

Analysis of Prescription Drug to Over-the-Counter
(Rx-to-OTC) Switch Movement

Final Report

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Analysis of Prescription Drug to Over-the-Counter (Rx-to-OTC) Switch Movement

Executive Summary

Introduction

Approximately **600** over-the-counter (OTC) products currently available use ingredients and dosages available only by prescription **20** years ago. While there has been a steady stream of OTC switches since the **mid-1970s**, the number of switches has accelerated in recent years. Between 1988 and 1994 there were 14 switches, while in the last three years there were at least 19 switches. There are a number of possible reasons for this trend, including: (1) a growing emphasis on individual autonomy and self-help; (2) a trend toward deregulation in the US; (3) health care cost containment efforts; and (4) pharmaceutical industry self-interest/profit. The issue of Rx-to-OTC switching deserves considerable attention because of the large number of people who could be affected by the trend, including consumers, pharmaceutical companies, physicians, pharmacists, and payers.

The purpose of this project is to provide a comprehensive review and analysis of the **Rx-**to-OTC switch movement in order to inform policy and define relevant research questions. This report focuses on the impact of “switched drugs” and the switch trend--that is, prescription drugs which have been switched to over-the-counter status, with a bias towards an analysis of more recent switches and potential switches. Since this project centers on the *impact* of the switch drugs, almost all of our discussion focuses on post-switch issues. The discussions of a few **pre-**switch issues, found in the Literature Review and in the Key Informant chapters of this report, are limited and generally confirm the sentiment that those involved in the switch process are quite satisfied with its effectiveness and efficiency.

Project Overview

Our project began with an exhaustive literature review. The results of the literature review in conjunction with discussions with the Research Advisory Group formed the basis for our key informant interviews. Key informant interviews were undertaken to refine the issues and further develop-research questions. The final portion of this study involved limited analyses of select data sets **to focus on** key issues, **such as** the cost and benefits of particular OTC switch drugs and the impact **of insurance** on OTC demand, given the constraints of available data sources.

This research is intended to be exploratory--each of the tasks informs and refines the next step and builds on the former step. Accordingly, the approaches taken are investigative rather than prescriptive. It is hoped that the documents produced from this study will inform policymakers and researchers, provoke thought and discussion, and provide direction for further research.

Literature Review/Policy Synthesis

Chapter 1 presents a relatively exhaustive review of the literature related to the **Rx-to-OTC** switch movement. Our literature review identifies four major forces that are driving the switch movement: the market expansion motive on the part of **pharmaceutical companies**; the individual autonomy/self-help **movement**; the trend toward deregulation in the U.S.; and health care cost containment efforts. We then discuss the impact of the Rx-to-OTC switch movement on a number of important groups: consumers, **pharmaceutical** companies, physicians, pharmacists, and payers. In order to clarify how recent switch drugs are creating unique policy considerations, we provide data on two recent switch drugs: vaginal antifungal treatments and

H2 blockers. Chapter 1 concludes with a discussion of the potential policy issues that arise in the context of our literature review. One pre-switch issue is discussed:

- ❑ Are the right drugs getting switched for the right reasons?

In addition, the following post-switch issues are raised:

- ❑ **What** types of post-marketing surveillance should be conducted?
- ❑ Are consumers receiving the appropriate information through advertising?
- ❑ Does lack of insurance coverage for **OTCs** represent an access to care issue?
- ❑ How is consumer sophistication/knowledge to be **gauged/measured**?
- ❑ How can vulnerable populations best be protected? and
- ❑ How can we get better data on OTC use?

Summary of Key Informant Interviews

Chapter 2 summarizes the results of our key informant interviews. An interview guide containing 21 open-ended questions was administered to seven key informants representing pharmacists, consumers, policymakers, physicians, pharmaceutical companies, and payers. Three principal areas related to the switch movement were covered in this guide: understanding the trend, understanding the process for switching drugs, and policy issues. Respondents were encouraged to provide both opinion and evidence in response to questions.

In general, interviewees viewed the switch trend as a positive one, providing increased access to safe and effective drugs and cost savings, primarily through reduced physician office visits and work time lost. The FDA process for reviewing potential switches was seen as adequate and the number and type of switches as appropriate. Drug safety and efficacy profiles as well as the ability of individuals to appropriately self-diagnose and self-medicate were seen as

the critical elements in the timing of an OTC switch. The best types and levels of OTC information and the translation of that information into consumer knowledge of appropriate OTC use were cited as critical policy issues. Insurance coverage of **OTCs** was not seen as an issue of significant policy concern at this time, although several interviewees noted that if more “maintenance” medications are switched to OTC, this could become a more important issue, especially for chronically ill populations who must purchase those medications regularly.

Data Analyses

Chapters 3-6 contain data analyses of four separate data sets. Chapter 3 contains an analysis of the demand for OTC switch drugs. Our analysis provides evidence on the magnitude of OTC sales and the importance of recent switch drugs within the **OTC** market. Sales data for three recent switch drugs (vaginal anticandidals, H2 blockers, and nicotine replacement products) are analyzed to estimate price and income elasticities **of demand** and to investigate the relationship between **demand** for these **OTCs** and other market and demographic characteristics. Based on estimation of market demand curves for H2 blockers, nicotine replacement medications, and vaginal anticandidals, we find

- Demand for nicotine replacement medications is relatively insensitive to **price** (inelastic demand), yielding significant market power to manufacturers to raise price without losing consumers.
- Demands for H2 blockers and vaginal anticandidals are relatively elastic, implying that increases in price will lead consumers to purchase less of the product.
- a All three products appear to be “normal” goods (in the economic sense), meaning that increases in income lead consumers to purchase more of the product.

- ❑ Interestingly, the percentage of the region's population below the poverty line (a measure of the skewness of the income distribution, not the average) is also associated with an increase in demand suggesting that lower income populations are more likely to use **OTCs**.
- ❑ That **OTCs** may actually serve as a substitute for conventional medical care (physician and hospital care) is suggested in the negative relationship between demand for these OTC products and physicians per 1,000 (population) and hospital beds per 1,000.

The results **of our** estimation of individual demand curves for specific OTC brands within the three categories are generally consistent with our hypothesis that these OTC markets are characterized by monopolistic competition.

- ❑ **Coefficients** on competitors' prices are generally positive indicating substitution between products.
- ❑ Price elasticities for individual products tend to be larger than the overall market price elasticities.

Chapter 4 presents analyses related to the impact of OTC switch drugs on clinical practice patterns. Data from various years of the National Ambulatory Care Survey (**NACS**) are used to empirically examine the impact of specific Rx-to-OTC switches on clinical practice patterns. Our analyses highlight that the average number of vaginitis visits per woman (15 – 64) has fallen significantly in the post-switch time period (1990-1994), and it does not appear that this decrease 'is entirely attributable to the overall **decline** in physician **office visits**. In fact, we estimate that the OTC switch of vaginal anticandidals resulted in a decrease of approximately 1.1 million vaginitis visits per year. Our data also indicate that the OTC switch of the more potent version of

hydrocortisone (1 %) had

dermatitis complaints.

Although prescription rates for clotrimazole and

these medications stitches

prescription rates for other “substitute medications”.

fell after the medication went OTC. The only related dermatitis drugs that were

significantly more often in 1994 than in 1990 and 1985 were those used for the tr

% will have conditions that could lead to serious long-term complications. We estimate the costs of OTC anticandidal availability to be approximately \$3.83 per person (**direct** medical costs only). Weighed against an estimated benefit of \$61.96 per person, the overall benefit-cost ratio is approximately 16.17. Sensitivity analysis indicate that our model is especially sensitive to estimates of partial relief rates for non-candidal causes of vaginitis (as a result of using an anticandidal) and continued self-medication rates (with no relief of symptoms). Two-way sensitivity analyses highlight that there are significant interdependencies between the various probabilities of the model. Changes in the values of one probability (e.g. partial relief rate) have a significant impact on other one-way sensitivity analyses.

Our research highlights a number of gaps in our knowledge of anticandidal self-medication:

- How often do women experience partial relief with anticandidals for non-candidal causes of vaginitis?
- How often do women continue to self-medicate when they have experienced partial relief? No relief?
- How often do women with infectious (non-candidal) causes of vaginitis later experience **PID**?
- What is the rate of recurrent **PID**?

Chapter 6 presents data from state Medicaid plan coverage of **OTCs**. Medicaid is one of the only major insurers that covers at least some **OTCs**. This coverage, however, varies significantly from state to state. In this chapter, we provide descriptive data on the types and levels of OTC coverage provided by Medicaid plans in each state.. In addition, to explore whether coverage of specific **OTCs** (or lack of coverage) has clinical and cost implications for

state Medicaid plans, we compare utilization of “alternative” prescriptions (as described in Chapter 4) and overall cost per beneficiary for plans that do and do not cover specific **OTCs**.

The data presented in this chapter highlight a number of important trends in Medicaid coverage of **OTCs**:

- ❑ Medicaid coverage of **OTCs** varies significantly **from** state to state. In 1997, the number of **OTCs** covered ranged from 0 (Colorado, Nevada, and Oklahoma) to 408 (New York).
- ❑ The average level of (Medicaid) OTC expenditures per state in **1997** was \$296 million.
- ❑ OTC expenditures represent approximately 3 % of Medicaid pharmaceutical budgets.
- ❑ Medicaid OTC costs per beneficiary rose 38 % between 1994 and 1997, an increase slightly less than the increase in pharmaceutical costs per beneficiary (48 %) over that same time period.
- ❑ Expenditures on acetaminophen and aspirin make up a small but significant portion of total OTC expenditures for state Medicaid plans (5 % or **\$15.6** million in 1997).
- ❑ Medicaid expenditures on common **OTCs** (acetaminophen, aspirin, ibuprofen, and insulin) vary widely from state to state.
- o In general, Medicaid cost per beneficiary for OTC substitute drugs does not appear to differ significantly between states that do and do not cover OTC vaginal anticondicals.

Summary

A great deal of information is presented in this report to highlight the numerous research and policy issues associated with **the Rx-to-OTC** switch movement. A number of recurring themes present themselves:

The significant impact of the Rx-to-OTC switch movement: The market is large, the consumers are many, and the interests of various “players” are diverse.

The rapidly changing health care environment will present ongoing challenges to policymakers and researchers: The types of drugs being considered for OTC switch today would surprise many clinicians and policymakers 10 years ago. Consumers are demanding an increasingly active role in their own health care. The health care industry is constantly restructuring to more efficiently and effectively provide health care. All of these factors will mean that the appropriate decisions for OTC regulation today may not be the best decisions tomorrow.

How little we know: In the face of this important policy/research area, it is frightening to realize how little we really know. How do consumers make decisions to purchase OTCs versus seek professional care? How do clinicians treat patients in the presence of OTC products and (usually) lack of insurance coverage? What is the impact on health outcomes? Is it cost-effective for health plans to cover OTCs? How will decision-making change as more products become OTC? These are all questions that must be addressed with further research.

Chapter 1: Literature Review/Policy Synthesis

I. Overview

The purpose of this literature review and policy synthesis is to review the current literature, including academic as well as trade journals, to summarize these findings, and to identify key policy issues surrounding the Rx-to-OTC switch movement which should be considered by the appropriate federal agencies. Since publications and information discussing the switch movement and **related** issues are numerous and cover a somewhat diffuse topic, this review does not claim to be exhaustive. Instead, we have sought to obtain detailed information on the following (sub-) topics: description of the Rx-to-OTC trend (facts and figures), reasons for the switch movement, current FDA policy regarding switches and the history of this policy, groups affected by the switch movement (consumers, pharmaceutical companies, physicians, pharmacists, and payors), the impact of advertising on consumers, and specific Rx-to-OTC switch drugs which illustrate the issues associated with current switches. The paper concludes with a discussion of the potential policy issues raised by the Rx-to-OTC switch movement.

II. Description of Rx-to-OTC Trend

Americans suffer many minor ailments during the course of their lives. According to a study by Heller Research Group(1992), the average American reports having some sort of health complaint about once every three days. With this **volume** of complaints, it should not be surprising that many individuals are inclined to self-treat many of their ailments. OTC medications are an important tool for individuals seeking to self-treat and this trend is increasing: according to the 1992 Heller study, 38 % of ailments are treated with some sort of OTC medication', up **from** 35 % in 1983. This trend is expected to continue, especially as increasingly effective pharmaceuticals for widely-experienced ailments move from Rx to OTC.

¹Other treatments of health problems included: do nothing (30 %), treat with home remedy (16 %), **treat with** prescription medication already in the home (13 %) or seek professional advice (17 %) (Heller Group, 1992).

There are currently more than 100,000 OTC products available on the market in various dosages and strengths (Hesselgrave, 1997). All of these products, however, represent fewer than 1,000 active ingredients and many of these products have been available well before **OTCs** were distinguished from prescriptions (1951). Approximately 600 OTC products currently available use ingredients and dosages available only by prescription 20 years ago (Snyder, 1997). Table 1-1 contains a list of important switch drugs that have moved from **Rx** to OTC in the last 10 years. Of particular interest is the relative increase in switches during recent years: between 1988 and 1994 there were 14 switches, while in the last three years (not yet complete) there were 19 switches.

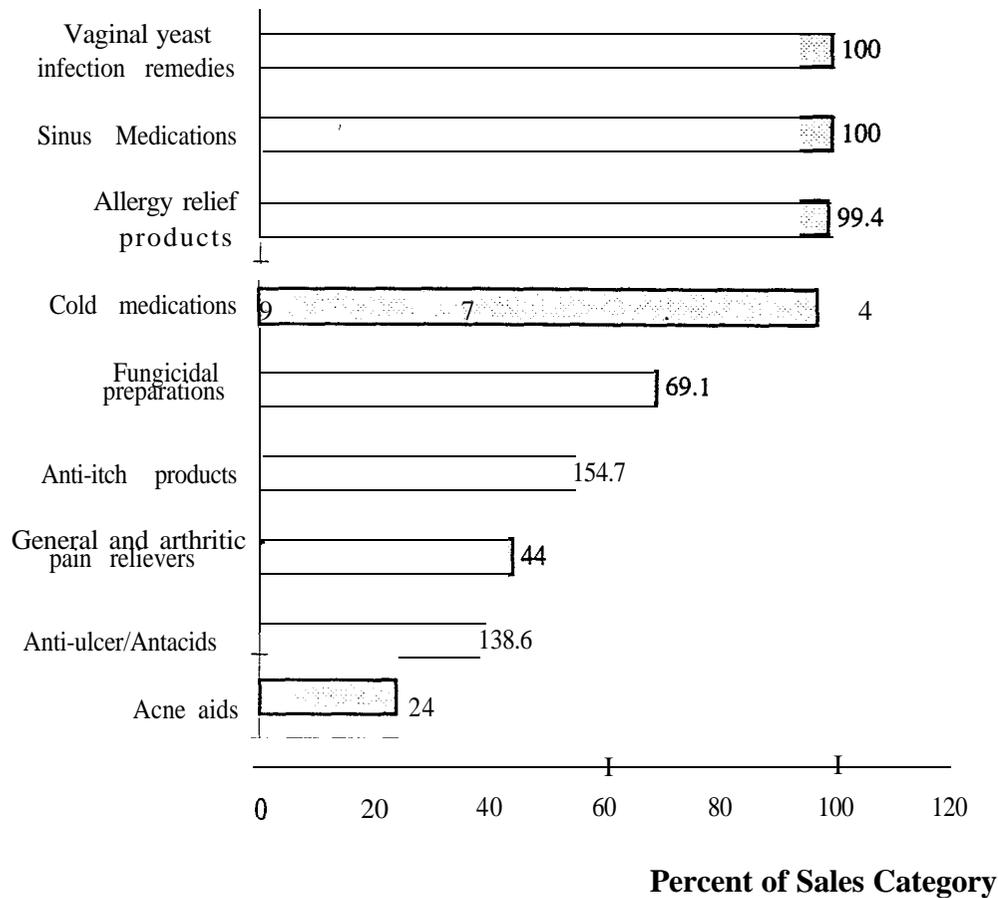
Table I-I. Important Rx-to-OTC Switches, 1988-1997 (October)

Year	Drug	Product Category	Brand Names
1988	Loperamide	antidiarrheal	Immodium A-D, Kaopectate II, Maalox
1989	Hydrogenated soybean oil and lecithin	cholecystokinetic	Lipospense
1989	Clotrimazole	antifungal	Lotrimin AF
1989/1990	Clotrimazole	anticandidal	Femcare, Gyne-Lotrimin, Mycelex-7
1990	Permethrin	pediculicide (head lice)	Nix
1991	Miconazole nitrate	anticandidal	Monistat-7
1991	Hydrocortisone	antipruritic (anti-itch)	Cortaid, Lanacort
1991	Hydrocortisone Acetate	antipruritic (anti-itch)	Bactine, Caldecort
1992	Clemastine fumarate	antihistamine	Antihist-1, Tavist-1
1992	Clemastine fumarate w/ phenylpropanolamine HCL	antihistamine/decongestant	Tavist-D
1992	Dexchlorpheniramine maleate	antihistamine	
1994	Naproxen sodium	analgesic/antipyretic	Aleve
1994	Antazoline phosphate	ophthalmic antihistamine/decongestant	Vasocon A
1994	Pheniramine maleate	ophthalmic antihistamine/decongestant	Naphcon A, Opcon A, Ocuhist
1995	Cimetidine	acid reducer (H2 blocker)	Tagamet H13
1995	Famotidine	acid reducer (H2 blocker)	Pepticid AC
1995	Ranitidine	acid reducer (H2 blocker)	Zantac 75
1995	Ibuprofen suspension	analgesic/antipyretic	Children's Motrin
1995	Ketoprofen	analgesic	Actron, Orudis KT
1995	Butoconazole nitrate	anticandidal	Femstat 3
1996	Minoxidil	hair grower	Rogaine
1996	Nicotine polacrilex	smoking cessation	Nicorette Gum
1996	Nizatidine	acid reducer (H2 blocker)	Axid AR
1996	Miconazole nitrate	anticandidal	Monistat-3
1996	Clotrimazole	anticandidal	Gyne-Lotrimin 3
1996	Nicotine transdermal system	smoking cessation	Nicoderm CQ
1996	Nicotine transdermal system	smoking cessation	Nicotrol
1996	Bentoquatam	poison ivy protection	Ivy Block
1997	Cromolyn sodium	allergy prevention & treatment	Nasalcrom
1997	Tioconazole	anticandidal	Vagistat- 1
1997	Loperamide/simethicone	antidiarrheal/antigas	Immodium Advanced
1997	Triclosan (dentifrice)	antigingivitis	Total
1997	Ketoconazole	1 % shampoo	Nizoral

Source: Non-Prescription Drug Manufacturers Association, 1997.

With the significant increase in the number of switches in recent years, switch drugs are playing an increasingly important role in the OTC market. As Figure I-1 illustrates, sales of Rx-to-OTC switch products comprise significant portions of many OTC categories.

Figure I-1. Percent of OTC Sales Categories Comprised of Switch Drugs



Source: Kline and Company, Inc., 1997

III. Forces Driving the Rx-to-OTC Switch Movement

There are a number of forces which are credited with driving the switch trend. We present some of the more popular and frequently discussed factors.

A. The Market Expansion Motive

Pharmaceutical companies have an opportunity to benefit greatly from an Rx-to-OTC switch, especially for drugs that are approaching the end of their normal patent life. Drugs which successfully switch from Rx to OTC may be afforded an extra three years on their patent life (Snyder, 1997; Karig et al., 1995). This extension protects the pharmaceutical company from competition for **another** three years and also allows it to establish the OTC brand name in the mind of the consumer. In many cases, the pharmaceutical company also enjoys a significant market expansion. One example of this is the case of topical hydrocortisone lotion (0.5 %). Topical hydrocortisone was introduced as an OTC at the end of 1979. Prescription sales of topical hydrocortisone actually increased during 1980 and 1981 relative to their 1979 levels (\$11 million in 1979, compared to \$14.3 and \$14.5 million in 1980 and 1981), while OTC sales soared (wholesale sales of \$29.4 million in 1980 and \$30.7 million in 1981) (Temin 1983). Monistat 7 became the top-selling vaginal antifungal within three months of going OTC in 1991 (Karig et al., 1995). According to one industry survey, 14 of the 23 drugs switched between 1975 and 1994 are now either first or second in their markets (Karig et al., 1995). Because most, if not all, recent Rx-to-OTC switches are the result of pharmaceutical company requests (through a New Drug Application (NDA) modification²), it is critically important to recognize the motivations of these companies in the switch movement. In other words, while precautions are taken to assure the appropriateness of switches, the motivation for switching most medications from prescription to OTC is market expansion.

B. Individual Autonomy and the Self-Help Movement

The United States was founded on the premise of individual rights to self-determination. This **commitment** to individualism was codified in the Constitution and is evident in many laws and regulations. Even when drafting the laws which established prescription drug status,

²The process by which drugs move from Rx to OTC will be discussed in greater length in subsequent sections.

legislators explicitly intended to protect the right of the consumer to self-medicate (GPO, 1983; Temin, 1980).

For many years consumers seemed content to consult physicians regarding their health and to comply with those recommendations without question. This model of patient care, however, is becoming increasingly unpopular (Beauchamp, 1990). “Consumerism”, as the trend is often referred to today, is increasingly popular. Many health care plans are establishing programs which “empower” patients to control their own health: through exercise, diet, and knowledge. And many patients are seeking that “power“. Prescription status of medications may limit the ability of consumers to choose, to exercise control over their health. The switch trend is just one of many trends in health care today which emphasizes the central role of the patient and affirms individual control over their own health and health care.

C. Deregulation Trends

During the post-World War II era, most Americans supported the view that the government had a strong responsibility ". . .to protect citizens in areas in which choices [were] technical or complicated or in which the citizen [was] unlikely to have full information.” (Rosenau, 1994). Government regulation has come to be viewed by many as “. . .intrusive, restrictive of free competition and innovation, causing higher taxes, higher prices, and lower overall welfare of the American public” (Fletcher, 1967). Enthusiasm for removing government regulation began in the Reagan years and continues today. Prescription-only status of many substances, along with the significant marketing and distribution restrictions that this status implies, can be viewed as highly regulatory. The switch movement, therefore, can be viewed as further evidence of our country’s desire for *laissez-faire*—a return to freer markets and less regulation.

D. Health Care Cost Containment

While the United States is at the forefront of medical technology development, it has paid a sizable price for its leading position. National health expenditures have topped \$950 billion per year and consume almost 14 % of our gross domestic product (GDP) (Department of Health and Human Services, 1996). Employers and the federal and state governments, the groups who foot the bill for most of our nation's health care, have been frantically searching for ways to stem the growth of health care expenditures. Cost containment efforts generally have two foci: control the cost of individual treatments and control the number or volume of treatments.

Switching drugs from prescription to OTC can potentially control costs in both areas: price reduction and volume control.

1. Price Reduction. It is possible that a switch from Rx to OTC can result in a reduction in the price of the product because competition may be enhanced and because a pharmacy dispensing fee is no longer included.
2. Volume Control. Generally, the consumption of switch drugs does not fall after the product moves from Rx to OTC. In fact, there is strong evidence that the market expands (Gossel, 1991). What does happen, however, is that insurance companies are usually no longer responsible for footing the bill for the medication, effectively lowering the volume of medical care for which they pay.³ OTCs are also found to reduce the volume of physician visits which were previously necessary to obtain a prescription. Finally, OTCs may also reduce the volume of future health services utilization to the extent that they assist in the prevention of diseases.

³Only about 13 % of HMOs surveyed by the HMO Prescription Drug Class Report in 1995 indicated that they cover "some" OTC medications (Hesselgrave, 1997). In general, plans which insure patients for medication only cover prescription drugs.

IV. Legislative History of Food and Drug Administration (FDA) Policy

Regarding Switch Drugs'

In the early 1900s there were two major pieces of federal legislation regarding drugs: the 1906 Food and Drugs Act and the 1938 Federal Food, Drug, and Cosmetic Act. Neither of these statutes contained any specific language regarding the dispensing of drugs. Following the 1938 Federal Food, Drug and Cosmetic Act, however, the FDA began to make public notices (known as “trade correspondences”) to the industry regarding the labeling and dispensing of drugs. It was through these public notices that the FDA produced the first distinction between prescription and OTC medications. Specifically, the agency required that all drug products on the market carry a label with adequate directions for use. An exemption from this requirement was available if the drug contained carried the “Caution Legend”: “Caution: To be used only by or on the prescription of a physician”. An additional requirement for exemption was that the labeling for the drug could not contain any directions which were “...likely to be understood by the ordinary individual.” (i.e. the directions should only be understood by the physician.)

At this point, which particular drugs would receive the “Caution” legend and which ones would not was at the discretion of the manufacturer. In 1944, the FDA sought to preclude the “Caution” legend from drugs that it considered a layman could safely use. An amendment to the 1938 Federal Food, Drug, and Cosmetic Act indicated that the “Caution” legend should be limited to products which “...because of their toxicity or other potentiality for harmful effect of their method of use or collateral measures necessary to their use are not generally recognized among experts as safe and efficacious for use except under the supervision of a physician.”

In 1951, the Durham-Humphrey Amendment set forth a more concrete statutory basis for distinguishing between prescription and OTC medications. Specifically, a medication must be classified as a prescription drug if it falls into one of the following three categories:

1. A “habit-forming” drug;
2. New drugs, which under their approved new drug application (NDA), have been restricted to use under the professional supervision of a physician.

3. Any drug which "...because of its toxicity or other potentiality for harmful effect of its method of use or collateral measures necessary to its use is not generally recognized among experts as safe and **efficacious** for use except under the supervision of a practitioner licensed by law to administer such a drug."

Up to this point, legislation was primarily concerned with the safety of OTC drugs. It was only in 1962, in the wake of the Thalidomide tragedy, that Congress passed the **Kefauver-Harris Amendments**, requiring that all drugs that entered the market after 1938, including OTCs, be tested for efficacy as well (**Bruch and Larson, 1989**). The actual review of all drug products did not begin **until** 1972 when the FDA set up a series of expert advisory committees, made up of external staff, to review medication ingredients. It was during these reviews that a significant number of OTC medications were actually withdrawn from the market or reformulated due to their lack of efficacy.

The FDA was free to accept or reject the recommendations of these advisory committees. Manufacturers who were very interested in the results of these reviews began to monitor advisory committee activities closely. In a few cases, these companies prematurely switched a drug from prescription to OTC based on advisory committee recommendations which were later not accepted by the FDA. In 1975, the FDA decided to formalize the process of Rx to OTC switches by establishing three methods for switching drugs:

1. An individually-initiated petition;
2. A supplement to a New Drug Application (NDA) submitted by the manufacturer;
or
3. An OTC review and Final Monograph issued by the FDA.

While many of the cold, cough, and allergy products available today were the result of OTC reviews during the 1970s, today most switches take place through the NDA process (i.e. initiated by the manufacturer). While no formal guidelines exist regarding which medications are suitable candidates for switch, FDA officials discuss the following areas of consideration:

1. Safety: acceptable safety margin and a proven track record;

2. Low potential for misuse and abuse;
3. Ability of the average consumer to self-diagnose, self-recognize, and self-treat the condition for which the medication is appropriate without the supervision of a physician; and
4. Labeling must be adequately understood by the average consumer.

More recently, the FDA has established a Nonprescription Drug Advisory Committee whose purpose is to provide independent, expert, and scientific advice to the agency. The committee, which first met in December of 1992, has 10 core members, including physicians, pharmacists and nurses with experience in the use of OTC products. The committee also includes a voting consumer representative and a non-voting industry liaison person. Supplemental members are added to the committee when appropriate to the drug under consideration (Rheinstein, 1997).

V. Groups Affected by the Rx-to-OTC Switch Movement

There are a number of relatively distinct groups who are affected by the Rx-to-OTC switch movement: consumers, pharmaceutical companies, physicians, pharmacists, and payors. The interests of each group are somewhat different, so we will discuss each group separately. Since consumers are, by far, the largest group with an interest in this movement and, arguably, the group most deserving of protection and benefit, we will discuss them first.

A. Consumers

Who uses OTCs? OTC use is very common. As discussed in the introduction, the 1992 Heller study found that Americans treat approximately 38 % of health problems with an OTC. Given the relative prevalence of health problems, this figure translates into use of OTCs approximately 2.3 times during a 2-week period. According to the study, teenagers were likely to use OTCs for health problems at about the average rate (male teens, 40 %; female teens, 38 %), while parents were more likely to use OTCs for children under 12 (46 % of illnesses), but also more likely to

consult a professional for young children (29 % of illnesses compared with 15 % of illnesses for adults). Elderly were less likely than other adults to use OTCs (28 % of illnesses) and more likely to contact a professional than younger adults (21 % vs. 12 %). No significant differences in OTC usage were found between men and women, education levels (high school or less vs. some college or more), or income levels (less than or greater than \$20,000).

Most studies of OTC usage focus on the more vulnerable members of the population: the elderly, children, and those suffering specific chronic illnesses. These groups warrant particular attention because they are also the most likely groups to suffer adverse consequences of OTC use.⁴

Although the Heller study found that the elderly were less likely to treat a particular health problem with an OTC, the incidence of ailments in the elderly far exceeds that of the general population, making overall use of OTCs greater. Seventy-eight percent of the elderly have at least one chronic disease, and 30 percent have three or more (Williams and Rush, 1986). Several researchers have found that use of both prescriptions and OTCs increases with age (Williams and Rush, 1986; Bush and Rabin 1976). Within the elderly, OTC medication use has been found to be associated with being female and having higher education. In addition, use of “symptom-relief” OTCs (e.g. laxatives and antacids) was positively associated with health services use, while use of “preventive” OTCs (e.g. vitamins and mineral supplements) was not related to physician, ER, or hospital visits (Stoehr et al., 1997).

Young children are also frequent OTC users. A national study of 8,145 children found that 53.7 % of 3-year-olds were given some OTC medication in a 30-day period. The most common medications reported were Tylenol (66.7 % of children receiving OTCs) and cough or cold medications (66.7 %). After adjusting for recent child illness, the researchers found that

⁴The costs associated with OTC use will be considered later in this section.

likelihood of OTC medication was associated with being white (odds ratio⁵ (OR): 1.32), having more education (OR: 1.58), and having higher incomes (OR: 1.75). In addition, lack of health insurance was positively related (OR: 1.27) and any provider visit in last 30 days was negatively related (OR: 0.74) to OTC medication usage. The authors conclude that OTC medications are an important component of health care for treating illnesses in US pre-school age children (Kogan et al., 1994).

