

Development and Refinement of an Elective Pharmacy Law Course to Prepare Student Pharmacists for Leadership Roles

Joseph L. Fink III

Joseph L. Fink III, B.S.Pharm., J.D., F.A.Ph.A., is Professor of Pharmacy Law and Policy as well as Kentucky Pharmacists Association Professor of Leadership, Department of Pharmacy Practice and Science, University of Kentucky College of Pharmacy, Lexington, KY 40536-0596 (E-mail: jfink@uky.edu).

Acknowledgement: The late Maven J. Myers, J.D. Ph.D., Dean of Pharmacy Emeritus and Professor of Pharmacy Administration Emeritus at the Philadelphia College of Pharmacy, University of the Sciences in Philadelphia, was an invaluable faculty mentor when I was a new faculty member and greatly encouraged the development of this course. Also deserving of acknowledgement is Maureen M. Fink, R.Ph., my wife, with whom I missed numerous dinners over the years to teach this course.

Abstract. An elective course in the law applicable to pharmacy, pharmacists, and pharmaceuticals is described. Course goals, content, materials, and grading are detailed as are comments from selected student course evaluations over the years. Students who have elected to enroll have appreciated gaining a greater understanding of how the U.S. legal systems work.

Introduction

Pharmacists, pharmacies, and pharmaceuticals are highly regulated, either at the state or federal level. As a result, colleges and schools of pharmacy have included instruction on issues related to pharmacy law for decades. The traditional approach has been that pharmacy law information is a required component of the curriculum, usually delivered through a free-standing required course or, on occasion, by integration of the material with other information in a combined course. Often the only debate is whether to place it early in the curricular flow so the students can put it to use and perhaps even share the up-to-date information with preceptors and employers, or place it late in the curriculum to reassure those students who want to be certain they have the most current information for the licensure examination. (1)

Material covered typically includes, among other topics, information about the Federal Food, Drug and Cosmetic Act and the attendant regulations adopted by the U.S. Food and Drug Administration, the Federal Controlled Substances Act and the regulations from the U.S. Drug Enforcement Administration, the Poison Prevention Packaging Act and regulations of the U.S. Consumer Product Safety Commission related to use of child-resistant closures on medication containers, as well as state-level statutory and regulatory enactments related to the practice of pharmacy and distribution of pharmaceuticals. These topics are all subject to being covered on either the Multistate Pharmacy Jurisprudence Examination prepared by the National Association of Boards of Pharmacy, or the pharmacy law portion of the licensure examination developed by state officials, either for use with first-time licensees or for those transferring licenses. (2-15)

Other legal topics of relevance to pharmacists may also be included in the contemporary curriculum. Examples of additional subjects often encountered in required course content are the Health Insurance Portability and Accountability Act (HIPAA), malpractice and professional liability insurance issues, and the regulatory framework (or lack thereof) for dietary or nutritional supplements.

These two lists leave an abundance of legal topics related to pharmacy available for coverage in a pharmacy law elective course. A course to highlight the many other facets of the law that impact pharmacy was developed as an elective course first offered at the Philadelphia College of Pharmacy and Science during 1974-75. This was offered at least once per annum each academic year from then until 2006, with the class being offered at the University of Kentucky College of Pharmacy from 1981 to 2006 when an expanded required pharmacy law course was added to the Pharm.D. curriculum. In a number of years the demand was such that the elective course was offered during both semesters in order to keep the enrollment at a level conducive to discussion in class.

The Course

Course Descriptions

The course content was described to potential students this way in the course syllabus:

This course will include an introduction to the law and its impact on pharmacy practice. Topics covered will include Constitutional safeguards of individuals' rights, Constitutional rights, intellectual property,

intentional torts, the law of employment and other issues of contemporary importance.

This was slightly different from the official course description appearing in institutional publications so that, taken together, they presented a more complete impression of the content:

Discussion of the legal framework for and specific legal issues in pharmacy practice. Topics will include: Constitutional rights; application of antitrust laws to pharmacy; patent, copyright, and trademark issues relevant to pharmacy; legal issues related to prescription drug insurance programs; the law of employment; and legislative issues such as drug product selection. Contemporary legal issues in pharmacy will be addressed as they arise.

