

PHARMACOLOGY FOR NURSES

A Pathophysiologic Approach

FOURTH EDITION



MICHAEL NORMAN CAROL
ADAMS • HOLLAND • URBAN



Brief Contents

UNIT 1 CORE CONCEPTS 1

- Chapter 1 Introduction to Pharmacology 2
Chapter 2 Drug Classes and Schedules 11
Chapter 3 Principles of Drug Administration 18
Chapter 4 Pharmacokinetics 36
Chapter 5 Pharmacodynamics 46

UNIT 2 PHARMACOLOGY AND THE NURSE-PATIENT RELATIONSHIP 55

- Chapter 6 The Nursing Process in Pharmacology 56
Chapter 7 Medication Errors and Risk Reduction 66
Chapter 8 Drug Administration Throughout the Life Span 76
Chapter 9 Psychosocial, Gender, and Cultural Influences on Pharmacotherapy 89
Chapter 10 Herbal and Alternative Therapies 97
Chapter 11 Substance Abuse 107
Chapter 12 Emergency Preparedness and Poisonings 119

UNIT 3 THE NERVOUS SYSTEM 131

- Chapter 13 Drugs Affecting the Autonomic Nervous System 132
Chapter 14 Drugs for Anxiety and Insomnia 155
Chapter 15 Drugs for Seizures 171
Chapter 16 Drugs for Emotional, Mood, and Behavioral Disorders 188
Chapter 17 Drugs for Psychoses 209
Chapter 18 Drugs for the Control of Pain 222
Chapter 19 Drugs for Local and General Anesthesia 243
Chapter 20 Drugs for Degenerative Diseases of the Nervous System 259
Chapter 21 Drugs for Neuromuscular Disorders 274

UNIT 4 THE CARDIOVASCULAR AND URINARY SYSTEMS 285

- Chapter 22 Drugs for Lipid Disorders 286
Chapter 23 Diuretic Therapy and Drugs for Renal Failure 299
Chapter 24 Drugs for Fluid Balance, Electrolyte, and Acid-Base Disorders 313
Chapter 25 Drugs for Hypertension 328
Chapter 26 Drugs for Heart Failure 347

- Chapter 27 Drugs for Angina Pectoris and Myocardial Infarction 361
Chapter 28 Drugs for Shock 377
Chapter 29 Drugs for Dysrhythmias 389
Chapter 30 Drugs for Coagulation Disorders 404
Chapter 31 Drugs for Hematopoietic Disorders 422

UNIT 5 THE IMMUNE SYSTEM 439

- Chapter 32 Drugs for Immune System Modulation 440
Chapter 33 Drugs for Inflammation and Fever 458
Chapter 34 Drugs for Bacterial Infections 472
Chapter 35 Drugs for Fungal, Protozoan, and Helminthic Infections 501
Chapter 36 Drugs for Viral Infections 520
Chapter 37 Drugs for Neoplasia 541

UNIT 6 THE RESPIRATORY SYSTEM 567

- Chapter 38 Drugs for Allergic Rhinitis and the Common Cold 568
Chapter 39 Drugs for Asthma and Other Pulmonary Disorders 584

UNIT 7 THE GASTROINTESTINAL SYSTEM 601

- Chapter 40 Drugs for Peptic Ulcer Disease 602
Chapter 41 Drugs for Bowel Disorders and Other Gastrointestinal Conditions 616
Chapter 42 Drugs for Nutritional Disorders 635

UNIT 8 THE ENDOCRINE SYSTEM 655

- Chapter 43 Drugs for Pituitary, Thyroid, and Adrenal Disorders 656
Chapter 44 Drugs for Diabetes Mellitus 678
Chapter 45 Drugs for Disorders and Conditions of the Female Reproductive System 694
Chapter 46 Drugs for Disorders and Conditions of the Male Reproductive System 714

UNIT 9 INTEGUMENTARY SYSTEM, EYES, AND EARS 729

- Chapter 47 Drugs for Bone and Joint Disorders 730
Chapter 48 Drugs for Skin Disorders 750
Chapter 49 Drugs for Eye and Ear Disorders 768

Become PRACTICE-READY using your PEARSON RESOURCES

Simplify your study time by using the resources included with this textbook at <http://nursing.pearsonhighered.com>.

This book includes the following materials for you to use:

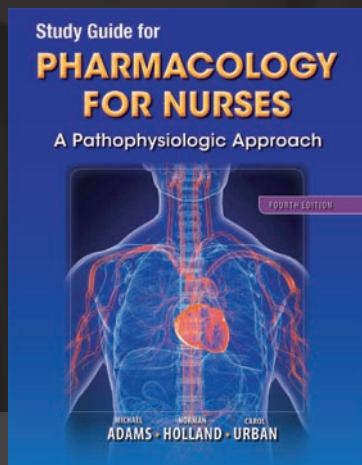
- Learning Outcomes
- NCLEX® Review Questions
- Critical Thinking Activities
- Case Studies
- Media Links
- and More...

Enhance your SUCCESS with the additional resources below.
For more information and purchasing options visit www.mypersonstore.com.

For Your Classroom Success

Study Guide for Pharmacology for Nurses: A Pathophysiologic Approach, 4th Edition.

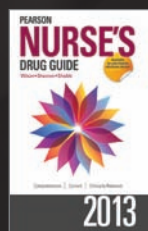
Practice, reinforce, and apply pharmacology content through a variety of activities and question types, including nursing applications and case studies.



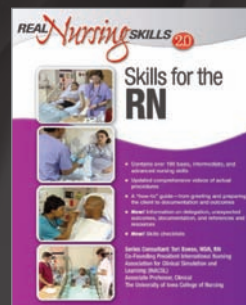
For Your Clinical Success

MyNursingApp™

Clinical references across the nursing curriculum available!



Pearson's Nurse's Drug Guide



visit:
www.realnursingskills.com

For Your NCLEX-RN® Success

MaryAnn Hogan, MSN, RN, provides clear, concentrated, and current review of "need to know" information for effective classroom and NCLEX-RN® preparation.



MyNursingLab[®]

www.mynursinglab.com

Learn more about and purchase
access to MyNursingLab.

MyNursingApp[™]

www.mynursingapp.com

MyNursingApp puts all the information
you need in the palm of your hand.

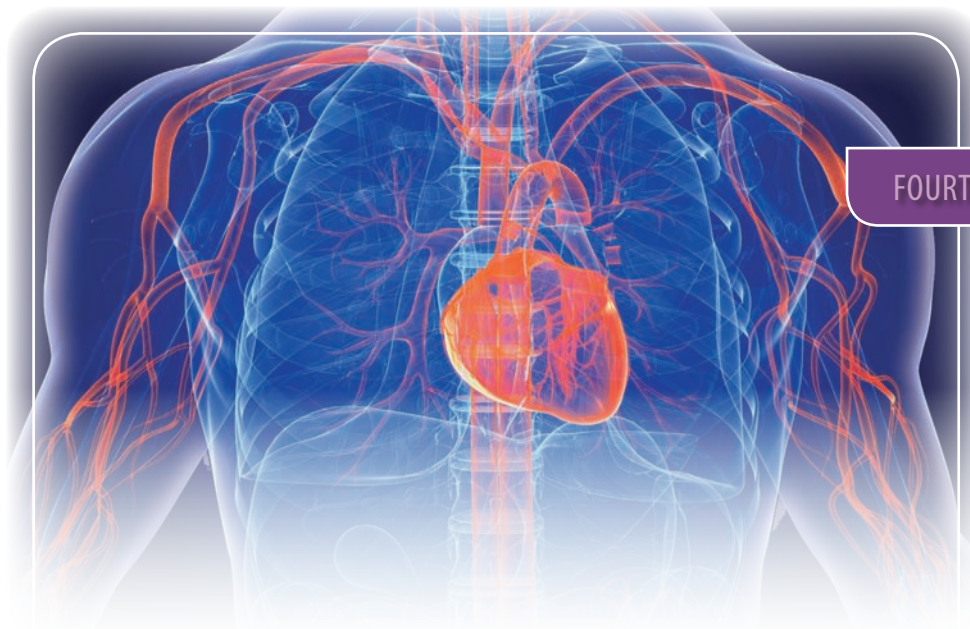
myPEARSONstore.com

Find your textbook and everything
that goes with it.

This page intentionally left blank

PHARMACOLOGY FOR NURSES

A Pathophysiologic Approach



FOURTH EDITION

Michael Patrick Adams

Professor of Anatomy and Physiology
St. Petersburg College
Formerly Dean of Health Professions
Pasco-Hernando Community College

Leland Norman Holland, Jr.

Program Manager
Hillsborough Community College
SouthShore Campus and
Professor of Pharmacology, MSN Nursing Program
Liberty University

Carol Quam Urban

Assistant Dean for Undergraduate Nursing
Assistant Professor, George Mason University
School of Nursing

PEARSON

Boston Columbus Indianapolis New York San Francisco Upper Saddle River
Amsterdam Cape Town Dubai London Madrid Milan Munich Paris Montreal Toronto
Delhi Mexico City São Paulo Sydney Hong Kong Seoul Singapore Taipei Tokyo

Publisher: Julie Levin Alexander
Publisher's Assistant: Regina Bruno
Executive Acquisitions Editor: Pamela Fuller
Development Editor: Anne Seitz, Hearthsides Publishing Services
Editorial Assistant: Cynthia Gates
Managing Production Editor: Patrick Walsh
Production Liaison: Cathy O'Connell
Production Editor: Mary Tindle, S4Carlisle Publishing Services
Manufacturing Manager: Lisa McDowell
Art Director: Christopher Weigand
Cover and Interior Design: Christine Canera
Director of Marketing: David Gesell

Senior Marketing Manager: Phoenix Harvey
Marketing Manager: Deborah Doyle
Marketing Specialist: Michael Sirinides
Marketing Assistant: Crystal Gonzalez
Assistant Editor for Media: Sarah Wrocklage
Media Project Managers: Rachel Collett, Leslie Brado, and Michael Dobson
Composition: S4Carlisle Publishing Services
Printer/Binder: Courier/Kendallville
Cover Printer: LeHigh Phoenix Color/Hagerstown
Cover Image: Sebastian Kaulitzki/Shutterstock

Credits and acknowledgments for content borrowed from other sources and reproduced, with permission, in this textbook appear on appropriate page within text except for the following:

Unit 1 opener, chapter openers 1–6: ARCHITECTE®/Shutterstock
Unit 2 opener, chapter openers 6–12: Sebastian Kaulitzki/Shutterstock
Unit 3 opener, chapter openers 13–21: Sebastian Kaulitzki/Shutterstock
Unit 4 opener, chapter openers 22–31: CLIPAREA 1 Custom media/Shutterstock
Unit 5 opener, chapter openers 32–37: Sebastian Kaulitzki/Shutterstock
Unit 6 opener, chapter openers 38–39: CLIPAREA 1 Custom media/Shutterstock
Unit 7 opener, chapter openers 40–42: CLIPAREA 1 Custom media/Shutterstock
Unit 8 opener, chapter openers 43–46: CLIPAREA 1 Custom media/Shutterstock
Unit 9 opener, chapter openers 47–49: Sebastian Kaulitzki/Shutterstock

Copyright © 2014, 2011 and 2008 by Pearson Education, Inc.

All rights reserved. Manufactured in the United States of America. This publication is protected by Copyright and permission should be obtained from the publisher prior to any prohibited reproduction, storage in a retrieval system, or transmission in any form or by any means, electronic, mechanical, photocopying, recording, or likewise. To obtain permission(s) to use material from this work, please submit a written request to Pearson Education, Inc., Permissions Department, One Lake Street, Upper Saddle River, New Jersey 07458 or you may fax your request to 201-236-3290.

A Note about Nursing Diagnoses: Nursing Diagnoses in this text are taken from *Nursing Diagnoses—Definitions and Classification 2012–2014*. Copyright © 2012, 1994–2012 by NANDA International. Used by arrangement with John Wiley & Sons Limited. In order to make safe and effective judgments using NANDA-I nursing diagnoses it is essential that nurses refer to the definitions and defining characteristics of the diagnoses listed in this work.

Notice: Care has been taken to confirm the accuracy of information presented in this book. The authors, editors, and the publisher, however, cannot accept any responsibility for errors or omissions or for consequences from application of the information in this book and make no warranty, express or implied, with respect to its contents.

The authors and publisher have exerted every effort to ensure that drug selections and dosages set forth in this text are in accord with current recommendations and practice at the time of publication. However, in view of ongoing research, changes in government regulations, and the constant flow of information relating to drug therapy and drug reactions, the reader is urged to check the package inserts of all drugs for any change in indications of dosage and for added warnings and precautions. This is particularly important when the recommended agent is a new and/or infrequently employed drug.

Library of Congress Cataloging-in-Publication Data

Adams, Michael, (Date)
Pharmacology for nurses: a pathophysiologic approach / Michael
Patrick Adams, Leland N. Holland, Carol Urban. — 4th ed.
p. ; cm.
Includes bibliographical references and index.
ISBN-13: 978-0-13-302618-4
ISBN-10: 0-13-302618-3
I. Holland, Leland Norman, (Date) II. Urban, Carol Q. (Carol Quam) III. Title.
[DNLM: 1. Drug Therapy—Nursing. 2. Pharmacological Phenomena—Nurses'
Instruction. 3. Pharmacology—Nurses' Instruction. WB 330]
LC Classification not assigned
615'.1—dc23

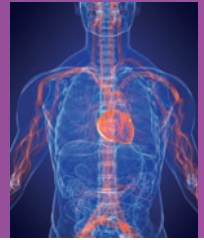
2012039180

10 9 8 7 6 5 4 3 2 1

PEARSON

ISBN-10: 0-13-302618-3
ISBN-13: 978-0-13-302618-4

About the Authors



Michael Patrick Adams, PhD, is an accomplished educator, author, and national speaker. The National Institute for Staff and Organizational Development in Austin, Texas, named Dr. Adams a Master Teacher. He has published two other textbooks with Pearson Publishing: *Core Concepts in Pharmacology* and *Pharmacology for Nurses: A Pathophysiologic Approach*.

Dr. Adams obtained his master's degree in pharmacology from Michigan State University and his doctorate in

education from the University of South Florida. Dr. Adams was on the faculty of Lansing Community College and served as Dean of Health Professions at Pasco-Hernando Community College for 15 years. He is currently Professor of Anatomy and Physiology at St. Petersburg College.

I dedicate this book to nursing educators, who contribute every day to making the world a better and more caring place.

