chapter 1

Orientation to Medications

In this chapter you will learn where drugs come from, how they are standardized, and how their use is governed by law. You will also learn how to use drug references and drug cards to gather information about medications.

Learning Outcomes

After studying this chapter, you should be able to:

1-1 Define *pharmacology, pharmacodynamics, pharmacokinetics, anatomy, physiology,* and *pathology.*

1-2 Define *drug, therapeutic effect,* and *side effects.*

1-3 List the major sources of drugs and give examples of each.

1-4 List the seven uses of drugs.

1-5 Define *drug standards* and tell how they are determined.

1-6 Explain why drug standards are necessary.

1-7 List and describe four types of names by which drugs are known.

1-8 List three drug references and explain how to use at least one.

1-9 Use drug references to prepare a drug card.

1-10 List three major drug laws and list their main features.

1-11 List the federal agencies that enforce drug laws.

1-12 Explain why health workers must be familiar with drug laws.

Key Terms

action: a drug's chemical effects on body cells

administration: how a drug is given

adverse reaction: an unintended and undesirable effect of a drug

anatomy: the study of the structure of body parts

brand name: licensed name under which a drug prepared by a specific manufacturer is sold; also known as *proprietary* or *trade name*

chemical name: name that describes the chemical structure of a compound

contraceptives: drugs used to control fertility and prevent pregnancy

contraindications: conditions in which the use of a certain drug is dangerous or ill-advised

controlled substances: potentially dangerous or habit-forming drugs whose sale and use are strictly regulated by law

Controlled Substances Act of 1990: law that regulates manufacturing and distribution of controlled substances; also known as *Comprehensive Drug Abuse Prevention and Control Act*

diagnostic drugs: drugs used to diagnose disease

drug: chemical substance used in the diagnosis, treatment, cure, or prevention of a disease; also known as *medication*

drug card: index card on which you write drug information for your own reference

Drug Enforcement Administration (DEA): since 1973, the only legal U.S. drug enforcement agency

Food and Drug Administration (FDA): enforcement agency for the FDCA

Food, Drug, and Cosmetic Act (FDCA) of 1938: law that mandates that drug manufacturers test all drugs for potentially harmful effects and that drug labels must be complete

generic name: official nonproprietary name assigned to a drug by the manufacturer, with the approval of the United States Adopted Names Council

health maintenance: process of developing a healthy lifestyle, keeping existing diseases under control, and getting regular checkups

indications: diseases and disorders for which a certain drug may be used

legend drugs: prescription drugs

nonproprietary name: generic name of a drug

official name: generally, the same as the generic name of a drug; name of a drug as it appears in the official reference, the *United States Pharmacopeia/National Formulary (USP/NF)*

over-the-counter (OTC) drugs: drugs available without a prescription

package insert: printed information about a pharmaceutical product

palliative drugs: drugs used to improve quality of life but not to cure or treat a condition

pathology: study of the disease process, including changes in structure and function of the body

pharmacodynamics: study of the body's response to a drug

pharmacokinetics: the absorption, distribution, metabolism, and excretion of drugs

pharmacology: study of drugs (uses, preparation, routes, laws, etc.)

Physicians' Desk Reference (PDR®): a widely used drug reference book that gives information about the drug products of major pharmaceutical companies

physiology: the science that deals with the functions of cells, tissues, and organs of living organisms

precautions: warnings to use care when giving drugs under certain conditions

prescription drugs: drugs that can be dispensed only with a physician's order or the order of another designated healthcare provider such as a nurse practitioner or physician's assistant

proprietary name: brand name of a drug

psychology: study of the normal and abnormal processes of the mind

side effects: desirable or undesirable effects of a drug apart from the primary purpose of giving the drug

standards: rules ensuring uniform quality, strength, and purity

synthetic drugs: drugs created in the laboratory from various chemicals

therapeutic effect: desired or predicted physiological response caused by a drug

United States Adopted Names (USAN) Council: organization that adopts the generic name of a drug

United States Pharmacopeia Dispensing Information (USPDI): official reference for pharmacists or persons administering medications

United States Pharmacopeia/ National Formulary (USP/NF): official book listing standardized drugs

1-1 Definition of Terms

Not long ago, only doctors and nurses were allowed to administer medications. But times are changing; many other members of the health occupations are now asked to give or know about medications. They are also expected to observe how patients react after taking medications. These are important new responsibilities. They demand that you, a member of the healthcare team working with medications, also have knowledge of many health-related topics. You must know the basic principles of **pharmacology,** which is the study of drugs and their uses. You must understand how the body responds to drugs, or **pharmacodynamics.** You must also understand **pharmacokinetics,** the absorption, distribution, metabolism, and excretion of drugs. These areas require some knowledge of human **anatomy,** the study of body parts, and of **physiology,** the science that deals with the functions of cells, tissues, and organs of living organisms. You must understand the study of disease processes, including changes in the structure and function of the body, or **pathology,** and how drugs change the course of disease. You must also give attention to **psychology,** the study of the normal and abnormal processes of the mind, because a patient's mental state influences how the body reacts to drugs.

This textbook will teach you, step by step, the basics of pharmacology, pharmacodynamics, pharmacokinetics, anatomy, physiology, and pathology. You will also find suggestions for responding to patients' psychological needs, along with information you should tell patients about medications they may be taking. The uses of specific drugs for treatment of disease are discussed in connection with the body systems on which they act. As you learn general principles, most of you will also carry out practice tasks that give you experience in giving medications.

