

Last Name	First Name

Student Number							

**Pharmacy 543 – Pharmacy Laws & Ethics
MIDTERM EXAMINATION
November 2, 2009**

Instructions

Questions 1-30 are multiple choice. Please record your answers on Side 2 of a Standard Answer Sheet, Form 1158 ("ScanTron"). Follow the instructions on Side 1. Carefully complete your name and student number (both characters and bubbles).

Select the BEST answer from the available choices.

- Multiple choice, one point each, 30 points.
- Questions 31-35 are short-answer, 10 points.
- Ethics question, 10 Points.
- Exam total: 50 points.

Legibility: please verify that your written answers can be read by mere mortals, and your name and student ID number are legible, correct, and present on any papers you turn in. Please double-check your student ID number for accuracy. Errors or omissions may delay or impact your grades.

Turn in:

- (1) the Standard Answer Form ("ScanTron"),
- (2) your answers to the short answer questions (**1 sheet 2 sides**) and the ethics question (**1 sheet 2 sides**)
- (3) this page, only if necessary (see below).

Please do not turn in pages that do not need to be graded.

You may NOT ask questions during the exam. However, if you believe that a question is technically flawed, identify the question and "flaw" below.

Terms such as **NOT, TRUE, FALSE** are presented in **BOLD, ALL-CAPS**.

If you believe that a question is technically flawed, please describe below and turn in this page.

Question Number	Describe the "flaw"

Page left intentionally blank

MULTIPLE CHOICE QUESTIONS

1. Which of the following are required for compliance with Washington rules when compounding a commercially available prescription drug?
 - I. Authorization by the prescriber
 - II. Ingredients are listed in an official compendium
 - III. Patient agrees
 - a. I only
 - b. III only
 - c. I and III only
 - d. I, II and III

2. Under Washington law, which of the following is **NOT** permitted?
 - I. Offer for sale compounded drug products for subsequent resale by doctors
 - II. Compound limited quantities of drug products in anticipation of receiving prescriptions
 - III. Compound a commercially available product for an individual patient
 - a. I only
 - b. III only
 - c. I and III only
 - d. I, II and III

3. You are asked by a customer to adjust the flavor of an OTC oral liquid cough/cold preparation. Which term **BEST** describes this activity?
 - a. Compounding
 - b. Cooking
 - c. Manufacturing
 - d. Repackaging

4. In *Western States Med. V. Shalala*, the US Supreme Court found that the FDA Modernization Act violated the First Amendment in prohibiting "promoting or advertising a particular compounded drug". Washington regulations state: "...[compounding pharmacies] shall not solicit business (e.g., promote, advertise, or use salespersons) to compound specific drug products". Which of the following is **TRUE**?
 - a. State law preempts the Court ruling because it is more restrictive
 - b. The Court ruling preempts state law because it is an interpretation of the constitution
 - c. Preemption would depend on the fact situation for each case
 - d. Through the Tenth Amendment, state laws would prevail

5. Which of the following differentiate a drug from a medical device under the federal Food, Drug and Cosmetic Act?
- I. articles recognized in the official United States Pharmacopoeia or official National Formulary
 - II. articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease
 - III. is not dependent upon being metabolized for the achievement of its primary intended purposes
- a. I only
 - b. III only
 - c. I and III only
 - d. I, II and III
6. Which of the following modification(s) to the Investigational New Drug process permit access to investigational drugs for therapeutic purposes?
- I. Parallel track
 - II. Phase 3
 - III. Treatment IND
- a. I only
 - b. III only
 - c. I and III only
 - d. I, II and III
7. Which of the following applications would a generic drug manufacturer file with the FDA?
- a. New Drug Application
 - b. Biologics License Application
 - c. Premarket Approval
 - d. Abbreviated New Drug Application
8. Which of the following is **NOT** a basis for classifying a medical device?
- a. Amount of information known about the device for its intended use and indications for use
 - b. The devices' intended use in supporting/sustaining life
 - c. The market price of the device
 - d. Risk of causing injury or illness
9. Which of the following is **NOT** a dietary supplement under the Dietary Supplement Health Education Act?
- a. Oral Vitamins
 - b. Injectable vitamins
 - c. Intended as a sole item of a meal
 - d. Herbs and botanicals

Questions 10 - 13 refer to Washington's Medical Records Health Care Information Access and Disclosure law and the federal Health Information Portability and Accountability Act.

