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9th Edition

Essentials of Pharmacology

for Health Professions

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Adam J. James, PharmD
Elizabeth D. Katrancha, DNP, CCNS, RN, CNE

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***Essentials of Pharmacology for Health Professions*, Ninth Edition**

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Dedication

In Memorial

To my loving wife Patty whose love, zestful spirit, and especially smile inspired my life and work. She was the loving mother of two great kids, Joshua and Jeremy, and her wonderful daughter-in law Ali. While Bubba only had a little time with her granddaughter Lenyx, she left a spirit impression that will be with her all her life and is now watching over her and her new brother Luxton. Heaven has indeed gained a very bright light!

Bruce Colbert

To Ruth Woodrow, the original author of this textbook whose passion for education and providing a meaningful learning experience for her students was ever foremost in both her mind and heart. We spoke often about the need to keep the material simple, relevant, and meaningful for the students. I remember a dedication she wrote to her grandchildren Ashston, Jeff, Samantha, and Eric that said, "may you realize that knowledge is power and seek to learn all your lives." She was a sweet gentle soul who will be missed by her family and dear husband Roger.

Bruce Colbert

Ruth Woodrow spoke often of her belief in lifelong learning. Throughout her life, she helped others on their learning journey through her teaching, tutoring, volunteering, and sharing of knowledge. Ruth would often break into teaching moments during our conversations as she pointed out connections between the content, real-world illnesses, and the drugs used to treat them. I felt privileged to engage in a private "lesson" on pharmacology as Ruth guided me to the section of content that I should read to learn more. Her commitment and dedication to making learning pharmacology accessible to everyone by focusing on what students need to know will continue to guide the text.

Debra Myette-Flis, Learning Designer, Cengage

Message to the Students

When I first started teaching over 40 years ago it quickly became clear that many of my students had a fear of pharmacology, which they thought was the most difficult course in our program. I set out to change that mindset and while it took a few years for me to figure out the solutions, it was well worth it.

I found that many students were solely relying on mass memorization and this became overwhelming given the type and amount of material. I worked to change their method to truly "learning" the material and it led to not only short-term success in the course but long-term success in their professions. So, what are some main strategies to truly learn? One of the first is to take difficult material and relate it to something you know and understand. In Chapter 13 on the autonomic nervous system, for example, I use a snarling dog to show the sympathetic responses instead of simply listing them. Now you "know" that when the sympathetic nervous system is stimulated, your pupils dilate to get more light in to see the situation, and your heart rate and breathing (along with bronchodilation) increase to get more vital oxygen to your muscles to ready you for fight or flight. Now you know this forever thanks to a relatable story.

Some other methods that foster true learning are:

- Study in groups and select areas to teach each other (you really learn something when you have to teach it).
- Make up stories and use visualization to relate material. For example, visualize a congested highway opening up another lane to relieve the pressure, which relates to vasodilators used to treat hypertension.
- You probably have family members on some of the medications and if appropriate discuss with them, especially how it makes a difference in their lives.

I hope the way the text is written in a friendly style along with the engaging electronic assets helps you truly "learn" the material, which will carry you through this class and on to your professional career.

Bruce Colbert

Preface

Goals of This Book

The main purpose of this textbook is to serve as an engaging and relevant source for students studying nursing, medical assisting, and various allied health fields such as surgical technology and respiratory care. In addition, it can serve as an excellent resource for continuing education updates for professionals in health care.

The goal of this book is to provide an extensive framework of knowledge that can be acquired within a limited amount of time. A varied and engaging series of electronic experiences is available to complement the text to bring the material to life for today's students.

This book will be especially helpful for learners in 1-year training programs with limited time allotted to the study of medications. This book has been specially designed to meet the needs of learners in nursing and medical assistant programs. However, learners in all health care programs will find the concise format adaptable to their needs.

This text has been field tested in several classes with learners in various health professions. Learners who have already used this book for updating or supplemental education include registered nurses, licensed practical nurses, medical assistants, surgical technologists, respiratory therapists, and pharmacy technicians.

Those employed in health professions now have increased responsibilities for providing the necessary information to their patients regarding the safe administration of medications, side effects, and interactions. Patient education is presented in every chapter in Part II. Even if you are not directly involved in patient education, it is imperative you understand what information is being conveyed.

Organization and Features of the Text

The quantity of information could be overwhelming and confusing to the learner unless presented in a reader-friendly manner.

The book's comprehensive yet concise format reduces the massive quantity of information and unnecessary detail that may tend to overwhelm or confuse the learner. Outdated or rarely used medications, obsolete information, and complex descriptions are eliminated. The information is both factual and functional.

The textbook is broken down into two specific parts. ***Part I*** can stand alone as a basic but comprehensive review of pharmacologic principles. ***Part I*** introduces the learner to the fascinating subject of drugs, their sources, legal concerns, and their medical uses. *Review questions* at the end of each chapter help the learner master the information. Medication preparation, supplies, and specific information on each route of administration are covered. *Administration checklists* allow the learner to put the knowledge into practice. *Illustrations* and *videos* that are part of the *online resources* facilitate the visual learning process. Upon the completion of Part I the student will have all the foundational knowledge to study and understand the specific drug classifications in Part II.

Part II organizes the drugs according to classifications, arranged in logical order. Each classification is described, along with the characteristics of typical drugs, their purposes, side effects, cautions or contraindications, and interactions. Please note cautions and contraindications are combined as one category since it is clear from the explanation where the drug *is not to be used* in a certain situation (contraindication) and where it *can be used* in a certain situation but should be monitored closely (cautions). A special icon ! identifies the most common or most important side effects of drugs. This special icon is meant to serve as a valuable guide for learners. Rather than memorizing every side effect for each drug, the icon emphasizes the side effects with which health care professionals should be most familiar. *Patient education boxes* for each category are highlighted. These special boxes will assist health care professionals to educate patients and answer their questions about the medications they are taking.

Easy-to-use *reference tables* with each classification list the most commonly prescribed drugs according to their generic and trade names, with dosage and available forms.

Reality-based case studies in each chapter in Part II present drug usage scenarios in a variety of settings and stimulate critical thinking by providing practical application of drug information.

Chapter *review quizzes* assist learners to identify areas for further study. *Comprehensive review quizzes* for Part I and Part II encourage learners to practice for the final test.

An extensive *glossary* lists and defines key terms used in the book and defines non-key terms that might not be common knowledge such as unusual side effects. A comprehensive index includes both generic and trade names.

New to This Edition

Before discussing what has changed in this edition, it is important to note what hasn't changed. We have dedicated the revision to enhancing the user-friendly writing style with more analogies and learning hints to keep the style that has made this pharmacology text popular.

Global Textbook Changes

- Chapters were slightly reorganized to move the more commonly used and seen classifications of cardiovascular and respiratory drugs earlier in Part II.
- Each drug classification was updated with the latest and most frequently prescribed drugs available.
- Tables were added and updated to give concise and practical information.
- Patient education boxes were expanded.
- Clinical Connection features were added to give a real-life application to the material being discussed to enhance its relevancy.
- Several new illustrations and photos were added to provide learners with a visual connection to the material.
- All relevant websites were updated.
- Additional art was updated to reflect the rapid changes in pharmacology.
- Review questions were updated and new questions were added to cover new material.
- The glossary was expanded to include new terms beyond just the key terms.

The following chapters in the text had significant additions concerning topics of current interest.

Chapter	Specific Changes in Textbook
1	Added National Drug Code Directory (NDC) information Updated Controlled Substances Schedule Added medication labels and questions
5	Expanded information on computerized physician order entry (CPOE), e-prescribing (eRx), and the electronic medication administration record (eMAR) Expanded explanation and simplification of converting within the metric system and from the English to the metric system
6	Added basic math review to include percentages, ratios and proportions, decimals, and fractions Added drug labels to drug dosage problems Added section on pediatric dosing
7	Added sentinel event Added right technique to the now seven rights of medication administration
8	Updated all administration techniques by the gastrointestinal route Rearranged chapter so less common routes of percutaneous endoscopic gastrostomy (PEG) and nasogastric tube (NGT) are at end
9	Updated all administration techniques Added material on vaccines

10	Enhanced patient education on poisoning
11	Changed title to be more inclusive of nutritional concepts of pharmacology such as nutrition recommended to boost immune system during COVID pandemic Added complete section on cannabidiol (CBD)
12	Added diabetic foot ulcer prevention and treatment Added information on Shingrix vaccine
13	Added simplified anatomy and physiology section along with real-life "snarling dog" analogy to simplify concepts and relationships in the autonomic nervous system Added relevant learning hints to help students with this difficult material
14	Added updates on statin patient education and niacin therapy
15	Added more learning hints and illustrations to contrast how the various diuretics work
16	Added more learning hints and illustrations to contrast how the various gastrointestinal drugs work Added section on monoclonal antibodies
17	Added information on black box warnings Added newer pseudoephedrine (PSE) abuse deterrent agents
19	Retitled and reorganized chapter for better flow Added information on extended-release (ER) agents Added lidocaine patches and orexin antagonists
20	Added more on substance abuse and withdrawal treatment Added more learning hints
21	Enhanced learning hints and updated websites
22	Expanded information on proper weaning off of certain medications
23	Expanded information on diabetes
25	Added COVID-19 and Shingrix information
26	Added information on dose-limiting side effects
27	Changed title to "Age-Related Medication Issues" Added entire section on pediatric considerations to complement the older adult information

Instructor and Student Resources

Additional instructor and student resources for this product are available online. Instructor assets include an Instructor's Manual, Educator's Guide, PowerPoint® slides, Solution and Answer Guide, and a test bank powered by Cognero®. Student assets include PowerPoint® slides including images, focus on the key concepts from each chapter. Medication administration videos that allow learners to "see" concepts in action are available for students on the online resources.

- Electronic Instructor's Manual includes the following tools:
- Additional review quizzes with answers
- Comprehensive drug worksheets with answers
- An alternate Comprehensive Exam for Part II with answers

- Answers to review quizzes and comprehensive review exams in the text
- Answers to case studies in Part II in the text

Sign up or sign in at **www.cengage.com** to search for and access this product and its online resources.

