Chapter 1. Conscientious and Rational Prescribing in the 21st Century

Multiple Choice
Identify the choice that best completes the statement or answers the question.

____ 1. Which statement regarding herbals, vitamins, minerals, and food supplements is true?
A. Herbals, vitamins, minerals, and food supplements are not regulated by the U.S. Food, Drug, and Cosmetic Act (FDCA).
B. Manufacturers must prove the safety of their herbals, vitamins, minerals, and food supplements.
C. Manufacturers must prove that their herbals, vitamins, minerals, and food supplements are free from adulteration.
D. Manufacturers must prove the legitimacy of any claims they make about their herbals, vitamins, minerals, and food supplements.

____ 2. Which amendment to the FDCA established the two classes of drugs: legend or prescription only and over the counter?
A. Durham-Humphrey Amendment (Prescription Drug Amendment)
B. New Drug Application Amendment
C. Health Education and Welfare Amendment
D. Kefauer Harris Amendment

____ 3. The package insert (PI) attached to a prescription drug contains all of the following information except:
A. U.S. Food and Drug Administration (FDA)-approved drug information.
B. Highly detailed adverse effects and dosage information for the prescriber.
C. Information in layman's terms for the patient.
D. Pharmacodynamic and pharmacokinetic drug information.

____ 4. Which of the following best defines the term *adulteration of drugs*?
A. Adding contaminants or anything not stated on a drug label
B. Claiming a drug is a cure for a certain condition, such as cancer
C. Advertising a drug for a poorly defined condition, such as miasma
D. Claiming a drug is safe when its safety has not been established in preclinical trials

____ 5. The majority of "off-label" or unapproved usages for drugs are prescribed for which patient groups?
A. Pediatric patients and patients on chemotherapy
B. Patients with neurologic diseases
C. Obese patients
D. Pregnant patients

____ 6. The major goals of the Controlled Substances Act (CSA) include all of the following except:
A. Improving the manufacturing, distribution, prescribing, and dispensing of controlled substances by legitimate persons in the health-care sector.
B. Providing research into issues of drug addiction and rehabilitation.
C. Stopping the widespread diversion of controlled substances into illicit or "street" channels.

D. Establishing laws and criminal sentences for the possession and sale of illicit controlled substances.

____ 7. Which statement is true regarding the Drug Enforcement Administration (DEA) categories of scheduled drugs?
A. Schedule I drugs have a high potential for abuse and no accepted medical use in the United States.
B. Schedule I drugs have a low potential for abuse and no accepted medical use in the United States.
C. Schedule II drugs have a low potential for abuse.
D. Schedule V drugs have a high potential for abuse.

____ 8. Which statement regarding extemporaneous compounding is false?
A. Extemporaneous compounding is the pharmacist's art of preparing a drug product for a specific patient using a physician's prescription, a drug formula, or a recipe.
B. Calculated amounts of ingredients are measured out and made into a uniform mixture.
C. Extemporaneous compounding is the pharmacist's art of preparing a drug product for a patient using his own drug formula rather than a physician's prescription.
D. Pediatric dosages are commonly compounded when only adult dosages are available.

____ 9. *Clinical pharmacology* is best defined as:
A. The study of the optimum use of medication in patients.
B. The study of the human body's reaction to a drug over a specified time.
C. The biologic actions of a drug at its site of action.
D. The study of the effects of genetic variations on pharmacologic processes.

____ 10. Which statement regarding over-the-counter (OTC) drugs is true?
A. OTC drugs are rarely associated with toxicity or overdose.
B. No OTC drugs are also available in a higher dosage form by prescription.
C. OTC drugs are generally more expensive than prescription drugs.
D. OTC drugs contain directions and information on the label and packaging to allow consumers to self-medicate.

