A COMPARISON OF EMPIRICAL STUDIES OF PHARMACY PRACTICE WITH JUDICIAL DESCRIPTIONS

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TABLE OF CONTENTS

I. INTRODUCTION

The program brochure indicates that scientific comparisons of pharmacy practice will be compared with judicial descriptions of such practice. This Article will present a pharmacist's "map of Pharmacyland" and will ask legally-trained participants to compare the following:

1. The Pharmacy Student's Dilemma,
2. The Pharmacy Professor's Dilemma,
3. Social Utility v. Stare Decisis, and
4. Temporal Considerations in Pharmacy Practice.

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II. CONTRASTS

A. *Contrast I: The Pharmacy Student's Dilemma*

The first contrast places the expertise and professionalism of pharmacy students in direct conflict with case rulings stating that the pharmacist has no duty to warn patients. Pharmacy students' reactions to many duty-to-warn cases range from disbelief to severe shock. After completing two years of pre-pharmacy studies, three years of study in the pharmaceutical sciences, and one year of clinical clerkships, the students' learning and practice paradigm is both science-based and patient-centered. The imperatives of warning patients of risks of irrational drug use and of possible adverse reactions to use of rationally-prescribed prescription drugs are written permanently in the students' professional minds and hearts. Fifth year students are, typically, both confused and angered after studying decisions holding: 1) responsibility for warning patients of hazards associated with prescription drug use is limited to the physician-patient relationship, and 2) pharmacists have no duty to warn patients about well-known and serious interactions, such as concurrent use of Valium and alcohol consumption.[1]

B. *Contrast II: The Pharmacy Professor's Dilemma— Science v. Current Case Law*

The contrast for the pharmacy law instructor parallels the student's dilemma. This second contrast places hard scientific evidence about the demonstrated value of pharmacist drug therapy and patient counseling in conflict with judicial rulings that recognize only the physician as the learned intermediary.[2] Pharmacists' abilities conflict with rulings which confuse the physicians' diagnostic and prescriptive role with the pharmacists' existing and ongoing drug monitoring role. This contrast raises fundamental questions about decision-making abilities in all pharmacist duty-to-warn cases: 1) how do judges and juries know what pharmacists do, and 2) how many cases have been decided with the full benefit of evidence of well-validated national studies of pharmacists' practice behaviors introduced as part of the standard of care.

A stark contrast exists between published scientific research describing pharmacists' impact on the drug use process and the universal absence of such reported research introduced to show the pharmacists' patient counseling duties. The research to be presented here is irreconcilable with rulings that state the pharmacist has no duty to warn the patient, to notify the prescriber that a drug is being prescribed in dangerous amounts or that a drug

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1. *See, e.g.*, Ingram v. Hook's Drugs, Inc., 476 N.E.2d 881, 887 (Ind. Ct. App. 1985) (deciding that the physician has the duty to warn of the hazards of the drug and that the pharmacist has the duty to include those warnings found in the prescription).

2. *See, e.g.*, Leesley v. West, 518 N.E.2d 758, 760-61 (Ill. App. Ct.) (holding that the pharmacist was not strictly liable for failure to warn consumers of side effects), *appeal denied*, 522 N.E.2d 1246 (Ill. 1988).

prescribed could cause adverse reactions.[3] It is also irreconcilable with the courts' rationale that requiring warnings to patients would "second guess" the physician's original prescribing decision.[4]

C. *Contrast III: Social Utility v. Stare Decisis*

The third contrast poses the social utility theory against the legal concept of stare decisis. It asks why pharmacists, who are required by law to warn patients about the dangers of drug use, are underutilized as patient advisors.[5]

Lay persons may question whether judicial decisions made on a pharmacist's duties are based on precedents from an earlier era. In an earlier era, pharmacist's duties involved "mixing drug ingredients in a bottle." While a pharmacist's duty to conduct accurate compounding remains an appropriate and demanding one, today the mixing which is most important occurs when patients' drugs are "mixed in their bodies." Drug-drug interactions, an unwanted synergism between two drug products, and drug-food interactions all present imminently greater risks than those involved in mixing drug ingredients at a pharmacy. The former requires enhanced drug information services to the patient.[6] Yet, by failing to recognize a pharmacists' duty to warn, stare decisis limits the public to protection only from drugs mixed in the bottle. Current law disserves society by failing to use pharmacists to protect patients from the effects of drug interactions.

