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OPINIONS OF MISSISSIPPI PHARMACISTS
ON THE PRESCRIPTION TO OTC SWITCH, AND
THE OTC STATUS OF IBUPROFEN

BY

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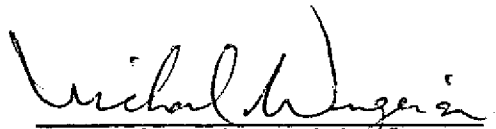
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CHAPTER I
INTRODUCTION

WHAT IS THE SWITCH ?

Some drugs which once were available only with a doctor's prescription now have government approval to shed their Rx label and be sold over the counter. In the slang of the drug industry, that change in status is called "Rx to OTC switch".¹

WHY HAVE THE SWITCH ?

Before the first half of the century, Federal laws, enacted by Congress to regulate drugs, were designed to assure the integrity of drug products sold to the American public without addressing the prescription/non-prescription issue.² The Federal Food, Drug, and Cosmetic Act in 1938 also made no attempt explicitly to resolve the problem of a lack of legal delineation separating prescription-only from non-prescription drugs.³

To eliminate the confusion and protect the public health, Congress enacted the Druham-Humphrey Amendment to the Food, Drug, and Cosmetic Act in 1951.⁴ This legislation categorized drugs into two classes: prescription and non-prescription. A drug is considered a prescription only if⁵:

1. It is habit forming.
2. It is not safe for use, because of toxicity and harmful effect, except under a practitioner supervision.
3. It is limited to prescription use under a New Drug Application (NDA).

The Kefauver-Harris Amendment in 1962 required the Food and Drug Administration (FDA) to review all drugs marketed during 1938-1962. Drugs were reviewed pursuant to the NDAs to show the safety and effectiveness.⁶ The Amendment established the massive review of OTC drug products which FDA is only now completing. Many previous "prescription-only" drugs have been shifted from Rx to OTC status as a result of this review.⁷ A drug must fit the criteria of being safe and effective for OTC sale.

1. An OTC drug is SAFE if it has a low incidence of adverse reactions or significant side effects under adequate directions for use as well as low potential for harm which may result from abuse under conditions of widespread availability.⁸
2. An OTC drug is EFFECTIVE if there is a reasonable expectation that in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use,⁹ will provide clinically significant relief of the type claimed.

SWITCH - THE PROCESS

A drug's status can be changed from Rx to OTC by three methods.

(1) Switch Regulation: any interested person may petition the FDA to exempt a prescription drug from its prescription-use requirement. What FDA considers is its toxicity, harmful effect, method of use, and collateral measure.¹⁰

(2) NDA Supplement: any interested person could initiate the switch through filing and obtaining approval of a supplemental NDA. Under this procedure, the FDA's office of Drug Research and Review determines whether the drug, previously limited under the terms of its NDA, has now been shown to be safe for OTC use.¹¹

(3) OTC Drug Review System: the system was initiated in 1972 to establish

conditions under which OTC drugs within various classes and product label would be generally recognized as safe and effective and adequately labeled. First, advisory review panels review the ingredients to determine which could be generally recognized as safe and effective for use in self-treatment. Then, the panels reclassify the prospective ingredients into one of the following three categories :¹²

- (I) Generally recognized as safe and effective for the claimed therapeutic indications.
- (II) Not generally recognized as safe and effective or unacceptable for the claimed indications
- (III) Insufficient data to permit final classification at this time.

After that, the FDA evaluates panel's recommendations, public comments, and new data. In the last phase, the review involved publication of the "final monographs" which represented the regulatory standards for marketing non-prescription drugs.¹³

SWITCH - THE TREND

During the past few years, many previously "prescription-only" drugs have been shifted to OTC status. According to Peter Godfrey, chairman of the Proprietary Association in 1982, there is a significant trend in the pharmaceutical industry, as a result of the Federal Food and Drug Administration proposal, toward converting prescription drugs to OTC .¹⁴

There are several forces promoting the movement of drugs from Rx to OTC.

THE HEALTH MARKET

As Robert Helms pointed out, the health market is becoming more cost

conscious.¹⁵ Concerns about cost are putting pressure on all third party payers, on the federal government which pays for Medicare and Medicaid, and on private insurance carriers to cut down on the cost of health care. The economic efficiencies introduced by OTC agents, are expected to have an overwhelming impact in an era of critical concern over health spending.

THE PHARMACEUTICAL INDUSTRY

In the game of "Rx to OTC switch", pharmaceutical industries play the most important roles. Pharmaceutical companies have recognized that Rx-to-OTC switch is useful way to extend the product life cycle, and to improve profits on a product. Although the success of any switch is not absolutely guaranteed, previous successes with changing drugs from Rx to OTC have given the industry some confidence and encouragement.

Hydrocortisone 0.5% enjoyed a sales increase of over 400% within the year of its reclassification. In 1984, Micatin was available for the first time as an OTC agent, and sales increased 172% to \$3.4 million.¹⁶

CONSUMERS

Both the increasingly educated public and the ones who have a heightened sense of self awareness require that more drug products be available for self-medication. A recent New York Times survey on health care and the high price of health revealed that nearly six out of every ten people would be willing to have their routine illness treated by self-medication.¹⁷ The cost of health care in the United States has risen at an astronomical rate over the past decade and there is no relief in sight. This situation, to some degree, has encouraged the trend of self-medication and the increased availability of OTC drugs.

THE REGULATORY ENVIRONMENT

The establishment of a specific regulatory division within FDA for OTC drugs raises the possibility that the process of change may proceed along another administrative path. The FDA has moved beyond self-diagnosis as an OTC criterion and is more willing today, than at any time before, to recognize that even though a particular condition may have to be diagnosed by physicians, once such a diagnosis has been made, it is no longer essential that drugs be limited to a prescription status.¹⁸

There are also several forces opposing the change from Rx to OTC.

THE PHYSICIANS

The Rx-to-OTC switch of products may appear to threaten physicians' status because patients could become less dependent. Switching products could result in fewer patient visits and thus have a negative economic impact on physicians. However, most physicians' arguments against the switch have been based on reasons of safety and the patients' inability to determine proper indications, rather than economic motives. In a review of relevant research, Zelnio concluded that physicians did not consider cost when prescribing a drug.¹⁹ The potential side effect and the efficacy of the drug product are the most important factors influencing the physicians' prescribing habits.

THE CONSUMERISTS

The consumerists are quite distinct from consumers. They want the maximum amount of service but expect somebody else to help them pay the bill. They consider the availability of former prescription drugs on an OTC basis as a plot by big industry to turn former recipients of social

welfare programs into mere paying consumers.

THE PHARMACISTS

Pharmacists have probably been the most vociferous in their comments on the switch issues. Some pharmacists perceive an economic benefit from increased sales of switched products and having more products available for patient drug consulting to improve the pharmacist-patient relationship. Others, however, think they have been hurt by drugs which were once sold only by prescription but now are available at convenience stores, grocery stores, and other drug outlets.

In addition to their concerns about safe and effective OTC use, pharmacists use the switch issue to strengthen their campaign for the "third class drugs" or the "pharmacist legend" of drugs which are similar to the "ethical OTCs" promoted by the drug manufacturer in the past.²⁰

IBUPROFEN

THE SWITCH

The FDA does not perceive the OTC availability of ibuprofen as a switch from prescription status.²¹ Although ibuprofen had been available by prescription in the United States for years, the 200 mg dosage was brought to the OTC market through application as a new drug. But, the word "switch" shares common issues in corporate strategy, organization structure, and product management and marketing.²²

HISTORICAL BACKGROUND

Ibuprofen was introduced into the U.S. market by Boots Corp., a British pharmaceutical company in 1968, (see Figure I) and approved by

Figure 1

Ibuprofen Product History (1960 - 1986)

Year	Events
1960	Synthesized by Boots Pharmaceutical Co. in England.
1968	Introduced into U.S. health market by Boots Pharma. Co. FDA approved as a Rx drug
	Exclusive marketing rights 1974 - 1981
1974	Upjohn Co. Motrin 300 mg, 400 mg
1976	Motrin 600 mg
1981	Boots U.S. Rufen 400 mg
1982	Rufen 300 mg
	OTC Ibuprofen 200 mg licensed to
1984	Bristol-Myers Nuprin 200 mg
	Whitehall Advil 200 mg
	Boots U.S. Rufen 600 mg
1985	Rx ibuprofen patent expired
	Upjohn Co. Motrin 800 mg
1986	OTC ibuprofen 200 mg exclusive marketing period for Advil & Nuprin ended
	Boots U.S. Rufen 800 mg

the FDA as a prescription drug. It was prescribed mainly for rheumatoid arthritis and osteoarthritis in higher dosage strength (300 mg, 400 mg, 600 mg, 800 mg) than the current OTC dosage (200 mg).²³ Upjohn received exclusive marketing rights from Boots to manufacture and launch ibuprofen as Motrin from 1974 to 1981. In 1981, Boots marketed its own brand of ibuprofen, Rufen, in the United States. By 1984, ibuprofen, including Motrin and Rufen, had become the fifth largest selling prescription drug. Rx ibuprofen was being used by 7 million patients annually and had reached approximately \$210 million in U.S. sales.²⁴ With this prominent sales record, ibuprofen was approved in May, 1984 by the FDA to be sold over the counter in a lower dosage strength, 200 mg. OTC ibuprofen was recommended for the temporary relief of minor aches and pains associated with common cold, headache, backache, muscular aches, toothache, for the minor pain of arthritis, for the pain of menstrual cramps, and for fever reduction.²⁵

For years, aspirin and acetaminophen were the only two products available in the OTC internal analgesic market, the second largest non-prescription drug market, \$1.2 billion, in 1984. No doubt 200 mg ibuprofen was the single most important product to make the Rx-to-OTC switch in 1984 with the almost immediate launching of Advil (by Whitehall) and Nuprin (by Bristol-Myers).²⁶ These two products made a respectable impact on the OTC internal analgesic market, and occupied approximately 8% of the total OTC analgesic market in 1985. After the exclusive marketing period for Advil and Nuprin ended in September 1986, more products entered the market, and the sales of OTC ibuprofen reached

\$150 million annually. These sales represented 35% of the total internal analgesic market.²⁷ OTC ibuprofen really slashed a "healthy slice" of the analgesic market, and took business from both aspirin and acetaminophen. It was estimated to have a certain degree of effect on the Rx version of ibuprofen although the strengths were different.

STATEMENT OF THE PROBLEM

In the last 10-15 years, the trend toward self-medication and the switch of important Rx drugs to OTC status have been significant and will likely continue. Consumers' needs for health and drug information will place increasing importance upon the pharmacist's role as an interpreter of health information related to the solution of specific individual problems. Relied upon by consumers to provide confirmation and reassessment of many health-related problems, pharmacists are in a unique position to aid and advise patients who choose self-medication. Serving at the interface between the public and drugs, pharmacists might have distinct opinions toward the Rx-to-OTC switch. Pharmacists' attitudes toward this issue should be evaluated and considered by regulatory agencies and policy makers in the future development of laws and regulations related to Rx-to-OTC switch. Their attitudes and perceptions toward switched products and products which might be switched in the future could directly influence patients' drug purchasing behavior and affect the market success of these products. Therefore the attitudes and perceptions of pharmacists toward the Rx-to-OTC switch should be considered carefully by the pharmaceutical industry in developing marketing strategies.

Ibuprofen 200 mg might be the most important drug to recently made the Rx-to-OTC switch. The sales market impact of both prescription ibuprofen and other OTC internal analgesics, and its convenience as an OTC drug for millions of people to take for pain-relief, have made ibuprofen 200 mg the target of widespread market attention. Having been launched in the OTC market for three years, ibuprofen 200 mg provides a good subject to explore pharmacists' attitudes and perceptions toward the switch from Rx to OTC status.

As of yet, no attempt has been made to assess the attitudes and perceptions of the community pharmacists' toward the Rx-to-OTC switch and ibuprofen 200 mg. Therefore this research was conducted to better understand the current opinions of Mississippi community pharmacists towards the conversion of prescription drugs to OTC status, and especially ibuprofen 200 mg. The data obtained from this study will aid pharmaceutical companies in preparing promotional strategies toward the pharmacists for both the existing product and future products making the Rx-to-OTC switch.

RESEARCH OBJECTIVES

The objectives of this research are:

- (I) To describe pharmacists' general attitudes toward the switch of prescription drugs to over the counter status.
- (II) To describe pharmacists' general attitudes toward the Rx-to-OTC switch of ibuprofen 200 mg.
- (III) To determine the pharmacists' perception of the competition in the OTC medications business.

- (IV) To evaluate pharmacists' attitudes toward potential ways to manage the transition of prescription to over the counter status.
- (V) To describe pharmacists' attitudes toward potential Rx-to-OTC switch for selected drug categories.
- (VI) To describe pharmacists' perceptions of the market share impact of Rx-to-OTC switch of ibuprofen 200 mg on other selected Rx products and OTC internal analgesics.
- (VII) To determine pharmacists' recommendations of selected ibuprofen 200 mg products for the approved indications.
- (VIII) To determine the relative importance of selected marketing factors in pharmacists' decisions to recommend an ibuprofen 200 mg product.

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CHAPTER II

LITERATURE REVIEW

This chapter presents a review of the literature concerning the Rx-to-OTC switch, the pharmacists' response toward it and the Rx-to-OTC switch of ibuprofen 200 mg.

SWITCH - HISTORICAL BACKGROUND

Switches from Rx-to-OTC are not new phenomena. During the fifteen year period, beginning in 1956 and prior to the beginning of the OTC Drug Review System in 1972, the Food and Drug Administration (FDA) approved the transfer from prescription (Rx) to over the counter (OTC) status of twenty three single ingredients and two combinations through the Switch Regulation.¹⁻² The Switch Regulation is fairly simple. One simply filled out a petition with FDA. Through the petition process, it is possible to turn a competitors' drug into an OTC product, even against their will.³

Since the OTC Drug Review System began to work in 1972, the switch phenomenon has emerged as a major force in the drug business. By June 1984, nineteen ingredients formerly available on a prescription-only basis had been judged to be safe and effective for non-prescription use.⁴ Dr. William Gilbertson, Director of the Division of OTC Drug Evaluation at FDA, indicated that the OTC Drug Review System was changing the entire industry by switching selected prescription drugs to OTC status, by providing a more extensive market for OTC drug

manufacturers and by expanding choices in self-medication for OTC consumers.⁵ He also pointed out that at the end of 1986, only 5% of the OTC monographs were completed, while 60% remained in the tentative stage.⁶ Some 200 of the 731 ingredients that panelists reviewed had been placed in or recommended for, category (I). The Enforcement Policy issued by FDA in 1976, states that a prescription ingredient may be marketed OTC after a panel report recommending Category (I) classification has been published in the Federal Register and the FDA has not dissented from the recommendation.⁷ This policy prevents some manufacturers from marketing an OTC drug that may not be safe and effective to use, yet benefits consumers because it allows the rapid availability of drugs that are considered safe and effective for self-treatment by the experts and the FDA.

The NDA Supplement, issued by FDA in 1956, is the third method by which a drug can be transferred from Rx to OTC status. This method provides the NDA supplement as an alternative to a citizen's petition. The supplement, or an original NDA, can provide for OTC labeling. A supplement or NDA can only be initiated by the NDA holder or sponsor.⁸ Under the newly enacted Price Competition and Patent Term Restoration Act of 1984, a change provided for in a supplement was entitled to three years of exclusiveness against competing ANDAs if clinical trials, necessary for approval of the supplement, were contained in the submission. Ann Wion, Associate Chief Counsel for the OTC Drug Office of the General Counsel at FDA, used two 2x2 matrixes to show the current drug categories (figure II) and the established procedure for drugs

switching from Rx to OTC status⁹ (figure III).

