

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

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

PHARMACY 543 – PHARMACY LAWS & ETHICS

**MIDTERM EXAMINATION 1**

October 24, 2003

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.

There are 5 short answer questions and one ethics essay. Limit your answers to the space provided for each question.

Turn in:

- (1) the Standard Answer Form,
- (2) your answers to the short answer and essay questions, and
- (3) other pages as necessary (see below).

Complete your **name and student number on any sheet you turn** in if you want credit for that work.

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

Grading: multiple choice questions are 1 point each (total 30 points); short answer questions are 2 points each (total 10 points) and the ethics question is 10 points. Exam total is 50 points.

Asking questions during the exam: you may **NOT** 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 in a comment on the exam page and turn it in with your answer sheets.

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

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1. In considering the chronological sequence of making a regulation, which of the following does **NOT** occur:
    - a. Someone alerts an agency that problem that may require adoption of a rule
    - b. Impact analysis and draft of proposed rule
    - c. Joint Administrative Rules Review Committee hearing \*
    - d. Officially propose rule and file with Code Reviser
    - e. Rule adoption

2. In Washington law, if the Governor signs a bill that has been passed by the legislature, it is collected into:
  - a. USC
  - b. State Reprter
  - c. CFR
  - d. WAC
  - e. RCW \*
  
3. The judicial branch is responsible for:
  - a. Developing statutes to implement laws
  - b. Promulgating regulations pursuant to "notice & comment rulemaking"
  - c. Interpreting & defining statutes to be written into the States' constitutions \*
  
4. The powers of administrative agencies such as the Board of Pharmacy are granted exclusively by the executive branch.
  - a. True
  - b. False \*
  
5. For cases involving Washington law, which is the "court of last resort"?
  - a. U.S. Supreme Court
  - b. U.S. Circuit Courts of Appeals. Washington State is in the 9th Circuit
  - c. U.S. District Courts. Washington State has two
  - d. Washington Supreme Court \*
  - e. Washington Court of Appeals
  
6. Which of the following relationships is **INCORRECT**?

	federal	State of Washington
a.	Code of Federal Regulations	Washington Administrative Code
b.	United States Code	Revised Code of Washington
c.	Federal Register	Washington State Register
d.	Statutes at Large and Public Laws	Laws of Washington
e. *	Bills	Session Laws

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7. Which is **NOT** an objective of most Phase 1 clinical trials?
- Safety
  - Dose ranging
  - Pharmacokinetics and pharmacodynamics
  - Efficacy \*
  - Single and multiple dose tolerability
8. Under US Food and Drug Administration law, which of the following would **NOT** make the product in question a "drug"?
- Identified in the Homeopathic Pharmacopeia of the United States
  - Any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product
  - Labeling claims that the article can "cure diabetes"
  - Does not depend upon metabolism to achieve its principle intended purposes \*
  - Intended to affect the structure or function of the body
9. Which of the following could be a misbranding violation under US FDA law?
- Failure to follow "current good manufacturing practices"
  - Preparation in circumstances where the product could be contaminated with objectionable microorganisms
  - Failure to include a "could be habit forming" warning on the label when appropriate \*
  - Potency analysis reveals 20 mg per tablet while the label claims 25 mg
  - The drug could partition into the container/closure system (for example, nitroglycerin packaged in a non-glass container)
10. A "voluntary" recall at the consumer level is:
- Class I
  - Class II
  - Class III
  - Level 1 \*
  - Level 2
  - Level 3
11. Which of the following is **NOT** associated with the Durham-Humphrey Act of 1951?
- Definition in law of "habit forming" \*
  - Requirement of the federal "Caution" statement
  - Safe use requires collateral measures, such as laboratory tests
  - Prescription status for drugs with potentially harmful effects
  - Manufacturer's desire for prescription status

