Adams and Urban, *Pharmacology: Connections to Nursing Practice*, 3e Test Bank

Chapter 2

Question 1
Type: MCSA

Which was the greatest problem with patent medicines in early America that lead to drug legislation?

1. They were only distributed in elixir formulation.

2. They had dangerous or addictive substances.

3. They smelled like medicine.

4. They could only be made out of natural products.

Correct Answer: 2

Rationale 1: They could be distributed in many forms, such as tablets and creams, not just elixirs.

Rationale 2: Many did contain dangerous or addictive substances such as morphine or cocaine.

Rationale 3: Some did smell like medicine, but this was not dangerous.

Rationale 4: They could be made out of many products, not just natural ones.

Global Rationale: In early America, many patent medicines did contain dangerous or addictive substances which lead to legislation. Patent medications were distributed in many forms, such as tablets and creams, not just elixirs. While some patent medicines did smell like medicine, this is not dangerous. Patent medicines could be made out of many products, not just natural ones.

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings

NLN Competencies: Knowledge and Science: Defining how sciences are developed, and by whom
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-1 Explain the role of patent medicines in the history of pharmacology and the legislation of drugs.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 2
Type: MCMA

During the rise of patent medicines in America in the 1800s, there were few attempts to regulate drugs. Which statements accurately depict this situation?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. Patent medicines contained a brand name that clearly identified the product.

2. Patent medicines claimed to cure just about any disease or condition.

3. Patent medicines were often harmless and ineffective.

4. Many patent medicines contained addictive substances.

5. Patent medicines could not make false therapeutic claims.

Correct Answer: 1,2,3,4

Rationale 1: Patent medicine did contain the brand name clearly identifying the product.

Rationale 2: Patent medicine claimed to cure everything from consumption to "all forms of weakness."

Rationale 3: Many patent medicines contained coloring and flavoring and were both harmless and ineffective.

Rationale 4: Some elixirs contained up to 50% morphine. In the late 1800s, Coca-Cola contained about 9 mg of cocaine per serving.

Rationale 5: It was not until the Sherley Amendment was passed in 1912 that false therapeutic claims were prohibited.

Global Rationale: The statements that accurately depict the situation regarding patent medicines in the 1800s include that patent medicine did contain the brand name clearly identifying the product; patent medicine claimed to cure everything from consumption to "all forms of weakness"; many patent medicines contained coloring and flavoring and were both harmless and ineffective; and some elixirs contained up to 50% morphine. In the late 1800s, Coca-Cola contained about 9 mg of cocaine per serving. It was not until the Sherley Amendment was passed in 1912 that false therapeutic claims were prohibited.

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies

QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: NLN Competencies: Knowledge and Science: Defining how sciences are developed, and by whom
Nursing/Integrated Concepts: Nursing Process: Implementation

Learning Outcome: 2-1 Explain the role of patent medicines in the history of pharmacology and the legislation of drugs.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 3
Type: MCSA

The student nurse taking a pharmacology class is studying the Food, Drug, and Cosmetic Act of 1938. What is important for the student to remember?

1. It prevented the sale of drugs that had not been tested before marketing.

2. It gave the government the power to change labeling content of medications.

3. It helped to standardize the quality of prepared food, drugs, and cosmetics.

4. It prohibited the sale of drugs labeled with false therapeutic claims to defraud the public.

Correct Answer: 1

Rationale 1: It did prevent sale of drugs that had not been tested before marketing.

Rationale 2: It did not give the government power over labeling contents; the Pure Food and Drug Act did.

Rationale 3: It did not standardize quality of food, drugs, or cosmetics.

Rationale 4: It did not prohibit sale of drugs labeled with false therapeutic claims to defraud the pubic; this was the Sherley Amendment.

Global Rationale: The Food, Drug, and Cosmetic Act of 1938 did prevent sale of drugs that had not been tested before marketing. The Act did not give the government power over labeling contents; the Pure Food and Drug Act did. It did not standardize quality of food, drugs, or cosmetics. It also did not prohibit sale of drugs labeled with false therapeutic claims to defraud the pubic; this was the Sherley Amendment.

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Policies and procedures
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-2 Outline the key U.S. drug regulations and explain how each has contributed to the safety and effectiveness of medications.

MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 4
Type: MCSA

A client is talking to the nurse and is expressing doubt about whether to take a drug that is advertised on television. The client does not believe that commercials for drugs tell the truth. Which rationale will the nurse use when responding to the client?

1. Advertisements are not legally binding and can be misleading.

2. All drugs must be advertised in media to inform the public.

3. Manufacturers have some ability to change things when advertising drugs.

4. False claims of a drug's therapeutic effect are prohibited by law.

Correct Answer: 4

Rationale 1: It is illegal to advertise false claims; advertisements are legally binding.

Rationale 2: Drugs do not have to be advertised in the media.

Rationale 3: Manufacturers may not change the truth when advertising drugs.

Rationale 4: The Sherley Amendment of 1912 prohibits sale of drugs labeled with false therapeutic claims.

Global Rationale: The nurse will respond to the client using the knowledge that the Sherley Amendment of 1912 prohibits sale of drugs labeled with false therapeutic claims. It is illegal to advertise false claims; advertisements are legally binding. Drugs do not have to be advertised in the media. Manufacturers may not change the truth when advertising drugs.

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Policies and procedures
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-2 Outline the key U.S. drug regulations and explain how each has contributed to the safety and effectiveness of medications.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 5
Type: MCMA

The Pure Food and Drug Act (PFDA) of 1906 was significant in that it gave the government the power to prohibit drug labels from claiming false therapeutic benefits. However, there were still several weaknesses in the legislature of this act. Which statements most accurately describe these weaknesses?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. This law did not require drug manufacturers to prove that the drug was effective in its claims.

2. This law did not prevent drugs from being marketed for any disease.

3. This law required all drug labels to accurately describe their contents.

4. This law required adequate testing for safety prior to marketing.

5. This law did not encourage the development of drugs for rare or unusual disorders.

Correct Answer: 1,2

Rationale 1: The fact that manufacturers did not have to prove efficacy was a tremendous weakness in the regulation of drugs in the early 20th century.

Rationale 2: The PFDA of 1906 did not address false therapeutic claims.

Rationale 3: Requiring drug labels to identify their contents is not a weakness of the PFDA.

Rationale 4: The PFDA did not require testing for safety prior to marketing. It was not until Congress passed the Food, Drug, and Cosmetic Act that drugs had to be tested for safety prior to marketing.

Rationale 5: The act that encouraged the research and development of drugs for rare or unusual disorders is called the Orphan Act.

Global Rationale: The weaknesses of the PFDA of 1906 include the fact that manufacturers did not have to prove efficacy in the regulation of drugs in the early 20th century and the Act did not address false therapeutic claims. Requiring drug labels to identify their contents is not a weakness of the PFDA. The PFDA did not require testing for safety prior to marketing. It was not until Congress passed the Food, Drug, and Cosmetic Act that drugs had to be tested for safety prior to marketing. The act that encouraged the research and development of drugs for rare or unusual disorders is called the Orphan Act.

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes

AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Policies and procedures
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-2 Outline the key U.S. drug regulations and explain how each has contributed to the safety and effectiveness of medications.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 6
Type: MCSA

One of the first standards used by pharmacists for preparation and potency of drugs was a formulary. What did early formularies contain?

1. Names of patent medicines and natural drugs

2. Lists of pharmaceutical products and drug recipes

3. Lists of various drugs' strengths based on individual pharmacies

4. Lists of various drugs' potency based on geographic region

Correct Answer: 2

Rationale 1: Early formularies did not contain the names of patent medicines and natural drugs.

Rationale 2: Early formularies did contain a list of pharmaceutical products and drug recipes.

Rationale 3: Formularies did not list drugs based on the individual pharmacies.

Rationale 4: Formularies did not list drugs by their geographical region.

Global Rationale: Early formularies contained a list of pharmaceutical products and drug recipes. Early formularies did not contain the names of patent medicines and natural drugs, list drugs based on the individual pharmacies, or list drugs by their geographical region.

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Current best practices
Nursing/Integrated Concepts: Nursing Process: Implementation

Learning Outcome: 2-3 Describe how the *United States Pharmacopeia-National Formulary* (USP-NF) controls drug purity and standards.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 7
Type: MCMA

In the early 1800s, it became clear that the standardization of drug purity and strength was necessary. Which reasons reflected this need?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. Strength and purity of products varied from region to region and batch to batch.