—MPA

Leland Norman Holland, Jr., PhD (Norm), over 20 years ago, started out like many scientists, planning for a career in basic science research. He was quickly drawn to the field of teaching in higher medical education, where he has spent most of his career since then. Among the areas where he has been particularly effective are preparatory programs in nursing, medicine, dentistry, pharmacy, and allied health. Dr. Holland is both a professor and supporter in nursing education nationwide. He brings to the profession a depth of knowledge in biology, chemistry, and medically related

subjects such as microbiology, biological chemistry, and pharmacology. Dr. Holland's doctoral degree is in medical pharmacology. He is very much dedicated to the success of students and their preparation for careers in health care. He continues to motivate students in the lifelong pursuit of learning.

To the greatest family in the world, Karen, Alexandria, Caleb, and Joshua.

—LNH

Carol Quam Urban, PhD, RN, is the Assistant Dean for Undergraduate Nursing and an Assistant Professor in the School of Nursing, College of Health and Human Services, at George Mason University in Fairfax, Virginia. She has worked to develop and presents at conferences new models for RN-to-BSN education to answer the IOM's call for a seamless transition for continuing nursing education and practice. She serves on advisory boards for nurse residency programs and for community home health/hospice

agencies where she also provides education on topics in pharmacology, medication reconciliation, and patient education. She has published the Pearson textbook *Pharmacology: Connections to Practice* with Dr. Adams.

To my daughter, Joy, an extraordinary and resilient young woman and future nurse. And in memory of my son, Keith, the bravest and happiest soul I know.

—CQU



Thank You

Our heartfelt thanks go out to our colleagues from schools of nursing across the country who have given their time generously to help create this exciting new medical-surgical nursing textbook. These individuals helped us plan and shape our book and resources by reviewing chapters, art, design, and more. *Pharmacology for Nurses:*

A Pathophysiologic Approach, Fourth Edition, has reaped the benefit of your collective knowledge and experience as nurses and teachers, and we have improved the materials due to your efforts, suggestions, objections, endorsements, and inspiration. Among those who gave their time generously are the following:

Robin Adams-Weber, DNP, WHCNP-C, RN
Professor, Malone University
Canton, Ohio

Candyce Antley, RN, MN
Full-time Instructor, Midlands Technical College
Columbia, South Carolina

Mary Ann Balut, RN, MSN, APN
Professor, Raritan Valley Community College
Branchburg, New Jersey

Staci M. Boruff, MSN, RN
Course Coordinator, Walters State Community College
Morristown, Tennessee

Heather Campbell-Williams, MSN, RN
Professor, Oklahoma City Community College
Oklahoma City, Oklahoma

Darlene Clark, RN, MS
Course Coordinator, Penn State University
University Park, Pennsylvania

Joyce Coleman, MS, RN, WHNP-BC
Adjunct Instructor, Riverside School of Health Careers
Newport News, Virginia

Angela Collins, DSN, RN, CCNS, ACNS, BC
Professor, Capstone College of Nursing
Tuscaloosa, Alabama

Tamara Condrey, MSN, RN, ACNS-BC, CCRN
Professor, Columbus State University
Columbus, Georgia

Cynthia Cross, CCRN, APN
Professor, County College of Morris
Randolph, New Jersey

Diane Daddario, MSN, ACNS-BC, RN, BC, CMSRN
Adjunct Instructor, Pennsylvania College of Technology
Williamsport, Pennsylvania

Amanda Denno, MSN, MBA, RN
Full-time Instructor, Lakeview College of Nursing
Danville, Illinois

Sherika P. Derico, MSN, RN
Professor, Columbus State University
Columbus, Georgia

Janice Di Falco, RN, MSN, CNS, CMSRN, FAACVPR
Professor, San Jacinto College
Pasadena, Texas

Mary Easley, RN, MSN
Professor, Moberly Area Community College
Moberly, Missouri

Jacqueline Frock, MSN, RN
Professor, Oklahoma City Community College
Oklahoma City, Oklahoma

Yolanda Green
Professor, Chattanooga State Community College
Chattanooga, Tennessee

Sheri Gunderson, MS, RN
Full-time Instructor, Jamestown College
Jamestown, North Dakota

Carolyn E. Holl, RN, MA, CPN, CNE
Full-time Instructor, Raritan Valley Community College
Somerville, New Jersey

Monica Holland, MS, RN
Professor, Oklahoma City Community College
Oklahoma City, Oklahoma

Karen Hughes
Professor, Columbus State Community College
Columbus, Ohio

Shirley E. Keckley, RN, MSN, CNE
Professor, Columbus State Community College
Columbus, Ohio

Carol Kramme, MSN, CNE
Other, Cox College
Springfield, Missouri

Coleen Kumar, RN, MS, CNS
Professor, Kingsborough Community College
Brooklyn, New York

Cecilia Langford, EdD, MSN, ARNP, PMHNP-BC
Full-time Instructor, Florida State College
Jacksonville, Florida

Constance Lawrence, MS, FNP-BC, DNP
Adjunct Instructor, SUNY Brockport
Brockport, New York

Angela P. Lukomski, RN, DNP, CPNP
Professor, Eastern Michigan University
Ypsilanti, Missouri

Alice L. March, PhD, RN, FNP-C, CNE
Professor, The University of Alabama
Tuscaloosa, Alabama

Antoinette McCray, RNC, MSN, CNS
Full-time Instructor, Norfolk State University
Norfolk, Virginia

Susan McDonald, PhD, CPNP, CNS, RN
Full-time Instructor, Stephen F Austin State University
Nacogdoches, Texas

Bethany J. Mello, DNP, NP-c
Adjunct Instructor, Jamestown College
Jamestown, North Dakota

Mimi Merriman
Full-time Instructor, Columbus State University
Columbus, Georgia

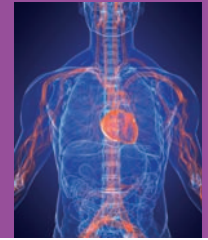
Michelle Montpas, RN, MSN, EdD, CNE
Professor, Mott Community College
Flint, Michigan

Amy Ragnone, MSN, MA, RN
Professor, College of Southern Nevada
Las Vegas, Nevada

Rose Marie Smith, RN, MS
Professor, Platt College
Oklahoma City, Oklahoma

Regina Tuma
Full-time Instructor, Cuyahoga Community College
Cleveland, Ohio

Benson Kar Leung Yeung, MSN, RN
Full-time Instructor, CSULA
Los Angeles, California



When students are asked which subject in their nursing program is the most challenging, pharmacology always appears near the top of the list. The study of pharmacology demands that students apply knowledge from a wide variety of the natural and applied sciences. Successfully predicting drug action requires a thorough knowledge of anatomy, physiology, chemistry, and pathology as well as the social sciences of psychology and sociology. Lack of adequate pharmacology knowledge can result in immediate and direct harm to the patient; thus, the stakes in learning the subject are high.

Pharmacology cannot be made easy, but it can be made understandable if the proper connections are made to knowledge learned in these other disciplines. The vast majority of drugs in clinical practice are prescribed for specific diseases, yet many pharmacology textbooks fail to recognize the complex interrelationships between pharmacology and pathophysiology. When drugs are learned in isolation from their associated diseases or conditions, students have difficulty connecting pharmacotherapy to therapeutic goals and patient wellness. The pathophysiology focus of this textbook gives the student a clearer picture of the importance of pharmacology to disease and, ultimately, to patient care. The approach and rationale of this textbook focus on a holistic perspective to patient care, which clearly shows the benefits and limitations of pharmacotherapy in curing or preventing illness. Although difficult and challenging, the study of pharmacology is truly a fascinating, lifelong journey.

NEW TO THIS EDITION

The fourth edition of *Pharmacology for Nurses: A Pathophysiologic Approach* has been thoroughly updated to reflect current pharmacologic drugs and processes.

- **NEW!** Evidence-Based Practice features apply medical research to pharmacology.
- **NEW!** Black Box Warnings issued by the FDA now appear for all appropriate drug prototypes.
- **NEW!** Incorporation of the QSEN competencies: The QSEN competencies related to patient-centered care, teamwork and collaboration, evidence-based practice, and patient safety are incorporated throughout the features and Nursing Process Focus charts.
- **EXPANDED!** Includes more than 40 new drugs, drug classes, indications, and therapies that have been approved since the last edition.
- **EXPANDED!** Pharmacotherapy Illustrated diagrams to help students visualize the connection between pharmacology and the patient.

- **UPDATED!** Nursing Process Focus charts have been revised to contain current applications to clinical practice.
- **ENHANCED AND REVISED!** End-of-chapter NCLEX-RN® questions now include alternative format items and complete rationales.
- **REVISED!** Many Mechanism in Action animations have been enhanced to identify the key drug mechanisms.

ORGANIZATION AND STRUCTURE— A BODY SYSTEM AND DISEASE APPROACH

Pharmacology for Nurses: A Pathophysiologic Approach is organized according to body systems (units) and diseases (chapters). Each chapter provides the complete information on the drug classifications used to treat the disease(s) classes. Specially designed numbered headings describe key concepts and cue students to each drug classification discussion.

The pathophysiology approach clearly places the drugs in context with how they are used therapeutically. The student is able to locate easily all relevant anatomy, physiology, pathology, and pharmacology in the same chapter in which the drugs are discussed. This approach provides the student with a clear view of the connection among pharmacology, pathophysiology, and the nursing care learned in other clinical courses.

The vast number of drugs available in clinical practice is staggering. To facilitate learning, this text uses drug prototypes in which the most representative drugs in each classification are introduced in detail. Students are less intimidated when they can focus their learning on one representative drug in each class.

Prototype Drug
Procainamide

Therapeutic Class: Class IA antiarrhythmic **Pharmacologic Class:** Sodium channel blocker

ACTIONS AND USES
Procainamide is an older drug, approved in 1950, that is chemically related to the local anesthetic procaine. Procainamide blocks sodium ion channels in myocardial cells, thus reducing automaticity and slowing conduction of the action potential across the myocardium. This slight delay in conduction velocity prolongs the refractory period and can suppress dysrhythmias. Procainamide is referred to as a broad-spectrum drug because it has the ability to correct many different types of atrial and ventricular dysrhythmias. The most common dosage form is the extended-release tablet; however, procainamide is also available in intravenous (IV) and intramuscular (IM) formulations. The therapeutic serum drug level is 4 to 8 mcg/mL. The use of procainamide has declined significantly due to the development of more specific and safer drugs.

ADMINISTRATION ALERTS

- Use the supine position during IV administration because severe hypotension may occur.
- Pregnancy category C.

PHARMACOKINETICS (PO)		
Onset	Peak	Duration
immediate IV, 10–30 min IM	1–1.5 h	3–4 h

ADVERSE EFFECTS
Nausea, vomiting, abdominal pain, hypotension, and headache are common during procainamide therapy. High doses may produce CNS effects such as confusion or psychosis.

Black Box Warning: Chronic administration may result in an increased titer of antinuclear antibodies (ANAs). A lupus-like syndrome may occur in 30% to 50% of patients who are taking the drug for more than a year. Procainamide should be reserved for life-threatening dysrhythmias because it has the ability to produce new dysrhythmias or worsen existing ones. Agranulocytosis, bone marrow depression, neutropenia, hypoplastic anemia, and thrombocytopenia have been reported, usually within the first 3 months of therapy. Complete blood counts should be monitored carefully and the drug discontinued at the first sign of potential blood dyscrasia.

Contraindications: Procainamide is contraindicated in patients with complete AV block, severe HF, blood dyscrasias, and myasthenia gravis.

INTERACTIONS
Drug–Drug: Additive cardiac depressant effects may occur if procainamide is administered with other antiarrhythmics. Additive anticholinergic side effects will occur if procainamide is used concurrently with anticholinergic drugs.
Lab Tests: Procainamide may increase values for the following: AST, ALT, serum alkaline phosphatase, LDH, and serum bilirubin. False-positive Coombs test and ANA titers may occur.
Herbal/Food: Unknown.

Treatment of Overdose: Supportive treatment is targeted to reversing hypotension with vasopressors and preventing or treating procainamide-induced dysrhythmias.

This text uses several strategies to connect pharmacology to nursing practice. Throughout the text the student will find interesting features such as Complementary and Alternative Therapies, Treating the Diverse Patient, and Lifespan Considerations that clearly place the drugs in context with their clinical applications. Evidence-Based Practice features illustrate how current medical research is used to improve patient teaching.

COMPLEMENTARY AND ALTERNATIVE THERAPIES

Fish Oils for Inflammation

Fish oils, also known as marine oils, are lipids found primarily in coldwater fish. These oils are rich sources of long-chain polyunsaturated fatty acids of the omega-3 type. The two most studied fatty acids found in fish oils are eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). These fatty acids are known for their triglyceride-lowering activity. Several mechanisms are believed to account for the anti-inflammatory activity of EPA and DHA. The two competitively inhibit the conversion of arachidonic acid to the proinflammatory prostaglandins, thus reducing their synthesis.

TREATING THE DIVERSE PATIENT

Sleep Disturbance in the Patient with Alzheimer's and Parkinson's Diseases

Both Alzheimer's and Parkinson's diseases are progressive degenerative neurologic disorders and sleep disturbances are common in both conditions. Loss of sleep may increase agitation and physical symptoms and it is difficult for both the patient and the family or caregiver when the patient often awakens. Promoting good sleep hygiene is important at any age, but it is particularly important for patients where sleep disturbances are common. Strategies that may improve sleep or sleep habits include:

- Establish regular schedules of activities throughout the day for mealtimes, toileting, and short rest periods.
- When possible, provide the patient with the opportunity to see the sun or sunlight to help maintain the body's circadian rhythms.

Students learn better when supplied with accurate, attractive graphics and rich media resources. *Pharmacology for Nurses: A Pathophysiologic Approach* contains a generous number of figures, with an unequalled art program. Pharmacotherapy Illustrated features appear throughout the text, breaking down complex topics into easily understood formats. Animations of drug mechanisms take the student step-by-step on how drugs act.

LIFESPAN CONSIDERATIONS: GERIATRIC

Dental Health and Dysrhythmias in the Older Adult

Studies have begun to link poor dental health with many diseases related to inflammation. Dental caries (tooth decay) has been shown to increase inflammatory chemicals in the body and some studies link the rise of these chemical mediators to coronary heart disease. Kaneko, Yoshihara, and Miyazaki (2011) studied adults age 70 or older for a period of 4 years. For nonsmokers, an increase in the number of oral sites with periodontal disease was associated with a statistically significant elevated risk of dysrhythmias. The same increase in risk was not found among those elders who smoked, although smoking is associated with the development of periodontal disease.