The first class meeting of the academic term included emphasis that completing this course was unlikely to assist the aspiring pharmacist with the jurisprudence portion of the licensure examination, i.e., “we don’t talk about five refills in six months, or issues like that in this course.” At the Philadelphia College of Pharmacy and Science those topics were covered during a required course designated Pharmaceutical Jurisprudence. At the University of Kentucky those topics were covered at various times either by a self-instructional module taught by another member of the faculty while students were on experiential rotations or by being integrated at appropriate points in the dispensing-related courses until the aforementioned expanded law course was implemented during 2006.

The type of material covered in this course was often totally new to the students, unlike other hierarchical portions of the curriculum where, for example, general chemistry leads to organic chemistry and on to biochemistry, medicinal chemistry, etc. This led to the students being concerned about how they would be tested on the material. That concern was addressed by liberal use of examples related to their professional and personal experiences to illustrate how the information being presented might be encountered on an examination.

The point is made that the students probably have absorbed an introductory understanding of the law and the legal system from living in the U.S. and being surrounded each day by discussion in the media of legal issues and topics. If a good deal of the material covered in the pharmacy curriculum is viewed as advanced, applied chemistry or advanced, applied biology, then the legal topics, issues and systems discussed in this course may be thought of as advanced, applied history, an area of study sometimes escaping emphasis by pharmacy students.

It should be noted that international students sometimes had more of a challenge with this course because they had not had the advantages of U.S. students who have grown up in the system and likely have had a course in Civics or Problems of Democracy in high school. Directing international students to appropriate sources of additional information they can read to strengthen their backgrounds proved helpful. The advent of the Internet helped them locate valuable resources as well.

Desired Course Outcomes

The desired course outcomes related to the ability of students to perform were described this way:

Upon satisfactory completion of this course, the student should be able to:

[1] discern when significant legal issues exist in a situation and when consultation with legal counsel is appropriate; [2] have a basic familiarity and facility with legal terminology to be in a position to consult effectively with legal counsel; and [3] understand the legal system in a way that facilitates being a civic leader in society and being able to understand and critically assess news reports related to legal issues.

The level of familiarity addressed in [1] was described to the students as being similar to that needed to detect potential drug-drug interactions prior to the advent of computerized databases. No one knows every possible drug interaction; the key is to be able to recognize when the potential for such problems exists so reference works can be consulted to retrieve the specifics. Outcome [2] was heavily emphasized in the mid-semester examination because terminology and structure of legal systems were mainly covered in the first one-third of the course. Outcome [3] was specifically addressed by examination questions that, for example, asked the students to assume they are chair of the Legislative Affairs Committee of the state pharmacists association and then presented them with relevant questions about the legislative process.

It was emphasized that the goal of the course was not to make a lawyer out of the students; that cannot be accomplished in an elective course of one semester duration. Rather, the goal was to position them to be effective consumers of legal information and citizens who can effectively understand, use, and negotiate through the legal system. An additional goal was to provide students with an overview of a variety of legal issues they

may encounter when assuming leadership roles in professional associations, community organizations, or voluntary health-related groups.

Topics Included in the Course

A topical outline of the course material was provided to the students at the outset so they could see how the pieces of the puzzle come together::

Introduction to the law

Why have law?

Law versus ethics versus mores

Why have government?

Structure of government in the U.S.

Types of law

Law versus equity

The legislative process

Court structure and processes

Civil versus criminal procedures

Burden of proof in court

How to read a court decision

How to use legal citation forms

Alternative Dispute Resolution

Constitutional safeguards of individuals' rights

Search and seizure

Pharmacy inspections

Exclusionary rule

Miranda warnings

Fifth Amendment rights

Constitutional rights

Freedom of speech

Freedom of religion

Due process rights

Privileges and immunities clause

Equal protection clause

Right to privacy

Antitrust and prescription drug insurance programs

Case law from pharmacy

Robinson-Patman Act

Business organizations

Alternative forms of organization

Fiduciary duties

Intellectual Property

Patents

Copyright

Trade Secrets

Trademarks

Law of employment

Employment at will

Giving references for employees

Business torts

Slander/libel

False imprisonment

Refusal to deal

Special considerations with tax-exempt organizations

As time permitted brief discussion of miscellaneous non-pharmacy-related topics such as these was included as well:

Nature of the law school curriculum and the Socratic method of instruction

Admission to the Bar and issues in legal ethics such as confidentiality of client information

