

Name: \_\_\_\_\_  
Last First  
Student Number |\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|

**Pharmacy 543 – Pharmacy Laws & Ethics**  
**MIDTERM EXAMINATION**  
**October 29, 3007**

Questions 1-30 are multiple choice. Please record your 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). **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,
- (2) your answers to the short answer questions (1 sheet 2 sides) and the ethics question (1 sheet 2 sides)
- (3) other pages as 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, please circle the faulty question number and briefly describe your concern. Turn in that (those) exam page(s) and your concerns will be addressed.

So as to NOT confuse you, terms like **NOT, TRUE, FALSE** are presented in **BOLD, ALL-CAPS**.

.....  
**MULTIPLE CHOICE QUESTIONS**

1. John has been diagnosed with late-stage prostate cancer. Today he went to see his oncologist, Dr. Philips, to determine a course of treatment for his cancer.

At the office visit with Dr. Philips, which of the following most closely reflects an issue of autonomy from the physician's perspective?

- a. John's unexpressed desire to receive no treatment at this time
  - b. Dr. Philips' desire to do no harm to John
  - c. Dr. Phillips' ability to offer John the best treatment available in his professional opinion
  - d. John's desire to have his options presented to him in a manner consistent with how he would present options to someone else
2. According to the Belmont Report, which of the following is **NOT** a primary purpose of the informed consent process in clinical research?
- a. Information
  - b. Comprehension
  - c. Voluntariness
  - d. Safety

3. Which of the following is considered a "covered entity" under the Health Information Portability and Accountability Act (HIPAA)?
- a. Pharmacist at a large hospital
  - b. Insurance sales agent
  - c. Pharmaceutical company sales representative
  - d. CEO of a biotech company
4. For an individual living in a large and diversely populated city, which of the following is considered to be individually identifiable information under Health Information Portability and Accountability Act (HIPAA) regulations?
- a. Eye color
  - b. Home telephone number
  - c. Weight
  - d. Age in years
5. Permitted disclosures of Protected Health Information (PHI) under HIPAA include a provision for the purposes of "healthcare operations". Which of the following most closely reflects an example where PHI can be disclosed by a covered entity as part of "healthcare operations"?
- a. Sharing information with the manufacturer of a new drug so that they can recruit clinical trial subjects
  - b. Undertaking a quality assurance project to improve the safety of a certain process
  - c. Educating the public about a disease at a hospital-sponsored seminar
  - d. Presenting the results of a clinical trial at a national conference
6. Which document evolved from historical lapses in human subject research ethics and serves as a fundamental guideline to ethical biomedical and behavioral research?
- a. Institutional Review Board (IRB) guidelines
  - b. "9 points of light"
  - c. Common Rule
  - d. Belmont Report
7. What key characteristic of "research" defines and distinguishes the term from other similar qualifying terms? Research must ...
- a. be systematic
  - b. contribute to generalizable knowledge
  - c. provide therapy to patients
  - d. evaluate a hypothesis
8. Which of the following is **NOT** an element of informed consent?
- a. assessment of patient understanding
  - b. patient autonomy
  - c. financial gain
  - d. assessment of alternatives

Name: \_\_\_\_\_

Last

First

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

9. Which of the following is **NOT** a source of personal health information confidentiality duty?
- a. Belmont Report
  - b. Revised Code of WA (RCW)
  - c. Individual pharmacy policies
  - d. Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
10. In the state of WA, the following are required on a patient authorization of personal health information disclosure **EXCEPT**:
- a. Description of the nature of information being disclosed
  - b. Name of the person to whom information is being disclosed
  - c. Expiration date of disclosure period
  - d. Signature of the patient
11. Which Federal official is responsible for defining what constitutes an "emergency" that would justify the issuance of a verbal Schedule II prescription.
- a. U. S. Surgeon General
  - b. Secretary of Health and Human Services
  - c. U. S. Attorney General
  - d. DEA Administrator
12. When a pharmacy applied for a DEA registration, the application was signed by the President of the Corporation. The President later issued a power of attorney to the Corporate Attorney, and her Executive Assistant. Which of the following persons may sign DEA form 222 order forms for the purchase of Schedule II drugs?
- I. Pharmacist in Charge
  - II. Corporate Attorney
  - III. Executive Assistant
- a. I only
  - b. II only
  - c. II and III only
  - d. III only
13. In Washington State, when specifically directed by a prescriber, it is acceptable to issue a written prescription by signing the prescriber's name followed by the nurse's initials.
- a. True
  - b. False
14. If a prescriber omits his/her signature on a Schedule II prescription it is legal for a pharmacist to insert the signature after obtaining the prescriber's permission.
- a. True
  - b. False