While increasing age is often associated with increasing dental concerns and tooth loss, the nurse should continue to encourage the older adult to maintain adequate dental hygiene, not only as a method for preserving teeth and dental function, but as a possible preventive measure

EVIDENCE-BASED PRACTICE

Folic Acid Supplements During Pregnancy for Mothers with Diabetes

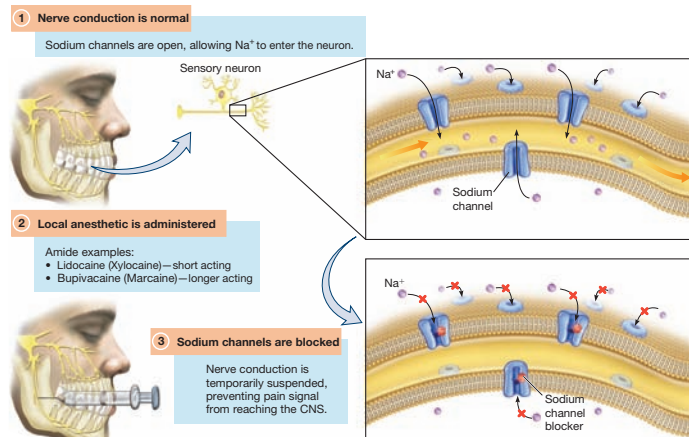
The Question: Does the use of perinatal vitamin supplements containing folic acid reduce the incidence of birth defects in infants born to mothers with diabetes?

Evidence: It has been established for several decades that folic acid deficiency during pregnancy increases the risk of neural tube and other defects in the newborn, and that receiving adequate amounts of folic acid during pregnancy can reduce the risk. Women with diabetes are also at higher risk for having a child with birth defects than women without diabetes.

Correa et al. (2012) used data from the National Birth Defects Prevention Study (1997–2004) to study the pregnancy outcomes in women with diabetes (type 1 or 2) who took vitamin supplements with folic acid compared to those who took no supplements during pregnancy. Compared to women with diabetes who took such supplements, the authors estimated a twofold

PHARMACOTHERAPY ILLUSTRATED

19.1 Mechanism of Action of Local Anesthetics



One of the strongest components of *Pharmacology for Nurses: A Pathophysiologic Approach* is the Nursing Process Focus feature. This feature clearly and concisely relates pharmacotherapy to patient assessment, nursing diagnoses, planning patient outcomes, implementing patient-centered care, and evaluating the outcomes. Student feedback has shown that these Nursing Process Focus tables are a significant component of planning and implementing nursing care plans.

No pharmacology text is complete unless it contains a method of self-assessment by which students may gauge their progress. *Pharmacology for Nurses: A Pathophysiologic Approach* contains an end-of-chapter review of the major concepts. NCLEX-RN® and case study questions, with the answers provided, allow students to check their retention of chapter material.

ACKNOWLEDGMENTS

When authoring a textbook like this, many dedicated and talented professionals are needed to bring the vision to reality. Pamela Fuller, Executive Acquisitions Editor, is responsible for guiding the many details in the production of the fourth edition. Our Development Editors, Laura Horowitz and Anne Seitz, supplied the expert guidance and leadership to keep everyone on track and be certain our project would be created on time. Providing the expertise for our comprehensive supplement package was Nicole Coady.

The superb design staff at Pearson, especially Chris Weigand, created wonderful text and cover designs. The

Nursing Process Focus PATIENTS RECEIVING ERYTHROPOIESIS-STIMULATING DRUGS	
ASSESSMENT	POTENTIAL NURSING DIAGNOSES
<p>Baseline assessment prior to administration:</p> <ul style="list-style-type: none"> Obtain a complete health history including cardiovascular (including hypertension [HTN], MI) and peripheral vascular disease, respiratory (including previous pulmonary embolism), neurologic (including stroke), or hepatic or renal disease. Obtain a drug history including allergies, current prescription and over-the-counter (OTC) drugs, herbal preparations, and alcohol use. Be alert to possible drug interactions. Obtain baseline weight and vital signs, especially blood pressure. Evaluate appropriate laboratory findings (e.g., CBC, aPTT, INR, transferrin and serum ferritin levels, renal and liver function studies). <p>Assessment throughout administration:</p> <ul style="list-style-type: none"> Continue assessment for therapeutic effects (e.g., Hct, RBC count significantly improved, patient's activity level and general sense of well-being have improved). Continue frequent monitoring of appropriate laboratory values (e.g., CBC, aPTT, INR). Monitor vital signs frequently, especially blood pressure, during the first 2 weeks of therapy. Assess for adverse effects: HTN, headache, neurologic changes in level of consciousness or premonitory signs and symptoms of seizure activity, angina, and signs of thrombosis development in peripheral extremities. 	<ul style="list-style-type: none"> Ineffective Tissue Perfusion Activity Intolerance Fatigue Deficient Knowledge (drug therapy) Risk for Injury, related to adverse drug effects
<p>PLANNING: PATIENT GOALS AND EXPECTED OUTCOMES</p>	



Chapter Review

KEY CONCEPTS

The numbered key concepts provide a succinct summary of the important points from the corresponding numbered section within the chapter. If any of these points are not clear, refer to the numbered section within the chapter for review.

- 29.1** The frequency of dysrhythmias in the population is difficult to predict because many patients experience no symptoms. Persistent or severe dysrhythmias may be lethal. Dysrhythmias are classified by the location (atrial or ventricular) or type (flutter, fibrillation, or block) of rhythm abnormality produced.
- 29.6** Antidysrhythmic drugs are classified by their mechanism of action, namely, classes I through IV. The use of antidysrhythmic drugs has been declining.
- 29.7** Sodium channel blockers, the largest group of antidysrhythmics, act by slowing the rate of impulse conduction across the heart.

production process was guided by Production Editor Cathy O'Connell. Mary Tindle and her colleagues at S4Carlisle provided expert, professional guidance in all aspects of the art and production process.

Although difficult and challenging, the study of pharmacology is truly a fascinating lifelong journey. We hope we have succeeded in writing a textbook that makes that study easier and more understandable so that nursing students will be able to provide safe, effective nursing care to patients who are undergoing drug therapy. We hope students and faculty will share with us their experiences using this textbook and all its resources.



Contents

ABOUT THE AUTHORS v

THANK YOU vi

PREFACE vii

UNIT 1 CORE CONCEPTS 1

<i>Chapter 1</i>	Introduction to Pharmacology	2
1.1	History of Pharmacology	3
1.2	Pharmacology: The Study of Medicines	3
1.3	Pharmacology and Therapeutics	4
1.4	Classification of Therapeutic Agents as Drugs, Biologics, and Complementary and Alternative Medicine Therapies	4
1.5	Prescription and Over-the-Counter Drugs	4
1.6	Drug Regulations and Standards	5
1.7	The Role of the Food and Drug Administration	6
1.8	Phases of Approval for Therapeutic and Biologic Drugs	7
1.9	Changes to the Drug Approval Process	8
1.10	Nurses, the Drug Approval Process, and the Need for Effective Safety Practices	9
<i>Chapter 2</i>	Drug Classes and Schedules	11
2.1	Therapeutic and Pharmacologic Classification of Drugs	12
2.2	Chemical, Generic, and Trade Names for Drugs	13
2.3	Differences Between Brand-Name Drugs and Their Generic Equivalents	13
2.4	Controlled Substances, Drug Schedules, and Teratogenic Risks	15
<i>Chapter 3</i>	Principles of Drug Administration	18
3.1	Medication Knowledge and Understanding	19
3.2	The Rights of Drug Administration	20
3.3	Patient Compliance and Successful Pharmacotherapy	20
3.4	Drug Orders and Time Schedules	21
3.5	Systems of Measurement	22
3.6	Enteral Drug Administration	23
	TABLETS AND CAPSULES	24
	SUBLINGUAL AND BUCCAL DRUG ADMINISTRATION	25
	NASOGASTRIC AND GASTROSTOMY DRUG ADMINISTRATION	26
3.7	Topical Drug Administration	26
	TRANSDERMAL DELIVERY SYSTEM	26
	OPHTHALMIC ADMINISTRATION	26
	OTIC ADMINISTRATION	28
	NASAL ADMINISTRATION	28
	VAGINAL ADMINISTRATION	29
	RECTAL ADMINISTRATION	29

3.8	Parenteral Drug Administration	30
	INTRADERMAL AND SUBCUTANEOUS ADMINISTRATION	30
	INTRAMUSCULAR ADMINISTRATION	32
	INTRAVENOUS ADMINISTRATION	34

<i>Chapter 4</i>	Pharmacokinetics	36
4.1	Pharmacokinetics: How the Body Handles Medications	37
4.2	The Passage of Drugs Through Plasma Membranes	37
4.3	Absorption of Medications	37
4.4	Distribution of Medications	39
4.5	Metabolism of Medications	40
4.6	Excretion of Medications	41
4.7	Drug Plasma Concentration and Therapeutic Response	42
4.8	Onset, Peak Levels, and Duration of Drug Action	43
4.9	Loading Doses and Maintenance Doses	44
<i>Chapter 5</i>	Pharmacodynamics	46
5.1	Pharmacodynamics and Interpatient Variability	47
5.2	Therapeutic Index and Drug Safety	47
5.3	The Graded Dose–Response Relationship and Therapeutic Response	48
5.4	Potency and Efficacy	49
5.5	Cellular Receptors and Drug Action	49
5.6	Types of Drug–Receptor Interactions	51
5.7	Pharmacology of the Future: Customizing Drug Therapy	51

UNIT 2 PHARMACOLOGY AND THE NURSE–PATIENT RELATIONSHIP 55

<i>Chapter 6</i>	The Nursing Process in Pharmacology	56
6.1	Overview of the Nursing Process	57
6.2	Assessment of the Patient	57
6.3	Nursing Diagnoses	60
6.4	Planning: Establishing Goals and Outcomes	60
6.5	Implementing Specific Nursing Actions	61
	PATIENT EDUCATION	62
6.6	Evaluating the Effects of Medications	63
<i>Chapter 7</i>	Medication Errors and Risk Reduction	66
7.1	Defining Medication Errors	67
7.2	Factors Contributing to Medication Errors	67
7.3	The Impact of Medication Errors	67

- 7.4 Reporting and Documenting Medication Errors 69
 - DOCUMENTING IN THE PATIENT'S MEDICAL RECORD 69
 - Reporting the Error* 70
 - Sentinel Events* 70
- 7.5 Strategies for Reducing Medication Errors 70
- 7.6 Medication Reconciliation 72
- 7.7 Effective Patient Teaching for Medication Usage 72
- 7.8 How the Health Care Industry Is Reducing Medication Errors 72
- 7.9 Governmental and Other Agencies That Track Medication Errors 73

Chapter 8 Drug Administration Throughout the Life Span 76

- 8.1 Pharmacotherapy Across the Life Span 77
- 8.2 Pharmacotherapy of the Pregnant Patient 77
 - PHYSIOLOGICAL CHANGES DURING PREGNANCY THAT AFFECT PHARMACOTHERAPY 77
 - Absorption* 77
 - Distribution and Metabolism* 78
 - Excretion* 78
 - GESTATIONAL AGE AND DRUG THERAPY 78
 - PREGNANCY DRUG CATEGORIES AND REGISTRIES 78
 - PREGNANCY REGISTRIES 79
- 8.3 Pharmacotherapy of the Lactating Patient 79
- 8.4 Pharmacotherapy of Infants 81
- 8.5 Pharmacotherapy of Toddlers 82
- 8.6 Pharmacotherapy of Preschoolers and School-Age Children 82
- 8.7 Pharmacotherapy of Adolescents 84
- 8.8 Pharmacotherapy of Young and Middle-Aged Adults 84
- 8.9 Pharmacotherapy of Older Adults 85

Chapter 9 Psychosocial, Gender, and Cultural Influences on Pharmacotherapy 89

- 9.1 The Concept of Holistic Pharmacotherapy 90
- 9.2 Psychosocial Influences on Pharmacotherapy 90
- 9.3 Cultural and Ethnic Influences on Pharmacotherapy 91
- 9.4 Community and Environmental Influences on Pharmacotherapy 92
- 9.5 Genetic Influences on Pharmacotherapy 93
- 9.6 Gender Influences on Pharmacotherapy 94

Chapter 10 Herbal and Alternative Therapies 97

- 10.1 Alternative Therapies 98
- 10.2 Brief History of Therapeutic Natural Products 98
- 10.3 Herbal Product Formulations 100

- 10.4 Regulation of Herbal Products and Dietary Supplements 100
- 10.5 The Pharmacologic Actions and Safety of Herbal Products 102
- 10.6 Specialty Supplements 103
- 10.7 Patient Teaching Regarding CAM 104

Chapter 11 Substance Abuse 107

- 11.1 Overview of Substance Abuse 108
- 11.2 Neurobiologic and Psychosocial Components of Substance Abuse 108
- 11.3 Physical and Psychological Dependence 108
- 11.4 Withdrawal Syndrome 109
- 11.5 Tolerance 110
- 11.6 CNS Depressants 111
 - SEDATIVES AND SEDATIVE-HYPNOTICS 111
 - OPIOIDS 111
 - ETHYL ALCOHOL 112
- 11.7 Cannabinoids 113
 - MARIJUANA 113
- 11.8 Hallucinogens 113
 - LSD 113
 - OTHER HALLUCINOGENS 114
- 11.9 CNS Stimulants 114
 - AMPHETAMINES AND METHYLPHENIDATE 114
 - COCAINE 115
 - CAFFEINE 115
- 11.10 Nicotine 115
 - TOBACCO USE AND NICOTINE 115
- 11.11 The Nurse's Role in Substance Abuse 116

Chapter 12 Emergency Preparedness and Poisonings 119

- 12.1 The Nature of Bioterrorism 120
- 12.2 Role of the Nurse in Emergency Preparedness 122
- 12.3 Strategic National Stockpile 122
- 12.4 Anthrax 123
- 12.5 Viruses 124
- 12.6 Toxic Chemicals 124
- 12.7 Ionizing Radiation 125
- 12.8 Poisonings and Fundamentals of Toxicity Treatment 126

UNIT 3 THE NERVOUS SYSTEM 131

Chapter 13 Drugs Affecting the Autonomic Nervous System 132

- 13.1 Overview of the Nervous System 133
- 13.2 Sympathetic and Parasympathetic Divisions 134
- 13.3 Structure and Function of Autonomic Synapses 135

