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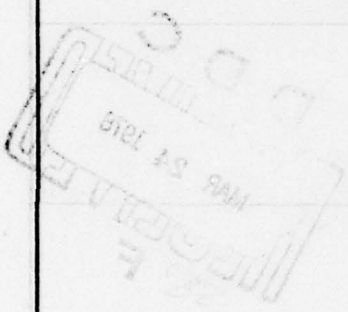

DRUG RECLASSIFICATION: AN ANALYSIS OF ORGANIZATIONAL AND PROFESSIONAL PERSPECTIVES

A THESIS
SUBMITTED TO THE FACULTY OF THE GRADUATE SCHOOL
OF THE UNIVERSITY OF MINNESOTA

By

Stephen John Sweeney

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF
DOCTOR OF PHILOSOPHY

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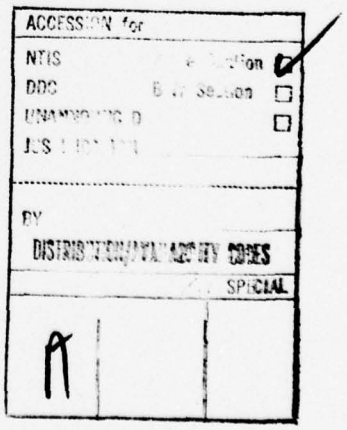

Abstract

STEPHEN JOHN SWEENEY

Drug Reclassification: An Analysis of Organizational and Professional Perspectives

University of Minnesota, Graduate Program in Pharmacy Administration

Under the Direction of Dr. Albert I. Wertheimer

The concept of establishing a non-prescription intermediate class of drugs, available only from pharmacists, was analyzed to determine the primary obstacles to its gaining acceptance. The concept holds critical implications for the future of the pharmacy profession. Its sanction by the legislative system would serve to officially recognize the pharmacist's role in applied clinical therapeutics.

The study examined the forces acting on the concept by securing the perspectives of numerous individuals and representatives of organizations, associations, and government agencies that have been or could be involved in future reclassification debates. Personal interviews, written correspondence, questionnaire survey techniques, telephone discussions and the background literature review were employed to gather data for the study. The analysis was divided into three sections. The initial phase developed organizational perspectives, the intermediate phase evaluated state level drug reclassification activities, and the final

phase utilized a questionnaire to measure attitudes of pharmacist practitioners and secretaries of state pharmacy boards and associations.

The analysis of organizational perspectives on the concept indicated few organizations outside the drug industry were aware of it; only the APhA is its outspoken advocate; the NARD primarily supports the pharmacist sales control aspect; prescription drug manufacturers fear associated government intervention; legislators are unresponsive towards it; the FDA has opposed it on the basis of no demonstrated need; and the most active opponents view it as having adverse economic impact, eg.) proprietary drug manufacturers.

The analysis of state level activities revealed that only Oregon has a true intermediate drug class; the history of conflict between pharmacists and other distribution sources of OTC drugs has been decided to the disadvantage of pharmacists; state level attempts to restrict certain OTC's to pharmacy sales have only resulted in the labeling of pharmacists as "sales monopolists"; and state court decisions indicate that unless a clear public danger is proven for an OTC drug, it should not be restricted to professional distribution.

Questionnaire results showed that practitioners favor the basic concept of restricting OTC drugs to pharmacist sales but are divided over the role

pharmacists should play in dealing with patients and the new class drugs; the Secretaries are generally more in favor than practitioners of mandating the direct intervention of the pharmacist in the sale of new class drugs; the economic importance of the concept is rated much less significant by practitioners and Secretaries than its professional impact; the concept is considered very important to the profession; and membership in pharmacy associations by practitioners is not related to their positions on the concept.

The conclusions and implications of these findings for the future of the concept and the future of legislative recognition for the clinical therapeutic role of pharmacists are not favorable. The proprietary drug industry's hard core opposition to the reclassification concept has been transformed into opposition to the expanded role functions of pharmacists. This presents a serious threat to professional role revitalization for pharmacists.

The study recommends that pharmacists need to resolve their differences of opinion on professional role functions, establish a restricted class from OTC drugs now available to them to demonstrate their concern and ability, develop a unified politically active organizational structure, and begin to solicit outside support for their positions.

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CHAPTER I

INTRODUCTION

General Problem Area to be Addressed

The general problem area of concern to this study is the need for the infusion of new legislatively and/or regulatively recognized professional role functions into the practice of pharmacy, such as the advising, counseling, and recommending of drug products to patients and physicians. The public's need of such services is amply demonstrated by the ever increasing use and misuse of prescription and non-prescription drugs by our public, and the needless illness and death resulting from it.[1] The magnitude of this problem is evidenced by the fact that the annual cost of hospitalization alone due to adverse drug reactions has been estimated at 900 million dollars.[2] This figure does not reflect any of the associated costs such as diagnosis, treatment, or loss of work capacity. Similarly, it is well known that "...much drug therapy avails little or nothing in terms of patient benefits."[3] These figures and statements demonstrate that drug misuse in our society is a multi-billion dollar problem. The pharmacist, possessing the aforementioned expanded role functions, can be at least a part of the needed solution to this enormous problem.

The pharmacy profession's need to acquire official recognition of new professional role activities to replace outdated and archaic functions, was recently placed in perspective by U. S. Supreme Court Chief Justice, Warren Burger, who filed a separate opinion as part of a recent Supreme Court decision on prescription price advertising. In the statement Chief Justice Burger said "... It is clear in this regard [the dispensing of prepackaged drugs] he [the pharmacist] no more renders a true professional service than does a clerk who sells law books."[4] The fact that over 99% of the prescriptions that a pharmacist dispenses are composed of such prepackaged or preformulated drug products[5] should stimulate the profession of pharmacy into seeking legislative and regulative support for its members true professional capabilities.

Specific Problem to be Addressed

The inability of the pharmacy profession to gain legislative and/or regulative recognition for its true professional role capabilities (the advising, counseling, and recommending of drug products to patients and physicians), forms the specific problem of concern to this study. The vehicle utilized to study this problem is the drug reclassification concept, one that could be of great benefit to the public as well as the pharmacy profession, but one that has not gained either legislative

or regulative sanction to date. Drug reclassification envisions the creation of a new non-prescription drug class, the drugs of which would be available only through pharmacies and/or pharmacists. The pharmacist would be able to consult with the patient, recommend a suitable medication if necessary, and advise the patient on the safe and effective use of the selected drug. It is the examination of this concept and the controversy surrounding it, that forms the central focus for this research project.

Background Information on the Pharmacist's Diminished Role

The professional role functions of pharmacists have undergone dramatic changes in character over the past 30-40 years. The traditional pharmacist's role was centered on the manufacturing, compounding, distributing, and controlling of drug products. With the development of large scale pharmaceutical manufacturing plants, particularly during World War II, the foundations on which traditional pharmacy practice rested, began to erode. As recently as 1948, extemporaneous prescription compounding by pharmacists comprised over 25% of all prescriptions dispensed.[6] Today, that figure has decreased to something less than 1%.[7] The extent of control over the distribution of drug products by pharmacists has similarly undergone drastic changes. Early in

this century pharmacists enjoyed a true monopoly over the sale of drug products. In 1932 for example, fully 95% of all drug products sold to the public in the United States were through drug stores.[8] In 1974, approximately 40% of the non-prescription products sold at retail reached the public through outlets other than pharmacies.[9] Industrial efficiencies and economies of scale have justifiably altered and diminished the manufacturing and compounding roles of pharmacists.

The concomitant diminished role of pharmacists in drug distribution can be at least partially accounted for by tracing the historical development of drug classification legislation at both the federal and state levels. Early federal level drug control legislation of importance to this study was focused primarily at gaining removal from the market of many misbranded and/or adulterated proprietary drug products. Among the products removed from the market as a result of the 1906 Food and Drug Act for example, was a headache mixture containing massive doses of acetanilid with the intriguing but deceptive name of Cuforhedake Brane-Fude.[10] The activities of the Food and Drug Administration (FDA) during this time period centered mainly on controlling the quality of the drug product being manufactured by businesses other than pharmacies. It is interesting to note, however, that in the jurisdictions of Puerto Rico

and the District of Columbia (where the FDA has powers similar to those held by state pharmacy boards), examinations of pharmacist dispensing and compounding practices during the 1920's revealed a need for corrective measures.[11] This was prologue for the investigations by the FDA that developed during the 1940's. The 1938 Amendments to the Food, Drug, and Cosmetic Act were passed by the Congress when revelations showing more than 100 recorded deaths from the ingestion of an improperly formulated pharmaceutical product were made public. The 1938 Amendments created two basic classes of drugs, those that were intended for dispensing by pharmacists on a prescription basis, and those that could be sold to the public directly without need of a doctor's prescription.[12] Prescription class drugs were to bear the following legend on their labels, "Caution: To be used only by or on the prescription of a physician." All other drug products were to be sold as non-prescription drugs and would be labeled with directions that would permit self-administration of the drug by the patient. During the 1930's and 1940's, amphetamines and barbiturates were becoming increasingly subject to abuse.[13] These drugs were originally permitted to be sold without prescriptions. The Federal Security Agency (FSA) Administrator (the forerunner to the Secretary of Health, Education, and Welfare) subsequently classified these

drugs as being "Dangerous".[14] This was meant to indicate to pharmacists that prescriptions were required for patients to henceforth obtain these drugs. Many pharmacists continued to dispense these products either on long expired prescriptions or without benefit of any prescription what-so-ever. The FDA began to vigorously prosecute pharmacists during the 1940's for these violations, since state pharmacy boards were reluctant to do so. Many pharmacists claimed that they were unaware of the prescription requirements for these drugs, or that the situation was ambiguous by the fact that some manufacturers labeled a drug with the legend caution, while others labeled the same drug with directions for self-administration.[15] This controversy resulted in the American Pharmaceutical Association (APhA),* and the National Association of Retail Druggists (NARD),** to seek remedial legislation that would not only resolve this ambiguous situation but would remove any control over the dispensing practices of pharmacists from the

*The APhA was formed in 1852 to represent "...all fields of pharmaceutical enterprise and interest, the scientific and educational as well as the commercial, the ethical and the legal."[16] Today, it represents approximately 40,000 pharmacists.

**The NARD was formed in 1898 as a result of dissatisfaction among community drug store owners that their economic interests were not being adequately represented by the APhA.[17] Today, the NARD represents approximately 30,000 pharmacists, the majority of which own community drug stores.

FDA and place this responsibility in the hands of the state pharmacy boards.[18] Since this proposal did not meet with the FDA's approval, the pharmacy associations began to negotiate with the FDA on legislation that would be acceptable to both. The APhA was opposed to changing its basic position on state level control over dispensing and this resulted in the APhA opposing the bill that was introduced for the NARD and the FDA in 1950 by Senator Hubert H. Humphrey and Representative Aubrey Durham.[19] The bill that finally was passed by the Congress in 1951 had several important features: Pharmacists would be allowed to receive new prescriptions or prescription refill authorizations from physicians via the telephone and pharmacists could not refill prescriptions based upon their professional judgment if the prescribing physician did not specifically authorize the refilling of the prescription.[20] An additional important provision of the Durham-Humphrey Amendments was the release from all liability of the pharmacist who sold drug products falsely labeled by the manufacturer.[21] The provision of the 1951 Amendments that is most directly involved with this study is that which created a legal definition for prescription drugs and for non-prescription drugs. Prescription drugs were defined in the Act as those which "...because of toxicity or other dangers in substance or mode of use,

were unsafe unless administered by a licensed practitioner."[22] All other drugs, for which adequate directions for lay use could be written, had to be classified in the non-prescription or Over-The-Counter (OTC) drug class.[23] The prescription only drugs were to be labeled with the following legend, "Caution: Federal law prohibits dispensing without a prescription." After the passage of the Durham-Humphrey Amendments to the Food, Drug and Cosmetic Act in 1951, several important changes in the distribution of drug products by pharmacists began to become apparent. Since the new Federal law required that drugs be sold as OTC products if adequate directions for use by the public could be written, many drug products that had formerly been restricted to sales in pharmacies were made available for OTC sales. State pharmacy practice laws that had been effective in limiting the sales of all but a few specifically enumerated proprietary or patent drug products to pharmacies became difficult to substantiate by pharmacists after the Federal law was passed. Unless pharmacists were able to prove that certain OTC products presented a clear or present danger to the public, the drugs were allowed to be sold in any retail outlet.[24] Pharmacists were depicted in many of the court decisions that were rendered on this controversial issue as having nothing to do with the safe use of OTC drug products

by patients.[25] The declassification of prescription drugs to OTC status became less frequent during the 1960's as opposed to the rapid declassification of over 23 products in the 1950's.[26] In the 1970's, however, an increasingly greater number of prescription drugs are either being considered for OTC status or have been approved for marketing as OTC's by the FDA.[27]

Early state level drug control legislation began during the 1870's, with the enactment of pharmacy practice acts that governed the licensing of pharmacists and the conducting of pharmacy operations.[28] Associated with these laws were provisions that limited the sale of drugs to pharmacists for the protection of the public's welfare. The pharmacy acts actually gave pharmacists a sales monopoly over drug products that was felt to be justified on the basis of the protection afforded the public through this professional control mechanism. During this same period of time, and closely aligned with the passage of pharmacy acts, most states enacted legislation that excluded certain proprietary or patent products from sales control by pharmacists.[29] However, most states did not define the terms "proprietary" or "patent" in their laws, and it was therefore left to the state courts to decide on a case by case, product by product basis, as to what was the intent of the legislation. The courts generally applied two definitions

in attempting to clarify the ambiguousness of the exempting statutes. The "common usage" approach evolved by the courts for defining these products contains five provisions:

> 1. It must be a medicine in which a property right exists in the producer and which the public buys in reliance primarily on the producer or the proprietor, and not the retailer;
> 2. the property right may be attributed to a patent, trademark, special formula, or unique process for preparation;
> 3. distribution is in pre-packaged and fully prepared form ready for use by the consumer with adequate directions for use;
> 4. there is extensive advertising by brand name so that the public relies upon the name; and
> 5. no prescription is needed.[30]

The second method, the so-called "technical" approach, adds an additional stipulation to the "common usage" definition, "...the condition that there be secret processes of manufacture, or exclusive ownership of a secret formula."[31] This situation created numerous confrontations between pharmacy and non-pharmacy retail interests as to what actually represented a drug that was covered by the particular state's exempting statute. Some of the drug products most frequently associated with early state court cases were milk of magnesia, citrate of magnesia, and aspirin. Depending on the state jurisdiction involved, the decisions were often conflicting and inconsistent. For example, a 1927 Minnesota court decision was rendered in favor of the

pharmacy interests. The case involved the proprietor of a small candy store in Minneapolis, who sold pre-labeled packages of aspirin to customers. The State Pharmacy Board contended that this practice was in violation of the State law which stated that "...anyone not a registered pharmacist or a dealer having such a pharmacist in charge of his place of business was prohibited from retailing drugs or medicines or poisons."[32] The State's position was upheld on the basis that public health and welfare were primarily the issues at stake, not the sales monopoly aspect as was contended by the candy store operator. The trial court found that "...the pharmacist knows where to procure a pure and genuine article,"[33] inferring that the candy store owner did not possess this ability. The 1951 Durham-Humphrey Amendments, by placing the liability for properly formulating and labeling drug products on the manufacturer and not the pharmacist, effectively nullified the basis for this type of argument. However, even during this time period courts in other state jurisdictions did not consistently uphold this opinion. For instance, a 1936 Montana court ruling stated that "Whether or not a drug in its original package was classed as a proprietary medicine, a provision in a statute limiting its sale to druggists or pharmacists was unconstitutional as an invalid exercise of the police

power."[34] This ruling had the effect of reversing the conviction of a retail grocer for selling aspirin without a license. Such rulings became increasingly common after the passage of the Durham-Humphrey Amendments in 1951.

Background Information on the Drug Reclassification Concept

The professional role functions that characterized the traditional practice of pharmacy, have been shown to have undergone a diminution in scope over the past 30-40 years. This has been attributed at least in part, to the impact of an expanded pharmaceutical manufacturing industry and of restrictive drug control legislation. A concept that has direct implications for redressing the balance between professional and non-professional role functions for pharmacists is drug reclassification. Some of the more important developments in the evolution of the drug reclassification concept are depicted in the following chronological listing.

Important Developments

1951: The Durham-Humphrey Amendments to the Food, Drug, and Cosmetic Act were signed into law. They established the drug classification system presently in use by the FDA, the Legend or prescription only drug class and the OTC or non-prescription drug class.[35]

1955: The APhA's convention resolved to seek amendment of the Durham-Humphrey Act's provisions to permit

> chronically ill patients, so certified by physicians, to receive medications without undue delay or hardship and without need for new prescriptions or without requirement that pharmacists obtain specific permission from prescribers.[36]

1957: Dr. Eric W. Martin, a respected pharmacy educator, outlined a new drug classification system in an editorial published by the Journal of the APhA. His proposal consisted of the creation of three drug classes.

> Class I: Drugs sold only on a prescription due to their habit forming or highly toxic potential, and drugs that have been in use for less than 10 years. These drugs would require a prescription from a physician.
>
> Class II: Drugs that would require the signature of the purchaser such as exempt narcotics and poisons. These drugs would not require a prescription, but would be restricted to pharmacy sales only.
>
> Class III: Drugs sold in pharmacies without prescriptions and without requiring the signature of the purchaser. This class of drugs would consist of all other drug products not found in the first two drug classes.[37]

1961: The former executive director of the APhA, Dr. Robert Fischelis, testified before the Kefauver Subcommittee on Anti-Trust and Monopoly as to the changing role of the pharmacist and

the need to restructure the drug classification system to facilitate pharmacist-patient interaction. Dr. Fischelis suggested that an advisory committee to the FDA be established to determine those drugs to be restricted to sales in pharmacies. No action was taken by the Subcommittee to implement Dr. Fischelis's proposals.[38]

1963: A statement was filed before Senator Hubert H. Humphrey's Subcommittee on Reorganization and International Organizations by the APhA, that described a new class of drugs. The new drug class would be developed from the following criteria and these drugs would be available only through pharmacists.

> 1. Drugs that had been removed from Legend status for a period of ten years following the declassification.
>
> 2. All declassified Legend drugs and non-prescription drugs that had not been advertised to the lay public within the past five years.
>
> 3. Drugs that contained active ingredients in concentrations of 50% or more of the minimum strength classified as a prescription drug, or for which the usual adult dose was 50% or more of the recommended prescription drug dose.[39]

1964: The APhA testified before a House Subcommittee on Intergovernmental Relations that an improved four category system for drug classification should be created.

> Class I: To be dispensed on prescription only and to be renewed at the prescriber's discretion only.
>
> Class II: To be initially dispensed on prescription order only but renewable at pharmacist's discretion.
>
> Class III: To be dispensed personally by the pharmacist at the request of the patient.
>
> Class IV: To be directly available to the public without professional direction or control.[40]

The NARD developed its position on drug reclassi- that contained the following provision:

> To initiate and support such corrective efforts in the interest of public health and safety, including if necessary, an amendment of the Federal Food, Drug and Cosmetic Act, so that drugs capable of producing harm or concealing disease be made available to the public with adequate professional control through licensed pharmacies.[41]

The lack of federal legislative or regulative support for these proposals induced the APhA[42] and the NARD[43] to suggest that state level efforts to gain the restriction of certain OTC drugs to pharmacists be instituted.

1971: Senator Gaylord Nelson's Subcommittee on Monopoly in their investigation on the "Effect of promotion and advertising of Over-The-Counter drugs," received testimony from an APhA representative, that would have supported development of a new drug class. This drug class would contain drugs

not allowed to be advertised to the general public and would be dispensed personally by a pharmacist only if the pharmacist determined that the patient had an actual need for the drug.[44]

1973: In conjunction with the FDA's on-going evaluation of the effectiveness and safety of all OTC drug products, the APhA filed suggestions that specific drugs be made available only from pharmacists, who maintain patient records concerning the dispensing of these products and that public promotion of these drugs be prohibited.[45]

This account of the significant developments surrounding drug reclassification has served to clarify the concept's intent and to place it in the proper perspective. It has been formulated and redefined several times over the past 20 years by the APhA, its primary protagonist, but this has not resulted in producing the legislative and/or regulative support needed to permit the concept's translation into reality. It is this situation that forms the basis and sets the stage for the following study.

Organization of Study

The study is composed of three separate but interdependent phases: the determination of the positions and activities of involved or affected organizations on

drug reclassification; an assessment of state level OTC drug restriction activity; and the ascertaining of pharmacist support for drug reclassification.

The objective of the initial phase is to reveal the major points of controversy surrounding drug reclassification as viewed from the perspective of concerned parties. The objective of the second phase of the study is to provide information on the success of pharmacists working at the state level in obtaining recognition for the need to restrict sales of certain OTC's to pharmacies, while the objective of the final phase of the study is to determine the attitudes and perceptions of practitioners on the creation of a new intermediate class of drugs.

Assumptions

Four basic assumptions guide the development of the study:

1. By obtaining and examining the statements of individuals and the positions of organizations, associations, or agencies involved in the drug reclassification controversies of the past, and of those most likely to be involved in future reclassification controversies, the primary problems associated with the concept should become apparent.

2. Knowledge about these problems will provide a basis for understanding the reasons behind the non-

acceptance of previous drug reclassification proposals, and thus permit more effective planning for future drug reclassification efforts.

3. The results of the study should be useful in revealing the extent and character of those forces acting to prevent legislative and/or regulative recognition of a revitalized professional role for pharmacists.

4. The implications drawn from the study's findings and the research techniques employed for examining the concept of drug reclassification should be applicable to understanding and analyzing problems that other professional groups must encounter when they attempt to gain relief from inflexible or excessively restrictive legislation governing their members' professional activities. This expectation of a more generalized applicability of the study to areas outside of the pharmacy profession should greatly enhance the value and the potential impact of the research endeavor.

Research Questions

1. What are or have been the positions of concerned or potentially concerned organizations, associations, or government agencies on the drug reclassification concept?

2. What activities have been undertaken and with what results in respect to restricting certain OTC drug sales to pharmacists at the state level?

3. Do pharmacists favor the basic concept of creating a restricted OTC drug class?

4. Do pharmacists support the direct, mandatory involvement of the pharmacist with the patient regarding the dispensing of OTC restricted drugs?

5. Do pharmacists feel that their positions on reclassification are similar to those of other pharmacists on the issue?

6. Do pharmacists feel the national pharmacy associations would support their proposal?

7. Do pharmacists view reclassification as being motivated primarily by economics or primarily by professionally oriented desires?

8. How important is drug reclassification to pharmacists when compared to other issues that are currently affecting the profession?

9. Is membership in the professional associations independent from the positions assumed by pharmacists on drug reclassification?

FOOTNOTES

[1]Philip R. Lee, M.D., "The Family Pharmacist," Journal of the American Pharmaceutical Association (JAPhA), NS 16:7, pp. 396-397.

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[3]Ibid.

[4]Lesley Oelsner, "Court Prohibits Ban on Revealing Price in Drug Advertising," Minneapolis Tribune, May 25, 1976, p. 4A.

[5]A recent survey reported that only 0.4% of over 15,000 examined prescriptions required compounding. See: APhA Pharmacy Weekly, 15:22, May 29, 1976, p. 3.

[6]Edward C. Elliot, The Pharmaceutical Survey (American Council on Education, 1948), p. 34.

[7]APhA Pharmacy Weekly, 15:22, May 29, 1976, p. 3.

[8]C. Rufus Rorem and Robert P. Fischelis, The Costs of Medicine, (Chicago, 1932), p. 18.

[9]Joel H. Goldberg, ed., Drug Topics' 1975 Marketing Guide, 1975, p. 4.

[10]K. H. Larsen, American Law Review, 2d, New York, (1964), p. 1068.

[11]James Harvey Young, "Drugs and the 1906 Law," Safeguarding the Public, ed. John B. Blake (Baltimore, 1970), p. 148.

[12]Ibid., p. 153.

[13]Charles W. Crawford, "The Federal Drug Law and the Druggist," Journal of the NARD (JNARD), 72:21, November 6, 1950, pp. 1740, 1742.

[14]Herman S. Waller, "Drugs Restricted by Federal Statute," JNARD, 71:9, May 2, 1949, pp. 710-711.

[15]Roy Warnack, "Federal Drug Legislation," JNARD, 71:7, April 4, 1949, pp. 536-538.

[16]Glenn Sonnedecker, Kremers and Urdang's History of Pharmacy, (Philadelphia, 1963), p. 181.

[17]Ibid., p. 188.

[18]H. R. 4203, 80th Congress, as reprinted in JNARD, 71:11, 1949, p. 729.

[19]H. R. 8904, 81st Congress, as reprinted in JNARD, 72:13, July 3, 1950, p. 1046.

[20]Hearings before the Subcommittee on Health, S. 1186 and H. R. 3298, 82nd Congress, 1st Session, p. 3.

[21]Ibid.

[22]Federal Food, Drug, and Cosmetic Act, 21 USC Sec. 353.

[23]Ibid.

[24]Larsen, p. 1083.

[25]Ibid.

[26]"Three Drugs Switched to OTC," JAPhA, 20:1, January, 1959, p. 35.

[27]"Panel Advises FDA to Move Some Rx Cough-and-Cold Ingredients to OTC Status," PMA Newsletter, February 16, 1976, p. 3.

[28]James F. Hoge, "Legislative History of Home Remedies," Home Medication and the Public Welfare, Annals of the New York Academy of Sciences, Vol. 120, Art., 2, ed. Harold E. Whipple (New York, 1965), p. 833.

[29]Ibid.

[30]Larsen, p. 1078.

[31]Ibid.

[32]"State v. Mike Zotalis," Minnesota Reports, Vol. 172, (July 8, 1927), p. 133.

[33]Ibid.

[34]Larsen, p. 1068.

[35]Federal Food, Drug, and Cosmetic Act, 21 USC Sec. 353 (b).

[36]"APhA Convention Resolution," JAPhA, 16:6, June, 1955, p. 365.

[37]Eric W. Martin, "Editorials," JAPhA, 18:6, June, 1957, pp. 356-357.

[38]Robert P. Fischelis, Testimony on the Drug Industry Antitrust Act, S. 1552, 87th Congress, 1st Session, December 12, 1962, p. 2629.

[39]"APhA Urges 3rd Class of Drugs," APhA Newsletter, No. 19, September 28, 1963, pp. 1-4.

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[42]"Report by the Committee on Social and Economic Relations," JAPhA, NS7:6, June, 1967, p. 308.

[43]Sidney Waller, "Much Additional Information Needed Before Action on Reclassification of Drugs," JNARD, 86:10, May 18, 1964, p. 36.

[44]Dr. Richard Penna, Testimony before the Subcommittee on Monopoly, 92nd Congress, 1st Session, *Advertising of Proprietary Medicines: Part 1*, May 25, 1971, p. 113.

[45]Carl Roberts, "Comments of the APhA on Proposal Establishing a Monograph for OTC Antacid Products," stated in a letter addressed to the Hearing Clerk, Department of HEW, June 1, 1973.

CHAPTER II

METHODOLOGY

Chapter II is divided into three major sections. The first section describes the methods employed in obtaining information on organizational perspectives towards the drug reclassification concept; the second section deals with the methods utilized in assessing state level OTC drug restriction activity; while the third section discusses the techniques applied to measure pharmacist attitudes and opinions on the drug reclassification concept. The first two sections correspond to addressing Research Questions 1 and 2 respectively, while Research Questions 3-9 are studied by the methods detailed in Section III.

Section I: Methods Utilized to Address Research Question 1—What are or have been the positions of concerned or potentially concerned organizations, associations, or government agencies on the drug reclassification concept?

Background

The organizations included in the study met the following criteria: They were active in past reclassification efforts or were thought to be potential active

participants in future reclassification efforts, and they reflected a national scope of interest. The list of organizations that met these criteria was developed from information revealed through the background literature review and from discussions held with the pharmacy administration faculty and graduate students at the University of Minnesota. The organizations or groups so identified were classified into seven categories according to their common areas of endeavor. The following material provides a brief description of the organizations composing these categories.

Professional Pharmacy Associations

Three associations represent the pharmacist practitioner in national level legislative or regulative controversies, the American Pharmaceutical Association (APhA), the National Association of Retail Druggists (NARD), and the American Society of Hospital Pharmacists (ASHP). The APhA represents approximately 40,000 pharmacists employed in all aspects of pharmacy practice, while the NARD consists of approximately 30,000 pharmacists who are primarily owners of retail drug stores. The ASHP membership stands at approximately 10,000 pharmacists, the majority being employed in the hospital or other institutionally based setting.

Non-Pharmacy Professional Associations

Three non-pharmacy professional associations were

included in the study, the American Medical Association (AMA), the American Optometric Association (AOA), and the National Association of Physician Assistants (NAPA). The AMA represents approximately half of the practicing physicians in the United States and as such exerts a powerful influence over all health related matters. The remaining two associations, the AOA and the NAPA, represent health care practitioners thought to be interested in changing the rigid drug classification system presently used by the Federal government.

Federal Government Agencies and Regulative Bodies

The positions of four federal level governmental bodies were felt to be of particular interest to this study, the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), the Drug Enforcement Agency (DEA), and the anti-trust division of the Justice Department. The FDA is responsible for implementing the provisions of the Federal Food, Drug, and Cosmetic Laws, while the FTC oversees and regulates the advertising and promotion of drug products to the public. The DEA is charged with the responsibility of assuring that drugs are not diverted from legitimate uses into illegal channels of distribution, while the Justice Department's anti-trust division has demonstrated a concern for the impact of drug reclassification on the competitive nature of the free enterprise system.

Drug-Industry Related Associations

This cateogry of organizations was composed of four groups, the Pharmaceutical Manufacturers Association (PMA), the Proprietary Association (PA), the National Association of Chain Drug Stores (NACDS), and the National Pharmaceutical Council (NPC). The PMA represents prescription drug manufacturing concerns, while the PA is the spokesmen for the manufacturers of non-prescription drugs. Some overlap of membership exists between the PMA and the PA since most large drug manufacturers produce both prescription and non-prescription drugs. The NACDS represents those retail drug stores having multiple outlets controlled by one corporate entity. Chain drug stores are a rapidly expanding component of the retail drug distribution system. The NPC gains its support mainly from the manufacturers of prescription drug products and serves as an additional source of information about the drug manufacturing industry.