Pharmacy practice, pharmacy education, legislation, and administrative law have all established new social policies. In an earlier era, a pharmacist's service was incidental to the product. In pharmacy practice today, the product is often incidental to the service—particularly a pharmacist's drug therapy monitoring, patient counseling, and physician consultation services. At a time when legislative activity has supported the pharmacists' patient care role, a fresh approach in defining the pharmacists' duty to protect society seems necessary as well.[7] An eminent legal scholar and jurist opined that "the true science of the law does not consist mainly in . . . a study of it as an

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3. *See, e.g.*, Jones v. Irvin, 602 F. Supp. 399, 402 (S.D. Ill. 1985) (holding that the pharmacist had no duty to warn the patient or physician that a drug was being prescribed in dangerous amounts).

4. *Id.*

5. *See* 42 U.S.C. 1396r(g)(2)(A)(i)(I) (1994).

6. Robert G. Mrtek, *Pharmaceutical Education in These United States—An Interpretive Historical Essay of the Twentieth Century*, 40 AM. J. PHARMACEUTICAL EDUC. 339, 361 (1976); Charles D. Hepler, *The Third Wave in Pharmaceutical Education: The Clinical Movement*, 51 AM. J. PHARMACEUTICAL EDUC. 369, 373 (1987) (stating that many drug failures and injuries could be avoided by providing general information to patients and physicians).

7. Henri R. Manasse, Jr., *Medication Use in an Imperfect World: Drug Misadventuring as an Issue of Public Policy, Part I*, 46 AM. J. HOSP. PHARMACY 929, 932 (1989); Henri R. Manasse, Jr., *Medication Use in an Imperfect World: Drug Misadventuring as an Issue of Public Policy, Part II*, 46 AM. J. HOSP. PHARMACY 1141, 1141-42 (1989).

anthropological document from the outside."[8] Justice Holmes changed society when he affirmed that the law was concerned with the "establishment of [legal] postulates . . . upon accurately measured social desires."[9]

D. *Contrast IV: Temporal Considerations*

The fourth and final contrast is a temporal one. The practice of pharmacy has changed, is changing, and it will continue to change. It is interesting to contemplate how case law will track the progress of academic clinical pharmacy and of certain pharmacy practice specialties. This paper, however, is intended to focus only on the past and the present general practice of pharmacy. The greatest public good may be achieved by taking a practical approach. A few new socially enlightened decisions, based on evidence of what general practice pharmacists can and actually do, could change the practices of many pharmacists. Their refocused attention on a clearer duty to warn, consistent with the pharmacy profession's social purpose, might, in myriad patient encounters, yield safer and more effective drug use.

Part of the temporal theme is the evolution of pharmacy education: increasing clinical practice emphasis in the Bachelor of Science (B.S.) degree curriculum and then creating a new six-year degree program—the Doctor of Pharmacy (Pharm.D.) which provides an additional year of patient contact in experiential education.[10] The profession supports a universal Pharm.D. degree from the nation's seventy-six colleges of pharmacy by the year 2000.[11] These educational changes could be a distraction to an examination of the general standard of care exercised by pharmacists in patient counseling. One does not need a Pharm.D. degree to provide the most fundamental warnings. The standard of care is not defined by a degree program, but by observable practice behaviors. The behaviors at issue in duty-to-warn cases are basic, fundamental, and deliverable by educated and licensed pharmacists whether they hold a B.S. or Pharm.D. degree.

Methods for determining pharmacists' competence will now be described. First, a note about how competency identification and validation studies are shown to be valid, then two definitions of competence in pharmacy will precede the study descriptions.

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8. OLIVER WENDELL HOLMES, *Law in Science and Science in Law, in* COLLECTED LEGAL PAPERS 210, 225-26 (1920) (originally appearing at 12 HARV. L. REV. 443 (1899)).

9. *Id.*

10. *See generally* AMERICAN COUNCIL ON PHARMACEUTICAL EDUC., THE ACCREDITATION MANUAL (Jan. 1995) (describing standards for both the B.S. and Pharm.D. programs as well as continuing education standards).

11. Daniel A. Nona, *Annual Report of the American Council on Pharmaceutical Education to the Profession and the Public*, 54 AM. J. PHARMACEUTICAL EDUC. 202, 203 (1990).

