Holland/Adams/Brice, *Core Concepts in Pharmacology* 5th Edition Test Bank
Chapter 1

Question 1
Type: MCSA

A nurse educator wants to define the term pharmacology for the student. Which definition is most appropriate?

1. The study of medicine
2. The use of medicine to treat disease
3. The branch of medicine concerned with the treatment of disease and suffering
4. The use of herbs, natural extracts, vitamins, minerals, or dietary supplements to treat diseases

Correct Answer: 1

Rationale 1: *The study of medicine* is the definition of pharmacology.
Rationale 2: *The use of medicine to treat disease* is incorrect because this is the definition of pharmacotherapeutics.
Rationale 3: *The branch of medicine concerned with the treatment of disease and suffering* is incorrect because this is the definition of therapeutics.
Rationale 4: *The use of herbs, natural extracts, vitamins, minerals, or dietary supplements to treat diseases* is incorrect because this is the definition of natural alternative therapies.

Global Rationale: Pharmacology is the study of medicine. *The use of medicine to treat disease* is incorrect because this is the definition of pharmacotherapeutics. *The branch of medicine concerned with the treatment of disease and suffering* is incorrect because this is the definition of therapeutics. *The use of herbs, natural extracts, vitamins, minerals, or dietary supplements to treat diseases* is incorrect because this is the definition of natural alternative therapies.
Cognitive Level: Remembering
Client Need: Health Promotion and Maintenance
Page Number: 3
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-1 Explain the expansive nature of pharmacology, and give examples of interrelated subject areas needed to master the discipline.

Question 2

Type: MCSA

Nurses are responsible for administering medications. Nurses do not prescribe medications. Which best explains the reason why nurses study pharmacology?

1. To educate and advise patients regarding their healthcare needs

2. To clarify the reasons why a prescriber may prescribe a certain medication to the patient

3. To understand how adverse effects of medications can be avoided

4. To generate research for medications

Correct Answer: 1

Rationale 1: Knowledge of pharmacology is essential to properly educate and advise patients regarding their healthcare needs.

Rationale 2: The prescriber should provide the reasons why a particular drug is prescribed for a patient. The nurse is responsible for educating the patient about the medication.

Rationale 3: The action of the drug, its side effects, and adverse reactions of the drug are all necessary for patient education. Adverse effects of medication cannot always be avoided.

Rationale 4: Drug development generates research about how a medication works, the side effects, interactions with other medications, and adverse effects. Nurses study pharmacology in order to assist in patient education.

Global Rationale: Some healthcare providers, such as nurses, may administer drugs on a daily basis, whereas others may administer drugs occasionally. An extensive knowledge of pharmacology is necessary to properly educate and advise patients regarding their healthcare needs.

Cognitive Level: Understanding

Client Need: Safe Effective Care Environment

Page Number: 4

Nursing/Integrated Concepts: Nursing Process: Assessment

Learning Outcome: 1-1 Explain the expansive nature of pharmacology, and give examples of interrelated subject areas needed to master the discipline.

Question 3

Type: MCMA

In addition to physicians, which healthcare providers are able to prescribe medications? (Select all that apply.) Note: Credit will be given only if all correct choices and no incorrect choices are selected.

1. Physician's assistants
2. Advanced nurse practitioners
3. Dentists
4. Medical assistants
5. Registered nurses

Correct Answer: 1, 2, 3

Rationale 1: Physician's assistants are able to prescribe medications.
Rationale 2: Advanced nurse practitioners are able to prescribe medications.
Rationale 3: Dentists are able to prescribe medications.
Rationale 4: *Medical assistants* is incorrect because medical assistants are unlicensed and unable to prescribe medications.
Rationale 5: *Registered nurses* is incorrect because prescribing medications is not in their scope of practice.

Global Rationale: Physician's assistants, advanced nurse practitioners, and dentists are able to prescribe medications. Medical assistants and registered nurses are able to dispense medications, but they are unable to prescribe medication.
Cognitive Level: Remembering
Client Need: Health Promotion and Maintenance
Page Number: 3–4
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-2 Identify professions in which knowledge of pharmacology is important, and explain how the disciplines of therapeutics and pharmacology are interconnected.

Question 4
Type: MCSA

Which branch of medicine is concerned with the treatment of disease and suffering?

1. Pharmacology
2. Therapeutics
3. Pathophysiology
4. Pharmacotherapeutics

Correct Answer: 2

Rationale 1: Pharmacology is the study of medicine.
Rationale 2: Therapeutics is the branch of medicine concerned with the treatment of disease and suffering.
Rationale 3: Pathophysiology is the study of the functional changes associated with or resulting from disease or injury.
Rationale 4: Pharmacotherapeutics is the use of medicine to treat disease.

