# *Pharmacology for Nurses A Pathophysiologic Approach 5th edition Adams Solutions Manual*

SKU: 9780134255163-SOLUTIONS

**CHAPTER 2**
**DRUG APPROVAL AND REGULATION**

## Learning Outcomes

**1. Identify key U.S. drug regulations that have provided guidelines for the safe and effective use of drugs and drug therapy.**

- **Suggested Classroom Activity:** Have USP-NF copies available, and assign students to look for different drugs.
- **Suggested Classroom Activity:** Have the student access the FDA.gov website for the safe and effective drug review process and report on their findings.
- **Suggested Clinical Activity:** During clinical, have the students research the therapeutic dosage range for each of the drugs the patients are receiving. Have them discuss whether this is a safe dosage.
- **Suggested Clinical Activity:** During clinical, have the students research each of the drugs the patients are receiving. Discuss whether the medications are effective in attaining the treatment goals.

**2. Discuss the role of the U.S. Food and Drug Administration (FDA) in the drug-approval process.**

- **Suggested Classroom Activity:** Have the students access the FDA.gov website for the development and approval process of drugs and the application form for approval, and present to the class their findings.
- **Suggested Classroom Activity:** Have the students research two pharmaceutical companies' websites to see what drugs are currently in various stages of clinical trials.
- **Suggested Clinical Activity:** Go to the FDA.gov website and select one research study being conducted for a new drug. Identify the stage of the clinical trial, patient population, indications for use, and current monitoring protocol.
- **Suggested Clinical Activity:** On the assigned unit, have the students research the protocol for the administration of investigational drugs in that facility.

**3. Explain the four phases of approval for therapeutic and biologic drugs.**

- **Suggested Classroom Activity:** Discuss the rationale for each drug-approval stage. Identify the pros and cons of this process.
- **Suggested Classroom Activity:** Have students research drugs that have been removed from the market because of harmful effects and present their findings to the class.
- **Suggested Clinical Activity:** Discuss the Med Watch program and its purpose.
- **Suggested Clinical Activity:** On assigned patients, have each student identify therapeutics and pharmacotherapy of newly developed medications.

©2017 by Pearson Education, Inc.


Pharmacology for Nurses A Pathophysiologic Approach 5th edition Adams Solutions Manual

**4. Discuss how the FDA has increased the speed with which new drugs reach consumers.**

- **Suggested Classroom Activity:** Divide the class into groups of four to research the pros and cons of speeding up the approval process for new drugs.
- **Suggested Classroom Activity:** Identify five new drugs released in the past 5 years, and have the students find why each drug was developed, effectiveness of the drug, and the cost of the drug.
- **Suggested Clinical Activity:** On assigned patients, have each student identify if the patients are receiving newly approved drugs and whether they are covered by their prescription plan.
- **Suggested Clinical Activity:** Have the students research the issues regarding the safety and efficacy of new drugs developed in the past 5 years and their effects on clinical practice.

**5. Identify the nurse's role in the drug-approval process and in maintaining safety practices.**

- **Suggested Classroom Activity:** Have students identify the role and responsibilities of the clinical nurse researcher in drug development and safety.

- **Suggested Classroom Activity:** Discuss the issues of women and children as they relate to drug development. Identify why these populations have special drug-need considerations.

- **Suggested Clinical Activity:** Have the students obtain from the pharmacy the policy and procedure for research experimental drugs in the clinical area. Discuss the roles and responsibilities of the prescriber, the administration of the drug, and the patients' rights.

- **Suggested Clinical Activity:** Have the students research the ethical and legal issues in the administration of newly developed drugs.

**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.**

- **Suggested Classroom Activity:** Ask students to give examples of legal and illegal controlled substances.
- **Suggested Classroom Activity:** Discuss why tobacco, alcohol, and caffeine, which have abuse potential, are not regulated. Should they be regulated? Why or why not?
- **Suggested Clinical Activity:** Have students observe nursing personnel in the dispensing and administration of a controlled substance.
- **Suggested Clinical Activity:** Have the students review the social history of assigned patients and how these behaviours will impact on drug efficacy or toxicity.

©2017 by Pearson Education, Inc.


Pharmacology for Nurses A Pathophysiologic Approach 5th edition Adams Solutions Manual

**7. Discuss why drugs are sometimes placed on a restrictive list, and the controversy surrounding this issue.**

- **Suggested Classroom Activity:** Have the students review the Institute for Safe Medication practices and identify restricted drugs and issues surrounding their usage.
- **Suggested Clinical Activity:** Assign the students to a substance abuse clinic and discuss the issues of substance abuse.
- **Suggested Clinical Activity:** Have the students research the usage and issues of marijuana, pro and con.

