

**THE ROLE
of
THE STATE
in
THE REGULATION
of
PHARMACY**

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FOREWORD

When the Board of Pharmacy in the summer of 1960 formulated, for the first time, regulations designed to implement the provisions of Chapter 71, Revised Laws of Hawaii 1955, as amended, which governs the practice of pharmacy, questions were raised by physicians, nurses, hospital administrators and others who practice the medical arts. Disagreements existed concerning the dispensing of drugs in small hospitals, filling of oral prescriptions, dispensing of medicines by employees of physicians and other similar matters. The Board of Pharmacy, after consideration of the problem areas, determined that additional study was required.

The Legislative Reference Bureau, in accordance with a legislative request, was asked to make a study of these and related problems in the field of pharmacy. As the Bureau's work proceeded, it became clear that the existing disagreements were symptomatic of deeper problems, many of which had their origins in the economics of the distribution of drugs and medicines in Hawaii and in the legal regulation of an occupational area of endeavor by the practitioners of the regulated occupation. Thus the original study was broadened so that the more specific and obvious problems could be placed in a more meaningful perspective.

The central concern of this report is expressed in its title: "The Role of the State in the Regulation of Pharmacy." In order to examine the question of what this role should be, the report addresses itself to the definition of pharmacy, the development of pharmacy and its practice today, and the relationship of professionalism to occupational licensing. The report concludes with an analysis of pharmacy laws in Hawaii and an exploration of alternative approaches to regulation

of drugs as a commodity and pharmacy as a profession.

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Tom Dinell
Director

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SUMMARY

State regulation of pharmacy in Hawaii, as is true in most states, is designed to control two different aspects of pharmacy: (1) the practice of the occupation of pharmacy, and (2) the traffic in drugs. Historically, in Hawaii and in the mainland, laws designed to control the practice of pharmacy have taken the form of occupational licensing laws and have been administered by boards or commissions composed of licensed pharmacists, whereas laws controlling drug traffic have been administered by other agencies. Allowing pharmacists to administer the pharmacy licensing law makes the vocation self-regulating; it is an example of legislative delegation of public powers to a private group. As citizens and government officials, members of the Hawaii Board of Pharmacy have motivations encouraging the use of these public powers to serve a general public interest; as pharmacists, Board members have motivations encouraging the use of these public powers to serve the private interests of pharmacists.

The Board of Pharmacy has followed the general tendency of most organized groups in attempting to expand the scope of its activities and increase its powers. This expansion has largely been directed toward claiming responsibility for control of drug traffic. Under existing laws the Board's jurisdiction in this area is almost nil and its attempts to claim jurisdiction have brought it into conflict with government agencies responsible for regulating drug traffic and with those individuals and groups (doctors, hospital administrators, pharmaceutical manufacturers, wholesale druggists) affected by such regulation.

Failure to be able to expand as desired under present laws has led the Board to strive for the necessary legal basis by amending the existing pharmacy licensing law and enacting new legislation to give the Board additional powers. For example, the Board's 1963 legislative program includes a bill modeled after the Ohio Dangerous Drug Act which would give the Board powers to regulate the distribution and possession of all dangerous drugs in the State. Dangerous drugs are defined in the bill as prescription drugs, certain narcotic drugs, and injectables.

The need to define clearly and limit, in statute, the responsibilities and powers of the Board of Pharmacy is the central and most critical issue, at present, in Hawaii State regulation of pharmacy. Resolving this issue requires the consideration of several questions relating to the United States as a free economy and a democratic society.

Pharmacy licensing laws restrict the basic freedom in a democratic society of the individual to follow the vocation of his choice. Laws regulating drug traffic interfere with the free flow of goods, an interference which it is considered desirable to avoid in a capitalist economy. Legislation which produces such results can be justified only in terms of meeting some more pressing social need. This report concludes that such legislation is necessary to protect the public health and safety in the area of drug consumption. The problem is how to provide the necessary regulation at the lowest cost to society or, stated another way, how to maximize the use of public powers to benefit a general public interest while minimizing their use to benefit the private interests of pharmacists.

A partial solution is to remove, as far as possible, motivations to use public powers to serve private ends. On this basis, the report suggests a number of alternative courses of action designed to limit the use of public powers to situations furthering a general public interest. One safeguard to the public interest, as long as the Board of Pharmacy consists of pharmacists, can be provided by amending the existing pharmacy law to limit the Board's powers to regulating the practice of pharmacy and placing responsibility for controlling drug traffic with other agencies.

Regulating the practice of pharmacy includes examining applicants for licensure, issuing licenses to those who qualify, and setting and enforcing minimum standards governing the operations of pharmacists and pharmacies. Even should the Board, as presently composed, be limited to these activities there remains the question of whether there are other ways to accomplish these activities which further lessen the possibility of using public powers to serve private ends. The delegation of public powers for occupational self-regulation should be limited, as far as possible, to instances in which other alternatives are not feasible and then only to occupations with traditions and standards leading to action primarily in the public interest. Vocations which meet this requirement are designated as professions in the fullest sense of the term. Pharmacy is not a profession in the fullest sense of the term and feasible alternatives to self-regulation are available; therefore pharmacy should not be self-regulating.

Alternative means of regulating pharmacy are considered in chapter six. These various alternatives involve modifying (1) the functions of the Board, (2) the composition of the Board, or (3) both functions and composition. Probably the alternative which would best

serve the public interest would provide for a board composed predominantly of non-pharmacists with the functional emphasis on advisory rather than administrative activities.

This report examines occupational licensing legislation in a democratic society as it applies to pharmacy, but clearly many of the observations are applicable to other self-regulating occupations. Few occupations are professions in the fullest sense of the term; therefore it is likely that serious questions may be raised concerning the delegation of public powers to most occupations which are now self-regulating or seeking self-regulatory powers. Thus, the analysis of occupational licensing laws in chapter five may be useful in reassessing existing licensing laws governing occupations other than pharmacy and in evaluating additional or new legislation.

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CHAPTER I

INTRODUCTION

The practice of pharmacy, which can trace its antecedents back several thousand years,¹ has for most of its history combined elements of a scientific or technical occupation with elements of the merchant's trade. In this century scientific and technical progress and the effects of new marketing techniques have had a tremendous impact on pharmacy. The basic functions of pharmacists have been radically affected and serious problems of adjustment have arisen due to changes originating within as well as without the pharmaceutical industry and which for the most part were beyond the control of pharmacists.

Increased complexity, in a field such as pharmacy, frequently creates problems which lead to the enactment of additional laws to protect the public weal. This has been true for pharmacy in this century. The number of potentially harmful drugs and medicines has grown tremendously and the control of their preparation and distribution has become the subject of several federal and state laws. Local governments have rarely acted in this area. Enacting new laws to solve existing problems has, in some instances, created other problems such as conflicts among statutes or the assigning of legal responsibility for certain functions to more than one agency. Occasionally, the factors or situation which produced the need for a law will change, but the law will not and this may also result in conflicts or problems.

The nature of the problems of pharmacy often make

¹Edward Kremers and George Urdang, History of Pharmacy (Philadelphia: J. B. Lippincott Co., 1951), pp. 8, 12-13.

them difficult to understand and even when the problems are recognized and defined they do not yield to easy solution. There is general feeling among organized pharmacists today that their future as a profession depends upon the successful analysis and solution of their numerous problems.²

Pharmacy groups have relied on a wide variety of activities in attempts to solve their problems. Generally speaking, these activities divide into those that pharmacists can accomplish through private effort as individuals or groups, and those that require public or governmental effort. Self-improvement projects, public relations programs, and lobbying fall into the first category. The second category includes passage of legislation protective of the interests of pharmacists, sympathetic administration of laws and regulations by government agencies, and the obtaining of favorable court decisions.

The Type of Pharmacy Practiced in Hawaii

The purpose of this report is to study the role of the State in the regulation of pharmacy in Hawaii. Pharmacy is involved, to some degree, in all the processes of getting drugs and medicines from their original sources

²There is extensive literature in this area. A particularly good summary of current thinking on the subject is provided in the Fall, 1961 issue of the American Journal of Pharmaceutical Education, Vol. XXV, No. 4, which includes an editorial and five articles discussing "The National Purpose of Pharmacy". The articles are by officers or staff members of the National Association of Boards of Pharmacy, American Pharmaceutical Association, National Association of Retail Druggists, American Association of Colleges of Pharmacy, and the American Council on Pharmaceutical Education.

to the ultimate consumer including: (1) basic research in developing new products or improving existing ones, (2) collecting or gathering drugs from their original sources, (3) manufacturing crude drugs in bulk, (4) formulating bulk drugs into dosage forms at the point of manufacture, and (5) marketing. Table 1 shows the employment distribution of pharmacists. Almost ninety per cent of the registered pharmacists in the United States are engaged in marketing operations as retail pharmacists.

TABLE 1

NUMBER OF REGISTERED PHARMACISTS BY TYPE OF PRACTICE

MAINLAND UNITED STATES^a

JANUARY 1, 1961

	<u>Number</u>	<u>Per Cent of Total</u>
In Retail Pharmacies	105,734	89.4
In Hospital Pharmacies	4,691	4.0
In Manufacturing and Wholesale Establishments	2,864	2.4
Representing Manufacturing and Wholesalers	2,654	2.2
In Teaching and Government Positions	1,036	.9
In Other Capacities as Registered Pharmacists	1,348	1.1
Total	118,327	100.0

Source: National Association of Boards of Pharmacy.

^aDoes not include Alaska, Hawaii, and Puerto Rico

Parallel statistics are not available for Hawaii. However, it is possible to make some assumptions about the 230 registered pharmacists in the State. There are no manufacturing or teaching positions for pharmacists in Hawaii. Most of those who practice pharmacy work in

retail stores; several are employed in public and private hospitals; some are detail men (salesmen) for manufacturers or wholesalers; and a small number operate wholesale outlets.³

Of the pharmaceutical industry operations listed, only marketing, which includes sales by manufacturers to wholesale, retail, and other outlets, sales by wholesalers to retail and other outlets, warehousing, and the dispensing to consumers by hospital pharmacists, physicians, retail pharmacists and others, is performed in Hawaii. The marketing process and those individuals engaged therein can be expected to be the subject of state pharmacy regulation in Hawaii, and, by extension, the basic subject of this report. The processes of the pharmaceutical industry, however, are interdependent and interrelated; therefore, to the extent necessary to understand pharmacy as practiced in Hawaii, the report does consider other aspects of the industry.

Laws Affecting the Practice of Pharmacy in Hawaii

Several federal and State laws regulate the preparation, sale, and dispensation of drugs and medicines in Hawaii. The most important federal laws in this field are found in the United States Code, Title 21, Food and Drugs, chapters six and nine. Chapter six is administered by the Department of Treasury and pertains to the importation, exportation, production and distribution of narcotic drugs. The Food and Drug Administration (FDA) of the Department of Health, Education, and Welfare administers chapter nine, the "Federal Food, Drug, and

³The Legislative Reference Bureau prepared and sent a questionnaire to all registered pharmacists. The returns indicated that at least one person worked in each of the categories mentioned above and a few listed themselves as employed in other categories as pharmacists.

Cosmetic Act", which, in part, was designed to prohibit the movement in interstate commerce of adulterated and misbranded drugs and has since been extended to include positive approval of all new prescription drugs. It was not until 1961 that the FDA stationed personnel in Hawaii. Prior to that time the State Department of Health served as the enforcement agency for the FDA.

Administration of Hawaii laws regulating pharmacy is divided between the Department of Health and the Hawaii Board of Pharmacy. Activities of the Food and Drug Branch of the Department of Health include enforcement of the following chapters of the Revised Laws of Hawaii 1955: Chapter 51, "Food, Drugs and Cosmetics"; Chapter 52, "Narcotics"; Chapter 53, "Sale of Poisons";⁴ and Chapter 302A, "Prophylactics". The Department of Health also has general responsibility for regulating hospitals under Chapter 46, "Board of Health"; and Chapter 48A, "Hospital and Medical Facilities Construction", which seems to include pharmacy operations within hospitals.

The heart of State regulation of the vocation of pharmacy is contained in Chapter 71, "Pharmacists and Pharmacy", of the Revised Laws which creates the Hawaii Board of Pharmacy and generally spells out its powers. Under the provisions of Chapter 71 the Board determines who will practice pharmacy in Hawaii and has wide latitude in defining what does or does not constitute the practice of pharmacy. The Board and its activities under Chapter 71 are the main subject of this report.

⁴Hawaii also has a law regulating economic poisons (Chapter 25, Revised Laws of Hawaii 1955) administered by the State Department of Agriculture. It is not considered here because it is concerned with pharmacists only as one among many groups of potential wholesale and retail outlets, and not with any of the functions peculiar to pharmacy.

All the federal and state laws share the common purpose of protecting the public weal. Each law also has other, more specific purposes. These other purposes fall into two general categories: (1) laws that control the preparation and distribution of drugs and medicines as a commodity affecting life and health; and (2) laws designed to regulate entrance to and practice of pharmacy as an occupation. The federal laws and most Hawaii laws under the jurisdiction of the Department of Health are in the first category; in the second category are the pharmacy licensing law and the Department of Health's regulation of hospitals. The distinction between the two is not always clear and occasionally jurisdictional disputes arise when the licensing board attempts to extend its activities into matters involving drugs as a commodity or when an agency regulating drugs as a commodity affects the practice of pharmacy. There appears to be a clear jurisdictional overlap in the case of the pharmacy licensing law, which permits the Board of Pharmacy to set and enforce standards for all pharmacies, and the law giving the Department of Health authority to regulate hospital pharmacies.

Another potential overlap exists in the case of federal and state laws controlling drugs as a commodity. Technically, the federal government's jurisdiction extends only to drugs and medicines involved in interstate commerce and states have jurisdiction over drugs and medicines in intrastate commerce. Interpretations of the "Federal Food, Drug, and Cosmetic Act", provide that "an article which has been in the channels of interstate commerce remains subject to the Act though it is in the hands of a retail druggist who secured it by an intrastate transaction."⁵ State laws must not be in conflict with

⁵William R. Arthur, The Law of Drugs and Druggists (St. Paul: West Publishing Co., 1955), p. 285.

federal laws on the same subject and where there is concurrent jurisdiction, the federal government predominates.⁶ In Hawaii, where there is little drug manufacturing, this means that most drugs and medicines enter the State in interstate commerce and the federal government has jurisdiction over their distribution until their final sale to the consumer. The State is free to supplement federal laws or to enact legislation to control aspects of drug traffic not regulated by the federal government.

Current Problems in State Regulation

Board of Pharmacy activities in administering Chapter 71 have resulted in several major conflicts between the Board and other medical groups. One conflict arises from provisions in Chapter 71 restricting the dispensing of drugs and medicines. Registered pharmacists and assistant pharmacists, under the direct supervision of a registered pharmacist, are authorized to dispense.⁷ In addition, "any legally licensed practitioner of medicine, osteopathy, dentistry or veterinary medicine" may "personally" dispense to his patients.⁸

There is widespread dispensation by doctors in Hawaii. Although the pharmacy law specifically states that doctors must dispense personally, the practice has

⁶Ibid., p. 287.

⁷Revised Laws of Hawaii 1955, 71-9. Dispense is defined as furnishing drugs or medicines upon the legal prescription from a person legally entitled to prescribe. In contrast, administer refers to furnishing individual doses of drugs to patients on the order of a person legally authorized to make such orders (Legislature of Hawaii, Senate, An Act Relating to Pharmacists and Pharmacy, First State Legislature, Regular Session, 1961, S.B. No. 972, S.D. 2, p.1).

⁸Revised Laws of Hawaii 1955, 71-19.

grown over the years of doctors permitting their nurses, receptionists, or other employees to dispense.⁹ The Board of Pharmacy has declared its intention of enforcing the legal provisions limiting dispensing. Many doctors in Hawaii feel that this is an infringement on their rights as professional practitioners. They cite Chapter 64, "Medicine and Surgery", of the Revised Laws which defines the practice of medicine to include the use of drugs and medicines and, in the same section, provides "that nothing herein contained shall forbid any person from the practice of any method, or the application of any remedial agent or measure under the direction of a licensed physician. . . ."¹⁰ This provision appears to permit doctors to dispense drugs and medicines through their employees. One part of the problem, then, is conflicting provisions in the law.

Another part of the problem is that if doctors were required personally to dispense drugs it is likely that most of them would limit their activities to drugs that should be administered under the immediate supervision of a doctor. This might adversely affect the income of some doctors while increasing the prescription business of retail pharmacists. There have been suggestions¹¹ that

⁹That such is the case in hospitals without pharmacists is obvious. In the case of doctors in independent or clinic practice this statement is based on files of the State Department of Health.

¹⁰Revised Laws of Hawaii 1955, 64-1.

¹¹The following quotation from a respondent to a questionnaire sent to over 600 physicians in Hawaii by the Legislative Reference Bureau (see Appendix A and Table 8, page 68) is representative of many comments made on questionnaires and in interviews during the course of the study:

The impression which many of us have gotten from the discussions with the Board of Pharmacy is that the motivation for regulation is largely one of financial interest to the pharmacists despite their oft-repeated assertions that their sole motive is the "protection of the patient".

the Board of Pharmacy is acting, in this case, to further the private economic interests of pharmacists and not in the general public interest.

The second conflict results from the Board of Pharmacy interpreting the present law as requiring every hospital where drugs and medicines are dispensed to employ a pharmacist. Provisions recently proposed by the Board for inclusion in their rules and regulations reflect their understanding of the law:

Only a pharmacist may have access to the pharmacy stock of narcotics

Only a pharmacist may have access to the pharmacy stock of prescription drugs except that in the absence of the pharmacist, a registered nurse, intern, resident or licensed physician. . . may obtain. . . such drugs (except narcotics) as are needed in an emergency . . .¹²

In effect, this limits dispensing in hospitals to individuals legally authorized to dispense: pharmacists, doctors, and dentists.

Few of the hospitals in Hawaii with more than 100 beds have dispensing practices which would satisfy the Board's interpretation of the law. The situation is even worse in Hawaii hospitals with less than 100 beds. Of the eighteen hospitals in this category only one employs either a full or part-time pharmacist.¹³

¹²Hawaii Board of Pharmacy, "Proposed Rules and Regulations", dated December 4, 1962. On January 11, 1963 the Board of Pharmacy approved rules and regulations. The Board will not consider the rules and regulations effective until approved by the head of the Department of Treasury and Regulation and the Governor. Although the sections pertaining to hospitals were omitted pending further consideration, the Board's interpretation of the law remains unchanged. (Interview with Executive Secretary, Board of Pharmacy, January 13, 1963.)

¹³See Table 3 below, p. 51.

If the Board rigidly enforces the law, as they understand it, all hospitals will have to employ a pharmacist or require doctors to take the time to dispense personally. In 1961 the Board supported a bill which would have relaxed the present law to permit "a nurse, attendant or other employee" to dispense "in a doctor's office or place of business where there is no pharmacy within three miles . . .".¹⁴ The small hospitals believe they do not have enough work for a full-time pharmacist and do not want to assume the additional financial burden represented by the salary of a professional pharmacist. In addition, there is some feeling that it would be impossible to find sufficient pharmacists to fill the jobs given such factors as rural isolation and existing low salaries. Again, there have been suggestions¹⁵ that the Board is acting out of selfish motives to the detriment of the public interest.

As was the case with physician dispensing there is also a problem of conflicting laws in this situation. Subsection 46-13(j) and Section 48A-10 of the Revised Laws place the responsibility for hospital regulation with the State Department of Health which has issued regulations governing hospital operations including pharmacies or drug rooms. The Hawaii Medical Association

¹⁴An Act Relating to Pharmacists and Pharmacy, 1961, S.B. 972, S.D. 2, p. 2. The original bill was sponsored by the Board of Pharmacy and added to the existing law requiring doctors to dispense personally the restriction "that such drugs may not be dispensed by a nurse, attendant or other employee." This was amended in a later draft of the bill and the amendment was supported by the Board of Pharmacy. The Board still plans to introduce legislation to ease the situation for rural hospitals (interview with Executive Secretary, Board of Pharmacy, January 14, 1963).

¹⁵See above, footnote 11, page 8.

and the Hospital Association of Hawaii both feel that the control of drugs within hospitals should be with the Department of Health under the division responsible for regulating hospitals.¹⁶

Recently, there was some friction between the Board and medical service representatives (salesmen for drug manufacturers and wholesalers), resulting from Board action requiring medical service representatives to obtain a license from the Board. The issue was resolved when the Board rescinded its action. A similar conflict now involves the Department of Health and the medical service representatives. The Department believes that detail men have been required to obtain a permit under existing poison regulations in effect since 1955 and to keep records of all samples distributed which are Schedule "A" or Schedule "B" poisons. However, many detail men have not obtained permits and the Department has not pressed the issue. The conflict has flared up over amended poison rules and regulations proposed by the Department which would remove all doubt about the requirement for medical service representatives to obtain a permit and keep records of samples they distribute.

Problems involving the Board of Pharmacy are compounded to a certain extent by the fact that all five members of the Board are practicing retail pharmacists. As Board members they are legal officials committed to serving the best interests of the public; as pharmacists they share the common problems of pharmacists. There is always a possibility that they

¹⁶ Interviews with the Chairman, Subcommittee on Pharmacy, Legislative Committee, Hawaii Medical Association, January 21, 1963, and the Executive Director, Hospital Association of Hawaii, January 21, 1963.

may consciously or subconsciously use the legal powers of the Board to further the private interests of pharmacists rather than the more general public interest.

Ideally, state regulation of pharmacy would consist of laws, rules and regulations, and administrative activities so clearly in the public interest that questions of using public powers to further private interests would not be raised. The subject of public versus private interests is open to a wide range of honest differences in opinion. For the most part, such differences are the cause of present problems and conflict in state regulation of pharmacy.

Before it can be determined where the public interest in the regulation of pharmacy lies, it is necessary to examine both the nature of pharmacy, especially in Hawaii, and the nature of occupational regulation.

Scope of the Study

Present problems in state regulation of pharmacy can be classified according to their cause. First, are problems that arise over the question of which state agency has jurisdiction in a specific area when laws appear to give overlapping grants of authority. Second, are problems arising over the question of whether federal laws sufficiently guard the public interest or whether an unmet need requires supplementary or complementary state action. Most of the problems in these two classifications concern controlling the commodity of drugs. They yield readily to analysis and, often, possible solutions are clearly definable.

A third set of problems relates to the regulation of pharmacy as a vocation and arises from the fact that occupational licensing laws simultaneously serve both public and private interests. These problems do not

yield to easy analysis or solution. The delegation of public powers to private interest groups through occupational licensing laws raises complex and basic questions in a democratic society. Problems inherent in the nature of the pharmacy licensing law have potentially more serious consequences in terms of their possible effect on a free economy and democratic government than do the first two classes of problems.

It has been necessary to expand considerably the scope of the study to develop an understanding of the pharmacy licensing law and to determine if such a law is the most effective way to serve the public interest. For example, the resolution of the conflict between the Board of Pharmacy and physicians is dependent, in part, on understanding the relative professional status of pharmacists and physicians and the relationships between the two groups. This leads to one of the basic assumptions of this study: that present problems in state regulation of the vocation of pharmacy are symptomatic of crucial problems facing pharmacy generally.

Discussion of the first two groups of problems is largely limited to chapter six. Content and organization of most of the study is directed toward placing the third group of problems in a meaningful perspective. A guiding principle throughout the study is the attempt to determine what government action is required in the public interest and how this action can be obtained with the minimum adverse effect on society.

CHAPTER II

THE DEFINITION OF PHARMACY

In recent years an increasing amount of attention has been paid to the problem of concisely defining the practice of pharmacy in terms that fit the present situation. The difficulties of definition are symptomatic of the uncertainties which exist as a result of basic recent changes in the practice of pharmacy and accompanying doubts concerning the status of pharmacy as a profession.

One of the reasons for the intensified concern with definitions is the filing in the last two years by the Antitrust Division of the federal Department of Justice of civil complaints against pharmaceutical associations in several states claiming the associations have been acting in restraint of interstate trade and commerce in violation of section 1 of the Sherman Act. Pharmacists view the Justice Department's activities as an attempt "to equate the professional activities of the pharmacist with the commercial activities of the merchant"¹ and so the question of definitions has been and is now before the courts.

For the sake of convenience the problem of defining pharmacy in this study is considered in two parts. First, pharmacy is defined in terms of the objectives and functions performed by those who work as pharmacists and, then, the question of pharmacy as a profession is considered.

¹"What Are We Fighting For?", Journal of the American Pharmaceutical Association, NS1, No. 5 (May, 1961), 279.

Early Definitions

In 1906 pharmacy was defined in The Century Dictionary and Cyclopedia as "the art or practice of preparing, preserving, and compounding medicines, and of dispensing them according to the formulae or prescriptions of medical practitioners." Although elaborated on over the years this was the accepted basic definition into the 1950's.

Major emphasis in the earlier definitions was on those functions of the pharmacist leading to the preparation of a drug or medicine for human consumption. Dispensing to a patient or what has come to be known as the distributive function received less emphasis. This placement of emphasis reflected the fact that most of the time of the pharmacist was spent in gathering together drugs and medicines and transforming these raw materials, by the process of compounding,² into the final medicinal product for the patient, including putting the drug into the form, such as powder, tablet, or capsule, in which it was to be administered.

