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Student Number |__|__|__|__|__|__|__|

PHARMACY 543 – PHARMACY LAWS & ETHICS
MIDTERM EXAMINATION 1
October 20, 2000

Questions 1 – 35 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, (3) the ethics essay, and other pages if necessary (see below). **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.

In answering multiple choice questions, select the “best” answer among the choices provided.

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.

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1. Which of the following is **TRUE** about a medical device.
- I. medical devices are available by prescription only
 - II. a medical device does not achieve any of its principal intended purposes through chemical action and is not dependent upon being metabolized
 - III. a component^a used in the preparation of the the medical device is a medical device
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II and III

^a 21 CFR§ 210.3 Definitions. (3) Component means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.

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Pseudomonas aeruginosa is a microorganism commonly found in fresh water and soil, and is an opportunistic^b pathogen. *P. aeruginosa* is detected in the make-up water of a manufacturer formulating an antibiotic oral suspension.

2. Under the Food, Drug and Cosmetic Act, the U.S. Food and Drug Administration may allege two major violations against the manufacturer of a potentially defective drug product. If the manufacturer prepared the antibiotic oral solution during the time that *P. aeruginosa* was present in the make-up water, what term would be used to describe the product?
- I. adulterated
 - II. misbranded
 - III. contaminated

A. I only

B. III only

C. I and II only

D. II and III only

E. I, II and III

3. The U. S. Food and Drug Administration would have the burden of proof to demonstrate that the product described in question 2. was, in fact, defective.

A. True

B. False

4. The Durham-Humphrey Act of 1951 established the current framework for determining prescription versus over-the-counter status for a drug. Which of the following could determine the prescription status of a new drug?

I. the article is habit forming

II. the method of use would not be safe unless administered by an appropriately licensed practitioner

III. the preference of the manufacturer

A. I only

B. III only

C. I and II only

D. II and III only

E. I, II and III

^b opportunistic infection: an infection by a microorganism that normally does not cause disease but becomes pathogenic when the body's immune system is impaired and unable to fight off infection. [American Heritage 2000]

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5. Under Washington regulations,

WAC 246-899-030 Product selection responsibilities. (1) The determination of the drug product to be dispensed on a prescription is a professional responsibility of the pharmacist, and the pharmacist shall not dispense any product that in his/her professional opinion does not meet adequate standards.

What information resources may a pharmacist use as a basis for selecting "generic equivalent" drugs:

- I. Official compendia
- II. The Orange Book
- III. The Teal Book

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

6. An agency is created by the Legislative Branch in order to:

- I. further some interest or policy which it has embodied in law
- II. promulgate rules and regulations within its designated sphere of authority
- III. create statutes within its designated sphere of authority

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

7. The State Legislative Branch :

- I. requires one-half + 1 of its members' votes to pass a bill
- II. is responsible for creating agencies
- III. requires two-thirds of its members' votes to pass a bill

- 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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8. The difference between a statute and a regulation is:

- I. a regulation provides detail to statutes
- II. a regulation is created by the legislature
- III. a statute is created by agencies

A. I only

B. III only

C. I and II only

D. II and III only

E. I, II and III

9. The Washington State document that is equivalent to the United States Code is:

A. Revised Code of Washington

B. State Register

C. Washington Administrative Code

10. Which of the following is **NOT** a part of the sequence of a bill becoming a law:

- I. the bill must be written by a Code Revisor
- II. the bill is submitted to leadership, who sends it to the appropriate committee
- III. the Rules Committee is the 'traffic control' and selects bills that will go to the floor

A. I only

B. III only

C. I and II only

D. II and III only

E. I, II and III

11. Washington State statutes prohibiting discrimination have broader coverage (more protection) than the federal statutes.

A. True

B. False

12. The federal statutes that protect against discrimination are:

- I. Title VII of the 1964 Civil Rights Act
- II. National Labor Relations Act
- III. Americans with Disabilities Act

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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13. Examples of individuals who would not be covered under the Americans with Disabilities Act include:

- I. person in an Alcohol Rehabilitation Program
- II. person with a hepatitis C virus infection (communicable disease)
- III. person with heroin dependency

A. I only

B. III only

C. I and II only

D. II and III only

E. I, II and III

14. Ashley works at Joe's Pharmacy and has worked there for 5 years. There are a total of 10 employees at Joe's Pharmacy. Ashley is pregnant and wants to take Family Medical Leave. Under the Family Medical Leave Act she is entitled to:

- I. 12 weeks unpaid leave
- II. her exact position when she returns
- III. 12 weeks paid leave

