

Chapter 1: Drug Development and Ethical Considerations

OBJECTIVES

- Explain the three core ethical principles in using human subjects in the drug development process.
- Describe the objectives of each phase of human clinical experimentation.
- List the nine provisions of the 2015 American Nurses Association Code of Ethics.
- Explain the ethical role of nurses in the clinical research process.
- Summarize the standards, legislation, and regulation that guide drug development.
- State how nursing practices are established and regulated.
- Describe the problem posed by counterfeit drugs and initiatives being implemented to combat it.
- Describe the names and types of drugs used in the United States and resources to learn about them.

Commented [SL1]: The list of objectives has been revised so that each Terminal Learning Objective (TLO) listed here aligns one-to-one with a main (H1) heading in the chapter. (p. 6)

Commented [SL2]: Each objective should start with a clear and measurable verb that aligns with the intended student learning outcome. (p. 3)

OUTLINE

Core Ethical Principles

- Respect for Persons
- Beneficence
- Justice

Objectives and Phases of Pharmaceutical Research

- Preclinical Trials
- Human Clinical Experimentation
- Clinical Research Study Design

American Nurses Association Code of Ethics

The Nurse's Role in Clinical Research

- Nursing Process: Patient-Centered Collaborative Care—Clinical Research

Drug Standards, Legislation, and Regulation

- U.S. Drug Standards
- Federal Legislation
- Controlled Substances in the United States
- Canadian Drug Regulation

Nurse Practice Acts

Initiatives to Combat Drug Counterfeiting

Drug Naming and Resources

- Drug Names
- Over-the-Counter Drugs
- Drug Resources

Critical Thinking Case Study

NCLEX Study Questions

Commented [SL3]: The chapter outline has been adjusted to align with changes made to the headings. (p. 9)

KEY TERMS

American Nurses Association (ANA) Code of Ethics, p. 6

autonomy, p. 3

beneficence, p. 4

brand (trade) name, p. 11

chemical name, p. 11

controlled substances, p. 8

Critical Path Initiative, p. 2

dependent variable, p. 4

Commented [SL4]: Key terms are a critical component to measure, evaluate, and help remediate student understanding in digital lessons. All key terms listed should be essential to student understanding of the core chapter content. (p. 17)

- generic name, p. 11
- genotoxicity, p. 4
- Good Clinical Practice (GCP) Consolidated Guideline, p. 4
- independent variable, p. 4
- informed consent, p. 3
- justice, p. 4
- over-the-counter (OTC), p. 11
- placebo, p. 6
- respect for persons, p. 3
- risk-benefit ratio, p. 4
- U.S. Food and Drug Administration (FDA), p. 2

Approval of new drugs by the **U.S. Food and Drug Administration (FDA)** has been steady since the early 2000s, reaching an all-time high in 2014 with the approval of 44 new drugs. To facilitate this increase, in 2004 the FDA established its **Critical Path Initiative**, a national strategy “to drive innovation in the scientific processes through which medical products are developed, evaluated, and manufactured.” One focus of this initiative is on “improving the prevention, diagnosis, and treatment of rare and neglected disorders.” Initiative successes include developing biomarkers and other scientific tools, streamlining clinical trials, and ensuring product safety.

The process of drug discovery and manufacturing takes 10 to 12 years, with a cost of more than \$1 billion for each drug. Out of every 5000 to 10,000 compounds that begin preclinical testing, only one makes it through the FDA approval process. The steps of the process are shown in **Fig. 1.1**. Drug research and development is a complex process that is of particular interest and importance to professional nursing practice.

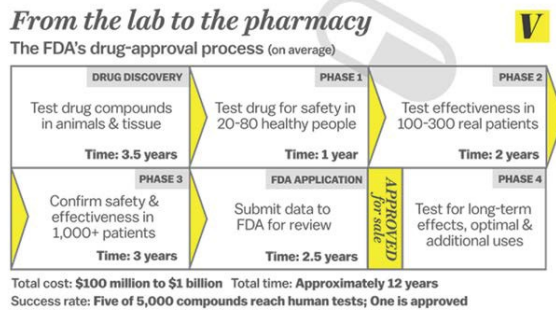


FIG. 1.1 The Food and Drug Administration (FDA) Drug Approval Process. From Belluz, J. (2015). This new bill would add \$9 billion for medical research. Here are 5 reasons critics are terrified. *VOX Science & Health*.

This chapter is devoted to a description of basic ethical principles that govern drug development and the nurse’s role in this process.

H1: CORE ETHICAL PRINCIPLES

TLO: Explain the three core ethical principles in using human subjects in the drug development process.

Three core ethical principles are relevant to research involving human subjects: **respect for persons**, beneficence, and justice. Derived from the Belmont Report, the World Medical Association Declaration of Helsinki set out ethical principles for medical research that involves human subjects. These ethical principles are integral to the issues of informed consent and risk-benefit ratio in such research.

H2: Respect for Persons

ELO: Summarize how respect is shown for patients.

Patients should be treated as independent persons who are capable of making decisions in their own best interests. Patients with diminished decision-making capacity are entitled to protection. When making health care decisions, patients should be made aware of alternatives available to them as well as the consequences that stem from those alternatives. The patient’s choice should be honored

Commented [SL5]: Ideally, for digital lessons, all key terms should be deployed in the context of a learning objective to better capture for digital consumption and lesson creation. (p. 17)

Commented [SL6]: All figures should be referred to in the text. Figures should be placed immediately following their in-text reference. (p. 18)

Commented [SL7]: Ensure that all figures are given a clear and descriptive title. (p. 18)

Commented [SL8]: Because this heading is a main (H1) heading, a Terminal Learning Objective (TLO) has been created and aligned with it. (p. 6)

Commented [SL9]: Because this is a second-level (H2) heading, an Enabling Learning Objective (ELO) has been created and aligned with it. (p. 6)

Note that the Bloom’s level of the ELO is always at or below the level of the TLO. (p. 7)

whenever possible. It is imperative that nurses recognize when patients are not capable of making decisions in their own best interest and are therefore entitled to protection. The nurse can assist with the determination of decision-making capacity through frequent assessment of the patient's cognitive status.

