Pharmacology for Nurses 6th edition Adams Test Bank

SKU: 9780135218334-TEST-BANK

***Pharmacology for Nurses, 6e* (Adams)**
Chapter 2 Drug Approval and Regulation

1) A pharmaceutical representative comes to the physician's office and says his company's pharmaceutical laboratory is marketing a drug that does not need approval by the Food and Drug Administration (FDA). What is the best response by the nurse?
    1. "Any pharmaceutical laboratory in America must have approval from the Food and Drug Administration (FDA) before marketing a drug."
    2. "Is this an over-the-counter (OTC) drug? They do not need approval by the Food and Drug Administration (FDA)."
    3. "Is your pharmaceutical laboratory private? Only public pharmaceutical laboratories need approval from the Food and Drug Administration (FDA)."
    4. "Your pharmaceutical laboratory must be involved in academic research because they are exempt from approval by the Food and Drug Administration (FDA)."

Answer: 1
Explanation:
    1. Any pharmaceutical laboratory must obtain approval from the Food and Drug Administration (FDA) before marketing a drug.
    2. Pharmaceutical laboratories that manufacture over-the-counter (OTC) drugs must obtain approval from the Food and Drug Administration (FDA) before marketing these drugs.
    3. Private pharmaceutical laboratories must obtain approval from the Food and Drug Administration (FDA) before marketing a drug.
    4. Pharmaceutical laboratories involved in academic research must obtain approval from the Food and Drug Administration (FDA) before marketing a drug.

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Cognitive Level: Applying
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.1 Demonstrate basic knowledge of healthcare policy, finance and regulatory environments; including local, state, national, and global healthcare trends. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Analysis
Learning Outcome: 2-2 Discuss the role of the U.S. Food and Drug Administration (FDA) in the drug approval process.
MNL Learning Outcome: 2.2 Examine the role of the U.S. Food and Drug Administration in the process of drug approval and drug safety.

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2) A nurse is employed by the Food and Drug Administration (FDA) and is involved in clinical investigation. The nurse's primary role in this phase of the FDA review and approval is to perform tests on which of the following?
    1. The population-at-large
    2. Various species of animals
    3. Human cells cultured in the laboratory
    4. Human clients

Answer: 4

Explanation:

1. Performing tests on the population-at-large is the stage of postmarketing surveillance.
2. Performing tests on various species of animals is the preclinical investigation stage.
3. Performing tests on human cells cultured in the laboratory is the preclinical investigation stage.
4. Clinical investigation includes performing tests on healthy volunteers, and later, on selected clients with a particular disease.

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation

Learning Outcome: 2-3 Explain the four phases of approval for therapeutic and biological drugs.

MNL Learning Outcome: 2.2 Examine the role of the U.S. Food and Drug Administration in the process of drug approval and drug safety.

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3) A student nurse is taking a pharmacology course and studying about the Food and Drug Administration (FDA). Which statement indicates the student understands how the FDA has decreased the amount of time involved in bringing a new drug to the market?
    1. "The Food and Drug Administration (FDA) is not as strict as it once was with regard to drug approval."
    2. "Since consumers have demanded more drugs, the Food and Drug Administration (FDA) has streamlined the review/approval process."
    3. "Drug manufacturers are required to pay yearly user fees, which allow the Food and Drug Administration (FDA) to hire more employees to increase its efficiency."
    4. "Drug manufacturers are required by the Food and Drug Administration (FDA) to test more drugs on an annual basis."

Answer: 3

Explanation:

1. The Food and Drug Administration (FDA) is just as strict now as it always was with regard to drug approval.
2. The Food and Drug Administration (FDA) has not streamlined the review/approval process.
3. In 1992, the Prescription Drug User Fee Act was passed. This required drug manufacturers to provide yearly product user fees so the Food and Drug Administration (FDA) could restructure, hire more employees, and operate more efficiently.
4. The Food and Drug Administration (FDA) does not require drug manufacturers to test more drugs on an annual basis.

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Evaluation

Learning Outcome: 2-4 Discuss how the FDA has increased the speed with which new drugs reach consumers.