Global Rationale: Therapeutics is the branch of medicine concerned with the treatment of disease and suffering. Pharmacology is the study of medicine. Pathophysiology is the study of the functional changes associated with or resulting from disease or injury. Pharmacotherapeutics is the use of medicine to treat disease.
Cognitive Level: Remembering
Client Need: Health Promotion and Maintenance
Page Number: 4
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-2 Identify professions in which knowledge of pharmacology is important, and explain how the disciplines of therapeutics and pharmacology are interconnected.

Question 5
Type: MCSA

Which definition best describes the term pharmaceutics?

1. The science of preparing and dispensing drugs, and a very important part of pharmacotherapy
2. The use of medicine to treat disease
3. Agents naturally produced in animal cells, in microorganisms, or by the body itself
4. Herbs, natural extracts, vitamins, minerals, and dietary supplements

Correct Answer: 1

Rationale 1: Pharmaceutics is the science of preparing and dispensing drugs, and is a very important part of pharmacotherapy.
Rationale 2: *The use of medicine to treat disease* is incorrect because this is the definition of pharmacotherapeutics.
Rationale 3: *Agents naturally produced in animal cells, microorganisms, or by the body itself* is incorrect because this is the definition of biologics.
Rationale 4: *Herbs, natural extracts, vitamins, minerals, and dietary supplements* is incorrect because this is the definition of natural alternative therapies.

Global Rationale: Pharmaceutics is the science of preparing and dispensing drugs, and is a very important part of pharmacotherapy. *The use of medicine to treat disease* is incorrect because this is the definition of pharmacotherapeutics. *Agents naturally produced in animal cells, microorganisms, or by the body itself* is incorrect because this is the definition of biologics. *Herbs, natural extracts, vitamins, minerals, and dietary supplements* is incorrect because this is the definition of natural alternative therapies.
Cognitive Level: Remembering
Client Need: Health Promotion and Maintenance
Page Number: 5
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-2 Identify professions in which knowledge of pharmacology is important, and explain how the disciplines of therapeutics and pharmacology are interconnected.

Question 6
Type: MCMA

Which items are considered medically therapeutic? (Select all that apply.) Note: Credit will be given only if all correct choices and no incorrect choices are selected.

1. Traditional drugs
2. Sunscreens
3. Biologics
4. Natural alternative therapies
5. Antiperspirants

Correct Answer: 1, 3, 4

Rationale 1: Traditional drugs are produced in a laboratory, and are routinely used by practitioners.
Rationale 2: Sunscreens can alter the body's normal activities, but they are not considered to be medically therapeutic.
Rationale 3: Biologics are routinely used by practitioners, and are naturally produced. Vaccines and hormones are included in this type of medication.
Rationale 4: Natural alternative therapies include herbs, extracts, vitamins, minerals, and dietary supplements.
Rationale 5: Antiperspirants can alter the body's normal activities, but they are not considered to be medically therapeutic.

Global Rationale: Traditional drugs are produced in a laboratory, and are routinely used by practitioners. Biologics are routinely used by practitioners, and are naturally produced. Vaccines and hormones are included in this type of medication. Natural alternative therapies include herbs, extracts, vitamins, minerals, and dietary supplements. Sunscreens and antiperspirants can alter the body's normal activities, but they are not considered to be medically therapeutic.
Cognitive Level: Understanding
Client Need: Safe Effective Care Environment
Page Number: 4
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-3 Compare and contrast traditional drugs, biologics, and natural alternative therapies.

Question 7
Type: MCSA

Insulin would fall into which therapeutic drug category?

1. Biologics
2. Alternative therapies
3. Natural therapy
4. Traditional therapeutic drug

Correct Answer: 1

Rationale 1: Insulin is naturally produced by the body itself, in animal cells, and in microorganisms. Biologics also include hormones and vaccines, and are routinely used by healthcare practitioners.
Rationale 2: Alternative therapies are produced naturally, and include herbs, extracts, vitamins, minerals, and dietary supplements.
Rationale 3: Natural therapies are produced naturally, and include herbs, extracts, vitamins, minerals, and dietary supplements.
Rationale 4: Traditional drug therapies are chemically produced in a lab.

Global Rationale: Insulin is naturally produced by the body itself, in animal cells, and in microorganisms. Biologics also include hormones and vaccines, and are routinely used by healthcare practitioners. Natural and alternative therapies are produced naturally, and include

herbs, extracts, vitamins, minerals, and dietary supplements. Traditional drug therapies are chemically produced in a lab.
Cognitive Level: Remembering
Client Need: Physiological Integrity
Page Number: 4
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-3 Compare and contrast traditional drugs, biologics, and natural alternative therapies.

Question 8
Type: MCSA

Which statement best describes how a traditional drug is different from a biologic agent?

1. Biologics and traditional drugs are identical chemically.
2. Traditional drugs are naturally produced by the body or in animal cells, whereas biologic agents are chemically produced in a laboratory.
3. Traditional drugs are chemically produced in a laboratory, whereas biologic agents are naturally produced by the body or in animal cells.
4. Biologics include herbs, natural extracts, vitamins, minerals, and dietary supplements.