**8. Explain the meaning of a controlled substance and teratogenic risk in pregnancy.**

- **Suggested Classroom Activity:** Have the students form groups and give each group five drugs to research their effects on pregancy and teratogenic risk.
- **Suggested Classroom Activity:** Ask the students to research the usage of controlled substances within specific age groups.
- **Suggested Clinical Activity:** On assigned patients, have each student identify controlled substances the student's patients are receiving and why.
- **Suggested Clinical Activity:** Have the students review the teratogenic classification of the assigned patients' drug therapy. Discuss the issues involved.

**9. Identify the five drug schedules and give examples of drugs at each level.**

- **Suggested Classroom Activity:** Have the students identify from a list of ten controlled substances which drug schedule they find most appropriate**.**
- **Suggested Classroom Activity:** Discuss the issues of drug addiction, both physiological and psychological dependence, in our society.
- **Suggested Clinical Activity:** Assign students to observe how controlled substances are monitored in the hospital and/or at a pharmacy. Identify which drug schedule their patients may be receiving.
- **Suggested Clinical Activity:** Assign the students to obtain the policy and procedure on controlled substances wastage.

**10. Identify the five categories of teratogenic drug classification.**

- **Suggested Classroom Activity:** Have the students form four groups and give each group five drugs to research their effects on pregancy and teratogenic risk.
- **Suggested Classroom Activity:** Identify OTC and herbal drugs that have pregnancy and teratogenic risks.

©2017 by Pearson Education, Inc.


Pharmacology for Nurses A Pathophysiologic Approach 5th edition Adams Solutions Manual

- **Suggested Clinical Activity:** During clinical, have the students analyze the prescribed drugs for their patients and determine the teratogenic drug classification.
- **Suggested Clinical Activity:** Discuss the issue of essential drugs for a mother's health that must be taken during pregnancy that pose a teratogenic risk, such as seizure medication.

**Key Concepts**

2.1 Drug regulations were created to protect the public from drug misuse and to ensure continuous evaluation of safety and effectiveness.

2.2 The regulatory agency responsible for ensuring that drugs are safe and effective is the U.S. Food and Drug Administration (FDA).

2.3 There are four phases of approval for therapeutic and biologic drugs. The phases progress from cellular and animal testing to use of the experimental drug in patients with the disease. These four phases are as follow: 1. Preclinical investigation. 2. Clinical investigation. 3. Review of the New Drug Application (NDA). 4. Post-marketing surveillance.

2.4 Once criticized for being too slow, the FDA has streamlined the process to get new drugs to market more quickly.

2.5 Nurses may participate in several phases of the drug-approval process. They will have the most frequent opportunities during Phase 4, post-marketing surveillance. Medication safety is a matter of paramount importance in health care.

2.6 Drugs with a potential for abuse are restricted by the Controlled Substances Act and are categorized into schedules. The Controlled Substances Act is also called the Comprehensive Drug Abuse Prevention and Control Act. Schedule I drugs are the most tightly controlled; Schedule V drugs have less potential for addiction and are less tightly controlled. Drugs are also categorized according to their teratogenic risk. Category A drugs are the safest to take during pregnancy. Category X drugs are the most dangerous to the fetus.

©2017 by Pearson Education, Inc.


Pharmacology for Nurses A Pathophysiologic Approach 5th edition Adams Solutions Manual

# DECISION-MAKING CASE SUMMARIES

## PHARMACOLOGY #6: ASTHMA

| CASE NAME | OVERVIEW | MAJOR CASE DECISIONS |
|---|---|---|
| Mr. Brandon Walsh | Mr. Walsh is a 43 year old male presenting with severe dyspnea plus headache, sore throat, and palpitations. He can barely breathe or talk. He was diagnosed with exercise-induced asthma at the age of 16, which has been controlled with albuterol until he had viral pneumonia 4 months ago. He now has dyspnea even at rest. | 1. Prioritizing which presenting symptoms to address first<br>2. Selecting appropriate diagnostic tests to administer to monitor medication effectiveness<br>3. Selecting client teaching topics related to medication administration and medication side effects<br>4. Prioritizing actions when treatment is unsuccessful<br>5. Recognizing incorrect dosing instructions<br>6. Selecting an appropriate IV insertion site |

**Estimated Case Length:** 15 minutes
**Difficulty Level:** Hard

**Learning Objectives:**

- Prioritize nursing care for clients in need of pharmacological intervention for complications related to asthma.
- Identify contraindications for medication therapies given to clients with asthma.
- Administer medications to clients experiencing complications related to asthma.
- Monitor clients with asthma for side effects related to medication administration and drug interactions.
- Advocate for effective care of clients with asthma.
- Provide client teaching about medications to clients with asthma.