____ 11. In the early 1960s, the serious birth defects caused by thalidomide prompted which of the following amendments to the FDCA?
A. Kefauver Harris Drug Efficacy Amendment
B. Dietary Supplement and Health Act
C. Orphan Drug Status Act
D. Controlled Substances Act

____ 12. Which medication is an example of a schedule I (C-I) drug?
A. oxycodone
B. mescaline
C. fentanyl
D. diazepam

____ 13. Which statement regarding schedule II (C-II) controlled substance drugs is true?

A. Heroin is an example of a schedule II drug.
B. Prescribers can write orders that include up to five refills of schedule II prescription drugs.
C. Cough syrup with codeine is an example of a schedule II drug.
D. Emergency verbal orders for a schedule II drug must be confirmed with a written prescription within 72 hours.

____ 14. According to the Centers for Disease Control and Prevention, the number of preventable medical errors per year is approximately:
A. 100,000.
B. 25,000.
C. 1 million.
D. 500,000.

____ 15. Adverse drug events:
A. Occur once a day in every hospital in the United States.
B. Do not increase health care-related costs.
C. Are less common among Medicare patients.
D. Are not common among residents in a long-term care facility.

____ 16. In 1994, the World Health Organization (WHO) released recommendations for rational prescribing that included all of the following recommendations except:
A. Use only brand (trade) name drugs.
B. Ensure medication choices are safe and effective for the defined problem.
C. Monitor the results of treatment.
D. Stop the use of a drug when the treatment period is complete.

____ 17. Which statement is true regarding medication errors?
A. Telephone communication of drug orders decreases the frequency of medication errors.
B. Mail order medications are less likely to cause issues with medication errors.
C. Lack of patient history information is a common source of medication errors.
D. Patient education regarding medications should be left to the pharmacist to avoid medication errors.

____ 18. Which statement is true regarding medication errors?
A. They are most commonly the result of a single event.
B. They are most commonly the result of multiple events.
C. They are usually caused by a single careless person.
D. A faulty system will not contribute to medication errors.

____ 19. The "Signa," or *signatura*, component of a written prescription includes:
A. Patient data, such as age, name, and gender.
B. Prescriber data, such as name, practice location and phone number, and professional degree.
C. Instructions the prescriber has given to the patient, which will appear on medication label.
D. Brand or generic name and strength of medication.

____ 20. Which of the following examples could be the inscription component on a prescription?
A. John Smith, RPA-C, License number
B. Dispense # 20
C. Cefuroxime 500 mg
D. Take one tablet PO twice daily for 10 days

____ 21. Which of the following examples could be the subscription component on a prescription?
A. Dispense # 100 ml
B. John Smith, RPA-C, License number
C. Patient name and address
D. Take 5 ml PO twice daily for 10 days

____ 22. A prescriber wants a patient to receive the Dilantin brand and does not wish to substitute with the generic, phenytoin. Which of the following statements is false regarding generic and brand substitution?
A. The Drug Substitution Law allows a pharmacist to substitute a generic bioequivalent drug for one stated on a prescription.
B. A prescriber can write "DAW," meaning "dispense as written," to ensure that a patient receives the brand name drug.
C. The FDA regulates and reports on bioequivalence testing for generic drugs.
D. All brand drugs can be switched to generic without biologically significant fluctuations.

____ 23. Which abbreviation indicates that a patient should take their medication at bedtime?
A. HS
B. BID
C. AC
D. PRN

____ 24. A patient is instructed to apply one drop to each eye. Which abbreviation for these instructions is accurate?
A. One gtt ou
B. One gr ad
C. One gtt au
D. One gtt od

____ 25. Which abbreviation indicates that a medication should be taken by mouth twice daily?
A. po BID
B. po ac
C. po qd
D. po TIW

____ 26. Which abbreviation indicates that three drops should be placed in both ears?
A. Three gtt as
B. Three gtt ad
C. Three gtt au
D. Three gtt od

____ 27. Which of the following statements is *false* regarding prescriptions?

A. Prescriptions for schedule II controlled substances may be refilled.
B. Medications are dispensed in childproof containers unless otherwise noted.
C. The date of the prescription is required on all prescriptions.
D. The prescriber's DEA number should be included when necessary.

