Chapter 01: Information Sources, Regulatory Agencies, Drug Legislation, and Prescription Writing
Haveles: Applied Pharmacology for the Dental Hygienist, 8th Edition

MULTIPLE CHOICE

1. Knowledge of pharmacology aids the dental professional in

   a. obtaining a patient's health history.
   b. administering drugs in the office.
   c. handling emergency situations.
   d. selection of a nonprescription medication.
   e. All of the above

   ANS: E
   All of the choices are true. Because many of our patients are being treated with drugs, knowledge of pharmacology helps in understanding and interpreting patients' responses to health history questions. Knowledge of the therapeutic and adverse effects of medications obviously helps in their proper administration in the office. Emergency situations may be caused by drugs or treated by drugs; thus, knowledge of pharmacology is of great help, especially because a rapid response is sometimes required. A clear understanding of the concepts of drug action, drug handling by the body, and drug interactions will allow the dental practitioner to make proper judgments and grasp the concepts relevant to new drug therapies on the market.

   DIF: Application REF: Role of the Dental Hygienist | p. 2 & 3
   OBJ: 1 TOP: NBDHE, 6.0. Pharmacology

2. Which of the following statements is true regarding planning appointments?
   a. Whether or not patients are taking medication for systemic diseases is of little consequence in the dental office.
   b. Asthmatic patients should have dental appointments in the morning.
   c. Diabetic patients usually have fewer problems with a morning appointment compared with afternoon appointments.
   d. Both B and C are true.

   ANS: D

Asthmatic patients who experience dental anxiety should schedule their appointments when they are not rushed or under pressure early in the morning. Diabetic patients usually have relatively fewer problems with a morning appointment. Patients taking medication for systemic diseases may require special handling in the dental office.

DIF: Comprehension
REF: Role of the Dental Hygienist (Appointment Scheduling) | p. 3
OBJ: 1 TOP: NBDHE, 6.0. Pharmacology

3. Nutritional or herbal supplements
   a. carry the U.S. Food and Drug Administration (FDA) approval for disease states.
   b. are not drugs.
   c. can cause adverse effects.
   d. will not interact with other drugs the patient may be taking.

ANS: C
Nutritional or herbal supplements are quite capable of causing adverse effects. The majority of nutritional or herbal supplements do not carry FDA approval for treating disease states. These supplements are drugs and can cause adverse effects and interact with different drugs.

DIF: Comprehension
REF: Role of the Dental Hygienist (Nutritional or Herbal Supplements) | p. 3
OBJ: 1 TOP: NBDHE, 6.0. Pharmacology

4. Which type of drug name usually begins with a lowercase letter?
   a. Brand name
   b. Code name
   c. Generic name
   d. Trade name

ANS: C
Before any drug is marketed, it is given a generic name that becomes the "official" name of the drug. Each drug is assigned only one generic name selected by the U.S. Adopted Name Council, and the name is not capitalized. The brand name is equivalent to the trade name and is capitalized. Although the brand name is technically the name of the company marketing the product, this term is often used interchangeably with the trade name. The code name is the initial term used within a pharmaceutical company to refer to a drug while it is undergoing investigation and is often a combination of capital letters and numbers, the letters representing an abbreviation of the company name.

DIF: Comprehension REF: Drug Names | p. 4
OBJ: 3 TOP: NBDHE, 6.0. Pharmacology

5. A drug's generic name is selected by the
   a. pharmaceutical company manufacturing it.
   b. Food and Drug Administration (FDA).
   c. U.S. Adopted Name Council.
   d. Federal Patent Office.

ANS: C

Each drug is assigned only one generic name (e.g., ibuprofen). It is selected by the U.S. Adopted Name Council. The generic name is not selected by the FDA or the Federal Patent Office. The pharmaceutical company manufacturing the drug clearly has an influence on the generic name given its drug, but the final decision is not the company's.

DIF: Recall REF: Drug Names | p. 4 OBJ: 3
TOP: NBDHE, 6.0. Pharmacology

6. Which of the following is true concerning generic and trade names of drugs?
   a. A drug may only have one generic name and one trade name.
   b. A drug may only have one generic name, but it may have several trade names.
   c. A drug may have several generic names, but it may only have one trade name.
   d. A drug may have several generic names and several trade names.