- 13.4 Norepinephrine and Adrenergic Transmission 135
- 13.5 Acetylcholine and Cholinergic Transmission 137
- 13.6 Classification and Naming of Autonomic Drugs 138
- 13.7 Clinical Applications of Adrenergic Drugs 138
- 13.8 Clinical Applications of Adrenergic-Blocking Drugs 140
- Nursing Process Focus** Patients Receiving Adrenergic Drug Therapy 141
- Nursing Process Focus** Patients Receiving Adrenergic-Blocker Therapy 144
- 13.9 Clinical Applications of Cholinergic Drugs 145
- Nursing Process Focus** Patients Receiving Cholinergic Drug Therapy 147
- 13.10 Clinical Applications of Anticholinergics 149
- Nursing Process Focus** Patients Receiving Anticholinergic Drug Therapy 152
- Chapter 14 Drugs for Anxiety and Insomnia** 155
- 14.1 Types of Anxiety Disorders 156
- 14.2 Specific Regions of the Brain Responsible for Anxiety and Wakefulness 156
- 14.3 Anxiety Management Through Pharmacologic and Nonpharmacologic Strategies 157
- 14.4 Insomnia and Its Link to Anxiety 158
- 14.5 Use of the Electroencephalogram to Diagnose Sleep Disorders 159
- 14.6 Treating Anxiety and Insomnia with CNS Drugs 160
- 14.7 Antidepressants for Symptoms of Panic and Anxiety 161
- 14.8 Treating Anxiety and Insomnia with Benzodiazepines 163
- 14.9 Use of Barbiturates as Sedatives 164
- 14.10 Other CNS Depressants for Anxiety and Sleep Disorders 165
- Nursing Process Focus** Patients Receiving Drugs for Anxiety Disorders 167
- Chapter 15 Drugs for Seizures** 171
- 15.1 Causes of Seizures 172
- 15.2 Types of Seizures 173
- 15.3 General Concepts of Antiseizure Pharmacotherapy 173
- 15.4 Mechanisms of Action of Antiseizure Drugs 175
- 15.5 Treating Seizures with Barbiturates 176
- 15.6 Treating Seizures with Benzodiazepines 176
- 15.7 Treating Seizures with Hydantoins and Related Drugs 178
- 15.8 Treating Seizures with Succinimides 181
- 15.9 Treating Seizures with Amino Acid Compounds 182
- Nursing Process Focus** Patients Receiving Antiseizure Drug Therapy 183
- Chapter 16 Drugs for Emotional, Mood, and Behavioral Disorders** 188
- 16.1 Characteristics and Forms of Depression 189
- 16.2 Assessment and Treatment of Depression 190
- 16.3 Mechanism of Action of Antidepressants 191
- 16.4 Treating Depression with Tricyclic Antidepressants 191
- 16.5 Treating Depression with SSRIs 191
- 16.6 Treating Depression with Atypical Antidepressants 195
- 16.7 Treating Depression with MAO Inhibitors 196
- 16.8 Characteristics of Bipolar Disorder 197
- Nursing Process Focus** Patients Receiving Pharmacotherapy for Mood Disorders 198
- 16.9 Pharmacotherapy of Bipolar Disorder 200
- 16.10 Characteristics of ADHD 202
- 16.11 Pharmacotherapy of ADHD 203
- Nursing Process Focus** Patients Receiving Pharmacotherapy for Attention Deficit/Hyperactivity Disorder 205
- Chapter 17 Drugs for Psychoses** 209
- 17.1 The Nature of Psychoses 210
- 17.2 Schizophrenia 210
- 17.3 Pharmacologic Management of Psychoses 211
- 17.4 Treating Psychoses with Phenothiazines 212
- 17.5 Treating Psychoses with Conventional Nonphenothiazine Antipsychotics 214
- Nursing Process Focus** Patients Receiving Antipsychotic Pharmacotherapy 216
- 17.6 Treating Psychoses with Atypical Antipsychotics 218
- 17.7 Treating Psychoses with Dopamine System Stabilizers 219
- Chapter 18 Drugs for the Control of Pain** 222
- 18.1 Assessment and Classification of Pain 223
- 18.2 Nonpharmacologic Techniques for Pain Management 223
- 18.3 The Neural Mechanisms of Pain 224
- 18.4 Classification of Opioids 225
- 18.5 Pharmacotherapy with Opioid Agonists 225
- 18.6 Pharmacotherapy with Opioid Antagonists 228
- Nursing Process Focus** Patients Receiving Opioid Therapy 229
- 18.7 Treatment for Opioid Dependence 231
- 18.8 Pharmacotherapy with NSAIDs 233
- ASPIRIN, IBUPROFEN, AND COX-2 INHIBITORS 233
- ACETAMINOPHEN 234
- CENTRALLY ACTING DRUGS 234

- 18.9 Classification of Headaches 234
Nursing Process Focus Patients Receiving NSAID Therapy 235
- 18.10 Drug Therapy for Migraine Headaches 237
Nursing Process Focus Patients Receiving Triptan Therapy 239

Chapter 19 **Drugs for Local and General Anesthesia** 243

- 19.1 Regional Loss of Sensation Using Local Anesthesia 244
- 19.2 Mechanism of Action of Local Anesthesia 244
- 19.3 Classification of Local Anesthetics 246
 ESTERS 246
 AMIDES 247
Nursing Process Focus Patients Receiving Local Anesthesia 248
- 19.4 Characteristics of General Anesthesia 250
- 19.5 Pharmacotherapy with Inhaled General Anesthetics 250
 GAS 251
 VOLATILE LIQUIDS 251
- 19.6 Pharmacotherapy with IV General Anesthetics 252
Nursing Process Focus Patients Receiving General Anesthesia 253
- 19.7 Drugs as Adjuncts to Surgery 255

Chapter 20 **Drugs for Degenerative Diseases of the Nervous System** 259

- 20.1 Degenerative Diseases of the Central Nervous System 260
- 20.2 Characteristics of Parkinson's Disease 260
- 20.3 Treating Parkinsonism with Dopaminergic Drugs 261
- 20.4 Treating Parkinsonism with Anticholinergic Drugs 263
- 20.5 Characteristics of Alzheimer's Disease 265
Nursing Process Focus Patients Receiving Pharmacotherapy for Parkinson's Disease 266
- 20.6 Treating Alzheimer's Disease with Acetylcholinesterase Inhibitors 268
- 20.7 Characteristics of Multiple Sclerosis 270
- 20.8 Treating Multiple Sclerosis with Disease-Modifying Drugs and Drugs to Improve Walking 271

Chapter 21 **Drugs for Neuromuscular Disorders** 274

- 21.1 Causes of Muscle Spasms 275
- 21.2 Pharmacologic and Nonpharmacologic Treatment of Muscle Spasms 275
- 21.3 Treating Muscle Spasms at the Level of the Central Nervous System 275

- 21.4 Causes and Treatment of Spasticity 277
- 21.5 Treating Muscle Spasms Directly at the Muscle Tissue 278
- 21.6 Blocking the Effect of Acetylcholine at the Receptor 279
Nursing Process Focus Patients Receiving Pharmacotherapy for Muscle Spasms or Spasticity 280

UNIT 4 **THE CARDIOVASCULAR AND URINARY SYSTEMS** 285

Chapter 22 **Drugs for Lipid Disorders** 286

- 22.1 Types of Lipids 287
- 22.2 Lipoproteins 287
- 22.3 LDL and Cardiovascular Disease 288
- 22.4 Controlling Lipid Levels Through Lifestyle Changes 289
- 22.5 Pharmacotherapy with Statins 290
- 22.6 Bile Acid Sequestrants for Reducing Cholesterol and LDL Levels 292
- 22.7 Pharmacotherapy with Niacin 293
- 22.8 Pharmacotherapy with Fibrin Acid Agents 294
- 22.9 Pharmacotherapy with Cholesterol Absorption Inhibitors 295
Nursing Process Focus Patients Receiving Lipid-Lowering Pharmacotherapy 295

Chapter 23 **Diuretic Therapy and Drugs for Renal Failure** 299

- 23.1 Functions of the Kidneys 300
- 23.2 Renal Reabsorption and Secretion 301
- 23.3 Diagnosis and Pharmacotherapy of Renal Failure 301
- 23.4 Mechanisms of Action of Diuretics 302
- 23.5 Pharmacotherapy with Loop Diuretics 303
- 23.6 Pharmacotherapy with Thiazide Diuretics 305
- 23.7 Pharmacotherapy with Potassium-Sparing Diuretics 305
- 23.8 Miscellaneous Diuretics for Specific Indications 306
Nursing Process Focus Patients Receiving Diuretic Pharmacotherapy 308

Chapter 24 **Drugs for Fluid Balance, Electrolyte, and Acid–Base Disorders** 313

- 24.1 Body Fluid Compartments 314
- 24.2 Osmolality, Tonicity, and the Movement of Body Fluids 314
- 24.3 Regulation of Fluid Intake and Output 315
- 24.4 Intravenous Therapy with Crystalloids and Colloids 315
 CRYSTALLOIDS 315

- COLLOIDS 316
- Nursing Process Focus** Patients Receiving IV Fluid and Electrolyte Replacement Therapy 316
- 24.5 Physiological Role of Electrolytes 319
- 24.6 Pharmacotherapy of Sodium Imbalances 320
- HYPERNATREMIA 321
- HYPONATREMIA 321
- 24.7 Pharmacotherapy of Potassium Imbalances 322
- HYPERKALEMIA 322
- HYPOKALEMIA 323
- 24.8 Buffers and the Maintenance of Body pH 323
- 24.9 Pharmacotherapy of Acidosis 323
- 24.10 Pharmacotherapy of Alkalosis 325
- Chapter 25 Drugs for Hypertension 328**
- 25.1 Definition and Classification of Hypertension 329
- 25.2 Factors Responsible for Blood Pressure 330
- 25.3 Physiological Regulation of Blood Pressure 330
- 25.4 Etiology and Pathogenesis of Hypertension 331
- 25.5 Nonpharmacologic Management of Hypertension 332
- 25.6 Factors Affecting the Selection of Antihypertensive Drugs 333
- 25.7 Treating Hypertension with Diuretics 335
- 25.8 Treating Hypertension with ACE Inhibitors and Angiotensin Receptor Blockers 336
- 25.9 Treating Hypertension with Calcium Channel Blockers 338
- Nursing Process Focus** Patients Receiving Antihypertensive Pharmacotherapy 340
- 25.10 Treating Hypertension with Adrenergic Antagonists 342
- BETA-ADRENERGIC BLOCKERS 342
- ALPHA₁-ADRENERGIC BLOCKERS 343
- ALPHA₂-ADRENERGIC AGONISTS 343
- 25.11 Treating Hypertension with Direct Vasodilators 344
- Chapter 26 Drugs for Heart Failure 347**
- 26.1 The Etiology of Heart Failure 348
- 26.2 Cardiovascular Changes in Heart Failure 348
- 26.3 Pharmacologic Management of Heart Failure 349
- 26.4 Treatment of Heart Failure with ACE Inhibitors and Angiotensin Receptor Blockers 350
- 26.5 Treatment of Heart Failure with Diuretics 352
- 26.6 Treatment of Heart Failure with Cardiac Glycosides 353
- 26.7 Treatment of Heart Failure with Beta-Adrenergic Blockers (Antagonists) 354
- 26.8 Treatment of Heart Failure with Vasodilators 355
- 26.9 Treatment of Heart Failure with Phosphodiesterase Inhibitors and Other Inotropic Drugs 355
- Nursing Process Focus** Patients Receiving Pharmacotherapy for Heart Failure 357
- Chapter 27 Drugs for Angina Pectoris and Myocardial Infarction 361**
- 27.1 Pathogenesis of Coronary Artery Disease 362
- 27.2 Pathogenesis of Angina Pectoris 362
- 27.3 Nonpharmacologic Management of Angina 363
- 27.4 Pharmacologic Management of Angina 364
- 27.5 Treating Angina with Organic Nitrates 365
- 27.6 Treating Angina with Beta-Adrenergic Blockers 366
- 27.7 Treating Angina with Calcium Channel Blockers 366
- Nursing Process Focus** Patients Receiving Pharmacotherapy with Organic Nitrates 367
- 27.8 Diagnosis of Acute Coronary Syndrome 370
- 27.9 Treating Myocardial Infarction with Thrombolytics 372
- 27.10 Drugs for Symptoms and Complications of Acute Myocardial Infarction 372
- Chapter 28 Drugs for Shock 377**
- 28.1 Characteristics of Shock 378
- 28.2 Causes of Shock 378
- 28.3 Treatment Priorities for a Patient with Shock 378
- 28.4 Treating Shock with IV Fluid Therapy 380
- 28.5 Treating Shock with Vasoconstrictors/Vasopressors 381
- 28.6 Treating Shock with Inotropic Drugs 381
- Nursing Process Focus** Patients Receiving Pharmacotherapy for Shock 382
- 28.7 Pharmacotherapy of Anaphylaxis 385
- Chapter 29 Drugs for Dysrhythmias 389**
- 29.1 Etiology and Classification of Dysrhythmias 390
- 29.2 Conduction Pathways in the Myocardium 390
- 29.3 The Electrocardiograph 391
- 29.4 Nonpharmacologic Therapy of Dysrhythmias 392
- 29.5 Phases of the Myocardial Action Potential 393
- 29.6 Mechanisms and Classification of Antidysrhythmic Drugs 394
- 29.7 Treating Dysrhythmias with Sodium Channel Blockers 394
- Nursing Process Focus** Patients Receiving Antidysrhythmic Drugs 396