Figure II

Current Drug Category

	Rx	OTC
" New Drug "	1	3
	-----	-----
Not "New Drug" (GRAS/E) and market for material time / extent *	2	4

- Box 1 : A prescription "New Drug"
- Box 2 : A prescription drug that is not a "New Drug"
FDA consider all prescription drugs to be "New Drug", therefore, no actual drugs now falls within this box.
- Box 3 : An OTC "New Drug"
- Box 4 : An OTC drug that is not a "New Drug"
- * GRAS: Generally Recognized As Safe
- * GRAE: Generally Recognized As Effective

Figure III

Established Process for Rx-to-OTC Switch

	Rx	OTC
"New Drug"	1 (A)	3
	-----	-----
Not "New Drug"	2	4

----->

- Route (A) : Through the Supplement NDA.
- Route (B) : Through the OTC Drug Review System.

THE DRUG INDUSTRY - ECONOMICS

A large number of drug candidates may be suitable for Rx-to-OTC switch. An NDA holder, one who can file a supplement NDA, the competitor to the NDA holder, any member of the public, an FDA committee, or the FDA itself could start the switching procedure through one of the three drug reclassification methods. Yet, Peter Hutt, former Chief Counsel for the FDA, pointed out that initiating the switch would largely remain in the hands of the drug industry.¹⁰ Any future trend in the realm of changing drugs from Rx-to-OTC status might be based on maximizing the interest of the pharmaceutical industry because they would be able to keep these materials mainly under their own control.

Owing to the high costs and uncertain market success in introducing a new drug product (not switched from Rx-to-OTC) into the market, pharmaceutical companies have started to examine the existing Rx drug list. They hope to identify drugs which have a long and established history as safe and effective and might receive FDA's approval to be switched to the OTC market.¹¹

The drug industry's view on the Rx-to-OTC switch is quite different from those of the FDA, consumers, physicians, and pharmacists. One survey showed that the major four incentives that motivate the drug companies to proceed with the Rx-to-OTC switch are (1) to increase market size & share, (2) to introduce superior OTC product, (3) to increase company profit and (4) to enter new OTC market.¹² To reduce health care expenditure, lower consumers' cost, and increase pharmacy profits are less important stimuli when a pharmaceutical company makes the switching

decision. Most drug companies shift a product's promotional emphasis from health professionals directly to the consumers when the product is switched to OTC status. They spend a large amount in direct consumer advertising and coupon mailing and they commence selling their newly switched products to non-pharmacy outlets.¹³ They evaluate the switching success mainly by looking at the increased market share, greater sales volume and increased profits.¹⁴

THE CONSUMER - SELF MEDICATION

The increasing sophistication and independence of consumers accompanied by increasing innovation and the economic imperatives of the individual and public levels make self-care considerably more popular than ever. OTC drug products are now taken by more people for self-medication than ever before. A World Health Organization household survey indicated that at least forty million persons in the United States take an OTC drug on any given day.¹⁵ A comprehensive study of self-medication among 234 families found that the access to self-medication could be compared to calling a physician.¹⁶ OTC medicines were readily available and easily used by most families.

During a symposium in 1978 on the Rx-to-OTC switch issue, it was stated that consumers need more OTC drug products which are tested, safe and effective drugs for self-medication.¹⁷ They also need drugs which have good information available at the point of sale and promise a lower, more affordable price. Dr. Peter Temin, Professor of Economics in Massachusetts, analyzed the costs and benefits in switching some drug products from Rx to OTC status. He concluded that the benefits of

switching those drugs greatly exceeded the costs, and the benefits of the drugs could be immediately seen and monitored by the consumer.¹⁸

The potential benefits to consumers include health care cost savings due to fewer physician visits, the availability of new, safe and effective drugs for self-medication, and better labeling information that promote consumer safe self-medication and self reliance.

SWITCH - PHARMACIST RESPONSE

In a perfectly working patient-physician-pharmacist model, all three parties are involved in an exchange of information and data, each communicating effectively with the other. But, in the area of non-prescription drugs, the pharmacist should be the first resource person and advisor for the patients' selection of drug products.¹⁹ In recent years, pharmacists have taken important steps to expand their knowledge of OTC drugs in order to be competent for the increasing professional responsibility placed by the trend toward self-medication and the switch of important drugs from Rx to OTC status.

The American Pharmaceutical Association (APhA) published their first edition of the Handbook of Non-Prescription Drugs in 1967.²⁰ It was designed to help the pharmacists live up to their professional responsibilities and to earn the trust and confidence of the public as pharmacists become more clinically involved in serving self-diagnosing and self-medicating patients. A number of pharmacy colleges also have begun devoting a portion of their curriculum to OTC counseling.²¹

According to John Walden, Senior Vice President and Director of Public Affairs for the Proprietary Association, the pharmacist should be

one of the winners in the switchover game.²² The Rx-to-OTC switch trend should hold enormous promise for pharmacists in improving both their professional roles and their contribution to medicine. Some pharmacists agree that the Rx-to-OTC switch would enhance their professional role and improve the relationship between them and the patients.²³ Having more effective products available will certainly enable pharmacists to have more chances to exercise their technical knowledge in patient consulting and patient education.²⁴

However, questions about when pharmacists could find the time for these activities, who is going to pay them for this work, and whether patients will be willing to pay for these services make pharmacists question whether they will be winners in the switchover game.²⁵ A 1981 survey of retail pharmacists, conducted by Drug Topics found that although 69% of the respondents would continue to recommend an ethically promoted OTC drug which went directly to the consumer ad campaign, nearly 31% said they would not.²⁶ Pharmacists were angry to see the drug companies apparently try to bypass them, promote the switched products directly to the consumers, and disregard their professional knowledge to consult the patients about the switched products. Facing the increasing market competition from other non-pharmacy drug outlets for the OTC medication business, some pharmacists indicated they would prefer to recommend products found primarily in a pharmacy.

In 1983, a mini survey was conducted by Drug Topics of 175 pharmacists and 60 chain executives.²⁷ Survey findings were, in some instances, puzzlingly and contradictory. It indicated that the jury may

still be out for much of the profession, or it may be that practitioners are a bit fuzzy on the real implications and long term ramifications of the Rx-to-OTC switch trends. Nearly two thirds of respondents declared that they favor Rx-to-OTC switches. Yet, upon further questioning, it became apparent that many had no concrete reason or, after reflection, might not be quite so sure. The vast majority of respondents believed that pharmacy stood to benefit the least from the Rx-to-OTC switch trend; the greatest benefit was ascribed to the manufacturer, and second to the patient.

Another survey of 1458 pharmacies done by the American Druggist in 1984 found that among the 42% of pharmacists who said the switchover trend would be good for pharmacy, a large proportion added an important qualification: they said it would be good for pharmacy only if it enabled the pharmacist to enhance his/her role as a medication consultant to the consumers.²⁸ This survey also showed that most of the respondents agreed that the Rx-to-OTC switch would be good for manufacturers but bad for the public, unless purchases were made from pharmacies. In both surveys, more than 50% of the respondents agreed that there should be a third class of drugs available over the counter but restricted to being dispensed by pharmacists.

Both the American Pharmaceutical Association (APhA) and the National Association of Retail Druggists (NARD) represented their members in calling for an interim pharmacist-only restriction on switched drugs.²⁹ They wanted this category to be designated as "pharmacist-legend drugs". The "pharmacist-legend drugs" were defined

as "items which, when released from prescription status, would be available only from a pharmacist until the public's health protection needs have been met".³⁰ In another survey conducted by the American Druggist, with 655 pharmacists in 1985, 50% of respondents supported the idea of establishing the drug category, "pharmacist-legend drugs", for the newly switched drugs.³¹ Yet, nearly 37% of the respondents expressed a preference that the drugs switched from Rx to OTC should be put into a permanent "third class", and dispensed by pharmacists only.

The Proprietary Association (PA), on the contrary, has attacked such moves as efforts to impose a "druggists' monopoly" on OTC products.³² The consumer protection groups also disagreed with such moves and indicated that restricting OTC drug products to pharmacists may tend to direct the consumer away from self-medication to unwarranted and expensive visits to medical practitioners.³³

SWITCH - IBUPROFEN

Because ibuprofen in the 200 mg dose had not been used to a material extent and for a long time, the approval of ibuprofen 200 mg for the OTC market was viewed as a new drug application rather than an Rx-to-OTC switch by the FDA.³⁴ As Boots and Upjohn were still marketing their Rx ibuprofen to physicians in 1984, neither Bristol-Myers nor Whitehall could use the established brand names, Rufen and Motrin, to promote their OTC ibuprofen 200 mg products.³⁵ Both makers presented the OTC ibuprofen as a new entity, rather than a line extension.

With a warning that aspirin-sensitive individuals should not use the products, Bristol-Myers' Nuprin and Whitehall's Advil were launched

right after FDA's approval of OTC ibuprofen 200 mg in May, 1984. In 1985, Whitehall spent approximately \$35 million in Advil advertising and produced retail sales of more than \$85 million; Bristol-Myers estimated \$25 million in promotion, with sales of only around \$35 million for Nuprin.³⁶ But Upjohn was displeased to see that Whitehall's Advil looked like Motrin in its TV commercial, mentioned it contained the same ingredient as Motrin, and sued the company.³⁷

Although ibuprofen 200 mg was approved by FDA as a safe and effective drug for the OTC market, and the necessary warnings appear on the label, there is still a risk of kidney failure at high, repeated dosage. Fourteen cases of kidney problems were known by FDA among people who were taking ibuprofen 200 mg.³⁸ A mini survey conducted with the patients who took OTC ibuprofen found that patients were not aware of the maximum dosage, the potential drug interactions and lacked specific ibuprofen knowledge.³⁹

Some community pharmacists made an announcement that they were putting ibuprofen 200 mg behind the counter, to be dispensed - with appropriate warning - only by a pharmacist.⁴⁰ Explaining the pharmacists' action, Sol Kesselman, Chairman of the Illinois Association of Community Pharmacists, declared: "I felt a moral and a professional responsibility to advise my customer exactly how to take the drug and to take it without any ill effects, if there are any."⁴¹

Precipitated by the switch of ibuprofen 200 mg from Rx to OTC, the NARD reinforced the statement on " pharmacist legend " drugs and proclaimed that the issue would be their major battleground.⁴² They

said a prescription drug should move over the counter by first being classified as an ethical OTC for a few years, as Robitussin and Actifed had.⁴³ Yet, critics of a third class of drug or the pharmacist legend drugs said what pharmacists really worried about was the loss of sales when the prescription product went over the counter. In 1983, 60% of all the OTC drug sales took place in supermarket and convenience stores, and 26% of them took place in large chain drugstores.⁴⁴ Facing the ibuprofen Rx-to-OTC switch, pharmacists might just see \$210 million, Motrin and Rufen's combined annual sales in prescription, threatening to evaporate.

The same survey done by American Druggist in 1985, found that 50% of the respondents indicated that the arrival of OTC ibuprofen had reduced the sales volume of other analgesics and the number of prescriptions for Rx ibuprofen.⁴⁵ Nearly 80% of pharmacists said they made special efforts to counsel customers who asked for OTC ibuprofen and 26.6% of them said they did that by keeping the customers in the Rx department.

When exclusive marketing rights for Advil and Nuprin ended in September 1986, a bevy of new OTC ibuprofen brands - Mediprin (by McNeil), Midol 200 (by Glenbrook), Haltran (by Upjohn), Pamprin (by Chattem), Trendar (by Whitehall) entered the scene. Because of lower prices and no restrictions on talking about Motrin in advertisements, ibuprofen 200 mg has decreased sales of Rx ibuprofen, Motrin and Rufen, to some degree.⁴⁶ Moreover, as more ibuprofen brands have entered the OTC analgesic market and been targeted to different segments of the

consumer market, other OTC internal analgesic products have lost the additional market share to ibuprofen 200 mg.

In summary, the literature reveals that the discussion regarding the Rx-to-OTC switch has not been limited to any one interest group. Regulatory agencies (FDA), pharmaceutical manufacturers, health consumer groups and practicing pharmacists all have entered into the debate thus far. Perhaps the most important group, and the subject of the present study, is the practicing pharmacists. Several studies have shown that most pharmacists are not sure whether they should favor or oppose the Rx-to-OTC switch, specifically, the switch of ibuprofen 200 mg. Some pharmacists have addressed the issues by advocating the establishment of categories of "third class drugs" or "pharmacist-legend drugs" for the newly Rx-to-OTC switched drugs, but have little information regarding how to operate the "third class" drugs and what will be the time period for the "pharmacist-legend" drugs. Furthermore, the pharmacists' attitude and recommendation toward ibuprofen 200 mg might influence the patients' purchasing behaviors, thus, the market success of ibuprofen 200 mg brand products. However, as yet, no study has been conducted to explore this topic. The methods used in the present study to accomplish the objectives stated in Chapter I are presented in the following chapter.

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CHAPTER III

METHODOLOGY

This chapter presents a discussion of the research methodology used to accomplish the eight objectives stated in chapter I. Included are: a presentation of the development of the questionnaire; a description of data collection; and a summary of statistical techniques used.

DEVELOPMENT OF THE QUESTIONNAIRE

The survey was conducted as a part of the 1987 Survey of Mississippi Pharmacies which is an annual survey sponsored by the Pharmaceutical Marketing and Management Research Program at the University of Mississippi Research Institute of Pharmaceutical Sciences. The major advantage of including the survey as a part of the 1987 Survey of Mississippi Pharmacies was to provide a relatively inexpensive means of administering a large number of questionnaires.

A nine-page booklet-type questionnaire which included questions relating to three major studies was developed. In order to reduce the response bias caused by the length of the questionnaire, two versions of the questionnaire, (A) and (B), were designed to contain a different order of the research topics. Four pages of the nine pages questionnaire presented the questions for the current study. Attention was given to the design layout of the questionnaire in an effort to make it pleasing to look at and easy to complete.

The mail questionnaire format was selected for the study because the data desired could easily and inexpensively be collected, coded and analyzed. Furthermore, the mail questionnaire is a format that is familiar to most community pharmacists and one that provides them the time flexibility of completing the questionnaire according to their individual schedule and more time to think about their replies. In addition, the mail questionnaire is less costly and provides the respondents a greater confidentiality than personal or telephone interviews.¹

The questions for the current study consisted of three major sections: (1) Pharmacy and Pharmacist Information (2) Prescription-to-OTC Shift (3) Rx-to-OTC Switch of Ibuprofen 200 mg.

PHARMACY AND PHARMACIST INFORMATION

(A) Pharmacy and Pharmacist Demographic Section

Six questions were asked for the current study in the pharmacy and pharmacist information section. Five demographic questions were included in the initial section of the questionnaire. Sex, years in practice, and current job setting were collected for the pharmacist demographic section. The average daily prescription volume and the annual sales volume of the pharmacy were collected for the pharmacy demographic information. A fixed sum scale which asked what percentage of the total sales volume was represented by Rx drugs, OTC drugs and other merchandise, was also collected as part of the pharmacy demographic data.