1-2 Pharmacology

A **drug** is a chemical substance used in the diagnosis, treatment, cure, or prevention of a disease. Pharmacology is the study of drugs: their uses, preparation, routes, and laws. Pharmacology includes the study of how drugs affect the human body. Healthcare professionals are particularly interested in the desired or predicted physiological response that a drug causes, or the drug's **therapeutic effect.**

Pharmacology attempts to describe a drug's desirable or undesirable effects apart from the primary reason for giving the drug. These are called **side effects.** Pharmacology also focuses on the proper amounts of drugs to give and how to give them. Knowledge of the laws and responsibilities surrounding drug use, along with practical experience in giving medications, will prepare you to play a vital role on the healthcare team.

1-3 Drug Sources

Drugs come from four sources: plants, animals, and minerals, as well as chemicals **(synthetic drugs)** by means of biotechnology or genetic engineering.

Our ancestors long ago discovered that the roots, leaves, and seeds of certain plants had the power to cure illnesses, ease pain, and affect the mind. Today many drugs are still extracted from parts of plants. An example is digitalis, a cardiac glycoside used to treat congestive heart

failure. Digitalis is made from a wildflower, purple foxglove. Drugs from the poppy plant are morphine and codeine, which are potent analgesics. Other drugs of plant origin are gums and oils. An example of a gum is psyllium seed, which is a bulk-forming laxative. Castor oil from the castor bean acts as a stimulant laxative.

Drugs of animal origin are prepared by extracting natural substances, such as hormones, from animal tissues and organs. Insulin, for example, is extracted from the pancreases of cattle and pigs. Insulin is a valuable drug used to treat diabetes mellitus by lowering the blood glucose level. Heparin, used to reduce the formation of blood clots, is taken from the intestinal linings of cattle and pigs.

Iron, iodine, calcium, sodium chloride (salt), magnesium hydrochloride (milk of magnesia), and magnesium sulfate (Epsom salts) are examples of minerals used in drug therapy. They are derived from rocks and crystals.

Many drugs are made, or synthesized, in the laboratory through chemical processes. Sulfonamide drugs such as *Bactrim* and *Septra,* for example, are frequently used in the treatment of urinary tract infections. An advantage of synthetic drugs is that they are generally less expensive than nonsynthetic drugs because they are produced in mass volume. Biotechnology and genetic engineering combine DNA material from different organisms, making new drugs and drug products available. Insulin and vaccines can be produced this way. Humulin® insulin is a genetically engineered drug used in the treatment of diabetes mellitus.

1-4 Drug Uses

The study of drug uses will give you an understanding of one phase of healthcare, drug therapy. The four most familiar uses of drugs relate to disease: prevention, treatment, diagnosis, and cure. Three types of drugs have other uses: **contraceptives,** used for the prevention of pregnancy; drugs to promote **health maintenance;** and palliative drugs.

Disease prevention involves the administration of drugs, such as vaccines, that inoculate the body against disease microorganisms. Health maintenance helps patients maintain or enhance their current levels of health. Drugs such as vitamins and minerals are given to help keep the body healthy and strong or to keep the body systems functioning normally.

Treating disease means relieving the symptoms while the body's natural disease-fighting mechanisms do their work. Aspirin and antihistamines are examples of drugs used to treat disease symptoms. An antihistamine such as *Benadryl* is an example of a drug used to treat allergy symptoms or motion sickness. Aspirin is used to treat fever and pain. Curing disease often means eliminating disease-causing microorganisms. Antibiotics such as erythromycin and penicillin are drugs given to cure a disease such as pneumonia.

Diagnostic drugs are considered drugs because they are chemical substances used to diagnose or monitor a patient's condition. A diagnostic drug may have side effects and adverse reactions just like any other drug. For example, radiopaque dye (a contrast medium that shows up on fluoroscopes or x-rays) is administered to detect gallbladder malfunctions. A radiopaque dye such as iodine may cause anaphylaxis, an immediate, severe, and frequently fatal reaction, in a patient previously sensitized to the chemical (iodine). It is therefore important to ask patients if they have a shellfish allergy, which indicates a predisposition to an iodine allergy.

The prevention of pregnancy is possible with the use of contraceptives, drugs that control fertility.

Drugs often have more than one use. The drug promethazine hydrochloride (*Phenergan*), for example, is used in a variety of ways. It can control allergic reactions, treat motion sickness, induce sleep, and prevent vomiting after surgery. Some drugs have the ability to prevent as well as cure or treat disease.

Palliative drugs are used to improve the quality of life but not cure or treat the disease. They are generally used in terminal illness such as cancer. Most frequently analgesics are used for pain management in these illnesses. Hospice has been instrumental in helping healthcare professionals realize that opioid dosing frequently exceeds the dose used in other conditions or surgery.

1-5, 1-6 Drug Standards

Drugs differ widely in strength, quality, and purity, depending on how they are manufactured. To control these differences, certain rules or **standards** have been set up that products must meet. Drug standards are required by law. The law states that all preparations called by the same drug name must be of a uniform strength, quality, and purity. A drug prepared in Indiana must meet the same standards for strength, quality, and purity as the same drug prepared in California or New Jersey. Because of drug standards, physicians who order penicillin, for example, can be sure that patients anywhere in the country will get the same basic substance from the pharmacist. Drug standards also help doctors prescribe accurate dosages and predict the results.

Drugs for which standards have been developed are listed in a special reference book called the ***United States Pharmacopeia/National Formulary (USP/NF).*** The *USP/NF* is recognized by the U.S. government as the official list of drug standards, which are enforceable by the U.S. Food and Drug Administration.