How to effectively work with your attorney

Need for a standard will, living will and durable power of attorney documents

U.S. Supreme Court Cases Discussed

A special emphasis was placed on discussion of cases involving pharmacy that had been decided by the U.S. Supreme Court, or cases decided at that level that have application to pharmacy or pharmacists. Cases that have proceeded completely through the judicial system present an excellent opportunity to review not only the legal questions at issue but also the procedural history of how the case advanced to that level of the judicial system. Examples of cases discussed include:

- *Abbott Laboratories, et al. v. Portland Retail Druggists Association, et al.*, 425 U.S. 1 (1976). [Robinson-Patman Act applicability to drugs sold at preferential prices]
- *Camara v. Municipal Court*, 387 U.S. 523 (1967). [Governmental search and

seizure]

- *Group Life & Health Insurance Co., et al. v. Royal Drug Company, et al.*, 440 U.S. (1979). [Exemption of provider contracts in prescription drug insurance programs from the antitrust laws]
- *Marshall v. Barlow's, Inc.*, 436 U.S. 307 (1987). [Governmental search and seizure]
- *Miranda v. Arizona*, 384 U.S. 436 (1966). [Fifth Amendment right against self-incrimination]
- *North Dakota Board of Pharmacy v. Snyder's Drug Stores, Inc.*, 414 U.S. 156 (1973). [Constitutionality of legislation mandating that pharmacies be predominantly owned by pharmacists]
- *See v. City of Seattle*, 387 U.S. 541 (1967). [Governmental search and seizure]
- *Virginia State Board of Pharmacy, et al. v. Virginia Citizens Consumer Council, Inc., et al.*, 425 U.S. 748 (1976). [Freedom of speech/regulation of prescription drug price advertising]

Resource Materials

There was no required text for the course. Three resources are recommended, one of which the students are likely to already own:

- Aboud RR. **Pharmacy Practice and the Law** (latest edition), Sudbury, MA: Jones and Bartlett.
- Fink III JL, Vivian, JC and Bernstein IG. (eds.) **Pharmacy Law Digest** (latest revision) St. Louis, MO: Facts & Comparisons.

- Vivian, JC and Fink III, JL.. “Laws Governing Pharmacy” Chapter in **Remington: The Science and Practice of Pharmacy** (latest edition) Baltimore, MD: Lippincott Williams & Wilkins.

The following supplemental materials were distributed to supplement class discussion of the topics:

The Declaration of Independence

The English Common Law

How a Bill Becomes Law

What to Expect When a Lawsuit Is Started

Chart of the U.S. Court Systems

Example of an Appellate Court Decision

Handout on Legal Citation Forms

Map of the Thirteen Federal Judicial Circuits

Selected Provisions in the U.S. Bill of Rights

Handout on Forms of Intellectual Property

Handout on the Robinson-Patman Act

Academic Affairs Issues

Course Prerequisites

The only prerequisite for enrollment was completion of the first two semesters of the pharmacy curriculum. During that first professional year the students are given a general framework for considering legal and regulatory issues related to the profession and introduced to prescription drug insurance programs along with other types of health insurance.

Course Credit Allocation

The course carried two semester hours of credit. While most other elective courses in the UK College of Pharmacy were allocated three credits, this did not unduly dissuade students from enrolling.

The course was designated as a dual-level course (500-599 course number in the UK system), which has proven to be a distinct advantage. A dual level course is defined as a course open to juniors, seniors, and graduate students that can be taken either for undergraduate or graduate credit. (16) Graduate students who enroll in this course need to complete an additional assignment as required by University academic rules, in this case an additional writing assignment:

Expectations in 500-level courses

Combined instruction of graduate and undergraduate students in 500-level courses must be structured to ensure appropriate attention to both groups, and a corresponding differentiation in expectations. This differentiation is to be accomplished by (i) the completion of additional or distinct assignments by the enrolled graduate students that are consistent with graduate-level scholarship; and/or (ii) the establishment of different grading criteria in the course for graduate versus undergraduate students, reflecting a higher standard for graduate students. The grading scale for both graduate and undergraduate students must be clearly stated in the syllabus. (17)

This flexibility to accommodate graduate students proved valuable several years ago when a unique opportunity arose. The University of Kentucky cooperated with

Georgetown University in offering a graduate education program for government administrators from Eastern European countries formerly dominated by the Soviet Union, the East Central European Scholars Program. Supported by the U.S. Agency for International Development, the goal of the program was to facilitate adjustment of these key officials to operating in a free market economy; nearly all had lived their entire lives in the highly managed economy characteristic of communism.