H3: Autonomy

Autonomy is an integral component of respect for persons. **Autonomy** is the right to self-determination. In health care settings, health care personnel must respect the patient's right to make decisions in their own best interest, even if the decision is not what the health care personnel want or think is best for the patient. Generally, patients can refuse any and all treatments (right of autonomy) except when the decision poses a threat to others—such as with tuberculosis, when taking medications is legally mandated. Autonomy is as relevant to the conduct of research as it is in health care decision making: Patients have the right to refuse to participate in a research study and may withdraw from studies at any time without penalty.

H3: Informed Consent

Informed consent has its roots in the 1947 Nuremberg Code. The two most relevant aspects of the Code are the right to be informed and that participation is voluntary, without coercion. If coercion is suspected, the nurse is obligated to report this suspicion promptly. Informed consent has dimensions beyond protection of the individual patient's choice:

- It is a mutual sharing of information, a process of communication.
- It expresses respect for the person.
- It gains the patient's active involvement in their care.
- It respects the patient's right to self-determination.

It is the role of the health care provider, *not* the nurse, to explain the study and what is expected of the patient to the patient and to respond to questions from the patient. While giving written consent, the patient must be alert and able to comprehend; consent forms should be written at or below the eighth-grade reading level, and words should be kept to fewer than three syllables.

Nurses are patient advocates. In collaboration with the health care provider and the pharmacist, the nurse must be knowledgeable about all aspects of a drug study—including all inclusion and exclusion criteria for participants (Box 1.1), study protocol, and study-related documentation—in order to promote participant safety and quality study results.

BOX 1.1 Sample Inclusion and Exclusion Criteria

Inclusion

- Persons between the ages of 18 and 65
- Persons weighing between 50 and 100 kg
- Persons on a stable dose (i.e., no dose change in the previous 3 months) of cardiac medications (e.g., anticoagulants, angiotensin-converting enzyme inhibitors [ACEIs], angiotensin II–receptor blockers [ARBs], beta blockers, and diuretics)
- Persons adhering to a no-added-salt diet

Exclusion

- Women who are pregnant or nursing
- Women of childbearing age who do not use oral contraceptives
- Persons with symptomatic cardiac disease, hepatic dysfunction, chronic kidney disease, neurologic disorders, or musculoskeletal disorders
- Persons with clinically significant abnormal laboratory values (chemistry and hematology)

Commented [SL10]: It is best to not have just one third-level (H3) head under an H2. Subheads should be deployed in a set of two or more for clearer digital lesson creation. Because "Informed Consent" was an existing H3 below, an H3 was added here, "Autonomy," to align with the key term. (p. 8)

Third-level (H3) heads *do not* require an associated learning objective. However, these headings help chunk the content so that students are better able to parse it. In addition, these headings help the digital team better understand important concepts in creating digital instruction, exercises, and assessments. (p. 8)

Commented [SL11]: Use of a bulleted list here helps students more easily retain information. (p. 14)

Commented [SL12]: As is the case with figures, boxed features should be placed as near as possible to their in-text reference. (p. 18)

Commented [SL13]: The boxed feature works well by chunking content into two separate categories: Inclusion and Exclusion. (p. 11)

Fig. 1.2 shows a sample of an informed consent form for a clinical drug trial, and Box 1.2 shows an informed consent checklist.

Sample Informed Consent Form for Randomized Clinical Trial of a Drug

Title of study: Comparison of a new drug [A] with an existing drug [B] used in treatment of disease X

Principal investigator: Dr. ABC

Institute: Department of Pediatrics, Aga Khan University

Introduction:

I am Dr. [SAK] from Department of Pediatrics, the Aga Khan University and doing a research on treatment of disease [X, for example malaria]. There is a new drug [A] which is being recommended for its treatment. I want to see if the new drug [A] is as good as or better than the commonly used drug [B] for the treatment of disease [malaria]. Since you are a patient of (or suffering from) disease [malaria], I would like to invite you to join this research study.

Background information

Disease X (Malaria) is a common disease in Pakistan, Asia and Africa, caused by a germ (parasite) spread by mosquito. It causes high grade fever. Some patients may have complications and even die. The commonly used drugs are losing their

effectiveness and germs are getting resistant to it. A new drug known as [A] is supposed to be effective in treatment of disease (malaria) but there is not enough evidence that it is as good as other drugs used for treatment of disease (malaria).

Purpose of this research study

The purpose of study is to find out if the new drug is as good as or better than other drugs used for treatment of malaria in our population and; also to see if germs are not resistant to it.

Procedures

In this study, all patients aged 15 to 50 years of age, presenting at the clinic with fever for less than one week duration and having no other diagnosis will be registered and screened for malaria. For diagnosis of disease (malaria), one ml of blood will be taken from the patients and checked for presence of germs (malarial parasite). Those patients having positive test for the disease (malaria), will be included in the study. They will be divided randomly in to two groups by a computer draw. One group will get the new drug (A) and the other group will get the commonly used drug (B). Neither the doctor nor the patient will know which drug he/she is getting for treatment of his/her disease. A record will be kept for the duration of fever and other symptoms including any other side effect. Other necessary treatment will also be provided if needed.

Possible risks or benefits

No significant side effects have been reported for this new drug (A). However, some patients may feel nausea or may have vomiting. Drawing of blood may cause some discomfort or blue discoloration at the site of bleeding. Lowering of white blood cells and platelet is a common feature of the disease.

There is no direct financial or other benefit for the participant of the study. However, all the investigations will be done free of cost to the patients and; the drugs (A) or (B) will be provided free. Treatment of any side effect will also be provided free of cost. Sponsor of the study will bear the cost of drugs, investigations and treatment of side effects related to the study drugs.

Right of refusal to participate and withdrawal

You are free to choose to participate in the study. You may refuse to participate without any loss of benefit which you are otherwise entitled to. You child will receive the same standard care and treatment which is considered best for him irrespective of your decision to participate in the study. You may also withdraw any time from the study without any adverse effect on management of your child or any loss of benefit which you are otherwise entitled to. You may also refuse to answer some or all the questions if you don't feel comfortable with those questions.

