame for achieving these goals. The patient and pharmacist work together to establish realistic and observable goals. A care plan is a detailed schedule outlining the activities and responsibilities of the pharmacist and patient.⁶ A care plan is constructed to:

1. Resolve any drug therapy problems identified during the assessment.
2. Meet the goals for each of the patient's medical conditions.
3. Prevent future drug therapy problems.

A pharmacist may create a care plan without having all desired information. Areas of uncertainty may exist, but a well-designed plan can help the patient properly manage his or her medical conditions. For a more detailed description of documentation systems and principles pertinent to recording a patient's care plan, the reader is referred to texts that review these subjects in detail.^{6,12} The importance of documenting care delivered to a patient cannot be overstated. Developing a sound care plan for a patient with self-care needs will most likely include the following five steps:

1. Collect additional information.
2. Refer the patient to a primary care provider, if warranted.
3. Select self-treatment, if appropriate.
4. Advise the patient about self-treatment.
5. Evaluate progress toward achieving treatment goals.

COLLECT ADDITIONAL INFORMATION

The pharmacist may need more information to assess the patient's condition, which may require specific action such as either talking to a parent/caregiver or calling a health care provider. Communication between the pharmacist and health care provider is often desirable to avoid conflict in managing the patient and to overcome problems of overlapping responsibilities. When such communication becomes necessary, the pharmacist should do the following:

- Obtain data on preexisting medical conditions to determine whether self-treatment is appropriate.
- Determine whether the health care provider wants to address the patient's problem over the telephone.
- Determine whether the health care provider wants to see the patient or whether the patient should be referred to an urgent care center or a hospital emergency department.
- Provide information on the reason for referral.

PATIENT-PHARMACIST CONSULTATION

Collecting Additional Information and Referring Patient

One month after accepting your decision to start a stool softener, Mrs. E.J. returns to your pharmacy to inquire which iron product is best to "help give her more red blood cells." During the course of the assessment, the patient reveals that she has felt a little run-down, because she has been losing a little blood in her stools. As you collect additional information, the patient reports that this condition started about a week ago and that she has had three instances in which she noted blood in the stool. Without alarming the patient, you recommend that she consult her health care provider and offer to help her set up the appointment.

REFER PATIENT

When enough information is available to evaluate the condition, the pharmacist must decide whether to refer the patient to a health care provider or to advise on self-treatment. If the plan involves a medical referral, the pharmacist must consider both the type of treatment center to which the patient will be referred (clinic or emergency care facility) and the urgency for treatment. Some conditions do not require the immediate attention or extensive evaluation by emergency care personnel.

When advising a patient to see a health care provider, the pharmacist should discuss with the patient why the referral is being made. The pharmacist must use tact and firmness so the patient is not unnecessarily frightened but is convinced of the need for concern. Medical referral is indicated in the following situations:

- The symptoms are too severe to be endured by the patient without definitive diagnosis and treatment.
- The symptoms are minor but persistent and do not appear to be the result of some easily identifiable cause.
- The symptoms have repeatedly returned with no readily recognizable cause.
- The pharmacist is in doubt about the patient's medical condition.

In the case of Mrs. E.J., the pharmacist collected additional information from the patient to address her concerns about fecal blood loss. However, her condition is persistent (lasting 1 week), there is no readily recognizable cause, and the pharmacist is in doubt about the patient's condition without a definitive medical diagnosis. Therefore, a referral for medical evaluation is warranted.

SELECT SELF-TREATMENT

Selecting self-treatment in collaboration with a patient requires the pharmacist to consider several factors. First, the pharmacist must identify a measurable and achievable therapeutic objective, based on the patient's condition and clinical status. A therapeutic modality—either drug or nondrug—may then be recommended. Choosing a specific treatment requires reviewing drug variables (e.g., dosage forms, ingredients, adverse reactions, relative effectiveness, and price) and matching them with patient variables (e.g., age, gender, drug history, other physiologic problems, and ability to pay).

If self-treatment without the use of a medication is indicated, selection of the nondrug modality would similarly be modified using patient variables. For example, the pharmacist may suggest that a patient with vomiting and diarrhea consider drinking only fluids for a brief period. However, if the patient has insulin-dependent diabetes, the pharmacist must modify this possible course of action, because patients with diabetes have specific caloric requirements. Communicating with the patient, and possibly another health care provider, about modifying the dose of insulin to compensate for changes in caloric intake would be prudent in this situation.