New manufacturing techniques, mass production, and the desirability of controlled standardization of dosage forms resulted in the shifting of the burden of compounding from individual druggists to the pharmaceutical manufacturers. Today more than 90 per cent of all prescriptions are dispensed in the form prepared by the manufacturer.³ Clearly, the earlier

²In pharmacy, compounding is the combining of elements into dosage forms for the use of patients.

³There are several studies supporting this figure. One of the most recent is David D. Stiles, "The 1960 Prescription Market", The South Dakota Journal of Medicine and Pharmacy, XIV, No. 11 (November, 1961), 441-443.

emphasis in pharmacy definitions on collecting and compounding drugs is no longer valid. This change has created problems. "With the increasing trend toward 'ready to use' medicinals--away from the compounded prescription--it is quite easy for medical students and the physician to think of the pharmacist as little more than a 'pill counter'." ⁴

Pharmacy Redefined

There has been, for some years, general recognition of the need to redefine pharmacy. In 1958 the National Association of Boards of Pharmacy (NABP) and The American Association of Colleges of Pharmacy (AACP) appointed a joint committee to redefine the term. ⁵ In its report to the 1960 convention the joint committee endorsed the following definition as "applicable for inclusion in various laws regulating and governing the practice of pharmacy":

The "practice of pharmacy" is the practice of that profession concerned with the art and science of preparing from natural and synthetic sources drugs and medicines for use in the diagnosis, treatment, and prevention of disease, including

⁴Harold J. Black, "Indoctrination of Medical Students in Matters Relating to Pharmacy", Proceedings of the Twenty-Third Annual Meeting of the National Association of Boards of Pharmacy and the American Association of Colleges of Pharmacy (Chicago: The National Association of Boards of Pharmacy, 1960), pp. 68-69.

⁵1958 Proceedings of the National Association of Boards of Pharmacy (Chicago: The Association, n.d.), p. 165.

their proper and safe distribution, whether dispensed on the prescription of a medical practitioner or legally dispensed or sold directly to the ultimate consumer.⁶

This definition does partially shift the emphasis from compounding to dispensing and distribution. In the eyes of many pharmacists compounding should be even further de-emphasized and more weight placed on the distribution functions of pharmacists. One other criticism directed at this definition by pharmacists is that it fails to bring out that pharmacists act as a double check for physicians on prescriptions and advise and answer questions of physicians and customers.

Two points require consideration before accepting this definition in its entirety. In the first few words pharmacy is described as a profession. There seems to have been some feeling on the part of the committee that questions as to the professionalism of pharmacy could be answered by simply defining pharmacy as a profession.⁷ This fairly widespread misconception on the part of some defenders of the professional status of pharmacy appears in numerous published articles as well as legislation. The difficulty here lies, of course, in treating the proposition "pharmacy

⁶1960 Proceedings of the National Association of Boards of Pharmacy (Chicago: The Association, n.d.), pp. 249-251. The National Association of Boards of Pharmacy has not yet adopted this legal definition on the suggestion of legal counsel that it would be inadvisable to do so while many state pharmaceutical associations were debating the question of definition before the courts as defendants in antitrust suits. There may be further changes once the National Association again takes up consideration of the definition.

⁷1959 Proceedings of the National Association of Boards of Pharmacy (Chicago: The Association, n.d.), p. 227.

is a profession" as a self-evident truth. That the proposition does not enjoy universal acceptance is suggested in the interpretation by pharmacists of the antitrust complaints filed by the Department of Justice and by their consciousness of having need for recognition as a profession. As one pharmacist has put it: "Persons outside the profession who stand to profit greatly by the demotion of pharmacists to a non-professional status, and the practice of pharmacy to a purely economic enterprise...are anxious to reduce the scope of professional pharmaceutical services. . . ." ⁸ Acceptance of this part of the definition must wait for a more basic examination in this report of the concepts of professionalism and pharmacy and the relation between the two.

Care must also be exercised in accepting the passage concerning the proper and safe distribution of drugs and medicines "legally dispensed or sold directly to the ultimate consumer." This is, in part, an attempt to emphasize the importance of the distributive function of the pharmacist in insuring "the proper and safe distribution of drugs and medicines." ⁹ The safe distribution of drugs is a desirable objective in the eyes of most people and to the extent that pharmacists are motivated by such objectives they are credited with acting altruistically. However, the passage under discussion would, in effect, assign responsibility to the pharmacist for dispensing not

⁸ George P. Hager, "On Entering a Profession", South Dakota Journal of Medicine and Pharmacy, XV, No. 2 (February, 1962), 72.

⁹ 1959 Proceedings of the National Association of Boards of Pharmacy, p. 226.

only prescription drugs, but also those items which may be sold without a prescription such as patent medicines. Historically, most of these latter items have been sold through other retail outlets as well as through pharmacies. The major objection to restricting the sales of non-prescription items to pharmacists has been stated by the Executive Secretary of the California State Board of Pharmacy:

It only stands to reason that if a delivery boy, a soda-clerk, or a cosmetic girl, employed in a pharmacy can sell these preparations without having special training or knowledge, or without the advice or supervision of a pharmacist, the same products can also be sold by untrained clerks in other businesses.¹⁰

There is a need to clarify and justify this part of the definition before it can be accepted.

With these qualifications in mind, the definition of pharmacy as presented by the committee is the definition adopted for the purposes of this report.

As a supplement to this definition of pharmacy, it might be helpful to note Heffron's list of functions performed by pharmacists:

1. They [pharmacists] serve the people by accurately compounding the medicines prescribed for them by their doctor.
2. They instruct, guide, and advise them as to the use of prescribed medications.
3. They advise them and counsel them on other medicinal preparations purchased by them.
4. They advise them as to warnings and cautions which should accompany certain kinds of medication when it is to be self-administered, as to contraindications, side effects, sensitivity, etc.

¹⁰Floyd N. Heffron, "The Pharmacist's Professional Function! What Is It?", Utah Pharmaceutical Association Bulletin News, LXX, No. 11 (November, 1961), 10.

Those are considered to be professional functions. In addition to those functions, they also have the responsibility of keeping themselves informed of new drugs, new preparations, etc., so that they may serve as consultants and advisors to the practitioner. As medical consultants, they should be prepared to answer questions for the doctor in reference to the use, dosage, method of administration, frequency of dosage, limitations, side effects, contraindications, warnings, and other information of this nature. If not prepared to answer questions of this nature, they should know where such information can be found and have the references readily available for their use.¹¹

¹¹Ibid., p. 14.

CHAPTER III

THE DEVELOPMENT OF PHARMACY

The history of pharmacy, which spans many centuries, has been marked by continuing struggle on the part of the pharmacists in Europe and the United States to achieve the independent and respected professional status which they believe their function entitles them to. On the one hand they have sought to raise their standards and to eliminate unqualified practitioners while simultaneously de-emphasizing the mercantile aspects of their work. On the other hand they have had to contend with physicians who practice the very art that pharmacists believe should be reserved to them.

Early History

Medicine in earlier periods was the responsibility of priests and largely a matter of magic modified by empiricism.¹ Later, in Greece and Rome medicine was divorced from magic, but pharmaceutical treatment remained the responsibility of physicians. As early as 2100 B. C. there were separate shops for the sale of drugs, but the shopkeepers were merchants, not drug preparers or compounders. Pharmacy, as a specific practice, was first established in Bagdad about the eighth century.

¹Kremers and Urdang, p. 3. A primary source for material in this chapter was Kremers and Urdang. Also helpful was E. H. LaWall, Four Thousand Years of Pharmacy (Philadelphia: J. B. Lippincott Co., 1927).

European Developments

There were public pharmacies in Italy and France as early as the eleventh century. German Emperor Frederick II in 1240 issued an edict which recognized pharmacy as a distinct vocation with defined functions and legally regulated services. Even before this edict pharmacists had created their own guilds. Under the guilds the practice of pharmacy was further formalized and specific educational and practical experience requirements introduced. Entry to the profession was restricted and standards of conduct and performance designed to protect consumers were developed and enforced.

England was the exception among European countries for it was not until the nineteenth century that a profession of pharmacy developed. Prior to that time apothecaries (pharmacists) were minor medical practitioners with a monopoly, granted by charter in 1617, over the preparation and administration of medical remedies. Apothecaries gradually devoted more time to medical than pharmaceutical functions and their monopoly was invaded by the chemists and druggists who proceeded to gain legal recognition of the vocation of pharmacy.²

The key to the rise of pharmacy as a distinct vocation in Europe was the guild. Guilds, under powers granted by charter and occasionally by law, were able to define clearly the vocational functions that only they could perform. Thus the functions of gathering, preparing, compounding, and dispensing drugs became the recognized province of the apothecary or pharmacist.

²A. M. Carr-Saunders and P. A. Wilson, The Professions (Oxford: Clarendon Press, 1933), pp. 132-135.

Their claims were accepted by society and pharmacy guilds were permitted the power of economic and social self-regulation. These powers allowed guilds to demand that members carry on the vocation in a way that would not endanger public health and well-being. In turn, the guilds were forced to make this demand of members if they were to retain self-regulatory powers. The enforcement of standards raised the status of the profession in medieval European society.

As pharmaceutical guilds gradually disappeared in Europe, their functions were assumed in part by voluntary professional associations and in part by government. Today, in most European countries there are comprehensive laws regulating the practice of pharmacy, and the enforcement and administration of the law is assumed by government agencies alone or in cooperation with pharmacy associations. Present European laws restrict entry into the profession to those meeting certain educational and experience requirements and provide standards of practice for the protection of the public.

The Development of Pharmacy in the United States: 1600 to 1800

Despite the presence in the United States of a large number of continental European immigrants with training and experience as pharmacists, they were not a dominant force in seventeenth and eighteenth century American pharmacy. Instead of benefiting from the established traditions of Italian, French, and German pharmaceutical practice as a distinct, organized profession, pharmacy in the United States followed the English pattern. Physicians and surgeons prepared and dispensed their own drugs. Apothecaries were

primarily another class of medical practitioner. Trained pharmacists who restricted themselves to the functions of pharmacy found themselves in competition with and out-numbered by "self-styled" pharmacists. This latter group can be compared with the druggists and chemists in England who originated as grocers specializing in drugs and medicinal compounds. The practice of physician prescribing for filling by pharmacists was almost totally unknown. Lack of professional business volume and competition from untrained pharmacist-merchants forced qualified pharmacists to broaden the line of goods in their shops resulting in their often becoming more merchant than pharmacist. Many pharmacists chose the alternative of combining medical practice with dispensing.

Pharmacy, medicine, and other vocations claiming professional status in the United States shared the common problem of not having the benefit of a guild system. The alternative ways of accomplishing the objectives of a guild were through (1) voluntary associations, (2) government action, or (3) both. This last course was successfully adopted in the nineteenth century.

By the end of the eighteenth century there were a growing number of individuals, largely qualified pharmacists and druggists, interested in separating pharmacy from the general practice of medicine and taking the necessary steps to raise the profession's status in society. Before the advocates of professional pharmacy could realize their objectives many difficult problems had to be solved including: (1) defining the functions and responsibilities of pharmacists (To do this requires, in effect, defining medical functions and responsibilities which should be performed by physicians and other medical practitioners); (2) gaining acceptance

of the definition of a separate vocation of pharmacy by pharmacists, other medical practitioners, and the general public; (3) developing and enforcing, through legislation or self-regulation, minimum standards for the practice of pharmacy to prevent the preparation, dispensation, or use of adulterated drugs and the preparation and sale of harmful nostrums to the end of protecting the health and welfare of the consumer; (4) limiting the practice of pharmacy to qualified, trained individuals; (5) defining common goals of pharmacy and organizing to effectively achieve those goals; and (6) emphasizing and promoting the professional aspects of pharmacy as opposed to the mercantile or trade elements. Attempts to solve these problems largely form the story of pharmacy in the nineteenth century.

The Development of Pharmacy in the United States: 1800 to 1900

In the effort to strengthen their profession, pharmacists used the powers available to private interest groups as well as the public powers of government.

Voluntary Associations

Central to pharmacy's development were the growth of pharmaceutical associations. Local associations were the first to appear, followed by national and, finally, state organizations. Philadelphia druggists organized the College of Apothecaries in 1821 which was chartered in 1822 as the College of Pharmacy. The College founded the first American school of pharmacy in 1823 and began publishing the Journal of the Philadelphia College of Pharmacy, the first

pharmaceutical journal in the English language. Pharmaceutical associations were founded in New York and Boston during the 1820's and in other cities in later years. The first national organization, the American Pharmaceutical Association (APhA) was established in 1852.

Associations gained quick acceptance. In addition to the APhA the following national associations, originating in the year indicated, were active before 1900: (1) Conference of Teaching Colleges of Pharmacy (1870); (2) National Wholesale Druggists' Association (1876); (3) The Proprietary Association of America (1881); (4) National Retail Druggists' Association (1883); and (5) Association of Boards of Pharmacy and Secretaries of State Pharmaceutical Associations.³ Perhaps the most significant accomplishment of these associations was that they provided a forum for the promotion of common interests and the development of group and vocational unity.

Maine organized the first state pharmaceutical association in 1867. Early state organizations were encouraged and fostered by the APhA and were often originated by APhA members. Their growth was stimulated by the need for effective groups to solve problems originating within the state. For example, the New Jersey Pharmaceutical Association was founded (1870) after the state Medical Society sought the passage of legislation to control dispensers of medicines. The growth of state and territorial associations was phenomenal and by 1900 only Arizona, Wyoming, and

³Kremers and Urdang, pp. 266-269.

Nevada were without one. Their growth paralleled the passage of state pharmacy laws which were also the result of APhA action.⁴

Professional Literature

The development of pharmaceutical literature paralleled the growth of professional associations. It helped distinguish pharmacy as a separate occupation, encouraged standard practices, promoted scientific and professional activities, and provided a forum, especially in the journals, for the shaping of opinion in the profession. A major step in the scientific and professional advancement of pharmacy was the publication of the first edition of The Pharmacopeia of the United States of America in 1820, which lists drugs and medicines and describes their properties, preparation, and use. Periodically revised, the book remains to this day one of the essential tools of the pharmacist. Textbooks and journals were published as early as the 1850's and by the turn of the century there were numerous scientific, professional, and trade publications devoted to one or another aspect of pharmacy.

Educational Institutions

During the same period pharmacy colleges and apprenticeship or experience requirements were developed. They provided for better trained practitioners and opened the way for claims to professional status. It should be pointed out that these early colleges were not schools in the usual sense of the word, but were associations of pharmacists interested in improving

⁴Ibid., pp. 257-258.

the quality of drugs sold to the public. Their educational activities were limited to lectures and occasional courses and were regarded as supplementary to the practical training provided by the apprenticeship system. It was not until the Civil War that the first regular college of pharmacy became operative.⁵ The shift from reliance on the apprenticeship system to formal education did not really begin until the 1880's. It was not until 1904 in New York that graduation from a recognized school of pharmacy became a legal requirement for licensing. Graduation is now a prerequisite for licensing in all states since Massachusetts and Nevada adopted the requirement in 1948.⁶

Legislation and Enforcement

Voluntary associations, professional literature, and educational institutions were essential factors in helping pharmacists achieve recognition as a separate branch of the healing arts with some claim to professional status. Not all of the common objectives could be accomplished by voluntary activities; some required legislation and government enforcement. Two such objectives were (1) limiting entry to the profession to qualified individuals, and (2) enforcing minimum standards of practice to protect the consumer. Once the need for governmental participation was recognized and accepted, voluntary pharmaceutical associations could expand their activities to include lobbying.

⁵George Urdang, "The Way of American Pharmacy to Its Present Stage", The General Report of the Pharmaceutical Survey: 1946-49 (Washington: American Council on Education, 1950), p. 18.

⁶Ibid., pp. 20-21.

Early legislation regulating pharmacy was largely at the local level and ineffectual.⁷ By the 1870's most of the pharmaceutical legislative activity was being carried on at the state level. This was necessary for a number of reasons including the fact that local legislation was too limited in scope to be successful while the federal constitution, reinforced by court decisions, had reserved to the states the sort of police powers incorporated in pharmacy laws. There is a striking relationship in most of the states between the year in which the state pharmaceutical association was organized and the year a pharmacy law was passed. By 1900 45 states or territories had adopted such laws.⁸

The state laws accomplished, at least in part, several of the objectives sought by pharmacists for they "defined the difference between a pharmacist and a mere merchant [and] they established professional pharmacy as a distinct entity, existing for the public good."⁹ In addition, they restricted the practice of pharmacy to licensed practitioners, and created boards of pharmacy, composed of pharmacists, authorized to examine and license applicants, and to enforce "regulations governing the drug trade within, and to some extent outside of, the pharmacies".¹⁰

⁷Ibid., p. 23.

⁸Kremers and Urdang, p. 276.

⁹Ibid., pp. 276-277.

¹⁰Urdang, p. 23. Urdang does not clarify what regulations boards enforce "outside of" pharmacies but his article is drawn from Kremers and Urdang, History

The Pharmaceutical Industry

The organization of a pharmaceutical industry for development of new products, production of medicinal chemicals, formulation of drugs into the various dosage forms, and marketing of pharmaceutical preparations, commenced in the nineteenth century when these functions began to be transferred from the wholesale-retail pharmacists and individual researchers to drug manufacturers.

The reliance on Europe as the source of drug supplies is the primary reason why most early apothecary or drug shops were both retail and wholesale operations and why manufacturing was begun by retail-wholesale druggists. As the number of pharmaceutical manufacturers grew and competition intensified, however, they assumed an increasing share of the research work and responsibility for controlled standardization through the formulation of drugs into individual dosage forms.

of Pharmacy, where the statement is made:

The expansion of state as well as federal legislation pertaining to drugs, within and without the field of pharmacy, has considerably expanded the general law-enforcing duties of the State Boards of Pharmacy. Still, the main task of the Boards consists in the examining, the licensing and the registering of pharmacists: the guardianship of the identity and the integrity of a well-defined profession of pharmacy. (p. 277)

From this it seems clear that the enforcement of laws concerned with drugs as a commodity is generally entrusted to an agency other than a board of pharmacy.

The general pattern of drug marketing in America prior to the Civil War consisted of the importation of crude or raw drugs from Europe by combination wholesale-retail merchants operating general stores with drugs as a sideline. The bulk of their retail operation consisted of selling drugs directly to the public without prescriptions. As wholesalers "their main professional activity was to provide the country physicians with drugs, . . . and with compounded medicines which they often produced in their own laboratories."¹¹ Stores dealing in drugs were largely in the hands of merchants and physicians.

The separation of wholesale from retail establishments became both necessary and economically feasible with increased population, the settling of new areas, and improved means of communication and transportation and the rapid increase in the number of drug items and dosages available. This separation became clear with the creation of the Western Wholesale Druggists' Association (renamed National Wholesale Druggists' Association) in 1876 and the National Retail Druggists' Association in 1883. Both groups grew out of the feeling of druggists that the APhA was not an adequate vehicle for the protection and promotion of business interests.¹² As was the case with so many pharmaceutical organizations these two were the result of defensive moves on the part of those in the occupation to meet specific problems. In this instance, the most serious threats were price cutting and a tendency on the part of the growing manufacturing industry to deal directly with the consumer.

¹¹Kremers and Urdang, p. 400.

¹²Ibid., p. 267.

It was not commercially sound in the nineteenth century nor is it now, with few exceptions, for retail druggists to deal exclusively in drugs. Prescribing by physicians, while it has continued to grow, never provided sufficient volume to permit more than a small percentage of retail pharmacists to limit their operation to the professional activities of preparing and dispensing ethical drugs. Almost all retail pharmacies sell proprietary and patent medicines, and many offer a wide range of sundries for sale, and operate soda fountains or lunch counters.

The Pharmacist's Problem

The major problem facing pharmacists at the end of the nineteenth century was still the gaining of professional status in society. While pharmacists were in general agreement on what their functions should be they had yet to convince others. Professionalization required raising the vocational standards of pharmacists to a level comparable with other professions, maintenance of strong voluntary associations to promote common goals, emphasis on professional as opposed to mercantile duties of pharmacists, and the encouragement of pharmacists' activities motivated by ethical and altruistic considerations to the end of earning general acceptance by other professionals and the general public of pharmacy as a profession.

The Development of Pharmacy in Hawaii

Three major historical factors have inhibited the development of pharmacy in Hawaii: (1) the forced growth of physician dispensing and drug store ownership due to lack of trained druggists in early years; (2) the following by pharmaceutical manufacturers of

foreign rather than domestic marketing policies in Hawaii sales; and (3) the development of plantation medicine.

The Lack of Trained Pharmacists

Medicine, as practiced by the Hawaiians in early times, was a primitive mixture of magic and empiricism. Local medicine men (kahuna lapa 'au) relied largely on herbs, physical manipulation (lomi-lomi), and religious ritual. For about a century following the discovery of the Islands by Europeans, pharmacy did not exist separately from medicine. It was another function of the physician. The Hawaiians were first introduced to Western medicine as it was practiced by ships' captains and an occasional ship physician. In 1820 missionaries reaching Hawaii brought with them the first resident medical practitioner. By the 1840's there were many doctors throughout the islands.¹³

These early resident physicians did their own drug dispensing, depending for supplies of drugs and medicines on passing ships, mainland druggists or, if missionaries, on shipments by the Missionary Board from Boston. The first public pharmacy was opened in 1847. It was owned by a doctor, establishing a pattern of doctor-owned pharmacies that lasted into the 1880's. The first drug store not owned by a doctor or a dentist appears to have been established in 1869. A few years later, Benson, Smith, and Company was founded and was probably the initial drug store in Hawaii owned and operated by a trained druggist. Within the next three

¹³"Early Hawaii Medicos", The Hawaiian Annual for 1933 (Honolulu: The Printshop Company, Ltd., 1932), pp. 55-56.

years Hollister and Company were also listed as druggists.¹⁴ By 1889, the Honolulu Business Directory included a listing for a hospital pharmacist.

Shortly before the turn of the century there were only four drug companies; but there were also twenty-one Chinese druggists. The popularity of Chinese druggists or "herbalists" is one of the factors which explains the small number of pharmacists in Honolulu in 1900. Perhaps more important was the continued practice of physician dispensing in lieu of prescribing. Hollister Drug Company and Benson, Smith were wholesalers as well as retailers. As retailers they did a prescription business and as wholesalers they sold directly to doctors on the same terms as they sold to other retail outlets.

The Application of Foreign Marketing Policies

Further complicating the early development of pharmacy in Hawaii was Hawaii's status as a foreign country. American pharmaceutical manufacturers, therefore, did business in Hawaii through their foreign marketing divisions. Policies applicable in the domestic market did not govern the trade with Hawaii. Manufacturers would sell directly to doctors, retailers, wholesalers, hospitals, and other outlets at the "net trade price" (the price paid to the wholesaler by the buyer). On the mainland the growth of retail pharmacists' associations preceded the development of the pharmaceutical manufacturing industry in sufficient time to enable pressure to be brought on the manufacturers to limit their sales to wholesale and retail druggists.

¹⁴Honolulu Business Directory (Honolulu: J. E. Brown & Co., 1889), n.p.

Most of the companies were agreeable to this restriction because it minimized their distribution problems and costs. Almost without exception, those firms that continued selling directly to doctors and others charged the same price the doctor would have had to pay a wholesaler or retailer. The effect of the higher price was to remove part of the economic motivation for physician dispensing.

Plantation Medicine

Pharmacists were late arrivals to Hawaii and were slow in organizing. They faced an uphill battle to gain equal economic treatment with their mainland counterparts. At the very time that pharmacists were increasing in Hawaii and beginning to act as a group, their problems were further complicated by the growth of plantation medicine. Although the sugar industry began in 1835 it was not until the 1900's that plantations became large enough to employ physicians and build hospitals. Plantation hospitals and dispensaries dominated rural medicine well into the 1950's when collective bargaining led to the acceptance of health insurance plans by plantations and workers and the rapid curtailment of plantation medical activities.

Usually the staff of a plantation hospital or dispensary consisted of a physician, nurse, and other personnel necessary to operate the facility. Pharmacists were not employed and doctors, nurses, or other employees did whatever dispensing was required.

Physicians and patients accepted alike the practice of physician dispensing as normal. Many patients are not satisfied unless they receive some medication when treated by the physician. Thus, the factor of habit or custom was added to other motives for its continuance.

The Status of Pharmacists

To achieve the status pharmacists in Hawaii desire and believe they deserve requires disturbing the position of other groups. Chief among these other groups are physicians who are accustomed to dispensing as an integral part of their practice and have, in addition, an economic motivation to dispense that mainland doctors generally lack. Fear that competitors would not follow suit has kept wholesalers and manufacturers from changing their practices. Over sixty years have passed since annexation and the marketing of drugs in Hawaii still follows patterns established under the monarchy. One way to explain this situation is in terms of the relative strengths of the groups involved. Pharmacists in Hawaii have always been a small, loosely organized group. They depend for successful achievement of their goals on the cooperation of other interested parties because they lack the strength to overpower large, well organized groups such as the doctors. The necessary cooperation on the part of physicians, manufacturers, and wholesalers to change marketing policies, however, has not been forthcoming.

CHAPTER IV

MODERN PHARMACY

Because the focus of this study is on state regulation of pharmacy, and, more specifically, on Hawaii regulation of pharmacy as it concerns the marketing operation of the pharmaceutical industry, the emphasis in this report is on retail pharmacy. This is not, however, an unnatural emphasis for nearly 90 per cent of those claiming pharmacy as their profession work in the retail establishments popularly called drug stores. Manufacturing and wholesaling are less the practice of pharmacy than activities which make it possible for pharmacy to be practiced. Only slightly more than five per cent of registered pharmacists are employed in pharmaceutical manufacturing and wholesaling (Table 1, page 3). Most of these five per cent are salesmen or businessmen and not practicing pharmacists. Practicing pharmacists are found mainly in retail pharmacies with a smaller sprinkling in hospital pharmacies.