Correct Answer: 3

Rationale 1: Biologic agents are naturally produced by the body or in animal cells, and traditional drugs are chemically produced in a laboratory.
Rationale 2: Biologic agents are naturally produced by the body or in animal cells, and traditional drugs are chemically produced in a laboratory.
Rationale 3: Biologic agents are naturally produced by the body or in animal cells, and traditional drugs are chemically produced in a laboratory.
Rationale 4: This is the definition of natural alternative therapies.

Global Rationale: Biologic agents are naturally produced by the body or in animal cells, and traditional drugs are chemically produced in a laboratory. *Biologics that include herbs, natural extracts, vitamins, minerals, and dietary supplements* is the definition of natural alternative therapies.
Cognitive Level: Analyzing
Client Need: Physiological Integrity
Page Number: 4
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-3 Compare and contrast traditional drugs, biologics, and natural alternative therapies.

Question 9
Type: MCSA

Which medication change often occurs when a drug demonstrates a wide margin of safety and is used over long periods of time?

1. Prescription-only to over-the-counter (OTC) drug
2. One classification to a lower, less restrictive one
3. Traditional drug therapy classification to biologics classification
4. Therapeutic to effective

Correct Answer: 1

Rationale 1: Medications with wide margins of safety that are used over long periods of time are often changed to over-the-counter medications.
Rationale 2: A wide margin of safety does not change the classification of the drug.
Rationale 3: Biologics are produced by the body itself, in animal cells, or in microorganisms. Traditional drug therapies are chemically produced in the laboratory.
Rationale 4: The safety of a drug is related to the effectiveness of the medication without producing serious side effects.

Global Rationale: Medications with wide margins of safety that are used over long periods of time are often changed to over-the-counter medications. A wide margin of safety does not change the classification of the drug. Biologics are produced by the body itself, in animal cells, or in microorganisms. Traditional drug therapies are chemically produced in the laboratory. The safety of a drug is related to the effectiveness of the medication without producing serious side effects.
Cognitive Level: Remembering
Client Need: Physiological Integrity
Page Number: 5
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-4 Identify the advantages and disadvantages of prescription and over-the-counter drugs.

Question 10
Type: MCMA

Which statement best describes the advantages of prescription drugs versus over-the-counter (OTC) drugs? (Select all that apply.) Note: Credit will be given only if all correct choices and no incorrect choices are selected.

1. The cost of the drug is always less than the cost of an OTC drug.
2. The practitioner can maximize therapy by ordering the proper medication for the client's condition.
3. There are fewer side effects of prescription drugs than of OTC drugs.
4. The practitioner is able to control the dose and frequency of dosing of the drug.
5. Prescription drugs do not require a practitioner order.

Correct Answer: 2, 4

Rationale 1: There are a variety of prices for prescription and OTC drugs.
Rationale 2: The practitioner can maximize therapy by ordering the proper medication for the client's condition, and can control the dose and frequency of dosing.
Rationale 3: There are many possible side effects for prescription or OTC drugs, but with prescription drugs, the practitioner is able to inform the client of potential side effects.
Rationale 4: The practitioner can maximize therapy by ordering the proper medication for the client's condition, and can control the dose and frequency of dosing.
Rationale 5: To obtain prescription drugs, patients must get a physician's order authorizing them to receive the drugs.

Global Rationale: The practitioner can maximize therapy by ordering the proper medication for the client's condition, and can control the dose and frequency of dosing. There are a variety of prices for prescription and OTC drugs. There are many possible side effects for prescription or OTC drugs, but with prescription drugs, the practitioner is able to inform the client of potential side effects. To obtain prescription drugs, patients must get a physician's order authorizing them to receive the drugs.
Cognitive Level: Analyzing
Client Need: Physiological Integrity
Page Number: 5
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-4 Identify the advantages and disadvantages of prescription and over-the-counter drugs.

Question 11
Type: MCMA

The nurse is discussing the advantages of over-the-counter (OTC) medications with a client. Which statements are disadvantages of OTC drugs versus prescription drugs? (Select all that apply.) Note: Credit will be given only if all correct choices and no incorrect choices are selected.

1. OTC drugs can react with foods, herbal products, and prescriptions, or with other OTC drugs.
2. A client can obtain OTC drugs more easily than prescription drugs.
3. Self-treatment is sometimes ineffective.
4. Choosing the proper medication for a specific problem can be challenging.
5. OTC drugs are more expensive than prescription drugs.

Correct Answer: 1, 3, 4

Rationale 1: This is a disadvantage of OTC drugs.
Rationale 2: An advantage of OTC drug is that the client can obtain these drugs more easily than prescription drugs.
Rationale 3: This is a disadvantage of OTC drugs.
Rationale 4: This is a disadvantage of OTC drugs.
Rationale 5: Not all OTC drugs are more expensive than prescription drugs.