Consumer Groups

Three consumer groups were selected that reflected a national scope of interest. They were the Health Research Group (HRG), associated with Ralph Nader's Public Citizen Organization, the Consumer Federation of America (CFA), and the American Association of Retired Persons (AARP). These organizations have

expressed positions in the past on matters of concern to both their constituents and the pharmacy profession.

Federal Level Legislators

Drug reclassification legislation would require hearings before several Congressional subcommittees. Four subcommittees were identified as being of potential importance in future reclassification debates, Senator Kennedy's Subcommittee on Health, Senator Moss's Subcommittee on the Consumer, Senator Nelson's Select Committee on Small Business, and Representative Rogers' Subcommittee on Health and the Environment. Forty-one Congressmen were identified as serving on one or more of these subcommittees and they were contacted to determine their positions on drug reclassification.

Other Pharmacy Oriented Groups

Three additional pharmacy related groups were included in the study: The Study Commission on Pharmacy, pharmacist members of the FDA's OTC Drug Advisory Panels, and the American Association of Colleges of Pharmacy (AACP). The Study Commission on Pharmacy, chaired by Dr. John S. Millis, recently published its findings on the future course of pharmacy education in the United States,[1] while the pharmacist members of the FDA's OTC Drug Advisory Panels are currently involved in activities closely associated with the proper classification of drug products in the United States.

The current officers of the AACP were contacted to obtain pharmacy educators' views on the drug reclassification concept.

Section I: Research Methods

Several different data gathering techniques were employed to obtain information on these organizations' perspectives towards drug reclassification, but all of these methods focused on determining three major points: their leaderships' awareness of the concept, their organizations' positions (if any) on the concept, and the reasons for their organizations' assuming these postures on the concept. The following material describes the various research methodologies employed to obtain the necessary organizational perspectives.

Literature Review

The literature review conducted to develop background information on drug reclassification was extremely helpful in characterizing the perspectives of those organizations actively involved in past drug reclassification efforts. The professional journals of the APhA and the NARD provided a running account of these pharmacy associations' drug reclassification activities during the past 25 years. Similarly, the FDA's utilization of the Federal Register to publish its findings and regulations in matters such as drug reclassification, was particularly useful in

developing the Federal government's position on the concept. Additional helpful sources of information were reprints of speeches and addresses presented before various conventions and organizational gatherings by officials of the groups being studied.

Written Correspondence

Letter writing was employed to obtain some necessary information, especially if the organization's position on reclassification could not be found in the literature. The format for all of these letters followed a similar pattern. Letterhead stationery from the University of Minnesota, College of Pharmacy, was utilized in all cases. The introductions to these letters generally served to identify the researcher as a Doctoral Candidate in Pharmacy Administration at the University of Minnesota, and included a statement describing the reasons for the correspondence. The introduction emphasized the importance to the researcher of obtaining the requested information. This material was followed by a list of several specific questions, each designed to provide basic information on the organization's drug reclassification perspectives. The letters generally concluded with a statement that responses would be held in the strictest confidence. Assurance was given that no individual respondent would be identified with his

particular answers. The organizations that were sent letters are listed in Table 1. The Appendix contains copies of the letters sent to the various organizations, see Figures I-IX.

Table 1

Organizations Contacted by

Written Correspondence

1.	American Association of Colleges of Pharmacy
2.	American Association of Retired Persons
3.	American Medical Association
4.	Consumer Federation of America
5.	Justice Department, Anti-Trust Division
6.	National Association of Physician Assistants
7.	National Association of Retail Druggists
8.	Pharmacist members, FDA OTC Drug Advisory Panels
9.	Study Commission on Pharmacy

Telephone Discussions

The telephone was useful as a follow-up mechanism in cases where parties contacted by mail had not responded. In addition, such calls provided information of a more personal nature than might normally be communicated in a written document. Table 2, on the following page, lists those organizations that provided information useful to the study through personally conducted telephone interviews.

Table 2

Organizations Providing Information

Via Telephone Discussions

1.	American Society of Hospital Pharmacists
2.	Drug Enforcement Agency
3.	American Optometric Association
4.	Health Research Group

In-Person Interviews

Representatives of several organizations included in the study were questioned during personal conversations with the researcher. Since many of the organizations maintained offices in the District of Columbia, a data gathering excursion with the purpose of meeting with these various representatives was conducted during the month of August, 1975. Appointments with the organizations' representatives were scheduled well in advance of the visit, and each individual was fully informed of the purpose for the meeting. The questions asked during these interview procedures centered primarily on determining the extent of the awareness by the individual of the concept, the position of the organization and/or the individual on the concept, and the reasons behind this position. Organizations contacted through this procedure are listed in Table 3 on the following page. Written notes were taken during

Table 3

Organizations Contacted Through

Personal Interview Methods

1.	American Pharmaceutical Association
2.	National Association of Retail Druggists
3.	Pharmaceutical Manufacturers Association
4.	Proprietary Association
5.	National Association of Chain Drug Stores
6.	National Pharmaceutical Council

the interviews, and immediately following each discussion. They were then further annotated so as to obtain maximum benefit from the interview. Tape recordings of these discussions were considered, but it was decided that the presence of the recorder might alter the spontaneity and validity of the remarks made by the person being interviewed.

Questionnaires

Two mail-out surveys were conducted in this initial section of the study. One was directed to the attention of selected member companies of the PMA, while the other was mailed to specific Congressmen serving on at least one of the four Congressional subcommittees mentioned previously as being important to the development of a drug reclassification proposal.

Survey of Individual PMA Member Companies

The survey of individual PMA member companies was

conducted because a given manufacturing concern might differ with the PMA position on drug reclassification, depending upon the company's policies governing product development and marketing. A booklet published by the PMA in September, 1973,[2] listed 111 member companies. From this list, 13 corporations along with the names and addresses of their presidents were selected to be contacted. The companies chosen for participation in the study were primarily the producers of broad product lines that covered both the prescription and OTC drug markets. They were companies that might be expected to be interested in the reclassification concept as regards its impact on the marketing of their products. Table 4 lists the manufacturers with which correspondence was initiated.

Table 4

PMA Member Companies Contacted

for Perspectives on Drug Reclassification

1.	Abbott Laboratories
2.	Ayerst Laboratories
3.	Lederle Laboratories
4.	Lilly and Co., Eli
5.	Merck, Sharp and Dohme
6.	Parke, Davis and Co.
7.	Pfizer Laboratories
8.	Robins Co., A. H.
9.	Schering Corporation
10.	Smith, Kline and French Laboratories
11.	Squibb and Sons, E. R.
12.	Upjohn Co., The
13.	Wyeth Laboratories

A letter was drafted according to the basic format described previously in the methodology for written correspondence. The letters were addressed to the presidents of the drug manufacturing concerns. Each was asked to refer the inquiry to the attention of an individual within the company who could respond to matters concerning the organization's policy formulation and long range planning operations. An attached document summarized the APhA's 1964 reclassification proposal. This proposal differed from more recent elaborations of the concept by suggesting that a fourth class of drugs be established. The drugs of the "fourth class" would be available from a pharmacist directly, once having been made initially available to the patient on a prescription basis from a licensed prescriber. The 1964 reclassification scheme was utilized in this section of the study because it emphasized the pharmacist's potential role as an intermediary between drugs placed in the most restricted prescription only status, and drugs placed in the completely non-restricted status of OTC's. The letters included five open-ended questions focusing on the organization's marketing policies as they might relate to the drug reclassification proposal. Figures X and XI of the Appendix are reproductions of the material sent to the PMA member companies. Usable responses were

obtained from eight of the thirteen (62%) companies contacted, with one company, Merck, Sharp, and Dohme, deferring from answering the questions because of its lack of an OTC product line.

Survey of Federal Level Legislators

A second survey was conducted in this section of the study. It involved contacting federal level legislators to obtain their impressions and perspectives on drug reclassification.

Since drug reclassification proposals have existed for some 25 years, and the concept has been presented before several Congressional subcommittees during the past quarter century with little apparent effect, a survey was conducted to clarify present day attitudes of key legislators on the subject. Forty-one Congressmen were selected from the membership roles of four committees that could play important roles in future reclassification proposals. These were Senator Kennedy's Subcommittee on Health, Senator Moss's Subcommittee on the Consumer, Senator Rogers' Subcommittee on Health and the Environment, and Senator Nelson's Select Committee on Small Business. The individual senators and representatives surveyed by this study are listed in Tables 5-8 according to their committee assignment and their party affiliation.

Table 5

Senators Contacted by Study Serving on the Senate Subcommittee on Consumers, Committee on Commerce—94th Congress

1. Frank E. Moss, Utah, Chairman, Democrat
2. Philip A. Hart, Michigan, Vice Chairman, Democrat
3. John O. Pastore, Rhode Island, Democrat
4. Vance Hartke, Indiana, Democrat
5. Daniel K. Inouye, Hawaii, Democrat
6. Howard W. Cannon, Nevada, Democrat
7. John V. Tunney, California, Democrat
8. Adlai E. Stevenson, III, Illinois, Democrat
9. James L. Buckley, New York, Republican
10. J. Glenn Beall, Jr., Maryland, Republican
11. Lowell P. Weicker, Jr., Connecticut, Republican

Table 6

Senators Contacted by Study Serving on the Senate Subcommittee on Monopoly, Select Committee on Small Business—94th Congress

1. Gaylord Nelson, Wisconsin, Chairman, Democrat
2. Thomas J. McIntyre, New Hampshire, Democrat
3. James Abourezk, South Dakota, Democrat
4. Floyd K. Haskell, Colorado, Democrat
5. Dewey F. Bartlett, Oklahoma, Republican
6. Bob Packwood, Oregon, Republican

Table 7

Senators Contacted by Study Serving on the Senate Subcommittee on Health of the Committee on Labor and Public Welfare—94th Congress

1. Edward M. Kennedy, Massachusetts, Chairman, Democrat
2. Harrison A. Williams, Jr., New Jersey, Democrat
3. Thomas F. Eagleton, Missouri, Democrat
4. Alan Cranston, California, Democrat
5. Claiborne Pell, Rhode Island, Democrat
6. Walter F. Mondale, Minnesota, Democrat
7. William D. Hathaway, Maine, Democrat

8. Richard S. Schweiker, Pennsylvania, Republican
9. Jacob K. Javits, New York, Republican
10. Robert Taft, Jr., Ohio, Republican
11. Robert T. Stafford, Vermont, Republican

Table 8

Representatives Contacted by Study Serving on the House Subcommittee on Health and the Environment, Committee on Interstate and Foreign Commerce—94th Congress

1. Paul G. Rogers, Florida, Chairman, Democrat
2. David E. Satterfield III, Virginia, Democrat
3. Lunsford R. Preyer, North Carolina, Democrat
4. James W. Symington, Missouri, Democrat
5. James H. Scheuer, New York, Democrat
6. Henry A. Waxman, California, Democrat
7. W. G. 'Bill' Hefner, North Carolina, Democrat
8. James J. Florio, New Jersey, Democrat
9. Charles J. Carney, Ohio, Democrat

10. Tim L. Carter, Kentucky, Republican
11. James T. Broyhill, North Carolina, Republican
12. Henry J. Heinz III, Pennsylvania, Republican

A questionnaire was developed with the assistance of the faculty and graduate students in Pharmacy Administration at the University of Minnesota. Research assistants assigned to the University of Minnesota's Measurement Services Center were also consulted. The questionnaire's cover letter was prepared according to the standard format previously described in the written correspondence methodology, and the signature blocks of both the Dean, College of Pharmacy, University of Minnesota, and the researcher, were included. The questionnaire was printed on a distinctive green colored paper and each was coded to allow for follow-up procedures if necessary.

The questions that were included in the instrument were designed to obtain the legislators' impressions about the drug reclassification concept in general, their awareness of the concept, and their interpretation of the reasons behind the formulation of the proposal by the pharmacy profession. An additional question was included that asked the Congressmen to rate the three national pharmacy associations on their effectiveness in communicating to members of Congress the pharmacy profession's position on matters of [illegible] copy of [illegible] cover letter and the questionnaire are found in [illegible] Appendix, see Figures XII and XIII.

Of the 41 questionnaires sent out, only 1 was returned completed. Six other Congressmen responded that they were interested in the concept but that they were not familiar enough with it to answer the questionnaire. In an attempt to obtain a more representative response from the Congressmen, letters were sent to the administrative assistants of the chairmen of the four committees. Two of the assistants responded to this correspondence, but only to indicate that either the committee members did not wish to participate in the survey, or that time did not permit the busy Congressmen to complete the survey.

Limitations to Research Methods, Section I

There are several inherent limitations to the research methods applied in determining organizational perspectives on drug reclassification. The posing of sensitive questions to individuals does not by itself guarantee that a response will be obtained, nor does it assure one of gaining a true picture of the individual's beliefs. The literature review was invaluable in clarifying positions of organizations that have been actively involved in past reclassification activities, but little information is available to either support or refute the stated perspectives of individuals representing organizations that have not played an active role in previous reclassification controversies.

An additional problem with this aspect of the research is the lack of any compelling reason for the individuals questioned to respond. Since the researcher does not represent any organized or powerful group, the individuals and organizations contacted could very easily chose to ignore the correspondence with little fear of the consequences.

Section II: Methods Utilized to Address Research Question 2—What activities have been undertaken and with what results in respect to restricting certain OTC drug sales to pharmacists at the state level?

Background

Early state level court decisions rendered on laws that were intended to either restrict or free OTC drugs from pharmacist control have been discussed. Decisions were reached that proved to be as variable as the number of jurisdictions involved. However, after the Durham-Humphrey Amendments were enacted in 1951, non-pharmacy interests were able to argue their cases more convincingly. Most recent state court decisions have reflected the position that since the Federal government allowed these products to be sold as OTC's to the general public, then unless a clear and present danger to the public could

be proven, the drugs should not be restricted to pharmacist sales.[3] Opponents to pharmacist only control over any OTC product argue that the point of purchase of a drug has little to do with how the patient ultimately chooses to use it, thereby making little difference (it is contended) if the drug is purchased in a pharmacy or a grocery store.[4]

Section II: Research Methods

To provide information on the current status of pharmacy restricted OTC drugs in the United States, and on activities related to this aspect of drug reclassification, a questionnaire was developed and mailed to the attention of each State Board of Pharmacy Executive Secretary, and to each State Pharmacy Association Executive Secretary, including the District of Columbia. A total of 99 inquiries was mailed out to the 51 jurisdictions, since in 3 states, Idaho, North Dakota, and South Dakota, both secretary positions are held by one individual. The survey was intended to provide an accurate assessment of the current level of activity to restrict OTC drugs to pharmacists or pharmacy sales. The names and addresses of the current secretaries were obtained through the assistance of the Minnesota State Board of Pharmacy, Executive Secretary's Office. The cover letter that was drafted to explain the purpose of the

survey referred only to the development of some "background information" for the College of Pharmacy. Mention was not made of the fact that the data was to be included in a thesis on drug reclassification. This disclosure, it was felt, might limit the response rate. The correspondence reflected the signatures of both the Dean of the College of Pharmacy and the researcher. The cover letter and the questionnaire are reproduced in the Appendix, Figures XIV and XV. The survey forms were numerically coded for follow-up purposes and yellow colored paper was utilized to enhance visibility. A follow-up letter was prepared to obtain the information from the more recalcitrant secretaries. This follow-up letter is reproduced in the Appendix, Figure XVI.

Rationale Behind Questions

The questionnaire asked four basic questions:

1. What is the present status of exempt narcotics* in your State (prescription or OTC)?
2. Does your State restrict for sale to pharmacies other non-prescription products and if so, what are they?
3. Have attempts been made in the past 5 years to restrict any OTC drugs to pharmacy sales? (Respondents were

*Exempt narcotics are those products containing small amounts of narcotics that are permitted to be sold by the Federal government without a prescription. They have been included in Schedule V (the least restricted category) for habit forming or dangerous drugs.

asked to list the source of opposition to these proposals.)

4. What has been the basis used for initiating these reclassification attempts?

The questions were posed to examine several points of interest. The exempt narcotics have been referred to by some individuals as a "third class" of drugs. Indeed, they are restricted to sales in pharmacies by all states and in this respect, they would qualify as an intermediate class of drugs. However, it is the abuse potential for these products that limits their channels of distribution, not the pharmacist's role in aiding a patient to select a proper medication for his or her needs. Even with this distinction in mind, the fact that pharmacists are willing to exercise some degree of responsibility by supervising the sale of these controlled products, is important to the reclassification concept. Several states have placed exempt narcotic preparations in the prescription only class because of demonstrated cases of abuse. The extent of this reclassification was not available and the first question was meant to provide this information. The second question was designed to obtain information on the extent of restriction that has occurred for non-narcotic preparations at the state level, while question three was included to determine the present level of activity surrounding OTC restrictive

legislation at the state level in the past 5 years. The last question was included to obtain information on the arguments used by proponents of OTC restricted drugs to support their contentions.

Included in the mail-out was an additional questionnaire that asked the Secretaries about their personal attitudes and impressions on the drug reclassification concept. The development of this lengthy and detailed instrument is discussed in the following section of this chapter.

Response to Questionnaire

Responses were obtained from 49 of the 51 State Board Secretaries and from 32 of the 48 State Association Secretaries. (The states of Idaho, North Dakota and South Dakota are included in these figures as State Board Secretary respondents.) The resulting 81 responses (82%) provided information from 50 of the 51 jurisdictions surveyed, with Oklahoma being the only state not responding.

Section III: Methods Utilized to Address Research Questions 3-9.

Background

Research Questions 3-9 are listed on the following page in Table 9, for ease of reference. They were designed to determine how the practicing pharmacist of

today views the concept of drug reclassification.

Table 9

Research Questions Concerning Practitioners' Perspectives on Drug Reclassification

1.	Research Question 3: Do pharmacists favor the basic concept of creating a restricted OTC drug class?
2.	Research Question 4: Do pharmacists support the direct, mandatory involvement of the pharmacist with the patient regarding the dispensing of OTC restricted drugs?
3.	Research Question 5: Do pharmacists feel that their positions on reclassification are similar to those of other pharmacists on the issue?
4.	Research Question 6: Do pharmacists feel the national pharmacy associations would support their proposal?
5.	Research Question 7: Do pharmacists view reclassification as being motivated primarily by economics or primarily by professionally oriented desires?
6.	Research Question 8: How important is drug reclassification to pharmacists when compared to other issues that are currently affecting the profession?
7.	Research Question 9: Is membership in the professional associations independent from the positions assumed by pharmacists on drug reclassification?

A fundamental aspect of any reclassification effort must be pharmacist practitioner support. Since little information was available on the opinions of these individuals on the concept, the remainder of the research project was devoted to ascertaining these perspectives.

Section III Research Methods

Questionnaire Development

A mail-out questionnaire was selected as the most practical method of obtaining the information required to adequately address the seven remaining research questions. In addition to practitioner pharmacists, the questionnaire could be included with the previously discussed survey of State Board of Pharmacy and State Pharmacy Associations Secretaries. By obtaining the personal views of the Secretaries on reclassification, an interesting comparison with practitioner views on the subject could be accomplished.

The development of the questionnaire was begun in October of 1975. With the assistance of the pharmacy administration faculty and graduate students, several versions of the questionnaire were developed and tested for ease of completion and clarity of wording before a final version was perfected. See the Appendix, Figure XVII, for a sample of the questionnaire. The instrument consisted of seven sets of questions. Each set of questions was designed to obtain information on different but related aspects of the drug reclassification concept.

The first set of six questions was designed to gather information on the socio-economic and demographic characteristics of the respondents. The

information provided by the answers to these questions was used to determine the degree of representativeness of the sample as compared to the general population of practitioner pharmacists. In addition, the responses provided the information on professional association membership needed to study the relationship between association membership and views on drug reclassification. The second set of two questions, questions 7 and 8, gathered information on the respondent's awareness of the concept and whether or not he/she supported the basic proposal. Questions 9-13 of the instrument were included to permit the respondent to indicate what additional provisions to the basic drug reclassification proposal would be desirable. These queries composed the third set of questions. The fourth set of questions, numbers 14, 15, and 16, inquired as to the respondent's perception of other pharmacists' views on reclassification and predicted positions of the professional pharmacy associations on the proposals. The material provided by the answers to these questions was important in establishing the degree of consensus that exists within the pharmacy community on drug reclassification. Questions 17-28 of the instrument represented the fifth set of questions. They were designed to obtain information

on the feelings of the respondents towards related aspects of the drug reclassification concept, while the sixth set of questions, consisting of questions 29-36, obtained the respondents' feelings regarding the stances pharmacy associations should assume towards other issues of importance to the pharmacy profession. The relative importance of drug reclassification in comparison to the other important issues was examined by the seventh and final set that consisted of eight questions, numbers 37-44. The perceived importance by pharmacists of drug reclassification to the pharmacy profession was thus obtained in both individual and comparative terms.

The 44 questions were printed front to back on one 8½ x 14 inch page to enhance acceptance by sampled pharmacists. A high quality, buff colored bond paper was utilized to provide a professional appearance to the finished document.

Practitioner Sample Selection Procedure

A simple random sample of practitioner pharmacists was selected as the most appropriate method to obtain insight into the opinions of pharmacists throughout the United States on drug reclassification. The National Association of Boards of Pharmacy (NABP) in Chicago, maintains a computerized listing of the names and addresses for all licensed pharmacists in

the United States. The number of pharmacists appearing in the NABP's file was 126,813. By supplying the NABP with a list of 500 randomly selected numbers from the range of 1-126,813, the NABP was able to select the names and addresses of those pharmacists whose file numbers corresponded with these randomly selected numbers.

The sample size of 500 practitioners represented a compromise between a sample that was large enough to measure significant association membership differences in response, while being small enough to manage considering funding and temporal constraints. A formula useful for estimating the necessary sample size required for a study such as this is represented in Figure 1 on the following page.

It was generally known that the APhA's membership consisted of approximately 40,000 pharmacists, while the NARD membership reflected approximately 30,000 pharmacists. The ASHP represented approximately 10,000 pharmacists, and from these figures it was estimated that approximately 50,000 of the 130,000 pharmacists in the United States, would not be a member of any national pharmacy association. A hypothetical response rate of 50% was used to estimate the number of association members and non-association members that would respond to the survey. These

Figure 1

Sample Size

Estimation Procedure*

$$n = \frac{(P)\ (Q)}{S^2} = \frac{(.5)\ (.5)}{(.025)^2} = 400$$

n = Sample size
P = The population parameter for the binomial, eg.) the proportion of the population favoring reclassification
Q = 1-P, eg.) the proportion of the population not favoring reclassification
S = The standard error allowed for the sample estimates of "P" and "Q"

calculated numbers were sufficiently large to allow for analyzing the data according to the procedures described in the analysis part of this section of Chapter II.

Mail-out Procedure

Several methods were utilized to maximize the response rate to the mail-out questionnaire. Stamped, self-addressed envelopes, reflecting a professionally printed return address, as opposed to being stamped on the envelope with a rubber stamp, were used to

*For a population of 126,000, the sampling fraction of 500/126,000 would not appreciably reduce the calculated sample size. The sample size required reaches a maximum value when "P" and "Q" have values of 0.5 for a given standard error. The sample calculation demonstrates that with an acceptable standard error of + or - 2.5%, a sample size of 400 would result. This procedure is discussed in: Earl R. Babbie, Survey Research Methods (Belmont: Wadsworth Publishing Co., 1973), p. 86.

impart a professional appearance to the questionnaire. The address of each of the sampled pharmacists was typed directly on the face of the envelopes to further enhance the personalized nature of the communication. Each of the questionnaires was numerically coded for follow-up procedures, if required.

Cover letters for the questionnaire sent to practitioners reflected the salutation, "Dear Mr. (or Ms.) _____:". A sample of the cover letter that accompanied the questionnaire appears in the Appendix, Figure XVIII, and a copy of the follow-up letter for the practitioner survey is provided as Figure XIX of the Appendix. Each of these cover letters contained the signature block of the Dean, College of Pharmacy, as well as the researcher's to emphasize the importance of the survey.

The first set of questionnaires was included in the mail-out to State Board of Pharmacy and State Pharmacy Association Executive Secretaries on January 10, 1976. This was followed by a second mail-out on February 2, 1976. The cover letters for these two mailings are reproduced in the Appendix as Figures XIV and XVI, respectively. This aspect of this study satisfied several requirements. It served as an extended "pretest" for the practitioners' survey, and it demonstrated a high degree of interest from two

groups whose members have been intimately involved in past discussions surrounding the concept. The questionnaire generated a 90% response rate (46/51) with the State Board Secretaries, and a 65% response rate (31/48) from the State Association Secretaries, with an overall response rate of 81%.

The satisfactory results from this initial segment of the study prompted the first mailing of the questionnaire survey to the practitioner sample on March 29, 1976. One follow-up mailing was conducted on April 19, 1976. The last date for inclusion of responses into the analysis of results was May 31, 1976. The effective response rate for the practitioner sample was 59% (230/388). Of the 500 questionnaires mailed out, 230 were returned and able to be analyzed for the study. The original mailing produced 150 usable questionnaires, while the follow-up mailing produced 80 usable questionnaires. The 112 questionnaires that were unable to be included in the study represented 10 that were returned from pharmacists no longer practicing pharmacy but involved in some other form of employment; 15 that were returned uncompleted due to retirement, death, or refusal to participate; and 87 returned unopened due to being undeliverable as addressed. According to the practice recommended by Babbie[5] for computing response rates, these 112

questionnaires were subtracted from the original 500 and the net response rate of 59% was computed. Babbie considers this to fall in the "good" response rate category for this type of research. The large number of letters that were returned unopened, indicates the slow process of updating the NABP's computer files from state pharmacy boards' input.

Methods Employed to Analyze Questionnaire Responses

The data obtained from the completed questionnaires were keypunched onto computer cards for ease of tabulation. A computer program utilizing the Statistical Package for the Social Sciences (SPSS) system[6] was prepared with the assistance of Mr. Timothy Church, of the Pharmacy Administration Department. The resulting program permitted automating the tallying of responses for each question of the instrument, as well as the calculating of descriptive statistics for each question's responses, eg.) means, modes, medians. This summary information permitted the answering of all but the final research question, and provided comparative statistics for the State Board of Pharmacy and State Pharmacy Association Secretaries' responses.

Research Question 9, the final research question, "Is membership in the professional associations independent from the positions assumed by pharmacists on drug reclassification?," was conducive to being

resolved by a more definitive statistical approach. The SPSS system was utilized to cross tabulate the responses[7] to nine specific questions by association membership. The relationship of association membership with the response to several of the aspects associated with drug reclassification was examined through the hypothesis testing approach as applied to contingency table analysis. The Chi-square test statistic was utilized and a significance level of .05 was set. For contingency tables with one degree of freedom, the critical value for this level of significance with the Chi-square statistic is 3.84. The null hypothesis (H_O) and the research hypothesis (H_A) used to examine this relationship are as follows:

H_O: Association membership is independent from response.

H_A: Association membership is not independent from response.

Four membership groups were to be studied:

1. No NARD or APhA membership,
2. APhA membership only,
3. NARD membership only, and
4. Both NARD and APhA membership.

For purposes of analysis, the responses to each of the nine survey questions were collapsed to form two response categories per question. This action was

needed to provide expected response frequencies of a sufficiently large magnitude to permit application of the Chi-square test statistic. The following material presents each of the specific survey questions included by this aspect of the study and discusses the two response categories created to analyze each of the question's answers.

Question 7 of the instrument is stated below.

> Prior to receiving this letter, were you aware of the proposal to create a new class of non-prescription drugs available only through pharmacies?
> 1. Yes 2. No

Since it was answered by circling one of only two options, no collapsing of responses was necessary to obtain two mutually exclusive response categories. Question 8 of the instrument, reproduced below,

> Do you favor creating a class of non-prescription drugs available only through pharmacies?
> 1. Yes 2. No 3. Undecided

had three choices for an answer. Two response categories were created by combining the "No" with the "Undecided" alternative. This permitted a "Yes" and a "Not-Yes" analysis to be undertaken. Question 10 inquired as to the degree of public accessibility to the drugs of the new class that should be allowed. It is restated on the following page.

The new class of drugs should be accessible to the public: (circle one only)
1. Directly, with no differentiation from other OTC's within pharmacies.
2. Directly, but with some mechanism of differentiating them from other OTC's within pharmacies.
3. Only by asking the pharmacist.

The first two responses were combined to form one response category while the third choice was utilized as the second response category for analytical purposes. The two response categories formed by this procedure provided a "Yes" or "No" pattern of analysis on mandatory pharmacist involvement. Question 11 concerned the role that pharmacists should play in counselling the patient on the use of the drugs of the new class. It stated,

Pharmacist-patient *professional consultation* concerning new class drugs should be: (circle one)
1. Mandatory.
2. Optional.

Since there were only two response categories for this question, no combining of responses was required. The necessity of maintaining records concerning the sales of new class drugs was investigated by question 12 below.

Record keeping requirements for new class drugs should be: (circle one only)
1. The same as for prescription drugs.
2. Required, but not as extensive as for prescription drugs.
3. Optional.

The first two choices were combined to form one

response category, while the third alternative formed the second response category. Record keeping is an essential part of monitoring patient drug therapy, and by not requiring this action, the pharmacist would receive a sales monopoly over third class drugs without being required to provide professional services. The perceived role that economic gain played in the formulation of the concept was measured by the responses to the following Question 18.