III. QUALITY OF THE EVIDENCE

A. *Validation*

It should first be noted that the cartographers who developed the competency maps for pharmacy were, themselves, subject to professional and legal standards of care.[12] The goals of the studies were to lay a foundation of pharmacist competence for three purposes: 1) curriculum design (including the practicum); 2) licensure examination development; and 3) provisions for continuing professional education. Quality control in these types of studies is determined by how valid the performance descriptions are—how well they can logically and statistically be shown to accurately reflect contemporary practice.[13] Such validity is demonstrated through four methods: 1) development by panels of practice experts; 2) practitioner surveys; 3) critical incident studies; and 4) on-site observation of practice. Combinations of these methods make a stronger case for the validity of the performance description than single methods alone.[14]

B. *Definitions of Competence*

1. *Competence as Demonstrated Performance*

Competence as defined in these projects relates to observable, verifiable behaviors of practicing pharmacists. These behaviors are measurable in specific practice settings.[15]

2. *Competence as Capacity for Performance*

Competence is sometimes defined as the capacity or ability to perform. Thus, the relationship to curricular content provides evidence of competence, provided that logical linkages between curriculum and practice can be shown. According to this second definition, minimum competence is a necessary condition for competence in practice, but does not provide a sufficient basis for practice competence.[16]

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12. *See* WILLIAM C. BYHAM & MORTON EDWARD SPRITZER, THE LAW AND PERSONNEL TESTING (1971); Uniform Guidelines on Employee Selection Procedures, 43 Fed. Reg. 38,290-38,315 (1978) (codified at 29 C.F.R. § 1607 (1995)). *See generally* AMERICAN EDUC. RESEARCH ASS'N, STANDARDS FOR EDUCATIONAL AND PSYCHOLOGICAL TESTING (1985).

13. R.A. Zeller, *Validity*, *in* THE INTERNATIONAL ENCYCLOPEDIA OF EDUCATIONAL EVALUATION (Herbert J. Walberg & Geneva D. Haertel eds., 1990).

14. Samuel Messick, *Validity of Test Interpretation and Use*, *in* 4 ENCYCLOPEDIA OF EDUCATIONAL RESEARCH 1487-95 (Marvin C. Alkin ed., 6th ed. 1992).

15. William G. Spady & Douglas E. Mitchell, *Competency Based Education: Organizational Issues and Implications*, 2 EDUC. RESEARCHER 9 (1977).

16. *See generally* Paul G. Grussing, *Education and Practice: Is Competency-Based Education Closing the Gap*, 48 AM. J. PHARMACEUTICAL EDUC. 117 (1984).

IV. THE EVIDENCE: PERFORMANCE STUDIES AND EDUCATIONAL QUALIFICATIONS

A. *Pharmacists' Competence as Demonstrated Performance*

Pharmacists' duties have been demonstrated in four projects. Table 1 summarizes the validated competencies of pharmacists in projects spanning a sixteen year period. The two general areas of competence pertinent to this symposium are in the center of the table and italicized.

The first study, in 1978, was based on a tentative panel-developed set of competency statements, and validated by a nationwide survey of pharmacists.[17] Data on the importance of the judgment required, and the time spent on pharmacist behaviors was collected. The data was analyzed to yield the four broad categories. A total of 78 general responsibilities and 264 specific tasks were validated in the national study and described in the professional standards.

A concurrent study, reported in 1977, although conducted only within Minnesota, relied on four converging methods for validation of the pharmacists' competencies. A panel generated thirty-six tentative competency statements.[18] Most of these were corroborated in an on-site job analysis. A separate critical incident study led to the identification of eleven discrete dimensions of practice as shown. Finally, a practitioner survey, based on the previous work, demonstrated twenty-three competencies and numerous subordinate behaviors.[19]

In 1980, based on the previous two validation studies, a panel of expert practitioner/teachers developed a description of pharmacy practice behaviors. These were intended for use in experiential education sites supervised by boards and colleges of pharmacy. Seventy-two tasks and more than 200 subordinate behaviors were identified.[20]

The latest project, designed for the evaluation of practical experience in college-supervised clerkships and externships, was based on the three earlier projects.[21] It added a series of six generalized and personal competencies and thirty subordinate behaviors, useful in describing the performance quality of the principal observable behaviors included in clerkships and externships. Examples of these categories include two which indicate effective communication with patients and health professionals: 1) Demonstrates Human Relations Skills, and 2) Displays Independence/Assertiveness.

