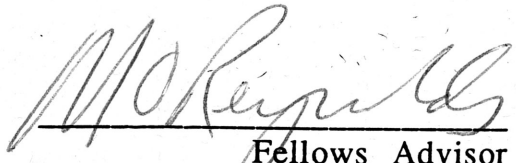
The State of The Pharmacist:
A Preliminary Economic History

Virginia Kathryn Sanders
University Undergraduate Fellow, 1992-1993
Texas A&M University
Department of Economics



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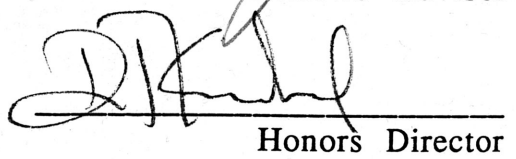


Honors Director

The State of the Pharmacist: A Preliminary Economic History

> "The primary function of pharmacy is to prepare medicines for those who require them. It is, therefore, a highly specialized calling, which may rise to the dignity of a true profession or sink to the level of the lowest commercialism, according to the ideals, the ability, and the training of the one who practices it."
>
> (LaWall 1927 p. v)

Pharmacy has had various definitions in its four thousand years. Originally, the pharmacist was called an apothecary, derived from the Middle Ages, serving as both the compounder and dispenser of medications. He worked with or in place of a physician, had little or no formal training, and could set up shop as he desired. With the advent of regulation and the development of pharmacy as a separate profession came a new definition of the pharmacist. No longer was he allowed to compound medicine or create his own filing system.

Changing the name from apothecary to pharmacist affected not only the pharmacist's title, but his job was altered as well. The professional now has at least five years of professional schooling, culminating in a state board exam and licensure procedure. Further education may be required of him and legal and ethical restraints are placed upon him, which are enforced by the state board. No longer working in place of the physician, he is part of the medical team, working with patients.

This paper provides an economic analysis of the last two centuries in the history of the pharmacist. It explains the reasons behind the changes in his job and focuses on new duties, regulations, interactions with physicans, the demand for and supply of pharmacists, and their earnings.

History

The art and science of pharmacy have developed and advanced the duties of the pharmacist over the last four thousand years. According to Sprowls (1966, p.2), "Of the early writings which have been discovered to date, many give evidence of an already developed practice of medicine involving the use of drugs. Sir William Osler once wrote that 'the desire to take medicines is perhaps the greatest feature which distinguishes man from the animals' ". Archeological discoveries and research indicate that all historic cultures had well-developed procedures for treatment of disease, which included use of various drugs. "All of these [ancient cultures] made use of drugs, even though in many instances the physical substances administered were thought to be effective only because of some accompanying ritual or religious practice" (Sprowls, p.3). Therefore, it was not uncommon to have drugs administered on a full moon or at the time of the rising or setting of certain planets. In the fourth and fifth centuries B.C., drugs were classified in one of four groups -- warm, cold, moist, or dry according to Galen's Humoral Pathology Scheme, depending on the qualities that the drug possessed. In Sigerist's account of this period (1955, p.10), he reports "the art of medicine consisted of selecting the right drugs, preparing them in the magically correct way, and speaking the appropriate words over them."

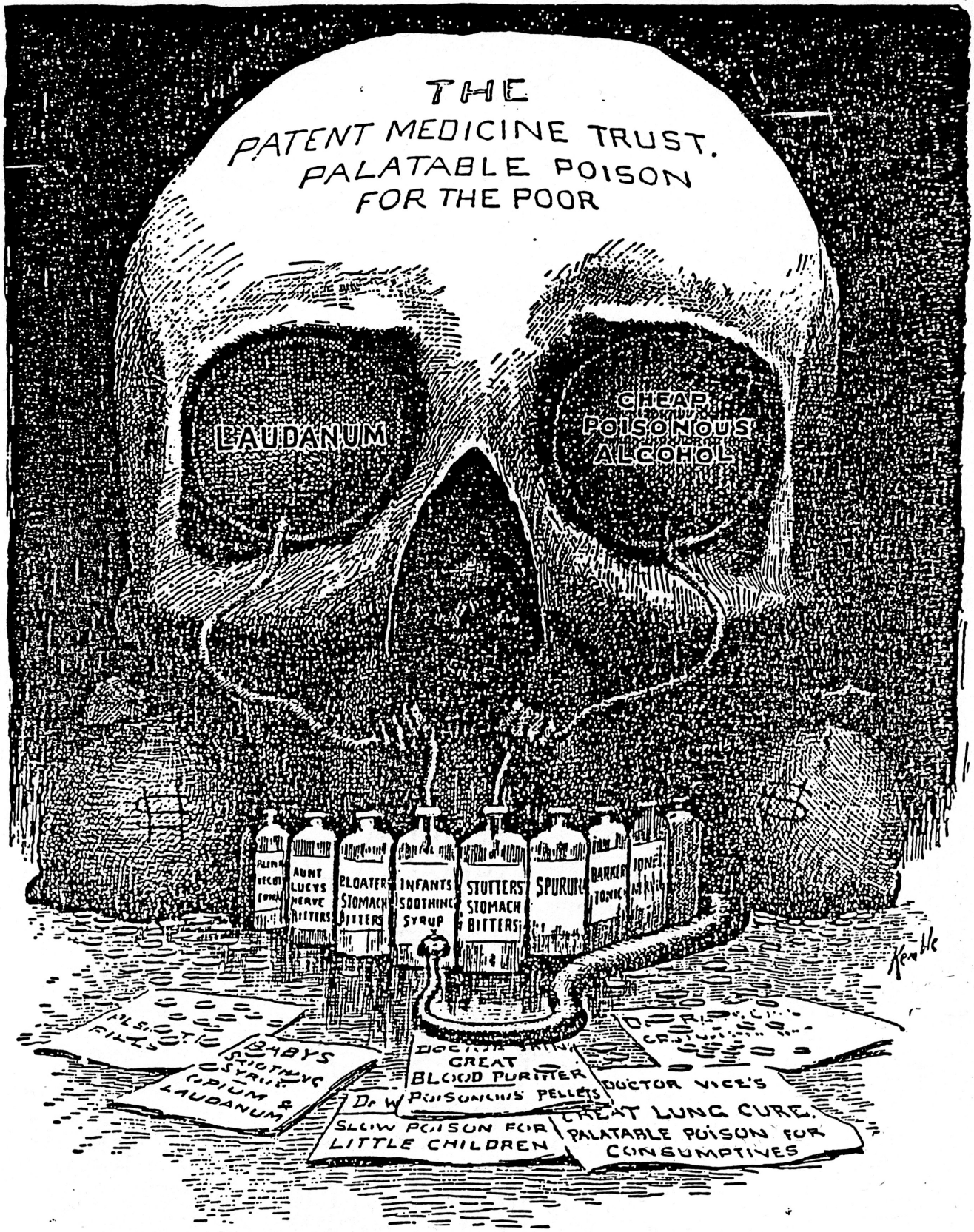
In the second Babylonian Empire (600 B. C.), the Chaldeans had a practical method of dealing with disease. They put the sick member of the household on the side of the road in hope that some

passer-by would recognize the disease and recommend a cure (LaWall 1927 p.16).

Serapion of Alexander in 150 B.C. chose the most revolting and unpleasant tasting drugs in use and passed these on to future generations (See related photo). "His influence gave rise to the long-existent feeling in European medicine that the value of drugs could be measured in terms of their disagreeable nature" (Sprowls, p.7). It was not until the late eighteenth century that successful challenges in the United States brought in pleasantly flavored medicines that were generally accepted.

The art and development of science advanced even in the "Dark Ages," using old manuscripts and Latin treatises as the source of knowledge. Since the church was the center of life at this time, monks were the only people "allowed" to perform scientific experiments. Monastaries had herb gardens and the ancient names for most drugs, such as St. John's wort, had their origins there. "The record of medieval pharmacy comes to us largely through a number of publications called herbals or 'leech books,' which are mostly of unknown authorship" (Sprowls, p.11). Such publications include, *Book of the Bald, Herbarum Apuleii Platonici, Lacnunga,* and *The Hortus Sanitatus.*

Bridging the gap between medieval and arabic pharmacy and the growth of pharmacy in Europe were the religious crusades. As the travelers returned home, they brought with them drugs and pharmacy research from other cultures and countries. Evidence of this knowledge can be seen in the works of Mesue Junior, a monk,:



Source: **Pharmacy: An Illustrated History 1990.**

"For a long time these manuscripts were attributed to an Arabian authority who was believed to have lived during the tenth century. More recently it has been concluded that the manuscripts were prepared by an Italian writer of the thirteenth century who drew on Arabian Byzantine authors for his formulas" (Spowls, p.13).

With the influence of arabic medicine coming into Europe, translations of other culture's pharmaceutical techniques could be done. The invention of the printing press further advanced pharmacy by allowing the work to be done faster (monks no longer needed to transcribe) and to be sent all over Europe. According to Sprowls, the wide distribution of books of formulas could then be distributed, providing an opportunity for pharmacists in various parts of the world to exchange information.

Now American pharmacists could send their discoveries to Europe and improve the image of professional American pharmacists. " A national pharmaceopia [a book describing the "proper" way to compound and dispense] is highly important to our national character (See related photo)," Dr. James Thatcher [1754-1844], a physician of Boston, wrote in 1817 (Cowen 1990, p.137). Dr. Thatcher recognized the importance of such advances to the profession in the "New World."

Since industrialization narrowed the range of responsibilities of the apothecarist, a new title was needed to distinguish between the job of the modern pharmacist and that of the ancient compounder and manufacturer. The pharmacist of the past not only created the drugs, but he also processed, packaged, and sold them. Once industrialized, the pharmacist's new job was reduced to

FIG. 6. Title page of the Pharmacopoeia Londonensis, 1618. (From the American Institute of the History of Pharmacy)

Source: Four Thousand Years of Pharmacy, 1927.

dispenser of medicines. The English practitioners had shifted their influence to medicine and Americans felt changing their title would create a different image for the professionals. The French word *apothicaire* had been replaced by *pharmacien* in the late eighteenth century, and was considered the European designation for the entire pharmaceutical field. Germany, as well, had the word *pharmacie* replace the expression *Apothederkunst* to stand for the profession as a whole. Taking these European ideas, the word "apothecary" was dropped from American pharmacy in the 1880s.

Once the preparers and distributors of medicines, pharmacists in the late twentieth century have moved into a more patient-oriented practice with five principal areas:

- counseling patients
- monitoring patient drug therapy
- providing consultation as to drug purpose and reactions
- relating drug information to physicians, nurses, dentists, and other health care providers
- prescribing medicines in addition to physician-prescribed and over-the-counter drugs.

PHARMACY EDUCATION IN MEDICAL SCHOOLS

During the late eighteenth and early nineteenth centuries, the only formal training available was to become a physician as taught by other physicians in the medical schools. Common subjects taught in medical school included toxicology, materia medica [medical material], chemistry and pharmacy. However, Harvard Medical School required exams in both materia medica and pharmacy.

Then the medical school of Virginia separated its medical school into a "School of Anatomy and Medicine" and a "School of Chemistry and Materia Medica," which included studies in pharmacy. Students were required to take courses in both colleges. This was the first time pharmacy was given a college of its own inside the realm of a medical school. Thus, from the beginning pharmacy played an integral role as a useful tool in the education of the physician.

The first school to institute new curriculum that included pharmacy was the Pennsylvania School of Medicine in 1765. The *Pennsylvania Gazette* said that "to render courses more extensively useful, we [the Pennsylvania School of Medicine] intend to introduce into them as much of the Theory and Practice of Pharmacy, Chemistry, and Surgery as can be conveniently admitted." Pharmacy was important to the physician because he compounded his own prescriptions. At the Dartmouth School of Medicine in 1840, materia medica was more pharmacy [writing prescriptions and compounding them] than pharmacology [developing the drugs and mixing them] because of this.

"Medical education of necessity has had to deal with a great amount of subject matter related to pharmacy" (Cowen 1978, p. 17). By the late eighteenth century, drugs dispensed accounted for the majority of the physicians livelihood as can be seen by fee bills for the age (Wickes, p.70). Thus, the physician did the job of the pharmacist, so it was a large part of his medical school education. According to Cowen (1978), the dispensing physician was an American institution from the beginning.

A continuing influence of pharmacy on medical schools is evident by their inclusion at the 1847 national medical convention. According to the committee, pharmacy was one of "several branches" of medical education that should be taught in every medical school. It was also during this time that "doctor's shops," drug stores operated by physicians, were common. "At the New England Female Medical College the techniques of pharmacy such as pill rolling and folding powder papers were taught in the late 1860s" (Cowen 1978, p.19). The University of Virginia opened a new department of pharmacy within their medical school in 1886-1887, providing instruction in pharmaceutical manipulations in preparing and dispensing drugs.

At the turn of the century the emphasis on pharmacy in medical curricula changed. John Jacob Abel (1857-1938), "father" of American pharmacology, suggested only a brief course in pharmacy, stating that preparing drugs did not require "a prominent place in the better medical schools" (Abel, p.68). Although pharmacy remained a part of the curriculum in medical schools, it was a minor one. Jefferson Medical School in 1902 still offered a program in

materia medica and therapeutics that encompassed pharmacy, but the session lasted only six weeks.

Abraham Flexner's report on medical education in 1910 hastened the decline of instruction of pharmacy, stating "few lessons must be separately devoted to pharmacy" (Flexner, p.195). Courses in pharmacy lingered on into the mid-twentieth century, for example, at the Medical School of Utah, but the focus shifted away from compounding to the art of writing prescriptions.

Two prominent reasons can be cited as factors leading to the decline of pharmacy in the medical school curricula: growing competence and professionalization of the pharmacist and the growing burden on the physician from increased scientific knowledge and pressure (including higher financial rewards) to do other tasks. Abel suggested to the physician, when he downplayed the importance of pharmacy to the medical student, "often [the physician] might rely upon the friendly hand of the professional pharmacist" (Abel, p.69). Thus, the separation of pharmacy and medicine is a product of the twentieth century, due to prefessionalization of the pharmacist and increased demands on the physician.

SCHOOLS OF PHARMACY

"Pharmacists of Philadelphia, disturbed by the prospect of the education of the pharmacist falling completely into the hands of the medical profession, formed a local association called the Philadelphia College of Apothecaries in 1821," according to Cowen (1990, p.147). The name of the association was eventually changed to the Philadelphia College of Pharmacy. Philadelphia's program was part-time; therefore, apprentices worked full-time and attended classes at night. During the college's first twenty-five years it graduated five or six students per year and by the Civil War about 500 pharmacists (cumulative) possessed diplomas.

"In 1821, Hampton Hoch pointed out that when that 'the field of instruction for the pharmacist was organized, it followed the patterns already set in the medical college,' but this would not continue for long" (Cowen 1986, p.18). Ranging from a twenty-week course in one school to a four month evening program in another, training varied from one school to the next.

The College of Pharmacy of the University of Texas, established primarily by the Texas State Pharmaceutical Association (TSPA), had the prime objective to "restrict the dispensing and sale of medicines to regularly educated druggists and pharmacists" (Burlage and Beutler 1978, p. 15). Until the passage of restrictive legislation, anyone could dispense medications and the TSPA initiated a school of pharmacy to begin the process toward a regulated profession, where only licensed individuals could perform such tasks. The initial curriculum consisted of two years of work, culminating in a Ph.G.

(Graduate in Pharmacy). The description in the *University Course Catalogue* said:

> "The teaching consists of two lectures upon Pharmacy, two upon Chemistry, two upon Materia Medica, one on Botony, and one on Physics, each week throughout the term, with... three days each week in the Laboratories of Pharmacy and Chemistry" (*Catalogue*, 1893-94).

An address given at the meeting of the American Pharmaceutical Association in 1854 stated that "our country has been deluged with incompetent drug clerks, whose claim to the important position that they hold or apply for is based on a year or two's service in the shop, perhaps under circumstances illy calculated to increase their knowledge" (Kremers and Urdang, p 282). Though the association did not expect those who practiced to immediately enroll in school, it was an attempt on its part to persuade pharmacists to read pharmaceutical literature and become aware of the advancements made in their field.

During this same time frame, the Philadelphia College of Pharmacy trustees divided the chair of materia medica into two fields: medicine and pharmacy; William Procter, Jr., father of American Pharmacy, was named the chair of pharmacy (See photo). This helped to establish pharmacy as a separate branch of instruction rather than a residual part of the medical profession.

In order for pharmacy students to understand what they would do as future pharmacists, they needed education by pharmacists, rather than the physicians, who had trained them since

WILLIAM PROCTER, JR.

1765. Edward Parrish began the School of Practical Pharmacy in Philadelphia in 1843 that would do just that. He believed that "pharmacy had a right to declare its own standards and to insist on its own curriculum, which meant only those who had mastered its scientific foundations could serve as teachers" (Kremers and Urdang, p.285). To further this idea, Parrish bought a drugstore adjoining the University of Pennsylvania and started a School of Practical Pharmacy in the rear of his building to educate students in the art of compounding and dispensing medicines.

"Many variables affect the kind and quality of pharmaceutical education obtained by a student" (Smith, p.61), including the particular pharmacy school in which the student enrolls. All schools must meet certain minimum standards for accreditation, but setting and faculty play a large part in individualizing the schools. Regardless of location, the pharmacy school is the smallest of the professional schools. "It is not unusual for many university departments to be larger in faculty size than the entire school of pharmacy" (Smith, p.61). In 1970-71, the average class size was seventy students. During the same year, five pharmacy schools had total enrollment of over four hundred students in their last three years of training (cumulative) and eight had enrollment of less than one hundred.

Although the Medical Practice Act of 1907 required a degree from a recognized medical school for licensure, no degree requirement was placed on pharmacists to have a high school or college diploma. "The endeavor of the pharmacist to attain status comparable to that of the physician has been exacerbated by the low

entrance requirements of schools of pharmacy" (Burlage and Beutler 1978, p.26). When the University of Texas pharmacy school opened in 1893, the only entrance requirement was to test the individual's literacy and general scientific background. The medical school, on the other hand, required a high school diploma. By 1910, pharmacy school required one year of high school, while medical school required one year of college. It was not until 1922 that the board of regents authorized a high school diploma as an entrance requirement. The College of Pharmacy had a three-year program by 1925, and a four-year Bachelor of Science program by 1936. However, it was fourteen years earlier that the physican had reached this status. "In the 1890s a drug clerk received no more pay than a grocery or dry-goods salesman" (Burlage and Beutler 1978, p.53). It was the TSPA's hope that by increasing degree and entrance requirements that the pharmacist would become a professional and receive a large pay increase.

