CHAPTER 1: CONSUMER SAFETY AND DRUG REGULATIONS

TRUE/FALSE

1. The pharmaceutical manufacturer has the authority to add additional active ingredients to a previously approved pharmaceutical product.

   ANS: F
   According to the 1938 Federal Food, Drug, and Cosmetic Act and Amendments of 1951 and 1962, all labels must be accurate and include a listing of all active and inactive ingredients.

   PTS: 1

2. Drug strength may vary with each lot number of a medication.

   ANS: F
   The 1906 Pure Food and Drug Act established that all drugs marketed in the United States meet minimal standards of strength, purity, and quality.

   PTS: 1

3. The Pure Food and Drug Act of 1906 established drug standards and official drug references.

   ANS: T
   This act established that all drugs marketed in the United States meet minimal standards of strength, purity, and quality. It also established two official references that established the standards for making each drug: The U.S. Pharmacopeia (USP) and the National Formulary (NF).

   PTS: 1

4. The 1906 Pure Food and Drug Act established consumer protections to prevent the inclusion of "dangerous ingredients" without the knowledge of the consumer.

   ANS: T
   Morphine is one example of a dangerous ingredient that may have been included without the knowledge of the consumer.

   PTS: 1

5. Medication labels need only include the trade name of the drug.

   ANS: F
   Labels must include a listing of all active and inactive ingredients, warning labels on certain preparations, and generic names for the medication

   PTS: 1

6. The prescriber of the medication is the only health care professional who is responsible for being aware of new medications, laws, and restrictions.

   ANS: F

The health care worker involved in administration of a medication also bears the responsibility of being aware of the laws and restrictions pertinent to that medication.

PTS: 1

7. A double-locked system is the recommended method for maintaining security of controlled substances.

   ANS: T
   A double-locked system may include two separate key entries or an electronic user identification and password access system.

   PTS: 1

8. Health care workers are responsible for maintaining records of all controlled substances received, dispensed, and destroyed.

   ANS: T PTS: 1

9. Controlled substance records are to be kept for 10 years.

   ANS: F
   Records for the previous 2 years must be available at all times for inspection.

   PTS: 1

MULTIPLE CHOICE

1. Identify the drug standard in the following list.
   a. Color
   b. Strength
   c. Shape
   d. Taste

   ANS: B

	Feedback
A	Color is not a standard.
B	Correct!
C	Shape is not a standard.
D	Taste is not a standard.

   PTS: 1

2. The risk of death from the use of *street drugs* versus *prescription medications* is mostly due to:
   a. a lack of control over quality, purity, and strength makes street drugs dangerous.
   b. the risk is the same for both sources of the same substance.
   c. street drugs are approved for use.
   d. the need for a prescription makes drugs hard to obtain.

   ANS: A

	Feedback
A	Correct!
B	The lack of enforcement of drug standards in illegal street drugs poses a significant

	danger for the consumer.
C	The exact composition of a street drug is unknown, and it may contain dangerous contaminants or undisclosed additional drugs.
D	Street drugs are illegal.

PTS: 1

3. Drug standards regulate drug manufacture so that medications of the same name will be of the same:
   a. strength, purity, and quality.
   b. shape, color, and taste.
   c. purity, shape, and color.
   d. quality, color, and shape.

   ANS: A
   Drug standards state that all preparations of the same drug name must be of uniform strength, purity, and quality.

   PTS: 1

4. The 1906 Pure Food and Drug Act includes which of the following provisions?
   a. Regulation of drugs sold in the United States and Canada
   b. Requires labeling to indicate if a medication contained a "dangerous ingredient"
   c. Regulates illicit drugs
   d. Requires information regarding medications to be handed down from one practitioner to the next

   ANS: B

	Feedback
A	The Pure Food and Drug Act regulates ALL drugs MARKETED in the United States. If a drug is manufactured in Canada, it must meet USFDA requirements to be marketed here.
B	Correct!
C	Illicit drugs are not regulated.
D	The Pure Food and Drug Act established two references of officially approved drugs, the USP and the NF.