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17. MICHAEL ROSENFELD ET AL., A NATIONAL STUDY OF THE PRACTICE OF PHARMACY 49-50 (1978); *see also* Samuel H. Kalman & John F. Schlegel, *Standards of Practice for the Profession of Pharmacy*, NS19 AM. PHARMACY 133-47 (1979).

18. CURRICULUM IMPROVEMENT OFFICE, UNIVERSITY OF MINN., PROGRESS REPORT, PHASE I: COMPETENCY IDENTIFICATION (1976).

19. CURRICULUM IMPROVEMENT OFFICE, UNIVERSITY OF MINN., PROGRESS REPORT, PHASE II: COMPETENCY IDENTIFICATION (1977).

20. *See* NATIONAL ASS'N OF BOARDS OF PHARMACY & AMERICAN ASS'N OF COLLEGES OF PHARMACY, THE INTERNSHIP EXPERIENCE: A MANUAL FOR PHARMACY PRECEPTORS AND INTERNS 27-60 (Paul G. Grussing ed., 1987).

21. LARRY E. BOH ET AL., THE EXPERIENTIAL EVALUATION SYSTEM (1993).

Behaviors describing the pharmacist's duty to warn in all four studies are summarized in Table 2. Note that these behaviors were both rated by practitioners as being important in the national study and were also observed in the Minnesota study.[22] In the national study, pharmacists were asked to estimate the time spent on several patient monitoring, patient counseling, and physician communication behaviors. Table 3 provides the details of those behaviors and includes notes indicating a rating of the estimated time spent. It should be noted that pharmacists use their judgment to determine when patient counseling is necessary and beneficial. These behaviors occur infrequently in practice as reflected in the time estimates.

The Minnesota study involved observation of pharmacies on two separate occasions.[23] The types of pharmacies are described in Table 4. The monitoring, patient consultation, and physician communication behaviors observed and recorded by trained observers are summarized in Table 5. Note that these are not verbatim descriptions of the behaviors listed in other studies. Observers described their observations in their own words, which are summarized in the table.

Evidence has been provided for the kinds of patient consultation behaviors pharmacists perform in practice. A sequel to the national study is underway. Designed to, once again, survey reported practice tasks, this study will also contrast pharmacist behaviors with those tasks delegated to and performed by pharmacy technicians.

B. *Pharmacists' Competence as Capacity to Perform*

1. *Undergraduate Professional Degree Programs*

Major changes in pharmacy education were driven by forces both within and outside the profession. Inside forces foresaw the end of the pharmacists compounding era and sought to focus the pharmacists' expertise on a drug use process stressing rational therapy. External forces supported this educational trend.[24] A simplified description of the trends in pharmacy practice as a result of these changes is depicted in Figure 1. The trends are anchored in three pharmacy manpower studies, reported in 1965, 1973, and 1991. The figure shows changes in proportion of: 1) pre-1965 educated pharmacists; 2) pharmacists educated at the Pharm.D. level; and 3) pharmacists educated at the B.S. level. The trend lines represent proportions of the total estimated manpower pool, calculated as a percentage of the total pharmacist population. The declining numbers of pre-1965-educated pharmacists are based on a seven percent separation rate, and may underestimate the numbers of those pharmacists in the work force.

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22. *See id.* at 27, 29, 33.

23. *Id.* at 12-16.

24. National Center for Health Services Research and Development, *Report of the Task Force on the Pharmacist's Clinical Role*, 11 J. AM. PHARMACEUTICAL ASS'N 482 (1971); *see also* 42 U.S.C. § 1395 (1994).

Both degree programs emphasize clinical pharmacy education—the Pharm.D. programs offering a longer experiential program preceded by a stronger emphasis in pathophysiology and pharmacotherapeutics. The trend toward Pharm.D. degrees is based on "first degree" Pharm.D. graduates[25] only, and underrepresents the total number of pharmacists trained at the Doctoral level. Many students, after earning a B.S. in Pharmacy return to obtain their Pharm.D degree. Pharmacists educated before 1965 were sufficiently educated to effectively counsel patients. In fact, their expertise was recognized in the 1965 Medicare Conditions of Participation which required intermediate care facilities and small hospitals to secure the consulting services of pharmacists to provide education to staff professionals and monitor patients' drug therapy.[26]

2. *Postgraduate Education*

Superimposed on the proportions of pharmacists entering the profession with either of the practice degrees, is their postgraduate education relating to patient counseling. Further, mandatory Continuing Professional Education (CPE) has grown during this same period.[27] Today, ninety percent of states have mandatory CPE laws. Table 6 shows this trend.