MNL Learning Outcome: 2.2 Examine the role of the U.S. Food and Drug Administration in the process of drug approval and drug safety.

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4) A client has skin lesions that have not responded to prescription drugs. He tells the nurse he has heard about some research going on with a new drug and asks why he can't take it. What is the best response by the nurse?
    1. "I know it is frustrating, but the Food and Drug Administration (FDA) approval process is in place to ensure that drugs are safe."
    2. "The Food and Drug Administration (FDA) has very strict rules about new drugs; it is important to be patient regarding the review/approval process."
    3. "Your skin lesions really aren't that bad, but maybe the new drug will be available soon."
    4. "Maybe you could contact the drug company about becoming involved in a clinical trial."

Answer: 1

Explanation:

1. Although the public is anxious to receive new drugs, the fundamental priority of the Food and Drug Administration (FDA) is to ensure that drugs are safe. Also, telling the client that the nurse knows he is frustrated is therapeutic because it communicates that the nurse recognizes what he is feeling.
2. Telling the client to be patient is a condescending response; the client wants relief from the skin condition.
3. Telling the client his skin lesions"aren't that bad" is a nontherapeutic response; the client's perception is his reality.
4. The client could contact the drug company, but this response fosters false hope as he may not be a viable candidate for this drug.

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

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5) A client asks a nurse how many Americans take at least one prescription drug per year. What is the nurse's best response?
    1. 50%
    2. 10%
    3. 40%
    4. 25%

Answer: 1

Explanation:
    1. About half of Americans take prescription drugs while about 17% take at least three prescription drugs.
    2. The percentage of Americans taking at least one prescription drug is higher.
    3. This is not the percentage of Americans taking at least one prescription drug.
    4. This is not the percentage of Americans taking at least one prescription drug.

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Cognitive Level: Analyzing

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: III.B.4 Read original research and evidence reports related to area of practice. | AACN Essential Competencies: III.1 Explain the interrelationships among theory, practice, and research. | NLN Competencies: Knowledge and Science: Relationships between knowledge/science and quality and safe patient care. | Nursing/Integrated Concepts: Nursing Process: Assessment

Learning Outcome: 2-1 Identify key U.S. drug regulations that have provided guidelines for the safe and effective use of drugs and drug therapy.

MNL Learning Outcome: 2.2 Examine the role of the U.S. Food and Drug Administration in the process of drug approval and drug safety.

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6) A nurse is teaching a medication class for parents of children with attention-deficit hyperactivity disorder (ADHD) who are receiving stimulant medications. The nurse has reviewed reasons why the medications are restricted. The nurse determines that learning has occurred when the parents make which responses?

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

1. "The use of these medications is restricted so that the pharmacies can track the rate of drug abuse in our city."
2. "The use of these medications is restricted because the physician needs to evaluate our child more often."
3. "The use of these medications is restricted because they have the potential for abuse."
4. "The use of these medications is restricted so that the drug companies can make a bigger profit."
5. "The use of these medications is restricted because this is the current law."

Answer: 3, 5

Explanation:

1. Pharmacies do not track the rate of drug abuse in cities.
2. More frequent evaluations is a good plan, but this is not the reason for restricted use of stimulant medications.
3. Medications with abuse potential are restricted.
4. Drug companies do not make a bigger profit when medications are listed as restricted.
5. The Controlled Substance Act is the law under which medications with abuse potential are restricted. Stimulant medications are considered controlled substances.

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Evaluation

Learning Outcome: 2-7 Discuss why drugs are sometimes placed on a restrictive list, and the controversy surrounding this issue.

MNL Learning Outcome: 2.4 Recognize controlled substances and drug schedules.

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7) A client says to a nurse, "My healthcare provider said my drug is a controlled substance; am I considered an addict?" What is the best response by the nurse?
   1. "Are you concerned about becoming an addict? We can discuss this in more detail if you would like to."
   2. "You are not an addict; the Drug Enforcement Administration (DEA) restricts the use of drugs with a high potential for abuse."
   3. "Why do you ask about becoming an addict? Not many of our clients have asked this question."
   4. "You are not an addict, but the Drug Enforcement Administration (DEA) will monitor you for this."