2. Strength and purity of products depended on the pharmacist's experience.

3. Strength and purity of products would vary in size, taste, and nutritional value.

4. Strength and purity were mostly guaranteed if products were produced locally, which caused a hardship for those outside the region.

5. Strength and purity could be trusted when the product had gone through extensive local testing.

Correct Answer: 1,2,3

Rationale 1: The strength and purity of the products varied considerably because they were dependent on the experience of the pharmacist and the quality of the local ingredients, which could vary from region to region and batch to batch.

Rationale 2: The strength and purity of the products varied considerably because they were dependent on the experience of the pharmacist and the quality of the local ingredients, which could vary from region to region and batch to batch.

Rationale 3: The strength and purity of the products varied considerably because they were dependent on the experience of the pharmacist and the quality of the local ingredients, which could vary from region to region and batch to batch.

Rationale 4: Strength and purity could not be guaranteed, even if produced locally. Causing a hardship on those outside the region had nothing to do with determining that standardization was needed.

Rationale 5: Extensive testing prior to marketing did not occur until the early 1930s.

Global Rationale: The strength and purity of the products varied considerably because they were dependent on the experience of the pharmacist and the quality of the local ingredients, which could vary from region to region and batch to batch. Because of this, standardization was necessary. Strength and purity could not be guaranteed,

even if produced locally. Causing a hardship on those outside the region had nothing to do with determining that standardization was needed. Extensive testing prior to marketing did not occur until the early 1930s.

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Current best practice
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-3 Describe how the *United States Pharmacopeia-National Formulary* (USP-NF) controls drug purity and standards.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 8
Type: MCSA

A pharmaceutical representative comes to the primary care office and states that his company is marketing a new drug that does not need approval by the Food and Drug Administration (FDA). What is the best response of the nurse?

1. "Is this a drug in clinical trials? Those are the only drugs that don't have to have FDA approval."

2. "Is this an over-the-counter drug? Over-the-counter drugs do not need FDA approval."

3. "Your company must be involved in academic research if the drug doesn't need FDA approval."

4. "Any pharmaceutical company must have FDA approval before marketing a drug."

Correct Answer: 4

Rationale 1: Drugs in clinical trials must have FDA approval to start and continue clinical trials.

Rationale 2: Over-the-counter drugs must have FDA approval before being marketed.

Rationale 3: Drugs involved in academic research must have FDA approval.

Rationale 4: All drugs marketed by pharmaceutical companies must have FDA approval.

Global Rationale: All drugs marketed by pharmaceutical companies must have FDA approval. Drugs in clinical trials must have FDA approval to start and continue clinical trials. Over-the-counter drugs must have FDA approval before being marketed. Drugs involved in academic research must have FDA approval.

Cognitive Level: Applying

Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: I.A.7 Explore ethical and legal implications of patient-centered care
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Current best practice
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-4 Evaluate the role of the U.S. Food and Drug Administration in the drug approval process.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 9
Type: MCSA

Nursing students are studying which drug types must have Food and Drug Administration (FDA) approval before being marketed. The students know that which drugs must have approval from the FDA before being marketed?

1. Biologics

2. Food supplements

3. Herbal preparations

4. Dietary supplements

Correct Answer: 1

Rationale 1: Biologics must have FDA approval before being marketed.

Rationale 2: Food supplements do not require FDA approval.

Rationale 3: Herbal preparations do not require FDA approval.

Rationale 4: Dietary supplements do not require FDA approval.

Global Rationale: Biologics must have FDA approval before being marketed. Food supplements, herbal preparations, and dietary supplements do not require FDA approval prior to being marketed.

Cognitive Level: Understanding
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: I.A.7 Explore ethical and legal implications of patient-centered care
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Current best practice

Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-4 Evaluate the role of the U.S. Food and Drug Administration in the drug approval process.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 10
Type: MCMA

Which statements regarding the role of the U.S. Food and Drug Administration (FDA) are true?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. The FDA is responsible for ensuring the security of human drugs.

2. The FDA publishes a summary of the standards of drug purity and strength.

3. The FDA ensures the availability of effective drugs.

4. The FDA takes action against any supplement that is deemed to be unsafe.

5. The FDA facilitates the availability of safe drugs.

Correct Answer: 1,3,4,5

Rationale 1: The mission of the FDA is to protect public health by ensuring the safety, efficacy and security of human and veterinary drugs, biologic products, medical devises, the nation's food supply, cosmetics, and products that emit radiation.