Several British studies have also reviewed OTC use in older children and teenagers (Dengler and Roberts, 1996; Rylance et al., 1988). These studies found that analgesics/ anti-inflammatories were the most commonly purchased OTC medications for this age group. Young people with chronic illnesses or previous injuries were more likely to use both prescribed and OTC medications. In addition, teenage girls were the most likely group to have used OTC medications. Usage was not found to be associated with socio-economic status.

Use of OTCs by populations with chronic illnesses is an extremely important area of study because these populations are more likely to need the continued supervision of a physician to manage their condition. An Australian study of asthmatics using inhaled bronchodilators, which are available in Australia both as an OTC and by prescription, revealed that all of the patients in the study were under-treated for their condition, regardless of how they purchased their medication (Comino et al., 1995). While under-treatment of the OTC group might have been expected, under-treatment of the prescription group was not. The authors speculate that automatic refills on prescriptions reduce the need for asthmatics to see their physicians regularly, leading to under-treatment for this group as well. The authors also found that asthmatics who were diagnosed more than five years ago were more likely to obtain their bronchodilators as an OTC. This study highlights the issue of what types of medications should be available OTC: drugs for

⁵Odds ratios (ORs) can be interpreted as the increased or decreased probability of using an OTC medication. For example, an OR of 1.32 for white mothers indicates that, all other things being equal, a white mother is 1.32 times more likely to treat her child with an OTC than a non-white mother. Conversely, an OR of 0.74 for children with any provider visit in the last 30 days indicates that, all other things being equal, a child who has visited a provider in the last 30 days is only 0.74 times as likely to use an OTC (less likely) when compared with a child who had not visited a provider in the last 30 days.

the treatment of acute, self-limiting conditions vs. drugs for the treatment of more chronic diseases and symptoms which may be relatively well recognized by chronic sufferers. While the former category presents fewer risks to the population, the benefits of switching medications in the latter category has led to some recent switches (e.g. anticandidals, H2 blockers). A more complete discussion of this topic is contained in the final section of the paper: "Potential Policy Issues".

Benefits of Switching Drugs. There are numerous benefits to consumers from the switch of certain medications from prescription to OTC status. In many situations, the ability to obtain needed medications from the nearest retail drug store or grocery store rather than visiting first the physician and then the pharmacy represents a significant increase in convenience. In addition, OTC availability may result in significant cost savings. Theoretically, the competition fostered over time between competing OTC products can result in significant price reductions. Evidence in this area is somewhat mixed, especially for more recent switch medications, and the cost savings in this area remain an empirical question (Klein and Company, Inc., 1997). Savings from reduced physician office visits and work time lost, however, are relatively well-documented and represent a significant source of cost savings to consumers (Fireman, 1997; Temin 1980).

An additional benefit to consumers from the switch movement may be the additional empowerment that the OTC purchase opportunity provides. There is some evidence, especially in chronically-ill populations, that patients who feel that they have some control over their health are more likely to have healthier habits and comply with their physician's instructions (Rosenau, 1994). It is conceivable that the ability to self-medicate will empower consumers to "take control" of their own health rather than relinquish that **control** to a physician. This empowerment could result in health-seeking behaviors such as smoking cessation, appropriate dietary intake, and exercise.

Costs of Switching Drugs. The benefits to consumers from switching drugs from prescription to OTC must be weighed against the very real costs of the **switch(es)**. These costs include the costs of inappropriate self-medication, over- or under-medication, adverse reactions, failure to obtain appropriate medical attention, and, possibly, the increased costs of medication because the drug is no longer covered under a health insurance plan.

One of the critical FDA criteria for considering an Rx-to-OTC switch is the ability of the average consumer to self-diagnose, self-recognize, and self-treat the condition for which the medication is appropriate, without the supervision of a physician. Clearly this criterion does not require that **no consumer** make a “mistake” (inappropriately self-medicate or over/under medicate); it requires that the **average consumer** have the required abilities. This implies that there will be some “mistakes” made by consumers and these “mistakes” will have costs. For example, H2 blockers (especially Tagamet [cimetidine]) have some adverse drug interactions with beta blockers (beta blockers) and anticoagulants (Warfarin) which have led to warning labels (Gonzalez and Grillo, 1994). Some consumers may not read the warning labels or may not understand them. Others may take too much of the medication with adverse health effects. Still others may take too little of the medication, not obtain relief, and either suffer further or seek medical advice. These mistakes will have costs: additional health care costs, transportation to the physician costs, costs of work time lost as well as the non-economic costs of pain and suffering.

Another potential cost of OTCs is that the ability of a consumer to **obtain** an OTC may hinder that consumer from obtaining appropriate medical attention. For example, vaginal anticondoidal treatments such as **Monistat**, Gyne Lotrimin, and Vagistat contain specific instructions to the consumer that she should not use this product if she has not been previously diagnosed by a physician as having a yeast infection. The underlying premise for switching anticondoidals to OTC was that a reasonable consumer, once diagnosed by a physician as having a yeast infection, would recognize the symptoms of a yeast infection and be able to self-treat. It is, however, possible that some women do not obtain an initial diagnosis from a physician before

self-treating. In some of these cases, the woman in question may not have **candida** but, in fact, may be suffering from a more serious condition such as pelvic inflammatory disease (PID) or a sexually-transmitted disease (STD). The presence of an OTC medication may, therefore, delay appropriate treatment of a condition. This delay may have costs associated with it if more timely treatment results in better health outcomes. Women may also inappropriately diagnose themselves with a yeast infection when, in fact, they have a self-limiting condition which would have gone away without treatment. While the potential harm of the additional treatment is small, the costs of this unnecessary treatment can add up.

One final category of costs that consumers face is the potentially increased out-of-pocket costs of medication because the drug is no longer covered under a health insurance plan. Many health plans, especially managed care plans, cover a significant portion of the costs of prescriptions, usually only charging a small copay ranging from \$2 to \$10 or 20 % of the prescription price; OTCs, however, are generally not covered by health plans (Hesselgrave, 1997). **While** the average cost of an OTC medication is approximately \$5 (Nonprescription Drug Manufacturers Association [NDMA], 1997), more recent switch drugs are considerably more expensive. According to the NDMA, the average wholesale price (which is lower than the retail price) for a vaginal yeast infection treatment was \$13.17 in 1996. H2 blocker (Pepcid AC, Tagamet, Axid AR, Zantac) prices range from \$10 to \$15. To the extent that the presence of these new switch drugs increases the price of medications to the consumer (from their copay amount to the price of the OTC), additional costs are imposed on the consumer. It is also possible that this price increase leads the consumer not to purchase the medication. The failure to use the appropriate medication may lead to future costs such as further medical care and work time lost.

Underlying Premise: The Knowledgeable Consumer. Wrapped up in the discussion of the benefits and costs of Rx-to-OTC switches is the underlying assumption that the general public is relatively knowledgeable, willing and able to read instructions, and capable of weighing all the

costs and benefits associated with OTC use before making a decision to consume them.’ While a number of vocal proponents of this viewpoint insist that the population is extremely knowledgeable and that more than 95 % of consumers read OTC labels when they first purchase the medication (NDMA, 1996), it is arguable that some members of society are not as knowledgeable or as responsible about reading instructions. Of particular concern are the more vulnerable populations who may be unable to read or comprehend OTC labeling.

Elderly consumers are more likely to have difficulty reading the small print on OTC labels, more at risk for drug interactions given the higher number of prescription and non-prescription medications they are taking (Williams and Rush, 1986; Tamblyn, 1996), and more likely to overlook potentially harmful drug interactions because of cognitive impairment. The issue of label readability has been under consideration for a number of years at the FDA, resulting in some recently-proposed labeling guidelines.⁶ Because of the multiple medication problems prevalent in the elderly, several researchers suggest that physicians should always ask elderly patients about the prescription and OTC medications they are taking at each visit, in order to screen for possible drug interactions (Roe, 1984; Wallsten et al., 1995; Torrible and Hogan, 1997).

Adolescents may also constitute a vulnerable group. Huott and Storow (1997) demonstrate that adolescent possess poor knowledge of the lethal potential of OTCs. Many of the adolescents surveyed believed that OTCs were benign medications. For example, 37 % of the survey respondents indicated that they believed that acetaminophen was not lethal at any level of overdose. This type of misperception emphasizes the role of appropriate and repeated education on the use of OTCs.

⁶ These FDA guidelines call for a new OTC label format, including 1) uniform, standardized headings, subheadings, and standardized order of format; 2) simplified language for certain words or phrases (e.g. “throw away” instead of discard); 3) a new bulleted, easier-to-read format, including minimum type size and type style (FDA, 1997).

B. Pharmaceutical Companies

The impact of the Rx-to-OTC switch movement on pharmaceutical companies is almost entirely positive. This statement can be made with a great deal of certainty because these companies have been responsible for **initiating** almost every switch in the past 15 years. If the impact of these switches was not positive, one would not expect manufacturers to initiate them.

Switch drugs offer greater market opportunities to the manufacturers for a number of reasons:

- ◆ drugs which reach the end of their patent life usually experience a 25 • 40 % drop in sales as generics enter the market (Winters and Freeman; 1990). Moving these drugs to OTC offers protected market expansion opportunities;
- ◆ switch drugs often experience significantly expanded markets (see page 5 “The Market Expansion Motive”);
- ◆ switching bypasses the intermediary agents of the physician and pharmacist, removing the “detailing” costs associated with marketing prescription drugs. These detailing costs can exceed \$5,000 per physician per year for a single company (Rosenthal, 1991); and
- ◆ switching may eliminate some of the pricing constraints created by third-party reimbursement programs (Gonzalez and Grillo, 1994).

c . Physicians

Although the Rx-to-OTC switch movement clearly affects physicians throughout the United States, they have been remarkably silent on this issue. While the underlying reasons for this lack of response are somewhat controversial (see, for example, Rosenau, 1994), it cannot be disputed that the increasing presence of OTCs affects physicians both professionally and economically.

Professionally, physicians are faced with the challenge of treating patients who are likely to be self-treating with one or more OTC medications. As noted earlier, physicians need to more carefully question the patient regarding their medication use and consider the potential drug

interactions of prescribed and non-prescription medications. In addition, it is also possible that patients taking OTCs wish to take a larger role in their overall health and treatment decisions. This type of behavior presents a challenge to the physician who is usually pressed for time and not always in a position to explain or “defend” medical courses of action.

Economically, the switch movement has extremely significant implications for physicians. As pointed out in the previous section, the majority of OTC cost savings to consumers result from reduced physician office visits. To physicians paid on a capitated basis, reduced office visits means increased income. Capitated physicians are a small but growing proportion of all physicians (AMA, 1997). To the majority of physicians who are paid on a fee-for-service basis, however, reduced office visits means reduced income. The cost savings to consumers who no longer see their fee-for-service physician, therefore, do not represent a net cost saving to society but, rather, a transfer payment from physicians to consumers.⁷ The fact that there is no notable response from physicians is subject to a number of explanations:

- ◆ Physicians do not feel that it is professionally appropriate to oppose the switch movement solely on economic grounds (Rosenau, 1994);
- ◆ Because of excess demand for physician services, the “unused” services were consumed by patients who were previously unable to obtain needed care or were unable to obtain the care as quickly;
- ◆ Because physicians are able to control the demand facing them,⁸ they have simply filled the “unused” services by “inducing demand”; or
- ◆ The size of the switch movement has been too small to have a noticeable impact on the physician community.

Which, if any, of these explanations is supported by the empirical data may not be clear until the switch movement is older and more data are available.

⁷ Economists make a distinction between true cost savings, which are savings to all members of society, and transfer payments which are savings to one group (consumers) at the expense of another group (physicians).

⁸ A number of researchers have suggested that physicians are able to induce demand for office visits by requiring that patients come back for follow-up visits, recommending further procedures, etc (Evans, 1974; Fuchs, 1978)

D. Pharmacists

The overall impact of the Rx-to-OTC switch movement on pharmacists is unclear. While there is strong potential for the switch movement to enhance the professional role of the pharmacist, there are also potentially negative economic implications as well. Pharmacists generally support the switch movement today, although they are often strong proponents of an alternative system of classifying drugs: prescription, OTC, and pharmacy-only. The third class of drugs, pharmacy-only, would be medications controlled by the pharmacist. Consumers would not be required to have a prescription to obtain the medication; however, they would be required to ask for the drug from the pharmacist and listen to any instructions the pharmacist may have. This alternative system for handling medications has been instituted in a number of countries (e.g. Great Britain, Canada) but has not met with considerable enthusiasm in the United States (outside of the pharmacy associations).

The Rx-to-OTC switch movement could benefit the pharmacy profession by placing pharmacists in a position of providing more advice and counseling. Pharmacists are highly trained individuals who spend a great deal of their time conducting tasks that do not require such high-level training. The presence of more effective (but also more risky) OTC medications allows pharmacists to assume a greater role in the treatment of patients by counseling them regarding choice of OTC as well as the appropriateness of seeking further medical attention. Pharmacists receive specific training in counseling patients about OTCs and typically recommend about 25 OTC products per day (Sierralta and Scott, 1995; Medical Economics, 1994). In theory, the expanded role of pharmacists could help ameliorate potential problems of less-informed or attentive consumers and even assist consumers in self-diagnosis. In reality, many pharmacists feel overburdened already in their position “behind the counter” and some are not sure how they will be able to spend considerably more time advising customers (Lavery and White, 1983). In addition, OTC products are also available in retail grocery and “mega” stores which do not contain pharmacies, preventing consumers from obtaining pharmacist advice. To

the extent that sale of OTCs through retail stores replaces previous prescription sales, pharmacies may also stand to lose economically from the switch movement.

E. Payors

The impact of the Rx-to-OTC switch movement on payors is also a complex interaction of benefits and costs, potential benefits and potential costs. Areas of impact include:

- 1) *Cost savings from medications that are no longer covered.* A one-year study of the Fallon Community Health Plan experience following the switch of vaginal antifungal products revealed system savings of \$42,528 in medication costs as well as savings of between \$12,768 and \$25,729 due to reduced physician office visits for a population of approximately 58,500 enrollees (Gurwitz, McLaughlin, and Fish, 1995);
- 2) *Potential cost savings from physician office visits which no longer occur.* For insurers who pay their physicians on a fee-for-service basis, OTC switches will result in cost savings due to a reduced volume of office visits. For insurers who pay their physicians on a capitated basis, the savings due to reduced volume will only be realized by the physicians.
- 3) *Additional costs due to misuse of OTC medications.* An 1983 revealed that at least seven percent of all hospital admissions are the result of misuse of pharmaceuticals (Luce 1988). With more of these pharmaceuticals moving to OTC and consumers given more latitude to self-medicate, it is conceivable that payors face significant medical bills associated with OTC misuse;
- 4) *Potential costs due to delayed treatment.* As discussed earlier, to the extent that OTC use prevents or delays the consumer from seeking appropriate medical attention, additional medical costs may be generated;
- 5) *Potential costs from use of more expensive prescription alternatives.* Even when a class of medications moves OTC, there are often close substitutes still available by prescription. For example, when miconazole went OTC, some physicians began to prescribe terconazole, a

more-costly, wider-spectrum antifungal, available only by prescription (Gurwitz, McLaughlin, and Fish, 1995); and

- 6) *Potential benefits from a more empowered patient base.* As discussed earlier, patients who are given more control over their treatment decisions through the use of **OTCs** may also exert more control over other aspects of their health, leading to a healthier (less-costly) lifestyle.

It should be noted here that in an insurance market where profits are driven down by competition the cost savings realized by insurers are eventually passed on to consumers in the form of lower premiums.

VI. Impact of OTC Advertising on Consumers

OTCs, especially the new switch drugs, are heavily promoted in both the television and print media. One recent study of 11 popular consumer magazines found that 7.5 % of all advertisements were for OTCs (Wofford et al., 1995). Historically, manufacturers have spent over 10 % of OTC sales on advertising expenses, although with the more recent switches that ratio may be higher (Donegan et al., 1979). Clearly manufacturers believe that advertising is an important tool in educating the consumer and promoting their products.

The impact of OTC advertising on consumption, however, is not well-documented and is deserving of further empirical scrutiny. The overall impact of pharmaceutical promotion expenditures on the size of the market and on market shares has been found to be relatively small (Montgomery and Silk, 1972; Parsons and Abeele, 1981) or non-existent (Mackowiak and Gagnon, 1985). Since most of the **advertising** considered in these analyses was directed to physicians, it is not clear what the implications of this literature are for the OTC market. What does appear clear is that traditional pharmaceutical advertising is extremely expensive (estimated detailing costs of \$5,000 per physician per year (Rosenthal, 1991)) and not overly effective. The ability to advertise directly to the consumer (for both OTCs and prescription-only medications) appears far less costly and more effective. This seems to be the opinion of manufacturers: in 1996, for the first time ever, the amount spent on direct-to-consumer (DTC) advertising exceeded

the amount spent on direct-to-physician advertising (“Special Feature”, 1996). There is limited evidence that consumers are responding to the growing DTC advertisements. Lipsky and Taylor (1997) found that 95 % of the physicians surveyed reported patients requesting specific prescriptions as a result of DTC advertisements. Hodnett (1995) found that prescription drug sales increased when the product(s) were advertised directly to the consumer.

VII. Recent Rx-to-OTC Switch Drugs

The preceding sections provided an overview of OTCs in general, providing information on the size of the market, the role of the FDA, the impact of OTCs on various groups, and the impact of advertising on OTC consumption. We have attempted to indicate the important role that switch drugs play in the OTC market. What may not yet be clear, however, is how different some of the new switch drugs are from earlier OTCs and the unique policy considerations that these drugs create. This section will provide specific data on two types of recent switch drugs: vaginal antifungal treatments and H2 blockers.

A. Vaginal Antifungal Treatments

Seventy-five percent of all women will get at least one vaginal fungal infection at some point in their lives, and millions will experience recurrent relapses (Covington, 1996). Since 1990, various anticandidal medications (Femcare, Gyne-Lotrimin, Mycelex-7, Monistat-7 (since 1991)) have been available over-the-counter to treat these infections. While labeling and informational package inserts contain specific instructions to obtain a diagnosis from a physician before using this medication for the first time, it is not clear that all women are following these instructions; consequently, it is possible that the presence of these antifungals as OTCs may prevent some women from obtaining timely care for more serious conditions with similar symptoms, such as pelvic inflammatory disease and sexually transmitted diseases (STDs). Thus, vaginal antifungal treatments illustrate an important tradeoff that often exists with newer switch drugs: benefits to the knowledgeable consumer versus costs to the less knowledgeable or less

careful consumer. A more sophisticated and knowledgeable consumer should be able to follow instructions (see a doctor for an initial diagnosis, do not use if specific contraindications exist) and benefit from the availability of the OTC medication (no cost of physician office visit, no work time lost), but a less knowledgeable or careful consumer may use the OTC medication inappropriately and suffer consequences.

More recently, alternative formulations of vaginal antifungals have become available in the form of three-day treatments (Femstat-3 in 1995; Monistat-3 and Gyne-Lotrimin-3 in 1996) and a one-day treatment (Vagistat-1 in 1997). These formulations may make self-treatment even more attractive because of added convenience. The vaginal antifungal market continues to grow with the introduction of new products. Sales of these remedies increased 12.1 % in 1996 to \$158 million (wholesale)⁹ (Kline and Company, 1996).

Estimates of the number of women who suffer from yeast infections vary considerably, with a range from 12.5 million (based on sales data) to 26.7 million (based on consumer survey (Kline and Company, 1995, 1997)). The consumer research also indicates that 52.6 % of women with a vaginal yeast infection self-treat with some sort of OTC remedy. Another 40.8 % of these women see a physician, and 10.4 % take some other action (ignore symptoms, use prescription product already in the home, or use home remedy).

With health plans and insurance companies financially responsible for a significant portion of physician office visits and prescriptions, the availability of OTC antifungal products may represent significant cost savings to them. Table 1-2 provides a rough estimate of the gross savings to payors from the OTC switch of vaginal antifungal products.

⁹Retail sales were estimated to be \$263 million in 1996.

Table 1-2. Gross Savings to Payers from OTC Switch of Vaginal Antifungal Products

Item	Source	Amount
Step 1: Calculate the the number of physician office visits saved because of the OTC switch (estimate using # of insured women who are self-treating instead of seeing physician)		
Number of women self-treating instead of going to physician	Kline & Co (1995), Kline & Co (1997)	12.5 • 26.7 million women
<i>Multiply by:</i> % of women insured	HIAA (1994)	87 %
<i>Equals:</i> # of office visits saved		10.875 • 23.229 million
Step 2: Calculate the savings from one office visit avoided		
Cost of physician office visit	HIAA (1994)	\$61
<i>Less:</i> Average co-pay (including enrollees who have not met their deductible)	Kline & Co (1997)	\$17.24
<i>Equals:</i> Estimated savings per office visit (avoided) [\$/visit]		\$43.76
Step 3: Calculate the number of prescriptions saved because of the OTC switch		
Estimated Rx rate (per office visit)	Kline & Co (1997)	80 % of office visits
# Rx saved because women don't see doctor		8.7 • 18.58 million prescriptions
Step 4: Calculate the savings from one prescription avoided		
Cost of Rx	Redbook AWP (1996)	\$24.49
<i>Less:</i> Average co-pay	HMO-PPO Digest 1996	\$6.33
<i>Equals:</i> Estimated savings per Rx (avoided) [\$/Rx]		\$18.16
Step 5: Calculate gross savings		
Gross Savings = # of office visits saved X \$/visit + #Rx saved X \$/Rx	min = 10.875 million X \$43.76 + 8.7 million X \$18.16 max = 23.229 million X \$43.76 + 18.58 million X \$18.16	\$634 million to \$1.46 billion

Chapter 1

While the range of savings is considerable, even at the low end of the estimate, the gross savings

to payors from the OTC switch

appears to be no consistent study of the costs of the switch to payors, although these costs are

certainly

non-negligible.

Treatments of

payors and consumers.

In

addition, some p

OTC vaginal treatment may reduce the rates of annual pap smears and pelvic exams, since

women are not as motivated to be in contact with their physician. The cost of delayed detection

of cervical cancer may also prove sizeable.

of H2 blockers, however, has been estimated to be minimal (Oster et al., 1990; Andersen and Shou, 1991).

Since 1995, a number of H2 blockers have been available OTC: Tagamet HB (Cimetidine), Pepcid AC (Famotidine), and Zantac 75 (Ranitidine) were approved in 1995, while Axid AR (Nizatidine) was approved in 1996. Each medication reduces acid production in the stomach and some have been approved for prevention of stomach acid production before meals. The entire market for antacids (including both traditional antacids and acid blockers) was \$1.1 billion in 1996, representing the third largest OTC sales category in that year.¹⁰ Sales in 1996 rose 26 % from their 1995 level, due almost exclusively to the introduction of H2 blockers.

Kalish et al. (1997) take a very detailed look at the costs and benefits of moving H2 blockers from prescription to OTC, considering the types of conditions which may exhibit dyspeptic symptoms, the efficacy of various prescription and OTC medications in relieving dyspeptic symptoms, the potential side effects of H2 blocker therapy, and the costs associated with various types of medical treatment. The authors conclude that health care costs associated with the **initial** treatment of dyspepsia (heartburn) are similar regardless of the availability of H2 blockers as OTCs. The reasons for their (somewhat) surprising findings is that

- 1) traditional antacids and H2 blockers have similar efficacy in relieving dyspeptic symptoms (although for potentially differing lengths of time);
- 2) physicians surveyed indicated that, despite the relatively similar efficacy of the two medications, they would be more likely to order more aggressive medical workups for patients who did not experience symptom relief with H2 blockers than if the patient had only failed to obtain relief through use of traditional antacids; and
- 3) the data seem to indicate that most users of OTC H2 blockers are former antacid users rather than people who would have sought the care of a physician. Thus, there are fewer cost savings to be derived from avoided office visits.

¹⁰Retail sales of antacids estimated to be \$1.54 billion.

VIII. Potential Policy Issues

A. Are the right drugs getting switched for the right reasons?

The majority of OTC medications can be used for the treatment of acute, self-limiting conditions. The use or misuse of these products poses few risks for the general population. More recently, however, entirely new classes of drugs have found their way to OTC: anticandidals and H2 blockers. Current switch candidates include Claritin and **Flonase**, medications for the treatment of chronic allergic rhinitis. How far should this trend go? How “self-limiting” do diseases need to be for associated medications to go OTC?

Almost all of the recent switch drugs which are currently on the market had their switch initiated by the manufacturer producing the product. While the rigorous review afforded these products prior to approval by the FDA appears to have prevented any hasty decisions or inappropriate switches, it is conceivable that this process may overlook other switch candidates. There **is** a process in place by which ingredients are regularly reviewed by the **FDA** for potential switching. The problem is that this “separate” process may not be “equal”. One alternative may be to devise a mechanism by which consumer groups or medical professionals may play a more active role in the switch initiation process. Drugs may be selected by a manufacturer on the basis of their ability to generate consumer demand from marketing, whether needed or not; other factors such as net savings to consumers or the potential to avoid unnecessary office visits should also be a source of switches. Perhaps the first three criteria for Rx-to-OTC switches (listed on page 10) should be the basis for a large scale review by the FDA, with consumer, physician, and, perhaps, payor input.

B. What types of post-marketing surveillance should be conducted?

While relatively rigorous review is required for products to be approved for OTC marketing, the post-marketing surveillance (PMS) of these products may be less comprehensive than necessary as more complex drugs go OTC and the potential for drug interactions increases. While PMS is limited for prescription drugs, at least the physician-based incident reporting

system provides some feedback to the FDA on possible unanticipated side effects. No such system is in place once the drug is OTC. Is the current system in place sufficient to protect consumers and ensure that they receive the benefits of the OTC product originally envisioned in the switch process? For prescription drugs, phase IV trials are often conducted in order to determine the efficacy of the drug in “normal” clinical practice, as opposed to the more sterile academic setting which usually characterizes phase III trials. It is also possible that the experience of consumers with OTC products may be quite different from that which was originally predicted, especially if data from other countries where the drug has already switched are not available to inform the US switch process.

C. Advertising and OTCs

Promotion of drugs, both OTC and prescription, has changed dramatically over the last decade. As late as the 1980s, advertising was relatively simple, using traditional print media and occasionally television; therefore, regulation was also relatively uncomplicated (Pines, 1996). As communication possibilities have expanded through video tapes, direct-to-consumer advertising (for prescriptions), the internet, and a host of other media and as the complexity of medications which have switched to OTC require presentation of important contraindications, risks; and side effects, a “myriad” of FDA policies have been developed (Pines, 1996). The challenge of a rapidly changing environment for the FDA and the FTC is to permit “...full and open scientific exchange”, as well as the transmission of useful information to consumers, without allowing premature and/or misleading statements.

D. Insurance coverage and price distortions

As an increasingly effective and broad range of medications moves from prescription to OTC, the issue of lack of insurance coverage for OTCs will take on increasing importance. At this point, very few commercial payors cover any OTCs. Medicaid coverage of OTCs varies significantly across states. While switching drugs from Rx to OTC may appear to be a financial

windfall for payors at this point, it is possible that the long term effects of these switches may not be so rosy. Lack of OTC coverage may cause physicians to prescribe more expensive prescription “substitutes” which may be less appropriate to the condition. If lack of insurance coverage for OTCs results in a failure on the part of some consumers to treat certain conditions, symptoms may become more severe resulting in costly emergency room or hospital visits. It is also possible that more serious and costly conditions would develop.

Even if cost savings to payors are passed on to consumers through lower premium rates, a serious price distortion is created between prescription and OTC drugs. Prescriptions are available at a low fixed price (equal to the individual’s copay), while OTCs are priced at the market level, which may be higher. Financial incentives will cause an individual to select one medication (the prescription) over another (the OTC) based solely on the out-of-pocket price, not on the clinical efficacy of the drug nor on the real price of the medication.

At a minimum, OTC coverage is a policy issue to be given serious consideration by Medicaid plans. To the extent that lack of OTC coverage affects the health and welfare of the general public, however, the importance of OTCs as a tool in maintaining and improving the overall health of the public needs to be stressed to the rest of the payor community. This awareness may be facilitated through studies of the effects of insurance coverage on OTC use and health outcomes.

E. How is consumer sophistication/knowledge to be gauged/measured?

An underlying premise to the OTC switch movement is that patients are more knowledgeable than they once were and that they are able to read, comprehend, and comply with instructions on the labels of current OTCs. There is, however, far more assertion than hard fact supporting this underlying premise. A few studies, mostly funded by the Nonprescription Drug Manufacturer’s Association (NDMA), have shown that over 90 % of consumers read OTC labels before using the product (NDMA, 1996). How much of the OTC labeling information is comprehended, how often consumers misuse OTC products, and which particular products are

particularly prone to misuse does not appear to have been empirically investigated. Are consumers becoming “medicalized”? That is, are consumers treating every symptom with an OTC simply because one is now available? This lack of information is especially troublesome in light of an apparent faith in the *growing* knowledge of consumers and the increasing numbers of switch drugs.

F. How can vulnerable populations best be protected?

Even if it can be established that the average consumer is capable of reading, comprehending, and complying with OTC labeling, it is possible that certain vulnerable populations (e.g. the elderly, teenagers, non-English speakers) do not have the capabilities of an “average” consumer. The FDA has already taken steps to ensure that OTC labels are of uniform presentation and reasonable font size. Other protections may be necessary, however. The special needs of certain populations should be empirically investigated and appropriate policies developed. Campaigns which increase the awareness of physicians of potential interactions of OTCs and prescriptions in their patients may save the life of an elderly person. Foreign language inserts may be a practical solution in geographic areas with significant non-English-speaking populations. OTC education campaigns in high schools or age restrictions on OTC purchasing may protect teenagers who might otherwise recklessly disregard instructions and warnings.

