Pharmacy 543 Laws & Ethics
Course Introduction

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

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, 4th Edition; Jones & Bartlett; Course reserve
- Pharmacy Law Digest, 37th Edition, Facts & Comparisons
- A few cases, interesting articles (e-journal availability in "Restricted Access")
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

Grades

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<thead>
<tr>
<th>Activity</th>
<th>Percent</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Group Effort</td>
<td>25</td>
<td>Interim submissions not graded; presentation and report are graded; group responsibility</td>
</tr>
<tr>
<td>Group Performance Evaluation</td>
<td>10</td>
<td>Evaluation of self, other group members</td>
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<tr>
<td>Ethics Case</td>
<td>5</td>
<td>Group responsibility</td>
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Individual Effort

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<tr>
<td>Quiz</td>
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<td>WebQ, open book, not open neighbor, 1 try, time limited (30 minutes)</td>
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<td>Course Evaluation</td>
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<tr>
<td>Midterm</td>
<td>20</td>
<td>Through 25 October</td>
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<tr>
<td>Final</td>
<td>20</td>
<td>Comprehensive</td>
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<tr>
<td>Homework</td>
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<td>Who Can Prescribe Prescription Label</td>
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<tr>
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Grade Table: Percent → NES

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Schedule, Topics & Due Dates
Homework & Other Deliverables

- ... weekly project updates (not graded); via eSubmit; **5PM on Thursdays**
- Substitutes for session before Thanksgiving; due December 1; Patricia Hedtke by 5PM
  - “Who Can Prescribe” exercise (individual effort)
  - Label exercise (individual effort)
- Ethics Case; due December 8; via eSubmit by 5PM; group effort
- Course evaluation; due December 8; Patricia Hedtke 5PM

Quiz

- Weekly
  - posted Friday afternoon, closes at 1:30PM Monday
  - 10 multiple choice questions
  - based on prior week’s lectures or assignments; representative of midterm and final
  - open book but not open neighbor (individual work)
  - first week – no credit, but please try it

Questions

- Ask in class (best!)
- “lab” session after each class – to 4:30 (Monday) or 4+ (Wednesday; I’ve another class)
- send e-mail to any of us
- fixed office hours for Catherine & Mindy
- office hours for Don or I by appointment (please request via e-mail)
- terminology & alphabet soup
  - acronym police

“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
Class Web Site

- Is web training necessary?
- Familiar with Adobe Acrobat?
- Posting of lecture notes, “homework”, etc. 
  http://courses.washington.edu/pharm543/
  - lecture notes will be posted at least 24 hours before lecture ... or we’ll bring them to class
  - typically posted by late Friday afternoon
- Link to NABP Online in Restricted Access
- Schedule & Due Dates (handout)
- Check frequently

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 4 & 6
  - report
  - oral presentation
- best – presentation to scheduled Board meeting, WSPA Midyear Meeting
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 5 Oct & via eSubmit @ 5PM; discussion in “lab” sessions
- “petition”, other, options

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, WSPA, others?
Project: Resources

- Librarians
  - Terry Jankowski, Health Sciences
  - Government Publications (Suzzallo)
  - Gallagher – different system, different rules
- NABPLaw Online – in “Restricted Access”
- Weekly meetings after class (Monday - 4:30 & Wednesday - 4)
  - resource folks available
- Getting a timely response

Suggested Topics

- Mandatory minimum stock levels for specified medical products
- Mandatory dispensing
- DSHS Audit Guidelines, Appeals
- Rural hospitals
- DEA Revisions (via petition to BOP)
- Identify stuff in 21CFR1300 et seq. regulating practice of pharmacy (cf. Gonzales v. Oregon decision)
- Comment on Notice of Proposed Rulemaking re C-II issues (refills for chronic meds, partial fills, etc.)
- Extend renewal date to 2 years (petition before the Board)
- Review collaborative practice agreement templates
- Legibility – mandatory eRx, eSignature
- Free clinics and prescription drugs
- Mandatory inclusion of a "Notation of purpose" on all prescriptions
- Dispensing via kiosk’s
- Pharmacist involvement in verification from remote sites
- Anything related to "tele-pharmacy"
- Appropriate practices for pharmacist verification of technician admixture preparation in hospitals
- Appropriate pharmacist/patient counseling procedures
- C-II prescription expiration date in WA (petition Board)

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

Ethics Case Write-up

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

- no makeup exams, late homework
- date of final: 2:30-4:20 PM, Dec. 11
- 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

Classroom Safety

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

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
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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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” ...
- Communications to class: via e-mail
  - please check frequently
  - if NetID@u.washington.edu address is redirected, please maintain
... For Monday

- check out class web site

http://depts.washington.edu/pharm543

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