According to statistics, increased regulation in the early 1950s could have led to a reduction in the number of degree candidates (See Appendix 1). Since the increased legal requirements could be weighed by students prior to choosing pharmacy as a profession, the probability of high correlation of lowered enrollment and increased regulation is possible. However, professionalization did increase earnings per year (See Appendix 2). Once distinguished as a true profession, the wages of the pharmacist increased to "professional status," measuring closer to the doctors, lawyers, and dentists (which were deemed the professionals) than the average worker. Therefore, the effects of both changes account for the flucuation in pharmacy

school enrollment in the 1950s. Depending on the outlook of the individual, he must decide between higher wages and more restrictions or freedom to work without restrictions and lower wages.

Once trained as pharmacists-to-be, students would "graduate," but no official degree was conferred. "The question of what degree, if any, should be awarded to graduates of schools of pharmacy has revealed many divergencies of opinion" (Kremers and Urdang, p.307). The first degree agreed upon, awarded in 1826, was named "a Graduate in the Philadelphia College of Pharmacy." Other degrees that were eventually added included the degrees of Pharmacy, Pharmaceutical Chemist (1916) (See related photo), Master of Pharmacy (1875), Doctor of Pharmacy (1895), Bachelor of Pharmacy (1938), Bachelor of Science (1938), and Master of Science (1938).

By 1972, there were seventy-three accredited schools of pharmacy in the nation. Although graduating for an accredited school was not a necessity to practice or pass the state licensing exam, the "benefits" convinced many to attend accredited schools anyway. All but the University of California, San Francisco, and the University of Southern California offer Bachelor of Science programs. These schools had only Doctorate of Pharmacy degree plans.

The Bachelor degree is the first professional degree offered to pharmacy students, comprising five years of study. A study in 1950 by the American Council on Education developed the five year program as a compromise between the four year and six year plans. An additional year of schooling earned the student a Doctorate degree. The Doctorate has a heavy emphasis on clinical aspects and has been the choice for hospital pharmacists to obtain a Master of

THIS LICENSE EXPIRES THE FIRST MONDAY IN NOVEMBER 1919.

And is Forfeitable for any Violation of the Laws of the State of Connecticut, under which it is issued, Relating to the Manufacture and Sale of Intoxicating Liquors.

DRUGGIST'S

LICENSE

1918-1919

WE THE COMMISSIONERS OF THE COUNTY OF

WINDHAM,

DO LICENSE

a Druggist, regularly Sworn by the Commissioners of Pharmacy, to use

SPIRITUOUS AND INTOXICATING LIQUORS

for compounding Prescriptions, and to sell Spirituous and Intoxicating Liquors upon the Prescription of any Practising Physician, and to sell Spirituous and Intoxicating Liquors in quantities not containing less than one gallon, and other than Distilled Liquors in quantities not containing less than one gallon, and Alcohol in quantities not less than one gallon, from the date hereof to the first Monday in November, 1919, at No. Street, in the Town of

$ has been paid for this License.

This License does not authorize the sale of Spirituous and Intoxicating Liquors to be drunk on the premises.

In Testimony Whereof, we have subscribed our names at

this day of 19

County Commissioners.

18

Science in hospital pharmacy. Master's programs were also available to students; however, they were not research oriented, but intended to train future public sector bureaucrats. Courses were similar to those taken by Master's of Business Administration students and many were completed in the business school (not a joint program).

As the amount of pharmaceutical knowledge became more complicated, post-high school graduate courses were required. This led to a "great proliferation of schools and programs offering education in pharmacy" (Cowen, p.149). Schools ranged from state, private, or church affiliation. The University of Michigan was one such state school, becoming the first state supported school in 1868 to offer a course in pharmacy. Full-time attendence for two years and some laboratory work earned the student a degree. As early as 1900, more than sixty state universities had similar programs in pharmacy. Education of pharmacists in the state universities had two major effects. It took the responsibility of the pharmacists's education away from "practical-minded" practitioners and provided students with a regularized program of studies within a wider range of sciences (Cowen, p.147).

Industrialization, new drugs, and advances in pharmacology led to the lengthening of the pharmacist's required education. By increasing the time required for one to obtain their degree, pharmacy schools had students enrolled for a greater amount of time, which would benefit the school's income as well as (perhaps) further educate the students. In 1907, a two-year course became a requirement for all states. It was increased to three years in 1925, four years in 1936, five years in 1960, and by 1972, two California

schools required six year programs. Currently, the typical program lasts five years, three of which must be completed at the technical school. Curricula can consist of attending a non-pharmacy school for zero, one, or two years, then the degree is completed from an accredited pharmacy school.

Pharmacy programs offered a wide variety of scientific and professional courses, but there was also a significant exposure to humanities and the social sciences. A strong background in basic sciences was essential for the technical work environment of the profession. Fundamental courses include inorganic and organic chemistry, qualitative and quantitative analysis, basic biology and microbiology, human anatomy, and physiology (See Appendix 3 for entrance requirements for 1975). Concentration in the pharmaceutical sciences is divided into four areas for detailed study -- pharmacognosy, pharmaceutical chemistry, pharmacology, and pharmacetics. Each approaches the topic in a unique manner. Pharmacognosy is the study of drugs of natural origin, their source, isolation, and purification, emphasizing biochemical and analytical chemistry. Chemical structure is the focus of pharmaceutical chemistry, showing how structure relates to function. Pharmacology studies the effects of drugs on the body, and pharmaceutics, the newest area, deals with the effect of dosage forms on the delivery of drugs to their action source in the body. It was the culmination of such technical courses with a broad humanities background that was used to educate the pharmacy student.

Though basic pharmacy classes were well-developed by the end of World War II, graduate work had been greatly neglected. In

1946, only five schools offered doctoral degrees. "This lack of adequate opportunity for graduate study seriously limited the availability of teaching personnel to staff the gradually growing number of undergraduate institutions" (Burlage and Beutler 1978, p.298). Since students had a limited number of pharmacy schools that offered graduate work, it was difficult to obtain a higher degree and fewer individuals were qualified to teach. Most schools of pharmacy, including the University of Texas, were more interested in producing pharmacists for the pharmaceutical community than for the scientific and academic positions in the field. However, as the medical research field grew, the need for more pharmacists to train the profession became evident (or were they trying to capture the higher salaries that the medical profession commanded?). According to the dean of the University of Texas School of Pharmacy in 1952, "Twenty or thirty years ago, the College of Pharmacy might have trained men for the retail field only, but now it must train for teaching, manufacturing and research as well as retail work" (Burlage and Beutler 1978, p.312).

In the mid-sixties, more than twenty-five schools took a step foreward on the road to professionalization and initiated courses in clinical pharmacy, which embraces patient-oriented learning. Many notables of the health profession supported this move, including Dean Sprowls and Victor A. Yanchick of the University of Texas, because it brings the pharmacy student in contact with people and teaches them how to interact with patients as a professional. A new type of course instruction, clinical pharmacy permits the pharmacy student to actually observe treatment of the disease in patients. "A

prime objective of the program was to achieve a close and continuous working relationship between the clinical-pharmacy faculty and the students" (Burlage and Beutler 1978, p.511). By doing so, the school not only taught the fundamentals of the profession, but allowed students to learn how to interact with the patients to provide "the entire spectrum of pharmaceutical services required by a society expecting and demanding increasingly effective health care" (Burlage and Beutler 1978, p.514).

In addition to academic knowledge, practical experience was important in the education of the apothecary, but could not be acquired in the schools of pharmacy. This experience is also a legal requirement in some states; however, Mississippi, Rhode Island, and Alaska do not require such experience. All or part of this experience requirement can be obtained during summers after one or two years of college, depending on state licensure laws. Other states require three to six months of internship after graduation. These internship programs are under the supervision of the state boards, which exemplifies the extensive regulation of the profession (see Regulation for more details). In order to gain this experience, the students must work in a hands-on environment and be faced with the every day problems of a pharmacist. Kremers and Urdang suggests that the problem of dealing in a balanced way with the science and with the practice of pharmacy has been solved through the development of the state board examinations.

Another important topic related to education of the pharmacist is continuing education. According to Carl DeMarco, there was a trend in the 1980s to require continuing education, based on the

(alledged) desire to maintain a certain level of competency among pharmacy practitioners. Another possible reason could be to raise barriers to entry or an attempt to increase demand. With the rapid advance of change in all areas of life, no pharmacy school can prepare the student for a lifetime in the profession. For this reason, conferences and seminars are widely available to keep the pharmacist up-to-date on the latest developments and breakthroughs. Some are even compulsory.

Some state boards even require professionals to attend lectures in order to receive license renewal. Others have gone as far as mandatory reexamination for license renewal. Restrictions and regulation again are evident. In 1967, Florida and Kansas adopted laws requiring continuing education for relicensure. By 1984, California, Indiana, Michigan, Minnesota, Nevada, New Jersey, New Mexico, Ohio, Oklahoma, and Washington adopted such policies as well. These increases in requirments have been pushed by the associations and established professionals, who have a monetary investment in the conferences since they are paid for attendence or lecturing. Whatever the state law, it is obvious that education of the pharmacist does not end with the completion of pharmacy school.

Professionalization

> "The history of progress of society is that of the division of labour, and there is no surer indication of the advancement in the arts of civilization, than the multiplicity and subdivision of occupations"
> (*Journal of the Philadelphia College of Pharmacy* 1825, p.1)

According to the *Journal of the Philadelphia College of Pharmacy*, America was ready for a change in the job of the pharmacist by 1825. By this time pharmacy had practitioners with advanced knowledge and expertise beyond the medical field, due to actual pharmacy experience, separate schools of its own, and local, state, and national associations to support its interests. The practitioners wanted pharmacy to be recognized as a separate profession and it was at this particular time that a group of pharmacists gathered together to discuss the road to professionalization. "A small group of men connected with the drug trade successfully championed the concept of a practictioner whose *raison d'etre* (purpose in life) was the preparation of medicines" (Higby 1986, p.115).

By the late nineteenth century, medicine and drugs were handled in most towns and cities by men who had formal training in pharmacy. The subject of pharmacy was taken out of the medical schools and handed to the schools of pharmacy that were being established. Doctors were relying more and more on the knowledge and trade of the pharmacist to dispense medications. Higby claims (p.115) that it was these fifty years (1821-1870) that crystallized

the present form of pharmacy practice. It was also during the late nineteenth century that the pharmacist joined the rank of professionals.

A profession was defined by Glenn Sonnedecker, a historian of the pharmacist, as having five qualities (p.245):

- a relatively specific, socially necesary function upon the regular performance of which the practitioner depends for his livelihood and social status
- a special technique, competence in which is demanded, resting upon
- a body of knowledge embracing generalized principles, the mastery of which requires theoretical study
- a traditional and generally accepted ethic subordinating its adherent's immediate private interests to the most effective performance of the function
- a formal association fostering the ethic and improvement of performance

The pursuit of professionalism by the nineteenth century pharmacist can be seen in the organization of associations, schools, and periodicals. With the prominence of the job of the pharmacist came the use of the medicines dispensed by such practitioners. Improper use by patients and incorrect distribution by some pharmacists led to deaths and incidents such as the Sulfanilamide (1906) and Thalidomide (1962) disasters, which led to various laws regulating and licensing the practice of pharmacy. Other pharmacy laws were also passed during this time frame, due to heightened concern of the public.

Historians of pharmacy, such as Kremers and Urdang's *History of Pharmacy*, give credit to an elite group of pharmacists, such as William J. Procter, Fredrich Mohr, Theophilus Redwood, and Edward Parrish, for the development of pharmacy as a profession, explaining the events that occurred and legislation that was passed . However, they do not include in their history the changing views of this elite group from the mid-to-late nineteenth century. It is these different views and ideas that led to the development of the profession and played an important part in the "hows and whys" of the change.

Pharmacists in the early nineteenth century included all who made pharmacy a prominent part of their livelihood. The definition of the job was " the art and practice of preparing, preserving, and compounding substances, whether vegatable [sic], mineral or animal, for the purposes of medicine" (Goodrich 1854, p.821). It is also important to note that "professionalism," especially in the early nineteenth century, was as much conferred [by the general public] as it was claimed and earned" (Higby 1986,.p.117).

"During the Jacksonian era, an occupational group gained the designation of 'profession' by demonstrating to the public that they provided a special service, together with 'seriousness of purpose and honesty of intention'" (Higby 1986, p.118). Though the American pharmacist took his role model from the British, he was always trying to do something new in order to send results back to Britain, showing how American pharmacists were advancing their craft. They saw themselves as servants of medicine, since the field was yet to be split, and wanted to prove to the public and the world that

American pharmacists were distinguished enough to be a separate profession.

The leading apothecarists of the nineteenth century had two important beliefs: (1) the "traditional" view of recognitition through non-vocational education and (2) the sharing of information through the idea of the "invisible hand" rather than governmental regulation. Though they wanted to be admired for more than simple nostrums which they sold, it was profit from these cheap (what the pharmacist considered of little value) goods that kept them in business. Envious of the Continental *pharmaciens* (pharmacists) and *apothekers* (apothecaries) and the high position in society that they held, American pharmacists wanted to "separate themselves from the majority of drug sellers who drifted in and out [of the business] depending on the state of the market" (Higby 1986, p.118). They rejected ideas of legislation and regulation. As Jacksonians they believed that the number of practitioners should not be limited or judged by quality, but that the public should decide who is to be a professional.

As the nineteenth century continued, pharmacists changed their minds about the idea of professionalism. The 1840s contributed to this by emphasizing the science more heavily. It was at this time that the title "pharmaceutist," which implies a practitioner of pharmaceutical science, evolved (Higby 1986, p.118). Now that they had become more secure in the job of dispensing drugs, pharmacists had the "courage" to make a break from the medical field.

The American Pharmaceutical Association, established in 1825, was the culmination of pharmacist's attempts to organize themselves into a trade group. At its meetings, various members stated their ideas about professionalization and how to achieve it. William Proctor supported the old way of achieving professional status through self-improvement, saying that if each pharmacist would work hard to improve his skills and ethical behavior, then the public would recognize pharmacists as full professionals. Thus, he was supporting the Jasksonian view of how to achieve professionialization.

Edward Parrish opposed Proctor, suggesting elevation of the individiual pharmacist's status through recognition of the group activities of pharmacists. According to Parrish, "If pharmacists in a locality could meet together and agree on standards of practice such as hours, pay for assistants, and, most of all, prices, then the public would see pharmacists as a professional group, not a competitive board" (Parrish 1854, p.115).

However, both men seemed to agree on the focus of their professional ideology: individual freedom, the ideal of the "independent democrat," one who succeeded on his personal merit alone, which does not allow for governmental intervention and regulation (Higby, p.119). Parrish thought that group organization would make the business more profitable and respectable, leading to collective independence. Supposedly, organizations of this type fostered internal improvements to gain professionalization rather than relying on governmental favors to get ahead. Supposedly, such groups aided economic efficiency and price competition by putting

private resources to best use rather than using them to "make good with government."

In the 1840s and 1850s, the biggest threat to the rise of the pharmacist to professional status was "secret remedy makers and nostrums." If the public felt that anyone could make such potions, why would the pharmacist be anyone special? It was these same nostrums that kept the pharmacist's shops open during these days. "Throughout the nineteenth century, the patent medicines on his [the pharmacist's] shelves served as a constant reminder to the aspiring pharmacist of how far he was from full professionalism" (Higby 119). Since the pharmacist had to rely on sales of such patent medicines for financial reasons, the pharmacist believed himself to be a long way from the professional who makes his money through good service and quality products.

To differentiate themselves, pharmacists focused their talent on the mastery of in-house manufacturing and prescription compounding, strongly opposing industrialization of pharmaceutical products for this reason. Procter explained their worries by stating, "if the preparation of the medicines is taken from the apothecary and he becomes the dispenser of them his business is shorn of half its dignity and importance, and he relapses into a simple shopkeeper" (Procter 1858, p.516). But industrialization was to come about whether the pharmacist wanted it or not. "By the late 19th century, the grinding of drugs was taken over by large-scale establishments using power-driven mills, putting the covered mortar and pestle in the category of the artifact" (Bogard, p.108).

Pharmacy leaders of the decades 1840-1860 argued that it was the preparation of drugs that made the pharmacist an important part of the community. Once industrialization began, it became necessary for the pharmacist to find a different focus for his knowledge. After European travel, Procter announced to the American Pharmaceutical Association that he was in favor of regulation of pharmacists by allowing only graduates of pharmacy school to practice, but left competition to regulate the number of practitioners.

In addition to regulating practice by requiring a pharmacy school degree, the graduate must be licensed by a state board and to become licensed, graduates are required to serve an intership and to pass a state board examination. States vary in their specific requirements. For example, Alabama requires a year of practical experience while Rhode Island has no such requirement. Only licensed pharmacists may perform certain tasks as defined by the laws and regulations of the particular state.

Many pharmacists did not agree with Procter's idea, moderate as it may have been. Parrish, one such opponent, believed that " all laws and legislation, whether among ourselves or elsewhere, tend to confine our profession and keep it back, should be carefully guarded against" (Procter 1866, p.51). Backing Parrish were other practitioners, such as Oscar Oldberg from Sweden who had fled Europe in favor of America, where restrictions did not limit the field of pharmacy.

Nevertheless, the late 1860s saw state restrictions set in place. Regulations such as university degrees, state licensing, and institutional certification, did, however, set "new professionals" (the

pharmacist) apart from the public. This was an attempt to make a distinction between the professionals (as they wished to be referred to) and the general public. To instigate this separation from the public, only members of the profession were held worthy to judge other professionals. "By controlling admissions to professional schools and raising examination standards, destructive competition could be reduced or even eliminated" (Beal 1900, p.180).

What started out as the road to professionalism based on competition and the free market, as defined by Sonnedecker, eventually embraced regulations and legislation to "protect their own." Early leaders in pharmacy, including William Procter, Jr., and Edward Parrish, stressed the importance of individual effort to achieve professional status. It was not until the 1870s-1880s when pharmacists followed in the footsteps of the medical and other professional fields, turning to regulation of the industry to achieve unique priviledges. However, unlike the other professions, pharmacy did not throw out the old system completely, but incorporated it into the "new" professionalism, striving for both the goals of the individual and the group as a whole.