MindTap

MindTap is a fully online, interactive learning experience built upon authoritative Cengage Learning content. By combining readings, multimedia, activities, and assessments into a singular learning path, MindTap elevates learning by providing real-world application to better engage students. Instructors customize the learning path by selecting Cengage Learning resources and adding their own content via apps that integrate into the MindTap framework seamlessly with many learning management systems.

The guided learning path demonstrates the relevance of basic pharmacology principles to health care professions through engagement activities, interactive exercises, and procedural videos. The Pronounce activity ensures correct pronunciation of the top 200 drugs, plus additional hospital drugs. Easy-to-use *reference tables* with each classification list the most commonly prescribed drugs according to their generic and trade names, with dosage and available forms, special considerations, and audio to encourage correct pronunciation of the drugs most likely to be encountered in health care. Learners apply an understanding of pharmacology through application-based media quizzes. These media quizzes elevate the study of pharmacology by challenging students to apply concepts to practice.

To learn more, visit www.cengage.com/training/mindtap.

About the Authors

Bruce Colbert is an Associate Professor and Director of the Allied Health Care Department at the University of Pittsburgh at Johnstown. The author of 10 traditional books, he also developed an interactive worktext and DVD program on student success. Focusing on such topics as stress and time management, he has presented more than 250 regional and national lectures and workshops devoted to professional skills, enhancing critical and creative thinking, and effective decision making. In addition, Mr. Colbert consults with educational programs to improve teaching effectiveness as well as presents active teaching workshops.

Adam James is the Manager for Immunization and Clinical Programs for Rite Aid Pharmacy, focusing on immunization planning, implementation, and organization for almost 2,500 Rite Aid locations. He is the co-author of two textbooks, as well as a contributor to educational materials for Cengage. He continues to be a preceptor for Duquesne University School of Pharmacy, and was awarded Duquesne University Preceptor of the Year in 2020. In addition, Dr. James is a published CPE author, certified through ACPE.

Elizabeth Katrancha is an Associate Professor and Program Coordinator of the Baccalaureate Nursing Program at the University of Pittsburgh at Johnstown. She has been published in peer-reviewed journals such as *Trauma Nurse*, *Orthopedic Nurse*, and *Western Journal of Nursing Research*.

Acknowledgments

There are a lot of people to thank in a project of this scope. First and foremost, I would like to thank Ruth Woodrow for the honor to continue her vision on such a quality textbook.

I would also like to thank Adam James, who served as the pharmacist consultant and co-author on this project to make sure we got it right. I have known Adam for several years and I'm very impressed with his work ethic, knowledge, and professionalism. His updates with the latest and greatest information concerning specific drugs and dosages have been truly appreciated.

Co-author Liz Katrancha deserves a big thank you for being the nursing consultant to make sure we keep the textbook patient centered, clinically applied, and up to date. I have had the pleasure of working with Liz on several projects and her attention to detail and quality of work are greatly appreciated.

Last but certainly not least, I want to personally thank all the people at Cengage that have worked on this project. Of special mention is Laura Stewart, my editor, who has given me tremendous support and encouragement over the years. Debra Myette-Flis, the learning designer, deserves a special thank you for her tremendous assistance, organizational skills, professional knowledge, and guidance in helping to make this project a joy on which to work. Finally, Ken McGrath, who oversees this multifaceted revision process with technical expertise and is always great to work with.

Bruce J. Colbert

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PART 1

Introduction to Pharmacologic Principles

Chapter 1

Consumer Safety and Drug Regulations

Key Terms and Concepts

Controlled substances
Drug Enforcement Administration (DEA)
Drug standards
Food and Drug Administration (FDA)
National Drug Code (NDC) Directory
Orphan drugs
Over-the-counter (OTC) medication

Objectives

Upon completion of this chapter, the learner should be able to

1. Explain what is meant by drug standards
2. Discuss the historical development of pharmacology
3. Name the first drug law passed in the United States for consumer safety, and give the year it was passed
4. Summarize the provisions of the Federal Food, Drug, and Cosmetic Act of 1938 and its amendments
5. Interpret what is meant by *USP/NF*
6. Summarize the provisions of the Controlled Substances Act of 1970
7. Contrast the responsibilities of the FDA and DEA
8. Define *orphan drug*
9. Define schedules of controlled substances, and differentiate between C-I through C-V schedules
10. State several responsibilities you have in administering medications as a direct result of the three major drug laws described in this chapter

Your decision to pursue a career in the health care field probably took a great deal of thought. No doubt you have questioned whether you will be able to handle the unique situations that arise in a clinic, health care facility, or physician's office. Have you ever stopped to consider the impact *you* will make on the lives of others as a health care professional? Not only can you make a tremendous difference in the facility where you work, but you can also have a positive impact on your friends and family, as well as the patient or client.

It is inevitable that you will receive many questions about medications, prescriptions, and drug therapy. A great majority of patients are far too inhibited to tell their physicians

that there are things they do not understand about their medications. They feel much more at ease discussing their questions with health care professionals. Your potential for informing others with knowledgeable answers about medications can be quite an asset!

The key to reaching that potential is having knowledgeable answers coupled with a serious, responsible attitude about all aspects of drug therapy. Consider yourself a potential prime resource of medication information for your friends, family, and future patients as you begin to examine the foundations of facts about drugs. It may be necessary for you to clarify some of the layperson misunderstandings about the legalities of dispensing medications. Consider the following misconceptions and facts.

False	Fact
Only nurses can give medications to patients.	Trained and certified health care professionals who may legally give medications include physicians; physician assistants; paramedics; medical office assistants; unlicensed assistive personnel; practical, vocational, and registered nurses; and other allied health specialists such as respiratory therapists and pharmacists.
Only physicians may write prescriptions.	Dentists, physicians, physician assistants, veterinarians, nurse practitioners, and registered pharmacists may write prescriptions for their specific field of work, as governed by state law. For example, veterinarians write prescriptions only for animal use.
Prescriptions are required for narcotics only.	Specific drugs ruled illegal to purchase without the use of a prescription include the following: Those that need to be controlled *because they are addictive and tend to be abused and dangerous* (e.g., depressants, stimulants, psychedelics, and narcotics) Those that may cause dangerous health threats from side effects if taken incorrectly (e.g., antibiotics, cardiac drugs, and tranquilizers)
All drugs produced in the United States are made in federally approved laboratories.	Numerous illegal laboratories that produce illicit substances such as methamphetamines exist and operate within the United States today.
Prescriptions cannot be written for over-the-counter (OTC) medications.	Prescribers are able to write prescriptions for any FDA-approved medication and all OTC medications. Many times medications that were once available by prescription only are now available over the counter. Additionally, if a prescriber wishes for the patient to take an OTC medication differently from the instructions on the label, a prescription can be written to help the patient with compliance.
All herbal medicines and dietary supplements are safe.	Herbal remedies and other dietary supplements are not approved or manufactured per production standards regulated by the Food and Drug Administration (FDA) and may have serious interactions with prescribed medications. Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. The FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market and against marketed products that make false or misleading claims. (See Chapter 11.)

Drug History

Have you wondered how the numerous types of natural drugs and even immunizations ever came to be? Who were the first people to begin to treat diseases with drugs and who was the first person to create synthetic scientifically made medications? What were the major discoveries that led to better therapy outcomes? All of these questions are important in understanding pharmacology and how it evolved over

time to achieve this amazing degree of success that we have in treating patients with medications today. This success includes improving not only on life expectancy but also on quality of life.

From the very first documented use of "pharmacology" in ancient Egypt, where they used substances such as berries, beer, poppies, salt, and even crushed precious stones to treat ailments, it was clear the human race was determined to overcome diseases by any means necessary. Please refer to the timeline that shows some of the most important developments, discoveries, dates, people, and even setbacks in the history of pharmacology as we know it today.

Pharmacology Timeline

Date	Pharmacologic Event
16th century BCE	Earliest documented pharmacologic examples found recorded on papyri from ancient Egypt
2nd century BCE	Earliest evidence of actual "prescriptions"
1st century BCE	Greek physician Dioscorides writes the *De Materia Medica*, which is considered the most influential work in the history of western pharmacology
1885	Pasteur develops precursor to rabies vaccine Oswald Schmiedeberg, known as the founder of modern pharmacology, publishes *Outline of Pharmacology*
1897–1899	Aspirin discovered and first marketed for use
1905	German chemist Alfred Einhorn discovers Novocain
1906	The Pure Food and Drug Act passed in United States
1922	Insulin first used to treat diabetes
1928	Alexander Fleming discovers penicillin
1936	Chemotherapy first used to treat cancer
1937	Over 100 people die in the United States of a sulphanilamide elixir, leading to passage of the Federal Food, Drug, and Cosmetic Act in 1938
1953	Watson and Crick describe the structure of DNA
1960	First contraceptive pill
1958–1960	Thalidomide crisis where approximately 10,000 babies were born with deformities after thalidomide was used to treat morning sickness; this led to passage of a drug amendment act establishing the Food and Drug Administration in 1962
1969	Ibuprofen is developed in Great Britain
1991	FDA approves the first ever treatment for hepatis C (interferon alpha-2b)
2000	First draft of the human genome is released to public; this sets the stage for genetically targeted drugs
2017	Shingrix, the vaccine to treat shingles, is approved
2020–2021	Several vaccines developed in an attempt to mitigate the COVID-19 global pandemic

Drug Laws

As you can see from the Drug History section, individuals have been using substances and drugs for healing purposes for centuries. Due to scientific advances and changes in our society in the last century, consumer safety has become a critical issue. During the 1900s, laws were passed that specifically addressed the matter of safely dispensing drugs in the United States.

Drug standards are rules set to assure consumers that they get what they pay for. The law says that all preparations called by the same drug name must be of *uniform strength*, *quality*, and *purity*.

Because of drug standardization, when you take a prescription to be filled, you are assured of getting the same basic drug, in the same amount and quality, regardless of the pharmacy or the part of the country where you take the prescription. According to drug standards, drug companies must not add other active ingredients or varying amounts of chemicals to a specific drug preparation. They must meet the drug standards (federally approved requirements) for the specified strength, quality, and purity of the drug.