Since 1975, USP has engaged in a program to include all drug substances and, to the extent possible, all drug products in the United States. The book is updated regularly, and a new edition is published every five years to keep the information up to date.

1-7 Drug Names

All drugs have more than one name. In fact, most have four: a chemical name, a generic name, an official name, and one or more brand or trade names.

The **chemical name** describes the chemical composition and molecular structure of the drug. Acetylsalicylic acid is an example of a chemical name.

The **generic name** is the official **nonproprietary name** assigned by the manufacturer with the approval of the **United States Adopted Names (USAN) Council.** The generic name is simpler than the chemical name. For example, aspirin is the generic name for acetylsalicylic acid.

The **official name** is usually the same as the generic name.

Also known as the trade or **proprietary name,** the **brand name** is the name under which the drug is sold by a specific manufacturer. The name is owned by the drug company, and no other company may use it. The symbol ® to the right of the name shows that its use is restricted. A drug that is manufactured by several companies may be known by several different brand names. For example, the drug with the generic name

nitroglycerin is sold by several manufacturers under such brand names as *Nitro-Bid, Nitrong,* and *Nitrostat. Bufferin* is an example of a brand, proprietary, or trade name for aspirin.

Brand-Name Drugs Versus Generic-Name Drugs

Most drugs are known to the general public by their brand names. *Dimetane* and *Dimetapp* are much more familiar-sounding to someone who is not in the profession than is the name brompheniramine. But you and your fellow health workers must be familiar with both the brand and generic names of many drugs. First, a physician may prescribe a drug by a generic name or a brand name. Because several brand names may exist for the same ingredient, such as acetaminophen, physicians are encouraged to order drugs by their generic names. In fact, state and federal governments now permit, encourage, and in some cases mandate that the consumer be given the generic form when buying prescription drugs. Another reason for using generic names is that doing so avoids confusion among similar brand names. A prescription written for a generic product allows the pharmacist to choose among nonbranded drugs available from several companies. Generic drugs are therapeutically equivalent to and much cheaper than brand-name drugs.

Another reason for knowing the generic name is that drugs often have several brand names but only one generic name. If you learn the generic names, you can organize information about several brand-name drugs in your mind. Of course, it is not possible to memorize all the generic and brand names for medications, but you should try to become familiar with both names of the drugs you handle daily in your work.

Where this book mentions specific drugs, generic names are given first and are not capitalized. Brand names are capitalized, italicized, and shown in parentheses following the generic names. Only one or two common brand names are given in each case. Keep in mind that many other brand-name products may be available.

1-8 Drug References

Several reference books or computer websites provide useful information about drugs on the market. Doctors, nurses, and others in the health occupations often refer to them when planning and administering drug therapy. Drug references can help you understand why and how a particular drug is administered. For each drug, they usually include the following information:

- *Description*—what the drug is made of.
- *Action*—how the drug works.
- *Indications*—what conditions the drug is used for.
- *Interactions*—undesirable effects produced when drugs are taken with certain foods or with other drugs.
- *Contraindications*—conditions under which the drug should not be used.
- *Precautions*—specific warnings to consider when administering drugs to patients with specific conditions or diseases.
- *Side effects/adverse reactions*—unintended and undesirable effects.
- *Dosage and administration*—correct dose for each possible route of administration.
- *How supplied*—how the drug is packaged and stored.

Computer websites are rapidly becoming the most popular way to check information on drugs. Websites include:

- http://www.rxlist.com
- http://www.fda.gov
- http://www.safemedication.com
- http://www.drugdigest.com

Learning how to use the drug references will help you meet the new responsibilities of health workers in administering medications.

A common reference book is the ***Physicians' Desk Reference (PDR®),*** which is available in many health facilities. The *PDR®* gives information about the drug products of major pharmaceutical companies. It is useful for checking description, clinical pharmacology, mechanism of **action, indications, contraindications,** warnings, **precautions, adverse reactions,** overdosage, dosage and **administration,** and how the product is supplied.

The ***United States Pharmacopeia Dispensing Information (USPDI)*** is another drug reference, first published in 1980 in three volumes. It provides pharmacists and other healthcare workers with easy-to-follow information about official drugs and products. You will find Volume II useful, as this volume is written in nontechnical language that is easy for patients to understand. It is called *Advice for the Patient.* Volume III is the "Orange Book," *Approved Drug Products and Legal Requirements.* This volume includes state and federal requirements for prescribing and dispensing drugs. These volumes are updated each month in the *USPDI Update.*

Another valuable reference is the *Handbook of Nonprescription Drugs,* published by the American Pharmaceutical Association. It deals with over-the-counter information in general categories. Pharmacology textbooks and articles in nursing and other professional journals are also helpful sources of information. Some healthcare facilities keep their own reference lists of the drugs they use most often.

Another reference is the *American Hospital Formulary Service (AHFS) Information Book.* It contains an objective overview, in outline form, of almost every drug available in the United States. This book is updated yearly, and information is easily located with just one index at the back of the book.

In addition, there are many *Nursing Drug Reference* books on the market, many available as convenient handbooks. These nursing drug books similarly cover the action, uses, dose and route, adverse effects, contraindications, and precautions of the drug but also focus on nursing considerations, interventions, and patient teaching. Many individuals who are administering medications find it extremely helpful to have the nursing interventions listed, such as monitoring a temperature, measuring intake and output, or encouraging the patient to drink fluids.

No one text is a complete source for all the drug information necessary for the administering of medications. Therefore, it is important that you gather information from the various sources and select the drug reference source that you feel best meets your needs when you administer medications and provide patient and family teaching about those medications.

