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 Register
   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 statutes *

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?

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<th>federal</th>
<th>State of Washington</th>
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<td>c.</td>
<td>Federal Register</td>
<td>Washington State Register</td>
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<td>d.</td>
<td>Statutes at Large and Public Laws</td>
<td>Laws of Washington</td>
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<td>e. *</td>
<td>Bills</td>
<td>Session Laws</td>
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</table>
7. Which is **NOT** an objective of most Phase 1 clinical trials?
   
   a. Safety
   
   b. Dose ranging
   
   c. Pharmacokinetics and pharmacodynamics
   
   d. Efficacy *
   
   e. 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”?

   a. Identified in the Homeopathic Pharmacopeia of the United States
   
   b. Any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product
   
   c. Labeling claims that the product can “cure diabetes”
   
   d. Does not depend upon metabolism to achieve its principle intended purposes *
   
   e. Intended to affect the structure or function of the body

9. Which of the following could be a misbranding violation under US FDA law?

   a. Failure to follow “current good manufacturing practices”
   
   b. Preparation in circumstances where the product could be contaminated with objectionable microorganisms
   
   c. Failure to include a “could be habit forming” warning on the label when appropriate *
   
   d. Potency analysis reveals 20 mg per tablet while the label claims 25 mg
   
   e. 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:

    a. Class I
    
    b. Class II
    
    c. Class III
    
    d. Level 1 *
    
    e. Level 2
    
    f. Level 3
11. Which of the following is **NOT** associated with the Durham-Humphrey Act of 1951?

a. Definition in law of “habit forming” *

b. Requirement of the federal “Caution” statement

c. Safe use requires collateral measures, such as laboratory tests

d. Prescription status for drugs with potentially harmful effects

e. 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 **NOT** 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" use *

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. Prof. Downing provided the definition “one party offers money or some other form of inducement to another party in return for increased (Medicare or Medicaid) business” for:

a. A tort
b. Upcoding
c. Unwitting fraud
d. Kickbacks *
e. Unbundling

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*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)
18. If state law provides greater protection of protected health information than HIPAA, then the “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 (i.e., 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. **question technically flawed and discarded**

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

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 Codeine²

²Active Ingredients: Aspirin - 325 Mg; Butalbital - 50 Mg; Caffeine - 40 Mg; Codeine - 30 mg
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

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
Short Answer Questions.
Please limit your answer to the space provided. (2 points each)

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”. 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

21CFR56.111(a)(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

3Random House Webster’s Unabridged V3.0 1998.
35. What recourse does the legislature have for correcting problems with administrative agencies in Washington? Name 2 methods.

- “JARRC review” under the APA
- Substantive change in law
- Appropriation adjustment
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\(^4\) 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 (Health Care Information Access and Disclosure RCW 70.02) law. (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)

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\(^4\)C-II, contains hydrocodone 10mg/5ml; current formulation also contains chlorpheniramine 8mg/5ml
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<tr>
<th>Nonmaleficence</th>
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<td>really seems crumby that manufacturers would put kids at risk by evading their public responsibilities for evaluating a drug’s safety in kids; if they suspect that the drug will be used on kids, shouldn’t they be sure that the drugs are safe rather than shifting the responsibility to pediatricians?</td>
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Autonomy doesn’t seem applicable in consumer-with-attitude scenario |

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<td>Hey, why do kids deserve any less than adults in being provided safe and effective drugs?</td>
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<td>How can those drug manufacturers sleep at night knowing that they are putting kids at risk.  How would they like it if someone did this to them?</td>
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