

PHAR 6236:
SURVEY OF LAWS AFFECTING PHARMACY PRACTICE
Fall 2007
2 Credits Elective

LOCATION & TIME

Fridays 2:30 – 4:25* (9/4/07 – 12/12/07)

Rooms: (TC) Moos Health Sci Tower 1-450G (Duluth) TBD

* End times may vary

INSTRUCTOR INFORMATION

Andrew Shim, PharmD, JD

Office: Off-campus

Office Hours: By appointment

Office Phone: 651-308-6284 (7 days a week, 8 AM – 6 PM)

E-mail: andrew.shim@novartis.com

My accessibility goal is to be open and flexible. I will be available few minutes before and after each class session and at other times by appointment. In consideration of student schedules and my off-campus office location, students may contact me 7 days a week, between 8 AM – 6 PM.

My preferred mode of communication is by e-mail. Alternatively, you may also reach me at my office phone number. I will generally respond back to students within 24-48 hours. I have an open communication policy so please feel free to contact me about any issues relating to the course.

PREREQUISITES

There are no specific prerequisite coursework for this class.

COURSE DESCRIPTION & GOALS

The law is pervasive in our society, especially affecting professionals practicing in a highly regulated industry such as pharmacy. This is a survey course geared towards pharmacy students that introduces diverse areas of legal topics of potential interest and impact in their future. Knowledge, perspective, and familiarity with topics covered in this course will provide a good general background and foundation to recognize and be familiar with pharmacy legal issues.

The goal is for the students to gain practical understanding and unique insights on the U.S. food and drug (FDA) law, civil liability of malpractice and duty of pharmacy professionals, implications of intellectual property rights of others, and business law topics especially in managed markets ranging from contracts and non-compete agreements to pay for performance.

OBJECTIVES OF THE COURSE

Upon completion of this course, the student will understand:

1. Civil liability concerns impacting pharmacists including but not limited to duty to warn and negligence.
2. Basics of business law especially in managed markets covering diverse topics involving contracts, general employment law concerns, non-competes, and pay for performance that may impact pharmacy professionals.
3. Food and Drug Administration jurisdiction and regulation as it pertains to
 - a. Defining what a drug is, adulteration, and misbranding
 - b. Drug development process pertaining to discovery, IND, IRBs, informed consent, and clinical trials
 - c. Drug approval (NDA, generics, OTC drugs, combination products, accelerated approval, and post-market surveillance)
 - d. Product information dealing with labeling, advertising, detailing, and First Amendment right of commercial free speech
 - e. Biologics, false claims act, anti-kickback statute, and re-importation
4. Principles of intellectual property law as it pertains to pharmaceuticals
 - a. Introduction to differences between trademark, copyright, and patents
 - b. Patent law covering patentable subject matter, patent prosecution or process of obtaining a patent, ownership & other rights, conditions of patentability, defenses, infringement, patent litigation, and incentives for innovation

EXPECTATIONS

General: Class will be a combination of lectures and related discussions using law cases applicable to pharmacy professionals. Students will be encouraged to participate by being called upon to explain the general facts of the legal case readings, discussing the court's opinion, critically evaluating implications to pharmacy, and examining any public policy issues.

This class is not meant to be a memorization of applicable law or case readings. Rather, we will primarily focus on critical analysis of how and what the law or case means to pharmacy professionals. Additionally, guest speakers when available, may cover such areas as liability, regulatory affairs, FDA law, and patents to augment the student's learning experience.

Student Roles: To facilitate an interactive class session, all students are expected to come prepared for class by reading the assigned cases and thinking about how the facts of the case and court's opinion affect pharmacy. My suggestion is to read only 1 week in advance, in the event assigned cases are changed per discovery of more applicable cases. Students are required to attend classes on time and provide notice in the event of extended absence.

GRADING POLICY

The following format will be used to determine student's course grade for the semester.

- **35% of final grade – Exam #1: Open notes take home exam** consisting of multiple choice, T/F, and/or short answer type of questions based on contents of lectures and discussions.
- **35% of final grade – Exam #2: Open notes take home exam** consisting of multiple choice, T/F, and/or short answer type of questions based on contents of lectures and discussions.
- **10% of final grade – Participation:** Regular, positive, and constructive class participation based on instructor's subjective evaluation of case preparations and comments.
- **20% of final grade – Critical Analysis:** The critical analysis is a thoughtfully written 3 - 5 page double spaced critical analysis, on a research topic assigned by the instructor. Students must submit their written assignment via e-mail to the instructor within 48 hours of assigned date.
- **Extra Credit – Optional:** - Students may submit an optional research paper for an increase in their final grade. This paper is due no later than last day of class. Paper must be a B quality or better as assessed by the instructor, and if accepted, final course grade will be raised one half grade (for example from B to B+). The optional paper must be limited to the following suggested topics or other topics with prior approval.

Suggested extra credit paper topics: Hatch-Waxman Act (generic drugs), off-label use of approved drugs, direct-to-consumer advertising of drugs, post marketing surveillance & adverse event reporting, access to medications, drug importation, combination products, pediatric studies, issues of medical malpractice reform, U.S. or international patent rights.

