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**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.

Page Ref: 12-13

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.

Page Ref: 13

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.

Page Ref: 15

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.

Page Ref: 13

Cognitive Level: Applying

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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: Implementation

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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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.

Page Ref: 11

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.

Page Ref: 16

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.

Page Ref: 16

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.

Page Ref: 16

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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- 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.

Page Ref: 16

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

Page Ref: 16

Cognitive Level: Applying

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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: 2-7 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.