   ANS: B
   Each drug has only one generic name but may have several trade names. For each drug, there is only one generic name. It is not capitalized, and it becomes the "official" name of the drug. The pharmaceutical company discovering the drug gives the drug a trade name. The trade name is protected by the Federal Patent Law for 20 years from the earliest claimed filing date, plus patent term extensions. Although the brand name is technically the name of the company marketing the product, it is often used interchangeably with the trade name.

   DIF: Comprehension REF: Drug Names | p. 4
   OBJ: 3 TOP: NBDHE, 6.0. Pharmacology

7. Two drugs that are found to be chemically equivalent, but not biologically equivalent or therapeutically equivalent are said to differ in
   a. potency.
   b. efficacy.
   c. bioavailability.
   d. therapeutic index.

   ANS: C
   A preparation can be chemically equivalent yet not biologically or therapeutically equivalent. These products are said to differ in their bioavailability. The potency of a drug is a function of the amount of drug required to produce an effect. The efficacy is the maximum intensity of effect or response that can be produced by a drug. The therapeutic index is the ratio of the lethal dose for 50% of the experimental animals divided by the effective dose for 50% of the experimental animals. If the value of the therapeutic index is small, toxicity is more likely.

   DIF: Recall REF: Drug Substitution | p. 5 OBJ: 4
   TOP: NBDHE, 6.0. Pharmacology

8. How many years must pass after a drug patent expires before other drug companies can market the same compound as a generic drug?
   a. 20 years
   b. 17 years
   c. 7 years
   d. 0 years

   ANS: D

Once a drug patent expires, competing companies may immediately market the same compound in generic form. After 17 years, the patent of the original drug expires, and other companies can market the same compound under a generic name.

DIF: Application REF: Drug Names (Drug Substitution) | p. 5
OBJ: 4 TOP: NBDHE, 6.0. Pharmacology

9. Two drug formulations that produce similar concentrations in the blood and tissues after drug administration are termed _____ equivalent.
   a. chemically
   b. biologically
   c. therapeutically

   ANS: B
   Biologic equivalence refers to identical pharmacokinetic parameters of two drug formulations (bioequivalence, for short). Chemical equivalence indicates that two formulations of a drug meet the chemical and physical standards established by the regulatory agencies. Therapeutic equivalence means that two formulations produce the same therapeutic effects over the same duration.

   DIF: Application REF: Drug Names (Drug Substitution) | p. 5
   OBJ: 4 TOP: NBDHE, 6.0. Pharmacology

10. The federal body that determines whether a drug is considered a controlled substance and to which schedule it belongs is the
    a. Food and Drug Administration (FDA).
    b. Federal Trade Commission (FTC).
    c. Drug Enforcement Administration (DEA).
    d. U.S. Pharmacopeia (USP).

    ANS: C
    The DEA regulates the manufacture and distribution of substances with abuse potential. Hence prescriber DEA numbers must appear on prescriptions for controlled substances. The FDA does not have any special powers in regard to drugs of abuse. The FTC regulates commerce and advertising claims of foods, over-the-counter (OTC) products, and cosmetics. The USP regulates the uniformity and purity of drugs.

    DIF: Comprehension
    REF: Federal Regulations and Regulatory Agencies (Drug Enforcement Administration) | p. 5
    OBJ: 5 TOP: NBDHE, 6.0. Pharmacology

11. Which federal regulatory agency decides which drugs require a prescription and which drugs may be sold over-the-counter (OTC)?
    a. FDA
    b. OSHA
    c. FTC
    d. DEA

    ANS: A

The Food and Drug Administration (FDA) is part of Department of Human and Health Services (DHHS), and determines what drugs may be sold by prescription and OTC and regulates the labeling and advertising of prescription drugs. The Occupational Safety and Health Administration (OSHA) ensures the safety and health of workers in the United States by setting and enforcing standards. The Federal Trade Commission (FTC) regulates the trade practices of drug companies and prohibits the false advertising of foods, nonprescription (OTC) drugs, and cosmetics. The Drug Enforcement Administration (DEA) is a part of the Department of Justice and regulates the manufacture and distribution of substances that have a potential for abuse, including opioids, stimulants, and sedatives.

