Name: _____ Student Number: |__|__|__|__|__|__|__|

PHARMACY 543 – PHARMACY LAWS & ETHICS
MIDTERM EXAMINATION
30 October 2006

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 2-part ethics question. 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 ethics questions (separate pages), 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 question points are indicated (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.**

MULTIPLE CHOICE QUESTIONS (30 points)

1. Drugs in which of the following controlled substances Schedules may NOT be prescribed unless the FDA authorizes the drug to be utilized for investigational purposes.

   a. Schedule I
   b. Schedule II
   c. Schedule III
   d. Schedule IV
   e. Schedule V

2. Which controlled substances Schedule includes drugs from another schedule that are combined with other therapeutic ingredients. Examples include Acetaminophen 325mg with Hydrocodone 5 mg or Acetaminophen 325 mg with Codeine 30 mg.

   a. Schedule I
   b. Schedule II
   c. Schedule III
   d. Schedule IV
   e. Schedule V

3. A multi-state corporation desires to operate a pharmacy in Washington. The corporation's Chief Financial Officer signs the application for a DEA Certificate of Registration. Who may sign the Schedule II controlled substance Order Form?

a. A non-pharmacist district manager
b. Only pharmacists employed at the location
c. Only the Chief Financial Officer
d. Any person for whom a power of attorney is executed
e. Only those individuals registered with the DEA

4. Receipt of controlled substances listed in Schedule II and completion of the Order Form may only be performed by:

a. pharmacists
b. the pharmacist in charge
c. any person to whom a power of attorney is granted
d. any person designated by the pharmacist in charge
e. the person who signed the initial application for a DEA Certificate of Registration

5. A pharmacist receives a request from a patient to transfer two prescriptions from another store within the same chain. The stores share an on-line, real-time computer system. The prescriptions are for alprazolam 0.25mg (a Schedule IV drug) and omeprazole 20mg capsules (a legend drug.) The omeprazole prescription has 3 refills remaining and the alprazolam has 1 refill remaining. The record also reflects that the prescriptions were originally dispensed at another pharmacy that did not share an on-line, real time computer system. The pharmacist may transfer and dispense:

a. the omeprazole and the alprazolam.
b. the omeprazole and the alprazolam only if she contacts the original pharmacy.
c. the omeprazole only
d. the omeprazole and the alprazolam for one dispensing only
e. the omeprazole and alprazolam only if done by oral communication between pharmacists

6. In the State of Washington, for which of the following medical conditions or diagnoses may authorized practitioners prescribe stimulant drugs that are controlled in Schedule II?

I. A.I.D.S
II. Narcolepsy
III. ADHD

a. I only
b. II only
c. II and III only
d. III only

7. Under the new Federal law that restricts the amount of ephedrine, pseudoephedrine and phenylpropanolamine that may be purchased at retail, what is the maximum amount of pseudoephedrine that may be purchased by one person in any 24 hour period?

a. 60 mg
b. 1.0 Gm
c. 3.0 Gm
d. 3.6 Gm

8. Who may dispense a controlled substance prescription?

   a. Pharmacy technician who is supervised by a pharmacist
   b. Pharmacy intern who is supervised by a pharmacist
   c. Physician intern at a registered hospital
   d. Emergency room nurse in an urban Washington hospital

9. A Pharmacist receives a prescription for Oxycontin® and notices a few errors. What information on the prescription may the pharmacist **NOT** change?

   a. Spelling of the drug name
   b. Spelling of the patient's name
   c. Strength of drug
   d. Date of prescription issue

10. During a DEA inspection, which of the following need **NOT** occur?

   a. Statement of purpose must be provided
   b. Written notification of inspection must be provided
   c. DEA must receive consent to conduct the inspection
   d. DEA inspection must be at a reasonable time

11. According to FDA Compliance Policy Guide on Pharmacist Compounding, pharmacists may **NOT** compound which of the following?

   a. Drug approved by FDA but removed from the market due to lack of demand
   b. A compounded drug request made over the phone
   c. Drugs containing ingredients that meet official compendial standards
   d. Drugs approved by FDA but removed from the market due to safety concerns
   e. Drug that has similar ingredients to one that is approved by FDA and commercially available

12. 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. Request by individual of his/her protected health information (PHI)
   b. Request for PHI by a health care operation
   c. Request for PHI by a public health agency
   d. Request for PHI by a hospital for organ donation purposes
   e. Request for PHI by a physician for treatment purposes