Regulation

The pharmacy profession has had a firm grasp on the concept of monopoly as it is highly regulated. Regulation increases earnings by limiting supply. Cowen (1990) argues that it was not until the last part of the nineteenth century that Americans were "mature" enough to accept government regulation. More likely, the American pharmacist had not put the ideas into action to increase their salary until this time.

Historians believe this was accomplished by laws that regulated the practice of pharmacy as well as that of medicine. According to LaWall, prices to be charged for medicines were regulated by the local law, the number of drug-dispensing establishments was limited and regulated by local law as well , and the compounding of certain drugs had to be performed in the presence of inspectors who were selected from the best qualified pharmacists in the community. Penalties for improprieties were as harsh as property confiscation and even death. "It was found convenient to suffer [license] dealers in drugs gradually to acquire more monopolies. It was thought that those who devoted themselves to pharmacy should be indemnified by an exclusive trade; and monopolists could be kept under close inspection" (LaWall 1927, p.138). Since prices were regulated as well, pharmacists tried to ensure customers that they were getting their money's worth and "illusory treatment by placebo was permissible" (LaWall 1927, p.139).

To be an effective (not necessarily economically efficient) field on its own, pharmacists had a central plan of filling and dispensing pharmaceuticals, which continues to the present. In order to legally fill a prescription, the prescribing physician had to be on a list of practitioners, his signature must be present, and the medication must be wrapped in a sealed package. The only legality that dealt with pharmacists by 1859 was that which restricted other branches of industry in the United Kingdom (LaWall 1927, p.439).

From the outset of pharmacy consistency and accuracy were important, which explains the continuation of the initial systems set up in the early eighteen hundreds. Pharmacist's labs had been the predominant source of research and production up until the 1820s. A general store with drugs as a small part of their income and the physician with an open store were common until the Civil War. Due to changing economic and social structure of the era, "small pharmacies expanded into industrial undertakings that later grew into factories, transferring the primary function of the traditional pharmacists, the making of medicines, to the more efficient factories" (Boussel, p.7). Economies of scale could be exploited on an industrial level and pharmacists shifted their emphasis from the making of drugs to professionally counseling patients, a more lucrative task in their opinion.

According to Kremers and Urdang (p. 289), "as early as 1847, William Procter, Jr., in his introductory lecture as professor of pharmacy, stressed the necessity of state-controlled practice of medicine and pharmacy." There is no economic rationale for the "necessity" of state-controlled practice, rather it is looked upon as a

regulation of the supply of pharmacists. Although Procter agreed that government was to interfere as little as possible in order for private interests and competition to determine market levels, he believed that medicine needed some sort of qualification required by law to ensure that an apothecary was aware of his duties and responsibilities.

John M. Maisch instigated the establishment of state pharmaceutical associations, to create and enforce pharmaceutical state legislation internally. Once the American Pharmaceutical Association (APhA) was established in 1852, Maisch worked dilligently with them and in his position at the *American Journal of Pharmacy* to further advance the practice of pharmacy. He joined the APhA in 1856 and was elected in 1860 to the position of chairman of the progress of pharmacy. It was in this position that he took a leading part in the revising of the Pharmacoepoeia, an important work used to standardize and internally regulate pharmacy. *The Universal Formulary* and *The National Dispensatory* were the other two works he revised to help create a universal pharmacy practice.

"Having laid down in its constitution the fundamentals of professional pharmacy and striving to realize them partially, it is not surprising that the Philadelphia College of Pharmacy became the model and sometimes the advisor of other local American pharmaceutical associations" (Kremers and Urdang, p.246). Growth of early local pharmaceutical associations made the separation from the medical field an economic triumph to the members of the associations, but not necessarily for all pharmacists. Although as a

profession the pharmacist earned a higher wage than the non-professional worker, the doctors, lawyers, and dentists still averaged more than the pharmacist (See Appendix 4). So the separation from the medical field was not an economic triumph for the pharmacist since his wages were below the average for professionals. Physicians were daily abandoning the practice of compounding or dispensing medicines, beginning a heavy dependence on druggists to fill the vacancy.

Although intervention into the market price system was generally considered an economic bad during the nineteenth century, pharmacists considered the field of pharmacy a special case. Direct price competition was deemed an evil, but competition related to the quality of the medicines and attention to business would increase the respectability and standing of the profession. "It was this typically American spirit that defeated the early medical endeavor to regulate legislatively the practice of medicine in all its branches, including pharmacy, by forcing it under the control of legally authorized and chartered medical associations" (Kremers and Urdang, p.251).

Regulation proceeded most rapidly during the eighteen seventies and eighteen eighties, establishing state laws to regulate the licensure of pharmacists. The imposition of these laws continued heavily in the nineteenth century, especially in the West.

> "Since its inception in 1879, the Texas State Pharmaceutical Association had been trying to impress the public with the necessity of education and training in pharmacy to protect the sick as well as the healthy and of regulating the practice of pharmacy to safeguard the public from the incompetent and the unscrupulous. By 1900, however, TSPA had failed 'to

awaken the public to its own interests' " (Burlage and Beutler 1978, p.98).

The announced reason for such a move was to protect the public. "The original objective therefore was to ensure quality of the stated article" (Smith, p.46). Other stated reasons for regulation include increasing the quality of drugs, drug addititons, and a "demand" for safety. These various regulations were aimed at the pharmaceutical industry, but had subsidary effects on the job of the pharmacist, limiting his discretion and increasing his "cost" of doing business.

Every aspect of pharmacy is the subject of numerous governmental controls at federal, state, and local levels. Using its own standards to issue licenses, each state has an administrative body to administer the state pharmacy act. Most boards have practicing pharmacists and twenty-eight have at least one public member with one including four public representatives. Boards of pharmacy have numerous responsibilities, including administration of the state licensure exam, issuance of licenses to pharmacists and pharmacies, and the imposition and monitoring of regulations.

The state board could be considered a legal barrier to entry into the market, which would supposedly increase quality while controlling entrance into the field. Initially, there were several boards rather than one consolidated state board. "The very nature of a board of examiners composed of the influential professionals within a community made it succeptible to the abuses of influence, favoritism, and bribery" (Burlage and Beutler 1978, p.19). If a person was denied a license in one district, he could simply go to another and bribe him to grant a license. The definition of the

"proper" education in order to be granted a license was also vague, saying "a regularly incorporated college of pharmacy." Therefore, the intial intent of the TSPA-- to create uniform standards-- was not obtained.

By the late sixties and early seventies, a uniform state board was set up in each state. Once established, these boards would administer the licensure exam. A problem encountered was that there were numerous exams in use in different states. To solve this problem the National Association of Boards of Pharmacy (NABP) elected a committee to create a standardized test for use by all state boards. In 1970, the committee created the NABP Licensure Exam, which has become the standard exam of pharmacy administered by each state, except California, Louisiana, Florida, Oklahoma, and Puerto Rico. The exam is comprised of two parts: theoretical and practical. Most states also require an individual to be eighteen or twenty-one in order to practice pharmacy.

The examination was comprised of two parts: an eight hour theme, written in the presence of the examiners and a practical part, comprised of pharmaceutical and analytical (LaWall, p.447). This gave practitioners the opportunity to appraise practical experience, as well as the knowledge possessed by each pharmacist candidate. Pharmacists in practice before state boards were established were recognized and registered without an examination. State board examinations were instituted to ensure the education the future practitioners in the art of pharmacy and its intricacies and to limit entry in the pharmaceutical profession.

As far as penalties for improper behavior, boards impose fines, suspend or revoke licenses, and otherwise regulate activity of the profession and their practices. Each state has its own set of pharmacy laws and penalties for breaking these laws. "For example, in New Jersey, the fine for the first offense is not less than $25 nor more than $100, for the second offense, $100 to $300, and for the third offense $300 to $500" (DeMarco 1984, p.303). Some states even have criminal sanctions for violation of a pharmacy act, but few were convicted. The state of Nevada has such a law, stating "Any person who does or commits any of the acts or things prohibited by this act, or otherwise violates any of the provisions thereof shall be quilty of a Class II misdemeanor" (DeMarco 1984, p.304). Laws also give the state board of pharmacy the right to revoke or suspend an individual's pharmacy license. The state of Oklahoma allows the state board to revoke licenses for numerous reasons, including violation of any provision of this Act, including conviction of a felony, or anyone who conducts himself in a manner likely to "lower esteem" for the profession of pharmacy. By imposing vague regulations, the state boards of pharmacy have great discretion in granting and revoking licenses.

Many "qualified" experts believe that this control over the field enhances quality over quantity of pharmacists. According to Carl DeMarco (1984), by limiting practice of pharmacy to licensees, a state can assure a certain level of competence and quality of service, while unqualified persons and sub-standard practice can be reduced and eventually eliminated.

These boards were created to "help the public," or so their purpose was stated. However, licensing and regulatory boards serve only the function of restricting entry. "The great truth that is never spoken directly, but anybody in the field with two bourbons in them will tell you, is that these boards work primarily to protect the practitioners and have little or nothing to do with protecting the public" (Young, p.41). They are judged by a group of their peers, since "no one else is qualified to judge them." Many licensees are not disiplined, but are frowned upon if they reveal any "unsavory activities of a fellow member to the public" (Haug, p.66).

Evidence on pharmacist's salaries shows that they command a higher wage than other non-professional fields (See Appendix 5). However, as Friedman and Kuznets concluded, "differences between professional and nonprofessional workers' incomes seemed larger than necessary to account for the extra skill and training of the professionals" (Young, p.49). This suggests leaving the rest of the wage differential to the greater difficulty of entry into medicine or pharmacy than into unregulated industries. Regulation may play a part because decreased supply allows an increase in price.

Others base their views in support of regulation on the welfare of society. Every act of a board of pharmacy is supposed to be based upon the welfare of society. According to John Krantz (1931), to permit these basic necessities to be compounded under unsatisfactory conditions and by unqualified people would be to deny to society the certainty of protection which the social impulse (i.e. the public) demands. Courts in the 1930s recognized the value of the pharmacists professional skill in protecting the health and

welfare of the public by controlling quality of medicines. DeMarco concurs with this valuation of the pharmacist, stating that since the effect of pharmacy is important to health and safety, it is necessary to be licensed to practice the profession. Some evidence supports the argument that restrictions enhance quality. A study by Samuel Martin (1982) showed that more restrictive standards were associated with higher quality (and more expensive) service. (Young, p.53) With such emphasis on the welfare of society and the absence of any contrary evidence, the era of pharmacy regulation began.

The American Pharmaceutical Association joined the tide toward regulation in the 1860s by publishing a model pharmacy act (See Appendix 6), claiming increased public protection and occupational security. This model act basically outlined the "model" of the job of the professional pharmacist. To counteract the attitude some pharmacists had toward physicians or bureaucrats having authority over them, this model law was sent to a committee of the APhA to be written. In the spirit of "straddling the fence," the association did not endorse the law it created.

Once the wave of legislation started, there seemed to be no stopping it. In the 1870s, state legislatures began considering numerous pharmacy laws, supported predominantly by non-pharmacists to regulate the field and provide for public safety. In reaction to these bills, pharmacists organized state-wide association meetings to send their thoughts on the bills to the individual legislatures. "Although not enthusiastic at first about governmental regulation of their business, pharmacists wanted a voice in the process" (Higby, p.120). The result was a shift in the way to obtain

professionalism away from the free market and competition toward the bureaucratic method of credentialism laws and regulations. Individual effort was less emphasized and the collective identity became the main focus of pharmacists.

The controversy concerning the emphasis of pharmacy has been fought by the APhA and The National Association of Retail Druggists (NARD) since late nineteenth century. The NARD advocated the old nineteenth century (Jacksonian) model, "by individually gaining public conferral of professional status within the marketplace" (Higby, p.122). In their opinion, if all pharmacy providers have an equal chance for success by reducing the "unfair advantage" of larger chains and stores, then consumers would reward those pharmacists who practiced professionally by patronizing them. On the other hand, the APhA (See Appendix 7 for Code of Ethics) and affiliated organizations believe in working as a cohesive group to elevate the collective stature of pharmacy to that of a profession, advocating stringent educational and testing requirements -- the "new" professionalism. The result of this debate between subjects of emphasis resulted in a compromise, but regulation was to increase and limit individual choices anyway.

The first modern law specified for pharmacists was passed in 1870 in Rhode Island and by 1900 government legislation was in effect in some aspect in all but one state. Most laws date back to 1870 with only nine originally enacted in the twentith century. Creating such laws had an important economic implication because they provided for a "subordinate class of pharmacists." By setting minimum standards and curtailing competition professionals had no

pressure to excel above the minimum qualifications. DeMarco suggests that if the government were interested in inproving efficiency and quality of the profession as a whole, they should limit regulation and do away with ancient, outdated laws.

Another controversy of the late 1900s was that of generic drug substitution for name brand drugs. What has become a way to increase competition and lower prices to consumers in the 1990s was prohibited by state laws in the early 1900s before large-scale manufacturing. By 1984, drug substitutuion was defined as the dispensing of a different drug or brand of drug in the place of the one ordered or prescribed without the express permission of the presciber. Thirty-four states mandate that cost savings will be passed on to the consumer as well. "In filling a prescription for a brand name product, a pharmacist may dispense a different, lower cost, drug product of the same dosage form and strength if the different drug product is generically equivalent. The pharmacist shall pass any savings on to the consumer" (DeMarco 1984, p.111). Allowing a choice by the pharmacist made him more competitive, since prices could vary due to lower cost of generics. Once permitted by law, drug substitutions increased the competition among professional and gave the patient a way to diffentiate between his choices (of pharmacist), which increased the salaries paid to pharmacists.

The most far reaching federal law in the pharmaceutical field was the Federal Food, Drug, and Cosmetic Act (FDCA) passed in 1938, which might explain the decrease in the number of pharmacists in the 1940s that continued into the 1970s (See Appendix 8). The

Federal Drug Admnistration (FDA) is the central regulatory and enforcement agency under the FDCA, having joint responsibility with the FTC to control advertising of prescription drugs. It shares with the Federal Trade Commission the regulation of marketing of nonprescription drugs and responsibility for all drug promotion. Established by the FDA in the mid 1970s, the Over the Counter advisory panel made strict and scientific assessments of the ingredients in over-the-counter products. As a result of these studies, the panel reported that only approximately one-third of the ingredients in the 300,000 brands of over-the-counter products studied were safe and effective for their intended uses (Sanberg 1986, p.19). In the 1970s, the FDA increased its regulatory action, not without considerable criticism from drug manufacturers, some pharmacists, and some physicians.

In the United States as a whole, regulation on the national level began with the Pure Food and Drug Act of 1906. "That year more than 100 people died after taking 'elixir of sulfanilamide' (DeMarco 1984, p.145). Regulating domestic production of drugs, this legislation did not require premarket testing for safety or efficiency. Following this tragedy was the enactment of the Federal Food, Drug, and Cosmetic Act of 1938. Becoming the first federal law to be applied to devices and cosmetics as well as drugs, it prohibited adulterated or misbranded [which included habit-forming labels, proper directions, and precautionary measures] items from commerce, required "adequate" testing affirmed by state government, and made it mandatory to have a warning label if habit forming. The Harrison Narcotic Act of 1914 was also passed to ban

certain items from the hands of the public, stating that a pharmacist could dispense addictive substances only on prescription and only physicians having a special federal license could prescribe or dispense such substances. Again regulation was aimed at "protecting the public," but in doing so government officials raised the cost of these physicans and pharmacists by regulating their activity, consequently increasing the prices of these services (See Appendix 9).

Increasing the amount of legislation revolving aroung pharmaceuticals, the Federal Food, Drug , and Cosmetic Act of 1938 extended their drug coverage to batch certification of insulin and antibiotics by the FDA before such drugs could be marketed. The Durham-Humphrey Amendment was passed in 1951, called the "prescription drug amendment." "This law etablished which drugs may be dispensed only by pharmacists pursuant of the order of a practitioner authorized by law to administer such drugs" (DeMarco 1984, p.146). In 1962 another amendment was passed, resulting from the "thalidomide disaster," introducing the concepts of good manufacturing practices, premarket testing for effectiveness as well as safety, factory inspection every two years, and the use of established (generic) names.

Dissatisfied with the "lack" (?) of consumer protection, the Drug Amendment of 1962 provided that one and only one "offical name" be applied to any single official drug -- to the exclusion of all others. The Drug Listing Act of 1972 further restrained manufacturers by requiring that they maintain a current list of each of its drugs. According to David Cowen (1990), legislation passed in 1984 restored

some of the effective patent life lost during the FDA approval process. Development of such regulation was accompanied by a comparable growth in regulatory sophistication.

Pharmaceutical education got its fair share of regulation as well. In 1900, the Conference of Pharmaceutical Faculties was founded, representing twenty-one pharmacy schools in the United States. In 1925, its name was changed to the American Association of Colleges of Pharmacy and it presently has seventy-three accredited institutions. The Health Professions Education and Training Act included schools of pharmacy for the first time in 1970, providing entitilements for grants based on professional enrollment. Since then the federal government has had a significant involvement in the financing of graduate education and research in pharmacy through research grants and contracts, pre- and post-doctoral fellowships, and training grants.

As pharmacy regulation increased, so did the cost of prescription drugs. Now some drugs cost sixty dollars for a ten day supply (i.e. Ceclor), leading to the search for relief from such high prices. Patients found some relief in the third-party system of prescription drug payment. It was predicted in 1969 that within three years over seventy million Americans will have their prescriptions paid for by third parties. And by the 1950s Blue Cross coverage included a social security system and covered numerous pharmaceuticals. "The involvement of private practitioners of pharmacy in government and non-government 'third party drug payment' programs is inevitable" (Gable, p.23). Regulations of this

part of the drug industry are stringent. The laws restrict the freedom of the pharmacist and add to the patient's cost.

Although these numerous and varied laws are aimed at the pharmaceutical industry, their effects reach into the job of the pharmacist. Unit dose labeling is regulated just as the large manufacturing companies are and the individual pharmacist must follow stringent guidelines in packaging, labeling, and distributing these individual packages. Since this type of manufacturing is only common in hospital pharmacists, the retail pharmacy does not have to register as a manufacturer. According to the FDCA, in *United States v. Sullivan* (1948), the United Stated Supreme Court held that once drugs are released for retail, the pharmacist must comply with the same laws the industry is subject to follow (DeMarco 1984, p.143). Increasing the amount of regulation pertaining to the pharmacist, this law increased the "cost" of doing business for the retail pharmacist.