DIF: Recall
REF: Federal Regulations and Regulatory Agencies (Food and Drug Administration) | p. 5
OBJ: 5 TOP: NBDHE, 6.0. Pharmacology

12. Which federal regulatory body regulates the trade practices of drug companies and prohibits false advertising of foods, nonprescription drugs, and cosmetics?
    a. FDA
    b. FTC
    c. DEA
    d. OBRA

ANS: B
Consumers who refer to care labels on their clothes, product warranties, or stickers showing the energy costs of home appliances are using information required by the FTC. Businesses must be familiar with the laws requiring truthful advertising and prohibiting price fixing. These laws are also administered by the FTC. When the FTC was created in 1914, its purpose was to prevent unfair methods of competition in commerce. Over the years, the U.S. Congress has passed additional laws giving the agency greater authority to police anticompetitive practices. The FDA grants approval so that drugs can be marketed in the United States. Before the FDA can approve a drug, the drug must be determined to be both safe and effective. The DEA regulates the manufacture and distribution of substances that have a potential for abuse. OBRA (Omnibus Budget Reconciliation Act) is not a regulatory body; it is an act that mandates that pharmacists must provide patient counseling.

DIF: Recall
REF: Federal Regulations and Regulatory Agencies (Federal Trade Commission) | p. 5
OBJ: 5 TOP: NBDHE, 6.0. Pharmacology

13. An investigational new drug application (INDA) is submitted _____ trials.
    a. before preclinical trials
    b. before phase 1 clinical trials
    c. after phase 2 clinical trials
    d. before phase 3 clinical trials

ANS: B
Preclinical testing usually lasts about 3 years. After the preclinical trials have been completed, an INDA must be filed with the FDA before a drug company can commence phase 1 clinical trials. Animal testing data must be accumulated from preclinical trials before filing an INDA. Phase 1 is the first trial using patients, and phases 2 and 3 follow phase 1. An INDA must be filed before any testing in humans can commence.

DIF: Recall REF: Clinical Evaluation of a New Drug | p. 5

OBJ: 6 TOP: NBDHE, 6.0. Pharmacology

14. Phase 1 clinical trials involve all of the following *except* which one?
    a. Safe dose range
    b. Toxic effects of the drug
    c. Metabolism
    d. Effectiveness

    ANS: D
    In phase 1 clinical trials, small and then increasing doses are administered to a limited number of healthy human volunteers, primarily to determine safety. This phase determines the biologic effects, metabolism, safe dose range in humans, and toxic effects of the drug. The main purpose of phase 2 is to test effectiveness. Biologic effects, metabolism, safe dose range in humans, and toxic effects of the drug are, in fact, goals of phase 1 clinical trials.

    DIF: Comprehension REF: Clinical Evaluation of a New Drug | p. 5
    OBJ: 6 TOP: NBDHE, 6.0. Pharmacology

15. Which of the following is determined during a phase 3 clinical evaluation of a new drug?
    a. Effectiveness
    b. Safety and efficacy
    c. Dosage
    d. Both A and B
    e. Both B and C

    ANS: E
    Both safety and efficacy must be demonstrated during phase 3 of the clinical evaluation of a new drug. Dosage is also determined during this phase. During phase 3, clinical evaluation takes place involving a large number of patients who have the condition for which the drug is indicated. The main purpose of phase 2 clinical evaluation is to test a drug's effectiveness.

    DIF: Recall REF: Clinical Evaluation of a New Drug | p. 6
    OBJ: 6 TOP: NBDHE, 6.0. Pharmacology

16. Which of the following is a schedule II controlled substance?
    a. Heroin
    b. Propranolol
    c. Amphetamine
    d. Dextropropoxyphene (Darvon)

    ANS: C
    Amphetamine, oxycodone, morphine, and secobarbital are all schedule II controlled substances. Heroin is a schedule I substance. Propranolol is a nonscheduled prescription drug. Dextropropoxyphene is a schedule IV substance.

    DIF: Recall REF: Schedules of Controlled Substances | p. 6
    OBJ: 6 TOP: NBDHE, 6.0. Pharmacology

17. Controlled substances in schedule _____ require a written prescription with the provider's signature and do not permit refills.
    a. II, III, and IV
    b. II and III
    c. III and IV

d. II only
e. III only

ANS: D
Controlled substances in schedule II require a written prescription with the provider's signature and do not permit refills. Any prescription for schedule II drugs must be written in pen or indelible ink or typed. A designee of the dentist, such as the dental hygienist, may write the prescription, but the prescriber must personally sign the prescription in ink and is responsible for what any designee has written. Prescriptions for controlled substances in both schedule III and schedule IV may be telephoned, and no more than five prescriptions in 6 months are permitted.