13. What is true about electronic records for controlled substances?

   a. Prescription summaries must be printed daily and signed by the pharmacist
   b. Electronic records may be used to track controlled substance transfers
   c. An on-line controlled substance prescription must include the prescriber's name and DEA number
   d. A bound logbook must be used for documentation during times of computer failure

14. Under WA law, what quality standards are required for ingredients used in compounding?

    a. Certificate of analysis
    b. Prescriber's recommendations
    c. FDA Quality Guidance
    d. International Conference on Harmonization (ICH)
    e. Pharmacists' professional judgment

15. Complete prescription labels are **NOT** required for C-IIs if no more than a 5 day supply is dispensed at one time if dispensed:

    a. To a board and care home patient
    b. To an inpatient in an acute care hospital
    c. To a hospice patient
    d. To a patient in a skilled nursing facility

16. Under HIPAA, which is **NOT** a right of a patient?

    a. Patients may request for communication through their cell phone rather than their office phone.
    b. Patients may complain about privacy practices used at their dentist office.
    c. Patients may request to see the credentials of their pharmacist
    d. Patients may correct errors in their protected health information (PHI)
    e. Patients may choose to restrict disclosure of their protected health information (PHI)

17. A statute differs from a regulation in that a statute:

    a. is created by legislatures
    b. is created by agencies
    c. is not reported in a federal or state register for public comment
    d. may be invalidated by the court

18. The Washington Board of Pharmacy is established by the legislature by enacting or amending the:

    a. Revised Code of Washington
    b. Washington Administration Code
    c. United States Code
    d. Code of Federal Regulations

19. Justice, in the context of ethics, refers to:

    a. Doing things in accordance with the law
    b. Ensuring an equal distribution of society's "goods"
    c. Ensuring an fair distribution of society's "goods"
    d. Making decisions that are fair only to the patient

20. According to the US Food, Drug and Cosmetic Act, which of the following substances are **NOT** defined as drugs?

    a. its active ingredient is contained in the United States Pharmacopeia
    b. it is used in manufacturing an active ingredient
    c. if the prescriber intends to use it for curative purposes
    d. if it is intended to affect the structure of the body of man or other animals

21. *Stare decisis* refers to:

a. a form of statutory law
b. is established by previous court decisions
c. is binding on the rulings of courts in other jurisdictions
d. is applicable only to lower courts in a jurisdiction

22. Which of the following DEA numbers would be valid for Mark Jones, MD?

a. MJ 5831791
b. AJ 5831791
c. MJ 5831794
d. AJ 5831792
e. BM 5831792

23. Which of the following statements is true about drug recalls?

a. Recalls are usually conducted by the Food and Drugs Association
b. A manufacturer may initiate recall without FDA authorization
c. Class III recalls apply to products likely to cause serious harmful effects
d. Type 2 recalls are conducted at the consumer level

24. A prescription for controlled substances must have all of the following **EXCEPT**:

a. The prescriber's address
b. Date of issue
c. The symbols C-I to C-V
d. Prescriber's DEA number
e. Prescriber's signature

25. For cases involving Washington law, which is the "court of last resort"?

a. U.S. Supreme Court
b. 9th Circuit of U.S. Circuit Courts of Appeals
c. U.S. District Courts
d. Washington Supreme Court
e. Washington Court of Appeals

26. What is the difference between common law and state law? Which of the following is true?

a. State law derives from previous court decisions
b. Common law may derive from court decisions about agency rules
c. Common law derives from state laws
d. Common law and state law are equivalent

27. Who may **NOT** sign a request for additional schedule II order forms (DEA-222)?

a. Pharmacist in charge
b. Signatory on original DEA application
c. Pharmacist with durable power of attorney
d. Technician with durable power of attorney

28. If you wanted to know if a generic and brand name drug had similar bioavailability, you could check the:

a. Red Book
b. Orange Book
c. Salmon Book
d. Green Book
e. Purple Book

29. 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 would **NOT** be important in determining the prescription status of a new drug?

a. the drug substance is habit forming
b. the finished drug contains ethanol
c. the method of use would not be safe unless administered by an appropriately licensed practitioner
d. the preference of the manufacturer

30. Generally, emergency outpatient medications may be provided by emergency room nurses so long as all the following conditions are met **EXCEPT**:

a. The medications are prepackaged and labeled by a pharmacist
b. Up to a 48 hour supply
c. Applicable only to legend drugs
d. Nurse applies patient's name before presenting to patient

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Short Answer Questions. (10 points) Confine your answers to the space provided.