Retail and hospital pharmacies are the major outlets for ethical drugs and proprietaries.¹ In 1961 there were 54,345 retail pharmacies and 2,781 hospital pharmacies

¹"By definition, a proprietary medicine or health preparation is one that is manufactured and sold only by the owner of the patent, formula, brand name or trademark which identifies the product. More specifically, however, it is a packaged medicine which is advertised to the public--a home remedy for treating a minor temporary ailment for which it is indicated." Health News Institute, Inc., Facts About Pharmacy and Pharmaceuticals (New York: The Institute, 1958), p. 62. The term patent medicines is still often used in reference to proprietary medicines. Ethical drugs are those that are advertised only to pharmacists, physicians, and other related professions and usually can be sold only through a prescription.

in the United States, employing a total of 110,425 registered pharmacists or 93.4 per cent of all employed pharmacists.² Clearly, the activities of such a large proportion of pharmacists are going to be equated with the general public's definition of the practice of pharmacy. In a very real sense pharmacy as practiced by retail and hospital pharmacists is the practice of pharmacy.

Legal regulation of manufacturers to protect consumers is primarily carried on by the federal government. This is because pharmaceutical manufacturers are generally engaged in interstate commerce and not subject to state or local legislation which may be interpreted as interference with interstate commerce. In addition to regulating the manufacture of drugs as a commodity, the federal government also regulates interstate drug traffic which involves most manufacturers, wholesalers, and retailers. State laws also cover manufacturing and intrastate drug traffic but play a minor role in relation to federal statutes. States with pharmaceutical manufacturing industries are interested in them as businesses as much as in their functions as drug manufacturers. The predominant legal interest of states in drug wholesalers is as businesses and as a part of the intrastate drug traffic. It is with pharmacists in their function as drug dispensers that state pharmacy laws are primarily concerned. It is impossible, however, to discuss the changes and problems of marketing without considering the other interrelated operations of the pharmaceutical industry, so these are also discussed in the pages which follow. Further, where applicable, the practices

²1961 Proceedings of the National Association of Boards of Pharmacy (Chicago: The Association, n.d.), pp. 61, 64. Figures do not include Alaska, Hawaii and Puerto Rico.

prevalent in Hawaii will be compared to those of the mainland.

In most respects pharmacy is practiced in Hawaii today as it is on the mainland. State law requires that an applicant for licensing be a graduate of an accredited pharmacy college. Since Hawaii does not have a pharmacy college, local pharmacists receive their training in mainland schools, beginning practice with the same general skills and knowledge as those starting in practice on the mainland. The distribution of practitioners among the various areas of pharmacy parallels the mainland pattern with the overwhelming majority in retail operations, a smaller number in hospital practice, and several employed as detail men. Operations of the pharmaceutical industry found in Hawaii are limited to the activities of manufacturers' representatives (detail men), manufacturers' local sales and warehouse branches performing functions identical to wholesale druggists, wholesale druggists, retail druggists, and hospital pharmacists. These operations are carried on largely as they are on the mainland and many of the problems, strengths and weaknesses are similar. The problems facing wholesale druggists in Hawaii, for example, are common to wholesalers throughout the country.

The differences between pharmacy in Hawaii and the mainland are chiefly ones of degree rather than kind. Nationally, the ratio of pharmacists to population is 64.3 pharmacists per one hundred thousand population. The District of Columbia leads with a figure of 117

while Hawaii is the lowest in the country with 30.1 pharmacists per hundred thousand population.³

Pharmaceutical Manufacturing

The manufacture of pharmaceutical preparations is a multi-billion dollar a year business in the United States. Domestic sales alone are over two billion dollars as the data in Table 2 show. Dollar volume has increased by over 60 per cent in six years.

The synthetic organic chemical industry has been growing in importance since the turn of the century and especially since the First World War when the industry was successful in securing federal legislation making German patents available to American companies. Prior to this time competition among manufacturers was predominantly a matter of promoting proprietary medicines. Even more important to the ultimate growth of the industry was its recognition of the importance of research, and the consequent development of new products. The multiplication of available products, the demand for

³NABP Bulletin, XII, No. 12 (October, November, December, 1961), 6-7. The data do not necessarily imply that there is a shortage of pharmacists in Hawaii; many other variables need to be considered in analyzing such ratios, including the extent of physician dispensing, the pattern of population concentration, and the sales volume of goods usually sold in drug stores in other outlets such as plantation stores, department stores, and discount houses. In the course of the study no consensus was found on the question of whether a shortage of pharmacists exists in Hawaii. Some employers in interviews reported difficulty in finding pharmacists while others did not find this a problem. The most commonly mentioned reasons for difficulty in hiring pharmacists were (1) low salaries in Hawaii as compared to California, other Western states, and many other areas in the mainland, and (2) the geographical isolation of Hawaii.

TABLE 2

TRENDS IN DOMESTIC SALES OF PHARMACEUTICAL
PREPARATIONS IN MANUFACTURERS' SALES DOLLARS
UNITED STATES
1954, 1958 and 1960

	<u>1954</u>	<u>1958</u>	<u>1960 Estimated</u>
Prescription Sales	\$ 536,954,800	\$ 851,658,000	\$ 930,806,400
Hospital and Institutional Purchases	225,540,000	295,520,000	323,588,800
Physician Purchases	<u>196,895,000</u>	<u>263,344,000</u>	<u>288,216,300</u>
Total Domestic Ethical Sales	\$ 959,389,800	\$1,410,522,000	\$1,542,611,500
Proprietarys	<u>369,226,000</u>	<u>576,582,000</u>	<u>616,940,000</u>
Total Pharmaceuticals for Human Use--Domestic Consumption ^a	\$1,328,615,800	\$1,987,104,000	\$2,159,551,500

Source: Modern Medicine Medical Market Guide
(Minneapolis: Modern Medicine Publications
Inc., 1960), p. 6.

^aFigures adjusted for interplant transfers and export-import balance excluding
preparations for veterinary use from Census of Manufacturers source.

greater quantity production and the need for uniformity of product were responsible for the adoption of new mass production manufacturing processes and quality control procedures.

Uniformity of Dosage

Logically, the place to insure the uniformity of individual dosages was at the point of manufacture. Here it was possible to use machines and mass production techniques to compound identical dosages, whereas the distribution of bulk drugs to pharmacists for compounding increased the possibility of variations in individual dosages. Pharmaceutical manufacturers now compound well over ninety per cent of prescriptions. A 1960 analysis indicated the figure was close to 95 per cent; the comparative figure for 1945 was 71.3 per cent.⁴

Turnover of Drugs

There are about 1,200 ethical products under more or less heavy promotion to the medical professions at any one time. About 400 of these appear five or more times per 10,000 prescriptions and thus are considered in the profitable category. A study of the 1958 prescription market showed a heavy turnover in this profitable group involving relatively new products which was attributed to (1) competitive research for new products and (2) modern "crash" promotional programs

⁴"A Report on the 1960 Prescription Market", Modern Medicine Topics, XXII, No. 10 (October, 1961), 2.

that create almost immediate acceptance and prescription demand in the medical profession.⁵

Research Activities

Manufacturers, to maintain a share of this lucrative market, are motivated to carry on vigorous research and promotion programs. While society benefits greatly from new products there has been increasing criticism of manufacturers for some of their practices both from within and outside the profession, particularly for marketing products that were not efficacious. The comprehensive drug bill passed by the last federal congress now requires the FDA to check the efficacy of a new drug before it is marketed.

Promotional Activities

Vigor in promotional activities has also received its share of praise and blame. It is important that the medical profession and pharmacists are informed of new drugs and their uses, contraindications, and dosage. The most effective means of promoting drugs is personal contact by detail men (medical service representatives) employed by the manufacturers to call on physicians, pharmacists, and other professionals. Approximately 15,000 detail men are active today. Direct mailing of literature and samples and advertising in medical and allied journals are also employed.

⁵David D. Stiles, "More Drugs Die Younger As More People Live Longer", Modern Medicine Topics, XX, No. 9 (September, 1959).

Retail Cost of Drugs

Most criticism of the ethical pharmaceutical industry is centered on the unduly high retail price of drugs when related to production costs. Complaints about the costs of drugs led to the hearings by the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary chaired by Senator Estes Kefauver (therefore, commonly referred to as the Kefauver Drug Hearings), beginning in December, 1959 and continuing intermittently well into 1962. It was suggested by the Subcommittee that the high costs of drugs were attributable to: (1) unnecessary research costs directed toward duplicating successful products marketed by competitors, (2) excessive promotional costs, especially if the view is adopted that the market (sick people) is there from the start, and promotion can not expand it, and (3) price-fixing agreements among manufacturers.⁶

The purposes and results of the Kefauver Drug Hearings are largely beyond the scope of this report. However, some of the developments of the hearings have implications for the practice of pharmacy in Hawaii. For example, the high costs of promotion (24 per cent of total sales dollars)⁷ encourages manufacturers to reduce costs elsewhere. This may lead them to bypass

⁶Frank Cacciapaglia, Jr., and Howard B. Rockman, "The Proposed Drug Industry Antitrust Act--Patents, Pricing, and the Public", The George Washington Law Review, XXX, No. 5 (June, 1962).

⁷Ibid., p. 880. This is an average figure and for some companies promotion costs may be considerably higher.

the wholesaler and, in some cases, the retail druggists and use their detail men to sell directly to hospitals, clinics, doctors, and other large volume customers.

The Wholesale Druggist

There are two classes of wholesale druggists: specialty-line wholesalers who usually stock the products of a single manufacturer and tend to be small; and multiple-line wholesalers who stock a wide variety of products from many manufacturers and are frequently large. The potential stock of a wholesaler is indicated by the fact that in 1957 a retail druggist had access to 172,320 separate items produced by over 7,200 manufacturers. Over 15,000 ethical pharmaceutical items alone were available.⁸ The expansion of wholesaling is a phenomenon of this century and reflects the growth of pharmaceutical manufacturing as well as the increase in sundry items sold by retail druggists.

Wholesalers are a service operation. Retailers benefit by having a wide variety of items available from a single source close at hand, allowing them to maintain a smaller inventory, and by receiving credit on purchases. Manufacturers benefit by not having to fill countless small orders and being able to rely on others to take care of distribution.

However, since World War II the lot of the wholesaler has been an increasingly unhappy one. The biggest problem facing the wholesaler is the continuous increase in manufacturer's direct sales to large volume customers. The net effect is to leave wholesalers primarily with the small accounts. Wholesalers

⁸Facts About Pharmacy and Pharmaceuticals, pp. 67-68.

contributed to this problem when their need to limit their purchasing, cut inventory investment, and reduce losses on obsolete merchandise resulted in a basic change in their buying policy. Whereas they once purchased a three to four months supply now they found it more expedient to buy small quantities more frequently. The effect on manufacturers was to force them to increase their inventories and warehousing facilities and thus raise their distribution costs. Some manufacturers responded by setting up their own distribution system, completely bypassing the wholesaler. Others continued to supply wholesalers while increasing their direct business with large volume consumers. Many manufacturers, in any case, had been complaining that wholesalers failed to aggressively sell their lines.⁹ By 1960 Eli Lilly and Company was the only major ethical pharmaceutical manufacturer distributing exclusively through wholesalers.¹⁰

At the same time wholesalers are also faced with competition from retail druggists organizing cooperative wholesale operations and by the increase in large medical clinics which, unlike the independent doctor, can purchase a large enough volume of drugs to warrant the manufacturers selling to them directly.

For the most part the wholesale drug business in Hawaii is similar to mainland operations. Hawaii's geographical location accounts for the biggest single difference which is the time it takes for merchandise

⁹A. Hamilton Chute and Esther J. W. Hall, The Pharmacist in Retail Distribution (Austin: Hemphill Publishing Co., 1960), p. 21.

¹⁰"Drug Industry: Filling Prescriptions Under Fire", Business Week (December 10, 1960), p. 148.

to arrive from the manufacturer. Many mainland wholesalers can get approximately 70 per cent of their merchandise overnight. Shipments to Hawaii customarily take four to six weeks. One result of this time lag is that the average local wholesaler carries a greater inventory than the mainland wholesaler. This requires a heavier dollar investment in inventory and larger warehousing facilities. There are six wholesale drug firms in Hawaii selling ethical drugs and other merchandise and an equal number of branches of pharmaceutical manufacturers who also perform warehousing functions. There is also one cooperative association of retail druggists purchasing for about twenty members. Wholesalers here benefit to some extent from Hawaii's position as a geographically limited market. Because of this fact many manufacturers, who bypass wholesalers on the mainland, sell only through them in Hawaii.

Hospital Pharmacy

Pharmaceutical purchases by hospitals have grown phenomenally in relation to the prescription business of retail druggists. In 1929 hospitals sold 3.4 per cent of the volume of pharmaceuticals sold by retail druggists; in 1960 this percentage figure had risen to 34.8.¹¹ There are 4,691 pharmacists practicing in 2,781 hospital pharmacies which makes them the second largest group of employed pharmacists, ranking only behind retail pharmacists.

¹¹Derived from "Lower Prices Helped Many Pharmacies Withstand Rx Discounters, Study Shows", American Druggist (March 19, 1962) and "The Hospital Pharmacy Market", Modern Medicine Topics, XXI, No. 10 (October, 1960).

The trend toward larger, better equipped, fully staffed hospitals has resulted in the employment of more pharmacists by hospitals. As a review of the data in Table 3 indicates, a higher proportion of hospitals with large bed capacities have pharmacy departments than the smaller hospitals. This is equally true of Hawaii as it is of the United States.

Functions of the hospital pharmacist are limited to purchasing pharmaceutical supplies, compounding, manufacturing certain drugs such as injectables, dispensing, and education, formally or informally, of other staff members. A comparison of hospital pharmacy functions with Floyd Heffron's list of pharmacy functions¹² indicates two significant differences between hospital and retail pharmacists. First, hospital pharmacists do not have any retail merchant functions to perform. They do not "sell" drugs and medicines or other items, but devote themselves solely to what Heffron considers "professional functions". Second, in retail pharmacy there exists a physician-pharmacist-patient relationship which almost disappears in hospital pharmacy. Hospital pharmacists rarely dispense directly to the inpatient consumer except on his discharge; most often a nurse administers the drug to the inpatient. Of course, pharmacists do some direct dispensing to outpatients and employees in many hospitals.

Hospital pharmacy in Hawaii does not differ significantly from mainland practices except that there is a lower percentage of hospitals with pharmacies in Hawaii than on the mainland (Table 3). There is no clear trend indicating this percentage will be increasing in the near future.

¹²See above, pp. 20-21.

TABLE 3

HOSPITALS WITH PHARMACY DEPARTMENTS

UNITED STATES AND HAWAII

Number of Beds	United States		Hawaii	
	Number of Hospitals	Per Cent With Pharmacy	Number of Hospitals	Per Cent With Pharmacy
Under 25	182	22.5	3	--
25-49	461	33.2	9	11.1
50-99	681	54.4	6	--
100-199	851	87.8	6	50
200-299	450	97.8	3	33
300-499	288	99.7	4	50
Over 500	110	100	1	100

Source: Data for the United States from "The Hospital Pharmacy Market",
Modern Medicine Topics, XXI, No. 10 (October, 1960).

Data for Hawaii from "The U. S. Medical Market: Hawaii",
Modern Medicine Topics, XXI, No. 9, (September, 1960) and
Hawaii Board of Pharmacy.

Retail Pharmacy

Most of the general problems of pharmacy today are related, in one way or another, to retail pharmacy. The history of pharmacy differs from that of most businesses because of its dual objectives. In common with other businesses, pharmacy sought to gain a part of the market sufficient to insure practitioners a livelihood. To this objective, pharmacy added the desire for professional status. Pharmacists based their claim to professionalism on those functions they performed involving drugs and medicines and, primarily, on the function of compounding. Increased prescribing by physicians strengthened their claim by shifting a greater share of the responsibility for drug preparation and dispensation to pharmacists. Another favorable factor encouraging the recognition of specialization was the rapid expansion of the number of drugs available. Other medical professions and the general public tended, in the early decades of the twentieth century, to honor pharmacists' claim to professionalism. There were always doubters and skeptics¹³ and the battle for status was never wholly won.

Problems of Retail Pharmacy

Pharmacists, having relied so heavily on the compounding function in this struggle, received a blow to their professionalism from which they have never recovered when compounding was largely transferred to

¹³Carr-Saunders and Wilson, pp. 435-436 state: "The case of the pharmacist calls for no special comment. He is a shopkeeper and he observes the customs of shopkeepers."

the pharmaceutical industry. "With those skills went the public recognition formerly accorded to the pharmacist for them. Despite the profession's satisfaction with its new role as an expert consultant and custodian of potent chemotherapeutic agents, there is today less recognition for the professional contributions of the pharmacist by the public and by medical practitioners."¹⁴ This is the dominant problem discussed in pharmaceutical literature today.

Other problems and the outlook for the future have been discussed by one pharmacist in these terms:

It is evident that the turmoil in pharmacy overflows with complexity. Is it transitory or must we prepare for a situation in which pharmacy as we know it today will undergo a drastic change? The answer cannot be more than a guess. Nevertheless there are certain possibilities that must be considered:

1. The unions may open drug stores in every sizable city of the country.
2. The giant food chains and supermarkets may invade pharmacy services on a scale that would destroy numerous thousands of independent retail druggists.
3. Chains of drug stores which belong to the category of predatory merchandisers may multiply.
4. Mail order firms in the drug field may grow instead of diminish.
5. Pharmacy facilities owned by clinics and physicians in group practice may become usual.

¹⁴William S. Apple, "Pharmacy's Neglected Challenge", American Journal of Pharmaceutical Education, XXV, No. 4 (Fall, 1961), 518.

6. Outpatient departments of the hospitals may make it regular to provide pharmacy services in competition with the drug stores.

The enumerated possibilities added together total enough to make it appear that the future of the independent retail druggists is abysmal indeed and that the profession of pharmacy is headed for a status composed for the most part of employees with meager prestige and circumscribed opportunities. . . .

It is rash, perhaps, to forecast in detail the things that will happen in the retail drug areas. Nevertheless it is said quite often that:

1. Most of the "papa and mama" drug stores are "on the way out".
2. The independent drug stores will average much larger than most of them are now; a sizable amount of floor space is needed for effective displays of merchandise.
3. The number of independent drug stores per capita will decrease despite the growth in population. (The capital needed to purchase a profitable pharmacy or to establish one will become too much for most of the younger employed pharmacists to raise. Also the extent of tough competition will tend to discourage investments in independent drug stores.)
4. The ratio of employed pharmacists to independent owners of drug stores will increase a sizable amount.
5. Most of the employed pharmacists will be unionized in order to bargain in strength on wages, hours, duties, fringe benefits, etc.¹⁵

¹⁵John W. Dargavel, "Pharmacy and the Onrush of Change", American Journal of Pharmaceutical Education, XXV, No. 4 (Fall, 1961), 525-526.

As on the mainland, most of the problems of pharmacy in Hawaii are problems of retail pharmacy and it is in this area that some significant differences between Hawaii and the mainland are evident. In Hawaii the average retail drug store has a greater sales volume but does less prescription business than its mainland counterpart. This fact is symptomatic of the major role physicians play in dispensing medicine in Hawaii which leads to a fair amount of conflict between the two groups as well as to a number of questions as to what constitutes the public interest.

Drug Store Sales

A wide variety of products are sold in drug stores as is apparent from a review of the data in Table 4. Prescriptions accounted for almost 28 per cent of sales in 1961. (A higher figure, compiled by Eli Lilly and Company covering different drug stores cites a figure of 35 per cent. See Table 5.) Other health aids such as over-the-counter ethicals, advertised remedies, prescription accessories and health supports, make up almost 25 per cent of sales. Other important categories, measured in terms of sales, include toiletries and cosmetics, the fountain, and tobacco. Almost 50 per cent of total sales may be attributed to items which bear no relation to pharmacy; another 25 per cent represents sales of items commonly available through retail outlets other than pharmacy equipped drugstores.

Generally, the distribution of the drugstore sales dollar was quite similar in 1961 to what it was in 1954 with two notable exceptions: prescription sales increased from 22.1 to 27.6 per cent of the total and fountain sales dropped from 12.2 to 8.0.

TABLE 4

DISTRIBUTION OF DRUG STORE SALES DOLLAR
BY CATEGORY OF GOODS SOLD
UNITED STATES
1954 and 1961

Category	1954 Per Cent of Total Sales	1961 Per Cent of Total Sales
Prescriptions	22.1	27.6
Over-Counter Ethicals	6.4	7.3
Advertised Remedies ^a	11.1	9.9
Rx Accessories	4.6	3.9
Health Supports	na	2.7
Toiletries, Cosmetics	10.5	10.3
Fountain	12.2	8.0
Packaged Ice Cream	1.8	1.3
Candy, Gum, Nuts	3.7	3.2
Tobacco ^b	6.4	5.8
Magazines ^c	3.0	2.5
Liquor, Wine, Beer	4.9	3.9
Photo Products	1.9	2.5
Photo Finishing	0.9	1.5
Writing Items	2.4	2.3
All Other	8.1	7.3
Totals	100.0	100.0

Source: American Druggist quoted in Facts About Pharmacy and Pharmaceuticals (1954 sales); American Druggist (1961 sales).

^aIncludes household drugs and insecticides, animal and poultry health goods, and pet items.

^bIncludes some toiletries sold at the tobacco counter.

^cIncludes books, magazines, newspapers.

^dIncludes stationery, greeting cards, writing tools.

TABLE 5

PRESCRIPTIONS AS PORTION OF TOTAL SALES IN AVERAGE
LILLY DIGEST PHARMACY
UNITED STATES
1940-1961

Year	Total Sales	Prescription Sales	Percentage of Prescription Sales to Total Sales	Number of Prescriptions	Prescription Price	Per Cent of Stores With 25 Per Cent or More of Total Sales in Prescription Volume
1940	\$ 34,882	\$ 4,416	12.7	4,756	\$.93	na
1945	59,907	8,477	14.2	7,065	1.20	na
1950	78,190	15,987	20.4	9,020	1.77	na
1955	101,593	27,688	27.3	11,273	2.46	53
1960	138,342	47,825	34.6	14,972	3.19	78
1961	139,176	49,144	35.3	15,135	3.25 ^a	79

Source: Lilly Digest: 1961.

^aOther tabulations for the average price per prescription for 1961: 1962 Drug Topics Marketing Map: \$2.97; "Marketing Research Memo", Abbott Laboratories: \$3.25; R. A. Gosselin and Company, National Prescription Audit: \$3.22 (Abbott Laboratories and R. A. Gosselin & Co. figures quoted in "A Report on the 1960 Prescription Market", Modern Medicine Topics, XXII, No. 10[October, 1961]); American Druggist, March 19, 1962: \$3.22.

In Hawaii prescriptions represent only 17.2 per cent of total sales.¹⁶ Data for other departments in Hawaii drugstores were not available, but clearly the Hawaii retail pharmacist is not getting the same share of the prescription business as his mainland counterpart. Probably, however, he is getting more prescription business now than he was seven years ago.¹⁷

Prescription Sales

The increasing importance of the prescription business to retail druggists, while suggested in Table 4, is more pronounced among those stores participating in the Lilly Digest survey. Trends in prescriptions are shown in Table 5 from 1940 to 1961 during which span of time the relative volume of prescription sales has risen from 12.7 per cent of total sales to 35.3 per cent and the average number of prescriptions filled per store from 4,284 to 15,135¹⁸ a year. From 1952, when the portion of stores with 25 per cent or more of total sales in prescription volume was 38 per cent, the number has more than doubled until now 79 per cent of the stores reach this figure. Digest data, based on a sampling of less

¹⁶1962 Drug Topics Marketing Map of the U. S. Retail Trade.

¹⁷Interviews with wholesalers, local manufacturer's representatives, and retail pharmacies suggest that the trend is a steady increase in the prescription business of the Hawaii retail pharmacist.

¹⁸Other 1961 tabulations for average number of prescriptions per store: 1962 Drug Topics Marketing Map of the U. S. Retail Drug Trade: 13,724; American Druggist: 12,701.

than five per cent of the drug stores in the United States, may exaggerate the degree of growth, but all available studies support the fact that significant growth in the prescription business has occurred.¹⁹

The price of the average prescription, according to Lilly, has risen steadily since 1940 when it cost \$.93. Now the average price is \$3.25. (Other estimates ranged between \$2.97 and \$3.25.) The Kefauver Subcommittee charged that prescription prices were too high and their cry was echoed in many magazine and newspaper articles.²⁰ A favorite industry response to this charge was to point out that the \$2 or \$10 or \$20 paid for a prescription today often cures or prevents what would have been a costly, even fatal, illness a few years ago. Since the hearings began prescription prices have tended to decline. On the other hand, the industry's claim is unquestionably true, even if it has not much to do with the issue of excessive profits.

The Hawaii store fills only 60 per cent of the prescriptions filled by the average drug store in the United States but its dollar volume is 81 per cent of the U. S. average, reflecting the higher price

¹⁹American Druggist (March 19, 1962) figures show prescriptions as 34.8 per cent of total dollar volume for independent retail drug stores. The comparable per cent for chain drug stores is 7.3 per cent which is sufficient to bring the total for all drug stores down to 27.6 per cent. This may indicate that a higher proportion of independents participate in the Lilly Digest survey than do chains.