G. How can we get better data on OTC use?

When it comes to answering questions on prescription drug usage, researchers are able to conduct extremely detailed analysis of the use of individual drugs, by disaggregated market areas. These analyses can be conducted because there is a lot of data. There is a lot of data on prescription use because payors pay for prescriptions and keep detailed claims databases. This, unfortunately, is not the case for OTCs. Medicaid plans are one of the only set of payors collecting data on OTC utilization, and that is only for the OTCs they cover. Until OTCs are regularly covered by health plans, claims data will not provide us with a comprehensive look at

Chapter 1

OTC usage combined with other prescription consumption and health services utilization.

need better data.

One suggestion for getting better OTC data was made by a Walgreen's employee.

people up to voluntarily register all of their OTC purchases

benefit to the

consumer

is that the pharmacists can

interactions and provide advice on purchases. The benefit to the pharmacy is that they now have

one of the only contemporaneous databases on combined OTC and pharmacy utilization which

can theoretically be merged with

X. Bibliography

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develop research questions. The results of the key informant interviews are presented in this document. The final portion of this study will involve limited data analyses of select data sets to focus on key issues such as the cost-effectiveness of particular OTC switch drugs and the impact of insurance on OTC demand, given the constraints of available data sources.

This research is intended to be exploratory--each of the tasks informs and refines the next step and builds on the former step. Accordingly, the approaches taken are investigative rather than prescriptive. It is hoped that the documents produced from this study will inform policymakers and researchers and provoke thought and discussion and provide direction for further research.

II. Brief Summary of Literature Survey Results

In an earlier report, we presented a relatively exhaustive review of the literature related to the Rx-to-OTC switch movement (Waters et al., 1998). We will only briefly summarize those results here to support the rationale for questions directed to the key informants.

Our literature review identified four major forces that are driving the switch movement. The first of these forces is profit-seeking motive on the part of pharmaceutical firms. Since virtually all recent Rx-to-OTC switches have been initiated by pharmaceutical companies (through a New Drug Application [NDA] modification), the motivation of these companies is a critical factor in understanding the switch movement. OTC switch drugs provide a new market for an old product, especially for drugs that are approaching the end of their patent life.

A second driving force identified in the literature is the move toward individual autonomy and the “Self Help” movement. Patients no longer seem content to consult physicians regarding their health and to comply with these recommendations without questions. Patients are becoming more informed health care consumers and playing an active role in maintaining their health.

The trend toward deregulation in the United States also drives the switch trend. The prescription-only status of many products, along with the significant marketing and distribution restrictions that this status implies, can be viewed as highly regulatory. Since the federal legislation that established prescription-only status specifically states that any substance that can be OTC must be OTC, safe and effective drugs that have a demonstrated track record are now actively sought as switch candidates.

Finally, the literature also suggests that health care cost containment efforts may be playing a role in the switch movement. Health care cost containment efforts focus on two areas when seeking to reduce costs: price reductions and volume reductions. The OTC switch movement can potentially supply both types of reductions. OTC drugs are more likely to engage in significant price competition, lowering prices. In addition, the presence of OTC drugs may decrease the number of physician office visits used by patients, since they no longer need a (physician’s) prescription to obtain the drug.

The literature review highlighted five distinct groups that are affected by the OTC switch movement: consumers, pharmaceutical companies, physicians, pharmacists, and payers. Each group has the potential to be a “winner” or a “loser” from increased switching of prescriptions to

OTCs. Consumer concerns are perhaps of the greatest policy concern, since this **is**, by far, the biggest group, and, arguably, the group most deserving of protection and benefit.

Seven potential policy issues were identified as a result of the literature review. They were (in no particular order of priority):

1. Are the right drugs getting switched for the right reasons?
2. What types of post-marketing surveillance should be conducted?
3. Does advertising OTC products provide useful information to consumers, and is this advertising being appropriately regulated and monitored?
4. Does the general lack of insurance coverage for OTCs present a serious access issue?
Are serious price distortions being created by the price of OTCs (which may cost up to \$20 or more) relative to the fixed, low out-of-pocket price to consumers of (insurance-covered) prescriptions?
5. Are consumers more sophisticated today than they were 10 or 20 years ago? How can we measure relevant consumer sophistication?
6. How can vulnerable populations best be protected?
7. How can we get better data on OTC use?

III. Key Informant Interview Methods

Selection of Key Informants

Potential key informant names were solicited from the research group (Drs. Waters, Lipsky, and LoSasso; Northwestern University), the project officer (Burke Fishburne) and the Research Advisory Group. A conference call meeting was then used as the forum to determine the final

list of nine (9) persons to be contacted. Candidates were selected to optimize representativeness of key stakeholder groups: consumers, pharmaceutical companies, physicians, pharmacists, payers, and policymakers.

Contact of Key Informants

Potential key informants were contacted by telephone to solicit their participation. Individuals who consented to participate were faxed or **emailed** a brief description of the project as well as the list of questions to be covered. A mutually agreeable time for a telephone interview was determined after the participant had a chance to review these materials and his/her calendar.

Interviews lasted approximately one hour and were conducted by telephone by either Dr. Waters or Dr. Lipsky.

Content of Key Informant Interviews

A semi-structured interview instrument was developed by the Northwestern University researchers and approved by the Research Advisory Group and the Project Officer (see Appendix A). The interview instrument contained 21 questions covering three principal areas related to the Rx-to-OTC switch movement: understanding the trend, understanding the process, and policy issues. Respondents were encouraged to provide both opinion and evidence in response to questions.

Key Informants

Seven of the nine individuals contacted agreed to participate in the key informant survey. Table 2-1 lists the key informants and their current positions.

Table 2-1. Key Informants

Key Informant	Position	Stakeholder Group
Betty Chewning, Ph.D.	Assistant Professor, University of Wisconsin School of Pharmacy	Pharmacy, Policymakers
Linda Golodner	President, National Consumers League	Consumers
David Gross, Ph.D.	Senior Policy Advisor, American Association of Retired Persons (AARP)	Consumers Policymakers
Lou Morris, Ph.D.	Senior Vice President Publishing, Research, and Representation, Inc. Huntington, NY	Policymakers
Robert Rapp, Pharm.D.	Professor and Chair, Department of Pharmacy Practice and Science, Professor, Department of Surgery, And Associate Director, Department of Pharmacy, University Hospital Medical Center, University of Kentucky Author, <i>The Pill Book Guide to Over-The-Counter Medications</i>	Pharmacy, Physicians
R. William Soller, Ph.D.	Senior Vice President, and Director of Science & Technology, Nonprescription Drug Manufacturers' Association (NDMA)	Pharmaceutical Companies
Peter Temin, Ph.D.	Elisha Gray II Professor of Economics, Department of Economics, Massachusetts Institute of Technology (MIT)	Policymakers, Payers

IV. Key Informant Interview Results

Understanding the Trend

Six principal drivers of the OTC switch movement were noted by key informants. Three of these drivers were factors also noted in the literature review. These include:

1. *Empowerment of Consumers.* In general, consumers are believed to be more knowledgeable today, and they desire to exert more control over their own health care.

- In addition, consumers are thought to have greater familiarity with the drugs that are moving OTC, and, therefore, more specific knowledge of how to appropriately **self-medicate**.
2. *Profit Motive*. Pharmaceutical companies seek to switch drugs from prescription-only to OTC primarily because it is profitable. Many drugs that are identified for switching are reaching the end of their patent life. Switching to OTC has the potential to lengthen that patent life up to an additional three years, protecting the product from generic brand competition. Switching a drug to OTC also provides new markets that are not totally controlled by payers and physicians. Many OTC switches result in the drug being used for new purposes, also expanding the market (e.g. H2 Blockers being used for heartburn, instead of ulcer treatment).
 3. *Health Care Cost Containment Efforts*. Payers tend to support Rx-to-OTC switches. This is especially true for payers operating in a competitive managed care (**capitated**) environment. The presence of safe and effective OTCs not only reduces the number of prescriptions for which the health plan is responsible (if pharmacy **benefits** are covered), but it also reduces the desire/need on the part of patients to visit their physician. The switch of relatively expensive OTCs, however, may have a cost-increasing result, if physicians end up prescribe a more expensive prescription drug because it is covered by insurance. While there is some anecdotal information that this may be happening, a more formal study is necessary to document the extent of this practice.

Three additional factors that may be driving the switch movement were noted by the key informants:

1. *Length **of** Time Particular Drugs Have Been in the **Rx** Arena.* Time and volume of use are critical components in the identification of rare side effects and in the development of familiarity of use. Part of the reason the switch movement may have escalated recently may be that there are simply more potential candidates (drugs) that have a long history of safety, efficacy, and high volume use.
2. *The Rx Halo **of** OTC Switch Drugs.* One of the reasons that recent switches have been so popular may be that these drugs are seen as more effective than other **OTCs**. If the public perceives that prescriptions, as a group, are more powerful and effective than **OTCs** as a group, the fact that a drug has recently switched from being a prescription to being an **OTC** may enhance its perceived power and effectiveness.
3. *Electronic Media Stimulate Consumer Demand.* The amount of information and the relatively detailed quality of the information to which consumers are exposed are increasing with every passing year. Television and internet provision of information on **OTCs** is no exception to this trend. Since consumers are constantly exposed to increasing levels of information on **OTCs**, it is understandable that demand for **OTCs** is increasing. The resulting profitability of switch drugs, in turn, stimulates pharmaceutical firms to pursue additional switches.

When asked whether the appropriate number of drugs were being switched to **OTC**, key informant responses were mixed. Several of the respondents felt that about the right number of drugs had been switched. These individuals noted that the **FDA** process was relatively rigorous and a great deal of science was used to evaluate safety and efficacy profiles. “The obvious switches have been made,” remarked one pharmacist. “The next switches will be more difficult

and require significant caution.” This caution was echoed by the majority of respondents, citing a need for thorough review of switch candidates and for more studies on consumer **decision-making**. Two informants felt that there were several **switch** candidates that were not being considered seriously enough by the FDA (e.g. Statens). One respondent believed that while the decision to switch drugs to OTC should be based on scientific exchange, communication between manufacturers and the FDA often dissolves into little more than “. . .**discussions** and arguments.”

Understanding the Process

In general, respondents felt that the FDA process used for reviewing potential switch drugs was adequate. As several noted, the FDA is mainly concerned about safety and efficacy. A large number of switches have been made to provide consumers with easy access to effective medications. With the exception of metaproterenol (a bronchodilator for the treatment of asthma), no drugs that have switched to OTC have been switched back to prescription-only status, a sign that, for the most part, this volume of switching has not harmed **public** health safety. Suggestions for improving the process included:

1. *Strategic Thinking on the Subject of “OTC-ness”*. Currently, OTC applications are considered on a case-by-case basis, making it very difficult for the FDA and the public to have a good sense of what would be a good OTC switch candidate. Emphasis on some “intellectual scaffolding” might improve the switch process and provide a basis for proposing future switches.
2. *Speeding up the Process*. While the number of OTC switches has escalated in recent years, several respondents felt that the length of time necessary to process an OTC

application (usually an amendment to an NDA) was overly burdensome. This time lag may deprive consumers of easy access to safe and effective drugs that are appropriate for self-medication.

Types of Drugs Appropriate for OTC Switch. Interviewees were asked to **comment** on the types of drugs that should be candidates for switch to OTC. Several general criteria were noted:

1. Drugs which have a long and strong safety profile;
2. Drugs for common ailments;
3. Drugs for conditions that are easy to self-diagnose; and
4. Drugs which, if switched, would drive down the price of health care without significantly compromising that care.

Several respondents also discussed specific drugs or classes of drugs that they felt were candidates for switch:

1. Statins for hypercholesterolemia (lipid lowering); --
2. Alprosidil for impotence;
3. Beta agonists for asthma;
4. Antifungals for acne and toenail fungus;
5. Acyclovir for cold sores; and
6. Additional pain medications.

Timing of OTC Switch. Key informants indicated that they felt that the timing of an OTC switch was a function of both the properties of the drug being considered for switch and the

ability of the consumer to appropriately use that drug. At a minimum, a medication must have a well-established track record as a safe and effective drug and the candidate must be useful for common ailments. Time on the market and volume of use are also important elements needed to identify rare side effects. But the potential consumers of that drug must also have the knowledge and experience necessary to self-diagnose the condition in question as well as appropriately use the drug. Unfortunately, many of the respondents felt that researchers and policymakers know very little about how people make decisions in this area-highlighting an area where research is sorely needed. It is only when both of these conditions are met (good drug profile, knowledgeable consumers), can a medication make a successful and safe switch from prescription to OTC.

The Role of Post-Marketing Surveillance. The majority of key informants (5 out of 7) felt that increased post-marketing surveillance on the part of the FDA was not warranted. Most categories of drugs that move to OTC have extensive safety profiles. Also, by NDA requirements, manufacturers already file 15-day reports and one-year summaries . . . In addition, some companies have been required to do special post-marketing studies. Most felt that these measures were sufficient. Several, however, indicated significant interest in seeing research on the use of OTCs put in the public arena. Although it is likely that manufacturers have conducted studies in this area, very little of this research is available for broad consumption.

Regulation and Monitoring of OTC Advertising. Most of the respondents interviewed felt that the advertisement of OTCs was appropriately regulated. Several, however, felt that monitoring was almost absent. In addition, several interviewees expressed concern that

advertisements may be the only source of information that an individual gets or uses. One policymaker called for “. . . more research to determine if the information in advertisements is adequate and if consumers are getting the types of information/education they need.” One key informant noted that OTC manufacturers are conducting a “fair amount” of advertising self-regulation. If manufacturers provide false or imprecise information in their advertisements, they would be subject to potential litigation for product liability and from other competitors. Several organizations, including the Nonprescription Drug Manufacturers’ Association (NDMA), have also established a “voluntary code” of advertising.

Policy Issues

Insurance Coverage. Most of the key informants agreed that insurance coverage of OTCs (or lack thereof) was not an issue of significant concern at this point in time. They felt that OTCs are generally not expensive, especially when compared to the wholesale/retail price of prescription drugs. Patients who cannot afford an OTC because it is not covered under a pharmaceutical benefit plan can see a physician, get a prescription for a similar medication, and only pay the modest prescription co-pay. If the prescription substitute is more expensive than the OTC, the switch may lead to higher overall costs, especially if the practice of writing “substitute” prescriptions is widespread. Several respondents also noted that, as more “maintenance” drugs move to OTC, the issue of insurance coverage for OTCs might increase in importance, especially in the context of chronically ill populations. One consumer advocate called for the establishment of a policy that if a physician recommended a medication, it should be covered by a pharmacy benefit, whether it was prescription or OTC.

Consumer Knowledge/Information. Almost all of the interviewees believed that consumers are sophisticated enough to appropriately use current **OTCs**. Several respondents, however, noted that their conclusion in this area is based on the concept of an “ordinary individual” and the capabilities of that individual. Members of vulnerable populations who are not “ordinary” may not be knowledgeable enough to appropriately use these medications. Again, the relative dearth of information on OTC use in general and use by vulnerable populations in particular makes it very difficult to address this issue with more confidence and evidence.

When interviewees were asked whether they believed that the sophistication or knowledge base of consumers was growing, most stated that although this was a generally-held belief, there was very little concrete evidence to support this hypothesis. Several respondents noted that while there are more people graduating from high school and college than in earlier years, this is only indirect evidence on increasing sophistication. As noted by one of the policymakers, one of the only studies published in a research journal addressing this issue does not support the notion of increasing consumer knowledge or knowledge-seeking behavior (Morris, Tabak, and Gondek, 1997). This study finds that the percentage of individuals who look up prescription drug information in a book has remained relatively constant over a 12-year time period (1982-1994) at 12-13 %.

Several key informants also noted that knowledge might not be growing at a uniform rate across population segments. For example, it is conceivable that the well-educated “baby boomers” may be becoming extremely sophisticated, while other groups are unchanged or regressing. Most of the interviewees felt that there were certain populations of particular concern: elderly, young

people, low income populations, and those who are poorly educated. They did not, however, agree on the role that the government might play in protecting these populations. Since it is difficult to identify those who are vulnerable, and OTC medications are quite freely available on the shelves of most pharmacies and retail outlet stores, the education and protection of vulnerable populations was seen as a difficult and complex issue. Some suggestions included: lecturing in schools, innovative programs for teenagers in “their own” media (e.g. MTV), alternative packaging to target specific populations and providing in-depth information, and websites designed to provide unbiased information.

Respondents were skeptical about whether the information provided with OTCs was adequate to assure appropriate use. While two of the informants stated unequivocally “Yes”, the rest expressed various concerns about the sources and amounts of information provided. For example, one pharmacist felt that “. . . labels are not set up for patient education, but rather for liability concerns. Labels should be better organized around patient decision-making.” Another consumer advocate worried that advertising may be the only source of information that people use: “. . .it is not clear how many patients actually read labels.” In general, respondents cited a lack of concrete evidence on the use and processing of information by OTC consumers as a significant policy concern.

When asked how information can most effectively be communicated to consumers, key informants acknowledged that the communication of information to consumers was a difficult and challenging task. Labeling was most commonly cited as the primary method for conveying drug-specific information. Advertising was also cited, but many noted that this could be a biased

source of information. A couple of innovative approaches were recommended to provide consumers with more and better information:

(1) *Develop an FDA website* with detailed OTC information as well as links to manufacturer sites (for more information), pharmacy sites, and medical information sites (for related condition-specific information); and

(2) *Set up database marketing*-OTC consumers fill out a “warranty card” to get personalized information.

One respondent felt strongly that we did not yet know enough about the best methods of communicating information to OTC users and that we need to conduct research in this area before we invest a significant amount of money into any initiatives.

The Role of Professionals (Pharmacists, Physicians). Key informants unanimously indicated that, in theory, pharmacists have the potential to fulfill the consumer’s need for unbiased information when choosing an OTC product. They also unanimously agreed that, in reality, pharmacists do not meet the consumer’s need for information because they are too busy. As one pharmacist put it, “Pharmacists bill 300-400 prescriptions per shift. While they are certainly capable of providing counseling, they simply do not have the time.” Managed care contracts may further erode the pharmacist’s ability to provide information, as pharmacy staff struggle to complete their prescription-filling tasks on a timely basis. It is these same contracts that channel more and more people toward the high-volume chain drug stores and away from the independent pharmacies where pharmacists may have more time.

Physicians may also provide OTC information to consumers. Their role, however, is seen as somewhat limited, since it is precisely for self-diagnosed (rather than physician-diagnosed) conditions that OTCs are usually purchased. When asked whether physicians perceive OTCs as “friend or foe”, key informants felt that the response was generally positive. They noted, however, that the physician’s response is, to a significant degree, driven by the predominant form of financing present in the physician’s market. If a physician (or his group practice) is primarily reimbursed on a capitated basis, OTCs are seen as cost-reducing, revenue-enhancing products (since the incentive is to reduce prescriptions and office visits). On the other hand, physicians in a fee for service (FFS) environment may be less positive towards OTC medication, since they directly limit (all other things being equal) the number of times a patient seeks a physician’s advice (and schedules an office visit).

Key informants were also asked whether the role of a “physician contact” should be a consideration when thinking about switching a drug. For example, when considering the switch of vaginal anticondicals from prescription to OTC, several opponents argued that this switch would reduce the likelihood that some people would get annual pap smears (because they would not visit their physician as often). Respondents were of relatively mixed opinion on this point—several felt that people are generally smart enough to make decisions for themselves. If individuals choose to get less preventive care, that is their choice. Other interviewees noted that this issue has been and should continue to be an important consideration for the FDA, since this is a public health concern.

Other Policy Issues. Four questions in the key informant survey addressed other policy issues.

1. *How can we get better data on utilization of OTCs?*

Most of the respondents felt that the only way to get good data in this area was to conduct detailed (and expensive) consumer surveys. A couple of creative suggestions in this area included:

- (a) Add OTC utilization questions to existing longitudinal health surveys to get rich data on not only OTC use, but also demographics, medical history, pharmaceutical use, and other health services utilization. This approach will provide rich data at a relatively low cost; and
- (b) Design a research project whereby people can belong to a voluntary registry at their local pharmacy. OTC and prescription data, as well as some basic demographic and geographic information can be used to profile OTC users.

2. *Does the use of OTCs pose significant dangers by masking symptoms or creating potential for drug interactions?*

In general, the key informants felt that while the potential for OTC to create significant dangers is present, there is no empirical evidence that this is a serious problem. If a condition is refractory to OTC treatment (i.e. patient does not experience relief of symptoms), the consumer will go to see a physician. In general, OTC-treatable conditions are self-limiting. Two respondents did, however, express some concern about the ability of vaginal yeast treatments to mask symptoms of AIDS and sexually transmitted diseases, since a vaginal yeast infection is often the first presenting symptom that leads to the diagnosis of these diseases.

3. ***Does the presence of any of the current OTC products lead to overuse or waste of the drug?***

Key informants agreed that there is some level of OTC overuse or waste. If individuals misdiagnose themselves, they may treat themselves with OTCs that are not necessary or appropriate. In general, however, they did not believe that this was a significant policy consideration. In addition, as one policymaker pointed out, it is virtually impossible to quantify or monitor this. Even consumer surveys cannot tell us how often individuals have mistakenly diagnosed themselves.

4. ***Does moving drugs from prescription to OTC save money?***

All of the key informants agreed that, based on our experience to date, moving drugs from prescription to OTC saves a significant amount of money. Although there are some costs associated with switches (waste, inappropriate use), these costs appear relatively small compared with the cost savings. For the most part, however, these cost savings are not generated through decreased drug prices, but rather through reduced number of physician visits and reduced work time lost (as a results of no longer needing to see a physician for treatment; see, for example, Kline and Company, 1997).

It should also be noted that while there is reasonably good evidence that switching drugs from prescription to OTC saves money (from a societal point of view), it does not always save the consumer money. To the extent that OTCs cost more than the consumer's usual co-payment (which averages \$6.33 for a prescription [HMO-PPO Digest 1996] and \$17.24 for an office visit [Kline & Co. 1997]), and OTCs are not covered by prescription drug benefits, consumers may be

paying more after the switch. This is especially true when considering the case of maintenance medications. In this case, a patient sees a doctor once and receives a prescription that may cover up to a year's supply of the medication. If the medication switches to OTC, the patient may save the cost of one physician office visit but must pay the higher cost of the 12-month supply of the OTC drug.

V. Summary

Key informants representing a number of different stakeholder groups were interviewed to provide both insight and evidence on various facets of the OTC switch movement. In general, interviewees viewed the switch trend as a positive one, providing increased access to safe and effective drugs and cost savings, primarily through reduced physician office visits and work time lost. The FDA process for reviewing potential switches was seen as adequate and the number and type of switches as appropriate. Drug safety and efficacy profiles as well as the ability of individuals to appropriately self-diagnose and self-medicate were seen as the critical elements in the timing of an OTC switch. The best types and levels of OTC information and the translation of that information into consumer knowledge of appropriate OTC use were cited as critical policy issues. Insurance coverage of OTCs was not seen as an issue of significant policy concern at this time, although several interviewees noted that if more “maintenance” medications are switched to OTC, this could become a more important issue, especially for chronically ill populations who must purchase those medications regularly.

VI. Areas for Further Research

The key informant interviews highlighted a number of areas for further research. At a very basic level, policymakers, researchers, and manufacturers may benefit from strategic thinking on the subject of “OTC-ness”. This type of concept-building could improve the switch process and provide a basis for proposing future switches.

Based on both the literature review and the key informant surveys, it has become clear that there is very little basic information on use of OTCs. Who uses OTCs (demographics)? How do specific vulnerable populations (e.g. elderly, youth, low income, low education, disabled) use OTCs? How is OTC use related to prescription drug use? How is OTC use related to health services utilization (e.g. physician office visits, ER visits, and inpatient days)? How is OTC use related to the presence of specific medical conditions? These are some very basic questions for which there are very few answers.

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A recurring theme throughout the key informant responses was our lack of understanding in the related areas of consumer decision-making, information, and consumer knowledge. How do consumers get and process OTC information? Are consumers getting the types of information that they need? What are the best methods of conveying information? Is knowledge of OTCs and their appropriate use growing? Is OTC knowledge growing at different rates in different segments of the population? The answers to these research questions are of critical public health concern.

Finally, while insurance coverage was not considered a significant policy issue at this time, if “maintenance” medications are switched to OTC, we must carefully investigate the impact of these switches on the specific chronically ill populations who are affected. In general, almost of the future switches proposed require serious consideration of the populations affected as well as follow-up research to investigate whether anticipated effects of the switch were, in fact, realized.

The OTC switch movement has provided increased consumer access to safe and effective drugs as well as significant cost savings. According to several of the key informants, however, the logical candidates have been switched and the more difficult decisions are yet to be made. As a research and policymaking community, we know very little about users of OTCs or their decision-making processes. There is a critical need for research in order to develop evidence-based policy.

VII. References

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- Morris LA, Tabak ER, and Gondek K. “Counseling patients about prescribed medication: 12-year trends,” *Medical Care* 1997; 35(10): 996- 1007.
- Waters TM, Lipsky M, LoSasso T, Analysis of Prescription Drug to Over-the-Counter (Rx-to-OTC) Switch Movement: Literature Review/Policy Synthesis. Final Report to the Assistant Secretary for Planning and Evaluation, February 25, 1998.

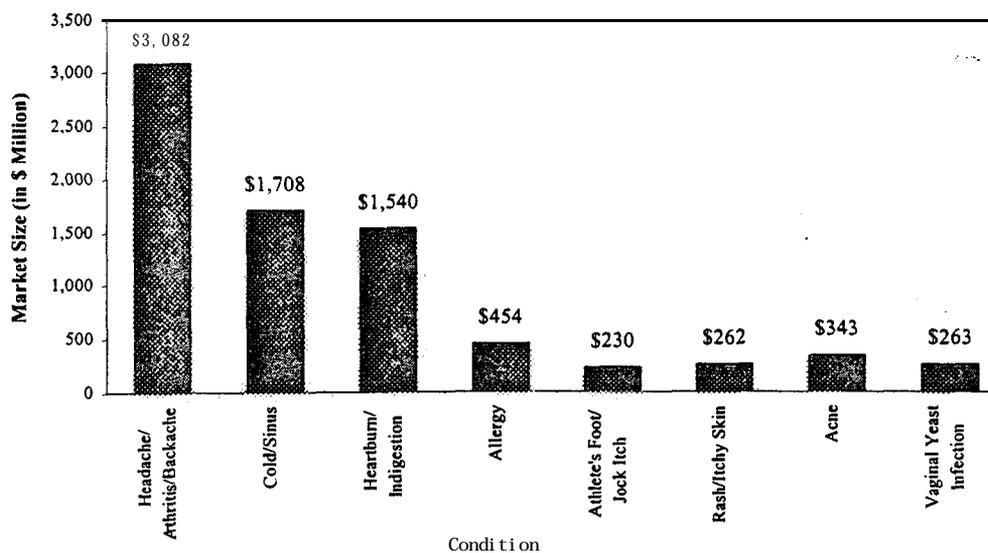
Chapter 3: Demand for OTC Switch Drugs

Introduction

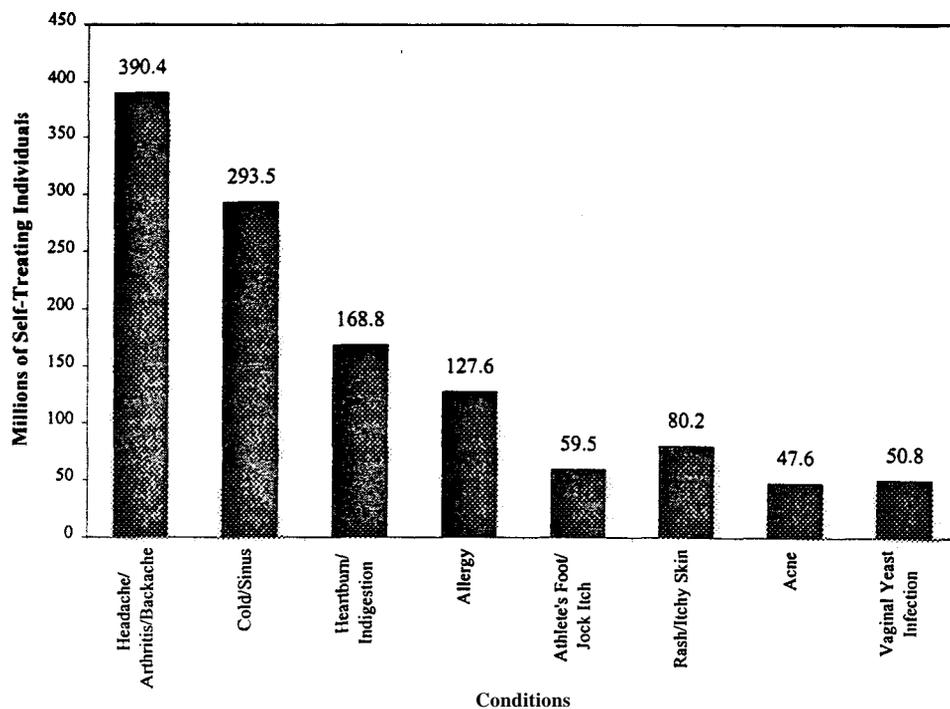
More than 600 over-the-counter (OTC) products today have ingredients or dosages that were available only by prescription 20 years ago (Snyder, 1997). OTC agents currently account for about 10 % of all drugs prescribed or recommended by physicians (Karig, O'Brien, and Weintraub, 1995). OTCs will become increasingly important in medical decision-making as the number of drugs switching from prescription to OTC continues to rise.

OTCs are also generating a lot of attention because of the dollars involved and the size of potential markets (see Figures 3-1 and 3-2). Internal analgesics make up the largest OTC market, with 1996 sales of approximately \$3.1 billion. Cold and sinus medications come in second with \$1.7 billion in sales. Heartburn and indigestion medications are a fast-growing category with sales growing 26 % between 1995 and 1996 (Kline & Company, Inc., 1997).