10. When could you provide a copy of a detailed pharmacy billing record to the parent of a patient without the patient's permission?
- 10-year-old receiving ivermectin for scabies mites
 - 14-year old who received a dose of naloxone
 - 16-year old receiving an atypical antipsychotic (e.g., clozapine, olanzapine, quetiapine)
 - 18-year old receiving treatment for chlamydia
11. Which of the following is **NOT** a "health care facility"?
- Hospital
 - Clinic
 - Pharmacy
 - Billing office
12. Which of the following would **NOT** be required for a patient to authorize disclosure of protected health care information?
- Written document, dated, signed by the patient
 - Name and institutional affiliation of persons to whom information will be disclosed
 - Expiration date or event related to the purpose of the disclosure
 - Name, title and institutional affiliation of the person releasing the information
13. In which of the following situations could you release protected health care information **WITHOUT** the patient's permission?
- To a person who the provider reasonably believes is providing health care to the patient
 - To a health care provider reasonably believed to have previously provided care
 - To any person if the health care provider reasonably believes that disclosure will avoid imminent danger to the patient
- I only
 - III only
 - I and III only
 - I, II and III
14. Under federal law, if the President signs a bill that has been passed by the legislature, it is collected into the:
- United States Code
 - Federal Register
 - Code of Federal Regulations
 - Washington Administrative Code

15. Which of the following actions should you take when you receive an electronically transmitted prescription for a Schedule III drug?
- Dispense the prescription.
 - Dispense only a 72-hour supply.
 - Return the unfilled prescription to the patient.
 - Call the prescriber to request verbal confirmation of the prescription.
16. Which of the following is considered **NOT** to be exempt from DEA registration?
- A Public Health Service Physician
 - A Navy Dentist
 - A County Health Officer
 - A National Guard Advanced Registered Nurse Practitioner
17. Which of the following prescriptions may **NOT** be filled more than 11 months after the prescription was issued?
- A prescription for a legend drug.
 - A prescription for a Schedule II drug.
 - A prescription for a Schedule III drug.
 - A prescription for a Schedule V drug.
18. Which of the following DEA registrants is required to have security measures that include locked vaults, alarms, and perimeter security?
- A 1,000 bed psychiatric hospital.
 - A Prison hospital.
 - A small wholesale drug distributor.
- I only
 - III only
 - I & III only
 - I, II and III
19. Which of the following records may **NOT** be stored at the headquarters office of a pharmacy chain?
- Financial Records.
 - Pharmacist Personnel files.
 - Controlled Substances invoices.
 - Legend drug prescriptions.
20. Which of the following is **NOT** required on a pharmacy's Biennial Inventory?
- The responsible pharmacy manager's signature.
 - The pharmacy DEA number.
 - The time that the inventory was performed.
 - The date of the inventory.

21. How many hours of Internship experience must you have in order to be licensed as a pharmacist in the State of Washington?
- 1,000 hours
 - 1,200 hours
 - 1,500 hours
 - 1,740 hours
22. The Pharmacist Professional Responsibilities rule that is on hold pending the outcome of litigation provides some exceptions to the requirement that a pharmacist must dispense all presented prescriptions. Which of the following is **NOT** included in the list of exceptions?
- A National or State emergency is affecting the availability of the drug.
 - The prescription is potentially fraudulent.
 - A pharmacy that is willing to dispense the prescription is located only 100 feet away.
 - The pharmacy does not have the means to compound the prescription.
23. A controlled substance prescription may only be transferred one time to another pharmacy. How many times may a legend drug prescription be transferred?
- 1 time
 - 3 times
 - 5 times in six months
 - Unlimited times
24. If your pharmacy receives an inspection score of 75 points, how many days do you have to bring that score up to 90 points?
- 7 days
 - 14 days
 - 30 days
 - 60 days
25. Which of the following DEA numbers would be a valid number for Martin E. Winters, MD?
- AM 9743382
 - AW 5248415
 - MW 8804999
 - BE 1159347
26. If you were cited for a violation articulated in one of the following documents, which would **NOT** be enforceable?
- FDA Compliance Policy Guide
 - United States Code
 - Revised Code of Washington
 - Code of Federal Regulations