To measure the success of treatment, the pharmacist should set goals and measurement parameters based on the therapeutic objective, the toxic or adverse effects of treatment, the nature and severity of the condition, the patient's ability to understand the condition and its treatment, and the anticipated time to symptom resolution. Toxicity includes those symptoms associated with an excess dose or an untoward reaction. The pharmacist should identify toxicities that suggest the problem may be worsening and require special attention. Finally, queries related

to the patient's understanding of the condition and its treatment can include determining the appropriateness of the patient's questions to the pharmacist as well as the patient's response to those questions.

ADVISE PATIENT ON SELF-TREATMENT

The fourth step in the care plan is to advise the patient about self-treatment. The primary purposes are to develop a plan of action with the patient and obtain the consent necessary to enact the plan. Specifically, the pharmacist should provide advice in the following areas:

- Reasons for self-treatment
- Description of the medication and/or treatment
- Administration of the medication and/or treatment
- Adverse reactions and precautions
- General treatment guidelines

In advising the patient about a suggested treatment plan, the pharmacist should summarize the patient's condition, explain the significance of the symptoms, and outline the reasons for treatment. The pharmacist should clearly explain the therapeutic objectives and provide a realistic time frame for achieving the objectives. If the patient desires information on alternative treatments, the pharmacist should be prepared to present such information about their relative merits and drawbacks without biasing the information and jeopardizing the patient–health care provider relationship. The pharmacist should then discuss the nonprescription medications selected, describing in lay terms both the therapeutic action of the ingredients (e.g., decongestants, antihistamines, and laxatives) and the effect the products will have on the patient's symptoms and condition.

The pharmacist should explain administration guidelines clearly and concisely. Because many patients may remember only part of the information, some thought should be given to deciding what is most important for the patient to remember. Covering a few of the most important points is better than overwhelming a patient with a lot of information. In addition, patients will remember dosage instructions better if administration is linked to specific times of the day, rather than just “three times daily.” Having a patient review normal daily activities will help establish the best times to take the medication. It is also important to include information about the duration of treatment.

The patient should be told about the most common adverse reactions associated with a medication and be instructed on how to manage them. The pharmacist should describe activities, other medications, foods, or beverages that should be avoided, as well as discuss which of the patient's medical conditions may be complicated by use of the medication. Information should be written down if it is extensive or complex.

The pharmacist should offer the patient some general treatment guidelines that may be helpful in managing the condition. These guidelines might include lifestyle changes, additional products or services, informational sources, and a list of signs and symptoms that indicate whether the medication is working, whether it is causing adverse effects, and when a health care provider's advice is needed. The patient should be informed about the expected response time to the treatment, the time required for the condition to resolve, and what to do if response is delayed.

PATIENT–PHARMACIST CONSULTATION

Advising Patient on Treatment and Care Plan Development

Mrs. E.J. visits her primary care provider for assessment of blood loss and returns to your pharmacy 1 week later with a copy of her laboratory results. She presents a note from the physician asking you to help the patient select an iron product for her to take twice a day that is easy on the stomach. On questioning, the patient indicates that her physician did a full medical workup and she is happy to report that she does not have any type of serious anemia. In collaboration with the patient, you determine that the patient will begin taking ferrous gluconate 324 mg twice daily. Mrs. E.J. then reports that she is scheduled for follow-up blood work in the clinic in 3 weeks.

EVALUATE PROGRESS TOWARD ACHIEVING TREATMENT GOALS

The final area in the patient care process is follow-up evaluation. Evaluation is defined as the practitioner's determination—at planned intervals of follow-up—of the patient's outcome and current status.⁶ The purpose of the evaluation is to determine whether previous drug therapy problems have been resolved, to evaluate the patient's progress toward achieving therapeutic goals, and to assess whether new problems have developed from the drug therapy.

PATIENT–PHARMACIST CONSULTATION

Evaluation of Patients' Outcomes

You determined that the use of ferrous gluconate, rather than ferrous sulfate, might cause Mrs. E.J. less gastric irritation. The pharmacist would advise the patient on the proper use of ferrous gluconate and encourage her to return to the clinic in 3 weeks to see how the medication is working. In a pharmaceutical care practice, the pharmacist would review the patient's copy of her laboratory results to set goals of therapy and the anticipated time frame for achieving those goals. A follow-up appointment would then be made with Mrs. E.J. after her clinic appointment to account for progress toward achieving goals of therapy and to reassess for additional drug-related needs.