Answer: 2
Explanation:
   1. It is premature at this time to ask the client if he is concerned about addiction; there is no information to support an addiction.
   2. Drugs that have a high potential for addiction are considered controlled substances.
   3. "Why" questions are considered nontherapeutic because they put the client on the defensive mood.
   4. The Drug Enforcement Administration (DEA) does not monitor clients for addiction when they receive controlled substances.

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Cognitive Level: Applying
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-6 Explain the U.S. Controlled Substance Act of 1970 and the role of the U.S. Drug Enforcement Administration in controlling drug abuse and misuse.
MNL Learning Outcome: 2.4 Recognize controlled substances and drug schedules.

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8) A client is receiving methadone (which is a Schedule II drug). The client says to the nurse,"A pharmacist told me the pharmacy must register with the Drug Enforcement Administration (DEA) to give me this drug; will DEA agents be snooping around my house?" What is the best response by the nurse?
   1. "It is probably unlikely that Drug Enforcement Administration (DEA) agents will be bothering you."
   2. "No, the Drug Enforcement Administration (DEA) restricts drugs that have a high potential for abuse."
   3. "No. I think our system should be more like Europe; they have fewer controlled drugs."
   4. "That's an interesting question. Are you worried about the Drug Enforcement Administration (DEA)?"

Answer: 2
Explanation:
   1. Telling the client that Drug Enforcement Administration (DEA) agents will "probably" not bother him can lead the client to think DEA agents might bother him.
   2. The Controlled Substance Act of 1970 restricts the use of drugs that have a high potential for abuse. Hospitals and pharmacies must register with the Drug Enforcement Administration (DEA) to obtain a specific registration number that will enable them to purchase controlled drugs.
   3. By saying that our system should be more like Europe's, the nurse is introducing her beliefs and this is nontherapeutic; the client may not agree.
   4. Asking the client if he is worried about the Drug Enforcement Administration (DEA) puts him on the defensive mode and is nontherapeutic.

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Cognitive Level: Applying
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation
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MNL Learning Outcome: 2.4 Recognize controlled substances and drug schedules.

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9) During the admission assessment, a client tells a nurse, "Sure I smoke a little weed (marijuana) to manage my stress. Doesn't everyone?" What is the nurse's best response?
    1. "What other ways do you think you might use to help you to manage your stress?"
    2. "Aren't you afraid of going to jail for a long time if you get caught?"
    3. "Do you really believe that everyone smokes marijuana to manage stress?"
    4. "How often do you smoke marijuana, and how much each time?"

Answer: 4

Explanation:

1. Stress management is not the main concern during the admission assessment.
2. Asking the client if he is afraid of going to jail is not an assessment question and is not the issue during the admission assessment.
3. Asking the client if he really believes something is not an assessment question and can lead to an argument with the client.
4. The nurse must assess the amount and frequency of any drug the client uses, including illegal drugs.

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation

Learning Outcome: 2-9 Identify the five drug schedules and give examples of drugs at each level.

MNL Learning Outcome: 2.4 Recognize controlled substances and drug schedules.

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10) A parent of an adolescent receiving methylphenidate (Concerta) for ADHD asks why she needs a new prescription each month. What is the best response by the nurse?
    1. "Just drop by and I will get you a prescription."
    2. "We can't do that; maybe you can find another doctor's office that will do it."
    3. "The law does not allow us to give you refills on this medication."
    4. "How do you feel about having to get a new prescription each month?"

Answer: 3

Explanation:

1. Although it's true that the parent will need to get a new written prescription each month, this response doesn't really answer the parent's question, so it's not the best answer.
2. Referring the parent to another office is nontherapeutic and implies that other medical offices violate the law.
3. Telling the mother about the law is accurate and is the only response that answers the parent's question.
4. Although this is a therapeutic response, it doesn't answer the parent's question

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation

Learning Outcome: 2-7 Discuss why drugs are sometimes placed on a restrictive list, and the controversy surrounding this issue.