DIF: Comprehension REF: Schedules of Controlled Substances | p. 6
OBJ: 7 TOP: NBDHE, 6.0. Pharmacology

18. Schedule III controlled substances may be telephoned to the pharmacist *and* may be refilled no more than five times in 6 months.
a. Both parts of the statement are true.
b. Both parts of the statement are false.
c. The first part of the statement is true; the second part is false.
d. The first part of the statement is false; the second part is true.

ANS: A
Both parts of the statement are true. Schedule III controlled substances may be telephoned to the pharmacist *and* may be refilled as many as five times in 6 months. Both parts of the statement are true for schedule III and schedule IV controlled substances. Schedule I controlled substances have no accepted medical use. Schedule II controlled substances require a written prescription with the provider's signature, and no refills are permitted. Schedule V controlled substances can be bought OTC in some states.

DIF: Recall REF: Drug Legislation (Scheduled Drugs) | p. 6
OBJ: 7 TOP: NBDHE, 6.0. Pharmacology

19. What is the purpose of a "black box warning" on a package insert?
a. It is used to reconstruct the events leading to a fatality resulting from a medication error.
b. It is issued by the Drug Enforcement Administration (DEA) to indicate medications that may be used to manufacture illicit drugs such as methamphetamine.
c. It is used to draw attention to potentially fatal, life threatening, or disabling adverse effects for different medications.
d. It means that the effects of the drug have not yet been determined.

ANS: C
A black box warning is about a drug the FDA has required a manufacturer to prominently display in a box in the package insert. The intent of the black box is to draw attention to the specific warning and make sure that both the prescriber and patient understand the serious safety concerns associated with that drug. A black box on an airplane is used to reconstruct events prior to a tragedy; however, the black box warning on a medication package insert is used to warn about safety concerns with the drug. A black box is not used as a warning about illicit use of medications. All drugs must go through preclinical and clinical trials prior to being marketed.

DIF: Recall REF: Drug Legislation (Black Box Warning) | p. 6 & 7
OBJ: 7 TOP: NBDHE, 6.0. Pharmacology

20. An "orphan drug" is
    a. not related to any other medication currently available.
    b. developed specifically to treat a rare medical condition.
    c. a drug that has been on the market for longer than 20 years and generic substitution is permitted.
    d. no longer available for use as newer, more effective medications are available.

    ANS: B
    Rare medical conditions with orphan status refer to diseases that occur in fewer than 200,000 people in the United States. Orphan drugs may be related to other medications. Orphan drug status is not related to the time the drug has been available. Many newer drugs have been assigned orphan status.

    DIF: Recall REF: Drug Legislation (Orphan Drugs) | p. 7
    OBJ: 7 TOP: NBDHE, 6.0. Pharmacology

21. The word *stat* on a prescription means
    a. before meals.
    b. at bedtime.
    c. immediately.
    d. every.

    ANS: C
    The word *stat* on a prescription means immediately (now). The abbreviation *ac* means before meals, *hs* means at bedtime, and *q* means every.

    DIF: Recall REF: Table 1-3: Abbreviations Commonly Used in Prescriptions | p. 8
    OBJ: 7 TOP: NBDHE, 6.0. Pharmacology

22. The abbreviation used on prescriptions for *four times a day* is
    a. bid.
    b. qid.
    c. qd.
    d. ud.

    ANS: B
    qid is the abbreviation for quarter in die, or four times a day. *bid* stands for twice a day, *qd* stands for every day, and *ud* stands for as directed.

    DIF: Recall REF: Abbreviations Commonly Used in Prescriptions | p. 8
    OBJ: 7 TOP: NBDHE, 6.0. Pharmacology

23. The heading of a prescription contains the following information *except* the
    a. name and address of the prescriber.
    b. name and address of the patient.
    c. telephone numbers of the patient and the prescriber.
    d. date of birth of the prescriber.
    e. date of the prescription.

    ANS: D

Including the date of birth of the patient on the prescription is important, both to determine the proper dose for age and also the patient is not confused with another family member (i.e., mother or daughter). The heading of a prescription contains the name, address, and telephone number of the prescriber, as well as the name, address, age, and telephone number of the patient, and the date of the prescription.