Rationale 2: It is the role of the U.S. Pharmacopeia (USP) to publish a summary of drug standards (purity and strength).

Rationale 3: Ensuring the availability of effective drugs is one of the FDA's roles.

Rationale 4: It is the FDA's role to take action against any supplement that is deemed to be unsafe.

Rationale 5: It is the role of the FDA to facilitate the availability of safe drugs.

Global Rationale: The mission of the FDA is to protect public health by ensuring the safety, efficacy and security of human and veterinary drugs, biologic products, medical devises, the nation's food supply, cosmetics, and products that emit radiation. Ensuring the availability of effective drugs is one of the FDA's roles. It is the FDA's role to take action against any supplement that is deemed to be unsafe. It is the role of the FDA to facilitate the availability of safe drugs. It is the role of the U.S. Pharmacopeia (USP) to publish a summary of drug standards (purity and strength).

Cognitive Level: Remembering

Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: I.A.7 Explore ethical and legal implications of patient-centered care
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Current best practice
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-4 Evaluate the role of the U.S. Food and Drug Administration in the drug approval process.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 11
Type: MCSA

The nurse explains to the client that during the Food and Drug Administration (FDA) drug approval process, clinical investigators from many different medical specialties address concerns. What concerns are addressed?

1. Whether a New Drug Application (NDA) must be filed

2. The marketability of the drug

3. What the cost of the drug should be

4. Whether or not the drug is safe

Correct Answer: 4

Rationale 1: The pharmaceutical company files the NDA.

Rationale 2: The clinical investigators do not determine marketability of the drug.

Rationale 3: Clinical investigators do not determine the cost of the drug.

Rationale 4: Safety is determined by the FDA during the Investigational New Drug Application process.

Global Rationale: During the FDA drug approval process, clinical investigators address concerns on whether or not the drug is safe. Safety is determined by the FDA during the Investigational New Drug Application process. The pharmaceutical company files the NDA. The clinical investigators do not determine marketability of the drug or determine the cost of the drug.

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: I.A.7 Explore ethical and legal implications of patient-centered care

AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Policies and procedures
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-5 Categorize the four stages of new drug approval.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 12
Type: MCSA

The client receiving a newly released medication is experiencing adverse effects. Why does the nurse report these adverse effects as part of the postmarketing surveillance stage of the drug approval process?

1. The clinical trials are continuing to collect new data.

2. Individual client response is compared with the clinical trial data.

3. The efficacy of the drug is determined for new drugs.

4. Harmful effects in the larger population continue to be monitored.

Correct Answer: 4

Rationale 1: The clinical trials end before the drug is released for use by the general public.

Rationale 2: The client's response is not compared with previous clinical trials.

Rationale 3: The efficacy for the drug is not evaluated via the adverse effects.

Rationale 4: Some harmful effects are subtle, take longer to appear, and are not identified until the drug is prescribed to a large number of people; thus, postmarketing surveillance for harmful effects must be reported.

Global Rationale: The nurse reports the adverse effects because some harmful effects are subtle, take longer to appear, and are not identified until the drug is prescribed to a large number of people; thus, postmarketing surveillance for harmful effects must be reported. The clinical trials end before the drug is released for use by the general public. The client's response is not compared with previous clinical trials. The efficacy for the drug is not evaluated via the adverse effects.

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Policies and procedures

Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-5 Categorize the four stages of new drug approval.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 13
Type: MCMA

Which statements regarding the preclinical research stage of drug development are true?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. Most drugs do not proceed past the preclinical stage because they are found to be too toxic or just ineffective.

2. At the end of the preclinical research stage, client variability is determined and potential drug-to-drug interactions are examined.

3. The preclinical stage of research involves extensive testing on animals in the laboratory to determine if the drug will cause harm to humans.

4. Preclinical research results are always inconclusive.

5. The Food and Drug Administration (FDA) is responsible for extensive testing for safety before the pharmaceutical company can begin the preclinical research stage of development.

Correct Answer: 1,3,4

Rationale 1: Most drugs do not proceed past the preclinical research stage of development because they are found to be either too toxic or just ineffective.

Rationale 2: Client variability and potential drug-to-drug interactions are examined in Phase 3 of the clinical investigation process after Food and Drug Administration (FDA) approval.