> Pharmacists are motivated primarily by economic gain in proposing drug reclassification.
> 1. Strongly Agree 3. Neutral 5. Strongly
> 2. Agree 4. Disagree Disagree

The "Strongly Agree" and "Agree" answers were combined to form one response category while the last three answers, "Neutral," "Disagree," and "Strongly Disagree," were incorporated to form the second response category. This provided a basis for comparing respondents that "Agreed" with those that "Did Not Agree". Question 28 was posed to determine the perceptions of the practitioner on the perceived role that professional concern played in the development of the drug reclassification concept. This question is restated below:

> Pharmacists are motivated primarily by professional concern in proposing drug reclassification
> 1. Strongly Agree 4. Disagree
> 2. Agree 5. Strongly Disagree
> 3. Neutral

As with the analysis of Question 18, the five choices were combined for form two response categories by combining the "Strongly Agree" and "Agree" alternatives into one group, and the "Neutral," "Disagree," and "Strongly Disagree" choices to form the other group. This allowed the comparison of the "Agree" responses with the "Not Agree" answers. Question 35 asked the pharmacists to indicate the position they felt national pharmacy associations <u>should</u> assume in regard to:

Creation of the new class of non-prescription drugs

1. Strongly Support
2. Support
3. Neutral
4. Oppose
5. Strongly Oppose

"Strongly Support" and "Support" responses were combined to form one response category, while the "Neutral," "Opposed," and "Strongly Oppose" alternatives were combined to form the second response category. Those respondents that "Supported" the concept could be compared to those that "Did Not Support" the creation of a new drug class. The final question, number 43, asked the pharmacists to indicate <u>how</u> <u>important</u> they felt the following issue was to the profession of pharmacy:

Creation of the new class of non-prescription drugs

1. Very Important
2. Important
3. Not Important

The "Very Important" and "Important" responses were combined to form one category while the "Not Important"

choice was utilized as the second response category. This provided for a comparison of "Important" with "Not Important" feelings by respondents.

Constructed from each of the two response combinations for each of the four membership groups listed previously, were nine 2 x 4 contingency tables. Each 2 x 4 contingency table was further subdivided into three non-overlapping 2 x 2 contingency tables. The following set of four tables depicts the procedure utilized for this analysis.[8] Table 10 demonstrates a sample 2 x 4 contingency table created by comparing question responses to membership groups.

Table 10

Sample 2 x 4 Contingency Table Created to Demonstrate the Analysis of Question Response by Association Membership

	Association Membership			
	1 None	2 APhA Only	3 NARD Only	4 Both NARD and APhA
Response Category 1	R1C1	R1C2	R1C3	R1C4
Response Category 2	R2C1	R2C2	R2C3	R2C4

Key:

(1.) R1C1 represents the number of non-association members answering the question as response category 1, eg.) Yes.

(2.) R2C1 represents the number of non-association members answering the question as response category 2, eg.) No.

The remainder of the table is completed according to this pattern.

Table 11 is constructed from Table 10 to compare the responses of pharmacists with no association membership to the responses of pharmacists belonging to one or more of the professional associations.

Table 11

Sample 2 x 2 Contingency Table Developed to Compare Responses From Non-Association Members to Association Members

	Association Membership			
	1 None	2 APhA Only +	3 NARD Only +	4 Both NARD and APhA
Response Category 1	R1C1	R1C2 +	R1C3 +	R1C4
Response Category 2	R2C1	R2C2 +	R2C3 +	R2C4

Key:

(1.) R1C1 represents the number of non-association members answering the question as response category 1, eg.) Yes.

(2.) R2C1 represents the number of non-association members answering the question as response category 2, eg.) No.

(3.) R1C2+R1C3+R1C4 represents the sum of the category 1 responses by association members.

(4.) R2C2+R2C3+R2C4 represents the sum of the category 2 responses by association members.

Table 12 is constructed from Table 10 to compare the responses from pharmacists that belonged only to the APhA, to those that belonged to the NARD only plus those that belonged to both organizations.

Table 12

Sample 2 x 2 Contingency Table Developed to Compare Responses From APhA Only Members to NARD Only plus NARD and APhA Members

	Association Membership			
	1 APhA Only	2 NARD Only	+	3 Both NARD and APhA
Response Category 1	R1C1	R1C2	+	R1C3
Response Category 2	R2C1	R2C2	+	R2C3

Key:

(1.) R1C1 represents the number of APhA only members answering as Response Category 1.

(2.) R2C1 represents the number of APhA only members answering as Response Category 2.

(3.) R1C2+R1C3 represents the NARD only plus the NARD and APhA members who answered in Response Category 1.

(4.) R2C2+R2C3 represents the NARD only plus the NARD and APhA members who answered in Response Category 2.

Table 13 is constructed from Table 10 to compare the responses from pharmacists that only belonged to NARD, to those from pharmacists that belonged to both the NARD and the APhA.

Table 13

Sample 2 x 2 Contingency Table Developed to Compare Responses From NARD Only Members to NARD and APhA Members

	Association Members 1 NARD Only	2 Both NARD and APhA
Response Category 1	R1C1	R1C2
Response Category 2	R2C1	R2C2

Key:

(1.) R1C1 represents the number of NARD only members answering as Response Category 1.

(2.) R2C1 represents the number of NARD only members answering as Response Category 2.

(3.) R1C2 represents the number of respondents belonging to both the NARD and the APhA that answered Response Category 1.

(4.) R2C2 represents the number of respondents belonging to both the NARD and APhA that answered Response Category 2.

A sample calculation that serves to demonstrate the process used in analyzing the 2 x 2 contingency tables for significant differences between membership groups and response combinations is given in the Appendix, Figure XX.

The application of the methods discussed in this

chapter produced the findings presented in Chapter III.

Limits on Questionnaire Analysis

The conducting of a more extensive quantitative analysis to explore the relationships between specific respondents characteristics and practitioner views on drug reclassification was not performed. The main focus of this section was to employ summary statistical techniques to develop an over-all general picture of practitioner views on the subject. The more intensive examination of the relationship between association membership and practitioner positions on reclassification was conducted, however, because the background study indicated this to be a major problem in preventing acceptance of the concept. It was not apparent from the literature review whether opposing positions of the NARD and the APhA on the concept were attributable to actual differences in the perspectives of the practitioner members of these organizations, or simply a difference in the leadership's positions.

FOOTNOTES

[1]John S. Millis, Pharmacists for the Future (Ann Arbor, 1975), pp. 1-160.

[2]C. Joseph Stetler, Pharmaceutical Manufacturers Association, Administrative Officers of the Member Firms (PMA: Washington, September, 1973), pp. 1-51.

[3]K. H. Larsen, American Law Review, 2d (New York, 1964), p. 1083.

[4]Ibid.

[5]Earl R. Babbie, Survey Research Methods (Belmont: Wadsworth Publishing Co., 1973), p. 165.

[6]Norman H. Nie, et. al., Statistical Package for the Social Sciences, 2nd ed. (New York: McGraw-Hill, 1975), pp. 1-675.

[7]Ibid., pp. 218-245.

[8]This procedure was made known to the researcher through discussions with and classroom presentations by Dr. Donald G. MacEachern, University of Minnesota, Department of Psychological Foundations, Courses PsyF 110 and 111, Summer Sessions I and II, 1974.

CHAPTER III

PRESENTATION OF FINDINGS

Chapter III is divided into three major sections following the pattern set forth in Chapter II. The first section deals with the presentation of findings of organizational perspectives on drug reclassification, while the second section centers on the results of state level activities to restrict the sale of certain OTC drugs to pharmacists and/or pharmacies. The final section relates the findings produced by analyzing the responses to the questionnaires returned by pharmacy practitioners and State Pharmacy Board and State Pharmacy Association Secretaries on their attitudes and opinions towards the concept.

Section I: Findings on Organizational Perspectives

Professional Pharmacy Associations

The background literature review was extremely important in developing the pharmacy associations' positions and perspectives on drug reclassification. It revealed the extent of interest and involvement of the American Pharmaceutical Association (APhA) in developing and refining the drug reclassification

concept over the last 25 years.

American Pharmaceutical Association (APhA)

The proposal was originally formulated by APhA as a response to the restrictions placed upon the practice of pharmacy by the Durham-Humphrey Amendments. The APhA's central role in the development of the concept can be traced to the Association's strong opposition to the enactment of the Durham-Humphrey Amendments in 1951.[1] The early efforts of the APhA in regard to reclassification centered on amending the Federal law to correct what the Association viewed as needless restrictions on the pharmacist's prerogatives regarding the refilling of prescriptions.[2] Prior to the enactment of the 1951 Amendments, pharmacists routinely refilled prescriptions at the patient's request unless specifically prohibited by the prescribing physician. This exercise of professional judgment by pharmacists became a violation of Federal law after 1951. This point of contention was most recently reflected in the 1964 APhA proposal and has not reappeared in any subsequent proposals to date.*

Dr. Eric Martin's 1957 proposal, restated

*It is interesting to note that during the 1975 California physicians' strike, pharmacists were authorized by the FDA to refill prescriptions based on their professional judgment. See: APhA Pharmacy Weekly, 15:7, February 14, 1976, p. 4.

below, is significant for several important reasons.

Figure 2

Dr. Eric Martin's 1957 Drug Reclassification Proposal

> Class I: Drugs sold only on a prescription due to their habit forming or highly toxic potential, and drugs that have been in use for less than 10 years. These drugs would require a prescription from a physician.
>
> Class II: Drugs that would require the signature of the purchaser such as exempt narcotics and poisons. These drugs would not require a prescription, but would be restricted to pharmacy sales only.
>
> Class III: Drugs sold in pharmacies without prescriptions and without requiring the signature of the purchaser. This class of drugs would consist of all other drug products not found in the first two drug classes.[3]

It reflected the traditional belief held by pharmacists that all drugs should be sold only in pharmacies. This approach to drug classification has been responsible for creating the almost fanatical opposition endured by past reclassification proposals from retail interests such as the grocers, variety stores, and union organizations. The 1964 APhA proposals recognized the realities of the situation concerning this approach and consequently incorporated a class of drugs into its classification scheme that would define those drugs able

to be sold in other than pharmacy settings. Dr. Martin's proposals also reflected an attempt to provide a scientific basis for drug reclassification. Drugs limited to prescription sale only would be those possessing significant habit forming or highly lethal characteristics, eg.) minimum lethal dose for humans lmg/Kg or less, as well as those drugs with a low therapeutic index, eg.) minimum lethal dose in humans 10 or less times the usual therapeutic dose.[4] This would represent a significant departure from the "expert judgment" criteria presently employed. The concept of restricting a newly developed drug to prescription sales for a 10 year period following its introduction on the market is illustrative of a philosophy that seems to find expression in all drug reclassification proposals, namely, that the safety of new drugs should be verified through actual use by practitioners before being allowed to be sold in any drug class other than the most restricted class. Similar intent was demonstrated by the 1963 APhA proposal that defined the new class of drugs as the proper level of restriction for prescription drugs that were to undergo declassification, rather than allowing these products to reach the public directly with no professional supervision what-so-ever.[5]

In an editorial in the Journal of the APhA, Dr. Martin listed three important benefits that his

proposed classification scheme would produce:

> 1. Largely prevent the lay public from harming themselves through indiscriminate self medication.
> 2. Enable all agencies and groups concerned to make sounder decisions concerning the manner in which all drugs should be distributed.
> 3. Prevent the occurrence of serious errors now being made by grocers and other merchants who attempt to sell drugs without adequate knowledge and training.[6]

Convincing the FDA and the Congress of the need for addressing these problems and for creating the new drug class to solve them, has proved to be extremely difficult.

Several Congressional committees have received testimony from APhA representatives on the drug reclassification concept. The concept of developing a new drug class available only from pharmacists was first presented to Congress by Dr. Robert Fischelis in 1961. Dr. Fischelis, at that time, was the immediate past Executive Director of the APhA, and had played an extremely active role in opposing the Durham-Humphrey Amendments 10 years earlier. The Congressional committee before which Dr. Fischelis testified, was the Kefauver Subcommittee on Anti-Trust and Monopoly. This Subcommittee was investigating the pharmaceutical industry for possible anti-trust violations. Dr. Fischelis contended before the Subcommittee that, "Most of the testimony seems

to assume that prescription drugs somehow reach the consumer through the manufacturer."[7] This approach according to the APhA representative, left the impression that the Subcommittee had overlooked the important role of the pharmacist in dispensing the drug to the patient. Citing the dramatic changes that had occurred in pharmaceutical education during the 1950's, he outlined the new role that pharmacists were being trained to assume, that of drug therapy consultant. This new role was intended to replace the manufacturing and compounding of drug products that once were the hallmarks of professional pharmacy practice. Dr. Fischelis went on to state that:

> - While there is disagreement among producers of drugs as to which classes of products offered to the public on a non-prescription status should be sold only under the supervision of pharmacists, there is general agreement that there are drugs in the non-prescription category whose sale should be restricted to pharmacies under the personal supervision of pharmacists. This is a phase of drug distribution which is not covered in S. 1552 [the Bill that later became the Drug Safety Act of 1962], but which should be incorporated in the interests of public safety.[8]

To resolve this situation, Dr. Fischelis recommended that an advisory committee to the FDA be appointed to select those drugs best suited for sale in this restrictive class. It is important to note that APhA at this time felt the FDA was legally empowered

to create such a drug class by regulation without gaining further congressional legislative direction. After the 1963 APhA proposal was developed, the FDA reflected the position that it required additional federal guidelines in the form of legislation before it could act to create a new drug class.[9] Although no action was taken by the Kefauver Committee with regard to the creation of either the new drug class or the formation of an advisory committee specifically charged with creating such a drug class, the testimony of Dr. Fischelis before the Subcommittee served to introduce the concept to Congress.

The next major development concerning drug reclassification was the September, 1963, statement filed by the APhA for inclusion into the record of Senator Hubert H. Humphrey's Subcommittee on Reorganization and International Organizations.[10] This Subcommittee was holding hearings on matters associated with drug safety and the FDA's role in assuring that the drugs it allowed to be marketed conformed to the safety and newly enacted effectiveness provisions of the Food and Drug Laws. The proposal, which was contained in the APhA's statement, envisioned the creation of a new drug class. The new class was to consist of the following:

1. Drugs that had been removed from legend status for a period of ten years

following the declassification.

2. All declassified legend drugs and non-prescription drugs that had not been advertised to the lay public within the past five years.

3. Drugs that contained active ingredients in concentrations of 50% or more of the minimum strength classified as a prescription drug, or for which the usual adult dose was 50% or more of the recommended prescription drug dose.[11]

It reflected the concern APhA had with the release of once legend drugs to the OTC drug class. (During the period from 1951-1959, approximately 23 legend drugs had been declassified to OTC status.)[12] The APhA proposal also contained a provision to place "ethical proprietaries" (those drug products not promoted to the public by the manufacturer and sold primarily through drug stores) into the new drug class that would be restricted to pharmacist sales. The APhA astutely recognized the fact that most all of the previous Food and Drug legislation enacted at the federal level since 1906 had been as a result of tragic circumstances surrounding the manufacture or distribution of certain drugs.* With this in mind, the APhA's statement included a paragraph to the

*1938 Act: Over 100 deaths from ethylene glycol based sulfanilamide elixir.
1951 Act: Resulting from abuse of amphetamines and barbiturates due to unethical dispensing.
1962 Act: Thalidomide tragedies.

effect that:

> Pharmacists and other health professionals wonder, however, whether there are not proprietary preparations now available in the United States as devastatingly deceptive and even potentially more dangerous than thalidomide.[13]

Senator Humphrey's Subcommittee did not hold additional hearings on this matter, and it was not until March of 1964, that the concept was presented in personal testimony by the APhA before the Subcommittee of the House on Intergovernmental Relations.[14] This Subcommittee had been formed to investigate the progress that had been made on implementing the 1962 Drug Safety Amendments to the Food, Drug, and Cosmetic Act. Dr. William S. Apple, APhA's Executive Director, testified to the need of implementing the APhA's drug reclassification proposals to counteract potential OTC drug problems. He warned the House Subcommittee that the FDA must not overlook OTC drugs as sources of potential dangers, and he indicated that the pharmacists can play an important role in aiding the public to select drugs for self-medication. The four classes of drugs envisioned by the 1964 proposal[15] not only created a class of drugs restricted to pharmacist's sales but also reflected the granting of limited refill authority to pharmacists. In a 1964 survey of its members, APhA stated that over 90% of the members

indicated full support for the Four Drug Class Proposal.[16] No further action resulted from either the 1963 or the 1964 APhA efforts. These attempts marked the most concerted effort by the APhA to obtain support for its reclassification proposals. Following these unsuccessful efforts, the APhA recommended that state pharmacy associations attempt to gain passage of state laws to restrict certain OTC drugs to pharmacies.[17]

Since this period of time, the drug reclassification concept has been intermittently raised by the APhA as a peripheral issue to other drug related discussions. Senator Gaylord Nelson's Subcommittee on Monopoly of the Select Committee on Small Business, for example, began hearings in 1971 on the "effect of promotion and advertising of over-the-counter drugs on competition, small business, and the health and welfare of the public."[18] APhA has always contended that the advertising and promotion of OTC drug products to the public by the drug manufacturers was a primary reason for their abuse. They have testified to the fact that the pharmacist, who could be the source of objective information to the patient on the use of non-prescription drugs, is by-passed because of the "gimmickery" applied by the advertisers. Dr. Richard Penna of the APhA, testified in 1971 before the Nelson

Subcommittee that a new intermediate class of OTC's for which public advertising would be prohibited and for which personal dispensing by the pharmacist would be required, would provide a much needed counter-measure to the promotional practices of the drug industry.[19] The most recent significant development surrounding the drug reclassification proposals of the APhA occurred in 1973 as a result of FDA sponsored studies meant to determine the safety and efficacy of OTC product ingredients begun in 1971. One of the outcomes of this massive ongoing study was the development of approved monographs for the proper labeling of non-prescription products within specific therapeutic classes. The monographs would clearly delineate all of the required information that any OTC product found in the therapeutic category covered by the monograph was required to contain on its label. The first monograph developed utilizing this procedure concerned the antacids, and the initial version of the monograph reflected the following statement, "Do not take this product concurrently with prescription drugs except on the advice of your physician or pharmacist."[20] This precautionary statement was intended to appear only on antacids that contained activated charcoal as an ingredient, due to this chemical's interference with the absorption of other drugs. The FDA asked that

comments be filed regarding the proposed monograph and numerous parties responded. The APhA commented that they not only supported the statement suggesting pharmacist's consultation to patients, but again brought up the possibility of establishing a third class of drugs, based on whether or not the drugs so restricted had potential drug interaction significance.[21] The APhA contended that by requiring pharmacists to maintain patient records concerning the dispensing of these restricted products, patients would benefit by being able to "consult with a knowledgeable practitioner concerning the drug product in question."[22] This would allow the pharmacist to "provide the patient specific information or warnings which may be appropriate according to the situation."[23] This statement by the APhA resulted in numerous opposition arguments being filed by those opposing formation of a new drug class. The result of this most recent APhA elaboration of the reclassification concept was the removal of the controversial caution statement from the proposed antacid monograph. No further effort by the APhA to gain acceptance for their reclassification concept has occurred since 1973, although the concept arises repeatedly in discussions surrounding the future roles that pharmacists might be expected to fulfill.[24]

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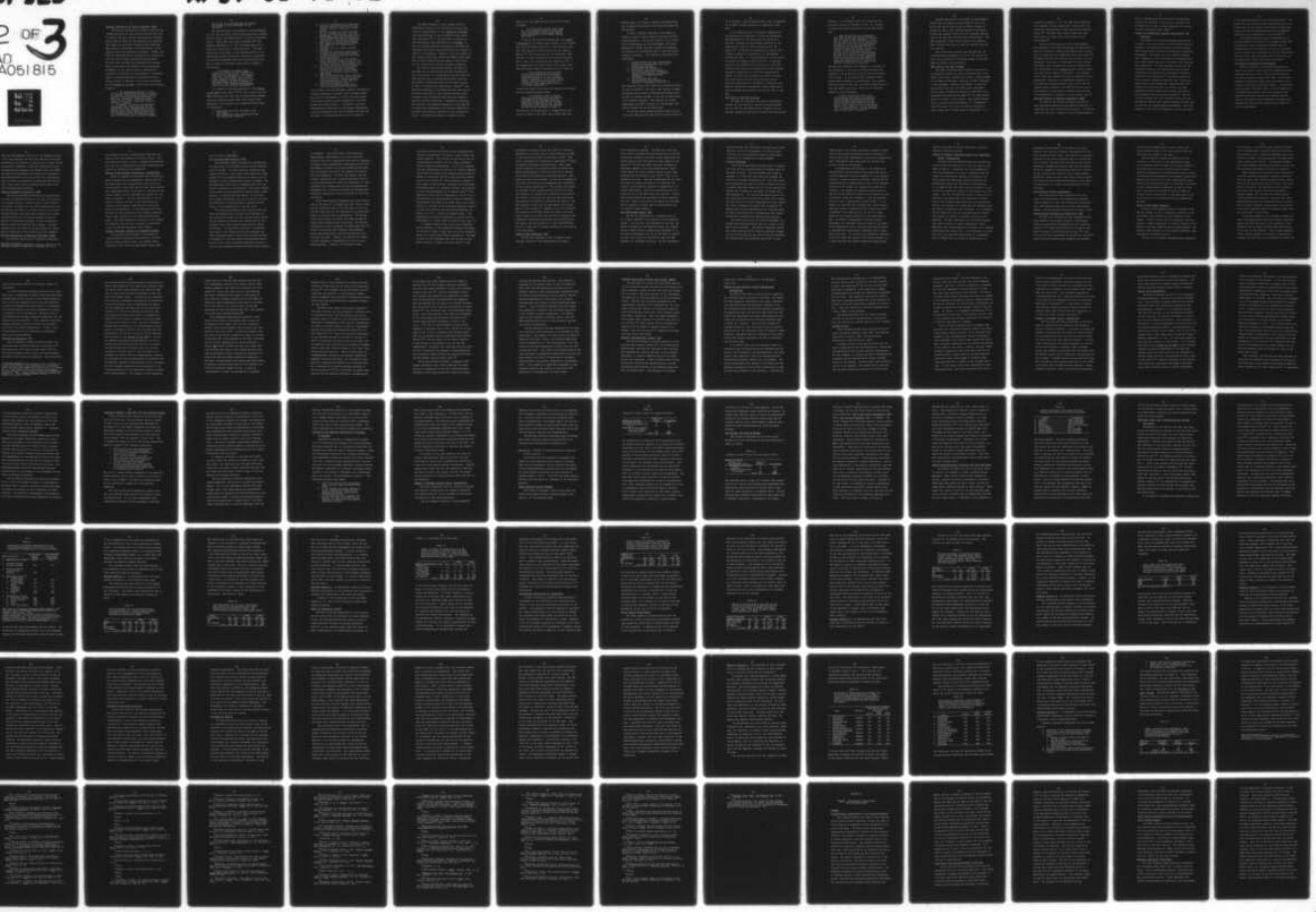

National Association of Retail Druggists (NARD)

The National Association of Retail Druggists has assumed positions on drug reclassification that tend to support the basic concept of creating an intermediate class of drugs but has generally not supported that aspect of the APhA's proposals that would mandate personal involvement of the pharmacist in dispensing these drug products to patients. Rather, the NARD has supported direct supervision by a pharmacist over the sale of these restricted drug products. The fact that the NARD had introduced this concept during discussions surrounding the Durham-Humphrey Amendments in the 1949-51 period, indicated the Association's concern for the Amendments' inevitable impact on reducing pharmacy controlled OTC sales. Senator Hubert H. Humphrey, in an article published by the Journal of the NARD, stated that drug reclassification

> ...was thoroughly explored in 1951-52 when the Humphrey-Durham Act was passed by Congress, but because of sharp differences of view among interested groups, it was left unresolved. There was even a split in the usually harmonious ranks of pharmacy, I recall.
>
> I remember how we met with pharmacy representatives, with the grocers, the proprietary drug manufacturers and many others, and I also remember that your own John Dargavel fought the good fight for the incorporation in the Humphrey-Durham Act of the "third-class of drugs" concept.

> But it had to be dropped when the concept threatened to block enactment of any new law.[25]

The years between the enactment of Durham-Humphrey in 1951, and the APhA's 1963-64 reclassification efforts did not reflect any NARD activity to achieve reclassification. After APhA filed their statement with the Humphrey Subcommittee in 1963, the NARD began to examine their position on reclassification. The 1964 objectives of the NARD, a list prepared yearly to reflect NARD's annual convention resolutions, contained the following statement that has continued during the past 12 years as the NARD's basic policy regarding the concept.

> To initiate and support such corrective efforts in the interest of public health and safety, including if necessary, an amendment of the Federal Food, Drug and Cosmetic Act, so that drugs capable of producing harm or concealing disease be made available to the public with adequate professional control through licensed pharmacies.[26]

In a series of articles published in the Journal of the NARD during 1964,[27,28,29] legal counsel for the NARD identified what they saw as representing problems requiring attention before NARD could support APhA proposals. The following list summarizes these areas of contention:

1. What drugs are to be included in the new class?
2. What additional legal responsibilities are pharmacists assuming?

3. Will drug reclassification mean more Federal regulation and control and possibly Federal licensing of pharmacies?
4. Who will absorb the additional cost of the increased service? Can the pharmacist? Will the consumer do so?
5. Would pharmacists become so-called "counsellors" and thereby assume the position of a medical practitioner?
6. What image are pharmacists creating for themselves by supporting the concept?
7. May this not be a "State" control problem?
8. Is there now regulatory machinery to accomplish some of the basic needs of drug control associated with drug reclassification?
9. Do the pharmacists of the country fully grasp and understand all of the issues involved in this problem? Do we really know what their attitude is?
10. How will the new drug class affect our present day type of pharmacy retailer in relation to his investment in self-service merchandising equipment?
11. What could pharmacists tell a customer that may not be on the label such as proper directions, proper cautions, and restrictions for use, short of invading the medical field?
12. Will drug reclassification really serve to decrease self-medication?

It is evident from the decidedly negative connotations of these enumerated "problems" that the NARD leadership was not predisposed to involve the Association in the drug reclassification proposals of the APhA during the 1963-64 period. In addition, the basic philosophical differences on the proper professional role for pharmacists that exists between the NARD and the APhA, is reflected by this list of questions.

The NARD attempted to gain insight into its membership's views on drug reclassification by publishing a questionnaire in the Journal of the NARD that reflected most of the 12 problem areas listed just previously.[30,31] The fact that no results of this survey were ever published in the Journal, or that the present Executive Secretary of the NARD who conducted this survey during 1964 would not comment on them,[32] is interesting. Whether or not the results of this survey should have altered the NARD's early position on drug reclassification remains a moot point, but its implications could be extremely important.

The hostile relationship between the NARD and the APhA that existed during the 1964 reclassification controversy, is illustrated by the fact that the APhA was the only interested organization that did not attend a conference called by the NARD in April of 1964, to discuss the third class of drugs.[33] The Executive Secretary of the NARD indicated that one of the main conclusions of this meeting was that more information and discussions were essential before a solution could be formulated. Immediately following this meeting, the Executive Committee of the NARD met to review many suggestions that had been submitted to the NARD concerning its position on drug reclassification. No action was taken as a result of this

meeting but the Committee did issue the following statement:

> It was pointed up that legislation for the reclassification of drugs must avoid the burden of additional compliance restrictions that carried serious penalties.[34]

In one of the articles prepared for the Journal of the NARD by the NARD's legal counsel, it was stated that many new drugs being sold in the OTC drug class were "not safe for unsupervised use by the general public."[35] The article went on to state that, "The need for revising legislation to alleviate the problem at this time is becoming most imperative."[36] It was suggested by the legal counsel that rather than seek additional Federal legislation that it might be

> ...more practical and a quicker solution to provide that those drugs and compounds which on their labels, require warnings as to use, are sufficiently dangerous to use without supervision, and such drugs shall be restricted to sale under supervision of a licensed pharmacist.[37]

It was also stated that using this approach as a basis for drug reclassification would

> ...necessitate urging a concept that oral restatements or cautions by a pharmacist of the directions and warnings already provided by the manufacturer as required by law, is more efficacious than leaving the label to be read by the purchaser or user.[38]

This article was concluded by a recommendation that action be taken at the state level rather than the

federal level as a means of reducing the opposition and increasing the chances of gaining acceptance for the proposal.

In 1964, a special committee of the NARD was formed to explore certain issues involved with drug reclassification. One of the results of this committee's deliberations was the development of several categories of drugs that were viewed as possessing the possibility of producing harm if used indiscriminately by patients. The following categories were elaborated:

1. Antihistamines and their derivatives, as well as antinauseants and sleep-producing sedatives,
2. Non-narcotic analgesics,
3. Antibiotics for topical use,
4. Vaso-constricting and bronchial-dilating preparations, containing ephedrine and ephedrine-like compounds,
5. Irritant laxatives, and
6. Any substance or medication intended for hypodermic injection.[39]

The committee stated that these drug categories should be made available to the public only through licensed pharmacies where properly registered personnel would be able to counsel patients in the use of these potentially harmful products. This appears to closely approximate the APhA's position on the personal dispensing aspects of the new drug class.

No further drug reclassification oriented activity by the NARD could be discerned from this review of

the literature. Drug reclassification has not appeared in the NARD's annual Statement of Objectives since 1972.

In an address before a conference sponsored by the University of Wisconsin in 1973, the Washington representative of the NARD stated that there is a need for "changing the distribution patterns on non-prescription drugs for better protection of the public."[40] He called for improving the present distribution system by providing for an intermediate category of drugs, "...the distribution of which would be related to community pharmacies."[41] It was mentioned in this address that in the past it has been primarily the province of pharmacists to gain greater regulatory flexibility in the drug classification system, but that this situation is likely to change when new types of health care providers such as physician assistants are considered. Apparently the NARD has become more predisposed toward supporting a drug reclassification effort than was the case in the past.

APhA Views of the NARD Position

The APhA has indicated that one of the primary reasons for its ceasing to pursue drug reclassification in 1964 was the NARD's lack of support for the personal dispensing provision of APhA's reclassification

proposal. In an address before the University of Wisconsin College of Pharmacy in 1967, Dr. William S. Apple, the Executive Director of the APhA stated that

> Some pharmacists have complained that APhA is not working hard enough for this reclassification proposal. I can tell you that we want this to be the law of the land but we have to be realistic. Pharmacy still has not resolved how we can explain to the Congress and the federal agencies that there is an organization in American pharmacy which doesn't think it matters whether drugs are sold by a clerk or by a pharmacist. We want to do more but those interests which would work against reclassification will capitalize on the failure of specialty organizations to support your national professional society.[42]

The APhA has considered the mandatory involvement of the pharmacist in the sale of these restricted OTC products to be an essential part of the reclassification concept. In the APhA's 1963 statement filed before Senator Humphrey's Subcommittee, this concern manifests itself along with the APhA's dissatisfaction with the NARD's position as shown by the following segment of this statement:

> Certain drug store owners view requiring the distribution of proprietary preparations through pharmacists as an economic disadvantage, for certainly professional counseling of the patient will take the time of the pharmacist. This, however, is a contribution the profession feels it should and must make in the public interest.[43]

Another indication of the extent of disagreement between the two pharmacy associations on this issue during the 1963-64 period was the APhA's refusal to attend the April, 1964, meeting called by the NARD to discuss the proposal along with all concerned parties, such as the AMA, FDA, and the drug manufacturers. The APhA apparently viewed these efforts by the NARD as delay tactics that were not meant to achieve constructive results.