Confidentiality

The information provided by you will remain confidential. Nobody except principal investigator will have an access to it. Your name and identity will also not be disclosed at any time. However the data may be seen by Ethical review committee and may be published in journal and elsewhere without giving your name or disclosing your identity.

Available Sources of Information

If you have any further questions you may contact Principal Investigator (Dr. SAK), department of pediatrics at Aga Khan University on following phone number 486xxxx

AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Participant's Name (Printed or Typed): Date:

Participant's Signature or thumb impression: Date:

Principal Investigator's Signature: Date:

Signature of Person Obtaining Consent:

Date:

FIG. 1.2 Sample Informed Consent for a Clinical Trial of a Drug.

From Sample Informed Consent for a Randomized Clinical Trial of a Drug. (n.d.) Aga Khan University. Retrieved from <http://www.aku.edu/research/urc/ethicalreviewcommittee/sampleconsentforms/Pages/sampleconsentforms.aspx>

BOX 1.2 Informed Consent Checklist: Basic Items

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any experimental procedures
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others that may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research that involves more than minimal risk, an explanation as to whether any compensation will be paid and whether any medical treatments are available if injury occurs, and if so, what the treatments consist of or where further information may be obtained
- Research, Rights or Injury: An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

From Office for Human Research Protections (OHRP). (2014). U.S. Department of Health & Human Services. Retrieved from <http://www.hhs.gov/ohrp/policy/consentckls.html>

H2: Beneficence

ELO: Define beneficence and how it is determined in drug research.

Beneficence is the duty to protect research subjects from harm. It involves assessing potential risks and possible benefits and ensuring the benefits are greater than the risk.

The **risk-benefit ratio** is one of the most complex problems faced by the researcher. All possible consequences of a clinical study must be analyzed and balanced against the inherent risks and the anticipated benefits. Physical, psychological, and social risks must be identified and weighed against the benefits. A requirement of the Department of Health and Human Services (DHHS) is that institutional review boards (IRBs) determine that risks to subjects be reasonable in relation to the anticipated benefits, if any, for subjects. No matter how noble the intentions, the calculation of risks and benefits by the researcher cannot be totally accurate or comprehensive.

H2: Justice

ELO: Describe what justice means in using human subjects in drug research.

Justice requires that the selection of research subjects be fair. Research must be conducted so that the distribution of benefits and burdens is equitable (i.e., research subjects reflect all social classes and racial and ethnic groups).

H1: OBJECTIVES AND PHASES OF PHARMACEUTICAL RESEARCH

TLO: Describe the objectives of each phase of human clinical experimentation.

The FDA requires clinical research to follow the **Good Clinical Practice (GCP) Consolidated Guideline**, an international ethical and scientific quality standard for designing, conducting, monitoring, auditing, recording, analyzing, and reporting clinical research. It is the foundation of clinical trials that involve human subjects. Additional guidance and information sheets are available from the FDA on multiple topics related to clinical research.

H2: Preclinical Trials

ELO: Summarize the purpose and process of preclinical trials.

Prior to the implementation of clinical research, the FDA requires preclinical trials to determine a drug's toxic and pharmacologic effects through in vitro and in vivo animal testing in the laboratory. Through these trials, drug developers are able to determine **genotoxicity**, the ability of a compound to damage genetic information in a cell, in addition to drug absorption, distribution, metabolism, and excretion.

H2: Human Clinical Experimentation

ELO: Explain the process and objectives of human clinical experiments.

Historically, drug research was done only with Caucasian males, causing uncertainty as to the validity of research results for people of other ethnicities and for women and children. In 1993, Congress passed the National Institutes of Health (NIH) Revitalization

Commented [SL14]: An ELO has been created and aligned with this H2. (p. 6)

Commented [SL15]: The third-level (H3) head "Risk-Benefit Ratio" was deleted to avoid there being only one H3 under the H2 "Beneficence." (p. 8)

Commented [SL16]: An ELO has been created and aligned with this H2. (p. 6)

Commented [SL17]: A TLO has been created and aligned with this H1. (p. 6)

Commented [SL18]: An ELO has been created and aligned with this H2. (p. 6)

Commented [SL19]: An ELO has been created and aligned with this H2. (p. 6)

Act, which helped to establish guidelines to include women and minorities in clinical research. Additionally, the Best Pharmaceuticals for Children Act (BPCA) of 2002 and the Pediatric Research Equity Act (PREA) of 2003 encourage pharmaceutical companies to study their drugs in children.

Clinical experimentation in drug research and development encompasses four phases, each with its own objectives (see Fig. 1.1). A multidisciplinary team approach that includes nurses, physicians, pharmacologists, statisticians, and research associates is required to ensure safety and quality in all phases of clinical research. A brief description of each phase follows:

- **Phase I:** Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- **Phase II:** The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
- **Phase III:** The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- **Phase IV:** Studies are done after the drug or treatment has been marketed to gather information on the drug's effects in various populations and to assess any side effects associated with long-term use.

Pharmaceutical companies are eager to bring new drugs to market. To reduce delays in the FDA approval process, in 1992 congress passed the Prescription Drug User Fee Act, which provided the FDA with funds to expedite the review process. As a result, the average drug approval time has decreased from 30 months to 12.

H2: Clinical Research Study Design

ELO: State the primary process and purpose of clinical research study design in pharmaceutical research.

An appropriate experimental design is important to answer questions about drug safety and efficacy. Studies are designed to determine the effect of the **independent variable** (treatment, such as with a drug) on the **dependent variable** (outcome, such as clinical effect). Intervening (extraneous) variables are factors that may interfere with study results, and these may include age, sex, weight, disease state, diet, and the subject's social environment. It is important to control for as many of the intervening variables as possible to increase study validity.

The *experimental group* in drug trials is the group that receives the drug being tested. The *control group* in drug trials may receive no drug; a different drug; a **placebo** (pharmacologically inert substance); or the same drug with a different dose, route, or frequency of administration.

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H1: AMERICAN NURSES ASSOCIATION CODE OF ETHICS

TLO: List the first nine provisions the American Nurses Association (ANA) Code of Ethics.