Rationale 3: The preclinical stage of development involves extensive testing on human, microbial cells, and animals to determine drug action and to predict whether the drug will cause harm to humans.

Rationale 4: Because lab tests cannot accurately predict human response to a drug, these results are always inconclusive.

Rationale 5: This extensive testing is done by the pharmaceutical company in the preclinical research stage of drug development, not the FDA.

Global Rationale: The true statements include: most drugs do not proceed past the preclinical research stage of development because they are found to be either too toxic or just ineffective; the preclinical stage of developmentinvolves extensive testing on human, microbial cells, and animals to determine drug action and to predict whether the drug will cause harm to humans; and because lab tests cannot accurately predict human

response to a drug, these results are always inconclusive. Client variability and potential drug-to-drug interactions are examined in Phase 3 of the clinical investigation process after Food and Drug Administration (FDA) approval. Extensive testing is done by the pharmaceutical company in the preclinical research stage of drug development, not the FDA.

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Policies and procedures
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-5 Categorize the four stages of new drug approval.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 14
Type: MCSA

Clients enrolled in a clinical drug trial are told that they might receive a placebo drug as part of a control group. A client asks the nurse what a placebo is. Which response by the nurse is the most appropriate?

1. “A placebo is a substance that has no therapeutic effect.”

2. "A placebo is a similar drug that is safe."

3. "A placebo is a drug that has been tested before."

4. "A placebo is an over-the-counter drug."

Correct Answer: 1

Rationale 1: A placebo is an inert substance that has no therapeutic effect and is used as a control.

Rationale 2: A placebo is not a similar drug

Rationale 3: A placebo is generally not another drug.

Rationale 4: A placebo is not an over-the-counter drug

Global Rationale: A placebo is an inert substance that has no therapeutic effect and is used as a control. A placebo is not a similar drug, generally not another drug, and is not an over-the-counter drug.

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies

QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Current best practice
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-6 Explain the role of a placebo in new drug testing.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 15
Type: MCSA

The nursing student is studying how priority drugs receive accelerated approval by the Food and Drug Administration (FDA) as part of the FDA modernization. Which conditions are the priority drugs used to treat?

1. Diseases that previously were treated with older and less popular drugs

2. Diseases that affect only a small percentage of the population

3. Diseases for which the community raises money for treatment

4. Serious and life-threatening conditions that lack effective treatments

Correct Answer: 4

Rationale 1: The process does not cover only diseases that were covered with older drugs, but also diseases that are serious and lack effective treatment.

Rationale 2: There are serious diseases that affect only a small percentage of the population, but this is not a criterion for the accelerated process.

Rationale 3: Although the community might raise money for serious and life-threatening conditions, that is not a criterion for accelerated FDA approval.

Rationale 4: The accelerated approval process is for drugs for serious and life-threatening conditions.

Global Rationale: The accelerated approval process is for drugs for serious and life-threatening conditions. The process does not cover only diseases that were covered with older drugs, but also diseases that are serious and lack effective treatment. There are serious diseases that affect only a small percentage of the population, but this is not a criterion for the accelerated process. Although the community might raise money for serious and life-threatening conditions, that is not a criterion for accelerated FDA approval.

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes

AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Policies and procedures
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-7 Discuss how changes to the approval process have increased the speed at which new drugs reach consumers.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology.
Page Number:

Question 16
Type: MCSA

The nurse is teaching a class about over-the-counter (OTC) medications at a senior citizen center. Which statement by a participant indicates the teaching was effective?

1. "Over-the-counter medications are safe, as long as we don't take them at the same time as our prescription medications."

2. "Over-the-counter medications are safe; otherwise, they would require a prescription."

3. "We should not take any over-the-counter medications without first calling our primary health care provider because these medications can interact with other prescriptions or products."

4. "We must read all the label directions before taking any over-the-counter medications."

Correct Answer: 3

Rationale 1: Some OTC medications can be taken with prescription medications; others cannot.

Rationale 2: Although they have a high margin of safety, OTC medications are not without risks.

Rationale 3: Elderly clients often take multiple medications and should consult with their health care provider before taking any over-the-counter medication or supplement to ensure there are no risks for drug interactions.

Rationale 4: It is important for clients to read all directions on the label, but this will not protect them if there is a contraindication with another medication they are taking; therefore, they must consult their primary health care provider before taking any OTC medications.