A. I only

B. III only

C. I and II only

D. II and III only

E. none of the above

15. Which of the following may be refilled as directed by the prescriber, up to one year from the date written?

- I. C-II
- II. C-III and IV
- III. C-V

A. I only

B. III only

C. I and II only

D. II and III only

E. E. none of the above

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16. You are protected from sexual harassment under the 1964 Civil Rights Act. This protects you from:

- I. "Quid Pro Quo" sexual harassment
- II. hostile environment sexual harassment
- III. having to wear a revealing lab jacket that would attract sexual harassment

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

17. You are a pharmacist working in a community pharmacy. A large chain pharmacy opens nearby and threatens your financial viability. The owner is concerned about the store's profitability and encourages some changes, some of which make you pretty uncomfortable. Which of the following could result in penalties, including debarment:

- I. dispense a generic drug and bill the insurance company for branded drug
- II. bill for services provided by non-pharmacists
- III. become certified to provide/administer vaccines & bill Medicare for your services

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

18. You have a patient (who you know has a low income) who will not be covered by her insurance company for prescription drugs until 11/01/2000. She presented you with a prescription that was written today 10/20/2000. You are sympathetic with her situation and would like to help. In order to be in compliance with the law, you may:

- I. give her the option of waiting until 11/1/2000 to fill the prescription
- II. fill the prescription today but have the patient pay
- III. fill the prescription today but bill the insurance company on 11/01/2000 with the date of dispensing as 11/01/00.

- 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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19. Which of the following are examples of unwitting fraud:

- I. dispense one strength of the medication, but bill for another
- II. provide a service that takes one hour and the usual reimbursement is for 15 minutes. Bill the insurer under a code that will reimburse for one hour.
- III. dispense a prescription and bill the insurer. When patient does not pick up the medication, return it to stock but don't reverse the claim to the insurer.

A. I only

B. III only

C. I and II only

D. II and III only

E. I, II and III

20. Excluding the initial inventory, Controlled Substance inventories must be taken every _____ years and they must be kept on location for _____ years.

A. 1,1

B. 1,2

C. 2,1

D. 2,2

E. None of the above

21. Within the basic model of the legal system there are 3 branches. A pharmacist's wrongful act such, as selling a controlled substance without a prescription, may subject him/her to which of the following:

- I. criminal action
- II. civil action
- III. administrative action

A. I only

B. III only

C. I and II only

D. II and III only

E. I, II and III

22. Complete prescription labels are **NOT** required for controlled substances dispensed in institutions (hospitals, skilled nursing facilities, etc.) if

- I. the C-II drugs are not in the possession of the patient prior to administration
- II. no more than seven days of C-II drugs are dispensed at one time
- III. the institution maintains appropriate safeguards and records regarding administration, control, dispensing and storage of the drugs

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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23. According to the Belmont Report, use of a radically new procedure is not necessarily "research". Rather, "research" depends on the intent of the investigator to:

- I. solely enhance the wellbeing of the patient
- II. test an hypothesis
- III. contribute to generalizable knowledge

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

24. The Occupational & Safety Health Administration (OSHA) focuses on prevention of injuries. It establishes duties in the workplace. Which of the following is **FALSE**:

- I. employee has the duty to correct an unsafe environment
- II. employer has the duty to maintain a safe environment
- III. employer has the duty to comply with specific safety standards

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

25. It is possible to buy a scheduled substance over the counter in the state of Washington.

- A. True**
- B. False

26. For which of the following drugs must you provide an exact count when you perform your required DEA inventory?

- I. A bottle containing 457 Morphine Sulfate 10 mg Tablets (CII)
- II. A bottle containing 4,900 Tylenol with Codeine 30 mg Tablets (CIII)
- III. A bottle containing 999 Meprobamate Tablets (CIV)