(B) Competition In the OTC Business Forced Ranking Scale

A forced ranking scale was utilized to ascertain the respondents' perceptions about competition among all OTC drug outlets in the OTC market. Respondents were instructed to rank each type of drug outlet from 1 to 3, with 1 being the most important competitor. The OTC drug outlets which were not ranked by the respondents were assigned a value 0. The forced ranking scale was included here for several reasons. With a forced ranking scale, the "relativity" or relationship is measured among the items. The parallel between the actual life choice situation and the measurement format is another advantage of forced ranking.²

PRESCRIPTION-TO-OTC SHIFT

Four questions were asked in the prescription-to-OTC shift section of the questionnaire. First, the respondents were asked to rate eleven statements on a five-point Likert scale according to their general degree of agreement/ disagreement toward the Rx-to-OTC switch. These statements included issues of economic incentives (items a, c, d, h, i, and j), professional role (item b), patient welfare (items e and k), and switched products labeling (items f and g). The Likert scale was selected for its presumed familiarity to the sample population since it had been used in a previous survey. The principle advantages of this type of scale include flexibility, economy and ease of composition.³ Furthermore, this scale provides answers in the format of coded data that are comparable and can readily be manipulated.

Second, the respondents were asked to rank four statements concerning the methods which should be used to manage the drug

reclassification, and switch of products from Rx to OTC status. The statements were ranked from 1 to 4, with 1 being the most preferable. Statements included were a) the establishment of "third class drugs", for the switched products, b) the establishment of "pharmacist-legend drugs" for the newly switched products, c) the current drug reclassification system, and d) stopping the switch process. The forced ranking scale was included here for the same reasons mentioned previously.

Finally, the respondents were asked to respond to a multiple response question in order to indicate which product(s) they thought might be appropriate to be switched from prescription to OTC status. The products listed were selected because they had been suggested as candidates for a switch from Rx to OTC in the literature.⁴ The multiple choice(s) questions were included here because they are very common, simple, and versatile.⁵ Moreover, they can be used to obtain either a single or several response(s).

Rx-TO-OTC SWITCH OF IBUPROFEN 200 MG

Four questions were asked in this section. First, the respondents were asked to rate seven statements on a five-point Likert scale according to their degree of agreement/ disagreement toward the Rx-to-OTC switch of ibuprofen 200 mg. Statements included here were the issues of product safety, effectiveness, labeling, and the patient reimbursement schemes of ibuprofen 200 mg.

Second, the respondents were asked to complete a multiple choice grid to indicate which ibuprofen 200 mg product they would recommend for

each of seven approved indications. The multiple choice grid was used because it allowed the presentation of 72 data points with sufficient ease and very little space.⁶ As a follow-up, the respondents were asked two open-ended questions to indicate which ibuprofen product they would most often recommend and which indication they would most frequently recommend ibuprofen 200 mg for.

Third, the respondents were asked to use a five-point Likert scale to rate their perception of the impact of Rx-to-OTC switch of ibuprofen 200 mg on sales volume of three OTC analgesic drug categories and on the number of prescription filled for selected Rx products. A value of 1 indicated "increased greatly" and a value of 5 indicated "decreased greatly". Leading OTC internal analgesic drug categories (aspirin, acetaminophen, and combination analgesics)⁷ were used to explore the pharmacists perception of the sales volume change. The Rx version of ibuprofen (Motrin and Rufen) and other competing NSAIDs (Naprosyn and Feldene)⁸ were selected to examine the respondents' perception of the change on the number of prescriptions.

Finally, the respondents were asked to rate nine statements on a five point Likert scale according to their degree of agreement/disagreement with the importance of several marketing factors in their recommendation of ibuprofen 200 mg product.

PRETESTING THE QUESTIONNAIRE

Due to time and financial limitations, the questionnaire was not pretested by administering it to any community pharmacist. However, the questionnaire was reviewed by the faculty and graduate students of the

department of Health Care Administration, University of Mississippi to enhance its clarity and legibility.

DATA COLLECTION

The study population consisted of the pharmacists who were listed as the permit holders for the 835 community pharmacies in Mississippi. All individuals were assigned an identification number according their location in the master file. The ones who were assigned with an odd number received version (A) questionnaires and those with an even number received version (B) questionnaires.

The mailing package consisted of the questionnaire with a postage-paid reply mail back cover and a cover letter explaining the purpose of the study. Copies of the cover letter and the two versions of the questionnaire appear as Appendices (A), (B) and (C). All questionnaires were coded with an identification number to make follow-ups possible.

Four weeks after the first mailing, another copy of the questionnaire and second cover letter (Appendix D) were mailed to all pharmacists who did not respond to the first mailing. The identification numbers used on the second questionnaires were coded such that they could be identified as second mailing. If two questionnaires were received from the same pharmacist, only the questionnaire from the first mailing was included in the data analysis.

DATA ANALYSIS

After the data were collected, all questionnaires were coded, typed into the computer, and verified. The accuracy of the data was further ascertained utilizing a computer program, the Statistical

Package for the Social Sciences for the personal computer (SPSS/PC+), to verify that responses were valid values. Data cases which had invalid responses were identified by the identification number. The data for these cases were visually checked against the questionnaires and corrected when necessary by the researcher.

Data analysis was conducted using SPSS/PC+ on a microcomputer. The specific analyses are discussed below with respect to the eight objectives of the study.

OBJECTIVE I : To describe pharmacists' general attitudes toward the switch of prescription drugs to over the counter status.

OBJECTIVE II: To describe pharmacists' general attitudes toward the Rx-to-OTC switch of ibuprofen 200 mg.

General descriptive statistics were used to meet objective I and objective II individually. Mean scores for each statement rated on a five point Likert Scale were obtained to indicate respondent's degree of agreement/disagreement. The items were then ranked in descending order from most to least agreement with items favoring Rx-to-OTC switch.

OBJECTIVE III : To determine the pharmacists' perception of the competition in the OTC medications business.

General descriptive statistics and weighted forced ranking scales were utilized to accomplish objective III. A rank order of seven OTC drug outlets was obtained from the Competition in the OTC Business Forced Ranking Scale by utilizing a weighting procedure.

The statements received a total weight when ranked as described in Table I. Each of the potential competitors in OTC drug outlets for the respondents received its rank by summing all weight values for that characteristic. The items then were ranked in descending order with highest total weight score ranked first.

Table I
WEIGHT PROCEDURE FOR FORCED RANKING SCALE

Rank	Frequency	Weight	Rank Weight
1	n_1	3	$3n_1$
2	n_2	2	$2n_2$
3	n_3	1	$1n_3$
			=====
			* Total Weight

* Total Weight equals the sum of the rank weight for each OTC drugs outlets.

Cross-tabulations were used to measure the association of the

competition for OTC business vis-a-vis the following respondent demographics : (1) the annual sales volume (high, medium, and low) (2) the percentage of OTC sales volume in total sales volume (1-10, 11-20, and more than 20), and (3) type of pharmacy practice. Category ranges for annual total sales volume and percentage of OTC sales in total sales volume were derived from a frequency distribution obtained from the demographics in pharmacist and pharmacy information section.

OBJECTIVE IV : To evaluate pharmacists' attitudes toward potential ways to manage the transition of prescription to over the counter status.

In order to accomplish objective IV, again, general descriptive statistics and weighted forced ranking scales were utilized. A rank order of the four statements describing the methods to manage Rx-to-OTC switch was obtained by using a weighting procedure. The statements received a total weight when ranked as described in Table II. Each of the methods to manage the Rx-to-OTC switch received its rank by summing all weight values for that characteristic. The items then were ranked in descending order with highest total weight score ranked first.

A two-tailed t-Test was used to test the difference of the mean rank scores for each method to manage Rx-to-OTC switch between the two groups of respondents (years of practice as a community pharmacist less than or equal to 20 years and more than 20 years).

It was hypothesized that these two groups of respondents were

taught differently with respect to OTC drugs counseling in their college education and might have different attitudes toward the methods to manage Rx-to-OTC switch.

Table II
WEIGHT PROCEDURE FOR FORCED RANKING SCALE

Rank	Frequency	Weight	Rank Weight
1	n_1	4	$4n_1$
2	n_2	3	$3n_2$
3	n_3	2	$2n_3$
4	n_4	1	$1n_4$
			=====
			* Total Weight

* Total Weight equals the sum of the rank weight for each method to manage Rx-to-OTC switch.

OBJECTIVE V : To describe pharmacists' attitudes toward potential Rx-to-OTC switch for selected drug categories.

In order to meet objective V, general descriptive statistics were utilized. Twelve drug categories were listed and respondents were asked to check the one(s) they thought was(were) appropriate to be switched

from Rx to OTC status. Frequencies of positive response for each drug categories were calculated and ranked in descending order, with highest positive response rates ranked first as a indication of pharmacists' preferences.

OBJECTIVE VI : To describe pharmacists' perception of the market share impact of Rx-to-OTC switch of ibuprofen 200 mg on selected Rx products and OTC internal analgesics.

In order to meet objective VI, general descriptive statistics were utilized. Mean scores for each product category were calculated using the responses from the five-point Likert-like scale.

One-way analysis of variance was utilized to test two sets of hypotheses. The first set of hypotheses is that all respondents with different OTC sales percentage perceived the same market change of dollar volume on OTC internal analgesics. The second set of hypotheses is that respondents with different daily Rx volumes perceived the same market change the number of prescriptions for selected Rx products.

OBJECTIVE VII : To determine pharmacists' recommendations of selected ibuprofen 200 mg products for the approved indications.

General descriptive statistics were utilized to accomplish objective VII. Response frequencies for each OTC ibuprofen product were

obtained for each approved indication listed. OTC ibuprofen products were ranked in descending order with highest response rates ranked first to indicate the product most often recommended by the respondents. Seven selected indications were also ranked in descending order with the highest response rate ranked first, indicating the indication for which ibuprofen 200 mg is most frequently recommended .

OBJECTIVE VIII: To determine the relative importance of selected marketing factors in pharmacists' decision to recommend an ibuprofen 200 mg.

In order to meet the objective VIII, descriptive statistics were utilized. Each marketing factor statement such as profit margin, quality, company reputation, advertising, information, prices, inventory, and relationship was rated using a five-point Likert scale. Mean scores were calculated and the items were ranked in descending order according to the degree of importance the factor had in influencing pharmacists' recommending an OTC ibuprofen product.

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CHAPTER IV

DATA ANALYSIS AND RESULTS

This chapter presents a discussion of the data analysis and results. It begins with a quantification of responses received and a description of the data preparation procedure. Each objective of the study is presented respectively, along with an explanation of the analysis used and the results found.

RESPONSES RECEIVED AND DATA PREPARATION

Responses were received from 272 (32.6%) pharmacists, and 265 (31.7%) responses were usable for study purpose. The 265 responses included 135 respondents who received type A questionnaire and 130 respondents who received type B questionnaire. There were 157 responses to the initial mailing and 115 responses to the follow-up mailing which took place four weeks later. No questionnaire was returned undeliverable by the postal service. Table III presents a summary of the mailing, the responses received, and the reasons for excluding responses from the study.

The data were coded, typed into the computer, and verified by the researcher. The accuracy of the data was further ascertained utilizing a computer program to verify that responses on all items were valid values. Data cases which had invalid responses were identified, visually checked against the questionnaire, and corrected. Items with missing values were omitted from statistical computing

TABLE III
 SURVEY RETURNS AND REASONS FOR
 EXCLUDING RESPONSES FROM THE STUDY

Disposition	Number	Percent
Initial Questionnaire Mailed	835	100.0
Type A	418	50.6
Type B	417	49.4
Returned by Postal Service undeliverable	0	0.0
Total Responses Received First Mailing	157	18.8
Follow-Up Questionnaire Mailing	678	81.2
Total Responses Received Second Mailing	115	13.8
Total Responses Received	272	32.6
Type A	141	(33.7)*
Type B	131	(31.4)*
Total Responses Excluded by Investigator	7	0.8
Respondent did not wish to participate	2	0.2
Respondent Neglected to Answer a Full Page or More of Questionnaire	4	0.5
Respondents No Longer Employed	1	0.1
Total Usable Responses	265	31.7
Type A	135	(32.3)*
Type B	130	(31.2)*

* Denominators for percentages are the total number of type A and type B questionnaires mailed respectively.

using the option available in the Statistical Package of the Social Sciences for the personal computer (SPSS/PC+).

Because mail surveys typically have low response rates and are susceptible to a self-selection bias of the respondents, it is desirable to test for a response bias. The effect of a response bias could not be tested in this study because the expense of conducting telephone or personal interviews with non-responding pharmacists exceeded the financial resources available for the study.

The demographic and practice characteristic of the respondents included in the study are shown in Table IV. More than half of the respondents indicated that they had practiced in community pharmacy for 20 years or less and 72.2% of the respondents worked in single location community pharmacy. The data also show that most pharmacies have 51-125 daily Rx volume, \$200,000 - \$599,999 annual sales volume, and 11-20 percentage of OTC sales in total sales volume.

Although, no statewide information concerning the operation of Mississippi pharmacies was available for comparison with the data collected from the current study, there are no reasons to suspect that the demographic and practice characteristic of the respondents are not representative of the pharmacies in the state. Caution should be exercised however, in generalizing the finding, from this study to the total population of pharmacies in the state.

DATA ANALYSIS AND RESULTS

The data analysis and results are discussed in terms of satisfying the eight research objectives described in Chapter I.

Table IV
DEMOGRAPHIC AND PRACTICE CHARACTERISTICS OF RESPONSES

Characteristic	Number	Percent
Sex		
Male	250	94.3
Female	15	5.7
Years in Practice		
20 and less	158	59.8
more than 20	106	40.2
Type of Pharmacy		
Single location community pharmacy	189	72.7
Multilocation community pharmacy	25	9.6
Chain pharmacy	46	17.7
Daily Rx volume		
< 50	30	11.4
51 - 75	54	20.5
76 - 100	72	27.3
101 - 125	56	21.2
126 - 150	26	9.8
> 151	26	9.8
Annual sales volume		
< \$200,000	16	6.1
\$200,000 - \$299,999	41	15.7
\$300,000 - \$399,999	43	16.5

Table IV (continued)

Characteristic	Number	Percent
Annual sales volume		
\$400,000 - \$499,999	43	16.5
\$500,000 - \$599,999	37	14.2
\$600,000 - \$699,999	18	6.9
\$700,000 - \$799,999	18	6.9
\$800,000 - \$899,999	14	5.4
> \$900,000	31	11.9
Percentage of OTC sales in pharmacy's total sales volume		
1 - 10	61	24.0
11 - 20	116	45.7
more than 20	77	30.3

OBJECTIVE I: To describe pharmacists' general attitudes toward the switch of prescription drugs to over the counter status.

Objective I was achieved by having the respondents rate the eleven statements on Rx-to-OTC shift Question 1 (see Appendix (B)). Each statement was rated on a five-point Likert scale where a value of one represented "strongly agree" and a value of five represented

"strongly disagree". Scores for items d, e, h, j, and k were reverse coded because they were negatively worded with respect to favoring the Rx-to-OTC switch. Responses from all the respondents were included in the calculation of mean scores.

Table V shows the ranking of the mean scores for the items. "OTC products could be labeled adequately" (mean=2.40, S.D.=1.09) was rated as the most agreed with item while "Lose sales to other types of retailers" (mean=4.28, S.D.=1.06) was the least agreed with item with respect to favoring Rx-to-OTC switch.

Overall, the issues concerned with product labeling and enhancing professional role were agreed with by respondents to favor the Rx-to-OTC, while issues concerning with pharmacy's benefits and consumer's welfare were strongly disagreed with by the respondents.