In the market of illegal (illicit) drugs, the lack of enforcement of drug standards poses danger to the consumer. With no controls on the quality of illegal drugs, many deaths have occurred from overdose. Consider the heroin user, accustomed to very poor-quality heroin, who accidentally overdoses when given a much higher quality of heroin from a new source. In general, across the country, opioid and other drug overdoses have become a major problem. This will be highlighted throughout following chapters, but it is important to be aware of the problems that can arise when certain drugs are abused.

The laws that have evolved to provide consumer safety can be summed up by three major acts. They are described in the order they became necessary for consumer safety, beginning with the 1906 Pure Food and Drug Act.

The importance of the timing of the 1938 Federal Food, Drug, and Cosmetic Act should be noted. It came about as the answer to a disastrous occurrence in 1937. A sulfa preparation, not adequately tested for safety, was responsible for 100 deaths that year. Thus, the need was recognized for more proof of the safety of new drugs. Several amendments were later added, such as the 1962 amendment due to the thalidomide crisis.

1906 Pure Food and Drug Act

First government attempt to establish consumer protection in the manufacture of drugs and foods.

Required all drugs marketed in the United States to meet minimal standards of strength, purity, and quality.

Demanded that drug preparations containing dangerous ingredients have a labeled container indicating the ingredient. Originally there were 11 "dangerous" ingredients, such as morphine.

Established two references of *officially* approved drugs. Before 1906, information about drugs was handed down from generation to generation. No official written resources existed. After the 1906 legislation, two references specified the official U.S. standards for making each drug. These references, listed here, have since been combined into one book, referred to as the *USP/NF*:

- *United States Pharmacopeia (USP)*
- *National Formulary (NF)*

1938 Federal Food, Drug, and Cosmetic Act and Amendments of 1951, 1962, and 1972

Established the **Food and Drug Administration (FDA)** under the Department of Health and Human Services to enforce the provisions of the act.

Established *more specific* regulations to prevent adulteration of (tampering with) drugs, foods, and cosmetics:

- All labels must be accurate and must include a listing of all active and inactive ingredients. Figure 1-1 shows an example of required product information for an **over-the-counter (OTC) medication** (no prescription [Rx] needed).
- All new products must be approved by the FDA before public release.
- "Warning" labels must be present on certain preparations, for example, "may cause drowsiness," "may cause nervousness," and "may be habit-forming."
- Certain drugs must be labeled with the legend (inscription) "Caution—federal law prohibits dispensing without a prescription." Thus, the term *legend drug* refers to such preparations. The act also designated which drugs can be sold without a prescription.
- Prescription and nonprescription drugs must be shown to be *effective* as well as *safe*.
- In 1972, the **National Drug Code (NDC) Directory** was established. This provided the FDA with a list of all drugs manufactured for commercial distribution. Each drug is identified by an NDC number, made up of three parts (see Figure 1-2).
  - The first part is five numbers and identifies the manufacturer.
  - The second part is four numbers and identifies the drug.
  - The third part is two digits and identifies the package size.
    - Example: 00406-0123-01; note it is a common practice to omit a leading zero in the first or second part of the NDC number, so this drug could also be written as 0406-123-01.

The five schedules of **controlled substances** are arranged with those with the highest potential for abuse at level I and those with the least abuse potential at level V. It should be noted that even those drugs in class level V have more potential for abuse than most drugs. Additionally, the lower the number, the stricter are the restrictions for control by the DEA. Therefore, it makes sense that Schedule I drugs are illegal and are not approved for medicinal purposes in the United States.

Drugs are frequently added, deleted, or moved from one schedule to another. If, for example, the DEA determines that drug A is becoming more of a societal problem, with an increased incidence of overdoses, drug A may be moved from the C-IV schedule to C-III. It is extremely important that the health care professional keep informed of any changes in drug scheduling. For the most part, using the most current drug reference book will keep you up to date.

You will recognize the schedule of a particular controlled substance by noting a *C* with either *I*, *II*, *III*, *IV*, or *V* after it. Some references show the capital *C* with the Roman numeral inside the curve of the *C* (Cɪv). Labels on controlled substances are also designated with a *C* and a Roman numeral to indicate their level of control. Drug inserts (information leaflets accompanying drugs) are also marked with a *C* and the appropriate schedule number. (See Table 1-1 and Figure 1-3.)

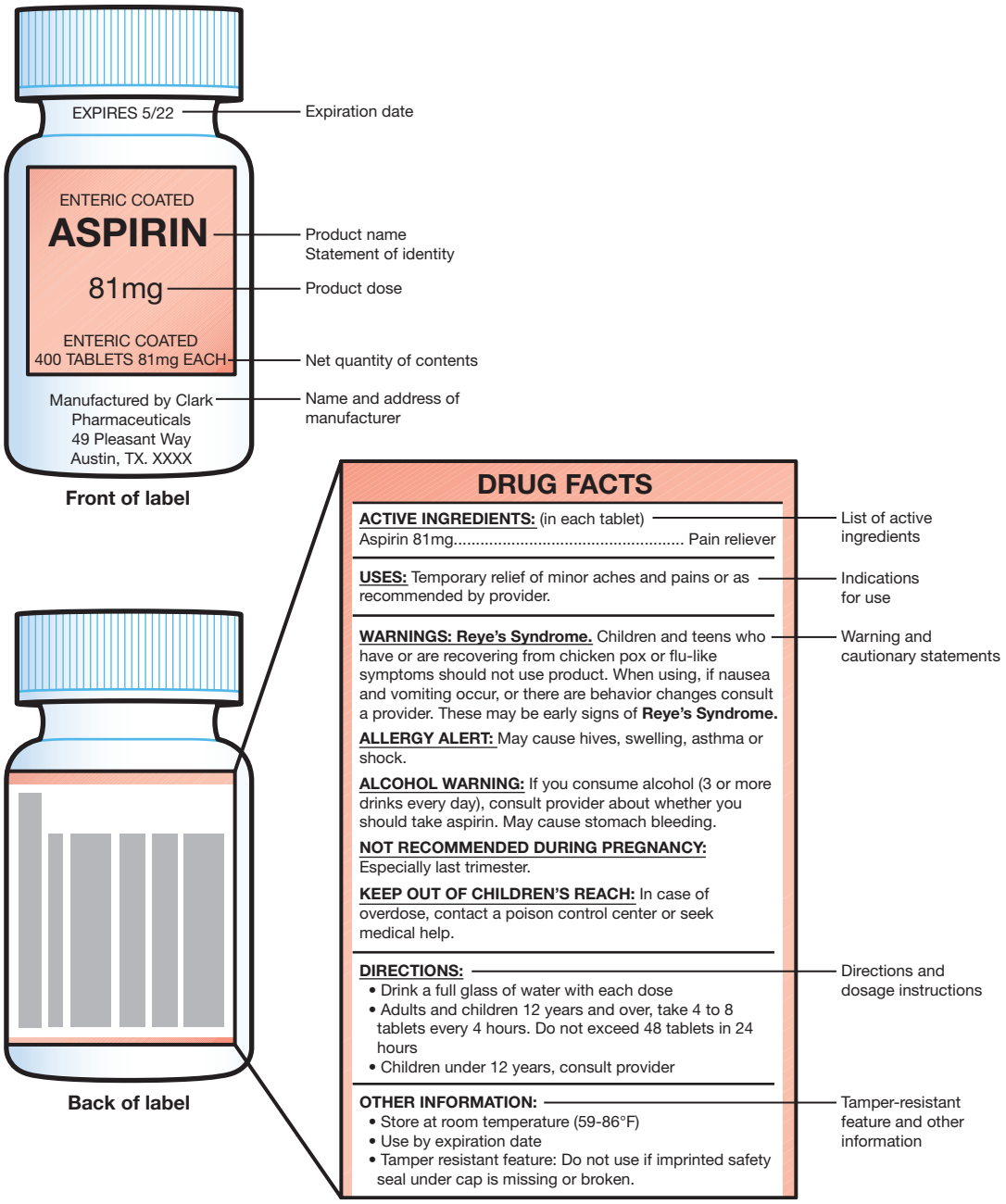

FIGURE 1-1 Consumer medication labels contain valuable information for safe and effective use of the drug.

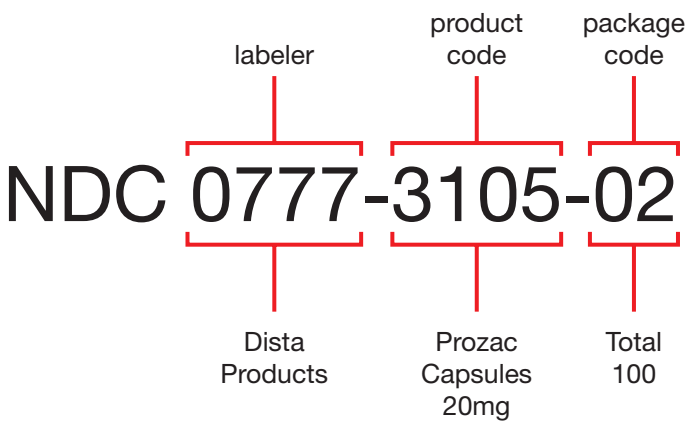

FIGURE 1-2 NDC code for the drug Prozac.

1970 Controlled Substances Act

Established the **Drug Enforcement Administration (DEA)** as a bureau of the Department of Justice to enforce the provisions of the act.

Set much tighter controls on a specific group of drugs: *those that were being abused by society*; the name of the act indicates that such *substances needed to be controlled*. These substances include depressants, stimulants, psychedelics, narcotics, and anabolic steroids. The act:

- Isolated the abused and addicting drugs into five levels, or schedules, according to their medical value, harmfulness, and potential for abuse or addiction: C-I, C-II, C-III, C-IV, and C-V.
- Demanded security and accountability related to **controlled substances**; anyone (e.g., pharmacists, hospitals, physicians, and drug companies) who dispenses, receives, sells, or destroys controlled substances must keep on hand special DEA forms, indicating the exact current inventory and a two-year inventory of every controlled substance transaction.
- Set limitations on the use of prescriptions; guidelines were established for each of the five schedules of controlled substances, regulating the number of times a drug may be prescribed in a six-month period as well as for which schedules prescriptions may be phoned in to the pharmacy and so on.
- Demanded that each prescriber of these substances register with the DEA and obtain a DEA registration number, to be present on their prescriptions of controlled substances; drug manufacturers must also be registered and identified with their own DEA numbers, as must pharmacists, physicians, veterinarians, and so on.