Global Rationale: Drug interactions, ineffective self-treatment, and choosing the proper medication for specific problems are all disadvantages of OTC drugs. Not all OTC drugs are more expensive than prescription drugs. An advantage of OTC drugs is that the client can obtain them more easily than prescription drugs.
Cognitive Level: Analyzing
Client Need: Physiological Integrity
Page Number: 5
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-4 Identify the advantages and disadvantages of prescription and over-the-counter drugs.

Question 12
Type: MCSA

Which science is known for preparing and dispensing drugs?

1. Pharmacology
2. Pharmaceutics
3. Traditional drug therapy
4. Therapeutics

Correct Answer: 2

Rationale 1: *Pharmacology* is incorrect because pharmacology is the study of medicine and of how drugs improve the health of the human body.
Rationale 2: Pharmaceutics is the science of preparing and dispensing drugs.
Rationale 3: *Traditional drug therapy* is incorrect because traditional drug therapy refers to medications that are chemically produced in a laboratory.
Rationale 4: *Therapeutics* is incorrect because therapeutics is the branch of medicine concerned with the treatment of disease and suffering.

Global Rationale: Pharmaceutics is the science of preparing and dispensing drugs. *Pharmacology* is incorrect because pharmacology is the study of medicine and of how drugs improve the health of the human body. *Traditional drug therapy* is incorrect because traditional drug therapy refers to medications that are chemically produced in a laboratory. *Therapeutics* is incorrect because therapeutics is the branch of medicine concerned with the treatment of disease and suffering.
Cognitive Level: Remembering
Client Need: Safe Effective Care Environment
Page Number: 5
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-5 Distinguish between pharmaceutics and pharmacology.

Question 13
Type: MCSA

A client expresses concerns about a newly prescribed medication. The nurse explains that the safety and effectiveness of the medication have been proven, according to the statutes of which law?

1. Public Health Service Act
2. FDA Modernization Act
3. Food, Drug, and Cosmetic Act
4. Pure Food and Drug Act

Correct Answer: 3

Rationale 1: The Public Health Service Act of 1944 covers many health issues, including biological products and the control of communicable diseases.

Rationale 2: The FDA Modernization Act is the largest reform effort of the drug review process since 1938.
Rationale 3: The Food, Drug, and Cosmetic Act, passed in 1938, prevents the marketing of drugs that have not been thoroughly tested prior to marketing. Drug companies are required to prove the safety and efficacy of any drug before it can be sold in the United States.
Rationale 4: The Pure Food and Drug Act gives the government power to control the labeling of medicine.

Global Rationale: The Food, Drug, and Cosmetic Act, passed in 1938, prevents the marketing of drugs that have not been thoroughly tested prior to marketing. Drug companies are required to prove the safety and efficacy of any drug before it can be sold in the United States. The Public Health Service Act of 1944 covers many health issues, including biological products and the control of communicable diseases. The FDA Modernization Act is the largest reform effort of the drug review process since 1938. The Pure Food and Drug Act gives the government power to control the labeling of medicine.
Cognitive Level: Analyzing
Client Need: Safe Effective Care Environment
Page Number: 7
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 1-6 Discuss the history of U.S. standards, acts, and organizations leading to the requirement that drug safety must be proven before marketing.

Question 14
Type: MCSA

A client asks the nurse whether the claims made regarding a new medication are true. The nurse responds based on which act or amendment passed in 1912 that prevents the sale of drugs with false therapeutic claims intended to cheat the consumer?

1. Food, Drug, and Cosmetic Act
2. FDA Modernization Act
3. The Sherley Amendment
4. Pure Food and Drug Act

Correct Answer: 3

Rationale 1: The Food, Drug, and Cosmetic Act prevents the marketing of drugs that have not been thoroughly tested prior to marketing. Drug companies are required to prove the safety and efficacy of any drug before it can be sold in the United States.

Rationale 2: The FDA Modernization Act is the largest reform effort of the drug review process since 1938.
Rationale 3: The Sherley Amendment was passed in 1912 to prohibit the sale of drugs labeled with false therapeutic claims intended to cheat the consumer.
Rationale 4: The Pure Food and Drug Act gives the government power to control the labeling of medicine.

Global Rationale: The Sherley Amendment was passed in 1912 to prohibit the sale of drugs labeled with false therapeutic claims intended to cheat the consumer. The Food, Drug, and Cosmetic Act prevents the marketing of drugs that have not been thoroughly tested prior to marketing. Drug companies are required to prove the safety and efficacy of any drug before it can be sold in the United States. The FDA Modernization Act is the largest reform effort of the drug review process since 1938. The Pure Food and Drug Act gives the government power to control the labeling of medicine.
Cognitive Level: Analyzing
Client Need: Safe Effective Care Environment
Page Number: 7
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 1-6 Discuss the history of U.S. standards, acts, and organizations leading to the requirement that drug safety must be proven before marketing.

