

Legal Education of the Pharmacy Undergraduate

To the Editor:

An understanding of the law is becoming increasingly important to the practicing pharmacist. It has been observed that "Academic pharmacy instruction and the licensure examination place greater emphasis on jurisprudence than any other health profession; and pharmacists advise and counsel their medical, dental and nursing colleagues on legal requirements as an important service in their daily practice."⁽¹⁾ Among the most important events affecting the practice of pharmacy in recent years have been the decisions of the United States Supreme Court upholding the pharmacy ownership restrictions enacted by the legislature of the State of North Dakota⁽²⁾ and APhA's successful protection of the pharmacist's right to dispense any lawfully approved drug against an attempt by the Food and Drug Administration to limit the channels of distribution of methadone⁽³⁾. Also of significance were the action of the United States Supreme Court in clarifying the meaning of the phrase "own use" as it pertains to sale of drugs by hospitals⁽⁴⁾ and the decision from the same court overturning the Commonwealth of Virginia's ban on prescription drug advertising⁽⁵⁾.

As the pharmacist moves into new areas of practice, the legal aspects of new endeavors must be given due consideration⁽⁶⁾. What is the potential liability exposure of the pharmacist who does or does not maintain patient medication records^(7,8) or who serves a skilled nursing facility?⁽⁹⁾ Is the pharmacist who participates in hypertension screening "practicing medicine?"¹ What is the pharmacist's legal duty to caution patients about potential adverse side effects of drugs?⁽¹⁰⁾

The pharmacy graduate must have sufficient legal background to identify potential legal issues when confronted with them in his daily practice. The purpose of educating pharmacy students in the law is not to make them lawyers, but rather to instill in them an appreciation for legal principles so that they may recognize potential legal difficulties before they materialize or advance to a stage beyond retrieval. Hence, the pharmacist must not only be expert in the statutory and regulatory framework of pharmacy practice with specific knowledge relating to the drug-use process, but must also be attuned to the legal and sociopolitical environment within which pharmacy is practiced. The government is increasing its influence within the profession and the pharmacist should understand the workings of government and the limits on its powers.

CATALOG SURVEY

A study was undertaken to determine the types and amount of exposure which students in the nation's colleges of pharmacy receive in the discipline of law. Data was collected by reviewing the catalogs or bulletins of the 71 colleges of pharmacy in the continental United States for the academic year 1975-6. The College of Pharmaceutical Sciences of Columbia University closed its doors in June 1976, and a catalog was not obtained from that institution.

A shortcoming in the methodology utilized is due to the fact that education is not static and faculty are continually revising and updating their curricula as well as the content of their courses. Hence, it should be borne in mind that the data presented here were collected from catalogs representing one year only, and that catalog information may quickly become antiquated. Moreover, pharmacy college catalogs were found to vary significantly in size — from those composed of a single sheet of paper to those which approached one inch in thickness. Another factor which complicated the collection and analysis of the data presented here is that course information for colleges which were in a transitional stage at the time of the survey was often sketchy.

REQUIRED LAW CLASSES

Those colleges which require at least one specific course in pharmaceutical law number 65 (91.5 percent). This figure includes three colleges which mandate two courses dealing primarily with legal subject matter, and one college which requires three courses of this nature. Four additional colleges (5.6 percent) which require a course in the legal aspects of pharmacy offer this material as part of a course not completely devoted to coverage of legal matters. One college includes the legal aspects of drug use in a course which also covers extemporaneous compounding and pharmaceutical calculations. At another college a similar course is taught dealing with the technology and art of pharmaceutical services and the legal matters pertaining to that. One college of pharmacy requires a course which combines the principles of both pharmacy management and pharmacy law. The final school to require some presentation of legal material includes the subject matter in a course dealing primarily with social and professional behavior. Of the two remaining institutions, one offers the pharmacy law course on an elective basis and the other has no indication in its catalog of any courses which include coverage of legal material.

The number of credit hours assigned to the traditional course, which restricts coverage to matters related directly to pharmaceutical jurisprudence, varies widely whether the institution is operated on a semester or quarter basis. Although not all list the number of credits for their course, the 55 colleges (77.5 percent), which do provide this information, list their law class as requiring either two or three semester-credit hours or three quarter-credit hours. While eight colleges (11.3 percent) list courses which were four or five semester- or quarter-hours of credit, none of the institutions listed a one credit hour course. This seems to indicate that colleges of pharmacy are taking a more uniform approach to the teaching of pharmaceutical jurisprudence, as compared to instruction in this field nearly 30 years ago. In a 1952 report prepared for the Committee on Curriculum of the Association, it was reported that 52 colleges of pharmacy, representing 81.3 percent of the colleges accredited then, offered instruction in pharmacy law⁽¹¹⁾. Using data collected during the 1947-8 academic year, the semester hours of instruction in jurisprudence reported ranged from a high of six hours in one college to a low of one hour in five colleges with the median being two semester-hours⁽¹¹⁾.