TABLE 1-1 Five Schedules of Controlled Substances

Schedule Number	Abuse Potential and Legal Limitations	Examples of Substances
1, CI	High abuse potential Not approved for medical use in the United States (discussed in Chapter 20)	heroin, LSD, methamphetamine, ecstasy
2, CII	High abuse potential May lead to severe dependence Written prescription only (or electronic prescription that meets DEA standards) Some states do not allow phoning or faxing in of prescriptions by the office health care professional; in an emergency, physician may phone in, but handwritten prescription must go to the pharmacy within seven days No refills without new written prescription Electronic prescribing systems may be used for C-II prescriptions, if both the prescriber and the pharmacy are verified to have approved computer systems to send and receive these types of prescriptions All C-II prescriptions are uploaded to the state's (if available) prescription drug monitoring program (PDMP)	morphine, codeine, methadone, Percocet, Dilaudid, Ritalin, Oxycontin, meperidine (Demerol), hydrocodone with Tylenol
3, CIII	May lead to moderate dependence Written, faxed, or verbal (phoned in) prescription, by physician only May be refilled up to five times in six months All C-III prescriptions are uploaded to the state's (if available) prescription drug monitoring program (PDMP)	codeine, anabolic (muscle-building) steroids

Schedule Number	Abuse Potential and Legal Limitations	Examples of Substances
4, CIV	Lower abuse potential than the previous schedules Prescription may be written out by the health care professional but must be signed by the physician Prescription may be phoned in by the health care professional or faxed May be refilled up to five times in six months All C-IV prescriptions are uploaded to the state's (if available) prescription drug monitoring program (PDMP)	Valium, Ativan, Xanax, phenobarbital, Librium, Restoril, Ambien
5, CV	Low abuse potential compared to the previous schedules Consists primarily of preparations for cough suppressants containing codeine and preparations for diarrhea (e.g., diphenoxylate) May be refilled up to five times in six months	promethazine with codeine, Cheratussin AC, Lomotil

Note: This control schedule can vary from state to state. Some states may have stricter schedules than the federal regulations. You must be aware of the regulations in your area.

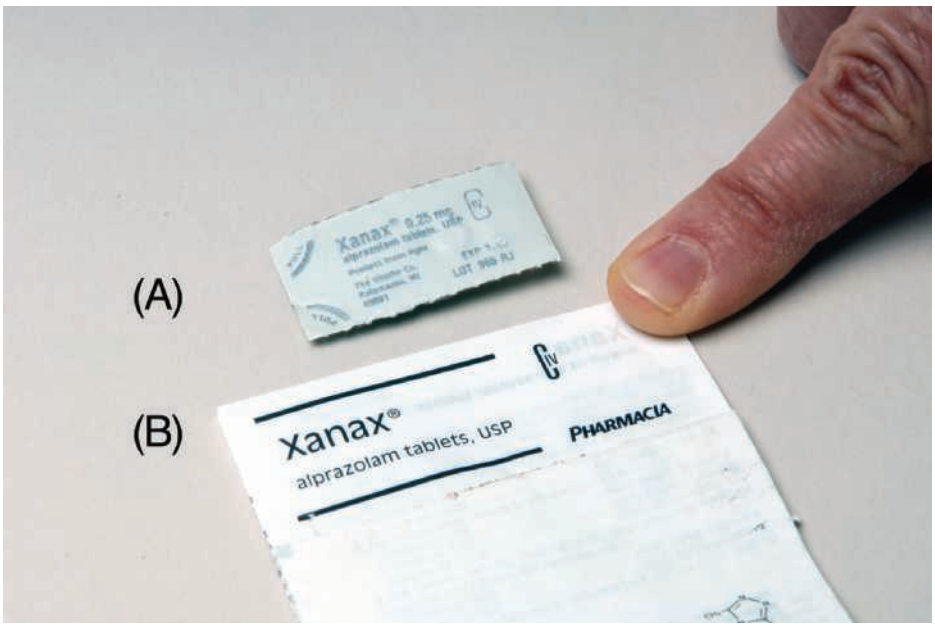

FIGURE 1-3 Controlled substance schedule numbers appear in a variety of drug information resources, including (A) drug packages and (B) drug inserts. Schedule numbers are also found in drug reference sources.

Clinical Application

Although many other drug laws exist, there are two significant pieces of drug legislation that are important to mention here. The 1983 Orphan Drug Act gives pharmaceutical companies financial incentives to develop medications for diseases that affect only a small number of people. This encourages the companies to develop **orphan drugs** that would otherwise be of low profitability. The other legislation is the strangely named Omnibus Budget Reconciliation Act (OBRA) of 1990. This act mandates that all OTC drugs a patient is taking must be documented as part of the medical record. OBRA also mandates that pharmacists provide drug use review and patient counseling before dispensing prescriptions to a patient.

FDA and DEA

The increase in the number of drugs produced for marketing brought dangers to the public. The federal FDA was established to ensure that some basic standards would be followed. Its responsibilities include:

- Overseeing testing of all proposed new drugs before they are released into the U.S. market
- Inspecting plants where foods, drugs, medical devices, or cosmetics are made
- Reviewing new drug applications and petitions for food additives
- Investigating and removing unsafe drugs from the market
- Ensuring proper labeling of foods, cosmetics, and drugs

When the need for better control of addictive drugs became urgent, the FDA had its hands full just trying to enforce basic drug standards. It became imperative to set up a new department, the DEA, in 1970 to handle all the needs and safety controls for the more dangerous drugs. Thus, the two agencies—FDA and DEA—were established with their own specific areas of drug control.

As a health care professional and an informed citizen, you must be aware of the latest developments concerning these two agencies. Hardly a week goes by without mention of the activities of the FDA or the DEA in the news. You should be able to recognize their separate areas of control.

FDA

Concerned with general safety standards in the production of drugs, foods, and cosmetics.

Responsible for approval and removal of products on the market.

Special note on drug withdrawals: In rare cases, the FDA may need to reassess and change its approval decision on a drug. A conclusion that a drug should no longer be marketed is based on the nature and frequency of the adverse events and how the drug's benefit and risk balance compares with treatment alternatives. When the FDA believes that a drug's benefits no longer outweigh its risks, the agency will ask the manufacturer to withdraw the drug. Interestingly, the FDA does not have the legal authority to withdraw a marketed drug product itself.

DEA

Concerned only with controlled substances.

Enforces laws against drug activities, including illegal drug use, dealing, and manufacturing.

Monitors need for changing the schedules of abused drugs.

Health Care Professionals and the Law and Ethics

In some ways, you will be as involved as the physician in observing the restrictions of the drug laws. You will have the responsibility of keeping accurate records of the medications dispensed. You will maintain the supply of drugs at your facility. If you work in a physician's office, a clinic, or an ambulatory care setting, you will also be involved with phoning in prescriptions and securing prescription forms at your facility.

You must act ethically to ensure that the ordered medications are given in the appropriate amount to the appropriate patient.

The following guidelines should be followed by the health care professional involved in dispensing medications:

1. Keep a *current* drug reference source available at all times. You should be able to readily identify substances that are controlled by the DEA.
2. Keep controlled substances locked securely. Double-locking is required in most situations. This means:
   a. Placing the drugs in a locked safety box
   b. Placing the locked box in a cupboard that is also locked
3. Conceal and secure prescription pads at your office, clinic, or facility. Do not leave pads out in the open, especially in patient examination rooms. The prescription pads, with the physician's DEA registration number, are a possible source of fraud and drug tampering when forged and used illegally. Keep the pads locked up and in a designated location (e.g., a drawer), out of the public areas of the office or nursing station. One of the most common ways prescriptions are forged is through a stolen prescription pad.
4. Keep accurate records of each controlled substance administered, received, or destroyed at your facility. These records, as well as the records from the previous two years, must be available at all times. Properly destroy expired drugs and old records.
5. Be responsible for keeping up to date with current news of the activities of the FDA and the DEA. If working for a physician, monitor the DEA registration renewal date. Keep informed of any changes in the scheduling of controlled substances.
6. Establish a working rapport with a pharmacist. A local pharmacist is an excellent resource for you when you are unsure of your legal responsibilities with drugs or have any uncertainties about drug therapy.
7. If you work in an office, maintain a professional rapport with the pharmaceutical representatives who leave drug samples there. As part of the Affordable Care Act, the Sunshine Act now requires reporting of compensation and gifts paid to physicians by pharmaceutical representatives. It is important that you are aware of the ethical dilemma that may occur when a physician is "rewarded" or compensated for prescribing certain medications.

Chapter Review Quiz

Complete the following statements

1. The first major U.S. drug law was passed in the year _____ and was called the _____

_____

2. USP stands for _____

3. NF stands for _____

4. Which drug law established the USP and NF (which are now one)? _____

5. The agency that requires you to keep a record of each controlled substance transaction is the _____

_____

6. Schedule C-_____ has the lowest potential for abuse.

7. How long must you keep an inventory record of each controlled substance transaction at your office? ____

_____

8. Three responsibilities of the FDA include: _____

_____

_____

9. What types of drugs are listed in the C-V schedule? _____

_____

10. What method is recommended for securing the controlled substances at your office? _____

_____

11. If a patient calls to request a refill of a Percocet (C-II) prescription, how would you reply? _____

_____

12. Dawn Vasquez has a rare disease that requires medication for only a small population of patients. Which act has allowed her drug to be produced even though it is not profitable to the pharmaceutical industry?

_____

13. A patient calls into the office asking for a new prescription for a narcotic medication that he has been taking for six months. You bring up his chart and notice that he has been requesting new prescriptions every 23 days, whereas the medication should last 30 days. Additionally, the patient also mentions that he feels that he is in need of a higher dose and gets agitated and irritable when you tell him that he will need an appointment. What do you think of this? What should you do?