The law very closely controls and regulates the division of public health that actively engages in the production and distribution of drugs,. To some there is an understandable desire to "do something" - but without any calculation of cost or economic effectiveness no true benefit can be estimated.

HOSPITAL PHARMACY

One major branch of the field that developed in the 1900s was the area of hospital pharmacy. Leading the extension into hospital pharmacy were John Morgan, Charles Rice, and Martin Wilbert. Morgan was an activist in creating pharmacy as a separate field from medicine; although he received his medical degree he remained loyal to pharmacy and supported its separation into a new field.

Charles Rice arrived in the United States about the time of the Civil War and enlisted in the Navy as a surgeon's steward. After being honorable discharged and returned to New York, Rice came down with malaria and was sent to Bellevue Hospital. "Even as a patient, he so impressed the administration with his scientific knowledge that he was appointed assistant to the hospital apothecary" (Folkemer, p.30). Continued achievement led Rice to be named chemist and superintendent of the general drug department for Bellevue and eventually he was appointed as chairman of the American Pharmaceutical Association's committee revision of the U.S. *Pharmacpoeia.*

Martin Wilbert began his career as an apothecary in the German Hospital in Philadelphia. His photography skills as well as his expertise as a scientist, led to his creation of the first x-ray machine used in the hospital.

Contributions by these men led to the diversity of the job of a pharmacist, but "the identity crisis of the hospital pharmacist has persisted from the early days of John Morgan through the latter part of the nineteenth century." Hospital pharmacists who served in the

Civil War had no professional status, rather they were given the title of hospital steward. Hospital pharmacy remained, as Kremers and Urdang called it, "a quiet tributary of the profession until after World War I."(p.451).

Improvements began when the hospital system as a whole began to change. The American Hospital Association along with the American Medical Association advocated the cause of reform in the hospitals. Pharmacists gained new opportunities within the structure of the new system, which emphasized specialties, efficient management, and therapeutic effectiveness. Gaining a larger hold on the field, hospital pharmacists began contributing more to journals and making a name of their own.(Folkemer 31).

Parallel to the local and national associations of the retail field, hospital pharmacists created the American Society of Hospital Pharmacists (ASHP) to publicize their interests. Started in 1942, the ASHP made large organizational strides in the first fifty years of its existence, but whether these strides were toward efficiency or not has not been determined. It approved minimum standards for pharmacies in hospitals and for pharmacy internships. With economies of scale leading to industry production of the majority of all prescription drugs and the increase in patient load, the hospital pharmacist, like the retail pharmacist, changed his course of direction. More technicians were hired and some automation evolved due to the increase in demand.

Pharmacists then had time to shift their emphasis to providing information to physicians and patients. "As health-care professionals expanded, the demand for pharmacists became more diversified

[1924-25]" (Burlage and Beutler 1978, p.121). The pharmacist who operated the hospital dispensary needed specialized training, leading to the addition of courses in hospital pharmacy to college curricula. Starting in 1924, pharmacy students received thirty hours of practical experience in hospital pharmacy, at the University of Texas Pharmacy School, under the supervision of the hospital pharmacist, Bernetta Michel. The students gained experience and the hospital received the dispensing of the students free of charge.

Hospital pharmacy, as retail pharmacy, has been affected by numerous regulations and restrictions. However, the hospital pharmacist has a different client base -- patients instead of reselling to the public -- allowing him to avoid regulation aimed directly at the pharmaceutical industry. Nevertheless, he has been subject to the same problems, relating to dispensing restrictions and licensure requirements, that have already been discussed.

Conclusion

Beginning as early as 1870, the goal of the pharmacist was to make a name for himself while increasing his salary and becoming a true professional. In order to achieve this goal, many people came to the United States where regulation and licensure were non-existent. William J. Procter, Jr. and his collegues believed that if all "apothecaries" believed in hard work and virtue rewarded them, that professionalization would occur without enacting any specific laws. However, practitioners in England were achieving a high prestige in the eyes of the public and the American counterparts wanted to do the same. After Procter's visit to England, he proposed a "new" way to achieve their goal -- regulation of who could practice. Though initial opposition was strong, the idea of increased wages and decreased competition convinced many that regulation would benefit all practitioners.

Once professionalized, leaders in the local, state, and national organizations tried to implement increased regulation to further limit supply and raise wages above the non-professional salaries. Initially, this movement was unpopular because practitioners did not want laws to regulate their work. However, organizations were successful in passing such legislation and increasing wages (See Appendix 9).

Economics played a large part in the development of pharmacy as a profession. Elites of the nineteenth century realized that to improve themselves financially they could use regulation to achieve their aims, saying it was to protect the public. By restricting entry,

increasing licensing requirements, and developing state boards, the profession of the pharmacist followed in the footsteps of the medical field. Their own self-interest served as the incentive to better themselves individually and collectively. As seen in Appendix 4, the monetary wage ratio of the pharmacist to the non-professional worker has increased over time, showing that regulation has increased the financial rewards of the profession. In addition, the standards of the job and the work environment have improved substancially, but this is only an added benefit rather than the goal of the practitioners.

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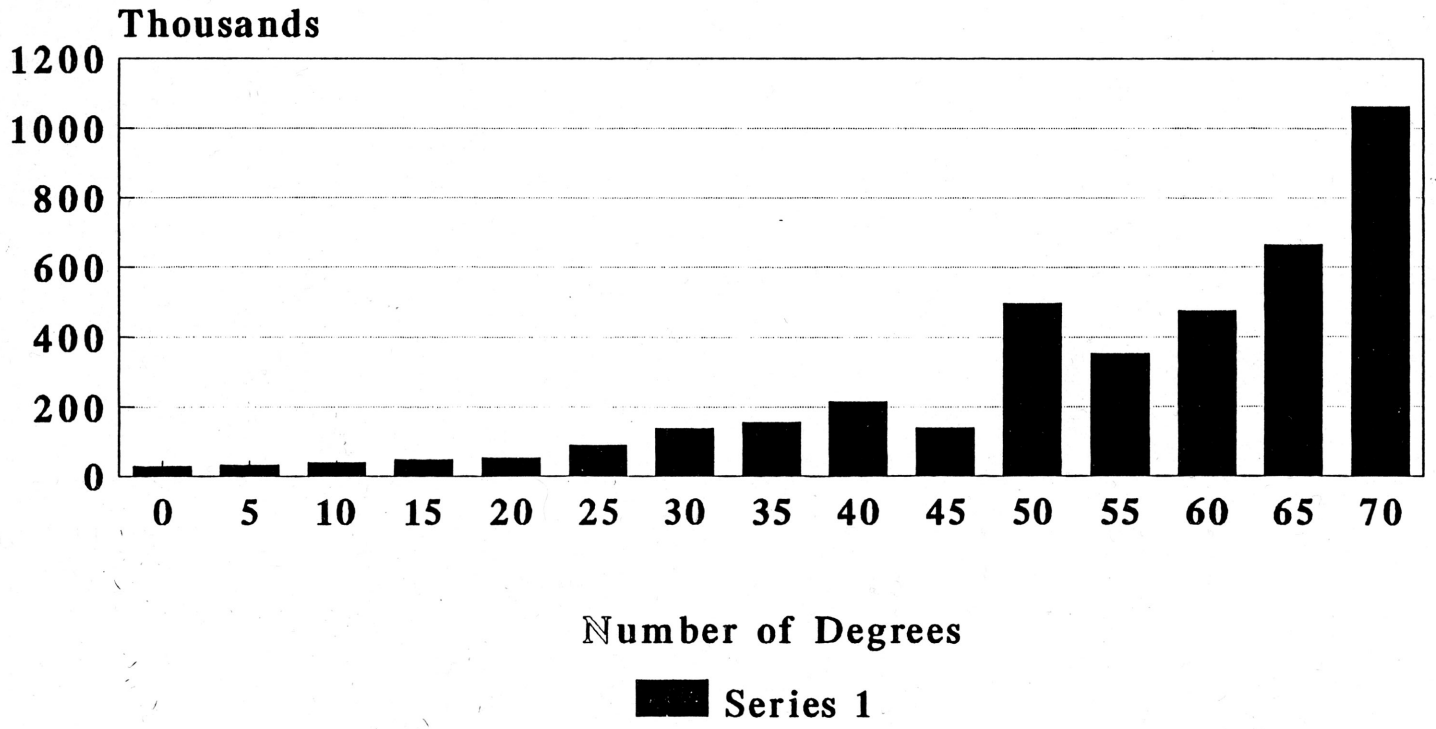
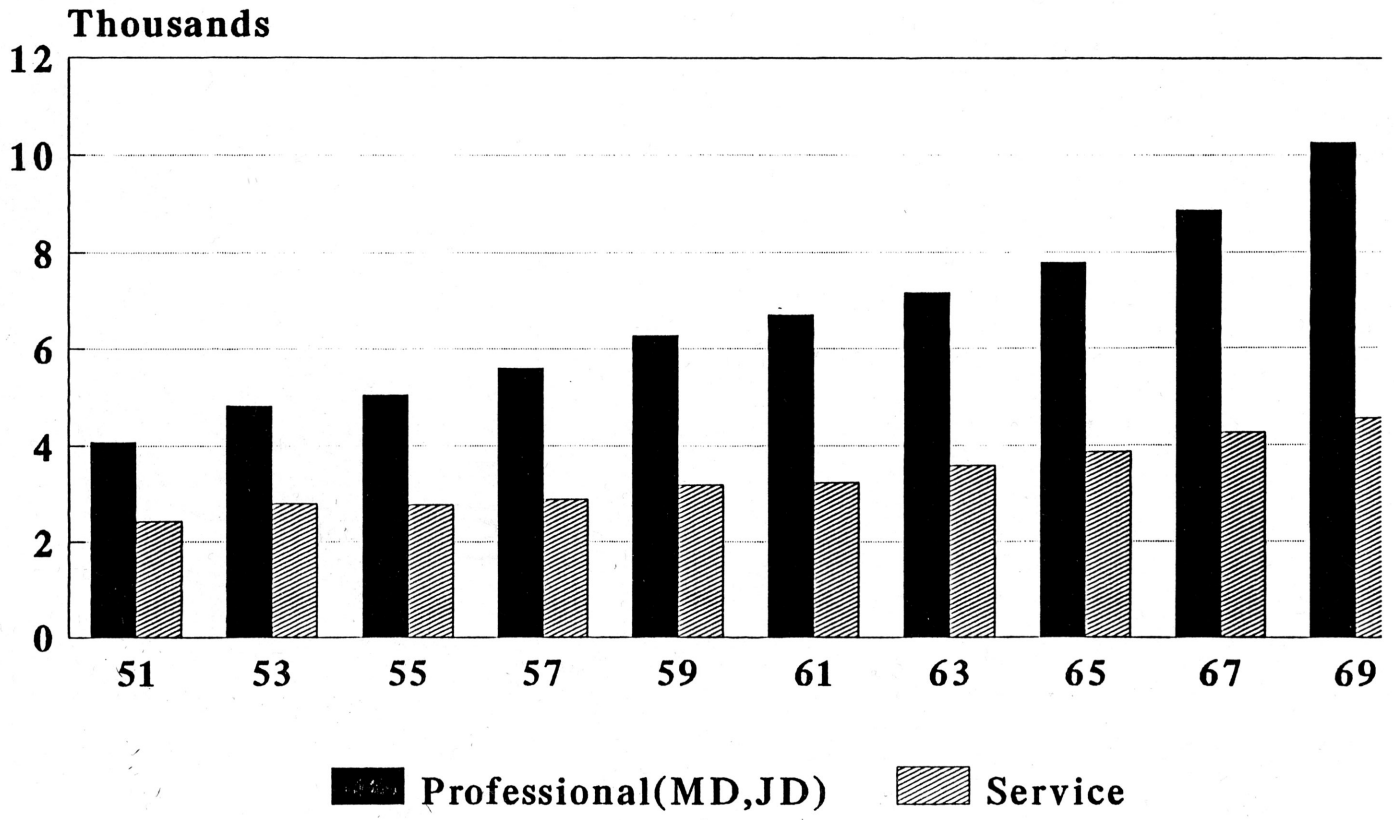
Appendix 1
Degrees Granted in U.S. Higher Education (1900-1970)



Source: Historical Statistics of the United States 1975, p.385

Appendix 2

Median Annual Money Wage (1951-6



Source: Employment and Earnings, 1975
p.304

Appendix 3

The University of Texas at Austin
College of Pharmacy
2-3 Program Type

GENERAL INFORMATION

In 1893 the twenty-third Texas Legislature added $2,500 to the budget of the Medical Branch of The University of Texas for the purpose of establishing "A School of Pharmacy." The School was thereupon established at Galveston in the fall of 1893, with Dr. James Kennedy, a practicing physician from San Antonio, elected as the first Professor of Pharmacy. Prior to studying medicine, Dr. Kennedy had been engaged in the practice of retail pharmacy in San Antonio, having learned the art in the Louisville (Kentucky) College of Pharmacy. Eleven students registered the first year, but Dr. Kennedy found the duties of his office not to his liking and resigned before the year ended. He was succeeded by R. R. D. Cline, a young man of twenty-six years, who for about thirty years guided the destiny of pharmaceutical education in Texas and came to be known affectionately by his students as "Daddy" Cline. It is his portrait that hangs in the Pharmacy Library.

The course of instruction, consisting at first of two sessions of seven months each, has been gradually increased to meet the demands of a progressing profession until it has attained its five-year program. In order to administer the rapidly expanding program of instruction with greater efficiency, the School was moved from Galveston to the Main University campus in 1927, the name changed to the College of Pharmacy, and the College became autonomous. Professor W. F. Gidley, who succeeded Dr. Cline in 1924 as Professor of Pharmacy was thereupon named as the first Dean of the College of Pharmacy. In this year the College was also admitted to membership in the American Association of Colleges of Pharmacy, the national accrediting group at that time. In 1947, Dr. Henry M. Burlage succeeded Professor Gidley in the deanship and served the College in this capacity until 1962. During his administration graduate programs were added; those leading to the Master of Science in Pharmacy were offered for the first time in the 1948-1949 Long Session and those leading to the Doctor of Philosophy for the first time in 1954-1955.

Thus, the College of Pharmacy has completed eighty-two years of service to the state and nation in the education of community and hospital pharmacists, teachers, and research workers. More than 4300 students have been awarded undergraduate or graduate degrees by the College, many of whom have attained national or international prominence in pharmacy or in related health fields.

CURRICULUM

The function and objectives of the College of Pharmacy are to expose young men and women who desire an education in the pharmaceutical sciences to the tutelage of teacher-scholars and an intellectually stimulating curriculum within adequate physical facilities so as to produce competent practitioners in the various branches of pharmaceutical services: Community pharmacists, hospital pharmacists, medical sales representatives, public health pharmacists, industrial pharmacists; and equally important, to stimulate and provide facilities for research and reflection at the graduate level with the aim of producing teachers, scholars-scientists in pharmaceutics, pharmacognosy, pharmaceutical chemistry, pharmacology, and pharmacy administration, who will be qualified to join with members of the other health sciences in the promotion of public health. Another important function of the College is to provide a program in continuing education for alumni and other pharmacists. This program consists of annual seminars and conferences held at the college and area seminars throughout various sections of the state and is a function of the Extension Division of the College.

REQUIREMENTS FOR ADMISSION

Admission to the College of Pharmacy, as to all other colleges and schools of The University of Texas at Austin, is under the control of the Director of Admissions. All correspondence prior to official acceptance to The University of Texas at Austin should be sent to that office. For general admission requirements, consult the General Information bulletin.

Credit may be given for pharmacy courses taken in another college of pharmacy accredited by the American Council on Pharmaceutical Education, this credit not to exceed the quantity of such courses prescribed in the first four years of the pharmacy curriculum of The University of Texas at Austin. Requests for advanced standing and transfer of credits from other schools should be sent to the Registrar of the University. For additional information, consult the General Information bulletin.

No student may begin the sequence of professional courses in the pharmacy curriculum until he has applied to and been formally accepted by the Acceptance Committee of the College of Pharmacy. In the event the number of eligible applicants exceeds the number of students that can be accommodated by the available facilities, final selection will be made by the Acceptance Committee.

At the present time the College of Pharmacy require the Pharmacy College Admissions Test (PCAT) for all students who plan to apply to the professional program beginning in the Fall of 1975.

It should be pointed out that submission of an application does not guarantee admission to the sequence of professional courses in the College of Pharmacy. The College of Pharmacy is operating on a limited enrollment, and the number of applications received usually exceeds the number of students that can be accepted. Therefore, each application will be examined carefully for evidence of scholastic merit, and each applicant will be notified by mail soon after the deadline date for submission regarding the action taken by the Acceptance Committee.

To be accepted:

1. The applicant must have completed at least sixty semester hours, including the following forty-five:

	Semester Hours
General biology or zoology.....at least	6
General chemistry (with laboratory).... " "	8
English composition (freshman level)... " "	6
Mathematics (thru 1st semester calculus)" "	6
Organic chemistry (with laboratory)....." "	8
General physics (with laboratory)..... " "	8
Economics..... " "	3

2. The remaining fifteen hours may be selected from:

	Semester Hours
History (United States)	6
Government (American)	6
English or speech (sophomore level)	6
Microbiology	4
Electives, not more than	8

3. The applicant should have a 2.0 grade-point average (c average) in all work undertaken, whether passed or failed. Work done at The University of Texas at Austin and work done elsewhere will be averaged separately.

4. Applicants who have not previously been registered in the College of Pharmacy must, in addition to the preceding, satisfy all of the University's requirements for admission as prescribed in the Catalogue for their specific classifications.

5. Applications for admission to the sequence of professional courses should be made on appropriate forms obtainable from the Office of the Dean, College of Pharmacy.

a. Students whose most recent registration has been in The University of Texas at Austin must submit a complete set of university transcripts and a photograph along with completed application blank.

b. Students who are transferring to The University of Texas at Austin for the first time must first be approved for admission to the University by the Registrar's Office. Upon receipt of such approval, the Dean's Office will furnish the appropriate blank for application to the professional courses. The completed application blank must be accompanied by a photograph and an additional set of transcripts from the college or colleges previously attended. These transcripts are in addition to one supplied to the Registrar's Office in applying for admission to the University.

The deadline dates for submission of applications are as follows:

Long Session	Fall -June 1
	Spring -October 1
Summer Session	February 1

Applications received after the deadline dates shown above will be considered only if the class is not already filled.