12. Which of the following is **NOT** associated with the National Drug Code (NDC)?
- a. NDC serves as a universal product identifier for human drugs
  - b. A numbering configuration such as 4-4-2, 5-3-2, or 5-4-1: labeler, product, packaging
  - c. NDC numbers for essentially the same product could change over time
  - d. The central digits of the NDC reflect the drug class, such as antidepressant or antihypertensive \*
  - e. Pharmacy electronic billing relies on accurate NDC transcription
13. Which of the following is not addressed directly or by implication in the Belmont Report recommendations?
- a. Nonmaleficence
  - b. Beneficence
  - c. Autonomy
  - d. Justice
  - e. Virtue \*
14. In the Belmont Report, which of the following concepts is associated with respect for persons?
- a. Voluntariness
  - b. Comprehension
  - c. Benefit proportionate to risk \*
  - d. Sufficient information
  - e. Capacity
15. Medical experimentation or research includes all of the following **EXCEPT**:
- a. Use of a drug or device in or upon a human subject in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefitting the subject
  - b. The investigational use of a drug or device
  - c. Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject
  - d. Systematic investigation designed to develop or contribute to generalizable knowledge
  - e. "Off-label"<sup>1</sup> use \*

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<sup>1</sup>of, pertaining to, or designating a drug prescribed for a particular indication even though the drug has not yet received approval from the Food and Drug Administration for that disease, condition, or symptom. (Random House Webster's 1998)

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16. Under the Uniform Health Care Information Act (RCW 70.02), which of the following does **NOT** include "health care information"?
- a. Orally transmitted information about a person's deoxyribonucleic acid and identified sequence of chemical base pairs
  - b. A patient's HIV test results \*
  - c. Information about a patient recorded on a health care provider's computer hard drive, such as insurance identification or medical record number
  - d. Information that identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care
  - e. A record of disclosure of health care information
17. Which of the following is a "required disclosure" of health care information under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA)?
- a. To individuals (or their personal representatives) specifically when they request access to, or an accounting of the disclosures of, their protected health information (PHI) \*
  - b. For the purposes of treatment, payment, and health care operations such as quality assurance activities
  - c. Public interest and benefit activities for essential government functions (e.g. protect health/safety of inmates in federal correctional facilities)
  - d. Disclosure of PHI that occurs as a result of, or as "incident to" an otherwise permitted use or disclosure is allowed as long as the covered entity has adopted reasonable safeguards as required by the Privacy Rule, and the information shared was limited to the "minimum necessary"
  - e. To facilitate organ or tissue donation
18. If state law provides greater protection of protected health information than HIPAA, then Privacy Rule allows state law to prevail.
- a. True \*
  - b. False
19. The Washington State Legislature has 98 Representatives and 49 Senators. How many votes does it take for the Legislature to enact a law and send it to the Governor?
- a. 147
  - b. 111
  - c. 98
  - d. 75 \*
  - e. 70

20. Under the Uniform Health Care Information Act (RCW 70.02), disclosure of health care information is permitted **EXCEPT**
- a. To a person reasonably believed to be providing health care to the patient
  - b. To previous provider, to the extent necessary to provide health care to the patient, unless patient has instructed the health care provider in writing not to make the disclosure
  - c. To the spouse of the patient requesting a list of prescriptions dispensed in the previous year \*
  - d. To any other person who requires information for health care education, or to provide planning, quality assurance, peer review, or administrative, legal or financial services to health care provider (malpractice coverage)
  - e. For assisting the health care provider in the delivery of health care
21. The Rules Committees of the House and Senate perform which of the following:
- a. Make rules for the legislators to follow
  - b. Decide which bills move forward \*
  - c. Review rules promulgated by State Agencies
  - d. Decide which legislators are appointed to the various committees
  - e. Determine the winner when there is a tie vote
22. A controlled substance prescription issued by a doctor in one of the uniformed services must include which of the following?
- I. Patient's social security number
  - II. Patient's age
  - III. Practitioner's social security number
- a. I only
  - b. III only \*
  - c. I and II only
  - d. II and III only
  - e. I, II, and III
23. Which of the following classes of drugs would be found in Schedule V?
- I. Anti-diarrheal drugs
  - II. Codeine cough syrups 20 mg/5mL
  - III. Benzodiazepines
- 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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24. Which of the following is **NOT** a Schedule II drug?
- a. Morphine Sulfate
  - b. Codeine
  - c. Ritalin (methylphenidate)
  - d. OxyContin (oxycodone)
  - e. Vicodin (hydrocodone and acetaminophen) \*
25. Which of the following is **NOT** a Schedule III drug?
- a. Tylenol (acetaminophen) with Codeine 30 mg
  - b. Aspirin with Codeine 30 mg
  - c. Valium (diazepam) 10 mg \*
  - d. Hydrocodone 5 mg with Acetaminophen
  - e. Fiorinal with Codeine<sup>2</sup>
26. How many times may a Schedule III prescription be refilled when authorized by the prescriber?
- a. Up to 5 times in 6 months \*
  - b. Up to 6 times in 6 months
  - c. Up to 7 times in 6 months
  - d. Up to 8 times in 12 months
  - e. Up to 12 times in 6 months
27. What can you determine when you receive a prescription that includes a DEA number followed by a 3 character suffix?
- I. The prescription may not be filled in Washington State
  - II. The prescription is a forgery
  - III. The prescriber is using his/her hospital's DEA number
- 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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<sup>2</sup>Active Ingredients: Aspirin - 325 Mg; Butalbital - 50 Mg; Caffeine - 40 Mg; Codeine - 30 mg