14. Each drug is given a _____ number to identify the manufacturer, the drug, and the package size.

a. FDA
c. DEA
b. USP
d. NDC

15. Drug standards insure consistency in all the areas EXCEPT

a. strength
c. quality
b. purity
d. size

16. The Federal Food, Drug, and Cosmetic Act of 1938 established which agency?

a. NDC
c. FDA
b. DEA
d. USP

17. The earliest recorded use of drugs occurred during which civilization?

a. Egyptian
c. Greek
b. Roman
d. Aztec

18. Answer the questions concerning the following three drug labels:

a. Which drug(s) requires a prescription?

b. Which drug(s) can be bought without a prescription?

c. Which drug(s) requires a DEA number?

(A)

Steve Heap/Shutterstock.com.

(B)

Margaret M Stewart/Shutterstock.com.

(C)

Chapter 2

Drug Names and References

Key Terms and Concepts

Actions
Adverse reactions
Cautions
Classifications
Contraindications
Generic names
Indications
Interactions
Legend drug
Official name
Off-label drug
Pharmacology
Prototype
Side effects
Tall Man Lettering
Trade names

Objectives

Upon completion of this chapter, the learner should be able to

1. Describe drug classification systems
2. Differentiate among the following drug names: generic name, official name, trade name, and chemical name
3. Explain what is indicated by a number included in a drug trade name (e.g., Tylenol No. 3)
4. Discuss the purpose of Tall Man Lettering
5. Explain the restrictions of drug sales implied by the following: over-the-counter (OTC) drug, legend drug, off-label drug use, and controlled substance
6. Discuss the various terms indicating drug actions contained in reference sources
7. Describe drug references available today
8. Discuss characteristics that you consider important in choosing the best drug reference

Pharmacology can be defined as the study of drugs and their origin, nature, properties, and effects on living organisms. We need to know why drugs are given, how they work, and what effects to expect. The thousands of drug products on the market would make this subject difficult to tackle if it were not for:

- Numerous drug references, geared to a variety of levels of readers, from layperson to pharmacist
- Grouping of drugs under broad subcategories
- Continuity in the use of basic identifying terms for the names and actions of drugs

Classifications

Each drug can be categorized under a broad *subcategory*, or *subcategories*, called **classifications**. Although drugs can be classified in several different ways, grouping them together according to their therapeutic use is most helpful to the health care professional. Drugs that affect the body in similar ways are listed in the same classification. Drugs that have several types of therapeutic effects fit under several classifications. For example, aspirin has a variety of effects on the body. It may be given to relieve pain (analgesic), to reduce fever (antipyretic), to reduce inflammation of tissues (anti-inflammatory), or as an anti-platelet (anti-thrombotic agent). Therefore, aspirin is categorized under four classifications of drugs (as shown in parentheses).

Another drug, cyclobenzaprine (Flexeril), however, is known to be used for only one therapeutic effect: to relieve muscle spasms. Flexeril, therefore, is listed only under the one classification of muscle relaxant.

Examples of some common drug classifications are listed in Table 2-1. Are you familiar with any of them already?

Clinical Application

What is the difference between drug classifications and drug classes? While drug classifications place drugs in broad categories according to their therapeutic use, under that category can be several types of drug classes grouped together on how they work or their mechanism of action. For example, hypertensive agents are the drug classification and under this classification are several drug classes (beta blockers, alpha blockers, calcium channel blockers, ace inhibitors, etc.) that are all different drug classes that treat hypertension by different means.

TABLE 2-1 **Common Drug Classifications and Examples**

Classification	Therapeutic Use	Drug Example(s)
1. Lipid-lowering agents	Lower low-density lipoprotein (LDL) cholesterol	simvastatin, atorvastatin, rosuvastatin
2. Antidepressants	Improve symptoms of depression; also used for anxiety and other neurological disorders	escitalopram, sertraline, paroxetine, venlafaxine
3. Narcotic analgesics	Relieve severe pain	hydrocodone with acetaminophen, oxycodone, oxymorphone, fentanyl
4. Antihypertensives	Lower blood pressure	lisinopril, enalapril, valsartan
5. Diuretics	Increase urinary output	furosemide
6. Antidiabetics	Reduce blood glucose (sugar) levels	insulin, metformin, glipizide, Januvia
7. Antibiotics	Eliminate infection	amoxicillin, cephalexin, doxycycline
8. Anticoagulants	Decrease clotting in blood	warfarin, Xarelto

The second part of this text compares the characteristics of the various major drug classifications. In each chapter, as a classification is explained, you will learn what general information to associate with drugs of that classification, including:

- Therapeutic uses
- Most common side effects
- Precautions to be used
- Contraindications (when *not* to use the drug)
- Interactions that may occur when taken with other drugs or foods
- Some of the most common product names, their usual dosages, and comments on administration

You may also be given a **prototype** of each drug classification. A prototype is a *model example*, a drug that typifies the characteristics of that classification. For example, propranolol (Inderal) is the prototype of the beta-adrenergic blockers that will be explained in the cardiovascular chapter.

You can find the classification as well as the various names of a drug by referring to a drug reference source.

Identifying Names

Drug names can seem very complicated because a single drug will have many names attached to it. Four specific names can apply to each approved drug:

1. ***Generic name***
   a. Common or general name assigned to the drug by the United States Adopted Name (USAN) council
   b. Differentiated from the trade name by initial lowercase letter
   c. Never capitalized
2. ***Trade name*** (also known as proprietary or brand name since it is owned by a company)
   a. The name by which a pharmaceutical company identifies its product
   b. Copyrighted and used exclusively by that company
   c. Distinguished from the generic name by capitalized first letter
   d. Often shown on labels and references with the symbol ® after the name (for "registered" trademark)
3. ***Chemical name***
   a. The exact molecular formula of the drug
   b. Usually a long, very difficult name to pronounce
   c. Of little concern to the health care professional
4. ***Official name***
   a. Name of the drug as it appears in the official reference, the *United States Pharmacopeia/National Formulary (USP/NF)*
   b. Generally, the same as the generic name

The use of **generic names** and **trade names** for drugs can be compared to the various names of grocery products. Two examples of generic names are orange juice and detergent. Corresponding trade names for orange juice are Tropicana and Minute Maid, whereas Cheer and Tide are trade names for detergents. Although there is only one generic name, there may be many trade names marketed by different companies.

When a company produces a new drug for the market, it assigns a generic name to the product. After testing and approval by the Food and Drug Administration (FDA), the drug company gives the drug a trade name (often something short and easy to remember when advertised). For five years, from the time the company submits a *new drug application (NDA)* to the FDA for approval, the company has the exclusive right to market the drug. Once approved, the drug is listed in the *USP/NF* by an **official name**, which is usually the same as the generic name. After five years have passed and the patent has expired (although patent extensions are requested and frequently granted), other companies may begin to combine the same chemicals to form that specific generic product for marketing. Each company will assign its own specific trade name to the product, or the drug can be offered simply by its generic name and strength, such as acetaminophen 325 mg. See Table 2-2, which compares the names for two drugs.

Concerning prescription drugs, most states have enacted legislation encouraging physicians to let pharmacists substitute less expensive *generic equivalents* for prescribed brand name drugs. Specific provisions of drug *substitution laws* vary from state to state.

The physician may indicate "no substitutions" on the prescription, usually indicated by a *dispense as written (DAW) order*. Often physicians have preferences for certain products, or patients may be difficult to stabilize on a certain class of medications (such as thyroid preparations). Even though the drug contents are the same, the "fillers," or ingredients that are used to hold the preparation together, may be slightly different. This difference in fillers may affect how quickly the drug dissolves or takes effect. Dyes in some products may alter effects in some sensitive patients by leading to an allergic response.

Many products are combinations of several generic components. You will recognize this when you see several generic names (not capitalized) and their corresponding amounts listed under one trade name (capitalized). Examples are given in Table 2-3.

TABLE 2-2 Comparison of Drug Names

Generic Name	Chemical Name	Trade Names (Drug Company)
doxycycline hyclate	2-naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11, 12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, (4S,4aR,5S,5aR,6R,12aS)-(564-25-0)	Vibramycin (PD-RX Pharmaceuticals) doxycyclinehyclate[a] (West-Ward)
chlordiazepoxide hydrochloride	7-chloro-2-methylamino-5-phenyl-3H-1,4-benzodiazephine-4-oxide hydrochloride	Librium

[a]Some companies simply elect to market the product by the generic name.

TABLE 2-3 **Examples of Combination Drugs**

Trade Name	Generic Name and Amount
Dyazide (used to treat high blood pressure)	hydrochlorothiazide 25 mg/triamterene 37.5 mg
Glucovance (used to treat type 2 diabetes mellitus)	glyburide 1.25 mg/metformin 250 mg glyburide 2.5 mg/metformin 500 mg glyburide 5 mg/metformin 500 mg
Robitussin DM 5 mL syrup	dextromethorphan 10 mg/guaifenesin 100 mg

Patient Education

Patients may ask you about the difference between generic and trade (brand) name products. The FDA regulates the manufacturing of generic drugs, so patients can be assured that they are safe and cost-effective alternatives. Generally, trade name products are more expensive, although the basic active ingredients (drug contents) are the same as those in the generic. The higher price helps to pay for the costs of drug development and advertisements promoting the trade name. (Can you think of certain trade names that are heavily advertised in television commercials or on the Internet?)

Because generic drug equivalents may exist for both prescription and OTC drug products, it is often economically wise to check for medicines that have the same generic components and strengths. For example, several cough syrups may have exactly the same contents, but the prices may vary widely.

Read and compare all ingredients on the labels.

It should be noted that a number may be part of the trade name. The number often refers to an amount of one of the generic components and helps to differentiate it from an almost identical product. Identify the significance of the numbers in comparing the following trade names:

Trade Name	Generic Name and Amount
Tylenol No. 2	acetaminophen 300 mg codeine 15 mg
Tylenol No. 3	acetaminophen 300 mg codeine 30 mg
Tylenol No. 4	acetaminophen 300 mg codeine 60 mg

Note that each product contains the same amount of acetaminophen, with varying amounts of the controlled substance codeine. *The larger the number in the name, the greater is the amount of controlled substance present.*

Many drug errors have occurred because the trade name was misinterpreted for the number of tablets to be given. So . . .