Documentation systems used by pharmacists in a pharmaceutical care practice typically have a way of tracking the safety and effectiveness of drug therapies that may include an evaluation of outcomes for each of the patient's medical conditions and a resolution status of drug therapy problems. Pharmacists may also include a brief progress note in a patient's pharmaceutical care chart after each patient encounter. Evaluation notes help pharmacists convey important aspects of the patient's care in a clear and concise manner to fellow practitioners.

Aspects of care that pharmacists convey, in written format, may include the patient's expression of drug-related needs, goals of therapy, monitoring parameters, assessment of drug therapy problems, and a plan for resolving and preventing drug therapy problems and achieving treatment goals. An evaluation note can take on an appearance similar to the SOAP (subjective data, objective data, assessment, plan) format used in the

field of medicine for the problem-oriented medical record system. When the pharmacist assumes responsibility for all the patient's drug-related needs within each of the patient's medical conditions, the evaluation note may reflect this holistic approach to care.

Follow-up allows the pharmacist to determine whether self-treatment has resulted in an appropriate therapeutic response and whether the patient has used medications appropriately or experienced any drug therapy problems, including drug-related toxicity.

Follow-up provides feedback that allows pharmacists to determine whether their communication skills require modification and whether useful information has been provided. At the same time, the patient will sense that the pharmacist cares. The pharmacist's concern for the correct use of nonprescription medications will also reinforce the notion that these products are medications and must be used carefully.

Pharmaceutical Care for High-Risk and Special Groups

Pharmaceutical care should be an important part of health care for all of our patients, but it is especially important for vulnerable populations. Certain groups of patients—infants and children, persons of advanced age, and pregnant and breast-feeding women—may experience a higher incidence of drug therapy problems than other patients. Because such problems can have dire consequences, these high-risk patients require special attention. Awareness of the physiologic state, possible pathologic conditions, and social context of these patients is necessary to properly assess their medical conditions and recommend appropriate treatment.

In many respects, persons of advanced age, infants, and children require surprisingly similar considerations. They all have a need for drug dosages that differ from those for other age groups because of the following features:

- They have altered pharmacokinetic parameters.
- Their ability to cope with illness or adverse drug events is decreased because of physiologic changes associated with either normal aging or child development.
- Their patterns of judgment are impaired because of either altered sensory function or immaturity.
- They have drug effects and potential adverse reactions that are unique to their age groups.
- They have a need for special consideration in administering medications.

Yet, because each of these groups of patients is heterogeneous, it is important to consider these features for each individual patient.

Special Considerations in Infants and Children

A study of the prevalence of nonprescription medication use in 3-year-old children found that 53.7% had been given a nonprescription medication within the preceding 3 months. The most commonly used medications were acetaminophen and cough or cold products.²³ An analysis of vitamin supplement use found that 54.4% of 3-year-olds in the United States were given vitamin and mineral supplements within the preceding 3 months. Providing pharmaceutical care to pediatric patients is challenging because of differences in physiology and pharmacokinetics,

lack of clinical data, insufficient drug labeling, and problems associated with drug dosing and administration.²⁴ In considering nonprescription medications for infants and children, the pharmacist should note that the pediatric population might vary substantially among age groups. It is appropriate to differentiate among relatively distinctive pediatric ages as follows^{25,26}:

- *Premature*: gestation of less than 36 weeks
- *Neonate*: first postnatal month of life
- *Infant (baby)*: ages 1 to 12 months
- *Toddler*: ages 1 to 3 years
- *Preschool or early childhood*: ages 3 to 6 years
- *Middle childhood*: ages 6 to 12 years
- *Adolescence*: ages 13 to 18 years

For most products, the Food and Drug Administration (FDA) recommends against self-medication in children younger than 2 years, especially using cough and cold products. Pharmacists can provide recommendations regarding medications with which they are familiar and for which dosage guidelines are readily available (e.g., pediatric acetaminophen products), but they should recommend evaluation by a primary care provider for medical conditions or medications for which they do not have pediatric experience. Some package labeling provides dosage guidelines by age group rather than by weight.

Physiologic and Pharmacokinetic Differences

Pediatric patients are at risk for drug therapy problems given that their body and organ functions are in a continuous state of development. Not only do the pharmacokinetic properties of medications differ in children compared with adults, but these properties can undergo rapid change as children grow and mature.²⁶ Furthermore, illness in children is potentially more serious than in adults, because the physiologic state of children is less tolerant of changes. Fever, vomiting, and diarrhea represent greater potential risks to children, because they are more susceptible to the effects of fluid loss. Therefore, the pharmacist should consider referral to a health care provider sooner for a condition in a child than for an adult with the same condition.

