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3. On December 1, 1999, the Supreme Court justices heard arguments in a case testing the Food and Drug Administration's authority to regulate the nicotine in tobacco products. Under current food and drug law, which of the following would **NOT** make nicotine a drug?
- manufacturer's intent to modify form & function of the body
 - manufacturer's intent to mitigate disease
 - a component of another drug
 - a compendial item (listed in USP/NF)
 - recognized adverse effects
4. Which of the following would render a compounded drug "adulterated"?
- the drug was made from filthy and putrid ingredients
 - a parrot was observed in the pharmacy
 - the drug's strength or quality differs from labeled claim
- I only
 - III only
 - I and II only
 - II and III only
 - I, II, and III only
5. Which of the following is **TRUE** about the "Orange Book"?
- it is a list of all drugs approved by FDA
 - it is a list of therapeutically equivalent drugs
 - it is a list of currently marketed multisource drug products
- I only
 - III only
 - I and II only
 - II and III only
 - I, II, and III only
6. Female employees in a pharmacy that compounds progesterone suppositories complain of menstrual irregularities. With which agency should a complaint be filed?
- Board of Pharmacy
 - US Food and Drug Administration
 - Washington Industrial Safety and Health Administration
- I only
 - III only
 - I and II only
 - II and III only
 - I, II, and III only

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7. A bill introduced into the legislature affecting the practice of pharmacy would generally be introduced into which of the following committees?
- I. House Health Care Committee
 - II. House Judiciary Committee
 - III. House Insurance Committee
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III only
8. Which of the following practitioners licensed to practice in Washington is authorized to prescribe Percodan, a Schedule II controlled substance, for an 18 year old pregnant college student?
- a. physician / osteopathic physician
 - b. naturopath
 - c. nurse practitioner
 - d. midwife
 - e. veterinarian
9. Which of the following practitioners is **NOT** authorized to prescribe birth control pills for a high school student?
- I. physician assistant
 - II. dentist
 - III. a registered nurse working for Planned Parenthood
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III only
10. How long must a pharmacy maintain records to comply with Drug Enforcement Administration regulations?
- a. 6 months
 - b. 12 months
 - c. 18 months
 - d. 24 months
 - e. 36 months
11. Which of the following records is required when a pharmacy sells a Schedule II drug for "office use" to a practitioner licensed to practice in Washington?
- a. DEA Form 222 signed by the physician
 - b. DEA Form 222 signed by the pharmacist
 - c. An invoice signed by the pharmacist and physician
 - d. a prescription signed by the physician
 - e. A "power of attorney" signed by the physician

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12. Which of the following prescriptions intended for home use may be filled based on a FAX received from a physician licensed to practice in Washington?
- I. Demerol 50 mg/ml 30 ml vial (a Schedule II narcotic)
 - II. Morphine Sulfate 10 mg/ml 20 ml vial (a Schedule II narcotic)
 - III. MS Contin 30 mg extended release tablets #40 (a Schedule II narcotic)
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III only
13. Which of the following is **NOT** required on a prescription label for a controlled substance dispensed in Washington?
- a. pharmacy name
 - b. pharmacy DEA number
 - c. patient name
 - d. prescriber name
 - e. prescription serial number
14. Which of the following is **NOT** required on a prescription label for a controlled substance dispensed in Washington?
- I. name of drug
 - II. patient address
 - III. directions for use
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III only
15. A patient comes into the pharmacy complaining of back pain unrelieved by ibuprofen and other OTC analgesics and asks for a codeine product. May you dispense Robitussin AC (a Schedule V controlled substance containing codeine phosphate 10 mg/5 ml) to this patient?
- a. yes
 - b. no