²⁰"Lower Prices Helped Many Pharmacies Withstand Rx Discounters, Study Shows", American Druggist, p. 6.

per prescription.²¹ No study has been made to determine if the prescriptions filled by Hawaii retail pharmacists are similar to those sold by their mainland counterparts. It may be that Hawaii physicians tend to dispense the more common, lower cost drugs themselves, and to rely on pharmacies for the more exceptional and more expensive medicine.²²

Economic Competition in Retail Pharmacy

Retail pharmacy in the United States grew out of combination wholesale-retail operations owned by individual druggists or businessmen, giving rise to the term "independent" in contrast to the "chain store" which is one of many under the same ownership. Independents still number more than ninety per cent of all drug stores, but receive competition from several sources: (1) chain drug stores and voluntary associations of druggists; (2) price cutters and discount houses; (3) manufacturers who sell directly to consumers; and (4) physicians who dispense.

Chain Drug Stores. Chains and similar operations represent the most serious competitive threat to the independents. United Drug Company and Walgren, which have paced the rapid development of the chain drug stores, established the pattern of placing their outlets

²¹The cost of the average drug store filled prescription in Hawaii was \$4.10 as compared to \$2.97 nationwide. (These data are derived from the Drug Topics Marketing Map; the United States figure is \$.28 lower than Lilly's.)

²²This has been suggested in several interviews and the point made that such a practice would enable dispensing physicians to lower their inventory investment at a minimum loss of customers.

predominantly in urban centers where the potential volume was high. The number of chain drug stores increases each year and they are predominant in shopping centers. The effect of this pattern is clear. Chain drug stores with prescription departments, comprising less than 10 per cent of all drug stores, do 25 per cent of the total business. Their sales per square foot of floor space exceed \$108 as compared to \$70 per square foot for the independents; their volume of sales per store is three times greater nation-wide. (In Hawaii the sales volume of chains was only slightly more than twice as high as the independents which is probably attributable to the high proportion of chains to independents in Hawaii [1:2.6] as compared to the country [1:9.4].) Chains throughout the nation, however, earned only 7 per cent of their gross revenues from prescriptions as compared to 35 per cent for the independents. The chain drug store specializes in volume sales; the independent retail pharmacist more in prescriptions.²³

That chain drug stores occupy the more favorable business locations in terms of potential sales volume compared with independents is borne out by two studies of the 1961 drug store market.²⁴ While there is a

²³Compiled from "Gain By Sundries Tops All Other Departments for Second Year in a Row, Study Shows", American Druggist (May 14, 1962); "Space for 'Better Living' Departments Grows", American Druggist (June 25, 1962); and, 1962 Drug Topics Marketing Map of the U. S. Retail Drug Trade.

²⁴"Lower Prices Helped Many Pharmacies Withstand Rx Discounters, Study Shows", American Druggist and 1962 Drug Topics Marketing Map of the U. S. Retail Drug Trade.

significant difference between the two studies as to average sales per chain store even the lower figures indicate an average sales volume three times that of the independent.

Fair Trade Laws. Price cutting and cut-rate stores brought the National Association of Retail Druggists into the legislative field in support of fair trade laws. The effect of fair trade laws is, "that any manufacturer, by signing a contract with a merchant for the sale of a product at a particular price, for all practical purposes licenses all others to sell the product at not less than the stipulated price."²⁵ Druggists were one of the key groups responsible for the passage of fair trade laws in many of the states. These laws relieved some of the pressures of price cutting, particularly in the area of ethical drugs. However, in the past decade some fair trade laws have been repealed or nullified by court action.

The retail druggists in Hawaii have been fairly successful in gaining the cooperation of manufacturers in the maintenance of fair trade prices. There is not presently any active discount drug operation in the state. In a recent case where a retail outlet began discounting drugs some seventeen manufacturers filed injunctions calling for the outlet to cease selling the manufacturers' products at less than fair trade prices. In this situation, it appears that the retail druggists acted effectively as a group. However, price maintenance on ethical drugs has created some problems

²⁵Frederick C. Irion, A Survey of Licensing in New Mexico (Albuquerque: University of New Mexico, 1949), p. 3.

for the retail druggists, as witness a recent complaint filed by the federal Department of Justice against the Hawaii Retail Druggists Association charging violation of section 1 of the Sherman Antitrust Act which forbids pricing actions resulting in restraint of trade.

Discount Houses. After the Second World War, the so-called "discount houses" began to appear in ever increasing numbers. Relying on price cutting to attract business they had almost overnight success in establishing themselves as serious competitors with other retail merchants. Having begun with non-fair trade items for the most part, they soon began to sell merchandise comparable with fair trade products and, increasingly, fair trade products themselves. In the latter case, injunctions were brought by manufacturers, and if the law stood the test of court action, discounters had to sell at minimum fair trade prices. Independents felt they benefited (some said, existed) because of fair trade laws. The benefit to manufacturers was more intangible. Their dilemma was, on the one side, that they would lose retail outlets if discount houses forced independents out of business and, on the other side, their enforcement of fair trade laws was losing them the lucrative discount house business. Discount houses now appear to be a permanent feature of the retail market and the tendency is away from fair trade laws. The situation in Hawaii is uncertain at present. While the retail druggists have stopped discount drug sales they may begin again at any time. This is especially possible in view of the fact that the Hawaii Retail Druggists Association no longer exists as an independent organization, having been absorbed as a committee of the Hawaii Pharmaceutical Association following the filing of the Justice Department's complaint.

Shopping Center Drug Stores. Chain drug stores in shopping centers were briefly mentioned above. Shopping center pharmacies, whether chains or not, are getting a bigger share of drug store sales volume each year. According to the 1962 shopping center study by the American Druggist, 10.5 per cent of drug stores are now in shopping centers and claim 27.7 per cent of total retail drug sales. Table 6 reveals the rapid growth of drug stores and sales in shopping centers. The shopping center drug store is bigger in size and dollar volume than is the one located outside a center. It also is better able to withstand discount house competition.

TABLE 6

PER CENT OF DRUG STORES AND DRUG STORE
SALES IN SHOPPING CENTERS
UNITED STATES
1956-1962

<u>Year</u>	<u>Per Cent of Drug Stores in Shopping Centers</u>	<u>Per Cent of Drug Store Sales in Shopping Centers</u>
1956	3.3	7.6
1957	3.9	9.2
1958	4.7	11.1
1959	6.4	15.8
1960	7.8	18.9
1961	8.8	22.8
1962	10.5	27.7

Source: American Druggist, August 20, 1962.

There are no specific sales figures available for Hawaii but the general trend has been similar to the mainland pattern of chain drug stores expanding into new urban population centers as well as shopping centers.

Other Competition. Prescription competition also comes from hospitals, clinics, and public and private dispensaries maintaining internal pharmacies and, occasionally, opening them to the general public.

Other competition in drug and related health aids comes from mail order companies, health food centers (dietary specialties and food supplements), industrial firms and insurance company offices selling barbiturates, amphetamines, tranquilizers, estrogens, and antibiotics to employees at discount prices, labor unions with mail-order prescription services for members, and cooperative buying groups such as veterinarians.²⁶ However, the biggest competition for prescription business comes from the dispensing physician.

Physician Dispensing

Approximately 19 per cent of total domestic ethical drugs sold in the United States in 1960 were purchased by physicians. Of the remainder, drug store prescription purchases constituted 60.3 per cent and hospital and institutional purchases 21 per cent (See Table 2, page 43).

Extent of Physician Dispensing in Hawaii. In Hawaii, however, physicians purchased more drugs than they prescribed, as the data in Table 7 show.

²⁶Chute and Hall, p. 217.

TABLE 7

ESTIMATED PHARMACEUTICAL SALES - HAWAII^a

1960

(Manufacturers' Sales Dollars)

<u>Prescription Sales</u>	<u>Hospital Purchases</u>	<u>Physician Purchases</u>	<u>Total Ethical Pharmaceuticals</u>
\$1,444,000	\$1,380,600	\$1,546,000	\$4,370,600

Source: Modern Medicine Medical Market Guide
(Minneapolis: Modern Medicine Publications,
Inc., 1960), p. 219.

^aThese figures are not exact. As pointed out in the source (p. 5) "the data used were accumulated through the help of physicians, executives of manufacturers, detail men selling in this market, and individuals living in [this state]". The relative distribution of total sales among prescription sales, hospital purchases, and physician purchases is generally accepted as accurate by those involved in local pharmaceutical activities.

A recent study of the Hawaii medical market concluded, "Hawaiian physicians purchase as great a volume as they prescribe, whereas physicians in the other 48 [sic] states prescribe four to five times the volume of drugs they purchase for their office, bag, or for dispensing."²⁷ Considering physician purchases as a per cent of prescription sales results in a figure of 107 per cent for Hawaii, 65 per cent for Vermont (the state with the highest percentage

²⁷"The U. S. Medical Market: Hawaii", Modern Medicine Topics, XXI, No. 9 (September, 1960), n.p.

after Hawaii), and 31 per cent for the nation as a whole.²⁸

Of the 333 physicians responding to a questionnaire sent out by the Legislative Reference Bureau, 211 physicians replied that they dispensed drugs other than those drugs that should be administered by or under the immediate supervision of a physician and those administered while on a house call as the data in Table 8 indicate. Dispensing contributes less than 10 per cent of gross income for most physicians who are dispensing. Less than three per cent of the reporting physicians earned more than 20 per cent of their income from dispensing.

Reasons for Physician Dispensing in Hawaii. Hawaii's history as a foreign nation, a frontier, and the paternalistic society of the plantations, provides a partial explanation for the high physician purchases of drugs in Hawaii. However, other parts of the United States have experienced similar historical development, with different consequences for pharmacy. There is, however, an economic motivation for physician dispensing in Hawaii that does not exist in most of the mainland, with the exception of a few areas in the southeastern parts of the United States. Even there the situation is not strictly analogous because the emphasis is on proprietary rather than ethical drugs. In Hawaii pharmaceutical manufacturers and wholesale druggists sell drugs to doctors at the same price as they do to retail druggists, but on the mainland they generally do not sell to doctors at all. Thus mainland medical practitioners must buy their

²⁸ Modern Medicine Medical Market Guide (Minneapolis: Modern Medicine Publications, Inc., 1960), pp. 62-65.

TABLE 8

NUMBER OF PHYSICIANS DISPENSING DRUGS AND INCOME
DERIVED FROM SUCH DISPENSING
HAWAII 1962

Per Cent of Income ^a	Independent Practice	Clinic or Group Prac- tice With- out a Phar- macy ^b	Clinic or Group Prac- tice With a Pharmacy ^c	Other	Total
Zero or No Answer	5	1	12	1	19
0-5	64	8	60	1	133
6-10	25	5	12	--	42
11-20	8	2	1	--	11
21-30	1	1	--	--	2
31-40	2	1	--	--	3
41-50	--	--	--	--	--
Over 50	<u>1</u>	--	--	--	<u>1</u>
Subtotals	106	18	85	2	211
Limited Dispensing Only ^d	<u>67</u>	<u>23</u>	<u>19</u>	<u>13</u>	<u>122</u>
Total	173	41	104	15	333

Source: This table is compiled from questionnaires sent to the 606 doctors in Hawaii on the Hawaii Medical Association mailing list. The questionnaire is reproduced as Appendix A.

^aIn some cases more than one percentage range was checked. Those cases have been tabulated in the lowest range checked.

^bIncludes twelve doctors with combined independent-clinic practices.

^cIncludes two doctors with combined independent-clinic practices.

^dIncluded in this category are all the physicians who responded that they dispensed only (1) injectables; (2) those drugs that should be taken under the immediate supervision of a physician; and (3) those drugs administered while on a house call.

drug supplies from retail druggists, usually at a 25 per cent professional discount from the suggested retail price, an insufficient discount to cover the costs involved in preparing and dispensing drugs and still provide a profit.²⁹ Doctors in Hawaii have the same potential margin from dispensing as do retail druggists. The pricing practices appear in Table 9.

Pharmacist Opposition to Physician Dispensing.

Pharmacists have distinguished between "professional dispensing" and "economic dispensing" by doctors.³⁰ "Professional dispensing" is defined as providing drugs to patients only in emergencies, or where administration of the drug should be under the immediate supervision of the physician, or where no pharmacy service is available, or when the patient is impecunious. All other dispensing is "economic" and represents undesirable or improper competition with the pharmacist, whether he practices on the mainland or in Hawaii. In fact, physician dispensing has been attacked on the basis that it limits free choice of pharmacist:

Is it not also likely that the dispensing physician and the clinic affiliated pharmacy will tend to restrict the patient's choice? Free choice of physician is, of course, a traditional right, which is to be vigilantly guarded and preserved. Free choice of pharmacist is also a traditional part of our pattern of health service. The dispensing physician and the clinic pharmacy do not, of course, literally deprive the patient of free choice. But in actual practice, it seems highly probable that the availability of drugs in the doctor's office or the clinic pharmacy will create a psychological situation where

²⁹Chute and Hall, p. 296, referring to prescription departments in retail drug stores state: "The prescription department should operate at an average gross margin of 40 to 50 per cent or more to be profitable."

³⁰Ibid., pp. 219-220.

TABLE 9

PRICING PRACTICES OF WHOLESALE DRUGGISTS
AND PHARMACEUTICAL MANUFACTURERS
HAWAII AND THE MAINLAND

Customers:	Per Cent Discount From Suggested Retail Price Given by Wholesale Druggists ^a		Per Cent Discount From Suggested Retail Price Given by Pharmaceu- tical Manufacturers ^a	
	<u>In Hawaii</u>	<u>In Mainland</u>	<u>In Hawaii</u>	<u>In Mainland</u>
Doctors	40	Do not normally sell directly to doctors.	40	Most pharmaceutical manufacturers do not sell directly to doctors.
Retail Druggists	40	40	40	40
Hospitals	40	Most hospitals buy either from pharmaceutical manu- facturer or retail druggist.	40	20-40 ^b
State and Local Government Institutions ^c	40-45	Most state and local institutions buy either from pharmaceutical manu- facturer or retail druggist.	40-50	20-50 ^b
Wholesale Druggists (courtesy sales only)	40-45	Not usually done.	50-60	50-60

^aThe listed percentage discounts are intended to represent the average. Actual discounts may fluctuate greatly. For example, on a bid to a large hospital the discount might go as high as 80 per cent.

^bThis broad range is attributable to a number of variables such as the size of the order.

^cFederal institutions not included because uniform prices are set in Washington D.C.

the patient will almost feel compelled to purchase prescriptions there.³¹

The wide variety of arguments produced by pharmacists against dispensing physicians are ultimately based on an appeal for cooperation from physicians as fellow professionals. It is another part of the long battle of pharmacists for recognition of their functions as separate from other medical functions. In the eyes of pharmacists it is a matter of professional ethics: pharmacists do not practice medicine and, therefore, doctors should not practice pharmacy.

Pharmacists consider licensing as society's recognition of their abilities as preparers and dispensers of drugs and medicines. These are the professional functions of pharmacy and to diffuse them is to weaken pharmacy's professional status. Therefore, the attempt to obtain a larger volume of prescription business is partially motivated by the desire for greater professional status. The reverse may also be true, i.e., that the desire for professionalization is motivated by the wish for a larger share of prescription business.

Most Hawaii pharmacists recognize the right of the physician to dispense drugs personally. What they question is the right of the physician to delegate the function of dispensing to nurses, attendants, or other employees. In support of their argument, the pharmacists point to Section 71-19, Revised Laws of Hawaii 1955 requiring physicians to dispense personally. The response of physicians is that they are legally responsible for all aspects of patient medical care

³¹Henry M. Moen, "Dispensing Physicians and Clinic Pharmacies", Minnesota Medicine, XLVIII, No. 10 (October, 1960), 701.

including the use of drugs to prevent or treat injury or sickness. Physicians cite Section 64-1 of the Revised Laws in support of their claim that their responsibility for the care of the patient includes the responsibility to delegate to individuals under their direction authority to perform the activities that make up the practice of medicine, including dispensing. Many physicians feel that nurses are as qualified to dispense as are pharmacists.³² The obvious solution appears to be to amend the law to clarify who may legally dispense. Following this tack, the Board of Pharmacy has introduced legislation to limit clearly the right of physicians to dispense through their employees to certain specified situations such as when there is not a retail pharmacy within three miles of the doctor's place of business.³³ Physicians oppose any restrictions on their right to dispense through employees. This conflict is the heart of one of the major problems in pharmacy regulation in Hawaii.

Actually, in 1955 the medical profession liberalized the Principles of Medical Ethics as they relate to dispensing. The rule which read "an ethical physician does not engage in barter or trade in the appliances, devices or remedies prescribed for patients, but limits the sources of his professional income to professional services rendered the patient", has been

³²This view, as well as many other expressions of opinion on both sides of this conflict, were expressed in the responses to the questionnaires sent to physicians and pharmacists by the Legislative Reference Bureau.

³³The Board of Pharmacy considers this a measure liberalizing the present restrictions on physicians. Conversely, the physicians view it as an attempt to clarify the Board of Pharmacy's authority to restrict the practice of medicine by physicians.

revised to read "it is not unethical for a physician to prescribe or supply drugs, remedies or appliances as long as there is no exploitation of the patient."³⁴ Pharmacists, and others, argue that dispensing physicians will always be subject to temptation and open to questions in the minds of others in the matter of dispensing samples, "cheap" drugs, and what is on hand rather than what the patient needs.

To date, pharmacists have not convinced physicians, legislatures, or the general public that dispensing by physicians should be restricted. In fact, the number of new prescriptions per doctor has declined in the last two years from 2,110 in 1959 to 2,034 in 1960 and 1,989 in 1961.³⁵ The future possibilities for pharmacy to capture a bigger share of this part of the drug market still appear to depend on the cooperation of physicians.

The Nature of the Conflict. One part of the conflict is economic. As small businessmen, retail druggists want to increase their sales volume. If they could get some of the ethical drug sales now made by physicians this would mean a substantial rise in dollar volume. The other side of the economic conflict is the natural inclination on the part of physicians against giving up a part of their income. Insofar as economic motivations are concerned the battle belongs in the arena of private economy with the ultimate resolution dependent on the actions of pharmacists, physicians and their customers and patients

³⁴"Pharmacies", Journal of the American Medical Association, CLXXXI, No. 2 (July 14, 1962), 47.

³⁵"Lower Prices Helped Many Pharmacies Withstand Rx Discounters, Study Shows", American Druggist, p. 6.

in their roles as private individuals or interest groups.

Another part of the conflict is based on the public interest in the preparation and dispensation of drugs and medicines. The average layman has no way of evaluating medicines that are prescribed for him. The consequences of prescribing or dispensing improperly can be serious. The inability of the individual to protect himself leads society to assume the responsibility through such means as pure food and drug laws, narcotic control laws, and licensing laws designed to insure that only qualified individuals practice vocations such as medicine and pharmacy. The question that remains is whether the public interest is served by present practices.

CHAPTER V

PROFESSIONALISM AND OCCUPATIONAL LICENSING

In the last three chapters pharmacy has been defined and the pharmaceutical industry and the practice of pharmacy described to the end of explaining the social and economic roles of pharmacists and pharmacy. With this background the next step is to examine the existing laws regulating drug manufacturing and distribution and the vocation of pharmacy and to determine if there is a need for modification of existing legislation or enactment of new laws. The first part of this chapter briefly outlines the present federal and state laws relating to drugs and the practice of pharmacy. Those laws pertaining to drugs and connected with specific problems in Hawaii are discussed further in chapter six. The balance of chapter five is devoted to the pharmacy licensing law.

Current economic problems facing pharmacists are depicted in the preceding chapters. These are problems of pharmacists as a private interest group competing in a free economy and, as such, should probably be resolved through private action in the market place. They are not related to a more general public interest and thus would not appear to justify the exercise of government action or the use of public powers. Some recent actions of the Hawaii Board of Pharmacy would clearly help alleviate some of the economic problems of pharmacists. An example is the attempt to exert pressure on dispensing physicians to stop using employees to dispense drugs and to rely more heavily on prescribing. Given that the Board's action may further a general public interest, it is also clear that if prescribing by physicians increases so will the sales volume of the retail druggist. Again, by

requiring all hospitals to have a pharmacist, the Board may be acting in the public interest, but it is also creating new jobs for pharmacists. Further, these jobs will be largely in small, rural hospitals geographically isolated from the mainland. To counteract these factors the hospitals may have to pay more than the prevailing salary rate to obtain pharmacists; this may have an upward effect on other pharmacist's salaries. A shortage of available pharmacists will heighten this effect. A natural question arises over whether the public interest cannot be met in a way that less obviously and directly furthers the private interests of a small group. The basic issue is whether delegation of public power in the form of self-regulation should be done at all. A general analysis of occupational licensing laws in the second part of this chapter suggests that such delegation is occasionally necessary, but should be limited to a few professions. This conclusion leads to developing criteria for distinguishing professions from non-professions. These criteria are then applied to pharmacy.

The delegation of public powers to a private group is not, of course, unique to pharmacy. Medicine, and a number of other occupations, enjoy the advantages of wielding public powers. Questions raised about the wisdom of making pharmacy self-regulating are equally valid for these other vocations.

The Laws Governing Pharmacy

Pharmacy, as a vocation and a business, must be practiced in accord with the multitude of federal, state, and local laws and regulations which are generally applicable to all, or most, businesses and vocations. In addition, pharmacy must comply with specific legislation which controls the composition and

labeling of drugs, restricts the use of certain drugs, and specifies who shall prescribe, prepare, and distribute certain categories of drugs. These laws share the common purpose of protecting public health by insuring that drugs are safe, effective, correctly and informatively labeled, properly prepared or compounded, and safely distributed.

Regulatory activities are almost exclusively divided between federal and state governments. The pertinent federal laws are the "Federal Food, Drug, and Cosmetic Act" of 1938, as amended, which controls quality and distribution of drugs; the 1938 Wheeler-Lea Amendment to the "Federal Trade Commission Act" which gives the Federal Trade Commission control over false drug advertising; and the federal "Narcotic Drugs Import and Export Act". While these laws are applicable in Hawaii, they are not central to the problems of pharmacy in Hawaii which are considered in this report.

States have a wide variety of laws relating to drugs including: (1) counterparts of the "Federal Food, Drug, and Cosmetic Act"; (2) sanitary laws governing manufacturers, wholesalers, and retailers; (3) pharmacy licensing laws; (4) laws limiting dispensing of certain drugs to a prescription basis; (5) special legislation controlling distribution of samples, auctions, vending machine sales, and prescription drug substitution; and (6) miscellaneous laws pertaining to animal medicine, poisons, prophylactics, economic poisons, and disinfectants and insecticides. The key law relating to the practice of pharmacy in every state is the occupational licensing law limiting entrance to the occupation to those meeting certain requirements. Most of the other state laws relating to pharmacy involve less, or little, controversy for their subject (poisons, for example), objective (protect the public

health and welfare), and methods of obtaining the objective (control of sales of certain poisons) are capable of much clearer definition than is licensing. This is due, in part, to the fact that these laws are directed to controlling a commodity--drugs. On the other hand, occupational licensing laws are concerned with controlling the practice of pharmacy as a vocation and do not normally pertain to drugs as a commodity.

Occupational licensing laws differ from other state laws relating to pharmacy because they tend to serve, almost equally, two contradictory ends. Public health, safety, and morals are protected by restricting entrance to the occupation to qualified people and requiring that their practice meet certain standards. At the same time, such laws further the private interests of members of the occupation by providing the means to create a monopoly situation, limit competition, and raise prices. The task of government is to establish a balance between public and private interests acceptable in a democratic society.

Occupational Licensing Laws

Licensing "is the granting by some competent authority of a right or permission to carry on a business or do an act which otherwise would be illegal. The essential elements of licensing involve the stipulation of circumstances under which permission to perform an otherwise prohibited activity may be granted--largely a legislative function; and the actual granting of the permission in specific cases--generally an administrative responsibility."¹

¹Occupational Licensing Legislation in the States (Chicago: The Council of State Governments, 1952), p. 5.

Legislative Aspects

The rise of occupational licensing laws in the United States has been characterized as a modern resurrection of the medieval guild system.² By the time America was colonized the guild system was in decline. It never was established in the United States although some features were adopted such as the classification of workers as apprentice, master, or journeyman, regulation of apprentices, and state authority to regulate prices. Late in the eighteenth century most of the states began to license medical practitioners and this appears to be the beginning of occupational licensing laws. The power to control and license was delegated to medical societies.³ Once other vocations realized the advantages of being licensed there was rapid expansion of such legislation.

The constitutionality of licensing laws is well established. Courts assume legislatures to have knowledge of local conditions sufficient to support the position that restrictive legislation was required to protect the public health, welfare, safety, or morals.⁴ Legislatures have great freedom in passing licensing laws and this, in part, accounts for the large number of occupations (Gellhorn estimates well over 80) licensed by one or more states.

²J. A. C. Grant, "The Gild Returns to America", The Journal of Politics, IV, No. 3 (August, 1942).

³Occupational Licensing Legislation in the States, p. 16.

⁴Walter Gellhorn, Individual Freedom and Governmental Restraints (Baton Rouge: Louisiana State University Press, 1956), p. 119.

