Pharmacology: Connections to Nursing Practice, 4e **(Adams)**
Chapter 2 Drug Regulations

1) Which was the greatest problem with patent medicines in early America that led 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.
Answer: 2
Explanation: Many did contain dangerous or addictive substances such as morphine or cocaine.
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Cognitive Level: Remembering
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: 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 LO: 1.1.1 Apply basic concepts related to pharmacology.

2) 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.
Select all that apply.
1. Patent medicines contained a trade 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.
Answer: 1, 2, 3, 4
Explanation: Patent medicine did contain the trade 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. Some elixirs contained up to 50% morphine. In the late 1800s, Coca-Cola contained about 9 mg of cocaine per serving.
Page Ref: 15
Cognitive Level: Remembering
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3) The student nurse taking a pharmacology class is studying the Food, Drug, and Cosmetic Act of 1938. What was important about this regulation?
1. It prevented the sale of drugs that had not been tested before marketing.
2. It gave the government the power to change the 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.
Answer: 1
Explanation: It did prevent the sale of drugs that had not been tested before marketing.
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Cognitive Level: Applying
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
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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 LO: 1.1.1 Apply basic concepts related to pharmacology.

4) 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 the 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.
Answer: 4
Explanation: The Sherley Amendment of 1912 prohibits the sale of drugs labeled with false therapeutic claims.
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Cognitive Level: Applying
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
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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 LO: 1.1.1 Apply basic concepts related to pharmacology.

5) 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, the act still had several weaknesses. Which statements most accurately describe the weaknesses?
Note: Credit will be given only if all correct choices and no incorrect choices are selected.
Select all that apply.
1. This law required drug manufacturers to prove that the drug was effective in its claims.
2. This law prevented 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 encouraged the development of drugs for rare or unusual disorders.

Answer: 1, 2, 4, 5
Explanation: The fact that manufacturers did not have to prove efficacy was a tremendous weakness in the regulation of drugs in the early 20th century.
Another weakness of the PFDA of 1906 was that drugs could be still marketed for any disease.
The PFDA did not require testing for safety prior to marketing. It was not until Congress passed the Food, Drug, and Cosmetic Act of 1938 that drugs had to be tested for safety prior to marketing.
The PFDA did not encourage the development of drugs for rare or unusual disorders. The act that did so is called the Orphan Act.
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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 LO: 1.1.1 Apply basic concepts related to pharmacology.

6) 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
Answer: 2
Explanation: Early formularies did contain a list of pharmaceutical products and drug recipes.
Page Ref: 17
Cognitive Level: Remembering
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Learning Outcome: 2-3 Describe how the United States Pharmacopeia-National Formulary (USP-NF) controls drug purity and standards.
MNL LO: 1.1.1 Apply basic concepts related to pharmacology.

7) 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.
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 varied 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.
Answer: 1, 2, 3
Explanation: 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.
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MNL LO: 1.1.1 Apply basic concepts related to pharmacology.

8) 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."
Answer: 4
Explanation: All drugs marketed by pharmaceutical companies must have FDA approval.
Page Ref: 19
Cognitive Level: Applying
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Learning Outcome: 2-4 Evaluate the role of the U.S. Food and Drug Administration in the drug approval process.
MNL LO: 1.1.1 Apply basic concepts related to pharmacology.

9) 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. Cosmetics
3. Herbal preparations
4. Dietary supplements
Answer: 1
Explanation: Biologics must have FDA approval before being marketed.
Page Ref: 18
Cognitive Level: Understanding
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Learning Outcome: 2-4 Evaluate the role of the U.S. Food and Drug Administration in the drug approval process.
MNL LO: 1.1.1 Apply basic concepts related to pharmacology.

10) 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.
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.
Answer: 1, 3, 4, 5
Explanation: 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 devices, 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.
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Learning Outcome: 2-4 Evaluate the role of the U.S. Food and Drug Administration in the drug approval process.
MNL LO: 1.1.1 Apply basic concepts related to pharmacology.

11) 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
Answer: 4
Explanation: Safety is determined by the FDA during the Investigational New Drug application process.
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Cognitive Level: Remembering
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Learning Outcome: 2-5 Categorize the four stages of new drug approval.
MNL LO: 1.1.1 Apply basic concepts related to pharmacology.

