CHAPTER 1
INTRODUCTION TO PHARMACOLOGY

LEARNING OUTCOME 1
Identify key events in the history of pharmacology.

Concepts for Lecture
1. The history of pharmacology begins with records describing the use of plants (herbs) to relieve symptoms of disease in virtually every culture dating to antiquity. During the Dark Ages, herbal medicine continued to be practiced, but there are few records.
2. The first recorded reference to pharmacology is found in the 1693 text *Pharmacologia sen Manuducto and Materiam Medicum* by Samuel Dale.
3. Modern pharmacology is thought to have begun in the early 1800s, when chemists were beginning to isolate the pharmacological agents from their natural products and pharmacologists could study their effects in animals or use themselves as test subjects. Some of the early active agents that scientists isolated from their natural sources were morphine, colchicine, curare, and cocaine.
4. Pharmacology was officially recognized as a distinct discipline when the first department of pharmacology was established in Estonia in 1847. In 1890 John Jacob Abel, known as the father of American pharmacology, founded the first pharmacology department in the United States at the University of Michigan.
5. Beginning in the 20th century and continuing to the present day, advancements in pharmacology have allowed for synthesizing drugs in a laboratory instead of extracting active agents from their natural sources. Observations of drugs can now be made on a molecular level. Although the method of pharmacology has changed, the primary purpose of pharmacology has always been, and continues to be, the improvement of the patient's quality of life.

SUGGESTIONS FOR CLASSROOM ACTIVITIES
- Have students prepare a time line of the history of pharmacology, including important dates and individuals.
- Invite a representative from a pharmaceutical company to speak to the class on the research and development of a new drug.

POWERPOINT SLIDES
SLIDES 2–8

LEARNING OUTCOME 2
Explain the interdisciplinary nature of pharmacology, giving examples of how knowledge from different sciences impacts the nurse's role in drug administration.

Concepts for Lecture

1. Pharmacology is the study of drugs, which includes understanding how drugs are administered, where they travel in the body, and the responses they produce.
2. In order to thoroughly understand pharmacology, related subjects—such as anatomy and physiology, chemistry, microbiology, and pathophysiology—must be understood as well.
3. Pharmacology is a challenging, ever-changing subject. Of the over 10,000 drugs currently available, each has its own therapeutic application, interactions, side effects, and mechanisms of action. Many drugs are prescribed for more than one disease. Individual factors, such as age, sex, body mass, health status, and genetics, may elicit different responses.

SUGGESTIONS FOR CLASSROOM ACTIVITIES

- Discuss how knowledge of anatomy and physiology, chemistry, microbiology, and pathophysiology are helpful in understanding pharmacology. Give an example not found in the book.
- Discuss the importance of continuous learning in pharmacology as a health care practitioner.

SUGGESTIONS FOR CLINICAL ACTIVITIES

- Have students list the drugs their assigned patient is receiving. For each drug, students should identify its therapeutic applications, interactions, side effects, and mechanisms of action. During postclinical conference, have students share this information.
- Discuss why patients receiving the same drug may have different responses.
- Assign each student a drug to look up in the PDR; have the student note the drug's chemical structure, what body system(s) it affects, and what disease the drug is used to treat.

POWERPOINT SLIDES

SLIDES 9–12

LEARNING OUTCOME 3

Compare and contrast therapeutics and pharmacology.

Concepts for Lecture

1. The nurse is often the health care provider most directly involved with patient care and is active in educating, managing, and monitoring the proper use of drugs.
2. Therapeutics and pharmacology are closely connected. Therapeutics is concerned with the prevention of disease and treatment of suffering, and when the application of drugs is used for therapeutics it is called pharmacotherapy.

SUGGESTION FOR CLASSROOM ACTIVITIES

- Discuss different examples of therapeutics and pharmacotherapy and how they prevent disease and treat suffering.

SUGGESTION FOR CLINICAL ACTIVITIES

- On assigned patients, have each student identify therapeutics and pharmacotherapy and how these areas prevent disease and/or treat suffering in the assigned patient.

POWERPOINT SLIDES

SLIDE 13

LEARNING OUTCOME 4

Compare and contrast traditional drugs, biologics, and complementary and alternative medicine (CAM) therapies.

Concepts for Lecture

1. Traditional drugs are chemical agents synthesized in a laboratory that produce biological responses in the body. The responses may be desirable (therapeutic) or undesirable (adverse). Once drugs are administered they are called medications.
2. Biologics are naturally produced in animal cells, by microorganisms or by the body itself, and are used to treat a variety of illnesses and conditions. Examples of biologics are hormones, monoclonal antibodies, natural blood products and components, interferon, and vaccines.
3. Other therapeutic approaches, such as natural plant extracts, herbs, vitamins, minerals, dietary supplements, acupuncture, hypnosis, biofeedback, and massage, are classified as complementary and alternative medicine (CAM) therapies. They are considered by some to be unconventional, but show promise in treating some diseases.