| Questions | Correct Answers |
|---|---|
| 1. Which of Mr. Walsh's symptoms is most important to address first? | *Dyspnea* |
| 2. What important question(s) should you ask Mr. Walsh about his albuterol use before you administer additional medications? **Select all that apply.** | *How long have you been taking albuterol?*;<br>*When was the last time you took a dose of albuterol;*<br>*How many puffs of albuterol do you take daily on average?* |

| | |
|---|---|
| 3. To address the client's dyspnea, the provider has ordered 500 mcg (1 vial of 0.02% solution) ipratropium (Atrovent) via nebulizer. Based on provider orders, which tests will you need to administer to monitor drug effectiveness? **Select all that apply.** | *FEV1 (Forced Expiratory Volume, 1 sec); FVC (Forced Vital Capacity); PEF (Peak Expiratory Flow)* |
| 4. What drug class is ipratropium, and what is its mechanism of action? | *Anticholinergic drug that causes bronchodilation of airway smooth muscles.* |
| 5. Why would the provider have chosen to prescribe an anticholinergic drug for Mr. Walsh rather than a short-acting beta adrenergic agonist? | *Mr. Walsh was already taking a short-acting beta adrenergic agonist without success.* |
| 6. You are now preparing to administer ipratropium via mouthpiece. What client teaching is important for you to provide? **Select all that apply.** | *During drug administration, keep lips sealed around mouthpiece;*<br>*Breathe deeply and slowly through your mouth;*<br>*Rinse your mouth after the treatment is complete* |
| 7. Now that Mr. Walsh is on his nebulizer treatment, you would like to evaluate his other symptoms. What is one potential cause of Mr. Walsh's complaints of headache, sore throat, and palpitations? | *Albuterol overdose* |
| 8. After 15 minutes of treatment with the nebulizer, you re-assess Mr. Walsh's vital signs as well as his lung functions tests, which have the following results:<br>FEV1: 2.0 L (predicted 4.1 L; 48.8%)<br>FVC: 3.9 L (predicted 5.2 L; 75.0%)<br>PEF: 238 L/min (predicted 643 L/min; 37.0%)<br>FEV1/FVC: 51.3%<br>SpO2: 86%<br>What steps should you take next? **Select all that apply.** | *Increase oxygen flow to 6L/min;*<br>*Consult with the provider about other medications to administer* |
| 9. You decide to increase Mr. Walsh's oxygen flow to 6 L/min and consult his provider about additional medications to administer. When you discuss Mr. Walsh's condition with the provider, what | *Cortiscosteroid* |

| | |
|---|---|
| drug class would you anticipate him ordering? | |
| 10. The provider has ordered you to administer methylprednisolone (Solu-Medrol) via IV injection. Which dosing instructions would prompt you to double check the instructions with the provider? | *Administer 0.5 g methylprednisolone in 2 mL isotonic saline solution by IV injection* |
| 11. You confirm with the provider that you should immediately administer 125 mg methylprednisolone in 2 mL isotonic saline solution. You are preparing to insert the IV for the injection. Which is the best choice for the IV for Mr. Walsh? | *Place a 22-gauge needle in the cephalic vein of his non-dominant arm* |
| 12. Thirty minutes after methylprednisolone administration, you again check Mr. Walsh's pulmonary function tests. The results are:<br><br>FEV1: 2.9 L (predicted 4.1 L; 70.7%)<br>FVC: 4.5 L (predicted 5.2 L; 86.5%)<br>PEF: 427 L/min (predicted 643 L/min; 66.4%)<br>FEV1/FVC: 64.4%<br>SpO2: 92%<br>Although Mr. Walsh still has reduced pulmonary function, his breathing is less labored. The provider plans to admit Mr. Walsh for observation and continued medication administration. He also plans to add salmeterol + fluticasone (Advair Diskus 250/50) to Mr. Walsh's maintenance drug regimen at a dose of 1 puff twice daily.<br>What risk diagnosis is appropriate for Mr. Walsh based on his new medication regimen? | *Risk for Infection* |
| 13. What client teaching will you provide Mr. Walsh about salmeterol + fluticasone? **Select all that apply.** | *Salmterol + fluticasone may mask the symptoms of any infection.;*<br>*Salmeterol + fluticasone should not be used as a rescue inhaler.* |

Pharmacology for Nurses A Pathophysiologic Approach 5th edition Adams Solutions Manual