Evidence for the pharmacists' continued competence in areas relating to their patient drug monitoring and counseling skills is provided in Table 7. Four curricular areas add to pharmacist competence: 1) communication skills; 2) professional standards and legal standards; 3) the drug products and disease state content which supports patient counseling; and 4) methods for enhancing patient compliance. Table 7 shows that in a sample of five colleges of pharmacy offering CPE instruction, nearly ninety percent of the contact hours are devoted to duty-to-warn submects.

V. SUMMARY

Pharmacy practice has changed to meet society's needs, and society has generally benefited. However, the case law has not universally recognized the change.

Cases, governed by precedents from an earlier era, frustrate the pharmacy profession's goal of serving society. The result encourages profit-motivated, nonpharmacist decision makers to create incentives to block progress, to retain only a product-distribution service, thus underutilizing and frustrating the pharmacy profession.

The profession will always lead the law. The data does not call for new legal prescriptions to create new roles for pharmacists. The data merely show

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25. A "first degree" Pharm.D graduate refers to a graduate of a professional doctoral program who graduates without having previously received the B.S. in Pharmacy degree.

26. *See* 42 C.F.R. 482.25(b)(6)(8) (1995).

27. *See* NATIONAL ASS'N OF BOARDS OF PHARMACY, SURVEY OF PHARMACY LAW (1991); W. Robert Kenny, *Regulatory Considerations, in* CONTINUING EDUCATION IN PHARMACY, 277-78 (Jack R. Arndt & Stephen J. Coons eds., 1987).

that when a profession sets its own standards and meets them, the case law should recognize the standards, thereby benefiting society.

Following professional trends, federal and state statutes have been amended to support pharmacist counseling.[28] Duty-to-warn cases which contradict professional standards and legislative intent, and special interest amendments which permit mere offering of counseling services in limited circumstances, however, create economic incentives to deny society the benefits of its investment in the profession of pharmacy. Pharmacy practice has changed. Let social consciousness allow society to benefit.

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28 *See, e.g.*, N.J. STAT. ANN. § 45:14-15.2 (West 1995); UTAH CODE ANN. § 58-17a-612 (Supp. 1996); VA. CODE ANN. § 54.1-3319(B) (Michie 1994).

Table 1
A HARMONY OF FOUR PHARMACY PRACTICE VALIDATION PROJECTS

SOURCES

National Study of the Practice of Pharmacy 1978[a]	ACTIVITIES RELATED TO PROCESSING THE PRESCRIPTION			*PATIENT CARE FUNCTIONS*		
	19 Responsibilities 70 Tasks			*18 Responsibilities* *63 Tasks*		
Minnesota Competency Project 1976-77b	Selecting products and ingredients	Compounding prescriptions	Dispensing prescriptions	*Monitoring, evaluating therapy*	*Communicating with patients about legend drugs*	*Communicating with patients on selection of OTC drugs*
	2 competencies	2 competencies	4 competencies	*2 competencies*	*1 competency*	*4 competencies*
AACP-NABP Internship Project 1980c	Selecting products and ingredients	Compounding prescriptions	Dispensing prescriptions	*Monitoring evaluating therapy*	*Communicating with patients about legend drugs*	*Communicating with patients on selection of OTC drugs*
	2 tasks 10 behaviors	3 tasks multiple subordinate behaviors	13 tasks multiple subordinate behaviors	*7 tasks multiple subordinate behaviors*	*3 tasks multiple subordinate behaviors*	*3 tasks multiple subordinate behaviors*
AACP Experiential Project 1993d	Provides drug products		Compounds	*Monitors and evaluates drug therapy: initial and ongoing*	*Communicates with patients about prescription drugs*	*Communicates with patients about nonprescription products, devices, and diagnostics*
	3 tasks		4 tasks	*4 competencies* *11 tasks*	*5 tasks*	*6 tasks*

a. ROSENFELD ET AL., *supra* note 17; *see also* Kalman & Schlegel, *supra* note 17.