OBJECTIVE II: To describe pharmacists' general attitudes toward the Rx to OTC switch of ibuprofen 200 mg.

Objective II was accomplished by having the respondents rate the seven statements on question five, Rx-to-OTC shift section. (see Appendix (B)). Each statement was rated on a five-point Likert scale with "one" being strongly agree and "five" being strongly disagree.

Table VI shows the ranking of the mean scores for the item. "Ibuprofen 200 mg is effective for its approval indications" (mean=1.88, S.D.=0.87) had the highest rate of agreement and "Ibuprofen 200 mg should be reimbursed by Medicaid" (mean=3.96, S.D.=1.38) had the lowest rate of agreement.

TABLE V

RANKING OF GENERAL ATTITUDES TOWARD Rx-TO-OTC SWITCH ACCORDING TO MEAN SCORE (N=265)

Rank*	Item Letter and Description	Mean**	S.D.
1	G Switched OTC products <u>could be</u> labeled adequately to promote safe self-medication by consumers	2.40	1.09
2	B The Rx-to-OTC switch can enhance the professional role of the pharmacists by providing the opportunity to counsel customers about OTC products	2.50	1.27
3	F Switched OTC products <u>are currently</u> labeled adequately to promote safe self-medication by customers	2.69	1.12
4	A Switching more products from Rx-to-OTC will be beneficial to pharmacists in the longrun	3.13	1.41
5	D*** The Rx-to-OTC switch will increase the inventory carrying costs of the product	3.35	1.23
6	C The Rx-to-OTC switch will increase the pharmacy's net profits from prescription and OTC drug sales	3.57	1.16
7	I Pharmacy can make a better profit margin from sales of the OTC version than from the prescription version of a product	3.78	1.17
8	K*** As more products move from Rx to OTC, customers are more likely to misuse these medications	3.96	1.02
9	H*** When a product is made available OTC, the volume of the prescription version will decrease	4.13	1.10
10	E*** As more products move from Rx to OTC, there is an increased risk to customers of drug interactions	4.14	1.04
11	J*** When a switched OTC product is a market success, pharmacy will lose sales of that product to other types of retailers	4.28	1.06

* Ranking with mean score carried to two decimal places.

** Mean based on average scores from a five point Likert Scale with the following values and anchors : (1) strongly agree (2) agree (3) neutral (4) disagree (5) strongly disagree.

*** Score of the item was reverse coded as 5=1, 4=2, 3=3, 2=4, 1=5.

TABLE VI
RANKING OF GENERAL ATTITUDES TOWARD
Rx-TO-OTC SWITCH OF IBUPROFEN 200 MG ACCORDING TO MEAN SCORE

Rank*	Item Letter and Description	Mean**	S.D.
1	C Ibuprofen 200 mg is effective for its approved indications	1.88	0.87
2	A In general, ibuprofen 200 mg was a good choice made for Rx-to-OTC switch	1.93	1.05
3	B Ibuprofen 200 mg is a safe drug for OTC use by the customer	2.17	1.00
4	D Ibuprofen 200 mg is adequately labeled to promote safe use	2.18	0.97
5	E Customers can use ibuprofen 200 mg safely without pharmacist advise	3.05	1.13
6	G Prescriptions written for ibuprofen 200 mg should be reimbursable <u>as prescription</u> by third parties	3.35	1.57
7	F Ibuprofen 200 mg should be a reimbursable OTC medication under Mississippi Medicaid	3.96	1.38

* Ranking with mean score carried to two decimal places.

** Mean based on average scores from a five point Likert Scale with the following values and anchors : (1) strongly agree (2) agree (3) neutral (4) disagree (5) strongly disagree.

Generally, the issues of ibuprofen's efficacy and the switch of it were agreed with by respondents, but the reimbursement issues were rated between neutral and disagreement by the respondents.

OBJECTIVE III: To determine the pharmacists' perception of the competition in the OTC medication's business.

Objective III was achieved by utilizing a weighted procedure with the forced ranking from Pharmacy and Pharmacist Information Question 11 (see Appendix (B)). Each store received its score by summing all weight values for that characteristic. Scores were ranked in descending order with highest total weight score ranked first. This order indicates the most to least important competitor in the OTC medication business. Table I presents the detail weighting procedure (see Chapter III).

Table VII shows the results of this procedure. Discount stores without pharmacies (rank weight=415) were ranked as the number one competitor in the OTC medication business, followed by discount stores with pharmacies (rank weight=333). Independent pharmacies (rank weight=122) were perceived as the least important competitor in the OTC business.

Table VIII, Table IX and Table X present responses for each type of store being indicated as number one competitor and top three competitors by (1) pharmacy's annual sales volume, (2) percentage of OTC sales in total sales volume, and (3) type of pharmacy.

Annual sales volume was recoded into three ranges based on the

TABLE VII
 RANKING OF COMPETITION IN OTC MEDICATION'S BUSINESS
 ACCORDING TO A WEIGHTING PROCEDURE (N=265)

Rank	Type of store	No. of times store was selected as indicated choice			Rank* weight
		1st	2nd	3rd	
1	Discount stores without pharmacies	85	63	34	415
2	Discount stores with pharmacies	76	33	39	333
3	Supermarket/groceries without pharmacies	35	69	55	298
4	Chain pharmacies	25	40	56	211
5	Supermarket/groceries with pharmacies	20	35	36	166
6	Independent pharmacies	14	22	36	122

* Calculated as the sum of (1) the number of first choice designations multiple by 3 (2) the number of second choice designations multiple by 2 (3) the number of third choice designations multiple by 1.

TABLE VIII

PERCEPTION OF COMPETITION IN THE OTC MEDICATION BUSINESS
BY PHARMACY ANNUAL SALES VOLUME

Pharmacy annual sales volume	Type of store					
	Independent pharmacy	Chain pharmacy	Discount store with pharmacy	Supermarket with pharmacy	Discount store without pharmacy	Supermarket without pharmacy
	No. of stores chosen as the first competitor*					
Low	4(1.6)	8(3.2)	24(9.6)	7(2.8)	37(14.7)	12(4.8)
Medium	7(2.8)	6(2.4)	20(8.0)	5(2.0)	29(11.6)	12(4.8)
High	3(1.2)	11(4.4)	29(11.6)	8(3.2)	18(7.2)	11(4.4)
	No. of stores mentioned as top 3 competitors**					
Low	26(3.4)	46(6.1)	47(6.2)	23(3.0)	83(10.9)	64(8.4)
Medium	24(3.2)	32(4.2)	43(5.7)	32(4.2)	52(6.8)	48(6.3)
High	21(2.8)	41(5.4)	55(7.2)	35(4.6)	43(5.7)	45(5.9)

* Denominator for percentages is total number of respondents indicating a store as number one competitor.

** Denominator for percentages is total number of responses for top three competitors.

TABLE IX

PERCEPTION OF COMPETITION IN THE OTC MEDICATION BUSINESS
BY PERCENTAGE OF OTC SALES IN TOTAL SALES VOLUME

Percentage of OTC sales	Type of store					
	Independent pharmacy	Chain pharmacy	Discount store with pharmacy	Supermarket with pharmacy	Discount store without pharmacy	Supermarket without pharmacy
	No. of stores chosen as the first competitor*					
1 - 10	1(0.4)	8(3.3)	15(6.1)	1(0.4)	22(9.0)	8(3.3)
11 - 20	7(2.9)	9(3.7)	31(12.7)	10(4.1)	39(16.0)	17(7.0)
> 20	6(2.5)	7(2.9)	26(10.7)	6(2.5)	24(9.8)	7(2.9)
	No. stores mentioned as top 3 competitor**					
1 - 10	15(2.0)	27(3.7)	35(4.7)	21(2.8)	45(6.1)	33(4.5)
11 - 20	32(4.3)	45(6.1)	60(8.1)	42(5.7)	83(11.2)	75(10.1)
> 20	23(3.1)	43(5.8)	46(6.2)	22(3.0)	48(6.5)	44(6.0)

* Denominator for percentages is total number of respondents indicating a store as number one competitor.

** Denominator for percentages is total number of responses for top three competitors.

TABLE X
PERCEPTION OF COMPETITION IN THE OTC MEDICATION BUSINESS
BY TYPE OF PHARMACY

Type of pharmacy	Type of store					
	Independent pharmacy	Chain pharmacy	Discount store with pharmacy	Supermarket with pharmacy	Discount store without pharmacy	Supermarket without pharmacy
	No. of stores chosen as the first competitor*					
Single**	8(3.2)	14(5.6)	46(18.3)	12(4.8)	70(27.9)	30(12.0)
Multi***	3(1.2)	1(0.4)	8(3.2)	3(1.2)	9(3.6)	1(0.4)
Chain****	3(1.2)	10(4.0)	22(8.8)	3(1.2)	5(2.0)	3(1.2)
	No. of stores mentioned as top 3 competitors*****					
Single	53(8.5)	82(13.1)	96(15.4)	54(8.6)	143(22.9)	120(19.2)
Multi	6(1.0)	11(1.8)	17(2.7)	10(1.6)	14(2.2)	16(2.6)
Chain	12(2.0)	26(4.2)	32(5.1)	24(3.8)	21(3.4)	18(2.9)

* Denominator for percentages is total number of respondents indicating a store as number one competitor.

** Single location community pharmacy.

*** Multilocation community pharmacy (2-3 locations owned by 1 company/person).

**** Chain pharmacy (4 or more pharmacies owned by 1 company/person).

***** Denominator for percentages is total number of responses for top three competitors.

frequency distribution obtained from Question 5 on Pharmacy and Pharmacist Information section (see Appendix (B)).

Discount stores without pharmacies were perceived as the most important OTC competitor by most pharmacies with low level (under \$399,999) and middle level (\$400,000 - \$599,999) annual sales volume as well as with pharmacies with low (1-10) and middle (11-20) percentage of OTC sales.

Coincidental, discount stores with pharmacies were perceived as the number one OTC competitor by most pharmacies with high level (above \$600,000) annual sales volume and with high percentage of OTC sales.

Most single location and multilocation community pharmacies indicated that discount stores without pharmacies were their major OTC competitor while discount stores with pharmacies were perceived as number one by most chain pharmacies.

OBJECTIVE IV: To evaluate pharmacists' attitudes toward potential ways to manage the transition of prescription to over the counter status.

Objective IV was met by utilizing the weighting procedure which was similar to the one used to accomplish objective III. Table II (Chapter III) shows the detailing weighting procedure. Pharmacists' preferences regarding potential ways to manage the transition of products from Rx to OTC status were obtained with Question 2 from the Rx-to-OTC Shift section (see Appendix (B)). Table XI presents the

rank order of preferences for the different methods. Table XII shows responses regarding specific aspect of the transition.

"Creation of a third class drugs which are available without a prescription, but only from a pharmacy" (rank weight=967) was rated as the most favored way to manage Rx-to-OTC switch, and "Things remain as they are so that drug products switched from Rx-to-OTC are immediately available from numerous outlets, including pharmacies" (rank weight=453) received the lowest score as the least favored way to manage the Rx-to-OTC switch.

If a third class of drugs were created, 78.1% of the respondents indicated that they would not charge for drug counseling with patients. If a transitional phase were created, 40.1% of the respondents indicated that they would like to have 7-12 months period for the newly switched products.

Two-tailed t-Tests were utilized to test the difference of the mean rank scores for each of the method to manage Rx-to-OTC switch between the two groups of respondents. Group 1 (59.8%) included the respondents who have less than or equal to 20 years experience in community pharmacies and Group 2 (40.2%) included the respondents who have more than 20 years experience as a community pharmacist. The tests were performed at the 0.05 level of significance.

Table XIII shows the results of the tests. No differences were seen between the two groups to each statement except "no more products are switched from Rx-to-OTC classification". Respondents with more than 20 years experiences in community pharmacy appeared favor this

TABLE XI
 RANKING OF POTENTIAL WAYS TO MANAGE RX-TO-OTC SWITCH
 ACCORDING TO A WEIGHTING PROCEDURE (N=265)

Rank	Potential way	No. of way was selected as indicated choice				Rank* weight
		1st	2nd	3rd	4th	
1	Creation of a third class of drugs which are available without a prescription, but only from a pharmacy	207	38	10	5	967
2	Creation of a transitional phase in which Rx-to-OTC switched products are available initially only from pharmacies for a limited time period	22	161	57	14	699
3	No more products are switched from Rx-to-OTC classification	31	43	49	124	453
4	Things remain as they are so that drug products switched from Rx-to-OTC are immediately available from numerous outlet, including pharmacies	12	20	131	83	475

* Calculated as the sum of (1) the number of first choice designations multiple by 4 (2) the number of second choice designations multiple by 3 (3) the number of third choice designations multiple by 2 (4) the number of fourth choice designations multiple by 1.

TABLE XII
METHOD TO MANAGE Rx-TO-OTC SWITCH

Method description	Number	Percent
If a third class of drugs <u>were</u> created, would you charge for OTC counseling ?		
Yes	56	21.9
No	200	78.1
If a transitional phase <u>were</u> created, how long should the phase last ?		
1 - 6 months	25	11.0
7 - 12 months	91	40.1
13 - 24 months	60	26.4
more than 3 years	51	22.5

TABLE XIII
 RELATIONSHIP BETWEEN YEARS IN PRACTICE AND
 MEAN RANKING FOR WAYS TO MANAGE Rx-TO-OTC SWITCH

Way to manage Rx to OTC switch	Number	Mean*	S.D.	T-value
Creation of a third class of drugs which are available without a prescription, but only from a pharmacy				
(1) less than or equal to 20 years	156	1.25	0.62	-0.97
(2) more than 20 years	104	1.33	0.65	
Creation of a transitional phase in which Rx-to-OTC switched products are available initially only from Pharmacies for a limited time period				
(1) less than or equal to 20 years	154	2.26	0.66	0.34
(2) more than 20 years	100	2.23	0.74	
Things remain as they are so that drug products switched from Rx-to-OTC are immediately available from numerous outlets, including pharmacies				
(1) less than or equal to 20 years	149	3.20	0.71	0.87
(2) more than 20 years	96	3.11	0.83	
No more products are switched from Rx-to-OTC classification				
(1) less than or equal to 20 years	150	3.21	1.04	2.36**
(2) more than 20 years	97	2.88	1.13	

* Mean based on average ranking score with the following value and anchors :
 (1) the first favorable way to manage Rx-to-OTC switch (2) the second favorable way to manage Rx-to-OTC switch (3) the third favorable way to manage Rx-to-OTC

method more than the pharmacists with less than or equal 20 years experience did.

OBJECTIVE V: To describe pharmacists' attitudes toward potential Rx-to-OTC switch for selected drug categories.

Objective V was accomplished by having respondents indicate which of twelve drug categories they thought were appropriate for switches from Rx to OTC status.

The results are shown in Table XIV. The selected drug categories were ranked in descending order according to the percent of pharmacists' approving of the drug category as a potential product for Rx-to-OTC shift.

Hydrocortisone 1% was recognized as the most favorable drug category to be switched from Rx to OTC status (74.0% approved) and Diazepam (1.9% approved) was perceived as the least favorable product to be switched for OTC use.

OBJECTIVE VI : To describe pharmacists' perceptions of the market share impact of Rx-to-OTC switch of ibuprofen 200 mg on other selected Rx ibuprofen products and OTC internal analgesics.