Other Potential Drug Therapy Problems

The pharmacist should be sensitive to the potential for drug therapy problems among children. In some illnesses such as diarrhea, nondrug therapy is often more appropriate than therapy with nonprescription antidiarrheal medications. In some situations, specific medications are contraindicated; for example, aspirin should not be administered to young children with certain viral illnesses (especially influenza and varicella) because of its association with Reye's syndrome (see Chapter 5). After warnings against using aspirin in children with viral illnesses were issued, the number of cases of Reye's syndrome dropped dramatically.²⁷ Pharmacists should counsel parents of children and adolescents with febrile viral illnesses against using aspirin. For younger children, solid dosage forms are inappropriate, and the pharmacist will need to guide parents to liquid medications or chewable tablets.

INACCURATE DOSING

Labeling for nonprescription medications generally uses age-based guidelines to determine dosages; however, many products do not provide dosage information for children younger than

6 years. Following the nonprescription medication's label, instructions for dosing a child older than 6 years can result in too high a dose and potential toxicity for the younger child. Inaccurate dosing by parents can result from determining an incorrect dose from the label instructions, by measuring out an incorrect amount, or both. A study of 200 children, 10 years of age and younger, who had been given a dose of acetaminophen or ibuprofen in the preceding 24 hours, found that 51% of them had been given an incorrect dose by their caregiver.²⁸ Pharmacists must better educate parents about dosing and administering nonprescription medications by helping parents interpret labels and demonstrating the appropriate use of measuring devices.

IMPROPER ADMINISTRATION/DOSAGE FORMS

Selecting the proper medication and dosage is not beneficial unless a medication is actually administered. Proper administration of medications to pediatric patients requires an appreciation of dosage forms, delivery methodology, routes of administration, palatability, and other factors. The discussion that follows focuses on oral medications.

Liquids are relatively easy to administer, and the dose can be titrated to the patient's weight; therefore, liquid medications are often used in pediatric populations. Because elixirs and syrups can have high alcohol and sugar content, respectively, these liquid forms may be less desirable than suspensions and solutions. A suspension may also mask the disagreeable taste of a medication.

Problems with drug administration can result in the child receiving the wrong dose. In a mock dosing scenario in which caregivers had the choice of using teaspoons, tablespoons, syringes, droppers, measuring cups, and measuring tubes, only 67% of the caregivers accurately measured the dose they intended to administer.²⁸ The volume delivered by household teaspoons ranges from 2.5 to 7.8 mL and may also vary greatly when the same spoon is used by different individuals. The American Academy of Pediatrics Committee on Drugs highly recommends the use of appropriate devices for liquid administration, such as a medication cup, cylindrical dosing spoon, oral dropper, or oral syringe. Ease of administration and accuracy should be considered when choosing a dosing device. Plastic medication cups are fairly accu-

rate for volumes of exact multiples of 5 mL (i.e., 5 mL, 10 mL, 15 mL). An oral syringe is preferable to the other oral dosing devices for higher viscosity liquids, because the syringe completely expels the total measured dose. Potent liquid medications should be administered with an oral syringe to ensure that the correct dose is given; the pharmacist should briefly explain to caregivers how to use and read an oral syringe. However, drawing up the dose in the syringe requires dexterity.

The use of precision devices for oral dosing helps ensure adequate therapeutic response by reducing the incidence of underdoses and eliminating adverse drug effects from potential overdoses. These devices may also enhance acceptance of medication by infants and children. Parents or caregivers may need instructions on using these devices to measure doses accurately, as well as advice on giving medications to reluctant or struggling children. The pharmacist may need to demonstrate to parents and older children how to take the medication.

A child older than 4 years can usually swallow tablets or capsules. Tablets that are not sustained-release or enteric-coated formulations may be crushed. Most capsules may be opened and the contents sprinkled on small amounts of food (applesauce, jelly, or pudding) to ensure that all the medication is taken. If the child does not eat the full portion, underdosing can occur. If multiple medications are prescribed, the child may be more cooperative if allowed to choose what flavored drink to use and which medication to take first. Table 2-1 presents selected guidelines for administering oral medications to pediatric patients.