- 29.8 Treating Dysrhythmias with Beta-Adrenergic Antagonists 398
- 29.9 Treating Dysrhythmias with Potassium Channel Blockers 398
- 29.10 Treating Dysrhythmias with Calcium Channel Blockers 400
- 29.11 Miscellaneous Drugs for Dysrhythmias 401
- Chapter 30 Drugs for Coagulation Disorders 404**
- 30.1 The Process of Hemostasis 405
- 30.2 Removal of Blood Clots 406
- 30.3 Alterations of Hemostasis 406
- 30.4 Mechanisms of Coagulation Modification 408
- 30.5 Pharmacotherapy with Anticoagulants 408
- ORAL ANTICOAGULANTS 410
- Nursing Process Focus** Patients Receiving Anticoagulant and Antiplatelet Pharmacotherapy 411
- 30.6 Pharmacotherapy with Antiplatelet Drugs 414
- 30.7 Pharmacotherapy with Thrombolytics 416
- Nursing Process Focus** Patients Receiving Thrombolytic Pharmacotherapy 417
- 30.8 Pharmacotherapy with Hemostatics 419
- Chapter 31 Drugs for Hematopoietic Disorders 422**
- 31.1 Hematopoiesis 423
- 31.2 Pharmacotherapy with Erythropoiesis-Stimulating Drugs 425
- 31.3 Pharmacotherapy with Colony-Stimulating Factors 425
- Nursing Process Focus** Patients Receiving Erythropoiesis-Stimulating Drugs 426
- Nursing Process Focus** Patients Receiving Colony-Stimulating Factors 428
- 31.4 Pharmacotherapy with Platelet Enhancers 430
- 31.5 Classification of Anemias 431
- 31.6 Pharmacotherapy with Vitamin B₁₂ and Folic Acid 432
- 31.7 Pharmacotherapy with Iron 433
- Nursing Process Focus** Patients Receiving Pharmacotherapy for Anemia (Folic Acid, Vitamin B₁₂, Ferrous Sulfate) 434
- UNIT 5 THE IMMUNE SYSTEM 439**
- Chapter 32 Drugs for Immune System Modulation 440**
- 32.1 Innate (Nonspecific) Body Defenses and the Immune Response 441
- 32.2 Humoral Immune Response and Antibodies 441
- 32.3 Administration of Vaccines 442
- 32.4 Cell-Mediated Immunity and Cytokines 444
- 32.5 Pharmacotherapy with Biologic Response Modifiers 445
- Nursing Process Focus** Patients Receiving Immunostimulant Therapy 449
- 32.6 Immunosuppressants for Preventing Transplant Rejection and for Treating Inflammation 451
- TRANSPLANTATION 451
- ACUTE INFLAMMATORY DISORDERS 451
- Nursing Process Focus** Patients Receiving Immunosuppressant Therapy 454
- Chapter 33 Drugs for Inflammation and Fever 458**
- 33.1 The Function of Inflammation 459
- 33.2 The Role of Chemical Mediators in Inflammation 459
- 33.3 General Strategies for Treating Inflammation 460
- 33.4 Treating Inflammation with NSAIDs 461
- SALICYLATES 462
- IBUPROFEN AND IBUPROFEN-LIKE NSAIDs 463
- COX-2 INHIBITORS 464
- 33.5 Treating Acute or Severe Inflammation with Corticosteroids 464
- 33.6 Treating Fever with Antipyretics 465
- Nursing Process Focus** Patients Receiving Anti-Inflammatory and Antipyretic Pharmacotherapy 467
- Chapter 34 Drugs for Bacterial Infections 472**
- 34.1 Pathogenicity and Virulence 473
- 34.2 Describing and Classifying Bacteria 473
- 34.3 Classification of Anti-Infective Drugs 473
- 34.4 Actions of Anti-Infective Drugs 474
- 34.5 Acquired Resistance 475
- 34.6 Selection of an Effective Antibiotic 476
- 34.7 Host Factors 477
- HOST DEFENSES 477
- LOCAL TISSUE CONDITIONS 477
- ALLERGY HISTORY 478
- OTHER PATIENT VARIABLES 478
- 34.8 Pharmacotherapy with Penicillins 479
- 34.9 Pharmacotherapy with Cephalosporins 480
- 34.10 Pharmacotherapy with Tetracyclines 482
- 34.11 Pharmacotherapy with Macrolides 483
- 34.12 Pharmacotherapy with Aminoglycosides 485
- 34.13 Pharmacotherapy with Fluoroquinolones 486
- 34.14 Pharmacotherapy with Sulfonamides 487
- 34.15 Carbapenems and Miscellaneous Antibacterials 489
- Nursing Process Focus** Patients Receiving Antibacterial Pharmacotherapy 491

- 34.16 Pharmacotherapy of Tuberculosis 494
Nursing Process Focus Patients Receiving
 Antituberculosis Drugs 496

Chapter 35 Drugs for Fungal, Protozoan, and Helminthic Infections 501

- 35.1 Characteristics of Fungi 502
 35.2 Classification of Mycoses 503
 35.3 Mechanism of Action of Antifungal Drugs 503
 35.4 Pharmacotherapy of Systemic Fungal Diseases 503
Nursing Process Focus Patients Receiving
 Antifungal Drugs 505
 35.5 Pharmacotherapy with the Azole Antifungals 507
 SYSTEMIC AZOLES 507
 TOPICAL AZOLES 508
 35.6 Pharmacotherapy of Superficial Fungal Infections 508
 35.7 Pharmacotherapy of Malaria 510
 35.8 Pharmacotherapy of Nonmalarial Protozoan Infections 512
 35.9 Pharmacotherapy of Helminthic Infections 514
Nursing Process Focus Patients Receiving
 Pharmacotherapy for Protozoan or
 Helminthic Infections 516

Chapter 36 Drugs for Viral Infections 520

- 36.1 Characteristics of Viruses 521
 36.2 Replication of HIV 522
 36.3 General Principles of HIV Pharmacotherapy 523
 36.4 Classification of Drugs for HIV-AIDS 524
 36.5 Pharmacotherapy with Reverse Transcriptase Inhibitors 525
 36.6 Pharmacotherapy with Protease Inhibitors 527
 36.7 Pharmacotherapy with Entry Inhibitors and Integrase Inhibitors 527
 36.8 Prevention of Perinatal Transmission of HIV 528
Nursing Process Focus Patients Receiving
 Pharmacotherapy for HIV-AIDS 529
 36.9 Postexposure Prophylaxis of HIV Infection Following Occupational Exposure 532
 36.10 Pharmacotherapy of Herpesvirus Infections 532
 36.11 Pharmacotherapy of Influenza 534
 36.12 Pharmacotherapy of Viral Hepatitis 535
 HEPATITIS A 535
 HEPATITIS B 535
 HEPATITIS C AND OTHER HEPATITIS VIRUSES 536
Nursing Process Focus Patients Receiving
 Antiviral Pharmacotherapy for Non-HIV Viral
 Infections 537

Chapter 37 Drugs for Neoplasia 541

- 37.1 Characteristics of Cancer 542
 37.2 Causes of Cancer 542
 37.3 Goals of Cancer Chemotherapy: Cure, Control, and Palliation 543
 37.4 Growth Fraction and Success of Chemotherapy 544
 37.5 Achieving a Total Cancer Cure 544
 37.6 Special Chemotherapy Protocols and Strategies 545
 COMBINATION CHEMOTHERAPY 545
 DOSING SCHEDULES 545
 37.7 Toxicity of Antineoplastic Drugs 545
 37.8 Classification of Antineoplastic Drugs 547
 37.9 Pharmacotherapy with Alkylating Agents 548
 37.10 Pharmacotherapy with Antimetabolites 548
 FOLIC ACID ANALOGS 549
 PURINE AND PYRIMIDINE ANALOGS 549
 37.11 Pharmacotherapy with Antitumor Antibiotics 551
 37.12 Pharmacotherapy with Natural Products 553
 37.13 Pharmacotherapy with Hormones and Hormone Antagonists 554
 CORTICOSTEROIDS (GLUCOCORTICOID) 556
 GONADAL HORMONES 556
 ESTROGEN ANTAGONISTS (ANTIESTROGENS) 556
 ANDROGEN ANTAGONISTS 557
 37.14 Pharmacotherapy with Biologic Response Modifiers and Targeted Therapies 557
 37.15 Miscellaneous Antineoplastics 559
Nursing Process Focus Patients Receiving
 Antineoplastic Pharmacotherapy 560

UNIT 6 THE RESPIRATORY SYSTEM 567

Chapter 38 Drugs for Allergic Rhinitis and the Common Cold 568

- 38.1 Physiology of the Upper Respiratory Tract 569
 38.2 Pharmacotherapy of Allergic Rhinitis 570
 38.3 Pharmacology of Allergic Rhinitis with H₁-Receptor Antagonists and Mast Cell Stabilizers 570
 38.4 Pharmacotherapy of Allergic Rhinitis with Intranasal Corticosteroids 574
 38.5 Pharmacotherapy of Nasal Congestion with Decongestants 575
 38.6 Pharmacotherapy with Antitussives 577
 38.7 Pharmacotherapy with Expectorants and Mucolytics 578

Nursing Process Focus Patients Receiving Pharmacotherapy for Symptomatic Cold Relief 579

Chapter 39 Drugs for Asthma and Other Pulmonary Disorders 584

- 39.1 Physiology of the Lower Respiratory Tract 585
- 39.2 Bronchiolar Smooth Muscle 585
- 39.3 Administration of Pulmonary Drugs Via Inhalation 586
- 39.4 Pathophysiology of Asthma 587
- 39.5 Treating Acute Asthma with Beta-Adrenergic Agonists 588
- 39.6 Treating Chronic Asthma with Anticholinergics 590
- 39.7 Treating Chronic Asthma with Methylxanthines 591
- 39.8 Prophylaxis of Asthma with Corticosteroids 592
 - Nursing Process Focus** Patients Receiving Pharmacotherapy for Asthma and COPD 594
- 39.9 Prophylaxis of Asthma with Leukotriene Modifiers 596
- 39.10 Prophylaxis of Asthma with Mast Cell Stabilizers 596
- 39.11 Monoclonal Antibodies for Asthma Prophylaxis 597
- 39.12 Pharmacotherapy of COPD 597

UNIT 7 THE GASTROINTESTINAL SYSTEM 601

Chapter 40 Drugs for Peptic Ulcer Disease 602

- 40.1 Normal Digestive Processes 603
- 40.2 Acid Production by the Stomach 603
- 40.3 Pathogenesis of Peptic Ulcer Disease 603
- 40.4 Pathogenesis of Gastroesophageal Reflux Disease 605
- 40.5 Pharmacotherapy of Peptic Ulcer Disease 605
- 40.6 Pharmacotherapy with Proton Pump Inhibitors 607
- 40.7 Pharmacotherapy with H₂-Receptor Antagonists 608
- 40.8 Pharmacotherapy with Antacids 609
- 40.9 Pharmacotherapy with Combination Antibiotic Therapy 610
 - Nursing Process Focus** Patients Receiving Pharmacotherapy for Peptic Ulcer (PUD) and Gastroesophageal Reflux Disease (GERD) 611
- 40.10 Miscellaneous Drugs for Peptic Ulcer Disease 613

Chapter 41 Drugs for Bowel Disorders and Other Gastrointestinal Conditions 616

- 41.1 Normal Function of the Lower Digestive Tract 617
- 41.2 Pathophysiology of Constipation 618
- 41.3 Pharmacotherapy with Laxatives 618
- 41.4 Pathophysiology of Diarrhea 620
- 41.5 Pharmacotherapy with Antidiarrheals 621
- 41.6 Pharmacotherapy of Irritable Bowel Syndrome 622
- 41.7 Pharmacotherapy of Inflammatory Bowel Disease 623
 - Nursing Process Focus** Patients Receiving Pharmacotherapy for Bowel Disorders 625
- 41.8 Pathophysiology of Nausea and Vomiting 626
- 41.9 Pharmacotherapy with Antiemetics 627
 - SEROTONIN (5-HT₃) ANTAGONISTS 627
 - ANTIHISTAMINES AND ANTICHOLINERGICS 627
 - PHENOTHIAZINE AND PHENOTHIAZINE-LIKE DRUGS 627
 - CORTICOSTEROIDS 627
 - OTHER ANTIEMETICS 629
 - EMETICS 629
- Nursing Process Focus** Patients Receiving Antiemetic Pharmacotherapy 630
- 41.10 Pharmacotherapy of Pancreatitis 632

Chapter 42 Drugs for Nutritional Disorders 635

- 42.1 Role of Vitamins in Maintaining Health 636
- 42.2 Classification of Vitamins 636
- 42.3 Recommended Dietary Allowances 636
- 42.4 Indications for Vitamin Pharmacotherapy 637
- 42.5 Pharmacotherapy with Lipid-Soluble Vitamins 638
- 42.6 Pharmacotherapy with Water-Soluble Vitamins 639
- 42.7 Indications for Mineral Pharmacotherapy 641
 - Nursing Process Focus** Patients Receiving Vitamin and Mineral Pharmacotherapy 643
- 42.8 Pharmacotherapy with Minerals 644
 - MACROMINERALS 644
 - MICROMINERALS 645
- 42.9 Etiology of Undernutrition 647
- 42.10 Enteral Nutrition 647
- 42.11 Total Parenteral Nutrition 648
- 42.12 Etiology of Obesity 648
- 42.13 Pharmacotherapy of Obesity 648
 - Nursing Process Focus** Patients Receiving Enteral and Parenteral Nutrition 649

UNIT 8 THE ENDOCRINE SYSTEM 655

Chapter 43 Drugs for Pituitary, Thyroid, and Adrenal Disorders 656

- 43.1 The Endocrine System and Homeostasis 657
- 43.2 Indications for Hormone Pharmacotherapy 657
- 43.3 The Endocrine Structures of the Brain 658
- 43.4 Pharmacotherapy with Pituitary and Hypothalamic Hormones 658
 - GROWTH HORMONE (GH) 659
 - ANTIDIURETIC HORMONE 661
 - Nursing Process Focus** Patients Receiving Pharmacotherapy with Hypothalamic and Pituitary Hormones 662
- 43.5 Normal Function of the Thyroid Gland 664
- 43.6 Pharmacotherapy of Hypothyroidism 666
- 43.7 Pharmacotherapy of Hyperthyroidism 666
- 43.8 Normal Function of the Adrenal Glands 667
 - GONADOCORTICOIDS 668
 - MINERALOCORTICOIDS 668
 - Nursing Process Focus** Patients Receiving Pharmacotherapy for Thyroid Disorders 668
 - GLUCOCORTICOIDS 670
- 43.9 Regulation of Corticosteroid Secretion 670
- 43.10 Pharmacotherapy with Corticosteroids 670
- 43.11 Pharmacotherapy of Cushing's Syndrome 673
 - Nursing Process Focus** Patients Receiving Systemic Corticosteroid Therapy 674

Chapter 44 Drugs for Diabetes Mellitus 678

- 44.1 Regulation of Blood Glucose Levels 679
- 44.2 Etiology and Characteristics of Type 1 Diabetes Mellitus 680
- 44.3 Pharmacotherapy for Type 1 Diabetes Mellitus 680
 - INSULIN ADJUNCT 683
- 44.4 Etiology and Characteristics of Type 2 Diabetes Mellitus 683
- 44.5 Pharmacotherapy for Type 2 Diabetes Mellitus 684
 - Nursing Process Focus** Patients Receiving Insulin Pharmacotherapy 686
 - SULFONYLUREAS 688
 - BIGUANIDES 688
 - ALPHA-GLUCOSIDASE INHIBITORS 688
 - THIAZOLIDINEDIONES 689
 - MEGLITINIDES 689
 - INCRETIN ENHANCERS AND MISCELLANEOUS DRUGS 689
 - Nursing Process Focus** Patients Receiving Pharmacotherapy for Type 2 Diabetes 690