The **American Nurses Association (ANA) Code of Ethics** "was developed as a guide for carrying out nursing responsibilities in a manner consistent with quality in nursing care and the ethical obligations of the profession." It was first adopted in 1950 and most recently was revised with interpretive statements in 2015. The ANA Code of Ethics is founded on the principles first identified by Florence Nightingale, who believed that a nurse's ethical duty was first and foremost to care for the patient. It contains nine provisions (Box 1.3). The 2015 update addresses advances in nursing leadership, social policy and global health, and the challenges nurses face related to social media, electronic health records, and the nurse's expanded role in clinical research.

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BOX 1.3 Provisions of the American Nurses Association Code of Ethics

Provision 1

The nurse practices with compassion and respect for the inherent dignity, worth, and unique attributes of every person.

Provision 2

The nurse's primary commitment is to the patient, whether an individual, family, group, community, or population.

Provision 3

The nurse promotes, advocates for, and protects the rights, health, and safety of the patient.

Provision 4

The nurse has authority, accountability, and responsibility for nursing practice; makes decisions; and takes action consistent with the obligation to promote health and to provide optimal care.

Provision 5

The nurse owes the same duties to self as to others, including the responsibility to promote health and safety, preserve wholeness of character and integrity, maintain competence, and continue personal and professional growth.

Provision 6

The nurse, through individual and collective effort, establishes, maintains, and improves the ethical environment of the work setting and conditions of employment

that are conducive to safe, quality health care.

Provision 7

The nurse, in all roles and settings, advances the profession through research and scholarly inquiry, professional standards development, and the generation of both nursing and health policy.

Provision 8

The nurse collaborates with other health professionals and the public to protect human rights, promote health diplomacy, and reduce health disparities.

Provision 9

The profession of nursing, collectively through its professional organizations, must articulate nursing values, maintain the integrity of the profession, and integrate principles of social justice into nursing and health policy.

From American Nurses Association. (2015). Code of ethics for nurses with interpretive statements. Retrieved from http://nursingworld.org/DocumentVault/Ethics_1/Code-of-Ethics-for-Nurses.html

H1: THE NURSES ROLE IN CLINICAL RESEARCH

TLO: Explain the ethical role of nurses in the clinical research process.

Nurses are at the forefront of clinical research. Regardless of the setting (inpatient or outpatient), nurses are likely to encounter patients who are eligible to participate, considering participation, or actively participating in clinical research. As such, nurses are responsible for both the safety of the patient and the integrity of the research protocol.

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NURSING PROCESS

Patient-Centered Collaborative Care

Clinical Research

Assessment

- Identify patients who are eligible to participate in or who are participating in clinical research.
- Assess response to the study agent and identify adverse events (an unfavorable or unintended sign, symptom, or disease that was not present at the time of study enrollment and is associated with the treatment or procedure).

Planning

- Have a process in place to identify persons who are eligible to participate in a clinical research or to identify participants actively participating in clinical research studies.
- Have a process in place to facilitate education and informed consent of eligible study participants.
- Plan educational programming for staff who provide direct care to study participants.
- Plan participant care to ensure integrity and compliance with study protocol.

Nursing Interventions

- Support the process of informed consent in a culturally competent manner.
- Provide an interpreter when necessary.
- Provide enough time for the person to read the consent and ask questions.
- Serve as a witness to informed consent.
- After reviewing the study protocol, administer study agent(s).
- Accurately document all participant care, assessment findings, and study agent administration.
- Accurately and safely collect biospecimens.
- Act as advocate, educator, and collaborator in the research process.
- Ensure safe care.
- Ensure integrity of study data.
- Communicate clearly.

Evaluation

- Determine if the potential participant understands what it means to participate in the study by asking open-ended questions.
- Monitor response to the study agent or other interventions.
- Determine whether participants understand how to take their study agents, what to do if they miss a dose, how to store the study agent, and when to call their health care provider.

Commented [SL23]: If the author believes the content in this feature "Nursing Process" is core content, then the author would want to consider moving that content into the main text. (p. 8)

Each of the four parts of the feature—Assessment, Planning, Interventions, and Evaluation—could be a second-level (H2) head with an accompanying ELO. This would help capture the content for digital transformation:

H2: Assessment
ELO: Identify the role of nurses in the assessment phase.

H2: Planning
ELO: Describe what nurses do in the planning phase.

H2: Nursing Interventions
ELO: Summarize nursing interventions during the clinical research process.

H2: Evaluation
ELO: List the ways in which nurses help in evaluation during the clinical research process.

H1: DRUG STANDARDS, LEGISLATION, AND REGULATION

TLO: Summarize the standards, legislation, and regulation that guide drug development.

This section addresses U.S. drug standards, federal legislation, as well as Canadian drug regulations.

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H2: U.S. Drug Standards

ELO: Identify the authoritative source for drug standards in the United States.

The set of drug standards used in the United States is the United States Pharmacopeia (USP). The *United States Pharmacopeia and the National Formulary* (USP-NF), the authoritative source for drug standards (dosage, forms, drug substances, excipients, biologics, compounded preparations, and dietary supplements), is published annually. Experts in nursing, pharmaceuticals, pharmacology, chemistry, and microbiology all contribute. Drugs included in the USP-NF have met high standards for therapeutic use, patient safety, quality, purity, strength, packaging safety, and dosage form. Drugs that meet these standards have the initials “USP” following their official name, denoting global recognition of high quality.

The *International Pharmacopeia*, first published in 1951 by the World Health Organization (WHO), provides a basis for standards in strength and composition of drugs for use throughout the world. The book is published in English, Spanish, and French.

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H2: U.S. Federal Legislation

ELO: List the major pieces of legislation throughout U.S. history that help shape drug standards today.

Federal legislation attempts to protect the public from drugs that are impure, toxic, ineffective, or not tested before public sale. The primary purpose of the legislation is to ensure safety. America’s first law to regulate drugs was the Food and Drug Act of 1906, which prohibited the sale of misbranded and adulterated drugs but did not address drug effectiveness and safety.

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H3: 1912: The Sherley Amendment

This act prohibited false therapeutic claims on drug labels. It came about as a result of Mrs. Winslow’s Soothing Syrup, a product advertised to treat teething and colic, which contained morphine and led to the death of many infants. Under the Sherley Amendment, the government had to prove intent to defraud before a drug could be removed from the market.