One of the students during 1997 was Zofia Ulz, mgr farm., a pharmacist from Poland who was a Regional Director of the Inspectorate of Pharmaceutical Supervision, an agency that combined the functions of the U.S. Food and Drug Administration with those of a board of pharmacy, i.e., regulating pharmaceutical manufacturers, pharmacies and pharmacists. Due to program requirements, she needed to be enrolled for graduate credit and having that flexibility with this course was quite valuable because at that time UK did not have a didactic required basic pharmacy law course she could take, the topics having been disseminated across a variety of required courses or offered through the self-instructional module mentioned earlier. She also completed a number of independent study projects related to comparative evaluation of regulatory approaches to assuring quality of pharmaceuticals and pharmaceutical services, that work being completed under the rubric of Independent Study in Public Administration, a graduate course. The conclusion of that experience was that she returned to her country and is now Director of the Main Pharmaceutical Inspectorate of Poland, a position equivalent to the Commissioner of the U.S. Food and Drug Administration in the United States.

Course Scheduling

Having this course open to both second professional year and third professional year pharmacy students created a challenge when identifying a scheduling timeslot that could be accommodated in the schedules of students in both years. Consequently, the course met late in the day, either 4:00 – 6:00 PM or 5:00 – 7:00 PM. An additional advantage of scheduling late in the day was that this approach enabled the instructor to continue teaching the course while serving in time-consuming university administrative roles for sixteen years.

Initially, concerns existed about students coming to class at the conclusion of a full day of others classes – how attentive would they be? But students repeatedly reported that the course content is so different from what they normally have and the topics so interesting that they don't mind having these sessions at the end of a very full day of other classes.

Course Grading

The grade for the course was determined by two examinations, one approximately half way through the semester and the other at the conclusion of the course during the week for final examinations. Each examination contributed 50 percent of the course grade. Question formats included true-false, completion, and discussion, with the first two used primarily for questions about terminology and legal systems, e.g., legislative, executive, and judicial, and the third format, the majority of points on an examination, requiring application of the principles and doctrines discussed in class.

Attendance Policies

The attendance policies for courses at the University of Kentucky are committed to the discretion of the lead instructor; there is no institution-wide requirement or standard. The policy for this course was described this way:

Attendance at class sessions is the responsibility of the student. Be advised that examinations draw heavily from information discussed in class and absence during the discussions may cause one to be at risk with regard to material covered, specifically the nuances of legal rules.

Student attendance was not a problem, as should be expected with a course in which the students have chosen to enroll, presumably due to interest in the subject matter.

Course Evaluations

As may be expected with a course the students have selected for enrollment, as opposed to a required course, the course evaluations were quite positive. Selected excerpts from the written comments portions of past course evaluations include:

“I never had a civics class in high school so this course really gave me an insight into the justice system.”

“This course was interesting and provided information that will be useful in pharmacy practice and elsewhere.”

“This course was a welcome relief from the standard run of courses in the curriculum.”

“This class is interesting and is good because it brings a break from our regular pharmacy courses.”

“This course takes the opportunity to emphasize issues that will be important to our functioning as pharmacists and as responsible citizens.”

Student Performance

The vast majority of students enrolled in the course over thirty years earned grades of “A” or “B.” There was an occasional grade of “C” but that was quite rare.

Given their backgrounds in science-related courses, it should not be surprising that students sometimes have difficulty with the possibility existing in a course of this nature that there may be several final answers, all of which are “right” or “correct.” Their past educational experiences have conditioned them to seek the one correct answer, eschewing all others. The opportunity to study a field where several correct answers may well exist was a learning experience for the students in itself.

Teaching Approach and Philosophy

Students have described the teaching style as “conversational”, which has been interpreted to mean that it was relaxed and quite understandable. Rhetorical questions were frequently used to challenge the students to think about what was being covered and the discussion regarding some legal principle or doctrine was nearly always followed with an illustration from professional practice or everyday life to illustrate how the concept was applicable to many things the students will be doing.