15. If the DEA adds a drug to a controlled substance schedule, when is a pharmacist required to record the pharmacy's inventory of that drug?
- Immediately
  - At the time of the next DEA biennial inventory
  - Within 30 days
  - Upon receipt of notification from DEA
16. A physician's office may store controlled substances in a glass front locked cabinet.
- True
  - False
17. Under Washington law, compounding and distribution of a drug is considered manufacturing unless:
- A valid prescriber/patient/pharmacist relationship exists
  - Ingredients meet USP/NF standards
  - Each preparation step is double-checked
- I only
  - II only
  - II and III only
  - III only
18. A dominant concern for compounding of veterinary drug products is:
- Safety and Efficacy
  - Long-term toxicity
  - Food chain
  - Patent violations
19. Pharmacy A is part of the nation-wide retail chain "Drugs R Us." A "Drugs R Us" policy requires each pharmacy to maintain some of its records at the national headquarters. Pharmacy A may maintain all of the following records at headquarters, **EXCEPT**:
- Location-specific legend drug receiving documents
  - Employee payroll records
  - Controlled substance inventory records
  - Employee training records
20. A pharmacist receives a Schedule II prescription. Which of the following is **NOT** true? The pharmacist may change the ...
- drug from brand name to generic
  - dosage strength to be dispensed
  - name of the patient
  - directions for use

Name: \_\_\_\_\_

Last

First

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

21. With passage of the Patriot Act 2006, which of the following is **TRUE** about pharmacy pseudoephedrine transactions in WA state?
- a. Pseudoephedrine may only be sold to persons 21 years of age or older.
  - b. Pseudoephedrine products may be shelved with other OTC products.
  - c. A pharmacist may sell two 60 mg tablets of pseudoephedrine without ID verification.
  - d. Pseudoephedrine transaction log books are retained by pharmacies for 2 years.
22. When a pharmacist transfers a controlled substance prescription to another pharmacy, what things must the "transferor pharmacist" do to the original prescription?
- I. Write "void" on the prescription
  - II. Write name, address, DEA number of receiving pharmacy on the back of the prescription
  - III. Record name of receiving pharmacist
- a. I only
  - b. II only
  - c. II and III only
  - d. I, II and III
23. Which is the correct sequence regarding development of regulations by a federal or WA state agency? Assume that "public notice" is part of the agency's promulgation requirements.
- a. Guideline → Regulation → Statute → Public notice
  - b. Statute → Regulation → Public Notice → Guideline
  - c. Public Notice → Statute → Guideline → Regulation
  - d. Statute → Public Notice → Regulation → Guideline
24. Why is the Supreme Court's decision in *Gonzales v. Oregon* important in Washington?
- a. Permits assisted suicide in WA
  - b. Excludes the federal Attorney General from medical policy decisions under the Controlled Substances Act
  - c. Invalidates many of the regulations in Controlled Substances regulations
  - d. Interprets the Controlled Substances Act "legitimate medical use" limitation to permit lethal injection
25. *Gonzales v. Oregon* is an example of which of the following:
- I. Administrative Law
  - II. Criminal Law
  - III. Civil Law
- a. I only
  - b. II only
  - c. II and III only
  - d. III only

26. The Nuremberg Code is a set of normative research principles that resulted from the research atrocities of what era?
- First World War
  - Second World War
  - Korean War
  - Vietnam War
27. The Washington State Supreme court is hearing a case regarding the applicable standard of care to pharmacy technicians. This is a *case of first impression* in Washington, i.e., the first time the Washington Supreme Court has heard this issue. They granted *certiorari*<sup>1</sup> from a decision of Washington State Appellate Court, Division I. Which of the following sources of law may they consider in rendering a decision?
- An Oregon State statute holding technicians legally responsible in part for prescription errors they initiated (and the pharmacist did not correct).
  - The RCW and WAC sections applicable to pharmacy assistants.
  - An Illinois Supreme Court decision stating that pharmacy technician are not professionals and therefore cannot be held to a professional standard.
- I only.
  - II only.
  - II and III only.
  - I, II and III.
28. You have a friend who went to UW School of Pharmacy and graduated a couple of years ago. She just appeared before the Board of Pharmacy (located in Thurston County in Tumwater, south-east of Olympia) for a disciplinary hearing and the Board decided against her and suspended her license for six months. She is devastated, and thinks that she was judged unfairly. What is her best option at this point, considering the decision was made last week?
- Appeal the decision of the Board to the Washington State Superior Court for Thurston County.
  - Move to another state and apply for licensure there
  - Appeal the decision of the Board to the Washington State District Court in Tumwater.
- I only.
  - II only.
  - II and III only.
  - I, II and III.
29. The Board of Pharmacy, as an administrative agency, has the power to do all **EXCEPT** the following:
- Fine a pharmacist \$500 for misconduct.
  - Write a regulation clarifying the state law regarding sale of ephedrine.
  - Send a pharmacist to jail for 90 days for failing to permit inspection of his pharmacy by the Board.
  - Rewrite a WAC regulation regarding pharmacist's professional responsibilities assuming the requirements of the Administrative Procedure Act are followed.