Be certain you can clearly read and understand the order!

Another type of drug error involves preventable allergic reactions to one of the generic components of a medication. The problem stems from:

- Not consulting the patient's chart for the history of allergies before a new medication is ordered or given
- Not checking a reference to find out if a medication being ordered or given contains any generic components to which the patient has a known allergy

For example, if a patient has an allergy to aspirin, do not administer the first dose of any new medication to the patient without finding out if the product contains aspirin. Although the physician is in error for ordering the medication, you are also in error for administering a medication with which you are unfamiliar. A proficient health care professional should check the history and chart for known allergies and pick up any discrepancies. Alertness is the key to safety in any setting.

According to the Institute for Safe Medication Practices (ISMP) and the FDA, look-alike and sound-alike medications are a leading cause of drug errors. For example, the drug clonidine used for high blood pressure can be confused with the drug clonazepam used for anxiety; Celebrex for arthritis can be confused with Celexa for depression. To help health care professionals differentiate between look-alike and sound-alike drugs, **Tall Man Lettering** is often used to highlight the differences between the two drugs. For example, Celexa would be written CeleXA, whereas Celebrex would be written CeleBREX. This ensures that the health care professional reads and recognizes the correct medication.

These two agencies have created a long-standing relationship with a goal of preventing drug errors. The ISMP has developed tools such as the "List of Confused Drug Names" as a quick drug reference that is available on its website at http://www.ismp.org.

Always keep a drug reference handy, and use it when you are unfamiliar with the generic components of a drug ordered for a patient with known drug allergies. With experience, you will learn and remember the names of products most commonly used at your facility.

Legal Terms Referring to Drugs

A drug may be referred to by terms other than its classification, generic name, trade name, chemical name, or official name. As mentioned in Chapter 1, the following terms imply the legal accessibility of a drug:

1. ***Over-the-counter (OTC) drug.*** No purchasing restrictions by the FDA (with some exceptions, such as pseudoephedrine, which is OTC, but kept behind the pharmacy counter; see Chapter 20).
2. ***Legend drug.*** Prescription drug; determined unsafe for OTC purchase because of possible harmful side effects if taken indiscriminately; includes birth control pills, antibiotics, cardiac drugs, and hormones.
3. ***Controlled substance.*** Drug controlled by prescription requirement because of the danger of addiction or abuse; indicated in references by schedule numbers C-I to C-V (see Chapter 1).
4. ***Off-label medication.*** Drug used in a way not indicated on the FDA label. An example would be an antidepressant that is used to treat nerve pain.

In time and with patient research, some prescription drugs can be deemed safe enough to be sold OTC. The OTC Drugs Advisory Committee was formed in 1992 to review prescription or legend drugs and assist the FDA in determining which

ones are safe for OTC designation. Some recent examples of previously prescribed medications now available OTC are fexofenadine (Allegra) and triamcinolone (Nasacort), which were approved for nasal allergies in 2011 and 2014, respectively.

The legend drug is so named because it requires a legend or warning statement that says, "Federal law prohibits dispensing without a prescription."

Figure 2-1 shows the information contained on a drug label, including the trade name (Percocet) and the generic names of the two drugs (oxycodone and acetaminophen) that it contains. In addition, can you find the controlled substance marking?

FIGURE 2-1 Information contained on a drug label, including the trade name (Percocet) and the generic names of the two drugs (oxycodone and acetaminophen) that it contains.

Terms Indicating Drug Actions

Most references follow a similar format in describing drugs. When you research drug information, you will find the following terms as headings under each drug. You will find specific information more quickly if you understand what is listed under each heading.

Indications. A list of medical conditions or diseases for which the drug is meant to be used (e.g., the drug diphenhydramine hydrochloride [Benadryl] is indicated to treat allergic rhinitis, mild allergic skin reactions, motion sickness, and mild cases of Parkinsonism).

Actions. A description of the cellular changes that occur as a result of the drug. This information tends to be very technical, describing cellular and tissue changes. Although it is helpful to know what body system is affected by the drug, this information is geared more for the pharmacist (e.g., as an antihistamine, Benadryl appears to compete with histamine for cell receptor sites on effector cells).

Contraindications. A list of conditions for which the drug should *not* be given (e.g., two common contraindications for Benadryl are breast-feeding and hypersensitivity).

Cautions. A list of conditions or types of patients that warrant closer observation for specific side effects when given the drug (e.g., due to atropine-like activity, Benadryl must be used cautiously with patients who have a history of bronchial asthma or glaucoma, or with older adults).

Side effects** and **adverse reactions. A list of possible unpleasant or dangerous secondary effects, other than the desired effect (e.g., side effects of Benadryl include sedation, dizziness, disturbed coordination, epigastric distress, anorexia, and thickening of bronchial secretions). This listing may be quite extensive, with as many as 50 or more side effects for one drug. Because it is difficult to know which are most likely to occur, choose a reference that highlights the most common side effects. Certain drugs may have side effects with which you are not familiar. Note the definitions of the following three side effects associated with specific antibiotics.

- Ototoxicity causes damage to the eighth cranial nerve, resulting in impaired hearing or ringing in the ears (tinnitus). Damage may be reversible or permanent.
- Nephrotoxicity causes damage to the kidneys, resulting in impaired kidney function, decreased urinary output, and renal failure.
- Photosensitivity is an increased reaction to sunlight, with the danger of intense sunburn.

Interactions. A list of other drugs or foods that may alter the effect of the drug and usually should not be given during the same course of therapy (e.g., monoamine oxidase [MAO] inhibitors will intensify the effects of Benadryl; you will find MAO inhibitors listed under interactions for many drugs; the term refers to a group of drugs that have been used for the treatment of depression; it has been found that they can cause serious blood pressure changes, and even death, when taken with many other drugs and some foods).

Other headings often listed under information about a drug include "How Supplied" and "Usual Dosage." "How Supplied" lists the available forms and strengths of the drug. "Usual Dosage" lists the amount of drug considered safe for administration, the route, and the frequency of administration. For example:

How supplied: tablets (tabs): 20 mg and 40 mg; suppository: 20 mg

Clinical Application

While oftentimes side effects are negative and cause other issues, sometimes side effects can be beneficial. A side effect is an unintended secondary effect of a drug and in some cases can be good. For example, the medication Proscar is used to treat an enlarged prostate gland known as benign prostatic hyperplasia (BPH). The active ingredient in Proscar is finasteride, which promotes hair growth. So if you are a man with BPH and hair loss, the side effect of increased hair growth might be welcomed! Keep in mind that *adverse reactions* are always bad!

Usual dosage: 10 mg orally every four hours (q4h)

For a listing of common abbreviations regarding drug administration and medication orders, see Tables 4-1 and 5-1 in the upcoming chapters.

Drug References

Physicians' Desk Reference (PDR) is one of the most widely used references for drugs in current use. It is available online, as a mobile app, and in book form. There are three versions of the *PDR*, one for physicians, one for nurses, and one for consumers. In addition, there are many new choices of references available today. Three are compared here, including the *PDR*. You must find the reference most suitable for you, one that you can interpret quickly and easily. By becoming knowledgeable about the drugs you administer, you may prevent possible drug errors from occurring.

*Physician's Desk Reference (PDR)**

Pros	Cons
1. *PDR* for physicians—available for free online, as a mobile app, and for a fee in book form. Benefits include the following: —Product labeling —FDA drug safety communication —Medication guide —Drug alerts, recalls, and approvals —Patient resources —Various tools such as e-Books and mobile *PDR* —Ability to report adverse reactions —Photographs of many drugs for product identification 2. *PDR* for nurses—available for a fee with free mobile apps —Includes 1,500 FDA-regulated drugs —Includes critical black box warnings 3. *PDR* for consumers—written in patient-friendly language —Includes over 300 prescribed drugs —Color images of medications —Comparison tables of OTC drugs —Guide to safe medication use	Contains only those drugs that manufacturers pay to have incorporated Incomplete with regard to OTC drugs, making it necessary to buy *PDR* OTC book

*Published annually by PDR Network, LLC, Montvale, New Jersey.

United States Pharmacopeia and the National Formulary (USP/NF)†

Pros	Cons
Information is available online at http://www.usp.org Provides information on and standards for chemical and biological drug substances, dosage forms, and compounded preparations; medical devices; and dietary supplements	No photographs of drugs Geared for laboratory and manufacturing use No easily identified nursing implications Can be confusing to use

†Published annually by U.S. Pharmacopeial Convention, Inc., Rockville, Maryland.

AHFS Drug Information (American Health-System Formulary Service)‡

Pros	Cons
Distributed to practicing physicians; single paperback volume, includes mobile drug reference and handbook of injectable drugs Good, concise information; easy to read Arranged by classifications, with a general statement about each classification at the beginning of each section Off-label drug indications are listed (not FDA approved) http://www.ashp.org/	Some parts (e.g., "Chemical Information" and "Drug Stability") not necessary for the health care professional No photographs of drugs

‡Published annually by American Society of Health-System Pharmacists, Bethesda, Maryland.

Other references (e.g., *The Pill Book, Handbook of Nonprescription Drugs*) may be found in bookstores, but they may not contain information adequate for health care professionals. Your school may recommend a specific drug reference other than the three listed in this text. Many new references geared to the nurse or health care professional are currently being published. Electronic drug references such as Lexi-Drugs, Micromedex, or Epocrates are also widely used. There are applications available for smartphones, and many electronic medication administration records (EMARs) are connected directly to an electronic drug reference.

The Internet as Reference

The Internet offers a wealth of information regarding medications and the conditions they treat. However, there can be serious dangers associated with some online sources that may not be reliable, professional, or even legitimate. Therefore, care must be taken to identify and use only websites that are supervised and controlled, such as those under the auspices of government agencies or sponsored by professional pharmacist groups. It is important for the health care professional to obtain accurate information and also be able to direct the patient or client to reliable sources of information regarding medicines. It is the health care professional's responsibility to caution the layperson regarding the controversial and dangerous practices of "online prescribing" without ever evaluating the patient in person, or obtaining medicines without prescriptions through the Internet.