Question 15
Type: MCSA

The nurse is discussing a medication with a patient. This approved medication is discovered to have serious problems. Which FDA response does the nurse expect?

1. Require the medication to have additional clinical trials conducted
2. Issue a warning to practitioners to watch for side effects in clients taking the drug
3. Continue to monitor the medication in postmarketing studies
4. Require that the drug be withdrawn from the market and its use discontinued

Correct Answer: 4

Rationale 1: *Require the medication to have additional clinical trials conducted* is incorrect because the drug will be withdrawn from the market and its use discontinued.
Rationale 2: *Issue a warning to practitioners to watch for side effects in clients taking the drug* is incorrect because the drug will be withdrawn and its use discontinued.

Rationale 3: *Continue to monitor the medication in postmarketing studies* is incorrect because the drug will be withdrawn from the market and its use discontinued.
Rationale 4: The FDA requires that the drug be withdrawn from the market and its use discontinued.

Global Rationale: The FDA requires that the drug be withdrawn from the market and its use discontinued. *Require the medication to have additional clinical trials conducted* is incorrect because the drug will be withdrawn from the market and its use discontinued. *Issue a warning to practitioners to watch for side effects in clients taking the drug* is incorrect because the drug will be withdrawn and its use discontinued. *Continue to monitor the medication in postmarketing studies* is incorrect because the drug will be withdrawn from the market and its use discontinued.
Cognitive Level: Applying
Client Need: Safe Effective Care Environment
Page Number: 10
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 1-6 Discuss the history of U.S. standards, acts, and organizations leading to the requirement that drug safety must be proven before marketing.

Question 16
Type: MCSA

The nurse is caring for a client with migraine headaches. The client asks why she has been prescribed a medication for seizures. Which legislation allows drug companies to share off-label drug use information with healthcare practitioners to allow such a prescription to occur?

1. Therapeutic Products Programme
2. Food and Drugs Act
3. Prescription Drug User Fee Act
4. Health Products and Food Branch

Correct Answer: 3

Rationale 1: The Therapeutic Products Programme is a piece of Canadian legislation to ensure safety of that country's medications and drugs.
Rationale 2: The Food and Drugs Act is a piece of Canadian legislation to ensure safety of that country's medications and drugs.

Rationale 3: The FDA Modernization Act reauthorized the Prescription Drug User Fee Act, which allows drug companies to give healthcare practitioners information about non–FDA-approved tests of certain drugs. When a drug provides benefits for treatment of a different problem than that for which it was originally prescribed, the drug company is allowed to share accurate information with other physicians about the drug's "unapproved" but effective use in treating that other condition.
Rationale 4: The Health Products and Food Branch is a piece of Canadian legislation to ensure safety of that country's medications and drugs.

Global Rationale: The FDA Modernization Act reauthorized the Prescription Drug User Fee Act, which allows drug companies to give healthcare practitioners information about non–FDA-approved tests of certain drugs. When a drug provides benefits for treatment of a different problem than that for which it was originally prescribed, the drug company is allowed to share accurate information with other physicians about the drug's "unapproved" but effective use in treating that other condition. The Therapeutic Products Programme is a piece of Canadian legislation to ensure safety of that country's medications and drugs. The Food and Drugs Act is a piece of Canadian legislation to ensure safety of that country's medications and drugs. The Health Products and Food Branch is a piece of Canadian legislation to ensure safety of that country's medications and drugs.
Cognitive Level: Analyzing
Client Need: Physiological Integrity
Page Number: 10
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 1-7 Discuss the emerging roles and responsibilities of the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration (FDA) with its branches in determining the safety of drugs and whether they may be used for therapy.

Question 17
Type: MCSA

A client asks the nurse if all herbal supplements undergo the same testing that prescription drugs undergo. Which statement is the best response by the nurse?

1. "Herbal and dietary supplements may not be marketed without prior approval from the FDA."
2. "The Center for Food Safety and Applied Nutrition (CFSAN) regulates use of herbal supplements, which means the medication must be safe."
3. "Herbal products and dietary supplements are regulated by the Dietary Supplement Health and Education Act of 1994. This act does not require the same research for herbal or dietary supplements."

4. "All medications and herbal supplements undergo the same testing before being made available for purchase."

Correct Answer: 3

Rationale 1: Herbal and dietary supplements may be marketed without prior approval from the FDA.
Rationale 2: Herbal and dietary supplements do not undergo the same testing that prescription or OTC medications do.
Rationale 3: Herbal products and dietary supplements are regulated by the Dietary Supplement Health and Education Act of 1994. This act does not require the same research for herbal and dietary supplements.
Rationale 4: Herbal supplements may be marketed without prior approval from the FDA, and are not required to be tested in clinical trials.