Global Rationale: Elderly clients often take multiple medications and should consult with their health care provider before taking any over-the-counter medication or supplement to ensure there are no risks for drug interactions. This statement indicates adequate understanding of the session. Some OTC medications can be taken with prescription medications; others cannot. Although they have a high margin of safety, OTC medications are not without risks. It is important for clients to read all directions on the label, but this will not protect them if there is a contraindication with another medication they are taking; therefore, they must consult their primary health care provider before taking any OTC medications.

Cognitive Level: Applying

Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Current best practice
Nursing/Integrated Concepts: Nursing Process: Evaluation
Learning Outcome: 2-8 Compare and contrast prescription and over-the-counter drugs
MNL Learning Outcome: 1.1.3 Relate processes of pharmacokinetics and pharmacodynamics to the therapeutic effect(s) of a drug.
Page Number:

Question 17
Type: MCSA

The client was taking a prescription medication that is now available over the counter. The client asks the nurse, "Why do some medications become available over the counter and other medications remain prescription drugs?" Which response by the nurse is the most appropriate?

1. "Drugs with the least amount of side effects can become over-the-counter."

2. "Drugs that have a high safety margin may be reclassified to over-the-counter."

3. "The longer the drug is on the market, the better its chance of going over-the-counter."

4. "If the pharmaceutical company pays the FDA a large amount of money, it can have its drug reclassified."

Correct Answer: 2

Rationale 1: The number of side effects does not determine whether a drug is to be considered for over-the-counter (OTC) classification.

Rationale 2: Drugs that have a high safety margin may be reclassified as OTC drugs.

Rationale 3: The amount of time a drug is on the market does not influence the ability to change to OTC. Many drugs have been available for over 100 years and remain prescription.

Rationale 4: The FDA does not select drugs for OTC status based on fees paid by drug companies.

Global Rationale: Drugs that have a high safety margin may be reclassified as OTC drugs. The number of side effects does not determine whether a drug is to be considered for over-the-counter (OTC) classification. The amount of time a drug is on the market does not influence the ability to change to OTC. Many drugs have been available for over 100 years and remain prescription. The FDA does not select drugs for OTC status based on fees paid by drug companies.

Cognitive Level: Applying
Client Need: Physiological Integrity

Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Current best practice
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-8 Compare and contrast prescription and over-the-counter drugs
MNL Learning Outcome: 1.1.3 processes of pharmacokinetics and pharmacodynamics to the therapeutic effect(s) of a drug.
Page Number:

Question 18
Type: MCMA

A client says to the admitting nurse, "Why do you need to know the names of all the over-the-counter supplements I take? They aren't drugs." Which responses by the nurse are the most appropriate?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. "The admitting physician needs to know everything you are taking."

2. "You're right. I'm not sure why the admitting paperwork asks for this information. Would you mind listing them anyway?"

3. "The law requires us to keep a list of over-the-counter drugs and supplements that you are taking."

4. "It is true that supplements are not considered drugs; however, some of these products can cause adverse effects with prescribed drugs."

5. "We need to know if you are having an allergic reaction to one of them."

Correct Answer: 1,4

Rationale 1: The health care providers involved in this client's care will need to know everything she is taking—both prescription and over-the-counter (OTC).

Rationale 2: While it is true that supplements are not considered drugs, there is a specific reason why the health care team needs to know this information, which is the reason for the requested list on the paperwork. The nurse's answer did not address the client's question appropriately.

Rationale 3: No law requires hospitals to keep records of OTC drugs and supplements that clients take. This information is needed, however, for other reasons.

Rationale 4: Supplements are not subject to the same regulatory process as drugs, and some of these products can cause adverse effects and interact with medications.

Rationale 5: It is possible that this client could be having an allergic reaction, but there is not enough information to determine this, and this is not the main reason why the health care team needs to know what OTC medications she is taking.

Global Rationale: The health care providers involved in this client's care will need to know everything she is taking—both prescription and over-the-counter (OTC). Supplements are not subject to the same regulatory process as drugs, and some of these products can cause adverse effects and interact with medications. While it is true that supplements are not considered drugs, there is a specific reason why the health care team needs to know this information, which is the reason for the requested list on the paperwork. The nurse's answer did not address the client's question appropriately. No law requires hospitals to keep records of OTC drugs and supplements that clients take. This information is needed, however, for other reasons. It is possible that this client could be having an allergic reaction, but there is not enough information to determine this, and this is not the main reason why the health care team needs to know what OTC medications she is taking.