DIF: Comprehension REF: Prescription Writing (Format) | p. 7
OBJ: 7 TOP: NBDHE, 6.0. Pharmacology

24. Which of the following is located in the body of the prescription?
    a. The date of the prescription
    b. The amount of the drug to be dispensed
    c. Directions to the prescriber
    d. Refill instructions

ANS: B
The *Rx* symbol, name and dose size or concentration of the drug, amount to be dispensed, and directions to the patient are all found in the body of the prescription. The date of the prescription is found in the heading. The directions to the patient rather than prescriber are found in the body of the prescription. Refill instructions are found in the closing of the prescription.

DIF: Recall REF: Prescription Writing (Format) | p. 7 & 8
OBJ: 7 TOP: NBDHE, 6.0. Pharmacology

25. Where is the information regarding the prescriber DEA number commonly found on the prescription?
    a. Superscription
    b. Heading
    c. Body
    d. Closing

ANS: D
The signature area of the prescription is found in the closing. It should also include a space for the DEA number. The superscription is a classical description for where the patient information and the symbol *Rx* are found. The heading contains prescriber and patient contact information, the patient's date of birth, and the date of prescription. The body contains the *Rx* symbol, dosage instructions, and directions to the patient.

DIF: Recall REF: Prescription Writing (Format) | p. 8
OBJ: 7 TOP: NBDHE, 6.0. Pharmacology

26. On a prescription, the directions to the patient are preceded by
    a. *Rx*.
    b. Sig.
    c. #.
    d. Disp.

ANS: B
Sig. is the abbreviation for the Latin word *signa,* or write. This word precedes the instructions to the patient. *Rx* means *take thou* and precedes the prescription instructions, # denotes the number of tablets, capsules, and so forth to be dispensed. *Disp*. is short for *dispense* and precedes the amount to be dispensed, analogous to #.

DIF: Recall REF: Prescription Writing (Format) | p. 8
OBJ: 7 TOP: NBDHE, 6.0. Pharmacology

27. Each is an advantage of electronic and fax prescribing *except* one. Which is the *exception*?
    a. It reduces the likelihood of errors in reading handwritten prescriptions.
    b. It reduces the patient's ability to tamper with a prescription.
    c. There is no record of the prescription in the patient's record.
    d. Prescriptions can be faxed to the pharmacy.

    ANS: C
    A written record of the prescription is kept in the patient's record. Electronic prescribing is the electronic transmission of a prescription to a pharmacy, which reduces the incidence of errors in reading handwritten prescriptions and the patient's ability to tamper with a prescription. Prescriptions can be faxed to the pharmacy.

    DIF: Comprehension
    REF: Prescription Writing (Prescriptions [Electronic and Fax Prescribing]) | p. 9
    OBJ: 7 TOP: NBDHE, 6.0. Pharmacology

28. Which drug legislation act was instrumental for the growth of electronic prescribing?
    a. Controlled Substance Act
    b. Medicare Modernization Act
    c. Food, Drug and Cosmetic Act
    d. Harrison Narcotic Act

    ANS: B
    The inclusion of e-prescribing in the Medicare Modernization Act of 2003 (MMA) gave momentum to its use in provider practices across the country. The Controlled Substance Act of 1970 replaced the Harrison Narcotic Act of 1914, and the Drug Abuse Control Amendments (1965) to the Food, Drug and Cosmetic Act (1938).

    DIF: Comprehension
    REF: Prescription Writing (Prescriptions [Electronic and Fax Prescribing]) | p. 9
    OBJ: 7 TOP: NBDHE, 6.0. Pharmacology

29. What would be an advantage for a dentist to call the pharmacy with a prescription for Tylenol #3 rather than hydrocodone for a patient who calls late at night requesting medication for pain following root canal therapy?
    a. Tylenol #3 is available over-the-counter and does not require a prescription.
    b. Tylenol #3 is a not a controlled substance and hydrocodone is a controlled substance.
    c. A prescription for Tylenol #3 (Schedule III) may be telephoned, whereas hydrocodone (Schedule II) requires a written prescription.
    d. Tylenol #3 has greater potency than hydrocodone.

    ANS: C
    Tylenol #3 has moderate abuse potential and prescriptions may be telephoned. Hydrocodone has high abuse potential and requires a written prescription with the provider's signature. Tylenol #3 is a Schedule III controlled substance. It is not available over-the-counter and requires a prescription. Hydrocodone has more potency and a higher abuse potential than Tylenol #3.