Gutierrez: Pharmacotherapeutics: Clinical Reasoning in Primary Care, 2nd Edition

Test Bank

Chapter 1: Introduction to Pharmacotherapeutics

MULTIPLE CHOICE

1. A pharmaceutical company is attempting to develop a new drug. An expected outcome of the development process will be monitoring of the new drug by the:
   a. Drug Enforcement Agency (DEA)
   b. Food and Drug Administration (FDA)
   c. National Institutes of Health (NIH)
   d. United States Pharmacopeia (USP)

   ANS: B
   The FDA is responsible for overseeing the development of new drugs. The DEA is responsible for administering the regulations of the Controlled Substances Act. NIH is not involved with drug development. The USP is a drug-related publication.

   DIF: Cognitive Level: Knowledge REF: Page 2

2. A clinical drug trial is being conducted on 3000 people using a double-blind research design. Which clinical trial phase does this study represent?
   a. Phase 1
   b. Phase 2
   c. Phase 3
   d. None of the phases are applicable

   ANS: C
   A phase 1 clinical drug trial involves healthy people. Phase 2 uses diseased or ill volunteers. Phase 3 uses a sample of people using a double-blind research design to eliminate research bias.

   DIF: Cognitive Level: Comprehension REF: Page 3

3. The Orphan Drug Act was passed in 1983. Which statement describes the purpose of the Orphan Drug Act?
   a. To limit the development of single-purpose drugs for common illnesses
   b. To provide a means for rewarding cost-effective behavior by pharmaceutical companies
   c. To encourage pharmaceutical companies to produce a greater number of novel, or one-of-a-kind, drugs
   d. To provide tax incentives to pharmaceutical companies who develop drugs to treat rare diseases

ANS: D
The Orphan Drug Act of 1983 was passed to motivate companies to develop orphan drugs, which are defined as those used for the diagnosis, prevention, or treatment of diseases that affect less than 200,000 people in the United States. The law offers substantial tax incentives and longer patent protection to companies that develop drugs that would not otherwise be good financial investments.

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4. A controlled substance has high abuse potential but also has acceptable medical uses despite the risk of psychologic or physiologic dependence. What classification of controlled substances describes such a medication?
   a. Schedule I
   b. Schedule II
   c. Schedule III
   d. Schedule IV

   ANS: B
   Schedule II drugs have a high abuse potential, but they have accepted medical uses. The inappropriate or indiscriminate use of Schedule II drugs may result in physiologic or psychologic dependence. The schedules range in number from I to V, with the lowest number having the highest degree of control.

   DIF: Cognitive Level: Comprehension REF: Page 7

5. A health care provider desires to research drug information in the only official book of drug standards in the United States. What publication should be recommended to him?
   a. United States Pharmacopeia–National Formulary (USP-NF)
   b. U.S. Pharmacopeia Drug Information (USPDI)
   c. American Hospital Formulary Service–Drug Information (AHFS-DI)
   d. *Physician's Desk Reference* (PDR)

   ANS: A
   The USP-NF is a privately issued compendium that is the only official book of drug standards in the United States. The other publications listed are widely known and respectable reference sources.

   DIF: Cognitive Level: Knowledge REF: Page 9

6. Four distinct stages evolved as humankind searched for substances to treat illness and cure disease. These stages chronicle the development of medicinal treatment by natural and derived substances. In what stage did the belief exist that “humors” were essential requirements for life?
   a. Mystical
   b. Empirical
   c. Medieval

d. Contemporary

ANS: C
The medieval period began during the 1200s AD and lasted through the 1800s. During these 600 years, many myths and superstitions about hygiene and health existed. A balance of four body fluids, or "humors," were seen as essential requirements for life: fire equaled yellow bile or choler, water equated to phlegm, the earth to black bile, and the air to blood.

DIF: Cognitive Level: Knowledge REF: Page 1

7. What piece of legislation prohibited the use of drug labels containing false therapeutic claims intended to defraud the purchaser?
   a. Harrison Narcotic Act
   b. Sherley Amendment
   c. Durham-Humphrey Amendment
   d. Kefauver-Harris Amendment

   ANS: B
   Choice B is correct. The Supreme Court had ruled in 1911, in *United States v. Johnson,* that the 1906 Food and Drug Act did not prohibit false therapeutic claims, but only false and misleading statements about the ingredients or identity of a drug. In 1912, Congress went further and enacted the Sherley Amendment to prohibit drug labels containing false therapeutic claims intended to defraud the purchaser.

   DIF: Cognitive Level: Knowledge REF: Page 6

MULTIPLE RESPONSE

1. Which of the following would be information provided during the phases of clinical trials? Select all that apply.
   a. Purity
   b. Bioavailability
   c. Potency
   d. Efficacy
   e. Safety
   f. Toxicity
   g. Therapeutic value

   ANS: A, B, C, D, E, F
   The clinical phase of product development extends from a sponsor's initial submission of the investigational new drug (IND) application to begin testing a new drug in humans (i.e., clinical studies), to submission of a complete new drug application (NDA) or biologic license application (BLA) to the Food and Drug Administration (FDA) for marketing approval. The four phases of clinical trials are designed to provide information about a drug's purity, bioavailability, potency, efficacy, safety, and toxicity.

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