6. In the event that the number of eligible applicants exceeds the facilities available, the final selection will be made by the College of Pharmacy on the basis of the applicant's previous scholastic record and priority of date of application.

FINANCIAL AID

Even though tuition and fees are reasonable at the University, many students need more money than parents or relatives can furnish. The University provides assistance for such students in the form of scholarships, grants, loans, and assistance in finding employment.

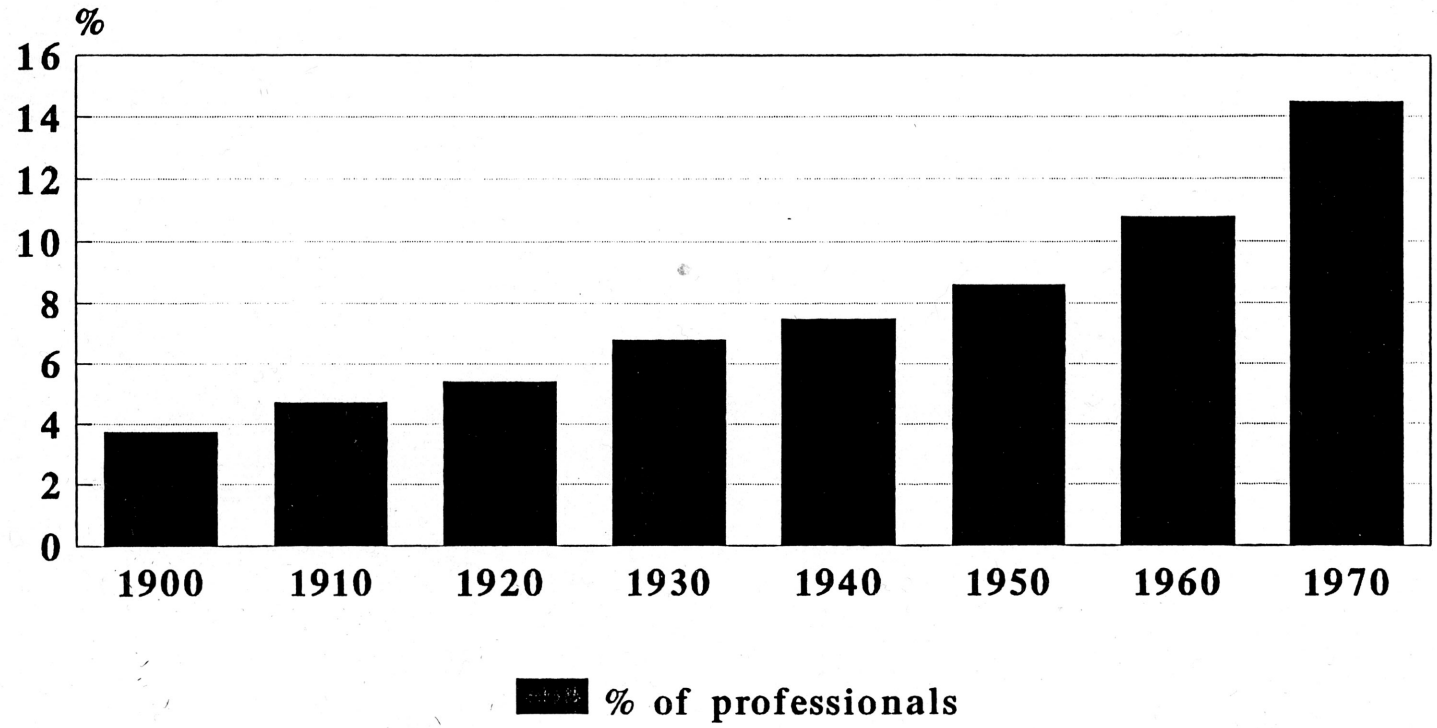
EXPENSES PER YEAR

Registration fee (for normal 15-hour load)	
For Texas Residents	$ 120.00
For citizens of other states of the U.S.	1200.00
For citizens of other countries than the U.S.	420.00
Required additional fees (hospital, required student activities, services, building use, and Union)	142.00
Miscellaneous fees (laboratory and physical training)	12.00
Optional student activities fee	18.40
Board and room	1100.00
Books and supplies	250.00
Personal expenses (excluding entertainment not included in student activities fee)	500.00
TOTAL, including optional fee	
For Texas residents	2142.40
For citizens of other states of the U.S.	3222.40
For citizens of other countries than the U.S.	2442.40

The figures given are representative, although some students manage on less, and many spend more.

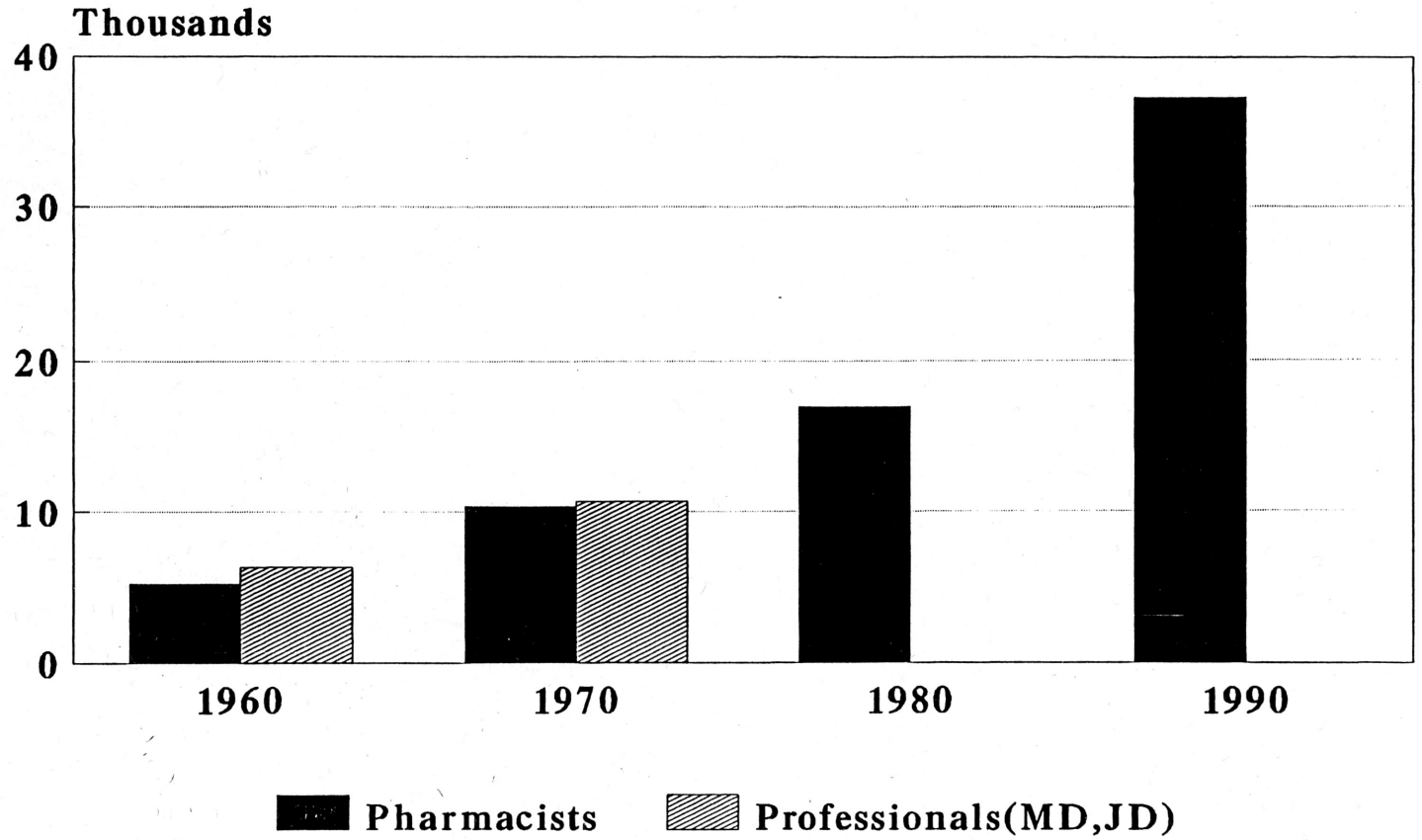
Source: University of Texas Pharmacy School Catalogue, 1975.

Appendix 4
Pharmacists as a Percent of Professionals



Source: Historical Statistics of the United States 1975, p.140

Appendix 5
Yearly Earnings (1960-90)



Source: Occupational Outlook Handbook

Model State Pharmacy Act

This model act was published by the National Association of Boards of Pharmacy in 1977.

An ACT concerning the regulation of the Practice of Pharmacy and related matters.

Be it enacted . . .

Introductory Comment to Article I

Article I of the MSPA sets forth the foundation upon which the Act is constructed. It clearly declares and acknowledges that safeguarding the public interest is the foremost compelling reason for regulating the Practice of Pharmacy. It also circumscribes the activities included within the Practice of Pharmacy, as well as the definitions of several other technical terms used through the Act.

The NABP believes that it is both desirable and necessary to recognize that the public interest must be the central precept in the MSPA and its administration, and that State Boards of Pharmacy must constantly strive to achieve the principals enunciated in Article I of the Act.

ARTICLE I

Title, Purpose and Definition

Section 101. Title of Act.

This Act shall be known as the "(Name of State) Pharmacy Act."

Section 102. Legislative Declaration.

The Practice of Pharmacy in the State of _____ is declared a professional practice affecting the public health, safety and welfare and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the Practice of Pharmacy, as defined in this Act, merit and receive the confidence of the public and that only qualified persons be permitted

to engage in the Practice of Pharmacy in the State of _____. This Act shall be liberally construed to carry out these objects and purposes.

Comment

Pharmacy is a learned profession affecting public health and welfare and should be declared as such by the State Legislature. The Practice of Pharmacy from time to time has been erroneously viewed, even by governmental agencies, as a commercial business rather than a profession. The status of pharmacy as a profession has been and will continue to be of particular importance in litigation.

Section 103. Statement of Purpose.

It is the purpose of this Act to promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the Practice of Pharmacy and of the registration of Drug Outlets engaged in the manufacture, production, sale and distribution of drugs, medications, devices and such other materials as may be used in the diagnosis and treatment of injury, illness and disease.

Comment

The Statement of Purpose is designed to define the general scope of the Pharmacy Act. It provides for the control and regulation of the practice and the registration of facilities engaged in the distribution of drugs. A board will have full knowledge of the whereabouts of drugs in the legitimate stream of intrastate commerce providing it with the ability to better prevent diversion, effectuate recalls and effectively protect the public.

Section 104. Practice of Pharmacy.

The "Practice of Pharmacy" shall mean the interpretation and evaluation of prescription orders; the compounding, dispensing, labeling of drugs and devices (except labeling by a manufacturer, packer or distributor of Non Prescription Drugs and commercially packaged legend drugs and devices); the participation in drug selection and drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records therefore; the responsibility for advising, where necessary or where regulated, of therapeutic values, content, hazards and use of drugs and devices; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy.

Comment

The definition of the "Practice of Pharmacy" is one of the most important and, perhaps, one of the most discussed clauses in the NABP Model Act. The Act limits the Practice of Pharmacy to those persons who are licensed pharmacists (with certain limited exceptions of Practitioners) and anyone not so licensed who engages in any of the facets of the practice as defined in this Section would be subject to penalties set forth in the Act.

The definition is purposely expressed in extremely broad terms to provide substantial latitude to the Board of Pharmacy in the adoption of implementing rules and regulations. Pharmacy has been a very dynamic profession, particularly, over the past several years and a broad definition of the practice will permit the Board to make necessary changes from time to time to meet the changing practice. Such changes may be effected by new or amended rules and regulations which would be promulgated pursuant to the requirements of the State Administrative Procedures Act affording all interested parties opportunity to review and comment on any proposed regulations.

The language "participation in drug selection" as used in the definition, refers to consultation with physicians in the selection of the best possible drug for a particular patient. It would most generally be applicable to the clinical setting. The Model Act was not intended to cover the question of drug substitution by a pharmacist and it is not contemplated that this provision be interpreted or implemented by a board in this regard. Drug substitution is a policy question which should be decided by each individual state and specifically covered by statute.

Section 105. Definitions.

1. "Board of Pharmacy" or "Board" means the _____ State Board of Pharmacy.

2. "Deliver" or "Delivery" means the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

3. "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under federal or state law to be prescribed by a Practitioner and dispensed by a Pharmacist.

Comment

The federal government exercises strict control over the production and sale of devices pursuant to the Federal Food Drug & Cosmetic Act (21 U.S.C.A. 360 et seq.). These federal restrictions are not applicable to pharmacies, however (21 U.S.C.A. 360 (g) (1)). The MSPA is made applicable only to these devices which are required to be dispensed by a pharmacist and it is contemplated that the Board would regulate only the dispensing aspects of devices. Boards must carefully avoid regulations that may be contrary to or pre-empted by federal law.

4. "Dispense" or "Dispensing" shall mean the preparation and delivery of a prescription drug pursuant to a lawful order of a Practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

5. "Distribute" means the delivery of a drug other than by administering or dispensing.

6. "Drug" means:

(i) Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homepathic Pharmacopia, other drug compendium or any supplement to any of them;

(ii) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal;

(iii) Articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(iv) Articles intended for use as a component of any articles specified in clause (i), (ii) or (iii) of this subsection.

7. "Drug Outlet" shall mean all pharmacies, nursing homes, convalescent homes, extended care facilities, drug abuse treatment centers, penal institutions, hospitals, family planning clinics, retail stores, wholesalers, manufacturers and mail order vendors with facilities located in this state which are engaged in dispensing, delivery or distribution of drugs.

8. "Labeling" shall mean the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a Non Prescription Drug or commercially packaged legend drug or device. Any such label shall include all information required by Federal and State law or regulation.

9. "Manufacture" shall mean the production, preparation, propagation, compounding, conversion, or processing of a Device or a Drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a drug by an individual for his own use or the preparation, compounding, packaging or labeling of a drug (i) by a pharmacist or practitioner as an incident to his administering or dispensing of a drug in the course of his professional practice or (ii) by a practitioner or by his authorization under his supervision for the purpose of or as an incident to research, teaching, or chemical analysis and not for sale.

10. "Manufacturer" shall mean a person engaged in the manufacture of drugs in facilities located within this state.

11. "Person" shall mean an individual, corporation, partnership, association or any other legal entity.

12. "Pharmacist" shall mean an individual licensed by this State to engage in the Practice of Pharmacy.

13. "Practitioner" shall mean a physician, dentist, veterinarian, scientific investigator or other person (other than pharmacists) licensed by this State and permitted by such license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research in this state.

Comment

The definition of "Practitioner" anticipates that those persons other than pharmacists who are permitted to distribute, dispense, administer or otherwise work with drugs will be specifically so authorized in other legislation. The phrase ". . .other persons licensed by this state and permitted by such license to dispense . . ." is meant to include individuals not specifically named such as podiatrists, osteopaths, etc. Such individuals could, of course, be specifically included in this definition if such inclusion is deemed desirable.

14. "Prescription Drug or Legend Drug" shall mean a drug which, under Federal Law is required, prior to being dispensed or delivered, to be labeled with either of the following statements: (i) "Caution: Federal law prohibits dispensing without prescription;" (ii) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian;" or a drug which is required by any applicable Federal or State Law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.

15. "Prescription Drug Order" shall mean a lawful written or verbal order of a Practitioner for a drug.

16. "Non Prescription Drugs" shall mean non-narcotic medicines or drugs which may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this State and the federal government.

17. "Wholesaler" shall mean a person with facilities located in this State, who buys drugs for resale and distribution to persons other than consumers.

Introductory Comment to Article II

Before it can regulate the Practice of Pharmacy, the State must first establish and empower the Board of Pharmacy. Accordingly, Article II of the MSPA defines and creates the Board of Pharmacy by specifying elements necessary to its formation, organization and operation.

Each of the fifteen sections contained in this article covers elements which the NABP felt necessary to the proper formation and efficient operation of the Board. Several of these sections, especially those which contain innovative or infrequently utilized provisions, are supplemented by individual explanatory comments.

Among the sections of Article II that may be of particular interest to users of the MSPA are the following: Sections 202 and 203(a), pertaining to the inclusion of public members as Board members; Section 204(c), which contains language to clarify the legal status of newly-appointed Board members during pendancy of their confirmation proceedings; Section 207, which provides grounds and procedures for removal of Board members, something which most State acts do not now address; and, Section 215(f), which enables Boards to avail themselves of research and study grants and other non-State monies without having to deposit such funds in State general revenue accounts (thereby loosing control over expenditure of such funds).

It is also important to note that Section 212 specifically empowers the Board to make such rules and regulations as are necessary to fully administer and implement the MSPA. This is a most significant feature of the Act. The underlying philosophy of this approach is that the statute should create goals, guidelines and policies in general areas, and permit the Board to provide the specifics in its rules and regulations. This approach recognizes that it is impossible for State legislatures to enact comprehensive provisions regarding all of the matters with which a Board of Pharmacy may be confronted or to anticipate the rapidly changing conditions of the professions. Consequently, NABP recommends that Boards have adequate power to adopt and amend rules and regulations with greatest possible flexibility and autonomy. Section 212 of the MSPA accomplishes this objective. (Caution: See Comment to Section 212.)

ARTICLE II

Board of Pharmacy

Section 201. Designation.

The responsibility for enforcement of the provisions of this Act is hereby vested in the Board of Pharmacy. The Board shall have all of the duties, powers and authority specifically granted by and necessary to the enforcement of this Act, as well as such other duties, powers and authority as it may be granted from time to time by appropriate statute.

Section 202. Membership.

The Board of Pharmacy shall consist of (number) members, [one (1) of whom shall be a representative of the public, and the remainder] (each) of whom shall be licensed pharmacists who possess the qualifications specified in Section 203.

Comment

The number of Board members should be determined by each individual State according to its particular requirements. Variable factors such as State population, number of pharmacists, number of pharmacies and other local considerations may all be relevant to determining the number of Board members needed to most effectively enforce the Act. In most States, the total number of Board members selected is an odd number so that determinations by a clear majority may be made.

In the event a state prefers to limit the board membership to licensed pharmacists, the bracketed language pertaining to a public member should be deleted, as should Section 203(a). In this event, the alternative "each" should be selected, and Section 203(b) should be renumbered as Section 203.

Section 203. Qualifications.