____ 28. Pregnancy safety category C is best described by:
A. Adequate and well-controlled studies have indicated no risk to a fetus in the first trimester of pregnancy and have produced no evidence of risk in later trimesters.
B. Animal studies have indicated no risk to a fetus; however, no well-controlled studies in pregnant women have been conducted.
C. Animal studies have indicated adverse effects on a fetus; however, no well-controlled studies in humans have been conducted.
D. Positive human fetal risk has been reported in investigational or marketing experience or human studies.

____ 29. Which pregnancy category indicates that the risks of using a drug outweigh the benefits and, therefore, that drugs in this category should not be used by pregnant women?
A. Category A
B. Category C
C. Category X
D. Category D

____ 30. Principles of conscientious prescribing include all of the following *except:*
A. Consideration of the cost of medications and drug formularies.
B. Consideration of the patient’s ability to adhere to the prescribed medication regimen.
C. Consideration of comorbidities and polypharmacy.
D. Preference for brand name drugs for all prescribed medications.

____ 31. Which of the following should a prescriber do when possible?
A. Prescribe the least expensive but most effective medication.
B. Prescribe the medication chosen by the patient.
C. Prescribe the most efficacious drug despite the side effect profile.
D. Prescribe without fully disclosing all side effects to spare the patient any distress.

____ 32. Which statement regarding the current evidence on the use of electronic medical records is false?
A. They can prevent transcription errors.
B. They eliminate issues caused by illegible handwriting.
C. They improve response time and accuracy.
D. They reduce the number of medication errors in facilities with computerized systems when compared to those without such a system.

____ 33. The American Medical Association publishes principles of conservative prescribing. These principles include all of the following *except:*
A. Treat underlying disease, not just symptoms.
B. Start with one drug at a time when possible.
C. Use new drugs as soon as they are approved by the FDA.
D. Be aware of potential adverse effects.

____ 34. Which statement regarding risk factors for adverse effects of medications is true?
A. Very old patients are at increased risk for adverse outcomes.
B. Pediatric patients experience fewer adverse effects than adults.
C. Patients with chronic illnesses on long-term medications are less prone to have adverse drug events.
D. Patients with mental illness have the same risk of adverse drug effects as the general population.

____ 35. Medication adherence can be greatly improved by educating a patient about:
A. The pharmacokinetics of the drug.
B. All possible side effects listed by the manufacturer.
C. Special instructions on using the medication.
D. The mechanism of action of the drug.

____ 36. Which question should a prescriber ask himself or herself before prescribing a drug?
A. Have I weighed all the risks and benefits?
B. Have I given the patient the medication they asked for?
C. Have I informed the patient of all possible side effects as written by the manufacturer?
D. Have I prescribed the newest drug on the market?

____ 37. Which statement regarding appropriate prescribing practices is false?
A. Directions such as "as directed" should be avoided.
B. The quantity of controlled substance to be dispensed should be written as a word; for example, "thirty" (30).
C. Roman numerals are preferred over Arabic numbers.
D. In the case of liquid medication or suspension, the dispensing can be in milliliters (ml).

____ 38. A patient presents with a self-diagnosed condition and believes she needs a medication she has seen on television. Which response to this patient would be most inappropriate?
A. Explaining the side effects of the requested drug
B. Explaining the appropriateness of the requested drug
C. Explaining the risks and benefits of the requested drug
D. Prescribing the medication to the patient without further discussion, as this is what she wants

____ 39. Which statement is false regarding prescribing medications to pregnant patients?
A. Teratogenicity varies between patients.
B. Susceptibility among humans varies widely.
C. All teratogenic agents cause malformations with every exposure.
D. Damage caused by teratogenic agents is usually a function of dosage, length of exposure, and a window of opportunity.

Completion
Complete each statement.

1. Lysergic acid diethylamide (LSD) is an example of a schedule _____ drug.

Chapter 1. Conscientious and Rational Prescribing in the 21st Century
Answer Section

MULTIPLE CHOICE

1. ANS: A
   Federal regulations for dietary supplements are very different from those for prescription and over-the-counter drugs.