ADVERSE DRUG EFFECTS

Adverse reactions are another potential drug therapy problem in children. Adverse drug events in children may differ from those in adults. For example, as in the older population, antihistamines and central nervous system (CNS) depressants may cause excitation in children. Except for Claritin (loratadine) syrup, FDA recommends not administering antihistamines to children younger than 6 years.²⁹ In contrast, sympathomimetics such as pseudoephedrine may cause drowsiness in children. In the United States, drug-induced acute liver failure is most commonly caused by acetaminophen, and about 18% of those cases were a result of accidental overdose. In addition, administration

TABLE 2-1 Selected Medication Administration Guidelines for Oral Medications

Infants

- Use a calibrated dropper or oral syringe.
- Support the infant's head while holding the infant in the lap.
- Give small amounts of medication to prevent choking.
- If desired, crush non-enteric-coated or non-sustained-release tablets into a powder and sprinkle them on small amounts of food.
- Provide physical comfort while administering medications to help calm the infant.

Toddlers

- Allow the toddler to choose a position in which to take the medication.
- If necessary, disguise the taste of the medication with a small volume of flavored drink or small amounts of food. A rinse with a flavored drink or water will help remove an unpleasant aftertaste.
- Use simple commands in the toddler's jargon to obtain cooperation.

- Allow the toddler to choose which of the medications (if multiple) to take first.
- Provide verbal and tactile responses to promote cooperative taking of medication.
- Allow the toddler to become familiar with the oral dosing device.

Preschool Children

- If possible, place a tablet or capsule near the back of the tongue; then provide water or a flavored liquid to aid the swallowing of the medication.
- If the child's teeth are loose, do not use chewable tablets.
- Use a straw to administer medications that could stain teeth.
- Use a follow-up rinse with a flavored drink to help minimize any unpleasant medication aftertaste.
- Allow the child to help make decisions about dosage formulation, place of administration, medication to take first, and type of flavored drink to use.

of acetaminophen at doses above the recommended daily dose over a period of 2 to 4 days can result in hepatotoxicity in children.³⁰

NONADHERENCE

Nonadherence may occur when children refuse to take medication or when caregivers give up before the child receives the entire dose. Adherence may be improved by recommending a sweetly flavored product, because children may be more willing to take a medication if they like the flavor, consistency, or texture.³¹ Nonadherence can also occur when caregivers do not understand instructions or do not pass them on to daycare providers, teachers, or school nurses. A 2003 survey study of 82 child daycare centers found that 52% of centers reported missing a dose during the preceding year, and 49% reported that the child's medication was not available.³²

Assessment and Consultation

Assessment and consultation for pediatric patients usually involve the parents or caregivers. A 2003 article by Sleath and coworkers,³³ list six overall steps for communicating with children and improving their medication use process (Table 2-2). One should remember that it is important to include the child and parent during the patient counseling process, and that the child's and parents' concerns or fears about the medication should be considered.

Special Considerations in Persons of Advanced Age

Social, economic, physiologic, and age-related health factors place persons of advanced age at high risk for medical problems, and prompt them to be large consumers of nonprescription medications. Indeed, this population as a group consumes more medications than any other age segment of our society. Although individuals aged 65 years or older take on average 1.8 nonprescription medications daily, geographic area, race/ethnicity, and gender affect this number.³⁴ Nonprescription drug use in this population is highest in the midwestern United States, in Caucasians, and in women. Analgesics, laxatives, and nutritional supplements are the most common nonprescription

medications used by persons of advanced age. A study in 86 women who were 65 years of age or older reported an average use of 3.8 nonprescription medications per person.³⁵ In the 45% of women who used herbal products, the average number of herbal products was 2.5. The response to drug therapy by older patients is more scattered and unpredictable than that of other populations. Pharmacokinetic, pharmacodynamic, and various nonpharmacologic factors predispose these patients to potential problems with nonprescription medications. Preexisting medical conditions in older persons may affect the use of some nonprescription medications. For example, antihistamines should be avoided in patients with emphysema, bronchitis, glaucoma, and urinary retention from prostatic hypertrophy. Although nasal and oral decongestants can be used without adverse effect in many older persons, caution may be necessary in some patients with heart disease, hypertension, thyroid disease, and diabetes because of potential adverse effects of sympathomimetics on blood pressure, heart rate, and blood glucose.