Judging the Public Interest

The problem confronting government is the determination of what is the public interest, when the public interest requires government action, and what is the best course of action. Finding adequate solutions to this problem becomes more critical as society becomes more complex, new occupations arise, and specialization increasingly adds to the distinctions among occupations. Normally, the pressure on legislators is all from the group desiring licensing. It is rare that organized opposition appears. Therefore, it is important that legislators and other concerned individuals and groups have some criteria for judging the merits of licensing legislation. One commentator has felt compelled to declare:

Occupational licensing has gone too far. It compresses rather than liberates the economy, stratifies society instead of furthering its democratization. Nevertheless, the excesses and abuses of licensing do not entirely obscure its utility. It does afford protection against suffering at the hands of the blatantly inept or patently corrupt. The question to be considered is whether such protection as is truly necessary (for, after all, there is such a thing as over-protection) can be obtained with less social risk.⁵

Ideally, of course, government actions should always be justifiable on grounds of serving the public interest. Groups seeking to be licensed may be concerned with the public interest as well as motivated by the desire for economic control of their occupation and prestige. As long as there are potential rewards, economic or prestige, to be gained from licensing there will be continued pressure for government action to further private interests.

⁵Ibid., pp. 144-145.

Defining the Public Interest. Before government can act in the public interest there must be some agreement on what constitutes the public interest. The concept of the public interest has been widely considered in recent years⁶ and if there is any consensus among the participants it is that there is no single definition.

Lack of a universal definition does not preclude the usefulness of the concept of public interest. Wayne A. R. Leys suggests that definite meanings can be attributed to the public interest "as a set of criteria for judging proposed governmental actions."⁷ He identifies three kinds of problems arising from government actions and develops a definition of the public interest applicable to each kind of problem. In other words, the public interest is one of the guiding ideas helpful in analyzing alternative sets of procedures in the attempt to determine which set best fits a particular situation.

The central problem involved in government action through occupational licensing laws (and in this report, the Hawaii pharmacy law) is which procedures are to be adopted to achieve the desired goals. Where the procedures of government are "problematic or in dispute" the public interest is defined "as a common good, an aggregate of interests, the maximization of interest-satisfactions. . . ."⁸ Application of this

⁶Both of the following works provide an excellent insight into current thinking on the public interest and will suggest other reference sources: Glendon Schubert, The Public Interest (Glencoe: The Free Press, 1960), and Carl J. Friedrich, ed., Nomos V: The Public Interest (New York: Atherton Press, 1962).

⁷Wayne A. R. Leys, "The Relevance and Generality of the 'Public Interest'", in Nomos V, p. 255.

⁸Ibid., p. 248.

definition as criteria requires that the interests (individual, private or public group) served by each set of procedures are identified. It is then possible to measure roughly the extent to which a particular set of procedures meets each of the interests involved and to rank the various sets of procedures in an order based on (1) the range of interests they serve, and (2) the degree to which they satisfy those interests.

The Basis for Pharmacy Licensing Laws. The goal of occupational licensing laws can be clearly spelled out as the protection of the public health, safety, morals, or general welfare. More specifically, the purpose of the Hawaii pharmacy law is "declared to be the protection of the public health and safety."⁹ What remains to be decided is how best to provide the needed protection. The evaluation of each occupational licensing law can be done by answering a series of questions:

1. Is there a problem affecting the public interest?

The overwhelming majority of Americans take proprietary or ethical drugs and medicines each year. These products are potentially harmful and the individual's interest in the proper preparation and dispensation of drugs is the very basic one of self-preservation. Society has an interest in preserving the safety and well-being of its citizens that encompasses forestalling harm resulting from drugs as well as other sources.

2. Is the problem of sufficient magnitude to warrant government action? In this case, the question can be rephrased in terms of what the individual can do to protect himself, i.e., can the average layman protect himself from harm when taking drugs and medicines?

⁹Revised Laws of Hawaii 1955, 71-4 (e).

Again, the answer is self-evident. It takes special skills to understand the ingredients of drugs, the effects of combining ingredients, and the effects a drug may have on the human system. Most laymen do not possess these skills and protection then becomes a proper responsibility of government.

3. If government action is necessary, what alternative courses (including licensing) are available?

One possible answer to this question is that government action taken in the past in the form of laws against fraud and improper business practices is sufficient to provide necessary protection. Pharmacists compound drugs and this calls for special skills and training. It is in the general public interest to insure that unqualified persons do not compound products potentially harmful to individuals. General fraud and related statutes are not sufficient to provide such assurance. Therefore, specific legislation is necessary to restrict the practice of pharmacy to qualified people. The alternative choices are licensing or certification.

4. Which of the alternative courses maximizes the satisfaction of the various interests involved? The choice of alternatives posed in question three depends on the answer to this question. Certification distinguishes between those in a vocation with certain characteristics and those without. It does not exclude persons from engaging in the occupation but only forbids the use of some designated label. An example is found in nursing. In many states the right to nurse is not restricted but only those who have met certain educational requirements may call themselves "registered nurses".¹⁰ Licensing, on the other hand, restricts the

¹⁰Gellhorn, p. 147.

practice of the occupation to those with licenses which are issued only after the applicant presents certain proofs of proficiency. When the activities of a practitioner may affect the vital affairs of man it is essential to insure that he is capable of adequately performing those activities. The preparation and dispensation of drugs which have potentially serious effects on the physical well being of the consumer is an activity related to a vital need of man. As long as the practice of pharmacy requires compounding, and the requisite skills necessary to compound, the choice must be licensing because of the need to have the applicant prove possession of compounding skills.

Answering the four questions for pharmacy leads to the conclusion that pharmacy is one of the vocations requiring licensing in the public interest of protecting the public health and well-being.

The Administration of Occupational Licensing Laws

Historically, licensing laws incorporate provisions limiting entrance into an occupation and requiring authorized practitioners to observe certain minimum standards in their work. The purpose of licensing laws is to regulate the practice of a vocation and, therefore, licensing laws indirectly affect the quality of the final product of the licensed practitioner. Licensing laws were not traditionally designed to control directly either the raw material the practitioner worked with or the final product he produced. This general statement applies to pharmacy licensing laws which were developed to restrict the right to practice pharmacy to qualified individuals and to enforce minimum standards of practice on those admitted to the occupation. Pharmacy licensing laws were not designed to control directly the quality or traffic of drugs as

a commodity. The commodity, drugs, has been controlled through federal laws and state laws other than the pharmacy law. This historical distinction is beginning to blur as some pharmacy boards expand the scope of their activities into controlling drug traffic.¹¹ Such expansion makes the issue of self-regulation more critical because the occupation is given additional power to further private interests.

Administration of the laws is usually placed with a board which, in turn, is usually composed exclusively of licensed practitioners in the respective occupations. "These men and women, most of whom are only part-time officials, may have a direct economic interest in many of the decisions they make concerning admission requirements and the definition of standards to be observed by licensees. More importantly they are as a rule directly representative of organized groups within the occupation."¹²

Board activities include examining credentials of applicants, determining schools meeting board standards, preparing and administering examinations for applicants, granting reciprocity, promulgating and enforcing rules and regulations establishing professional standards of practice, and collecting fees.

It is easy to make the statement that licensing measures should be adopted only in the public interest,

¹¹See, for example, the new Ohio Dangerous Drug Distribution Act which became effective at the beginning of 1962. This Act places with the Ohio Board of Pharmacy the responsibility to control all aspects of intrastate drug traffic with the exception of state and political subdivisions which were excluded through oversight (Letter from Dr. Rupert Salisbury, Executive Secretary, Ohio State Board of Pharmacy, October 8, 1962).

¹²Gellhorn, p. 140.

and once law, should be administered on the basis of maximum social welfare. Conversely, it is difficult to suggest methods of insuring legislative or administrative decisions based on the greatest general welfare. The attempt to weigh the advantages and disadvantages of licensing in terms of furthering the public interest requires an analysis of the many varied factors that make up the vocation of pharmacy. The end-in-view of determining the proper role of the state in the regulation of pharmacy is obtainable only by first understanding the occupation, its relationship to other institutions in society, and finally, the relationship between pharmacy and individuals in society.

Organizational Arrangements. Administration of licensing laws "has been delegated to five kinds of public agencies: (1) completely independent licensing boards; (2) departments of education or public instruction; (3) departments of health; (4) offices of the Secretary of State; and (5) central licensing departments. The decision as to the type to be selected depends upon the kind of occupation, the need for securing practitioner cooperation in enforcement, the strength of the occupational association, the need for uniformity in standards and the degree of responsibility to public officials desired."¹³

In Hawaii the lack of a Secretary of State office eliminates that alternative, and constitutional peculiarities preclude completely independent licensing boards. Further, there is no rationale in placing pharmacy regulation with an educational agency. This narrows the choice to the Department of Treasury and Regulation or the Department of Health. Administration

¹³Occupational Licensing Legislation in the States,
p. 61.

of the pharmacy regulation law is, at present, delegated to a Board of Pharmacy placed in the Department of Treasury and Regulation for administrative purposes. In effect, administrative purposes means that the Department is responsible for representing the Board in communications with the governor and legislature, submitting the Board's budget as a part of the Department's, approval of rules and regulations, approval of personnel actions, approval of purchases of supplies and equipment, and the allocation of office space. In other respects, the Board of Pharmacy may act independently of the Department.¹⁴

Delegation of Power to Private Groups. The initial determination that must be made is between assigning the administrative powers to a relatively autonomous board composed of licensed practitioners of the vocation, or to an agency with no representation from the vocation, or some combination of the two arrangements. In essence the issue is whether to delegate to a private interest group the power of self-regulation. Lodging decision-making powers with elected officials provides a line of direct responsibility to the general public. When the legislative or executive branch delegates decision or policy making power to another agency the line of direct responsibility is broken. Inherent in delegating public power to form policy to private groups is the possibility of subverting democratic government by eliminating responsibility to the people as a whole.

Delegation of a part of its powers by a legislative or executive body to a private group should be a rare

¹⁴Revised Laws of Hawaii 1955, 1961 Supplement,
14A-4.

exception to the norm in a democracy. It should be considered a last resort and its adoption should imply the failure to find less abhorrent alternative means to cope with a critical matter. Judging from the number of independent boards¹⁵ created to administer licensing laws, state legislatures may be said to have looked on delegation as a convenient device for shedding responsibility rather than as a last resort. In this study concern is centered on defining those cases where delegation of occupational regulatory powers to the occupation itself is justified and, more specifically, whether self-regulation is justified in the case of pharmacy.

Granting the power of self-regulation is equivalent to delegating legislative-executive responsibilities. This delegation is justifiable only when the activities required to carry out successfully the responsibilities are beyond the capacities or powers of the legislative or executive body. Even the lesser evil may be not to carry out the responsibilities. The direct electorate-elected relationship gives rise to a set of standards, a moral code, or code of ethics, which governs the conduct of men in office. The ability to understand the code and live within it is a necessary prerequisite to continued office holding. More importantly, the standards are the general determinants of policy in a democratic society. Perhaps, then, the determining factor in delegation has to be the finding of a group with a set of standards insuring that their actions and decisions are primarily in the general public interest and not predominantly furthering private ends.

¹⁵In their study, Occupational Licensing Legislation in the States, the Council of State Governments counted over a thousand independent licensing boards (p. 3).

Applying this to occupational licensing laws suggests that self-regulation should be restricted to those vocations with an equivalent set of standards leading to action primarily in the public interest. Talcott Parsons points out that the institutions of business and profession share similar activities and goals, and that business men and professional men can not individually be characterized as altruistic or egoistic. It is on the institutional level that a meaningful distinction can be made. Egoistic behavior is encouraged in the institutional environment of business. The institution "profession" encourages altruistic behavior.¹⁶ Altruistic behavior or concern for a general public interest is fostered by professions through such means as codes of ethics and the enforcement of those codes by effective voluntary associations. In effect, these codes provide a set of standards encouraging action in the public interest. It is, of course, possible for vocations other than professions to adopt codes of ethics, but this does not mean that they should be delegated public powers for controlling their occupation. There is a more basic distinction to be made between the standards of professions and those of non-professions. The assumption is that in those few cases where self-regulation is necessary, it should be restricted to those occupations qualifying as professions. Therefore, in the following section criteria are developed enabling professional vocations to be identified and those criteria applied to pharmacy.

¹⁶Talcott Parsons, "The Professions and Social Structure", Essays in Sociological Theory Pure and Applied (Glencoe: The Free Press, 1949), pp. 185-199.

The Concept of Profession

The problem is further compounded by the fact that the label of "profession" carries with it several desirable rewards in our society. There are widespread attempts by individuals and groups to label themselves as professionals and this often involves defining the term to suit their desired end.

Labor force statistics indicate that no group is growing as rapidly as the professional, technical and kindred worker category.¹⁷ Much of this growth is, of course, attributable to the changing demands of the labor market. On the other hand, some of the growth results from extending professional recognition to new groups. At any given time numerous occupations are to be found pressing for professional status. Examples in the recent past, to list just a few, include social workers, sanitarians, dieticians, contractors, accountants, and occupational therapists.¹⁸

This raises the question of what groups seeking professional status hope to gain. Two observers of professions have attempted answers:

Society gives the professions a mandate to do certain jobs and grants them autonomy in order to do those jobs. This autonomy can be thought of as a socially distributed reward for the discipline of a professional life and for what that discipline makes it possible to achieve. To a great extent, the professions themselves decide what they are to do, how they

¹⁷George W. Hardbeck, "Occupational Trends in the United States, 1900 to 1960 and Their Implications", Labor Law Journal, XIII, No. 5 (May, 1962), 362.

¹⁸The drive for professional status is examined by Everett C. Hughes, "The Professions in Society", The Canadian Journal of Economics and Political Science, XXVI, No. 1 (February, 1960), 54-61.

are to do it, and who is to do it. In short, they are granted the privilege of defining their functions, their standards, and their qualifications.¹⁹

An important though implicit criterion of profession is revealed through study of the dictionary definitions. The first point to be noted is that the professions are described as dealing with the practical affairs of men. The dictionary then adds that "profession" is traditionally applied specifically to "the three learned professions of divinity, law and medicine". If these two statements are combined, it may be observed that the traditional professions mediate man's relations to God, man's relations to man and state, and man's relations to his biological environment. The practitioner's activities, then, impinge radically upon the most basic concerns of man. Such a concept might help explain the value, status, privilege, and power that have accrued to profession. These are considerations that would tend to become attached to the experts who serve the vital needs of mankind.²⁰

Countless definitions of profession are available. The problem is not to find a definition but to find one that is clear, minimally arbitrary, and able to withstand the inevitable protests from those the definition excludes. The task is not an easy one. Such astute analysts of profession as Alexander M. Carr-Saunders and P. A. Wilson have refused to define the term. Further, they have denied the existence of any test which would distinguish vocations which are professions from those which are not. Their proposal is that the term profession stands for a complex of characteristics. "The acknowledged

¹⁹Robert K. Merton, "The Search for Professional Status", The American Journal of Nursing, LX, No. 5 (May, 1960), 663.

²⁰Morris L. Cogan, "Toward A definition of Profession", Harvard Educational Review, XXIII, No. 1 (Winter, 1953), 35.

professions exhibit all or most of these features; they stand at the centre, and all around them on all sides are grouped vocations exhibiting some but not all of these features."²¹ In other words, some vocations are clearly professional while others approach more or less closely to this condition.

Carr-Saunders, Wilson, and others who refuse definition do not hesitate to identify the characteristics of "those vocations occupying the central position" as acknowledged professions. (Acknowledged professions seem to be the same professions Cogan classifies as traditional.) Their basic problem appears to be an inability to measure the degree to which these characteristics must be present before profession exists.²²

Those vocations that fall at either end of the continuum present no difficulty. Problems arise in trying to clarify the status of vocations that fall somewhere in between. It is with these vocations that it is important to have general agreement on such points as the criteria for testing professionalism, how many of the criteria must be met and in what degree they must be present. The difficulty of reaching accord on these matters is not sufficient cause for

²¹Carr-Saunders and Wilson, p. 284. Relevant here is Ernest Greenwood's comment: "... we must think of the occupations in a society as distributing themselves along a continuum. At one end of this continuum are bunched the well-recognized and undisputed professions . . . ; at the opposite end are bunched the least skilled and least attractive occupations. . . ." ("Attributes of a Profession", Social Work, II, No. 3 [July, 1957], 46.)

²²Cogan, Harvard Educational Review, XXIII, No. 1, 47.

dismissing them as unsolvable. It may be true that no absolute, universal definition, or set of criteria, can be developed. On the other hand, it is imperative that some decisions, even if arbitrary, be made if the alternatives of irrational or unintelligent actions are to be avoided.

One example, particularly relevant in the context of this paper, of the need for criteria or definition is related to legislative action. Legislators, in considering bills authorizing self-regulation or related grants of authority, require some means of intelligently analyzing such measures before acting upon them. The public interest is one standard and has been discussed. Another standard is involved in defining the groups where self-regulation is in the public interest. There is general agreement in our society that professions are groups that meet this standard. Logically, the next step is to determine what vocations are professions. At this point the need for criteria is obvious. Without some ordered frame of reference legislators will be unable to intelligently deny or grant the demands of vocations seeking legalized professionalization. It is not implied that all future legislative decisions in matters of occupational licensing will be based on logical criteria. Obviously, decisions will continue to be shaped by pressures exerted by interested individuals and groups. What is suggested in this study is that at present there is little opposition to most existing and proposed occupational licensing laws by individuals or groups with competing interests. Legislatures generally hear only one side of the story, that presented by those who do or will benefit most from licensing--the present practitioners of the occupation.

Criteria Identifying Professions

The criteria which follow are adopted for use in this study with certain definite objectives in mind. Most important is the inclusion of all the significant factors that differentiate between professions and other vocations. To this end the literature on profession has been analyzed extensively.²³ Another major objective is to have criteria against which vocations can be meaningfully tested. Therefore, to the extent possible, abstractions and ambiguities have been avoided.

Vital Needs of Man. The first criterion is that the activities of a profession are carried on for purposes related to the vital needs of man. The needs of man that are vital are those that determine his physical health, social welfare, and moral well-being. The successful meeting of these needs permits man to function effectively in his society. Conversely, if these needs are not met man's relationship to society will be out of balance even to the point where he may cease to exist as a part of the society. For example, a physically ill man's effectiveness in meeting the demands placed upon him in a society is impaired. The extent of the impairment is dependent upon the severity of the illness. On the other hand, a man whose car breaks down is subject to some inconvenience but his ability to maintain his social role is not usually affected.

Intellectual Basis. Criterion two flows forth from the fact that professions are concerned with "man's relations to God, man's relations to man and state,

²³See Appendix B, below, which summarizes some of the analysis.

and man's relations to his biological environment."²⁴ These relationships are complex and continually changing. Successful performance of an occupation concerned with mediating any one of these relationships requires the practitioner to understand the nature of the factors comprising the relationship and the theory which orders these factors into a systematic body of knowledge. This permits forecasting the possible consequences of an action and modifying it, if necessary, to achieve the desired purpose.²⁵ In illustration, consider a physician's occupation. Surgical operations are one of the activities of this vocation. To complete successfully the purpose of the operation (the restoration of the individual's health) requires that the physician be capable of analyzing physiological changes and modifying his activities as required. In turn, understanding the changes requires an understanding of the factors making up the physical situation and the theory that orders these factors and explains their inter-relationships as well as the effect of outside factors acting upon them. An untrained individual may be able to follow a textbook and perform an appendectomy (an operation that has been successfully performed by untrained individuals) but will be unable to adjust his actions to take account of physiological changes because he has an inadequate understanding of the human body and how it functions and reacts to internal and external stimuli.

²⁴Cogan, Harvard Educational Review, XXIII, No. 1, 36.

²⁵Alfred North Whitehead, Adventures of Ideas (New York: The MacMillan Company, 1933), p. 72.

This criterion also rules out the applicability of caveat emptor to professional activities. The average layman can not reasonably be expected to have the theoretical training necessary to evaluate the services he purchases. Inapplicability of caveat emptor is an effect of this criterion, not a criterion in itself.

Responsibility of Practitioners. Occupations concerned with the vital needs of man include a large measure of individual responsibility. The complex theoretical and intellectual training that produce a professional prepare him to perform functions that will not be widely comprehensible to those of his fellows outside his profession. Actions of the individual practitioner have a direct effect on man's vital needs and this calls for a degree of responsibility not required by vocations less directly affecting man's welfare.

The individual responsibility of practitioners and the fact that few other individuals could evaluate the effectiveness of a practitioner's work place the additional responsibility for safeguarding the public health and safety on the members of the occupation. This, in turn, gives rise to sets of standards or codes of ethics and voluntary associations with sufficient power to enforce obedience of these codes upon members.

Altruistic Nature. It has already been stated that one characteristic of the institution "profession" is concern over the vital needs of man. This characteristic is the basis for the altruistic nature of professions. The vital needs of man are so essential to continued well-being and even existence that the first concern of a professional practitioner must always be the meeting of the need. Other motivations such as economic considerations or the convenience of the

practitioner receive secondary consideration. For example, a doctor takes the necessary steps to preserve life in emergencies without first inquiring as to the ability of the patient to pay. Even should it be ascertained that the patient cannot pay, the code of doctors requires that medical care be given. Conversely, automobile mechanics can be expected to respond to a request for service on the basis of their convenience as much as on the basis of the consumer's need. The public generally does not expect automobile mechanics to provide free services to the needy nor do they customarily do so.

Summary. In summary, professions are characterized by activities:

1. carried on for purposes directly related to the vital needs or affairs of man;
2. having an intellectual basis in that they require an understanding of the individual factors comprising the occupation, the theory that orders these factors into general laws, and the ability to apply general laws to separate acts to foresee their possible consequences and modify them, if necessary, to achieve desired purposes;
3. which center a high degree of responsibility on the individual practitioner for actions not easily understood by the lay person; and
4. the results of which benefit the consumer so basically as to give the occupation an altruistic nature.

The separate identification of four criteria is somewhat arbitrary because they are all closely inter-related. For example, the individual responsibility and altruistic motives credited to the professional practitioner are a direct consequence of the

practitioner's personal influence on the vital needs of humans. A mistake by a physician may cost a life or a lawyer's poorly prepared case may radically alter the future course of his client's career. The intellectual basis is also related to the first criterion in that the complexity and eternal change of man's affairs requires the ability to shift and reorder the aspects of human society into constantly new patterns.

The Continuum of Professionalism

These are not absolute criteria and cannot be used to draw a line neatly dividing all vocations into professions or non-professions. Their application is dependent on viewing "occupations in a society as distributing themselves along a continuum."²⁶ At one end of the continuum are those occupations which meet most closely the criteria for professions, and at the opposite end are those that least meet the criteria. These occupations are the easiest to identify. Most occupations will fulfill one or more of the criteria in varying degrees and will fall somewhere on the continuum between the extremes. Placing them along the continuum is a difficult task requiring the establishment of relations among occupations based on the accepted criteria. Pharmacy's place will be relative to that of other occupations, particularly those at the professional end of the continuum. Because placement on the continuum is a relative matter it is subject to change in either direction as the variable factors change. Thus, over a period of time

²⁶Greenwood, Social Work, II, No. 3, 46.

an occupation may become increasingly more or less professional.

Within each profession there is an internal continuum along which individual practitioners of the profession may be distributed. The work of some practitioners will establish them as professional in every sense of the criteria characterizing profession while other practitioners will qualify as professional only through the loosest use of the term. Specialization creates groups within a profession and the groups also will tend to fall along a continuum. It is possible for individuals or groups to move either way on the continuum as a result of their own efforts or because of external changes affecting their work.

Applying the Criteria to Medicine

Traditionally, the practices of divinity, law, and medicine have been placed at the professional end of the occupational continuum. They have been considered professions in the highest sense of the term. Applying the criteria adopted above to medicine will test the criteria at the same time it may define an occupation at the professional end of the continuum providing a starting point for the relative distribution of other occupations including pharmacy.²⁷

²⁷It should be clear that any other occupation could be substituted for medicine. The use of a vocation at the other end of the continuum would have resulted in relating pharmacy to a non-professional vocation, thereby placing emphasis on pharmacy as a non-profession. The choice of a vocation that fell somewhere between the ends of the continuum would have made the following analysis more complicated and, undoubtedly, longer. Medicine was chosen because (1) it is traditionally accorded a place at the professional end of the continuum, (2) the interest in this study is

The activities of medicine can be generally classified as preventing, diagnosing, and treating disease in humans. These activities are carried on for the purpose of preserving and restoring the health of individuals. The maintenance of health is essential to physical well-being and continued existence and is one of man's vital needs. Medicine, therefore, satisfies the first criterion.

The intellectual basis of profession is related to the span of alternatives that must be considered as each step of an activity is performed. The number of potential diagnoses and methods of treatment and their possible combinations are great. This immense number of variable factors makes it impractical if not impossible for a medical practitioner to consider each one in determining the acts he is going to take in relation to each case. As relationships are discovered among various sets of factors they are systematized into general laws or theory and enable a practitioner to consider fewer alternatives when deciding on the course of his actions. Given the almost infinite permutations in the practice of medicine it is necessary for doctors to have sufficient intellectual ability to comprehend medical theory and to understand the factors of a particular situation in terms of general laws which will suggest a limited number of alternatives.