[(a) Public Member. The public member of the Board of Pharmacy shall be a resident of this State who has attained the age of majority and shall not be nor shall he ever have been a member of the profession of pharmacy, or the spouse of a member of the profession of pharmacy, or a person who has ever had any material financial interest in the providing of pharmacy service or who has engaged in any activity directly related to the Practice of Pharmacy.]

Comment

Specific qualifying criteria for the public member have been deliberately omitted from this section. Reliance has been placed in the Governor to determine what attributes an individual should possess in order to meaningfully serve on a board of pharmacy. In order to help assure that such a member would be truly independent in his judgments, those persons who have a possible substantial relationship with the profession are rendered ineligible by this section.

(b) Licensed Pharmacists. The licensed pharmacist members of the Board of Pharmacy shall at the time of their appointment:

(1) Be residents of this State;

(2) Be licensed and in good standing to engege in the Practice of Pharmacy in this State;

(3) Be engaged in the Practice of Pharmacy in this State;

(4) Have five (5) years of experience in the Practice of Pharmacy in this State after licensure.

Comment

Section 203(b) of the Act requires that a pharmacist be engaged in the Practice of Pharmacy at the time of his appointment as a board member and that he have at least five (5) years of experience in the practice prior thereto. Since the Practice of Pharmacy is defined in Section 104 in broad terms, it renders a pharmacist involved in almost any phase of the practice eligible for appointment. These requirements should provide candidates who have divergent backgrounds and experiences and who are knowledgeable in the affairs of the profession.

Section 204. Appointment.

(a) Governor. The Governor shall appoint the members of the Board of Pharmacy, subject to the advice and consent of the Senate, and in accordance with other provisions of this Section.

(b) Senate. The Senate shall, in its discretion, either confirm or reject the Governor's appointments to the Board. A vote of (number or fraction) of the members of the Senate then present and voting shall be required for confirmation.

Comment

In certain jurisdictions the necessary vote for confirmation by the Senate of administrative appointments is set forth in the State Constitution. Any statutory provision should, of course, conform to the constitutional requirements.

(c) Effect of Appointment. The Board shall be properly constituted in all respects from the time of commencement of each member's term, including during pendency of Senate confirmation proceedings and until the Senate has acted upon each appointment. If an appointee is thereafter confirmed by the Senate, the Board shall continue to be properly constituted. If an appointee is thereafter rejected by the Senate, the rejected appointee shall cease to be a member of the Board upon being personally served with written notice of such rejection. The President of the Senate shall cause such notice to issue and to be served by the Executive Director of the Board. A copy of such notice shall also be personally served upon the President of the Board. Any action taken by the Board prior to the rejection of the appointee in which the appointee has participated shall be valid, but any action taken after such notice is duly served and in which the rejected appointee participates as a Board member shall be voidable.

Comment

In the past, there has been confusion concerning precisely when an appointee may fully participate in all Board matters. The lack of a Board member for lengthy periods is of concern because it may severely hamper the Board's efficiency, particularly in States with small Board membership or in those where legislatures meet biennially. In some states, where new appointees begin serving on the Board immediately, subsequent Senate rejection can raise questions concerning validity of proceedings. This has occurred in at least one case. See, **e.g., Board of Medical Examiners v. Steward,** *102 A. 2d 248 (Md., 1954);* **cf. Norris v. Gilmer,** *32 S.E. 2d 88, 183 Va. 367 (1944); but see* **Ricks v. Louisiana Milk Comm.,** *32 So. 2d 643 (La. App., 1947).*

Subsection 204(c) is intended to alleviate these potential problems and concerns. It clearly sets forth the status of appointees prior to their Senate confirmation; and, it enables the Board to conduct its business fully staffed and without fear of subsequent challenge. It would appear that such a provision is legally valid.

(d) Nominations. Nominations for appointment to the Board may be made to the Governor by any interested individual, association or any other entity provided that such nomination shall be supported by a nominating petition executed by at least 100 individuals who shall be qualified to vote in the state elections in this State. Such nominations shall be recommendations only and shall not be binding in any manner upon the Governor.

Comment

The purpose of Section 204(d) is to provide a mechanism through which any interested person or group may designate a candidate for the board. The requirement of the nominating petition is to insure the genuine interest of the nominating party or group and, at least, minimal support for the nominee. Since the petitions are recommendations only, the Governor retains complete discretion in regard to the appointees.

Section 205. Terms of Office.

(a) Length. Except as provided in subsection (b), members of the Board of Pharmacy shall be appointed for a term of (number) years, except that members of the Board who are appointed to fill

vacancies which occur prior to the expiration of a former member's full term shall serve the unexpired portion of such term.

(b) Staggered Terms. (1) The terms of the members of the Board shall be staggered, so that the terms of no more than (number) member(s) shall expire in any year.

(2) The present members of the Board shall serve the balance of their terms.

(3) Any present board member appointed initially for a term of less than (number) years shall be eligible to serve for two (2) additional full terms.

(c) Successorship. No member of the Board shall serve more than two (2) consecutive full terms. The completion of the unexpired portion of a full term shall not constitute a full term for purposes of this Section.

(d) Commencement. An appointee to a full term on the Board shall be appointed by the Governor before the expiration of the terms of the member being succeeded, and shall become a member of the Board on the first day of the state fiscal year next following his appointment. Appointees to unexpired portions of full terms shall become members of the Board on the day next following such appointment. In the event the number of Board members is increased, the term of any new member shall commence at such time as is designated in the statute providing for the enlargement of the board.

(e) Expiration. Each term of office on the Board shall expire at midnight on the last day of the state fiscal year in the final year of the Board member's term or on the date his or her successor is appointed and qualified (except for Senate confirmation) whichever shall later occur.

Section 206. Vacancies.

Any vacancy which occurs in the membership of the Board for any reason, including expiration of term, removal, resignation, death, disability or disqualification, shall be filled by the Governor in the manner prescribed by Section 204. The Governor shall fill vacancies which occur by expiration of full terms within ninety (90) days prior to each date of expiration, and shall fill vacancies which occur for any other reason within sixty (60) days after each such vacancy occurs. Any nominating petition submitted to the Governor pursuant to Section 204 within one (1) year previous to the time when any vacancy occurs may be resubmitted to the Governor to nominate an individual to fill such vacancy.

Section 207. Removal.

(a) Grounds. The Governor may remove a member of the Board, pursuant to the procedures set forth in subsection (b) hereinbelow, upon one or more of the following grounds.

(1) The refusal or inability for any reason of a Board Member to perform his duties as a member of the Board in an efficient, responsible and professional manner;

(2) The misuse of office by a member of the Board to obtain personal, pecuniary or material gain or advantage for himself or another through such office;

(3) The violation by any member of this Act or any of the rules and regulations adopted hereunder.

(b) Procedures. The following procedures shall be utilized to remove a member of the Board from office for any of the grounds specified by subsection (a) above.

(1) Any person including the Governor or a Board member may file a complaint with the Executive Director of the Board against a member of the Board alleging specific facts which constitute grounds for removal from the Board. The Executive Director shall notify the President of the Board, the accused member and the Governor of the filing of any such allegations and supply each with a copy of the complaint.

(2) Upon the written recommendation of the Governor or two-thirds (2/3) of the members of the Board, a hearing shall be conducted before an impartial hearing officer pursuant to the State Administrative Procedures Act. The hearing officer shall submit a transcript of the hearing to the Governor and shall recommend whether or not the Board member shall be removed.

(3) The Governor shall review the transcript of any such hearing, determine whether there is substantial evidence to support a finding that a member of the Board has engaged in conduct which constitutes grounds for removal from the Board, and shall enter a finding in accordance with such determination. In the event a Board member is removed hereunder, his removal shall be effective as of the date of the Governor's finding for removal, and a vacancy shall be deemed to exist.

(4) Any individual subjected to possible removal under this Section 207 shall be entitled to those privileges, protections and rights granted all persons under the Administrative Procedures Act of this State, including the right of a review by a court of competent jurisdiction.

Comment

In certain jurisdictions there may be general statutory provisions which establish the procedures and grounds for the removal of appointed public officials. In these jurisdictions you may wish to disregard Section 207.

See Comment to Section 212 for discussion of the reference in subsection 207(b) to an Administrative Procedures Act.

Section 208. Organization.

(a) Officers. The Board of Pharmacy shall elect from its members a President and such other officers as it deems appropriate and necessary to the conduct of its business. The President of the Board of Pharmacy shall preside at all meetings of the Board and shall be responsible for the performance of all of the duties and functions of the Board required or permitted by this Act. Each additional officer elected by the Board shall perform those duties normally associated with his position and such other duties assigned to him from time to time by the Board.

(b) Terms of Office. Officers elected by the Board shall serve terms of one (1) year commencing with the day of their election, and ending upon election of their successors and shall serve no more than (number) consecutive full terms in each office to which they are elected.

(c) Executive Director. The Board shall employ a licensed pharmacist who shall be an ex officio member of the Board without vote to serve as a full-time employee of the Board in the position of Executive Director. The Executive Director shall be responsible for the performance of the regular administrative functions of the Board and such other duties as the Board may direct. The Executive Director shall not perform any discretionary or decision-making functions for which the Board is solely responsible.

Comment

The NABP urges that every Board have a permanent administrative official, an Executive Director, to perform and supervise the administrative duties and functions for which the Board is responsible on a day-to-day basis. The Executive Director should be an ex officio member of the Board (without vote) to insure his eligibility to serve on committees and in elected positions with NABP.

Section 209. Compensation.

(a) Board Members. Each member of the Board of Pharmacy shall receive, as compensation, the sum of (number) per day for each day on which the member is engaged in performance of the official duties of the Board, and reimbursement for all expenses incurred in connection with the discharge of such official duties.

(b) Executive Director. The Executive Director of the Board of Pharmacy shall receive, as compensation, an annual salary payable monthly, the amount of which shall be determined by the Board, and reimbursement for all expenses incurred in connection with performance of his official duties.

Section 210. Meetings.

(a) Number. The Board of Pharmacy shall meet at least once every (number) months to transect its business. One such meeting held during each fiscal year of the State shall be designated as the annual meeting and shall be for the purpose of electing officers and for the reorganization of the Board. The Board shall meet at such additional times as it may determine. Such additional meetings may be called by the President of the Board or by two-thirds (2/3) of the members of the Board.

(b) Place. The Board shall meet at such place as it may from time to time determine. The place for each meeting shall be determined prior to giving notice of such meeting and shall not be changed after such notice is given without adequate subsequent notice.

(c) Notice. Notice of all meetings of the Board shall be given in the manner and pursuant to requirements prescribed by the State's applicable statutes, rules and regulations.

(d) Quorum. A majority of the members of the Board shall constitute a quorum for the conduct of a Board meeting and, except where a greater number is required by this Act, or by any rule or regulation of the Board, all actions of the Board shall be by a majority of a quorum.

(e) Open Meetings. All Board meetings and hearings shall be open to the public. The Board may, in its discretion and according to law, conduct any portion of its meeting in executive session closed to the public.

Comment

Many states have adopted "sunshine" laws which provide for open meetings. Section 210 (e) may not be necessary or may need revision to eliminate executive sessions.

Section 211. Employees.

(a) Authority. The Board of Pharmacy may, in its discretion, employ persons in addition to the Executive Director in such other positions or capacities as it deems necessary to the proper conduct of Board business and to the fulfillment of the Board's responsibilities as defined by this Act.

(b) Compensation. The employees of the Board other than the Executive Director shall receive, as compensation, an annual salary payable monthly, the amount of which shall be determined by the Board (or by State statute where required), and reimbursement for all expenses incurred in connection with performance of their official duties.

Section 212. Rules and Regulations.

The Board of Pharmacy shall make, adopt, amend and repeal such rules and regulations as may be deemed necessary by the Board, from time to time, for the proper administration and enforcement of this Act. Such rules and regulations shall be promulgated in accordance with the procedures specified in the Administrative Procedures Act of this State.

Comment

Sections 207(b), 212, 215(k), and others of the MSPA refer to a State Administrative Procedures Act (SAPA's). The entire MSPA has been drafted so as to rely upon the existence of SAPA's in each State for specification of appropriate constitutionally required procedures for rule-making, conduct of hearings and other Board functions that may touch upon the right of the public and affected individuals to be afforded due process of law in such matters. These procedures are necessary to meet the fundamental fairness criteria of procedural due process, e.g., notice, specification of charges, opportunity to be heard, fair and impartial tribunal, cross-examination, and the like.

The NABP recognizes that not all states have SAPA's, that all SAPA's are not alike, and that some states enact procedural provisions directly as part of each Pharmacy Act. Nevertheless, to provide a uniform procedural basis for the MSPA, it has been assumed that all States have SAPA's and that all SAPA's are substantially similar to the Revised Model SAPA promulgated by the National Conference of Commissioners on Uniform State Laws. These assumptions were predicated upon a NABP study indicating that at least 41 States have SAPA's of one sort or another; 17 of these States have adopted the Revised Model SAPA substantially in tact; and, another 12 States have SAPA's that are very similar to the Revised Model SAPA.

For those states without a SAPA or whose procedures acts or provisions are not at all similar to the Revised Model SAPA, the NABP strongly urges its adoption by enactment or appropriate Board rule.

For all states, the NABP urges that their respective SAPA's include provision for meeting the following minimum standards:

(i) personal service on individuals accused of violations of disciplinary provisions;

(ii) written, specific allegations of charges;

(iii) specification of some maximum time within which the accused may respond to the complaint, and of a minimum time thereafter within which to hold the hearing (both such times should be reasonable);

(iv) representation of accused by legal counsel;

(v) hearing by Hearing Officer or other impartial person or persons, where practical;

(vi) subpoena power for accused to compel attendance of witnesses at hearings;

(vii) confrontation (cross-examination) of witnesses by accused;

(viii) rules for conduct of hearings;

(ix) rules for promulgation and adoption of rules and regulations, including public notice and public hearing prior to adoption; and,

(x) appellate procedures for judicial review of administrative board decisions.

Section 213. Licensure and Discipline.

(a) Responsibility. The Board of Pharmacy shall be responsible for the control and regulation of the Practice of Pharmacy in this State including, but not limited to, the following:

(1) The licensing by examination or by reciprocity of applicants who are qualified to engage in the Practice of Pharmacy under the provisions of this Act;

(2) The renewal of licenses to engage in the Practice of Pharmacy;

(3) The determination and issuance of standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this State, and the specification and enforcement of requirements for practical training, including internship.

Comment

Great care should be exercised by the Boards with respect to this Section. Many states have statutes or regulations which provide that approved or accredited degree programs of schools or colleges of pharmacy are those approved by the American Council on Pharmaceutical Education (ACPE).

It is a well-established rule of administrative law that any delegation of governmental power must carry with it appropriate limitations and procedural safeguards for affected individuals. Thus, a direct, unequivocal grant of the accreditation function to a private organization, such as ACPE, might be deemed an unauthorized, improper and invalid delegation of Board or legislative authority. An NABP study of this question discovered at least one case where a court overturned a Board action based upon such invalid delegation to a private body. See Garces v. Department of Registration and Education, *254 N.E. 2d 622 (Ill. App., 1969).*

NABP urges all boards to adopt the standards of accreditation established from time to time by the ACPE, the recognized accrediting agency for pharmacy degree programs.

(4) The enforcement of those provisions of this Act relating to the conduct or competence of pharmacists practicing in this State, and the suspension, revocation or restriction of licenses to engage in the Practice of Pharmacy.

(5) The regulation of the training, qualifications and employment of pharmacy interns.

Section 214. Medications, Drugs, Devices and Other Materials.

(a) Responsibility. The Board of Pharmacy shall also have the following responsibilities in regard to medications, drugs, devices and other materials used in this State in the diagnosis, mitigation and treatment or prevention of injury, illness and disease:

(1) The regulation of the sale at retail and the dispensing of medications, drugs, devices and other materials including the right to seize any such drugs, devices and other materials found to be detrimental to the public health and welfare by the Board after appropriate hearing as required under the Administrative Procedures Act;

(2) The specifications of minimum professional and technical equipment, environment, supplies and procedures for the compounding and/or dispensing of such medications, drugs, devices and other materials within the Practice of Pharmacy;

(3) The control of the purity and quality of such medications, drugs, devices and other materials within the Practice of Pharmacy;

(4) The issuance and renewal of certificates of registration of Drug Outlets for purposes of ascertaining those persons engaged in the manufacture and distribution of drugs.

Section 215. Other Duties, Powers and Authority.

The Board of Pharmacy shall have such other duties, powers and authority as may be necessary to the enforcement of this Act and to the enforcement of Board rules and regulations made pursuant thereto, which shall include, but are not limited to, the following:

(a) Professional Associations. The Board may join such professional organizations and associations organized exclusively to promote the improvement of the standards of the Practice of Pharmacy for the protection of the health and welfare of the public and whose activities assist and facilitate the work of the Board.

(b) Bond. In addition to any statutory requirements, the Board may require such surety bonds as it deems necessary to guarantee the performance and discharge of the duties of any officer or employee receiving and disbursing funds.

(c) Seal. The Executive Director of the Board shall keep the seal of the Board and shall affix it only in such manner as may be prescribed by the Board.

(d) Reports. On or before the 60th day after the last day of each state fiscal year, the Board shall submit to the Governor a report summarizing its proceedings and activities during that fiscal year, together with a report of all monies received and disbursed by the Board. Such reports, or comprehensive summaries or abstracts thereof, as determined by the Board, shall be made available to the public.

(e) Fees. (1) Amount. The Board shall determine within thirty (30) days prior to the beginning of each state fiscal year the fees to be collected for:

(i) Examinations and re-examinations, which fee shall not exceed $_____;
(ii) The issuance of licenses, which fee shall not exceed $_____;
(iii) The issuance of certificates of registration and renewal certificates of registration, which fee shall not exceed $_____; and
(iv) The certification of approved providers of continuing education courses, which fee shall not exceed $_____.

(2) Accounting. [The procedures concerning fiscal policies are normally determined by the state constitution and state statutes. The appropriate procedures to be followed may be inserted as this subsection (i.e., whether fees should be paid into the state general revenue fund or directly to the Board.) It may not be necessary to cover this topic of adequately covered in other statutory provisions or in the State Constitution.]

(f) Grants. The Board may receive and expend funds, in addition to its [annual biennial] appropriation, from parties other than the State, provided:

(1) Such funds are awarded for the pursuit of a specific objective which the Board is authorized to accomplish by this Act, or which the Board is qualified to accomplish by reason of its jurisdiction or professional expertise;

(2) Such funds are expended for the pursuit of the objective for which they are awarded;

(3) Activities connected with or occasioned by the expenditures of such funds do not interfere with or impair the performance of the Board's duties and responsibilities and do not conflict with the exercise of the Board's powers as specified by this Act;

(4) Such funds are kept in a separate, special state account; and

(5) Periodic reports are made to the Governor concerning the Board's receipt and expenditure of such funds.

