

Name: _____

Student Number |_|_|_|_|_|_|_|_|_|_|

**PHARMACY 543 PHARMACY LAWS & ETHICS
MIDTERM EXAMINATION 1
October 22, 1999**

Questions 1 – 45 are multiple choice; please record answers on Side 2 of a *Standard Answer Sheet*, Form 1158. Follow the instructions on Side 1; carefully complete your name **and** student number (both characters and bubbles). There are five short answer questions and one ethics essay. Be sure that your name and student number are on all pages that you turn in. Please limit your answers to the space provided for each question.

Turn in (1) the Standard Answer Form, (2) your answers to the short answer questions, and (3) the ethics essay. Please complete your name and student number on any sheet you turn in if you want credit for that work.

Grading: multiple choice questions are 1 point each except as noted (total 30 points); short essay questions are 2 points each (10 points total); ethics question is 10 points. Exam total is 50 points.

Asking questions: you will *not* be allowed to ask questions during the licensure examination, so none will be permitted during the midterm. However, if you believe that a question is technically flawed, please indicate your concern on the exam and turn it in with your answer sheets.

1. A state legislature passed a law requiring that all pharmacies must paint the front of their building purple so that people could recognize pharmacies easily. If the law was challenged in court, which of the following would most likely be correct?
 - A. The law would likely be upheld as valid.
 - B. Laws cannot be challenged in court.
 - C. The law would likely be held invalid for not bearing a reasonable relationship to public health, safety, and welfare.
 - D. The legislature does not have the authority to pass this law.

2. Mary, a hospital pharmacist, received an order for conjugated estrogens for a female inpatient. Mary filled the order and sent it to the patient's floor. Under the Food, Drug, and Cosmetic Act which of the following would be correct?
 - A. Mary is required to provide a patient package insert to the nurse or physician.
 - B. Mary is required to provide a patient package insert to the patient.
 - C. Mary is not required to provide a patient package insert to anyone since this is a hospital and the patient is an inpatient.
 - D. Mary is not required to provide a patient package insert since they are not required for this type of drug.

3. True/False. Could a supervisor be liable for failing to take action when sexual harassment is alleged?
 - A. True
 - B. False

4. Which one of the following activities would **NOT** be considered fraud?
 - A. Downcoding a billing claim
 - B. Unbundling a lipid panel billing
 - C. Fee splitting
 - D. Kickbacks

Name: _____

Student Number |_|_|_|_|_|_|_|_|_|_|

5. What are the requirements to make a legally binding contract?
- I. offer
 - II. acceptance
 - III. mutual assent
 - IV. consideration
-
- A. I only
 - B. I and II only
 - C. I, II, III only
 - D. I, II, IV only
 - E. I, III, IV only
6. Which of the following defects would render a contract unenforceable?
- I. contract is coercive
 - II. contract is severely biased
 - III. one of the parties is an emancipated minor
-
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. None of the above

What is the difference between an employee and an independent contractor? (Questions 7 through 11 = 1 point)

	Employee	Contractor
7. Set hours of work	A	B
8. Provides own tools and materials (recall the bus full of drugs ...)	A	B
9. Is at risk for profit or loss	A	B
10. Has the right to quit	A	B
11. Offers services to the general public	A	B

12. Under the Drug-Free Workplace Act, when may an employee be required to participate in drug testing? Assume that the employer has an established policy for drug testing.
- I. upon offer of employment
 - II. at random
 - III. when drug use is suspected
-
- A. I only
 - B. III only
 - C. I and II only
 - D. I and III only
 - E. I, II and III

Name: _____

Student Number |_|_|_|_|_|_|_|_|_|_|

13. Accepting assignment on an influenza-immunization Medicare claim means: (choose one)
- A. Asking the patient to pay "up front"
 - B. Asking the patient to pay only the 20% deductible
 - C. Asking the patient to pay nothing
 - D. Asking the patient to submit their own claim to Medicare for reimbursement
14. Debarment may cause a pharmacist:
- A. To be excluded from Medicare and Medicaid participation
 - B. To lose his/her professional license
 - C. To have to start accepting assignment
 - D. A & B
 - E. C & D
15. All of the following are considered antitrust activity **EXCEPT**:
- A. Price fixing
 - B. You get a prescription transfer and ask what the patient was charged in the past
 - C. Accepting kickbacks
 - D. The WSPA membership votes to not accept the latest Medicaid contract
 - E. Collusion
16. The Campbell-Conyers Bill (HR 1304) is important in that it:
- A. Would create a larger rift between pharmacists and physicians
 - B. Would allow pharmacists to unite and negotiate terms and conditions of insurance contracts
 - C. Would limit the penalties of qui tam actions
 - D. Would further compromise pharmacy workload issues
17. An administrative action is brought by the Board of Pharmacy against a pharmacist for an alleged violation. The pharmacist "pleads the 5th".^a
- I. a jury could assume that silence = guilt
 - II. the pharmacist's silence could be interpreted by the Board as a failure to cooperate
 - III. a jury could assume nothing about silence
- A. I only
 - B. II only
 - C. III only
 - D. I and II only
 - E. I, II and III
18. When conducting a web-based search, the purpose of truncation is to
- A. limit the size of the search term so that the search requires less computer time
 - B. restrict the search so that only the most relevant information is provided
 - C. expand the search to include variations of the root search term
 - D. permit the computer to return a relevancy ranking