The practice of medicine involves an intimate relationship between patient and practitioner. Normally, the patient requires services he cannot

oriented toward professionalism rather than non-professionalism, (3) both medicine and pharmacy fall in the general category of health occupations, and (4) it facilitates a brief discussion.

evaluate as to adequacy or quality. The old saying that a doctor buries his mistakes reflects the direct nature of the patient-doctor relationship which does not yield to ready review by others. The preservation or restoration of a patient's health depends almost entirely on the individual practitioner. The physical well-being of a patient becomes the individual practitioner's responsibility. It is not a responsibility that can be shared nor one that society can afford to permit to be evaded or shirked. Therefore, the individual responsibility of a medical practitioner is great.

Medicine is carried on for the purpose of preserving and restoring health in individuals. In carrying out their functions medical practitioners fulfill the vital need of man for physical well-being. The alternatives to good health are undesirable and involve such serious potential consequences for the individual and society that doctors are expected to provide sufficient medical care to maintain minimum standards of general health. This care is to be provided irrespective of the ability of the individual to pay. Physicians have met this responsibility by adjusting their rates to take account of the individual's capacity to pay, by providing their services free through their own offices or clinics, and by contributing their time to medical activities devoted to serving those unable to pay. More and more, however, part of the responsibility is being assumed by government through welfare and public health programs.

Applying the criteria of profession to medicine leads to the conclusion that medicine fulfills each criterion to a great degree and therefore deserves placing at the end of the continuum with those occupations that are most clearly professional. That is not to imply that every doctor deserves equal recognition as a professional or that the most professional doctor

does not still engage in non-professional duties. For example, doctors in private practice must attend to certain purely business tasks such as paying overhead costs and hiring help. What is implied is that, in general, most doctors spend most of their work time engaged in clearly professional functions.

Pharmacy as a Profession

Before applying the professional criteria to pharmacy it is helpful to emphasize again the basic bifurcation that exists in the occupation. Most doctors would claim that the biggest part of their working time was spent on professional tasks and this claim would be generally accepted. In the case of pharmacy no similar claim is made by most pharmacists. Most pharmacists are retail pharmacists and their time is divided between professional duties and the tasks of the retail merchant. However, even as they grant that their time is divided between professional and non-professional work they claim full professional status. This is equally true of the pharmacist who spends 95 per cent of his time on professional duties and the pharmacist who spends five per cent of his time in professional work. The problem is clear. Not to distinguish between the two would be to remove all useful meaning from the classification professional as applied to pharmacy and, indeed, would weaken its usefulness in general. For the sake of convenience pharmacy as a profession will be considered as two separate problems. First, the functions that pharmacists claim are professional will be tested against the criteria and some attempt made at placing pharmacy on the continuum on the basis solely of their "professional" functions. Second, pharmacy as it is generally practiced (combining professional and mercantile

functions) will be evaluated and its relative place on the continuum suggested.

Applying the Criteria to Pharmacy

Heffron's listing of the professional functions (see above, pages 20-21) of pharmacists, which are listed below, is representative of the general literature in the field and provides a good starting point.

Compounding and dispensing prescription drugs to consumers including instructions as to use. Drugs play an important role in the preservation and restoration of health and in this sense are related to the vital needs of men. In turn, those responsible for compounding and dispensing drugs and advising on their use may be considered as engaged in activities concerned with the vital affairs of man. There is a difference, however, between medicine and pharmacy in respect to this criterion and it centers on the nature of the relationship between activities of the individual practitioner and the consumer whose vital needs the activities are meeting.

This is largely due to the relations between pharmacist and consumer as compared to the relations between physician and consumer. The latter relationship involves independent action on the part of the physician which directly affects the client. On the other hand the pharmacist does not act independently but only in response to the needs expressed by physicians. Compounding and dispensing await the order of the physician in the form of his prescription and the pharmacist's role as a drug consultant is wholly dependent on the demand of the physician. The physician-consumer relationship is critical in terms of the unlimited responsibility the relationship places on the physician. In the pharmacist-consumer relationship the pharmacist's

responsibility, although great, is limited by the actions of the doctor. Pharmacy, therefore, does meet the first criterion but not to the same degree that medicine does.

Determining if there is an intellectual basis for the activities of pharmacy requires an evaluation of the activities or methods involved in the work of pharmacy as well as the objectives or ends for which the work is performed. Consider, first, the complexities involved in the physical actions required to compound and dispense (consultation is considered later). The process begins with an order (prescription) from the physician. In most cases the order will be for a specific quantity of a precompounded drug and the pharmacist will select a proper container, fill it with the required quantity of the specified product, check and type the doctor's directions on a label and affix the label to the container, add a serial number or other identification to the label, price the prescription, record the prescription in a record book, file the original prescription, and give necessary directions on use to the customer and answer questions he may have. Not all these steps are essential to the successful accomplishment of the objective of providing the consumer with the product called for by the prescription. For example, pricing clearly will not affect the drug, whereas the selection of the proper container may affect the drug directly. However, even those steps essential to achieving the desired ends are closely circumscribed and present almost no room for variation if the correct result is to be obtained. The variable alternatives are so limited that they can be set forth in reference books such as the National Formulary or the United States Pharmacopeia. For new drugs not in the standard references the pharmacist may

maintain a file of descriptive literature from the manufacturer or clippings from the professional journals which review new drug products and, in some cases, publish information on new drugs in a format similar to the standard references. As far as the steps in filling a prescription calling for a pre-compounded product are concerned, the intellectual requirements do not extend beyond the ability to read with comprehension.

Those prescriptions requiring the pharmacist to compound a drug introduce more variables. Again, however, as long as the end product is known it is possible to supply the other terms by consulting accepted reference works or a well-maintained file on new products. The unknowns that exist in such profusion in medicine simply do not appear in the steps involved in the activities of compounding and dispensing. So much for the means employed by pharmacists to obtain desired ends.

Acting as expert drug consultant to the medical practitioner. Analyzing the arguments put forth by pharmacists in support of their status as professionals indicates they are based for the most part on the ends rather than the means of pharmacy. This emphasis is responsible for some of the inter-professional conflict between physicians and pharmacists. In the attempt to establish their professionalization, pharmacists state that they possess a knowledge of drugs and their effects on individuals as a result of their training that is not shared by doctors or other groups. Pharmacists feel that their training provides them with an understanding of the theory of drugs and their uses which enables them to act as a check on the prescribing doctor and thereby an additional

safeguard for the consumer.²⁸ This is the point where the need for an intellectual basis for pharmacy is defined most clearly by pharmacists. Their right to review a prescription or act as a consultant to a physician depends upon their being able to view the individual factors involved in compounding and dispensing medicines in relation to a theory explaining the possible consequences of different courses of action and suggesting the course most likely to yield the desired results. The implication, of course, is that the demands of practicing medicine make it difficult, if not impossible, to keep up with the field of pharmacy. The interest of the consumer, it is argued, is more adequately protected when drugs are dispensed through the professional pharmacist. Pharmacists grant that physicians are qualified to dispense but suggest that they should limit their dispensing to emergencies or drugs that must be administered under a doctor's supervision. Because of pharmacists' special knowledge of drugs, doctors should turn to them with questions. In the view of pharmacists, the combined efforts of physician and pharmacist results in the highest quality of medical care for the patient.

²⁸Should a physician make a mistake in the writing of a prescription he is legally liable for negligence. A pharmacist who fills an incorrect prescription may be liable for concurrent negligence but this does not relieve the prescribing doctor from liability for his act of negligence. Arthur, p. 96. In cases of illegible prescriptions (*Ibid.*, pp. 97-98) and those where pharmacists did not exercise the degree of "knowledge, care and skill. . . commensurate with the danger involved. . . [and] which the law requires" (*Ibid.*, pp. 108-112) the liability is the pharmacists'. The pharmacist is liable for any mistakes made in filling correctly written prescriptions, selling non-prescription items, or advising customers on the use of drugs and medicines.

Both the distribution and consulting roles of pharmacists have been challenged by the physician primarily on the grounds that a doctor has ultimate responsibility for all phases of patient treatment. It is the physician's responsibility to be sure of which drug should be used in each situation and if he is allowed to write the prescription he is equally capable of dispensing, with the possible exception of drugs requiring compounding. While a doctor may choose to consult a pharmacist, the decision is still the doctor's to make. In a sense, the very act of writing a prescription is consultation. The legal liability of a pharmacist entitles him to the cooperation of the physician. A pharmacist should always be able to call the physician to check any questions concerning a prescription. For that matter, in view of the potential liability of a physician he should welcome the pharmacist who double checks prescriptions.²⁹

It is impossible in this study to do more than point out the nature of the conflict and draw some tentative conclusions. Insofar as pharmacy has an intellectual basis, it appears to be related to the compounding functions of pharmacy. Some pharmacists may become specialized drug consultants to physicians but it seems clear that not all pharmacists desire this role nor are all trained for it. There is no general recognition by physicians at this time of pharmacists as trained drug consultants, although this too may develop in the future. It is true that some pharmacists act as a check on the prescribing doctor and, like compounding, this function may require the intellectual basis common to professions.

²⁹Ibid., p. 106.

In conclusion, pharmacy meets the second criterion to a very limited degree. Only a few functions of pharmacy, occupying a relatively small share of the total time devoted to all functions of the occupation, require an intellectual basis for their successful performance. It should be pointed out, however, that some pharmacists devote almost all of their time to such functions and these individuals may qualify as professionals under this criterion.

Advising consumers on effects and use of non-prescription drugs. Serious questions may be raised about this function as it relates to professionalization even before specific criteria are applied. The basic question centers on the fact that the sale of non-prescription drugs is not generally restricted to pharmacists. A wide variety of retail outlets from department stores to grocery stores sell non-prescription drugs without the services of a professional pharmacist. In effect, society through existing federal and state laws has declared that these drugs are safe enough for the individual consumer to buy whether or not he understands their use and effects. The potential danger is not sufficient to out-weigh the economic evils that would result from restricting the free flow of goods. This is not an absolute or final decision and the situation is continually changing as society removes prior restrictions on the flow of goods or introduces new ones. Relating the sale of non-prescription drugs to their professional functions makes the pharmacists vulnerable to the question of whether they are motivated, in this case, by possible economic gain that may result if sales are restricted to pharmacists or by a desire to serve the public interest.

Responsibility. The drugs dispensed by pharmacists may affect the individual's physical well-being, i.e.,

one of man's vital needs. In the preparation and dispensation of drugs the pharmacist assumes a large measure of responsibility for the well-being of others. While the responsibility exceeds that of most occupations it is not as great as in the case of physicians because the range of possible actions on the part of the pharmacist is more narrowly circumscribed and demands fewer independent decisions.

Altruistic Nature. Finally, in considering where altruism enters the practice of pharmacy and to what extent, it is necessary to review quickly the mode of operation of most pharmacists. Over ninety per cent of those in the occupation are retail pharmacists. They must make a living from their work just as must doctors. In the case of doctors the services they perform meet such a vital need of man that society demands the services be made available irrespective of other considerations such as the ability of the consumer to pay. Most actions of most pharmacists involve other activities than supplying drugs to consumers. These other activities, selling toothpaste, sundries, and related acts, do not serve a vital need of man. There are no acceptable alternatives available to the consumer requiring medical attention except to receive a physician's services. In the case of buying toothpaste or other sundries there are acceptable alternatives to buying from a pharmacist. These alternatives range from getting along without the item to buying it from another kind of retail outlet. The pharmacist will not provide these retail services except when paid. Therefore, the motivation underlying these activities is economic, not altruistic.

The opportunity for altruistic motivation in pharmacy arises most clearly in relation to the preparing and dispensing of drugs and medicines which

involve servicing a vital need of man. Even here the pharmacist's motivation is primarily economic and not altruistic. The first concern of the pharmacist is not to meet the need of the individual for drugs but to exchange drugs for a monetary payment. Druggists do not generally adjust their charges to the abilities of the individual to pay nor do they provide their services and goods free in cases of need.³⁰

Summary. The above application of professional criteria to pharmacy has been restricted to that part of the practice of pharmacy considered professional by pharmacists themselves. By testing the professional functions of pharmacy against the criteria and in relation to the earlier example of medicine, the conclusion is that, considering only the professional side of pharmacy, it does not merit placement at that end of the continuum with professions in the fullest sense of the term.³¹ Instead, pharmacy falls somewhere further down the continuum. When all aspects of the

³⁰Chute and Hall, p. 219, drawing from a paper by Professor J. H. Goodness of the Massachusetts College of Pharmacy, imply that dispensing by doctors should be limited to "professional dispensing" which includes "furnishing of drugs to impecunious patients at no cost in connection with medical services supplied at no advance over 'normal' fees for such service in the community."

³¹H. C. McAllister, when President of the National Association of Boards of Pharmacy, suggested as basic requirements "for a vocation to qualify as a profession:

1. that practitioners acquire an intellectually based technique;
2. that practitioners assume a relationship of responsibility toward clients;
3. that practitioners are organized into responsible associations, which set standards of practice

practice of pharmacy are considered, rather than just the professional functions, the place of pharmacy on the continuum is closer to that of the retail merchant than it is the physician. The conclusion is not that pharmacy is not a profession; it is that pharmacy is a profession in a lesser degree than is the case with a limited number of other vocations. This rough relative determination is sufficient for the purposes of this report. A more exact placement on the continuum could be made but would require elaborate analysis of other vocations to fill out a relative scale.

The Practicing Pharmacist and Professionalization

The trend toward professionalizing the drug store is a recent one. . . .from 45 to 50 per cent of the strictly professional drug stores of the United States were opened between 1925 and 1931. . . .the number of pharmacies [1931] "receiving 50 per cent or more of their total sales from their prescription departments" [is estimated] to be between 350 and 400." . . . It may be doubted whether such a high percentage of prescription receipts is necessary for the operation of a professional pharmacy. . . . Delgado regards "the professional pharmacy" not as an

and exert control over the actions of their members through codes of ethics." ("Codes of Ethics in Legal Control", mimeographed speech.)

In this speech McAllister states his belief that pharmacy meets the first two requirements but fails to meet the third. Using the same criteria in a later article McAllister suggests that before pharmacy can be said to meet any of the criteria there must be some agreement among pharmacists and others as to what pharmacy is and what are "the duties and responsibilities of the pharmacist." McAllister, "Pharmacy's National Purpose", American Journal of Pharmaceutical Education, XXV, No. 4 (Fall, 1961), 511-516. Other considerations by pharmacists of pharmacy as a profession are mentioned in Appendix B, below.

objective nor even a possibility to be achieved by and for the entirety of American retail pharmacy, but for "a specialist in the retail drug field."³²

Several pharmacy spokesmen have, in effect, said that the retail druggist is first a retailer and, second, a professional pharmacist. There are many pharmacists arguing for a reversal of this order on the grounds that professional recognition will come only if pharmacists regard themselves primarily as professionals with incidental retail duties. This group believes the danger to pharmacy as a profession is the possibility of being reduced to the status of purveyors of "pre-fabricated, presold, and prepriced medication to the public. The pharmacist, unfortunately, also has contributed to it by his preoccupation with the economics of his position in distribution, his failure to emphasize sufficiently his professional role, and his willingness to embrace the commodity concept as opposed to the service concept in his professional practice."³³

The internal conflict within pharmacy between those emphasizing the retail merchant aspects and those emphasizing the professional aspects offers a limited number of alternative possible solutions: (1) maintain the status quo, (2) curtail professional functions and expand retail merchant functions, and (3) curtail retailing and emphasize professional duties.

Maintain Status Quo. Maintenance of the status quo is probably the most likely alternative and implies the

³²Kremers and Urdang, p. 419.

³³Lloyd M. Parks, "What Price Professionalism?", American Journal of Pharmaceutical Education, XXV, No. 4 (Fall, 1961), 531.

continuing evolution of pharmacists toward status as retail merchants. There will remain a vigorous group seeking professional recognition but most pharmacists will continue to be concerned with the economic problems of the small businessman and will join the struggle for professional standing only insofar as they believe it will further their interests as retail merchants.

Curtail Professionalism; Expand Merchandising.

The end result of this alternative would be the same as the first. It differs in that it would require conscious formulation of programs designed to achieve the goals of pharmacists as retail merchants and exclusion of concern over professionalization. This occurs, to some extent, today in the activities of such groups as the National Association of Retail Druggists and the National Wholesale Druggists' Association. However, these organizations still exhibit some interest in "professional pharmacy".

Curtail Merchandising; Emphasize Professionalism.

Choice of this alternative by pharmacists is precluded from the start because of the concentration of most pharmacists in the retail drug business. Prescription volume is simply not large enough to support the existing number of drug stores.³⁴ Limiting the sale of drugs and medicines to pharmacies with no other interests would result in converting the overwhelming majority of drug stores into retail merchants with no professional functions or putting them out of business.

Pharmacists struggling to professionalize their vocation rely on an increasing variety of means to achieve this end. One example is the heavy emphasis

³⁴Chute and Hall, p. 2.

on the role of the pharmacist as unbiased drug therapy consultant to physicians.³⁵ Specialized knowledge of sufficient quality is a prerequisite to recognition as consultants by such highly trained men as physicians. Developing pharmacists with the necessary abilities has led to major changes in the curricula of pharmaceutical colleges and lengthening of the program in accredited schools from four to five years. Already there is a growing pressure for six year programs. Colleges of pharmacy appear to be responsive to those interested in promoting pharmacy as a profession and this tendency is reflected in the curriculum.

Membership in professional or voluntary occupational associations is also indicative of the interests of practitioners. In 1961 there were 117,800 registered pharmacists practicing in the United States. The most "professionally" oriented national association is the American Pharmaceutical Association which had, in that year, 32,000 members or 27.2 per cent of total pharmacists. Comparative figures for the National Association of Retail Druggists show 36,000 members or 30.6 per cent of all pharmacists. The total of both memberships is slightly more than half of all pharmacists. Overlapping memberships make the actual figure even lower. In this respect, pharmacists lag far behind physicians, psychologists,

³⁵Almost every printed discussion of the professional future of pharmacy considers this point. The following are cited as representative: George F. Archambault, "The Future of Pharmacy", Hospital Progress, XLII, No. 7 (July, 1961); "Doctors Phone Rx Men 51 Million Times a Year for Information, Survey Shows", American Druggist, October 29, 1962; Harold J. Black, "Indoctrination of Medical Students in Matters Relating to Pharmacy", Proceedings of the Twenty-Third Annual Meeting of the National Association of Boards of Pharmacy and the American Associations of Colleges of Pharmacy, 1960.

dentists, and even social workers, with ranges of association membership from 82 to 99 per cent.³⁶

Yet another effect of the professional advocates on the practice of pharmacy has been in the area of prescription pricing. There is growing interest in the idea of "the professional fee" for prescription pricing. Under this concept prescriptions are priced by adding a uniform fee to the cost of ingredients, container, compounding time, and overhead.

This concept has been advanced primarily as a step in establishing the professional nature of prescription practice. . . .

But it is likely that many of those adopting the fee concept hoped to achieve two ends by doing so--not only to boost their professional standing. . . but also to make their Rx prices more competitive with those of discounters.³⁷

Adoption of the professional fee creates some difficulties including, for example, integrating the fee schedule with fair trade prices. In those states where professional fee schedules have been used the tendency has been for pharmacists to agree among themselves on the fees to be charged based on the cost of the drug to the retailer. The federal government believes such agreements violate the Sherman Antitrust law and has taken court action in many states. In finding for the government, there have been indications by the courts that a fee schedule based on considerations

³⁶William S. Apple, "Blueprint for Professional Unity", Focus on Pharmacy 1962, ed., William L. Blockstein (Detroit: Wayne State University, 1962), p. 90.

³⁷"Lower Prices Helped Many Pharmacies Withstand Rx Discounters, Study Shows", American Druggist (March 19, 1962), p. 6.

other than the costs of commodities to retailers might be acceptable.³⁸

Bifurcation. The three alternatives above were all based on the assumption that those groups and functions now considered among the practitioners of pharmacy would continue to be included. Another likely alternative, however, is that pharmacy might divide into different occupations. The obvious division would be between professional pharmacists and retail druggists. Teachers, researchers, hospital pharmacists, and those retail pharmacists whose operations are limited to prescription business might be grouped among the professionals with most others being classed as retail merchants. Those with predominantly professional interests would become more professionalized and those with predominantly economic interests would become merchants. Most of these groups already have their own voluntary organizations and this factor might facilitate the process of separation.

The Self-Regulation of Pharmacy

For this report the significance of determining that pharmacy, as practiced today, is less a profession than it is a non-profession is in the implications this has for determining the role of the state in the regulation of pharmacy. The present situation in Hawaii is that the State has delegated the regulation of pharmacy to the practitioners of the occupation. The conditions justifying the delegation of state regulatory powers were previously suggested as being ultimately related to some features of professions.

³⁸United States of America v. Utah Pharmaceutical Association, 201 F. Supp. 29 (1962), pp. 29-36.

In particular, professions involve special intellectual skills and techniques. To determine their adequacy requires the same kinds of knowledge and it becomes expedient to turn to practitioners to control their own activities. Additionally, professions are concerned with the vital needs of man; the subsequent responsibility and altruism help develop a rigid set of internal standards guiding individual activities within the profession. Overt signs of these standards are to be found in written codes of ethics, in the extent and nature of voluntary professional associations, and in the ability of the profession to curb members activities which are detrimental to the general public of consumers.

Specifically, the question at this point is whether pharmacy should be self-regulating in view of the factors that have been discussed. Full self-regulation is ruled out by facts such as: (1) pharmacy is not a profession in the fullest sense of the term, (2) the evaluation of the work of a pharmacist can be done by persons trained in other fields such as chemistry or medicine as well as by pharmacists, (3) there is no indication that a general set of standards or code of ethics has been adopted by most practitioners or is followed by those who have accepted the APhA's code of ethics, and (4) voluntary associations are weak in the field of pharmacy, both in terms of number of members and in effective control of members professional activities.

A case may be drawn for not allowing pharmacists any measure of self-regulation in Hawaii or other states. This statement is based on the fact that limiting entry to the occupation to qualified individuals and setting and enforcing standards of practice can be carried on to adequately protect the public without the

participation of local pharmacists. A layman as well as a pharmacist could check an application for licensure for such qualifications as age, graduation from an accredited college and practical experience. Written and practical examinations could be given at the national level as is the case with medicine. A national board examination in pharmacy has been suggested but it appears that practitioners controlling their occupation within the various states are unwilling to relax control in the case of examination. If it was desirable to test an applicant on local laws and conditions such a test could be administered by public health officials or other trained groups as well as pharmacists. Minimum standards of practice might also be set at the national level for local enforcement by trained lay investigators or, if necessary, individuals with some science background.

An alternative to full self-regulation, or no self-regulation at all, is to permit pharmacists a limited degree of participation in their own regulation. This would enable using the training of pharmacists to facilitate certain regulatory matters, such as evaluating the compounding skills of pharmacists, while limiting the possibility of the regulatory body acting to further the private economic interests of pharmacists.

The foregoing discussion has been based on considering pharmacy as it is practiced today without suggesting future developments nor exploring the possibility of separating various categories of pharmacists for different kinds of treatment. These other alternatives should not be overlooked, however, because they are a central part of the developments in current pharmacy.

CHAPTER VI

PHARMACY LAWS AND PROBLEMS

This report is concerned with the regulation of pharmacy, a regulation which is required by the public interest. In the last chapter the concept of profession was examined and the conclusions reached that there are probably few occupations that qualify as professions in the fullest sense of the term and that pharmacy was not one so qualifying. It was also concluded that occupations which are not professions in the fullest sense of the term should not be granted full powers of self-regulation.

In this chapter the nature of Hawaii's pharmacy laws and regulations are examined, especially as they represent a delegation of public authority allowing the regulated group to regulate itself; the nature of the public interest and other interests in the regulatory process is analyzed; and, finally, a number of specific problems or conflict situations are reviewed. Several of the specific problems have been found to be symptoms rather than causes of present differences between the Board of Pharmacy and others in the medical arts or related fields. They may only be solved by reference to the broader questions discussed in this report.¹

¹While the major concern of this report is pharmacy, it should be pointed out that many of the parts of the study have wider application. The discussion of occupational licensing laws can be applied to other occupations which have or are seeking the power of self-regulation. Many, if not most, occupations now licensed are probably not professions in the fullest sense of the word and should not be self-regulating. For a list of other occupational licensing laws in Hawaii see Appendix C.

The Present Hawaii Pharmacy Law and the Proposed Rules and Regulations of the Board of Pharmacy

Provisions of the Hawaii pharmacy law and of the proposed rules and regulations of the Board of Pharmacy can be divided into three categories on the basis of what they do to accomplish the general purpose of the law, "the protection of the public health and safety": (1) limit entry into the occupation to those individuals meeting certain qualifications; (2) establish minimum standards of practice for licensed pharmacists and regulate activities such as pharmacy operation and drug sales; and (3) provide the means for achieving the purposes of the provisions in the above two categories by defining terms, establishing administrative agencies and their functions and setting penalties for violators.

Licensing

Chapter 71 of the Revised Laws of Hawaii 1955 specifies the following with respect to licensing:

71-5. Qualifications for License. Requires an applicant for a pharmacist's license to (1) be at least twenty years old, (2) possess good moral character and temperate habits, (3) be a graduate of a pharmacy school approved by the American Council of Pharmaceutical Education, (4) have one year of practical experience, (5) pass the Board of Pharmacy examination, and (6) have been a resident of Hawaii for one year.

71-6. Examination. Provides for the subjects to be covered in the examination, sets seventy per cent as the passing grade, and requires submitting of all application forms and payment of a fee prior to taking the examination.

71-7. Temporary License. Allows a temporary license to be issued to applicants who meet all requirements for licensing except residency.