MNL Learning Outcome: 2.4 Recognize controlled substances and drug schedules.

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11) A client who is terminally ill reports hearing about a drug that is in preclinical investigation. The client asks the nurse if the drug will be available to the public soon. What should the nurse consider when formulating an answer to this question?
    1. After preclinical investigation the drug has one more step before being released for public use.
    2. The average length of preclinical investigation is 18 months.
    3. When the drug reaches the clinical investigation stage it is usually released within 2 years.
    4. The drug will not be available until after the postmarketing studies are done.

Answer: 2

Explanation:

1. Preclinical investigation is the first of three stages the drug must go through before being released for use.
2. Preclinical investigation may last 1-3 years with 18 months being the average.
3. Clinical investigation may last 2-10 years with 5 years being the average.
4. Postmarketing studies are started as soon as the NDA review is completed and may continue for years after drug release.

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Planning

Learning Outcome: 2-3 Explain the four phases of approval for therapeutic and biological drugs.

MNL Learning Outcome: 2.3 Identify the 4 stages of drug approval.

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12) A nurse provides medication education to a client with terminal cancer. The physician has ordered morphine, a Schedule II drug, for the client. The nurse determines that learning has occurred when the client makes which statement?
    1. "I need to call the office for a refill before my medication runs out."
    2. "This drug is addictive so I should only take it when my pain becomes severe."
    3. "Maybe my physician could change me to a Schedule IV drug."
    4. "I need to see my doctor before my prescription runs out so I can get a refill."

Answer: 4

Explanation:
    1. Schedule II drugs cannot be refilled by phone order.
    2. Not taking pain medication until the pain becomes severe is an inappropriate use of pain medication for a client with terminal cancer.
    3. A Schedule IV drug may not effectively relieve the client's pain.
    4. The client must see the physician for a refill.

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Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Evaluation
Learning Outcome: 2-7 Discuss why drugs are sometimes placed on a restrictive list, and the controversy surrounding this issue.
MNL Learning Outcome: 2.4 Recognize controlled substances and drug schedules.

13) A nurse is teaching a student nurse about the stages of drug approval. A drug manufacturer that is studying the effects of a drug on laboratory animals would be in which phase of the new drug development timeline?
    1. Clinical Investigation
    2. Preclinical Investigation
    3. New Drug Application Review
    4. Postmarketing Studies

Answer: 2

Explanation: 1. Clinical investigation involves testing the drug on human subjects.
2. Preclinical investigation involves laboratory research on nonhuman subjects.
3. New Drug Application review occurs during human clinical trials.
4. Postmarketing Studies occur after the drug is being used by the general population.

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Cognitive Level: Applying
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN

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Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-3 Explain the four phases of approval for therapeutic and biological drugs.
MNL Learning Outcome: 2.3 Identify the 4 stages of drug approval.

14) While reading a medication package insert, a nurse notes the information contained within the "black box." What is the significance of this information to the nurse?
Note: Credit will be given only if all correct choices and no incorrect choices are selected. Select all that apply.
1. The drug can cause "special problems."
2. It identifies extreme adverse drug reactions.
3. It differentiates a prescribed medication from an over-the-counter medication.
4. It highlights the cost of the medication.
5. It signifies the medication is generic.

Answer: 1, 2
Explanation:
1. The FDA created boxed warnings in order to regulate drugs with "special problems."
2. The black box warning is a primary alert for identifying extreme adverse drug reactions.
3. Black box warnings are not a mechanism to differentiate a prescribed medication from an over-the-counter medication.
4. It does not highlight the cost of the medication.
5. It does not signify the medication as being generic.

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Cognitive Level: Analyzing
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Learning Outcome: 2-1 Identify key U.S. drug regulations that have provided guidelines for the safe and effective use of drugs and drug therapy.
MNL Learning Outcome: 2.2 Examine the role of the U.S. Food and Drug Administration in the process of drug approval and drug safety.