Understanding and Using the *PDR®*

The current edition of the *Physicians' Desk Reference (PDR®)* contains five sections that are color-coded and contain specific information. The first section is the Manufacturers' Index and is printed on gray pages. This section lists all the pharmaceutical manufacturers that participate in the *PDR®*. Participating manufacturers provide their addresses and

phone numbers and show their products along with their corresponding page numbers. The second section is the Brand and Generic Name Index, which is printed on white pages and lists drugs by both their brand and generic names and the page numbers they are listed on. Section three is the Product Category Index, which is printed on gray pages and lists the products by prescribing category. The Product Identification Guide comprises section four. This section provides color photos of the actual size of drugs arranged alphabetically by the manufacturer. These color photos will help you easily identify drugs.

Section five contains Product Information and is also printed on white pages. In this section, you will find detailed information on each drug such as the brand and generic name, description, clinical pharmacology, indications, contraindications, warnings, precautions, adverse reactions, dosage and administration, and lastly how supplied. The "description" of the drug lists its origin and chemical composition. The "clinical pharmacology" states the effect a drug has upon the body and the process by which the drug produces this effect. The diseases or conditions for which a drug is given are listed in the "indications and usage" section. The reasons a specific drug should not be given are included in the "contraindications" section. The potential dangers of a drug are listed under the drug "warnings." The "precautions" state possible undesirable effects a drug may have. Side effects of a drug are listed under "adverse reactions." Under "dosage and administration," you will learn the usual amount of a drug to be given to adults and children and the recommended times for administration. The possible drug forms and their dosages are included in the "how supplied" section.

After understanding the various sections of the *PDR®,* you will be able to look up information on any drug. For example, if the drug you want to give is *Tylenol,* look it up in the white pages or section two (Brand and Generic Name Index). The phonetic spelling is given for the brand name along with the generic name (acetaminophen). The route of administration, such as "for oral use," is also listed. Generally, the manufacturer's name appears in parentheses after the drug name, followed by one or two page numbers. The first page number refers to the Product Identification page number, which provides an actual-size color photo of the drug. The second page number refers to the Product Information page number, which provides all prescribing information.

You may also look for a specific drug by knowing its classification. The blue pages, or Product Category Index, provide the prescribing category. For example, look up antibiotics and you will find a variety of antibiotics such as penicillin.

Other features in the *PDR®* include a list of poison control centers, U.S. Food and Drug Administration agencies, drug information centers, and herb/drug interactions.

Now that you have learned the various sections of the *PDR®* and how to look up drug information, you have all of the information needed to safely administer a drug to your patient.

Coping with Technical Language

A problem with many drug references is that they are written in complex language. They use medical terms that may be unfamiliar, especially to new students. The descriptions of drugs assume that the reader has a background in anatomy, physiology, diseases, and pharmacology.

An important aim of this book is to help you learn enough about anatomy, physiology, diseases, and pharmacology to understand what you find in different drug references. You will learn important technical terms, basic principles to help you understand how drugs work, and basic

information about various diseases to understand why a particular drug is prescribed.

Coping with Changing Information

Information about drugs is constantly changing. New drugs appear all the time, and old drugs are taken off the market. Drug research turns up better ways of using drugs and administering them. This means that drug references quickly can become outdated. Some reference publishers such as the *PDR*® send out regular supplements with information updates. These updates should be checked along with the drug reference. Another place to look for current information on drug administration is **package inserts.** These are printed sheets of information inside the boxes in which drugs are packaged. Package inserts contain the same information that is provided in the *PDR*®.

This text will help you cope with changing information on drugs. After studying the various chapters, you will know general principles about groups or classifications of drugs. Any new information that becomes available should then fit easily into your general understanding of drugs.

1-9 Preparing Your Own Drug Cards

Because there are so many drugs and so much information exists about them, no one can expect to keep all of the important facts constantly in mind. Although drug cards can be purchased from college or local bookstores, many health workers in a variety of settings and students find it useful to prepare 5 × 7 index cards containing information about the drugs they use most often in their work. Some students may also prefer to develop a drug file or cards on the computer. Drug cards save time because healthcare workers can find the information more quickly in their card files than in a huge drug reference. Of course, the information on the cards must be updated regularly to remain current. **Drug cards** can be designed according to your own needs whether they are done on cards or on the computer. They should include this information:

- Drug name, both generic and brand.
- Drug classification, or the group a drug belongs to, such as analgesics (pain relievers), antipyretics (fever reducers), antacids, laxatives, and so on (you will learn the basic drug classifications in later chapters).
- Forms in which the drug is available (tablets, capsules, etc.).
- Action, or how the drug interacts with the organs or systems that it is supposed to affect.
- Uses of the drug.
- Side effects and adverse reactions.
- Drug interactions.
- Signs of drug poisoning (toxicity).
- Route of administration.
- Dosage range and usual adult dose.
- Special instructions for giving the medication, including the interventions required (for example, what to tell the patient about expected side effects, precautions, etc.).
- A note on where you got your information (specific drug reference, package insert, etc.).

Figure 1.1
Sample drug card.

Drug
Acetaminophen (*Tylenol*)

Action
Blockade of prostaglandin stimulation of the central nervous system. Increases peripheral blood flow and sweating.

Uses
Fever reduction, temporary relief of mild or moderate pain.

Doses
Adults and teenagers 325–500 mg oral every 3–4 hours, 650 mg oral every 4–6 hours, 1000 mg oral every 6 hours as needed.

