

Name: _____

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

PHARMACY 543 – PHARMACY LAWS & ETHICS
MIDTERM EXAMINATION 1
October 25, 2001

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, FALSE** are presented in **BOLD, ALL-CAPS**.

1. The role of the judicial branch is to:
 - a. Enact the law
 - b. Interpret the law
 - c. Implement the law
 - d. Formulate the law
 - e. Write the law

2. The Washington Administrative Code is a collection of:
 - a. The laws passed by the congress
 - b. Laws signed by the President
 - c. Rules applicable within the state of Washington
 - d. Federal regulations for the United States
 - e. Laws applicable within the state of Washington

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3. Which of the following features distinguishes a medical device from a drug?
- I. Intended for use in the diagnosis of disease in man or other animals
 - II. Intended to affect the structure or function of the body of man or other animals
 - III. Does not achieve any of its principal intended purposes through chemical action
 - IV. Intended for use in the cure of disease in man or other animals, but is not dependent on being metabolized
 - V. Recognized in an official compendium
- a. (III) only
 - b. Both (I) and (II)
 - c. Both (IV) and (V)
 - d. Both (III) and (IV)
 - e. (V) only
4. The Monograph for anti-caries products includes the active ingredient sodium fluoride .¹ A toothpaste's labeling shows sodium fluoride to be an active ingredient. In the product's labeling, the manufacturer also claims that the product helps tartar control, whitens and has a great minty flavor. Under the Food, Drug and Cosmetic Act, as amended, this toothpaste is regulated as:
- a. A drug, as it is intended for mitigation of disease (prevention of tooth decay)
 - b. A food, as it has a minty flavor
 - c. A cosmetic, as it is intended for cleaning, beautifying
 - d. A medical device, as it achieves its function through mechanical (abrasive) means
 - e. None of the above, as toothpaste is not an FDA-regulated commodity.
5. The FDA can exercise its jurisdiction on all drugs involved in:
- a. Inter-city commerce
 - b. Intra-state commerce
 - c. Inter-state commerce
 - d. Within state commerce
 - e. Intra-city commerce

¹ 21CFR355.10 – Anticaries Drug Products for Over-the-counter Human -- Anticaries active ingredients

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6. Which of the following would **NOT** be regarded as misbranding of a drug product?
- a. Failure to register the facility where regulated articles are manufactured or held
 - b. Selling the product after the expiration date
 - c. Labeling that is false or misleading
 - d. Failure to include a warning if the product is habit forming
 - e. Failure to use required tamper-resistant packaging
7. The manufacturer of Drug X has decided to recall this drug from the market. It would have to be a Class II recall if use or exposure :
- a. Is not likely to cause adverse health consequences
 - b. Can cause serious health consequences
 - c. Can cause death
 - d. Is likely to cause permanent disability
 - e. May cause temporary medically reversible health consequences
8. In which of the following situations would an exception to the policy of Informed Consent be permitted – that is, the therapy would be delivered without the patient’s explicit permission?
- a. The patient is unconscious and failure to treat would lead to serious harm
 - b. The physician believes that the patient would refuse therapy if possible adverse effects are disclosed
 - c. For the purpose of clinical trials to minimize refusal to participate
 - d. The therapy to be provided represents standard of care
 - e. “Personal health information” is provided by a pharmacy chain to a direct marketing company to persuade customers to switch therapies
9. The three ethical principles for conducting biomedical and behavioral research established by the Belmont Report were:
- a. Respect for persons, Virtue and Trust
 - b. Beneficence, Justice and Trust for persons
 - c. Equality, Beneficence and Respect for persons
 - d. Beneficence, Maleficence, Confidentiality
 - e. Beneficence, Justice, Respect for others
10. How long from the date of issuance by a prescriber may a Schedule IV prescription be filled?
- a. 72 hours
 - b. Five days
 - c. 30 days
 - d. 60 days
 - e. Six months

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11. How long from the date of issuance by a prescriber may a Schedule II prescription be filled?
 - a. 3 days
 - b. Five days
 - c. 30 days
 - d. Six months
 - e. 12 months

12. A controlled Substances Prescription issued by a doctor in one of the uniformed services must include which of the following?
 - a. Patient's Age
 - b. Practitioner's social security number
 - c. Patient's address
 - d. Practitioner's address
 - e. b. and c. only

13. Which of the following methods of controlled substance storage may be utilized by a physician's office?
 - a. Storage in a drawer near the examination room
 - b. Dispersed throughout the legend drugs
 - c. In a locked metal cabinet
 - d. Storage with professional drug samples
 - e. Motion and infrared sensors in the storage area