71-8. Renewal of Licenses. Establishes procedures and fees for license renewal.

The proposed rules and regulations include provisions elaborating on the license and permit procedures and education and experience requirements specified in statutes. Part four of the rules and regulations lists the subjects to be covered in the examination, permits the Board to give an oral examination in addition to the written and practical examination, modifies the seventy per cent passing grade to provide that an individual failing the examination but attaining a passing score in three parts of the examination and at least fifty per cent in each of the other parts may be re-examined once in just the parts he failed. In the law the only mention of an assistant pharmacist (section 71-9) is to state that an assistant pharmacist may fill prescriptions under the immediate supervision of a registered pharmacist; part five of the rules and regulations, however, requires that an assistant obtain a permit, meet specified education requirements, complete three months of his experience after graduation, and maintain a prescription record and record of experience.

Standards of Practice and Regulation of Other Pharmaceutical Activities

Chapter 71 specifies the following standards and regulations:

71-9. Pharmacist in Charge. Requires all pharmacies to be under the charge of a registered pharmacist and states that "no person other than a registered pharmacist or an assistant under his immediate supervision shall fill or compound prescriptions."

71-10. Pharmacies. Requires an owner or manager of a pharmacy to have a registered pharmacist in charge and provides that any person who compounds or vends drugs other than a registered pharmacist or someone under his immediate supervision is in violation of the law.

71-11. Duties of Registered Pharmacist. Requires a registered pharmacist to comply with laws and rules and regulations, be responsible for all activities in a pharmacy under his charge, and to notify the Board of a change of address within ten days.

71-12. Adequate Equipment. Requires the Board to prescribe by regulation the minimum equipment for pharmacies.

71-13. Prescription Record. Requires all prescriptions be kept in a book or file for five years after the date of dispensing.²

71-14. Permits for Operation of Pharmacy. Requires all pharmacies to obtain a permit from the Board and outlines requirements to be met by an applicant for a permit.

71-15. Miscellaneous Permits. Requires obtaining a permit from the Board (1) to auction drugs, (2) to distribute drug samples except directly to physicians, druggists, dentists, and veterinarians, (3) for wholesalers to sell, distribute or dispense drugs except to a pharmacist, physician, dentist or veterinarian, or industrial, agricultural, manufacturing or scientific user of drugs, and (4) for preparing, manufacturing, compounding, packing or repacking drugs.

71-19. Application of Law. Provides that Chapter 71 does not apply to a licensed practitioner of medicine, osteopathy, dentistry or veterinary medicine when handling drugs in the course of his duties and does not prohibit such practitioner from personally supplying his own patients with drugs.

71-20. Poison Law not Amended. Specifies that nothing in Chapter 71 shall amend the poison law, Chapter 53.

²Section 53-5.2 of the Hawaii law on sale of poisons and the Department of Health's poison rules and regulations require the keeping of prescriptions for two years.

In part one of the rules and regulations permissible absences of pharmacists from the pharmacy are spelled out, price advertising of prescription drugs is forbidden, phone prescriptions are authorized with certain limitations including the requirement that they be kept on file for two years,³ and coded prescriptions and return or exchange of prescription drugs are prohibited once they have been taken from the premises where dispensed or sold. Changes in the drug prescribed are prohibited except with the approval of the writer of the original prescription. Conditions for a pharmacy permit including space, fixtures, and professional and technical equipment required are the subject of section 6.1 and part of section 1.9. Section 6.2 spells out detailed conditions for the use of mechanical devices to furnish drugs and medicines for administration to patients in hospitals having a pharmacy permit issued by the Board.

Legal Procedures for Administration

The remaining sections of Chapter 71 and a few provisions of the rules and regulations relate to administration:

71-1. Definitions. Defines pharmacy, drug, patent medicine, cosmetic or toilet article, prescription, registered pharmacists, and board.

71-2. Board of Pharmacy; Appointment; Qualifications; Term. Creates a Board of Pharmacy consisting of five licensed, practicing pharmacists who must be graduates of accredited schools or colleges of pharmacy, three from Oahu and two from other counties, appointed for four year terms.

³This appears to conflict with Section 71-13 which requires that prescriptions be kept for a minimum of five years.

71-3. Officers. Provides that officers of the Board are a chairman, a secretary and a treasurer and indicates their duties.

71-4. Meetings; Powers and Duties of Board. Requires meetings at least every April and September and annual reports to the Governor including a list of all registrants. Delegates the power to the Board to: (1) suspend or revoke licenses in specific cases, (2) suspend or revoke permits for violations of the law or Board rules and regulations, (3) make such rules and regulations as are necessary to carry out the purpose of this law which purpose is declared to be the protection of the public health and safety, (4) inspect drugs, pharmacies and other premises where drugs are kept, (5) investigate violations or suspected violations of the law or rules and regulations, and (6) administer oaths. Provides that nothing in Chapter 71 shall modify or limit the powers of the Department of Health.

71-16. Fees for Permits; Renewal. Sets fees for pharmacy and miscellaneous permits, requires they be conspicuously displayed, and provides for their renewal.

71-17. Penalties. Provides for a maximum fine of \$500, six months imprisonment, or both for violators of the law or rules and regulations.

71-18. Right of Injunction. Authorizes Board to apply to a court for an injunction to restrain violations of the law.

The purpose of the rules and regulations are stated in part one and several terms, including "personally" are defined. Section 1.11 clarifies restrictions on the legal possession of prescription drugs. Applications are the subject of part two which provides for (1) application forms and instructions, (2) deadlines for filing applications for examination and re-examination, (3) determining if the applicant qualifies for admission to the examination, (4) issuing of temporary licenses, assistant permits, and pharmacy or miscellaneous permits, (5) filing an application for license on completion of residency and experience requirements, (6) Board

notification to applicants denied a license or permit including the reasons therefore and a statement notifying the applicant of his right to a hearing, (7) hearings for applicants denied a license or permit provided they file a demand for a hearing within sixty days of the mailing of the denial letter, and (8) hearings to be held in accordance with the provisions of the Hawaii Administrative Procedure Act.

General Considerations Relevant to State Regulation of Pharmacy

One goal of licensing may be defined as insuring that only qualified individuals are permitted to prepare and dispense drugs and medicines that have potentially serious effects on the physical well-being of man. This is a proper and desirable goal of government for two reasons: (1) the individual drug consumer is interested in maintaining his health and society is concerned in general with the physical well-being of its members, and (2) there is no other alternative course except government action which provides an adequate means of control because other social sanctions are insufficient to prevent unqualified individuals from practicing pharmacy.

Examining and licensing applicants is a way to insure that those entering practice are competent. Applying standards to the practice of pharmacy is designed to make sure that practitioners perform their services properly.

Legal procedures for administration provide the means to accomplish the goals which appear to be proper goals of government. It is these procedural provisions of an occupational licensing law that determine whether or not an occupation is to be self-regulating, as pharmacy is in Hawaii, or whether it is

to be controlled in other ways. Present provisions of Chapter 71 delegate to a Board of Pharmacy, composed of five practicing pharmacists, the power to control entry to the profession, control the number and kind of drug outlets, and set and enforce standards of performance for pharmacists and pharmacies.

Part of the Board's activities can be expected to be directed toward achieving the two goals of the law related to the general public interest. The same powers that enable the Board to act in the public interest, however, also enable actions that further the economic well-being of pharmacists as a private interest group. Board actions that further the private interests of pharmacists will probably not be challenged as long as they do not adversely affect other groups. There is no intent here to question the motivations of present or past Board members. The point that needs to be made is that government power has been delegated to five practicing pharmacists whose training, interests, and work have given them a certain frame of reference or perspective for looking at matters concerned with pharmacy. This frame of reference or perspective is that of the practicing pharmacist, most often the retail pharmacist, and includes a sensitivity to and concern with the problems, economic and other, facing pharmacy today. It is asking a great deal of Board members to divorce themselves from the point of view developed over a period of years and adopt a point of view directed clearly and wholly to the public interest.

The Public Interest and Regulatory Procedures ⁴

Assuming that government action is desirable to

⁴In this report, the term regulatory procedures is used in a broad sense and includes administrative, examining, and other activities employed to achieve the goals in the law.

achieve the two prime goals of the pharmacy law, the available alternatives for achieving those goals are: (1) leave the law as it is now, in effect, leaving pharmacists the power of self-regulation, (2) delegate the necessary powers to administer the law to an agency with no pharmacists, thereby completely ending the self-regulatory powers of pharmacy, or (3) modify the existing law to reduce the powers of pharmacists while still leaving them some voice in their own regulation. Whichever alternative is being discussed it will affect the interests of three identifiable groups: registered pharmacists, individuals engaged in pharmaceutical work in other capacities than as practicing pharmacists, and the general public as drug consumers and as beneficiaries of the competitive aspects of free enterprise in a democratic system.⁵ It is possible to examine each alternative in relative terms of how and to what extent it satisfies the interests of each group.

The Interests of the Pharmacists. The interests of the registered pharmacists will be best satisfied by retaining self-regulation. The organized and normally successful efforts of pharmacists to incorporate this alternative into pharmacy regulatory legislation is indicative of the fact that they themselves believe it maximizes their interests. It follows that alternative three, reducing the power of self-regulation, will be the second choice and alternative two, delegating

⁵Other individuals affected are those responsible for administering pharmacy licensing laws, in most cases civil servants or public administrators. They are not considered in more detail here because, technically, as public servants their interests are limited to carrying out the will of the people as expressed in the law rather than initiating or making public policy.

the regulatory powers to non-pharmacists, the least palatable of all for pharmacists. The further removed pharmacists are from control of their own activities the less well are their private interests served.

The Interests of Other Persons Engaged in Pharmaceutical Work. For individuals engaged in pharmaceutical work as wholesalers, manufacturers, salesmen and other non-pharmacist capacities or with a direct interest in some aspect of pharmacy (dispensing physicians, hospital administrators, nurses working in pharmacies without a pharmacist in charge), self-regulation by pharmacists would probably least well serve their interests. Alternative two, or three, regulation by an agency not dominated by pharmacists, would better serve the interests of this group by providing for objective, impartial treatment of their needs along with the needs of registered pharmacists, though some participation by pharmacists in the regulatory process is probably preferable to their elimination.

The Interests of the General Public. As drug consumers, the interest of the general public is that drugs are properly prepared and correctly and safely distributed. A prime factor in determining how well this interest is satisfied is the capabilities of the individuals responsible for regulating drug preparation and distribution. Pharmacists are clearly one of the groups best trained for this responsibility and, therefore, either the alternative permitting self-regulation or participation by pharmacists in regulation would be desired. Preference might be given to the latter alternative on the basis that under the first alternative pharmacists would be concerned with so many interests that they may not be able to give this one its rightful due.

Another interest of this group in occupational licensing laws is related to reaping the benefits of competition. Occupational licensing laws, irrespective of who administers them, limit the right of individuals to follow the vocation of their choice by limiting the right to practice to those meeting specified standards. In addition, occupational licensing laws granting self-regulation power to an occupation, permit further opportunities for the practitioners to limit artificially the supply of practitioners, thereby creating a monopoly situation and inhibiting market competition. On the other hand, a laissez-faire policy is unacceptable as long as a need exists for insuring the competence of practitioners in certain fields. It is a matter of providing the necessary restrictive regulation in the way that least affects economic competition. Alternatives three and two, eliminating and limiting the role of pharmacists will best serve this interest.

Democratic government is subverted to the extent that powers are delegated to individuals or groups not directly responsible to the people. The general public has an interest in minimizing such subversion which can be served by limiting the delegation of public powers to exceptional cases where needs exist that cannot be met in other ways. In delegating public powers, the preferable course will be the one that provides the greatest possibility that such powers will be used to further public rather than private interests. Again, the alternatives which limit or eliminate pharmacist participation best satisfy this interest.

In summary, the multiple interests of the general public would be least served by self-regulation. Alternative two, no participation by pharmacists, maximizes the public's interest in economic freedom

and democratic government while alternative three, some participation, best serves the interest of the public as drug consumers. Overall the choice lies between two and three.

Summation of Interests. In chapter five it was pointed out that the public interest in relation to government procedures may be defined as "a common good, an aggregate of interests, the maximization of interest-satisfactions."⁶ Obviously there is no single alternative, the adoption of which will provide the maximization of interest-satisfactions for each interested group as well as for the groups taken as a single universe. The preceding analysis of the interests of groups related to the practice of pharmacy indicates that with respect to the desired degree of exercise of governmental power in the control of pharmacy by pharmacists, this maximization would probably occur under a system which provided for limited participation by pharmacists in regulation rather than for self-regulation by pharmacists or divorce of pharmacists from the regulatory process.

Alternative Procedures for Regulating Pharmacy Involving the Limited Participation of Pharmacists

If it is desired to reduce the role of pharmacists in the regulation of pharmacy, this can be accomplished either by abolishing or transferring some of the duties and powers presently exercised by the Board of Pharmacy or by modifying the composition of the Board. These possible courses of action can be pursued either within the Department of Health or the Department of Treasury and Regulation.

⁶Leys, Nomos V, p. 248.

Organizational Placement of the Function. The Department of Health is charged with administering programs, "designed to protect, preserve, care for and improve the physical and mental health of the people. . . ,"⁷ and considering that the pharmacy law has similar goals there is some logic to placing pharmacy regulation with that Department. The major advantage to such a placement arises from the fact that the Department of Health has a staff which includes many physicians whose training may enable them to understand the pharmaceutical activities to be regulated and the problems that may arise from time to time, but this is also a major disadvantage. The same questions that have been raised concerning the wisdom of delegating the power of self-regulation to pharmacists also apply to physicians who are, for all practical purposes, self-regulating under the Department of Health. Granting control of para-medical occupations such as pharmacy to physicians increases the public powers delegated to this private interest group. It might be assumed from the desire of many physicians to have control of drugs in hospitals placed with the Department of Health that they expect more sympathetic treatment from the Department than from the Board of Pharmacy.

There are two primary advantages to placing the regulation of pharmacy with the Department of Treasury and Regulation. First, the staff of the Department is composed primarily of public administrators and civil servants who do not share the private interests

⁷Revised Laws of Hawaii 1955, 1961 Supplement,
14A-18.

of those whom the law regulates. Second, the Department is organized to administer many occupational licensing laws and related statutes and some operational advantages accrue from this centralization. For example, the Board of Pharmacy had never had available administrative and investigative staff until it was placed in the Department and could share a central staff. The major disadvantage to leaving the regulation of pharmacy with Treasury and Regulation is that the expertise in public health matters possessed by staff of the Department of Health might not be readily available.

It appears that the public interest would be best served by the organizational placement of pharmacy regulatory functions with the Department of Treasury and Regulation. Once the issue of organizational placement is resolved it is possible to consider alternative ways of modifying the self-regulatory powers of pharmacists.

Abolish or Transfer Present Duties and Powers of the Board of Pharmacy. Possible action under this alternative ranges from modifying a few functions to abolishing the Board. Moderate change could be effected by amending the present law to limit clearly the powers of the Board to license pharmacists and pharmacies and set and enforce standards for the practice of pharmacy. It could be clearly spelled out that regulation of drugs as a commodity is not within the jurisdiction of the Board. If desired, hospital pharmacies could be exempted from Board control. Another moderate course would be to increase the authority of the director of the department to review and supervise Board actions. Although these modifications would narrow the possibility of Board activities serving private interests, pharmacists would still be largely self-regulating.

A more radical change would be to abolish the Board and regulate pharmacy through non-pharmacist, civil servants in a government agency. This choice would probably minimize the possibility of pharmacists using public powers to serve their private interests. It also has serious disadvantages, one of which is that civil servants are no more and perhaps even less directly responsible to the general public than is an appointive board. Ideally, civil servants always perform their public functions to serve a public interest but, in reality, government officials develop vested interests in their activities and, in many cases, are not responsive either to the interests of concerned private groups or the general public. Another possible disadvantage is that civil servants would probably not possess medical or pharmaceutical knowledge equivalent to that of the staff of the Department of Health and the members of the Board of Pharmacy. The disadvantages of this alternative seem to outweigh the advantages.

It is also possible to limit the Board's duties to functions intimately related to the specialized knowledge and techniques of the trained pharmacist. By and large, the duties and powers of the Board to suspend and revoke licenses or permits, make rules and regulations, conduct inspections and investigations, and pass on the qualifications of applicants for licenses and permits, can be as well performed by non-pharmacists as pharmacists. The examining function is the one area where pharmacists can clearly do a more adequate job than can other groups. Public interest will be served if pharmacists, as the best qualified persons, perform this function provided that concessions are not made that are detrimental to other interests of the general public. Test preparation is a complex process and it may, therefore, be wise to arrange with

a mainland university with a pharmacy school or a testing service to prepare and grade examinations for Hawaii applicants.⁸ The test could be administered by a non-pharmacist. The administration and grading of a practical part of an examination would require the use of personnel in Hawaii and local pharmacists would probably be the most qualified. A local pharmacy board could be retained to prepare, administer, and score examinations. The interests of the public and applicants could be safeguarded by making the board's decisions on examinations subject to review by the director of the department whenever a question or appeal is initiated. The desirability of limiting the board to the examining function is that it minimizes, as far as possible, the likelihood of pharmacists using public powers to serve their private interests while at the same time it utilizes those special skills of pharmacists which further the general public interest. The board might also provide advisory services to the director on matters related to the regulation of pharmacy. This would give pharmacists some voice in their regulation, thereby serving their interests.

A fourth alternative involves removing all functions, including examinations, from the Board and

⁸In the study, Occupational Licensing Legislation in the States, pp. 51-52, the Council of State Governments found "much dissatisfaction with the examining process as it is conducted by most licensing boards. Some board members do not have sufficient time to prepare and grade examinations properly, and many are not equipped for these tasks. . . . most licensing examinations [in Illinois and Michigan] have not reflected recent advancements in [the] field [of testing]. . . Proper construction and administration of tests require the services of experts who can apply the knowledge and techniques gained from numerous investigations conducted in the testing field in recent years."

making it purely an advisory body. The advantages here are the same as for the preceding alternative and the only disadvantage is that it would make unavailable the services of local pharmacists to administer practical examinations. Of all the alternatives probably the third, in which the Board is limited to functions requiring the work of trained pharmacists, would be the choice which would best serve the public interest with the least damage to the private interests of pharmacists.

Modify the Composition of the Board. Consideration of this alternative is based on the assumption that it is first decided that a board is a desirable administrative body. Most present public administration theory, however, is highly critical of the usefulness or effectiveness of boards as administrative bodies as compared to strong, individual administrators or executives.⁹ There are a number of ways to vary the composition of the Board.

The variation most acceptable to pharmacists would be to add one non-pharmacist to the Board or provide that one of the present positions on the Board be filled by a non-pharmacist. Depending upon the capability of this lay member the public interest could be inadequately or relatively effectively represented. However, the voice would be one among many and the power of self-regulation would still lie clearly with the pharmacists.

At the other extreme would be a Board with no pharmacists as members. Pharmacists would be completely removed from possible use of public powers to serve

⁹See, for example, Leonard D. White, Introduction to the Study of Public Administration (New York: The MacMillan Company, 1955), pp. 189-191.

their private interests. There is the disadvantage to the general public interest in that the Board would not have available among its members the special skills of pharmacists for use in such cases as administering and scoring practical examinations.

The most acceptable modification in terms of adequately safeguarding the public interest while leaving pharmacists a voice in their regulation is the compromise solution of a Board with a majority of non-pharmacists as members. A majority of lay members would enhance the likelihood of actions in the public interest. The presence of pharmacists would enable the Board to draw on their knowledge and experience of the practice of pharmacy.

Many pharmacists fear the possible consequences of being regulated by physicians, either through the Department of Health, or through a Board composed in whole or in part of physicians. In view of the private interests that physicians in Hawaii do have in the regulation of pharmacy, this fear seems well-founded.

Pharmacy Problem Situations

Some of the problems discussed in the following section arise from overlaps in state laws or in the respective responsibilities of federal and state agencies. In such cases it is often possible to either solve the problem or minimize it through administrative action on the part of the agencies involved. This course of action has not always been given adequate consideration by government agencies in Hawaii concerned with the regulation of pharmacy. There are also situations where all the parties involved feel they have a legal responsibility mandating action on their part and these conflicts probably depend for resolution on legislative action.

The third group of problems considered below relate to the use of delegated public powers to serve a recognizable private interest of pharmacists and where the benefit to the public interest is difficult to discern. These problems are useful illustrations of the need for care in (1) deciding to delegate public powers, and (2) clearly delimiting any powers which are delegated.

Problems Involving Conflicting Provisions in Hawaii Laws

In general, problems in this area are attributable to two related factors common to much legislation. One factor is the lack of adequate consideration of the effect of proposed legislation on existing statutes and the second is due to a tendency to make broad grants of power to the agency responsible for administering a law rather than clearly limiting the powers delegated. There are cases, of course, where broad grants of authority are desirable and even essential for effective carrying out of the purposes of a law. On the other hand, the regulation of the vocation of pharmacy is a subject which is easily circumscribed and, therefore, lends itself to more precise and exact provisions in law.

Dispensing of Drugs by Physicians. Every state recognizes the right of doctors to dispense drugs and medicines to their patients but in no other state does it reach the proportions it does in Hawaii.

Section 71-19 permits "licensed practitioners of medicine" to "personally" supply their own patients with drugs. It is common for dispensing-physicians to dispense through members of their staff who are

not trained pharmacists.¹⁰ The Board of Pharmacy believes that physicians should do all their dispensing personally and has proposed "personally" be so defined as to eliminate the possibility of interpreting the term to imply "under the immediate supervision of". This requirement would limit the time that doctors, who do extensive dispensing, have to practice medicine and hopefully would encourage greater prescribing by doctors. It is likely, however, that physicians will not respond by increasing their prescribing but rather by pushing for legislation which would clarify their right to dispense through employees under their immediate supervision.

Physicians believe they already have this right under section 64-1 of the Revised Laws which permits "any person" to apply "any remedial agent or measure under the direction of a licensed physician". The resolution of the apparent conflict between sections 71-19 and 64-1 of the Revised Laws will clear up one part of the problem of physician dispensing. The choice to be made is between allowing pharmacists to regulate the dispensing practices of physicians or allowing physicians the authority to delegate to their employees certain functions involved in the practice of medicine. One basis on which to make the choice is to look again at what are the goals of the pharmacy licensing law. Specifically, these goals are to limit entry to the vocation of pharmacy to qualified individuals and to regulate the practice of pharmacy. Regulating dispensing practices of physicians does not appear to fall within the compass of these goals.

¹⁰This information is drawn from files of the State Department of Health.

Another factor requiring consideration is the large measure of individual responsibility necessarily placed on medical practitioners. As long as physicians bear the ultimate responsibility for the well-being of their patients they have strong justification for desiring to maintain control of those functions which affect patients, including dispensing.

Another part of this problem arises from the fact that both pharmacists and physicians have significant economic interests in the sale of drugs. Physicians maintain that the concern of the pharmacists in this area appears to be economically motivated rather than related to furthering a more general public interest.

Physicians, on the other hand, may also be economically motivated in the dispensing of medicine. A recent editorial in the St. Louis Post-Dispatch points out that the American Medical Association "clung to the existing policy that it is all right for doctors to own drug stores as long as they do not attempt to exploit their patients." This was in spite of the recommendation of the AMA Judicial Council that "any arrangement by which the physician profits from the remedy he prescribes or supplies is unethical." The Post-Dispatch suggests the central point is that "doctors should not be subject to the temptation to exploit their patients for profit in the drugs they prescribe, or made to appear as if they might be doing so."¹¹

The proper place to settle this part of the present conflict over physician-dispensing is probably in the open market place through individual and organized group efforts. It has been suggested that pharmacists

¹¹Quoted in the Honolulu Star Bulletin, January 7, 1963, p. 6.

in Hawaii will make progress in this struggle only to the extent that they win the respect and cooperation of the medical profession. Several pharmacists in Hawaii have built up a considerable volume of prescription business by gaining the confidence of doctors. Programs by the Hawaii Pharmaceutical Association could be helpful in building the image of the pharmacist as an expert drug consultant. Eventually, the success of pharmacy depends on the abilities and efforts of the individual pharmacist.

Pharmacists, it should be noted, are required by the Board of Pharmacy and the Department of Health to maintain certain records on the drugs they dispense. The purpose of these records is to provide an additional safeguard for the public. Most physicians who dispense do not maintain similar records.¹² Either the requirement should apply to both groups or be eliminated.

Hospital Pharmacies. The central issue in the regulation of drug preparation and dispensation in hospitals is whether the Department of Health or the Board of Pharmacy should have jurisdiction. Under existing laws (Chapters 71, 46 and 48A, Revised Laws of Hawaii 1955, as amended) both agencies presently have legal responsibility for regulating hospital dispensing practices. Both agencies have good reasons for claiming jurisdiction. The Board of Pharmacy can argue that its goals under the pharmacy licensing law include regulating the practice of pharmacy in hospitals as well as in other places. On the other hand, the

¹²State Department of Health files. The pharmacy law does not require physicians to maintain records but the poison law and rules and regulations of the Department of Health apply to physicians as well as pharmacists.

Department of Health may argue that effective regulation of hospitals (a proper responsibility of the Department) is impaired by arbitrarily dividing control over the interrelated activities and operations carried on within hospitals. Both agencies possess the necessary skills to regulate adequately in this area. As long as hospital dispensing is limited largely to inpatients and is, therefore, a part of the internal operations of hospitals it would appear preferable to place jurisdiction with the Department of Health. Hospitals with extensive outpatient dispensing or selling drugs to the general public are clearly in competition with retail pharmacies and might well be regulated on the same basis. Jurisdiction over such hospital pharmacies might then be assigned in full, or in part, to the Board of Pharmacy.