APhA last sought support from the NARD for its reclassification proposal in 1970.[44] The results of this effort produced no noticeable change in the NARD posture towards reclassification.

NARD Views of the APhA Position

The NARD considered APhA's 1963-64 criticism of its position as being an unfair representation of the NARD's true stance regarding the issues. Legal counsel of the NARD was obviously referring to APhA leadership in the statement, "Certain individuals, through the drug trade press and other media, have concocted a narrow issue [of personal pharmacist supervision] as separating the NARD and the APhA."[45] The NARD Counsel went on to state, "In my opinion, this rabble-rousing tactic is based upon emotionalism, it is designed to fend off attack or to hide the lack of activity on other issues and in other areas of importance; it is

a publicity gimmick...."[46] The NARD thus viewed the APhA proposal as being unrealistic, filled with "unattainable possibilities"[47] and "impractical considerations."[48] The NARD legal counsel urged the state level action be taken rather than federal level involvement.[49]

During the consideration of the 1964 proposal the President of the NARD articulated his Association's position as being in keeping with NARD's basic rationale of "protecting the independent drug store owner."[50] The NARD obviously felt during this time that the disadvantages that might be associated with drug reclassification would outweigh the potential benefits and that maintenance of the status quo was a better answer than seeking new Federal legislation. On a related point, when APhA attempted to gain recognition for the pharmacists' exercise of professional discretion in the refilling of prescriptions (part of the 1964 reclassification proposal), the NARD criticized this as being subject to opposition by Congress and the FDA for representing a "regression of the present law."[51]

American Society of Hospital Pharmacists (ASHP)

The ASHP is the national pharmacy association that represents pharmacists who practice primarily in hospitals and other institutional settings. It has not taken any position in regard to drug reclassification,

and in a telephone conversation with the Executive Director of the ASHP, it was clearly indicated that the ASHP did not wish to become embroiled in the controversy surrounding this issue.[52]

Summary of Professional Pharmacy Associations' Perspectives

The inability of national pharmacy associations to agree on the provisions of a drug reclassification proposal, has imparted a decidedly negative connotation to the course of events surrounding the concept's development. The basis for this internal disagreement, apparently stems from different interpretations as to what should constitute the proper role functions for pharmacists. The NARD expressed concern for the increased liability that pharmacists might subject themselves to by meeting the professional demands of the APhA's 1964 proposals.[53] The APhA, as early as 1961, however, assumed the position that reliance by pharmacists on the traditional compounding and dispensing role functions must be altered, and that pharmacists should become more actively involved in the therapeutic decision making process.[54] The historical precedent for this situation was set by the acrimonious debates that occurred between the NARD and the APhA on the Durham-Humphrey Amendments. This fact appears to find continued expression in the positions

of the two associations on drug reclassification. The possibility for resolving these differences may be improving due to the changing distribution patterns for drugs, and the increased expectations by pharmacists concerning their professional role functions.[55]

In personal interviews with representatives of both the APhA[56] and the NARD,[57] it became evident that although more recent discussions between the two organizations had not been held on the drug reclassification matter, the leadership of the two associations was not as far apart philosophically on the issue as the historical account might tend to indicate.

Non-Pharmacy Professional Associations

Three professional associations representing health care practitioners other than pharmacists were contacted for their views on drug reclassification, the American Medical Association (AMA), the American Optometric Association (AOA), and the National Association of Physician Assistants (NAPA). The AMA could be an extremely important force in either supporting or opposing the concept, while the optometric and physician assistant associations represent practitioners that should be as interested in gaining more flexibility from the drug classification system as are the pharmacists.

American Medical Association (AMA)

The AMA has generally remained non-committal toward the drug reclassification proposals of the APhA. Following the filing of APhA's statement with Senator Humphrey's Subcommittee in 1963, APhA directed a letter to the AMA urging that discussions between the two associations concerning the proposal be conducted.[58] During 1964, a meeting between the two professions (The Congress on Medicine and Pharmacy), was to consider drug reclassification as a topic for discussion.[59] It subsequently developed, however, that the main points for consideration at this meeting were physician dispensing practices and physician ownership of pharmacies. These two issues apparently took precedence over drug reclassification and no joint statement of support for the concept emanated from this meeting.[60] Some degree of support within the medical profession for drug reclassification appeared to exist during this time period, however. An editorial in Northwest Medicine, indicated that professional control over OTC sales was a desirable development, and support of the APhA's proposal was voiced.[61]

An attempt to determine what the AMA's current position might be if a new drug reclassification proposal was developed, was made by initiating correspondence with the Director for Professional Affairs of the

AMA, see the Appendix, Figure III. No response to this letter was received, and since the AMA has historically maintained a low profile in regard to this issue, follow-ups were not attempted. Since the complexion of drug reclassification proposals has changed since the 1950's and 1960's to incorporate the concept of prescription drug declassification as well as OTC drug reclassification, it might be expected that organized medicine may take a more active role in deciding the future of any drug reclassification efforts.

American Optometric Association (AOA)

The American Optometric Association was contacted in order to determine whether or not they were aware of this concept and how it might relate to their efforts to achieve a relaxation in the drug classification laws. The AOA was not aware of the APhA's efforts to achieve reclassification, and their main concern was to permit optometrists the use of certain diagnostic aids as opposed to therapeutic products in their profession.* Several states have approved this concept. The AOA indicated that they were not concerned with the therapeutic utilization of drug products by their members.

National Association of Physician Assistants (NAPA)

The National Association of Physician Assistants

*Personal telephone conversation with Dr. Hunter of the American Optometric Association, November 24, 1975.

was contacted and they responded that they were not aware of any such proposal by pharmacy groups. They indicated an interest in such a proposal and obviously felt that they could benefit from such legislation as much as the profession of pharmacy.[62]

Summary of Non-Pharmacy Associations' Perspectives

Since no response was obtained from the American Medical Association correspondence, nothing more can be stated about this organization's position on reclassification, other than the fact that their opinion will undoubtedly exert a good deal of influence on the decision makers of our government as regards the concept's acceptance. The AOA indicated that it has no desire to become involved in any controversy surrounding the therapeutic application of medicinal agents by optometrists. It was determined that the AOA had not been contacted by any pharmacy organization to gain support for the reclassification proposal. The NAPA expressed an interest in the concept but similarly had not been contacted by representatives of organized pharmacy on the concept.

Federal Government Agencies and Regulative Bodies

Four groups were included in this aspect of organizational perspective determination, the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), The Drug Enforcement Agency (DEA),

and the Justice Department.

Food and Drug Administration (FDA)

The government agency charged with implementing the provisions of the Federal Food, Drug and Cosmetic Laws is the FDA. Its basic position regarding drug reclassification is that unless the present two class system for drug categorization can be shown to be inadequate, no new classification system is needed. The FDA apparently feels that if problems exist with the safety or efficacy of OTC products, then those products should either be reclassified to legend status, reformulated, or removed from the market. On the other hand, legend class drugs that can be shown to be safe and effective if used according to labeled instructions, can be declassified to the OTC class.

The historical precedent that characterizes the FDA's involvement with the practice of pharmacy is such that the FDA must be rather cautious about granting the pharmacy profession any recognition for professional roles that the FDA cannot easily control and monitor. In the 1920's and 1930's, the FDA became aware of the rather poor quality pharmacy services being delivered in Puerto Rico and the District of Columbia.[63] The FDA warned state pharmacy boards at this time to more carefully supervise the activities of the pharmacists practicing within their domains

of authority. During the 1940's, when abuses of amphetamines, barbiturates, and sulfa drugs were traced by the FDA to pharmacists who were not adequately meeting their professional responsibilities,[64] the FDA began to develop its policies regarding the practice of pharmacy that guide its present relationship with the profession. In 1948, for example, the FDA issued a regulation that forbade pharmacists from refilling prescriptions on their own discretion.[65] This regulation was incorporated into the Durham-Humphrey Amendments and it greatly diminished the professional autonomy of pharmacists over the control of their own activities.

Drug reclassification proposals have been elaborated by the APhA on the supposition that certain drugs that are presently sold in the OTC class, as well as certain drugs that are now restricted to prescription, should or could be sold by pharmacists. The pharmacists could enhance the safety and effectiveness of these drugs through patient counseling. The FDA has recognized the basic necessity of determining that all drugs on the market must conform to the mandated safety and effectiveness criteria specified by the Food and Drug Laws. However, the FDA has not chosen to adopt pharmacy's recommendation on how to solve these problems. Instead, it has chosen to more

carefully evaluate prescription drug products[66] and OTC drug ingredients[67] for safety, effectiveness and proper labeling. The position of the FDA on drug reclassification, however, has not always reflected totally negative connotations. In 1970 for instance, the then Commissioner of the FDA, Dr. Charles Edwards, stated that he thought drug reclassification might be needed to counteract the drug abuse and drug overuse found in our society.[68] This perspective appears to have taken on less positive overtones with the former FDA Commissioner, Dr. Alexander Schmidt, who referred to drug reclassification as a "doubtful cause"[69] and apparently feels that the pharmacist's future role in the clinical environment should be based on personal negotiations with physicians rather than on new legislation.[70] The most recent published statement regarding the FDA's position on drug reclassification considers it to be "...solely an economic issue. The Commissioner therefore categorically rejects the establishment of a third class of drugs at this time."[71]

A closely related issue to the drug reclassification proposals is the question concerning the power of the FDA to create a drug class on its own authority rather than seeking new federal legislation. The APhA as early as 1961 suggested that the FDA did in fact have the power to create a new drug class.[72] The

government's position during this period of time was expressed in a letter from the Under-Secretary of HEW to the Executive Director of the APhA in 1963. This letter indicated that "substantive legislation"[73] would be needed to develop a new drug class. APhA subsequently submitted its proposals before the House and Senate Subcommittees in 1963 and 1964 but no legislative action was forthcoming from these efforts. More recently, within this context, the FDA has attempted to limit the distribution of an approved drug, methadone, to only certain pharmacies.[74] This action was opposed by the APhA on the grounds that the FDA did not have the authority to regulate the channels of distribution and indeed, if this was the case, the FDA should use these powers to establish a new class of drugs.[75] The APhA appears to have won its case against the government in this instance.[76] Whether or not this resolves the question of the FDA's power to create a new drug class remains to be seen, but the FDA is presently contemplating introducing legislation that would provide the agency with the authority to limit drug distribution as it sees fit,[77] thereby creating its own form of a new drug class.

Federal Trade Commission (FTC)

The FTC has responded to the criticism of promotional efforts by drug manufacturers for their

non-prescription products. The APhA has, since the early 1960's, expressed the philosophy that it was the promotional gimmickry utilized in many commercials for these products that contributed to their abuse by the public.[78] The FTC has begun receiving testimony to determine whether or not drug manufacturers' advertised claims for their products should be only those approved for that product by the FDA.[79] This is not presently the case. APhA has recommended the new class of drugs as a proper alternative to counteract the abuse of these products created by exaggerated or inflated advertising. The FTC has reacted to the situation but not as the APhA would have desired. Further advertising regulations conforming to FDA's approved uses are viewed by the FTC as the remedy for the problem as opposed to greater input by pharmacists into the sales of these products.

Drug Enforcement Agency (DEA)

The DEA was contacted via a telephone call to Mr. Delbert Konnor[80] of the agency's drug information bureau. The fact that the forerunner of the DEA, the Bureau of Narcotics and Dangerous Drugs, had allowed certain exempt narcotic preparations (Schedule V) to be sold by pharmacists only on an OTC basis in 1969,[81] and that this policy was continuing under the DEA, prompted the telephone interview. No new information

was provided by this discussion, but the policy still remains in effect and apparently, the DEA is satisfied with the role pharmacists play in responsibly overseeing the dispensing of these products.

Justice Department

The Justice Department has been asked to express its views on drug reclassification proposals twice in the past 15 years. The first comment was filed in response to a 1960 bill that would have amended the District of Columbia Pharmacy Act.[82] This bill would have prohibited the sale of any drug product for which a caution statement concerning its use was required by Federal law to appear on its label, by anyone other than pharmacists. The Justice Department stated that this provision would provide drug stores with a monopoly over the sale of most prepackaged OTC drugs including "such a necessary household item as aspirin."[83] Competition would be decreased and the consumer would be unduly inconvenienced if supermarkets and related stores were prevented from selling these products.

The second opinion by the Justice Department regarding drug reclassification came as a result of the APhA's 1973 proposals. The Justice Department stated that these proposals would "severely restrain competition in the distribution and sale of OTC drug products and inconvenience the consuming public."[84] In the

same opinion, the Justice Department included a statement in which they characterized the maintenance of patient records by pharmacists as being anti-competitive and a development that would serve to increase the price of drugs to the patient.

Correspondence was directed to the attention of the Assistant Attorney General who signed the latest Justice Department position statement on drug reclassification. Since the APhA's proposals involved the declassification of legend drugs as well as the reclassification of OTC drugs, the question was asked as to whether or not legend drug declassification into the new drug class would be viewed as anti-competitive and of negative import for consumers. (See the Appendix, Figure V, for a reproduction of this letter.) A response was received that indicated the Justice Department was unable to determine which of their position statements I was referring to, but that my letter might be more properly directed to the Department of HEW. No further correspondence with the Justice Department was conducted, since my question was based on the supposition that a new drug class would consist of declassified legend drugs, something that is speculative at best. It was felt that additional inquiries on my part would not result in any further comment as to what position the Justice Department might assume,

without being able to provide them with a specific pharmacy supported proposal.

Summary of Federal Government Agencies and Regulative Bodies' Perspectives

The Food and Drug Administration has assumed the position that the creation of a new drug class by the agency would be a recognition of a new professional role for pharmacists, and this is something that the former FDA Commissioner Schmidt, for instance, has stated should be negotiated between physicians and pharmacists rather than legislated into existence. It is apparent that the FDA is quite satisfied to work within the traditional context of the present two class system. The FTC, although not having a direct role in creating a new drug class, has attempted to resolve many of the problems associated with non-prescription drug use by limiting the claims that drug manufacturers can employ in promoting their products. It is possible the FTC might give the drug reclassification concept some support as a means to improve drug use by our populace. The DEA, that deals with controlling medicinal agents subject to abuse, habituation, and/or addiction, has allowed Schedule V products, eg.) codeine containing cough syrups, etc., to be marketed on an OTC basis but only under the supervision of a pharmacist. This is recognition by the DEA of the abilities of

pharmacists to contribute to the safe use of such products, and reflects favorable consequences for the drug reclassification issue. The position on reclassification of the final government body to be contacted by this study, the Anti-Trust Division of the Justice Department, exemplifies the fact that drug reclassification is impeded by controversies that have little to do with the safe and effective use of drug products. Describing pharmacist maintained patient drug profiles in terms of an anti-competitive maneuver by the pharmacy profession, is a total misrepresentation of the situation.

Drug Industry Related Associations

Four associations were contacted within this group of organizations, the Pharmaceutical Manufacturers Association (PMA), The Proprietary Association (PA), The National Association of Chain Drug Stores (NACDS), and The National Pharmaceutical Council (NPC).

Pharmaceutical Manufacturers Association (PMA)

The PMA is an organization that represents those drug companies "principally engaged in the manufacturing of prescription pharmaceutical and biological products."[85] These drug products are "primarily promoted to medical and dental practitioners."[86] Many of the drug firms represented by the PMA are also affiliated with drug manufacturing concerns that produce

primarily OTC products while several others have quite extensive lines of OTC drug products that are sold under the company's own label.

The PMA has not assumed any position on the creation of a new class of non-prescription drugs. In a discussion with the PMA's chief legal counsel, it was made quite clear that the PMA would not take a position regarding drug reclassification until a definite proposal was developed by the pharmacy profession.[87] Based on the activities of those organizations representing the drug manufacturers in the debates surrounding the Durham-Humphrey Amendment, as well as state level activities by the PMA,[88] anything viewed as placing further restrictions on the operations of the drug industry by the government would be opposed by the PMA.

Survey of PMA Member Companies

Thirteen drug companies listed as members of the PMA and thought to have a substantial interest in OTC drug sales, were selected for participation in the survey. A letter containing five questions, each designed to obtain information on specific aspects of the company's policies regarding drug reclassification, was mailed to the attention of each company president, (see the Appendix, Figures X and XI).

Of the 8 of 13 company representatives responding

to the survey, 5 stated that their company utilized only "professionally directed" promotions for their OTC products, while 3 companies responded that a combination of public and professionally directed promotional efforts was utilized. The reasons presented for these different company policies were varied, but they basically reflected two distinct viewpoints.

Those companies that promoted their products exclusively through professional channels, indicated that this was a long standing company policy, formulated as one manufacturer stated because, "The interests of the public, the pharmacist and the manufacturer were best served" under such conditions. Another company that utilized the professionally directed promotional approach, indicated that when physicians were observed prescribing their OTC products for their patients by pharmacists, that pharmacists would inevitably begin recommending their product to patients on this basis.

Those drug companies that employed a mixture of public and professional promotional effort, generally stated that this was based on the economics of the situation and the impact of mass media advertising on the sale of OTC products. One of these companies cited a recent example of how public promotion can increase the sales for a given product well above the

level achieved with only professionally directed promotional efforts. The drug in question was a high potency vitamin combination that was able to show a 500% increase in test market sales due to the change to public promotion.

The desirability of creating an intermediate drug class was viewed with a generally negative perspective by 5 out of the 8 respondents. These individuals regarded the present classification system as being satisfactory to meet their companies' needs and since these companies were not greatly involved in the sale of OTC products, a new drug class would have "negligible effect" on their operations. The 3 drug company respondents that indicated a basic degree of support for the concept did so with some reservation as to the additional government controls the industry might be subjected to with the creation of a new drug class. One of these respondents cited the beneficial effect of such a new drug class in aiding the pharmacist's professional role development in the area of safe and effective drug use by patients.

The final two questions generally produced negative responses. All of the individuals answering the survey were satisfied with the present clinical trials system for drug classification purposes and one individual stated that the declassification of legend

items to OTC status was not in the best interest of the patient.

It can be deduced from these responses that there does exist a difference of opinion among the large drug manufacturers on the concept of drug reclassification. Many of the drug companies still limit the promotion of their non-prescription drug products to professionally directed efforts, but this represents not simply a recognition of the pharmacists' important role in the transferring of these products to patients, but the economics of the situation. Those companies that have adopted promotional efforts directed at the public have done so to remain competitive.* Overall, drug reclassification did not generate much enthusiasm among surveyed PMA members.

Proprietary Association (PA)

The PA represents those drug manufacturers that "advertise their products directly to the public."[89] The Association was formed in 1881, about the time that state pharmacy practice laws were being enacted to restrict drug sales to pharmacies. Early PA efforts

*A further example of what appears to be a growing interest among ethical drug manufacturers to increase sales for their OTC products is that of the G. D. Searle Co. It has recently begun test marketing in supermarkets, several of its products such as Dramamine^{R} and Metamucil^{R}. See: Weekly Pharmacy Reports, Volume 24: Number 40, October 6, 1975.

were directed toward gaining passage of proprietary or patent drug exemptions from restrictive pharmacy laws. The PA has been a most outspoken and effective opponent of drug reclassification proposals at both the state and federal levels. Its position is consistent with the basic philosophy reflected in the objectives of the organization, that of preserving and improving "the integrity and stability of the proprietary industry."[90] The PA has adopted the position that drug reclassification would create a "druggists monopoly"[91] with no basis in Federal law and no demonstrated need in point of fact. The PA's influence in shaping the provisions of the Durham-Humphrey Amendments to exclude any mention of a new drug class was made known in an article written by Senator Humphrey and published in the Journal of the NARD.[92] During the debates surrounding Durham-Humphrey, the PA expressed concern that most drugs would be included in the prescription only class and very few would be included in the OTC class.[93] This was based on an assumption by the PA that the pharmaceutical industry was dominated by large manufacturers who preferred the professional channels of distribution of their products. The PA's arguments apparently were persuasive in influencing phrasing of the regulations written to implement Durham-Humphrey. For example, an FDA regulation

states that if a drug has been approved for OTC use, then misbranding results if the legend caution subsequently appears on the label of a container for that product.[94] Since 1953, well over 27 drug products have been transferred from legend to OTC status.[95] This trend was arrested somewhat during the 1960's by opposition from professional groups such as the APhA, but in the 1970's, as a direct result of the FDA sponsored OTC Drug Evaluation Study, the trend appears to be once again gaining momentum.[96]

The Proprietary Association maintained a relatively low profile at the federal level during the development of the APhA's 1963 and 1964 proposals. However, the PA was extremely active during this time period at the state level. In 1964 for example, when the State of New Jersey attempted to create a new drug class along the lines suggested by the NARD, testimony for the PA was presented by Dr. Morris Fishbein, a former JAMA editor and AMA official, who stated that "Our existing drug laws in most states and under the federal government afford a maximum of protection."[97] Before the same New Jersey Legislative Committee, a professor of pharmacology from George Washington School of Medicine testified that since all OTC products are sold with direction labels for use, it would be "Unreasonable to expect the pharmacist to dispense

medical advice, since diagnosis of ailments and prescribing of medicines are not among his professional duties."[98] This argument helped to bolster the PA's opposition and resulted in the proposal's defeat. Similar arguments were employed to effectively counter state level drug reclassification proposals throughout the country.

The APhA's most recent formulation regarding a new class of drugs and the pharmacist's potential role in over-seeing their safe and effective use by the patient, came as a result of the FDA Antacid Advisory Committee's recommendation that the word "pharmacist" be placed on certain product's labels as recommended sources of patient drug information along with the word "physician".[99] Since many states had attempted to use required warnings or cautions on labels as a basis for creating a new drug class in the past, the PA apparently felt that this was a dangerous recommendation, and posed a serious threat to its "anti" drug reclassification position. When the APhA filed its recommendations concerning the Advisory Committee's suggested labeling provisions, and included an argument that supported the creation of a new drug class as an alternative to placing expanded warnings on OTC drug products,[100] the PA attacked the APhA's suggestions and the Advisory Committee's recommendation

on the basis that these suggestions were simply a disguise for the old "druggist monopoly" proposals that had been soundly defeated in state level deliberations of the past.[101] The PA's statements called into question the capability of pharmacists to function as drug advisors to patients[102] and suggested that the proposal was not only an ill advised development for the PA, but it was also detrimental to pharmacists.[103] The PA stated that, "The registered pharmacist...like every merchant, must take full advantage of his non-professional personnel and modern self-service merchandising techniques in order to survive...."[104] The PA also attacked this most recent proposal on the basis that it was a denial to the consumer of his "right to purchase such products where both his convenience and his pocketbook would best be served."[105] The end result of this latest exposure of the concept at the federal level was the FDA Commissioner's statement that reflected the PA's point of view in depicting the proposal as being primarily one of economic import and not one that should hinder the OTC Advisory Review Panels' work.[106]

The PA was extremely helpful in supplying background information that clearly depicted the broad spectrum of opposition to the drug reclassification proposals within those groups who viewed the concept

as being economically detrimental. The opposition generated at the federal level to the 1973 APhA proposal came from wholesalers who serviced the non-pharmacy retailer, other associations representing manufacturers and distributors of OTC products, and the National Association of Food Chains, all of which characterized the proposal as being needlessly monopolistic. Even the AFL-CIO Community Services Department submitted a statement that indicated opposition to the change in federal regulations. The central theme of this statement reflected concern that the APhA proposal would result in the control of all OTC drug sales by pharmacists.

Similar opposition has been generated at the state level when drug reclassification is considered by state legislators. For example, the AFL-CIO and its American Federation of State, County, and Municipal Employees, filed in opposition to a 1975 Massachusetts' Bill that would have provided pharmacist's control over the sale of some OTC drugs. This effort was characterized by the Union as being an economically based effort and one that would deprive the public of being able to purchase these products from general merchants at a reasonable price. This argument is repeatedly expressed by such opponents whenever the concept of restrictive OTC legislation is discussed at the state level.

National Association of Chain Drug Stores (NACDS)

No great deal of insight into the NACDS position on drug reclassification resulted from discussions with their personnel, except for the fact that the concept was not given a very high priority by the association. The NACDS has no official position on drug reclassification. However, the contacted spokesman for the organization, appeared to be concerned that if a new class of drugs was created, the government might require that patients first visit their pharmacy before contacting a physician. This, the NACDS representative stated, might increase the overall drug costs to the patient.[107] Other issues that were deemed more important for the NACDS to become involved in at present, were the utilization of technicians and prescription price advertising.

National Pharmaceutical Council (NPC)

The NPC has assumed no official position on the drug reclassification concept.[108] The pharmaceutical manufacturers that the NPC represents have similarly not developed any official position on this concept. Therefore, it could be expected that the NPC would mirror this situation. A most valuable result of the discussions held with NPC representatives, was the information they provided on the Canadian system for drug reclassification. This material is provided

along with a short discussion, in the Appendix, Figure XXI.

Summary of Drug Industry Related Associations' Perspectives

The PMA has not taken an active role in opposing the reclassification concepts of the APhA. The survey of these companies conducted by this study, indicated that opposition might be expected to develop to any new reclassification effort by the pharmacy profession. The possibility that the new drug class might be associated with additional government regulations and controls over the manufacturing industry persuaded them to adopt the viewpoint. The potential economic advantage offered by a new drug class (such as would be associated with the declassification of numerous legend products), apparently does not outweigh the risk associated with unknown government activities concerning the new drug class.

It is obvious that the most concerted effort at preventing drug reclassification has emanated from the ranks of the Proprietary Drug Manufacturers, the organization that apparently feels drug reclassification would produce economic hardship for its members. The PA has historically been opposed to any efforts by the pharmacy profession to place sales restrictions on the products they produce for OTC marketing. Although the

APhA recognized the possibility of re-establishing complete control over the sale of all drug proudcts in their 1964 proposal,[109] the PA and the drug manufacturers it represents, have continued to oppose reclassification as though this concession by pharmacy did not exist. The opposition from the PA could be expected to diminish somewhat with a more specific indication of the OTC drugs being proposed for restriction. This list would most certainly represent only a small number of OTC products.

The NACDS apparently did not desire to become involved in the drug reclassification controversy, while the NPC had no official position on the concept.

Consumer Groups

Three consumer groups were contacted during the study, The Health Research Group (HRG), The Consumer Federation of America (CFA), and The American Association of Retired Persons (AARP).

Consumer groups at the national level have not taken a position on drug reclassification. Since drug reclassification does involve definite implications for the consumer, an attempt was made to determine the awareness and the impressions of several consumer groups on the concept. As can be seen from Figures II and IV of the Appendix, the letters sent to the CFA and the AARP contained an outline for a basic drug

reclassification scheme. The CFA responded to the letter, while the AARP did not, even after repeated telephone inquiries. The HRG, contacted by telephone, was the only responding organization able to state that they were even aware of the concept. The CFA on the other hand, stated that they were unable to comment on the proposal and suggested that Dr. Sidney Wolfe of the HRG be contacted, as well as other individuals, for further impressions on the consumer impact of the proposal. Dr. Wolfe, in a telephone conversation,[110] indicated that he was aware of the concept and felt that if the proposal were properly constructed it could be of definite advantage to consumers.

The early drug reclassification proposals that reflected the traditional pharmacy opinion that pharmacists should control the sale of all drugs and drug products, would undoubtedly be viewed as blatantly "anti-consumer" given todays trend towards the placement of greater responsibility for health care matters in the hands of the public. However, the more recent proposals, especially those that would serve to declassify certain legend drugs to the new pharmacist restricted class, would appear to reflect a more harmonious position in regard to the consumer movement. In one recent state level discussion of drug reclassification, that which occurred in New York in

1974,[111] the Commissioner for the New York City Consumer Affairs Department voiced her approval of the third class of drugs concept, but indicated that she supported its development at the federal level rather than the state level. The California proposal to license pharmacists for a limited prescribing role was also hailed by its supporters as being of a definite advantage to consumers.[112] It was learned, however, that consumer groups have been actively involved in opposing state level restrictive OTC legislation in at least two cases, Colorado and Maine.[113]

Summary of Consumer Groups' Perspectives

The drug reclassification proposals of the APhA have not received as much attention from consumer groups as might be expected. It appears as though the pharmacy profession has not chosen to clearly explain its proposals concerning the new drug class to those who could offer the most effective support. In state level controversies surrounding proposals to restrict certain OTC products to pharmacy sales, consumer groups have adopted the position that this would place an economic burden and an unnecessary inconvenience on the consumer. Consumer groups have obviously not been kept informed by the pharmacy profession on the intent of national level reclassification proposals. These proposals should be viewed by consumers as possessing

significant benefits, but the pharmacy profession must first take the initiative to gain this support. Consumer input would be a valuable addition towards enhancing the drug reclassification effort's success.