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16. When dispensing a drug to a patient in your pharmacy, what activity is required in Washington compared to OBRA/90?
- I. pharmacist must orally explain directions for use
 - II. pharmacist must offer to explain directions for use
 - III. pharmacist must provide written instructions for use
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III only
17. A recent K-Mart advertisement in the *Seattle Times* provided a listing of brand-name drugs including dosage form and price, at K-Mart and at competing stores. The ad noted, "If your prescription is not ready when promised, it is free". Which of the following must be added to make this a legal advertisement under Washington Board of Pharmacy rules?
- I. Generic names of the drugs
 - II. Strength of the drugs
 - III. Telephone number of the pharmacy
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III only
18. If the Washington legislature determined that Viagra sales in Washington via internet sites was a hazard to public health and welfare, could it place this drug in Schedule II?
- a. yes
 - b. no
19. You receive a prescription written for a brand-name drug by a physician licensed to practice in California and the "substitution OK" box has been checked, but there is only one signature line on the prescription blank. May a Washington pharmacist dispense a generic equivalent of the brand-name drug?
- a. yes
 - b. no
20. Under Washington law, if a generic drug is legally substituted for a brand-named drug and a patient sues for injury believed to be caused by the generic drug, has the pharmacist assumed a greater liability by dispensing the generic drug?
- a. yes
 - b. no

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21. Which of the following is/are **FALSE**?
- I. Pharmacists can initiate drug therapy under a protocol with an authorized prescriber.
 - II. A pharmacist is not required to submit a protocol signed by an authorized prescriber to the Board of Pharmacy in Washington State.
 - III. The prescription authority protocols, or collaborative drug therapy agreements, are mostly utilized in hospitals.
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III only
22. Which of the following is/are **FALSE**?
- I. Pharmacists in Washington State have the most experience with collaborative drug therapy in the U.S.
 - II. The number of protocols in Washington State has remained stable over the past 2 years.
 - III. In a survey of physicians and pharmacists using protocols, pharmacists were much more satisfied than physicians.
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III only
23. Which of the following is **NOT** an advantage of electronic "prescription order entry" systems?
- a. order security is maintained, i.e., the order cannot be altered after prescribing
 - b. non-formulary drug orders are obvious
 - c. prescribers can be alerted to allergies up front
 - d. PBMs and insurance companies will be able to adjust the prescription to match their formulary
 - e. incomplete or ambiguous orders are eliminated
24. Generally, which of the following is **TRUE** regarding drug diversion?
- a. obtaining prescriptions for controlled substances from prescribers is difficult
 - b. licit drugs, alone or in combination, do not mimic the effects produced by illicit substances such as heroin
 - c. intense scrutiny in the workplace has lead to a decrease in drug diversion by pharmacists in recent years
 - d. Schedule II controlled substances tend to be diverted more often than Schedule II substances because of less stringent record keeping requirements
 - e. Licensed health care practitioners that divert controlled substances are most often motivated by impairment

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25. Which of the following situations should cause a prudent pharmacist to suspect drug diversion?
- the issuance of a legend drug prescription by a physician for an immediate family member
 - hospitalized patients that complain of no pain relief when injectable narcotics are administered for pain
 - discovery of DEA 222 order forms misfiled with other controlled substance records
 - a dentist who usually prescribes Vicodin (hydrocodone and acetaminophen) instead of Tylenol #3 (codeine and acetaminophen) for pain
 - changes made to a written prescription by the prescriber
26. A Memorandum of Understanding between a state and the FDA, as required by the FDAMA97, addresses which of the following?
- Interstate distribution of commercially available products
 - DEA oversight of controlled substances, including steroids
 - Responsibilities of the states in regard to regulation of interstate distribution of compounded products
 - FDA oversight of approved bulk substances
 - FTC oversight of advertising of compounded products
27. Which of the following is **NOT** a condition or situation under which a compounded product could be considered to be manufactured, and thus subject to the current Good Manufacturing Practices provisions of the Food, Drug and Cosmetic Act?
- If it is repackaged for resale to another pharmacy
 - If it is sold to a pharmacy in another state
 - If it is sold to another health professional for resale to the ultimate consumer
 - If it is compounded in batches in anticipation of future prescription orders based on existing prescribing patterns
 - If it is essentially a copy of an existing commercially available product without a significant need to be compounded as determined by the prescriber
28. Which of the following would **NOT** be considered a legitimate compounded product, according to the FDAMA97 provisions?
- A prescriber indicates a need for a patient to receive a natural source of progesterone instead of the commercially available vaginal gel.
 - A pharmacist compounds ibuprofen in a gel, pursuant to a prescription order from an internist who had read an article that indicated some patients with intractable arthritis markedly improve when using the compounded formulation.
 - A pharmacist in a remote rural town compounds a vaginal suppository and supplies it to the other pharmacy in town that does no compounding.
- I only
 - III only
 - I and II only
 - II and III only
 - I, II, and III only