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

27. All drugs I-III in question 26 should be ordered on a DEA Form 222.

- A. True
- B. False**

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28. Which of the following DEA numbers would be **valid** for Bill Nash, M.D.?
- A. AB 2587193
 - B. BN 8645321**
 - C. AN 5506213
 - D. MN 7264586
 - E. PN 2442476
29. To whom are copies of an executed DEA Form 222 distributed?
- I. Copies 1, 2 and 3 are forwarded to the distributor, who retains Copy 2, forwards Copy 3 to the DEA and returns Copy 1 with the completed order.
 - II. Copy 1 is retained by the pharmacy. Copies 2, 3 and 4 are forwarded to the distributor, who retains Copy 2, forwards Copy 3 to the DEA, and forwards Copy 4 to the Board of Pharmacy for the state where the pharmacy is located
 - III. Copies 1 and 2 are forwarded to the distributor, and Copy 3 is retained by the pharmacy; the distributor returns Copy 1 to the orderer and forwards Copy 3 to the DEA.
- A. I only
 - B. III only**
 - C. I and II only
 - D. II and III only
 - E. I, II and III
30. How many times may a C-III drug be refilled?
- I. As directed by the prescriber, up to one year
 - II. Five times in 12 months
 - III. Five times in six months
- A. I only
 - B. III only**
 - C. I and II only
 - D. II and III only
 - E. I, II and III
31. Which of the following statements is **true** regarding dispensing of Schedule II drugs for any route of administration?
- I. Community pharmacies may receive FAXes for C-II drugs, but the original must be received and reviewed before dispensing.
 - II. Long Term Care pharmacies may dispense C-II drugs based on a FAXed order.
 - III. Home IV pharmacies may dispense C-II drugs based on a FAXed order.
- 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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32. What may a pharmacist alter on a Schedule II prescription?
- I. the drug name
 - II. the prescriber's signature
 - III. the prescription date and the prescriber's DEA number
- A. I only
B. III only
C. I and II only
D. II and III only
E. I, II and III
33. Which of the following is **NOT** required on the prescription label for a controlled substance?
- I. The address of the dispensing pharmacy
 - II. The address of the prescriber
 - III. The patient's address
- A. I only
B. III only
C. I and II only
D. II and III only
E. I, II and III
34. Recent changes in DEA regulations permit the use of computerized information in place of hard copies. What functions must the pharmacy computer software provide if computer records are substituted for hard copies?
- I. Transfer of Schedule II prescriptions
 - II. A 30-month audit trail for prescription refills
 - III. A method to document the accuracy of the computer record, with routine pharmacist verification
- A. I only
B. III only
C. I and II only
D. II and III only
E. I, II and III
35. Soap, whose manufacturer claims will it will "beautify" your face, would be regulated as a
- C. drug
 - D. biologic
 - E. medical device
 - F. cosmetic
 - G. none of the above

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36. A manufacturer's _____ that a product be used to diagnose, cure, mitigate, treat or prevent a disease in man or any other animal makes the product subject to federal food and drug regulations.
37. What are you required to do if DEA Form 222 are lost or stolen (other than individual forms in transit):
38. The False Claims Act of 1863, amended 1986 allows for reporting of illegal acts. A portion of the penalties assessed and money recovered will be given to the 'whistle-blower.' The procedure of reporting these illegal actions is called a _____ Action.
39. Gostin offers five steps for evaluation of public health regulations. What is the overall point of his article? (Please confine your response to two or three sentences)
40. Name a specific event discussed in class or from assigned reading that contributed to the development of current human subject protection regulations in the United States. (Two or three sentences maximum; one word might be enough).

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Consider the following and evaluate the five ethics principles and values discussed in class. State your perspective regarding "shyness" coverage (patient, insurer, society, etc.) and two or three sentences for each of the principles and values.

The treatment-enhancement distinction draws a line between services or interventions meant to prevent or cure (or otherwise ameliorate) conditions that we view as diseases or disabilities and interventions that improve a condition that we view as a normal function or feature of members of our species. The line drawn here is widely appealed to in medical practice and medical insurance contexts, as well as in our everyday thinking about the medical services we do and should assist people in obtaining...

The treatment-enhancement distinction is closely related to the concept of "medical necessity" that appears in the legislation surrounding public insurance in both the United States and Canada, and in private insurance contracts. Medically necessary services are those that effectively treat physical or mental disease and disability or ameliorate conditions deriving from them. Some medical services may effectively produce benefits for other conditions, but they do not count as medically necessary. For example, insurance coverage is provided by public and private schemes for growth hormone treatment for children projected to be very short, provided that there is an underlying disease condition, e.g., some diagnosable growth hormone deficiency. Insurers do not cover the treatment for children whose parents simply want them to be taller, regardless of how short they will be, if there is no underlying disease condition...

The same distinction plays a role in coverage for mental health therapies. An adult patient with a history of bipolar disorder had been stabilized on lithium for some years. He remained shy, however, and was referred to an out-of-plan group therapy situation, from which he clearly benefited over a period of several years. In its original benefit structure [offered by Harvard Community Health Plan], this long-term treatment could not have been covered by HCHP. HCHP revised its benefit structure, allowing an "extended benefit" that would cover protracted therapy of this sort without extensive copayments, provided the treatment was for a serious condition. But does treatment for shyness count as treatment of a serious disorder?^c

^c Abstracted from Daniels N. Normal functioning and the treatment-enhancement distinction. *Camb Q Healthc Ethics* 2000;9(3):309-22.