Evaluating Internet Drug Sources

Remember that all websites are not created equal. Pay attention to a few simple rules when seeking the most reputable ones.

1. Check the source. Have scientific studies been done with a large enough sample? Are results reliable and valid? Are there links to a page listing professional credentials or affiliations?
2. Check the date of articles. Medicine is a rapidly evolving field. Information can go out of date quickly.
3. Be wary of information from forums and testimonials. Motivations are unknown. The information is not necessarily valid, and there may be a hidden agenda.

The following websites are reliable professional sources of medical information:

http://www.pharmacist.com	Sponsored by the American Pharmacists Association (APhA), the national professional society of pharmacists.
http://www.fda.gov	U.S. Food and Drug Administration. Includes "Human Drugs" and Center for Drug Evaluation and Research (CDER).
http://www.safemedication.com	Sponsored by the American Society of Health-System Pharmacists. Covers correct dosage, side effects, and optimal use of most prescriptions and OTC drugs. Also offers reports on topics such as antibiotic-resistant bacteria.
http://www.usp.org	U.S. Pharmacopeial Convention (USP/DI).
http://www.cdc.gov/vaccines/	U.S. Centers for Disease Control and Prevention, National Immunization Program. Covers vaccines and immunizations.
http://www.nlm.nih.gov/medlineplus/	A service of the U.S. National Library of Medicine and the National Institutes of Health. A great source for medicine and related health topics.

Chapter Review Quiz

Match the definition with the term.

1. ___ List of conditions for which a drug is meant to be used

2. ___ Subcategories of drugs based on their effects on the body

3. ___ Description of the cellular changes that occur as a result of a drug

4. ___ Conditions for which a drug should not be given

a. Contraindications

b. Cautions

c. Indications

d. Prototype

e. Actions

f. Classifications

Refer to the following drug description to answer questions 5–8.

AZO Standard®
(phenazopyridine HCl tablets, *USP*)
Product of i-Health, a Division of DSM
Description: AZO Standard (phenazopyridine HCl) is a urinary tract analgesic agent, chemically designated 2,6-pyridinediamine, 3-(phenylazo), monohydrochloride.

5. The generic name of the drug is _____

6. The chemical name of the drug is _____

7. The trade name of the drug is _____

8. What is indicated by the® symbol after the drug name? _____

_____

9. Explain when Tall Man Lettering should be used._____

_____

10. Explain the difference between these two medication orders:

a. Give two Tylenol, PO.

b. Give one Tylenol No. 2 PO.

_____.

_____.

11. An older adult male was found unconscious in his bedroom with several pink and blue pills beside his bed, but no labeled pill bottle can be found. He is rushed to the emergency department for treatment. What drug reference source will be most helpful in this situation?

12. Place the following terms in the correct blank: OTC, controlled substance, legend drug, off-label drug

a. _____ a prescription is *not* needed

b. _____ term that means a prescription is required

c. _____ potential for abuse

d. _____ drug given for an unapproved use

Chapter 3

Sources and Bodily Effects of Drugs

Key Terms and Concepts

Adverse drug reaction
Anaphylactic reaction
Chemoinformatics
Cumulative effect
Dependence
Dosage
Drug interactions
Drug processes
Hypersensitivity
Idiosyncratic reaction
Keep Vein Open (KVO)
Local effect
Paradoxical reaction
Pharmacogenomics
Placebo effect
Prodrugs
Sources of drugs
Systemic effect
Teratogenic effect
Therapeutic range
Tolerance

Objectives

Upon completion of this chapter, the learner should be able to

1. Identify the five sources of drugs
2. Contrast systemic and local effects
3. Define the pharmacokinetic processes as they relate to the passage of drugs through the body
4. State conditions that may decrease the effectiveness of each pharmacokinetic process: absorption, distribution, metabolism, and excretion
5. Discuss several variables that can affect drug action
6. Define various adverse drug reactions
7. Describe the various routes of drug administration

Sources of Drugs

Any chemical substance ingested or applied on the body for the purpose of affecting body function is referred to as a drug. In earlier times, these substances were found in nature, sometimes accidentally. Plants were the primary **sources of drugs** used on the human body. Berries, bark, leaves, resin from trees, and roots were found to aid the body and are still very important drug sources.

Minerals from the earth also found their way into human use as drugs. Minerals such as iron, sulfur, potassium, silver, and even gold are used to manufacture drugs.

More sophisticated sources of drugs emerged as human beings progressed. Research led to the use of substances from *animals* as effective drugs. Substances lacking in the human body can be replaced with similar substances obtained from the glands, organs, and tissues of animals. Investigation of other animal sources of medicines still remains. For example, an investigational drug to treat type 2 diabetes by promoting weight loss was recently developed from the saliva of the Gila monster lizard.

Chemists use synthetic sources to make drugs to market for human consumption. The *synthetic* (manufactured) sources evolved with human skills in laboratories and advanced understanding of chemistry. Today, through advances in computers, millions of potential drug candidates can be screened on computers quickly and efficiently using a process called **chemoinformatics**. Chemoinformatics is the application of computer technology, statistics, and mathematics to study information about the structure, properties, and activities of molecules. This method is probably the most actively pursued source of drugs by major companies today. Competitive research is a big industry that involves experimenting with chemicals to discover cures for current medical problems. Numerous antibiotics are synthetic or semisynthetic, the results of researchers meeting the need for better treatment of infections. Someday the cure for cancer or human immunodeficiency virus (HIV) infection may be found from a synthetic source developed in a laboratory.

Genetic engineering of drugs and the recently developed technique of *recombinant DNA technology* has allowed for the production of biologically active substances that are present in the body and that can be used to treat certain diseases. DNA is the genetic material of the cells, and the DNA sequence determines the genetic code. Genetic engineering refers to the alteration of genes in a laboratory setting.

Recombinant DNA techniques involve combining the DNA of two or more different organisms for a desired change or improvement. Some examples of therapeutic agents derived from recombinant DNA technology are the hepatitis B vaccine, insulin, and growth hormone. One of the areas of most current interest in recombinant DNA technology is gene therapy. This therapy consists of essentially inserting normal genes into a human chromosome to counteract

the effects of an abnormal or a missing gene. This has not only huge implications for preventive medical therapy but also ethical considerations. See Figure 3-1 for examples of sources of drugs.

Sources of Drugs	Example	Trade Name	Classification
 Picture Partners/Shutterstock.com. Plants Foxglove where digitalis was originally found	Cinchona Bark Purple Foxglove Plant Poppy Plant (Opium)	Quinidine Digitalis Morphine, Codeine	Antiarrhythmic Cardiotonic Analgesic Analgesic, Antitussive
 macrowildlife/Shutterstock.com. Minerals	Magnesium Zinc Gold	Milk of Magnesia Zinc Oxide Ointment Auranofin	Antacid, Laxative Sunscreen, Skin Protectant Anti-inflammatory; Used in the Treatment of Rheumatoid Arthritis
 sal73it/Shutterstock.com. Animals	Thyroid Gland of Animals	Thyroid, USP	Hormone
 Vadim Petrov/Shutterstock.com. Synthetic	meperidine diphenoxylate co-trimoxazole	Demerol Lomotil Bactrim, Septra	Analgesic Antidiarrheal Anti-infective Sulfonamide; Used in the Treatment of Urinary Tract Infections (UTI) and some other Infections
DNA  metamorworks/Shutterstock.com. Genetic Engineered	Hepatitis B vaccine Insulin Growth hormone	Recombivax HB Humulin, Novolin Nutropin	Vaccine Anti-diabetic Hormone

FIGURE 3-1 Sources of drugs: plants, minerals, animals, synthetic, and genetically engineered.

Effects of Drugs

Regardless of the source, the common characteristic of all drugs is the ability to affect body function in some manner. When introduced into the body, all drugs cause cellular changes (drug actions), followed by some *physiological change* (effects of drugs). Generally, drug effects may be categorized as systemic or local:

1. **Systemic effect.** Reaches widespread areas of the body. For example, ibuprofen is often used as an analgesic and anti-inflammatory for pain associated with knee pain due to arthritis. Although you feel the effect in your knee, the medication is actually providing the same effect all over the body, which is why it can also be used for headaches, cramps, and sunburn just to name a few. Systemic effects are widespread because the medication reaches the bloodstream and is carried throughout the body.
2. **Local effect.** Is limited to the area of the body where it is administered (e.g., dibucaine ointment [Nupercainal], applied rectally, affects only the rectal mucosa to reduce hemorrhoidal pain). Many topical skin creams such as those used to treat pimples only work locally where they are applied and needed. Most medications taken by mouth have systemic effects, with exceptions being with medications that affect the inner mucosal layer of the stomach.

Drug Processing by the Body (Pharmacokinetics)

***Kinetics* means "movement" and therefore *pharmacokinetics* literally means what happens to the drug as it moves through our body.**

Within the body, drugs undergo several changes. From start to finish, the biological changes consist of four **drug processes** (abbreviated as *ADME*):

1. ***Absorption.*** Passage of a substance through a membrane into the bloodstream
2. ***Distribution.*** Moving from the bloodstream into the tissues and fluids of the body
3. ***Metabolism.*** Physical and chemical alterations that the substance undergoes in the body
4. ***Excretion.*** Eliminating waste products of drug metabolism from the body

Many variables affect how quickly or successfully substances go through the body via these four processes. If any of the four processes are altered, the drug action and effects will be altered, where the medication may have a greater or lesser effect or a longer or shorter duration. Table 3-1 lists conditions that may alter each process.