Physiologic and Pharmacokinetic Differences

Persons of advanced age often have impaired vision (e.g., difficulty reading and differentiating colors) and hearing loss. The pharmacist should be aware of patient behaviors that indicate visual or hearing loss and should consider these impairments when communicating with older patients. Additional instructions for nonprescription medications may need to be provided in larger, high-contrast, dark print. Asking the patient to repeat counseling instructions can ensure that the directions were heard correctly and understood.

Subtle changes in mental status, such as confusion, may be anticipated in older patients who are anxious about their state of health. Older patients with cognitive impairments may have difficulty comprehending directions. Patients may not remember the names of all their medications or may not be able to remember instructions. Because of memory lapses, some older patients may require special drug delivery systems (e.g., transdermal patches or sustained-release preparations) to help them adhere to their dosage regimen. Older patients with cognitive impairments are less likely to read and interpret labels correctly,³⁶ which further emphasizes their need for special dosage form considerations.

Older patients are believed to confuse at least one-third of their problems with age-associated problems and, therefore, misreport their symptoms. Accurate perception and reporting of symptoms is vital to the successful use of any medication. In addition, older patients are often reluctant to share health information with others.

The aging process, as well as many chronic diseases, can alter a patient's nutritional status. Older patients who are most at risk for undernourishment or malnutrition are homebound patients and nursing home residents. Poverty, multiple chronic diseases, multiple drug therapy, or a combination of these factors may cause malnutrition in these patients. The patient's nutritional status and weight are important, because these factors can alter the pharmacokinetics and pharmacodynamics of medications.

Aging alters the absorption, distribution, metabolism, and elimination of certain medications, increasing the susceptibility of older patients to drug therapy problems. Pharmacokinetic changes, which have been well described in the literature, are caused not only by advancing age but also by the effects of disease states, and often by multiple drug use.

TABLE 2-2 Six Steps for Improving Medication Use in Children

Pharmacists should use a patient-centered style that focuses on the following steps:

1. Educating both the child and parents about the medication.
2. Investigating any concerns or fears that the child or parents may have about the medication.
3. Asking the child and parents about priorities for improved quality of life.
4. Following up with the child and parents to learn if they consider the child's treatment effective.
5. Offering to follow up with the pediatrician to improve the child's therapy (if needed).
6. Encouraging the child or parents to ask questions about the medication.

Source: Reference 33.

Older persons appear to have a greater sensitivity to some medications, particularly to anticholinergic medications, which may relate in part to alterations in cholinergic transmission.³⁷ Nonprescription medications with anticholinergic effects, such as certain antihistamines, may worsen preexisting medical conditions such as angina, congestive heart failure, constipation, diabetes mellitus, glaucoma, urinary dysfunction, sleep disturbance, and dementia.³⁷ The risk of accidents such as falls may also increase as a result of pupillary dilatation induced by anticholinergic medications and the inability to accommodate the effect.

Both subjective and objective evidence indicates that older patients have an enhanced CNS sensitivity to medications, especially CNS depressants such as sedatives and antidepressants. Increased brain sensitivity and other changes (e.g., decreased coordination, prolongation of reaction time, and impairment of short-term memory) manifest as increased frequency of confusion, urinary incontinence, and number of falls, especially among older women. Drug therapy may exaggerate all these changes, particularly if medications are taken in the “usual” dose or if multiple medications are used.

Control of bowel and bladder function lessens with advancing age. A further decrease in efficiency is likely with laxative use. Anticholinergic and CNS medications may reduce neurologic control. Antihistamines have sedative properties that may reduce bladder control in older persons.³⁷ Adverse effects of nonprescription medications often increase when such medications are added to an existing medication regimen.

Nonsteroidal anti-inflammatory drugs (NSAIDs) are widely used, especially by patients with osteoarthritis and rheumatoid arthritis. The absolute number of events of NSAID-related toxicity is greater for older patients because of their frequent use of NSAIDs and the increased prevalence of comorbid conditions coupled with concomitant drug therapies.³⁸ These patients may be especially susceptible to NSAID-associated peptic ulcer disease as well as congestive heart failure in susceptible individuals.³⁹ There is also some evidence that the chronic use of NSAIDs may elevate blood pressure in women ages 31 to 50.⁴⁰ Many patients were switched from NSAIDs to a cyclooxygenase-2 (COX-2) inhibitor; the latter was thought to be safer because of fewer serious GI-related adverse events. However, recent evidence suggests that the risk of cardiac events from taking rofecoxib, such as thrombotic stroke and myocardial infarction, far outweigh the beneficial GI profile. Rofecoxib has already been withdrawn from the market because of the increased risk of cardiac events.⁴¹