12) 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.
Answer: 4
Explanation: 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.
Page Ref: 19
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Learning Outcome: 2-5 Categorize the four stages of new drug approval.
MNL LO: 1.1.1 Apply basic concepts related to pharmacology.

13) 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.
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—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: 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 development involves extensive testing on human and microbial cells and on animals to determine drug action and to predict whether the drug will cause harm to humans.
Because lab tests cannot accurately predict human response to a drug, preclinical research results are always inconclusive.
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Learning Outcome: 2-5 Categorize the four stages of new drug approval.
MNL LO: 1.1.1 Apply basic concepts related to pharmacology.

14) 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."
Answer: 1
Explanation: A placebo is an inert substance that has no therapeutic effect and is used as a control.
Page Ref: 19
Cognitive Level: Remembering
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Learning Outcome: 2-6 Explain the role of a placebo in new drug testing.
MNL LO: 1.1.1 Apply basic concepts related to pharmacology.

15) 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
Answer: 4
Explanation: The accelerated approval process is for drugs used to treat serious and life-threatening conditions.
Page Ref: 21
Cognitive Level: Applying
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
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Learning Outcome: 2-7 Discuss how changes to the approval process have increased the speed at which new drugs reach consumers.
MNL LO: 1.1.1 Apply basic concepts related to pharmacology.

16) 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 healthcare 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."
Answer: 3
Explanation: Older clients often take multiple medications and should consult with their healthcare provider before taking any OTC medication or supplement to ensure there are no risks for drug interactions.
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Learning Outcome: 2-8 Compare and contrast prescription and over-the-counter drugs.
MNL LO: 1.1.3 Relate processes of pharmacokinetics and pharmacodynamics to the therapeutic effect(s) of a drug.

17) 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 drugs."
2. "Drugs that have a high safety margin may be reclassified to over-the-counter drugs."
3. "The longer the drug is on the market, the better its chance of becoming an over-the-counter drug."
4. "If the pharmaceutical company pays the FDA a large amount of money, it can have its drug reclassified."
Answer: 2
Explanation: Drugs that have a high safety margin may be reclassified as OTC drugs.
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18) 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.
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."
Answer: 1, 4
Explanation: The healthcare 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.
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19) 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?"
Answer: 3
Explanation: The pharmacist recognizes that 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.
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Learning Outcome: 2-9 Explain how scheduled drugs are classified and regulated.
MNL LO: 1.7.1 Compare the classes of medications used to treat pain.

20) 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."
Answer: 2
Explanation: The client will need to see the provider each time a refill is needed.
Page Ref: 22
Cognitive Level: Applying
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MNL LO: 1.7.1 Compare the classes of medications used to treat pain.

22) 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.
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.
Answer: 1, 2, 3, 4
Explanation: 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*.
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*.
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.
If the research drug continues to show that it is effective and safe, an NDA will be submitted to the Federal Drug Administration (FDA).
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Learning Outcome: 2-6 Explain the role of a placebo in new drug testing.
MNL LO: 1.1.1 Apply basic concepts related to pharmacology.

23) A nurse educator is discussing the prescriptive authority of healthcare providers to a group of new employees. Which healthcare providers are able to prescribe medications to clients?
Note: Credit will be given only if all correct choices and no incorrect choices are selected.
Select all that apply.
1. Registered nurses
2. Physicians
3. Nurse practitioners
4. Nurse managers
5. Physical therapists
Answer: 2, 3
Explanation: Physicians are able to prescribe medications.
Nurse practitioners are able to prescribe medications.
Page Ref: 22-23
Cognitive Level: Understanding
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: QSEN Competencies: II.A.2 Describe scopes of practice and roles of healthcare 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 healthcare 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 LO: 1.3.3 Implement the nursing process in the administration of medications.

24) Which is a reason that delayed approval by the Food and Drug Administration (FDA) of newer drugs prior to 1990?
1. The FDA was using outdated guidelines.
2. There was not enough money from the drug companies to support the testing.
3. Drug companies identified a handful of drugs necessary for disease outbreaks.
4. The drug approval process was not supported by the larger federal government sector.
Answer: 1
Explanation: Delays in the FDA approval process were caused by outdated guidelines, poor communication, and not enough staff to handle the workload.
Page Ref: 21
Cognitive Level: Applying
Client Need/Sub: Physiological Integrity: Pharmacological and Parenteral Therapies
Standards: 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 LO: 1.1.1 Apply basic concepts related to pharmacology.