^a Fifth Amendment, an amendment to the U.S. Constitution, ratified in 1791 as part of the Bill of Rights, providing chiefly that no person be required to testify against himself or herself in a criminal case and that no person be subjected to a second trial for an offense for which he or she has been duly tried previously.

Name: _____

Student Number |_|_|_|_|_|_|_|_|_|_|

19. The purpose of a Congressional hearing document is to
- A. provide a permanent record of the hearing for a bill, including the persons that testified
 - B. serve as the location where newly passed laws are published
 - C. list the votes cast for or against a bill by each congressperson or senator
 - D. publish the opinion of the legislative branch of government with regard to a bill
20. Pharmacists practicing in Washington must consider *FDA's Approved Drug Products with Therapeutic Equivalence Evaluations* when selecting substitute generic drugs.
- A. True
 - B. False
21. The Rules Committees of the Washington State Legislature make Administrative rules that are binding on pharmacists and other health professionals
- A. True
 - B. False
22. What regulatory recourse does a consumer have if a doggie-bad-breath-product failed to perform?
- I. FDA could seize the product.
 - II. FDA could seek an injunction against the manufacturer.
 - III. FDA could ask the manufacturer to recall the product.
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. None of the above

Consider a viral disease and various methods for dealing with, preventing or treating it. Which agency would regulate the following? (Questions 23 through 27 = 1 point)

Product	Agency	CBER	CDER	CDRH	CFSAN	None of These
23. a vaccine to prevent catching the disease		A	B	C	D	E
24. an antiviral agent produced through organic chemical means		A	B	C	D	E
25. a gizmo that claims to filter the virus from the air and prevent infection		A	B	C	D	E
26. a soap that the lay press (but not the manufacturer) has advocated to prevent infection		A	B	C	D	E
27. a concealer ("cover up") product for viral-induced lesions (has no therapeutic function)		A	B	C	D	E

Name: _____

Student Number |_|_|_|_|_|_|_|_|_|_|

Considering FDA drug and biologics laws/regulations only, would alleged violations described below render a product *adulterated*, *misbranded*, or *neither*? (Questions 28 through 33 = one point)

28. Alleged Violation	Adulterated	Misbranded	Neither
29. the label for a legally marketed OTC drug whose labeling lists no dosing restrictions and is stable for ≥ 3 years has no expiration date	A	B	C
30. the container or closure (e.g., stopper) leaks	A	B	C
31. a product that has a compendial ^b name on its label, but differs in strength from the compendial article	A	B	C
32. packaging has a false bottom, so that the container appears to contain more than is actually present	A	B	C
33. expiration date on a OTC drug label states "10/99" and you sell the product today	A	B	C

34. If FDA determines that a product's labeling is misleading and that relying upon it could result in harm to the user (whether man or animal), what actions can FDA take?

- I. dispatch its agents to seize whatever violative product they can find
- II. go to court and seek an injunction to prevent the company from shipping any more product
- III. ask the manufacturer to recall the product

- A. I only
- B. III only
- C. I and II only
- D. II and III only
- E. I, II, and III

35. A researcher calls for information about a patient and the medications that she had taken in the early 1980's. Assume that appropriate consent documents have been obtained and that there are no confidentiality issues remaining. The researcher has the NDC number from a package of a drug product that was dispensed in 1982, but all of the other text is missing. What can you infer from the NDC?

- I. the name of the manufacturer or distributor (labeler) from the first five digits
- II. the drug identity from the last five digits
- III. the NDC may not accurately identify the product because NDC is voluntary and might change over time

- A. I only
- B. III only
- C. I and II only
- D. II and III only
- E. I, II, and III

^b e.g., specified in one of the official compendia (USP, NF, etc.)