Chapter 45 Drugs for Disorders and Conditions of the Female Reproductive System 694

- 45.1 Hypothalamic and Pituitary Regulation of Female Reproductive Function 695
- 45.2 Ovarian Control of Female Reproductive Function 695
- 45.3 Estrogens and Progestins as Oral Contraceptives 696
 - Nursing Process Focus** Patients Receiving Oral Contraceptives 700
- 45.4 Drugs for Emergency Contraception and Termination of Early Pregnancy 702
- 45.5 Hormone Replacement Therapy 704
- 45.6 Pharmacotherapy with Progestins 705
- 45.7 Pharmacologic Management of Uterine Contractions 707
- 45.8 Pharmacotherapy of Female Fertility 709
 - Nursing Process Focus** Patients Receiving Oxytocin 710

Chapter 46 Drugs for Disorders and Conditions of the Male Reproductive System 714

- 46.1 Hypothalamic and Pituitary Regulation of Male Reproductive Function 715
- 46.2 Pharmacotherapy with Androgens 716
- 46.3 Pharmacotherapy of Male Infertility 718
 - Nursing Process Focus** Patients Receiving Androgen Pharmacotherapy 719
- 46.4 Pharmacotherapy of Erectile Dysfunction 720
- 46.5 Pharmacotherapy of Benign Prostatic Hyperplasia 722
 - Nursing Process Focus** Patients Receiving Pharmacotherapy for Benign Prostatic Hyperplasia 725

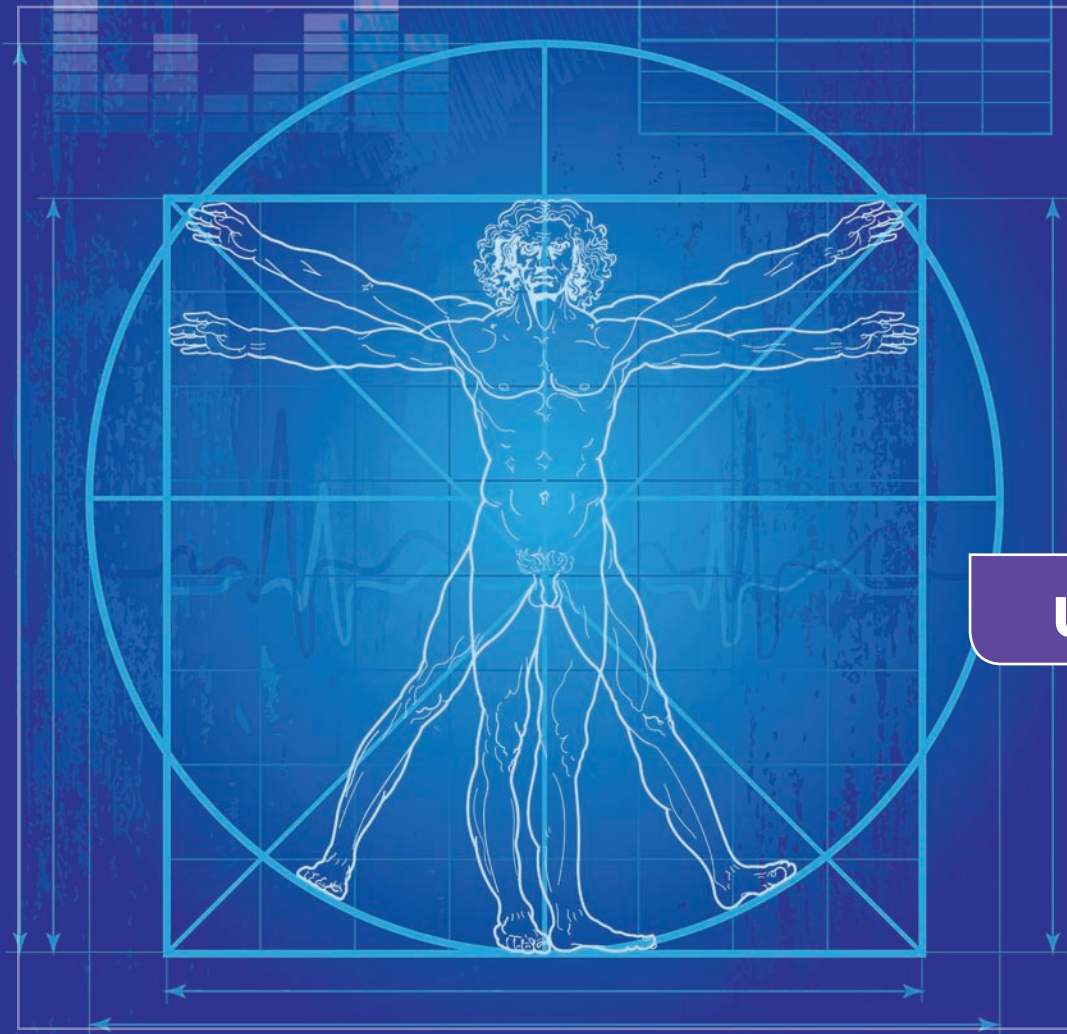
UNIT 9 INTEGUMENTARY SYSTEM, EYES, AND EARS 729

Chapter 47 Drugs for Bone and Joint Disorders 730

- 47.1 Role of Calcium and Vitamin D in Bone Homeostasis 731
- 47.2 Pharmacotherapy of Hypocalcemia 733
- 47.3 Pharmacotherapy of Osteomalacia 734
 - VITAMIN D THERAPY 735
- 47.4 Pharmacotherapy of Osteoporosis 735
 - BISPHOSPHONATES 736
 - SELECTIVE ESTROGEN RECEPTOR MODULATORS 736
 - CALCITONIN 737
 - OTHER DRUGS FOR MBD 737
 - Nursing Process Focus** Patients Receiving Pharmacotherapy for Osteoporosis 739

47.5	Pharmacotherapy of Osteoarthritis	742
47.6	Pharmacotherapy of Rheumatoid Arthritis	742
47.7	Pharmacotherapy of Gout	744
	TREATMENT OF ACUTE GOUT	744
	TREATMENT OF CHRONIC GOUT AND PROPHYLAXIS	745
	Nursing Process Focus Patients Receiving Pharmacotherapy for Gout	746
<i>Chapter 48</i> Drugs for Skin Disorders 750		
48.1	Structure and Function of the Skin	751
	EPIDERMIS	751
	DERMIS	752
	SUBCUTANEOUS TISSUE	752
48.2	Causes of Skin Disorders	752
48.3	Pharmacotherapy of Bacterial, Fungal, and Viral Skin Infections	753
48.4	Pharmacotherapy with Scabicides and Pediculicides	755
	Nursing Process Focus Patients Receiving Pharmacotherapy for Lice or Mite Infestation	756
48.5	Pharmacotherapy of Acne	757
48.6	Pharmacotherapy of Rosacea	759
48.7	Pharmacotherapy of Dermatitis	759
	Nursing Process Focus Patients Receiving Pharmacotherapy for Acne and Related Skin Conditions	760
48.8	Pharmacotherapy of Psoriasis	763
	TOPICAL THERAPIES	763
	SYSTEMIC THERAPIES	765
	NONPHARMACOLOGIC THERAPIES	765
48.9	Pharmacotherapy of Sunburn and Minor Skin Irritation	766
<i>Chapter 49</i> Drugs for Eye and Ear Disorders 768		
49.1	Anatomy of the Eye	769
49.2	Types of Glaucoma	770
49.3	General Principles of Glaucoma Pharmacotherapy	771
49.4	Pharmacotherapy of Glaucoma	771
	PROSTAGLANDIN ANALOGS	772
	AUTONOMIC DRUGS	773
	Nursing Process Focus Patients Receiving Pharmacotherapy for Glaucoma	774
	CARBONIC ANHYDRASE INHIBITORS	776
	OSMOTIC DIURETICS	776
49.5	Pharmacotherapy for Eye Exams and Minor Eye Conditions	776
49.6	Pharmacotherapy with Otic Medications	778
<i>Appendix A</i> ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations 781		
<i>Appendix B</i> ISMP's List of High-Alert Medications 784		
<i>Appendix C</i> Bibliography and References 785		
<i>Appendix D</i> Answers 801		
<i>Appendix E</i> Calculating Dosages 848		
Glossary 850		
Index 865		

This page intentionally left blank



Unit 1

Core Concepts

- CHAPTER 1 Introduction to Pharmacology
- CHAPTER 2 Drug Classes and Schedules
- CHAPTER 3 Principles of Drug Administration
- CHAPTER 4 Pharmacokinetics
- CHAPTER 5 Pharmacodynamics



Introduction to Pharmacology

Learning Outcomes

After reading this chapter, the student should be able to:

1. Identify key events in the history of pharmacology.
2. Explain the interdisciplinary nature of pharmacology, giving an example of how knowledge from different sciences impacts the nurse's role in drug administration.
3. Compare and contrast therapeutics and pharmacology.
4. Compare and contrast traditional drugs, biologics, and complementary and alternative medicine (CAM) therapies.
5. Outline the major differences between prescription and over-the-counter (OTC) drugs.
6. Identify key U.S. drug regulations that have ensured the safety and efficacy of medications.
7. Discuss the role of the U.S. Food and Drug Administration (FDA) in the drug approval process.
8. Explain the four phases of approval for therapeutic and biologic drugs.
9. Discuss how the FDA has increased the speed with which new drugs reach consumers.
10. Identify the nurse's role in the drug approval process and in maintaining safety practices.

Key Terms

biologics *page 4*

black box warnings *page 6*

boxed warnings *page 6*

clinical investigation *page 8*

clinical phase trials *page 8*

complementary and alternative medicine (CAM) therapies *page 4*

drug *page 4*

FDA's Critical Path Initiative *page 8*

Food and Drug Administration (FDA) *page 6*

formulary *page 5*

Investigational New Drug Application (IND) *page 8*

medication *page 4*

NDA review *page 8*

pharmacology *page 3*

pharmacopoeia *page 5*

pharmacotherapy *page 4*

postmarketing surveillance *page 8*

preclinical investigation *page 8*

therapeutics *page 4*

More drugs are being administered to patients than ever before. More than 3 billion prescriptions are dispensed each year in the United States. About one half of all Americans take one prescription drug regularly and one out of six persons takes at least three prescription drugs. The purpose of this chapter is to introduce the subject of pharmacology and to emphasize the role of government in ensuring that drugs, herbals, and other natural alternatives are safe and effective for public use. The chapter also serves as a starting point for connections between important introductory pharmacologic concepts and nursing practice.

1.1 History of Pharmacology

The story of pharmacology is rich and exciting, filled with accidental discoveries and landmark events. Its history likely began when humans first used plants to relieve symptoms of disease. One of the oldest forms of health care, herbal medicine has been practiced in virtually every culture dating to antiquity. The Babylonians recorded the earliest surviving “prescriptions” on clay tablets in 3000 B.C. At about the same time, the Chinese recorded the *Pen Tsao* (Great Herbal), a 40-volume compendium of plant remedies dating to 2700 B.C. The Egyptians followed in 1500 B.C. by archiving their remedies on a document known as the *Eber’s Papyrus*.

Little is known about pharmacology during the Dark Ages. Although it is likely that herbal medicine continued to be practiced, few historical events related to this topic were recorded. Pharmacology, and indeed medicine, could not advance until the discipline of science was eventually viewed as legitimate by the religious doctrines of the era.

The first recorded reference to the word *pharmacology* was found in a text entitled “Pharmacologia sen Manuductio and Materiam Medicum,” by Samuel Dale, in 1693. Before this date, the study of herbal remedies was called “Materia Medica,” a term that persisted into the early 20th century.

Although the exact starting date is obscure, modern pharmacology is thought to have begun in the early 1800s. At that time, chemists were making remarkable progress in isolating specific substances from complex mixtures. This enabled scientists to isolate the active agents morphine, colchicine, curare, cocaine, and other early pharmacologic agents from their natural sources. Using standardized amounts, pharmacologists could then study their effects in animals more precisely. Indeed, some of the early researchers used themselves as test subjects. Friedrich Serturmer, who first isolated morphine from opium in 1805, injected himself and three friends with a huge dose (100 mg) of his new product. He and his colleagues suffered acute morphine intoxication for several days afterward.

Pharmacology as a distinct discipline was officially recognized when the first department of pharmacology was

established in Estonia in 1847. John Jacob Abel, who is considered the father of American pharmacology owing to his many contributions to the field, founded the first pharmacology department in the United States at the University of Michigan in 1890.

In the 20th century, the pace of change in all areas of medicine continued exponentially. Pharmacologists no longer needed to rely on the slow, laborious process of isolating active agents from scarce natural sources; they could synthesize drugs in the laboratory. Hundreds of new drugs could be synthesized and tested in a relatively short time. More importantly, it became possible to understand how drugs produced their effects, down to their molecular mechanism of action.

The current practice of pharmacology is extremely complex and far advanced compared with its early, primitive history. The nurse who consults with a pharmacist in the use of pharmacologic substances and other health professionals who practice it must never forget its early roots: the application of products to relieve human suffering. Whether a substance is extracted from the Pacific yew tree, isolated from a fungus, or created totally in a laboratory, the central purpose of pharmacology is to focus on the patient and to improve the quality of life.

1.2 Pharmacology: The Study of Medicines

The word **pharmacology** is derived from two Greek words: *pharmakon*, which means “medicine,” and *logos*, which means “study.” Thus, pharmacology is most simply defined as the study of medicine. Pharmacology is an expansive subject ranging from understanding how drugs are administered, to where they travel in the body, to the actual responses produced. To learn the discipline well, nursing students must acquire a broad knowledge base from various foundation areas such as anatomy and physiology, chemistry, microbiology, and pathophysiology.