(g) Uniform State Number. The Board shall assign to each drug outlet under its jurisdiction, a uniform State number, coordinated where possible with all other states which adopt the same uniform numbering system.

(h) Investigatory Powers. The Board or its authorized representatives shall also have power to investigate and gather evidence concerning alleged violations of the provisions of this Act or of the rules and regulations of the Board.

(j) Embargo. (i) Notwithstanding anything in this Act to the contrary, whenever a duly authorized representative of the Board finds or has probable cause to believe that any drug, or device is adulterated or misbranded within the meaning of the (State) Food and Drug Act, he shall affix to such drug or device a tag or other appropriate marking giving notice that such article is or is suspected of being adulterated or misbranded, has been detained or embargoed and warning all persons not to remove or dispose of such article by sale or otherwise until provision for removal or disposal is given by the Board, its agent or the court. No person shall remove or dispose of such embargoed drug or device by sale or otherwise without the permission of the Board or its agent or, after summary proceedings have been instituted, without permission from the Court.

(ii) When a drug or device detained or embargoed under Paragraph (i) of this subparagraph (j) has been declared by such representative to be adulterated or misbranded, the Board shall, as soon as practical thereafter, petition the Judge of the _____Court in whose jurisdiction the article is detained or embargoed for an order for condemnation of such article. If the judge determines that the drug or device so detained or embargoed is not adulterated or misbranded, the Board shall direct the immediate removal of the tag or other marking.

(iii) If the court finds the detained or embargoed drug or device is adulterated or misbranded, such drug or device, after entry of the decree, shall be destroyed at the expense of the owner under the supervision of a Board representative and all court costs and fees, storage and other proper expense shall be borne by the owner of such drug or device. When the adulteration or misbranding can be corrected by proper labeling or processing of the drug or device, the Court, after entry of the decree and after such costs, fees and expenses have been paid and a good and sufficient bond has been posted, may direct that such drug or device be delivered to the owner thereof for such labeling or processing under the supervision of a Board representative. Expense of such supervision shall be paid by the owner. Such bond shall be returned to the owner of the drug or device on representation to the Court by the Board that the drug or device is no longer in violation of the embargo and the expense of supervision has been paid.

(iv) It is the duty of the Attorney General [State's Attorney] to whom the Board reports any violation of this subsection to cause appropriate proceedings to be instituted in the proper court without delay and to be prosecuted in the manner required by law. Nothing in this subparagraph (j) shall be construed to require the Board to report violations whenever the Board believes the public's interest will be adequately served in the circumstances by a suitable written notice or warning.

(k) Procedure. Except as otherwise provided to the contrary, the Board shall exercise all of its duties, powers and authority in accordance with the State Administrative Procedures Act.

Comment

See Comment to Section 212.

Introductory Comment to Article III

Article III of the MSPA specifies the requirements for initial licensure of pharmacists, licensure by reciprocity and renewal of licenses. In each of these areas, the Act sets forth basic criteria and delegates to the Board the authority for implementing those criteria. The Board does this by utilizing appropriate administrative enforcement mechanisms and by issuance of specific rules and regulations.

Section 301 establishes the basis for this Article by making it unlawful for any unlicensed person to engage in the Practice of Pharmacy, and by enabling the Board to exact penalties for unlawful practice.

In the area of initial licensure (Section 302), the Board must implement the Act by approving (accredited) degree programs of pharmacy, by specifying the examination to be employed (Section 302(a)) by establishing internship standards (Section 302(b)), and by insuring that all other prerequisites are met by each applicant to whom it issues a license.

The Act also reflects the efforts of NABP to continue uniform standards for licensure by reciprocity (Section 303).

ARTICLE III

Licensing

Section 301. Unlawful Practice.

(a) Applicability. It shall be unlawful for any person to engage in the Practice of Pharmacy unless licensed to so practice under the provisions of this Act; provided, however, physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of this State may dispense and administer prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by statute of this State.

(b) Penalties. Any person who shall be found by the Board to have unlawfully engaged in the Practice of Pharmacy shall be subject to a fine to be imposed by the Board not to exceed $_____for

each offense. Each such violation of this Act or the rules and regulations promulgated hereunder pertaining to unlawfully engaging in the Practice of Pharmacy shall also constitute a (misdemeanor) punishable upon conviction as provided in the criminal code of this State.

Comment

Boards of Pharmacy are often confronted with the problem of preventing unlicensed individuals from engaging in one or more facits of the Practice of Pharmacy. Most pharmacy acts do not confer jurisdiction in the Board to take action against individuals other than those who are licensed or seeking licensure in the profession. Since on many occasions, Boards have experienced difficulty in persuading local prosecutors to take action against persons not associated with the licensure aspects of the profession, these persons have not been effectively prevented from engaging in illicit practices.

The regulation of the Practice of Pharmacy including the control of unlicensed practice in the profession has a reasonable and rational relationship to public health, safety and welfare. See, e.g., State v. Wakeen, *57 N.W. 2d 364 (Wis., 1953).* cf. State v. VanKeegan, *113 A. 2d 141 (Conn., 1955)* and Williamson v. Lee Optical of Oklahoma, *348 U.S. 483 (1955) concerning prohibitions on the unlicensed practice of ophthalmology. For this reason vesting the power in the Board to regulate the illicit practice would not appear to be violative of the constitutional due process requirements. Since monetary fines are not generally considered criminal sanctions, it can be forcibly argued that there are no constitutional barriers impeding the imposition of fines by a Board of Pharmacy. See, e.g.,* Helvering v. Mitchell, *303 U.S. 376 (1938);* City of Waukegan v. Pollution Control Board, *311 N.E. 2d 146 (Ill., 1974);* County Council for Montgomery County v. Investors Funding Corp., *312 A. 2d 225 (Md., 1973);* Rody v. Hollis, *500 P. 2d 97 (Wash., 1972).*

One area that could present a serious question of law in regard to Section 301(b), however, involves the constitutional limitation on the delegation of authority to administrative agencies. It is likely that the delegation contemplated in Article III of the MSPA would be valid in a majority of jurisdictions. See, e.g., Jordan v. Board of Insurance, *334 S.W. 2d 278 (Tex., 1960);* Sutherland v. Ferguson, *397 P. 2d 335 (Kan., 1964);* Kovack v. Licensing Board of City of Waterville, *173 A. 2d 554 (Me., 1961); see generally L. Davis,* Administrative Law Treatise, *Section 2.10 (1970 Suppl.). You should be cautioned, however, that certain jurisdictions require very specific standards in a delegation of authority that could render Section 301(b) constitutionally suspect. See, e.g.,* People v. Tibbits, *305 N.E. 2d 152 (Ill., 1973);* Sarasota County v. Berg, *302 So. 2d 737 (Fla., 1974). In these jurisdictions, revisions of Article III may be necessary.*

Section 302. Qualifications for Licensure by Examination.

(a) Requirements. To obtain a license to engage in the Practice of Pharmacy, an applicant for licensure by examination shall:

(1) Have submitted a written application in the form prescribed by the Board of Pharmacy.

(2) Have attained the age of majority.

(3) Be of good moral character and temperate habits.

Comment

State legislatures have generally agreed that "good character" is a proper requirement for licensure of pharmacists. Defining precisely what constitutes good or bad character has caused health regulatory boards and courts considerable difficulty, however. A review of applicable case law reveals a considerable variance in the judicial opinions concerning the interpretation of good character requirements. Nevertheless, the courts have uniformly enforced such requirements, reasoning that because health regulatory boards are primarily composed of members of the profession being regulated, they are capable of applying such standards to their respective professions with specificity and exactness.

Thus, requirements of good character for licensure can be expected to be sustained by the courts so long as their enforcement is reasonably related to protection of the public health, safety and welfare. While specific character requirements for pharmacists may vary from state to state, and even may appear to vary from case to case, the purpose of these character requirements does not vary. The public has the right to expect the highest degree of integrity from members of the pharmaceutical profession. Boards of Pharmacy have a duty to make such expectations realized. Thus, pharmacy act provisions which bear a reasonable relationship to the purpose of protecting the public welfare will generally be sustained as constitutionally acceptable by most courts, so long as their enforcement by Boards is reasonably related to protection of the public.

(4) Have graduated and received the first professional undergraduate degree from an accredited pharmacy degree program which has been approved by the Board of Pharmacy.

Comment

It is contemplated that boards will accredit those programs whose standards are at least equivalent to the minimum standards required by the American Council on Pharmaceutical Education. This would include college structured externship programs and continuing education programs. See Comment to Section 213(a)(3) above for further discussion of the Board's proper role in the accreditation process.

(5) Have completed an internship or other program which has been approved by the Board of Pharmacy, or demonstrated to the Board's satisfaction experience in the Practice of Pharmacy which meets or exceeds the minimum internship requirements of the Board.

(6) Have successfully passed an examination given by the Board of Pharmacy.

(7) Paid the fees specified by the Board of Pharmacy for examination and issuance of license.

(b) Examinations. (1) The examination for licensure required under Section 302(a)(6) of the Act, shall be given by the Board at least two (2) times during each fiscal year of the State. The Board shall determine the content and subject matter of each examination, the place, time and date of administration of the examination, and those persons who shall have successfully passed the examination.

(2) The examination shall be prepared to measure the competence of the applicant to engage in the Practice of Pharmacy. The Board may employ and cooperate with any organization or consultant in the preparation and grading of an appropriate examination, but shall retain the sole discretion and responsibility of determining which applicants have successfully passed such an examination.

(c) Internship and Other Training Programs. (1) All applicants for licensure by examination shall obtain practical experience in the Practice of Pharmacy concurrent with or after college attendance, or both, under such terms and conditions as the Board shall determine.

(2) The Board shall establish standards for internship or any other program necessary to qualify an applicant for the licensure examination and shall also determine the necessary qualifications of any preceptors used in any internship or other program.

Comment

Because of the continuing lack of unanimity concerning internship programs, it was deemed expedient to allow each Board to establish its own such program. It is hoped that these programs will be relatively uniform and that boards will exercise the prerogative to accept comparable programs of other jurisdictions as provided in Section 302(a)(5) above.

Section 303. Qualifications for Licensure by Reciprocity.

(a) Requirements. To obtain a license as a pharmacist by reciprocity, an applicant for licensure shall:

(1) Have submitted a written application in the form prescribed by the Board of Pharmacy.

(2) Have attained the age of majority.

(3) Have good moral character and temperate habits.

Comment

This requirement is discussed in Comment to Section 302(a)(3) above.

(4) Have possessed at the time of initial licensure as a pharmacist such other qualifications necessary to have been eligible for licensure at that time in this State.

(5) Have engaged in the Practice of Pharmacy for a period of at least one (1) year or have met the internship requirements of this State within the one (1) year period immediately previous to the date of such application.

(6) Have presented to the Board proof of initial licensure by examination and proof that such license and any other license or licenses granted to the applicant by any other state or states have not been suspended, revoked, cancelled or otherwise restricted for any reason except non-renewal or the failure to obtain required continuing education credits in any state where the applicant is licensed but not engaged in the Practice of Pharmacy.

(7) Have paid the fees specified by the Board of Pharmacy for issuance of a license.

(b) Eligibility. No applicant shall be eligible for licensure by reciprocity unless the State in which the applicant was initially licensed as a pharmacist also grants reciprocal licensure to pharmacists duly licensed by examination in this State, under like circumstances and conditions.

Section 304. Renewal of Licenses.

(a) Annual Report. Each pharmacist shall apply for renewal of his license annually no later than the first day of _____. The Board shall renew the license of each pharmacist who is qualified to engage in the Practice of Pharmacy.

(b) Fees. The Board shall specify by rule or regulation the procedures to be followed, (in addition to those specified by Section 305 of this Act) and the fees to be paid for renewal of licenses.

Comment

The parenthetical clause should be omitted if a state does not require continuing education.

Section 305. Continuing Pharmacy Education.

(a) Findings and Declarations. The Legislature makes the following findings and declarations:

(1) Because of the continuous introduction of new therapeutic and diagnostic agents and the changing concepts in the delivery of health-care services in the Practice of Pharmacy, it is essential that a pharmacist undertake a continuing education program in order to maintain his professional competency and improve his professional skills; and

(2) To assure the continued competency of the pharmacist and to maintain uniform qualifications for registration and licensure in the profession for the protection of the health and welfare of its citizens, the Legislature of this State deems it in the public interest to adopt a continuing professional education program;

(b) Renewal Certification. Commencing (date), no annual renewal license shall be issued to a pharmacist until such pharmacist shall have submitted proof to the Board that he has satisfactorily completed an accredited program of continuing professional education during the previous _____year(s) to help assure his continued competence to engage in the Practice of Pharmacy. The Board shall from time to time determine the amount of continuing education to be required.

(c) Rules and Regulations. The Board shall adopt rules and regulations necessary to carry out the stated objectives and purposes and to enforce the provisions of this Section, which shall include the methods of determining accredited programs, any fees and such other rules and regulations consistent with this Section as the Board shall determine.

(d) Alternative Means of Meeting Requirements. The Board may grant to a pharmacist who meets all of the necessary requirements for renewal of licensure, except the continuing education requirements, alternate methods of obtaining continuing education through home-study courses, correspondence courses, audiovisual aids, or other such programs, examination or the like, substantially equivalent in scope and content to the continuing professional education programs regularly scheduled; provided, however, only those pharmacists shall be eligible for the alternative programs who, upon written application to the Board and for good cause shown, demonstrate that they are unable to attend a sufficient number of regularly scheduled continuing professional education programs for licensure. This section and all rules and regulations promulgated hereunder shall be uniformly applied by the Board.

Comment

For appropriate regulations for this Section and further information on continuing education see NABP Model Continuing Education Act (1979). Those states not wishing to adopt a continuing education program and those which desire to retain any program now maintained under other legislation should omit Section 305.

Introductory Comment to Article IV

At the very heart of any Pharmacy Act is the enforcement power of the Board of Pharmacy. The Board must have authority to discipline and/or prohibit unfit practitioners from continuing to threaten the public, if it is to fulfill its responsibilities. The Board must have the ability to stop wrongdoers, either permanently or temporarily, punish them, and, where appropriate, to guide and assist errant licensees in rehabilitating themselves.

The MSPA disciplinary provisions are contained in Article IV. They were drafted with the purpose of granting to the Board the widest possible scope within which to

perform its disciplinary functions. The grounds for disciplinary action were developed to insure protection of the public, while reserving to the Board the power to expand upon them and adapt them to changing or local conditions as necessary. The penalties permitted under the MSPA will afford the Board the flexibility to conform and relate punishments to offenses.

ARTICLE IV

Discipline

Section 401. Grounds.

(a) Refusal to Issue or Renew. The Board of Pharmacy may refuse to issue or renew, or may suspend, revoke or restrict the licenses of any person, pursuant to the procedures set forth in Section 402 hereinbelow, upon one or more of the following grounds:

(1) Unprofessional conduct as that term is defined by the rules and regulations of the Board;

(2) Incapacity of a nature that prevents a pharmacist from engaging in the Practice of Pharmacy with reasonable skill, competence and safety to the public;

(3) Being found guilty by a court of competent jurisdiction of one (1) or more of the following:

(i) A felony, as defined by the statutes of this State;

(ii) Any act involving moral turpitude or gross immorality; or

(iii) Violations of the pharmacy or drug laws of this State or rules and regulations pertaining thereto, or of statutes, rules or regulations of any other state, or of the federal government.

(4) Fraud or intentional misrepresentation by a licensee in securing the issuance or renewal of a license.

(5) Engaging or aiding and abetting an individual to engage in the Practice of Pharmacy without a license, or falsely using the title of pharmacist.

(6) Being found by the Board to be in violation of any of the provisions of this Act or rules and regulations adopted pursuant to this Act.

Comment

It is particularly important to emphasize the need for specifity in defining the grounds upon which a pharmacist's license to practice may be revoked or suspended. The term "unprofessional conduct" is particularly susceptible to judicial challenge for being unconstitutionally vague. Each offense included within the meaning of this term must be capable of being understood with reasonable precision by the persons regulated so that it can be readily enforced and relied upon during disciplinary proceedings, and so that those regulated by it may easily conform their professional conduct to its meaning(s).

These potential problems make it essential for Boards to issue appropriate rules and regulations making the grounds for disciplinary action specific, understandable and reasonable. In addition, the Boards must insure that such rules and regulations are published for the benefit of all licensees within their jurisdiction. Only by doing so, can Boards be assured of authority to take successful and meaningful disciplinary actions that will not later be overturned by the courts.

This section must be examined in light of other state legislation since some states, for example, restrict the circumstances under which a license may be denied to an individual because of the commission of a felony. In addition, an individual who has been convicted of a felony or an act involving gross immorality and who has paid his debt to society has restored constitutional protections that may prevent a strict application of Section 401(a)(3).

Section 402. Procedure.

Comment

The procedures which must be followed before disciplinary action can be taken in many of the states are determined by the Administrative Procedures Act. The MSPA was drafted on the assumption that such an Act was in effect. See Comment to Section 212.

Section 403. Penalties and Reinstatement.

(a) Penalties. Upon the finding of the existence of grounds for discipline of any person holding a license, seeking a license, or a renewal license under the provisions of this Act, the Board of Pharmacy may impose one (1) or more of the following penalties:

(1) Suspension of the offender's license for a term to be determined by the Board;

(2) Revocation of the offender's license;

(3) Restriction of the offender's license to prohibit the offender from performing certain acts or from engaging in the Practice of Pharmacy in a particular manner for a term to be determined by the Board;

(4) Imposition of a fine not to exceed (number) dollars for each offense;

(5) Refusal to renew offender's license;

(6) Placement of the offender on probation and supervision by the Board for a period to be determined by the Board;

(b) Reinstatement. Any person whose license to practice pharmacy in this State has been suspended, revoked or restricted pursuant to this Act, whether voluntarily or by action of the Board, shall have the right, at reasonable intervals, to petition the Board for reinstatement of such license. Such petition shall be made in writing and in the form prescribed by the Board. Upon investigation and hearing, the Board may in its discretion grant or deny such petition, or it may modify its original finding to reflect any circumstances which have changed sufficiently to warrant such modifications.