Federal Level Legislators

The survey conducted by mail of the 41 Senators and Representatives, provided little useful information. The negligible response prohibits any further discussion about the information requested on the questionnaire. However, it is interesting to note that the vast majority of the legislators contacted did not even have the courtesy to respond to the inquiry in any fashion what-so-ever. The reluctance of legislators to involve themselves in matters where jurisdictional disputes between or among professions or associations exists is well known. This is one of the reasons that it took three years to pass the Durham-Humphrey Amendments in 1951. It also might explain in part the poor response to this survey. In an article published by the Journal of the NARD in 1963, Senator Humphrey advised the membership of the NARD that Congress would not allow itself to get entangled in another debate over drug reclassification like it did in the 1950's.[114] Humphrey indicated in the article, that before new legislation was sought by pharmacy, every effort should be made to resolve differences

within the profession and outside of the profession on the provisions of the proposal. In the same article, Senator Humphrey stated that a proposal such as drug reclassification should be presented before the proper Congressional committee, in this case the Senate Labor and Public Welfare Committee. This was an obvious admonishment of the APhA, that previously had attempted to air its proposal before Senator Humphrey's Subcommittee on Reorganization and International Organizations. During the course of events that surrounded the 1963-1964 proposals, the APhA enlisted the support of the recently retired Representative Aubrey Durham, who had assisted in gaining passage of the Durham-Humphrey Amendments in 1951. In an address before the 1964 APhA Convention, Congressman Durham stated that "Now is an appropriate time for us to give professional consideration to improvement in our drug laws as they affect the responsibility and the opportunity for the pharmacist to be of service."[115] Apparently the time was not as auspicious as Mr. Durham thought, for no activity emanated from the Congress to create a new drug class in 1964.

More recently, the APhA has provided testimony on the effect of promotion and advertising on the use of over-the-counter drug products before Senator Nelson's Select Subcommittee on Small Business.[116] In discussing

the impact of this testimony on the members of the Subcommittee with a staff member of that Subcommittee, it was revealed that the proposal simply did not generate much legislative interest or concern.[117] In addition to this, the staff member indicated that there existed an inherent conflict of interest with these proposals in that the pharmacist was expected to both recommend and sell the drug product. He viewed this as an extremely detrimental aspect to the proposal's gaining any degree of acceptance by the legislators.

Other Pharmacy Related Groups

Three groups were included in this cateogry, the members of the Study Commission on Pharmacy, the pharmacist members of the FDA's OTC Drug Advisory Panels, and the current officers of the American Association of Colleges of Pharmacy.

The Study Commission on Pharmacy

The Study Commission on Pharmacy, chaired by Dr. John S. Millis, recently published its findings on the future course of pharmacy education in the United States.[118] Since the Millis Commission was apprised of the drug reclassification concept in a meeting called by the FDA Commissioner in March of 1974, and since no mention of this concept was found in the published reports of the Commission, correspondence was initiated to determine how the members

of the Commission viewed the concept's implications for the future practice of pharmacy, as well as to provide some insight into the substance of the FDA-Commission meeting, (see the Appendix, Figure IX). Of the fifteen letters sent, responses were obtained from ten Study Commission members.

The meeting between the FDA Commissioner and the members of the Study Commission, appeared to leave most of the members of the Commission with the feeling that the FDA was not in favor of such a concept and that the politics of the matter, such as was involved in the conflict between organized pharmacy and the manufacturers of non-prescription drugs, was something the Commission not only was not charged to deal with but did not care to deal with at that time. One Commission member cited FDA Commissioner Schmidt's interpretation of the concept to the Commission as one based on economic motivation.

Most of those individuals who replied were generally in favor of the basic concept of establishing a new drug class to control the sale of drugs that might be harmful to patients if used incorrectly or indifferently. The majority of respondents also supported the role of pharmacists as drug consultants to patients.

Pharmacist Members of the FDA's OTC Drug Advisory Panels

Since the most recent upsurge in activity by the APhA involving drug reclassification came as a result of their filing on the proposed drug monograph for antacids,[119] it was deemed appropriate to survey all pharmacist members of the OTC Review Panels to determine their personal impressions of the new class of drugs concept, (see the Appendix, Figure VIII). The 19 pharmacist members of the 27 OTC Review Panels were asked to respond to the following questions:

1. Were you aware of this concept prior to receiving this correspondence?
2. (a.) Are you inclined to support or oppose this concept?
   (b.) Why do you feel this way?
3. Have you found any drugs that could be included in such a restricted class if one were available?
4. Do you feel that such a drug class should be developed before deciding on declassifying present legend items to non-prescription status?

Ten of the 19 panel members responded to the questions posed, however, one of these respondents felt that it would not be "prudent" to answer any questions based on her position as a member of an OTC Advisory Committee.

All nine of the panel members who agreed to answer the questions were aware of the concept of drug reclassification. Six of these respondents fully supported the concept as being necessary to provide

the patient with the information needed to make the correct choice on matters of therapeutics, while two of the respondents opposed the concept, one because of its "inevitable increase in drug costs to the public" and the poor track record of pharmacists in executing their professional role regarding prescription only drugs, and the other relying on voluntary efforts by pharmacists to effect change in the role of pharmacists. The final respondent equivocated somewhat in answering the 2nd question based on reservations as to whether pharmacists would adequately meet the responsibilities of the new class.

In response to whether or not they had identified any drugs that should be included in such a new drug class, five said that they had identified such items while the others either responded that they had not found any such drugs in their review, or did not address this question directly.

The final question had direct implications for these pharmacists' activities on the OTC Drug Review Panels. Four of the respondents replied that they thought such a drug class should be created before legend drugs are approved for declassification to non-prescription status, or before any non-prescription drugs are reclassified to legend status. One individual indicated that it was his impression that the

FDA was "unalterably opposed" to the concept and that the time lag for creating such a drug class, while it was a needed reform, would place it too far in the future for OTC Panels to with-hold their recommendations until such a class of drugs was created. The other responses did not directly address this question.

Officers of the American Association of Colleges of Pharmacy

Graduates of Colleges of Pharmacy for the past 15 to 20 years have been exposed to training programs that have reflected an ever increasing orientation concerning the actions and uses of medicinal agents. Since the individuals responsible for training pharmacists have undoubtedly exerted an effect on how their students view such a concept as drug reclassification, letters were sent to those pharmacy educators currently serving as American Association of Colleges of Pharmacy (AACP) officers in an attempt to determine their impressions about the concept, (see the Appendix, Figure I). The following questions were asked:

1. Prior to receiving this correspondence, were you aware of such a concept?
2. Do you support the basic concept of a new, intermediate class of non-prescription drugs, restricted to pharmacy sales only?
3. Do you feel AACP would support this concept and take an active role in seeking its adoption at the Federal legislative level?

Nine letters were mailed and responses were obtained from eight of the individuals. Of these nine, one individual indicated that he did not care to comment on the questionnaire. The remaining seven respondents all indicated that they were aware of the concept and six of the seven respondents indicated that such a drug class would receive their personal support if it involved the personal dispensing of the drug by the pharmacist along with professional consultation between the pharmacist and the patient on the use of the drug. One of the respondents felt that no need for the creation of such a drug class exists.

In response to the last question, all seven educators indicated that they did not feel the AACP would take an active role in seeking the creation of a new drug class through federal legislation. Numerous reasons were cited, but the most frequently mentioned was that this was a more proper role for the professional association of practitioners rather than that of the educators.

Summary of Pharmacy Related Groups' Perspectives

The Millis Commission was not involved in dealing with specific issues within the pharmacy profession and therefore was not able to provide any additional information on drug reclassification.

From the comments submitted by the pharmacist

members of the OTC Drug Review Panels, it was apparent that although a completely uniform supportive position for a new drug class did not exist throughout this group of pharmacists, that enough support for the concept existed to produce a much greater effect than has here-to-fore been the case within the scope of the OTC Advisory Panel's findings and recommendations.

The pharmacy educators expressed mixed sentiments about their feelings towards reclassification but generally were predisposed to supporting it.

Section II: Findings on State Level Drug Reclassification Activity

The survey that was conducted to determine the number of states controlling OTC drugs by limiting their sale to pharmacies, and to ascertain the extent of such reclassification oriented activity throughout the United States, generated the data depicted in Appendix Tables I and II. This data and other material obtained from the survey is discussed in the following material.

Exempt Narcotic Control Methods

The variety of methods in use by the states for controlling exempt narcotics becomes apparent from Table 14, on the following page.

Table 14

Methods of State Control for Exempt Narcotics

Method of Control	Number of States	Percentage
Prescription only	10	20%
Pharmacy Restricted OTC only	26	52%
Combination of Prescription and Pharmacy restricted OTC	14	28%
Total	50	100%

The combination of legend and OTC classifications for the exempt narcotics reported in 14 states was primarily associated with the placing of codeine containing exempt narcotic cough syrups into the legend class, while classifying all other exempt narcotics, such as the anti-diarrheal preparations with small amounts of narcotics, as non-legend, but pharmacy restricted products. This action apparently was associated with the high abuse potential of the cough syrups and the low abuse potential of the other narcotic containing preparations. The fact that these states continue to allow the narcotic containing anti-diarrheals to be sold as non-prescription items, indicates support for the pharmacist's role in responsibly controlling these types of products. The 10 states that controlled all OTC exempt narcotic preparations as prescription drugs have in effect eliminated the pharmacist's exercise of discretionary

authority over the use of these products. Two of the states that responded, South Carolina and Virginia, indicated that they were able to retain non-prescription status for the exempt narcotic cough syrups only by actively opposing their State Boards of Health, that wished to place prescription only status on these products.

Non-narcotic OTC Control Methods

The different approaches to OTC drug control methods in use by the various states are summarized in Table 15, below.

Table 15

Methods of State Control for Non-narcotic OTC's

Methods of State Control for Non-narcotic OTC's	Number of States	Percentage
1. Pharmacy Restriction present	21	42%
2. Pharmacy Restriction not present	29	58%
Total	50	100%

The responses shown in Table 15, indicate that pharmacists in 21 (42%) of the jurisdictions responding were permitted to limit the sale of certain OTC's, other than the exempt narcotics, to pharmacy sales. The OTC products most frequently mentioned as being restricted to pharmacy sales were: prophylactics (6 states);

insulin (4 states); phenobarbital containing OTC drugs (4 states); and certain drugs listed in the official drug compendiums, The United States Pharmacopeia (USP) and/or The National Formulary (NF), (4 states). The latter category of restricted products, such as exists in South Dakota and Wisconsin, stems from early pharmacy practice laws in which only non-USP or non-NF products (basically the proprietary or patent drug products) could be sold through outlets other than pharmacies. Drug products labeled as conforming to USP or NF specifications had known formulations and ingredients. They were not considered to be proprietary or patent drug products, the formulations or contents of which were generally considered to be known only to the manufacturer. These pharmacy restricted OTC products represent a strange combination. The insulin apparently is restricted to pharmacist sales because of its storage requirements or the role pharmacists play in assisting the diabetic patient, while the phenobarbital containing products are evidently restricted due to their abuse potential. Whether or not the control of prophylactic sales by pharmacists is more associated with public health matters than moral concerns is debatable, but this item was the most frequently mentioned of the products comprising this class. Only the State of Oregon, was able to

demonstrate the existence of a true "third class" of drugs. Such products as Contac^{R}, topical antibiotic preparations, and motion sickness remedies are restricted to pharmacist sales in Oregon. In a telephone conversation with the Oregon State Board of Pharmacy Secretary,[120] it was learned that when products with ingredients similar to Contac^{R} were first introduced on the market in the early 1950's, the deaths of two Oregon children were traced to ingestion of this type of medication. Similarly, all of the other OTC products restricted for sale by Oregon, are done so on the basis that they pose a significant threat to the public's health and safety and thus should be subject to additional controls. This argument has not been substantiated by other state legislatures in recent years.

Recent Reclassification Activities and Their Rationale

The extent of recent activity at the state level to restrict OTC products to sales in pharmacies was assessed. Eight states indicated that attempts to restrict certain OTC drugs to pharmacist or pharmacy sales were made during the past 5 years, but none of these states indicated success in these efforts. These states are listed in Table 16, on the following page, along with the rationale used to substantiate the need for such restrictions, if provided in the responses to

Table 16

States Associated with Recent OTC Drug Restriction Activity and Related Rationale

	States	Rationale
1.	Colorado	Label Warnings
2.	Georgia	Label Warnings
3.	Maine	Label Warnings
4.	Michigan	FDA OTC Drug Study
5.	Mississippi	Abuse
6.	North Dakota	Not provided
7.	Pennsylvania	Not provided
8.	Rhode Island	Not provided

the questionnaire. The most frequently mentioned rationale behind the restriction activities at the state level was toxicity associated with several products now on the market, eg.) sleeping aids. The presence of warnings for use on the labels of such products as cough syrups was also used as a basis for seeking the restriction of these drugs to pharmacist sales. Several respondents indicated that pressure from retail interests, eg.) grocers, and from consumer groups, eg.) American Association of Retired Persons, was responsible for the defeat of the proposals in their states. One State Board Secretary stated that opposition to the proposal from pharmacists also was a significant reason for the proposal's defeat. These responses tend to indicate that the most effective opposition to reclassification at the state level has emanated from groups able to convincingly argue that

restriction of these products would do little to benefit the public's health and safety, and it could result in significantly increasing the prices charged the consumer for these products.

Additional State Level Reclassification Oriented Activities

Pharmacists in the State of New York, have been active in promoting the concept of a new OTC drug class during the past 10-15 years, but their efforts have never been rewarded by the enactment of restrictive legislation. The New York State Pharmacy Association was successful in gaining public exposure for the idea when the Association's Secretary appeared before a nationally televised audience on a program hosted by Barbara Walters.[121] He emphasized during the program, that the drugs envisioned for comprising the new class were "...those drugs labeled with warnings and contra-indications by the federal government."[122] He substantiated the need for the new drug class by citing a study that indicated "...85% of the people didn't even bother to read the label," for these precautionary labeled products.[123] He inferred that the pharmacist's function would be to fully explain and interpret the labeled precautions to the patient on the drugs of the restricted class.

An alternative to passage of restrictive legislation,

that would serve to recognize the professional role capabilities of pharmacists, has been proposed by a pharmacy advisory committee to the California legislature.[124] This proposal would grant qualified pharmacists the professional privilege of prescribing a small number of products that are presently limited to the legend class by Federal law. Since Federal law states that legend drugs must be prescribed only by a "...practitioner licensed by law to administer such drug,"[125] a pharmacist duly licensed by the State for a limited prescribing role, could prescribe legend drugs without contravening any Federal law. Associated with this proposal was a fairly extensive list of drugs that pharmacists would be allowed to prescribe. They ranged from such products as paregoric for use as an anti-diarrheal, to Darvon^{R} for use as an analgesic. Other selected products that presently can be dispensed only on a prescription basis, would become available to the pharmacist for use in treating emergency conditions. Nitroglycerin for angina and epinephrine injection for anaphylactic reactions, were listed as candidates for this category. The implications associated with this concept for the revitalization of the pharmacist's professional role are extremely exciting. Whether this proposal will develop into a landmark endeavor or fade into obscurity remains to be seen.

Section III: Findings on Practitioner Perspectives Towards Drug Reclassification

Practitioner perspectives concerning drug reclassification, as well as the views of State Pharmacy Board and State Pharmacy Association Secretaries, were revealed through their responses to the extensive questionnaire outlined previously in Chapter II, Section III. The information provided by the secretaries' responses is important due to the pivotal positions these individuals occupy within the profession. Their responses were compared with those of the practitioners to determine the extent of agreement that existed across the three groups.

Representativeness of Practitioner Sample

The practitioner sample obtained from the NABP's computer file appears to closely approximate the pharmacist population characteristics as reported in a 1969 HEW study concerning pharmacy manpower in the United States. Table 17, on the following page, summarizes key characteristics of the sampled pharmacists responding to the questionnaire and compares them to the population characteristics reported in the HEW study.

The observed differences between the characteristics of survey respondents and the population of pharmacists reported in the HEW study, were anticipated due

Table 17

Comparison of Selected Characteristics for the Responding Sampled Practitioners to the Population of Pharmacists in the United States

Characteristics	Practitioner Sample N=230	Practitioner* Population N=121,482
1. Median age in years	45.6	45.1
2. Percent holding pharmacy degree	84%	57%
3. Percent holding non-pharmacy degrees	16%	—
4. Employment status**		
a. Independent retail owner	31%	38%
b. Independent retail staff	24%	28%
c. Chain pharmacy	20%	14%
d. Hospital pharmacy	12%	8%
e. Other	13%	12%
5. Geographic location		
a. Northeast region	24%	29%
b. North central	25%	29%
c. South	27%	27%
d. West	23%	15%
e. U.S. territories	1%	—

*As reported in Pharmacy Manpower-United States, 1966 (National Center for Health Statistics, Series 14, Number 2, HEW, August, 1969).
**Sample adjusted to exclude retired pharmacists to permit comparison with the population of practitioners reported in HEW study. The survey respondents consisted of 12% (27/230) retired pharmacists.

to the 10 year time lapse between the two studies. The percentage of pharmacists holding 4 or 5 year pharmacy degrees has increased dramatically from the 1966 figures,

if the respondents to this survey are considered to be representative of the current population of pharmacists. The changes that are evident from the statistics regarding employment status, are consistent with generally acknowledged trends, eg.) a shift away from independent retail pharmacy practice to the chain pharmacy and hospital pharmacy settings.

The findings extracted from the questionnaire are presented as they relate to addressing each of the seven remaining research questions.

Research Question 3: Do pharmacists favor the basic concept of creating a restricted OTC drug class?

This question was posed directly to the sampled pharmacists and secretaries as seen by question 8 of the instrument. The summary data generated by the responses to this question are depicted in Table 18, below.

Table 18

Favor Expressed for Drug Reclassification by Practitioners (P), State Pharmacy Board Secretaries (SPBS), and State Pharmacy Association Secretaries (SPAS)

	P		SPBS		SPAS	
Favor	No.	(%)	No.	(%)	No.	(%)
Yes	186	(81)	35	(76)	28	(90)
No	19	(8)	1	(2)	1	(3)
Undecided	24	(10)	10	(22)	2	(7)
No response	1	(1)	0	(0)	0	(0)
Total	230	100	46	100	31	100

The results tend to indicate that a high degree of support for the creation of a pharmacy restricted OTC drug class exists among all three groups studied. The responding practitioners favored the creation of a new restricted drug class in 81% of the cases, while 76% of the State Pharmacy Board Secretaries (SPBS) and 90% of the State Pharmacy Association Secretaries (SPAS) favored such a drug class. This is a rather surprising development since the concept has been in existence for some 25 years, with no appreciable effort being undertaken by the pharmacy profession to secure such a drug class. An explanation for this strange situation is provided by the responses to another question of the instrument, number 7, that inquired as to the awareness of the basic concept by the pharmacists or secretaries. See Table 19, below.

Table 19

Awareness Shown for the Drug Reclassification Concept by Practitioners (P), State Pharmacy Board Secretaries (SPBS), and State Pharmacy Association Secretaries (SPAS)

Aware of Concept	P		SPBS		SPAS	
	No.	(%)	No.	(%)	No.	(%)
Yes	107	(47)	40	(87)	28	(90)
No	121	(53)	6	(13)	3	(10)
No Response	2	(0)	0	(0)	0	(0)
Total	230	100	46	100	31	100

Only 47% of the responding practitioners indicated that they were aware of this concept, while 87% and 90% of the SPBS and SPAS respondents were aware of the drug reclassification concept. In light of the 25 year history of drug reclassification, it is amazing that less than half of the practitioners were even aware of a concept that has such enormous implications for the profession. It also becomes apparent from these figures that the individuals occupying the positions of power and authority in the pharmacy profession are more aware of the concept. It is clear that pharmacists favor the basic concept of creating a restricted OTC drug class.

Research Question 4: Do pharmacists support the direct, mandatory involvement of the pharmacist with the patient regarding the dispensing of OTC restricted drugs?

A cluster of three questions in the instrument, numbers 10, 11, and 12, was utilized to answer this research question.

Extent of Pharmacist Control

The ease of public accessibility to the drugs of the new class within the pharmacy is a direct measure of the role that pharmacists are willing to play in aiding patients to select the proper medication. Table 20, on the following page, shows the extent of public accessibility the respondents would permit in

relation to the drugs of the new class.

Table 20

Extent of Public Accessibility to be Permitted for Drugs of the New Class as Indicated by Practitioners (P), State Pharmacy Board Secretaries (SPBS), and State Pharmacy Association Secretaries (SPAS)

	P		SPBS		SPAS	
Public Accessibility	No.	(%)	No.	(%)	No.	(%)
Direct, no difference	1	(0)	0	(0)	0	(0)
Direct, some difference	73	(32)	10	(22)	4	(13)
Only through pharmacists	134	(58)	34	(74)	25	(81)
No response	22	(10)	2	(4)	2	(6)
Total	230	100	46	100	31	100

Of the practitioners sampled, 58% indicated that the drugs of the new class should only be available by asking the pharmacist. The SPBS response in favor of restricting the drugs from public accessibility was 74% while the responding SPAS group was 81% in favor of this restriction. These results tend to indicate that the practitioners did not agree on the necessity of requiring the pharmacist to aid the patient in selecting the proper drug product. The responses of the secretaries, however, indicate a relatively greater concern for limiting the public's accessibility to such restricted drugs. It is reasonable to assume that a drug reclassification proposal must include the

mandatory involvement of the pharmacist in the selection of the restricted drug product. If this is not the case, one would be arguing that the simple fact of selling a drug in a pharmacy provides greater public safety than selling the drug in some other retail outlet. This argument has been shown to be unacceptable to numerous state legislatures. Mandatory pharmacist contact in the selection of the proper restricted OTC product is the very cornerstone for any viable reclassification concept. The secretaries appear to understand this fact more frequently than do the practitioners. This might be related to the secretaries' greater awareness to the concept and similarly to the problems that previous reclassification attempts have encountered.

Professional Consultation by Pharmacists

Closely aligned with mandating the pharmacist's involvement in the selection of the restricted drug product is his role as professional consultant to the patient. The pharmacist would be expected to ascertain any unique characteristics of the patient as regards his condition that might affect the selection of the proper drug product for the patient's needs. Question 11 of the instrument inquired as to whether or not such consultation should be of a mandatory or optional nature. The results are shown in Table 21, on the following page.

Table 21

Support Shown for Mandatory Pharmacist-Patient Consultation on Drugs of the New Class by Practitioners (P), State Pharmacy Board Secretaries (SPBS), and State Pharmacy Association Secretaries (SPAS)

Support for Mandatory Consultation	P		SPBS		SPAS	
	No.	(%)	No.	(%)	No.	(%)
Yes	110	(48)	35	(76)	22	(71)
No	98	(42.5)	9	(20)	8	(26)
No response	22	(9.5)	2	(4)	1	(3)
Total	230	100	46	100	31	100

The practitioner sample selected the mandatory choice in 48% of the cases while this percentage increased to 76% for the SPBS respondents and 71% for the SPAS group. These figures tend to indicate that the secretaries recognized the importance of mandating such professional consultation on the part of pharmacists if drug reclassification is to become a fact. Practitioners, not being aware of the concept in over half of the reported cases, are evidently not as aware of the need to require this mandatory service on the part of the pharmacist to meet the criticism of opponents.

Record Keeping Requirements

The final aspect of reclassification that was measured to assist in determining the extent of mandatory pharmacist involvement by practitioners was that of record keeping. An essential part of the pharmacist's contribution to the better use of drugs by

patients is the maintenance of patient drug profiles. Such record keeping systems can vary greatly in content but they all are directed at increasing the patient's safety in the use of drugs. The mandatory maintenance of a patient profile for the drugs belonging to the restricted class would provide an effective method for the pharmacist to contribute to the patient's safe use of these products. The acceptance of the reclassification concept by governmental bodies would similarly be enhanced if such record keeping requirements were incorporated into a reclassification proposal. Question 12 of the instrument examined this possible component to a new drug class proposal and the results, shown in Table 22 below, tend to indicate that once again practitioners are not in total agreement on an extremely important part of the concept.

Table 22

Extent of Record Keeping for Drugs of the New Class Indicated by Responding Practitioners (P), State Pharmacy Board Secretaries (SPBS), and State Pharmacy Association Secretaries (SPAS)

Extent of Record Keeping Supported	P		SPBS		SPAS	
	No.	(%)	No.	(%)	No.	(%)
Same as Legend	20	(9)	4	(9)	4	(13)
Some required	95	(41)	26	(56.5)	19	(61)
Optional	95	(41)	15	(32.5)	7	(23)
No response	20	(9)	1	(2)	1	(3)
Total	230	100	46	100	31	100

Only 50% of the responding practitioners felt that some form of record keeping should be required, while this figure increased to 66% in the case of the SPBS and to 74% of the SPAS. It is the researcher's conception that mandatory requirements for pharmacist involvement in the sale and handling of restricted drugs are directly related to the potential for acceptance of the concept by legislators or other government representatives. As the number or quality of mandatory requirements diminishes on the part of pharmacists, the chances of acceptance for the concept also decreases. The SPBS and SPAS apparently recognize this situation more readily than do the practitioners. The results obtained from these three questions indicate that on the average approximately half of the sampled practitioners selected the option associated with mandating the pharmacist's interaction with the patient concerning the drugs of the new class. The secretaries on the other hand, selected these restrictive provisions approximately 75% of the time on the average. Practitioners must be made aware of the necessity to support their involvement with these drugs if the concept is ever to be transformed into a reality.

Research Question 5: Do pharmacists feel that their positions on reclassification are similar to those of other pharmacists on the Issue?

Question 15 of the instrument posed this question directly to the pharmacists and secretaries. The results are shown in Table 23, below.

Table 23

Feelings Expressed by Responding Practitioners (P), State Pharmacy Board Secretaries (SPBS), and State Pharmacy Association Secretaries (SPAS) that Other Pharmacists Would Support their Reclassification Proposal

Feeling of Support	P		SPBS		SPAS	
	No.	(%)	No.	(%)	No.	(%)
Yes	177	(77)	37	(80.4)	27	(87)
No	7	(3)	2	(4.4)	1	(3)
Undecided	41	(18)	6	(13.0)	3	(10)
No response	5	(2)	1	(2.2)	0	(0)
Total	230	100	46	100	31	100

This question was extremely important to determine the extent of consensus that existed within the professional community on reclassification. Fully 77% of the responding practitioners indicated that they felt other pharmacists would support the reclassification proposal. The SPBS and SPAS respondents stated that in 80% and 87% of the cases respectively that pharmacists would support the proposal. Question 15 was asked in such a fashion as to determine whether or not the respondents felt that other pharmacists agreed with their proposal, eg.) the additional aspects selected by their responses on the extent of public accessibility, the requirement

for pharmacist-patient consultation, and the record keeping provision for drugs of the new class. It appears as though the practitioners believe that their feelings on drug reclassification are upheld by other practitioners more than is actually the case. The secretaries also responded to this question in such a way as to indicate a rather inflated estimate of practitioner support for the mandatory inclusion of the pharmacist in the sales transaction of restricted drugs to patients. These results suggest that all three groups of respondents feel that agreement exists within the pharmacy profession on the basic components for a drug reclassification proposal. However, as the information depicted in Tables 21-23 tend to indicate, differences of opinion do exist within the sampled groups on what should constitute a proposal for a new drug class.

Research Question 6: Do pharmacists feel the national pharmacy associations would support their proposals?

The literature review conducted to give direction to this research effort revealed a history of divisiveness between the National Association of Retail Druggists (NARD) and the American Pharmaceutical Association (APhA) on the drug reclassification concept. By asking sampled practitioners and secretaries to indicate whether or not they felt the national pharmacy

associations would support their conception of what should constitute a drug reclassification proposal, the respondents revealed the extent to which they believed their views corresponded with those of the NARD, the APhA, and the American Society of Hospital Pharmacists (ASHP); see Table 24, below, for the summarized responses.

Table 24

APhA, NARD, and ASHP Support for Drug Reclassification as Perceived by Responding Practitioners (P), State Pharmacy Board Secretaries (SPBS), and State Pharmacy Association Secretaries (SPAS)

/a

Organizations	P (N=230)	SPBS (N=46)	SPAS (N=31)
APhA	69%	76%	87%
NARD	65%	57%	81%
ASHP	38%	57%	58%

/a See the Appendix, Table VI

Practitioners saw virtually no difference between the positions that the NARD and the APhA would assume towards their reclassification proposal. NARD was believed to be supportive of the practitioners' viewpoint in 65% of the cases while APhA was felt to support the practitioners' proposal in 69% of the time. State Board Secretaries indicated that the NARD would support their proposals in 57% of the cases and the APhA in 76% of the cases. This evidently was a recognition

by the State Board Secretaries of the previous negative stance of the NARD on the drug reclassification issue. State Association Secretaries felt that the NARD would support their proposal 81% of the time with the APhA supporting it 87%. Only the State Board Secretaries appear to have felt that any difference in these associations' positions would exist. The ASHP was not felt to be supportive of the practitioners' proposals as only 38% of the responding practitioners felt that ASHP would support their concept. This figure rose to 57% for the SPBS and 58% for the SPAS group. Pharmacists apparently have reached the conclusion that the NARD and the APhA would not be far apart on their positions of support for reclassification.

Research Question 7: Do pharmacists view reclassification as being motivated primarily by economics or primarily by professionally oriented desires?

Whether or not pharmacists view the drug reclassification concept as primarily an economically motivated attempt to secure lost sales revenue, or as a professionally motivated effort to regain lost professional stature or role functions, holds important implications for the concept's acceptance by the public and by government leaders. Since professional and economic motivation are interdependent to a great extent,[126]

the problem posed by research question 7 was examined on the basis of a series of questions designed to explore the spectrum of motivations that exists between the professional and economic extremes. For ease in presenting and discussing the findings produced by these questions, numbers 17-28 of the questionnaire, the five response categories of Strongly Agree, Agree, Neutral, Disagree, and Strongly Disagree, were combined in such a fashion as to produce three response categories. Strongly Agree and Agree formed one response category, while Disagree and Strongly Disagree answers formed a second response category. Neutral responses will be discussed only if the number of respondents selecting this answer is large in comparison to the other two response categories. The raw data collected from these questions are represented in Appendix Table III.