Resolution of jurisdictional questions will not solve the problems of small hospitals dispensing through non-pharmacists. There are a number of compromise solutions available which would protect the public health and safety without placing an unreasonable burden on small hospitals. The definition of pharmacy in the law may leave sufficient leeway for a hospital to create a drug room as opposed to a pharmacy. In a drug room no compounding would take place and no registered pharmacist would be employed, but in other respects the operation would parallel a regular hospital pharmacy. Dispensing from a drug room could be limited to registered nurses. Any compounding the hospital needed, would be performed by a private pharmacist. Additional safeguards could be provided by arranging for the part-time services of a registered pharmacist who would be responsible for purchasing, checking the inventory, and setting up and reviewing the work procedures to be followed in the drug room.

Small hospitals with pharmacies where compounding is performed present a different problem. Pending amendment of the present law, the only acceptable alternative involves obtaining the full or part-time services of a registered pharmacist. As long as drugs are compounded, the services of a pharmacist are necessary for, with the possible exception of a chemist, no other group besides pharmacists is adequately trained to compound.

Placing a full or part-time registered pharmacist in charge of the hospital pharmacy will fulfill the legal requirements and satisfy the Board of Pharmacy, but several problems will remain to plague the small hospital. Chief among these is the difficulty of finding a full-time pharmacist willing to work in an isolated rural area or a part-time pharmacist willing to devote sufficient time to meet adequately the hospital's needs. Present low salaries appear to hamper recruitment. Payment of the pharmacist's salary is an additional cost to be passed on to the patient and, therefore, it would be incumbent upon the hospital to make the best use of the pharmacist's services by: (1) using the pharmacist only when absolutely necessary and paying him on the basis of services rendered; (2) using the pharmacist to perform other duties, such as doubling as the hospital purchasing agent; and (3) permitting the pharmacist to order his drug purchases with those of the hospital so as to obtain bulk discounts.¹³

Dispensing of Drugs by Nurses. There is some feeling among nurses that they should not be used to

¹³Alex Berman and John J. Zugich (eds.), Pharmacy Service in Smaller Hospitals (Ann Arbor: The University of Michigan, 1958), p. 253.

operate drug rooms or pharmacies or dispense extensively. They base their feeling on the fact that they are not trained to perform as pharmacists and dispensing places a large measure of responsibility on the dispenser including potential legal liability. Many nurses believe that there is a continued tendency in the field of medicine to assign to nursing a wide variety of disparate functions, a tendency which is destructive of nursing as a coherent, ordered body of knowledge with defined procedures designed to accomplish specific goals.

There is wide agreement that nurses should not compound, but requiring nurses to dispense appears to be a widely accepted practice. With respect to doctors in independent or clinic or group practice who require their nurses to dispense, there is probably no effective legal method to halt the practice short of hiring a staff of investigators to enforce the law requiring physicians to dispense "personally". This would not, however, answer the basic question of whether the responsibility of doctors permits the delegation of dispensing duties to employees.

There may be no feasible alternative to dispensing by nurses in small, rural hospitals. Certainly, it seems clear that doctors are unwilling to assume the chore. It does not appear that small hospitals with drug rooms have a need for full-time pharmacists nor can they be expected to attract and keep trained pharmacists at all times. Dispensing in small hospitals will probably continue to be a duty of registered nurses through default and lack of other trained, responsible groups.

It may well be that the only realistic possible solution for nurses is to work through their associations to strengthen acceptance of their image of nursing by

doctors, and other medically related groups--an image which excludes the function of dispensing if they so desire.

Overlap in Federal and State Regulatory Activities

The "Federal Food, Drug, and Cosmetic Act" is designed to "keep interstate channels free from deleterious, adulterated and misbranded articles of specified types to the end that public health and safety might be advanced."¹⁴ The constitutionality of the federal act rests upon the power of Congress to regulate interstate commerce. At first glance, this provides an easy basis for dividing jurisdiction over drugs as a commodity. States are responsible for drugs in intrastate commerce and the federal government is responsible for drugs in interstate commerce. In practice the division is not so clear. Almost all drugs in Hawaii enter the State in interstate commerce and are therefore subject to federal law until sale or dispensation to the ultimate consumer. The distinction is further blurred because the federal law's definition of adulterated and misbranded drugs covers a broad variety of situations.

A fairly recent conflict between detail men and the Department of Health is the outcome of the Department's proposed amendments to its regulations controlling poisons. Under these new regulations detail men would clearly be required to register with the Department, obtain a permit before they could possess and distribute drug samples, and maintain records of drugs they receive and distribute. It is

¹⁴United States Code Annotated: Title 21, Food and Drugs (St. Paul: West Publishing Co., 1961), p. 255.

the opinion of the Health Department that the existing regulations include substantially the same requirements. However, in the past, many detail men have not met these requirements and the Department has not taken steps to enforce them.

Pharmaceutical manufacturers and detail men have objected in the past to attempts by State agencies to require detail men to obtain permits and keep records. Their objections are, basically, that state regulation is interference with interstate commerce and that, anyway, there is no need for state regulation because the federal government's activities provide sufficient public protection. The question of interference with interstate commerce is one that will have to be settled in the courts but there are suggestions that under their police powers states can regulate some aspects of the business of out-of-state manufacturers.¹⁵

State regulation in addition to federal regulation can be justified if it supplements the federal law or meets some need not covered by federal law. Detail men and pharmaceutical manufacturers suggest that the public interest involved in the activities which the Department of Health desires to regulate is to insure that drugs are not improperly distributed. This public interest, they claim, is met by the federal requirement that drugs potentially harmful to humans must be labeled "Caution: Federal law prohibits dispensing without a prescription" and restricts the

¹⁵For example, see Stanley Mosk, "Control Over the Distribution of Prescription Drugs", a paper presented to the third session of the National Association of Boards of Pharmacy meeting of the Bureau of Law Enforcement, March 27, 1962.

distribution of such drugs to individuals legally authorized to prescribe or fill prescriptions.

The Department of Health's "justification for the rule requiring registration of these men is to enable the Health Department to ascertain which persons are selling or offering for sale drugs in the State. With this information the State, on those occasions when it becomes necessary, can withdraw adulterated or misbranded drugs from the market by quickly contacting the men involved. Another but perhaps subordinate reason why this rule is necessary is that it enables the Health Department to keep better surveillance over the activities of the detail men so that any regulatory action that may be required in the public welfare can be taken should such action be necessary. It should be pointed out that detail men are continually being transferred to the mainland or replaced so that the argument that no registration is necessary because a roster is available is valueless!"¹⁶

Problems Relating to the Use of Public Powers to Serve Private Interests

The following problems are typical examples of those which arise when a private interest group, given the power of self-regulation, has difficulty distinguishing between activities justified as serving the public interest which may incidentally serve private interests and activities which serve private interests and only incidentally a more general public interest.

¹⁶Letter from Mr. George H. Akau, Chief, Food and Drug Branch, Hawaii State Department of Health, January 11, 1963.

Regulation of the Sale of Prophylactics. The prophylactics law is administered by the Department of Health. The public interest in prophylactics, given their possible uses, is usually stated as: (1) insuring minimum quality of prophylactics to the end of protecting public health, and (2) limiting sales to responsible adults to protect the morals of the young. Health officials consider the public interest sufficiently well served as long as retail merchants sell only prophylactics meeting minimum quality standards and then only to adults.

Some retail pharmacists have occasionally urged that the public interest can only be adequately served if prophylactic sales are restricted to registered pharmacists. Inherent in this argument is the implication that pharmacists possess some quality lacking in other retail merchants which make them peculiarly well suited to protecting the public health and morals in this instance. This quality is not to be found in the public health aspect because minimum quality standards are not established at the outlet level no matter who the retailers are. Therefore, the quality, if it exists, must lie in the area of public morals. The prime motivation of retailers to violate public morals deliberately by selling to minors is economic. This suggests that the quality retail druggists are seeking to define and claim is that they are less likely violators because they lack economic motivation or have other standards (codes of ethics) superimposed over economic considerations. It is clear that pharmacists have an economic motivation and so the question is whether these motivations are controlled by higher standards. Based on such factors as membership in voluntary professional organizations it appears that some pharmacists probably subordinate their economic motives to considerations of the public

interest, but it is not clear that this is more true of pharmacists than of other retail merchants.

Assigning the regulation of prophylactics to the Board of Pharmacy is subject to the same objections raised over physicians owning drug stores. Pharmacists should not be subject to the temptation to limit the flow of goods in a free economy arbitrarily or made to appear as though they are doing so.

Authorization of Oral Prescriptions. Another problem pharmacists and physicians face in practicing their vocations in Hawaii is that oral or telephone prescriptions are legally forbidden¹⁷ except for certain narcotics with little or no addiction liability.¹⁸ Oral prescriptions are permitted in the "Federal Food, Drug and Cosmetic Act" provided they are reduced promptly to writing and filed by the pharmacist.¹⁹ Here is a situation where different levels of government have arrived at different conclusions concerning what restrictions are necessary to protect the public health.

Most pharmacists and physicians see no potential danger sufficient to justify the legal forbidding of oral prescriptions. In fact, they view oral prescriptions as a convenience to practitioners and to patients who do not have to wait while the pharmacist fills a written prescription. If it was within their power to do so, the Board of Pharmacy would authorize oral prescriptions on the basis that it would not damage the public interest while it would be a convenience

¹⁷Revised Laws of Hawaii 1955, 51-15(j).

¹⁸Ibid., 52-17.3.

¹⁹United States Code Annotated: Title 21, Food and Drugs, p. 464.

to patients, physicians, and pharmacists.²⁰ Legalizing oral prescriptions might also encourage more physicians to do more prescribing and result in economic benefits to retail pharmacists.

The Department of Health approaches the problem from the point of view that oral prescriptions may provide an opportunity for unauthorized individuals to obtain such drugs as narcotics. The Department also questions the advisability of oral prescribing as possibly leading to errors arising from misunderstanding of the doctor's orders by pharmacists. Another facet of the problem concerns the possibility of nurses or other employees unauthorized to prescribe giving oral prescriptions.²¹ This poses again the question of the relative responsibilities and legal liabilities of physicians, their employees, and pharmacists.

The advisability of legally authorizing oral prescriptions cannot be answered within the limits of this study. This situation points up a basic problem in self-regulation: if the Board of Pharmacy had the power to approve or disapprove oral prescribing would it raise the same questions the Department of Health raises, analyze them with equivalent objectivity, and include and weight the same factors in arriving at its decision.

²⁰Included in the Board of Pharmacy's 1963 legislative program is a bill which would define "prescription" to include oral as well as written orders for drugs or medicines.

²¹Records of the Department of Health indicate that, although illegal, there is a large amount of oral prescribing done in Hawaii and that both oral and written prescriptions are given by nurses not legally authorized to prescribe.

The Power to Make and Enforce Rules and Regulations.

A California legislative committee has found a need for "adequate and clear description, in the statute, of the exact nature and limits of the power conferred. . . [to express] the legislative intent so clearly that the administrator will have a truly accurate and certain guide in his exercise of the power, and the courts in their review of his action."²²

The Hawaii pharmacy licensing law states "the board may make such rules and regulations, not inconsistent with law, as may be necessary to carry out the purpose of this chapter, which purpose is hereby declared to be the protection of the public health and safety."²³ Almost any action can in some way be related to public health or safety so that the only meaningful restraint on the Board's power to make rules and regulations which will have "the force and effect of law" is that they do not conflict with the law. The intent of the legislature is certainly not clear in this case. If the intent had been to grant the Board the power to issue rulings interpretive of the law they administer this might have been better expressed by permitting "such by-laws and regulations not inconsistent with the laws of this State, as may be necessary for the protection of the public, and appertaining to the practice of pharmacy and the lawful performance of . . . the board's . . . duties."²⁴

²²Supplement to the Report of the Assembly Interim Committee on Administrative Regulation, Assembly of the State of California, 1947, p. 7.

²³Revised Laws of Hawaii 1955, 71-4(e)

²⁴Supplement to the Report of the Assembly Interim Committee on Administrative Regulation, p. 15.

Granting broad rule making powers to a board is equivalent to a greater degree of delegation of legislative powers and increases the possibility of using public powers to serve private interests. A brief review of some of the provisions of the rules and regulations adopted by the Hawaii Board of Pharmacy on January 11, 1963 indicates the kinds of problems that may develop when no clear limitations are set on a board's rule-making power.

Section 1.4 of the rules and regulations makes it unlawful to advertise the price of prescription drugs to the general public. The advisability of the rule can be debated in terms of whether or not it serves a general public interest. More to the point of the present discussion is the issue of the Board's legal authority to promulgate such a rule. There is nothing in the statute concerning advertising of drugs. If anything, the central concern of the law appears to be insuring that drugs are dispensed only by licensed pharmacists with adequate equipment who maintain required records. Sales methods do not appear to be a subject of the law as long as sales are made by qualified persons.

Section 1.11 makes it "unlawful for any person to possess or control prescription drugs except as provided by law or rule" and provides for certain exceptions. This is an attempt by the Board to establish control over drugs as a commodity.²⁵ Assuming the purposes of the pharmacy law are to control the practice of a vocation this rule exceeds the intended legal powers of the Board. In any

²⁵See also the Board's legislative proposal number two, dated January 22, 1963, which states:

Today's practice of pharmacy has made the pharmacist a professional drug consultant to the physician and the manufacture and distribution of drugs (poisons) on a national and international scale tremendously complicated the Board's purpose of "the protection

event, nowhere in the law is there any indication the Board should control possession of prescription drugs.

In both these instances, the Board can fall back on its broad grant of power to make rules for the protection of the public health and safety. There are other similar questionable provisions in the rules and regulations including authorizing phone orders except where a written prescription is required by law, generally prohibiting the return or exchange of drugs, and modifying the examination requirements. The issue is not really whether these rules or regulations protect the public health and safety but whether the intent of the legislature was to provide these safeguards through the pharmacy licensing law or through other laws administered by other agencies. The present grant of rule-making power to the Board facilitates conflicts between Board rules and regulations and the regulatory activities of other agencies. A more precise grant of power would probably clarify legislative intent and resolve some present conflicts.

Mrs. Karen Asano prepared the manuscript for printing.

of the public health and safety". . . in that this purpose can no longer be carried by simply examining and licensing qualified applicants. The Board must now also regulate and control a drug (poison) within the State to achieve its purpose.

This statement and the accompanying legislation show that the Board is attempting to expand its powers into new areas. It is this desire for increased regulatory powers and, more specifically, for control over drugs as a commodity that is the key to the present problems of state regulation of pharmacy in Hawaii.

APPENDIX A

Questionnaire Sent to Hawaii Medical Association Members

Physicians Questionnaire

Please note that this questionnaire does not require a signature. The questionnaires are confidential and will be destroyed at the completion of the study.

1. Is your practice primarily rural _____ or urban _____?
2. Are you in independent practice _____ clinic or group practice without a pharmacy _____ clinic or group practice with a pharmacy _____ other _____? (please specify)
3. Do you dispense drugs other than: (1) injectables; (2) those that should be taken under the immediate supervision of a physician; and (3) those administered while on a house call?
Yes _____ No _____
4. A. If you answer "yes" to Question 3, what per cent of your income (after overhead expenses are deducted but before income or other taxes are deducted) is derived from the dispensing of drugs?

0-5% _____
6-10% _____
11-20% _____
21-30% _____
31-40% _____
41-50% _____
Over 50% _____

Or

- B. If you are associated with a clinic or group which operates a pharmacy, what per cent of your income (after overhead expenses are deducted but before income or other taxes are deducted) is derived from the dispensing of drugs?

0-5% _____
6-10% _____
11-20% _____
21-30% _____
31-40% _____
41-50% _____
Over 50% _____

5. Are there modifications you think should be made to the existing laws governing pharmacy or to the proposed rules and regulations (which will have the force and effect of law when approved) of the Board of Pharmacy?

APPENDIX B

The Definition of Profession

Pharmacists and others concerned about the professional status of pharmacy have written much on the subject. They have not, however, proposed alternative criteria or definitions for profession, but have drawn on the work of others. McAllister's definition quoted above (footnote 31, page 110) was taken from the January, 1955 Annals of the American Academy of Political and Social Science. Heffron has consulted the dictionary and various court decisions as a basis for his discussion.¹ In articles on "The National Purpose of Pharmacy" in the Fall, 1961 issue of the American Journal of Pharmaceutical Education the authors again turn elsewhere for definitions of profession. The analysis of the general literature on profession, then, encompasses the use of the term by writers on pharmacy as a profession.

It has been stated that the problem of adequately defining profession has progressed little since Abraham Flexner in 1915 suggested six criteria against which vocations could be tested.² They were: (1) essentially intellectual operations with large individual responsibility, (2) raw material taken from science and learning, (3) working up of this material to a practical, definite end, (4) an educationally communicable technique, (5) tendency toward self-organization, and (6) an increasing altruism in motivation.³

Four of these six characteristics (1, 2, 5, 6) are to be found in some form in nearly every definition of profession. The other two (working up of raw material and an educationally communicable technique) have failed to stand the test of time primarily because they are too general to enable meaningful distinctions to be made

¹Heffron, Utah Pharmaceutical Association Bulletin News, LXX, No. 11, 10-15.

²Cogan, "The Problem of Defining a Profession", Annals of the American Academy of Political and Social Science: Ethical Standards and Social Conduct, CCXCVII (January, 1955), p. 106.

³Abraham Flexner, "Is Social Work a Profession?", School and Society, I, No. 26 (June 26, 1915), 904.

among vocations, especially as society becomes more complex and specialization leads to ever finer distinctions within and among vocations.

Carr-Saunders and Wilson in their four criteria place heaviest emphasis on "the existence of specialized intellectual techniques, acquired as the result of prolonged training, which gives rise to professionalism and accounts for its peculiar features."⁴ This largely overlaps Flexner's first two criteria and might well be used in place of them.

One other criterion suggested by Carr-Saunders and Wilson⁵ must be mentioned because of the frequent arguments it has raised among pharmacists. It reads: "This service they perform for a fixed remuneration whether by way of fee or salary."⁶ Pharmacists, and others, have suggested that developing fee schedules will lead to professionalization. Superficial consideration indicates this is not a useful criterion for distinguishing professionalism. Vocations, such as unskilled labor, furthest removed from the professions are mostly paid through salaries. Gardeners, however, are an example of a non-professional group many of whom work on a fee basis.

In Oliver Garceau's view interpretation of the concept of profession is a matter of personal temperament. Rather than propose a single definition he suggests it is possible to summarize the concept as a composite of ideas in broad categories. The initial categories concern the practitioner's relations with (1) the client, (2) his professional group, and (3) society. Garceau distinguishes within each category ideas and elements characterizing professions.⁷

Most of Garceau's characterizing ideas are inherent in the criteria listed by Flexner and Carr-Saunders and

⁴Carr-Saunders and Wilson, p. 285.

⁵Their other two criteria are not discussed separately because they overlap Flexner's criteria.

⁶Carr-Saunders and Wilson, p. 284.

⁷The discussion of these ideas and elements is found in Oliver Garceau, The Political Life of the American Medical Association (Cambridge: Harvard University Press, 1941), pp. 5-8.

Wilson. There is one interesting addition involving a reciprocal relationship between society and the professions. It is the responsibility of professions to exert a cultivated, educated influence in society, to perpetrate the humanistic tradition of a truly liberal culture.⁸ In turn, society must nurture professionalism and accept its guidance.

R. H. Tawney argues that "a profession may be defined most simply as a trade which is organized, incompletely, no doubt, but genuinely, for the performance of function" in opposition to those who work for the sole objective of earning a living. The directing principle of function is, in Tawney's mind, the solution to the problems of the acquisitive society which are attributable to the traditional theory of individual property rights. Organization of society on the basis of function would (1) insure maintenance of proprietary rights only when they are accompanied by the performance of service, (2) highlight producer's responsibility to the community, and (3) make industry a profession obligated to the professional organization for the maintenance of adequate service.⁹

One other definition of profession¹⁰ worth noting is Cogan's which does not suggest new concepts but is helpful for its well thought out phrasing:

⁸An example of this argument is found in The (London) Times Literary Supplement, May 24, 1957, p. 321: "... the case for protecting the professions is not merely that society depends so much on the work they do but that they have provided the soil in which habits of mind and conventions of behaviour on which society also depends have flourished; equally, in a world where these habits and conventions are despised, the professions will be unable to do even their specialized work efficiently and honourably."

⁹R. H. Tawney, The Acquisitive Society (New York: Harcourt, Brace and Company, 1955), pp. 92ff., 180.

¹⁰There are many other attempts to define profession or to develop criteria for determining whether a vocation is or is not a profession. The most comprehensive recent review of the literature on professions is Cogan, "Toward a Definition of Profession", Harvard Educational Review, XXIII, No. 1 (Winter, 1953). Some other interesting readings are: Paul Donham, "Is Management a Profession?", Harvard Business Review, XL

A profession is a vocation whose practice is founded upon an understanding of the theoretical structure of some department of learning or science, and upon the abilities accompanying such understanding. This understanding and these abilities are applied to the vital practical affairs of man. The practices of the profession are modified by knowledge of a generalized nature and by the accumulated wisdom and experience of mankind, which serve to correct the errors of specialism. The profession, serving the vital needs of man, considers its first ethical imperative to be altruistic service to the client.¹¹

One of the most significant parts of Cogan's definition is his modification of the intellectual aspect of professions. Cogan acknowledges in this article a debt to A. N. Whitehead whose definition of profession "cuts cleanly and economically through many confusions as to the general nature of the intellectual basis of profession. It is worth close examination." Whitehead's definition reads:

. . . the term Profession means an avocation whose activities are subjected to theoretical analysis, and are modified by theoretical conclusions derived from that analysis. This analysis has regard to the purposes of the avocation and to the adoption

No. 5 (September-October, 1962), 60-68; The entire issue of the Annals of the American Academy of Political and Social Science: Ethical Standards and Professional Conduct, CCXCVII (January, 1955) is devoted to articles related to profession; Lyman Bryson, "The Arts, The Professions, and The State", The Yale Review, XXXVI, No. 4 (Summer, 1947), 631-642; and T. H. Marshall, "The Recent History of Professionalism in Relation to Social Structure and Social Policy", The Canadian Journal of Economics and Political Science, V, No. 3 (August, 1939). A sociological analysis of the concept of profession may be found in Greenwood, Social Work, II, No. 3, 45-55.

¹¹Cogan, Harvard Educational Review, XXIII, No. 1, 48-49.

of the activities for the attainment of those purposes. Such criticism must be founded upon some understanding of the natures of the things involved in those activities, so that the results of action can be foreseen. Thus foresight based upon theory, and theory based upon understanding of the nature of things, are essential to a profession.¹²

Further clarification of this concept is provided in a later passage: "The antithesis to a profession is an avocation based upon customary activities and modified by the trial and error of individual practice. Such an avocation is a Craft, or at a lower level of individual skill it is merely a customary direction of muscular labour."¹³

¹²Whitehead, Adventures of Ideas, p. 72.

¹³Ibid., p. 73.

APPENDIX C

Occupational Licensing Laws in the State of Hawaii 1963

The following occupations are all self-regulating to some extent under present Hawaii statutes. Except for abstract makers, the agency responsible for administering the law consists, in whole or in part, of members appointed from the ranks of active practitioners of the regulated occupation. The Hawaii Supreme Court is responsible for administering the law regulating attorneys; the Department of Health administers the laws regulating fumigators and undertakers, embalmers and funeral directors; the administrative agencies for all other occupational licensing laws are organizationally assigned to the Department of Treasury and Regulation for administrative purposes, although in the case of some health occupations the Department of Health issues the licenses.

<u>Regulated Occupation</u>	<u>RLH¹</u>	<u>Regulated Occupation</u>	<u>RLH</u>
Abstract makers	163	Masseurs	63
Accountants	164	Physicians and surgeons	64
Attorneys	217	Automobile dealers,	
Barbers	58	brokers and salesmen	160
Hairdressers and		Naturopaths	66
cosmeticians	59	Nurses	67
Chiropractors	60	Dispensing opticians	69
Collection agencies	171A	Optometrists	68
Contractors	166A	Osteopaths	70
Dentists	61	Pharmacists	71
Dental hygienists ²	62	Photographers ⁴	169
Private detectives		Real estate brokers	
and guards	165A	and salesmen	170
Professional engineers,		Undertakers, embalmers	
architects, and surveyors	166	and funeral directors ⁵	72
Fumigators ³	62B	Veterinarians	73

¹Revised Laws of Hawaii 1955, as amended; references are to chapters.

²Dental hygienists are examined and licensed by the Board of Dental Examiners.

³This law provides for the Board of Health to examine and license fumigators and the Board "may" appoint an advisory committee of seven members, "two of whom shall be selected from the fumigation profession."

⁴The provisions of this licensing law have not been carried out because parts of the chapter were found to be an improper exercise of police power and thus invalid by the Attorney General (Attorney General's opinion 57-125, October 18, 1957).

⁵This law provides for the Board of Health "to examine, or cause to be examined by not less than two practicing embalmers, undertakers, or funeral directors," applicants for a license and requires the Board to issue a license to every person who qualifies to take the examination and passes it.