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29. Increased FDA scrutiny of pharmacist compounding resulted from:
- I. Notorious cases of improper compounding resulting in patient disfigurement and/or death
 - II. Cases of pharmacists engaging in manufacturing activities under the guise of compounding
 - III. Federal government revocation of the states' rights to govern the practice of pharmacy
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - a. I, II, and III only
30. Which of the following ingredients could **NOT** be used in a compounded product, according to FDAMA97?
- a. A substance listed in the USP-NF.
 - b. A drug whose source is an approved drug in a commercially available dosage form, such as a tablet or capsule.
 - c. A substance listed in the approved bulk substance compounding list, proposed through the FDA Compounding Advisory Committee
 - d. An over-the-counter topical preparation, such as 1% hydrocortisone cream
 - e. All of the above may be used in a compounded product
31. Which of the following are factors in causing prescription errors?
- I. Illegible handwriting
 - II. Poorly transmitted verbal orders
 - III. Inadequate staffing
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III
32. Which of the following are factors in causing prescription errors?
- I. Inadequate staffing of the pharmacy
 - II. Interruptions of the pharmacist by phones or patients
 - III. Poor organization of the pharmacy department
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III

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33. Which of the following should **NOT** be done when a patient confronts the pharmacist about a prescription error?
- I. Have the technician deal with the patient
 - II. Blame the patient
 - III. Apologize for the error
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III only
34. In order to meet federal standards for child resistant packaging, a manufacturer must test the container on which of the following groups?
- I. Senior adults 50 through 70 years old
 - II. Children between 42 and 51 months old
 - III. Ten year-old children only
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III
35. Which of the following drugs need **NOT** be dispensed in a child resistant container?
- I. Sublingual nitroglycerin tablets
 - II. Birth control pills in memory packages
 - III. Isosorbide oral tablets 40 mg
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III
36. Which of the following persons may **NOT** authorize the dispensing of a prescription in a non-child resistant container?
- I. The prescriber
 - II. The patient
 - III. The pharmacist
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III

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37. Which of the following OTC products may be sold in a **non-child resistant container**?
- I. Aspirin tablets 325 mg No. 6
 - II. Tylenol tablets 325 mg No. 12
 - III. Tylenol tablets 325 mg No. 100 marked "This package for households without children"
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II, and III only
38. When a drug is labeled with an expiration of "November 2004" what day of the month does the drug expire?
- a. November 1.
 - b. November 7.
 - c. November 15
 - d. November 30
 - e. December 1
39. According to the Robinson-Patman Act as interpreted in Abbott Labs et al VS Portland Retail Druggist Association (425 US 1 (1976)) a hospital's "own use" purposes may **NOT** include prescription drugs that it purchased at a special hospital discount for which of the following purposes?
- a. Inpatients of the hospital
 - b. Outpatients of the hospital
 - c. Hospital employee prescriptions
 - d. Hospital discharge prescriptions
 - e. Sales to physician staff members for dispensing in physician's offices
40. Which of the following drug recalls is the most serious?
- a. Class 1
 - b. Class 2
 - c. Class 3
 - d. Class 4
 - e. Class 5

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The following drama applies to questions 41 through 43. You are working a locum^b at Coyle Drugs & Mercantile and are approached by a private investigator, Sarah Sleuth. She presents you with the following form, completed in handwriting.