PTS: 1

5. The Pure Food and Drug Act of 1906 was formulated:
   a. to curb the use of street drugs.
   b. as the first government attempt to establish consumer protection in the manufacture of drugs and foods.
   c. in order to make drug manufacturing profitable for the drug companies.
   d. as a means to identify addicting drugs.

   ANS: B

	Feedback
A	This applies to the Controlled Substances Act of 1970.
B	Correct!
C	The Pure Food and Drug Act was in answer to a need for consumer safety.
D	The Pure Food and Drug Act was in answer to a need for consumer safety.

PTS: 1

6. Which act required that drug preparations containing morphine have a label indicating the presence of morphine?
   a. Federal Food, Drug, and Cosmetic Act of 1938
   b. Federal Food, Drug, and Cosmetic Act Amendment of 1965
   c. Controlled Substances Act of 1970
   d. Pure Food and Drug Act of 1906

   ANS: D PTS: 1

7. Identify a provision of the Federal Food, Drug, and Cosmetic Act and its Amendments:
   a. new products are required to be approved by the Food and Drug Administration.
   b. the FD&C Act defined schedules for substances that require specific controls.
   c. it set limitations on the use of prescriptions.
   d. the FD&C Act established USP.

   ANS: A

	Feedback
A	Correct!
B	This response applies to the 1970 Controlled Substances Act.
C	Prescription limitations were defined by the 1970 Controlled Substances Act.
D	USP was established by the 1906 Pure Food and Drug Act.

   PTS: 1

8. What drugs are referred to as "legend" drugs?
   a. Drugs that work so well they become "legendary."
   b. Drugs that have been available for over 100 years.
   c. Drugs that must carry the legend "Caution—federal law prohibits dispensing without a prescription."
   d. Drugs that are mentioned in urban legends.

   ANS: C PTS: 1

9. The Food and Drug Administration was created to:
   a. oversee testing of all proposed new drugs prior to release into the U.S. market.
   b. inspect plants where food, drugs, medical devices, and cosmetics are made.
   c. remove unsafe drugs from the market.
   d. all of the above.

   ANS: D PTS: 1

10. The USP/NF (U.S. Pharmacopeia/National Formulary) was established to:
    a. provide a reference for all officially approved medications.
    b. legalize the manufacture of medications.
    c. give the public the information needed to safely make their own drugs.
    d. all of the above.

    ANS: A PTS: 1

11. USP is the official abbreviation for:
    a. U.S. Post office. c. U.S. Police.

b. U.S. Patrol.
d. U.S. Pharmacopoeia.

ANS: D PTS: 1

12. NF is the official abbreviation for:
a. National Football.
b. National Fortress.
c. National Food.
d. National Formulary.

ANS: D PTS: 1

13. Prior to the 1906 establishment of the U.S. Pharmacopeia, drug information was related by:
a. the Internet.
b. encyclopedias.
c. passing to the next generation.
d. schools of medicine and pharmacology.

ANS: C PTS: 1

14. Which bureau of the Department of Justice was established by the Controlled Substances Act of 1970?
a. USP
b. DEA
c. FDA
d. NF

ANS: B

	Feedback
A	U.S. Pharmacopeia
B	Correct! Drug Enforcement Agency
C	Food and Drug Administration
D	National Formulary

PTS: 1

15. The Controlled Substances Act of 1970 set much tighter controls on a specific group of drugs that are:
a. at risk of being abused by society.
b. listed in the USP/NF.
c. those that contain herbal components.
d. available over the counter.

ANS: A

	Feedback
A	Correct!
B	This refers to the 1906 Pure Food and Drug Act.
C	The FDA does not approve dietary or herbal supplements.
D	OTCs were outlined in the 1938 Federal Food, Drug, and Cosmetic Act.

PTS: 1

16. The Controlled Substances Act may limit:
a. the number of refills that can be filled in a 6-month time frame.
b. at which pharmacies the patient may get the prescription filled.

c. the level of pain control to be maintained.
d. how the patient may maintain or store the medication.

ANS: A

	Feedback
A	Correct!
B	The government does not limit where prescriptions may be filled.
C	The Act does not address pain control.
D	The government does not regulate where private citizens may keep their medications.