Just as the number of credit hours differs from college to college, so does the curriculum year during which the course is offered. To equalize terminology, all of the programs examined were placed on par with the first year of college experience considered *year one*, the second as *year two*, etc. Therefore, no distinction was drawn between the various types of programs (0-5, 1-4, 2-3 etc.) and their accompanying class nomenclature. No institution presented legal material in the first college year, and only eight (11.3 percent) offered this subject matter in the second or third years. Fifty-seven colleges of pharmacy (80.3 percent) scheduled their pharmacy law class in the fourth or fifth year of academic instruction with an almost equal distribution between those two years. With the expansion of the clinical component of the curriculum in the last year of the curriculum, one would expect the jurisprudence course to precede the practical experience, whether that be the fifth year or the sixth year. That is apparently the philosophy which most institutions have followed. The limited number of law courses in the early college years can probably be attributed to the students' lack of professional background to put the issues in perspective.

¹ "Legality of BP Measurement by Pharmacists Considered," *National High Blood Pressure Education Program Special Bulletin for Pharmacists*, National Heart and Lung Institute, Bethesda MD (April 1976) p. 8.

LEGAL ELECTIVES

Over one-half of the colleges of pharmacy do not record in their catalogs electives which consist primarily of pharmacy law nor do they list electives which have any intimation of legal subject matter. However, it is likely that most pharmacy orientation courses touch upon the legal and ethical considerations of professional practice(12), even though this may not be indicated in catalog descriptions. Approximately one-fourth of the institutions include some optional exposure to the interaction between pharmacy and law in courses diversely labeled as "special problems," "seminar" or "case studies."

Business or commercial law is an elective choice in a number of institutions, but only a small number offer this type of course within the college of pharmacy. The survey data indicate that a class of this nature usually acquaints the students with the principles of contracts, sales, negotiable instruments, business organizations, agency law, and other commercial law principles which influence pharmacy practice. An equally small number of colleges of pharmacy include an undergraduate or dual-level elective which is oriented toward new drug development or more particularly, FDA laws, IND and NDA procedures, patents and antitrust law. Relatively few other electives related to law are taught within the confines of colleges of pharmacy. Those which are offered include some advanced pharmacy law classes, courses involving tax law, and electives involving pharmacy legislation.

LAW AND ETHICS

The fields of law and ethics are intertwined to a certain extent since both represent attempts to establish and enforce standards of conduct for individuals — the former through societal sanctions and the latter through professional sanctions. The combination of the two subject matters is seen in some courses offered in colleges of pharmacy. Six colleges (8.5 percent) list a course which explicitly merges law and ethics, and six others offer courses in jurisprudence in which ethical problems are also discussed.

Pharmaceutical ethics is offered as a separate required course at some institutions, while others require it combined with some subject other than law or offer ethics as an elective. Yet the vast majority of institutions do not indicate in their catalogs any coverage of pharmaceutical ethics. This is in sharp contrast to the findings of a 1964 survey of pharmacy deans conducted by Tatum and Smith in which it was found that "some form of formal instruction in ethics is a basic part of the curriculum of the majority of the schools of pharmacy."(12)

COURSE CONTENT

The traditional or typical pharmacy law class has been referred to above. The question remains whether such a course does indeed exist, and, if so, what is its nature?

As one would expect, university catalogs offer some very dispassionate reading and find their highest appeal, as a matter of necessity, among college students. Short, terse statements describing the pharmacy law course as "a study of federal, state and local laws affecting the professions of pharmacy" are commonplace. The catalog committees of many universities require this type of succinctness. Fortunately, brevity did not prevent ascertaining some useful information.

Thirty colleges of pharmacy (42.3 percent) describe their jurisprudence course as one which deals solely with federal state and local laws, rules, and regulations and court decisions governing the pharmacy profession. This type of course includes an introduction to the legal system along with an examination of the Food, Drug and Cosmetic Act, the Controlled Substances Act, poison regulations, and the state Pharmacy Practice Act. One could classify this as "pure" pharmacy law, and it is the type of course recommended and outlined in *The Pharmaceutical Curriculum*(13). Again, it should be emphasized that actual course content may vary a great deal from the brief abstract recorded in the college catalog.

Seven (10.6 percent) of the 66 schools for which detailed information was available, specifically include some material from the realm of business law along with pure pharmacy law subject matter. A similar proportion of the colleges of pharmacy form an amalgamation of pharmacy law and tort law, or more particularly, the liability aspects of professional practice, such as negligence. Nine other institutions mix

all three of the foregoing areas into one course offering. The remaining institutions either offer no legal material or give no description of the course contents in their catalogs.