41. Under RCW 70.02.020 Disclosure by health care provider, what should you do?
- I. provide copies of the requested prescriptions
 - II. chart the disclosure
 - III. respectfully decline to provide the documents
- a. I only
b. III only
c. I and II only
d. II and III only
e. I, II, and III only
42. If the requestor of information was Jefferson County Docs 'R Us (a legitimate managed care organization), what should you do?
- I. provide copies of the requested prescriptions
 - II. chart the disclosure
 - III. respectfully decline to provide the documents
- a. I only
b. III only
c. I and II only
d. II and III only
e. I, II, and III only
43. If Perry Kolase had AIDS, what must you do? **Assume requestor is Jefferson County Docs 'R Us.**
- I. provide copies of the requested prescriptions
 - II. chart the disclosure
 - III. respectfully decline to provide the documents
- a. I only
b. III only
c. I and II only
d. II and III only
e. I, II, and III only
44. Unless s/he is a spouse, sibling or adult child of a patient, **NONE** of the following may act as the attorney-in-fact for a patient under the Durable Power of Attorney for Health Care provisions of RCW 11.94.010(3): the patient's physicians, the physician's employees, or the owners, administrators or employees of the facility where the patient resides or receives care.
- a. True

^b *locum tenens* -- a temporary substitute, esp. for a doctor or member of the clergy

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b. False

45. In advance directives and end-of-life decision-making, one of the deciding elements is whether the patient's interests outweigh countervailing^c state interests. What are the state's interests?

- I. preservation of life and prevention of suicide
- II. protection of the interests of innocent third parties
- III. integrity of the medical profession

- a. I only
- b. III only
- c. I and II only
- d. II and III only
- e. I, II, and III only

46. The dose for a drug administered to a patient in an extended care facility is increased by the patient's physician from "one tablet each morning" to "one tablet each morning and ½ tablet each afternoon". May the extended care facility nurse change the label on the prescription vial to reflect this dosage increase?

- a. yes
- b. no

47. Under RCW 69.41.110 Substitution Of Prescription Drugs, Definitions, "therapeutically equivalent" means essentially

- I. the same efficacy and toxicity when administered to an individual in the same dosage regimen
- II. same active ingredient(s), are of the same dosage form, route of administration and are identical in strength or concentration
- III. comparable bioavailability when studied under similar experimental conditions

- a. I only
- b. III only
- c. I and II only
- d. II and III only
- e. I, II, and III only

48. Assume that the prescriber has signed a prescription on the LEFT-hand side, authorizing substitution of a therapeutically equivalent product. What must a pharmacist do in filling the prescription?

- I. Record the manufacturer's name and lot number of the drug actually dispensed on the prescription or in the patient medical record
- II. substitute an equivalent drug product which the pharmacy has in stock if its wholesale price to the pharmacist is less than the wholesale price of the prescribed product
- III. note the generic or trade name of the drug actually dispensed on the prescription label

- a. I only

^c countervail -- to act or avail against with equal power, force, or effect; counteract

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- b. III only
- c. I and II only
- d. II and III only
- e. I, II, and III only

49. Which of the following would be accurate regarding pharmacy ethics?

- a. Enforcement of ethical standards occurs through the Washington State Board of Pharmacy.
- b. The Washington State Board of Pharmacy establishes ethical standards.
- c. Violation of an ethical standard often carries no administrative penalty.
- d. Violation of an ethical standard carries penalties enforced by the Washington State Board of Pharmacy.
- e. The "relevant local community" determines ethical standards.

50. If the pharmacy and therapeutics (P&T) committee of a managed care organization decided to approve the use of a drug for persons age 55 or greater only, even though the drug has indications for use in all adults, what would be the most significant normative ethics principle breached?

- a. Autonomy
- b. Justice
- c. Beneficence
- d. Nonmaleficence