PTS: 1

17. The Controlled Substances Act sets tighter controls on:
a. common analgesics such as Tylenol or aspirin.
b. depressants, stimulants, psychedelics, narcotics, and anabolic steroids.
c. antibiotics, diuretics, antihypertensives, and diabetic medications.
d. common cold/allergy medications.

ANS: B

	Feedback
A	Tylenol and aspirin are provided over the counter and access to them is not regulated.
B	Correct!
C	These are prescription medications that are not considered to be at risk for abuse,
D	These currently remain as over-the-counter medications but more controls are being applied.

PTS: 1

18. Which of the following is required to have a DEA number?
a. The provider writing the prescription
b. The person receiving the prescription
c. All providers working in the physician's office or clinic
d. All providers working in the pharmacy

ANS: A

	Feedback
A	Correct!
B	People receiving the prescription do not need a DEA number.
C	Only the prescriber needs a DEA number.
D	Only the pharmacist needs a DEA number.

PTS: 1

19. Professionals needing a DEA number are:
a. registered nurses (RNs), licensed (vocational) nurses (LPN/LVNs), and certified medication assistants (CMAs).
b. pharmacists, physicians, veterinarians.
c. clients who have a professional license.
d. administrators of nursing care facilities, acute care hospitals, and home health care associations.

ANS: B

	Feedback
A	Health care providers administering medications do not need a DEA number.
B	Correct!
C	No client needs a DEA number, regardless of occupation.
D	Administrators of institutions do not need DEA numbers.

PTS: 1

20. DEA numbers appear on the:
    a. prescriber's professional license.
    b. prescription for a controlled substance.
    c. medication bottle that contains the controlled substance.
    d. receipt for the medication.

ANS: B

	Feedback
A	The DEA number does not appear on the professional's license.
B	Correct!
C	The DEA number does not appear on the medication container.
D	The DEA number does not appear on the receipt.

PTS: 1

21. A DEA number represents:
    a. the number of times the DEA has cited the person.
    b. the phone number for the local DEA office.
    c. registration with the Drug Enforcement Agency.
    d. the prescriber's professional state license number.

ANS: C
The DEA number refers only to the independent registration number assigned by the agency and is not reflected in any state's professional licensure.

PTS: 1

22. Agencies/persons that are required to have a DEA number are:
    a. acute care hospitals and nursing homes.
    b. pharmacies, grocery stores, and convenience stores.
    c. drug manufacturers and packaging facilities, pharmacists, physicians.
    d. schools of nursing, medical assisting, and radiology.

ANS: C

	Feedback
A	The DEA does not regulate hospitals and nursing homes.
B	The DEA does not regulate grocery stores or convenience stores.
C	Correct!
D	The DEA does not regulate schools.

PTS: 1

23. The schedule of controlled substances that has the highest risk of abuse potential is:
    a. Schedule C 2.
    b. Schedule C 3.
    c. Schedule C 4.
    d. Schedule C 5.

    ANS: A
    The lower the number, the higher the potential for abuse.

    PTS: 1

24. Drugs listed in Schedule 1 of Controlled Substances:
    a. are not approved for medical use in the United States.
    b. may be refilled up to five times in 6 months.
    c. may have prescriptions phoned in by health care workers.
    d. have low abuse potential compared to other schedules.

    ANS: A
    Schedule 1 drugs are not approved for medical use in the United States.

    PTS: 1

25. Prescriptions of the controlled substances listed in these schedules may not be called into the pharmacy:
    a. Schedule 1.
    b. Schedule 2.
    c. Schedule 3.
    d. All of the above.

    ANS: D

	Feedback
A	Schedule 1 drugs are illegal for use and are not available to be prescribed in any fashion in the United States.
B	Schedule 2 drugs may not be called in to the pharmacy unless in cases of emergency, and then only by a physician. The call must be followed by a handwritten prescription within 72 hours.
C	Schedule 3 drugs may be phoned in by a physician only.
D	Correct!