The course material was kept current by incorporating at appropriate points items from the current literature and, as available, news stories from the newspaper or television that they may well have seen, again reinforcing the relevance of what we had been discussing, e.g., the criminal case of *People of the State of California v. Orental James Simpson* and its civil law progeny, *Goldman v. Simpson*. One limitation, though, has come to the surface over the years – students predominantly get their news from the free daily campus newspaper, television, or the Internet so discussing a topic mentioned in a local or national newspaper often was met with blank stares.

Changes Over the Years

Offering any course over a period of thirty-plus years provided plentiful opportunities for fine tuning. Based on changes in the profession during that period along with perceptions of levels of interest by the students, the following changes occurred, among others:

Less time was later allocated for criminal law matters than originally;

Malpractice and professional liability insurance discussions have been shifted to the required curriculum;

Added the informal discussion about how to select a lawyer, the law school curriculum and method of teaching, the need for a will and durable power of attorney, etc.;

Contracts was shifted to a required course as were some issues related to business organizational forms;

Section on antitrust law was expanded over the years probably more than any other section. The portion on intellectual property was second in degree of expansion over the years; and

More time is now allocated to discussion of issues associated with the activities of tax-exempt organizations.

Conclusion

This was a thirty-plus year journey with two favorite companions – pharmacy students and the law. The excitement and drama sometimes associated with legal issues can easily be communicated to students to enliven a class. And when they can take what they’ve learned in class and apply it, if only by better being able to identify an unlawful search and seizure on “Law & Order” or other contemporary legal television show or movie with greater understanding, their lives are enhanced. They can also be more effective as leaders in community and professional organizations and perhaps be less intimidated by local lawyers who sometimes tend to dominate or even intimidate others.

References

- (1) Lewis RK. The pharmacy curriculum: Perspectives and expectations from a pharmacy student’s point of view. *Am J Pharm Educ.* 1989;53:60-1.
- (2) Abood RA. A basic pharmacy law course. *Am J Pharm Educ.* 1987;51:82-3.
- (3) Brushwood DB. Integrating law study into the pharmacy curriculum. *Am J Pharm Educ.* 1987;51:84-5.
- (4) Campbell NA. 1988 Institute for Teachers of Pharmacy Law: Current status of pharmacy law instruction. *Am J Pharm Educ.* 1989;53:53-5.

- (5) Dusik, CM. The pharmacy law curriculum: Perspectives and expectations from a clinical pharmacist. *Am J Pharm Educ* 1989;53:59.
- (6) Evanson RV. Law and ethics in practice. *Am J Pharm Educ*. 1989;53:61-5.
- (7) Fink III JL, Simonsmeier LM. Legal education of the pharmacy undergraduate. *Am J Pharm Educ*. 1977; 41:189-191.
- (8) Fink III JL. The role of pharmacy law instructors in inspiring professional excellence. *Am J Pharm Educ*. 1987;51:85-7.
- (9) Molzon JA, Pisano, DJ. The status of pharmacy law instruction in U.S. pharmacy schools: An addendum. Paper presented at the 1995 Annual Meeting of the American Society for Pharmacy Law, Orlando, FL, March 18, 1995.
- (10) Myers MJ. Education as a factor in the reduction of pharmacy law violations. *Am J Pharm Educ*. 1967;31:144-7.
- (11) Myers MJ. New dimensions in undergraduate education: Law and ethics. *Am J Pharm Educ*. 1970;34:873-76.
- (12) Nona DA. The pharmacy law curriculum: Perspectives and expectations from the American Council on Pharmaceutical Education. *Am J Pharm Educ*. 1989;53:57-8.
- (13) Pisano DJ, Ploude R. Status of pharmacy law instruction in U.S. pharmacy schools. Presented at the 1994 Annual Meeting of the American Society for Pharmacy Law, Seattle, WA, March 21, 1994.
- (14) Ryan MR. The pharmacy law curriculum: Perspectives and expectations from a college of pharmacy dean. *Am J Pharm Educ*. 1989;53:55-7.
- (15) Wickham FZ. The pharmacy curriculum: Perspectives and expectations from a state board of pharmacy. *Am J Pharm Educ*. 1989;53:59-60.

(16) University Senate Rule 3.1.0, University of Kentucky, Lexington, KY. Available at http://www.uky.edu/Faculty/Senate/rules_regulations/Rules%20Versions/MASTER%20RULES%20from%20February%202012_clean.pdf.

(17) University Senate Rule 3.1.4, University of Kentucky, Lexington, KY. Available as above.