Global Rationale: Herbal products and dietary supplements are regulated by the Dietary Supplement Health and Education Act of 1994. This act does not require the same research for herbal and dietary supplements. Herbal and dietary supplements may be marketed without prior approval from the FDA. Herbal and dietary supplements do not undergo the same testing that prescription or OTC medications do. Herbal supplements may be marketed without prior approval from the FDA, and are not required to be tested in clinical trials.
Cognitive Level: Evaluating
Client Need: Safe Effective Care Environment
Page Number: 7
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 1-7 Discuss the emerging roles and responsibilities of the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration (FDA) with its branches in determining the safety of drugs and whether they may be used for therapy.

Question 18
Type: MCSA

Which government agency has control over which prescription or OTC drugs may be used for therapy?

1. The Center for Biologics Evaluation and Research (CBER)
2. The Center for Food Safety and Applied Nutrition (CFSAN)
3. The Center for Drug Evaluation and Research (CDER)

4. The National Institutes of Health (NIH)

Correct Answer: 3

Rationale 1: The Center for Biologics Evaluation and Research (CBER) regulates the use of biologics, including serums, vaccines, and products found in the bloodstream.
Rationale 2: The Center for Food Safety and Applied Nutrition (CFSAN) regulates use of herbal products and dietary supplements.
Rationale 3: The Center for Drug Evaluation and Research (CDER) has powerful control over whether prescription drugs and OTC drugs may be used for therapy.
Rationale 4: The National Institutes of Health (NIH) do not have control over prescription or OTC drugs.

Global Rationale: The Center for Drug Evaluation and Research (CDER) has powerful control over whether prescription drugs and OTC drugs may be used for therapy. The Center for Biologics Evaluation and Research (CBER) regulates the use of biologics, including serums, vaccines, and products found in the bloodstream. The Center for Food Safety and Applied Nutrition (CFSAN) regulates use of herbal products and dietary supplements. The National Institutes of Health (NIH) do not have control over prescription or OTC drugs.
Cognitive Level: Remembering
Client Need: Health Promotion and Maintenance
Page Number: 7
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-7 Discuss the emerging roles and responsibilities of the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration (FDA) with its branches in determining the safety of drugs and whether they may be used for therapy.

Question 19
Type: MCSA

Which branch of the FDA is responsible for the use of biologics, including serums, vaccines, and products found in the bloodstream?

1. The Center for Biologics Evaluation and Research (CBER)
2. The Center for Drug Evaluation and Research (CDER)
3. The Center for Food Safety and Applied Nutrition (CFSAN)
4. The FDA does not have a branch responsible for the use of biologics.

Correct Answer: 1

Rationale 1: The Center for Biologics Evaluation and Research (CBER) is responsible for the use of biologics, including serums, vaccines, and products found in the bloodstream.
Rationale 2: The Center for Drug Evaluation and Research (CDER) has control over whether medications may be used for therapy.
Rationale 3: The Center for Food Safety and Applied Nutrition (CFSAN) regulates herbal and dietary supplements.
Rationale 4: The Center for Biologics Evaluation and Research (CBER) is responsible for the use of biologics, including serums, vaccines, and products found in the bloodstream.

Global Rationale: The Center for Biologics Evaluation and Research (CBER) is responsible for the use of biologics, including serums, vaccines, and products found in the bloodstream. The Center for Drug Evaluation and Research (CDER) has control over whether medications may be used for therapy. The Center for Food Safety and Applied Nutrition (CFSAN) regulates herbal and dietary supplements. The Center for Biologics Evaluation and Research (CBER) is responsible for the use of biologics, including serums, vaccines, and products found in the bloodstream.
Cognitive Level: Analyzing
Client Need: Health Promotion and Maintenance
Page Number: 7
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-7 Discuss the emerging roles and responsibilities of the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration (FDA) with its branches in determining the safety of drugs and whether they may be used for therapy.

Question 20
Type: MCSA

A client has been selected as a participant in the approval process of a particular drug. The client's dose and any effects from the medication are being monitored. Which phase of drug approval is this client participating in?

1. Postmarketing study
2. Clinical phase trial
3. Postclinical investigation
4. Preclinical investigation

Correct Answer: 4

Rationale 1: Postmarketing studies take place after clinical trials to check for any new harmful effects in a larger and more diverse population.
Rationale 2: Clinical investigation is the second and longest part of the drug approval process, and takes place in three different phases, termed clinical phase trials. During this phase, clinical investigators address concerns such as whether the drug worsens other medical conditions; establish drug doses; and try to identify adverse effects.
Rationale 3: Postclinical investigation is not a phase of the approval process.
Rationale 4: Preclinical investigation involves basic science research.