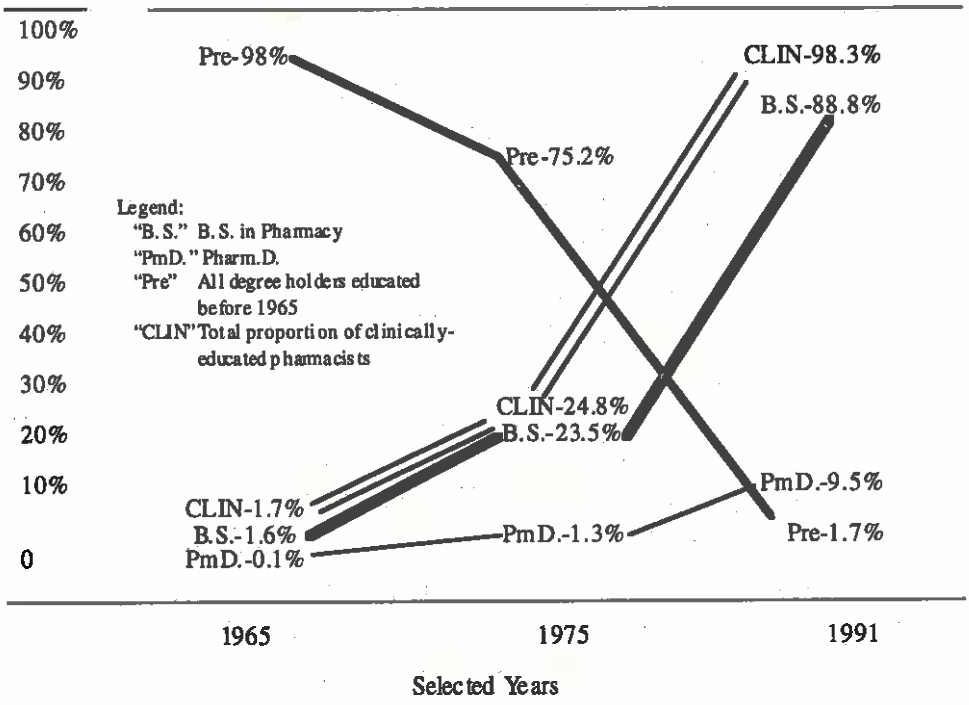
b. CURRICULUM IMPROVEMENT OFFICE, *supra* note 18; CURRICULUM IMPROVEMENT OFFICE, *supra* note 19. Under each of these 23 competencies, a complete and complex hierarchical set of terminal performance objectives and subordinate learning objectives are organized and reported.

c. NATIONAL ASS'N OF BOARDS OF PHARMACY & AMERICAN ASS'N OF COLLEGES OF PHARMACY, *supra* note 20.

d. BOH ET AL., *supra* note 21 (project supported through a grant from the American Association of Colleges of Pharmacy).

EDUCATION OF HEALTH CARE PROFESSIONALS		GENERAL MANAGEMENT AND ADMINISTRATION OF THE PHARMACY					
14 Responsibilities *31 Tasks*		27 Responsibilities 100 Tasks					
Communicating with health professionals		Managing pharmacy operations	Managing pharmacy personnel	Maintaining drug information	Maintaining professional and ethical standards		
1 competency		2 competencies	1 competency	2 competencies	2 competencies		
Communicating with health professionals		Managing pharmacy operations	Managing pharmacy personnel	Maintaining drug information	Maintaining professional and ethical standards	Providing emergency pharmacy services	Responsibilities in civics and public health
4 tasks *13 behaviors*		21 tasks multiple subordinate behaviors	9 tasks 25 behaviors	2 tasks 10 behaviors	10 behaviors	15 tasks 13 behaviors	
Communicates with health professionals	*Teaches to group and one-to-one*	Manages general pharmacy operations	Manages/ supervises pharmacy personnel	Retrieves and evaluates drug information	Maintains professional standards		
2 tasks	*5 tasks*	5 tasks	5 tasks	2 tasks	5 tasks		

Figure 1
TRENDS IN PERCENTAGES OF CLINICALLY-EDUCATED PHARMACISTS ENTERING THE WORK FORCE, 1965-91[a]



Sources: *AACP Reports of Degrees Conferred*, 29-55 AM. J. PHARMACEUTICAL EDUC. (1965-91); DEPARTMENT OF HEALTH EDUCATION AND WELFARE, PHS PUB. NO. 1509, REPORTS TO THE PRESIDENT AND CONGRESS ON THE STATUS OF HEALTH PERSONNEL IN THE U.S. (1975).