(c) Criminal Prosecutions. Nothing herein shall be construed as barring criminal prosecutions for violations of this Act where such violations are deemed as criminal offenses in other statutes of this State or of the United States.

(d) Judicial Review. All final decisions by the Board shall be subject to judicial review pursuant to the procedures of the Administrative Procedures Act.

Comment

See Comment to Section 212.

Introductory Comment to Article V

The fifth and last substantive Article of the MSPA concerns registration of Drug Outlets. The registration requirements of this Article will provide a Board with knowledge of all facilities involved in the storage, distribution and sale of drugs within the state. They will permit a Board to better insure against drug diversion from the legitimate channels of intrastate commerce and provide the necessary data for effective recalls and the dissemination of information.

ARTICLE V

Registration of Facilities

Section 501. Registration.

(a) Registration. All Drug Outlets shall annually register with the Board of Pharmacy.

(b) Classification. (i) Each Drug Outlet shall apply for a certificate of registration in one of the following classifications:

(1) Retail Drug Outlet;
(2) Institutional Drug Outlet;
(3) Manufacturing Drug Outlet;
(4) Wholesale Drug Outlet.

(ii) No individual who is employed by a corporation which is registered under any classification listed above need register under the provisions of Article V.

(c) Rules and Regulations. The Board shall establish by rule or regulation under the powers granted to it under Section 212 and 214 of this Act the criteria which each Drug Outlet, that has employees or personnel engaged in the Practice of Pharmacy, must meet to qualify for registration in each classification designated above. The Board may issue various types of certificates with varying restrictions to such outlets referred to in this subparagraph (c) where the Board deems it necessary by reason of the type Drug Outlet requesting a certificate.

Comment

Section 501(c) contemplates that the criteria established in an individual Drug Outlet classification could differ. For example, the criteria that must be met by a nuclear pharmacist's outlet will certainly differ from that of the community pharmacist even though both may fall within the classification of Retail Drug Outlet. This type of latitude places the responsibility on the Board to adopt appropriate rules and regulations to meet the situation at hand. It also provides a forum for change to meet the changing concepts of the practice.

(d) Non Prescription Drugs. It shall be lawful for a Drug Outlet registered under this Section 501 to sell and distribute Non Prescription Drugs. Drug Outlets engaging in the sale and distribution of such items shall not be deemed to be improperly engaged in the Practice of Pharmacy. No rule or regulation will be adopted by the Board under this Act which shall require the sale of Non Prescription Drugs by a licensed pharmacist or under the supervision of a licensed pharmacist or otherwise apply to or interfere with the sale and distribution of such medicines.

Section 502. Application.

(a) Procedures. The Board shall specify by rule or regulation the registration procedures to be followed, including but not limited to specification of forms for use in applying for such certificates of registration and times, places and fees for filing such application; provided, however, the annual fee for an original or renewal certificate shall not exceed $_____.

(b) Required Information. Applications for certificates of registration shall include the following information about the proposed Drug Outlet.

(i) Ownership;
(ii) Location;
(iii) Identity of pharmacist licensed to practice in the State, who shall be the pharmacist in charge of the Drug Outlet, where one is required by this Act, and such further information as the Board may deem necessary.

(c) Transferability. Certificates of registration issued by the Board pursuant to this Act shall not be transferable or assignable.

(d) Professional Responsibility. The Board shall specify by rule and regulation minimum standards for the professional responsibility in the conduct of any Drug Outlet that has employees or personnel engaged in the Practice of Pharmacy. The Board is specifically authorized to require that the portion of the facility to which such certificate of registration applies be operated only under the direct supervision of no less then one (1) pharmacist licensed to practice in this State and not otherwise, and to provide such other special requirements as deemed necessary.

Section 503. Notifications.

(a) Changes. All registered Drug Outlets shall report to the Board of Pharmacy the occurrence of any of the following changes:

(i) Permanent closing;
(ii) Change of ownership, management, location or pharmacist in charge;
(iii) Any and all other matters and occurrences as the Board may require by rules and regulations.

(b) Other Reportable Events. Disasters, accidents and emergencies which may affect the strength, purity or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness and disease shall be immediately reported to the Board.

Section 504. Violations and Penalties.

(a) Unlawful Conduct. No Drug Outlet designated in Section 501 of this Act shall be operated until a certificate of registration has been issued to said facility by the Board. Upon the finding of a violation of this Section, the Board may impose one or more of the penalties enumerated in Section 403 of this Act.

(b) Reinstatement. Reinstatement of a certificate that has been suspended, revoked or restricted by the Board may be granted in accordance with the procedures specified by Section 403(b) of this Act.

ARTICLE VI

Other

Section 601. Severability.

If any provision of this Act is declared unconstitutional or illegal, or the applicability of this Act to any person or circumstances is held invalid by a court of competent jurisdiction, the constitutionality or legality of the remaining provisions of this Act and the application of this Act to other persons and circumstances shall not be affected and shall remain in full force and effect without the invalid provision or application.

Section 602. Effective Date.

This Act shall be in full force and effect (number) days after its enactment.

Appendix 7

Code of Ethics *American Pharmaceutical Association*

Preamble

These principles of professional conduct are established to guide pharmacists in relationships with patients, fellow practitioners, other health professionals, and the public.

A Pharmacist *should hold the health and safety of patients to be of first consideration and should render to each patient the full measure of professional ability as an essential health practitioner.*

A Pharmacist *should never knowingly condone the dispensing, promoting, or distributing of drugs or medical devices, or assist therein, that are not of good quality, that do not meet standards required by law, or that lack therapeutic value for the patient.*

A Pharmacist *should always strive to perfect and enlarge professional knowledge. A pharmacist should utilize and make available this knowledge as may be required in accordance with the best professional judgment.*

A Pharmacist *has the duty to observe the law, to uphold the dignity and honor of the profession, and to accept its ethical principles. A pharmacist should not engage in any activity that will bring discredit to the profession and should expose, without fear or favor, illegal or unethical conduct in the profession.*

A Pharmacist *should seek at all times only fair and reasonable remuneration for professional services. A pharmacist should never agree to, or participate in, transactions with practitioners of other health professions or any other person under which fees are divided or that may cause financial or other exploitation in connection with the rendering of professional services.*

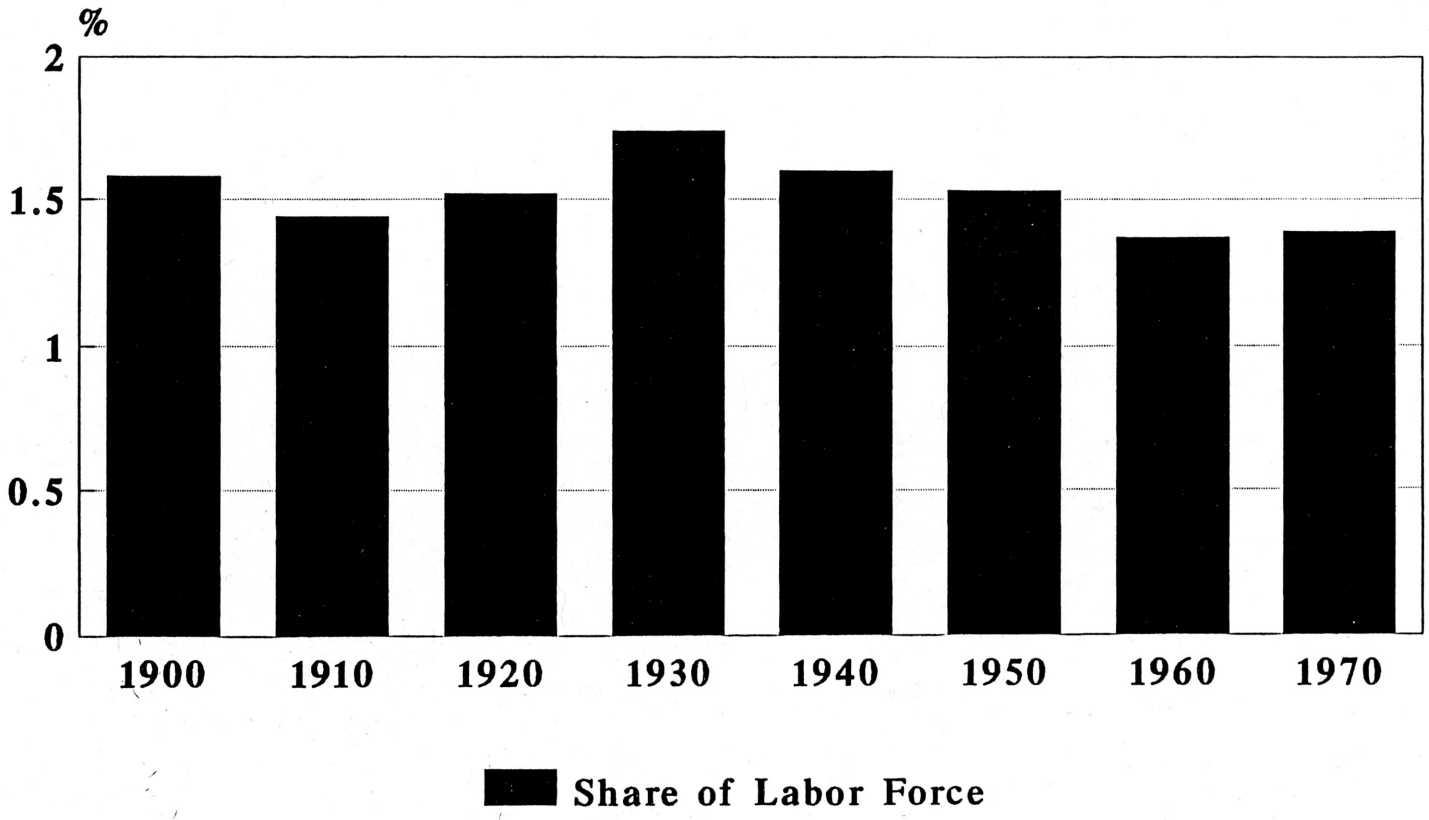
A Pharmacist *should respect the confidential and personal nature of professional records; except where the best interest of the patient requires or the law demands, a pharmacist should not disclose such information to anyone without proper patient authorization.*

A Pharmacist *should not agree to practice under terms or conditions that interfere with or impair the proper exercise of professional judgment and skill, that cause a deterioration of the quality of professional services, or that require consent to unethical conduct.*

A Pharmacist *should strive to provide information to patients regarding professional services truthfully, accurately, and fully and should avoid misleading patients regarding the nature, cost, or value of these professional services.*

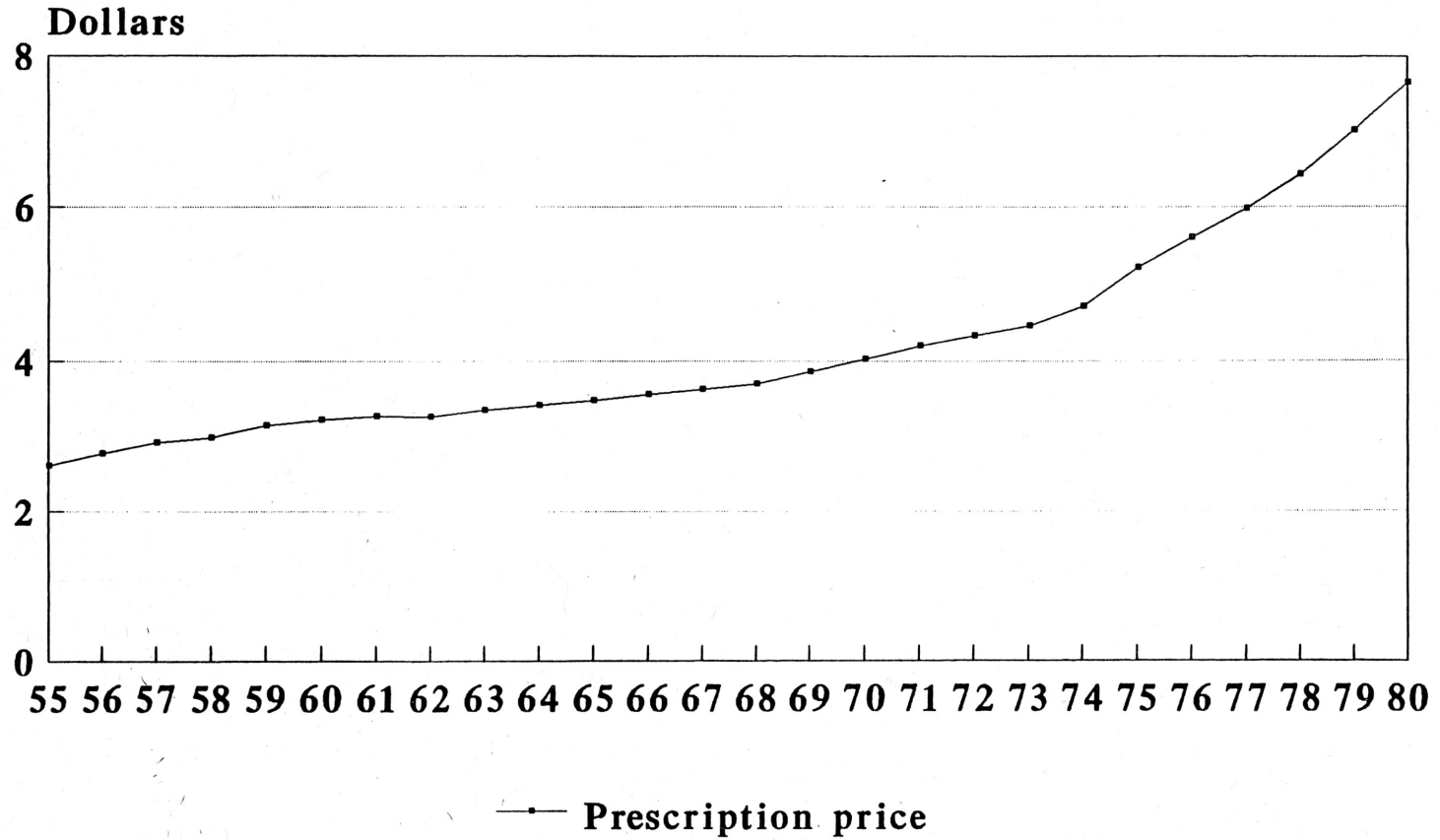
A Pharmacist *should associate with organizations having for their objective the betterment of the profession of pharmacy and should contribute time and funds to carry on the work of these organizations.*

Appendix 8
Licensed Pharmacists (1900-1970)



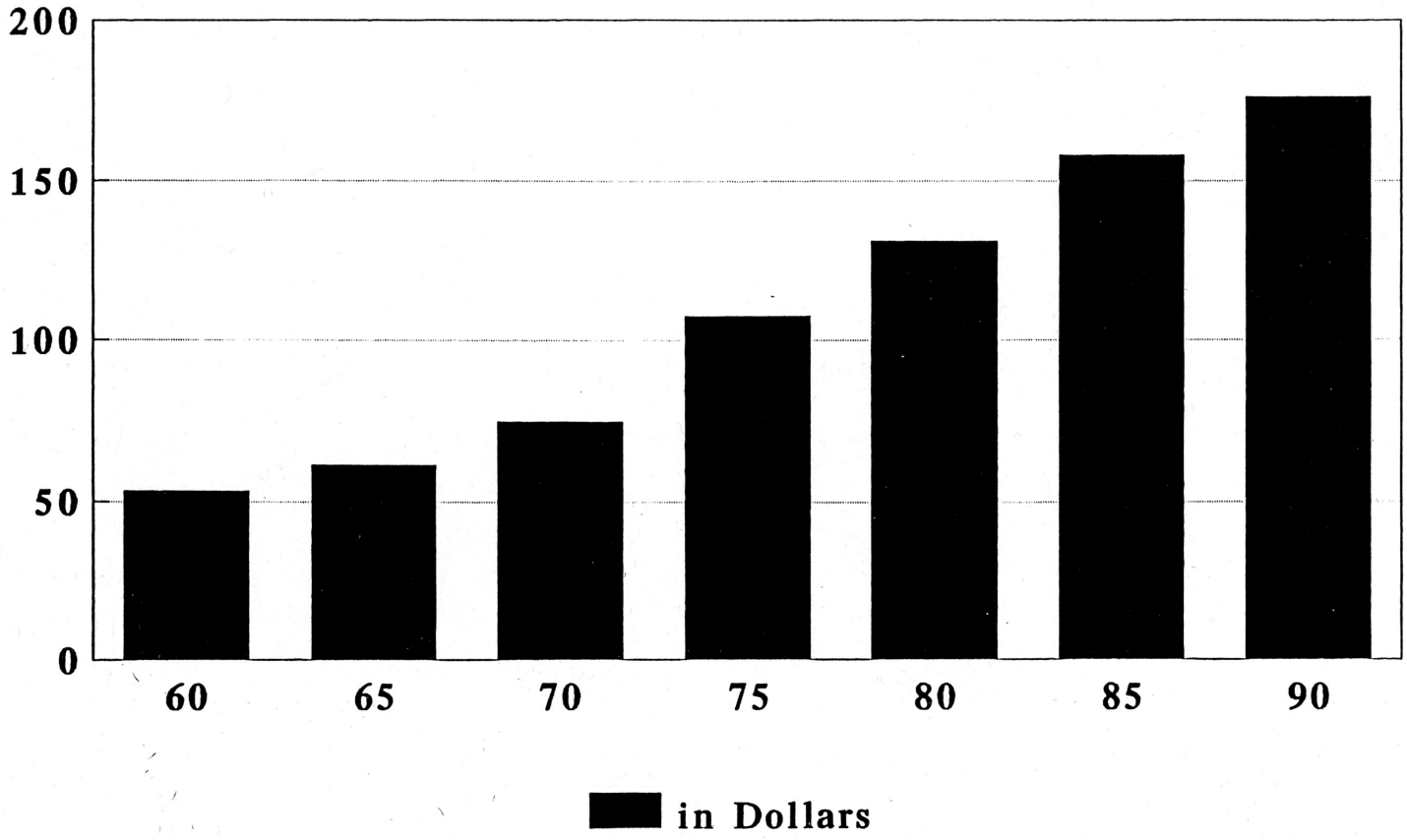
Source: Historical Statistics of the United States 1975, p.140.

Appendix 9
Ave. Price for New Prescriptions



Source: National Prescription Audit,1981

Appendix 10
Ave. Weekly Earnings (1960-90)



Source: Employment and Earnings