Global Rationale: Preclinical investigation involves basic science research. Postmarketing studies take place after clinical trials to check for any new harmful effects in a larger and more diverse population. Clinical investigation is the second and longest part of the drug approval process, and takes place in three different phases, termed clinical phase trials. During this phase, clinical investigators address concerns such as whether the drug worsens other medical conditions; establish drug doses; and try to identify adverse effects. Postclinical investigation is not a phase of the approval process.
Cognitive Level: Understanding
Client Need: Safe Effective Care Environment
Page Number: 8
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 1-8 Identify four stages of approval for therapeutic and biologic drugs.

Question 21
Type: MCSA

Which phase of clinical research involves basic science research?

1. Submission of NDA
2. Clinical phase trials
3. Postmarketing study
4. Preclinical investigation

Correct Answer: 4

Rationale 1: A review of the NDA is the third stage of drug approval. During this stage, clinical phase III trials and animal testing may continue, depending on the results obtained from preclinical testing. If the NDA is approved, the process continues to the final stage. If the NDA is rejected, the process stops until concerns are addressed.
Rationale 2: During these phases, clinical pharmacologists, researchers, and healthcare providers examine data from volunteers and large groups of selected patients with certain diseases.
Rationale 3: Postmarketing surveillance is the fourth stage of the drug approval process. It takes place after clinical trials and the NDA review process have been completed. Testing in humans is continued to check for any new harmful effects in larger and more diverse populations.
Rationale 4: Preclinical investigation involves basic science research.

Global Rationale: Preclinical investigation involves basic science research. A review of the NDA is the third stage of drug approval. During this stage, clinical phase III trials and animal testing may continue, depending on the results obtained from preclinical testing. If the NDA is approved, the process continues to the final stage. If the NDA is rejected, the process stops until concerns are addressed. During these phases, clinical pharmacologists, researchers, and healthcare providers examine data from volunteers and large groups of selected patients with certain diseases.
Cognitive Level: Remembering
Client Need: Safe Effective Care Environment
Page Number: 8
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 1-8 Identify four stages of approval for therapeutic and biologic drugs.

Question 22
Type: MCSA

The nurse is providing care to a client who is taking several different medications, both prescribed and over-the-counter (OTC). The nurse is consulting with the charge nurse about possible interactions. Which statement by the nurse explains the increased potential for adverse drug–drug and drug–herbal interactions?

1. "The restrictions placed by the FDA are stricter."
2. "People are using more herbs, so the risk for interaction is greater."
3. "Drugs are being developed at a faster rate than their risk can be assessed."
4. "Managed care has made a greater number of drugs available to consumers."

Correct Answer: 3

Rationale 1: *"The restrictions placed by the FDA are stricter"* is incorrect because FDA restrictions are broader, and cover information about non–FDA-approved uses of certain drugs.
Rationale 2: *"People are using more herbs, so the risk for interaction is greater"* is incorrect. While the use of herbal products has increased, this is not the underlying reason for increased adverse potential.
Rationale 3: *"Drugs are being developed at a faster rate than their risk can be assessed"* is correct. Because of the higher number of drugs being approved for therapy, the potential for adverse drug–drug and drug–herbal interactions is greater than ever before.
Rationale 4: *"Managed care has made a greater number of drugs available to consumers"* is incorrect because managed care involvement does not come into play with higher number of interactions.

Global Rationale: *"Drugs are being developed at a faster rate than their risk can be assessed"* is correct. Because of the higher number of drugs being approved for therapy, the potential for adverse drug–drug and drug–herbal interactions is greater than ever before. *"The restrictions placed by the FDA are stricter"* is incorrect because FDA restrictions are broader, and cover information about non–FDA-approved uses of certain drugs. *"People are using more herbs, so the risk for interaction is greater"* is incorrect. While the use of herbal products has increased, this is not the underlying reason for increased adverse potential. *"Managed care has made a greater number of drugs available to consumers"* is incorrect because managed care involvement does not come into play with higher number of interactions.
Cognitive Level: Analyzing
Client Need: Physiological Integrity
Page Number: 10
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 1-9 Discuss current challenges facing the FDA in approving new drugs for market.

Question 23
Type: MCSA

A public health nurse is seeking information on bioterrorist agents to present education regarding security and defense in case of attack. Which resource is the most appropriate?

1. U.S. Department of Homeland Security
2. FEMA
3. U.S. Armed Forces

4. U.S. National Guard

Correct Answer: 1

Rationale 1: The U.S. Department of Homeland Security was organized to provide additional security and defense for the United States in a terrorist attack.
Rationale 2: FEMA would be activated or utilized in cases of bioterrorist attack, if necessary, but does not have the bulk of information that the Department of Homeland Security has gathered for this need.
Rationale 3: The U.S. Armed Forces would be activated or utilized in cases of bioterrorist attack, if necessary, but do not have the bulk of information that the Department of Homeland Security has gathered for this need.
Rationale 4: The U.S. National Guard would be activated or utilized in cases of bioterrorist attack, if necessary, but does not have the bulk of information that the Department of Homeland Security has gathered for this need.