a. This figure shows, graphically, the increases in clinically-educated pharmacists and the decrease in proportion of practitioners educated before major B.S. and Pharm.D. curricular emphases on clinical pharmacy education. It is not intended for manpower reporting or planning purposes. Numerous demographic features of the pharmacist population are not represented, such as occupational outmobility, proportions of pharmacists not involved in direct provision of services to patients, proportions graduating and not entering practice, type of practice site, effect of board-certified specialization, and inactive license suspension or revocation. Percentages are based on the estimated total pharmacy manpower pool in the years shown. "Pre" is based on a recently published annual separation rate of 7%.

Table 2
REPRESENTATIVE RESPONSIBILITIES AND TASKS OF THE PHARMACIST[a]

BEFORE DISPENSING
Checks prescription against patient profile for presence of inappropriate drug use.
CONSULTATION WITH PATIENT
Counsels patient (or agent) concerning drugs to avoid while taking medication.
Advises patient of potential drug or health-related conditions which may develop from the use of the medication.
Explains possible effects of drug use to patient.
Explains how to recognize side effects.
Advises how to minimize side effects.
CONSULTATION WITH PRESCRIBER
Questions prescriber in cases where clinically significant drug interactions or contraindications exist.
Consults with prescriber in cases of drug under- or over-utilization by the patient.

a. Descriptors taken from ROSENFELD ET AL., *supra* note 17, and CURRICULUM IMPROVEMENT OFFICE, *supra* note 18. Each of the responsibilities and tasks is also recorded as having been observed in practice during the Minnesota Competency Project.

Table 3
RESPONSIBILITIES AND TASKS OF THE PHARMACIST RELATING TO THE PHARMACISTS' DUTY TO WARN: SHOWING TIME SPENT ON TASKS[a]

D. MONITORING AND EVALUATING THERAPY

3. Checks patient record for pertinent information before dispensing prescription medication. (II,3) [3], (III,2) [15], X = 2.50 (+/- .83)

b) Checks prescription order against patient-drug sensitivities/allergies (II,3) [3], (III,2) [15], X = 2.50 (+/- .83)

d) Checks prescription order against patient profile data for presence of inappropriate drug use, including:

(1) Drug-drug interaction
(2) Drug-diet interaction
(3) Drug-lab interaction
(4) Drug-disease interaction
(5) Inappropriate concurrent prescribing
(6) Inappropriate regimen for intended use
(7) Over- or underutilization
(8) Dosing frequency and amount
(9) Multiple prescribers (II,3) [3], (III,2) [15], X = 2.50 (+/- .83)

E. COMMUNICATING WITH PATIENTS ABOUT PRESCRIPTION DRUGS

1. Makes recommendations to the patient regarding drug therapy. (III, 13) [26], X = 2.47 (+/- .81)

a. ROSENFELD ET AL., *supra* note 17; Kalman & Schlegel, *supra* note 17, at 133-147; NATIONAL ASS'N OF BOARDS OF PHARMACY & AMERICAN ASS'N OF COLLEGES OF PHARMACY, *supra* note 20. The descriptors, based on the National Study, are taken from the Preceptors Manual. References in parentheses refer to the descriptions in the Kalman and Schlegel article based on the national study. Those in brackets reference the same responsibility as described in the national study. The data showing time spent by the respondents is based on the following scale. Care must be taken in interpreting the scale because of the effects of the (0) and (1) anchors. Because not all respondents may have practiced actively, and because of tasks delegated to others, e.g. students, the time spent by pharmacists may have been underreported.

TIME SPENT ON RESPONSIBILITY
(0) I do not have this responsibility
(1) I have this responsibility but spend no time on it
(2) I spend very little time on this responsibility
(3) I spend some of my time on this responsibility
(4) I spend a lot of my time on this responsibility

g) Counsels patient (or agent) concerning drugs and food to avoid while taking the medication.

h) Counsels patient (or agent) regarding any occupational precautions (i.e. drowsiness with use of antihistamines)

i) Advises patient (or agent) of potential drug or health related conditions which may develop from the use of the medication for which patient should seek other medical care. (III,6) [19], X = 2.60 (+/- .84)
   (1) Assesses benefit vs. risk of explaining side effect and/or expected response
   (2) Explains possible effects of drug use to patient (or agent)
   -Explains how to recognize the signs and symptoms that indicate: Therapeutic response, Therapeutic failure, or Pertinent side effects
   -Advises what to do if signs and/or symptoms occur
   -Advises how to minimize side effects
   (3) Notifies practitioner of pharmacist/patient consultation if indicated