Name: _____

Student Number |_|_|_|_|_|_|_|_|_|_|

36. How many days are scheduled in the Constitution for the Washington State Legislative Sessions that are held in odd-numbered years (budget sessions)?
- A. 30 days
 - B. 60 days
 - C. 105 days
 - D. 125 days
 - E. 205 days
37. Which of the following is **NOT** legal in order to authenticate a controlled substance prescription?
- I. An active duty U.S. Army physician uses his Social Security Number in place of a DEA number
 - II. A University of Washington Hospital medical resident uses the hospital's DEA number plus an identifying suffix provided by the hospital
 - III. An advanced registered nurse practitioner uses her physician employer's DEA number on a prescription for her patient.
- A. I only
 - B. I and II only
 - C. III only
 - D. II and III only
 - E. I, II, and III
38. When a pharmacy is applying for a DEA registration number, who has the burden of proof to show that the pharmacy should receive the registration?
- A. The pharmacy
 - B. The DEA
39. Which of the following controlled substances storage provisions are required for physician's offices?
- I. Substantially constructed locked cabinet
 - II. Dispersal among other prescription drugs
 - III. A hidden metal box
- A. I only
 - B. I or II only
 - C. III only
 - D. II or III only
 - E. I, II, and III
40. Which of the following controlled substances storage provisions are authorized for a community pharmacy offices?
- I. Substantially constructed locked cabinet
 - II. Dispersal among other prescription drugs
 - III. A hidden metal box
- A. I only
 - B. I and II only
 - C. III only
 - D. II and III only
 - E. I, II, and III

Name: _____

Student Number |_|_|_|_|_|_|_|_|_|_|

41. John Jackson, RPh was convicted of a felony and had his license suspended for two years by the State Board of Pharmacy because he sold controlled substances without prescriptions. After the Board has reinstated his license, he wants to return to work as a pharmacist. Which of the following must happen before John can work in a pharmacy?
- A. The pharmacy must obtain a waiver from the DEA
 - B. John must write a letter of apology to all pharmacists for publication in the State Pharmacist Association Journal
 - C. The pharmacy must agree that they will no longer accept Medicaid prescriptions.
 - D. John may only work under the supervision of another licensed pharmacist.
 - E. John may not dispense prescriptions for controlled substances.
42. When a chain of pharmacies wants to maintain controlled substances records at a central location, which of the following records must remain at the individual pharmacies?
- I. Prescriptions
 - II. Biennial inventories
 - III. Executed schedule II order forms
- A. I only
 - B. I and II only
 - C. III only
 - D. II and III only
 - E. I, II, and III
43. Which of the following is NOT required when a required controlled substances inventory is performed?
- I The inventory must be written.
 - II The inventory must show if it was taken at the opening or close of business.
 - III. The inventory must be taken by a licensed pharmacist.
- A. I only
 - B. I and II only
 - C. III only
 - D. II and III only
 - E. I, II, and III

Name: _____

Student Number |_|_|_|_|_|_|_|_|_|_|

Consider the following abstracts and *Federal Register* summary concerning the investigational use of pyridostigmine bromide during Operation Desert Storm.

The use of the drug pyridostigmine bromide (PB) by 250,000 soldiers during the Persian Gulf War "cannot be ruled out" as a cause of lingering illnesses in some veterans, according to a new report prepared for the Defense Department.^c

Pyridostigmine bromide pills were administered to U.S. troops in Operation Desert Storm under a sharply criticized landmark wartime emergency protocol that had been issued by the Food and Drug Administration (FDA) only weeks before the ground war in Iraq began. Under this protocol, FDA allowed the Department of Defense (DOD) to compel troops to take experimental drugs without first getting their informed consent. The DOD believed these drugs provided the best prophylactic protection against the effects of nerve gas attacks. Until the Persian Gulf War, FDA allowed the use of such investigational drugs only with the fully informed consent of the subjects, except in narrowly conscribed [to constrict or limit; circumscribe] emergency situations...^d

The Food and Drug Administration (FDA) is revoking its 1990 interim final regulations that permitted the Commissioner of Food and Drugs (the Commissioner) to determine that obtaining informed consent from military personnel for the use of an investigational drug or biologic is not feasible in certain situations related to military combat... Therefore, FDA is issuing a new interim final regulation with an immediate effective date to establish criteria and standards for the President to apply in making a determination that informed consent is not feasible or is contrary to the best interests of the individual recipients.^e

State your perspective (soldier, DOD, a public citizen, etc.), and evaluate the "normative" ethics of this case by applying the five principles discussed in class. Assume that there are no issues of law.

^c 'Gulf War Syndrome' Study Looks at Nerve Gas Protection. David Brown, Washington Post Staff Writer, Tuesday, October 19, 1999; Page A03

^d Ryan RP. Should combat troops be given the option of refusing investigational drug treatment? *Food Drug Law J* 1997;52(4):377-400

^e 64 *Federal Register* 54180 et seq.(Tuesday, October 5, 1999)