As an example, aminoglycosides are a class of antibiotics that are useful in the treatment of many infectious diseases. The mainstay of treatment for infective endocarditis is antibiotic therapy, and this is instituted as soon as possible to minimize valvular damage. Caution must be used, however, because some aminoglycosides can cause inner ear toxicity and neuromuscular impairment, especially if furosemide (a loop diuretic) is administered at the same time. You can see how, in this case, concepts from multiple science disciplines are integrated. A knowledge of chemistry would be implied by the terms *amino* and *glyco*. Further study about “infectives” would draw much information from the subject of microbiology including antibiotics and sensitivities to gram-positive and gram-negative bacteria. The fields of anatomy and physiology would correlate much information with emphasis on ear anatomy and organs of the muscular, nervous, renal, and cardiovascular systems. “Endocarditis” would be the central pathophysiological focus of treatment. Most of the time pharmacology incorporates knowledge from multiple areas, which health care providers use in making decisions about drug administration.

More than 10,000 brand-name drugs, generic drugs, and combination drugs are currently available. Each has its own characteristic set of therapeutic applications, interactions, side effects, and mechanisms of action. Many drugs are prescribed for more than one disease, and most produce multiple effects within the body. Drugs may elicit different responses depending on individual patient factors such as age, sex, body mass, health status, and genetics. Indeed, learning the applications of existing medications and staying current with new drugs introduced every year are among the formidable but necessary tasks for the nurse. These challenges, however, are critical for both the patient and the health care practitioner. If applied properly, drugs can dramatically improve the quality of life. If applied improperly, drugs can produce devastating consequences.

1.3 Pharmacology and Therapeutics

It is obvious that a thorough study of pharmacology is important to health care providers who prescribe drugs on a daily basis. The nurse is often the health care provider most directly involved with patient care and is active in educating, managing, and monitoring the proper use of drugs. This applies not only to nurses in clinics, hospitals, and home health care settings but also to nurses who teach and to students entering the nursing profession. In all these cases, it is necessary that individuals have a thorough knowledge of pharmacology to perform their duties. As nursing students progress toward their chosen specialty, pharmacology is at the core of patient care and is integrated into every step of the nursing process. Learning pharmacology is a gradual, continuous process that does not end with graduation. One never completely masters every facet of drug action and application. That is one of the motivating challenges of the nursing profession.

Another important area of study for the nurse, sometimes challenging to distinguish from pharmacology, is the study of therapeutics. Therapeutics is slightly different from the field of pharmacology, although the disciplines are closely connected. **Therapeutics** is the branch of medicine concerned with the prevention of disease and treatment of suffering. **Pharmacotherapy**, or *pharmacotherapeutics*, is the application of drugs for the purpose of disease prevention and the treatment of suffering. Drugs are just one of many tools available to the nurse for these purposes.


1.4 Classification of Therapeutic Agents as Drugs, Biologics, and Complementary and Alternative Medicine Therapies

Substances applied for therapeutic purposes fall into one of the following three general categories:

- Drugs or medications.
- Biologics.
- Complementary and alternative medicine (CAM) therapies.

A **drug** is a chemical agent capable of producing biologic responses within the body. These responses may be desirable (therapeutic) or undesirable (adverse). After a drug is administered, it is called a **medication**. From a larger perspective, drugs and medications may be considered a part of the body's normal activities, from the essential gases that we breathe to the foods that we eat. Because drugs are defined so broadly, it is necessary to clearly distinguish them from other substances such as foods, household products, and cosmetics. Many agents such as antiperspirants, sunscreens, toothpaste, and shampoos might alter the body's normal activities, but they are not necessarily considered medically therapeutic, as are drugs.

Although most modern drugs are synthesized in a laboratory, **biologics** are agents naturally produced in animal cells, by microorganisms, or by the body itself. Examples of biologics include hormones, monoclonal antibodies, natural blood products and components, interferons, and vaccines. Biologics are used to treat a wide variety of illnesses and conditions.

Other therapeutic approaches include **complementary and alternative medicine (CAM) therapies**. These involve natural plant extracts, herbs, vitamins, minerals, dietary supplements, and many techniques considered by some to be unconventional. Such therapies include manipulative and body-based practices such as acupuncture, hypnosis, biofeedback, and massage. Because of their great popularity, herbal and alternative therapies are featured throughout this text wherever they show promise in treating a disease or condition. Herbal therapies are presented in chapter 10 .

1.5 Prescription and Over-the-Counter Drugs

Legal drugs are obtained either by a prescription or over the counter (OTC). There are major differences between the two methods of dispensing drugs. To obtain prescription drugs, the person must receive a written order from a person with the legal authority to write such a prescription. The advantages to requiring an authorization are numerous. The health care provider or nurse practitioner has an opportunity to examine the patient and determine a specific diagnosis. The practitioner can maximize therapy by ordering the proper drug for the patient's condition and by conveying the amount and frequency of drug to be dispensed. In addition, the health care provider has an opportunity to teach the patient the proper use of the drug and what side effects to expect. In a few instances, a high margin of safety observed over many years can prompt a change in the status of a drug from prescription to OTC.

In contrast to prescription drugs, OTC drugs do not require a health care provider's order. In most cases, patients may treat themselves safely if they carefully follow instructions included with the medication. If patients do not follow these guidelines, OTC drugs can have serious adverse effects.

Patients prefer to take OTC drugs for many reasons. They are obtained more easily than prescription drugs. No

appointment with a health care provider is required, thus saving time and money. Without the assistance of a health care provider, however, choosing the proper drug for a specific problem can be challenging for a patient. OTC drugs may react with foods, herbal products, prescription medications, or other OTC drugs. Patients may not be aware that some OTC drugs can impair their ability to function safely. Self-treatment is sometimes ineffectual, and the potential for harm may increase if the disease is allowed to progress.

1.6 Drug Regulations and Standards

Until the 19th century, there were few standards or guidelines in place to protect the public from drug misuse. The archives of drug regulatory agencies are filled with examples of early medicines, including rattlesnake oil for rheumatism; epilepsy treatment for spasms, hysteria, and alcoholism; and fat reducers for a slender, healthy figure. Many of these early concoctions proved ineffective, though harmless. At their worst, some contained hazardous levels of dangerous or addictive substances. It became quite clear that drug regulations were needed to protect the public.

The first standard commonly used by pharmacists was the **formulary**, or list of drugs and drug recipes. In the United States, the first comprehensive publication of drug standards, called the *U.S. Pharmacopoeia (USP)*, was established in 1820. A **pharmacopoeia** is a medical reference summarizing standards of drug purity, strength, and directions for synthesis. In 1852, a national professional society of pharmacists called the American Pharmaceutical Association (APhA) was founded. From 1852 to 1975, two major compendia maintained drug standards in the United States: the *U.S. Pharmacopoeia*, and the *National Formulary (NF)* established by the APhA. All drug products were covered in the *USP*; pharmaceutical ingredients were covered in the *NF*. In 1975, the two entities merged into a single publication, the *U.S. Pharmacopoeia–National Formulary (USP–NF)*. USP–NF is an annual publication, comprising one main publication and two supplements each year. Today, the USP


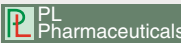
label can be found on many medications verifying the purity and exact amounts of ingredients found within the container. Sample labels are illustrated in ▲ Figure 1.1.

In the early 1900s, the United States began to develop and enforce tougher drug legislation to protect the public. In 1902, the Biologics Control Act helped to standardize the quality of serums and other blood-related products. The Pure Food and Drug Act of 1906 gave the government power to control the labeling of medicines. In 1912, the Sherley Amendment prohibited the sale of drugs labeled with false therapeutic claims that were intended to defraud the consumer. In 1938, Congress passed the Food, Drug, and Cosmetic Act. This was the first law preventing the sale of drugs that had not been thoroughly tested before marketing. Later amendments to this law required drug companies to prove the safety and efficacy of any drug before it could be sold within the United States. In reaction to the rising popularity of dietary supplements, Congress passed the Dietary Supplement Health and Education Act of 1994 in an attempt to control misleading industry claims. A brief time line of major events in U.S. drug regulation is shown in ▲ Figure 1.2.


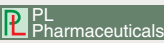

PHARMFACTS

Consumer Spending on Prescription Drugs

- Spending on prescription drugs accounts for over 10% of national health spending.
- At the turn of the 21st century (1999–2009), prescription drug expenditures increased by more than 39% while the population only grew 9%.
- The average number of prescription drugs taken per patient over the course of a year is about 13 compared to 8 prescriptions per person in the mid-1990s.
- In 2010, consumers in the United States spent nearly 1.8% of their per capita gross domestic product on prescription drugs and 2.3% of their per capita personal income after taxes.
- Total pharmaceutical expenditures in the United States increased from \$284 billion in 2008 to over \$307 billion in 2010.

LOT EXP		Each mL contains atropine sulfate 400 mcg (0.4 mg), sodium chloride 9 mg and benzyl alcohol 0.015 mL in Water for Injection. pH 3.0–6.5; Sulfuric acid added, if needed, for pH adjustment.
	Injection, USP	POISON
	10 X 20 mL Multiple Dose Vials FOR SC, IM OR IV USE	Usual Dose: See package insert. Store at controlled room temperature 15°–30°C (59°–86° F). Caution: Federal law prohibits dispensing without prescription.
	400 mcg/mL (0.4 mg/mL)	Product Code 2210-43
		B-32210

For educational purposes only

	Inactive ingredients: antifoam AF emulsion, flavors, purified water, sodium hydroxide or hydrochloric acid to adjust pH, sorbitol solution, and tragacanth. Sorbic acid 0.1% added as preservative.
237 mL ORAL SUSPENSION	USUAL DOSAGE: See accompanying circular. <i>Keep container tightly closed. Protect from freezing. SHAKE WELL BEFORE USING.</i> Store below 30°C (86°F). Avoid temperatures above 50°C (122°F).
25 mg per 5 mL	
Alcohol 1%	
Rx only	
237 mL No. 3376	
	
9108705	Lot Exp.

▲ **Figure 1.1** Medication with the USP label (left) and without USP label (right) Practice Label “for educational purposes only.”

TIME LINE	REGULATORY ACTS, STANDARDS, AND ORGANIZATIONS
1820	A group of health care providers established the first comprehensive publication of drug standards called the U.S. Pharmacopoeia (USP) .
1852	A group of pharmacists founded a national professional society called the American Pharmaceutical Association (APhA) . The APhA then established the National Formulary (NF) , a standardized publication focusing on pharmaceutical ingredients. The <i>USP</i> continued to catalogue all drug-related substances and products.
1862	This was the beginning of the Federal Bureau of Chemistry , established under the administration of President Lincoln. Over the years and with added duties, it gradually became the Food and Drug Administration (FDA).
1902	Congress passed the Biologics Control Act to control the quality of serums and other blood-related products.
1906	The Pure Food and Drug Act gave the government power to control the labeling of medicines.
1912	The Sherley Amendment made medicines safer by prohibiting the sale of drugs labeled with false therapeutic claims.
1938	Congress passed the Food, Drug, and Cosmetic Act . It was the first law preventing the marketing of drugs not thoroughly tested. This law now provides for the requirement that drug companies must submit a New Drug Application (NDA) to the FDA prior to marketing a new drug.
1944	Congress passed the Public Health Service Act , covering many health issues including biologic products and the control of communicable diseases.
1975	The <i>U.S. Pharmacopoeia</i> and <i>National Formulary</i> announced their union. The USP-NF became a single standardized publication.
1986	Congress passed the Childhood Vaccine Act . It authorized the FDA to acquire information about patients taking vaccines, to recall biologics, and to recommend civil penalties if guidelines regarding biologic use were not followed.
1988	The FDA was officially established as an agency of the U.S. Department of Health and Human Services .
1992	Congress passed the Prescription Drug User Fee Act . It required that nongeneric drug and biologic manufacturers pay fees to be used for improvements in the drug review process.
1994	Congress passed the Dietary Supplement Health and Education Act that requires clear labeling of dietary supplements. This act gives the FDA the power to remove supplements that cause a significant risk to the public.
1997	The FDA Drug Modernization Act reauthorized the Prescription Drug User Fee Act. This act represented the largest reform effort of the drug review process since 1938.
2002	The Bioterrorism Act implemented guidelines for registration of selected toxins that could pose a threat to human, animal, or plant safety and health.
2007	The FDA Amendments Act reviewed, expanded, and reaffirmed legislation to allow for additional comprehensive reviews of new drugs and medical products. This extended the reforms imposed from 1997. The FDA's Critical Path Initiative was a part of this reform.
2011	Provisions of the Health Care Reform law allowed the FDA to approve generic versions of biologic drugs. Additional drug rebates and benefits were provided to the American public. The FDA Food Safety Modernization Act represents the largest reform effort of food safety review since 1938.

▲ **Figure 1.2** A historical time line of regulatory acts, standards, and organizations

1.7 The Role of the Food and Drug Administration

Much has changed in the regulation of drugs in the past 100 years. In 1988, the **Food and Drug Administration (FDA)** was officially established as an agency of the U.S. Department of Health and Human Services. The Center for Drug Evaluation and Research (CDER), a branch of the FDA, exercises control over whether prescription drugs and OTC drugs may be used for therapy. The CDER states its mission as facilitating the availability of safe, effective drugs; keeping

unsafe or ineffective drugs off the market; improving the health of Americans; and providing clear, easily understandable drug information for safe and effective use. Any pharmaceutical laboratory, whether private, public, or academic, must solicit FDA approval before marketing a drug.

In 1997, the FDA created **boxed warnings** in order to regulate drugs with “special problems.” At the time no precedent had been established to monitor drugs with a potential for causing death or serious injury. **Black box warnings**, named after the black box appearing around drug safety information located within package inserts,

eventually became one of the primary alerts for identifying extreme adverse drug reactions discovered during and after the review process. It would be ideal if all of the potential adverse effects were identified before a drug goes to the market. Because this is not realistic, nurses must be increasingly mindful about the standards of care necessary to promote safety, including scanning of medications, medication reconciliation, and special alerts. Black box warnings are included throughout this text, for all prototype drugs.

Another branch of the FDA, the Center for Biologics Evaluation and Research (CBER), regulates the use of biologics including serums, vaccines, and blood products. One historical achievement involving biologics was the 1986 Childhood Vaccine Act. This act authorized the FDA to acquire information about patients taking vaccines, to recall biologics, and to recommend civil penalties if guidelines regarding biologics were not followed.