Economic Motivation:

Very little agreement was elicited from the pharmacists in support of economics as being the primary motivating force behind drug reclassification. Only 27% (63/230) of the responding practitioners agreed that economics was the primary motivating factor behind drug reclassification, while 22% (10/46) of the responding SPBS sample and only 3% (1/31) of the SPAS sample agreed that economics played a primary role in

developing the drug reclassification concept. These results, provided by the answers to question 18 of the instrument, may be a true indication of the respondents' feelings or they might simply represent the antipathy that professionals generate when their practice is discussed in economic terms. Several other questions were designed to further explore the economic side of the motivation spectrum. The desirability of seeking third party coverage for reimbursement of the pharmacist's services was agreed to by 44% (101/230) of the practitioners, 65% (30/46) of the SPBS respondents and 74% (23/31) of the SPAS sample. Pharmacists have traditionally been opposed to this type of reimbursement for their services, but apparently such extensive opposition is not characteristic of the sampled practitioners nor of the Secretaries concerning the new class drugs. Approximately one-third (86/230) of the pharmacists responding to this question, number 23 of the survey, disagreed with the propriety of seeking third party coverage. An additional question, number 24 of the instrument, queried the practitioners on whether or not they believed pharmacists would be reimbursed for all their expenses associated with the handling of such newly restricted drugs, eg.) professional consultation, record keeping provisions, etc. Approximately

one-half (128/230) of the practitioners responded that they felt recompensation would be adequate to meet their expenditures, while only 15% (35/230) of the practitioners responding felt that these expenses would not be recovered. Association and Board Secretaries mirrored the practitioners' sentiments on this matter. Apparently, most of the sampled pharmacists feel that patients would be willing to pay for services provided by the pharmacist in order to obtain the drugs of the new class.

Economic-Professional Motivation

Nearer the middle of the economic-professional motivation spectrum were two questions associated with clearly discernable economic as well as professional considerations. One of the questions, number 22, inquired as to the perceived impact potential malpractice suits might have on the pharmacists' willingness to perform the professional duties associated with the drugs of the new class. Only 24% (57/230) of the responding practitioners and even smaller percentages of both groups of Secretaries, agreed that the potential liability associated with the sale of the restricted drugs might prevent pharmacists from counselling patients. The threat of additional malpractice liability does not appear to be an extremely important aspect of reclassification in the minds of most

responding pharmacists. The effect that the new class of drugs might have on redistributing the pharmacists' time towards more patient contact and away from his traditional source of income, the drug product, was examined by question 19 of the questionnaire. More than three-fourths (178/230) of the responding pharmacists agreed that the pharmacist would be required to spend more of his time with the patient if the new class of drugs was created. Again this figure was similar to that found with the SPBS and SPAS respondents. The respondents are evidently committed to devoting a greater part of their time to patient oriented efforts if the new drug class is created.

Professional Aspects

Two questions from this set of twelve, inquired as to agreement within the practitioner ranks on the existence of non-prescription products and prescription products that should or could be included in the new drug class. Question 26, concerned with the presence of such misclassified OTC drugs, was answered by all three groups with extensive agreement that pharmacist sale restrictions were needed for some current OTC products. This was agreed to by 78% (179/230) of the practitioners sampled, 83% (38/46) of the SPBS sample, and 93% (29/31) of the SPAS respondents. The history of OTC restriction legislation, recounted in this

study's introduction, revealed the numerous attempts to limit the sale of certain non-prescription products to pharmacies; apparently this feeling still prevails. The existence of prescription products that could be placed in the new drug class, question 27 of the instrument, was generally agreed to by all three groups. Practitioner agreement was expressed in 78% (179/230) of the cases, while the Secretaries indicated agreement in 61% (28/46) of the SPBS and 84% (26/31) of the SPAS samples. This indicates that these pharmacists are not satisfied that the present drug classification system serves the purpose of adequately protecting the public safety and welfare. It is this basic dissatisfaction with the present system of classifying drugs that must serve as the stimulus for any professionally motivated drug reclassification oriented activity.

The traditional role of the pharmacist, that of compounding and dispensing prescriptions, has been greatly altered by the course of events as was depicted in the introductory material to this thesis. Question 17 of the survey asked the pharmacists whether or not they agreed that a need existed for pharmacists to expand their activities beyond these traditional role functions. The practitioners agreed that such a need existed in 83% (192/230) of the responding cases, while the Secretaries were even more

emphatic in their agreement that role function changes were a necessity for pharmacists. The impact that drug reclassification could exert on the professional role of pharmacists is a fact that most pharmacists appear to recognize by their overall acceptance of this concept. Since a basic tenet of this reclassification proposal is that the pharmacists' knowledge and expertise could permit the safe use of the restricted drugs in such a fashion as to allow sales without a prescription, the question of the pharmacists' perceived capability to meet the professional demands of the new drug class needed to be addressed. In response to question 20 of the survey, the responding practitioners as well as the Secretaries, indicated that they felt pharmacists possessed the knowledge to meet the professional demands of the new drug class. Fully 89% (204/230) of the practitioners, 87% (40/46) of the SPBS, and 96% (30/31) of the SPAS agreed that the pharmacists' knowledge was adequate in this regard. It is apparent that the sampled pharmacists do feel capable of counselling the patients on the selection and use of the restricted drug products. A closely related aspect was posed in question 25 of the instrument. It inquired as to whether or not specialized training should be required for pharmacists on the drugs composing the restricted class. A surprising

58% (135/230) of the practitioners sampled indicated that they agreed with the need for this requirement. The Secretaries responded in a similar fashion. It becomes clearly evident from these results, that the majority of pharmacists responding to the questionnaire felt strongly enough about establishing a new drug class that they would be willing to support a mandatory training requirement in conjunction with the creation of a new drug class. The sampled pharmacists seem to be secure in their knowledge and expertise and a specialized training requirement does not appear to represent a threat to their professional autonomy. Nearing the end of the professional side of the spectrum, a question was posed that dealt with the pharmacists' perception of the patients' receptivity to his advice on the drugs of the new class. The results obtained from this question, number 21 of the instrument, seemed to indicate that pharmacists and Secretaries alike visualize no problem in gaining the patients' acceptance of the pharmacist as a medication advisor and counsellor. Practitioners agreed in 77% (176/230) of the cases, SPBS respondents in 81% (37/46) of the cases, and SPAS respondents in 84% (26/31) of the cases, that patients would follow the pharmacists' advice. The responding pharmacists appear to support their role of medication counsellor to the patient and

believe that the patient will be receptive to the advice offered. A final question was asked that directly addressed the extent of professional motivation believed to be involved in the formulation of the reclassification concept. Question 28 of the instrument asked the practitioners and Secretaries to indicate the extent of their agreement on this matter. Approximately two-thirds (154/230) of the practitioners and SPBS respondents (31/46) agreed that professional concern by pharmacists was the primary motivating force, while 81% (25/31) of the SPAS respondents indicated similar sentiments. The fact that one-third (72/230) of the practitioner sample either did not agree or were neutral towards this question reveals the interdependence of economic and professional factors. Economics can never be totally divorced from the professional dimension. This fact has served as the basis for much of the criticism accorded drug reclassification from outside the ranks of the pharmacy profession. However, the fact that a majority of the sampled pharmacists indicated a willingness to accept the increased professional responsibilities associated with a new restricted drug class, should do much to counter the "economic monopolist" argument of the opposition.

Research Question 8: How important is drug reclassification to pharmacists when compared to other issues that are currently affecting the profession?

To address this research question, 7 other issues besides drug reclassification that currently confront the pharmacy profession were selected for comparison purposes. The practitioners were asked to indicate the positions, eg.) Strongly Support, Support, Neutral, Opposed, Strongly Opposed, they felt national pharmacy associations should assume towards the issues enumerated in questions 29-36 of the instrument. To facilitate the examination of the results produced by these questions, the five response categories were collapsed to form three categories. Strongly Support was combined with Support, Neutral remained the same, and Oppose was combined with Strongly Opposed.

The pharmacists were then asked to indicate their feelings on the importance, eg.) Very Important, Important, Not Important, of these 8 issues to the pharmacy profession in questions 37-44 of the questionnaire. Again, to facilitate the presentation and analysis of the responses, the Very Important and Important response categories were combined to form one category while the Not Important category was allowed to remain the same.

The raw data obtained from the responses to these

two sets of questions are represented, respectively, in Appendix Tables IV and V. The first set of 8 questions concerning the positions that national pharmacy associations should assume on the issues produced the results summarized in Table 25, below.

Table 25

Percentage of Responding Practitioners (P), State Pharmacy Board Secretaries (SPBS), and State Pharmacy Association Secretaries (SPAS) Desiring Support or Opposition by National Pharmacy Associations to Each of the Issues

Issue	Position	Percentage of Respondents Selecting the Position		
		P (N=230)	SPBS (N=46)	SPAS (N=31)
1. Continuing education	Support	69%	61%	42%
2. Mailorder prescriptions	Oppose	87%	77%	90%
3. Pharmacy technicians	Support	42%	26%	26%
4. Prescription price advertising	Oppose	72%	59%	71%
5. Pharmacy Ownership by pharmacist	Support	76%	53%	71%
6. Drug product selection	Support	75%	63%	93%
7. Creation of new drug class	Support	84%	87%	90%
8. Clinical pharmacy	Support	63%	76%	81%

It can be seen from these figures that only two issues generated a response of over 80% in either the support or the oppose categories for the practitioners, support

for the creation of a new drug class and opposition to mailorder prescriptions. The responding Secretaries indicated similar sentiments although for the Association Secretaries, drug product selection and clinical pharmacy were two additional issues that received support ratings in over 80% of the responding cases.

The second set of questions concerning the importance of the issues to the pharmacy profession produced the results indicated in Table 26, below.

Table 26

Percentage of Responding Practitioners (P), State Pharmacy Board Secretaries (SPBS), and State Pharmacy Association Secretaries (SPAS) that Felt the Issue was of Importance to the Pharmacy Profession

Issue	P (N=230)	SPBS (N=46)	SPAS (N=31)
1. Continuing education	81%	87%	81%
2. Mailorder prescriptions	62%	87%	87%
3. Pharmacy technicians	78%	91%	81%
4. Prescription price advertising	68%	78%	74%
5. Pharmacy ownership by pharmacist	80%	71%	91%
6. Drug product selection	88%	89%	97%
7. Creation of new drug class	87%	92%	97%
8. Clinical pharmacy	84%	85%	93%

The relatively low order of importance placed on prescription price advertising and mailorder prescriptions

by the responding practitioners is intriguing when compared to the effort being expended on these issues by the professional associations of pharmacy. These two issues received the practitioners' most frequent suggested opposition rating (see Table 25), but also received their lowest importance rating. Drug reclassification, however, received high ratings in both the Support and the Important categories indicating that it deserves a good deal more effort expenditure from our national pharmacy associations than has been the case in recent years. For a concept that has enjoyed such a low profile over the past decade, drug reclassification received surprisingly high marks from practitioners and Secretaries alike.

Research Question 9: Is membership in the professional associations independent from the positions assumed by pharmacists on drug reclassification?

Pharmacy association membership and its relationship to:

1. Awareness of the reclassification concept,
2. Position on the reclassification concept,
3. Provisions of the reclassification concept:
   a. Extent of public access to drugs of the new class,
   b. Mandatory/optional consultation between pharmacist and patient,
   c. Mandatory/optional record keeping requirements,
4. Economic motivation behind reclassification,
5. Professional motivation behind reclassification,

6. Support the national pharmacy associations should give drug reclassification,
7. Importance of drug reclassification to the pharmacy profession,

was tested utilizing the Chi-square test statistic and the methods described in Chapter II. After applying these procedures, the only significant relationship at the p=.05 level of significance between the respondents' association membership profile and the above points that could be demonstrated was for awareness to the basic concept. Association members' awareness of the concept, question 7 of the instrument, produced results that differed significantly from the awareness by non-association members at the p=.001 level of significance. Table 27, below, provides the results to question 7 organized by association membership and the associated Chi-square statistic.

Table 27

Number of Practitioner Respondents Indicating Awareness or Non-Awareness of the Drug Reclassification Concept, Organized by Association Membership or Non-Association Membership

Aware of Concept	Non-Ass'n Members	Ass'n Members	Totals
Yes	37	70	107
No	70	47	117
Totals	107	117	224

$X^2 = 14$, degrees of freedom = 1, N = 224, p = .001

No significant difference in awareness of the concept between the members of the NARD or the APhA could be detected. It appears as though the national associations may have had an impact on keeping their members aware of the drug reclassification concept, but the opposing positions of these associations on drug reclassification apparently are not shared by the members of the associations, or for that matter, by non-members of the associations. The fact that no other significant relationship between association membership or non-membership and such important aspects as those enumerated under Research Question 9, numbers "2." through "7." on the preceding pages, seems to indicate that there is no real difference in the way these practitioners view reclassification when considered in terms of their association membership profiles.* This finding may have important implications for the future course of action by the NARD and the APhA regarding the resolution of their past differences on the drug reclassification issue.

*An unanticipated extensive overlap in association membership of the practitioner respondents is depicted in Table VII of the Appendix.

FOOTNOTES

[1]"The Durham-Humphrey Fight," Drug and Cosmetic Industry, Vol. 58, August, 1951, p. 118.

[2]"APhA and NARD Governing Bodies Act on Mutual Problems," Journal of the American Pharmaceutical Association (JAPhA), January, 1949, p. 39.

[3]Eric W. Martin, "Editorials," JAPhA, 18:6, June, 1957, pp. 356-357.

[4]Ibid.

[5]"APhA Urges 3rd Class of Drugs," APhA Newsletter, No. 19, September 28, 1963, p. 1.

[6]Martin, p. 357.

[7]Robert P. Fischelis, Testimony on the Drug Industry Antitrust Act, S. 1552, 87th Congress, 1st Session, December 12, 1962, p. 2625.

[8]Ibid., p. 2626.

[9]Wilbur J. Cohen, Letter to William S. Apple of the APhA, on November 13, 1963, as reprinted in the APhA Newsletter, No. 23, November 23, 1963, p. 2.

[10]"APhA Urges 3rd Class...," pp. 1-4.

[11]Ibid.

[12]"Three Drugs Switched to OTC," JAPhA, 20:1, January, 1959, p. 35.

[13]"APhA Urges 3rd Class...," p. 2.

[14]William S. Apple, "Drug Safety Hysteria," JAPhA, NS4:5, May, 1964, p. 212.

[15]Ibid., p. 214.

[16]Thurman Miller, "Reclassification—Then and Now," address before the Midwinter Meeting of the Indiana Pharmaceutical Association, January 21, 1968.

[17]"Report by the Committee on Social and Economic Relations," JAPhA, NS7:6, June, 1967, p. 308.

[18]Dr. Richard Penna, Testimony before the Subcommittee on Monopoly, 92nd Congress, 1st session, Advertising of Proprietary Medicines: Part 1, May 25, 1971, p. 113.

[19]Ibid.

[20]"RxMan's Role as OTC Advisor Unclear," American Druggist Merchandising, December 1, 1973, p. 20.

[21]Carl Roberts, "Comments and Request for Oral Hearing of the American Pharmaceutical Association on 'Tentative Final Order for Antacid Products' and 'General Conditions for OTC Drugs'," December 12, 1973, p. 6.

[22]"Comments of the American Pharmaceutical Association on Proposal Establishing a Monograph for OTC Antacid Products," presented by the APhA to the FDA, June 6, 1973, p. 7.

[23]Ibid.

[24]Dr. Philip Lee's statements in APhA Pharmacy Weekly, 15:15, April 17, 1976, p. 3.

[25]Senator Hubert H. Humphrey, "Predatory Merchants Resort to Smoke-screens in Desperate Opposition to Q. S. Bill," Journal of the National Association of Retail Druggists (JNARD), 86:1, January 6, 1964, p. 42.

[26]"Objectives of the NARD for 1964," JNARD, 85:24, December 16, 1963, p. 4.

[27]Sidney Waller, "Much Additional Information Needed Before Action on Reclassification of Drugs," JNARD, 86:10, May 18, 1964, p. 36.

[28]Sidney Waller, "Reclassification of Medication," JNARD, 86:11, p. 26.

[29]Herman S. Waller and Sidney Waller, "The APhA Proposal for Reclassification of Drugs," JNARD, 86:19, October 5, 1964, p. 26.

[30]Willard B. Simmons, "Reclassification of Drugs Questionnaire," JNARD, 86:12, June 15, 1964, p. 14.

[31]Willard B. Simmons, "Reclassification of Drugs Questionnaire," JNARD, 86:17, September 7, 1964, p. 34.

[32]Personal correspondence with Willard B. Simmons, March 26, 1976.

[33]"Twelve Associations Participate in Drug Classification Meeting," JNARD, 86:9, May 4, 1964, p. 16.

[34]"Executive Committee Defers Final Action on Reclassification of Drugs," JNARD, 86:10, May 18, 1964, p. 23.

[35]Herman S. Waller and Sidney Waller, p. 27.

[36]Ibid.

[37]Ibid., p. 78.

[38]Ibid.

[39]"Special NARD Committee Issues Report on Reclassification of Medication," JNARD, 87:5, March 1, 1965, p. 20.

[40]William E. Woods, statements as reported in "Will NARD and APhA Join in Drive for 3rd Class of Drugs?", American Druggist Merchandising, December 1, 1973, p. 43.

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CHAPTER IV

SUMMARY, CONCLUSIONS, IMPLICATIONS, AND RECOMMENDATIONS

Summary

Organizational Perspectives on Drug Reclassification

Drug reclassification was found to have very few active organizational supporters outside the ranks of the profession of pharmacy and more specifically outside of the APhA. Although several non-pharmacy organizations expressed an interest in drug reclassification, the present situation is typified primarily by active opposition from such organizations as the Proprietary Association. The arguments used by the Proprietary Association against drug reclassification, that such a new drug class is not needed by the public, would result in an increase of drug prices to the public, and create a decrease in availability of the drugs to the public, have been effective in gaining the Food and Drug Administration's labeling of the concept as one of purely economic ramifications. The potential supporters of drug reclassification, such as Consumer groups or other non-pharmacy professional groups, have not been adequately apprised by the pharmacy associations and therefore their positions are

merely ones of interest as opposed to active support. Within the pharmacy profession itself, the bickering between the NARD and the APhA on the need for and the characteristics of a reclassification proposal has effectively stymied the development of the concept. The origin of this situation was shown to be attributable in great part to the ill feelings and rivalry that erupted between the two pharmaceutical associations during the debates surrounding the enactment of the Durham Humphrey Amendment in 1951. Since a harmonious situation between the NARD and the APhA on drug reclassification has yet to be established, it could be considered premature on the part of the APhA, for instance, to seek support for its proposals from those outside the pharmacy profession. This appears to be at least a partial explanation for the lack of support and indeed the lack of awareness of drug reclassification from non-pharmacy related organizations or associations.

State Level Drug Reclassification Activities

State level OTC drug restriction activities by pharmacists have met with much opposition. The "sales monopolist" argument propounded by the opponents to such drug restriction activities has effectively countered most all attempts at the state level. Several of the findings are extremely interesting,

however, and the possibility for gaining the restriction of certain selected OTC products to pharmacist sales at the state level appears to remain as a possible alternative to obtaining Federal legislative relief. The fact that 40 states allow certain exempt narcotic preparations to be sold only in pharmacies or by pharmacists represents such a positive step towards recognizing the pharmacists' potential role in the control of sale and the enhancement of use for these products. Similarly, since pharmacy sales restrictions for non-narcotic containing OTC products exist in 21 states, additional OTC drug restrictions may be acceptable to the state legislators under the proper circumstances, such as a distinct health hazard or drug safety problem from one or more of the OTC products in question. The need to identify an actual problem and not just a hypothetical case is evident in the results of the most recent state level attempts to restrict OTC drugs based on warnings found on their labels. The role of the pharmacist in calling the customer's attention to the warnings on the OTC drug labels has been considered to be an optional and not a mandatory component of the sales transaction for these products. This approach allows the sale of these items in stores other than pharmacies. The proposal by the pharmacy advisory

committee to the California legislature represents a new direction that state level drug reclassification activities might assume in the future. By licensing the pharmacist to practice in a limited prescribing role, the Durham-Humphrey Amendment could be effectively circumvented and certain legend items could be made more readily available to the public.

Practitioner Perspectives on Drug Reclassification Favor Towards Concept

The basic concept of drug reclassification, one that would provide the pharmacist with new recognition for his professional skills and knowledge as well as a new source of revenue, appears to be appealing to most pharmacists. The survey of practitioners found that fully 80% of the respondents expressed a favorable view of the basic concept. The responding State Pharmacy Board Secretaries (SPBS) and the State Pharmacy Association Secretaries (SPAS) indicated a similar level of support for the basic concept.

Mandatory Pharmacist Involvement

The basic proposal would provide the pharmacist with exclusive sales rights over a certain class of drugs. To this rudimentary proposal, additional provisions would most likely have to be incorporated to gain legislative approval. These additional provisions are envisioned as centering on the requirement

for the pharmacist to actively participate in the selection of the drug product with the patient or consumer. Three such possible provisions were listed in the questionnaire: limiting public accessibility to the drugs by requiring pharmacist contact (supported by 58% of the responding practitioners); mandatory consultation between the pharmacist and the patient (supported by 48% of the practitioner respondents); and mandatory record keeping (supported by 50% of the responding practitioner sample). The SPBS and SPAS respondents generally rated these additional provisions more favorably than did the practitioners. This may be related to the fact that the Secretaries were more aware of the problems encountered by past drug reclassification efforts than were the practitioners. Only 47% of the practitioner sample was even aware of the existence of the concept of drug reclassification, while 87% of the SPBS sample and 90% of the SPAS sample expressed awareness for the concept. The figures obtained from the practitioners on the potential additional provisions of a drug reclassification proposal tend to indicate that a fairly even split exists within the responding sample between pharmacists that would support required professional intervention in the sales of the new class drugs to the public, and those that desire to be granted the sales

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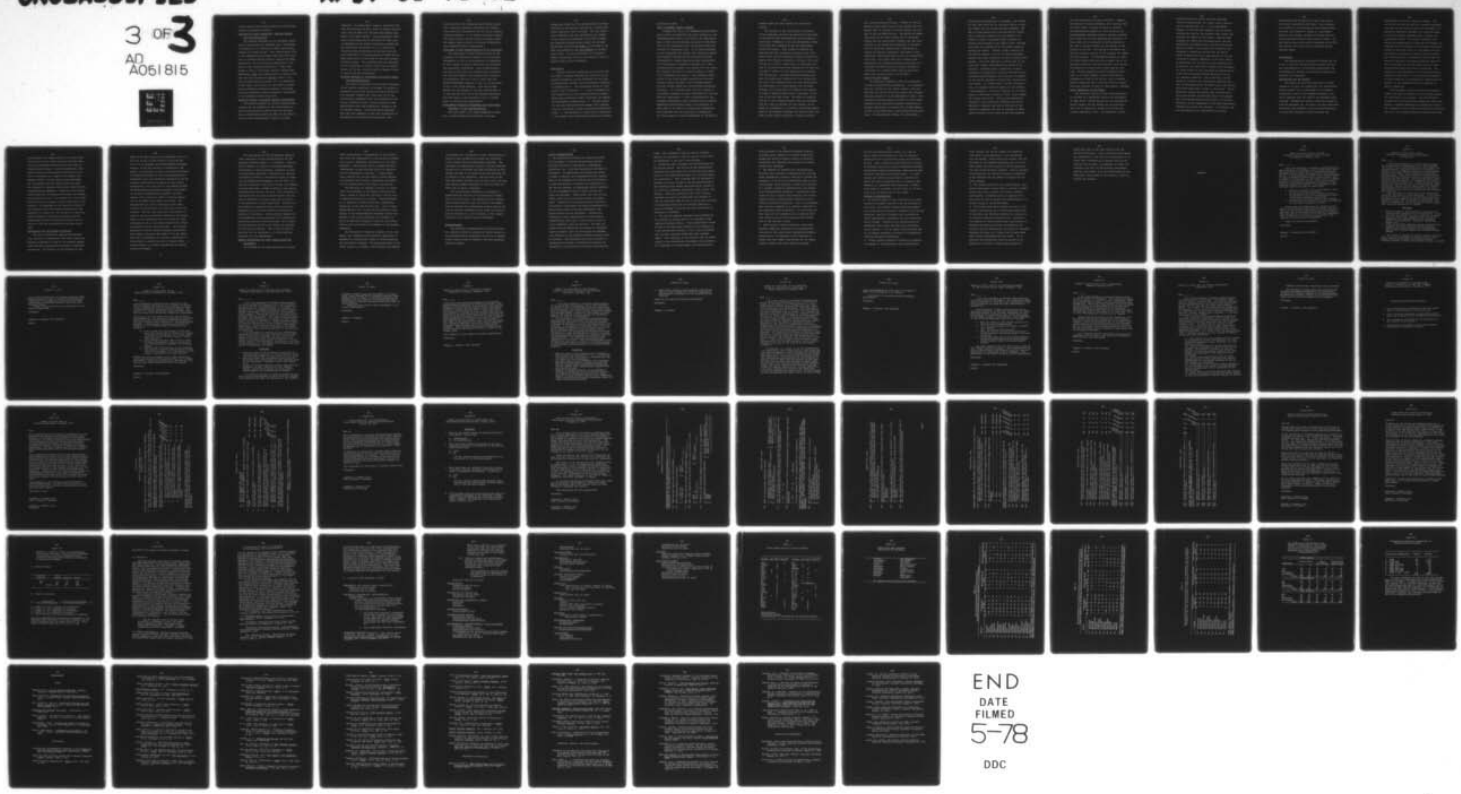

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control aspect without being required to provide the related professional services.

Perception of Other Pharmacists' Feelings Towards Drug Reclassification

The feelings expressed by the responding practitioners and Secretaries indicated that a high degree of consensus on the feelings of other practitioners towards the concept exists. Over three-fourths (77%) of the responding practitioners felt that their position on reclassification would be supported by other pharmacists, and this result was duplicated in the cases of the responding Secretaries. There does appear to exist a difference, however, between what pharmacists think other pharmacists will agree to and what the other pharmacists actually agree to in a drug reclassification proposal, eg.) as exemplified by the almost even division in the number of pharmacists supporting mandatory pharmacist involvement and those supporting optional pharmacist involvement in the transaction with the patient.

Perceived Support by National Pharmacy Associations

The perceived support by national pharmacy associations for the proposals of the practitioners on drug reclassification revealed that they saw basically no difference between the NARD and the APhA in terms of these organizations' support for their

proposals. The SPBS sample, however, apparently felt that the APhA would be more likely to support the proposal than the NARD (76% indicated APhA support compared to 57% NARD support). The practitioners' feelings on this matter may be indicative of their lack of awareness for the history behind this concept and the controversy surrounding it, or it might be an indication that practitioners do not feel that any great difference in ideology between the NARD and the APhA should exist or does exist on the drug reclassification concept. This sentiment has been expressed to this researcher by leaders within the two associations, but as yet, there has been no apparent effort to resolve the past differences.

Perceived Economic or Professional Motivation Behind Drug Reclassification

The series of questions that provided information on the relative importance of economic as opposed to professional motivation behind the drug reclassification proposal revealed that while only 27% of the practitioner respondents felt that economics was the primary motivating factor, fully two-thirds of the practitioners felt that professional imperative was the deciding factor. The practitioners indicated that they felt competent to meet the professional requirements of the proposed new drug class, and a

startling 58% of the responding practitioners agreed that a mandatory education requirement for pharmacists should be incorporated into any future reclassification proposals. It is evident from these figures that there exists a strong nucleus of support within the sampled practitioners for increased professional role responsibilities of pharmacists.

Importance of Drug Reclassification to the Profession

The importance of drug reclassification to the profession of pharmacy as viewed by the practitioner respondents as well as the Secretaries in comparison to other issues currently confronting the profession was exceedingly interesting. Drug reclassification has been an issue that has received little attention over the past decade by the organizations representing pharmacists and yet it was an issue that the sampled respondents appeared to feel was as important as any of the issues examined. Such practitioner support for the concept is even more amazing when it is realized that only 47% of the sampled pharmacists were even aware of the existence of such a concept prior to receiving the questionnaire.

Professional Association Membership and Practitioner Positions on Drug Reclassification

The final phase of the study attempted to determine if there existed any difference in the way

pharmacists viewed the drug reclassification concept depending on the pharmacy associations to which they either belonged or did not belong. The only significant difference that was uncovered by this aspect of the research was awareness to the basic concept. The awareness difference was evident only between pharmacists that were not members of the NARD or the APhA and pharmacists that were members of the NARD and/or APhA. No other differences in non-member/member practitioner views on the concept of drug reclassification could be detected.

Conclusions

Several revealing conclusions can be drawn from the study's findings regarding the inability of the pharmacy profession to gain acceptance for the drug reclassification concept and the arguments elaborated to substantiate it. The conclusions center on three primary areas of concern: 1. A lack of agreement on the components for a drug reclassification proposal within the professional ranks of pharmacy and between its professional organizations. 2. Minimal support for the drug reclassification concept from organizations or individuals outside the pharmacy profession's ranks. 3. The presence of a hard core of opposition to the concept from organizations outside the pharmacy

profession's ranks.

Lack of Agreement Within Pharmacy

Although over 80% of the responding practitioners were in favor of supporting the basic concept of a new intermediate drug class, only half of the respondents were in favor of the mandatory inclusion of the pharmacist in the transaction with the patient concerning the sale of restricted items. It is clearly apparent to this researcher that unless such features as pharmacist-patient consultation and counselling and the maintenance of records concerning these transactions are incorporated as mandatory components to a drug reclassification proposal, the concept will not attain the required legislative or public support it needs to be translated into reality. The responding Secretaries of the state pharmacy associations and state pharmacy boards indicated a more favorable predisposition towards supporting these mandated pharmacist functions. It is believed that this was related to the greater awareness by these individuals for the concept and undoubtedly, a better understanding of the problems encountered by past reclassification efforts. Responding practitioners appear to be committed in great part to the need for infusing new professional role functions into the activities of pharmacists but there appears to exist disagreement on the need to

mandate these new roles through the legislative process.

The analysis of the relationship of organizational membership profiles and practitioner positions on reclassification indicated that there existed no significant difference in the way NARD members viewed the concept when compared to the way APhA members viewed the concept. This finding is somewhat unexpected when the information provided by the literature review and the background research conducted to support this study is considered. However, this finding may be of crucial significance in explaining the lack of initiative and effort expended by the NARD and the APhA in seeking to gain support for the concept from legislators. Although the APhA leadership has been the professional advocate for this concept over the years, the leadership must have had reservations, and justifiably so it would appear from the study findings, on the positions its members would support in terms of mandated practitioner involvement in the sale of the new class drugs. The NARD, an organization with a drug reclassification position characterized by a lack of advocacy for the concept, can be viewed as responding in a similarly justifiable manner based on the apparent dichotomy that exists within its ranks on what should constitute a properly defined

drug reclassification proposal. Neither of the two pharmacy associations has the clear mandate from its members that it requires to further advance the concept of drug reclassification. The extent of support identified for the basic concept was no different between the two associations' members, nor was there evidence of any appreciable difference in the positions of these two organizations' memberships in support of mandatory pharmacist involvement in the transaction surrounding drugs of the new intermediate drug class. The almost even split between those pharmacists that supported mandatory pharmacist involvement and those selecting optional pharmacist involvement is a problem that requires resolution before any concerted action can be taken.