27. Which of the following is the agency responsible for Poison Prevention Packaging, including specifications for child resistant packaging?
- Food and Drug Administration
 - Consumer Product Safety Commission
 - Health and Human Services
 - Federal Trade Commission
28. Which of the following agencies is responsible for direct to consumer advertising for over-the-counter drugs?
- Food and Drug Administration
 - Consumer Product Safety Commission
 - Health and Human Services
 - Federal Trade Commission
29. In Mid-October 2009, Senator Leahy (Vermont) indicated that legislation would be introduced in the next several weeks to repeal portions of the McCarran-Ferguson Act (1945) which have effectively shielded insurance companies from federal prohibitions against monopolies. If enacted, which agency would likely be responsible for its enforcement?
- Food and Drug Administration
 - Consumer Product Safety Commission
 - Health and Human Services
 - Federal Trade Commission
30. Under Washington law, "distribute" means which of the following in the context of medical products?
- Delivery
 - Administering
 - Dispensing
- I only
 - III only
 - I and III only
 - I, II and III

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Short Answer Questions. Answers written outside the provided space will not be graded.

31. List the two situations where a covered entity **MUST** disclose protected health information under the Privacy Rule. (2)

32. A new codeine cough syrup is being developed and you are the pharmacy consultant on the project. The VP of marketing tells you it will be formulated at a concentration of 2mg/mL and asks you what schedule this controlled substance will receive. (2)

You indicate:

33. Your local physician called you to prescribe a Schedule II emergency oral medication. The doctor explained the situation and you agree that it was an emergency situation. How long do you have to receive the hard-copy prescription? (2)

34. What is your legal obligation under the Controlled Substance Act, if you did not receive the hard-copy of the prescription in the required time? (2)

35. Complete the table below. Briefly provide the purpose/objectives for each of the stages of drug development. An example is provided below for non-clinical stage. (2)

Stage	Study Objectives
Non-clinical	Assess pharmacology & toxicology in animals
Phase 1	
Phase 2	
Phase 3	
Phase 4	

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Ethics Question

The following was abstracted from the 28Oct10 Wall Street Journal.

Case Spurs Pharmacies' Fears of Lawsuits Over Drug Abuse
By AMY MERRICK

When Patricia Copening, a petite, 35-year-old doctor's office receptionist, bought nearly 4,500 doses of prescription painkillers one year, alarm bells sounded at the Nevada controlled-substance task force. The state board sent letters to 14 pharmacies in the Las Vegas area warning that Ms. Copening could be abusing drugs.

On the afternoon of June 4, 2004 -- a year after the letters were sent -- Ms. Copening climbed into a gray Dodge Durango, veered onto U.S. 95 and was seen weaving erratically in and out of three-lane traffic, witnesses later said. She plowed into 21-year-old Gregory Sanchez Jr., a delivery-van driver who had pulled over to repair a flat tire on the highway's shoulder, killing him at the scene. She also hit Robert Martinez, 33, who had been helping Mr. Sanchez move packages out of his van. Mr. Martinez suffered a head injury, a broken right leg and other wounds. Ms. Copening wasn't injured.

A lawsuit filed by Mr. Martinez, his family and Mr. Sanchez's family, now pending before the Nevada Supreme Court, may be the first U.S. case to address whether pharmacies can be held liable when a customer causes a fatal car accident. The case, Sanchez vs. Wal-Mart Stores et al, asks whether drugstores must use information at their disposal to protect the public from potentially dangerous customers.

36. If this above action was brought in Washington, what violation of both federal and state law could the plaintiff allege? Can be answered with a five-word phrase. (2)

Stay inside the box.

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37. Evaluate the pharmacy practice ethical considerations for the abstracted case. (8)

Stay inside the box.

Describe the dilemma	
Perspective	

Beneficence	
Nonmaleficence	
Autonomy	
Justice	
Virtue	
Root Cause	