   PTS: 1 TOP: Regulation of Herbals, Vitamins, Minerals, and Food Supplements
2. ANS: A
   Prior to the passage of this law, drug manufacturers were free to determine the category for each of their drugs.

   PTS: 1 TOP: Federal Drug Regulations
3. ANS: C
   The PI contains information for health professionals; the patient information leaflet provides information in layman's terms for the patient.

   PTS: 1 TOP: Federal Drug Regulations
4. ANS: A
   Passed in 1906, the FDCA established the FDA to protect the public from harm from drugs that had been adulterated and/or mislabeled.

   PTS: 1 TOP: Federal Drug Regulations
5. ANS: A
   Pediatric populations and patients on chemotherapy are the hardest groups to assemble for clinical trials; therefore, they are commonly prescribed "off-label" uses for medications.

   PTS: 1 TOP: Off-Label Prescribing
6. ANS: D
   The CSA does not establish criminal sentences for possession and sale of illicit controlled substances.

   PTS: 1 TOP: Opioids/Narcotics and Other Dangerous Drugs
7. ANS: A
   Schedule I drugs under the CSA for the United States are drugs or other substances that have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and lack accepted safety standards for use under medical supervision.

   PTS: 1 TOP: Opioids/Narcotics and Other Dangerous Drugs
8. ANS: C
   With extemporaneous compounding, the pharmacist prepares the drug product using a physician's prescription, a drug formula, or a recipe.

PTS: 1 TOP: Writing Prescriptions to Avoid Errors

9. ANS: A
Clinical pharmacology is the academic discipline on ethical, effective, safe, and economic use of drugs.

PTS: 1 TOP: Conscientious Prescribing

10. ANS: D
OTC drugs contain directions and information that allow consumers to self-medicate. In addition, they can be associated with toxicity and overdose, are usually available in higher dosages by prescription version, and are not necessarily more expensive than prescription drugs.

PTS: 1 TOP: Federal Drug Regulations

11. ANS: A
The Kefauver Harris Drug Efficacy Amendment requires that manufacturers provide proof of not only a drug's safety, but also its effectiveness for the purpose stated.

PTS: 1 TOP: Federal Drug Regulations

12. ANS: B
Mescaline is a schedule I drug, which means that it has no accepted medical use in the United States.

PTS: 1 TOP: Opioids/Narcotics and Other Dangerous Drugs

13. ANS: D
Emergency verbal orders for a schedule II drug must be confirmed with a written prescription within 72 hours. Prescribers may not write orders that include refills for schedule II controlled substance drugs.

PTS: 1 TOP: Opioids/Narcotics and Other Dangerous Drugs

14. ANS: A
The number of preventable medical errors is increasing each year due to the growing prevalence of methicillin-resistant Staphylococcus aureus (MRSA) and preventable hospital errors.

PTS: 1 TOP: Conscientious Prescribing

15. ANS: A
Adverse drug events cost nearly $8,750 per event and are common among patients on Medicare and patients receiving long-term care.

PTS: 1 TOP: Medication Errors

16. ANS: A
The WHO recommends that prescribers create a personal formulary of a few effective, safe medications they frequently use regardless of brand.

PTS: 1 TOP: Conscientious Prescribing

17. ANS: C
Telephone and mail order medications can both be sources of medication errors. Patient education

is the responsibility of the prescriber; the patient should fully understand how and why he or she is taking a medication.

PTS: 1 TOP: Medication Errors

18. ANS: B
Most medication errors result from multiple events, which compound themselves, rather than a single act by a careless person. They are usually a function of a faulty system, not faulty people.

PTS: 1 TOP: Medication Errors

19. ANS: C
The Signa, or signatura, tells the pharmacist what words to "sign" on the prescription label as directions for use.