Figure 3-1. 1996 OTC Market Size (in Dollars)

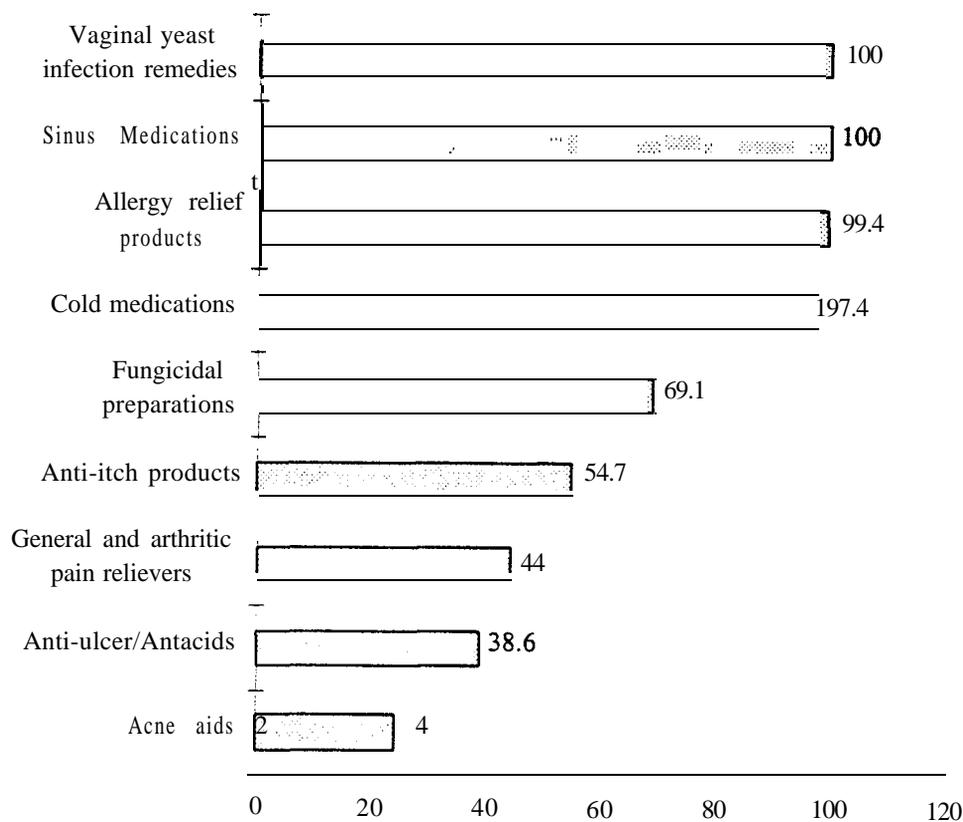


Source: Kline & Company, Inc., 1997.

Figure 3-2. Estimated Population Per Condition

Source: Kline & Company, Inc., 1997.

OTC switch drugs represent an increasingly important portion of total OTC sales (see Figure 3-3). According to industry analysts, the categories of vaginal yeast infection remedies, sinus medications, allergy relief products, and cold medications are almost completely populated by switch medications (switched from prescription to OTC in last 20 years).

Figure 3-3. Percent of OTC Sales Categories Comprised of Switch Drugs

Source: Kline & Company, Inc., 1997.

Because of their importance in treatment decisions and because of the sheer dollar volume associated with switch drugs, it is important to understand some of the “economics” of switch drugs: Are sales continuing to grow? Is growth related to regional or market characteristics? (e.g. per capita income, managed care penetration) Have prices of these OTCs fallen over time as competition increases? Is consumer demand for OTCs sensitive to price?

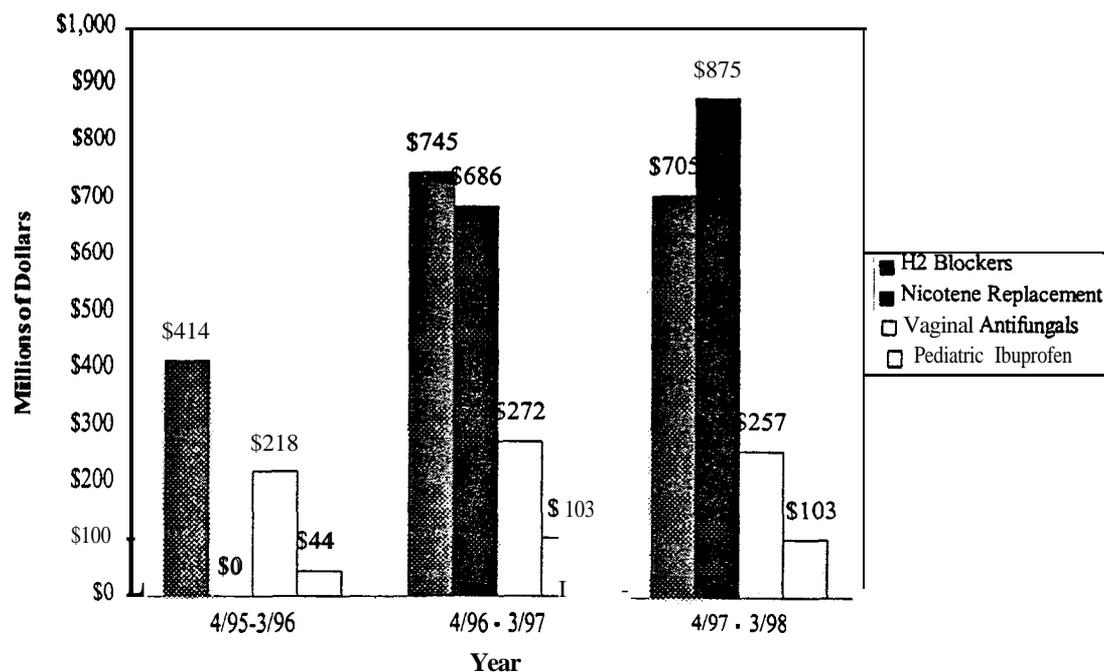
In the sections that follow, we outline findings based on sales data obtained from Information Resources, Inc. (IRI), a marketing firm that obtains check-out register scan data for a multitude of retail products sold in drug stores, grocery stores, and mass merchandisers (e.g.

Target, K-Mart). We obtained regional data for April 1995 through March 1998 for the following recent switch drugs: *H2 Blockers* (Axid AR, Pepcid AC, Tagamet HB, and Zantac 75), *Nicotine Replacement Systems* (Nicoderm CQ, Nicorette, and Nicotrol), *Vaginal Yeast Infection Remedies* (Femcare-7, Femcare-3, Gyne-Lotrimin-3, Gyne-Lotrimin-7, Monistat-3, Monistat-7, Mycelex-3, and Mycelex-7), and *Pediatric Ibuprofen Suspensions* (Children's Advil, Children's Motrin). Our data set contained detailed information on dollar and unit sales, and average weekly price reductions (to track local discounts), disaggregated by brand name and package. Because sales data for mass merchandisers were not disaggregated by region, we did not obtain these data. The IRI data were used to provide information on sales trends over time, major brand market shares (over time), and price elasticity of demand for specific OTCs and brands.

Sales Trends Over Time

Figure 3-4 presents annual estimates of sales volume for each of the four major switch drug categories. It should be noted that the IRI data is not an exhaustive data set on sales of these switch drugs since IRI does not obtain scan data from all retailers across the country. ... Using available 1996 aggregate data to derive estimates of percent of sales not accounted for in the IRI data, estimates were inflated in order to account for sales in mass merchandising stores and for sales of generic brands. All dollar amounts are adjusted to 1998 dollars for ease of comparison and to account for inflation.

Figure 3-4. Dollar Sales Volume for Four Categories of OTC Switch Drugs



A number of interesting trends are highlighted in Figure 3-4. Perhaps most striking is the rapid expansion of the Nicotine Replacement market with a jump from \$0 in sales in the initial period (4/95 – 3/96) to sales of close to \$700 million in Year 2 (4/96 – 3/97). This tremendous dollar volume can be attributed to both the large potential market for this OTC as well as the average price of the product. According to the Bureau of the Census, cigars, cigarettes, tobacco and smokers' accessories accounted for more than \$31 billion in sales in 1990. Our IRI data indicate that the price of nicotene replacement products ranges from \$29 (7 count Nicoderm CQ Patch) to \$5.1 (108 count Nicorette gum) per package. It is also interesting to note that the growth of the H2 Blocker market appears to be leveling off and even declining between 96/97

and 97/98, perhaps indicating a type of “market saturation”—almost all of the potential OTC H2 blocker users have been reached through various promotional campaigns. An alternative explanation for this leveling off of sales is changing medical technology: physicians are making increasing use of proton pump inhibitors and treatments that “cure ulcers” by eradicating *helicobacter pylori* (the bacteria that appears to cause a substantial proportion of ulcers). The steady and modest growth in the vaginal **antifungals** may be illustrative of a “mature” switch drug. While there has been some changes in the product composition of this category of the three years time period (most notably movement away from 7-day treatments to 3-day treatments), overall dollar sales have not been dramatically affected. The market for pediatric ibuprofens is of relatively modest size. Although the market grew quickly between the first two time periods, this growth appears to have leveled off.

Economic Theory of Competition

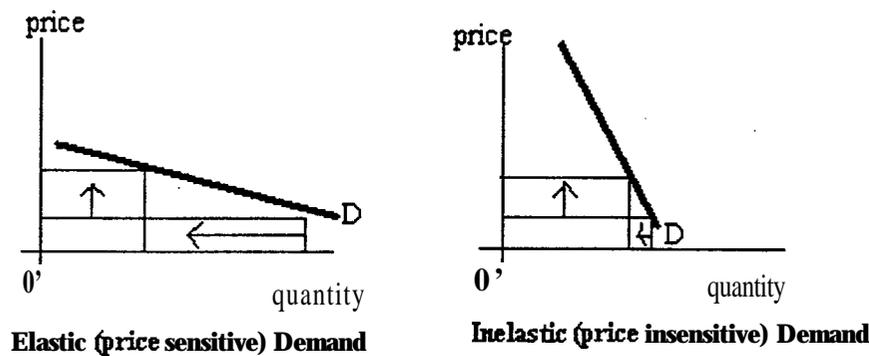
The competitive level of markets for OTCs is of critical policy concern because the level of competitiveness in a market determines whether or not prices closely reflect the underlying costs of producing those OTCs. In a perfect world, the price of an OTC will be set as close to the marginal (incremental) cost of producing that OTC. For example, suppose that a company needs to spend \$10,000 to set up a factory to produce aspirin pills and that the incremental cost of manufacturing one bottle of aspirin is \$1. Although the average cost of producing that first bottle of aspirin is \$10,001, the average cost of the **second** is only \$5,001, and the average cost falls rapidly with increases in volume. In fact, as long as the fixed costs of production (here \$10,000) are relatively small compared to the volume of production, the average cost of the product (often the basis for price) will be very close to marginal cost (\$1). Economists view

marginal cost pricing as efficient (and, therefore, desirable) because these prices assist consumers in purchasing products until the marginal benefit (to the consumer) is just equal to the marginal cost. If the price exceeds marginal costs, consumers will purchase the good only until the marginal benefit is equal to price (which exceeds marginal cost)---yielding an inefficient outcome.

Economic theory outlines the conditions under which a market will or will not be competitive. First of all, as illustrated earlier, fixed costs must be relatively low compared with volume in order to lower average cost and to make it easy for competitors to enter the market. Perfectly competitive markets are also characterized by many buyers and sellers. Because of the large number of sellers in the market, individual firm market shares are small. In addition, no individual seller has the ability to raise price above marginal cost. If a firm attempts to raise his price above marginal cost, another seller will find it worth his while to sell the product at a price closer to marginal cost, and buyers will only purchase from him. Conversely, if all sellers are attempting to sell at a price above marginal cost, one seller can cut his price slightly and all the buyers will come to him to purchase the product. This type of price-cutting will continue until price equals marginal cost. Price will not fall below marginal cost because to sell at such a price would mean that the incremental revenue from selling the product would be less than the incremental cost--something the firm cannot afford to do.

Unfortunately, perfect competition relies on a number of assumptions that are often unmet in the real world. On the other end of the competitive spectrum is a monopoly. In this case, there is one seller and a lot of buyers. There are two types of monopolies: natural monopolies and "protected" monopolies. Natural monopolies are associated with products that have very large fixed costs of production. In this case, it is impossible for other competitors to

make the large investments necessary to operate in the market. Utilities (electricity, gas) are often cited as examples of natural monopolies. ‘Protected’ monopolies are those that are afforded some sort of protection from market entry, usually through direct government intervention. Pharmaceutical companies are afforded a time-limited monopoly for products under patent law. A monopolist does not set price equal to marginal cost or even average cost. Because other competitors are unable to enter the market, a monopolist sets price at a level that maximizes his profit. How high that price should be depends on the sensitivity of market demand to price (*known as the price elasticity of demand*). If consumers are very price sensitive, the monopolist will not be able to raise price very high, because consumers will greatly reduce the amount they demand if price increases. If, on the other hand, consumers are very price insensitive, the monopolist will be able to raise price quite high before a significant number of consumers will decide not to purchase his product. Figure 3-5 demonstrates these two types of demand curves. This distinction is especially important in the area of pharmaceuticals and OTCs, since elasticity of demand is integrally related to the availability of product substitutes. Since some drugs have no good substitutes (e.g. **triptans** for migraines), people with conditions requiring treatment with those drugs are likely to have relatively inelastic (price insensitive) demand and monopolists will be able to raise the price of their product(s) well above marginal costs.

Figure 3-5. Impact of Price Increases on Quantity Demanded

While patents are common in the prescription pharmaceutical world, they are relatively uncommon in the OTC world because, in general, OTCs enjoy at most three years of patent protection. This limited protection, however, may afford first entrants into the OTC market a significant advantage if they can rapidly expand the number of buyers, create consumer loyalty, and establish a real or perceived difference between their product and later entrants. Once a dominant market share is established, the market for the OTC product is more likely to be monopolistic, or *monopolistically competitive*. Monopolistically competitive markets typically exhibit prices lower than monopolistic prices, but higher than marginal costs.

To understand the level of competition in OTC markets, we examine both major brand market shares over time and estimate demand equations for each product and brand. The market share data provide information on market *concentration*: Are market shares concentrated into the hands of one or a limited set of brands? In addition, our analysis can shed light on the role that “first entrant” plays in the competitiveness of the market: Does the first entrant maintain a dominant market share over time? Demand equations will provide important information on the price sensitivity of demand: Are consumers sensitive to the price of specific OTCs? Is the demand for one brand sensitive to the price of another (evidence of substitution)? In addition,

demand equations may shed light on the relationship between income and demand: do areas with lower incomes use more OTCs (as a substitute for more expensive physician care)?

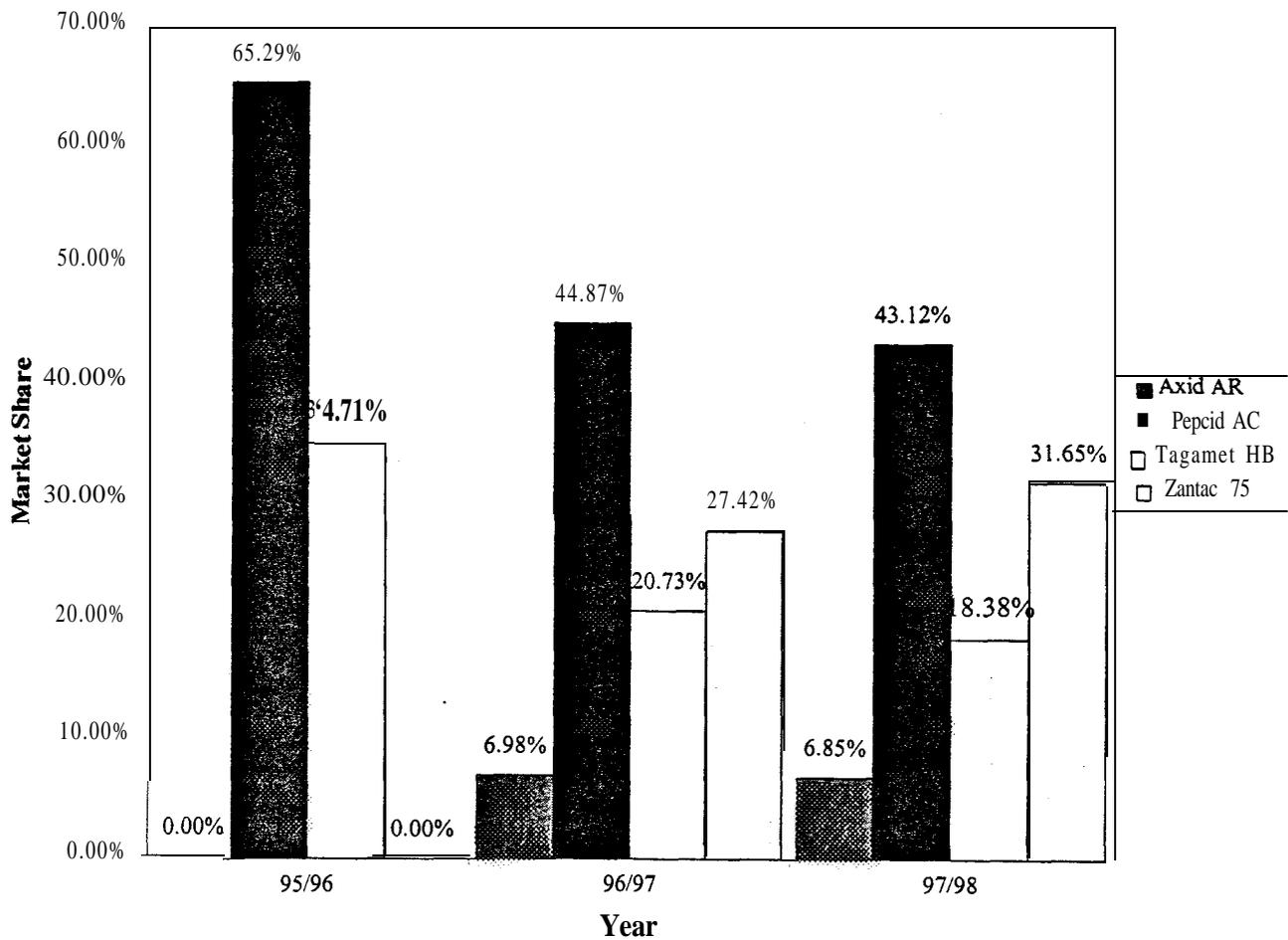
Major Brand Market Shares

We examine market share data for three of the four categories of OTCs: H2 blockers, nicotine replacement drugs, and vaginal anticandidals. Market shares for pediatric ibuprofen suspensions are not presented because they represent a small part of a much larger pediatric anti-inflammatory/anti-pyretic market (which includes acetaminophen products such as Tylenol).

Market Shares for H2 Blockers

There are currently four major brands of H2 blockers available OTC for the treatment of heartburn and indigestion: Axid AR, Pepcid AC, Tagamet HB, and Zantac 75. Pepcid AC (famotidine) was the first H2 blocker available OTC, being approved for OTC sale on April 28, 1995. Tagamet HB (cimetidine) was a close second in the market with approval on June 19, 1995. Zantac 75 (ranitidine), the H2 blocker that led its prescription drug category for the last 5 years, received approval 6 months later, and Axid AR (nizatidine) was cleared for OTC sale in May 1996.

Figure 3-6. Major Brand Market Shares for H2 Blockers

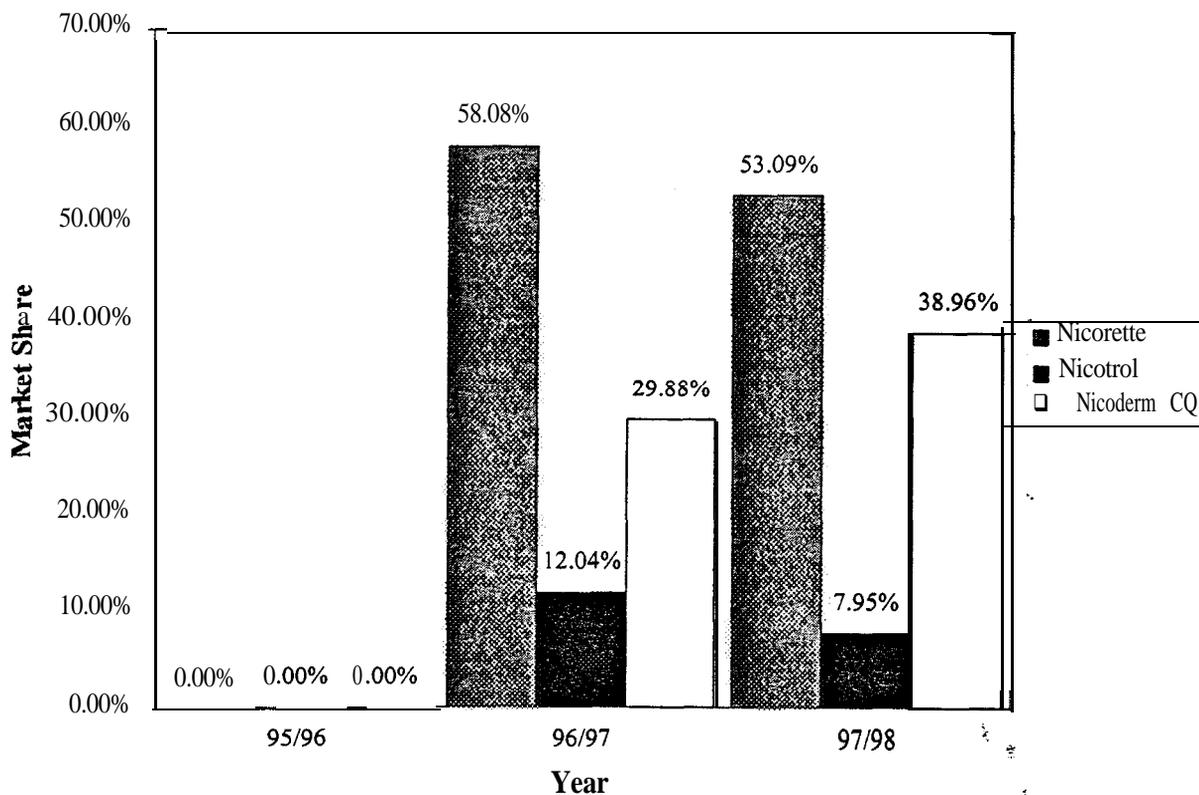


From the above figure, it is clear that being the initial market entrant lent Pepcid AC something of an advantage over its later competitors. Even after three additional entrants in the market, Pepcid maintains a dominant market share. Earlier entry, however, does not appear to be the sole determining factor of market domination. Tagamet was a short 7 weeks behind Pepcid in FDA approval and captured a respectable 34.7 % market share in the initial time period. Zantac's prior domination of the prescription market, however, appears to have played a role in its ability to quickly capture market share from both Pepcid and Tagamet, quickly outpacing Tagamet's market share.

Market Shares of Nicotine Replacement Drugs

There are currently three major brands of nicotine replacement drugs available OTC. Nicorette (nicotine polacrilex) was the first drug in this class to be cleared for OTC sale, receiving FDA approval on February 9, 1996. Nicotrol (nicotine transdermal system) was approved 5 months later (July 1996), and Nicoderm CQ a short month after that.

Figure 3-7. Major Brand Market Shares for Nicotine Replacement Drugs



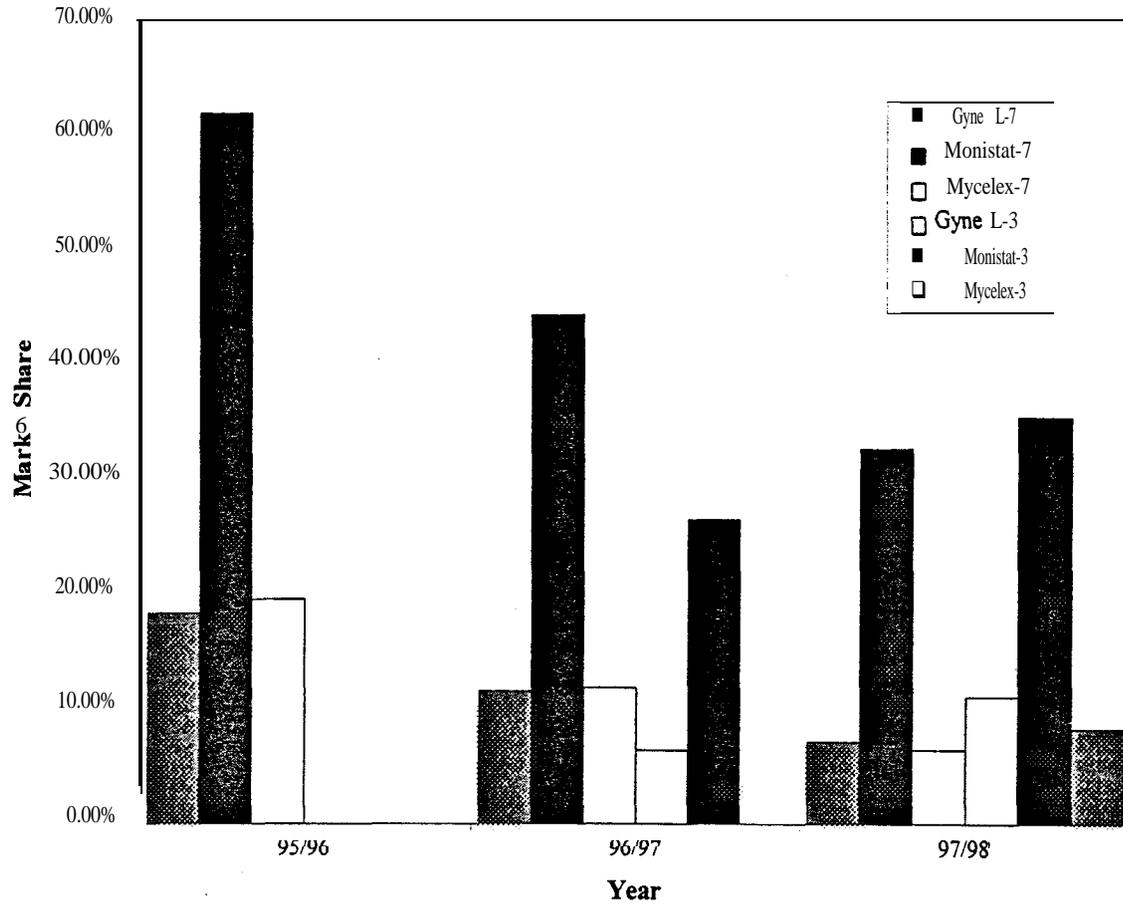
As Figure 3-7 indicates, Nicorette established a dominant market position in its first year of sales (3/96 – 2/97) and maintained most of its market share in the second year of sales (based on dollar sales volume). At least one more year's data are needed to determine whether this trend will continue. It should also be noted that Nicorette was also the market leader in the

prescription market prior to OTC introduction of nicotine replacement drugs. Nicotrol and Nicoderm CQ were introduced to the market at virtually the same time. Nicoderm enjoys a significant market advantage over Nicotrol, and its market share has risen since introduction. Most of Nicoderms' market gains have been at the expense of Nicotrol, rather than Nicorette.

Market Shares of Vaginal Anticandidals

There are currently three major brands of vaginal anticandidals available OTC: **Gyne-Lotrimin**, **Monistat**, and **Mycelex**.¹ The original anticandidal formulations (7-day treatments) went OTC in late 1990 and 1991. Gyne-Lotrimin and Mycelex-7 (clotrimazole) were approved by the FDA on November 30, 1990, with Monistat-7 (miconazole nitrate) following their lead on March 13, 1991. Three-day treatments were approved late 1995 and 1996: Femstat 3 (butoconazole nitrate) was approved on December 26, 1995, while Monistat-3 (miconazole nitrate) and Gyne-Lotrimin 3 (clotrimazole) in April and July of 1996, respectively. While 3-day treatments are relatively new OTCs, 7-day treatments have now been available for 8 years, opening the market to competition from generic brand anticandidals. Unfortunately, due to the plethora of "house" brands available, we were unable to obtain data on generic vaginal anticandidal sales from IRI.

¹ A new one-day treatment, **Vagistat-1** (Bristol-Myers Squibb), has recently been introduced to the market. Since our data only cover through 2/98, however, sales of this product in our database are relatively small.

Figure 3-8. Major Brand Market Shares for Vaginal Anticandidals

Prior to OTC introduction, Monistat enjoyed a dominant position in the prescription vaginal anticandidal market. Thus, it is not surprising that this prior dominant position, coupled with early OTC market entry, has yielded a dominant OTC market position for Monistat products. Monistat's total market share (7- and 3-day treatments) has remained relatively stable over the three-year time period, varying between 62 and 70 %. Market share for Gyne-Lotrimin products has also been remarkably stable at 18 %, while Mycelex appears to be slowly losing some market position, falling from 19 to 15 %.

It also appears that 3-day products are being viewed as substitutes for 7-day products. Market shares for Monistat-7, Gyne Lotrimin-7, and Mycelex-7 have fallen over the **three-**period, while market shares of the corresponding 3-day products have continued to rise and currently exceed those of 7-day products.

Our data on market shares for the H2 blocker, nicotine replacement, and vaginal anticandidal OTC markets indicate that, in general, these markets appear relatively concentrated. While we do not have data on generic brands, most of these markets are still dominated by the brand name OTCs. The level of concentration we find in these markets indicates that market competitiveness may be of policy concern. Specifically, because major brands may be acting in a monopolistically competitive manner, prices will exceed marginal cost. The extent to which prices exceed marginal costs will depend, in large part, on consumers' price elasticity of demand. This is the subject of our next section.

Demand for **OTCs**

...

Utilizing regional data on OTC sales for specific OTC brands and packages as well as demographic and market supply data from the Area Resource File (ARF)², we estimated demand functions for three categories of recent switch drugs (H2 blockers, nicotine replacement drugs, vaginal anticandidals) as well as individual, brand-specific demand functions. Demand functions provide a number of policy-relevant pieces of information. First, demand functions allow us to estimate price elasticity of demand for the product category. As discussed earlier,

² The Area Resource File contains county-level information on population demographics (e.g. population size, per capita income) as well as (medical) market supply characteristics (e.g. physician/population and hospital bed/population ratios). Elements from ARF were aggregated to the regional level and used as explanatory variables in the demand equations.