Objective VI was met by ranking the OTC analgesic products and selected Rx products in ascending order according to the mean ratings of the degree to which switching ibuprofen had a negative impact on sales and number of prescriptions of the products. Impact on sales and number of prescriptions was measured using a five-point Likert-type

TABLE XIV
RANKING OF DRUG CATEGORY FOR
Rx-TO-OTC SWITCH BY RESPONDENTS

Rank	Product category	Number	Percent
1	Hydrocortisone 1%	196	74.0
2	Nicotine polacrilex (Nicorette [*])	154	58.1
3	Terfenadine (Seldane [*])	118	44.5
4	Loperamide (Imodium [*])	95	35.8
5	Benzonatate (Tessalon [*])	65	24.5
6	Sucralfate (Carafate [*])	58	21.9
7	Naproxen (Naprosyn [*])	49	18.5
8	Theophylline	42	15.8
9	Hydrochlorothiazide	34	2.8
10.5 ^{**}	Loestrin 1/20 [*]	17	6.4
10.5 ^{**}	Penicillin (oral)	17	6.4
12	Diazepam (Valium [*])	5	1.9

* Brand product.

** Indicates a tie when response frequencies were calculated; drug categories assigned a rank equal to the average rank of the tied groups.

scale with "one" being increased greatly and "five" being decreased greatly (see Rx-to-OTC shift Question 7, Appendix (B)).

Table XV shows the ranking of the mean scores for the OTC internal analgesics and selected Rx products. All OTC products were rated as having negative impact on sales with respect to the Rx-to-OTC switch of ibuprofen. However, "Acetaminophen products" (mean=3.33, S.D.=0.61) were rated as the least decreased item in dollar sales followed by "Combination analgesic products" (mean=3.39, S.D.=0.62). Among the selected prescription products, the lower dose of ibuprofen products were perceived as having a negative impact on the number of prescriptions, while competing NSAIDs and higher dose ibuprofen products were believed to have benefited.

In addition, one-way analysis of variance was utilized here to test two sets of hypotheses. Set (1): three groups of pharmacies with low (1-10), medium (11-20), and high (> 20) percentage of OTC sales perceived that the Rx-to-OTC shift of ibuprofen had the same impact on the dollar sales volume of aspirin products, acetaminophen products, and combination analgesic products. Set (2): four groups of pharmacies with low (less than 51), medium low (51-75), medium high (76-100), and high (equal or more than 101) daily Rx volume perceived that switching ibuprofen from Rx to OTC status had the same impact on the number of prescriptions filled for Motrin 800mg, 600mg, 400mg, and 300mg, Rufen 800mg, 600mg, and 400mg, Naprosyn, and Feldene.

The tests were performed at the 0.05 level of significance. Only one result indicated that respondents with different percent OTC

TABLE XV

RANKING OF MARKET EFFECT ON DOLLAR VOLUME AND PRESCRIPTION NUMBER
BY THE RX-TO-OTC SWITCH OF IBUPROFEN 200 MG ACCORDING TO MEAN SCORE (N=265)

Product Category	Rank*	Product	Mean**	S.D.
OTC internal analgesic (dollar volume)	1	Acetaminophen products	3.33	0.61
	2	Combination analgesic products	3.39	0.62
	3	Aspirin products	3.55	0.60
Rx ibuprofen (prescription number)	1	Motrin 800 mg	2.60	0.79
	2	Motrin 600 mg	2.65	0.75
	3	Naprosyn	2.77	0.73
	4	Feldene	2.79	0.75
	5	Rufen 800 mg	2.95	0.75
	6	Rufen 600 mg	2.96	0.74
	7	Motrin 400 mg	3.28	0.79
	8	Rufen 400 mg	3.31	0.77
	9	Motrin 300 mg	3.83	0.97

* Ranking with mean score carried to four decimal places.

** Mean based on average scores from a five point Likert-type Scale with the following values and anchors: (1) increased greatly (2) increased somewhat (3) no change (4) decreased somewhat (5) decrease greatly.

sales perceived different impact on dollar volume of aspirin products after the shift of ibuprofen (see Table XVI). Respondents with low OTC sales perceived less negative market impact (mean=3.35) than the ones with high (mean=3.61) and medium (mean=3.63) OTC sales.

TABLE XVI

ANALYSIS OF VARIANCE FOR COMPARISON OF MEAN SCORE OF MARKET CHANGE IN DOLLAR VOLUME OF ASPIRIN ON THE BASIS OF PERCENTAGE OF OTC SALES VOLUME

	Degree of freedom	Sum of square	Mean square	F ratio
Between groups	2	3.3208	1.6604	4.6312*
Within groups	246	88.1973	0.3585	
Total	248	91.5181		

* Statistical significant (P < .05).

OBJECTIVE VII: To determine pharmacists' recommendation of selected ibuprofen 200 mg products for the selected approved indications.

Objective VII was accomplished by having pharmacists indicate the ibuprofen 200 mg products they would most likely recommend for seven approved indications (see Rx-to-OTC Shift Question 6, Appendix(B)). Table XVII presents the response rate and the percentage for each

TABLE XVII
RECOMMENDATION OF IBUPROFEN 200 MG PRODUCTS
BY INDICATION

Approved indication	Product name							
	Pamprin	Advil	Haltran	Nuprin	Mido1 200	Mediprin	Doan's ibuprofen	Generic
Headache	1(0.5)	82(37.1)	10(4.5)	20(9.0)	0(0.0)	3(1.4)	1(0.5)	104(47.1)
Muscle ache	1(0.4)	68(30.7)	11(4.9)	26(11.6)	0(0.0)	6(2.4)	4(1.7)	109(48.4)
Fever	2(1.2)	48(28.1)	8(4.7)	16(9.4)	1(0.6)	4(2.4)	1(0.6)	91(45.7)
Menstrual cramps	20(8.6)	36(15.5)	55(23.6)	13(5.6)	15(6.4)	3(1.3)	2(0.9)	89(38.7)
Backache	0(0.0)	58(24.4)	9(3.8)	22(9.2)	0(0.0)	7(3.0)	19(8.7)	103(47.2)
Minor pain arthritis	0(0.0)	80(33.6)	8(3.3)	26(10.9)	0(0.0)	5(2.1)	1(0.4)	118(49.6)
Toothache	0(0.0)	69(32.9)	9(9.0)	19(9.0)	1(0.5)	3(1.5)	1(0.5)	108(51.4)
Total*	24(1.6)	441(29.1)	110(7.3)	142(9.4)	17(1.1)	31(2.0)	29(1.9)	722(47.6)

* Denominator for percentages is the total number of respondents recommending ibuprofen for all indications.

ibuprofen 200 mg product by indication.

Table XVIII shows the ranking of which ibuprofen 200 products are most frequently recommended. Generic ibuprofen was the most frequently recommended product overall (41.8% choices) and was also the most frequently recommended product for each individual indication. Of the branded ibuprofen 200 mg products, Advil was the most frequently recommended for every indication except menstrual cramps. Haltran, which is targeted for this indication, was the most recommended branded product for menstrual cramps, while Midol 200, which is also targeted in this indication, was recommended by no respondent.

Table XIX shows the ranking of indications for which ibuprofen 200 mg products are most frequently recommended. More than half of the respondents (50.6%) indicated they would recommend ibuprofen 200 mg for the "minor pain arthritis" while no respondent indicated he/she would recommend ibuprofen 200 mg for "fever relief".

OBJECTIVE VIII: To determine the relative importance of selected marketing factors in pharmacists' decision to recommend an ibuprofen 200 mg.

Objective VIII was met by ranking the items in descending order from most to least agreed on importance according to their mean values as rated on a five-point Likert Scale. One meant strongly agree and five meant strongly disagree (see Rx-to-OTC Shift Question 8, Appendix (B)).

TABLE XVIII
RANKING OF MOST FREQUENTLY RECOMMENDED IBUPROFEN 200MG PRODUCTS
BY RESPONDENTS

Rank	Product	Number	Percent
1	Generic ibuprofen	102	41.8
2	Advil	98	40.2
3	Nuprin	24	9.8
4	Haltran	12	4.9
5	Mediprin	5	2.0
6	Doan's ibuprofen	2	0.8
7	Parprin	1	0.4
8	Mido1 200	0	0.0

TABLE XIX
 RANKING OF INDICATIONS FOR WHICH IBUPROFEN 200 MG IS MOST
 MOST FREQUENTLY RECOMMEND BY RESPONDENTS

Rank	Approval indication	Number	Percent
1	Minor pain arthritis	122	50.6
2.5*	Headache	35	14.5
2.5*	Menstrual cramps	35	14.5
4	Muscle ache	31	12.9
5	Backache	14	5.8
6	Toothache	4	1.7
7	Fever	0	0.0

* Indicates a tie; approval indications assigned a rank equal to the average rank of the tied groups.

Table XX shows the ranking of the mean scores for the items. Product quality (mean=1.71, S.D.=0.85) was rated as the most important factor influencing pharmacists' recommending an ibuprofen product, followed by price to the customers. "Relationship with the manufacturer's salesperson" (mean=3.25, S.D.=1.24) was perceived as the least important factor.

Overall, product quality and price are major factors said to be considered by most pharmacists in recommending an OTC ibuprofen product, while product advertising and other manufacturer's service characteristic are not so important.

TABLE XX
 RANKING OF IMPORTANCE OF MARKETING FACTORS IN
 RECOMMENDATION AN IBUPROFEN 200 MG PRODUCT (N=265)

Rank*	Item Letter and Description	Mean**	S.D.
1	B Product quality	1.71	0.85
2	F Price to the customers	1.83	0.89
3	C Manufacturer's reputation	1.95	1.00
4	A Product profit margin	2.30	1.15
5	G Amount of product in inventory	2.54	1.06
6	E Manufacturer provides more product services	3.05	1.10
7	D Product advertising	3.17	1.23
8	H Relationship with the manufacturer's salesperson	3.25	1.24

* Ranking with mean score carried to two decimal places.

** Mean based on average score from a five point Likert Scale with the following values and anchors: (1) strongly agree (2) agree (3) neutral (4) disagree (5) strongly disagree.

CHAPTER V

SUMMARY AND CONCLUSIONS

In the past few years, switching formerly prescription-only drug products to OTC status has become the target of widespread market attention. This switching phenomenon not only brought about the numbers of prescription decline since 1974, it also, according to one observer, generated the upheaval in the OTC market.¹ Henry Wendt, Chairman of SmithKline Beckman, characterized this upheaval by stating, "Competitors fight like hell and trade share but the market does not grow, until there is sort of an earthquake. And earthquakes are caused by the Rx-to-OTC switch".²

The trend of Rx-to-OTC switch is significant and will likely continue. The drug industry is the major party to reinforce this trend, yet the consumer groups and regulatory agencies are encouraging it in some ways. Some major market-leading prescription-only products have already been approved or are pending approval by FDA to shed their Rx labels and enter the OTC market. Ibuprofen, sold by prescription as Motrin, is probably the most important Rx-to-OTC switch made since 1984.

Simultaneously playing the roles as a health profession and a drug retailer, practicing community pharmacists might find conflicting pressures in confronting the trend of Rx-to-OTC switch. They are not quite sure whether the Rx-to-OTC switch will be good or bad for them,

especially the switch of ibuprofen.

The purpose of this study was to explore, by mail survey, what community pharmacists' opinions are toward the Rx-to-OTC switch in general and especially about ibuprofen.

Eight research objectives were established to investigate the community pharmacists' opinions and perceptions about the Rx-to-OTC switch, the switch of ibuprofen, the methods to manage the switch, the competition in the OTC business, the appropriateness of some switch candidates, the market change caused by the ibuprofen switch of some Rx and OTC products, the preference among branded ibuprofen products, the favorable indication for which ibuprofen was recommended, and the relative importance of selected marketing factors in their decision to recommend an ibuprofen product.

The study was conducted as a part of the 1987 survey of Mississippi pharmacies. A nine-page booklet type questionnaire, which included questions relating to three major studies, was developed. Four pages of it presented the questions to accomplish this study's objectives.

The study population consisted of the pharmacists who were listed as the permit holders for the 835 community pharmacies in Mississippi. The usable responses rate was 31.7 percent (265 responses).

SUMMARY OF RESULTS AND CONCLUSIONS

OBJECTIVE I: To describe pharmacists' general attitudes toward the switch of prescription drugs to over the counter status.

The first objective was accomplished by having the respondents rate the eleven items on a five point Likert Scale. Overall, pharmacists did not think they would benefit from the Rx-to-OTC switch in the long run; although, they agreed the switch could enhance their professional role by making available more drugs for consumer counseling. When the drugs were switched from RX to OTC status, pharmacists perceived that the sales of the switched products were lost to other non-pharmacy drug outlets, lower profits were made, and inventory carrying costs were increased.

Another finding was that the respondents agreed that most switched products were currently or could be labeled adequately to promote safe self-medication while they were also worried that consumers might misuse the switched drugs and ignore the drug interactions. This finding might reveal that pharmacists did not agree that consumers have enough medical knowledge to diagnose their conditions and be aware of the side effects and drug interactions of the switched products. The survey done by Benrimoj, Tucker, and Smith in 1986 on the consumers who took OTC ibuprofen supported this explanation.³

OBJECTIVE II: To describe pharmacists' general attitudes toward the Rx-to-OTC switch of ibuprofen 200 mg.

The second objective was also met by having the respondents rate the seven items on a five-point Likert scale. Pharmacists agreed that ibuprofen 200 mg was a good choice for the Rx-to-OTC switch but they disagreed that OTC ibuprofen should be reimbursed by third parties and

covered by the Mississippi Medicaid program. Because the reimbursement fees are too low might be one explanation for this attitude.⁴

OBJECTIVE III: To determine the pharmacists' perception of the competition in the OTC medication business.

The third objective was achieved by using a forced ranking scale and a weighted procedure. Discount stores with and without pharmacies were perceived as the two most important competitors in the OTC medication business. In comparing pharmacies with low and medium annual sales volume and OTC sales, pharmacies with high annual sales and OTC sales tended to view discount stores with pharmacies as the most important competitor. Most chain pharmacies also perceived the same situation. One explanation for this divergence might be that most discount stores with pharmacies, chain pharmacies, and pharmacies with higher sales volume tend to be located in higher density population areas and compete with one another.

OBJECTIVE IV: To evaluate pharmacists' attitudes toward potential ways to manage the transition of prescription to over the counter status.

The fourth objective was also met by using a forced ranking scale and a weighted procedure. "Creation of a third class of drugs and only available from pharmacies" was rated as the most favorable method, followed by "creation of a transitional phase for newly switched drugs (pharmacist-legend drugs)". This finding was different from the survey results done by the American Druggist in 1985 with 655 pharmacists which showed that "pharmacist-legend drugs" was preferable

than "third class drugs" by the respondents.⁵ The "pharmacist-legend drugs" category was also advocated by American Pharmaceutical Association (APhA) and National Association of Retail Druggist(NARD) to their members in 1985.⁶ Surprisingly, the current method in which switched drug products are immediately available from numerous outlets was chosen as the least favorable way to manage the Rx-to-OTC switch. Especially, respondents with more than 20 years experience in a community pharmacy tended to view "no more switch" as preferable to "the current switched method".

These findings revealed that pharmacists' attitudes toward the methods to manage the Rx-to-OTC switch are rather conservative. Facing the sales of switched products lost to other non-pharmacy drug outlets, the lower profits made after the switch, and the shortage of consumers' medical knowledge may have made pharmacists choose "third class drugs" as the best method.

OBJECTIVE V: To describe pharmacists' attitudes toward potential Rx-to-OTC switch for selected drug categories.