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H3: 1914: The Harrison Narcotic Act

This act required prescriptions for drugs that exceeded set narcotic limits. It also mandated increased record keeping by physicians and pharmacists.

H3: 1938: The Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act of 1938 empowered the FDA to ensure a drug was safe prior to marketing. It is the FDA’s responsibility to ensure that all drugs are tested for harmful effects; it also required that drugs be labeled with accurate information and have detailed literature in the drug packaging that explains adverse effects. The FDA can prevent the marketing of any drug it judges to be incompletely tested or dangerous. Only drugs considered safe by the FDA are approved for marketing.

H3: 1951: Durham-Humphrey Amendment

The Durham-Humphrey Amendment distinguished between drugs that could be sold with or without prescription by a licensed health care provider.

H3: 1962: Kefauver-Harris Amendment to the 1938 Act

The Kefauver-Harris Amendment resulted from the widely publicized thalidomide tragedy of the 1950s in which European patients who took the sedative-hypnotic thalidomide during the first trimester of pregnancy gave birth to infants with extreme limb deformities. The Kefauver-Harris amendment tightened controls on drug safety, especially experimental drugs, and required that adverse reactions and contraindications must be labeled and included in the literature. The amendment also included provisions for the evaluation of testing methods used by manufacturers, the process for withdrawal of approved drugs when safety and effectiveness were in doubt, and the establishment of effectiveness of new drugs before marketing.

H3: 1965: Drug Abuse Control Amendments

Enacted in 1965, the Drug Abuse Control Amendments attempted to control the abuse of depressants, stimulants, and hallucinogens.

H3: 1970: The Comprehensive Drug Abuse Prevention and Control Act

In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act. This act, designed to remedy the escalating problem of drug abuse, included several provisions:

- promotion of drug education and research into the prevention and treatment of drug dependence;
- strengthening of enforcement authority;
- establishment of treatment and rehabilitation facilities; and
- designation of schedules, or categories, for controlled substances according to abuse liability.

1983: The Orphan Drug Act

The Orphan Drug Act was designed to promote the development and manufacture of drugs used in the treatment of rare diseases (orphan drugs). The act's three primary incentives are:

- federal funding of grants and contracts to perform clinical trials of orphan products;
- a 50% tax credit for costs of clinical testing; and
- exclusive rights to market the drug for 7 years from the marketing approval date.

1994: Dietary Supplement Health and Education Act

This act established labeling requirements for dietary supplements and authorized the FDA to promote safe manufacturing practices. It classified dietary supplements as food.

1996: Health Insurance Portability and Accountability Act The Health Insurance Portability and Accountability Act (HIPAA) of 1996 protects health insurance coverage for workers who change or lose their jobs and sets the standard for the privacy of individually identifiable health information. The act provides patients more control over their health information, including boundaries on the use and release of health records.

1997: The Food and Drug Administration Modernization Act The five provisions in this act are (1) review and use of new drugs is accelerated; (2) drugs can be tested in children before marketing; (3) clinical trial data are necessary for experimental drug use for serious or life-threatening health conditions; (4) drug companies are required to give information on off-label (non-FDA-approved) use of drugs and their costs; and (5) drug companies that plan to discontinue drugs must inform health professionals and patients at least 6 months before stopping drug production.

2002: Best Pharmaceuticals for Children Act

The BPCA gives manufacturers a 6-month extension of patents to evaluate drugs on the market for their safety and efficacy in children.

2003: Pediatric Research Equity Act

This act authorizes the FDA to require that drug manufacturers test certain drugs and biologic products for their safety and effectiveness in children, noting that "children are not small adults." Additionally, studies that involve children must be conducted with the same drug and in the same disease process as adults.

2007: Food and Drug Administration Amendments Act

This act allows the FDA to do more comprehensive reviews of potential new drugs, mandates postmarketing safety studies, and affects the distribution of drugs found to be not as safe as premarket studies indicated.

2010: Patient Protection and Affordable Care Act

This act was signed into law in 2010 and became effective January 1, 2014. Essential provisions of the reform include:

- quality, affordable health care for all Americans;
- improved quality and efficiency of health care;
- prevention of chronic disease and improved public health;
- improved access to innovative medical therapies; and
- community living services and supports.

2012: Food and Drug Administration Safety and Innovation Act (FDASIA)

This act was signed into law on July 9, 2012. It strengthens the FDA's ability to safeguard and advance public health by:

- Collecting fees from industry to fund reviews of drugs with the "breakthrough therapy" designation, medical devices, generic drugs, and biosimilar biologic products

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- Expediting development of innovative, safe, and effective products
- Increasing stakeholder engagement in FDA processes
- Enhancing the safety of the global drug supply chain

H2: Controlled Substances in the United States

ELO: Describe the five schedules of controlled substances in the United States and nurses' role in creating a culture of accountability.

Based on their abuse potential and acceptable medical use practices, **controlled substances** are categorized into five schedules, which are listed in [Table 1.1](#). Schedule I drugs are not approved for medical use and have high abuse potential; schedule II through V drugs have acceptable medical use and decreasing potential for abuse leading to psychological and/or physiologic dependence.

Schedule	Examples	Description
I	Some examples of substances listed in Schedule I are heroin, lysergic acid diethylamide (LSD), <i>Cannabis</i> , peyote, methaqualone, and methylenedioxymethamphetamine (MDMA)	Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.
II	Examples of Schedule II narcotics include hydromorphone (Dilaudid), methadone (Dolophine), meperidine (Demerol), oxycodone (OxyContin, Percocet), and fentanyl (Sublimaze, Duragesic). Other Schedule II narcotics include morphine, opium, codeine, and hydrocodone. Examples of Schedule II stimulants include amphetamine (Dexedrine, Adderall), methamphetamine (Desoxyn), and methylphenidate (Ritalin). Other Schedule II substances include amobarbital, glutethimide, and pentobarbital.	Substances in this schedule have a high potential for abuse that may lead to severe psychological or physical dependence.
III	Examples of Schedule III narcotics include products containing not more than 15 mg of hydrocodone per dosage unit (acetaminophen with hydrocodone) or 90 mg of codeine per dosage unit (acetaminophen with codeine), and buprenorphine and naloxone. Examples of Schedule III nonnarcotics include benzphetamine, phendimetrazine, ketamine, and anabolic steroids such as Depo-Testosterone.	Substances in this schedule have a potential for abuse less than substances in Schedules I or II, and abuse may lead to moderate or low physical dependence or high psychological dependence.
IV	Examples of Schedule IV substances include alprazolam, carisoprodol, clonazepam, clorazepate, diazepam, lorazepam, midazolam, temazepam, and triazolam.	Substances in this schedule have a low potential for abuse relative to substances in Schedule III.
V	Examples of Schedule V substances include cough preparations containing not more than 200 mg of codeine per 100 mL or per 100 g (guaifenesin with codeine, promethazine with codeine), and ezogabine.	Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