Side Effects
Yellow eyes or skin (rare); bloody or black stools; pain in side and lower back; skin rash, hives, or itching; sores, ulcers, or white spots on the lips or mouth; sore throat; sudden decrease in the amount of urine; unusual bleeding or bruising; unusual tiredness or weakness.

Drug Interactions
Barbiturates, carbamazepine (*Tegretol*), hydantoins, rifampin (*Rifadin*), and sulfinpyrazone may reduce the therapeutic effects and increase the hepatotoxic effects of acetaminophen. Caffeine may increase the analgesic effect of acetaminophen.

A sample drug card is shown in Figure 1.1. Beginning with Chapter 6, you will find tables at the ends of chapters listing representative drugs in the major drug categories. These tables can serve as a guide for what to include on your drug cards or drug file. As you study the drugs in Chapters 6 through 19, make a habit of preparing drug cards or a drug file for the medications you expect to be giving in your health facility.

1-10 Drug Legislation

The U.S. government regulates the composition, uses, names, labeling, and testing of drugs. Since the early 1900s, many laws have been passed to enforce the official drug standards and to protect the public from unreliable and unsafe drugs. Federal agencies have been set up to see that these laws are followed. Table 1.1 lists the major drug laws and their enforcing agencies.

The first law, the Pure Food and Drug Act, was passed in 1906. This law states that only drugs listed in the *USP/NF* may be prescribed and sold, because these drugs meet the required standards. Various amendments to this act regulate prescriptions, require testing of new drugs, and call for complete information about drug effects and dangers. The **Food, Drug, and Cosmetic Act (FDCA) of 1938,** which replaced the 1906 act, spells out additional regulations concerning purity, strength, effectiveness, safety, labeling, and packaging of drugs. It also states that the federal government must review safety studies on new drugs before they can be put on the market. This provision was added after more than 100 deaths resulted from a poorly tested and mislabeled sulfanilamide product. This solution had been marketed as an "elixir" without investigating its toxicity. The FDCA is enforced by the **Food and Drug Administration (FDA).**

Table 1.1 Major Drug Laws

Legislative Act	Enforcement Agency
Pure Food and Drug Act of 1906 Approves *USP/NF* and requires that drugs meet official standards Requires labeling of medicines containing morphine and other narcotics Amendment of 1912 prohibits making false claims about health benefits of a drug	**None**
Food, Drug, and Cosmetic Act (FDCA) of 1938 (replaced the 1906 act) Regulates content and sale of drugs and cosmetics Requires accurate labeling and warnings against unsafe use Requires government review of safety studies before selling new drugs Amendment of 1952 allows certain drugs to be dispensed by prescription only and refilled only on a doctor's order; also recognizes OTC drugs as drugs that do not require a prescription Amendment of 1962 requires proof of effectiveness and safety before marketing new drugs and full information on advantages, side effects, contraindications Certain drugs must carry a warning label indicating possible side effects or if drug may be habit-forming Certain drugs must carry the label "Caution: Federal law prohibits dispensing without a prescription."	**Food and Drug Administration (FDA)** Under Department of Health and Human Services Can investigate manufacturers, withdraw approval of drugs, control shipment and testing Enforces FDCA by prosecuting offending firms and seizing goods Drug manufacturers must register with FDA and report to FDA all adverse reactions resulting from use of their products Reviews studies of safety and effectiveness of new drugs
Drug Regulation and Reform Act of 1978 Permits briefer investigation of new drugs, allowing consumers earlier access	**FDA**
Orphan Drug Act of 1983 Speeds up drugs' availability for patients with rare diseases	**FDA**
Drug Price Competition and Patent Term Restoration Act of 1984 Permits generic drug companies to prove bioequivalence without duplicating costly clinical trials done by original drug manufacturer Gives longer patent protection for new drugs	**FDA**
AIDS Test for Blood of 1985 Approves the first enzyme-linked immunosorbent assay (ELISA) test kit to screen for antibodies to HIV Protects patients from infected donors	**FDA**
Childhood Vaccine Act of 1986 Requires patient information on vaccines Gives the FDA permission to make necessary recalls	**FDA**
Controlled Substances Act of 1990 (original 1970) Identifies and regulates manufacture and sale of narcotics and dangerous drugs Provides research into drug abuse, prevention, and dependence Provides funding for education on drug abuse, rehabilitation, and law enforcement Classifies drugs into Schedules I–V according to medical usefulness and possible abuse (Table 1.2)	**Drug Enforcement Administration (DEA)** Under Department of Justice May punish violators by fines, imprisonment, or both

Table 1.1 *(continued)*

Legislative Act	Enforcement Agency
Nutrition Facts of 1992 Requires basic-serving nutritional information on the nutrition label of most prepackaged food	**United States Department of Agriculture (USDA)**
Nutrition Facts of 2003 Includes trans-fat content in food on the nutrition label	**USDA**
Food Allergen Labeling and Consumer Protection Act of 2004 Requires labeling food if it contains a protein from common allergy-causing foods, such as peanuts, soybeans, cow's milk, eggs, fish, crustacean shellfish, nuts, and wheat	**FDA**
Patriot Improvement and Reauthorization Act of 2005 (Combat Meth Act) Restricts the sale of over-the-counter products containing pseudoephedrine and ephedrine Makes these products available only by purchase through a pharmacy	**Congress**

Since 1962, the FDA has required proof that new drugs are effective as well as safe.

Another important law is the **Controlled Substances Act of 1990** (original 1970), also known as the Comprehensive Drug Abuse Prevention and Control Act. It identifies the drugs that are dangerous or subject to abuse, such as narcotics, depressants, and stimulants. This law strictly regulates the manufacture and distribution of controlled substances. It clearly stipulates that possession of a controlled substance is unlawful without a prescription. This law provides research into preventing drug abuse and drug dependence. It also provides for treatment and rehabilitation of drug abusers. It further improves the administration and regulation of the manufacture, distribution, and dispensing of controlled substances.