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15) A nurse is participating in the New Drug Review step for a new therapeutic agent. Which activities will the nurse most likely perform during this phase of the drug approval process?
Note: Credit will be given only if all correct choices and no incorrect choices are selected. Select all that apply.

1. Attend meetings to finalize the brand name for the drug.
2. Check on the results of animal testing.
3. Survey for harmful effects in a larger population.
4. Evaluate the results of the drug on cultured cells.
5. Provide the medication to large groups of people with a particular disease.

Answer: 1, 2
Explanation:

1. During the NDA or the third stage of the drug approval process, the drug's brand name is finalized.
2. During the NDA stage of the drug approval process, animal testing may continue.
3. Surveying for harmful effects in a larger population occurs during the postmarketing surveillance step of the drug approval process.
4. Evaluation of the results of the drug on cultured cells occurs during the preclinical investigation step of the drug approval process.
5. Providing the medication to large groups of people with a particular disease occurs during the clinical phase trials, which is in the second stage of the drug approval process.

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Cognitive Level: Applying
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation
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16) A nurse is teaching a group of nursing students about the role of the U.S. Food and Drug Administration (FDA). The nurse plans to include which of the following?

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

1. Responsible for improving the health of Americans.
2. Publishes a summary of the standards of drug purity and strength.
3. Ensures the availability of effective drugs.
4. Takes action against any supplement that is deemed to be unsafe.
5. Facilitates the availability of safe drugs.

Answer: 1, 3, 4, 5

Explanation:

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

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Planning

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17) A nurse is teaching a group of nursing students about the preclinical research stage of drug development. The nurse understands that the students understand the teaching by which of the following student responses?

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

Answer: 1, 3, 4

Explanation:

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.
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.
3. The preclinical stage involves extensive testing on human, microbial cells, and animals to determine drug action and to predict whether the drug will cause harm to humans.
4. Because lab tests cannot accurately predict human response to a drug, these results are always inconclusive.
5. This extensive testing is done by the pharmaceutical company in the preclinical research stage of drug development, not the FDA.

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Cognitive Level: Applying

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18) A nurse is developing a time line of drug regulations and standards. The nurse should list which of the following events as the first drug regulation and/or standard?
    1. Passage of the Sherley Amendment
    2. Passage of the Childhood Vaccine Act
    3. Development of the U.S. Pharmacopoeia
    4. Passage of the Biologics Control Act

Answer: 3

Explanation:

1. Passed in 1912, the Sherley Amendment made medicines safer by prohibiting the sale of drugs labeled with false therapeutic claims.
2. The Childhood Vaccine Act was passed in 1986 and allowed the FDA to acquire information about clients taking vaccines, to recall biologics, and to recommend civil penalties if guidelines regarding biologic use were not followed
3. The U.S. Pharmacopoeia was established in 1820 and served as the first comprehensive publication of drug standards.
4. The Biologics Control Act was passed in 1902 and controlled the quality of serums and other blood-related products.

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Analysis

Learning Outcome: 2-1 Identify key U.S. drug regulations that have provided guidelines for the safe and effective use of drugs and drug therapy.

MNL Learning Outcome: 2.1 Consider the history of drug legislation and its effect on drug standards and safety.

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19) A nurse is teaching a client about their medications. The client is worried about "getting addicted" to their medications. The nurse explains that which of the following drugs has the highest risk for dependence?
    1. Acetaminophen
    2. Codeine
    3. Heroin
    4. Diazepam

Answer: 3

Explanation:
    1. Acetaminophen does not have a high abuse potential.
    2. Codeine is a Schedule III drug.
    3. Heroin is a Schedule I drug and has the highest potential for abuse, physical dependence, and psychological dependence of the drugs listed.
    4. Diazepam is a Schedule IV drug.

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation

Learning Outcome: 2-9 Identify the five drug schedules and give examples of drugs at each level.

MNL Learning Outcome: 2.4 Recognize controlled substances and drug schedules.