Scattered throughout the catalogs are references to such diverse subject matter as antitrust law, Medicaid regulations, labor law, fair trade laws, and HMO's. These additional dimensions demonstrate the changes which are occurring in today's pharmacy practice with an accompanying shift from pharmacy law courses designed primarily for community pharmacy owners to courses designed for pharmacists who may practice in any number of settings(14). Indeed, the recent court cases mentioned previously are indicative of the changes taking place in modern pharmacy and should certainly be covered in all basic pharmacy law courses.

The Section of Teachers of Pharmacy Administration of the Association has recognized that rapid change is taking place in the law as well as in all aspects of pharmacy administration and has undertaken a project to "establish basic criteria and guidelines for the pharmacy administration discipline that relate to undergraduate, graduate and continuing education programs."² The group working on this task, the Committee for Establishing Standards for Undergraduate Education in Pharmacy Administration, has a Subcommittee on Pharmacy Jurisprudence³ and this work should do much to standardize minimal coverage in the field.

NATIONAL JURISPRUDENCE EXAM

The National Association of Boards of Pharmacy has yet to construct an examination in jurisprudence to be given in conjunction with its standard examination in pharmacy — NABPLEX. The explanation is quite obvious when one considers the nuances of the state and sometimes local pharmacy laws. A probe of the candidate's knowledge of federal legislation would appear to be more imminent, but until such time, the NABPLEX Review Committee has essentially recommended that state examiners follow the propositions established by the NABP's Blue Ribbon Subcommittee on Jurisprudence. Briefly, those propositions are as follows:

- (i) "The candidate shall be able to distinguish between statutory law and the rules and/or regulations issued by an administrative agency, such as the board of pharmacy.
- (ii) "The candidate shall demonstrate a comprehensive knowledge and understanding of the federal "Controlled Substances Act of 1970" and its regulations . . .
- (iii) "The candidate shall demonstrate a general knowledge of the federal "Food, Drug, and Cosmetic Act" and its amendments as these relate to the general practice of pharmacy . . .
- (iv) "The candidate shall demonstrate a general knowledge of torts, with primary emphasis on situation of potential negligence in the practice of pharmacy . . .
- (v) "The candidate shall demonstrate knowledge of the law of contracts and the "Uniform Commercial Code" . . .
- (vi) "The candidate shall be familiar with the general principles of jurisprudence and with miscellaneous nonpharmacy federal laws governing the pharmacist's extraprofessional activities.
- (vii) "The candidate shall possess comprehensive knowledge of the state pharmacy act, or its equivalent, regulating the practice of pharmacy in the state of application . . ." (15)

A catalog review indicates that propositions (ii), (iii), and (vii) above are incorporated into essentially all of the pharmacy law courses in colleges which have required courses. Propositions (i) and (vi) are undoubtedly included in pharmacy law classes, to give the student the proper perspective with which to view the substantive material. As previously set forth, a number of schools offer a discussion of proposi-

² Kirk, K. W., Tindall, W. N., Wertheimer, A. I. and Speranza, K. A., *Development of a White Paper for Pharmacy Administration: Report of the Task Force*, Presented to the AACP Section of Teachers of Pharmacy Administration, Kiamesha Lake NY, July 1975.

³ Tindall, W. N., *Interim Report of the Committee for Establishing Standards for Undergraduate Education in Pharmacy Administration*, Presented to the AACP Section of Teachers of Pharmacy Administration, Minneapolis MN, July 1976.

Table I. Academic Rank of lawyers employed full-time

Academic title	N	Percent
Professor	8	42.1
Associate professor	5	26.3
Assistant professor	6	31.6
Total	19	100.0

Table II. Academic rank of lawyers having adjunct appointments

Academic title	N	Percent
Professor	3	11.5
Associate professor	2	7.7
Assistant professor	6	23.1
Instructor	4	15.4
Lecturer	10	38.5
Professional affiliate	1	3.8
Total	26	100.0

tion (iv) above (torts) in their pharmacy law class, but a greater percentage make no mention of this area in their catalog descriptions. The Uniform Commercial Code and the law pertaining to warranties would most likely fall under the business law portion of a required course or under the business law elective. Again, a number of pharmacy colleges do not include business law material in their pharmacy law catalog statement, but they often have an elective available in this area.