Controlled substances are grouped into five categories, or schedules, each with its particular restrictions, as shown in Table 1.2. There is a Schedule VI in some states. Drugs with the highest abuse potential are placed in Schedule I. They have no accepted medical use in the United States. Drugs with the lowest abuse potential are placed in Schedule V. You need to be aware that these classifications are flexible. Occasionally, drugs may be added to a schedule or changed from one schedule to another without new legislation. A record is kept of each time a controlled substance is sold and of the amount. There are restrictions on how prescriptions can be refilled. All prescriptions must be written in ink. Oral emergency orders for Schedule II substances may be filled, but the physician must provide a written prescription within 72 hours.

Pharmacists must carefully follow the rules outlined in the Controlled Substances Act. Violation of the law is punishable by fine or imprisonment or both. The agency that enforces this act is the **Drug Enforcement Administration (DEA).**

Doctors must also follow the law in prescribing controlled substances. They need a special license from the DEA for each office from which they practice and must renew or register their licenses every three years. They are given one tax stamp and number for each license. This number, called

Table 1.2 Drug Classifications Under the Controlled Substances Act of 1990 (Original 1970)[a]

Drugs	Characteristics	Examples
Schedule I drugs	High potential for abuse, severe physical and psychological dependence No accepted medical use To be used for research only Not to be prescribed; unsafe in treatment	Alfentanil, fenethylline, hashish, heroin, lysergic acid diethylamide (LSD), marijuana, methaqualone (*Quaalude*), peyote, psilocybin
Schedule II drugs	High potential for abuse, severe physical and psychological dependence Acceptable medical uses, with restrictions Dispensed by prescription only No refills without new written prescription from physician	Amphetamines, cocaine, meperidine HCl (*Demerol*), methadone, methylphenidate hydrochloride (*Ritalin*), morphine, opium, pentobarbital (*Nembutal*), anabolic steroids, hydromorphone hydrochloride (*Dilaudid*), codeine
Schedule III drugs	Moderate potential for abuse, high psychological dependence, low physical dependence Acceptable medical uses By prescription only; may be refilled five times in 6 months if authorized by physician	Barbiturates, butabarbital (*Butisol*), glutethimide (*Doriden*), secobarbital (*Seconal*), *Tylenol* with codeine
Schedule IV drugs	Lower potential for abuse than Schedule III drugs; limited psychological and physical dependence Acceptable medical uses By prescription only; may be refilled five times in 6 months if authorized by physician	Chloral hydrate (*Noctec*), chlordiazepoxide (*Librium*), diazepam (*Valium*), flurazepam HCl (*Dalmane*), oxazepam (*Serax*), phenobarbital, propoxyphene HCl (*Darvon*), lorazepam (*Ativan*), meprobamate (*Equanil*), pentazocine HCl (*Talwin*), alprazolam (*Xanax*)
Schedule V drugs	Low potential for abuse Acceptable medical uses OTC narcotic drugs, but sold only by registered pharmacists; buyer must be 18 years and show ID	Cough syrups with codeine, e.g., guaifenesin (*Naldecon DX*) and *Cheracol* with codeine, diphenoxylate HCl with atropine sulfate (*Lomotil*[b]), *Novahistine* expectorant, *Parepectolin*
Schedule VI drugs	Some states such as North Carolina have adopted a Schedule VI	Marijuana is the only drug in this schedule; it has limited medicinal use by prescription in certain situations

[a] *Source: DEA, U.S. Department of Justice. Check with your local DEA office for current regulations.*

[b] *Requires a prescription.*

the DEA number, must be shown on any prescription for controlled substances.

To keep a supply of controlled substances in an office or a health facility, the staff must fill out special order forms and records. These forms show how many controlled substances are being kept at the facility, as well as who received doses of the drugs and how unused doses were disposed of. A physical inventory of all controlled substances in the office must be made every two years. (You will learn about these forms in Chapter 5.)

All drugs fall into one of the following categories:

- **Controlled substances.** These are drugs that have special restrictions as to who can prescribe and sell them and how often they can be prescribed.
- **Over-the-counter (OTC) drugs.** These can be bought and sold without a prescription.
- **Prescription drugs,** also called **legend drugs.** These are drugs that require a doctor's prescription (either oral or written) to be bought and sold.

Caution

Drug Warning

The Schedule IV drug propoxyphene HCl (*Darvon*) has received new FDA regulations for labeling and a black-box warning on the potential for overdose.

1-11, 1-12 You and the Law

As a member of the healthcare team, you are responsible for knowing the laws controlling drug use and the names of the regulatory agencies, such as the Federal Trade Commission (FTC) and the Consumer Product Safety Commission. The latter commission enforces the Poison Prevention Packaging Act (PPPA), which mandates "childproof" drug packaging. Claiming ignorance of the law will not stand up in court if you are ever accused of irresponsible handling and administration of drugs.

How can you be sure you understand the law? As a first step, study carefully Tables 1.1 and 1.2. These tables summarize a great deal of information about federal drug laws. Be aware that the specific drugs under each schedule in the Controlled Substances Act may change. Your health facility will have an up-to-date list of controlled substances from the DEA. Get copies of federal drug laws from the library or from the FDA.

As a next step, study the laws of your state. State laws regulate such things as who may give medications, what kinds of training and supervision are required, who may keep the records, and who may take prescriptions over the phone.

