Last Name:

Pharmacy 5002 Pharmacy Law and Ethics Exam I

Do not open the test booklet prior to being told to do so.

I, the undersigned student, agree to do my best on the exam and that I have only used resources that were readily available to other students in the class. I agree not to use any unapproved resources, including the exams of those around me, during the test.

Signature of Student
Date: October 4, 2011

By taking this test you agree I am the best teacher ever. If you disagree, raise your hand and I will give you a 'different' test. GOOD LUCK!!!!!!!!!

1. Two products approved in the US that are part of the NDC protocol have the following NDC's on them:
   12345-0155-10
   23423-0155-11

   What is the relation between the two products?
   A. The two products are the same product.
   B. The 12345 product is the brand name product, where as the 23423 product is the generic
   C. The products contain the same active ingredient
   D. The products are made by the same manufacturer, but are different products.
   E. There is no relationship between the products

2. _____ is a noncontrolled dangerous substance which by appearance would lead a reasonable person to believe that it is a controlled dangerous substance.
   A. Non-controlled dangerous substance
   B. Counterfeit controlled dangerous substance
   C. Imitation controlled dangerous substance
   D. Controlled substance analogue
   E. Controlled substance pre-cursor

3. Which of the following categories of pregnancy warnings would indicate that animal studies(conducted at high dosages) found risk to the fetus but well controlled human (conducted at normal dosages) studies found no risk?
   A. Category A
   B. Category B
   C. Category C
   D. Category D
   E. Category X

4. Which of the following forms must be filled out and sent to the wholesaler prior to receiving Schedule III drugs?
   A. DEA 104
   B. DEA 106
   C. DEA 222
   D. DEA 41
   E. None of the above

5. The iPledge program requires which of the following?
   A. No more than a 90 day supply be supplied to the patient at one time
   B. Patient must use one form of birth control
   C. That only females register with the program
   D. That female patients have a pregnancy test prior to receiving a prescription for the medication
   E. That registration of the patient in the database only occur if the patient has a side effect

6. Which of the following terms limits the amount of time a crime can be brought to trial?
   A. Administrative review
   B. Statute of limitations
   C. Breach limitations
   D. Contributory negligence
   E. Comparable negligence

7. Which of the following must appear on a commercial container of a medication?
   A. Street address of the maker
   B. Date medication was packaged
   C. NDC
   D. Ingredient information
   E. All of the above

8. Which of the following actions would be considered misbranding?
   A. Placing the city and state of the packager on the label
   B. Putting 90 tablets in a bottle labeled 100 tablets
   C. Attaching the patient package insert directly to the label of the drug bottle
   D. Providing correct instructions on an over the counter bottle
   E. Labeling a veterinary product for use in fish only

9. A schedule II narcotic may be partial filled today with the remainder being dispensed to the patient at a later date if
   A. the patient can only afford some today but will return within 72 hours
   B. the patient is terminally ill enrolled in hospice
   C. is 'well known' to the pharmacist
   D. is a physician or a physician's agent
   E. the patient wants to try the medication before paying for all of it.

10. Which of the following are reasons to control a medication substance as defined by the LA Uniform Controlled Dangerous Substances Law?
    i. It has a high street value
    ii. It has an actual potential for abuse
    iii. There is a history of abuse of the medication
    A. i only
    B. iii only
    C. i and ii only
    D. ii and iii only
    E. i, ii, and iii

11. A pharmacist misfills a patient's prescription during a refill. The pharmacist admits that he made the mistake, however argues that the patient had been taking the medication for over 5 years and should have known that the medication looked different and not consumed it. The courts agree that both the pharmacist and patient are negligent, if the court is in an area where only contributory negligence is present which of the following states is most true?
    A. The pharmacist is responsible for all damages
    B. The patient is responsible for all damages
    C. No damages would be awarded since damages are all or none
    D. The patient would be 25% responsible and the pharmacist 75%
    E. The patient would be 25% responsible, pharmacist 40%, and the pharmacy 35%.