G. COMMUNICATING WITH HEALTH CARE PROFESSIONALS

1. Makes recommendations regarding drug therapy to the physician, or other persons involved with the patient's care. (IV,2) [26], X = 2.47 (+/- .81)

   c) Questions prescriber in cases where clinically significant drug interactions or contraindications exist.

   d) Consults with prescriber in cases of drug under- or over-utilization by the patient.

Table 4
REPRESENTATIVE MINNESOTA PHARMACIES SELECTED FOR ON-SITE OBSERVATIONS[a]

HOSPITALS	Floor Stock System	Individual Prescription System	Unit Dose System
Small (0-99 beds)		X	X
Medium (100-299 beds)	X	X	
Large (>300 beds)		X	X
NURSING HOMES		On-Premises Pharmacy	
		X	
COMMUNITY PRACTICE	Rural	Urban	
Chain Pharmacy	X	X	
Independent Pharmacy	X	X	
Clinic Pharmacy	X	X	
Discount Pharmacy		X	
			N = 14 sites

a. CURRICULUM IMPROVEMENT OFFICE, *supra* note 18.

Table 5
PATIENT CONSULTATION BEHAVIORS OBSERVED
DURING ON-SITE JOB ANALYSIS[a]

COMPETENCY AREAS	Observed Behaviors
MONITORS DRUG THERAPY	Enters drugs dispensed into patients profile.
	Checks profile for drug interactions.
	Checks for continuity of therapy (including checks of prescribing, administration and patient compliance).
	Intervenes in cases of contraindicated requests for OTC drug products.
CONSULTS WITH PATIENTS REGARDING USES AND EFFECTS OF LEGEND DRUGS	Provides drug information to patient on the use, effects and cautions for proper use.
	Informs patients about therapeutic incompatibilities.
	Questions the patient to obtain feedback about proper usage of prescribed drugs.
COMMUNICATES EFFECTIVELY WITH OTHER HEALTH CARE PROFESSIONALS	Recommends alternate therapy.
	Discusses patients abusing drugs.

a. CURRICULUM IMPROVEMENT OFFICE, *supra* note 18, at 27, 29-31, 33. Observed behaviors are based on two separate visits, one six-hour and one two-hour, to fourteen representative pharmacy practice sites by two independent observers.

Table 6
MANDATORY CONTINUING PROFESSIONAL EDUCATION
IN PHARMACY: 1967-92[a]

	YEARS			
	1967	1981	1987	1992
Number of States	2	24	39	47
Percentage of States (%)	4%	48%	79%	94%

a. NATIONAL ASS'N OF BOARDS OF PHARMACY, *supra* note 27; Kenny, *supra* note 27.

Table 7
ESTIMATED CONTINUING PROFESSIONAL EDUCATION PROGRAMMING DEVOTED TO DUTY-TO-WARN SUBJECTS[a]

TOPICS	Estimated percent of contact hours offered for the following four C.P.E. program years.[b]			
	1	2	3	4
	1977	1982	1987	1992
1. Communication with patients and health care professionals (patient counseling theory, skills, methods)	2.75	5.0	7.5	13.75
2. The pharmacist's legal duty to warn (the professional standard of care for patient counseling)	9.0	5.75	6.25	12.5
3. Miscellaneous pharmacy topics forming the content of communication to patients (pharmacology, therapeutics, new product uses, contraindications, side effects, packaging, storage, and instruction for use)	72.5	74.5	65.0	56.25
4. Methods for compliance enhancement, (Patient profiles, computer printouts, history taking, patient package inserts)	4.0	4.5	9.5	7.5
Total content related to duty to warn:	88.25	89.75	88.3	90.0
All other C.P.E. programming (first aid, operations management, etc.)	11.75	10.25	12.0	10.0
	100%	100%	100%	100%

a. Telephone Conversations with the Directors of Five Continuing Pharmacy Education Programs (March 1994). This survey provides the estimated proportion of program contact hours.

b. Mean estimates, for live programming only, from five C.P.E. directors at U.S. colleges of pharmacy.