The fifth objective was accomplished by having respondents indicate which of the twelve drug categories they thought were appropriate to switch from Rx to OTC status. It was surprising to find that theophylline and loperamide, which are awaiting final FDA action on Panel recommendation,⁷ were approved for OTC status by less than 40% respondents. Nicorette, nicotine polacrilex in chewing gum form to help quit smoking, was approved by 58.1% respondents.

OBJECTIVE VI: To describe pharmacists' perceptions of the market

share impact of Rx-to-OTC switch of ibuprofen 200 mg on other selected Rx products and OTC internal analgesics.

The sixth objective was met by having respondents rate the selected Rx and OTC products on a five-point Likert-like type scale. Compared with two other kinds of OTC analgesic, aspirin products were perceived as being hurt most on the dollar volume after the switch of ibuprofen. Pharmacies with high and medium OTC sales felt this decrease more than pharmacies with low OTC sales did.

Respondents perceived the number of prescriptions on Rx ibuprofen with higher dose (800 mg and 600 mg) and competing NSAIDs (Feldene and Naprosyn) had increased somewhat due to the switch of ibuprofen. Data collected by the market research firm, IMS, showed the annual drug store sales for the selected Rx products decreased except Motrin 800 mg and Naprosyn.⁸ With unit prices increasing and sales volume decreasing after 1985,⁹ the number of prescriptions of Motrin 600 mg and Rufen 600 mg should have decreased. However, the reason for this divergence is not known.

OBJECTIVE VII: To determine pharmacists' recommendations of selected ibuprofen 200 products for the approved indications.

The seventh objective was achieved by having respondents indicate the ibuprofen products they would recommend for each indication. Generic ibuprofen was the most recommended product for every indication and among all the ibuprofen products by the respondents. Each brand product was also recommended for the indication for which it was

promoted, yet Advil outdid other products for each indication, except for menstrual cramps. Haltran, launched by Upjohn, ranked ahead of Advil as the most recommended brand product for cramps.

Being immediately launched to the OTC market, not any restriction on talking about Motrin in advertising, and intensively promoted to the public have made Advil the second most recommended ibuprofen product, next to generic products. With the success of Motrin in the anti-arthritis market, respondents may have felt more comfortable recommending OTC ibuprofen for the minor pain arthritis.

OBJECTIVE VIII: To determine the relative importance of selected marketing factors in pharmacists' decisions to recommend an ibuprofen 200 mg product.

The last objective was accomplished by ranking the items in descending order according to their mean value as rated on a five-point Likert scale.

Comparing these results with the results found from Objective VII, it was surprising to discover that respondents rated "product quality" as the most important factor, although they mostly recommended generic ibuprofen to consumers. This finding may reveal that pharmacists recognize the quality of generic products as well as brand products. Although "product advertising" was not rated as an important factor, the two mostly recommended brand name ibuprofen products, Advil and Nuprin, were estimated to have the highest advertising expenses.¹⁰ The reason for this divergence is unclear.

In conclusion, these results revealed that pharmacists tended to

favor the availability of the switched products from a pharmacy for permanent or for a period of time. Facing the sales competition from discount stores with or without pharmacies, benefits lost, and increasing drug utilization risks of consumers for the switched drug products made pharmacists feel the current method to manage the Rx-to-OTC switch is unsatisfactory.

Most pharmacists agreed that the switch of ibuprofen from Rx to OTC status was a good choice. They perceived the market of other OTC analgesics and Rx ibuprofen in lower doses had been hurt by the availability of OTC ibuprofen, yet other competing NSAIDs and Rx ibuprofen in higher doses had benefited. Although each brand product was recommended for the indication for what the manufacturer promoted it, the generic ibuprofen was mostly recommended for each indication. Product quality and price to the customers were the most important factors influencing their recommending an ibuprofen product.

As a result, pharmaceutical companies could benefit from these findings and prepare new marketing strategies for the switched products to gain pharmacists' support. Some of the suggestions are:

- 1) Based on these considerations: a) the shortage of consumers' medical knowledge, b) consumers' reliance on the pharmacist as an important source of drug informations,¹¹ and c) the OTC sales competition made by non-pharmacy outlets which might affect pharmacy sales, the pharmaceutical companies should develop marketing strategies to promote the switched products in cooperation with the pharmacist.
- 2) Switched products should be promoted to younger pharmacists

who accept this situation better than older pharmacists. (t-Test results, Table XIII, Chapter IV)

- 3) Companies should carefully develop dual marketing strategies for the Rx version product and OTC version product concerning dose form, product position, pricing and competition to maximize the benefits.
- 4) Companies should monitor and evaluate current marketing advertising strategies for the switched products to meet the desires of the pharmacists.
- 5) Companies should carefully evaluate the switching of some prescription products to OTC status based on pharmacists' opinions.

LIMITATIONS OF THE STUDY

The investigation is subject to at least four limitations.

1. The limits of generalizability of this research should be noted. The present study investigated a sample of pharmacists who are listed as the license holders for the 835 community pharmacies in Mississippi. The usable responses rate for the study was 31.7 percent. No demographic information about pharmacists' years in practice, pharmacy operation data, and type of the pharmacies were available to compare with the data collected from the current study. Thus, the findings of the study might not be generalizable to the entire universe of the community pharmacies in Mississippi or nationwide.

2. The potential of cross-contamination between respondents and lack of control over who completed the questionnaire existed with this research. Moreover, the effect of a response bias was not tested in this study because not enough financial resources were available to

contact non-responding pharmacists. However, while the usable returns represented a less than optimal proportion of total questionnaire mailed, there is no reason to believe that respondents differed significantly from non-respondents.

3. The items included are not a collectively exhaustive compilation of all the aspects perceived by pharmacists in regard to the Rx-to-OTC switch. These results can only reflect pharmacists' attitudes in three major aspects- economic issues, professional role enhanced, and safe self-medication.

4. As OTC ibuprofen has already been launched for three years, pharmacists' perceptions might be affected by this time gap and other factors. Perhaps the results would have been different if investigated right after the switch.

Even with these limitations, the conclusions made with respect to the results found from this sample would not be compromised.

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APPENDICES

APPENDIX A
FINAL QUESTIONNAIRE, TYPE A

1987 SURVEY OF MISSISSIPPI PHARMACIES



Pharmaceutical Marketing and Management Research Program

Research Institute of Pharmaceutical Sciences

The University of Mississippi

University, MS 38677

PHARMACY AND PHARMACIST INFORMATION

1. Sex: () Male () Female
 2. a. How many years have you practiced in community pharmacy? ____ years
 - b. Check all the settings in which you have had pharmacy work experience:
 - () a. Single location community pharmacy
 - () b. Multilocation community pharmacy (2-3 locations owned by 1 company/person)
 - () c. Chain pharmacy (4 or more pharmacies owned by 1 company/person)
 - () d. Hospital
 - () e. Other (Specify) _____
 - c. Which of the above settings best describes your current job setting?
 ____ (Place corresponding letter in blank)
 3. What is the population of the community where you practice?
 - () less than 5,000 () 10,000 - 14,999 () 20,000 - 24,999 () 30,000 or more
 - () 5,000 - 9,999 () 15,000 - 19,999 () 25,000 - 29,999
 4. What is your average daily prescription volume (new and refill)?
 - () less than 50 () 76 - 100 () 126 - 150
 - () 51 - 75 () 101 - 125 () 151 or more
 5. What is the annual sales volume of your pharmacy?
 - () under \$200,000 () \$400,000 - \$499,999 () \$700,000 - \$799,999
 - () \$200,000 - \$299,999 () \$500,000 - \$599,999 () \$800,000 - \$899,999
 - () \$300,000 - \$399,999 () \$600,000 - \$699,999 () \$900,000 or more
 6. Approximately what percentage of your total sales volume is represented by the following categories?
 - ____% Prescription Drugs
 - ____% OTC Drugs
 - ____% Other Merchandise
 -
 - 100 % TOTAL
 7. What percent of your prescription dollar volume is represented by Medicaid? ____%
 8. Do you think more OTC medications should be covered by Medicaid? () Yes () No
 - IF YES, which ones? _____
9. What was the percentage net profit for your pharmacy last year? ____%
 10. What was your inventory turnover rate last year...
 - ... for prescription medications? ____ turns
 - ... for other merchandise? ____ turns

11. What do you think is your main competition for the OTC business? Rank the top 3 competitors by placing a 1 beside your main competitor, a 2 beside your next major competitor, etc. (RANK THREE)

independent pharmacies
 chain pharmacies
 discount stores with pharmacies
 supermarkets/groceries with pharmacies
 discount stores without pharmacies
 supermarkets/groceries without pharmacies
 other (specify) _____

12. Do you know of any physicians in your trade area who are dispensing prescriptions?

() Yes () No

IF YES: How many? _____ What are their specialties? _____

WHOLESALE SERVICES

1. What percentage of your pharmaceuticals (dollar volume) is purchased from each of the following sources? (percentages should total 100)

Direct from the manufacturer
 Primary distributor or wholesaler
 Secondary distributor(s) or wholesaler(s)
 Cooperative buying groups or network
 Order through corporate office, not involved in selecting supplier
 Other, specify _____

100%

2. What percentage of your total annual sales volume is purchased from each of the following wholesaler sources? (percentages should total 100)

a. Durr-Fillauer Medical
 b. Mississippi Drug Company
 c. McKesson Drug Company
 d. FoxMeyer Drug
 e. Chapman Drug Company
 f. AMFAC
 g. Bergen Brunswick
 h. Malone & Hyde Distributors
 i. Other (specify) _____
 j. Other (specify) _____

100%

Which of the above wholesaler sources is currently your primary wholesaler? (Place corresponding letter in blank) _____

IF YOU ONLY USE ONE WHOLESALER -- SKIP TO QUESTION 5

3. Please indicate from the list below your reasons for using two or more wholesalers by writing a 1 in the blank to the left of the most important reason, a 2 in the blank to the left of the next most important reason and so on. You need not rank all reasons if not applicable.

- _____ For inventory back-up for shorted product(s)
- _____ For inventory back-up for product(s) not carried by primary wholesaler
- _____ Delivery services from primary wholesaler too infrequent
- _____ For price comparisons on merchandise, discounts, and special promotions
- _____ Receive better service by creating competition between wholesalers
- _____ Do not want to discontinue services with wholesaler I have done business with for a long time
- _____ One wholesaler does not offer all of necessary services
- _____ Other, specify _____

4. Would you consider using fewer wholesalers than you are currently using in order to maintain a high discount percentage on ordered merchandise?

() Yes () No

IF YES, do you plan to use fewer wholesalers in the next year than you are currently using?

() Yes () No

MANY WHOLESALERS ARE HAVING TO CONSIDER CHANGING THEIR CURRENT LEVELS OF SERVICES AND/OR DISCOUNTS AS A RESULT OF THE COMPETITIVE ENVIRONMENT. THE NEXT GROUP OF QUESTIONS FOCUS ON YOUR CURRENT LEVEL OF SERVICES AND YOUR WILLINGNESS TO TRADE OFF A WHOLESALER SERVICE IN ORDER TO MAINTAIN YOUR CURRENT DISCOUNT PERCENTAGE

5. What is the average discount you receive from your primary wholesaler for each of the following monthly order dollar amounts?

<u>Order dollar volume/month</u>	<u>Wholesaler discount</u>
Up to \$4,999	_____ %
\$5,000-\$9,999	_____ %
\$10,000-\$19,999	_____ %
\$20,000 or more	_____ %

6. During an average month, how many times does your primary wholesaler sales representative visit your pharmacy?

_____ times per month

IF MORE THAN 1 TIME PER MONTH: Would you approve of your primary wholesaler representative decreasing the number of visits to your pharmacy to one time per month in order for you to maintain a high discount percentage?

() Yes () No

How many times per month would you prefer your primary wholesaler representative visit your pharmacy?

_____ times per month

7. How many times per month would you prefer your primary wholesaler contact you by telephone to inform you about new products, deals and other special promotions?

_____ times per month

On what day of the week would you prefer that your wholesaler telephone you regarding new products, deals and other special promotions?

(Circle one only) Mon Tue Wed Thu Fri Sat Sun

8. During an average work week, how many times do you order from your primary wholesaler?

_____ times per week

During an average work week, on how many days do you place an order with your primary wholesaler more than once a day?

_____ days per week

In order to maintain a higher discount percentage on ordered merchandise, would you consider placing orders to your primary wholesaler ...

... three times per week? () Yes () No

... two times per week? () Yes () No

... once per week? () Yes () No

9. Select the method of inventory control which you most often use for determining how much merchandise to purchase from your primary wholesaler. (Check the appropriate method for each classification of merchandise)

PRESCRIPTION MERCHANDISE	OTHER MERCHANDISE	
()	()	Wantbook
()	()	Stock Record Card System
()	()	Open-To-Buy Budget System
()	()	Economic Order Quantity Model
()	()	Other (specify) _____

10. During an average work week, how many times does your primary wholesaler deliver to your pharmacy?
_____ times per week

Would you consider receiving deliveries from your primary wholesaler fewer times per week in order to maintain a high discount percentage on merchandise?

() Yes () No

Circle the days you would prefer your primary wholesaler to deliver merchandise to your pharmacy if they delivered ...

... five times per week? Mon Tue Wed Thu Fri Sat Sun (circle five)

... three times per week? Mon Tue Wed Thu Fri Sat Sun (circle three)

11. How many times per month are you making payments to your primary wholesaler for merchandise?

() once per month () twice per month () more than twice per month

IF ONCE PER MONTH, would you consider paying your primary wholesaler two times per month in order to maintain a high discount percentage on order merchandise?

() Yes () No

12. For each service listed below, please answer the following two questions regarding your primary wholesaler:

- (A) Is the service AVAILABLE to you and, if so, is it USED?
- (B) How IMPORTANT is this service in the operation of your pharmacy?

Please provide a rating from 1 to 4 for each customer services using the rating scales below.

(A)	(B)
<u>Availability and Usage</u>	<u>Importance</u>
4 Don't know if available	4 Don't know
3 Service not available	3 Unimportant
2 Service available, but not used	2 Important
1 Service used	1 Essential

(A)	(B)	
AVAILABILITY	IMPORTANCE	
_____	_____	a. Frequent pickup of returned merchandise
_____	_____	b. Prompt crediting for delivery errors
_____	_____	c. No minimum order requirements
_____	_____	d. Periodic product movement reports
_____	_____	e. Inventory management reports
_____	_____	f. Planogramming services
_____	_____	g. Cooperative advertising
_____	_____	h. Financial management consultation
_____	_____	i. Trade area analysis
_____	_____	j. Franchising services (Price Guard, Health Mart, Value Rite, etc.)
_____	_____	k. Coupon redemption
_____	_____	l. Liability insurance for pharmacists
_____	_____	m. Business insurance for store
_____	_____	n. 3rd party claims processing
_____	_____	o. Other (specify) _____

13. How would you characterize your primary wholesaler representative? (Check one characteristic in each pair)

- helpful well informed courteous available
- not helpful poorly informed discourteous unavailable

14. At what percentage NET PROFIT do you believe your primary wholesaler operates? _____ %

15. If your primary wholesaler was to develop a network of pharmacies in a Preferred Provider Organization (PPO) arrangement to compete for the provision of pharmacy services to large groups of organized employees, how likely would you be to participate?

- I definitely would be interested in participating
- I have concerns but would consider participating
- I would need more information before responding
- I definitely would not be interested in participating

Why or Why Not? _____

PRESCRIPTION-TO-OTC SHIFT

1. For each of the following statements, please indicate the degree to which you agree or disagree by circling the appropriate value to the right.