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Current best practice
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-8 Compare and contrast prescription and over-the-counter drugs
MNL Learning Outcome: 1.1.3 Relate processes of pharmacokinetics and pharmacodynamics to the therapeutic effect(s) of a drug.
Page Number:

Question 19
Type: MCSA

The client says to the nurse, "I wonder if I am considered a drug addict. I went to pick up my medication from the drug store and the pharmacist told me that the drug was a controlled substance." Which response by the nurse is the most appropriate?

1. "If you continue on this medication for a long time, you will become addicted to it."

2. "You are not an addict, but the Drug Enforcement Agency (DEA) will be watching your prescription drug habits now."

3. "Any drug that has a potential for abuse is considered a controlled substance and is restricted. This does not mean the pharmacist will think you are an addict."

4. "Do you think that you are addicted to your medication?"

Correct Answer: 3

Rationale 1: Clients can be on controlled substances for various lengths of time without becoming addicted.

Rationale 2: The DEA does not monitor the prescription drug habits of every client who receives a controlled substance.

Rationale 3: The pharmacist recognizes all drugs with the potential for abuse are considered controlled substances and carry restrictions but most likely will not think the client is a drug addict.

Rationale 4: Asking the client if he thinks he is addicted does not answer his question about controlled substances.

Global Rationale: The pharmacist recognizes all drugs with the potential for abuse are considered controlled substances and carry restrictions but most likely will not think the client is a drug addict. Clients can be on controlled substances for various lengths of time without becoming addicted. The DEA does not monitor the prescription drug habits of every client who receives a controlled substance. Asking the client if he thinks he is addicted does not answer his question about controlled substances.

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: I.A.7 Explore ethical and legal implications of patient-centered care
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Policies and procedures
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-9 Explain how scheduled drugs are classified and regulated.
MNL Learning Outcome: 1.7.1 Compare the classes of medications used to treat pain.
Page Number:

Question 20
Type: MCSA

The nurse is working in a cancer treatment center. A client diagnosed with terminal cancer has received a prescription for morphine (MS Contin), a schedule II drug for pain control. After medication teaching, which statement by the client indicates appropriate understanding?

1. "I should call the office three days before I need a refill called in to the pharmacy."

2. "I will need to see the provider each time for my refill."

3. "This is an addictive drug, so I should try not to take it."

4. "After the first prescription, my doctor will be able to call in my prescription."

Correct Answer: 2

Rationale 1: Schedule II drugs cannot not have refills called into the pharmacy.

Rationale 2: The client will need to see the provider each time a refill is needed.

Rationale 3: The client should take the drug as it is needed and directed. Addiction is not a concern at this time.

Rationale 4: Schedule II medications cannot be called into the pharmacy.

Global Rationale: The client will need to see the provider each time a refill is needed and this indicates the client has understood the information presented. Schedule II drugs cannot not have refills called into the pharmacy. The client should take the drug as it is needed and directed. Addiction is not a concern at this time. Schedule II medications cannot be called into the pharmacy.

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: I.A.7 Explore ethical and legal implications of patient-centered care
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Policies and procedures
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-9 Explain how scheduled drugs are classified and regulated.
MNL Learning Outcome: 1.7.1. Compare the classes of medications used to treat pain.
Page Number:

Question 21
Type: MCSA

A nurse educator is preparing a lecture regarding prescriptive authority for advanced practice registered nurses (APRNs). Which statement is appropriate for the educator to include in the lecture regarding this topic?

1. APRNs can only prescribe medications when under the supervision of a physician.

2. APRNs prescribe medication based on federal regulations.

3. APRNs prescribe medication based on state regulations.

4. APRNs prescribe medication based on local regulations.

Correct Answer: 3

Rationale 1: While some states mandate that APRNs can only prescribe under the supervision of a physician, this is not applicable for all states and is not an appropriate statement to include in the lecture.

Rationale 2: APRNs prescribe medication based on state regulations, not federal regulations.

Rationale 3: APRNs prescribe medication based on state regulations. This is an appropriate statement to include in the lecture.

Rationale 4: APRNs prescribe medication based on state regulations, not local regulations.