Lack of Outside Support

The APhA has consistently been the protagonist in drug reclassification discussions. It is apparent from the findings of this study, however, that the APhA has done little to solicit support for reclassification outside of its own membership's ranks. This perplexing situation might be related to the problem revealed in the preceding discussion concerning the apparent differences in opinion held by APhA members on what should constitute a drug reclassification proposal. By periodically raising the issue before a

Congressional subcommittee, for example, the concept has been kept alive but no noticeable impact on gaining support for the concept has been produced. The PMA, an organization that could possibly be considered a potential supporter for the proposal (if viewed in terms of increased market exposure for products now confined to the legend class), declined to provide any information on its present position towards the concept. However, member companies of the PMA did express a fear of increased government control over their operations if such a proposal were enacted. This fear appeared to prevent many of the individual company respondents from endorsing the proposal. Consumer groups, potentially of great importance in supporting a properly constructed drug reclassification proposal, were hesitant to respond to the inquiry designed to obtain their positions on the concept. Dr. Sidney Wolfe, the HRG representative, did express positive support for the concept; a rare exception. The dismal response of the legislators to the study's inquiry on their views towards the concept was vexing. Since the correspondence directed to their attention reflected both the researcher's signature and that of the Dean of the College of Pharmacy, the lack of response by these public servants to the mildly worded questionnaire

can only be explained through conjecture. However, the warnings of Senator Humphrey, that Congress would not allow itself to become involved in settling intraprofessional disputes as occurred during the Durham-Humphrey Amendment debates, possibly accounts for a great part of this Congressional reticence. A final point to be considered in this discussion of the lack of outside support for the concept is the position of the FDA. This agency is currently conducting a massive overview of OTC products for safety and effectiveness. The pharmacist members of these OTC Review Panels indicated their support for an intermediate class of drugs but mentioned that the FDA was opposed to creating such a drug class at this time. The FDA apparently stifles dissenting sentiments in its panel members if their views do not correspond to official FDA policy, for no minority reports suggesting that a new drug class be created have been included in texts of these panels' findings.

Active Opposition to the Concept

The recurrent raising of drug reclassification by the APhA as a peripheral issue to the discussion of other health related matters has not succeeded in gaining support for the concept but has produced a hard core of opposition, especially from the Proprietary Association (PA). The opposition to drug

reclassification by the PA and other adversely affected organizations, eg.) labor unions, food retailer organizations, etc., is well documented. However, it has been only recently that the PA has attacked the issue at the national level rather than limiting its efforts to the states. When the APhA attempted to insert drug reclassification into the discussions surrounding one of the FDA's OTC Review Panel's findings, the PA seized the initiative and succeeded in convincing the FDA that the APhA's latest efforts were simply resurrections of the old "druggist's monopoly proposals" of the early 1950's. No recognition for the fact that the proposals have evolved over the years from a concept that envisioned the total control of all drug sales by pharmacists to a much more restricted version was evident in the PA's opposing arguments. The PA similarly did not choose to recognize the increasingly important role that the declassification of legend drugs into the new drug class might begin to play in the future. The PA apparently retains the opinion that this would be a first step towards reclassifying many of the present OTC's and thereby depriving the public (and the manufacturers the PA represents) of the many distribution channels and outlets now available. In addition, the non-availability of an intermediate drug class

necessitates that declassified legend items enter the totally unrestricted OTC class. This situation is of benefit to the proprietary drug manufacturers. The APhA, not prepared to engage in a protracted battle on the concept, withdrew from these most recent discussions leaving little positive effect; the only result being a new position statement by the FDA that labeled the concept as one possessing purely economic import.

Implications

The implications of the study's findings for the future of the drug reclassification concept and for the legitimation of a revitalized professional role for pharmacists through the legislative process are generally not favorable.

Implications for the Concept

The concept of drug reclassification has been exposed to 25 years of redefinition and reformulation. Unified support has not developed at the national organization level of the pharmacy profession, nor has it appeared from the ranks of non-pharmacy organizations. Although the concept itself has changed in form and substance over the years, the well entrenched opposition has succeeded in gaining characterization of these past proposals as being needless and

unacceptable to the free enterprise system. The belief that the FDA can solve all problems associated with drug use and safety without the assistance of a pharmacist possessing expanded role functions seems to be the prevailing sentiment both in public and legislative circles. The public's belief in the safety and effectiveness of available OTC products is confirmed by the inability of the pharmacy profession, working at the state level, to gain support for the restriction of certain OTC drugs to pharmacy sales. The information that a pharmacist could provide the patient to maximize the effectiveness and safety of OTC drug products has at best been viewed as superfluous during these state level discussions. The isolation of the pharmacist in the drug distribution system, serving solely in the capacity of dispenser of drugs ordered by the physician or requested by the patient, is not compatible with the expertise of today's pharmacist.

The environment within the pharmacy profession itself also does not present a very favorable picture for the future of the concept. The even division uncovered by the study between pharmacists that would support a proposal mandating the pharmacist's role in the transaction with a patient concerning the selection and use of the proposed restricted products and those

practitioners that simply desired to be given sales control over the new class of drugs, has both favorable and unfavorable connotations for the drug reclassification concept. From one perspective, this equal division of practitioners would tend to indicate the existence of a good deal of support for a proposal worthy of being backed by both consumers and legislators; one that would effectively quell the arguments of economic exploitation raised by drug reclassification opponents. Conversely, the equally large proportion of pharmacists who would not mandate the pharmacist's role in the transaction, could effectively nullify any attempt to gain acceptance for the proposal. An assessment of the relative strength of the feelings within the pharmacy profession on the opposition or support for the inclusion of these mandatory pharmacist involvement provisions must be accomplished before a conclusive prediction on the future of the drug reclassification concept can be made.

Implications for the Pharmacy Profession

The lack of support for enhanced professional role functions for pharmacists from those inside the pharmacy profession in terms of the marginal support shown the drug reclassification concept is extremely interesting. The disunity in the positions of the

NARD and the APhA has been well documented and is in fact due in part to past conflicts involving the source of the problem, the Durham-Humphrey Amendment. However, if the past history of antagonism on the subject is discounted, and only the current positions of association members on drug reclassification are considered, then the differences expressed by the two pharmacy organizations are placed in their proper perspectives. With only half of the members of NARD and APhA supporting mandated pharmacist involvement in the drug reclassification proposal, the weak support of the concept by APhA and the weak opposition by the NARD can be better understood. The organizations are simply responding to the close division of practitioners on either side of the controversy. The fact that there was no difference in views of the two associations' members on the subject points to the possibility that the leaders of these organizations can in the future resolve their different stances on drug reclassification. The divergent positions of the two national pharmacy associations has created a situation that makes it all but impossible for the profession to influence legislators on this subject at either the state or federal level. A unified stance is a primary prerequisite to gaining legislative support.

The implications of the non-pharmacy organizations' positions on drug reclassification for the pharmacy profession appear less favorable. Drug industry leaders are fearful of increased government restrictions on their practices, consumers are wary of professional dominance, legislators are cautious of becoming involved in discussions similar to those that surrounded Durham-Humphrey, and the FDA is unwilling to advocate a new class of drugs, the creation of which would cast a shadow of doubt on the agency's operations over the past 25 years. This situation is intertwined with the lack of substantiation for the need to establish a new drug class and the ability of the pharmacist to meet these needs. The most recent debates on reclassification have pictured the pharmacist as just another merchant retailing his products to the public. Little positive support for the pharmacist's true professional role functions of counselling patients, monitoring their use of drugs, and rationalizing the drug use process was detected by this study's findings. This situation does not bode well for the acceptance of a revitalized professional role for pharmacists.

General Implications for Other Organizations and Researchers

The findings of the study should serve to alert

other organizations or associations to the pitfalls that await the disorganized or non-unified in attempting to gain a sympathetic legislative ear for their proposals. Action should not be attempted before a consolidated, unified position within the organization or association is achieved. A fractionated group achieves only limited support towards gaining its objectives and in effect strengthens the opposition by alerting them of the need to take action.

The difficulty in changing a law that is legislated into existence at the federal level also provides a lesson to those who view such a step as only a temporary solution to a problem. Changing Federal Law is generally a long and difficult proposition, especially in the food and drug area. This is amply demonstrated by the 3-4 year period required to gain passage of the Durham-Humphrey Amendment and the subsequent 25 year period following its enactment in which the APhA has attempted to diminish its restrictions on the activities of the members of the pharmacy profession.

The difficulty of obtaining unbiased, or for that matter, any information from potential supporters or opponents to controversial issues is readily apparent from the study's findings. The characterization of the forces acting on a concept in the internal and external

environments of a profession or other organizations or groups is best accomplished through the literature review process and the questionnaire approach. The positions on controversial issues of various concerned parties can be clarified only when discussions on this subject are held in the public arena and accounted for by reports in the literature. The acid test is not what individuals indicate they will do or say, but what they actually commit themselves to when the issue becomes open to public discussion.

The questionnaire technique is invaluable in determining the feelings of an association's membership on a given issue. The comparison of the leadership's stated position with the views of the members obtained through the questionnaire process permits the type of analysis conducted by this study and serves to provide information on the legitimacy of the leaders' positions on the subject being investigated.

Recommendations

The following recommendations are meant to serve as a possible source for guiding the future actions of drug reclassification proponents as well as to suggest further fertile areas of research into this extremely important subject.

Action Recommendations

1. The pharmacist's professional capabilities and his willingness to provide patients with the professional services of counselling, recommending, monitoring, etc., have been determined to be open to conjecture. To demonstrate the pharmacist's effectiveness in meeting the responsibilities and requirements of an expanded role function and his sincerity in exploring methods to enhance his contribution to the drug use process, the pharmacist should establish his own intermediate class of drugs from the OTC drugs now available. These drugs, when sold in drug stores, would only be available through the pharmacist. Records would be maintained after obtaining the patient's concurrence and proper documentation of prescription drugs having been dispensed to the patient should also be undertaken. Through this mechanism an actual demonstration of what drug reclassification could mean to the patient as well as to the pharmacist would be attained. The costs involved could be documented, the patient's acceptance could be studied, and a proving-ground for expanded role functions in the community pharmacy setting would be achieved. This mechanism would also be useful in documenting the extent of problems uncovered by the pharmacist in the utilization of these restricted OTC

drugs. This information could be used to convince skeptics of the public's need for greater contact with the pharmacist in the use of drug products.

2. Pharmacists need to become more professionally and politically active. The results of the questionnaire indicated that only about half of the practicing pharmacists in the United States belong to a national pharmacy organization. This situation must be corrected if pharmacy is to gain access to the legislative process. The profession must become more politically visible at all levels of government operations, local, state, and federal. Since the constraints that limit the professional activities of pharmacists are recorded in law, the profession must be able to exert some influence in determining which laws are actually required to guide its members' practices and which laws could be modified or eliminated.

3. The clinical pharmacy programs being developed by the colleges of pharmacy need to be expanded to the community pharmacy setting. Since approximately three-fourths of all practicing pharmacists are employed in a non-institutional setting, it is in this environment that clinical teachings could make their greatest impact. The acceptance of the clinical role for pharmacists in the institutional environment can be used to good advantage in gaining support for such practices

being provided in the community pharmacy setting. Increased public exposure to clinical practice by pharmacists would contribute greatly to achieving recognition for expanding the pharmacist's legally defined role functions.

4. The approach of expanding the legitimate professional role functions of pharmacists by altering state professional licensure statutes to include the pharmacist in the list of professionals able to prescribe drugs, could represent a state level solution to a problem created for pharmacists by the federal level Durham-Humphrey Amendment. Pharmacists could prescribe from a limited drug formulary and in this respect could be differentiated from other practitioners permitted to prescribe. Such is the approach that has been suggested by an advisory committee to the California State Legislature. No action has yet been taken on this suggestion but it deserves much more attention by all state pharmacy associations than it has received to date.

5. There exists a need to establish a high level planning committee, consisting of representatives from each of the associations representing pharmacy practitioners, to establish uniform policies on issues that hold common implications for all pharmacists no matter what their practice settings.

The drug reclassification concept, as a case in point, holds ramifications not only for community pharmacists but institutionally based practitioners as well. Such a committee would minimize the airing of divergent opinions by groups representing pharmacy practitioners before Congressional committee hearings and other legislatively oriented bodies. It could produce the unified stance needed to convince the public and their representatives in government that pharmacy is a profession that knows what it wants, knows where it is headed, and knows what it can contribute to the health care of our people.

Research Recommendations

1. An analysis based on data accumulated by a questionnaire instrument similar to the one employed by this study, and directed towards determining pharmacist practitioner patterns of response to the various questions, could be a valuable tool in predicting future developments surrounding the drug reclassification concept. Clarifying the characteristics of pharmacists that oppose the basic drug reclassification concept as well as those of practitioners who do not support mandatory involvement of pharmacists could be extremely enlightening.

2. Further analysis should be centered on determining whether or not pharmacists that supported the

basic concept, but did not support the mandatory involvement of the pharmacist in the transaction with the patient, would support the concept with the inclusion of the mandated pharmacist role if it became evident this was required to obtain passage of the drug reclassification proposal. Such an analysis would determine the relative strength of opposition to the mandated role as opposed to support for the basic concept.

3. The Canadian system of drug classification, that permits pharmacists a much greater latitude in determining what drugs a patient can receive without a prescription, is another source of essential data that could be used to support the establishment of a similar system in the United States.

4. The United States Public Health Service's utilization of pharmacists in a limited prescribing role is well known and should be explored for application in civilian treatment centers as well. Similarly, the granting of limited prescribing authorization to physician assistants and nurse clinicians by our military services demonstrates the ability to approach changing the impact of a federal law by means other than directly challenging the law itself. It is possible that pharmacists could be granted an expanded role function in these closed systems of

health care much as has been achieved with the physician assistants. Such a situation would permit the examination of the ability of pharmacists to increase their contribution to patient care and the rational use of drugs. An extension of these role functions into the civilian practice environment would be facilitated, once the effectiveness of the pharmacist, functioning in this capacity, could be studied and analyzed.

APPENDIX

Figure I

Sample of Letter Sent to Current Officers, American Association of Colleges of Pharmacy, February, 1976

Dear _____:

I am a PhD Candidate in Pharmacy Administration at the University of Minnesota, and my dissertation deals with the notion of creating an intermediate class of non-prescription drugs, available only through pharmacists. I am attempting to characterize the impressions of various pharmacy associations, organizations, practitioners, and educators on the scheme, and as a member of AACP and an educator of our future practitioners, I would be particularly interested in learning of your feelings towards the concept. Your responses to the following questions would be most helpful.

1. Prior to receiving this correspondence, were you aware of such a concept?
2. Do you support the basic concept of a new, intermediate class of non-prescription drugs, restricted to pharmacy sales only?
3. Do you feel AACP would support this concept and take an active role in seeking its adoption at the Federal legislative level?

Please take this opportunity to comment on any aspect of the drug reclassification concept that you feel is of particular importance to the profession of pharmacy, and to the health and safety of the public. Your response will be held in the strictest confidence with no reference in my thesis being given to the identity of the individual respondent.

Thank you for your assistance.

Sincerely,

Stephen J. Sweeney, PhD Candidate

SJS/sb

Figure II

Sample of Letter Sent to the
American Association of Retired Persons
October, 1975

Dear _____:

I am a PhD Candidate in Pharmacy Administration at the University of Minnesota, and I have selected the issue of drug reclassification as the subject for my dissertation. Reclassification is a proposal to create a new, intermediate category of drugs situated between the present "Over-The-Counter" and "Legend Only" classes. These drugs would be available to the consumer directly (without requiring a prescription), and only from pharmacists. The drugs themselves would be drawn from the present two categories, not exclusively from one or the other. Another possible aspect of drug reclassification is the liberalizing of refill provisions. Certain prescription items, for example maintenance drugs, would be refillable by the pharmacist without first obtaining approval by the prescribing physician.

I am interested in learning of your impressions regarding the merits of these proposals. If you would be kind enough to respond to the following questions, you would be providing a much needed ingredient to my research, namely, the advantages, disadvantages, and overall acceptability of the concept as seen by people most likely to experience its impact.

Questions

1. Were you aware of the existence of such drug reclassification proposals as outlined above? If so, how were they brought to your attention? By whom?
2. Could you state your impressions as to what the advantages and disadvantages of the proposals would be for consumers? (Economic, health and safety, etc.)
3. Could you delineate specific points concerning the proposals or their implications that require further clarification before your Organization would clearly support/oppose the reclassification scheme?

If I might be allowed one further request for your help, would it be possible to obtain from you information regarding the names and addresses of any Canadian consumer oriented organizations similar to yours?

Figure II, cont.

Since Canada already has in existence such an intermediate class of drugs, it would be exceedingly enlightening for my research to ascertain the actual experiences of Canadian consumers concerning drug reclassification.

Thank you very much for your assistance; it is greatly appreciated.

Sincerely,

Stephen J. Sweeney, PhD Candidate

SJS/cs

Figure III

Sample of Letter Sent to the
American Medical Association, November, 1975

Dear _____:

I am interested in obtaining the viewpoint of the American Medical Association on a proposal to create a new, intermediate class of drugs (between the present prescription and non-prescription classes). My advisor, Dr. Albert Wertheimer, suggested that I contact you about this matter and request your assistance.

The drugs of the new class would have the following characteristics: not require a prescription, be available to the public only through licensed pharmacies, and most likely be drawn from both of the existing drug classes. I would greatly appreciate receiving your comments on the following points concerning this proposal:

(1) Does the AMA see any features in this proposal that would tend to generate its support or muster its opposition, or is this a proposal that is not of major import to organized medicine?
(2) Does the AMA feel that there exists a need for more professional control over many of the non-prescription products on the market today?
(3) Does the AMA feel that many of the prescription products could be distributed in a less restrictive fashion, if an alternative to the present non-prescription class existed?

Please feel free to comment on any other aspects of this drug reclassification proposal that is of concern to the AMA. Allow me to thank you in advance for your help and the kind consideration given my inquiry.

Sincerely,

Stephen J. Sweeney, PhD Candidate

SJS/cs

Figure IV

Sample of Letter Sent to the Executive Director, Consumer Federation of America, October, 1975

Dear _____:

I am a PhD Candidate in Pharmacy Administration at the University of Minnesota, and I have selected the issue of drug reclassification as the subject for my dissertation. Reclassification is a proposal to create a new, intermediate category of drugs situated between the present "Over-The-Counter" and "Legend Only" classes. These drugs would be available to the consumer directly (without requiring a prescription), and only from pharmacists. The drugs themselves would be drawn from the present two categories, not exclusively from one or the other. Another possible aspect of drug reclassification is the liberalizing of refill provisions. Certain prescription items, for example maintenance drugs, would be refillable by the pharmacist without first obtaining approval by the prescribing physician.

I am interested in learning of your impressions regarding the merits of these proposals as they would affect health care consumers. If you would be kind enough to respond to the following questions, you would be providing a much needed ingredient to my research, namely, the advantages, disadvantages, and overall acceptability of the concept as seen by people most likely to experience its impact.

Questions

1. Were you aware of the existence of such drug reclassification proposals as outlined above? If so, how were they brought to your attention? By whom?
2. Could you state your impressions as to what the advantages and disadvantages of the proposals would be for consumers? (Economic, health and safety, etc.)
3. Could you delineate specific points concerning the proposals or their implications that require further clarification before you would clearly support/oppose the reclassification scheme?

If I might be allowed one further request for your help, would it be possible to obtain from you information regarding the names and addresses of any Canadian

Figure IV, cont.

consumer oriented organizations similar to yours? Since Canada already has in existence such an intermediate class of drugs, it would be exceedingly enlightening for my research to ascertain the actual experiences of Canadian consumers concerning drug reclassification.

Thank you very much for your assistance; it is greatly appreciated.

Sincerely,

Stephen J. Sweeney

SJS/cs

Figure V

Sample of Letter Sent to Antitrust Division,
Department of Justice, November, 1975

Dear _____:

I have read your position statement on the American Pharmaceutical Association's proposal to create a new class of non-prescription drugs available only through pharmacies, filed with the Hearing Clerk, Department of H.E.W., dated 4 February 1974. Since this statement appears to consider only those drugs that are now retailed in the Over-The-Counter category and does not seem to include drugs that presently are restricted to prescription sales exclusively, I would like to obtain your impressions on a proposal that would create a new class of non-prescription drugs, exclusively available through pharmacies, that would consist primarily of Legend items declassified to this intermediate category. This proposed classification system would closely parallel that which is found in Canada at the present time.

Your response to this inquiry is greatly appreciated.

Sincerely,

Stephen J. Sweeney, PhD Candidate

Figure VI

Sample of Letter Sent to the Executive Director, National Association of Physician Assistants, October, 1975

Dear _____:

I am a PhD Candidate in Pharmacy Administration at the University of Minnesota, and I have selected the issue of drug reclassification as the subject for my dissertation. This proposal basically would establish an intermediate class of drugs, between the Legend and Over-The-Counter categories, that would be available to the patient directly through the pharmacist without the need of a prescription.

In my research, I am contacting organizations, associations, and individuals that potentially could influence the direction of any legislative process initiated by pharmacy to achieve the objectives of the proposal. Since physician assistants (PA's) have to my knowledge, attempted to gain a greater role in the use of selected drugs for the treatment of their patients, and since the opposition encountered during the course of these efforts must be similar in nature to that encountered by pharmacists advocating drug reclassification, I am interested in obtaining your impressions as to how PA's and pharmacists might cooperate on this issue. With this background in mind, it would greatly aid my research if you would respond to the following questions about the reclassification proposal.

Questions

1. Were you aware of the existence of a reclassification effort by pharmacists? If so, in what context and by whom (individual or organization) was it brought to your attention?
2. Has there been to your knowledge, any discussion between national pharmacy associations and the PA's as regards mutual professional aspirations and the present drug classification system's constraints upon them?
3. Would drug reclassification, if it included a category of drugs able to be prescribed by PA's, be a desirable development for PA's, or would changes in state medical practice laws, redefining those practitioners licensed to prescribe drugs, be a more suitable alternative?

Figure VI, cont.

4. What points related to the proposal need clarification if any, before PA's could be expected to lend support to pharmacy in its reclassification efforts?

Thank you for your kind help and assistance.

Sincerely,

Stephen J. Sweeney

Figure VII

Sample of Letter Sent to the Executive Secretary, The National Association of Retail Druggists, January, 1976

Dear _____:

I am a PhD Candidate in Pharmacy Administration at the University of Minnesota, and I am writing my thesis on the concept of a "Third Class" or a new, intermediate class of non-prescription drugs, available exclusively from pharmacists. This past Fall, I was in Washington, D.C., and discussed this concept and NARD's position with Mr. Woods. The proposal has gained a relatively high degree of attention twice in the past 13 years, once in 1963-64, and more recently in 1973-74, as a result of discussions surrounding the FDA's proposed monograph on OTC antacids. In my discussion with Mr. Woods, I characterized the NARD's position on the 1963-64 APhA proposals as one of support for the concept of restricting certain non-prescription drugs to pharmacies, but one of opposition to the personal supervision by a pharmacist provision; the latter aspect being considered economically unfeasible. Mr. Woods did not choose to comment on this because it occurred before his tenure began with NARD, but he did feel that APhA and NARD would not be as divided today on the proposal, as was the case in the past. I would like to know if this reflects a fair representation of the NARD's position on the 1963-64 concept, as you see it, as well as of the present situation.

In addition, if I might not be too presumptuous, I am wondering if your Chicago office files might contain some information on the reclassification concept, that would be useful in further developing its historical background. Such data as NARD statements filed with Congressional Subcommittees on the proposals of 1963-64, special NARD Committee reports on the issue, or minutes of meetings held between the NARD, APhA, and/or others, on the subject would be very valuable. I hope this letter doesn't sound too much like one written by someone embarking on a fishing expedition. I am simply attempting to clarify the issues and accurately represent the positions of all participants in the reclassification effort, and it is only through

Figure VII, cont.

such correspondence as this, that I can hope to obtain the information I am seeking.

Your help in this matter would be greatly appreciated.

Sincerely,

Stephen J. Sweeney, PhD Candidate

Figure VIII

Sample of Letter Sent to all Pharmacist Members of the OTC Drug Review Study, February, 1976

Dear _____:

I am a PhD Candidate in Pharmacy Administration at the University of Minnesota. My dissertation deals with the concept of creating a new, intermediate class of non-prescription drugs for sale exclusively by pharmacists.

As a pharmacist closely involved with the on-going FDA evaluation of all OTC ingredients for safety and effectiveness, your personal impressions on the advisability of establishing such a drug class would be extremely valuable to my research. Your responses to the following questions would be most helpful.

1. Were you aware of this concept prior to receiving this correspondence?
2. (a.) Are you inclined to support or oppose this concept?
   (b.) Why do you feel this way?
3. Have you found any drugs that could be included in such a restricted class if one were available?
4. Do you feel that such a drug class should be developed before deciding on declassifying present Legend items to non-prescription status?

Any other comments that you would like to make on this subject would be welcome. Your responses will be held in the strictest confidence, and at no time will individuals be identified by their comments. Your assistance in this matter would be greatly appreciated.

Sincerely,

Stephen J. Sweeney, PhD Candidate

SJS/sb

Figure IX

Sample of Letter Sent to Millis Commission Members, February, 1976

Dear _____:

I am a PhD Candidate in Pharmacy Administration at the University of Minnesota. My dissertation deals with the concept of creating a new, intermediate class of non-prescription drugs, available exclusively from pharmacists. When this issue recently gained attention in the context of an APhA comment to the FDA's proposed monograph on the labeling of OTC Antacids, Commissioner Schmidt asked the Millis Commission what its feelings were on the subject. At that time, early in 1974, the Commission was not able to respond.

After reading the report of the Commission, and not finding any specific reference to this concept, I thought it might be appropriate for me to obtain your comments, as an active participant of the Commission, on any discussions that occurred during the development of the report on the reclassification issue, and how you personally view its potential implications for the pharmacy profession.

Your comments would be extremely interesting and informative and be held in the strictest confidence. Thank you for your assistance.

Sincerely,

Stephen J. Sweeney, PhD Candidate

SJS/sb

Figure X

Sample of Letter Sent to Selected PMA Members, September, 1975

Dear _____:

I am a PhD Candidate in Pharmacy Administration at the University of Minnesota. My research deals with the issues, controversies, and opinions surrounding the reclassification of drugs concept elaborated by the APhA for the past few years (see attached sheet). As a member of the pharmaceutical manufacturing community, your corporation would undoubtedly play an important role in developing position statements for your industry towards such a proposal, if and when that stage is ever reached.

I am initiating this correspondence in hopes of obtaining (with your assistance), some insight into your organization's current feelings on certain policy related matters closely associated with the reclassification issue. By directing this inquiry to the attention of an individual within your organization knowledgeable in areas of basic company policy and operating philosophy, you would aid me greatly in my research endeavors. If I haven't been too presumptuous then, I would be grateful for your company's comments on the following questions:

(1) What policy does your company have in regards to the promotion of your OTC products, eg.) professionally directed, public directed, or a combination of both?
(2) Could you discuss the factors that have influenced the development of this policy by your company, with specific reference to (but not limited to) the consideration given to the role played by pharmacists in OTC channels of distribution?
(3) Would a new intermediate class of drugs between Legend and OTC, available only through pharmacists, be a desirable proposal as far as your company is concerned?
(4) Would such a class serve a useful purpose if it was intended to be used as a proving grounds for the determination of OTC acceptability for Legend drugs?
(5) Would such a new class stimulate your company to explore the declassification from Legend status, or the reclassification from OTC status, of certain

Figure X, cont.

company products more vigorously than at present?

The responses to these questions should provide me with much needed information on the prevailing attitudes of prominent members of the pharmaceutical manufacturing industry towards drug reclassification. Thank you for your kind attention to my request.

Sincerely,

Stephen J. Sweeney, PhD Candidate

Figure XI

Sample of Attachment to the PMA Letter (Figure X) Outlining the 1964 APhA Proposed Reclassification Scheme, September, 1975

Proposed Reclassification Scheme:

1. To be dispensed on prescription order and renewable at the prescriber's discretion only.

2. To be initially dispensed on prescription order only, but renewable at the pharmacist's discretion.

3. To be dispensed personally by the pharmacist at the request of the patient.

4. To be directly available to the public without professional direction or control.

Figure XII

Sample of Letter Sent to
Selected Congressmen, December, 1975

Sir:

We are interested in obtaining your opinions on a proposal that has important implications not only for pharmacy, but for most other segments of the health care arena. The basic proposal is one that would create a new intermediate class of non-prescription drugs (located between the present prescription and non-prescription classes) available exclusively through pharmacies. This would closely parallel the classification system presently used by the Canadian government.

This concept has already received some airing before such Congressional bodies as the Senate Subcommittee on Reorganization and International Organizations (statement filed by the American Pharmaceutical Association, 26 Sept. 1963), the House Subcommittee on Intergovernmental Relations (25 March 1964), and the Senate Subcommittee on Monopoly (26 May 1971, and 6 June 1973). If pursued further by the pharmacy profession, the proposal will require a great deal more Congressional attention. Therefore, we are contacting all members of Congressional committees that might be involved in future hearings on this matter in an attempt to determine their present feelings towards the new class of drugs.

Your comments on the following questions would be greatly appreciated. We would like to thank you for your kind help and the earnest consideration you have provided this inquiry.

Very truly yours,

Lawrence C. Weaver, Ph.D.
Dean, College of Pharmacy

Stephen J. Sweeney, M.S.
Assistant

Figure XIII

Sample of Congressional Survey
December, 1975

Please answer all of the following questions by circling your responses.