From Controlled substance schedules. (n.d.). U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control. Retrieved from <http://www.deadiversion.usdoj.gov/schedules/#define>

Nurses are key to creating a culture of safety and accountability related to controlled substances. As such, nurses must:

- Verify orders prior to drug administration.
- Account for all controlled drugs.
- Maintain a controlled-substance log that ensures all required information is documented accurately.
- Document all discarded or wasted medication; wastage must be witnessed by another nurse.
- Ensure timely documentation in the patient record following drug administration, including patient response to drug administration.
- Keep all controlled drugs in a locked storage area; keep narcotics under double lock. Be certain that only authorized persons have access to the keys, including keys for patient-controlled analgesia and epidural pumps. Medication may also be administered via an automated dispensing cabinet, with bioidentical identifiers used for access.
- The ANA recognizes the significant threat to patient safety and liability to health care organizations caused by nurse drug diversion and recommends that all states have a peer-to-peer assistance program for addicted nurses. Reporting is mandatory if suspected or known diversion occurs.

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H2: Canadian Drug Regulation

ELO: Identify the primary governing body and pieces of legislation that regulate drug standards in Canada.

In Canada, prior to approval and becoming available to patients, drugs must be reviewed for safety, efficacy, and quality by the Health Products and Food Branch (HPFB) of Health Canada. Health Canada is a federal department tasked with the mission of improving the quality of life of all Canadians. (Further information can be found at www.hc-sc.gc.ca).

In 1996, the Canadian government passed the Controlled Drugs and Substances Act. This act broke controlled drugs and substances into eight schedules and two classes of precursors (Table 1.2). In 2012, the Safe Streets and Communities Act was passed in Canada, which reclassified amphetamines—including methylenedioxyamphetamine (MDA) and methylenedioxymethamphetamine (MDMA)—and also flunitrazepam and gamma hydroxybutyrate (GHB) from Schedule III to Schedule I drugs. This change imposed stiffer penalties for dealers and those in possession.

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TABLE 1.2 Canadian Controlled Drugs and Substances Schedule

Schedule	Examples	Description
I	Codeine, hydrocodone, oxycodone, coca, cocaine, levomethorphan, ketamine, sufentanil, methamphetamine, amphetamine, gamma hydroxybutyrate (GHB)	Opium poppy, coca leaves, phenylpiperidines, phenazepines, amidones, methadols, phenalkoxams, thiambutenes, moramides, morphinans, benzazocines, ampromides, benzimidazoles, phencyclidine, fentanyl, tilidine, methamphetamine, amphetamine, flunitrazepam, and GHB and its derivatives, alkaloids, and salts
II	<i>Cannabis</i> , nabilone, tetrahydrocannabinol	<i>Cannabis</i> , its derivatives, and similar synthetic preparations
III	Thirty-three compounds including methylphenidate, lysergic acid diethylamide (LSD), psilocybin, and mescaline	
IV	Twenty-six parent compounds including chlorphentermine, butorphanol, nalbuphine, meprobamate, and zolpidem	Barbiturates, thiobarbiturates, benzodiazepines, and their salts and derivatives; anabolic steroids and their derivatives
V		Propylhexedine and any of its salts
VI	Class A includes 23 compounds such as ephedrine, ergotamine, and pseudoephedrine. Class B includes six compounds such as acetone and sulfuric acid.	Part 1 – Class A precursors Part 2 – Class B precursors Part 3 – Preparations and mixtures
VII		<i>Cannabis</i> resin 3 kg <i>Cannabis</i> 3 kg
VIII		<i>Cannabis</i> resin 1 g <i>Cannabis</i> 30 g

For more detailed information, please see the Canadian Legal Information Institute at <http://www.canlii.org/>.

H1: NURSE PRACTICE ACTS

TLO: State how nursing practices are established and regulated.

All states and territories have rules and regulations in place to provide guidance and govern nursing practice, which includes drug administration by nurses. Generally, nurses cannot prescribe or administer drugs without a health care provider's order. Practicing nurses should be knowledgeable about the nurse practice act in the state where they are licensed. (Information can be found through the National Council of State Boards of Nursing at www.ncsbn.org.) Nurses are responsible for knowing their state's law and administrative code. Nurses who administer a drug without a licensed health care provider's order are in violation of the Nurse Practice Act and can have their licenses revoked.

In a civil court, the nurse can be prosecuted for giving the wrong drug or dosage, omitting a drug dose, or giving the drug by the wrong route.

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H1: INITIATIVES TO COMBAT DRUG COUNTERFEITING

TLO: Describe the problem posed by counterfeit drugs and initiatives being implemented to combat it.

Distribution of counterfeit drugs is a worldwide problem; it is estimated that more than 10% of all drugs available are counterfeit. Counterfeit drugs may contain the incorrect ingredients, insufficient amounts of active ingredients, or no active ingredients.

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Additionally, they may contain impurities and contaminants or may be distributed in fake packaging.

The most common drugs counterfeited are those used to treat erectile dysfunction, high cholesterol, hypertension, infections, cancer, and HIV/AIDS. The high cost of drugs, combined with the need for prescription drugs to treat chronic diseases—as well as the desire by consumers to misuse drugs (e.g., steroid-containing drugs for body building)—generate a constant demand easily filled by criminals via rogue Internet drug sites. The FDA and consumer groups are working on strategies to combat this problem, including tougher oversight of distributors, a rapid alert system, and better-informed consumers.