The FDA oversees administration of herbal products and dietary supplements through the Center for Food Safety and Applied Nutrition (CFSAN). Herbal products and dietary supplements are regulated by the Dietary Supplement Health and Education Act of 1994. This act does not provide the same degree of protection for consumers as the Food, Drug, and Cosmetic Act of 1938. For example, herbal and dietary supplements can be marketed without prior approval from the FDA; however, all package inserts

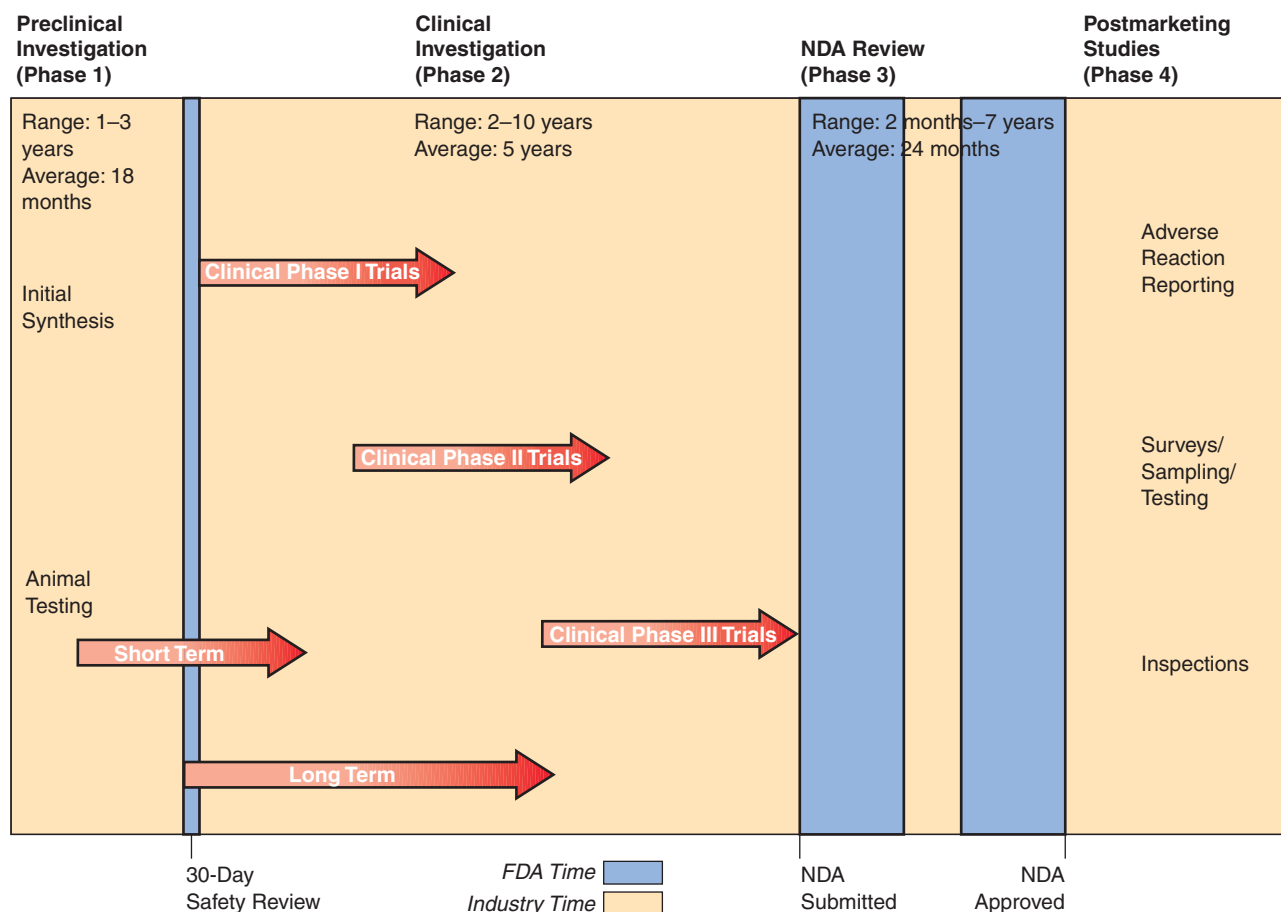
and information are monitored once products have gone to market. The Dietary Supplement Health and Education Act is discussed in more detail in chapter 10 [GO](#).

In 1998, the National Center for Complementary and Alternative Medicine (NCCAM) was established as the federal government's lead agency for scientific research and information about CAM therapies. Its mission is "to define, through rigorous scientific investigation, the usefulness and safety of complementary and alternative medicine interventions and their roles in improving health and health care." Among several areas of focus, this agency supports research and serves as a resource for nurses in establishing which CAM therapies are safe and effective.

1.8 Phases of Approval for Therapeutic and Biologic Drugs

The amount of time spent by the FDA in the review and approval process for a particular drug depends on several checkpoints along with a well-developed and organized plan. Therapeutic drugs and biologics are reviewed in four phases. These phases, summarized in [▲](#) Figure 1.3, are as follows:

1. Preclinical investigation.
2. Clinical investigation.
3. Review of the New Drug Application (NDA).
4. Postmarketing surveillance.



[▲](#) **Figure 1.3** A new drug development time line with the four phases of drug approval

Preclinical investigation involves extensive laboratory research. Scientists perform many tests on human and microbial cells cultured in the laboratory. Studies are performed in several species of animals to examine the drug's effectiveness at different doses and to look for adverse effects. Extensive testing on cultured cells and in animals is essential because it allows the pharmacologist to predict whether the drug will cause harm to humans. Because laboratory tests do not always reflect the way a human responds, preclinical investigation results are always inconclusive. Animal testing may overestimate or underestimate the actual risk to humans.

In January 2007, the FDA restated its concern that a number of innovative and critical medical products had decreased since the 1990s. The **FDA's Critical Path Initiative** was an effort to modernize the sciences to enhance the use of bioinformation to improve the "safety, effectiveness, and manufacturability of candidate medical products." Listed areas of improvement were the fields of genomics and proteomics, imaging, and bioinformatics.

Clinical investigation, the second phase of drug testing, takes place in three different stages termed **clinical phase trials**. Clinical phase trials are the longest part of the drug approval process. Clinical pharmacologists first perform tests on volunteers to determine proper dosage and to assess for adverse effects. Large groups of selected patients with the particular disease are then given the medication. Clinical investigators from different medical specialties address concerns such as whether the drug is effective, worsens other medical conditions, interacts unsafely with existing medications, or affects one type of patient more than others.

Clinical phase trials are an essential component of drug evaluations due to the variability of responses among patients. If a drug appears to be effective and without causing serious side effects, approval for marketing may be accelerated, or the drug may be used immediately in special cases with careful monitoring. If the drug shows promise but precautions are noted, the process is delayed until the pharmaceutical company remedies the concerns. In any case, a New Drug Application (NDA) must be submitted before a drug is allowed to proceed to the next phase of the approval process. An **Investigational New Drug Application (IND)** may be submitted for Phase I clinical trials when it is determined that there are significant therapeutic benefits, and that the product is reasonably safe for initial use in humans (e.g., patients who are HIV positive). Companies usually begin developing a brand name for drugs during Phase I of the IND process.

The **NDA review** is the third phase of the drug approval process. During this phase, the drug's brand name is finalized. Clinical Phase III trials and animal testing may continue depending on the results obtained from preclinical testing. By law, the FDA is permitted 6 months to initially review an NDA. If the NDA is approved, the process continues to the final phase. If the NDA is rejected, the process is suspended until noted concerns are addressed by the pharmaceutical company. The average

NDA review time for new drugs is approximately 17 to 24 months.

Postmarketing surveillance, the final phase of the drug approval process, begins after clinical trials and the NDA review have been completed. The purpose of this phase is to survey for harmful drug effects in a larger population. Some adverse effects take longer to appear and are not identified until a drug is circulated to large numbers of people. Examples of this process have been approval of the COX-2 selective nonsteroidal anti-inflammatory drugs (NSAIDs), which were evaluated by the FDA during 2004 and 2005. Manufacturers of valdecoxib (Bextra), celecoxib (Celebrex), and rofecoxib (Vioxx) were originally asked to revise their labeling owing to emerging concerns that some NSAIDs exhibited extreme cardiovascular and gastrointestinal risks. In September 2004, manufacturers of rofecoxib voluntarily withdrew their product from the market due to safety concerns of heart attack and stroke. In April 2005, the FDA asked the manufacturers of valdecoxib to remove their product from the market due to similar concerns. Although celecoxib remained on the market, the FDA announced that it would continue to analyze reports to determine whether additional regulatory action would be needed. The black box warning continues to warn patients that fatal cardiovascular disease, bleeding ulceration, and serious gastrointestinal reactions may result if certain precautions are not taken.

The FDA holds public meetings annually to receive feedback from patients and professional and pharmaceutical organizations regarding the effectiveness and safety of new drug therapies. If the FDA discovers a serious problem, it will mandate that the drug be withdrawn from the market. The FDA has a free e-mail subscription service to alert the consumer regarding drugs and products withdrawn from the market. MedWatch (www.fda.gov/Safety/MedWatch) and Drug Safety Communications, Podcasts, and Newsletters sponsored by the FDA (<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm>) continue to alert patients, consumers, and health care providers of drug risks. They also provide safety sheets, press announcements, and other pertinent drug fact information.

1.9 Changes to the Drug Approval Process

The process of isolating or synthesizing a new drug and testing it in cells, experimental animals, and humans can take many years. The NDA can include dozens of volumes of experimental and clinical data that must be examined in the drug review process. Some NDAs contain more than 100,000 pages. Even after all experiments have been concluded and clinical data have been gathered, the FDA review process can take several years.

Expenses associated with development of a new drug can cost pharmaceutical manufacturers millions of dollars. A recent study estimated the cost to bring a new drug to market at \$802 million. These companies are often critical of the

EVIDENCE-BASED PRACTICE

Informed Consent Procedures

Clinical Question: How can nurses assist in the informed consent procedures for patients considering participation in a clinical drug research trial?

Evidence: At some point in a nurse's career, he or she may care for a patient who is enrolled in, or considering participation in, a clinical drug research trial. The publication of the Belmont Report by the National Institutes of Health (Office of Human Subjects Research, 1979) provided guidance and principles for obtaining informed consent from patients enrolled in clinical trials. The FDA recently updated current regulations for obtaining informed consent to ensure greater transparency by making all participants aware that information about the trial would be submitted to a searchable, national databank (FDA Informed Consent Elements, 2011). Although providing the information about the research trial is beyond the scope of nursing practice and the responsibility of the researcher and health care provider, nurses can participate by helping to ensure that the patient has had any questions or concerns regarding participation addressed before signing the informed consent document. Special populations require careful assessment of the patient's ability to understand or make informed decisions about research participation. These populations may include children, patients with cognitive or mental impairments, and patients with sensory or language barriers. Cook, Moore-Cox, Xavier, Lauzier, and Roberts (2008) describe other circumstances in which obtaining informed consent for research participation is made more difficult. Situations in which the patient may be critically ill or suffering from a traumatic injury may delay obtaining consent directly from the patient and result in the patient's exclusion from the clinical trial. And differences in cultural background and beliefs about what is appropriate for a patient to know may run counter to the established guidelines that informed consent includes providing the patient with the information necessary to make an informed decision to participate.

Nursing Implications: Ensuring that a patient, family, or legal guardians have the information necessary to make informed decisions is a potential role for the nurse when caring for patients considering or participating in a clinical research trial. Whereas providing the information is beyond the scope of most nursing practice, the patient will often ask questions of the nurse and the nurse can relay these questions to the health care provider. This is especially important when working with patients or families who may have special needs, such as language or cultural differences, or in emergency situations, in which the patient is not able to receive the information and a family member or legal guardian must make the decision.

regulatory process and are anxious to get the drug marketed to recoup their research and development expenses. The public is also anxious to receive new drugs, particularly for diseases that have a high mortality rate. Although the criticisms of manufacturers and the public are certainly understandable—and sometimes justified—the fundamental priority of the FDA is to ensure that drugs are safe. Without an exhaustive review of scientific data, the public could be exposed to dangerous medications or those that are ineffective in treating disease.

In the early 1990s, owing to pressures from organized consumer groups and various drug manufacturers, governmental officials began to plan how to speed up the drug review process. Reasons identified for the delay in the FDA drug approval process included outdated guidelines, poor communication, and insufficient staff to handle the workload.

LIFESPAN CONSIDERATIONS: GERIATRIC

Prescription Drug Costs and the “Doughnut Hole” for Senior Citizens

In January 2006, prescription drug coverage through Medicare Part D went into effect, in part to help protect senior citizens (those over age 65) from catastrophic drug expenditures. Americans older than age 65 constitute only 13% of the population but account for about 34% of all prescriptions dispensed and 40% of all OTC medications. More than 80% of all seniors take at least one prescribed medication each day. The average older adult takes more than four prescription medications, plus two OTC medications. Many of these medicines—such as those for diabetes, hypertension, and heart disease—are taken on a permanent basis.

While Medicare Part D did make some substantial differences in helping seniors pay for their medications, a coverage gap has occurred when drug spending totals are between approximately \$2,800 and \$6,400. This gap has been termed the “doughnut hole” and studies have suggested that seniors reaching that doughnut hole reduce spending on their medications by 14% to 40%, depending on whether they have additional insurance coverage. With most seniors taking daily medications for chronic conditions, this decrease in spending may cause seniors to forego needed medications. The U.S. Affordable Care Act of 2010 included benefits to reduce this gap in coverage for seniors with the goal of closing it completely. Nurses should include questions about the ability to afford medications as part of taking an adequate drug history, especially when working with older adult patients.

In 1992, FDA officials, members of Congress, and representatives from pharmaceutical companies negotiated the Prescription Drug User Fee Act on a 5-year trial basis. This act required drug and biologic manufacturers to provide yearly product user fees. This added income allowed the FDA to hire more employees and to restructure its organization to more efficiently handle the processing of a greater number of drug applications. The result of restructuring was a resounding success. From 1992 to 1996, the FDA approved double the number of drugs while cutting some review times by as much as half. In 1997, the FDA Modernization Act reauthorized the Prescription Drug User Fee Act. Nearly 700 employees were added to the FDA's drug and biologics program, and more than \$300 million was collected in user fees. The FDA Amendments Act expanded the reform effort in 2007 by allowing more U.S. resources to be used for comprehensive reviews of new drugs. In 2008, the target base revenue for new drugs was over \$392 million. In 2011, the FDA expanded its reviews of drugs and legislation. Congress passed into law the FDA Food Safety Modernization Act to give the Department of Health and Human Services greater authority to recall certain potentially tainted products and to detect food-related illnesses and outbreaks.

1.10 Nurses, the Drug Approval Process, and the Need for Effective Safety Practices

In nursing, it is during the postmarketing surveillance period (Phase 4) that the nurse has the most frequent opportunities to participate in the drug approval process. While