Required format: Graduate or professional school standards (i.e. minimal APA format), approximately 3-5 pages (excluding title and bibliography), double spaced, 12 font text, 1" margins on sides, legal or scientific citation format is acceptable.

Make-up exams and Regrading of exams :

Under no circumstances will make up examination be given for unexcused absences.

Make-up exams will only be given to those students who have a legitimate excuse and who have prior permission. Excused absences include verified illness, family emergency, required U.S. military service, or verified University-sponsored or professional event. Additional excuses for other reasons will be determined by the course director.

Make-up exams may utilize an alternative format consisting of primarily short answer and/or essay questions.

Students may request to see their original copy of the examination, in which case, the exam must be returned directly to me within 7 days of receipt. Students are not permitted to photocopy or otherwise duplicate their exam. Students may submit correction requests in writing and explain why a change is justified. This will prompt a review of the entire exam which may cause points to go up or down.

Grades:

A	93-100%	A-	90-92%
B+	87-89%	B	83-86%
B-	80-82%	C+	77-79%
C	73-76%	C-	70-72%
D	60-69%	F/N	<60%

HONOR CODE

Each student is bound by the following specific provisions as part of the Code: academic misconduct is any unauthorized act which may give a student an unfair advantage over other students, including but not limited to falsification, plagiarism, misuse of test materials, receiving unauthorized assistance, and giving unauthorized assistance. Each student will be asked to sign a cover sheet on tests, quizzes, and other assignments as it applies to this course. Unless otherwise explicitly stated, you are required to do your own work on all quizzes, tests, or other assignments. Consistent with the University of Minnesota's Grading Policies, "academic dishonesty in any portion of the academic work for a course may be grounds for awarding a grade of F or N for the entire course and will be referred to the Honor Council."

DISABILITY ACCOMMODATION

Any student with a demonstrated disability who needs to arrange reasonable accommodations must contact the course director as well as the Office of Student Services and Disability (612-626-1333) at the beginning of the semester. All discussions will be held confidential.

REQUIRED TEXTBOOK

None. A list of reading assignments and handouts will be made available.

Optional (student should consult with the instructor to verify need prior to purchasing):

1. Lars Noah & Barbara A. Noah, *Law, Medicine, and Medical Technology: Cases and Materials* (Foundation Press, 2002).
2. Richard Abood, *Pharmacy Practice and the Law* (Jones and Bartlett, 2005)

ADDITIONAL INFORMATION

Instructor reserves the right to modify the contents or sequence of the syllabus, including reading assignments at any time during the semester. Any changes will be communicated to the students.

All reading assignments made available to students are for educational use only and may not be distributed.

Helpful hint: Students may look up unfamiliar legal terms discussed in the assigned cases by using the following internet reference site: <http://www.answers.com>

Telephonic learning (as circumstances arise)

Toll free number 1-866-866-5118

MEETING NUMBER: *6903481* (note “*” before and after the meeting number)

COURSE OUTLINE & SCHEDULE*

Timeline	Topics	Advance Reading Assignment
9/7/07	No PM classes per COP	N/A
9/14/07	Welcome, review of syllabus, and introduction <ul style="list-style-type: none"> ▪ How to read and analyze cases <ul style="list-style-type: none"> ▪ To review in class as handout - <u>Fourth Street Pharmacy v US DOJ & DEA</u> 	N/A
Part I 9/14/07 – 9/28/07	I. Introduction to pharmacist malpractice and professional risk management <ul style="list-style-type: none"> ▪ Overview of torts (civil liability) ▪ Malpractice ▪ Duty to warn? ▪ Professional errors? 	TBD on weekly basis
Part II 10/5/07 - 10/26/07	II. Business law in managed markets and its impact on pharmacists and pharmacy practice <ul style="list-style-type: none"> ▪ Business law <ul style="list-style-type: none"> ▪ Contracts in general ▪ Employment related issue ▪ Managed markets issues <ul style="list-style-type: none"> ▪ Introduction to managed markets ▪ Is there a “contractual obligation” by pharmacy professionals within scope of clinical pharmacy management (CPM)? ▪ Pay for performance and other incentive programs (CDHP) <p>Fall break, no class on 10/19/07 Take home exam #1: 10/26/07</p>	TBD on weekly basis

<p>Part III</p> <p>11/2/07 – 11/16/07</p>	<p>III. The FDA and what pharmacists should know!</p> <ul style="list-style-type: none"> ▪ What is a drug? What is regulated? ▪ Adulteration & misbranding ▪ Trial and approvals ▪ Product information ▪ Fraud and abuse ▪ Importation 	<p>TBD on weekly basis</p>
<p>Part IV</p> <p>11/30/07 - 12/7/07</p>	<p>IV. Intellectual Property, what is all the fuss?</p> <ul style="list-style-type: none"> ▪ Differentiating intellectual property <ul style="list-style-type: none"> ▪ Patents, TM, Copyrights, Trade Secrets ▪ Overview – what is IP, subject matter ▪ Specifics <ul style="list-style-type: none"> ▪ Prosecution, ownership, conditions of patentability, defenses, infringement, litigation <p>Thanksgiving holiday break, no class on 11/23/07</p> <p>Take home exam #2: 12/7/07</p> <p>Critical Analysis due on 12/7/07</p>	<p>TBD on weekly basis</p>

*This course outline & schedule are subject to change