Other Potential Drug Therapy Problems

DUPLICATE THERAPY

Patients of advanced age can receive unnecessary drug therapy when medications are added to their therapeutic regimen without a reevaluation of the entire regimen to determine whether certain medications should be deleted. Duplicate therapy may occur if these patients are seeing multiple health care providers for their various medical problems or using multiple pharmacies. Use of a single pharmacy can significantly lower the risk of inappropriate drug combinations. Nonprescription medications commonly involved in drug interactions in older persons include aspirin, other NSAIDs, antacids, cimetidine, and antihistamines.⁴² Many older patients have serious and multiple diseases such as coronary artery disease, chronic renal failure, or congestive heart failure, which can be aggravated by concurrent therapy for other acute problems. Concomitant illnesses or certain medications may contraindicate the use of other medica-

tions. It is important to consider whether an older patient is requesting a nonprescription medication to treat an adverse reaction from another medication.

INACCURATE DOSING/DOSAGE FORMS

Normal drug doses of analgesics and sedating antihistamines may be too high for patients of advanced age because of their impaired hepatic and renal function. These situations would necessitate either lowering the dose or increasing the dosing interval. Furthermore, older patients may experience difficulty with some dosage forms (e.g., swallowing large calcium or vitamin tablets, or using inhalers) because of physical impairments. Arthritis or tremors may make it difficult for older patients to open and close containers. Child-resistant containers may be especially difficult for older patients to open if they have deficits in physical dexterity. A pharmacist should direct older patients to products without child-resistant containers but also warn them of the potential poisoning hazard for visiting grandchildren or other young visitors.

NONADHERENCE

The prevalence of nonadherence with medications is high in the advanced-age population and is often the result of inadequate understanding of their medication regimen. Poor adherence may result from difficulty in swallowing or administering the medication. It may also result from an inability to afford the medication because of a limited or fixed income. Older patients may lack a social support network to supply the aid required by an illness. Pharmacists may need to involve caregivers in administering medications to these patients.

Special Considerations in Pregnant Patients

Drug therapy during pregnancy may be necessary to treat medical conditions or to manage common complaints of pregnancy such as vomiting or constipation. However, because most medications cross the placenta to some extent, a mother who takes a medication might expose her fetus to it. Therefore, the desire to ease the mother's discomfort must be balanced with concern for the developing fetus.

A 2001 study found that 13% of pregnant women from an academic setting birthing center used dietary supplements.⁴³ Of these women, 25% reported using supplements to relieve nausea and vomiting, and 25% reported stopping the use of these products because of concern for their fetus. The authors concluded that, although the use of dietary supplements was low among these women, the lack of safety data for these products is of concern. In another study, women attending an antenatal clinic reported using an average of 2.3 to 2.6 nonprescription medications in the three pregnancy trimesters, which was slightly higher than nonprescription drug use in the 3 months before pregnancy.⁴⁴ The most frequently taken medications were analgesics, vitamin and mineral supplements, and GI medications. Approximately 10% of pregnant women used herbal products.

Potential Drug Therapy Problems

Pregnant women should never presume that a nonprescription medication is safe to use during pregnancy. They should first consult with a pharmacist or primary care provider to determine whether a medication is teratogenic (i.e., causes abnormal embryonic development). Nausea and vomiting can cause

another medication-related problem: difficulty in taking oral dosage forms of medications.

TERATOGENIC EFFECTS

Several factors are important in determining whether a medication taken by a pregnant woman will adversely affect the fetus. Two such factors are the stage of pregnancy and the ability of the medication to pass from maternal to fetal circulation through the placenta. The first trimester, when organogenesis occurs, is the period of greatest risk for inducing major anatomic malformations. However, exposure at other periods of gestation may be no less important, because the exact critical period depends on the specific medication in question.