	STRONGLY AGREE				STRONGLY DISAGREE
a. Switching more products from Rx-to-OTC will be beneficial to pharmacies in the longrun - - - - -	1	2	3	4	5
b. The Rx-to-OTC switch can enhance the professional role of the pharmacist by providing the opportunity to counsel customers about OTC products - -	1	2	3	4	5
c. The Rx-to-OTC switch will increase the pharmacy's net profit from prescription and OTC drug sales - - - - -	1	2	3	4	5
d. The Rx-to-OTC switch will increase the inventory carrying costs of the product - - - - -	1	2	3	4	5
e. As more products move from Rx-to-OTC, there is an increased risk to customers of drug interactions - - - - -	1	2	3	4	5
f. Switched OTC products <u>are currently</u> labeled adequately to promote safe self-medication by customers - - - - -	1	2	3	4	5
g. Switched OTC products <u>could be</u> labeled adequately to promote safe self-medication by customers - - - - -	1	2	3	4	5
h. When a product is made available OTC, the volume of the prescription version will decrease - - - - -	1	2	3	4	5
i. Pharmacy can make a better profit margin from sales of the OTC version than from the prescription version of a product - - - - -	1	2	3	4	5
j. When a switched OTC product is a market success, pharmacy will lose sales of that product to other types of retailers - - - - -	1	2	3	4	5
k. As more products move from Rx-to-OTC, customers are more likely to misuse these medications - - - - -	1	2	3	4	5

2. Please read each of the following statements and rank them in order of your preference as to how drugs should be handled. Indicate your first choice with 1, your second choice with 2, and so on. (RANK ALL)

- _____ Creation of a third class of drugs which are available without a prescription, but only from a pharmacy.
- _____ Creation of a transitional phase in which Rx-to-OTC switched products are available initially only from pharmacies for a limited time period.
- _____ Things remain as they are so that drug products switched from Rx-to-OTC are immediately available from numerous outlets, including pharmacies.
- _____ No more products are switched from Rx-to-OTC classification.

If a third class of drugs were created, would you charge for OTC counseling?
 Yes No

If a transitional phase were created, how long should the phase last?
 _____ months _____ years

3. For each of the lists below, please check the one response which best describes your efforts to include OTC medications on patient profiles.

- | | |
|--|---|
| (CHECK ONLY ONE) | (CHECK ONLY ONE) |
| <input type="checkbox"/> include all OTC's | <input type="checkbox"/> do for most patients |
| <input type="checkbox"/> included selected OTC's | <input type="checkbox"/> do for some patients |
| <input type="checkbox"/> do not include OTC's | <input type="checkbox"/> do for no patients |

4. Which of the following categories do you think should be appropriate for additional Rx-to-OTC switch? (Check all that apply)

- Theophylline
- Hydrochlorothiazide
- Nicotine polacrilex (Nicorette)
- Loperamide (Imodium)
- Benzonatate (Tessalon)
- Terfenadine (Seldane)
- Hydrocortisone 1%
- Loestrin 1/20
- Diazepam (Valium)
- Naproxen (Naprosyn)
- Penicillin (oral)
- Sucralfate (Carafate)

THE NEXT GROUP OF QUESTIONS FOCUS ON THE SWITCH OF IBUPROFEN 200 MG. FROM PRESCRIPTION TO OTC STATUS

5. For each of the following statements, please indicate the degree to which you agree or disagree by circling the appropriate value to the right.

		STRONGLY AGREE				STRONGLY DISAGREE
a. In general, ibuprofen 200 mg was a good choice for Rx-to-OTC switch	--	1	2	3	4	5
b. Ibuprofen 200 mg is a safe drug for OTC use by the customer	--	1	2	3	4	5
c. Ibuprofen 200 mg is effective for its approved indications	--	1	2	3	4	5
d. Ibuprofen 200 mg is adequately labeled to promote safe use	--	1	2	3	4	5
e. Customers can use ibuprofen 200 mg safely without pharmacist advice	--	1	2	3	4	5
f. Ibuprofen 200 mg should be a reimbursable OTC medication under Mississippi Medicaid	--	1	2	3	4	5
g. Prescriptions written for ibuprofen 200 mg should be reimbursable as prescriptions by third parties	--	1	2	3	4	5

6. In the grid below, please indicate with an "X" the ibuprofen 200 mg product you are most likely to recommend for each of the conditions indicated. (CHECK ONLY ONE PRODUCT FOR EACH CONDITION)

CONDITION	PRODUCT								(Specify)
	Pamprin	Advil	Haltran	Nuprin	Midol 200	Mediprin	Doan's ibuprof.	Generic	Others
Headache									
Muscle ache									
Fever									
Menstrual cramps									
Backache									
Minor pain arthritis									
Tooth ache									
Other (specify)									

Of the ibuprofen 200 mg products listed above, which one do you most often recommend? _____

Of the conditions listed above, for which condition do you most frequently recommend ibuprofen 200 mg? _____

7. Please indicate the effects in your pharmacy of the switch of ibuprofen 200 mg from Rx-to-OTC for each of the drug products and drug product categories below. Indicate your answer by circling the appropriate value to the right of each product.

	Increased Greatly	Increased Somewhat	No Change	Decreased Somewhat	Decreased Greatly
<u>OTC DOLLAR VOLUME</u>					
Aspirin products	1	2	3	4	5
Acetaminophen products	1	2	3	4	5
Combination analgesic products	1	2	3	4	5
<u>NUMBER OF PRESCRIPTIONS</u>					
Metrin 800 mg	1	2	3	4	5
600 mg	1	2	3	4	5
400 mg	1	2	3	4	5
300 mg	1	2	3	4	5
Rufen 800 mg	1	2	3	4	5
600 mg	1	2	3	4	5
400 mg	1	2	3	4	5
Naprosyn (all strengths)	1	2	3	4	5
Feldene (all strengths)	1	2	3	4	5

8. For each of the following factors, please indicate how important the factor is in your decision to recommend a certain ibuprofen 200 mg product. Indicate your response by circling the appropriate value to the right.

	STRONGLY AGREE	STRONGLY DISAGREE
a. Product profit margin	1 2 3 4 5	1 2 3 4 5
b. Product quality	1 2 3 4 5	1 2 3 4 5
c. Manufacturer's reputation	1 2 3 4 5	1 2 3 4 5
d. Product advertising	1 2 3 4 5	1 2 3 4 5
e. Manufacturer provides more product services (information pamphlets, etc.)	1 2 3 4 5	1 2 3 4 5
f. Price to the customers	1 2 3 4 5	1 2 3 4 5
g. Amount of the product in inventory	1 2 3 4 5	1 2 3 4 5
h. Relationship with the manufacturer's salesperson	1 2 3 4 5	1 2 3 4 5
i. Others (specify) _____	1 2 3 4 5	1 2 3 4 5

THE FOLLOWING GROUP OF QUESTIONS FOCUS ON THE POSSIBLE SWITCH OF CIMETIDINE FROM PRESCRIPTION TO OTC STATUS

9. Do you think cimetidine 200mg is appropriate for the Rx-to-OTC switch? () Yes () No

On which two of the following reasons did you base your decision above? Please use a 1 to indicate the most important reason and a 2 for the next most important reason. (RANK TWO)

- _____ product effectiveness/ineffectiveness
- _____ degree of risk of side effects
- _____ competition from non-professional store
- _____ opportunity for customer counseling
- _____ Medicaid reimbursement possibilities
- _____ ability/inability of customer to identify condition
- _____ other (specify) _____

10. If cimetidine 200mg were available OTC, which indication(s) do you think would be appropriate? (Check all that apply)

- treatment of heartburn
 treatment of acid indigestion
 treatment of sour stomach
 treatment of upset stomach
 treatment of stomach ulcers

11. For which indication(s) would you feel comfortable recommending OTC cimetidine? (Check all that apply)

- treatment of heartburn
 treatment of acid indigestion
 treatment of sour stomach
 treatment of upset stomach
 treatment of stomach ulcers

12. Which products would be likely competitors for OTC cimetidine? Please rank the following with 1 representing the most likely competitor, 2 representing the second most likely competitor, and so on. (RANK ALL)

- _____ liquid antacids (such as Maalox)
 _____ liquid antacids with simethicone (such as Mylanta)
 _____ Pepto Bismol
 _____ Rolaids/Tums
 _____ other (specify) _____

13. What effect do you feel OTC cimetidine would have on the prescription volume of the following products? Please circle the appropriate number to the right of each product.

	Increase Greatly	Increase Somewhat	No Change	Decrease Somewhat	Decrease Greatly
Tagamet	1	2	3	4	5
Zantac	1	2	3	4	5
Pepcid	1	2	3	4	5

14. If cimetidine went OTC, should it be covered by Medicaid? Yes No

THANK YOU FOR YOUR TIME AND INFORMATION

If you are interested in receiving copies of the results from the 1986 or 1987 Mississippi Pharmacy Survey, please check the appropriate spaces below. After completing the questionnaire, please staple or tape shut and drop in the mail -- no postage is required.

- Please send me a copy of the 1986 Mississippi Pharmacy Survey results.
 Please send me a copy of the 1987 Mississippi Pharmacy Survey results when they are printed.

APPENDIX B
FINAL QUESTIONNAIRE, TYPE B

1987 SURVEY OF
MISSISSIPPI PHARMACIES



Pharmaceutical Marketing and Management Research Program

Research Institute of Pharmaceutical Sciences

The University of Mississippi

University, MS 38677

PHARMACY AND PHARMACIST INFORMATION

1. Sex: () Male () Female
 2. a. How many years have you practiced in community pharmacy? ____ years
 - b. Check all the settings in which you have had pharmacy work experience:
 - () a. Single location community pharmacy
 - () b. Multilocation community pharmacy (2-3 locations owned by 1 company/person)
 - () c. Chain pharmacy (4 or more pharmacies owned by 1 company/person)
 - () d. Hospital
 - () e. Other (Specify) _____
 - c. Which of the above settings best describes your current job setting?
 ____ (Place corresponding letter in blank)
 3. What is the population of the community where you practice?
 - () less than 5,000 () 10,000 - 14,999 () 20,000 - 24,999 () 30,000 or more
 - () 5,000 - 9,999 () 15,000 - 19,999 () 25,000 - 29,999
 4. What is your average daily prescription volume (new and refill)?
 - () less than 50 () 76 - 100 () 126 - 150
 - () 51 - 75 () 101 - 125 () 151 or more
 5. What is the annual sales volume of your pharmacy?
 - () under \$200,000 () \$400,000 - \$499,999 () \$700,000 - \$799,999
 - () \$200,000 - \$399,999 () \$500,000 - \$599,999 () \$800,000 - \$899,999
 - () \$300,000 - \$399,999 () \$600,000 - \$699,999 () \$900,000 or more
 6. Approximately what percentage of your total sales volume is represented by the following categories?
 - ____% Prescription Drugs
 - ____% OTC Drugs
 - ____% Other Merchandise
 -
 - 100% TOTAL
 7. What percent of your prescription dollar volume is represented by Medicaid? ____%
 8. Do you think more OTC medications should be covered by Medicaid? () Yes () No
 - IF YES, which ones? _____
9. What was the percentage net profit for your pharmacy last year? ____%
 10. What was your inventory turnover rate last year...
 - ... for prescription medications? ____ turns
 - ... for other merchandise? ____ turns

11. What do you think is your main competition for the OTC business? Rank the top 3 competitors by placing a 1 beside your main competitor, a 2 beside your next major competitor, etc. (RANK THREE)

independent pharmacies
 chain pharmacies
 discount stores with pharmacies
 supermarkets/groceries with pharmacies
 discount stores without pharmacies
 supermarkets/groceries without pharmacies
 other (specify) _____

12. Do you know of any physicians in your trade area who are dispensing prescriptions?

() Yes () No

IF YES: How many? _____ What are their specialties? _____

WHOLESALE SERVICES

1. What percentage of your pharmaceuticals (dollar volume) is purchased from each of the following sources? (percentages should total 100)

Direct from the manufacturer
 Primary distributor or wholesaler
 Secondary distributor(s) or wholesaler(s)
 Cooperative buying groups or network
 Order through corporate office, not involved in selecting supplier
 Other, specify _____

100%

2. What percentage of your total annual sales volume is purchased from each of the following wholesaler sources? (percentages should total 100)

a. Durr-Fillauer Medical
 b. Mississippi Drug Company
 c. McKesson Drug Company
 d. FoxMeyer Drug
 e. Chapman Drug Company
 f. AMFAC
 g. Bergen Brunswick
 h. Malone & Hyde Distributors
 i. Other (specify) _____
 j. Other (specify) _____

100%

Which of the above wholesaler sources is currently your primary wholesaler? (Place corresponding letter in blank) _____

IF YOU ONLY USE ONE WHOLESALER -- SKIP TO QUESTION 5

3. Please indicate from the list below your reasons for using two or more wholesalers by writing a 1 in the blank to the left of the most important reason, a 2 in the blank to the left of the next most important reason and so on. You need not rank all reasons if not applicable.

- For inventory back-up for shorted product(s)
 For inventory back-up for product(s) not carried by primary wholesaler
 Delivery services from primary wholesaler too infrequent
 For price comparisons on merchandise, discounts, and special promotions
 Receive better service by creating competition between wholesalers
 Do not want to discontinue services with wholesaler I have done business with for a long time
 One wholesaler does not offer all of necessary services
 Other, specify _____

4. Would you consider using fewer wholesalers than you are currently using in order to maintain a high discount percentage on ordered merchandise?

() Yes () No

IF YES, do you plan to use fewer wholesalers in the next year than you are currently using?

() Yes () No

MANY WHOLESALERS ARE HAVING TO CONSIDER CHANGING THEIR CURRENT LEVELS OF SERVICES AND/OR DISCOUNTS AS A RESULT OF THE COMPETITIVE ENVIRONMENT. THE NEXT GROUP OF QUESTIONS FOCUS ON YOUR CURRENT LEVEL OF SERVICES AND YOUR WILLINGNESS TO TRADE OFF A WHOLESALER SERVICE IN ORDER TO MAINTAIN YOUR CURRENT DISCOUNT PERCENTAGE.

5. What is the average discount you receive from your primary wholesaler for each of the following monthly order dollar amounts?

<u>Order dollar volume/month</u>	<u>Wholesaler discount</u>
Up to \$4,999	_____ %
\$5,000-\$9,999	_____ %
\$10,000-\$19,999	_____ %
\$20,000 or more	_____ %

6. During an average month, how many times does your primary wholesaler sales representative visit your pharmacy?

_____ times per month

IF MORE THAN 1 TIME PER MONTH: Would you approve of your primary wholesaler representative decreasing the number of visits to your pharmacy to one time per month in order for you to maintain a high discount percentage?

() Yes () No

How many times per month would you prefer your primary wholesaler representative visit your pharmacy?

_____ times per month

7. How many times per month would you prefer your primary wholesaler contact you by telephone to inform you about new products, deals and other special promotions?
 _____ times per month

On what day of the week would you prefer that your wholesaler telephone you regarding new products, deals and other special promotions?

(Circle one only) Mon Tue Wed Thu Fri Sat Sun

8. During an average work week, how many times do you order from your primary wholesaler?
 _____ times per week

During an average work week, on how many days do you place an order with your primary wholesaler more than once a day?
 _____ days per week

In order to maintain a higher discount percentage on ordered merchandise, would you consider placing orders to your primary wholesaler ...

