

Pharmacy 543 Laws & Ethics Course Introduction

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Outline

- usual suspects & backgrounds
- required reading
- course goals
- grades
- class schedule
- homework
- in-class quiz
- project
- ethics write-up
- *NABPLaw Online Study*
- makeup examinations, late homework
- classroom safety
- academic honesty
- comportment

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Usual Suspects

- ... me; thazlet@u..., 206.616.2732; H375S
 - not Hazlett (rhymes with hazard); horse thief thing
- Don Williams – Donhwms@msn.com
- Martha Dye-Whealan – mdwhale@comcast.net
- Kathryn Elliott – [kje2@u....](mailto:kje2@u...)
- others ...

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Reading

- Pharmacy Lawbook 2003 edition (“salmon book”)
 - Read in conjunction with “law” lectures
 - Web access
 - www.leg.wa.gov → search, OR
 - Board of Pharmacy – www.doh.wa.gov → Pharmacy, etc.
- Abood – *Pharmacy Practice and the Law, 4rd Edition*; Jones & Bartlett; **Course reserve**
- *Pharmacy Law Digest, 37th Edition*, Facts & Comparisons
- Bardach, Eugene. *A practical guide for policy analysis: the eightfold path to more effective problem solving*. Washington, D.C. : CQ Press, 2005
- A few cases, interesting articles (e-journal availability in “Restricted Access”)

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Course Goals

- Understand existing laws and regulations governing and defining the profession of pharmacy
- Understand the regulatory process so you may effect regulatory and statutory reform
- Understand how to identify and evaluate ethical dilemmas in the delivery of health care

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Grades

Activity	Percent	Comments
Group Effort		
Project	25	Interim submissions not graded; presentation and report are graded; group responsibility
Group Performance Evaluation	10	Evaluation of self, other group members
Ethics Case	5	Group responsibility
Individual Effort		
Quiz	9	WebQ, open book, not open neighbor, 1 try, time limited (30 minutes)
Course Evaluation	1	We read them all
Midterm	20	Through DEA 4 lecture
Final	20	Comprehensive
Homework	5	Who Can Prescribe
	5	Prescription Label
Total	100	Biostatistics Scheme

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Grade Table: Percent → NES

from	to	you get	from	to	you get	from	to	you get	from	to	you get	from	to	you get
0.00	37.49	0.0	51.00	52.49	1.3	60.00	62.99	2.0	72.00	73.49	2.7	82.50	83.99	3.4
37.50	43.49	0.7	52.50	53.99	1.4	63.00	64.49	2.1	73.50	74.99	2.8	84.00	85.49	3.5
43.50	44.99	0.8	54.00	55.49	1.5	64.50	65.99	2.2	-	-	2.9	85.50	86.99	3.6
45.00	46.49	0.9	55.50	56.99	1.6	66.00	67.49	2.3	75.00	77.99	3.0	87.00	88.49	3.7
46.50	47.99	1.0	57.00	58.49	1.7	67.50	68.99	2.4	78.00	79.49	3.1	88.50	89.99	3.8
48.00	49.49	1.1	58.50	59.99	1.8	69.00	70.49	2.5	79.50	80.99	3.2	-	-	3.9
49.50	50.99	1.2	-	-	1.9	70.50	71.99	2.6	81.00	82.49	3.3	90.00	100.0	4.0

from UW Biostatistics

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Questions

- Ask in class (best!)
- send e-mail to any of us
- fixed office hours for Kathryn Elliott <tba>
- office hours for Don or I by appointment (please request via e-mail)
- terminology & alphabet soup
 - acronym police

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“Useful” Acronyms

- ADA
 - OSHA
 - DEA
 - CPSC
 - HCFA → CMS
 - OBRA
 - FDA
 - DSHEA
 - FDAMA
 - PDMA
 - PDUFA
 - USC, CFR, FR
 - NABP
 - OBRA
 - DOH, DSHS, L&I, HCA, UMP
 - RCW, WAC
 - HIPAA
- More? Try HealthLinks, search “acronym” or www.fda.gov/cder/handbook/acronym.htm

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Class Web Site

- Is web training necessary?
- Familiar with Adobe Acrobat?
- Posting of lecture notes, “homework”, etc.; substantially complete now
 - <http://courses.washington.edu/pharm543/>
 - notes will be posted at least 24 hours before lecture ... or we'll bring them to class
 - typically posted by late Friday afternoon
- Schedule & Due Dates (handout)

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Homework & other Deliverables

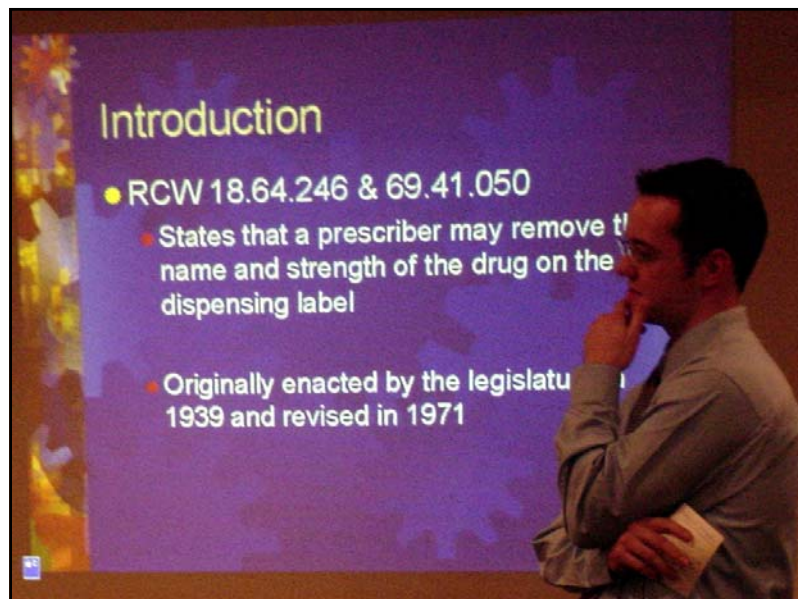
- Submitted electronically
 - Interim project updates (Wednesday by 5PM), PowerPoint presentation & report via *eSubmit*
 - Ethics case; *eSubmit*; WSPA publication?
- “Who can prescribe”, “Prescription Labeling” exercises; standard form
- *eSubmit* hot links on class web site
- Weekly quiz, *webQ*, posted Friday afternoon, closes at 1:30PM Monday; individual work

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The Project

- Origins
- Find a place in the law that’s “busted” and try to make it right
- 12 teams; team membership (handout)
- written updates via e-submit; feedback via e-mail
- final presentations December 5 & 7
 - report
 - oral presentation
- best – presentation to scheduled Board meeting, WSPA

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The Project -- Participation

- accountability -- group performance evaluation (see web site)
 - Trial run half way through if needed
 - Final due with presentations
- group disharmony → let us know

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CRITERION MATRIX

Score	Ability to work with the group	Amount of effort	Dependability	Intellectual Contribution	Overall Contribution to the Activity
1	Was disruptive to the group process	None	Highly dependent	Contributed little	Little
2	Participated, but wanted to go in different direction than the group	Undependable, sometimes helped, other times didn't	Accomplished things late	↓	Minimum
3	Okay	About what was expected	Usually done on time	Was helpful	Average
4	Always participated, made sure everyone had a chance to participate	↓	Always on time	↓	Above average
5	Helped get the group moving without dominating it	Did the most work	Could be counted on to pick up the slack	Provided helpful, meaningful suggestions	Wouldn't have been as successful without her/him

↓ = in between

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The Project -- Select a Topic

- Suggestions for topics
- No *exact* repeats of previous years' projects; we'll suggest modifications
- Due 3 Oct & via *eSubmit @ 5PM*; discussion in "lab" sessions
- "petition", other, options

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Project – Approach; Final Product

- Interim reports (not graded)
 - Title – identification & topic
 - Problem definition
 - Evaluation criteria
 - Alternatives to existing law
 - Stakeholders
 - Evaluation of Alternatives
 - Project Outcomes
 - Language of proposed law
 - Detailed outline
- Oral presentation – 10-15 minutes; use powerpoint if you like
- Written report via *eSubmit*
 - language
 - specified format
 - adequately referenced
 - authorship responsibility
- Best → BOP (others?)

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Project: Resources

- Librarians
 - <http://healthlinks.washington.edu/hsl/liaisons/jankowski/pharmlaw/>
 - Terry Jankowski, Health Sciences
 - Government Publications (Suzzallo)
 - Gallagher – different system, different rules
- *NABPLaw Online* – in “Restricted Access”
- Weekly meetings after class (Monday & Wednesday)
 - fixed schedule to see how it works
 - Groups 1-6 Monday, 7-12 Wednesday

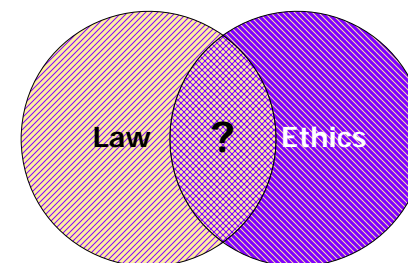
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Ethics Case Write-up

- History
 - origins
 - what we learned in previous years
- Instructions on web site soon
- Group effort
- Potential to publish, WSPA, etc.

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Law v. Ethics



- Law = must
- Ethics = should

- Other ethics courses
 - MHE 521 The Ethical Challenges of Modern Medicine (3) McCormick
 - MHE 514 Legal, Ethical, and Social Issues in Public Health Genetics (3) Kuszler, Mastroianni

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Administrative Details

- no makeup exams, late homework
- date of final: 2:30-4:20 PM, Dec. 12
- Archive – old exams [answers, if provided, were substantially correct at time of posting; not updated]
- review session before the Multistate Pharmacy Jurisprudence Examination
 - elective, Pharm 544
 - 2 consecutive Saturdays in March

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Classroom Safety

- Fire
- Earthquake
- Evacuate to [see map in classroom entrance]
- Keeping track ... buddy system
- Persons with disabilities

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Academic Honesty

- Group vs. individual effort
- UW / Legislature position on plagiarism
<http://depts.washington.edu/grading/issue1/honesty.htm>
- SOP Student handbook
<http://depts.washington.edu/pharminf/sha.htm>

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Academic Honesty & “plagiarism” [2]

- **Original:** If the existence of a signing ape was unsettling for linguists, it was also startling news for animal behaviorists.
- **Unacceptable borrowing of words:** An ape who knew sign language unsettled linguists and startled animal behaviorists.
- **Unacceptable borrowing of sentence structure:** If the presence of a sign-language-using chimp was disturbing for scientists studying language, it was also surprising to scientists studying animal behavior.
- **Acceptable paraphrase:** When they learned of an ape's ability to use sign language, both linguists and animal behaviorists were taken by surprise.

A Writer's Reference by Diana Hacker (New York, 1989, p. 171).

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Academic Honesty & “plagiarism” [3]

- “Adequately referenced”
 - find a style guide and stick to it
 - Instructions to authors – scholarly journals
 - UW Library –
www.lib.washington.edu/research/wri.html
- Google & similar *faux ami*

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Comportment

com·port·ment, *n.*

personal bearing or conduct; demeanor; behavior.

- Student class evaluation results
- Arriving late; leaving early; showing up at all ...
- Chit-chat & sharing your wisdom
- Cell phones, beepers, IM, other distractions
- Group responsibility

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More Comportment

- The Loo Break
- Audio recording – generally “OK”
- Video recording – generally “no” ...
 - ... worth the flog?
 - ... availability of resources
 - \$
 - bodies
 - but ask well (weeks) in advance

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... For Monday

- check out class web site

<http://depts.washington.edu/pharm543>

- download & read Pellegrino for Monday – in Restricted Access
 - for interest, read Callahan
- ... last minute brain cramps

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Questions