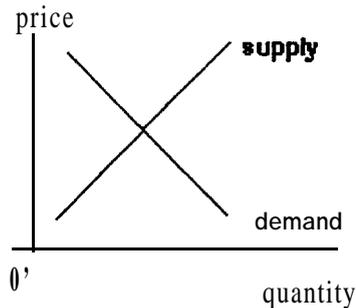
price elasticities are strongly related to how much producers can raise price above marginal cost. Second, individual, brand-specific demand functions provide useful information on the level of substitutability between brands. These OTC markets are generally considered to be monopolistically competitive. If consumers are willing to substitute one brand for another when the price of one of the brands rises, competitive pressures can keep overall prices low. Substitutability is indicated by positive *cross-price elasticities*-that is, demand for brand A will go up when Brand B raises its price. Finally, demand functions can provide useful insight into market and demographic factors that may be associated with OTC use.

The IRI sales data used to estimate the demand functions was based on eight major regions (California, West, Plains, South Central, Great Lakes, Mid-South, Southeast, and Northeast) and divided into 4-week observations over a 3-year time period. All prices were adjusted to March 1998 dollars based on the Consumer Price Index (Bureau of Labor Statistics, 1998).

A couple of difficult issues come up when attempting to estimate demand functions: 1) trying to figure out what is the demand curve (as opposed to the supply curve) or *identification* and 2) how to control for the fact that price is generally *endogeneous* or co-determined with quantity sold (demanded).

Consider the following graph-it is a very familiar one to anyone who has taken introductory economics.

Figure 3-9. Supply and Demand



Hopefully, the researcher will have data across several companies or individuals (cross-sectional) as well as data over time (longitudinal). The estimation of a demand function involves doing a regression of quantity on price. But how can the researcher be sure that s/he is estimating the demand curve and not the supply curve³ (or some combination thereof)? By identifying variables that drive (shift) demand but do not drive supply. Examples of these variables might be income, age, sex, race, and other measures of tastes and preferences.

Because manufacturers decisions of prices to charge and quantities to supply are not generally independent, we say that price is endogenous to (or co-determined with) quantity. This is a significant problem, because the most common type of regression (ordinary least squares analysis, standard multivariate regression) is based on the presumption that the dependent variables (here, quantity) and all independent variables (including price) are independently determined. When this is not true, errors in the independent variable and the dependent variables are not uncorrelated and alternative methods of estimation must be used. Two-stage least squares analysis is the most common technique to overcome endogeneity problems and is the method of estimation that we have employed.

Two sets of demand analyses were conducted. The first set of analyses provides estimates of the overall market demand functions for each of the three OTC categories: H2 blockers, nicotine replacement medications, and vaginal anticandidal preparations. These results are presented in Table 3-1. The second set of analyses provides estimates for the individual demand curves facing the various products within each OTC category. These results are presented in Tables 3-2 through 3-4. Price and its natural log (ln Price) were used in the demand specifications to allow for potentially non-linear demand curves. Quantity was calculated as a “dose” for each of the OTC categories: 1 pill = 1 dose for H2 blockers; a normal 24-hour dose (12 pieces of gum, 2 patches) for nicotine replacement; and 1 package for vaginal anticandidals.

Table 3-1. Estimates of Overall Market Demand Functions: H2 Blockers, Nicotine Replacement Medications, and Vaginal Anticandidal Preparations

Independent Variable ¹	Dependent Variable ^a		
	H2 Blockers (Q)	Nicotene Replacment (Q)	Vaginal Anticandidals (Q)
Intercept	63.10***	0.84***	0.22***
Price	58.30***	0.012***	0.0002***
Ln Price	- 58.30***	0.012***	0.0002***
Per Capita Income	0.0005***	0.0001***	0.00002***
% Below Poverty	8.98**	0.0001***	0.47***
Physicians per 1,000	- 0.47	- 0.26***	- 0.02***
Hospital Beds per 1,000	- 0.13***	- 0.010***	- 0.003***
% >= 65	- 10.80***	- 1.12***	- 0.23***
R²	0.76	0.83	0.89
N	267	176	280
Demand Elasticity	- 4.25	- 0.77	- 0.09
Income Elasticity	2.87	6.86	4.05

¹In Millions of Units

**Statistically significant, $p < 0.05$

***Statistically significant, $p < 0.01$

³In the context of monopolistic competition (the model that we believe is governing competition in these OTC markets), the “supply” curve is usually referred to as the “reaction” function—the prices and quantities that a firm sets in reaction to what its competitors are doing.

The results presented in Table 3-1 provide some interesting estimates of the price and income elasticities of demand for the three OTC categories. The price elasticities of demand for both vaginal anticandidals and for nicotine replacement medications are quite low. An elasticity with an absolute value less than 1 is considered to be “relatively inelastic”. This implies that the manufacturers of these products are able to raise prices quite high without losing any customers. Demand for H2 blockers is relatively elastic (-4.25). There are quite a few customers who cease to purchase the medications when prices rise, perhaps seeking relief through more conventional antacids. We estimate that for every 1 % increase in the price of an H2 blocker dose (1 pill), 4.25 % less of the product will be demanded.

The income elasticities presented in Table 3-1 indicate that the three categories of OTCs are “normal” goods—that is, as the average income in a region rises, so does the consumption of these goods. The consumption of nicotine replacement medications- and vaginal anticandidals, however, appear to be more sensitive to income than the H2 blockers. Thinking about this conversely, a decrease in a region’s average income will decrease consumption of nicotine replacement medications and vaginal candidals proportionately more than the decrease in H2 blocker consumption. The income elasticities for nicotine replacement medications and vaginal anticandidals are relatively high. A one percent decrease in income is associated with a 6.86 % decrease in the consumption of nicotine replacement medications and a 4.05 % decrease in the consumption of vaginal anticandidals preparations.

The other independent variables in Table 3-1 also provide some interesting insights into the demand for OTC switch drugs. The demand for H2 blockers appears to be particularly sensitive to the percentage of the population below the poverty line. In particular, for a one percent increase in the percentage of people below the poverty line in the region, sales of H2

blockers increase by almost 9 million units. This strong, positive relationship may indicate that H2 blockers serve as a substitute for other types of medical care in socio-economically disadvantaged areas. The negative coefficients on physicians per 1,000 and hospital beds per 1,000 are generally significant and also support the hypothesis that there is some room for substitution between demand for these OTCs and more conventional medical care. The negative and significant coefficients on percent of the population 65 and older indicates that the elderly tend to consume less of these OTCs than the general population. This relationship may be driven by the fact that elderly are more likely to be under the direct care of a physician and taking prescription medications.

Table 3-2. Estimates of Individual Product Demand Functions: H2 Blockers

Independent Variable	Dependent Variable ^a			
	Axid AR	Pepcid AC	Tagamet HB	Zantac 75
Intercept	• 0.18**	• 28.60***	• 1.47**	• 1.31***
Price (Axid)	• 0.70***	• 9.84***	1.11***	• 5.17***
Price (Pepcid)	0.18*	40.00***	2.65*	35.10**
Price (Tagamet)	• 0.06	• 6.56***	• 10.50***	0.49
Price (Zantac)	• 0.08	• 7.81***	3.58***	• 45.80**
Ln Price (Own Price)	0.67***	• 15.80***	3.11**	15.30**
% Below Poverty	0.12	3.08	0.48	3.38***
Physicians per 1,000	• 0.01	• 0.51**	• 0.39***	• 0.18*
Hospital Beds per 1,000	• 0.002***	• 0.07***	• 0.02***	• 0.03***
Per Capita Income	0.00001***	0.0003***	• 0.0001***	0.0002***
% >= 65	• 0.28***	• 6.50***	0.08	• 4.54***
R²	0.88	0.80	0.69	0.86
N[#]	166	166	166	166
Price Elasticity	• 12.22	26.54	• 12.35	• 66.33
Income Elasticity	3.87	3.03	1.39	4.70

^aIn Millions of Units * p < 0.10 ** p < 0.05 *** p < 0.01

[#]Because the price of all competitor's products enters into each demand equation, the sample size is reduced to the observations (time periods and regions) where all products are sold.

Three of the four individual price elasticities of demand (Axid AR, Tagamet HB, and Zantac 75) are negative and significantly higher than the overall market price elasticity (-4.25). For these

products, the coefficients on the competitors' prices are generally negative and significant (5 of 9) or insignificant (3 of 9). These elasticities and coefficients are consistent with our hypothesis of monopolistic competition—while there is some market power exhibited by each brand (otherwise elasticities would be infinite⁴), the elasticities for the individual products are large, indicating a fair amount of substitution (and, therefore, competition) between the products.

The coefficients in the Pepcid AC equation are somewhat anomalous and may be related to Pepcid's position as a market leader. For example, if Pepcid responds to increases in sales volume by raising price, a positive price elasticity could result. These same increases in sales volume may drive competitors to lower prices, yielding negative coefficients on their prices.

Table 3-3. Estimates of Individual Product Demand Functions: Nicotene Replacement Medications

Independent Variable	Dependent Variable ^a		
	Nicoderm CQ(Q)	Nicorette (Q)	Nicotrol (Q)
Intercept	- 0.38	0.17	0.06 ^b
Price (Nicoderm)	0.01	- 0.06 ^{**}	- 0.01 ^{***}
Price (Nicorette)	- 0.02	- 0.03	- 0.01 ^{***}
Price (Nicotrol)	- 0.004	- 0.03 ^{***}	0.003 ^{***}
Ln Price (Own Price)	0.01	0.12 ^{**}	0.01 ^{***}
% Below Poverty	0.43 ^{**}	0.46 ^{***}	0.07 ^{**}
Physicians per 1,000	- 0.14 ^{***}	- 0.08 ^{**}	0.00001
Hospital Beds per 1,000	- 0.005 ^{***}	- 0.01 ^{***}	- 0.0002 ^{**}
Per Capita Income	0.0001 ^{***}	0.00004 ^{***}	0.000003 ^{**}
% >= 65	- 0.54 ^{***}	- 0.48 ^{**}	- 0.008
R²	0.89	0.74	0.93
N	152	152	152
Price Elasticity	0.43	- 1.97	1.25
Income Elasticity	7.47	4.67	4.19

Millions of Units * p < 0.10 ** p < 0.05 *** p < 0.01

⁴ If none of these brands had market power, i.e. the market was perfectly competitive, an increase in price by any one of these producers would result in every consumer switching away from that brand. Elasticities, which measure the percentage change in quantity for a 1 percent change in price, would be arbitrarily large.

The results of the individual demand function estimations for nicotine replacement products are somewhat disappointing. Only Nicorette has a negative price elasticity (-1.97) and this elasticity significantly exceeds the overall market elasticity, supporting the hypothesis that there is some room for substitution between nicotine replacement medications. The negative coefficients on competitors' prices, however, do not support substitution efforts and call into question our ability to accurately analyze the sub-markets of nicotine replacement medications. We can report that we have explored a number of (common) alternative specifications for the demand equations and have been unable to determine the nature of the estimation problem. Our disappointing results may be due to the fact that only two years of data (96/97 and 97/98) were available for analyses. Obtaining additional data should increase the robustness of the analyses.

Table 3-4a. Estimates of Individual Product Demand Functions: Vaginal Antifungal 7-Day Preparations

Independent Variables	Dependent Variable ^a		
	Monistat 7	Gyne Lotimin (7)	Mycelex 7
Intercept	- 0.31***	• 0.04***	0.03**
Price (Monistat 7)	• 0.0054***	0.0023***	• 0.0024***
Price (Gyne Lotrimin)	0.0185***	• 0.0069***	• -0.0021***
Price (Mycelex 7)	0.0079***	• 0.0003	0.0106***
Price (Monistat 3)	0.0046***	0.00001	0.0017***
Price (Gyne Lotrimin 3)	• 0.0024***	0.0015***	0.0009***
Price (Mycelex 3)	- 0.0009	0.0016***	0.0022***
Ln Price (Own Price)	• 0.0223***	0.0017*	0.0055***
% Below Poverty	0.31***	0.08***	• 0.04**
Physicians per 1,000	• 0.02***	- 0.0003	- 0.001
Hospital Beds per 1,000	• 0.001***	- 0.0001***	• 0.0002***
Per Capita Income	0.00001***	0.000002***	• 0.0000002
% >= 65	• 0.20***	0.02***	0.02**
R²	0.82	0.63	0.38
N	96	96	96
Price Elasticity	- 2.01	• 5.68	• 6.78
Income Elasticity	5.47	2.52	• 0.30

^aIn Millions of Units * p < 0.10 ** p < 0.05 *** p < 0.01

Table 3-4b. Estimates of Individual Product Demand Functions: Vaginal Antifungal 3-Day Preparations

Independent Variables	Dependent Variable ^a		
	Monistat 3	Gyne Lotrimin 3	Mycelex 3
Intercept	- 0.16***	- 0.06***	- 0.03***
Price (Monistat 7)	- 0.0051***	0.0007	- 0.0014***
Price (Gyne Lotrimin)	0.0124***	- 0.0057***	0.0023***
Price (Mycelex 7)	0.0047***	0.0001	0.0038***
Price (Monistat 3)	0.0019***	- 0.0010**	0.0024***
Price (Gyne Lotrimin 3)	- 0.0027***	0.0051***	- 0.0012***
Price (Mycelex 3)	- 0.0003	0.0058***	- 0.0067***
Ln Price (Own Price)	- 0.0111***	- 0.0050***	0.0008
% Below Poverty	0.15***	- 0.04***	0.07***
Physicians per 1,000	- 0.01***	0.001	- 0.001***
Hospital Beds per 1,000	- 0.001***	- 0.0005***	- 0.336***
Per Capita Income	0.00001***	0.000002***	0.003***
% >= 65	- 0.16***	- 0.04***	- 0.04***
R²	0.89	0.70	0.76
N	96	96	96
Price Elasticity	0.66	5.23	- 8.91
Income Elasticity	6.86	3.71	9.46

^aIn Millions of Units * p < 0.10 ** p < 0.05 *** p < 0.01

Four of the six price elasticities for vaginal antifungal preparations (Monistat 7, Gyne Lotrimin (7), Mycelex 7, and Mycelex 3) are negative and significantly larger than the overall market elasticity (- 0.09). Coefficients on competitors' prices in the equations are generally positive, although these results are not as strong as those found in the H2 blocker equations. Given the difficulty of obtaining unconditionally "clean" results in this type of research, we can say that our results for the vaginal anticandidal preparations market(s) are relatively consistent with a monopolistic competition model. While the overall price elasticity for the product is almost zero, the price elasticities for individual products within the market are high enough to indicate that competition among substitutable products is occurring.

Summary

- ❑ OTC sales **are extremely large** and growing. For example, the largest category of **OTCs**, internal analgesics, had market sales of almost \$3.1 billion in **1996**.
- ❑ Recent switch drugs represent an increasingly important portion of OTC sales, **especially in** the categories of vaginal yeast infection remedies, sinus medications, allergy relief products, and cold medications.
- ❑ Dollar volume of sales for four recent switch drugs are large and have grown significantly over the past three years.
- ❑ Based on estimation of market demand curves for H2 blockers, nicotine replacement medications, and vaginal anticandidals, we find
 - ❑ Demand for nicotine replacement medications is relatively insensitive to price (inelastic demand), yielding **significant** market power to manufacturers to raise price without losing consumers.
 - ❑ Demands for H2 blockers and vaginal anticandidals are relatively elastic, implying that increases in price will lead consumers to purchase less of the product. ...
 - ❑ All three products appear to be “normal” goods (in the economic sense), meaning that increases in income lead consumers to purchase more of the product. These results are based on the average income for the region.
 - ❑ Interestingly, the percentage of the region’s population below the poverty line (a measure of the skewness of the income distribution, not the average) is also associated with an increase in demand suggesting that lower income populations are more likely to use OTCs.

- That OTCs may actually serve as a substitute for conventional medical care (physician and hospital care) is suggested in the negative relationship between demand for these OTC products and physicians per 1,000 (population) and hospital beds per 1,000.
- The results of our estimation of individual demand curves for specific OTC brands within the three categories are generally consistent with our hypothesis that these OTC markets are characterized by monopolistic competition.
- Coefficients on competitors' prices are generally positive indicating substitution between products.
- Price elasticities for individual products tend to be larger than the overall market price elasticities.
- Individual price elasticities for nicotine replacement medications are the least reliable, perhaps due to the fact that only two years of data (96/97 and 97/98) were available for analyses.

References

Bureau of Labor Statistics, Data available at <http://146.142.4.24/cgi-bin/dsrv>.

Chapter 2: Summary of Key Informant Interviews

I. Introduction

Approximately 600 over-the-counter (OTC) products currently available use ingredients and dosages available only by prescription 20 years ago. While there has been a steady stream of OTC switches since the mid-1970s, the number of switches has accelerated in recent years'. Between 1988 and 1994 there were 14 switches, while in the last three years there were at least 19 switches. There are a number of possible reasons for this trend, including: (1) a growing emphasis on individual autonomy and self-help; (2) a trend toward deregulation in the US; (3) health care cost containment efforts; and (4) pharmaceutical industry self-interest/profit. The issue of Rx-to-OTC switching deserves considerable attention because of the large number of people who could be affected by the trend, including consumers, pharmaceutical companies, physicians, pharmacists, and payers.

The purpose of this project is to provide a comprehensive review and analysis of the Rx-to-OTC switch movement in order to inform policy and define relevant research questions. This report focuses on "switched drugs" and the switch trend--that is, prescription drugs which have been switched to over-the-counter status, with a bias towards an analysis of more recent switches and potential switches.

Our project began with an exhaustive literature review. The results of the literature review in conjunction with discussions with the Research Advisory Group formed the basis for our key informant interviews. Key informant interviews were undertaken to refine the issues and further

Chapter 4: Impact of OTC Switch Drugs on Clinical Practice Patterns**Introduction**

The movement of a drug from prescription (Rx) to over-the-counter (OTC) status represents a significant shift in how clinical care is delivered. First, the patient is empowered to self-treat certain medical conditions on their own. Assuming a relatively constant incidence of the medical condition(s) covered by the OTC, the predicted result of an OTC switch is that physician office visits for that conditions will decrease. A number of other, less obvious, changes in clinical practice patterns may be possible. Preventive health services may be more difficult to deliver because patients have less contact with a health professional. If this is the case, the long-term health effects of OTC availability may need to be considered. It is also possible that physicians, seeking to spare their patients the cost of an OTC, may prescribe a different (although closely-related) medication. Although OTCs, on average, cost less than prescription drugs, OTCs are not generally covered by insurance plans.⁷ Patients who pay \$5 or \$7 for a prescription may find the OTC price too high and, therefore, may fail to purchase the necessary drug. Evidence in Chapter 1 suggests that there is some price sensitivity in the demand for OTCs.

In the sections that follow, we examine empirical evidence of the impact of specific Rx-to-OTC switches on clinical practice patterns. Data from various years of the National Ambulatory Care Survey (NACS) are used to assess the magnitude of any changes. The NACS includes physician-reported data for a random sample of office

visits during a one-week period for a (stratified) random sample of physicians across the US. Data on patient complaint, diagnoses, procedures, and prescribed medications (including OTCs) are collected. The policy implications of our findings and suggestions for further research are presented at the conclusion of this chapter.

Impact of OTC Switch on Physician Office Visits for Vaginitis and Dermatitis

The original antricanidial formulations ('1-day treatments) went OTC in late 1990 and 1991. Gyne-Lotrimin and Mycelex-7 (clotrimazole) were approved by the FDA on November 30, 1990, with Monistat-7 (miconazole nitrate) following their lead on March 13, 1991. In order to examine the impact of these switches on clinical treatment of vaginitis, we conducted a pre-post test analysis of key statistics associated with physician office care of vaginitis. While pre-post analyses cannot rule out the possibility that other factors may be responsible for the changes we observe over time, they do allow us to quantify the changes and carefully examine which factors may be responsible for those changes. In addition, in the absence of a more controlled environment, pre-post analyses may be the only tool available to researchers in assessing the impact of policy changes.

Using 1985, 1990, and 1994 NACS data, we calculated population estimates of the number of times women between the ages of 15 and 64 sought physician care for treatment of vaginitis complaints. Data on the total number of physician office visits for this population (also from NACS), as well as the total number of women in this age

¹Medicaid plans are the one major exception to this statement. Certain state Medicaid plans spend a considerable amount of money on OTCs. For a more complete discussion of Medicaid coverage of OTCs, see Chapter 4.

category (Bureau of the Census), were used to construct estimates (for each of the three years) of:

- (1) the average number of vaginitis visits per woman (15 - 64) per year;
- (2) the average number of physician office visits (all causes) **per** woman (15-64) per year; and
- (3) the ratio of vaginitis visits to all physician office visits for this population group.

Our results are presented in Table 4- 1.

Table 4-1. Average Number of Vaginitis Visits, Average Number of Physician Office Visits, and Ratio of Vaginitis Visits to All Physician Office Visits, Women Ages 15-64: 1985, 1990 and 1994.

	1985	1990	1994
Average Number of Vaginitis Visits Per Woman	0.101	0.09 1	0.070
Average Number of Physician Office Visits Per Woman	3.158	3.099	2.906
Ratio of Vaginitis Visits to All Physician Office Visits	0.032	0.029	0.024

As Table 4- 1 indicates, the average number of vaginitis visits per woman (15-64) have fallen in the post-switch time period (1990-1994). To explore whether the decrease in vaginitis visits is simply a reflection of a larger trend toward fewer physician office visits for this population group, we present data on the average number of physician office visits per woman and the ratio of vaginitis visits to all visits. While it is clear that

the average number of physician office visits per woman 15-64 is declining over the time period 1985-94, the rate of decline is markedly less than that found in the vaginitis visits per woman: the ratio of vaginitis visits to all office visits declines from 0.032 in 1985 to 0.024 in 1994.

Because the decrease in vaginitis visits per woman may also reflect an ongoing trend that began before the OTC switch, we include data from 1985 (pre-switch) for comparison. The average number of vaginitis visits per women fell 10 % in the 5-year period (or approximately 2 % per year) between 1985 and 1990 (from 0.101 per woman per year to 0.091). In contrast, the average number of vaginitis visits per woman fell 23 % in the 4-year period between 1990 and 1994 (from 0.091 to 0.070). If we assume that the 2 % per year decline is a “secular” trend (unrelated to the vaginal antifungal switch), then the other 15 % ($23 \% - 4 \times 2 \%$) decline may be attributable to the availability of OTC vaginal antifungals. This translates into a decrease of approximately 1.1 million vaginitis visits per year as a result of the OTC switch.

“Prescription-strength” hydrocortisone cream (above 0.50 % to 1.0 %) was approved for OTC sale by the FDA on August 30, 1991. In order to examine the impact of these switches on clinical treatment of dermatitis, we conducted a pre-post test analysis of key statistics associated with physician office care of dermatitis. Using 1985, 1990, and 1994 NACS data, we calculated population estimates of the number of times patients (ages 15-64) sought physician care for treatment of dermatitis complaints. Data on the total number of physician office visits for this population (also from NACS), as well as total population estimates (Bureau of the Census), were used to construct estimates (for each of the three years) of:

- (1) the average number of dermatitis visits per person per year;
- (2) the average number of physician office visits (all causes) per person per year; and
- (3) the ratio of dermatitis visits to all physician office visits.

Our results are presented in Table 4-2.

Table 4-2. Average Number of Dermatitis Visits, Average Number of Physician Office Visits and Ratio of Dermatitis Visits to All Physician Office Visits, Ages 15 - 64: 1985, 1990 and 1994

	1985	1990	1994
Average Number of Dermatitis Visits Per Person	0.063	0.058	0.049
Average Number of Physician Office Visits Per Person	2.516	2.555	2.324
Ratio of Dermatitis Visits to All Physician Office Visits	0.022	0.023	0.023

As Table 4-2 indicates, the average number of dermatitis visits has been declining steadily over the 10-year period 1985-94. Since the average number of physician office visits has also been generally declining over the same time period, it is not clear that this trend is nothing more than a reflection of the overall decline in physician office visits for persons 15-64. The ratio of dermatitis visits to all physician office visits has remained remarkably stable over the time period. Thus, it would appear that the switch of hydrocortisone 1 % cream has had little if any impact on the number of patients seeking physician care for dermatitis complaints. What these data cannot tell us is if the composition of patients with dermatitis complaints has changed. Specifically, it is

possible that while the number of dermatitis patients has not changed significantly over the time period, the types of dermatitis complaints may be different (i.e. not treatable with hydrocortisone 1 % cream). With the very general data we are working with, more specific conclusions cannot be drawn.

Impact of OTC Switch on Use of Preventive Services

Some medical experts argue that since the availability of certain OTC medications reduces the need for physician office care, some individuals may fail to obtain proper preventive care. This argument is most acutely voiced in the case of vaginal anticondicals. Public health officials and policymakers agree that pap smear screening for women in adolescence and beyond are a cost-effective method for the prevention of deadly cervical cancer. Yet many women may avoid or put off obtaining this annual exam. It should be noted that woman coming in for treatment of a vaginal yeast infection cannot receive a PAP smear until the infection has cleared. Many physicians note, however, that having contact with a patient will allow them to schedule follow-up visits for preventive care.

Data from the NACS shed some light on the importance of physician contact in delivering pelvic examinations/PAP smears. Using data from the 1985, 1990 and 1994 NACS files, we compared the number of physician office visits during which a pelvic exam or PAP smear was sought with the number of visits where one of these exams/procedures was recorded. Specifically, we calculated:

- (1) Number of office visits per woman (for women ages 15 to 64) for which the visit reason (up to 3 reasons supplied by the woman) was “pelvic examination” or “PAP smear”;
- (2) Number of office visits per woman during which one of the examinations or procedures recorded was “pelvic examination” or “PAP smear/culture”; and
- (3) The ratio of (2) to (3).

The results of our analyses are presented in Table 4-3.

Table 4-3. Number of Office Visits per Woman for Which Visit Reason was Pelvic Exam or PAP Compared With Number of Office Visits per Woman During Which Pelvic Exam or PAP Was Conducted, Ages 15 – 64: 1985, 1990 and 1994

	1985	1990	1994 ²
Number of visits per woman for which the visit reason was pelvic exam or PAP smear	0.068	0.074	0.058
Number of visits per woman during which pelvic examination or PAP smear/culture was done	0.641	0.566	0.300
Ratio of pelvic/PAP reason visits to actual pelvic/PAP visits	0.106	0.130	0.192

As Table 4-3 indicates, many women receive pelvic exams/PAP smears, even though the primary reasons they listed for the physician office visit did not include receiving such an examination. The NACS data support the hypothesis that the ability to

² Significant change in coding of procedures/examinations makes this data point somewhat suspect.

deliver preventive services (such as pelvic exams/PAP smears) is related to “incidental” contact between physicians and patients.

A more direct measure of the impact of OTC availability on preventive care use might be to conduct a pre-post analysis of rates of pelvic exams/PAP smears per woman per year. Although these data are presented in Table 4-3, the 1994 data, unfortunately, are highly suspect. NACS significantly changed the way in which pelvic exams/PAP smears were coded between 1990 and 1994. In both the 1985 and 1990 questionnaires, physicians are given a list of diagnostic services and asked to check all that were conducted for the visit in question. This list of diagnostic services included a pelvic examination. After 1990, physicians were asked to supply ICD-9 codes for all procedures and examinations conducted. Specific reference to pelvic exams/PAP smears was no longer made. Reporting of pelvic exams and PAP smears fell by almost 50 %. For completeness, we provide all of the data; however, given the limitations of this data set, it is impossible to judge the impact of OTC vaginal antifungal availability on use of these preventive services.

Impact of OTC Switch on Physician Prescribing Patterns

One disturbing element of the OTC switch movement is that patients previously relying on insurance-covered prescriptions may be forced to pay higher amounts for drugs that are now OTC instead of prescription-only. According to the Health Insurance Association of America (HIAA), 48 % of the population is enrolled in managed care plans. For this population, the average co-payment for either brand name or generic drugs in 1996 was \$6.33 (Hoechst Marion Roussel, *Managed Care Digest, HMO-PPO*

Digest 1996). Data on the average co-payments for the Fee-For-Service (FFS) population are not available (39 % of population in 1996). HIAA data suggest that coverage of prescription medications is less complete for this population. For those who do have prescription coverage, plans usually require the insured to pay 20 % of prescription costs after meeting an annual deductible. With an average wholesale price (AWP) of vaginal yeast infection drugs of \$24.49 in 1996, this amounts to a \$4.90 copayment. In that same year, the average price of an OTC vaginal anticondial was \$13.17 (Kline & Company, Inc., 1997). We do not have data on the average price of hydrocortisone products, although current prices are in the \$5 to \$7 range [CHECK].

Although the differences between prescription drug copayments and OTC prices are small to moderate, our data on price elasticities of demand (presented in Chapter 3) suggest that they may have an effect on an individual's willingness to use OTCs. It is possible that some physicians, sensitive to their patients' unwillingness or inability to pay, may prescribe alternative medications that are available by prescription. We are not suggesting that this modification in treatment plan is medically inappropriate; We will, however, point out that (1) the presence of OTC medications may affect physician treatment decisions; and (2) the cost savings normally attributable to OTC availability may be diminished by the practice of "substituting" prescriptions.³

Again using data from the 1985, 1990, and 1994 NACS, we calculate the prescription rates for commonly-prescribed (OTC and non-OTC) medications used in the treatment of vaginitis and dermatitis. Patient complaint (reason) was used to identify vaginitis and dermatitis visits. Physician-recorded data on recommended medications

³This point is more thoroughly discussed in Chapter 6, where we present data on Medicaid coverage of OTCs.

was used to identify whether one of the commonly-prescribed vaginitis (or dermatitis) drugs was prescribed. Data on dosages was not available.

Table 4-4 presents the percent of vaginitis physician office visits treated with commonly-prescribed (OTC and non-OTC) medications for women ages 15-64.