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20) A drug is withdrawn from a client who has been taking it routinely for many years. The client has developed muscle tremors. How will the nurse document this event?
    1. An adverse effect
    2. Evidence that the client had psychological dependence on the drug
    3. An expected therapeutic effect of no longer taking the drug
    4. Assessment finding associated with physical dependence on a drug

Answer: 4

Explanation:

1. Adverse effects are seen while the drug is being taken, not after it is withdrawn.
2. With psychological dependence, few physical signs are seen.
3. Therapeutic effects are seen while drugs are being used, not after they have been removed.
4. The presence of physical withdrawal symptoms (muscle tremors) is seen when a person is physically dependent on a drug and the drug is removed.

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: I.B.5 Assess levels of physical and emotional comfort. | AACN Essential Competencies: IX.3 Implement holistic, patient-centered care that reflects and 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: Integration of knowledge from nursing and other disciplines. | Nursing/Integrated Concepts: Nursing Process: Analysis

Learning Outcome: 2-8 Explain the meaning of a controlled substance and teratogenic risk in pregnancy.

MNL Learning Outcome: 2.2 Examine the role of the U.S. Food and Drug Administration in the process of drug approval and drug safety.

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21) The nurse is reviewing prescription refill request messages. The nurse understands that a prescription for which of the following drugs can be sent to the pharmacy by telephone?
    1. Morphine
    2. Cannabis
    3. Meperidine
    4. An anabolic steroid

Answer: 4
Explanation:
    1. Morphine is a Schedule II drug. Telephone prescription requests are not allowed. The client must be examined by a physician prior to a new prescription being written.
    2. Cannabis is a Schedule I drug. Telephone prescriptions requests are not allowed.
    3. Meperidine is a Schedule II drug. Telephone prescription requests are not allowed.
    4. Anabolic steroids are Schedule III drugs. Telephone prescription refills are allowed.

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Cognitive Level: Analyzing
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-5 Identify the advanced practice registered nurse's role in prescribing drugs.
MNL Learning Outcome: 2.4 Recognize controlled substances and drug schedules.

22) A nurse is administering a medication to a group of volunteers and is assessing for the development of adverse effects. The nurse is working in which phase of the development of this drug?
    1. Clinical Phase I Trials
    2. Preclinical Investigation
    3. Clinical Phase II trials
    4. Clinical Phase III trials

Answer: 1
Explanation:
    1. The Clinical Phase I Trial is when investigators first begin to administered the drug to volunteers to determine proper dosage and to assess for adverse effects.
    2. Preclinical investigation is done on human and microbial cells.
    3. Lasts about two years and involves 100-300 volunteer patients with the disease.
    4. Takes about three years and involves 1000-3000 patients in hospitals and clinic agencies.

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Cognitive Level: Applying
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and

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standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-3 Explain the four phases of approval for therapeutic and biological drugs.
MNL Learning Outcome: 2.3 Identify the 4 stages of drug approval.

23) A client has been chosen to participate in the clinical trial of a medication to treat chemotherapy-induced nausea. When the nurse takes the informed consent form to the bedside, the client says, "I am glad there is finally a medication to cure my cancer." How should the nurse respond?

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

1. "Who told you the medication would cure your cancer?"
2. "What questions do you have about this medication?"
3. "Let me explain how this medication works."
4. "Has anyone explained the research trial to you?"
5. "So am I. This research has been intense."

Answer: 2, 4
Explanation:

1. It is not important to discover who specifically gave the client this information.
2. The nurse should be certain the client has no questions prior to having the consent signed.
3. It is not the nurse's responsibility to explain how the medication works. It is the responsibility of the researcher or healthcare provider. The nurse should refer questions to those individuals.
4. It is the nurse's responsibility to ensure that the client has been provided with facts about the medication and the clinical trial prior to having the consent signed.
5. The nurse should identify that this client does not fully understand the purpose of this medication and should collaborate with the researcher or healthcare provider regarding this misunderstanding.

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Cognitive Level: Analyzing
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: QSEN Competencies: I.B.12 Facilitate informed patient consent for care. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-5 Identify the nurse's role in the drug approval process and in maintaining safety practices.
MNL Learning Outcome: 2.2 Examine the role of the U.S. Food and Drug Administration in the process of drug approval and drug safety.