14. How many legislator's affirmative votes does it take in the Washington State Senate does it take to pass a bill?
 - a. 25
 - b. 35
 - c. 49
 - d. 98
 - e. 99

15. DEA Form No. 222 is required for a pharmacy or practitioner to order drugs from which of the following schedules?
 - a. Schedule II
 - b. Schedule III
 - c. Schedule IV
 - d. Schedule V

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16. Even if authorized by the prescriber, prescriptions for drugs in which of the following schedules **MAY NOT** be refilled up to 5 times?
- a. Schedule II
 - b. Schedule III
 - c. Schedule IV
 - d. Schedule V
17. Some drugs in which of the following Schedules may be legally sold over the counter in Washington?
- a. Schedule II
 - b. Schedule III
 - c. Schedule IV
 - d. Schedule V
18. Following actions in the State of Texas, Congress changed DEA's authority to bring charges against pharmacists for violations. What is the current standard that DEA must apply when considering if a pharmacist has violated the law or rules that they enforce?
- a. Strict Liability Standard
 - b. Negligence Standard
 - c. Beyond a reasonable doubt standard
19. Which of the following DEA numbers would be valid for Albert Smith, PharmD?
- a. AS1984965
 - b. MS0984965
 - c. AS1376424
 - d. MS0376426
 - e. BS0376428
20. To whom among the following could prescription information **NOT** be provided for a 25 year old patient receiving methadone for detoxification without the patient's authorization?
- a. Medical personnel treating an immediate, health-threatening condition requiring immediate intervention
 - b. An FDA investigator exploring manufacturing problems with the methadone
 - c. A county sheriff
 - d. An auditor employed by the detox program
 - e. A researcher operating under an approved Institutional Review Board protocol

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21. If the Drug Enforcement Administration (DEA) wants to revoke your controlled Substances Registration, who has the responsibility for proving the case?
- a. You
 - b. DEA
22. Under Washington's Uniform Health Care Information Act (RCW 70.02), authorization for release of protected healthcare information generally must satisfy all of the following **EXCEPT**:
- a. In writing, dated, signed by the patient
 - b. Identifies the information to be disclosed
 - c. Identifies the name, address and institution to whom the information is being disclosed
 - d. Identifies the individual(s) providing the health care
 - e. Each disclosure must be charted, except to 3rd party payors
23. Which one of the following terms is **NOT** relevant to Qui Tam actions?
- a. Relators
 - b. Private insurance
 - c. False claims act
 - d. Medicare / Medicaid
24. Which one of the following clearly represents an example of insurance billing fraud?
- a. Filling a prescription on one day and submitting the bill at a later date
 - b. Collecting a monetary deductible from a Medicare-eligible patient
 - c. Instead of dispensing a doctor's order for a 60-day prescription, the patient's insurance demands only a 30-day supply: so you fill and bill for 30-day's supply with one refill remaining
 - d. Split in-half one strength of tablet and bill prescription as if an intact half-strength tablet had been dispensed
25. Which one of the following best represents a kickback?
- a. Stocking a product that a local physician asks you to keep on hand for his/her patients
 - b. Selling products to a local physician's office
 - c. Providing an honorarium to a local physician for each compounded prescription his/her patients have filled at your pharmacy
 - d. None of the above

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26. RCW 18.64.005 empowers the Board of Pharmacy to "Promulgate rules for the dispensing, distribution, wholesaling, and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare". Who gave the Board of Pharmacy these powers?
- The Secretary of the Department of Health
 - The Governor
 - Washington State Pharmacy Association
 - The Legislature
 - The Attorney General
27. In Washington, if someone believes that a state agency² has promulgated rules that are not intended in laws that established the agency, that person could seek relief through "judicial review" in the courts. A court may invalidate a rule if any of the following are true **EXCEPT**:
- The rule is unconstitutional
 - The rule exceeds the agency's statutory authority
 - The rule is more restrictive than a comparable federal rule
 - The rule was adopted without compliance with statutory rule-making procedures
 - The rule is arbitrary and capricious
28. You are requested to compound a sterile drug product that would normally be available through commercial channels but manufacturing problems are limiting supply. The requester practices in Washington and Idaho. Several patients who have received your compounded product develop infections, FDA gets involved, and alleges FD&C Act violations. Who has the burden of proof?³
- You
 - FDA
29. The "Orange Book" provides information on
- Average Wholesale Price for drugs distributed in the United States
 - FDA Approved Animal Drug Products
 - NIH Guidelines for the Conduct of Research Involving Human Subjects
 - Approved Drug Products with Therapeutic Equivalence Evaluation

²RCW 34.05.010(2): "Agency" means "any state board, commission, department, institution of higher education, or officer, authorized by law to make rules or to conduct adjudicative proceedings"

³burden of proof – n. Law – The responsibility of proving a disputed charge or allegation.