Table 4-4: Percent of Physician-Office-Based Vaginitis Cases Treated with Commonly-Prescribed (OTC and non-OTC) Medications, Women, 15-64: 1985, 1990 and 1994

	Percent of Vaginitis Cases Treated with Drug		
	1985	1990	1994
<i>Anti-Fungal Topical</i>			
Butoconazole Nitrate	0.00	2.62	0.36
Clotrimazole	8.56	3.10	3.96
Miconazole	17.24	11.43	5.04
Nystatin	1.53	1.19	1.08
Terconazole	0.00	10.00	9.35
Total Anti-Fungal Topical	27.33	21.53	19.78
<i>Non-Fungal Topical</i>			
Combination Product	26.05	20.00	0.00
Povidone-Iodine	2.30	0.24	0.36
Total Non-Fungal Topical	28.35	26.39	0.36
<i>Oral Medications</i>			
Antibiotics	12.01	13.89	10.07
Antifungals	13.54	17.71	17.27
Antivirals	0.89	0.69	0.36
Hormone Replacement	3.70	5.21	4.32
Total Oral Medications	30.14	37.50	32.01
Total All Medications	85.82	85.42	52.15

Table 4-4 highlights trends in a number of important topical anti-fungals used to treat vaginitis (caused by candidiasis). Two of these medications, clotrimazole and miconazole, switched to OTC late in 1990. A steady decrease in the number of prescriptions for these drugs reflects this switch. Interestingly, the number of terconazole prescriptions for vaginitis complaints increase significantly over the 10 year time period. However, this increase is more likely to be due to the introduction and popularity of the medication rather than the OTC switch of clotrimazole and miconazole-the prescription rate (per vaginitis visit) for terconazole remains virtually unchanged between 1990 (the year immediately preceding the switch) and 1994. Based on these data, we cannot find any significant impact of vaginal antifungal switches on physician prescription patterns.

In order to conduct a similar analysis for dermatitis and hydrocortisone, we examined physician-office-visit data from the same time periods (1985, 1990, and 1994). Table 4-5 presents the percent of dermatitis physician office visits treated with commonly-prescribed (OTC and non-OTC) medications for all patients ages 15 to 64.

Table 4-5: Percent of Physician-Office-Based Dermatitis Cases Treated with Commonly-Prescribed (OTC and non-OTC) Medications, Ages 15-64: 1985-1990 and 1994

	Percent of Dermatitis Cases Treated with Drug		
	1985	1990	1994
<i>Topical Steroids</i>			
Betamethasone	8.29	3.39	4.09
Clobetasol Propionate	0.00	3.54	2.37
Clocortolone	3.09	0.00	0.00
Desonide	1.11	1.33	2.80
Desoximetasone	3.34	2.95	1.29
Dexamethasone	2.23	1.62	0.86
Diflorasone	1.49	2.21	0.86
Fluocinolone	1.86	1.62	1.72
Fluocinonide	4.33	4.57	3.88
Hydrocortisone	9.03	8.85	6.25
Mometasone Furoate	0.00	3.98	3.45
Triamcinolone	11.26	6.64	10.99
All Other Topical Steroids (6)	2.22	2.20	1.52
Total Topical Steroids	48.27	42.92	40.09
<i>Oral Steroids</i>			
Methylprednisolone/Prednisolone	2.10	3.54	2.16
Prednisone	6.44	4.87	6.47
Total Oral Steroids	8.54	8.41	8.62
<i>Other Oral Agents</i>			
Cyproheptadine (antihistamine)	1.24	0.59	0.00
Diphenhydramine (antihistamine)	6.06	3.10	4.09
Hydroxyzine (anxiolytic/antipuritic)	0.12	7.67	6.25
Total Other Oral Agents	7.42	11.36	10.34
<i>Other Topical Agents</i>			
Acne Medications	0.99	3.83	8.62
Antibacterials	0.12	1.03	1.08
Antifungals	8.66	9.59	9.05
Cleansers	0.50	0.59	0.43
All Other Topical Agents (11)	3.84	4.57	3.88
Total Other Topical Agents	14.11	19.62	23.06
Total All Medications	78.34	82.30	82.11

As Table 4-5 indicates, prescription patterns for dermatitis complaints have changed somewhat over the 10 year period we examine. Specifically, hydrocortisone was prescribed less often after its switch, a number of topical steroids enjoyed increasing popularity in the 1990s (clobetasol propionate, mometsone furoate), hydroxyzine as an anxiolytic became more widely used to treat dermatological complaints, and more effective acne medications were available. There is very little evidence, however, that the OTC switch of hydrocortisone in 1990 had a significant impact on the treatment of dermatitis between 1990 and 1994. The only medications that were significantly more often prescribed in 1994 over 1990 and 1985 levels were acne medications. Given the relatively narrow therapeutic window for these medications and the advances in acne treatment over this time period, it is unlikely that this change is a result of the hydrocortisone switch.

Summary

- The average number of vaginitis visits per woman (15 - 64) has fallen significantly in the post-switch time period (1990-1994), and it does not appear that this decrease is entirely attributable to the overall decline in physician office visits.
- We estimate that the OTC switch of vaginal anticandidals resulted in a decrease of approximately 1.1 million vaginitis visits per year.
- Our data indicate that the OTC switch of the more potent version of hydrocortisone (1%) had little if any impact on the number of patients seeking physician care for dermatitis complaints.

- According to National Ambulatory Care Survey data, many women receive pelvic exams/PAP smears even though the primary reason for their physician office visit was not receiving these services. In fact, only 10 to 20 % of women who actually receive these preventive services indicated that a pelvic exam/PAP smear was the primary reason for their visit.
- Although prescription rates for clotrimazole and miconazole decreased significantly after these medications switches to OTC, there does not appear to be a significant increase in the prescription rates for other “substitute medications”.
- Prescription rates for hydrocortisone also fell after the medication went OTC. The only related dermatitis drugs that was prescribed significantly more in 1994 than in 1990 and 1985 were those used for the treatment of acne (e.g. benzoyl peroxide, tretinoin).

Chapter 5: Costs and Benefits of OTC Anticandidal Availability

Introduction

Estimates of the economic benefit of OTC anticandidal availability range from \$505 million (Kline & Company, Inc., 1997) to \$1.46 billion (see Chapter 3). These savings are certainly substantial. However, given the seriousness of the potential complications of non-candidal causes of vaginitis, it is important to carefully examine the impact of OTC anticandidal availability on health outcomes. In this chapter, we carefully outline the potential negative outcomes associated with the OTC switch and the likelihood of their occurrence in order to balance any negative effects on outcomes with the benefits of OTC switch. Drawing on a sizeable epidemiological and medical literature, we construct a decision tree that highlights what researchers do and do not know about treatment of vaginitis today. This analysis not only provides insight into the costs and benefits of OTC anticandidals, but it also highlights where further research is necessary to make evidence-based policy decisions.

Background

When a woman experiences symptoms of vaginal irritation, pain, or unusual discharge, a physician's initial diagnosis will often be "vaginitis"—inflammation or infection of the vagina. While *candida albicans* (the organism an OTC anticandidal is designed to treat) is a common cause of this condition, it is not the most common cause. In fact, only about 15 to 25 % of vaginitis cases prove to be caused by *candida* (Sobel, 1997; National Ambulatory Care Survey [NACS], 1994, 1995). Other common causes include bacterial vaginosis (30 – 40 %) and

Trichomonas Vaginalis (15 – 20 %) (Sobel, 1997). In post-menopausal women, atrophic vaginitis is also a common cause (20 %) (NACS, 1994,1995). Less common causes include other sexually transmitted diseases (STDs), pelvic inflammatory disease (PID), and non-infectious causes (irritants, allergic reactions) (Sobel, 1997). **Bacterial** vaginosis, Trichomoniasis, **STDs**, and PID have serious complications if left untreated: increased risk of premature labor and delivery in pregnant women, ectopic pregnancy, infertility, and recurrent PID. Having vaginal anticandidals available OTC increases the risk that some women will self-treat their vaginitis and fail to seek appropriate and timely medical care. These complications should be explicitly considered in any policy analysis of OTC anticandidal availability.

The analysis presented in this chapter is a cost-benefit analysis. Dollar values are assigned to all of the identified benefits and costs associated with the OTC switch in order to facilitate their comparison. If the magnitude of the benefits exceed the costs, this OTC switch is considered cost-beneficial. The Food and Drug Administration (FDA) does not require that manufacturer's demonstrate cost-benefit in their application to switch a drug from prescription to OTC. In fact, "cost" is not even one of the criteria. While the FDA has not established formal guidelines regarding which medications are suitable candidates for switch, FDA officials discuss the following areas of consideration:

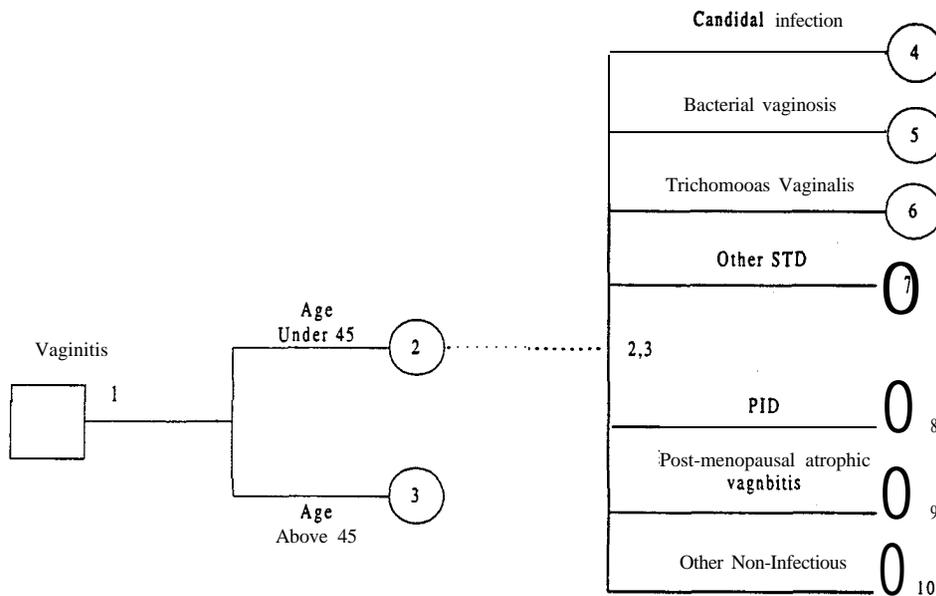
1. Safety;
2. Low potential for misuse and abuse;
3. Ability of average consumer to self-diagnose, self-recognize, and self-treat the condition for which the medication is appropriate without the supervision of a health professional; and
4. Labeling must be adequately understood by the average consumer.

We would argue that “costs” and “benefits” in a cost-benefit analysis quantify all that is positive (benefits) and negative (costs) about a policy change. This includes explicit consideration of the risks associated with unsafe use, misuse/abuse, inability to self-diagnose and self-treat without physician supervision, and inability to understand labeling. Thus, our analysis is useful for two reasons: (1) it provides a more complete picture of benefits and costs of an OTC switch; and (2) it highlights what is known about OTC use and where further research is needed (e.g. patterns of use, decisions to seek professional care when symptoms persist).

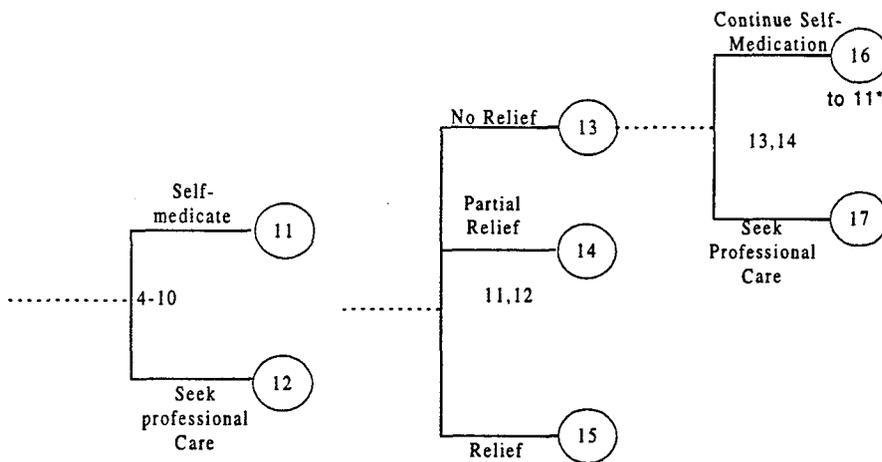
Methods

To evaluate the costs of OTC availability of vaginal anticandidals, we have modeled consumer decisions and health outcomes associated with vaginitis in the form of a decision tree (see Figure 5-1). We have attempted to highlight the important events and decisions in the process, while, at the same time, maintaining a simple and understandable model; thus, the model represents a simplification of all the decision and outcome points in the (self) treatment of vaginitis. Because the focus of our model is on the outcomes of self-care relative to professional care, we define “seek professional care” as an endpoint in the model. Relief of symptoms is also endpoint in the model (although long-term consequences of failure to appropriately treat may still follow). All outcomes associated with self care are defined relative to the outcomes that would be associated with a patient under the care of a physician or that would occur in the general population.

Figure 5-1. Decision Tree to Evaluate Costs Associated with OTC Anticandidal



Availability



* Each Cycle represents two weeks of self-medication

The model begins with symptoms of vaginitis. Given the relationship between age and underlying cause of vaginitis, we separate our analyses into two age categories: age 15 - 44 and over age 45. According to 1995 Census data, 57.65 % of woman ages 15 and older are between the ages of 15 and 44; correspondingly, 42.35 % of these women are 45 or older. After reviewing data from the National Ambulatory Care Survey (NACS; 1995,1996) as well as vaginitis epidemiology literature, we identified seven primary conditions causing vaginitis. The underlying causes of vaginitis are the next set of nodes in the decision tree. The probability that a woman suffers from one of these causes can differ by age category.

The next node in the tree determines whether or not a woman will self-medicate with an OTC anticandidal given her vaginitis symptoms. Data on this probability are extremely limited, and we based our estimate (52.6 %) on overall estimates published by Kline & Co. (1997). Assuming one rate for self-medication is certainly a simplification of reality. Since the labeling on anticandidal packages warns women who have not been previously diagnosed with a yeast infection to seek a physician's diagnosis before using the product, it is likely that first-time sufferers have a lower rate of self-medication. In addition, there is some evidence that the elderly are less likely to use OTCs than their younger counterparts. However, additional stratifications of the analysis (first-time user versus not; 65 and older vs all other age categories) would significantly increase the complexity of the analysis, and accurate data on self-medication within these categories is not available.

Women are next differentiated by the level of relief that they receive from the OTC anticandidals they use (given self-medication). Three outcomes are possible at this node: no relief, partial relief, and (complete) relief. For simplicity, we do not model recurrent symptoms (although this is certainly an important issue in treatment of vaginitis). Instead, we classify these

women as “partial relief”. While, technically, this is not an equivalent classification, the actions taken by women (self-medicate, seek professional care) and the timing of those actions can be modeled similarly.

Because we do not directly model recurrences, “relief” is considered an endpoint in the model. As Table 5-1 indicates, only women suffering from **candida** actually experience complete relief in our model. Women who experience partial relief or no relief have two options: continue self medication (in which case, they “loop back” to the self-medicate node (#1 1)) or seek professional care (which is an endpoint in the model). Women who “loop back” to self-medication are presumed to re-evaluate their condition on a two-week cycle. That is, those with partial relief and no relief who decide to continue self-medication will make subsequent decisions regarding self-medication at two-week intervals. If, at any point in time, a woman elects to seek professional care, she has reached an endpoint in the model and is no longer actively involved in the decision tree.

Table 5-1. Probabilities Used in Decision Analysis

Outcome	Probability By Age Group	
	15 - 44	> 45
Candidal Infection ^{1,2}	0.250	0.250
Bacterial Vaginosis ^{1,2}	0.300	0.300
Trichomoniasis ^{1,2}	0.200	0.200
Venerial Disease ²	0.024	0.001
Pelvic Inflammatory Disease ²	0.065	0.001
Post-Menopausal Atrophic Vaginitis ²	0.012	0.217
Other Non-Infectious Inflammation ²	0.149	0.031
Self Medicate ³	0.526	0.526
Relief with Anti-Candidal for Candidal Infection ⁴⁻²³	0.857	0.857
Relief with Anti-Candidal for Other Causes	0.333	0.333
Partial Relief with Anti-Candidal for Other Causes	0.333	0.333
Partial Relief – Seek Professional Care	0.100	0.100
No Relief – Seek Professional Care	0.500	0.500
<i>Complications (Increased Risk)</i>		
Bacterial Vaginosis (undiagnosed for 3 months)		
Pre-term Labor in Pregnancy/Pre-term Birth ²⁴⁻²⁵	0.013	0.000
Pelvic Inflammatory Disease (PID)	0.100	0.100
Trichomoniasis (undiagnosed for 3 months)		
PID	0.100	0.100
Venerial Disease		
PID ²⁶	0.200	0.200
PID (undiagnosed for 3 months)		
Recurrent PID	0.250	0.250
PID		
Ectopic Pregnancy ²⁶⁻²⁷	0.015	0.000
Infertility (1 episode) ²⁶	0.100	0.100

¹Sobel (1997); ²National Ambulatory Care Survey (1994, 1995); ³Kline & Co., 1997; ⁴Kaufman et al (1989); ⁵Brown et al (1986); ⁶Lebherz et al (1983); ⁷Hirsch (1989); ⁸Droegemueller et al (1984); ⁹Robertson (1978); ¹⁰Adamson (1986); ¹¹Miller et al (1984); ¹²Kjaeldgaard (1986); ¹³Brewster et al (1986); ¹⁴Mizuno and Cho (1983); ¹⁵Robertson (1980); ¹⁶Stein et al (1986); ¹⁷Milne and Wamock (1979); ¹⁸Loendersloot et al (1985); ¹⁹Lebhertz et al (1985); ²⁰Gabriel and Thin (1982); ²¹Milsom and Forssman (1982); ²²Stettendorf et al (1982); ²³Cohen (1985); ²⁴Eschenbach (1993); ²⁵Klebanoff et al (1989); ²⁶Padian and Washington (1994); ²⁷Anonymous (CDC) (1995).

Table 5-1 outlines the probabilities that were used in the decision tree. These data were derived from epidemiological and medical literature as well as NACS data for the years 1994 and 1995. Outcome or decision probabilities that do not have a source footnoted are estimates and will be discussed further in the sensitivity analysis.

Based on the data outlined in Table 5-1, we estimate that 1 percent of women with unresolved vaginitis symptoms will not seek professional care within a 3-month period (the overall time-frame for our model). Approximately 74 % of these women will have conditions that could lead to serious long-term complications.¹ Table 5-2 outlines the estimated costs of these adverse health outcomes. Combining these data with those in Table 5-1, we estimate that the cost per person of OTC anticandidal availability is approximately \$3.83. Note that this estimate only includes the direct costs of medical care associated with the adverse health outcomes. Including indirect costs such as work time lost, pain and suffering, and value of lives lost (through ectopic pregnancy and infertility) would substantially inflate this figure.

Table 5-2. Estimated Probabilities and Costs of Complications

Complication	Estimated Direct Cost	Data Source
Premature Labor/Delivery	\$5,963/case	NM Consensus Panel (1995) Klebanoff et al (1989)
PID	\$2,700/episode	Washington and Katz (1991)
Ectopic Pregnancy	\$6,937/case	Washington and Katz (1993) Alexander et al (1996) Creinin and Washington (1993)
Infertility	\$8,148/case seeking care Assume 50 % seek care	Griffin and Panak (1998) VanderLaan et al (1998)

¹ Undiagnosed *candida*, post-menopausal atrophic vaginitis, and other non-infectious causes of vaginitis are presumed to have negligible long-term side-effects. Of the 20 articles we reviewed assessing the effectiveness of miconazole and clotrimazole, very few side effects were noted, and all of these were mild to moderate, disappearing after use of these products was discontinued. While post-menopausal atrophic vaginitis may be somewhat painful, serious complications associated with this condition are very rare. Non-infectious causes of vaginitis may be serious if they lead to PID. However, given the relatively unspecific nature of the data available in the NACS, we have chosen not to speculate on this probability.

Comparing these costs with the estimated benefits estimated in our Literature Review (Chapter 3), we estimate that the benefit-cost ratio of OTC switch of vaginal anticandidals to be approximately 16.17 (Benefits per person = \$61.95; cost per person \$3.83). That is, based on the cost and probability data available to us, each \$1 cost incurred through increased risk of negative health outcomes is associated with a \$16.17 savings through office visits and prescriptions avoided (see Literature Search for benefits calculation). We would emphasize, however, that this ratio is based on a number of assumptions that need to be investigated more thoroughly before confidence can be placed in our estimates.

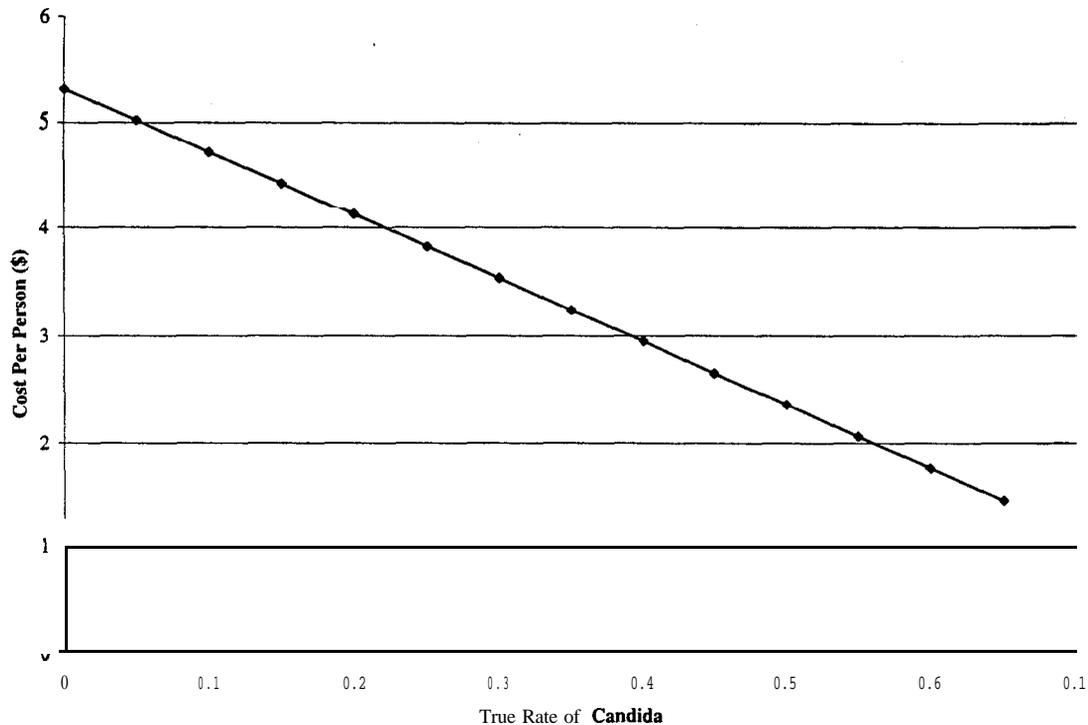
This cost estimate is also based on direct costs only. One study of the costs of PID (Washington and Katz, 1991) estimated the total direct costs of the disease to be \$2.7 billion and the indirect costs (including lost productivity due to PID-associated disability or premature death) to be \$1.5 billion—a ratio of indirect to direct costs of 0.55. The authors calculated the cost of premature death on the basis of lost productivity. Using this conservative estimate of indirect costs, the benefit-cost ratio falls to 10.42. Many economists elect a less conservative approach to valuation of life: willingness to pay. Instead of simply valuing a person's life based on how much they could have earned or produced, economists have tried to elicit how much a person's life is "worth" to them. The former approach can be extremely biased against older persons, women, and minorities, since they typically earn substantially less than white males. The "willingness to pay" framework elicits valuations by asking representative individuals how much they are willing to pay for a product or program that will reduce their risk of death and calculating their valuation of life based on responses. For example, "Are you willing to pay \$20 for a smoke detector that will reduce your probability of death by 0.0001 (over the life of the product)?" If yes, this person's valuation of their life is at least \$200,000 ($\$20/0.0001$). The

greatest problem with willingness to pay analysis is that a person's perception of the probability of death are often somewhat removed from reality. For example, some individuals appear to be willing to pay relatively large sums of money to marginally improve airline safety even though the probability of death in an airplane crash is extremely small. Many of these same people, however, do not purchase smoke detectors, even though the probability of a house fire is not nearly as remote. Both productivity and willingness-to-pay-based measures of the value of life are imperfect measures and should be used cautiously by policymakers.

Sensitivity Analyses

A number of probabilities used in the cost-benefit analysis presented above are only estimates based on impression rather than scientific evidence. Unfortunately, some of the data that we need for our analyses do not exist. In cases such as these, cost-benefit analyses can be augmented by sensitivity analyses. These analyses re-calculate benefit-cost ratio based on alternative assumptions for the probabilities in question to identify which estimates are critical to benefit-cost ratios derived and what range of estimates produce reasonable results;

Candida Rate. Although our data on the fraction of vaginitis cases that represent candida are based on published studies and publicly available data, in specific populations, these proportions may differ. Figure 5-2 presents the costs per person (of OTC anticandidal availability) for Candida rates ranging from 0 to 65 %, with the increases (or decreases) evenly divided over bacterial vaginosis and trichomoniasis.

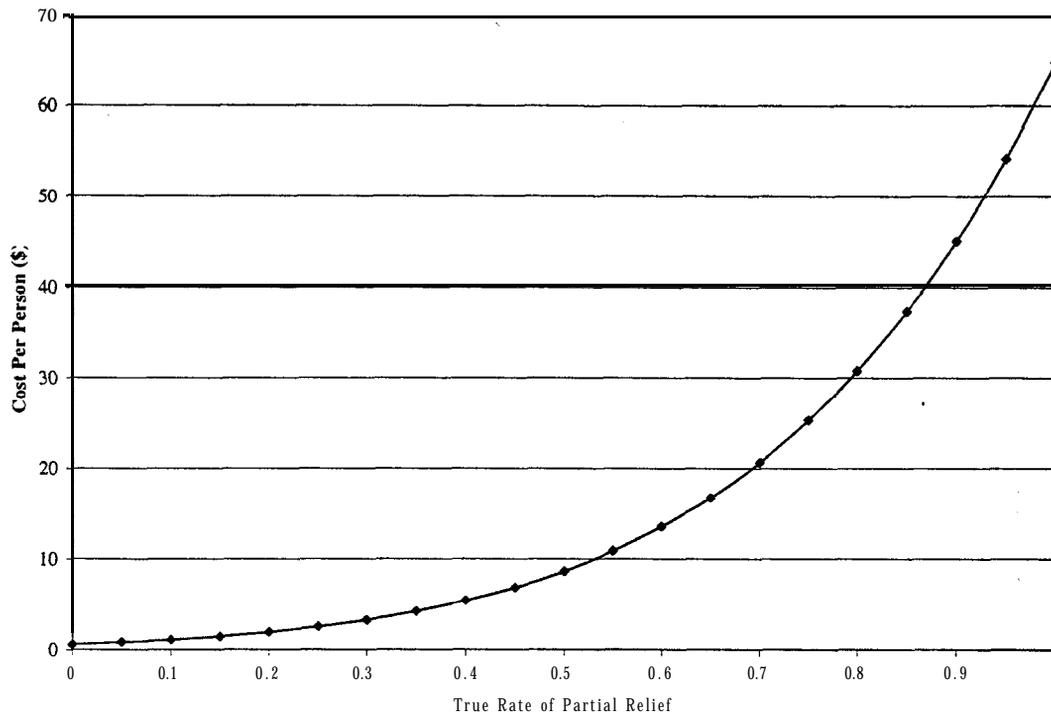
Figure 5-2. Cost Per Person for Various Candida Rates (As % of Vaginitis Cases)

As is evident from Figure 5-2, as the true rate of candida in the population increases, the cost per person from the OTC switch decreases. The range of costs (\$1.47 – \$5.31) is relatively small indicating that the model (and conclusions based on the model) is not particularly sensitive to the true rate of candida in the population.

Partial Relief for Non-Candidal Causes of Vaginitis. We were unable to find any data on levels of relief provided by anticandidals for non-candidal causes of vaginitis. Although it is clear that antifungals will not address the root cause of vaginitis caused by non-candidal infection (or non-infectious causes), the placebo effect and the passage of time may yield perceived “partial relief”. “Normal” women who have physiological symptoms such as discharge (which they interpret to be pathogenic) are also likely to experience “relief” from these

symptoms after OTC anticandidal use. Figure 5-3 presents the costs per person for partial relief rates ranging from 0 to 100 %.

Figure 5-3. Cost Per Person for Various Partial Relief Rates

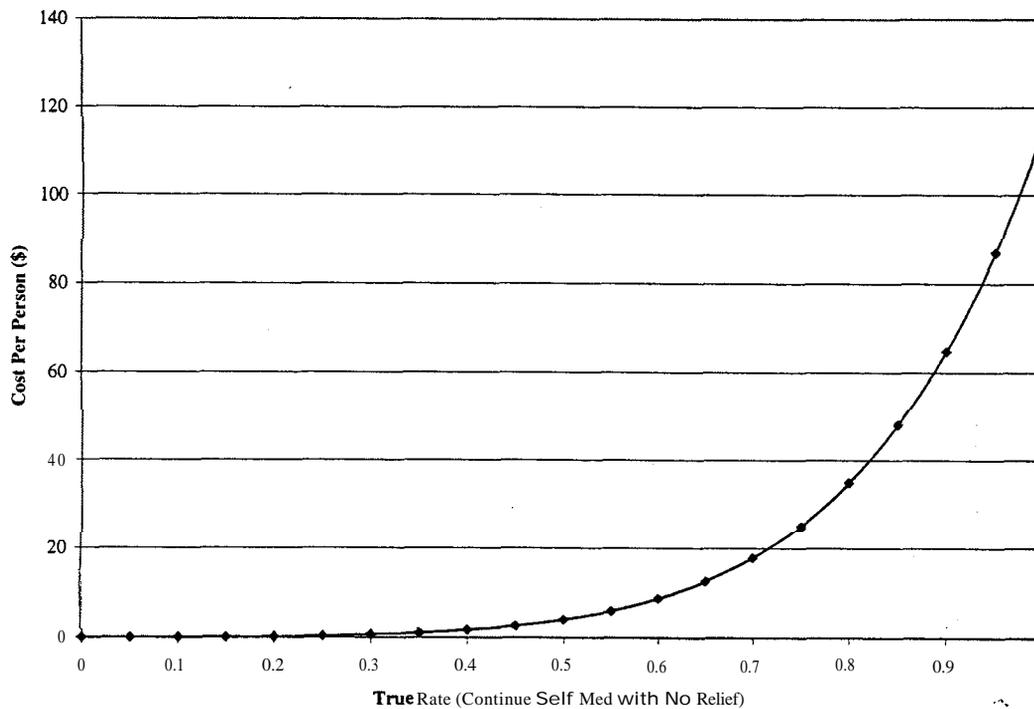


As Figure 5-3 indicates, there is an exponential relationship between true rates of partial relief and the cost per person of the OTC switch. Above partial relief rates of 30 to 40 %, costs per person start to escalate rapidly. The high range of costs per person (as high as \$64.85 for 100 % relief rates) indicate that this probability may be one that needs to be understood better.