- ... three times per week? () Yes () No
 ... two times per week? () Yes () No
 ... once per week? () Yes () No

9. Select the method of inventory control which you most often use for determining how much merchandise to purchase from your primary wholesaler. (Check the appropriate method for each classification of merchandise)

<u>PRESCRIPTION</u>	<u>OTHER</u>	
<u>MERCHANDISE</u>	<u>MERCHANDISE</u>	
()	()	Wantbook
()	()	Stock Record Card System
()	()	Open-To-Buy Budget System
()	()	Economic Order Quantity Model
()	()	Other (specify) _____

10. During an average work week, how many times does your primary wholesaler deliver to your pharmacy?
 _____ times per week

Would you consider receiving deliveries from your primary wholesaler fewer times per week in order to maintain a high discount percentage on merchandise?

- () Yes () No

Circle the days you would prefer your primary wholesaler to deliver merchandise to your pharmacy if they delivered ...

- ... five times per week? Mon Tue Wed Thu Fri Sat Sun (circle five)
 ... three times per week? Mon Tue Wed Thu Fri Sat Sun (circle three)

11. How many times per month are you making payments to your primary wholesaler for merchandise?

- () once per month () twice per month () more than twice per month

IF ONCE PER MONTH, would you consider paying your primary wholesaler two times per month in order to maintain a high discount percentage on order merchandise?

- () Yes () No

12. For each service listed below, please answer the following two questions regarding your primary wholesaler:

- (A) Is the service AVAILABLE to you and, if so, is it USED?
- (B) How IMPORTANT is this service in the operation of your pharmacy?

Please provide a rating from 1 to 4 for each customer services using the rating scales below.

(A)	(B)
<u>Availability and Usage</u>	<u>Importance</u>
4 Don't know if available	4 Don't know
3 Service not available	3 Unimportant
2 Service available, but not used	2 Important
1 Service used	1 Essential

(A)	(B)	
AVAILABILITY	IMPORTANCE	
_____	_____	a. Frequent pickup of returned merchandise
_____	_____	b. Prompt crediting for delivery errors
_____	_____	c. No minimum order requirements
_____	_____	d. Periodic product movement reports
_____	_____	e. Inventory management reports
_____	_____	f. Planogramming services
_____	_____	g. Cooperative advertising
_____	_____	h. Financial management consultation
_____	_____	i. Trade area analysis
_____	_____	j. Franchising services (Price Guard, Health Mart, Value Rite, etc.)
_____	_____	k. Coupon redemption
_____	_____	l. Liability insurance for pharmacists
_____	_____	m. Business insurance for store
_____	_____	n. 3rd party claims processing
_____	_____	o. Other (specify) _____

13. How would you characterize your primary wholesaler representative? (Check one characteristic in each pair)

- () helpful () well informed () courteous () available
- () not helpful () poorly informed () discourteous () unavailable

14. At what percentage NET PROFIT do you believe your primary wholesaler operates? _____ %

15. If your primary wholesaler was to develop a network of pharmacies in a Preferred Provider Organization (PPO) arrangement to compete for the provision of pharmacy services to large groups of organized employees, how likely would you be to participate?

- () I definitely would be interested in participating
- () I have concerns but would consider participating
- () I would need more information before responding
- () I definitely would not be interested in participating

Why or Why Not? _____

PRESCRIPTION-TO-OTC SHIFT

1. For each of the following statements, please indicate the degree to which you agree or disagree by circling the appropriate value to the right.

	STRONGLY AGREE					STRONGLY DISAGREE
a. Switching more products from Rx-to-OTC will be beneficial to pharmacies in the longrun - - - - -	1	2	3	4	5	
b. The Rx-to-OTC switch can enhance the professional role of the pharmacist by providing the opportunity to counsel customers about OTC products - -	1	2	3	4	5	
c. The Rx-to-OTC switch will increase the pharmacy's net profit from prescription and OTC drug sales - - - - -	1	2	3	4	5	
d. The Rx-to-OTC switch will increase the inventory carrying costs of the product - - - - -	1	2	3	4	5	
e. As more products move from Rx-to-OTC, there is an increased risk to customers of drug interactions - - - - -	1	2	3	4	5	
f. Switched OTC products <u>are currently</u> labeled adequately to promote safe self-medication by customers - - - - -	1	2	3	4	5	
g. Switched OTC products <u>could be</u> labeled adequately to promote safe self-medication by customers - - - - -	1	2	3	4	5	
h. When a product is made available OTC, the volume of the prescription version will decrease - - - - -	1	2	3	4	5	
i. Pharmacy can make a better profit margin from sales of the OTC version than from the prescription version of a product - - - - -	1	2	3	4	5	
j. When a switched OTC product is a market success, pharmacy will lose sales of that product to other types of retailers - - - - -	1	2	3	4	5	
k. As more products move from Rx-to-OTC, customers are more likely to misuse these medications - - - - -	1	2	3	4	5	

2. Please read each of the following statements and rank them in order of your preference as to how drugs should be handled. Indicate your first choice with 1, your second choice with 2, and so on. (RANK ALL)

- _____ Creation of a third class of drugs which are available without a prescription, but only from a pharmacy.
- _____ Creation of a transitional phase in which Rx-to-OTC switched products are available initially only from pharmacies for a limited time period.
- _____ Things remain as they are so that drug products switched from Rx-to-OTC are immediately available from numerous outlets, including pharmacies.
- _____ No more products are switched from Rx-to-OTC classification.

If a third class of drugs were created, would you charge for OTC counseling?
 () Yes () No

If a transitional phase were created, how long should the phase last?
 _____ months _____ years

3. For each of the lists below, please check the one response which best describes your efforts to include OTC medications on patient profiles.

- | | |
|-----------------------------|--------------------------|
| (CHECK ONLY ONE) | (CHECK ONLY ONE) |
| () include all OTC's | () do for most patients |
| () included selected OTC's | () do for some patients |
| () do not include OTC's | () do for no patients |

4. Which of the following categories do you think should be appropriate for additional Rx-to-OTC switch? (Check all that apply)

- Theophylline
- Hydrochlorothiazide
- Nicotine polacrilex (Nicorette)
- Loperamide (Imodium)
- Benzonatate (Tessalon)
- Terfenadine (Seldane)
- Hydrocortisone 1%
- Loestrin 1/20
- Diazepam (Valium)
- Naproxen (Naprosyn)
- Penicillin (oral)
- Sucralfate (Carafate)

THE FOLLOWING GROUP OF QUESTIONS FOCUS ON THE POSSIBLE SWITCH OF CIMETIDINE FROM PRESCRIPTION TO OTC STATUS

5. Do you think cimetidine 200mg is appropriate for the Rx-to-OTC switch? Yes No

On which two of the following reasons did you base your decision above? Please use a 1 to indicate the most important reason and a 2 for the next most important reason. (RANK TWO)

- _____ product effectiveness/ineffectiveness
- _____ degree of risk of side effects
- _____ competition from non-professional store
- _____ opportunity for customer counseling
- _____ Medicaid reimbursement possibilities
- _____ ability/inability of customer to identify condition
- _____ other (specify) _____

6. If cimetidine 200mg were available OTC, which indication(s) do you think would be appropriate? (Check all that apply)

- treatment of heartburn
- treatment of acid indigestion
- treatment of sour stomach
- treatment of upset stomach
- treatment of stomach ulcers

7. For which indication(s) would you feel comfortable recommending OTC cimetidine? (Check all that apply)

- treatment of heartburn
- treatment of acid indigestion
- treatment of sour stomach
- treatment of upset stomach
- treatment of stomach ulcers

8. Which products would be likely competitors for OTC cimetidine? Please rank the following with 1 representing the most likely competitor, 2 representing the second most likely competitor, and so on. (RANK ALL)

- _____ liquid antacids (such as Maalox)
- _____ liquid antacids with simethicone (such as Mylanta)
- _____ Pepto Bismol
- _____ Rolaids/Tums
- _____ other (specify) _____

9. What effect do you feel OTC cimetidine would have on the prescription volume of the following products? Please circle the appropriate number to the right of each product.

	Increase Greatly	Increase Soewhat	No Change	Decrease Somewhat	Decrease Greatly
Tagamet	1	2	3	4	5
Zantac	1	2	3	4	5
Pepcid	1	2	3	4	5

10. If cimetidine went OTC, should it be covered by Medicaid? () Yes () No

THE NEXT GROUP OF QUESTIONS FOCUS ON THE SWITCH OF IBUPROFEN 200 MG. FROM PRESCRIPTION TO OTC STATUS

11. For each of the following statements, please indicate the degree to which you agree or disagree by circling the appropriate value to the right.

	STRONGLY AGREE					STRONGLY DISAGREE
a. In general, ibuprofen 200 mg was a good choice for Rx-to-OTC switch	- - 1	2	3	4	5	
b. Ibuprofen 200 mg is a safe drug for OTC use by the customer	- - - - - 1	2	3	4	5	
c. Ibuprofen 200 mg is effective for its approved indications	- - - - - 1	2	3	4	5	
d. Ibuprofen 200 mg is adequately labeled to promote safe use	- - - - - 1	2	3	4	5	
e. Customers can use ibuprofen 200 mg safely without pharmacist advice	- - 1	2	3	4	5	
f. Ibuprofen 200 mg should be a reimbursable OTC medication under Mississippi Medicaid	- - - - - 1	2	3	4	5	
g. Prescriptions written for ibuprofen 200 mg should be reimbursable as prescriptions by third parties	- - - - - 1	2	3	4	5	

12. In the grid below, please indicate with an "X" the ibuprofen 200 mg product you are most likely to recommend for each of the conditions indicated. (CHECK ONLY ONE PRODUCT FOR EACH CONDITION)

CONDITION	PRODUCT								(Specify) Others
	Pamprin	Advil	Haltran	Nuprin	Midol 200	Mediprin	Doan's ibuprof.	Generic	
Headache									
Muscle ache									
Fever									
Menstrual cramps									
Backache									
Minor pain arthritis									
Tooth ache									
Other (specify)									

Of the ibuprofen 200 mg products listed above, which one do you most often recommend? _____

Of the conditions listed above, for which condition do you most frequently recommend ibuprofen 200 mg? _____

13. Please indicate the effects in your pharmacy of the switch of ibuprofen 200 mg from Rx-to-OTC for each of the drug products and drug product categories below. Indicate your answer by circling the appropriate value to the right of each product.

	Increased Greatly	Increased Somewhat	No Change	Decreased Somewhat	Decreased Greatly
<u>OTC DOLLAR VOLUME</u>					
Aspirin products	1	2	3	4	5
Acetaminophen products	1	2	3	4	5
Combination analgesic products	1	2	3	4	5
<u>NUMBER OF PRESCRIPTIONS</u>					
Motrin 800 mg	1	2	3	4	5
600 mg	1	2	3	4	5
400 mg	1	2	3	4	5
300 mg	1	2	3	4	5
Rufen 800 mg	1	2	3	4	5
600 mg	1	2	3	4	5
400 mg	1	2	3	4	5
Naprosyn (all strengths)	1	2	3	4	5
Feldene (all strengths)	1	2	3	4	5

14. For each of the following factors, please indicate how important the factor is in your decision to recommend a certain ibuprofen 200 mg product. Indicate your response by circling the appropriate value to the right.

	STRONGLY AGREE	STRONGLY DISAGREE
a. Product profit margin	1 2 3 4 5	
b. Product quality	1 2 3 4 5	
c. Manufacturer's reputation	1 2 3 4 5	
d. Product advertising	1 2 3 4 5	
e. Manufacturer provides more product services (information pamphlets, etc.)	1 2 3 4 5	
f. Price to the customers	1 2 3 4 5	
g. Amount of the product in inventory	1 2 3 4 5	
h. Relationship with the manufacturer's salesperson	1 2 3 4 5	
i. Others (specify) _____	1 2 3 4 5	

THANK YOU FOR YOUR TIME AND INFORMATION

If you are interested in receiving copies of the results from the 1986 or 1987 Mississippi Pharmacy Survey, please check the appropriate spaces below. After completing the questionnaire, please staple or tape shut and drop in the mail -- no postage is required.

- () Please send me a copy of the 1986 Mississippi Pharmacy Survey results.
- () Please send me a copy of the 1987 Mississippi Pharmacy Survey results when they are printed.

APPENDIX C
COVER LETTER

October 9, 1987

Dear Mississippi Pharmacists:

Last year we initiated our Annual Survey of Mississippi Pharmacies, which examines current management issues facing the community pharmacies in the state. The major objectives of the Annual Survey are: (1) to provide feedback to pharmacies about the impact of current trends and management issues in pharmacy and (2) to identify priority areas for further research by our Pharmaceutical Marketing and Management Research Program.

This year's survey addresses two issues, wholesaler services to retail pharmacies and the impact of shifting products from prescription to OTC status. Both of these are important topics which directly relate to the economic viability of your pharmacy.

The results of this year's Survey will be printed in a booklet format similar to the questionnaire and mailed to all respondents who check the appropriate box on the inside back cover. We provide the results to you in appreciation for your participation and so that you may compare your responses to those of your colleagues. Many use the results as a "yardstick" and a management tool for their pharmacy. If you did not receive a copy of the 1986 Survey Results and would like to receive one, please indicate so when you request a copy of this year's study.

Please take a few minutes to complete the questionnaire for your pharmacy. Although responding takes a few minutes, I'm sure you will agree that these are important topics and we think the information you will receive in return will be worth the effort.

Thank you for your participation and interest in the Annual Survey of Mississippi Pharmacies.

APPENDIX D
FOLLOW UP COVER LETTER

November 2, 1987

Dear Mississippi Pharmacists:

Last month we mailed you a copy of the enclosed questionnaire. This questionnaire is part of the Annual Survey of Mississippi Pharmacies which is conducted by the Pharmaceutical Marketing and Management program at the school of Pharmacy.

Although the response to date has been better than in previous years, there are still a large number of Mississippi Pharmacists who have not returned a completed questionnaire. It is important that we receive responses from as many pharmacies as possible in order for our study to be as representative as possible. Therefore, if you have not responded, please take a few minutes to complete the questionnaire for your pharmacy. If you have already responded, thank you for your participation.

A major objective of the Annual Survey is to provide marketing and management information to Mississippi pharmacies. Therefore, we have made it as easy as possible for you to request a copy of the results -- simple check the box on the last page of the questionnaire. You may also request a copy of last's study which addressed management trend, computer use and attitudes toward post-marketing surveillance studies.

As with all of our surveys, your individual responses are kept strictly confidential. The code number which appear on the questionnaire booklet are for tracking and follow-up mailing purposes only.

Thank you in advance for your participation in this survey.

BIOGRAPHICAL SKETCH OF THE AUTHOR

Li-Ly Emily Chang was born January 4, 1960 in Taiwan, Republic of China.(R.O.C.) She is the daughter of Mr. Tai-Li Chang and Mrs. Lin Tsai-Hun Chang.

Ms. Chang received her Bachelor of Science Degree in Pharmacy from Taipei Medical College in Taipei, Taiwan in 1982.

Before returning to graduate school in 1986, Ms. Chang worked in Bureau of Drug, National Health Administration in Executive Yuan as a Professional Assistant from 1982 till 1983. After that, Ms. Chang joined IMS, Taiwan until 1985. By the time she left IMS, she was a Coding Supervisor for eight staff. While at The University of Mississippi, Ms. Chang held research assistantship in The Research Institute of Pharmaceutical Sciences.

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