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30. Billing an insurance company for vaccine, syringe, and administration in providing influenza vaccine immunization services is:
- a. Unwitting fraud
 - b. Unbundling
 - c. A reasonable way to improve cash flow
 - d. Expected in Medicare/Medicaid participation
 - e. Incident-to billing

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Short Answer – **Please limit your responses to the space provided.** Two points each.

31. What circumstances would afford a person heightened confidentiality protections under Washington law – e.g., more restrictive than the Washington Uniform Health Care Information Act? 2 points; ½ point per circumstance

32. A mom asks you (pharmacy intern) about a prescription that has shown up in their insurance billing for their child. In checking the prescription number, you find that the prescription was for Suprax;⁴ you also note that the profile doesn't show the child's age. How should you respond to the mom?

33. What is the difference between beneficence and nonmaleficence?

34. Mrs. A comes to the pharmacy to pick up a prescription. The technician notices that there is also a prescription for Mrs. A's spouse, Mr. A and asks if Mrs. A would like to pick it up, too, which she does. Several hours later, an enraged Mr. A calls asking why his prescription had been given to Mrs. A. Turns out it was treatment for an STD that he had acquired extra maritally and things are rough at home. He threatens to sue.

Given your knowledge of pharmacy laws/rules and Washington's various confidentiality requirements, what should have been done?

⁴Suprax (cefixime) 3rd generation cephalosporin used to treat upper respiratory tract infections and uncomplicated gonorrhea

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35. "Upcoding" is a fraudulent billing practice. Describe a situation in a pharmacy that might be considered such an act.

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36. Short Essay

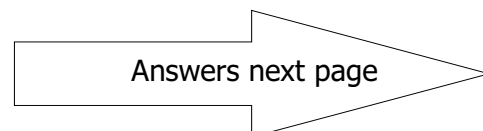
Consider the following downloaded from KAISER DAILY HEALTH POLICY REPORT for 10/21/02.

U.S. District Court Judge Henry Kennedy on Oct. 17 ruled that an FDA regulation that requires pharmaceutical companies to test their products for use in children "exceeds the FDA's statutory authority and is therefore invalid," the New York Times reports (Pear, New York Times, 10/19). In 1997, Congress passed legislation to encourage pharmaceutical companies to test their products in children, and the FDA implemented the Pediatric Rule in 1998 to enforce the law. Although the number of treatments tested in children has increased and pharmaceutical companies have "generally accepted" the rule, the Competitive Enterprise Institute, the Association of American Physicians and Surgeons and Consumer Alert filed suit against the FDA, arguing that the regulation "improperly expanded" the agency's authority (Kaufman, Washington Post, 10/19). In his decision, Kennedy said that the FDA regulation conflicts with two laws -- the FDA Modernization Act of 1997 and the Best Pharmaceuticals for Children Act, enacted in January -- that provide financial incentives for, but do not require, pharmaceutical companies to test their products in children. Kennedy wrote, "The pediatric rule may well be a better policy tool than the one enacted by Congress. It might reflect the most thoughtful, reasoned, balanced solution to a vexing public health problem. The issue here is not the rule's wisdom. The issue is the rule's statutory authority, and it is this that the court finds lacking" (New York Times, 10/19). FDA spokesperson Lawrence Bachorik said that the agency has not decided whether to appeal the decision. He added, "We still think it is vitally important that drugs be studied in children so that their safety and efficacy can be determined on the basis of sound data" (Washington Post, 10/19).

- a. Assume that Congress really does want manufacturers to routinely evaluate investigational drugs and biologics (that is, those being studied under an effective New Drug Application filed with the FDA) for their safety and efficacy in pediatric patients. What would be a straight-forward method for Congress to assure that their intent was being followed? Short answer, limit response to space provided, 3 points.

- b. An investigational drug sponsor is entering phase 3 for an antiviral that seems to extraordinarily effective against upper respiratory infections. The manufacturer has done the numbers and doesn't see any point in conducting pediatric trials in the US. Trials in third-world countries have shown strong efficacy and the manufacturer believes that a pediatric market will develop even without domestic efficacy studies.

Evaluate the ethics of this drug development perspective. Limit your response to the space provided. 7 points



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Perspective
Beneficence
Nonmaleficence
Autonomy
Justice
Virtue
Issues of law