12. Which of the following situations requires a prescription to be made when the product being administered is a controlled substance?
    i. A licensed prescriber administers the substance to the patient.
    ii. A licensed prescriber tells a licensed nurse in his office to administer the substance to the patient
    iii. A licensed prescriber tells a licensed pharmacist to administer the medication to the patient.
    A. i only
    B. iii only
    C. i and ii only
    D. ii and iii only
    E. i, ii, and iii

13. Which of the following is not considered to be a practitioner according to the Controlled Substance Act?
    A. Dentist
    B. Pharmacist
    C. A drug researcher using controlled substances in research trials
    D. Hospital
    E. Physician

14. The Kefauver-Harris Amendment in 1962 to the Food, Drug, and Cosmetic Act stated that:
    A. Extensive animal, pharmacological, and toxicological testing must occur prior to testing in humans
    B. Certain drugs could have an extended patent life
    C. Required tracking of samples
    D. Fees will be added to drug applications
    E. Dietary supplements would be excluded from being regulated by the FDA

15. A tablet containing only pentobarbital would be classified as a schedule
    A. I
    B. II
    C. III
    D. IV
    E. V

16. Which of the following is a key element of establishing malpractice?
    A. Breach of Duty
    B. Extension of responsibility
    C. Power to decide
    D. External damage application
    E. Applied care requirements

17. A prescription for a C-V medication may only be transferred a total of _____ between two pharmacies that do not share a common database.
    A. 0 times
    B. 1 time
    C. 2 times
    D. 3 times
    E. the maximum number of refills

18. Which of the following is a valid DEA number(s) for I.P. Freeley MD (a licensed Medical Doctor) of Southeast New Hampshire?
    A. AF 1246847
    B. MF 1246847
    C. NH 1246847
    D. PF 1246847
    E. None of the above

19. The S.T.E.P.S program helps ensure the safe use of
    A. Thalidomide
    B. Sodium Oxybate
    C. Buprenorphine
    D. Isotretinoin
    E. Bosenten

20. _____ is when one person is liable for the actions of another when engaged in some form of joint or collective activity.
    A. Vicarious liability
    B. The statute of limitations
    C. Causation
    D. Risk management
    E. Warning defect

21. How often must a patient who has been taking clozapine for seven months without any side effects have a CBC drawn?
    A. Once weekly
    B. Every two weeks
    C. Every four weeks
    D. Every six weeks
    E. Every six months

22. A pharmacy chain with stores in several states must obtain
    A. a DEA number in each state it owns a store
    B. a DEA number for each individual pharmacy location
    C. just on DEA number for the entire chain
    D. a DEA number for each of the chain's regional offices
    E. a DEA number for each Pharmacy Supervisor in the chain

23. A product containing only sibutramine would be classified as a schedule
    A. I
    B. II
    C. III
    D. IV
    E. V

24. Which of the following employees of the pharmacy are allowed to sell over the counter pseudophedrine assuming all of other applicable laws are followed?
    i. Pharmacist
    ii. Licensed Pharmacy Technician
    iii. Pharmacy clerk/cashier
    A. i only
    B. iii only
    C. i and ii only
    D. ii and iii only
    E. i, ii, and iii only

25. A product containing triazolam would be classified as a schedule
    A. I
    B. II
    C. III
    D. IV
    E. V

26. Which of the following are not required to be on a prescription label attached to an 'Rx only' medication dispensed to a patient per **Federal Law**?
    A. Address of Pharmacy
    B. Name of Physician
    C. Expiration date of medication
    D. Serial number of prescription
    E. Directions for use

27. Drug product Z is new to the market, and is required by the manufacturer to be stored in the refrigerator. Pharmacist Phil is unaware of this, and stores the product on the shelf at room temperature. A couple weeks after receiving the product, Phil dispenses it to a patient. Which of the following statements would be most accurate?
    A. Phil could be found to have violated the FDCA.
    B. Since Phil did not intend to improperly store the drug product, he can not be found to have violated the FDCA.
    C. Since Phil is not a manufacturer, Phil can not be found to have violated the FDCA.
    D. The FDCA would not apply to this situation.