Global Rationale: The U.S. Department of Homeland Security was organized to provide additional security and defense for the United States in a terrorist attack. FEMA would be activated or utilized in cases of bioterrorist attack, if necessary, but does not have the bulk of information that the Department of Homeland Security has gathered for this need. The U.S. Armed Forces would be activated or utilized in cases of bioterrorist attack, if necessary, but do not have the bulk of information that the Department of Homeland Security has gathered for this need. The U.S. National Guard would be activated or utilized in cases of bioterrorist attack, if necessary, but does not have the bulk of information that the Department of Homeland Security has gathered for this need.
Cognitive Level: Analyzing
Client Need: Safe Effective Care Environment
Page Number: 11
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 1-10 Discuss the challenges facing healthcare providers in view of modern-day pandemic and bioterrorist threats.

Question 24
Type: SEQ

A nurse is discussing how drugs are approved with a healthcare provider. Place the stages of approval for therapeutic and biological drugs in the appropriate sequence.

1. NDA submission with review

2. Preclinical investigation
3. Clinical investigation
4. Postmarketing studies

Correct Answer: 2, 3, 1, 4

Global Rationale: The correct order of drug review is preclinical investigation, clinical investigation, NDA submission with review, followed by postmarketing studies.

Cognitive Level: Understanding
Client Need: Safe Effective Care Environment
Page Numbers: 8–9
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 1-8 Identify four stages of approval for therapeutic and biologic drugs.

Question 25
Type: MCMA

Why do healthcare providers study pharmacology and pharmacotherapeutics? (Select all that apply.) Note: Credit will be given only if all correct choices and no incorrect choices are selected.

1. To understand how drugs improve the health of the human body
2. To educate clients
3. To gather medical data regarding results of drug therapy
4. To classify medications based on how they are produced

Correct Answer: 1, 2, 3
Rationale 1: Pharmacology is the study of medicine. Healthcare providers practice the discipline of pharmacology to study how drugs improve the health of the human body.
Rationale 2: An extensive knowledge of pharmacology is necessary to properly educate clients.
Rationale 3: Healthcare professions gather medical data from patients to follow up on results of therapy.
Rationale 4: Medicines are classified as traditional drugs, biologics, and natural alternatives. Healthcare providers do not classify medications.

Global rationale: For healthcare providers studying pharmacology, training in the fields of pharmacology and therapeutics are connected. Pharmacology is the study of medicine and pharmacotherapeutics is the use of medicine to treat disease. Knowing how medicines work, their side effects, and their adverse effects is essential to educate clients.

Cognitive Level: Remembering
Client Need: Safe Effective Care Environment
Page Numbers: 3–4
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-5 Distinguish between pharmaceutics and pharmacology.

Question 25
Type: MCSA

Certain drugs are produced and prescribed with a faster process of review. Why did this occur?

1. There was limited knowledge of certain diseases and people were dying.
2. There existed faster authorization of therapeutic drugs that met medical need.
3. Drug development was stagnant and time consuming.
4. The benefits outweighed the risks.

Correct Answer: 2

Rationale 1: There was not a limited knowledge about the disease process.
Rationale 2: The production and prescriptions met the medical need based on the rise of incidence of certain diseases.
Rationale 3: Drug development was not stagnant. Drug development is time consuming and expensive.
Rationale 4: The risks and benefits were not identified.

Global Rationale: The FDA has made more drugs available to the U.S. public and with a faster process of reviewing using four general approaches. These include priority review, breakthrough therapy, accelerated approval, and fast track. HIV/AIDS drugs were produced and prescribed to meet the challenging or unmet medical need.
Cognitive Level: Analyzing
Client Need: Safe Effective Care Environment
Page Number: 10
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-9 Discuss current challenges facing the FDA in approving new drugs for market.

Question 26
Type: MCMA

Which are considered infectious diseases that have impacted healthcare providers in the United States?

1. Influenza
2. Human immunodeficiency virus
3. Food poisoning
4. Tuberculosis
5. Asthma

Correct Answer: 1, 2, 3, 4

Rationale 1: Influenza is an infectious disease.
Rationale 2: HIV is an infectious disease.
Rationale 3: Food poisoning is an infectious disease.
Rationale 4: TB is an infectious disease.
Rationale 5: Asthma is a chronic disease.

Global Rationale: Throughout most of the history of the United States, concern about epidemic diseases mainly focused on the possible spread of traditional infectious diseases such as influenza, tuberculosis, cholera, and human immunodeficiency virus (HIV). Healthcare providers are also concerned about widespread food poisoning and sexually transmitted infections other than HIV.
Cognitive Level: Understanding
Client Need: Safe Effective Care Environment
Page Numbers: 10–11
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 1-10 Discuss the challenges facing healthcare providers in view of modern-day pandemic and bioterrorist threats.