The role of the nurse is critical in consumer education. The nurse must advise patients to report any differences in taste or appearance of a drug or in its packaging. Patients should be alert to slight variations in packaging or labeling (e.g., color, package seal), note any unexpected side effects, and buy drugs from reputable sources. Reputable online pharmacies carry the designation of Verified Internet Pharmacy Practice Site (VIPPS; a list of VIPPS-verified pharmacies can be found at www.nabp.net) and display an approval seal. If any suspicion of counterfeit arises, the patient, family, or nurse should contact the FDA at www.fda.gov/Safety/MedWatch/HowToReport.

H1: DRUG NAMING AND RESOURCES

TLO: Describe the names and types of drugs used in the U.S. and resources to learn about them.

H2: Drug Names

ELO: Explain the various ways in which drugs are named.

Drugs have several names. The **chemical name** describes the drug's chemical structure. The **generic name** is the official, *nonproprietary* name for the drug; this name is not owned by any drug company and is universally accepted. Nearly 80% of all prescription drugs in the United States are ordered by generic name. The **brand (trade) name**, also known as the *proprietary* name, is chosen by the drug company and is usually a registered trademark. Drug companies market a compound using its brand name. For example, Lunesta is the (proprietary) brand name of a drug whose generic name is eszopiclone.

Throughout this text, only generic names for each drug will be used because many brand names may exist for a single generic name—for example, the generic drug ibuprofen carries the brand names Advil, Medipren, Motrin, and Nuprin. Generic names are given in lowercase letters, whereas brand names always begin with a capital letter. An example of a generic and brand-name drug listing is *furosemide (Lasix)*.

Generic drugs must be approved by the FDA before they can be marketed. If the generic drug is found to be *bioequivalent* to the brand-name drug, the generic drug is considered *therapeutically equivalent* and is given an "A" rating. If there is less than a 20% variance in drug absorption, distribution, metabolism, and excretion, a generic drug is considered *equivalent* to the brand-name drug.

A list of FDA-approved drug products can be found at www.accessdata.fda.gov/scripts/cder/drugsatfda. Generic drugs have the same active ingredients as brand-name drugs but are usually less expensive because manufacturers do not have to do extensive testing; these drugs were clinically tested for safety and efficacy by the pharmaceutical company that first formulated the drug. However, all drugs have varying inert fillers, binders, and excipients used to shape tablets and control how fast or slow the drug is released in the body, and these factors may result in variations in drug bioavailability.

Health care providers and patients must exercise care when choosing generic drugs because of possible variations in their action or in the patient's response to them. In order to maintain stable drug levels, patients should be cautioned *not* to change generic drug manufacturers; this is particularly true when patients are prescribed phenytoin or warfarin. Nurses should check with the health care provider or the pharmacist when generic drugs are prescribed. Health care providers must note on prescriptions whether the pharmacist may substitute the generic drug when the brand name is prescribed.

H2: Over-the-Counter Drugs

ELO: Describe the benefits and risks of over-the-counter drugs.

Although all drugs carry risk, **over-the-counter (OTC)** drugs have been found to be safe and appropriate for use without the direct supervision of a health care provider. They are available for purchase without a prescription in many retail locations. Other OTC drugs (e.g., pseudoephedrine, emergency contraception) are available with some restrictions and must be kept behind the pharmacy counter; prior to dispensing, patient age and identity are verified, and education is provided.

More than \$23 billion is spent annually on OTC drugs, which include vitamin supplements, cold remedies, analgesics, antacids, laxatives, antihistamines, sleep aids, nasal sprays, weight-control drugs, drugs for dermatitis and fungal infections, fluoride toothpaste, corn and callus removal products, and herbal products. Information related to OTC drugs available on the market can be found at <http://www.drugs.com/otc>.

In 2002, the FDA standardized OTC labeling to provide consumers with better information and to describe the benefits and risks

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Commented [SL36]: The previous H1 was demoted to an H2 and an ELO was created and aligned with it to create a more cohesive clustered lesson for digital transformation. (p. 6, p. 9)

associated with taking OTC drugs. It is an important nursing responsibility to ensure that patients are able to read and understand OTC labels. All OTC drugs must have labels that provide the following information in this specific order (Fig. 1.3).

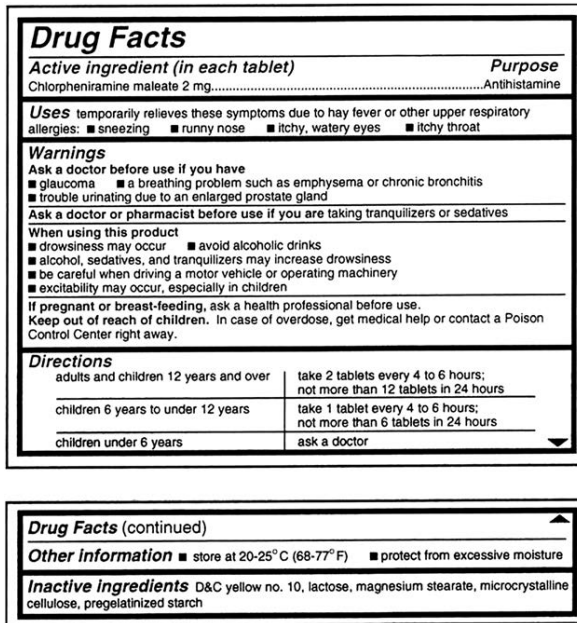


FIG. 1.3 Sample Over-the-Counter Drug Label.
From U.S. Food and Drug Administration. (2014). The current over-the-counter medicine label: Take a look.
U.S. Food and Drug Administration. Retrieved from
<http://www.fda.gov/drugs/emergencypreparedness/bioterrorismdrugpreparedness/ucm133411.htm>

- The product's active ingredients, including the amount in each dosage unit
- The purpose of the product
- The uses (indications) for the product
- Specific warnings, including when the product should not be used under any circumstances, substances or activities to avoid, side effects that could occur, and when it is appropriate to consult with a doctor or pharmacist
- Dosage instructions that include when, how, and how often to take the product
- The product's inactive ingredients and important information to help consumers avoid ingredients that may cause an allergic reaction

Nurses must be aware of OTC drugs and the implications of their use. OTC drugs provide both advantages and potential serious complications for the consumer. The nurse needs to emphasize that many of these drugs are potent and can cause moderate to severe side effects, especially when taken with other drugs. Additionally, many OTC drugs contain the same active ingredients, potentially leading to overdose. Self-diagnosis and self-prescribing OTC drugs may mask the seriousness of clinical conditions. See Box 1.4 for nursing considerations related to OTC drugs.