28. During the Harco drugs v. Halloway case, Harco drugs documented all of their mistakes that they made at their pharmacies. Normally, this information is protected from being introduced into court cases. Why was the data allowed in this case to be presented to the jury?
    A. A single pharmacist made over 200 errors in one month.
    B. Pharmacies corrected the causes of their errors.
    C. Pharmacists filled out the forms incorrectly.
    D. Harco did not do quality improvement when they identified issues.
    E. No patients were ever harmed before.

29. Which of the following forms would need to be completed if a pharmacy was robbed and Oxycontin (Oxycodone) was stolen?
    A. DEA 41
    B. DEA 106
    C. DEA 222
    D. DEA 104

30. Which of the following laws requires the batch verification of certain medications including insulin
    A. Pure Food and Drug Act
    B. Prescription Drug Marketing Act
    C. Food, Drug and Cosmetic Act
    D. FDA Modernization Act
    E. Poison Prevention Act

31. Which of the following forms must be completed to obtain registration with the DEA?
    A. 41
    B. 106
    C. 222
    D. 224
    E. 301

32. Which of the following was responsible for establishing two classes of drugs - prescription and over-the-counter?
    A. Durham-Humphrey Amendment
    B. Kefauver-Harris Amendment
    C. Prescription Drug Marketing Act
    D. Food and Drug Administration Modernization Act

33. Which of the following are NOT true of electronic prescribing of controlled substances?
    i. State rules barring electronic prescriptions are overridden by the Federal Law.
    ii. After prescribing an electronic controlled substance prescription, it must be followed-up by a written prescription within 72 hours.
    iii. All controlled substances must be prescribed electronically by 2014.

    A. i only
    B. iii only
    C. i and ii only
    D. ii and iii only
    E. i, ii, and iii

34. Which of the following would be the correct way to label a bottle from a manufacturer that contained an anabolic steroid?
    A. C-I
    B. C2
    C. CIII
    D. Schedule IV
    E. C-IV

35. When using a DEA Form 222, the center portion of the 3 - part form ultimately ends up with the
    A. purchaser
    B. state board of pharmacy
    C. supplier
    D. regional poison control center
    E. DEA

36. Which of the following pieces of legislation requires the tracking of drug samples?
    A. Durham-Humphrey Amendment of 1951
    B. Food, Drug, and Cosmetic Act of 1938
    C. Kefauver - Harris amendment of 1961
    D. Prescription Drug Marketing Act of 1987
    E. Nutrition Labeling and Education Act of 1990

37. Schedule II inventories must be completed every _____ per the Federal Controlled Substance Act.
    A. prescription
    B. day
    C. month
    D. year
    E. two years

38. According to Federal regulations, a color additive may not be added to which one of the following dosage forms?
    A. Parenteral solutions
    B. Capsules
    C. Syrups
    D. Tablets
    E. Topical lotions

39. The 'Sulfanilamide Tragedy' led to the
    A. Pure Food and Drug Act
    B. Durham-Humphrey Amendment
    C. Federal Food, Drug, and Cosmetic Act
    D. Kefauver - Harris Amendment
    E. Food and Drug Administration Modernization Act

40. Mrs. Smith and Mrs. Thompson are neighbors that both use Friendly Pharmacy for their prescription needs. Friendly Pharmacy misfilled one of Mrs. Thompson's prescriptions. Mrs. Thompson informed Mrs. Smith of the error. Mrs. Smith was outraged after learning about the error and now desires to sue Friendly Pharmacy. Would Mrs. Smith likely be successful in proceeding with a lawsuit?
    A. Yes. Mrs. Smith has a right to sue the pharmacy for any errors Friendly Pharmacy makes to help protect society.
    B. Yes. Mrs. Smith has a right to sue the pharmacy because Mrs. Thompson informed her of the error.
    C. No. Mrs. Smith had no harm caused to her by the error and has no interest to protect with a lawsuit.
    D. No. Mrs. Smith only learned of the error through her neighbor and not directly through the pharmacy.