SUGGESTION FOR CLASSROOM ACTIVITIES

- Divide the class into four groups. Assign one complementary therapy (acupuncture, hypnosis, biofeedback, or massage) to each group, and have each group provide information on that therapy to the class.
- Give the students a list of substances that contains medications, biologics, and ingested CAM substances and have the students classify them into the three categories.

SUGGESTION FOR CLINICAL ACTIVITIES

- Have students identify any complementary or alternative therapies on assigned patients.

POWERPOINT SLIDES

SLIDES 14–17

LEARNING OUTCOME 5

Outline the major differences between prescription and over-the-counter (OTC) drugs.

Concepts for Lecture

1. Prescription drugs offer the advantage of the patient's being examined by a health care

provider, as well as ensuring that the proper amount and frequency of a drug are prescribed. The patient also receives information on how to take the medication and on potential side effects. Disadvantages of prescription drugs include the need to schedule time for an appointment with a health care provider and only being able to obtain the drug with a prescription.

2. Advantages of OTC drugs include the ability to obtain the drug without seeing a health care provider, and OTC drugs are often less expensive than prescription drugs. Disadvantages of OTC drugs include the possibility of choosing the wrong drug, disease progression, and not knowing the side effects and interactions of the drug that can occur with both prescription and other OTC drugs.

SUGGESTIONS FOR CLASSROOM ACTIVITIES

- Discuss why some drugs are prescription drugs and other drugs are OTC drugs. Have students give examples of prescription drugs and OTC drugs.
- Discuss why a prescription drug sometimes becomes an OTC drug. Have students give examples.

POWERPOINT SLIDES

SLIDES 18–20

LEARNING OUTCOME 6

Identify key U.S. drug regulations that have ensured the safety and efficacy of medications.

Concepts for Lecture

1. There were few standards or guidelines to protect the public from drug misuse before the 19th century. Some contained hazardous levels of dangerous or addictive substances.
2. The *United States Pharmacopoeia* (USP), established in 1820, was the first comprehensive publication of drug standards in the United States. It summarizes standards of drug purity and strength and directions for synthesis.
3. In 1852, a national professional society of pharmacists called the American Pharmaceutical Association (APhA) was founded. From 1852 to 1975, two major compendia maintained drug standards in the United States, the *U.S. Pharmacopoeia* and the *National Formulary* (NF) established by the APhA. All drug products were covered in the USP; pharmaceutical ingredients were covered in the NF. In 1975, the two entities merged into a single publication, the *U.S. Pharmacopoeia–National Formulary* (USP-NF). The USP-NF is an annual publication, comprising one main publication and two supplements each year.
4. The United States began developing and enforcing tougher drug legislation in the 1900s. Some of the laws were the Biologics Control Act (1902), which helped to standardize the quality of serums and other blood products; the Pure Food and Drug Act (1906), which gave the government power to control the labeling of medicines; the Sherley Amendment (1912), which prohibited the sale of drugs labeled with fake therapeutic claims that were intended to defraud the consumer; the Food, Drug, and Cosmetic Act (1938) and its later amendments, which prevented the sale of drugs that had not been thoroughly tested and proven safe and effective; and the Dietary Supplement Health and Education Act (1994),

which prevented misleading claims.

SUGGESTIONS FOR CLASSROOM ACTIVITIES

- Have USP-NF copies available, and assign students to look for different drugs.
- Design a matching quiz for the different drug acts.

POWERPOINT SLIDES

SLIDES 21–29

LEARNING OUTCOME 7

Discuss the role of the U.S. Food and Drug Administration (FDA) in the drug-approval process.

Concepts for Lecture

1. The Food and Drug Administration was officially established as an agency of the U.S. Department of Health and Human Services in 1988.
2. Any pharmaceutical laboratory must solicit approval from the FDA before marketing a drug. The Center for Drug Evaluation and Research (CDER), a branch of the FDA, determines the safety and efficacy of a drug before it is placed on the market.
3. In 1997, the FDA created boxed warnings in order to regulate drugs with "special problems." Black box warnings, named after the black box appearing around drug safety information located within package inserts, eventually became one of the primary alerts for identifying extreme adverse drug reactions discovered during and after the review process.
4. The Center for Biologics Evaluation and Research (CBER) is another branch of the FDA; it regulates the use of biologics, such as serums, vaccines, and blood products. A result of the work of the CBER was the 1986 Childhood Vaccine Act, which authorizes the FDA to oversee all aspects of vaccines.
5. The Center for Food Safety and Applied Nutrition (CFSAN) is the branch of the FDA that oversees herbal and dietary products. In 1994 the Dietary and Supplemental Health and Education Act was established to regulate such substances. Herbal and dietary supplements can be marketed without prior approval from the FDA; however, all package inserts and information are monitored once products have gone to market.
6. In 1998, the National Center for Complementary and Alternative Medicine (NCCAM) was established as the federal government's lead agency for scientific research and information about CAM therapies.