Drug therapy problems are also important considerations for pregnant patients. Although dosage guidelines for some prescription medications (e.g., phenytoin) differ for pregnant patients, no information on dosage adjustments exists for nonprescription medications. Unnecessary drug therapy should be avoided. Nondrug therapy is often more appropriate than drug therapy for pregnant women. Use of cigarettes and ingestion of alcohol should be avoided or limited, because they have been associated with increased risk to the fetus.⁴⁵ Consumption of moderate doses of caffeine appears to be safe.⁴⁶

In pregnant patients, the primary concern is related to drug safety. All pharmacists should be familiar with the A-B-C-D-X system for evaluating the safety of medications in pregnancy that were first introduced in 1979.⁴⁶ However, the FDA has recently announced a plan to strengthen drug labels to give patients and health care providers more precise information about how medications affect women during pregnancy and breast-feeding. The Agency has stated that consumers and health care providers have expressed concerns that these categories are overly simplistic, confusing, and inaccurate. Under the proposed rule, there will not be any letter categories. Instead, information will be provided in three sections:

1. *Fetal Risk Summary*: What is the risk of the medication to the fetus and the basis for the information, that is, animal or human studies?
2. *Clinical Consideration*: Explains the risks to the woman who took the medication before learning she was pregnant.
3. *Data*: Available about the drug in human and animal studies.

Often the issue is not whether a more effective medication is available but whether a safer medication is available. For example, evidence exists that aspirin is associated with congenital defects, incidence of stillbirths, neonatal deaths, and reduced birth weight.^{43,46} Use of aspirin late in pregnancy has been associated with increases in length of gestation and duration of labor. These effects are related to aspirin's inhibition of prostaglandin synthesis. In addition, because aspirin affects platelet function, perinatal aspirin ingestion has been found to increase the incidence of hemorrhage in both the pregnant woman and the newborn during and after delivery. Therefore, a woman should avoid using aspirin during pregnancy, especially during the last trimester. Instead, because acetaminophen is generally considered safe for use during pregnancy, it is the nonprescription medication of choice for antipyresis and analgesia when taken in standard therapeutic doses.⁴³ NSAIDs such as ibuprofen and naproxen can be taken early in pregnancy.⁴⁶ However, they should not be used late in pregnancy given that they are potent prostaglandin synthetase inhibitors. Not only can they cause problems in the

newborn, but they can also affect the duration of gestation and labor. Chronic use of large doses of antitussive products that contain codeine may cause withdrawal in the newborn after delivery.⁴⁶ Severe CNS depression and hypoventilation at birth have been reported following maternal use of diphenhydramine, which was taken for several weeks prior to delivery for severe itching.⁴⁷

NONADHERENCE

Nausea and vomiting associated with pregnancy may make it difficult for the pregnant woman to adhere to instructions for taking oral medications. Pharmacists can recommend eating small meals, frequent snacks, and crackers to alleviate or minimize nausea and vomiting. The patient should avoid foods, smells, or situations that cause vomiting. If necessary, an effervescent glucose or buffered carbohydrate solution, or the use of ginger may be effective. Only if those measures are ineffective should an antihistamine or antiemetic be considered. Consultation with a primary care provider may be indicated at this point.

Management of the Pregnant Patient

The pharmacist can aid the self-treating pregnant woman in deciding which drug or nondrug treatments she should consider and when self-treatment may be harmful to her or her unborn child. The decision to suggest a medication must be based on both an up-to-date knowledge of the literature and a critical risk-benefit evaluation of the mother and the fetus. Pharmacists should consult a reference such as the *Drugs in Pregnancy and Lactation* by Briggs and others⁴⁶ to check for the safety of medications in this population.

When the pharmacist has a choice between two medications, the preferred medication will be the one that has been in use for a longer period. Ascertaining the trimester of pregnancy is important, because it is a factor in determining whether some nonprescription medications can be used safely. The pharmacist should discourage pregnant women from self-medicating with nonprescription medications without receiving counseling from a primary care provider or pharmacist. The assessment and management of the pregnant patient require observation of the following principles:

1. The pharmacist must be alert to the possibility of pregnancy in any woman of childbearing age who has certain key symptoms of early pregnancy, such as nausea, vomiting, and frequent urination. Any woman who fits this description should be warned not to take a medication that might be of questionable safety if she is pregnant.
2. The pharmacist should advise the pregnant patient to avoid using medications, in general, at any stage of pregnancy unless the patient's health care provider deems such use essential. In addition, because the safety and effectiveness of homeopathic and herbal remedies in pregnancy have not been established, their use should be discouraged.
3. The pharmacist should advise the pregnant patient to increase her reliance on nondrug modalities as treatment alternatives (see Nonadherence).
4. The pharmacist should refer the patient to a primary care provider for certain problems that carry increased risk of poor outcomes in pregnancy (e.g., high blood pressure, vaginal bleeding, urinary tract infections, rapid weight gain, and edema).