41. A product containing hydrocodone 12 mg and 325 mg of Aspirin per tablet would be classified as a schedule
    A. I
    B. II
    C. III
    D. IV
    E. V

42. A pharmacist misfills a patient's prescription during a refill. The pharmacist admits that he made the mistake, however argues that the patient had been taking the medication for over 5 years and should have known that the medication looked different and not consumed it. Additionally the pharmacist states that the pharmacy he works at is too busy and understaffed. The courts agree that both the pharmacist, pharmacy, and patient are negligent, if the court is in an area where only comparative negligence is present which of the following statements would be the most plausible?
    A. The pharmacist is responsible for all damages
    B. The patient is responsible for all damages
    C. No damages would be awarded since damages are all or none
    D. The patient would be 25% responsible and the pharmacist 75%
    E. The patient would be 25% responsible, pharmacist 40%, and the pharmacy 35%.

43. Which of the following schedules may the Attorney General reschedule a drug or medication to in an emergency situation?
    A. Schedule I
    B. Schedule II
    C. Schedule III
    D. Schedule IV
    E. Schedule V

44. When a prescription for Duragesic (fentanyl) was presented to your pharmacy, you only had seven of the ten patches requested by the prescription. The other 3 patches **must** be provided to the patient within _____ or the patient will lose them
    A. 24 hours
    B. 72 hours
    C. 10 days
    D. 30 days
    E. 6 months

45. A community pharmacy may fill prescriptions received from a licensed practitioner utilizing a manufacturer's
    i. drug samples
    ii. voucher or coupon
    iii. starter pack

    A. i only
    B. iii only
    C. i and ii only
    D. ii and iii only
    E. i, ii, and iii

46. Which schedule is carispodal in Louisiana?
    A. C-II
    B. C-III
    C. C-IV
    D. C-V
    E. Not scheduled, it is a legend drug

47. A pharmacist receives a prescription for a drug indication which she recognizes as not a recognized indication but recently described in the local newspaper. Which of the following actions is most appropriate for the pharmacist?
    A. Fill the prescription
    B. Fill the prescription but inform the patient that it is not for an appropriate use
    C. Call the prescriber and inform her that it is illegal to write such a prescription
    D. Request that the prescriber indicate on the prescription face 'off labeled use'
    E. Refuse to fill the prescription since it is illegal

48. Which of the following would be considered an legal activity under the LA Uniform Controlled Dangerous Substances Law?
    A. A pharmacist prescribing a controlled substance under a Collaborative Disease State Management agreement
    B. A physician prescribing a controlled substance for a fictitious person without knowing they are fictitious
    C. A pharmacist dispensing a controlled substance to a fictitious person with a fake ID
    D. A wholesaler who sells C-IIs to pharmacies without a CDS license
    E. A patient sees an emergency room doctor and obtains a C-III prescription but does not tell the emergency room physician that they have another C-Iv prescription from another physician

49. Working on the weekend at your local discount drug emporium, you receive a phone call from a local medical doctor asking you to take an emergency phone order for Percocet (Oxycodone and APAP). The pharmacist must receive a signed prescription from the physician within what time period?
    A. Within 24 hours
    B. Within 72 hours
    C. Within 7 days
    D. Within 1 month
    E. The phoned RX counts as the original.

50. The 'Thalidomide Tragedy' led to which of the following
    A. Pure Food and Drug Act
    B. The Durham-Humphrey Amendment
    C. The Federal Food, Drug, and Cosmetic Act
    D. The Kefauver-Harris Amendment
    E. The Food and Drug Administration Modernization Act

You have completed the test!