Directions for the administration of drugs may vary widely because the physical properties of the drugs vary widely. The specific directions ("Usual Dosage and

TABLE 3-1 **Processing of Drugs within the Body**

Process	Primary Site of Process	Conditions That May Alter Process
Absorption	Mucosa of the stomach, mouth, small intestine, or rectum; blood vessels in the muscles or subcutaneous tissues; or dermal layers	Incorrect administration may destroy the drug before it reaches the bloodstream or its site of action (e.g., giving certain antibiotics after meals instead of on an empty stomach)
Distribution	Circulatory system, through capillaries and across cell membranes	Poor circulation (impaired flow of blood) may prevent the drug from reaching tissues where it is to have its desired effect.
Metabolism	Liver, small intestine	Hepatitis, cirrhosis of the liver, or a damaged liver may prevent adequate breakdown of the drug, thus causing a build-up or accumulation of unmetabolized drug.
Excretion	Kidneys, sweat glands, lungs, or intestines	Renal damage or kidney failure may prevent passage of drug waste products, thereby causing an accumulation of the drug in the body

Administration," "Contraindications," and "Warnings") that accompany each drug are given to enhance the absorption, distribution, metabolism, and excretion of the drug. For example, directions to "Give on an empty stomach" ensure the most effective means of absorption. "Use cautiously in patients with renal dysfunction" implies possible effects on the excretion of a drug. "Decrease dose in patients with hepatic dysfunction" implies possible effects on the metabolism of a drug. *Read all labels carefully, and caution the patient to do so as well* (Figure 3-2).

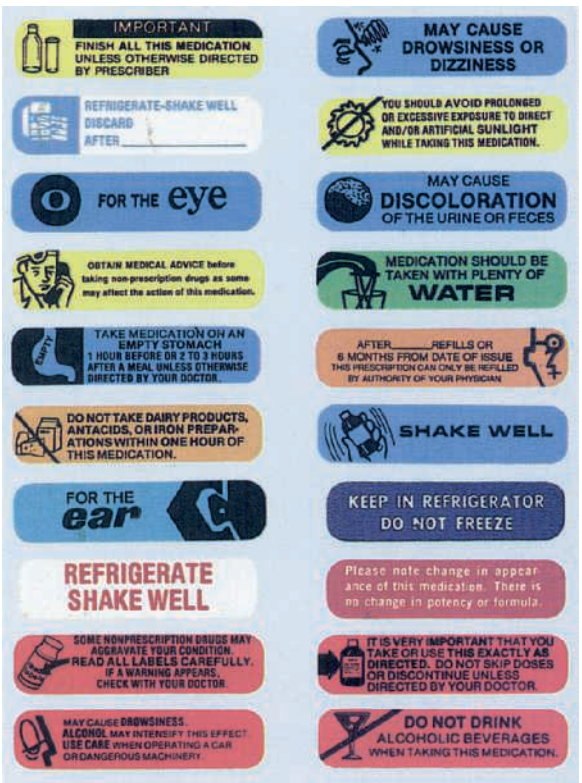

FIGURE 3-2 Warning labels are placed on prescription medication containers. Patients should be advised to read and follow the precautions or instructions.

Absorption

The site of absorption of drugs varies according to the following physical properties of each drug:

1. ***pH.*** Drugs of a slightly acidic nature (e.g., aspirin and tetracycline) are absorbed well within the acidic stomach environment. Drugs of an alkaline pH are not absorbed well through the stomach but are readily absorbed in the alkaline environment of the small intestine. The antibiotic tetracycline is not recommended to be administered with milk, dairy products, or antacids because it will not be properly absorbed. This is due to *chelation*—the formation of an insoluble complex of tetracycline with calcium in dairy products. pH effect may also play a role. Oral medications for infants (syrups and solutions) may not be absorbed well after infant feedings. The milk or formula neutralizes the acidity of the stomach. Thus, absorption may be enhanced when the infant is given medications on an empty stomach.
2. ***Lipid (fat) solubility.*** Substances high in lipid solubility are quickly and easily absorbed through the mucosa of the stomach. Alcohol and substances containing alcohol are soluble in lipids. They are rapidly absorbed through the gastrointestinal (GI) tract. Substances low in lipid solubility are not absorbed well through the stomach or intestinal mucosa and are absorbed best when given by a means other than the GI tract. An exception is the drug neomycin, which is not lipid soluble and yet is given orally. It is indicated for suppression of intestinal bacteria before intestinal or bowel surgery or for the treatment of bacterial diarrhea. By giving neomycin orally, it passes through the GI tract, unable to be absorbed. As a result, it tends to build up and accumulate in the bowel. The trapped antibiotic kills the bacteria in the bowel, for the desired effect.
3. ***Presence or absence of food in the stomach.*** Food in the stomach tends to slow absorption due to a slower emptying of the stomach. If a fast drug effect is desired, an empty stomach will facilitate quicker absorption. On the other hand, giving some medications on an empty stomach is contraindicated. Medications that are irritating to the stomach can be buffered by the presence of food. Directions may indicate "Give after meals" or "Take with food" to decrease side effects (e.g., nausea and gastric ulcers) in the GI tract.

Distribution

The movement of a drug from the bloodstream into the tissues and fluids of the body is also affected by specific properties of the drug. Reaching sites beyond the major organs may depend on the drug's ability to cross a lipid membrane. Some drugs pass the "blood–brain barrier" to reach the brain or the "placental barrier" to reach the developing fetus, whereas others do not. For example, propranolol is the only beta blocker (normally a cardiac medication) that passes the blood–brain barrier, and this allows it to be used for an adjunct therapy for migraine headaches because it can have an effect in the brain. You may also read about drugs contraindicated for lactating mothers because the drug has the ability to pass through cell membranes into the milk.

Some drugs have a *selective distribution*. This refers to an affinity, or attraction, of a drug to a specific organ or cell. For example, amphetamines have a selective distribution to cerebrospinal fluid. The human chorionic gonadotropin hormone, which is used as a fertility drug, has a selective distribution to the ovaries.

By virtue of their properties, some drugs are distributed more slowly than others. Thus, although two drugs may be categorized in the same drug classification, one may be known to act on the cells and achieve the effect more quickly than the other.

Metabolism

When transformed in the liver (biotransformation), a drug is broken down and altered to more water-soluble by-products (metabolites). Thus, the drug may be more easily excreted by the kidneys. Some drugs are inactive when administered and become active only when they are metabolized by the liver. This group of drugs is known as **prodrugs** (e.g., clopidogrel [Plavix]).

If hepatic disease is present, a patient may exhibit toxic (poisonous) effects of a drug or the drug may not work as intended. This occurs because the drug is not being broken down properly by the inefficient liver. The drug may accumulate, unchanged by the liver, and may be unable to pass out of the body's excretory system. Metabolism can also be altered by interactions between drugs, between drugs and food, and between drugs and disease states. For example, as mentioned above, clopidogrel is a prodrug, but its metabolism to the active form is inhibited by Nexium (esomeprazole). If these drugs are used together, clopidogrel will not have its intended antiplatelet effect.

It is possible for some drugs to bypass the process of metabolism. They reach the kidneys virtually unchanged and may later be detected in the urine.

Excretion

Although it is possible for some drugs to be eliminated through the lungs (e.g., exhaled gases and anesthetics) or through perspiration, feces, bile, or breast milk, most are excreted by the kidneys via urine.

If a drug is not excreted properly before repeated doses are given, a **cumulative effect** due to a drug build-up may eventually occur. A cumulative effect is an increased effect of a drug demonstrated when repeated doses accumulate in the body. Patients with decreased kidney function may be at risk of drug accumulation. If unnoticed, the cumulative effect may build to a dangerous, or toxic, level. This can be of particular concern with older adults.

Toxicity refers to a condition that results from exposure to either a poison or a dangerous amount of a drug that is normally safe when given in a smaller amount. In drug therapy, the goal is to give just enough of the drug to cause the desired (therapeutic) effect while keeping the amount below the level at which toxic effects are observed. It should be noted that toxicity can develop even with properly dosed or small amounts of a drug.

Digoxin is a cardiac drug that must be given cautiously because of its potential for causing a cumulative effect. Normally, digoxin slows the heart rate, but if the drug accumulates, the heart rate may slow to a dangerously low level. Circulation and renal function must be adequate, or the digoxin will accumulate, leading to digoxin toxicity.

Keep in mind that the purpose of most medication treatment is to have a desired effect by maintaining a drug level within a **therapeutic range**. The therapeutic

range is the range of drug levels in the blood that will give the desired effect without causing serious side effects. The blood can be tested for therapeutic levels. For example, the target therapeutic range for digoxin is 0.8–2.0 ng/mL. Lower than this level will not be effective and higher than this range can lead to toxicity.

Other Variables Affecting Drug Action

Many *variables* affect the speed and efficiency of drugs being processed by the body. The physical properties of the drugs themselves and the condition of the body systems have been discussed. Other variables affecting drug action and effect follow.

Age

Metabolism and excretion are slower in older adults, and therefore attention must be paid to possible cumulative effects. Refer to Chapter 27 for a detailed discussion on how the complex changes of aging affect how drugs are processed in the body. Children have a lower threshold of response and react more rapidly and sometimes in unexpected ways; therefore, frequent assessment is imperative.

Weight

Generally, the bigger the person, the greater the dose should be. However, there is great individual variation in sensitivity to drugs. Many drug dosages are always calculated on the basis of the patient's weight. With certain drugs in patients who are obese, it may be best to calculate their dose based on their ideal body weight rather than their total body weight.

Gender

Women respond differently than men to some drugs. The ratio of fat per body mass differs, and so do hormone levels. If a female is pregnant or nursing, drugs should be selected that are safe to use for both the mother and her child. For example, the common over-the-counter medications ibuprofen and naproxen (Advil and Aleve) should never be used during pregnancy unless under medical supervision.

Psychological State

It has been proven that the more positive the patient feels about the medication being taken, the more positive the physical response. This is referred to as the **placebo effect**.

A *placebo* is an inactive substance that resembles a medication, although no drug is present. For example, a sugar tablet or a saline solution for injection may be used as a placebo in a research study program.

Placebos are most often used in blind study experiments in which groups of people are given either a drug or a placebo. (Needless to say, placebos are not administered if doing so would risk serious or irreversible harm to those taking them.) The individuals, unaware of which they have been given, are studied for the effects. Often, by virtue of strong belief or by the natural fluctuation of a disease (e.g., headaches may get better without treatment), the placebo-administered individuals achieve the desired effect associated with the drug they think they have received.

It is also possible for a drug's effect to decrease when the attitude of a patient toward a medication is negative. Attitudes toward medicines can also be influenced positively or negatively by cultural or religious beliefs. The caregiver needs to understand the importance of these beliefs to the patient.