Your own health agency will also have regulations for you to follow. There will be special rules, for example, if your agency receives Medicaid or Medicare funds. You should also be aware of the lines of authority in your agency—in other words, who is in charge of what and who supervises whom. You will then be able to go to the right person when you have a legal question about giving a certain drug.

Knowing the law helps to protect you from errors and possible lawsuits. But there is a more important benefit—the safety of your patient. By showing your awareness of drug laws, you help to educate your patients. You also gain their cooperation in following the law. Drug laws are designed to protect the public. Members of the public depend on your example and your support.

Healthcare for Today and Tomorrow

Lower-Cost Drug Issues

With the soaring cost of prescription medications and with more and more people having computers and Internet capabilities, patients are searching the Internet to obtain their medications at a lower cost. However, some drug-dispensing websites are not legitimate and may even sell contaminated products, incorrect doses, or nothing at all. The Food and Drug Administration (FDA) suggests checking with the National Association of Boards of Pharmacy to safeguard drug purchases on the Web. You can also go to Internet Pharmacy (http://www.nabp.net/vipps/intro.asp) and click on Accreditation Programs and then VIPPS to find a VIPPS-certified pharmacy. You should advise patients to avoid sites that do not provide a company name, address, and phone number. Encourage your patients to always talk to their healthcare professional before using any medication for the first time.

Legal and Ethical Issues

Substituting Drugs

Although the physician or prescriber retains the prerogative to require the dispensing of a particular brand-name drug, every state has a drug substitution law that either mandates or may permit a drug substitution by the pharmacist. The prescriber may give permission to substitute the drug ordered by either checking the "may substitute" box or writing "may substitute" on the prescription. If the prescriber has an objection to a drug substitution, the prescriber will write "do not substitute" or "dispense as written." Some states have a mandatory substitution law to dispense a less expensive drug, and the prescriber must write "medically necessary" in order to ensure that the more costly brand-name drug is dispensed. Because you care for patients and hand them prescriptions, you need to be informed on the laws for drug substitution.

Summary

Learning Outcome	Summary Points
1-1 Define *pharmacology, pharmacodynamics, pharmacokinetics, anatomy, physiology,* and *pathology.*	• *Pharmacology* is the study of drugs and their uses. • *Pharmacodynamics* is the study of how the body responds to drugs. • *Pharmacokinetics* is the absorption, distribution, metabolism, and excretion of drugs. • *Anatomy* is the study of body parts. • *Physiology* is the science that deals with the function of cells, tissues, and organs of living organisms. • *Pathology* is the study of how drugs change the course of disease.
1-2 Define *drug, therapeutic effect,* and *side effects.*	• A *drug* is a chemical substance used in the diagnosis, treatment, cure, or prevention of a disease. • A *therapeutic effect* is the desired or predicted physiological response the drug causes. • *Side effects* are a drug's desirable or undesirable effects apart from the primary reason for giving the drug.
1-3 List the major sources of drugs, and give examples of each.	• The major drug sources are plants, animals, minerals, and chemicals, or synthesized drugs. An example of a plant source is the wildflower purple foxglove, from which digitalis is made. Insulin is extracted from an animal source, cattle and pigs. Sodium chloride is derived from a mineral drug source, rocks. *Bactrim* and *Septra* are synthetic drugs made from chemical sources.
1-4 List seven uses of drugs.	• Prevention, treatment, diagnosis, cure, contraceptive, health maintenance, and palliative are the seven uses of drugs.
1-5 Define *drug standards,* and tell how they are determined.	• Drug standards are certain rules that products must meet. Drug standards are required by law. • The law states that all preparations called by the same drug name must be of uniform strength, quality, and purity.
1-6 Explain why drug standards are necessary.	• Drug standards are necessary because drugs differ in strength, quality, and purity. All preparations called by the same drug name must be of uniform strength, quality, and purity.
1-7 List and describe four types of names by which drugs are known.	• The *chemical name* describes the chemical composition and molecular structure of the drug. • The *generic name* is the official, nonproprietary name assigned by the drug manufacturer with the approval of the United States Adopted Names (USAN) Council. • The *official name* is usually the same as the generic name. • The *brand* or *trade name,* also known as the *proprietary name,* is the name under which the drug is sold by a specific manufacturer.
1-8 List three drug references, and explain how to use at least one.	• *Physicians' Desk Reference (PDR®)* • *United States Pharmacopeia Dispensing Information (USPDI)*

Learning Outcome	Summary Points
	• *Handbook of Nonprescription Drugs* • Many of these drug references contain the drug description along with the action, indication, interactions, contraindications, precautions, side effects/adverse reactions, dosage, and administration, as well as how they are supplied. Look at the designated area for the specific information needed (e.g., Dosage).
1-9 Use drug references to prepare a drug card.	• The drug name, classification, action, use, dose, interactions, and side effects should be included on the drug card.
1-10 List three major drug laws, and list their main features.	• Orphan Drug Act of 1983, which speeds up drugs' availability for patients with rare diseases. • Nutrition Facts of 1992, which requires that nutritional information be on the nutrition label of packages of food. • Drug Regulation and Reform Act of 1978, which permits a briefer investigation of new drugs.
1-11 List the federal agencies that enforce drug laws.	• Food and Drug Administration (FDA) • Drug Enforcement Administration (DEA)
1-12 Explain why health workers must be familiar with drug laws.	• Knowing the laws helps health workers protect themselves from errors and possible lawsuits, provide patient education, and enhance patient safety.

Chapter 1 Review

NAME _____ **DATE** _____

Define each of the terms listed below.