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24) A student nurse asks a nurse why some medications get approved by the Federal Drug Administration (FDA) faster. What is the nurse's best response?
    1. The FDA collects a user fee from pharmaceutical companies and uses it to hire more employees to speed up the process.
    2. Pharmaceutical companies are allowed to skip the Preclinical Investigation phase if they are developing a chemotherapy drug.
    3. The Accelerated Approval Program allows earlier approval of a medication if it is a commonly used drug.
    4. A smaller group of patients with a particular disease are selected for the clinical phase trials.

Answer: 1

Explanation:

1. The Prescription Drug User Fee was enacted in 1992. Drug manufacturers are required to pay a user fee annually. The FDA uses this money to hire more employees and speed up the approval process.
2. Drug companies that manufacture medications for serious conditions, such as cancer, still have to follow the entire FDA new drug application process.
3. The Accelerated Approval Program allows for earlier approval of a new drug that is used to treat serious medical problems.
4. A large group of patients with that medical disease are selected for clinical trials.

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation

Learning Outcome: 2-5 Identify the nurse's role in the drug approval process and in maintaining safety practices.

MNL Learning Outcome: 2.4 Recognize controlled substances and drug schedules.

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25) A student nurse asks an advanced practice nurse (APRN) about the role of APRNs in prescribing medications. Which of the following is the best response by the nurse?
    1. The ability to prescribe drugs is regulated by federal law.
    2. All advanced practice nurses can prescribe medications.
    3. Nurse practitioners are an example of an advanced practice nurse.
    4. Advanced practice nurses may increase the cost of healthcare.

Answer: 3

Explanation:
    1. The ability to prescribe medications is regulated by state laws, not federal law.
    2. Some states have not authorized APRNs to prescribe medications.
    3. Nurse practitioners are an example of an advanced practice nurse.
    4. Advanced practice nurses can decrease the cost of healthcare.

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Cognitive Level: Applying
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Planning
Learning Outcome: 2-5 Identify the nurse's role in the drug approval process and in maintaining safety practices.
MNL Learning Outcome: 2.2 Examine the role of the U.S. Food and Drug Administration in the process of drug approval and drug safety.

26) A client says, "This morning's nurse told me that my pain medication is a scheduled drug. Aren't all drugs given on a schedule?" How should the nurse respond?
    1. "What time would you like to schedule your pain medication?"
    2. "Medications are usually scheduled every 4 hours."
    3. "Scheduled medications have a significant potential for abuse."
    4. "During preclinical investigation, scheduled medications are tested."

Answer: 3

Explanation:
    1. "Pain medication is usually given PRN (when needed)."
    2. "Some medications are ordered to be given every 4 hours."
    3. "Drugs with a significant potential for abuse are classified into five schedules or categories. These drugs are called 'scheduled drugs.'"
    4. During the preclinical investigation phase of drug approval, medications are tested to make sure they are safe.

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Cognitive Level: Applying
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4

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Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-9 Identify the five drug schedules and give examples of drugs at each level.
MNL Learning Outcome: 2.4 Recognize controlled substances and drug schedules.

27) A nurse teaches a client that the newly prescribed medication has a very high risk of causing fetal abnormalities and that reliable measures to prevent pregnancy are essential while taking the medication. The nurse has described a medication that falls into which category?
    1. A
    2. B
    3. D
    4. X

Answer: 4
Explanation:
    1. Category A are the safest medications to give during pregnancy.
    2. Category B medications have failed to demonstrate a risk to the fetus.
    3. Category D medications have positive evidence of fetal risk, but benefits may outweigh the risk.
    4. Category X drugs have animal and human studies that show fetal abnormalities. The drug is contraindicated in women who are or may become pregnant. Reliable pregnancy prevention measures must be followed.

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Cognitive Level: Applying
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-10 Identify the five categories of teratogenic drug classification.
MNL Learning Outcome: 2.2 Examine the role of the U.S. Food and Drug Administration in the process of drug approval and drug safety.