28. Which of the following controlled substances records may be maintained at a chain pharmacy's headquarters office after notifying the DEA of the chain's intent to maintain centralized records?
- a. Prescriptions
  - b. Biennial inventories
  - c. Controlled Substances loss reports
  - d. Unused Schedule II order forms \*
  - e. Controlled Substances loss reports
29. How often must you take a DEA controlled substances inventory?
- a. Every 6 months
  - b. Every 12 months
  - c. Every 18 Months
  - d. Every 24 months \*
  - e. Every 30 months
30. Which of the following are **NOT** examples of "purposeful fraud"?
- a. Dispense generic - bill brand
  - b. Dispense nothing - bill for drug
  - c. Medicare beneficiary paying for flu vaccination \*
  - d. Acquire drug samples - bill for them
  - e. Acquire non-retail drugs and bill for them

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Short Answer Questions. Please limit your answer to the space provided.

31. Define "casuistry".

"The casuist looks for cases that are obvious examples of a principle (ie, a case in which there is sure to be a high degree of agreement among most, if not all, observers). The casuist then moves from these clear cases to more dubious ones, ordering them by paradigm and analogy under some principle." Pellegrino JAMA 1993

32. What is the name of the process used for collecting parts of bills that have been passed into appropriate sections? (A single word is ok)

Codification

33. A popular dictionary definition for "justice" is "the administering of deserved punishment or reward".<sup>3</sup> How does this definition differ in an ethics context?

Distributional justice – fair access to goods and services, etc.

34. One of the responsibilities of an Institutional Review Board in its authority over the conduct of clinical trials is the protection of vulnerable persons. Provide three examples of vulnerable persons.

fetus in pregnancy  
prisoners  
mentally challenged  
pediatric / elderly

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<sup>3</sup>Random House Webster's Unabridged V3.0 1998.

35. What recourse does the legislature have for correcting problems with administrative agencies in Washington? Name 3 methods.

- "JARRC review" under the APA
- Substantive change in law
- Appropriation adjustment

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36. The following message was FAXed to participants in the Eastside Pharmacists' Hotline:

[patient's name] DOB 5/11/40, short brown hair, middle aged, nicely dressed, looks like a nice grandma. Tussionex<sup>4</sup> (C-II, contains hydrocodone 10mg/5ml; current formulation also contains chlorpheniramine 8mg/5ml) lover with poor coordination! Seems to have put the bottle in a vise in the garage to open it and it "explodes". Has happened with several M.D.s and pharmacies over the past few months. Then tries to get another bottle for free but is happy to pay for it too!

a. Evaluate this occurrence in light of federal (Health Insurance Portability and Accountability Act) and Washington law (specifically, Medical Records – Health Care Information Access and Disclosure RCW 70.02). (3 points) Please confine your response to the space provided immediately below.

One view: this distribution of protected health care information (patient's name, date of birth) is in violation of both HIPAA and RCW 70.02.

b. Evaluate the ethics of this occurrence, using the normative principles discussed in class. (7 points)

Perspective
Beneficence

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<sup>4</sup>C-II, contains hydrocodone 10mg/5ml; current formulation also contains chlorpheniramine 8mg/5ml

Nonmaleficence

Autonomy

Justice

Virtue