Global Rationale: APRNs prescribe medication based on state regulations. While some states mandate that APRNs can only prescribe under the supervision of a physician, this is not applicable for all states and is not an appropriate statement to include in the lecture.

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: II.A.2 Describe scopes of practice and roles of health care team members
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Teamwork: Scope of practice, roles, and responsibilities of health care team members, including overlaps
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 2-10 Discuss the requirements and regulations needed for nurses to have the ability to prescribe drugs
MNL Learning Outcome: 1.3.3 Implement the nursing process in the administration of medications.
Page Number:

Question 22
Type: MCMA

The nurse is teaching a client the importance that a placebo plays in drug research. Which items are appropriate for the nurse to include in the teaching session?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. The research drug must be compared to an inert substance to determine effectiveness.

2. The placebo will be given to a control group, and those results will be compared to the group taking the research drug.

3. During the trials, neither group will know if they have the placebo drug or the research drug.

4. The research drug will be considered for a New Drug Application (NDA) if it is found to be effective and safe when compared to the placebo drug.

5. Before the clinical trials, the research drug will be tested on select clients against another standard drug used for the same condition.

Correct Answer: 1,2,3,4

Rationale 1: The primary focus of a clinical trial is to provide information regarding the effectiveness of the research drug. The effectiveness of the research drug will be compared to an inert substance taken by a nontreatment group, called the *control group*.

Rationale 2: The primary focus of a clinical trial is to provide information regarding the effectiveness of the research drug. The effectiveness of the research drug will be compared to an inert substance taken by a nontreatment group, called the *control group*.

Rationale 3: Clients may have a perceived or actual improvement in a medical condition if they know they are taking the research drug. Clients may also feel there is no improvement if they know they are taking a drug that has inert properties.

Rationale 4: If the research drug continues to show that it is effective and safe, an NDA will be submitted to the Federal Drug Administration (FDA).

Rationale 5: In some cases, the research drug may be compared to a standard drug used for the same condition, but only during clinical trials. Preclinical research does not include testing on humans.

Global Rationale: The primary focus of a clinical trial is to provide information regarding the effectiveness of the research drug. The effectiveness of the research drug will be compared to an inert substance taken by a nontreatment group, called the *control group*. If the research drug continues to show that it is effective and safe, an NDA will be submitted to the Federal Drug Administration (FDA). In some cases, the research drug may be compared to a standard drug used for the same condition, but only during clinical trials. Preclinical research does not include testing on humans.

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: III.A.1 Demonstrate knowledge of basic scientific methods and processes
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Quality and Safety: Current best practices
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-6 Explain the role of a placebo in new drug testing.
MNL Learning Outcome: 1.1.1 Apply basic concepts related to pharmacology
Page Number:

Question 23
Type: MCMA

A nurse educator is discussing the prescriptive authority of health care providers to a group of new employees. Which health care providers are able to prescribe medications to clients?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. Registered nurses

2. Physicians

3. Nurse practitioners

4. Nurse managers

5. Physical therapists

Correct Answer: 2,3

Rationale 1: Registered nurses can administer medications but it is outside the scope of practice to prescribe medications.

Rationale 2: Physicians are able to prescribe medications.

Rationale 3: Nurse practitioners are able to prescribe medications.

Rationale 4: A nurse manager may or may not be able to prescribe medications; this is dependent on the nurse manager licensure.

Rationale 5: Physical therapists can prescribe therapies but not medications.

Global Rationale: Physicians and nurse practitioners are able to prescribe medications. Registered nurses can administer medications but it is outside the scope of practice to prescribe medications. A nurse manager may or may not be able to prescribe medications; this is dependent on the nurse manager licensure. Physical therapists can prescribe therapies but not medications.

Cognitive Level: Understanding
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
QSEN Competencies: II.A.2 Describe scopes of practice and roles of health care team members
AACN Essential Competencies: IX.3. Implement holistic, patient-centered care that reflects an understanding of human growth and development, pathophysiology, pharmacology, medical management and nursing management across the health-illness continuum, across lifespan, and in all healthcare settings
NLN Competencies: Teamwork: Scope of practice, roles, and responsibilities of health care team members, including overlaps
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-10 Discuss the requirements and regulations needed for nurses to have the ability to prescribe drugs.
MNL Learning Outcome: 1.3.3. Implement the nursing process in the administration of medications.
Page Number: