

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*
- stretch
- structure of the law
- if it's Friday, it must be ethics (or midterm)
- 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
- 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.
- Aboud – *Pharmacy Practice and the Law, 4rd Edition*; Jones & Bartlett; Course reserve
- *Pharmacy Law Digest, 37th Edition*, Facts & Comparisons
- Reiss & Hall: *Guide to Federal Pharmacy Law, 3rd Edition*, Apothecary Press
- Bardach -- *A practical guide for policy analysis : the eightfold path to more effective problem solving*
- 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, project report
Group Performance Evaluation	10	Evaluation of self, and other group members
Ethics Case	5	
Individual Effort		
Midterm	20	
Final	30	Comprehensive
Homework	5	Who Can Prescribe 5 Prescription Label Exercise
Total	100	Biostats Scheme

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 Josh Welborn -- *tba*
- office hours for Don or me 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 www.fda.gov/cder/handbook/acronym.htm 9

Class Web Site

- Is web training necessary?
- Familiar with Adobe Acrobat?
- Weekly posting of lecture notes, questions, etc.
<http://courses.washington.edu/pharm543/>
- Schedule & Due Dates (handout)

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“Death by PowerPoint”



“I need someone well versed in the art of torture—do you know PowerPoint?”

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Pharm 543 Pharmacy Laws & Ethics		Autumn 2004	
1	2	3	4
1	Topic: Introduction	09/20/04	09/20/04
2	Topic: Identification & Regulation of Drugs	09/27/04	09/27/04
3	Topic: Prescription Drugs	10/04/04	10/04/04
4	Topic: Evaluation Criteria	10/11/04	10/11/04
5	Topic: Identification & Regulation of Drugs	10/18/04	10/18/04
6	Topic: Prescription Drugs	10/25/04	10/25/04
7	Topic: Evaluation Criteria	11/01/04	11/01/04
8	Topic: Prescription Drugs	11/08/04	11/08/04
9	Topic: Evaluation Criteria	11/15/04	11/15/04
10	Topic: Prescription Drugs	11/22/04	11/22/04
11	Topic: Evaluation Criteria	11/29/04	11/29/04
12	Topic: Prescription Drugs	12/06/04	12/06/04
13	Topic: Evaluation Criteria	12/13/04	12/13/04
14	Topic: Prescription Drugs	12/20/04	12/20/04
15	Topic: Evaluation Criteria	12/27/04	12/27/04
16	Topic: Prescription Drugs	01/03/05	01/03/05
17	Topic: Evaluation Criteria	01/10/05	01/10/05
18	Topic: Prescription Drugs	01/17/05	01/17/05
19	Topic: Evaluation Criteria	01/24/05	01/24/05
20	Topic: Prescription Drugs	01/31/05	01/31/05
21	Topic: Evaluation Criteria	02/07/05	02/07/05
22	Topic: Prescription Drugs	02/14/05	02/14/05
23	Topic: Evaluation Criteria	02/21/05	02/21/05
24	Topic: Prescription Drugs	02/28/05	02/28/05
25	Topic: Evaluation Criteria	03/06/05	03/06/05
26	Topic: Prescription Drugs	03/13/05	03/13/05
27	Topic: Evaluation Criteria	03/20/05	03/20/05
28	Topic: Prescription Drugs	03/27/05	03/27/05
29	Topic: Evaluation Criteria	04/03/05	04/03/05
30	Topic: Prescription Drugs	04/10/05	04/10/05
31	Topic: Evaluation Criteria	04/17/05	04/17/05
32	Topic: Prescription Drugs	04/24/05	04/24/05
33	Topic: Evaluation Criteria	05/01/05	05/01/05
34	Topic: Prescription Drugs	05/08/05	05/08/05
35	Topic: Evaluation Criteria	05/15/05	05/15/05
36	Topic: Prescription Drugs	05/22/05	05/22/05
37	Topic: Evaluation Criteria	05/29/05	05/29/05
38	Topic: Prescription Drugs	06/05/05	06/05/05
39	Topic: Evaluation Criteria	06/12/05	06/12/05
40	Topic: Prescription Drugs	06/19/05	06/19/05
41	Topic: Evaluation Criteria	06/26/05	06/26/05
42	Topic: Prescription Drugs	07/03/05	07/03/05
43	Topic: Evaluation Criteria	07/10/05	07/10/05
44	Topic: Prescription Drugs	07/17/05	07/17/05
45	Topic: Evaluation Criteria	07/24/05	07/24/05
46	Topic: Prescription Drugs	07/31/05	07/31/05
47	Topic: Evaluation Criteria	08/07/05	08/07/05
48	Topic: Prescription Drugs	08/14/05	08/14/05
49	Topic: Evaluation Criteria	08/21/05	08/21/05
50	Topic: Prescription Drugs	08/28/05	08/28/05
51	Topic: Evaluation Criteria	09/04/05	09/04/05
52	Topic: Prescription Drugs	09/11/05	09/11/05
53	Topic: Evaluation Criteria	09/18/05	09/18/05
54	Topic: Prescription Drugs	09/25/05	09/25/05
55	Topic: Evaluation Criteria	10/02/05	10/02/05
56	Topic: Prescription Drugs	10/09/05	10/09/05
57	Topic: Evaluation Criteria	10/16/05	10/16/05
58	Topic: Prescription Drugs	10/23/05	10/23/05
59	Topic: Evaluation Criteria	10/30/05	10/30/05
60	Topic: Prescription Drugs	11/06/05	11/06/05
61	Topic: Evaluation Criteria	11/13/05	11/13/05
62	Topic: Prescription Drugs	11/20/05	11/20/05
63	Topic: Evaluation Criteria	11/27/05	11/27/05
64	Topic: Prescription Drugs	12/04/05	12/04/05
65	Topic: Evaluation Criteria	12/11/05	12/11/05
66	Topic: Prescription Drugs	12/18/05	12/18/05
67	Topic: Evaluation Criteria	12/25/05	12/25/05
68	Topic: Prescription Drugs	01/01/06	01/01/06
69	Topic: Evaluation Criteria	01/08/06	01/08/06
70	Topic: Prescription Drugs	01/15/06	01/15/06
71	Topic: Evaluation Criteria	01/22/06	01/22/06
72	Topic: Prescription Drugs	01/29/06	01/29/06
73	Topic: Evaluation Criteria	02/05/06	02/05/06
74	Topic: Prescription Drugs	02/12/06	02/12/06
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76	Topic: Prescription Drugs	02/26/06	02/26/06
77	Topic: Evaluation Criteria	03/05/06	03/05/06
78	Topic: Prescription Drugs	03/12/06	03/12/06
79	Topic: Evaluation Criteria	03/19/06	03/19/06
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81	Topic: Evaluation Criteria	04/02/06	04/02/06
82	Topic: Prescription Drugs	04/09/06	04/09/06
83	Topic: Evaluation Criteria	04/16/06	04/16/06
84	Topic: Prescription Drugs	04/23/06	04/23/06
85	Topic: Evaluation Criteria	04/30/06	04/30/06
86	Topic: Prescription Drugs	05/07/06	05/07/06
87	Topic: Evaluation Criteria	05/14/06	05/14/06
88	Topic: Prescription Drugs	05/21/06	05/21/06
89	Topic: Evaluation Criteria	05/28/06	05/28/06
90	Topic: Prescription Drugs	06/04/06	06/04/06
91	Topic: Evaluation Criteria	06/11/06	06/11/06
92	Topic: Prescription Drugs	06/18/06	06/18/06
93	Topic: Evaluation Criteria	06/25/06	06/25/06
94	Topic: Prescription Drugs	07/02/06	07/02/06
95	Topic: Evaluation Criteria	07/09/06	07/09/06
96	Topic: Prescription Drugs	07/16/06	07/16/06
97	Topic: Evaluation Criteria	07/23/06	07/23/06
98	Topic: Prescription Drugs	07/30/06	07/30/06
99	Topic: Evaluation Criteria	08/06/06	08/06/06
100	Topic: Prescription Drugs	08/13/06	08/13/06
101	Topic: Evaluation Criteria	08/20/06	08/20/06
102	Topic: Prescription Drugs	08/27/06	08/27/06
103	Topic: Evaluation Criteria	09/03/06	09/03/06
104	Topic: Prescription Drugs	09/10/06	09/10/06
105	Topic: Evaluation Criteria	09/17/06	09/17/06
106	Topic: Prescription Drugs	09/24/06	09/24/06
107	Topic: Evaluation Criteria	10/01/06	10/01/06
108	Topic: Prescription Drugs	10/08/06	10/08/06
109	Topic: Evaluation Criteria	10/15/06	10/15/06
110	Topic: Prescription Drugs	10/22/06	10/22/06
111	Topic: Evaluation Criteria	10/29/06	10/29/06
112	Topic: Prescription Drugs	11/05/06	11/05/06
113	Topic: Evaluation Criteria	11/12/06	11/12/06
114	Topic: Prescription Drugs	11/19/06	11/19/06
115	Topic: Evaluation Criteria	11/26/06	11/26/06
116	Topic: Prescription Drugs	12/03/06	12/03/06
117	Topic: Evaluation Criteria	12/10/06	12/10/06
118	Topic: Prescription Drugs	12/17/06	12/17/06
119	Topic: Evaluation Criteria	12/24/06	12/24/06
120	Topic: Prescription Drugs	12/31/06	12/31/06

Homework & other Deliverables

- Submitted electronically; typically due Monday or Wednesday by 5PM
 - Interim project updates, PowerPoint & report via *eSubmit*
 - Ethics case; *eSubmit*
- “Who can prescribe”, labeling exercises; standard form
- *eSubmit* hot links on class web site

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In-Class Quiz

- first 5-10 minutes of every session
- questions & answers posted on class web site

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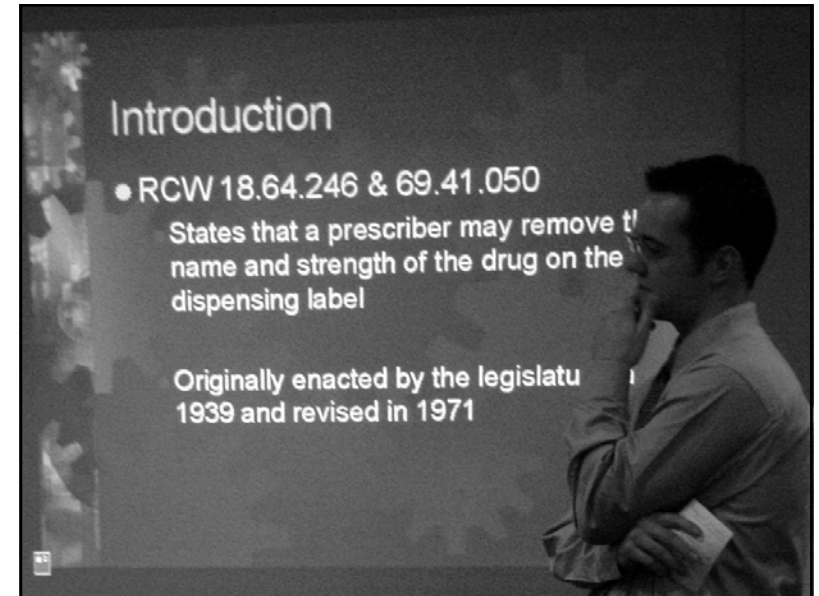
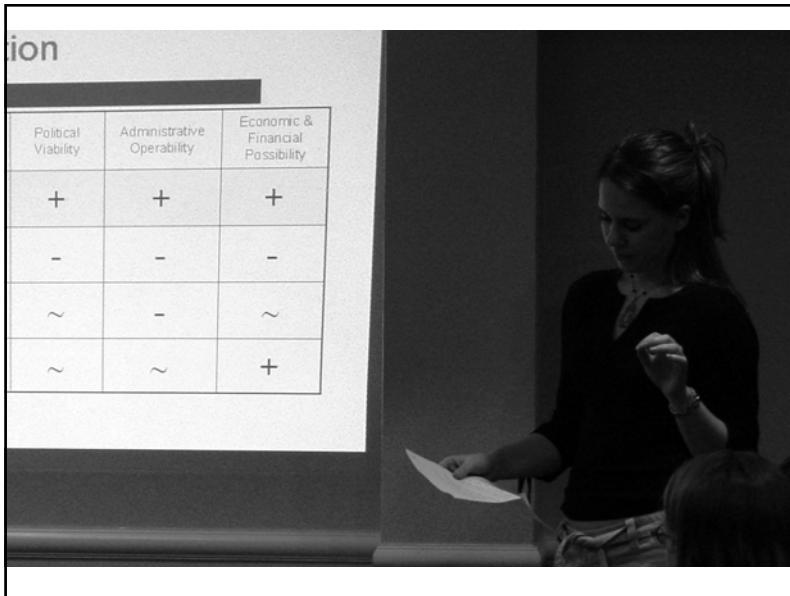
Stretch

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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 8 & 10
 - report
 - oral presentation
- best 4 – presentation to Board in January

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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

The Project -- Select a Topic

- Suggestions for topics
- No exact repeats of previous years' projects; we'll suggest modifications
- Due Wednesday Oct 4 via *eSubmit* @ 5PM
- "petition" option

Project -- Approach; Final Product

- Interim reports (not graded)
 - Title – identification & topic
 - Problem definition
 - Evaluation criteria
 - Alternatives to existing law
 - Stakeholders
 - Evaluation of Alternatives
 - 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
- 4 best → BOP

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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 last year
- instructions on web site soon
- group effort
- potential to publish

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NABPLaw Online

- Resource for project, through “restricted access”
- “study” on patterns of usage
- Plein Grant
 - application date July 1
 - \$5000
 - students eligible, too!

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Structure of the Law

- tripartite federally; states; *cf.*, Canada
 - congress (senate, house) – enact (presidential veto)
 - administrative branch – implement (“promulgate”)
 - judicial branch -- interpret

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Constitutional Stuff

- The powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people.
- Amendment X

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Terminology

Congress enacts

- congress passes bills that become (if signed by the president) *laws*, codified into USC; nationwide applicability when “necessary and proper” (preemption)
 - e.g., 21 USC 801 – Controlled Substances Act
- parallel state activities, Revised Code of Washington (RCW)
 - e.g., RCW 18.64.001 State Board of Pharmacy

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Terminology 2

Agencies promulgate (implement)

- administrative agencies implement the laws by developing *regulations*
 - e.g., Drug Enforcement Administration, 21CFR1300 *et seq.**
 - e.g., Board of Pharmacy’s “Model Procedural Rules for Boards”, *Washington Administrative Code* (WAC) 246-11-
- “administrative procedures”
 - public comment; agency evaluation
 - guidelines

*authority -- Controlled Substances Act, as amended (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act, as amended (84 Stat. 1285; 21 U.S.C. 951).

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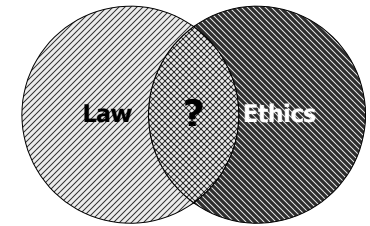
Terminology 3

Courts interpret

- common law; *stare decisis* (abide by decided cases)
 - much of the “medical device” regulatory structure
 - *cf.*, *McKee v. American Home Products Corporation*; Supreme Court of Washington, 113 Wn.2d 701, November 30, 1989
- evaluate “constitutionality” of laws / regulations

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Law v. Ethics



- Ethics on Fridays
- Law \equiv must
- Ethics \equiv 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. 13
- Archive – old exams [answers 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 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.

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Comportment

com·port·ment (kām pôrtmānt, -pôrtē), *n.*
personal bearing or conduct; demeanor; behavior.

- Student class evaluation results
- Arriving late; leaving early; showing up at all ...
 - ethics on Friday; lottery; everyone gets to play
- Chit-chat & sharing your wisdom
- Cell phones & beepers

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... For Friday

- check out class web site
- download & read Pellegrino for Friday –
in Restricted Access
 - for interest, read Callahan

Questions