---

<sup>1</sup>A writ of review issued by a higher court to a lower court. A means of getting an appellate court to review a lower court's decision. If an appellate court grants a writ of certiorari, it agrees to take the appeal. (Sometimes referred to as "granting cert.") [<http://www.id.uscourts.gov/terms-cd.htm>]

Name: \_\_\_\_\_

Last

First

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

30. You have been given a Privacy Disclosure Notice by your doctor. You observe that the notice contains citations to both the US Code and the RCW. This seems a bit confusing to you, because you remember that awful lecture from Pharmacy Law about federal pre-emption. You e-mail your aunt, who is a privacy officer for an HMO in Tacoma, and she says:
- a. Somebody messed up at that clinic, because HIPAA occupied the field with regard to health information.
  - b. The notice was unnecessary because the insurance company that covers your care should get the notice instead.
  - c. The notice is appropriate because there are parts of Washington State law that are more protective of health information than federal law.
  - d. The notice is only required in certain narrowly defined situations where privacy is critical, such as HIV testing, drug/alcohol rehabilitation, and mental health documentation.





Name: \_\_\_\_\_

Last

First

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

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

31. Describe the 3 of 4 characteristics that makes a drug a drug from FDA's perspective. (2 points)

32. Name three medical conditions for which Schedule II nonnarcotic stimulant drugs (e.g., Ritalin, Adderal, Dextroamphetamine, etc.) may be legally prescribed in the State of Washington. (2)

33. Your pharmacy has received a prescription, marked "LTCF Patient" for a Schedule II drug to be dispensed in partial quantities over the next two months. What information must be recorded in pharmacy records, each time that any quantity is dispensed? (2)

34. During an inspection of your pharmacy, a tableting machine, associated equipment and evidence of recent use, were found by the investigator. What might the investigator allege in the context of pharmacist compounding. (2)

35. Describe the current DEA-approved method for prescribing chronically used C-II drugs when you are limited by insurance contracts to dispensing a 30-day supply. (2)

36. Which of the following DEA numbers is valid? (2)

Check if valid	Name & Profession	DEA Number
<input type="checkbox"/>	Doctor Who, MD	AW6251211
<input type="checkbox"/>	Florance Nightengale, ARNP	FN5755662
<input type="checkbox"/>	Dudley Dorigt, PharmD	MD7041217
<input type="checkbox"/>	James Harriot, DVM	MH9925453

Name: \_\_\_\_\_  
Last First  
Student Number |\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|

**Ethics Question. Answers written outside the provided space will not be graded.**

The following was abstracted from Peter Lurie's (Public Citizen) recent testimony before FDA's Nonprescription Drugs and Pediatric Advisory Committees:<sup>2</sup>

There are two main ways drugs are approved for use in children. One is to show direct proof of effectiveness in children. Alternatively, if a drug is shown to be effective in treating adults, its effectiveness in treating children is often inferred.

According to Lurie's testimony, an FDA medical officer was able to find only 11 pediatric clinical trials involving cough and cold medications during the past 50 years. These lead the medical officer to conclude that there is no evidence that OTC cough and cold drugs are effective when given to children. This opinion was echoed by the American Academy of Pediatrics, which on Sept. 6, in comments submitted to the docket, wrote that 'the OTC cough and cold products, therefore, constitute a group of drugs that do not produce any discernable health benefits in this population [children under six] according to the published peer-review literature.'

This leaves the second method of approval for pediatric drugs: proven effectiveness in adults extrapolated to children. However, there is little evidence that cough and cold medications are effective even in adults, according to a meta-analysis of adult studies conducted in 2002 by the Cochrane Collaboration. The fact that these drugs are ineffective in adults, combined with the results of pediatric trials, should have been enough to prohibit use of OTC cough and cold medicines in children, Lurie said....

Several brand-name cough cold manufacturers have withdrawn their products.

37. The parent of a 6-year old with an obvious cold asks what has happened to the cough-cold preparation that s/he had previously purchased when the child had another of many colds. You explain that the big-name manufacturers had voluntarily withdrawn these products following the FDA Advisory Committee reports and you thought it prudent to return the remaining ones to the wholesaler. The parent asks if you could "mix up a similar medication".

Assume that you are technically capable of producing the requested medication. What would be required for you to do so legally. (2)

---

<sup>2</sup>Public Citizen; <http://www.commondreams.org/news2007/1019-05.htm>; accessed 24Oct07

Evaluate the ethical considerations for preparing the medication given the circumstances above. Stay inside the box.(8)

Describe the dilemma	
Perspective	
Beneficence	
Non-maleficence	
Autonomy	
Justice	
Virtue	
Root Cause	