Continuation of Self-Medication With No Relief From Anticandidal. We were unable to find data on continuation of self-medication in the face of “no relief”. Although public policymakers may presume this rate is low or zero, we believe that this is still an empirical question. Figure 5-

4 presents the costs per person for continuation of self-medication (with no relief) from 0 to 100 % of (no relief) individuals.

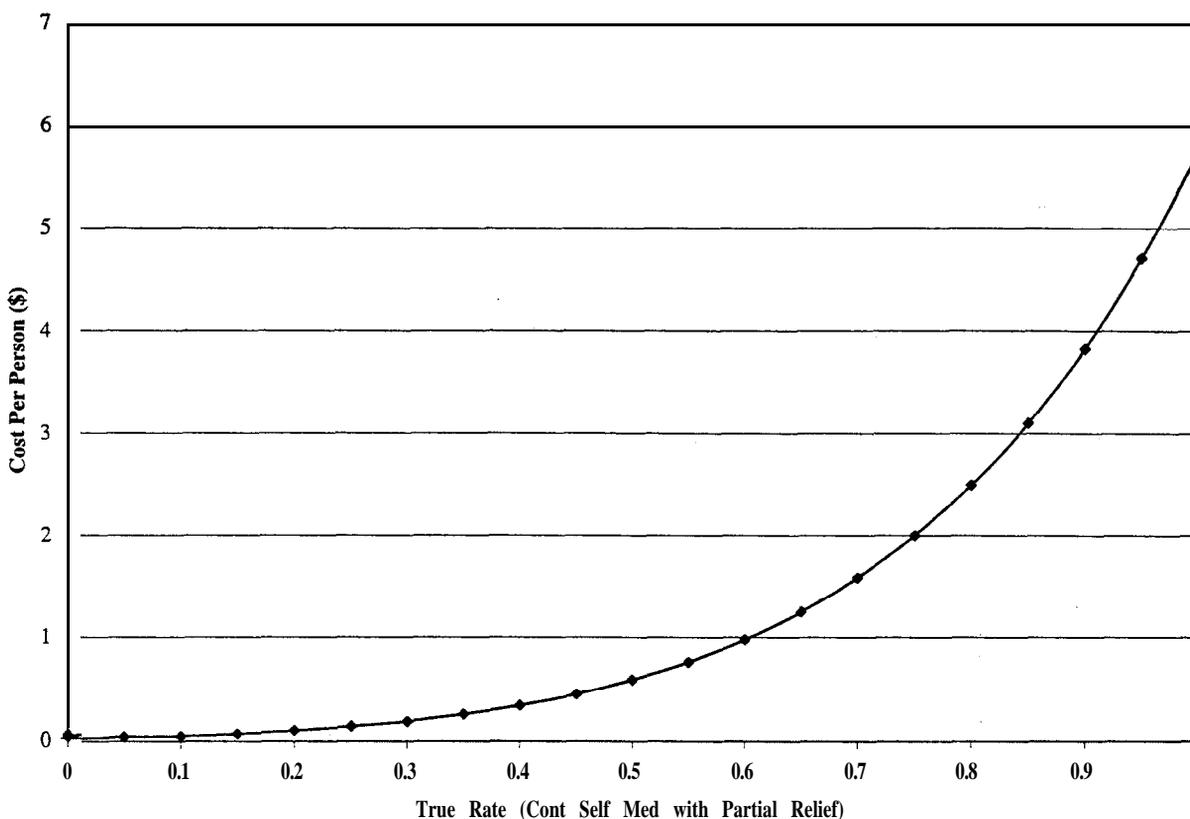
Figure 5-4. Cost Per Person for Various Self-Medication Continuation Rates (No Relief with Anticandidal)



Again, we observe an exponential relationship between the probability of interest and the cost per person of the OTC switch. This time, however, the cost per person does not appear to increase precipitously until the self-medication continuation rates (for no relief) exceed 0.5.

Continuation of Self-Medication with Partial Relief. It is quite likely that some women may continue to self-medicate if they obtain “partial relief” through the use of anticandidals. Figure 5-5 presents the costs per person for continuation of self-medication (with partial relief) for 0 to 100 % of (partial relief) individuals.

Figure 5-5. Cost Per Person for Various Self-Medication Continuation Rates (Partial Relief)



Again we see an exponential relationship between self-medication continuation rates and cost per person. In the case of these rates, it appears that even 100 % continuation rates would not produce significant costs. This outcome is primarily due to the fact that self-meditators “cycle back” every two weeks, and, therefore, have a 0.66 probability of experiencing “no relief” in each subsequent period (and increasing their likelihood of seeking professional care).

Probabilities of PID Following Vaginitis Due to Infectious Causes. The probability that STDs lead to PID is relatively well-documented at about 20 %, although some authors believe that this rate could be as high as 0.40.²⁶ Although there is considerable evidence to demonstrate

that bacterial vaginosis and trichomonal vaginalis are also associated with **PID**, no quantified relationship is reported in the literature. We have estimated that 10 % of these cases lead to **PID**. Figure 5-6 presents the costs per person for weak (0 %) to very strong (100 %) relationships between these causes of vaginitis (bacterial vaginosis and trichomonal vaginalis) and **PID**.

Figure 5-6. Costs Per Person for Various Probabilities of PID Following Vaginitis from Bacterial Vaginosis and Trichomonal Vaginalis

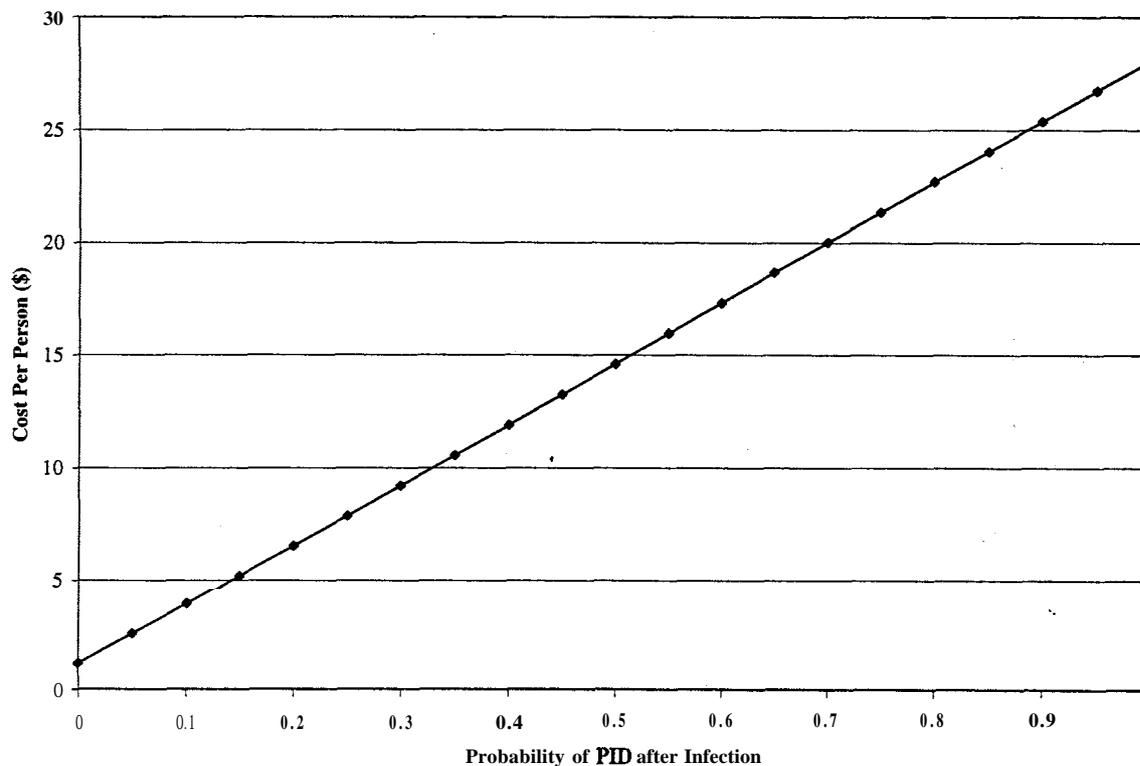
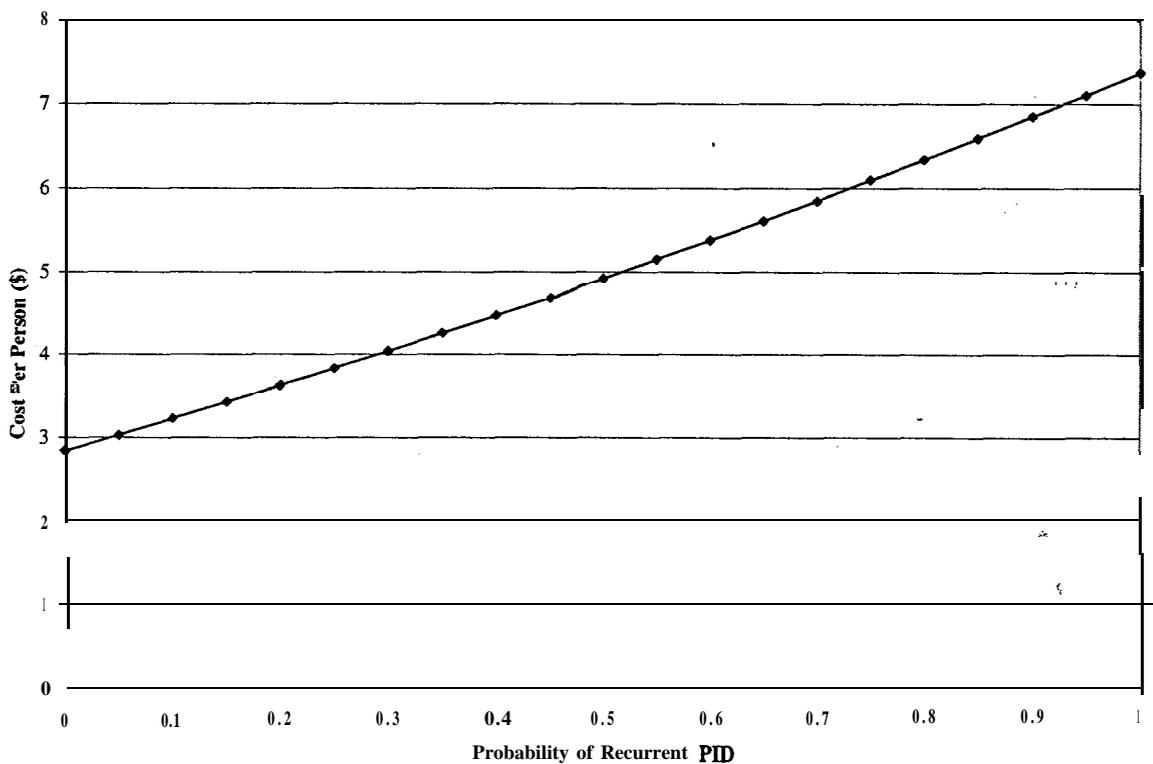


Figure 5-6 demonstrates that there is a relatively linear relationship between probability of **PID** following vaginitis (from bacterial vaginosis and trichomonas vaginalis) and cost per person. This figure also demonstrates that, given the relatively high number of individuals who eventually obtain professional care (in our baseline model), the probability of **PID** is not that important (range of costs for 0 to 100 % association: \$1.14 - \$28.10). The interactive relationship between this probability and partial relief rates (Figure 5-3) or the rate that women

continue self-medication with no relief (Figure 5-4) on costs per person is, however, substantial (see two-way sensitivity analysis in next section).

Probability of Recurrent PID. The epidemiological and medical literature document that there is a strong relationship between initial and subsequent episodes of PID (with increasing likelihood of infertility). We were unable to find a quantified probability that one episode of PID would lead to a recurrent episode. Figure 5-7 presents the costs per person for a range of probabilities for recurrent PID from 0 to 100%.

Figure 5-7. Cost Per Person for Various Rates of Recurrent PID

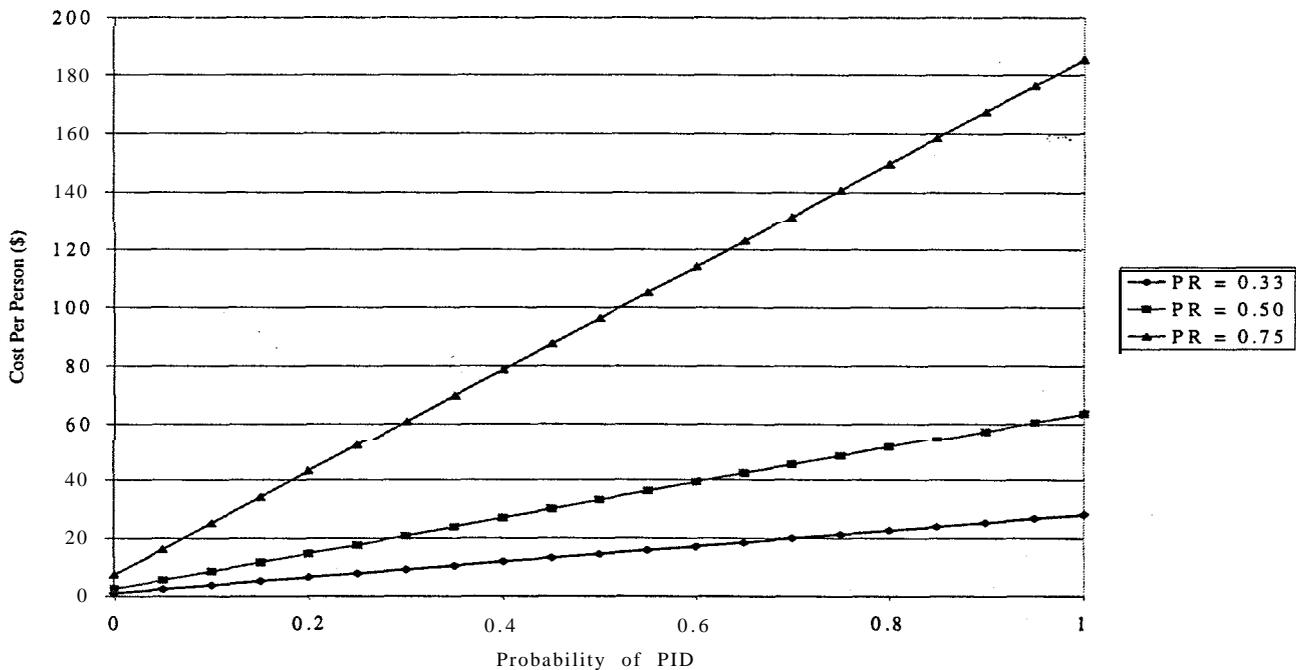


The relationship between probability of recurrent PID and cost per person is linear and within a relatively small range (\$2.84 - \$7.37). Similar to probability of PID following infectious

vaginitis, this range would be augmented by changes in partial relief rates and (no relief) self-medication continuation rates.

Two-way Sensitivity Analysis: Probability of PID Following Infectious Vaginitis and Partial Relief Rates. All of the sensitivity analyses presented so far have been one-way sensitivities. Because of the complexity of the model, however, these analyses may provide a somewhat incomplete picture of the costs of OTC anticandidal availability. Figure 5-8 illustrates how the interdependencies between the various probabilities may affect the costs of the OTC switch.

Figure 5-8. Cost Per Person for Various Probabilities of PID Following Infectious Vaginitis, by Rates of Partial Relief (PR): Two-Way Sensitivity Analysis



The lowest line in Figure 5-8 presents the initial one-way sensitivity analysis, plotting costs per person as a function of various probabilities of PID following infectious vaginitis (0.0 - 1.0). This plot is based on the (baseline) assumption that 33 % of women with non-candidal causes of vaginitis will experience partial relief of their symptoms using OTC anticandidals. The second and third plots illustrate the relationship between costs per person and probabilities of PID if the partial relief rate rises to 50 % or 75 %, respectively. While the range of costs per person are relatively small for the 33 % and 50 % partial relief rates, the range becomes quite alarming for 75 % partial relief rates. Consider the following example: a probability of PID following infectious vaginitis of 0.4 is associated with a cost per person of \$11.92 when the partial relief rate is 33 %. This cost rises to \$27.00 when the partial relief rate is 50 % and to \$78.59 when the partial relief rate is 75 %. Thus, while the one-way sensitivity analysis appeared to indicate that the probability of PID following infectious vaginitis is not of significant importance to the model, this finding is critically dependent on the true value of the partial relief rate (and, perhaps, other variables in the model).

Discussion

The analyses presented in this chapter highlight a number of important policy issues that deserve consideration. According to our estimates of the probabilities of certain events and decisions\ in the current self-treatment of vaginitis, the availability of OTC anticandidals is cost-beneficial. However, our analysis points out that a number of very important probabilities are not well understood. These probabilities include: rates of partial relief for non-candidal causes of vaginitis, self-medication continuation rates for no relief and partial relief of vaginitis

symptoms, probabilities of **PID** following vaginitis from non-candidal infectious causes, and rates of recurrent PID.

We believe that the estimated probabilities that we used in our model are somewhat conservative, but reasonable. Anecdotal evidence from physicians indicates that some women, either as a result of the passage of time or a failure to perceive the potential seriousness of their symptoms, experience “partial relief” of their symptoms. The National Ambulatory Care Survey provides evidence that some women may be seriously delaying treatment for non-candidal causes of vaginitis: in Chapter 4, we estimate that the OTC availability of vaginal anticandidals has led to a decrease in approximately 1.1 million physician office visits. While it is possible that many of these women are appropriately self-treating candidal infections, it is also likely that some percentage of these visits represent women inappropriately avoiding professional care for non-candidal causes of vaginitis.

Our analysis is based on assumption that once a woman obtains care from a professional, it will be the most appropriate care for her condition. This, of course, is an oversimplification of reality, since the differential diagnoses of candida, bacterial vaginosis, and trichomoniasis (not to mention other, more rare causes of vaginitis) are sometimes quite difficult to make. Professional care, however, remains the “gold standard” of care available to women with vaginitis, and, therefore, must serve as our baseline for comparison of costs. Given the long-term probability of a missed diagnosis, we believe that the bias introduced through this simplification is minimal.

Given the limitations our analysis, we believe that this chapter can make some important contributions to health services and health policy research. First of all, our analysis carefully delineates the major costs of OTC anticandidal availability and the mechanisms by which these

costs are imposed. The major costs appear through non-candidal causes of vaginitis. Decisions of women to continue self-medication are important mechanisms in increasing these costs.

Our analysis indicates that OTC availability of anticandidals appears to be **cost-beneficial**. Even if some of the parameters that we have estimated are somewhat larger (e.g. higher partial relief, higher recurrence of PID), benefits would exceed cost. Our analysis also highlights significant gaps in our knowledge of OTC anticandidal self-treatment that researchers need to address. How often do women experience partial relief with anticandidals for **non-candidal** causes? How often do women continue to self-medicate when they have experienced partial relief? No relief? These questions could be addressed, at least in part, through supplements to ongoing population-based surveys such as the National Health Interview survey (NHIS) or the National Health and Nutritional Survey CHECK (NHANES). How often do women with infectious (non-candidal) causes of vaginitis later experience PID? What is the rate of recurrent PID? These questions can be addressed in the context of ongoing epidemiological and medical research.

The research presented in this chapter not only highlights areas for further research, but it also provides a framework in which to determine the ranges of probabilities that are important to investigate. This type of information can be extremely valuable when determining sample size for a prospective study of one of these areas and establishing the (statistical) power of the study.

Summary

- The most common causes of vaginitis symptoms are bacterial vaginosis (30-40 %), trichomonos vaginalis (15 - 20 %), and candida albicans (15 - 25 %). Post-menapausal atrophic vaginitis is also a common cause in women over 45 (20 %).

- According to our model, approximately one percent of women with unresolved vaginitis symptoms will not seek professional care within a 3-month period. Of these, approximately 74 % will have conditions that could lead to serious long-term complications.
- We estimate the costs of OTC anticandidal availability to be approximately \$3.83 per person (direct medical costs only). Weighed against an estimated benefit of \$61.96 per person, the overall benefit-cost ratio is approximately 16.17.
- Sensitivity analysis indicate that our model is especially sensitive to estimates of partial relief rates for non-candidal causes of vaginitis (as a results of using an anticandidal) and continued self-medication rates (with no relief of symptoms).
- Two-way sensitivity analyses highlight that there are significant interdependencies between the various probabilities of the model. Changes in the values of one probability (e.g. partial relief rate) have a significant impact on other one-way sensitivity analyses.
- Our research highlights a number of gaps in our knowledge of anticandidal self-medication:
 - How often do women experience partial relief with anticandidals for non-candidal causes?
 - How often do women continue to self-medicate when they have experienced partial relief? No relief?
 - How often do women with infectious (non-candidal) causes of vaginitis later experience PID?
 - What is the rate of recurrent PID?

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Chapter 6

Chapter 6:

State Medicaid Plan Coverage of

Introduction

Medicaid is one of the only major insurers that covers at least

coverage, however, varies significantly from state to state. Although many of our

informants did not perceive insurance coverage to be a critical issue at this time, the

their opinion tended to rest on the fact that most people can quite easily afford

payment.² The concept behind formularies is to restrict choice of pharmaceuticals to those that the plan has deemed **cost-effective**.³ Formularies typically include large numbers of generic drugs (as opposed to their more expensive brand-name counterparts). In addition, these pharmaceutical lists often exclude expensive new drugs that are only marginally more effective than older “mainstays” (e.g. beta blockers, anti-hypertensives)

Although many OTCs are covered by state Medicaid plans, the coverage varies significantly from state to state. We were unable to obtain formularies from the individual plans. However, using the most recently available Health Care Financing Administration (HCFA) aggregate data (1994, 1996, and 1997) on state Medicaid plan drug payments, we calculated the number of different OTCs covered by each state.⁴ National Drug Codes (NDCs) were used to identify individual OTCs. Since some states are able to cover one or two prescriptions on an emergency basis, we set an arbitrary floor of 10 prescriptions per year for determining whether a state routinely covered a particular drug.

² Beneficiaries are sometimes allowed to appeal for use on non-formulary drugs.

³ Sometimes these medications are cost-effective because the plan has negotiated a large discount in exchange for making the medication the only one of its type on the formulary.

⁴ 1995 files were not available on HCFA's internet site due to problems with file conversion.

Table 6-1 Number of Different OTCs Covered, By State: 1994, 1996, and 1997²

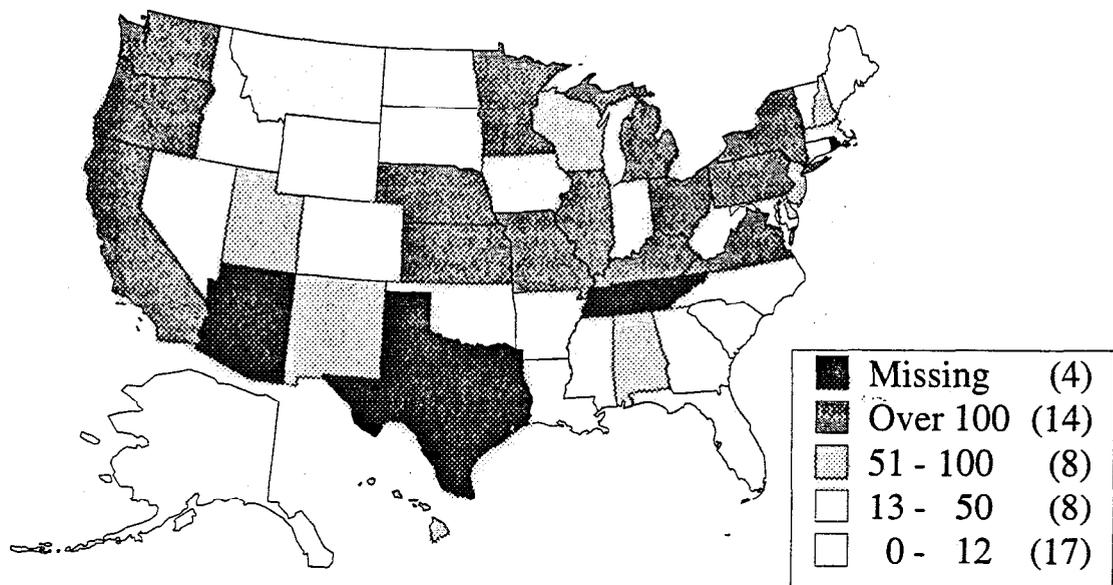
State	1994	1996	1997	State	1994	1996	1997
Alabama	12	24	77	Montana	7	20	20
Alaska	0	3	2	Nebraska	227	192	330
Arizona	*	*	*	Nevada	2	0	0
Arkansas	32	44	39	New Hampshire	115	23	84
California	43	245	303	New Jersey	12	60	60
Colorado	0	0	0	New Mexico	16	43	60
Connecticut	0	1	6	New York	73	372	408
D C	20	11	24	North Carolina	0	0	1
Delaware	46	49	55	North Dakota	6	5	11
Florida	17	25	34	Ohio	196	130	133
Georgia	6	10	11	Oklahoma	0	0	0
Hawaii	73	86	86	Oregon	28	95	104
Idaho	2	3	2	Pennsylvania	224	226	367
Illinois	257	371	126	Rhode Island	3	8	11
Indiana	231	18	13	South Carolina	8	4	5
Iowa	40	48	23	South Dakota	0	0	1
Kansas	76	9	134	Tennessee	1	*	*
Kentucky	129	187	222	Texas	50	*	*
Louisiana	1	4	5	Utah	23	68	66
Maine	3	5	10	Vermont	2	6	4
Maryland	2	5	3	Virginia	113	110	135
Massachusetts	2	18	18	Washington	109	153	192
Michigan	128	157	191	West Virginia	1	1	1
Minnesota	147	229	255	Wisconsin	69	91	91
Mississippi	31	31	34	Wyoming	1	9	11
Missouri	180	237	357				

*Data not available

Table 6-1 highlights the wide variation in number of OTCs covered by state Medicaid plans, ranging from 0 (six states in 1994, five in 1996, and three in 1997) to 408 (New York; 1997). Eighteen states covered fewer than 12 OTCs in any of the years studied, while 9 states covered more than 100 in each of the three years. Figure 6- 1 presents the number of OTCs

covered for 1997, by state. In 1997, 14 states covered more than 100 OTCs. These states are concentrated in the West (California, Oregon, Washington) and the Midwest (Minnesota, Illinois, Nebraska, Kansas, Missouri, Michigan, Ohio). States in the Southeast, the far Northeast, and the West Central states had lower than average coverage of different OTCs.

Figure 6-1 Number of OTCs Covered in 1997, By State



Expenditures on OTCs

While the state Medicaid expenditures on **OTCs** are relatively large (average of \$296 million per state in 1997), this represents only 2.84 % of total pharmaceutical expenditures for state Medicaid plans and a cost of approximately \$9.14 per beneficiary. Again, these expenditures vary widely from state to state, ranging from a high in 1997 of \$81 million (California) to a low of \$180,000 (Nevada). Tables 4-2 through 4-4 present detailed, state-level data on pharmaceutical, OTC, and recent switch drug expenditures for state Medicaid plans. Note that although several states do not, as part of standard policy, cover **OTCs**, all states have at least some OTC expenditures due to “emergencies” or “exceptions”.