PTS: 1 TOP: Writing Prescriptions to Avoid Errors

20. ANS: C
The inscription includes the brand or generic drug name and its strength.

PTS: 1 TOP: Writing Prescriptions to Avoid Errors

21. ANS: A
The subscription includes the quantity of the drug to be dispensed.

PTS: 1 TOP: Writing Prescriptions to Avoid Errors

22. ANS: D
For certain drugs, bioequivalence studies indicate that once a patient has started on a brand name drug, biologically significant fluctuations can be observed when brands are switched or substituted.

PTS: 1 TOP: Writing Prescriptions to Avoid Errors

23. ANS: A
HS stands for hora somni, which is Latin for "at bedtime."

PTS: 1 TOP: Writing Prescriptions to Avoid Errors

24. ANS: A
OU stands for oculus uterque, which is Latin for "each eye." OD stands for "right eye," and OS stands for "left eye."

PTS: 1 TOP: Writing Prescriptions to Avoid Errors

25. ANS: A
BID stands for bis in die, which is Latin for "twice a day."

PTS: 1 TOP: Writing Prescriptions to Avoid Errors

26. ANS: C
AU stands for auris utraque, which is Latin for "both ears." AD stands for "right ear," and AS stands for "left ear."

PTS: 1 TOP: Writing Prescriptions to Avoid Errors

27. ANS: A
Prescriptions for schedule II controlled substances may not be refilled.

PTS: 1 TOP: Writing Prescriptions to Avoid Errors

28. ANS: C
In pregnancy safety category C, animal reproduction studies have reported adverse effects on a fetus; however, there are no well-controlled studies in humans. Potential benefits may indicate the use of the medication despite potential risks.

PTS: 1 TOP: Federal Drug Regulations

29. ANS: B
Pregnancy safety category C drugs should not be used in pregnant women because studies have shown that these drugs produce fetal abnormalities or show positive evidence of fetal risk in humans.

PTS: 1 TOP: Federal Drug Regulations

30. ANS: D
Although brand name drugs are sometimes indicated, a prescriber should consider the cost of the brand name drug versus the cost of an equivalent generic drug.

PTS: 1 TOP: Conscientious Prescribing

31. ANS: A
A conscientious prescriber must couple knowledge of pharmacology with other elements that can impact the patient and the patient's ability to take the prescribed medication.

PTS: 1 TOP: Conscientious Prescribing

32. ANS: D
Computer prescription order entry may prevent errors from reaching and harming patients; however, it does not provide evidence that those facilities with computer prescription orders have fewer medication errors than do those facilities without.

PTS: 1 TOP: Conscientious Prescribing

33. ANS: C
Prescribers should not rush to use new drugs because new adverse effects commonly emerge later after the drug is released.

PTS: 1 TOP: Conscientious Prescribing

34. ANS: A
The very young and the very old are at increased risk for adverse outcomes.

PTS: 1 TOP: Conscientious Prescribing

35. ANS: C
To improve medication compliance, all patients should be instructed on how to best take the medication, which includes any special instructions, such as whether the drug should be taken with our without meals or whether specific foods should be avoided.

PTS: 1 TOP: Conscientious Prescribing

36. ANS: A
Before prescribing a drug, clinicians should carefully consider all the risks and benefits to the patient. Prescribing the newest drug on the market and scaring the patient by revealing every side effect that the manufacturer discloses may not be in the best interest of the patient.

PTS: 1 TOP: Conscientious Prescribing

37. ANS: C
Arabic numbers are preferred to Roman numerals in order to avoid confusion.

PTS: 1 TOP: Writing Prescriptions to Avoid Errors

38. ANS: D
A conscientious prescriber should be unafraid of refusing a treatment that is unnecessary. A discussion about a drug's risks and benefits, side effects, and cost commonly leads to nonpharmacologic alternatives for problems identified by consumers of health care.

PTS: 1 TOP: Conscientious Prescribing

39. ANS: C
Not all teratogenic agents cause malformations with every exposure. Teratogenicity itself is not fully understood.

PTS: 1 TOP: Federal Drug Regulations

COMPLETION

1. ANS:
I

LSD is considered a schedule I drug, as it has no accepted medical use in the United States.

PTS: 1 TOP: Opioids/Narcotics and Other Dangerous Drugs