BOX 1.4 Nursing Considerations Related to Over-the-Counter Drugs

Nurses should advise patients of the following when over-the-counter (OTC) drugs are considered:

- Always read the instructions on the label.
- Do not take OTC medicines in higher dosages or for a longer time than the label states.
- If you do not get well, stop treating yourself and talk with a health care professional.
- Side effects from OTCs are relatively uncommon, but it is your job to know what side effects might result from the medicines you are taking.
- Because every person is different, your response to the medicine may be different than another person's response.
- OTC medicines often interact with other medicines, and with food or alcohol, or they might have an effect on other health problems you may have.
- If you do not understand the label, check with the pharmacist.
- Do not take medicine if the package does not have a label on it.
- Throw away medicines that have expired (are older than the date on the package).
- Do not use medicine that belongs to a friend.
- Buy products that treat only the symptoms you have.
- If cost is an issue, generic OTC products may be cheaper than brand name items.

- Avoid buying these products online, outside of well-known Internet insurance company sites, because many OTC preparations sold through the Internet are counterfeit products. These may not be what you ordered and may be dangerous.

Parents should know the following special information about using OTCs for children:

- Parents should never guess about the amount of medicine to give a child. Half an adult dose may be too much or not enough to be effective. This is very true of medicines such as acetaminophen (Tylenol) or ibuprofen (Advil), in which repeated overdoses may lead to poisoning of the child, liver destruction, or coma.
- If the label says to take 2 teaspoons and the dosing cup is marked with ounces only, get another measuring device. Don't try to guess about how much should be given.
- Always follow the age limits listed. If the label says the product should not be given to a child younger than 2 years, do not give it.
- Always use the child-resistant cap, and relock the cap after use.
- Throw away old, discolored, or expired medicine or medicine that has lost its label instructions.
- Do not give medicine containing alcohol to children.

From Edmunds MW: *Introduction to Clinical Pharmacology*, ed 8, St. Louis, 2016, Mosby.

Interactions between prescription drugs and OTC drugs are potentially dangerous. Many individuals routinely reach for aspirin, acetaminophen, and ibuprofen to relieve discomfort or pain without being aware of these interactions. For example, ibuprofen can increase fluid retention, which can worsen heart failure; use of ibuprofen on a daily basis may decrease the effectiveness of antihypertensive drugs. Ibuprofen has also been linked with cardiovascular events, such as myocardial infarction and stroke; this risk increases with long-term use.

Some OTC drugs, such as cough medicine, are a combination product of two to four drugs. It is conceivable that there could be a drug-drug interaction with a cough medicine and one of the drugs prescribed by the patient's health care provider.

Patients with asthma should be aware that aspirin can trigger an acute asthma episode. Patients may be allergic to aspirin, or aspirin may act as a deregulator of leukotrienes. Aspirin is also not recommended for children with influenza symptoms or chickenpox because it has been associated with Reye syndrome. Patients with kidney disease should avoid aspirin, acetaminophen, and ibuprofen because these can further decrease kidney function, especially with long-term use. Also, patients taking moderate to high doses of aspirin, ibuprofen, or naproxen concurrently with an oral anticoagulant may be at increased risk for bleeding.

The previous examples are not all inclusive. Caution is advised before using any OTC preparation, including antacids, decongestants, and laxatives. Patients should check with their health care providers and read drug labels before taking OTC medications so they are aware of possible contraindications and adverse reactions.

The acronym *SAFER* is a mnemonic for the instructions that the FDA recommends before taking any medicine: speak up, ask questions, find the facts, evaluate your choices, and read labels.

H2: Drug Resources

ELO: List the resources available to learn about various drugs and drug standards.

Many drug references are available, including nursing texts that identify related nursing implications and areas for health teaching. Some recommended resources follow:

- *American Hospital Formulary Service (AHFS) Drug Information* is published by the American Society of Health-System Pharmacists in Bethesda, Maryland. It provides accurate and complete drug information for both the health care provider and the consumer on nearly all prescription drugs marketed in the United States. This text contains drugs listed according to therapeutic drug classification. The information given for each drug includes chemistry and stability, pharmacologic actions, pharmacokinetics, uses, cautions, contraindications, acute toxicity, drug interactions, dosage and administration, and preparations. This reference is updated yearly with monthly supplements that provide information on new drugs such as dosage forms and strengths, uses, and cautions. The text is unbiased. Drug information from the AHFS is available online or in print format.
- *United States Pharmacopeia—Drug Information (USP-DI)* is available in most hospitals and pharmacies either online or in print format. It provides drug information for the health care provider, including pharmacology, precautions to consider, side effects and

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adverse effects, patient consultation, general dosing information, and dosage forms. The USP-DI also contains patient information presented in a way that is easily understood. The topics include administration of drugs, drug effects, indications, adverse reactions, dosage guidelines, and what to do for missed doses.

- The *Medical Letter* on drugs and therapeutics is a nonprofit publication for physicians, nurse practitioners, and other health professionals. Each biweekly issue provides reviews of new FDA-approved drugs and comparisons of drugs available for common diseases.
- *Prescriber's Letter* is a newsletter published monthly by the Therapeutic Research Center in Stockton, California. It provides concise updates and advice concerning new FDA-approved drugs, various uses of older drugs, and FDA warnings.
- *MedlinePlus* is a service of the U.S. National Library of Medicine. Available at www.nlm.nih.gov/medlineplus/druginformation.html, it offers extensive information on prescribed drugs, as well as herbs and supplements, indexed by generic and brand names.
- A good source for OTC drug information is *The Handbook of Nonprescription Drugs*, published by the American Pharmacists Association in Washington, DC. This resource is available online and in text. The Internet can be another great resource, but only if credible websites are used.