Table 6-2 Total and Average (Per Beneficiary) Medicaid Expenditures for Pharmaceuticals, OTCs, and Recent Switch Drugs, 1994

State	Total \$ on Pharm	Avg \$ on Pharm	Tot \$ on OTC	Avg \$ on OTC	Tot \$ on Switches	Avg \$ on Switches
All States	\$8,609,440,931	\$270	\$257,756,752	\$6.63	\$7,234,005	\$0.11
Alabama	\$163,943,547	\$302	\$4,023,014	\$7.40	\$6,866	\$0.01
Alaska	\$17,060,521	\$248	\$171,873	\$2.50	\$8	\$0.00
Arizona	*		*		*	*
Arkansas	\$88,702,870	\$26;	\$1,592,221	\$4.6;	\$26,455	\$0.08
California	\$1,026,237,923	\$205	\$60,129,028	\$12.01	\$4,150,417	\$0.83
Colorado	\$54,310,231	\$188	\$767,500	\$2.65	\$759	\$0.00
Connecticut	\$95,206,708	\$269	\$1,547,760	\$4.37	\$7,437	\$0.02
Delaware	\$18642,007	\$249	\$465,695	\$6.23	\$14,199	\$0.19
D C	\$26,032,751	\$205	\$745,828	\$5.86	\$10,671	\$0.08
Florida	\$483,238,506	\$280	\$7,476,771	\$4.33	\$32,113	\$0.02
Georgia	\$312,873,242	\$288	\$5,830,463	\$5.37	\$11,323	\$0.01
Hawaii	\$27,626,119	\$229	\$1,277,754	\$10.58	\$34,686	\$0.29
Idaho	\$26,332,955	\$239	\$335,782	\$3.05	\$8	\$0.00
Illinois	\$361,529,353	\$251	\$19,400,087	\$13.46	\$513,468	\$0.36
Indiana	\$207,849,316	\$344	\$6,910,484	\$11.43	\$67,912	\$0.11
Iowa	\$98,116,598	\$324	\$2,070,940	\$6.85	\$4,849	\$0.02
Kansas	\$70,365,793	\$280	\$1,917,500	\$7.62	\$38,051	\$0.15
Kentucky	\$222,906,416	\$350	\$8,871,549	\$13.91	\$154,535	\$0.24
Louisiana	\$274,790,722	\$353	\$5,255,190	\$6.75	\$31,210	\$0.04
Maine	\$65,357,107	\$369	\$965,935	\$5.46	\$455	\$0.00
Maryland	\$129,002,533	\$311	\$2,053,492	\$4.95	\$276	\$0.00
Massachusetts	\$328,950,261	\$463	\$5,352,776	\$7.53	\$6,806	\$0.01
Michigan	\$292,224,245	\$246	\$7,311,635	\$6.16	\$62,736	\$0.05
Minnesota	\$188,294,505	\$442	\$5,824,874	\$13.69	\$88,955	\$0.21
Mississippi	\$146,589,561	\$273	\$4,624,151	\$8.61	\$58,487	\$0.11
Missouri	\$213,931,600	\$320	\$6,167,950	\$9.22	\$116,018	\$0.17
Montana	\$25,894,838	\$269	\$402,195	\$4.18	\$4,522	\$0.05
Nebraska	\$55,933,514	\$340	\$2,074,542	\$12.62	\$79,472	\$0.48
Nevada	\$19,009,110	\$199	\$238,140	\$2.50	\$173	\$0.00
New Hampshire	\$29,325,979	\$343	\$1,530,439	\$17.89	\$17,643	\$0.21
New Jersey	\$315,321,160	\$399	\$4,746,293	\$6.01	\$330,570	\$0.42
New Mexico	\$34,989,115	\$130	\$1,083,624	\$4.04	\$44,622	\$0.17
New York	\$359,924,754	\$124	\$12,564,710	\$4.32	\$127,998	\$0.04
North Carolina	\$217,320,408	\$221	\$3,409,337	\$3.46	\$8,235	\$0.01
North Dakota	\$18,056,460	\$288	\$311,029	\$4.96	\$3,766	\$0.06
Ohio	\$463,000,404	\$304	\$16,038,196	\$10.53	\$334,969	\$0.22
Oklahoma	\$93,612,647	\$240	\$1,159,021	\$2.97	\$1,285	\$0.00

Table 6-2 (Continued) Total and Average (Per Beneficiary) Medicaid Expenditures for Pharmaceuticals, OTCs, and Recent Switch Drugs, 1994

State	Total \$ on Pharm	Avg \$ on Pharm	Tot \$ on OTC	Avg \$ on OTC	Tot \$ on Switches	Avg \$ on Switches
All States	\$8,609,440,931	\$ 2 7 0	\$257,756,752	\$ 6 . 6 3	\$7,234,005	\$0.11
Oregon	\$88,747,470	\$216	\$1,529,949	\$3.72	\$9,346	\$0.02
Pennsylvania	\$504,994,551	\$402	\$12,358,244	\$9.84	\$256,600	\$0.20
Rhode Island	\$29,720,678	\$259	\$546,918	\$4.76	\$782	\$0.01
South Carolina	\$129,920,420	\$267	\$3,448,103	\$7.09	\$7,575	\$0.02
South Dakota	\$17,447,259	\$242	\$216,935	\$3.01	\$221	\$0.00
Tennessee	\$8,949,628	\$10	\$206,325	\$0.22	\$2,709	\$0.00
Texas	\$535,767,019	\$213	\$17,438,659	\$6.94	\$265,885	\$0.11
Utah	\$3 1,082,892	\$198	\$561,507	\$3.57	\$10,240	\$0.07
Vermont	\$28,572,044	\$303	\$485,198	\$5.15	\$3,883	\$0.04
Virginia	\$198,262,472	\$308	\$5,438,800	\$8.46	\$35,731	\$0.06
Washington	\$182,393,645	\$273	\$5,638,808	\$8.44	\$225,716	\$0.34
West Virginia	\$113,102,569	\$308	\$1,684,590	\$4.59	\$903	\$0.00
Wisconsin	\$166,950,430	\$352	\$3,543,102	\$7.48	\$22,204	\$0.05
Wyoming	\$1,026,075	\$20	\$11,836	\$0.23	\$256	\$0.01

Table 6-3 Total and Average (Per Beneficiary) Medicaid Expenditures for Pharmaceuticals, OTCs, and Recent Switch Drugs, 1995

State	Total \$ on Pharm	Avg \$ on Pharm	Tot \$ on OTC	Avg \$ on OTC	Tot \$ on Switches	Avg \$ on Switches
All States	\$9,458,745,605	\$342	\$285,356,153	\$8.87	\$5,232,901	\$0.16
Alabama	\$214,730,605	\$431	\$5,008,728	\$11.36	\$18,695	\$0.04
Alaska	\$22,652,809	\$259	\$212,511	\$2.43	\$2,310	\$0.03
Arizona	*	*	*		*	*
Arkansas	\$115,933,267	\$312	\$1,920,893	\$8.4;	\$24,697	\$0.11
California	\$1,229,953,016	\$227	\$83,068,264	\$19.95	\$2,021,874	\$0.49
Colorado	\$62,187,036	\$239	\$838,100	\$15.82	\$2,313	\$0.04
Connecticut	\$151,585,900	\$486	\$2,467,790	\$20.45	\$8,252	\$0.07
Delaware	\$25,980,004	\$352	\$585,483	\$35.39	\$16,390	\$0.99
DC	\$27,676,820	\$221	\$695,211	\$12.46	\$7,839	\$0.14
Florida	\$644,684,981	\$419	\$9,501,027	\$17.04	\$26,269	\$0.05
Georgia	\$312,873,242	\$323	\$6,711,197	\$10.19	\$19,238	\$0.03
Hawaii	\$30,285,486	\$186	\$1,446,153	\$45.23	\$20,681	\$0.65
Idaho	\$33,802,930	\$399	\$501,263	\$9.36	\$427	\$0.01
Illinois	\$463,162,052	\$331	\$22,021,960	\$18.06	\$561,808	\$0.46
Indiana	\$139,871,860	\$323	\$4,350,971	\$14.65	\$18,503	\$0.06
Iowa	\$81,793,436	\$361	\$1,535,099	\$11.55	\$7,618	\$0.06
Kansas	\$41,775,753	\$217	\$1,079,492	\$8.22	\$31,773	\$0.24
Kentucky	\$300,232,770	\$565	\$10,772,649	\$43.28	\$215,698	\$0.87
Louisiana	\$305,686,788	\$381	\$5,890,494	\$7.78	\$45,317	\$0.06
Maine	\$48,956,690	\$310	\$1,285,987	\$8.21	\$2,809	\$0.02
Maryland	\$158,449,646	\$340	\$2,455,863	\$14.44	\$10,016	\$0.06
Massachusetts	\$319,336,475	\$488	\$4,851,304	\$24.54	\$19,526	\$0.10
Michigan	\$357,733,315	\$312	\$9,281,676	\$29.58	\$106,690	\$0.34
Minnesota	\$147,496,432	\$309	\$4,970,503	\$15.60	\$131,706	\$0.41
Mississippi	\$173,525,005	\$340	\$5,142,471	\$10.82	\$44,372	\$0.09
Missouri	\$255,796,274	\$401	\$6,870,345	\$16.52	\$134,873	\$0.32
Montana	\$31,806,256	\$403	\$512,335	\$15.96	\$3,592	\$0.11
Nebraska	\$55,679,933	\$386	\$1,784,709	\$17.05	\$57,723	\$0.55
Nevada	\$18,986,569	\$293	\$252,135	\$6.60	\$983	\$0.03
New Hampshire	\$26,230,314	\$364	\$1,233,650	\$20.45	\$15,727	\$0.26
New Jersey	\$357,092,098	\$505	\$4,774,931	\$11.81	\$234,843	\$0.58
New Mexico	\$63,177,814	\$190	\$1,845,059	\$10.03	\$50,918	\$0.28
New York	\$977,820,831	\$356	\$28,301,732	\$13.45	\$592,699	\$0.28
North Carolina	\$264,294,909	\$323	\$4,462,392	\$8.69	\$16,795	\$0.03
North Dakota	\$22,850,433	\$491	\$389,311	\$18.43	\$4,040	\$0.19
Ohio	\$397,091,648	\$535	\$12,925,251	\$25.72	\$201,126	\$0.40
Oklahoma	\$102,607,487	\$308	\$1,332,845	\$4.96	\$987	\$0.00

Table 6-3 (Continued) Total and Average (Per Beneficiary) Medicaid Expenditures for Pharmaceuticals, OTCs, and Recent Switch Drugs, 1996

State	Total \$ on Pharm	Avg \$ on Pharm	Tot \$ on OTC	Avg \$ on OTC	Tot \$ on Switches	Avg \$ on Switches
All States	\$9,458,745,605	\$342	\$285,356,153	\$8.87	\$5,232,901	\$0.16
Oregon	\$68,725,123	\$179	\$1,192,884	\$34.33	\$35,362	\$1.02
Pennsylvania	\$421,115,681	\$261	\$10,122,914	\$13.31	\$190,880	\$0.25
Rhode Island	\$35,521,979	\$312	\$747,852	\$17.59	\$569	\$0.01
South Carolina	\$125,606,164	\$322	\$3,079,533	\$7.93	\$18,495	\$0.05
South Dakota	\$21,433,957	\$343	\$274,993	\$12.56	\$510	\$0.02
Tennessee	*	*	*	*	*	*
Texas	*		*		*	
Utah	\$47,544,380	\$42;	\$789,662	\$38.6;	\$13,187	\$0.6;
Vermont	\$30,756,828	\$372	\$532,381		\$6,549	
Virginia	\$220,487,910	\$324	\$5,700,186	\$25.96	\$39,216	\$0.18
Washington	\$187,573,985	\$269	\$5,680,146	\$5,182.61	\$205,514	\$187.51
West Virginia	\$121,710,100	\$396	\$2,018,135	\$9.44	\$5,004	\$0.02
Wisconsin	\$189,366,458	\$409	\$3,894,051	\$12.33	\$38,207	\$0.12
Wyoming	\$5,102,156	\$131	\$43,631	\$1.13	\$282	\$0.01

Table 6-4 Total and Average (Per Beneficiary) Medicaid Expenditures for Pharmaceuticals, OTCs, and Recent Switch Drugs, 1997

State	Total \$ on Pharm	Avg \$ on Pharm	Tot \$ on OTC	Avg \$ on OTC	Tot \$ on Switches	Avg \$ on Switches
All States	\$10,418,745,424	\$399	\$296,155,017	\$9.14	\$8,936,439	\$0.28
Alabama	\$222,347,022	\$447	\$5,438,468	\$10.93	\$171,506	\$0.34
Alaska	\$27,585,052	\$315	\$302,373	\$3.46	\$4,119	\$0.05
Arizona	*	*	*	*	*	*
Arkansas	\$131,945,903	\$493	\$2,117,347	\$7.91	\$43,624	\$0.16
California	\$1,349,830,608	\$282	\$80,894,245	\$16.88	\$3,163,553	\$0.66
Colorado	\$6,150,276	\$269	\$839,930	\$3.67	\$2,658	\$0.01
Connecticut	\$172,703,219	\$479	\$3,094,225	\$8.59	\$17,752	\$0.05
Delaware	\$34,703,938	\$431	\$725,681	\$9.01	\$79,665	\$0.99
D C	\$35,702,053	\$286	\$965,049	\$7.72	\$15,303	\$0.12
Florida	\$758,074,185	\$537	\$13,437,992	\$9.52	\$176,728	\$0.13
Georgia	\$330,136,220	\$374	\$6,735,392	\$7.64	\$89,053	\$0.10
Hawaii	\$3,148,297	\$189	\$1,434,644	\$8.60	\$36,696	\$0.22
Idaho	\$40,312,412	\$500	\$584,730	\$7.26	\$4,696	\$0.06
Illinois	\$26,137,528	\$191	\$12,281,909	\$8.96	\$569,645	\$0.42
Indiana	\$124,480,892	\$307	\$3,831,634	\$9.46	\$5,1097	\$0.13
Iowa	\$11,766,812	\$54	\$253,904	\$1.17	\$6,977	\$0.03
Kansas	\$106,259,048	\$573	\$2,680,897	\$14.47	\$137,350	\$0.74
Kentucky	\$327,732,496	\$622	\$11,719,881	\$22.23	\$486,593	\$0.92
Louisiana	\$316,864,458	\$498	\$6,173,506	\$9.71	\$94,434	\$0.15
Maine	\$102,201,935	\$657	\$1,644,186	\$10.57	\$37,533	\$0.24
Maryland	\$159,963,952	\$344	\$2,855,400	\$6.14	\$19,317	\$0.04
Massachusetts	\$411,990,407	\$575	\$6,895,296	\$9.62	\$45,958	\$0.06
Michigan	\$355,237,773	\$318	\$9,114,910	\$8.17	\$218,354	\$0.20
Minnesota	\$147,662,392	\$367	\$5,136,916	\$12.75	\$203,970	\$0.51
Mississippi	\$190,197,112	\$350	\$5,343,254	\$9.83	\$64,117	\$0.12
Missouri	\$326,483,795	\$531	\$8,720,302	\$14.18	\$228,560	\$0.37
Montana	\$35,778,069	\$505	\$575,373	\$8.12	\$7,571	\$0.11
Nebraska	\$82,182,372	\$570	\$2,612,972	\$18.12	\$158,924	\$1.10
Nevada	\$12,752,948	\$144	\$179,681	\$2.03	\$3,086	\$0.03
New Hampshire	\$38,876,236	\$548	\$1,582,161	\$22.31	\$83,556	\$1.18
New Jersey	\$352,204,095	\$514	\$4,205,882	\$6.14	\$203,270	\$0.30
New Mexico	\$60,521,173	\$250	\$1,788,990	\$7.38	\$96,078	\$0.40
New York	\$1,179,406,690	\$514	\$3,595,426	\$13.76	\$867,943	\$0.38
North Carolina	\$308,776,560	\$374	\$5,185,883	\$6.28	\$41,197	\$0.05
North Dakota	\$23,824,119	\$526	\$408,810	\$9.02	\$10,419	\$0.23
Ohio	\$450,955,768	\$412	\$13,977,756	\$12.76	\$406,508	\$0.37
Oklahoma	\$115,840,298	\$265	\$1,560,861	\$3.57	\$12,978	\$0.03

Table 6-4 (Continued) Total and Average (Per Beneficiary) Medicaid Expenditures for Pharmaceuticals, OTCs, and Recent Switch Drugs, 1997

State	Total \$ on Pharm	Avg \$ on Pharm	Tot \$ on OTC	Avg \$ on OTC	Tot \$ on Switches	Avg \$ on Switches
All States	\$10,418,745,424	\$ 3 9 9	\$296,155,017	\$9.14	\$8,936,439	\$0.28
Oregon	\$76,053,077	\$202	\$1,530,989	\$4.07	\$118,341	\$0.3 1
Pennsylvania	\$533,239,103	\$336	\$11,853,853	\$7.47	\$302,439	\$0.19
Rhode Island	\$38,260,157	\$335	\$796,598	\$6.98	\$1,878	\$0.02
South Carolina	\$147,955,713	\$376	\$3,595,421	\$9.14	\$72,613	\$0.18
South Dakota	\$28,560,5 10	\$473	\$376,218	\$6.23	\$8,404	\$0.14
Tennessee	*	*	*	*	*	*
Texas	*	*	*	*	*	*
Utah	\$50,379,465	\$426	\$828,725	\$7.00	\$31,668	\$0.27
Vermont	\$40,902,886	\$422	\$707,979	\$7.30	\$7,678	\$0.08
Virginia	\$250,075,5 15	\$479	\$6,55 1,722	\$12.55	\$91,355	\$0.17
Washington	\$204,6 16,208	\$280	\$6,066,445	\$8.3 1	\$326,651	\$0.45
West Virginia	\$130,794,560	\$421	\$2,26 1,689	\$7.28	\$14,589	\$0.05
Wisconsin	\$202,977,800	\$480	\$4,505,172	\$10.65	\$91,631	\$0.22
Wyoming	\$15,261,317	\$316	\$184,336	\$3.81	\$8,402	\$0.17

The percentage of pharmacy expenditures accounted for by OTCs has remained relatively constant over the time period in question (1994: 3.00 %; 1996: 3.02 %), with a slight drop in 1997 (2.84 %). This percentage, however, also varies significantly by state, with California spending the highest proportion of its pharmacy budget on OTCs (5.86 % in 1994; 6.75 % in 1996; 5.99 % in 1997) and Alaska spending the least (1 .0 1 % in 1994; 0.94 % in 1996; 1.10 % in 1997). Expenditures on recent switch drugs (since 1989) make up a negligible portion of pharmacy expenditures, accounting for less than one-tenth of one percent of these expenditures in 1994, 1996 and 1997.

Although OTC expenditures as a percentage of total pharmaceutical expenditures have remained constant in recent years, average expenditures per beneficiary have been increasing. This growth mirrors the increases in pharmaceutical costs per Medicaid beneficiary (See Figures 6-2 and 6-3).

Figure 6-2 Average Pharmacy Expenditures Per Medicaid Beneficiary: 1994, 1996 and 1997

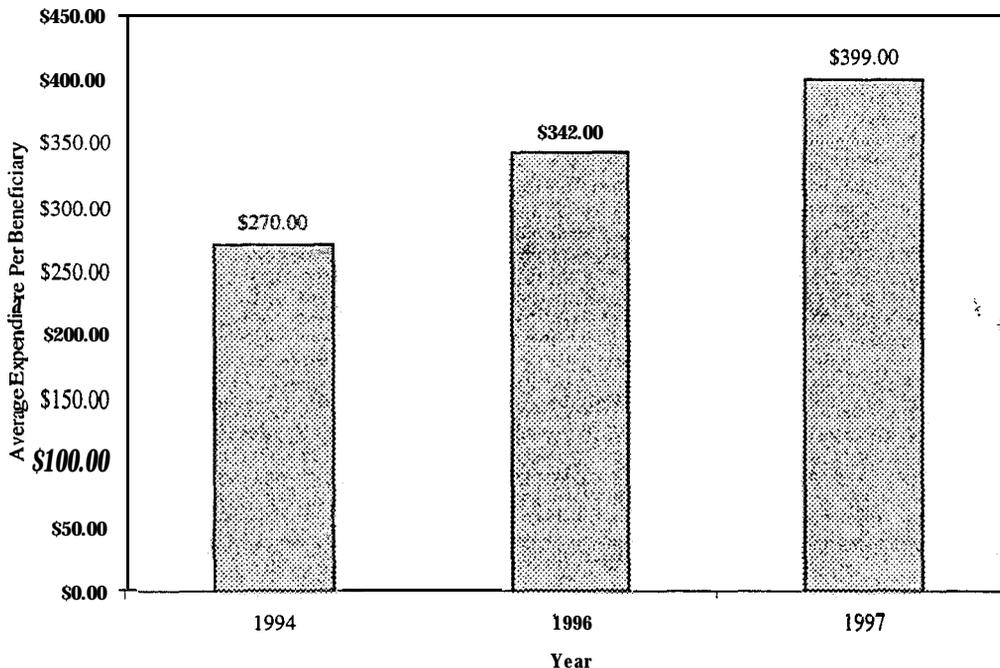
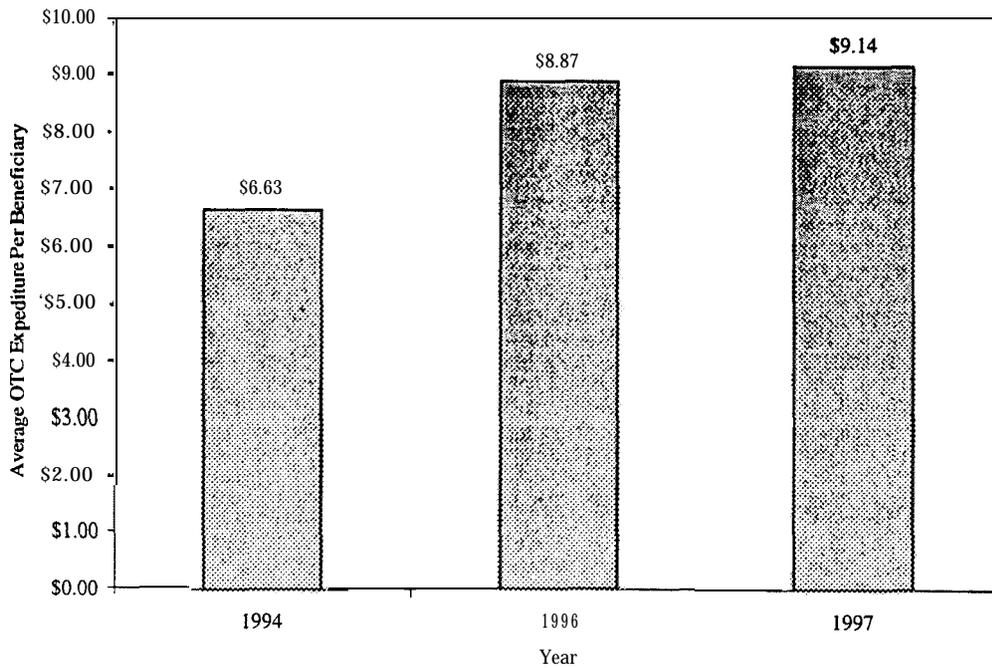


Figure 6-3 Average OTC Expenditures Per Medicaid Beneficiary: 1994, 1996 and 1997

Types of OTCs Covered

The spectrum of OTCs covered by state Medicaid plans is wide and diffuse. Virtually all states, however, spend money on drugs such as acetaminophen (Tylenol), acetylsalicylic acid (aspirin), ibuprofen (Advil, Motrin), and insulin. Table 6-5 presents expenditures on these common OTCs.

Table 6-5 Total, Average (Per State), Highest and Lowest Expenditures on Acetaminophen, Aspirin, Ibuprofen, and Insulin: 1994, 1996 and 1997

Total Expenditures	1994	1996	1997
ALL OTCs	\$257,756,752	\$285,356,153	\$296,155,017
Acetaminophen	\$6,573,959	\$11,929,868	\$9,125,621
Aspirin	\$4,889,971	\$6,577,916	\$6,499,516
Ibuprofen	\$413,527	\$231,317	\$693,062
Insulin	\$725,695	\$1,196,953	\$1,404,753
Average Expenditures	1994	1996	1997
ALL OTCs	\$5,155,135	\$5,944,920	\$6,169,896
Acetaminophen	\$182,610	\$340,853	\$285,176
Aspirin	\$108,666	\$149,498	\$147,716
Ibuprofen	\$9,189	\$7,010	\$17,771
Insulin	\$15,119	\$24,937	\$29,266
Highest Expenditure*	1994	1996	1997
ALL OTCs	\$60,129,028	\$83,068,264	\$80,894,245
Acetaminophen	\$2,929,330	\$10,779,388	\$8,214,907
Aspirin	\$1,069,376	\$1,670,311	\$2,069,095
Ibuprofen	\$61,258	\$51,364	\$234,655
Insulin	\$456,773	\$99,397	\$129,864
Lowest Expenditure**	1994	1996	1997
ALL OTCs	\$11,836	\$43,631	\$179,681
Acetaminophen	\$20	\$7	\$28
Aspirin	\$27	\$6	\$50
Ibuprofen	\$11	\$7	\$10
Insulin	\$30	\$59	\$625

*Highest (total) expenditure for any state in a given year.

**Lowest (total) expenditure for any state in a given year.

Clearly, some states spend a great deal of money on common OTCs such as acetaminophen and aspirin. Those states with high expenditures for these common OTCs also tended to have high overall expenditures for OTCs. Correlations between levels of overall OTC expenditures and

expenditures on insulin, aspirin, advil, and acetaminophen ranged between 0.46 and 0.90. The relationship between expenditures for these common OTCs and percentage of pharmaceutical expenditure accounted for by OTCs was less uniform. States with high expenditures for acetaminophen and aspirin also tended to spend more (higher %) of their overall pharmaceutical budget on OTCs (acetaminophen: $\rho=0.73$ (1994), $\rho=0.91$ (1996), $\rho=0.92$ (1997); aspirin: $\rho=0.71$ (1994), $\rho=0.84$ (1996), $\rho=0.82$ (1997)). The correlations between expenditures on ibuprofen and insulin and total OTC expenditures were far lower (ibuprofen: $\rho=0.01$ (1994), $\rho=0.12$ (1996), $\rho=0.19$ (1997); insulin: $\rho=0.45$ (1994), $\rho=0.34$ (1996), $\rho=0.22$ (1997)).

Impact of OTC Coverage on Payments for “Substitute” Prescriptions

One argument for covering OTC prescriptions for Medicaid recipients is that physicians, faced with the prospect that their patients will not purchase the recommended OTC, will prescribe more expensive, “substitute” prescriptions. This scenario is discussed in more detail in Chapter 4. In this section, we explore the impact of coverage of one OTC medication particularly appropriate for the Medicaid population-vaginal antifungals.⁵ Using 1994 data to identify states that covered OTC vaginal antifungals, we compared payments in 1996 and 1997 for three “substitute” prescriptions on a cost per beneficiary basis: Femstat, Terazol, and Mycostatin. A state was considered to cover OTC vaginal antifungals if it paid for one of these products 10 or more times during 1994. Table 6-6 presents the results of our analysis.

⁵We initially intended to explore the impact of coverage of H2 blockers as well, but found out that no state Medicaid plan covers OTC H2 blockers.

Chapter 6

Table 6-6

Cost Per Beneficiary of "Substitu

States That Do and Do Not Cover

Femstat

State

State

Does Not

Covers

Cover

OTC

OTC

1996

Total Pmt*

\$105,054

\$47,749

AvgPmt**

\$0.14

\$0.13

Chapter 6

beneficiary \equiv \$0.07 (1996); \$0.13

significance levels.

Summary

The data presented in this chapter highlight a number of

coverage of

OTCs:



Medicaid coverage of

Chapter 7: Discussion and Feedback

In order to generate discussion and obtain feedback **from** individuals involved in the project as key informants or those with knowledge and interest in the area of OTC switching, a one-day meeting was held on January 29, 1999, at the Embassy Row Hilton in Washington, D.C. The following individuals were present:

From the Office of the Assistant Secretary for Planning and Evaluation. DHHS:

Cheryl Austein-Casnoff, M.P.H.

Susannah Bruns

Key Informants and Discussants:

David Clark, R.Ph., M.B.A., Health Care Financing Administration

Lisa Foley, J.D., American Association of Retired Persons

Mary Lea Gora-Harper, Pharm.D., University of Kentucky Hospital, Drug Information Center

David J. Gross, Ph.D., American Association of Retired Persons

Brett Kay, M.P.P., National Consumers League

David Kreling, Ph.D., University of Wisconsin, School of Pharmacy

Lou Morris, Ph.D., Consultant and Senior VP of Publishing Research and Representation, Inc.

R. William Soller, Ph.D., Nonprescription Drug Manufacturers' Association

Lorna C. Totman, Ph.D., DABT, Nonprescription Drug Manufacturers' Association

From Northwestern University:

Teresa Waters, Ph.D., Research Associate Professor and Assistant Director, Institute for Health Services Research and Policy Studies

Martin Lipsky, M.D., Chair, Department of Family Medicine, Northwestern University Medical School

Nancy Oddi Jaffe, J.D., M.S.P.H., Research Associate, Institute for Health Services Research and Policy Studies

The meeting consisted of a series of discussions concerning the content of the final report and topics related to the OTC switch movement. The last hour was devoted to summarizing the findings of the study and the day's discussions as well as outlining a set of research priorities.

Discussion

A number of central issues were discussed over the course of the day:

Pre-Switch versus Post-Switch Issues: A concern was raised that the Final Report did not totally distinguish between pre-switch and post-switch issues. The authors of the Final Report clarified that the report was intended to focus mainly on post-switch issues. Discussion to that effect has now been added to the Executive Summary.

Consumer Knowledge and Behavior: In general, meeting participants echoed concerns raised in the Final Report that researchers and policymakers have limited information concerning consumers' level of knowledge and behavior. Dr. William Soller of the Non-Prescription Drug Manufacturer's Association (NDMA) as well as Dr. Lou Morris of Publishing Research and Representation (PRR) noted that a great deal of (proprietary) data is collected by the marketing

departments of the OTC manufacturers. Some of this information, in summary form, is available through the public records of New Drug Applications (**NDAs**). A review of this material would be helpful in determining how best to proceed with research in this area.

Role of Pharmacists in Patient Education: Most discussants felt that the role of pharmacists in patient education was currently limited by the volume of prescriptions that these professionals were asked to fill. Discussion focused on making better use of these highly trained professionals, as well as the increasing role of information systems in the pharmacy to track prescription and OTC use.

Impact of OTC Switch on Clinical Practice Patterns: While a number of the meeting participants agreed that the presence of safe and effective **OTCs** could greatly reduce the number of office visits consumers must make, they also noted that patients with established relationships with their physician may not have been making office visits to get prescriptions. Instead, a phone call to the physician's office could result in a call to the pharmacy. If this has been the case, the impact of clinical practice patterns may be less than previously thought, and the cost-savings attributed to **OTCs** may be overstated.

New Switch Drugs: Meeting participants generally agreed that while there were certainly some characteristics about drugs that made them good candidates for OTC switch, each OTC switch should be considered on a case-by-case basis. Several participants also argued that the case of "orphan" drugs-those whose market potential may be small relative to the costs of switching, but would otherwise be ideal candidates-deserves some policy attention.

Insurance Coverage of Switch Drugs: Although most participants agreed that coverage of **OTCs** is not a major issue for insurance coverage, they noted that this could change as more

medications switch to OTC. In addition, there was considerable interest in the issues related to Medicaid coverage of **OTCs** and the impact of this coverage on costs and outcomes.

Research Priorities

After spending most of the day in discussion of the issues raised by the Final Report, the meeting participants developed the following list of research questions that deserve further attention:

- What is the impact of insurance coverage on utilization of **OTCs**? Other health care utilization? What can we learn from more detailed Medicaid data (e.g. utilization, demographic data)?
- Is the current system of (post-switch) adverse event monitoring, which was basically designed for prescription drugs, adequate for **OTCs**?
- Who are OTC users? What do consumers know about **OTCs** and their use? How do consumers make decisions to use **OTCs** versus their alternatives (e.g. no treatment, seek professional care)? Where do consumers get information they need (post-switch)?
- What is the impact of OTC switches on the physician-patient relationship? The pharmacist-patient interaction?
- Are “orphan” drugs receiving adequate attention in the switching process?
- What are the implications of **OTCs** for chronic conditions?
- Where can we expect the OTC trend to go? What does the industry need to continue the trend? What do consumers need to know?
- To what extent have **OTCs** contributed to the “medicalization” of populations?
- How will dietary supplements factor in to the OTC market?