1. Were you aware of a proposal to create a new non-prescription class of drugs available only through pharmacies, prior to receiving this letter? Yes No

2. PLEASE INDICATE YOUR DEGREE OF AGREEMENT WITH EACH OF THE FOLLOWING STATEMENTS BY CIRCLING THE APPROPRIATE RESPONSE

Any new class of non-prescription drugs if available only through pharmacies, should reflect these additional provisions:

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
A. The new drug class must be restricted from direct public access within the pharmacy.	SA	A	N	D	SD
B. Pharmacist-patient consultations must precede all sales of new class drugs.	SA	A	N	D	SD
C. All new class drug sales transactions must be accompanied by a fairly extensive record keeping system.	SA	A	N	D	SD
D. The new drug class would consist of drugs drawn from both the present Legend and Non-prescription classes.	SA	A	N	D	SD

3. Assuming the final version of the new class of drugs proposal reflects the additional provisions outlined in question 2, please indicate your personal position on the proposal

Figure XIII, cont.

a. Tend to support the proposal
b. Tend to oppose the proposal
c. No inclination to support or oppose the proposal at present

4. Do you feel that consumers would benefit from this new drug class? Yes No Undecided

5. Do you feel the proposal is primarily based on economic gain for pharmacists? Yes No Undecided

6. Do you feel that the proposal is primarily based on professional concern by the pharmacist? Yes No Undecided

7. Please rate the following pharmacy associations as to their effectiveness in representing the positions of the profession of pharmacy to Congress.

	Very Effective	Effective	Ineffective
a. National Association of Retail Druggists (circle one)	VE	E	IE
b. American Pharmaceutical Association (circle one)	VE	E	IE
c. American Society of Hospital Pharmacists (circle one)	VE	E	IE

8. Please use the back of this form to comment on any points that you would consider significant in regards to the new class of non-prescription drugs proposal.

Please return to: Stephen J. Sweeney, College of Pharmacy, University of Minnesota, Minneapolis, Minnesota 55414

Figure XIV

Cover Letter for Initial Mailing to
State Board and State Association Secretaries
January 10, 1976

Dear Mr.

We are attempting to develop some background information concerning the proposal to create a new class of non-prescription drugs available only through pharmacies. The enclosed questionnaire is being sent to all State Pharmacy Association and all State Board Executive Secretaries, as well as to a random sample of pharmacists, to determine their opinions on this proposal.

In addition, we would like to gather data on some related questions to which we have not asked the practitioner pharmacist to respond. These are found on the attached sheet and are meant to provide us with a more complete picture of each State's efforts to establish a class of non-prescription, pharmacy restricted drugs.

Your assistance in this matter is greatly appreciated.

Sincerely,

Lawrence C. Weaver, Ph.D.
Dean, College of Pharmacy

Stephen J. Sweeney, M.S.
Assistant to the Dean

Figure XV

Sample of Survey Sent to State Board and State Association Secretaries, January, 1976

Questions

1. What is the present status of exempt narcotics in your State? (circle one)

   a. Prescription
   b. Non-prescription

2. Does your State restrict the sales of any non-prescription product to pharmacies at the present time? (circle one)

   a. Yes*
   b. No

   *If yes, please indicate what products are so restricted in the following spaces.

3. Have there been any attempts in the past 5 years to restrict certain non-prescription products to sales in pharmacies exclusively? (circle one)

   a. Yes*
   b. No

   *If yes, please indicate what products were involved and who represented the major opposition in the following spaces.

4. For any drugs that are restricted or have been unsuccessfully attempted to be restricted in your State, could you describe the rationale or basis used to support the proposals, eg.) warnings on label, toxicity, etc.?

Figure XVI

Cover Letter for Follow-up Mailing to
State Board and State Association Secretaries
February 2, 1976

Dear Mr.

On 10 January 1976, the College of Pharmacy sent out a survey addressed to all State Pharmacy Board and State Association Executive Secretaries, concerning the concept of creating a new class of non-prescription drugs, available exclusively from pharmacists. The survey was intended to obtain the personal views and opinions of those pharmacists serving in these special capacities on the drug reclassification issue. The unique perspectives of these pharmacists would be invaluable in gauging the degree of interest for the concept as it exists in the U.S. today.

Since we have not yet received your response, we hope that this letter will clarify our intentions for the survey and convince you of the need for responding.

Our survey is not sponsored by any pharmacy group or association. It is an independently supported project by the College, intended to provide an impartial assessment of the proposal's merits by those most closely associated with its implications. Confidentiality of responses will be strictly maintained, and at no time will respondents be identified by their comments. The number assigned to each survey sheet is simply for follow-up purposes, if needed.

It is only through your assistance that this study can be completed and meaningful conclusions drawn. Won't you please take a few minutes from your busy schedule to complete the survey?

Your help would be truly appreciated.

Sincerely,

Lawrence C. Weaver, Ph.D.
Dean, College of Pharmacy

Stephen J. Sweeney, M.S.
Assistant to the Dean

Figure XVII

Pharmacist Questionnaire

PLEASE ANSWER ALL OF THE FOLLOWING QUESTIONS BY circling the number(s) CORRESPONDING TO YOUR RESPONSE AND/OR filling in the appropriate blank.

(1) What was your age at your last birthday?_____.

(2) What pharmacy degree do you hold?

1. 4 year B.S.
2. 5 year B.S.
3. PharmD
4. Other (specify) _____.

(3) What year did you receive your pharmacy degree?_____.

(4) What other degree(s) do you hold? (place academic discipline in blank)

1. None
2. B.S. in_____.
3. M.S. in_____.
4. PhD in_____.
5. Other (specify)_____.

(5) In which of the following pharmacy associations do you hold membership?

1. No pharmacy association membership
2. APhA
3. NARD
4. ASHP
5. State Pharmacy Association
6. State Hospital Pharmacy Association
7. Others (specify)_____

Figure XVII, cont.

(6) What is your present employment status?

1. Independent retail pharmacy owner
2. Independent retail pharmacy staff pharmacist
3. Chain pharmacy manager
4. Chain pharmacy staff pharmacist
5. Hospital pharmacy chief
6. Hospital staff pharmacist
7. Other (specify) _____

(7) Prior to receiving this letter, were you aware of the proposal to create a new class of non-prescription drugs available only through pharmacies?

1. Yes 2. No

(8) Do you favor creating a class of non-prescription drugs available only through pharmacies?

1. Yes *2. No 3. Undecided

*If your response is "No", proceed directly to question 15.

THE FOLLOWING REPRESENT POSSIBLE ADDED PROVISIONS OR COMPONENTS TO THE BASIC PROPOSAL. PLEASE INDICATE YOUR PREFERENCES FOR INCLUSION OF EACH INTO THE FINAL VERSION OF THE PROPOSAL. FOR EACH QUESTION, CONSIDER ALL CHOICES CAREFULLY BEFORE RESPONDING.

(9) The new drug class should be selected from: (circle one only)
1. Legend drugs only.
2. Primarily Legend drugs.
3. Both Legend and Over-The-Counter drugs, equally.
4. Primarily Over-The-Counter drugs.
5. Over-The-Counter drugs only.

Figure XVII, cont.

(10) The new class of drugs should be accessible to the public: (circle one only)
1. Directly, with no differentiation from other OTC's within pharmacies.
2. Directly, but with some mechanism of differentiating them from other OTC's within pharmacies.
3. Only by asking the pharmacist.

(11) Pharmacist-patient professional consultation concerning new class drugs should be: (circle one only)
1. Mandatory.
2. Optional.

(12) Record keeping requirements for new class drugs should be: (circle one only)
1. The same as for prescription drugs.
2. Required, but not as extensive as for prescription drugs.
3. Optional.

(13) Use the following space to list any other provisions that you would like to see included in the final version of the new drug class proposal.

(Over)

Figure XVII, cont.

PLEASE ANSWER ALL OF THE FOLLOWING QUESTIONS BY circling the proper alternative.

(14) Would you fully support a proposal to create a new class of non-prescription drugs, available only through pharmacies, that reflects your recommended additional provisions? Yes No Undecided

(15) Do you feel other pharmacists would support this proposal? Yes No Undecided

(16) Do you feel the following organizations would support this proposal?

1. NARD.....Yes No Undecided
2. APhA.....Yes No Undecided
3. ASHP.....Yes No Undecided

PLEASE INDICATE THE EXTENT OF YOUR AGREEMENT WITH EACH OF THE FOLLOWING STATEMENTS BY circling the appropriate response:

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
(17) Pharmacists should expand their activities beyond the traditional compounding and dispensing functions.	SA	A	N	D	SD
(18) Pharmacists are motivated primarily by economic gain in proposing drug reclassification.	SA	A	N	D	SD
(19) Pharmacists, because of the new drug class, would spend a great deal more time with patients.	SA	A	N	D	SD
(20) Pharmacists possess the knowledge needed to meet the professional demands of the new drug class.	SA	A	N	D	SD
(21) Patients would follow the pharmacist's advice on drugs of the new class.	SA	A	N	D	SD

Figure XVII, cont.

(22)	Potential malpractice suits would prevent pharmacists from counseling patients on the new class drugs.	SA	A	N	D	SD
(23)	Third party coverage for drugs of the new class should be urged.	SA	A	N	D	SD
(24)	Pharmacists would recover all expenses associated with handling the new class of drugs.	SA	A	N	D	SD
(25)	Specialized training for pharmacists on drugs of the new class should be required.	SA	A	N	D	SD
(26)	There are many non-prescription products that should be restricted to the new class of drugs.	SA	A	N	D	SD
(27)	There are many prescription products that could be included in the new class of drugs.	SA	A	N	D	SD
(28)	Pharmacists are motivated primarily by professional concern in proposing drug reclassification.	SA	A	N	D	SD

PLEASE INDICATE THE POSITION YOU FEEL NATIONAL PHARMACY ASSOCIATIONS <u>SHOULD</u> ASSUME IN REGARD TO THE FOLLOWING ISSUES BY circling the appropriate response.

		Strongly Support	Support	Neutral	Oppose	Strongly Oppose
(29)	Mandatory continuing education for pharmacists	SS	S	N	O	SO
(30)	Mailorder prescriptions	SS	S	N	O	SO
(31)	Technicians in pharmacy	SS	S	N	O	SO
(32)	Prescription price advertising	SS	S	N	O	SO
(33)	Restricting pharmacy ownership to pharmacists	SS	S	N	O	SO
(34)	Drug product selection	SS	S	N	O	SO

Figure XVII, cont.

(35)	Creation of the new class of non-prescription drugs.....	SS	S	N	O	SO
(36)	Clinical pharmacy.....	SS	S	N	O	SO

PLEASE INDICATE HOW IMPORTANT YOU FEEL EACH OF THE FOLLOWING ISSUES ARE TO THE PROFESSION OF PHARMACY BY circling the appropriate response.

		Very Important	Important	Not Important
(37)	Mandatory continuing education for pharmacists.....	VI	I	NI
(38)	Mailorder prescriptions.....	VI	I	NI
(39)	Technicians in pharmacy.....	VI	I	NI
(40)	Prescription price advertising.....	VI	I	NI
(41)	Restricting pharmacy ownership to pharmacists.....	VI	I	NI
(42)	Drug product selection.....	VI	I	NI
(43)	Creation of the new class of non-prescription drugs.....	VI	I	NI
(44)	Clinical pharmacy.....	VI	I	NI

Figure XVIII

Cover Letter for Initial Mailing to
Pharmacy Practitioners March 29, 1976

Dear Mr.

Please allow us to take a few minutes of your time to explain the purpose of this letter and the reasons we are seeking your response to the attached questionnaire.

We are interested in obtaining pharmacists' opinions on a proposal to create a new category of drugs. The basic proposal consists of: (1) A new intermediate class of drugs; (2) Available exclusively through pharmacies; and (3) Not requiring a prescription. It is the intent of this study to provide pharmacy practitioners not only the opportunity to express their opinions about this new drug class proposal, but the chance to assist us in refining its basic formulation, as well.

The results of this study will be used to inform national pharmacy associations of pharmacy practitioner views on this matter, and should indicate the most appropriate course of action for the profession to follow as regards reclassification.

Since you represent one of only a small group of selected pharmacists that we have been able to contact, we hope that you will take advantage of this unique opportunity to express yourself and to provide a valuable contribution to your profession. It is only through your help that the important objectives of this study can be achieved.

Let us assure you that your comments will be held on a strictly confidential basis. The number appearing on your questionnaire is necessary only to permit follow-up of this letter, if needed. Thank you for your assistance; we are looking forward to reading your comments.

Sincerely,

Lawrence C. Weaver, Ph.D.
Dean, College of Pharmacy

Stephen J. Sweeney, M.S.
Assistant to the Dean

Figure XIX

Cover Letter for Follow-up Mailing to
Pharmacy Practitioners April 19, 1976

Dear Mr.

On March 29, the College of Pharmacy mailed out a survey addressed to you that concerned the concept of a new class of non-prescription drugs, available exclusively from pharmacies and/or pharmacists. Since we have not as yet received your reply, we hope that this letter will clarify our intentions for the survey and stimulate you to actively participate in the study by responding to the questionnaire.

The new class of drugs concept has important implications for the practicing pharmacist. This study represents an effort by the College to involve itself in examining issues having a direct bearing on the professional practice of pharmacy. Colleges of Pharmacy have not in the past taken as much of an active interest in problems faced by the practitioner as they might have, and this study represents one of the initial efforts by Minnesota's Pharmacy College to remedy this situation. However, without knowing what pharmacists desire in regard to a new intermediate class of drugs, the appropriate course of action for the profession remains in doubt. This is why it is so important that we obtain your response to our survey. You represent one of only a small number of pharmacists selected to participate in the survey and, for the results to be meaningful, we desperately require your input. Only by your returning the completed questionnaire, will we be able to accurately determine what practitioners want in the area of drug reclassification.

Please let us take this opportunity to thank you for your help. Your interest and assistance is truly appreciated.

Sincerely,

Lawrence C. Weaver, Ph.D.
Dean, College of Pharmacy

Stephen J. Sweeney, M.S.
Assistant to the Dean

Figure XX

Sample 2 x 2 Decision Table and Accompanying Calculation Indicating a Significant Difference in Awareness to the Drug Reclassification Concept by Non-Association Members as Compared to Association Members

A. Decision Table

Aware of Concept	Non-Members	Members	Totals
Yes	37	70	107
No	70	47	117
Totals	107	117	224

B. Sample Calculation

$$X^2 = \frac{(/ad-bc/)^2 N}{(a+c)(b+d)(a+b)(c+d)} = \frac{(37)(47)-(70)(70)^2(224)}{(107)(117)(107)(117)} = 14$$

a = number of "yes" responses by non-members
b = number of "yes" responses by members
c = number of "no" responses by non-members
d = number of "no" responses by members
N = sum of association and non-association responses

The null hypothesis that association membership is independent from awareness to the basic proposal is rejected because of the Chi-square value of 14. This result is significant at a "p" value of .001.

Figure XXI

Discussion and Listing of Canada's Schedule C Drugs

A. Discussion

The food and drug legislation of Canada closely parallels that found in the United States today, with one major exception. The Durham-Humphrey Amendments that created two specific drug classes in the United States, were not adopted by Canada. Canada does limit certain drug products to sale on a prescription only basis, and in addition (with the passage of a new law that took effect July 1, 1976), designates those non-prescription drugs that are forbidden to be included in proprietary products.[1] Proprietary products are those marketed by a manufacturer under a registered tradename and able to be advertised directly to the public. The Canadian system thus provides for differentiation between non-prescription OTC products, and non-prescription proprietary products. Canadian OTC products are generally limited to sale in pharmacies exclusively, while proprietary medications are able to be sold through non-pharmacy outlets.

What appears as strikingly different between the Canadian situation and that which occurs in the United States, is the wide variety of items requiring a prescription in this country, but sold as OTC products (restricted to sale in pharmacies) in Canada. The Canadian province of Ontario and its drug classification legislation, provides an example of the great disparity that exists between the professional responsibility accorded pharmacists in Canada and that permitted in the United States. The Ontario Health Disciplines Act, contains a list of drugs that are classified as "Schedule C". The following provisions are reflected in the Act.

> The Act requires that all "drugs" must be sold by a pharmacist, intern, or registered pharmacy student under supervision except where specified. Schedule C exempts substances from this requirement, provided

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[1]Dr. A. B. Morrison, Assistant Deputy Minister, Health Protection Branch, Ottawa, "The End of an Era," speech presented to the 20th Annual Mid-Year Meeting of the Proprietary Association of Canada, February 5, 1975.

a pharmacist or intern is "available to the purchaser for consultation."[2]

The vast majority of Schedule C drug products require a prescription in the United States. In a telephone discussion with a representative of the Ontario College of Pharmacists, it was revealed that some opposition from Ontario's pharmacists occurred when Schedule C was created.[3] These dissident pharmacists apparently did not desire to take the responsibility and the time to personally dispense these products to patients. This is one reason why the antihistamine and decongestant combination products (that are limited to prescription sale in the United States) were not included in Schedule C. These products can only be purchased in Ontario pharmacies, but they do not require the active participation of the pharmacist in the sales transaction.

A very revealing telephone conversation with an individual serving in the long range planning area of the Canadian Health Ministry,[4] indicated that although the classification system used in Canada might not represent an ideal or perfect situation, no need for change exists. Pharmacists in the past have demonstrated an ability and a concern for resolving problems of drug misuse or abuse, and have thereby nullified any need to place further restriction on the sale of these products. It was also mentioned in the telephone discussion that the Canadian government feels it is an advantage for patients to be able to discuss their drug product needs with the pharmacist. This provides an interesting contrast with the viewpoint expressed by present FDA Commissioner Schmidt, who referred to drug reclassification as a "doubtful cause" and motivated by economic concern.[5]

It is apparent from this description of the Canadian system for controlling OTC products, that the

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[2]"Ontario Health Disciplines Act Distributed," PMAC Bulletin, 70:75, September 12, 1975.

[3]Telephone conversation with Mr. Dunton of the Ontario College of Pharmacists, October 31, 1975.

[4]Telephone conversation with Dr. John Bachinsky, Long Range Planning, Canadian Health Ministry, Ottawa, November 6, 1975.

[5]Dr. Alexander Schmidt, "Third Class of Drugs Doubtful Cause," Weekly Pharmacy Reports, 23:19, May 13, 1974, p. 2.

Canadian pharmacist is recognized as contributing to their safe and effective use. This recognition of the pharmacist's expertise and knowledge does not occur in the United States. Unless pharmacists in Canada can be shown to possess a vastly superior education or competency when compared to their U. S. counterparts, or unless the Canadian system is demonstrated to be creating a hazardous situation for its people, then it becomes clear that our present two class system of drug classification does not represent the only possible alternative. Certainly, the Canadian system offers an acceptable and a less restrictive method for drug classification that should be closely examined for application in this country.

B. Listing of Some Schedule C Drugs*

ANESTHETICS, for topical (local) application:
- Benzocaine and its salts
- Lidocaine and its salts
- Tetracaine and its salts

ANALGESICS, ANTIPYRETICS, ANTIRHEUMATICS:
- Acctaminophen
- Codeine phosphate, in preparations which contain codeine phosphate not exceeding one-eighth grain or its equivalent per tablet or per unit in other solid form or one-third grain or its equivalent per fluid ounce in a liquid preparation, if
  (i) the preparation contains
    1. two additional medicinal ingredients other than a narcotic in a quantity of not less than the regular minimum single dose for one such ingredient or one-half the regular minimum single dose for each such ingredient; or
    2. three additional medicinal ingredients

*Excerpted from the "Schedule C" list, Health Disciplines Act, Ontario, Canada, as reprinted in the Pharmaceutical Manufacturers' Association of Canada Bulletin, No. 70/75, September 12, 1975.

other than a narcotic in a quantity of not less than the regular minimum single dose for one such ingredient or one-third the regular minimum single dose for each such ingredient; and

(ii) there is legibly and conspicuously printed on the main panel of the label and on any outer container the full formula or true list of all active ingredients and a caution to the following effect:

"This preparation contains codeine and should not be administered to children except on the advice of a physician."

Salicylic acid and its salts

ANTHELMINTICS:
- Piperazine and its salts
- Pyrantel pamoate
- Pyrvinium pamoate

ANTIBIOTICS FOR TOPICAL USE:
- Bacitracin and its salts
- Polymyxin B Sulphate

ANTIFUNGALS AND ANTIMONILIAL AGENTS:
- Candicidin
- Nystatin
- Tolnaftate

ANTIHYPERLIPIDEMICS:
- Cholestyramine resin

ANTIPARKINSONISM AGENTS:
- Benztropine mesylate
- Orphenadrine and its salts
- Trihexyphenidyl hydrochloride

ANTISPASMODICS, ANTICHOLINERGICS, MUSCLE RELAXANTS:
- Clidinium bromide
- Dicyclomine and its salts
- Glycopyrrolate and its salts
- Isopropamide or its salts or preparations thereof, containing 2.5 mg. or less per stated dose
- Mephenesin and its salts
- Methantheline and its salts

Methocarbamol
Propantheline and its salts

BRONCHODILATORS:
Theophylline and its derivatives

CHOLINERGICS:
Bethanechol chloride
Neostigmine and its salts
Pyridostigmine bromide

ENZYMES:
Pancreatin
Streptokinase-Streptodornase

GLAUCOMA THERAPEUTIC DRUGS:
Demecarium bromide
Dichlorphenamide
Isoflurophate

HEMATINICS:
Iron preparations, in tablet, capsule or liquid form, containing more than 60mg. of elemental iron per unit dose

HEMOSTATICS:
Carbazochrome and its salts

HORMONES:
Globin insulin with zinc
Insulin
Insulin made from zinc-insulin crystals
Insulin zinc suspension
N.P.H. insulin, Isophane insulin
Protamine zinc insulin

SEDATIVES:
Bromides or their salts or compounds or derivatives thereof

TRICHOMONACIDES, AMEBICIDES:
Diiodohydroxyquin
Glycobiarsol

URINARY ANTI-INFECTIVES/ANALGESICS:
Phenazopyridine hydrochloride

VASODILATORS:
Cyclandelate
Dipyridamole
Isosorbide dinitrate

Isoxsuprine and its salts
Nylidrin and its salts
Tolazoline and its salts

VITAMINS:

Products containing vitamins above a minimum dosage strength, eg.) Vitamin A=5000 units, Vitamin C=150 mg., etc.

MISCELLANEOUS DRUGS:

Gamma benzene hexachloride
Nitroglycerin in tablet form
Potassium salts containing more than 5 mEq. of potassium per tablet, capsule or 5 ml. of liquid dosage form
Quinacrine hydrochloride
Quinidine and its salts
Quinine and its salts
Trimethobenzamide and its salts

Table I

State Exempt Narcotic Control Methods

States	Rx*	OTC**	Both***	States	Rx*	OTC**	Both***
Ala.			X	Mo.		X	
Alaska		X		Mont.	X		
Ariz.		X		Neb.	X		
Ark.		X		Nevada		X	
Cal.	X			N. H.			X
Colo.	X			N. J.		X	
Conn.			X	N. M.		X	
Del.		X		N. Y.	X		
D.ofC.		X		N. C.		X	
Fla.		X		N. D.	X		
Ga.			X	Ohio		X	
Haw.		X		Okla.	No Response		
Idaho		X		Oregon			X
Ill.		X		Penn.			X
Ind.		X		R. I.			X
Iowa		X		S. C.		X	
Kansas		X		S. D.	X		
Ky.		X		Tenn.			X
La.	X			Texas			X
Maine		X		Utah	X		
Md.			X	Vt.	X		
Mass,			X	Va.		X	
Mich.			X	Wash.		X	
Minn.			X	W. Va.		X	
Miss.			X	Wisc.		X	
				Wyo.		X	

*Prescription
**Over-The-Counter
***Combination of Prescription and Over-The-Counter

Table II

States With Some Pharmacy
Restricted OTC Products

Arizona	New Hampshire
California	New Mexico
Colorado	New York
Idaho	North Carolina
Maryland	North Dakota
Michigan	Oregon
Minnesota	Pennsylvania
Montana	South Dakota
Nebraska	Utah
Nevada	Washington
	Wisconsin

No response was obtained from Oklahoma

Table III
Raw Data Obtained from Motivation Spectrum Inquiry,
Economic-Professional Aspects, Questions 17-28 of Instrument*

Aspects	Practitioners (N=230)						Board Secretaries (N=46)						Association Secretaries (N=31)					
	NR	SA	A	N	D	SD	NR	SA	A	N	D	SD	NR	SA	A	N	D	SD
17. Expanded roles	5	111	81	17	11	5	0	31	13	2	0	0	0	29	2	0	0	0
18. Economic motivation	4	18	45	50	92	21	0	3	7	9	23	4	0	0	1	7	19	4
19. Pharmacist time	5	51	127	23	20	4	0	9	31	2	4	0	0	9	14	3	5	0
20. Pharmacist's knowledge	3	91	113	14	7	2	0	10	30	5	1	0	0	11	19	1	0	0
21. Patient's acceptance	11	43	133	35	5	3	2	5	32	7	0	0	1	8	18	2	2	0
22. Malpractice suits	7	17	40	70	80	16	1	0	4	14	24	3	0	0	1	4	19	7
23. Third party coverage	5	41	60	47	39	38	0	7	23	10	5	1	0	14	9	4	3	1
24. Pharmacist expenses	13	33	95	54	27	8	2	4	25	9	6	0	1	8	11	7	4	0
25. Specialized training	12	40	95	33	35	15	2	12	19	4	8	1	0	4	18	5	3	1
26. Need to restrict OTC's	4	64	115	25	19	3	0	11	27	3	4	1	0	10	19	1	1	0
27. Legend de-classification	3	53	126	25	17	6	1	7	21	6	10	1	0	4	22	4	1	0
28. Professional motivation	4	43	111	44	19	9	1	5	26	9	5	0	0	7	18	6	0	0

*The numbers represent the responses recorded in each category for each question by each surveyed group.
NR=No Response, SA=Strongly Agree, A=Agree, N=Neutral, D=Disagree, SD=Strongly Disagree

Table IV

Raw Data Obtained on the Preferred Positions for National Pharmacy Associations on Issues of Importance to the Pharmacy Profession, Questions 29-36 of the Instrument*

Issues	Practitioners (N=230)						Board Secretaries (N=46)						Association Secretaries (N=31)					
	NR	SS	S	N	O	SO	NR	SS	S	N	O	SO	NR	SS	S	N	O	SO
29. Continuing education	5	67	91	28	4	5	0	16	12	12	4	2	0	8	5	10	7	1
30. Mailorder prescriptions	3	0	8	19	82	118	2	3	0	6	9	26	0	1	1	1	4	24
31. Pharmacy technicians	6	20	77	46	43	38	0	4	8	14	11	9	0	1	7	11	7	5
32. Prescription price ads	6	3	17	39	78	87	1	1	2	15	12	15	0	0	0	9	8	14
33. Pharmacy ownership	4	109	67	33	10	7	0	9	15	13	4	5	0	10	12	7	1	1
34. Drug product selection	7	78	94	35	7	9	1	10	19	8	7	1	0	18	11	2	0	0
35. New drug class	4	87	105	22	5	7	0	16	24	5	1	0	0	18	10	3	0	0
36. Clinical pharmacy	7	56	90	63	10	4	1	12	23	7	1	2	0	13	12	5	1	0

*The numbers represent the responses recorded in each category for each question by each surveyed group. NR=No Response, SS=Strongly Support, S=Support, N=Neutral, O=Oppose, SO=Strongly Oppose

Table V

Raw Data Obtained on the Perceived Degree of Importance to the Pharmacy Profession for the Issues Listed in Questions 37-44 of the Instrument*

Issues	Practitioners (N=230)				Board Secretaries (N=46)				Ass'n Secretaries (N=31)			
	NR	VI	I	NI	NR	VI	I	NI	NR	VI	I	NI
37. Continuing education	5	88	98	39	0	19	21	6	0	9	16	6
38. Mailorder prescriptions	6	73	70	81	2	18	22	4	0	15	12	4
39. Pharmacy technicians	9	57	122	42	0	11	31	4	0	8	17	6
40. Prescription price ads	8	92	65	65	1	14	22	9	0	10	13	8
41. Pharmacy ownership	6	113	72	39	0	14	19	13	0	8	20	3
42. Drug product selection	16	102	101	11	1	19	22	4	0	17	13	1
43. New drug class	8	84	116	22	0	15	27	4	0	16	14	1
44. Clinical pharmacy	11	50	120	49	2	15	24	5	0	15	14	2

*The numbers represent the responses recorded in each cateogry for each question by each surveyed group.
NR=No Response, VI=Very Important, I=Important, NI=Not Important

Table VI

The Numbers and Percentages of Responding Practitioners, Board Secretaries, and Association Secretaries that Felt the Listed Organizations Would/Would Not Support Drug Reclassification

Responses	Practitioners		Board Secretaries		Association Secretaries	
	#	%	#	%	#	%
NARD Support						
Yes	150	65	26	57	25	81
No	13	6	3	7	0	0
Undecided	55	24	13	28	5	16
No response	12	5	4	9	1	3
Total	230	100	46	100	31	100
APhA Support						
Yes	159	69	35	76	27	87
No	6	3	0	0	1	3
Undecided	50	22	8	17	2	6
No response	15	7	3	7	1	3
Total	230	100	46	100	31	100
ASHP Support						
Yes	87	38	26	57	18	58
No	28	12	0	0	1	3
Undecided	90	39	15	33	11	35
No response	25	11	5	11	1	3
Total	230	100	46	100	31	100

Table VII

Professional Association Membership of Responding Practitioners*

Association Membership	Number	Percent
1. None	108	47%
2. APhA only	51	22.2%
3. NARD only	29	13%
4. APhA and NARD	28	12%
5. ASHP only	3	1%
6. NARD and ASHP	1	.4%
7. APhA and ASHP	9	4%
8. NARD + APhA + ASHP	1	.4%
	230	100%

*It was interesting to discover the high percentage of overlap in membership that exists between the APhA and the NARD. It appears from the survey results, that roughly 35% of the APhA membership is composed of those pharmacists who are also NARD members, while 49% of the NARD membership appears to be comprised of pharmacists who are also APhA members. State pharmacy association membership, while not being utilized for analytical purposes, was indicated as being held by 56% of the responding pharmacists.

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