    PTS: 1

26. Prescriptions of the controlled substances listed in which of these schedules MAY be called into the pharmacy by health care workers other than the prescriber:?
    a. Schedules 1 and 2 only
    b. Schedules 2 through 4
    c. Schedules 4 and 5 only
    d. Schedules 1 through 3

    ANS: C

	Feedback
A	Schedule 1 is not approved for medical use in the United States. Schedule 2 may be phoned into the pharmacy by a physician in an emergency only, followed by a written prescription within 72 hours.
B	Schedule 2 may only be phoned in by the physician in an emergency. Schedule 3 may be phoned in by the physician only. Schedules 4 and 5 may be phoned in by an office health care worker.
C	Correct!
D	Schedule 3 may be phoned in by the physician only.

PTS: 1

27. Prescriptions of the controlled substances listed in these schedules may be refilled up to five times in 6 months:
    a. Schedules 1 and 2.
    b. Schedules 3 and 4.
    c. Schedules 3, 4, and 5.
    d. Schedules 1, 2, 3, 4, and 5.

    ANS: C

	Feedback
A	Schedule 1 drugs are not approved for medical use in the United States. Schedule 2 drugs may not be refilled.
B	Both may be refilled five times in 6 months, but there is a more complete answer.
C	Correct!
D	Schedule 1 drugs are not approved for medical use in the United States. Schedule 2 drugs may not be refilled.

PTS: 1

28. The least desirable information source regarding drugs is a:
    a. current drug reference.
    b. pharmacist.
    c. coworker.
    d. pharmaceutical company representative.

    ANS: C
    All except "coworker" are reliable sources of drug information.

    PTS: 1

29. Which act established the USP and NF?
    a. 1938 Federal Food, Drug, and Cosmetic Act
    b. 1906 Pure Food and Drug Act
    c. 1965 Pharmaceutical Consumer Protection Act
    d. 1962 Amendment to the 1938 Federal Food, Drug, and Cosmetic Act

    ANS: B

	Feedback
A	The 1938 Federal Food, Drug, and Cosmetic Act primarily addressed prevention of tampering with products.
B	Correct!
C	The "1965 Pharmaceutical Consumer Protection Act" does not exist.
D	The 1962 Amendment to the 1938 Federal Food, Drug, and Cosmetic Act was concerned with labeling and assuring that prescription and nonprescription drugs were both effective and safe.

PTS: 1

30. An *orphan drug* is defined as a(n):
    a. drug used only in children.

b. drug used to treat a disease that affects only a small number of people.
c. lone drug in a specific class of drugs.
d. unapproved drug used to treat a rare disease.

ANS: B
B is correct! Answers A and C are incorrect. Answer D describes other circumstances where a drug is used for an unapproved use or is used under what is called a "humanitarian exception," not covered in this chapter.

PTS: 1

31. Which legislation provides for financial incentives to be provided to pharmaceutical companies for the development of medications that would otherwise be unprofitable because they are designed to treat diseases that affect only a small number of people?
a. 1965 Pure Food and Drug Act
b. 1938 Orphan Drug and Cosmetic Act
c. 1983 Orphan Drug Act
d. OBRA of 1990

ANS: C
None of the other options exist.

PTS: 1

32. What new requirements were mandated by the Omnibus Budget Reconciliation Act of 1990?
a. All prescriptions are to be included as part of the permanent medical record.
b. Over-the-counter medications are to be entered into the permanent medical record.
c. Pharmacists are required to provide drug use review and patient counseling prior to dispensing prescriptions to patients.
d. Both B and C are correct.
e. All of the above.

ANS: D
Prescription medications were previously required to be included in the medical records. OBRA mandated the additional requirement of documenting over-the-counter medications and counseling to be provided by the dispensing pharmacist.

PTS: 1

33. Once a drug or device has been approved for use in the United States, the:
a. DEA may withdraw approval if a safety concern exists.
b. only actions that can be taken is requirement of additional warnings to be added to the labeling and recommendation for voluntary withdrawal by the manufacturer.
c. FDA may reconsider its approval and withdraw it from the market to protect the public safety.
d. DEA may demand withdrawal from the market.

ANS: B

	Feedback
A	The DEA is not involved in approvals or withdrawals.
B	Correct!
C	The FDA has the power to review and make recommendations regarding withdrawals of approved drugs, but it cannot enforce a withdrawal.
D	Withdrawals are made voluntarily by the manufacturer based on safety reports and review.

PTS: 1