1. (LO 1-2) Drug _____

_____

2. (LO 1-1) Pharmacology _____

_____

3. (LO 1-1) Anatomy _____

_____

4. (LO 1-1) Physiology _____

_____

5. (LO 1-5) Drug standards _____

_____

6. (LO 1-8) *PDR*® _____

_____

7. (LO 1-10) *USP/NF* _____

_____

8. (LO 1-11) Congress _____

_____

9. (LO 1-1) Pharmacokinetics _____

_____

Answer the following questions in the spaces provided.

10. (LO 1-3) Name four sources of drugs, and give an example of a drug that comes from each source.

Source	Example
_____	_____
_____	_____
_____	_____
_____	_____

11. (LO 1-4) Name the seven therapeutic uses of drugs. Give examples.

Use	Example
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

12. (LO 1-10) Name the three major drug laws and the agencies that enforce them.

Law and Date	Enforcing Agency
_____	_____
_____	_____
_____	_____

13. (LO 1-12) Differentiate between these legal classifications for drugs.

OTC drugs _____

_____

_____

_____

Prescription drugs _____

_____

_____

_____

Controlled substances _____

_____

_____

_____

From Column 2, select the term or phrase that best matches each item in Column 1.

	Column 1	Column 2
_____	14. (LO 1-3) Chemical name	a. *Bufferin*
_____	15. (LO 1-7) Generic name	b. aspirin
_____	16. (LO 1-7) Brand name	c. acetylsalicylic acid
_____	17. (LO 1-8) *PDR*®	d. contains information about drug products provided by pharmaceutical companies
_____	18. (LO 1-7) USAN	e. same as generic name
_____	19. (LO 1-7) Official name	f. system that adopts generic names

Match the drugs to their schedules or classes as spelled out in the Controlled Substances Act of 1990 (original 1970) (LO 1-12).

	Schedule	Drugs
_____	20. I	a. *Seconal, Doriden, Tylenol* with codeine
_____	21. II	b. opium, morphine, *Demerol,* amphetamines, *Dilaudid*
_____	22. III	c. cough syrup with codeine, *Lomotil, Novahistine* expectorant
_____	23. IV	d. *Librium, Valium,* phenobarbital, *Noctec, Dalmane, Darvon*
_____	24. V	e. heroin, hashish, LSD, peyote, alfentanil

Multiple Choice

Circle the correct letter.

25. (LO 1-10) Which of the following major drug laws speeds up drugs' availability for patients with rare diseases?
    a. Drug Regulation and Reform Act of 1978
    b. Orphan Drug Act of 1983
    c. Pure Food and Drug Act of 1906
    d. Food, Drug, and Cosmetic Act (FDCA) of 1938

26. (LO 1-8) What information is covered in a drug reference book?
    a. Type of doctors who can prescribe the drug
    b. Interactions with the drug
    c. Which healthcare workers can administer the drug
    d. Color of the drug

27. (LO 1-4) What are two uses of drugs?
    a. Produce side effects and adverse reactions
    b. Change the genetic and chemical makeup of the body
    c. Prevention and treatment of disease
    d. Test the knowledge and skill of the healthcare worker

28. (LO 1-6) Who requires the use of drug standards?
    a. Hospitals
    b. Patients
    c. Physicians
    d. The law

29. (LO 1-7) Which of the following drugs is listed by a generic name?
    a. Acetylsalicylic acid
    b. Bufferin
    c. Nitro-Bid
    d. Nitrostat

Chapter 1 Case Studies

30. You want to understand the sources of drugs before you administer them. What are the four sources of drugs? Your patient has been prescribed *Metamucil,* digitalis, insulin, *Bactrim,* and iron. What are these drugs, and what are their sources? _____

    _____

    _____

    _____

31. Nitroglycerin is prescribed by the healthcare provider, and *Nitrostat* was dispensed by the pharmacy. The patient tells you he is confused and wants to know what the difference means. What should you tell him? _____

    _____

    _____

    _____

Critical Thinking

Respond to the following questions in the spaces provided.

32. (LO 1-12) Janie has just been hired for a new job in a nursing home. She wants to make sure that she knows what she is and is not allowed to do with regard to giving medications. What advice would you give her?

_____

_____

_____

33. (LO 1-12) Why do we have drug standards and drug laws?

_____

_____

_____

Applications

Obtain a current copy of the *PDR*® and a medical dictionary from your school, nursing unit, or clinic. Use them to answer the questions that follow.

34. You are giving Mr. Jones regular-strength *Tylenol* every few hours after surgery. You would like to know something more about the drug, so you consult the *PDR*®. *Tylenol* is a brand or trade name. Find the section in the *PDR*® that lists drugs alphabetically by brand names. What color are the pages?

_____

35. Look up *Tylenol* in the section you turned to in question 34. How many different forms of *Tylenol* are listed there? _____ Is there a small diamond to the left of any *Tylenol* form? If so, the diamond means there is a photograph of the drug in the Product Identification section. Find the photograph.

36. Using the page number given for *Tylenol* tablets, look them up in the Product Information section. The generic name is listed just after the word *Tylenol.* What is it? _____

You may want to do the next activity as a collaborative learning activity. Each student should gather all drug information from a different drug reference; then students meet collaboratively and compare and contrast information.

37. You have an order to give Mrs. Lopez her daily *Cardizem* and to provide her with the education necessary for her to begin taking this medication at home. Consulting the various drug reference sources available to you, compare and contrast the advantages and disadvantages of these resources; discuss clinical situations for which each source might be the best one to consult.