31. The technical term used to describe the United States Code (USC) and the Revised Code of Washington (RCW) is: (1 point)

32. The technical term used to describe the Code of Federal Regulations (CFR) and the Washington Administrative Code (WAC) is: (1 point)

33. Name three characteristics of the Federal controlled substances distribution system. (3 points)

34. Which controlled substances Schedule includes drugs that have a high potential for abuse, have an approved medical use, require a written prescription, and may not be refilled? (1 point)

35. Excluding the initial inventory, controlled substance inventories must be taken every _____ years and documentation must be kept on-site for _____ years. (1 point)

36. Under WA state law, a person who has already made two purchases must wait _____ before the next purchases of over-the-counter codeine cough syrups. (1 point)

37. _____ has jurisdiction over general pharmacy compounding. (1 point)

38. HIPAA is the federal statute regulating confidentiality of health care information. What is the WA state statute described in RCW 70.02 that regulates confidentiality of health care information? _____ (1 point)

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Ethics Question. (10 points) Read the Wall Street Journal article by Tara Parker-Pope.

 Parker-Pope Tara. 2006 21/22 October, Page R3.

WHEN IS A HORMONE not a drug?

As scores of menopausal women look for alternatives to traditional hormone treatments, a debate is raging about what to call hormones that are custom mixed by pharmacists -- and whether they are any safer than commercial hormone preparations or prescription-drug alternatives.

Women are flocking to the products, which promoters call "bio- identical hormones," because they have the same molecular makeup as the hormones produced in a woman's body. As a result, the compounds are often promoted as "natural" hormones that don't carry the same risks as hormone drugs sold by pharmaceutical companies. "I don't consider them drugs," says Steven F. Hotze, founder of the Hotze Health & Wellness Center in Houston and a staunch supporter of compounded hormones. "They are identical to the hormones in your body. They are hormones. Drug companies make drugs that mimic hormones."

But critics say the terms "bio-identical" and "natural" are misleading to women who think the products act differently in their bodies than commercial hormone drugs. There's no published evidence that compounded hormones are any safer or have any fewer risks or more benefits than traditionally prepared hormones.

Wulf Utian, executive director of the North American Menopause Society, notes that pharmacies get many of the ingredients for compounded hormones from the same suppliers that drug companies use for certain hormone products. In addition, the estrogen used in compounded hormones is derived from yams or plant sources. "The terms 'natural' and 'bio-identical' are scientifically nonwords," Dr. Utian says. "Natural hormones from yams or cactus or beans are totally foreign to women."

The Food and Drug Administration has said women should assume all hormone preparations carry the same risks and benefits. While commercial hormone products carry that warning, custom-mixed pharmacy hormones do not. Drug maker Wyeth has petitioned the FDA to look into the issue and require all hormone products to carry the same warnings. The FDA has yet to respond to the request.

But the debate about compounded hormones has been reignited in recent weeks by actress Suzanne Somers, whose new book, "Ageless," promotes compounded hormones. Her earlier book "The Sexy Years" is often credited with spurring widespread consumer interest in compounded hormones.

Dr. Hotze says criticism that bio-identical hormones are derived from plants is irrelevant. "If it came from concrete it wouldn't make any difference," says Dr. Hotze. "It's the molecule -- the body doesn't care where it comes from."

Last week, the menopause society's annual meeting in Nashville hosted a session on compounded hormones attended by a crowd of about 400 physicians -- about double the usual attendance of the society's sessions. Dr. Utian says the main message he wants to promote is that women be informed about the products they are using, and be aware that all hormones, whether made by pharmacies or drug companies, likely carry the same risks and benefits.

"The argument is not against the use of compounded hormones," says Dr. Utian. "The argument is that women aren't being informed."

39. How do WA regulations differ from FDA's Pharmacy Compounding Compliance Policy Guide with regard to selecting the active ingredients? (2 points)

Confine response to space provided.

Ethics Evaluation (8 points) Evaluate the ethics of this case, using the normative principles discussed in class. Limit your answers to the space provided for each section.

Perspective	
Beneficence	
Nonmaleficence	
Autonomy	
Justice	
Virtue	
Root Cause	
Clinical	