POWERPOINT SLIDES

SLIDES 30–34

LEARNING OUTCOME 8

Explain the four stages of approval for therapeutic and biologic drugs.

Concepts for Lecture

1. The FDA reviews therapeutic and biologic drugs for approval in four phases: preclinical investigation, clinical investigation, review of the New Drug Application (NDA), and

postmarketing surveillance.

2. Preclinical investigation involves extensive laboratory research on human and microbial cells cultured in the laboratory and several species of animals, in order to examine the drug's effectiveness at various doses and to examine the side effects. Because this testing is not performed on humans, preclinical tests are always considered inconclusive.
3. The clinical investigation, which is the longest part of the drug-approval process, takes place in three different stages, termed "clinical phase trials," and evaluates the drug's effectiveness and safety in humans. An Investigational New Drug Application (INDA) may be submitted for Phase I clinical trials when it is determined that there are significant therapeutic benefits, and the product is reasonably safe for initial use in humans.
4. The NDA is reviewed by the FDA and either is approved and continues to the final stage or is rejected and the process is suspended until concerns are addressed by the pharmaceutical company. The average NDA review time is 17 to 24 months.
5. Postmarketing surveillance, the last stage of the approval process, begins after the clinical trials and NDA review are completed; this stage surveys for harmful drug effects on a larger population.
6. If the FDA discovers a serious problem in a drug, it will mandate that the drug be withdrawn from the market. The FDA provides safety sheets, press announcements, and other pertinent drug fact information to the public.

SUGGESTIONS FOR CLASSROOM ACTIVITIES

- Discuss why it takes so long for drugs to be approved by the FDA.
- Discuss why newly approved drugs are so expensive for the consumer.
- Have students research drugs that have been removed from the market because of harmful effects and present their findings to the class.

SUGGESTION FOR CLINICAL ACTIVITIES

- Discuss the MedWatch program and its purpose.

POWERPOINT SLIDES

SLIDES 35–44

LEARNING OUTCOME 9

Discuss how the FDA has increased the speed with which new drugs reach consumers.

Concepts for Lecture

1. The FDA review process can take several years. Expenses associated with development of a new drug can cost pharmaceutical manufacturers millions of dollars. A recent study estimated the cost to bring a new drug to market at $802 million.
2. In the early 1990s, owing to pressures from organized consumer groups and various drug manufacturers, governmental officials began to plan how to speed up the drug-review process. Reasons identified for the delays in the FDA drug-approval process included outdated guidelines, poor communications, and insufficient staff to handle the workload.
3. The Prescription Drug User Fee Act, established on a 5-year trial basis in 1992, required drug and biologic manufacturers to pay yearly product-user fees to the FDA. The fees

allowed the FDA to hire more employees and to restructure its organization to handle more drug applications. The results were a success. From 1992 to 1996, the FDA approved double the number of drugs and cut some review times by half.

4. There have been several other acts that increase the FDA's resources since the 1990s. The FDA Modernization Act in 1997 reauthorized the Prescription Drug User Fee Act. The FDA Amendments Act expanded the reform effort in 2007 by allowing more U.S. resources to be used for comprehensive reviews of new drugs. In 2008, the target base revenue for new drugs was over $392 million. In 2011, the FDA expanded its reviews of drugs and legislation.

SUGGESTION FOR CLASSROOM ACTIVITIES

- Discuss how the user fee increases the cost of prescription drugs.

POWERPOINT SLIDES

SLIDES 45–47

LEARNING OUTCOME 10

Identify the nurse's role in the drug-approval process and in maintaining safety practices.

Concepts for Lecture

1. Nurses participate in the drug-approval process during the postmarketing surveillance period of phase IV by monitoring for and reporting therapeutic effects and adverse reactions from the drugs they give to their patients.

SUGGESTION FOR CLASSROOM ACTIVITIES

- Have students identify the role of the nurse in drug research and postmarketing surveillance.

POWERPOINT SLIDES

SLIDES 48–49

GENERAL CHAPTER CONSIDERATIONS

1. Have students study and learn the key terms listed at the beginning of the chapter.
2. Have students complete the end-of-chapter exercises either in the book or on the Pearson Student Resources website.

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