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28) A nurse is providing preconception teaching to a group of women who wish to become pregnant. The nurse informs the group that which classifications of medications have shown no confirmed risk for fetal abnormalities if taken while pregnant?

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

1. Category A
2. Category B
3. Category C
4. Category D
5. Category X

Answer: 1, 2

Explanation:

1. Category A drugs are those in which controlled studies have failed to show a risk to the fetus and the possibility of fetal harm appears unlikely.
2. Category B drugs are those in which animal-reproduction studies have not shown a fetal risk or adverse effect. Risks have not been confirmed in controlled studies in women.
3. Category C drugs are those in which either studies in animals have revealed adverse effects on the fetus and there are no controlled studies in women or studies in women and animals are not advisable.
4. Category D drugs are those in which there is confirmation of human fetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used).
5. Category X drugs are those in which animal and human studies have shown fetal abnormalities. The drug is contraindicated in women who are or may become pregnant.

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation

Learning Outcome: 2-10 Identify the five categories of teratogenic drug classification.

MNL Learning Outcome: 2.2 Examine the role of the U.S. Food and Drug Administration in the process of drug approval and drug safety.

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29) A client at 14-weeks gestation is seen in the clinic with a sprained ankle. The healthcare provider prescribes a mild analgesic, rest, compression, and application of an ice bag. The client is very concerned about taking the prescribed medication, telling the nurse, "I don't want to hurt my baby." How should the nurse respond?

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

1. "The most dangerous time for birth defects is probably in the first semester and you are past that now."
2. "You are wise to avoid all drugs. I would only use the rest, compression, and ice."
3. "Let me check with the physician to see if he remembered you are pregnant."
4. "This is a category A drug, so there is very little risk to your baby."
5. "Don't worry, it will all be okay. You need to take care of yourself first."

Answer: 1, 4

Explanation:

1. The time of highest risk of birth defects is probably in the first trimester, and this client is past that time. It is not possible to predict that there is no risk from drug consumption.
2. While drug avoidance is preferred, in some cases it is necessary. If the nurse has concerns about the drug prescribed, collaboration with the prescriber is indicated.
3. Without further information about which drug was prescribed, it is nontherapeutic to make the client doubt the prescriber's choice of therapy.
4. With category A drugs, the risk of fetal harm is unlikely.
5. This statement is nontherapeutic and dismisses the client's concern.

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Cognitive Level: Analyzing

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation

Learning Outcome: 2-8 Explain the meaning of a controlled substance and teratogenic risk in pregnancy.

MNL Learning Outcome: 2.2 Examine the role of the U.S. Food and Drug Administration in the process of drug approval and drug safety.

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30) A nurse suspects a client has had an allergic reaction to a recently prescribed antibiotic. The nurse is responsible for providing emergency treatment and for reporting this suspected reaction to which persons?

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

1. Federal Drug Administration (FDA)
2. Healthcare provider
3. Hospital pharmacist
4. Medicare
5. Hospital risk management

Answer: 2, 3, 5

Explanation:

1. While it may be necessary to report this reaction to the FDA, it is not the bedside nurse's responsibility to do so.
2. The prescriber should be notified as this is an unexpected event. A change in therapy is likely to be required.
3. The hospital pharmacist should be advised of this possible reaction.
4. There is no reason for the bedside nurse to notify Medicare.
5. Hospital risk management should be notified of this event. A variance report may be required.

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Cognitive Level: Applying

Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies

Standards: QSEN Competencies: V.B.1 Demonstrate effective use of technology and standardized practices that support safety and quality. | AACN Essential Competencies: V.4 Examine legislative and regulatory processes relevant to the provision of healthcare. | NLN Competencies: Quality and Safety: Policies and procedures. | Nursing/Integrated Concepts: Nursing Process: Implementation

Learning Outcome: 2-5 Identify the nurse's role in the drug approval process and in maintaining safety practices.

MNL Learning Outcome: 2.2 Examine the role of the U.S. Food and Drug Administration in the process of drug approval and drug safety.

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