LAWYERS IN PHARMACEUTICAL EDUCATION

The field of pharmacy administration is generally deemed to include the somewhat separate but inter-related disciplines of accounting, law, management, marketing, and social and behavioral sciences.² In all of these disciplines except law the standard degree in the field for teaching in higher education is the PhD degree. However, in law the standard degree is now the Doctor of Law or Juris Doctor (JD) degree. This represents a relatively unique situation in that one of the major subdivisions of traditional discipline within pharmacy has as its standard degree one that is not the PhD, a distinction which it shares with the evolving discipline of clinical pharmacy.

Holders of a law degree have long been engaged in education both within university-level schools of law as well as other schools. Indeed, the first doctorate is believed to have been awarded in Bologna, Italy, in the twelfth century and it served as the root for all other doctorates through the ages. That first doctorate was in civil law(16). It is noteworthy that the first earned doctorate was awarded to one trained in law, not a physician.

Lawyers have also had distinguished careers as educational administrators in the nation's most respected educational institutions. In 1973, one survey reported that the presidents of Harvard, Yale, Indiana, Iowa, Ohio State, Florida, Case Western Reserve, Chicago, and Rutgers had backgrounds in the law.⁴

In order to determine the status of holders of law degrees in accredited colleges of pharmacy in the United States, a review of the 1975-6 edition of *AACP Roster of Teaching Personnel in Colleges of Pharmacy*(17) was undertaken. Of the 74 accredited colleges of pharmacy

listed in that directory, 38 (51.4 percent) had no law degree holders among the full- or part-time faculty. Twenty-eight colleges (37.8 percent) had one law degree holder while seven (9.5 percent) had two faculty members who possessed law degrees. One institution listed three lawyers on the faculty.

A total of forty-five lawyers were employed on either a full- or part-time basis in the nation's colleges of pharmacy. Of those, 19 were full-time employees of the college of pharmacy and 26 had adjunct appointments. The academic ranks of these individuals are indicated in Tables I and II. Of those who hold law degrees, a number of individuals also hold other degrees. One individual holds the degree Master of Laws (LL.M) while four lawyers on pharmacy faculties also hold the PhD degree. Four faculty members, all of whom hold adjunct appointments, possess an MD degree in addition to their law degrees. The degree Master of Science is held by two faculty members with law degrees while one holds a Master of Business Administration degree and another holds the degree Master of Public Health.

CONCLUSION

The importance of a solid knowledge of the law and legal principles to the practicing pharmacist can only be expected to increase. Changes in the practice roles of pharmacists and further governmental interests and intervention in professional affairs require that the pharmacist understand his responsibilities as well as his rights under the law. Formal education in the law has long been a part of the pharmacy curriculum and although variation in approaches between institutions is seen, nearly all faculties recognize the importance of this subject matter in that they require some exposure to legal aspects of pharmacy.

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References

- (1) *A Candidate's Guide to the National Association of Boards of Pharmacy Licensure Examination*, National Association of Boards of Pharmacy, Chicago IL (1976) p. 23.
- (2) North Dakota State Board of Pharmacy v. Snyder's Drug Stores Inc., 414 US 156 (1973).
- (3) American Pharmaceutical Association v. Matthews, 530 F.2d 1054 (DC Cir. 1976).
- (4) Abbott Laboratories, et al. v. Portland Retail Druggists Association Inc., 74 - 1274, 96 S.Ct. 30 (24 March 1976).
- (5) Virginia State Board of Pharmacy, et al. v. Virginia Citizens Consumer Council Inc., et al., 74 - 895, 96 S.Ct. 1817 (24 May 1976).
- (6) Fink III, J. L., *Drug Intell. Clin. Pharm.*, **10**, 444(1976).
- (7) Fink III, J. L., *J. Am. Pharm. Assoc.*, **NS15**, 496(1975).
- (8) Salisbury, R., *Am. J. Pharm. Educ.*, **40**, 68(1976).
- (9) Fink III, J. L., *J. Am. Pharm. Assoc.*, **NS17**, 95(1977).
- (10) Salisbury, R., *ibid.*, **NS17**, 97(1977).
- (11) Blauch, L. E. and Webster, G. L., *The Pharmaceutical Curriculum*, American Council on Education, Washington DC (1952) p. 173.
- (12) Tatum, J. R. and Smith, M. C., *Am. J. Pharm. Educ.*, **28**, 404(1964).
- (13) *Op. cit.* (11), p. 181.
- (14) Myers, M. J., *Am. J. Pharm. Educ.*, **34**, 873(1970).
- (15) *Op. cit.* (1), p. 23-24.
- (16) Smith, L. P., *Case and Comment*, **78**, 41(1973).
- (17) *Roster of Teaching Personnel in Colleges of Pharmacy, 1975-6*. American Association of Colleges of Pharmacy, Bethesda MD (1975).

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⁴ "Road to the Top," *Juris Doctor*, **3**(6), 62(June/July 1973).