Rx-to-OTC Switch: Changes in Physician and Patient Behavior

A Dissertation

Presented to the Faculty of the Graduate School

of Cornell University

In Partial Fulfillment of the Requirements for the Degree of

Doctor of Philosophy

by

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August 2007

RX-TO-OTC SWITCH: CHANGES IN PHYSICIAN AND PATIENT BEHAVIOR

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Cornell University 2007

When Claritin (a popular allergy/antihistamine drug) and Prilosec (a popular anti-ulcer/anti-acid drug) became available over the counter (OTC), a unique situation was created in which a drug was now available OTC while close substitutes remained prescription (Rx) only. The OTC/Rx status of a drug should not affect physician recommendations for it or others in its class as no chemical change has occurred. The theory developed here to model physician incentives suggests, however, that due to several institutional features of insurance markets, such as reimbursement methods, there may be differences in the incentives faced by physicians that lead to changes in which medications are prescribed as drugs switch regulatory status. In this model, capitated physicians are expected to use the lowest cost form of treatment since they can be held financially responsible for their treatment decisions. The existence of an OTC version of a drug is also hypothesized to alter patient behavior as well. The availability of an OTC is expected to increase the likelihood that patients will self-medicate and therefore should result in fewer visits to physicians with diagnoses related to that condition. Self-treatment with OTC drugs is likely to be greater when symptoms are not very severe. Consequently, it is also hypothesized that after the OTC drug is available those who do see a physician will manifest more severe symptoms. To test the theory empirically the National Ambulatory Medical Survey for the years 1997-2004 is utilized. The analysis shows that when a drug in a class becomes available in the OTC market, fewer patients visit physicians for the related diagnoses and the severity of ailments of patients visiting physicians does seem to

change somewhat after the availability of OTC medication. There is some evidence that physicians change their prescribing behavior, when a drug moves from prescription to OTC. In both the allergy and acid reflux markets, capitated physicians are found to utilize the least costly form of treatment. These physicians are found to cost shift away from the insurance company, while FFS cost shift away from the patient. Finally, both the allergy and acid reflux classes show some evidence of brand loyalty for drugs amongst patients.

BIOGRAPHICAL SKETCH

Sarah Hoda Neyaz was born and raised in the Corning, NY area. After graduating from Horseheads High School in 1996, she began her undergraduate career at the University of Rochester in Rochester, N.Y. In May, 2000 she completed a Bachelors degree in Molecular Genetics. After graduation, she enrolled in the Master's in Health Administration program at Cornell University, in the Department of Policy Analysis and Management and finished in May, 2002.

During the master's program, Sarah worked as a teaching assistant for a class in microeconomics. It was at this time she became interested in the research issues of applied economics and decided to pursue her Ph.D. Sarah continued on in the same department to do her doctorate work in the field of Policy Analysis and Management. Her concentration was in Consumer Policy and she had minors in subjects of Health Policy and Marketing. Sarah completed her Ph.D. in May, 2007.

The interdisciplinary program at Cornell University included training in Health Policy, Consumer Policy, Family and Social Welfare, and Evaluation. Sarah's studies provided her with knowledge of theories in Microeconomics and Policy issues, and she focused particularly on the health care industry. Her main areas of interest include pharmaceutical economics, physician behavior, cost/benefit analysis, and insurance/reimbursements.

In addition to course work and her own dissertation research, Sarah spent a significant amount of time as teaching assistant. The courses she assisted with included: microeconomics, health economics and policy, public policy and marketing, statistics, corporate finance, as well as others.

In 2007, Sarah moved to Lansing, Michigan with her husband and joined the Thomson Healthcare Group as a health economics researcher, studying issues related to the management of healthcare costs and quality.

This work is dedicated to my parents and to my husband, Danish.

ACKNOWLEDGMENTS

So many have been involved in the process of this dissertation. I would like to thank each and every one of them for all their help, guidance, and support.

I would like to acknowledge all of my committee members for their insight. Thank you, first, to my committee chair, Alan Mathios, who provided constructive discussions, interesting ideas for research, and useful comments. Professor Mathios was a model for what a mentor and teacher should be. Thank you to Kosali Simon, for all of her help, which went over and beyond anything I could have ever expected. Professor Simon, always found the time to guide me in any and every way she could, no matter how busy her schedule was. Sharon Tennyson, as my advisor during the Masters program, played an integral role in my decision to pursue the Ph.D. I wish to thank Professor Tennyson for her valuable suggestions, not only with the dissertation, but with all aspects of my graduate school career. Thank you to Vrinda Kadiyali for sharing her important inputs from a marketing perspective. Professor Kadiyali always had her door open and provided the most interesting and lively conversations.

All members of the Policy Analysis and Management faculty and staff have provided assistance in some way. I would like to thank Professor Don Kenkel, Professor Will White, and Professor John Cawley for their guidance. Thank you, especially, to Professor Sean Nicholson who provided his expertise, as well access to much needed data, and was always so helpful.

I am indebted to the wonderful PAM department staff. Thank you to Geysa Smiljanic, who had been a guide and a great source of support for seven years. I would not have gotten through the masters or the Ph.D. programs without her. Thank you to Kenna Snow Tompkins who has been so instrumental in this dissertation process and has always gone out of the way to help me. Thank you also to Justine Lynge for her support and willingness to always assist me.

Finally, this dissertation would not have been possible without my family. Thank you to Mummy and Papa, Shama Neyaz and Neyaz Hussain, for your understanding and patience with this long process. Thank you to Mommy and Daddy, Rafea and Syed N. Hoda, for always being there for me and for your unconditional support. Mommy, thank you for encouraging me to do the Ph.D. in the first place. Daddy, thank you for all of your suggestions and for proof-reading this dissertation so many times. Last, but not least, thank you to my husband, Danish, for your encouragement, consideration, and for always believing in me.

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CHAPTER 1

INTRODUCTION

Significant changes in the prescription (Rx) and over the counter (OTC) drug markets have recently developed. For the first time, drugs that were moved to the OTC market were equal in strength and effectiveness to prescription-only counterparts. This study explores how patients and physicians react to such changes when deciding treatment options. It also explores the impact of physician reimbursement methods on prescribing behavior.

The results of the study provide some evidence of a change in the patient case mix seen in physician offices after these equally effective medications move to the OTC market. In both the allergy and acid reflux groups, there is an increased use of specialist physicians after the availability of an OTC. In addition, acute patients are less likely to be seen in physician offices for acid reflux related conditions, and chronic flare-up patients are less likely to be seen for allergy related conditions. These results indicate that the overall severity of patients seen in physician offices increases after the availability of an OTC, since those with less severe conditions can self-treat.

This study also finds that physicians reimbursed under a capitated health plan provide their patients with the least costly form of treatment. In the allergy group, capitated physicians are significantly more likely than fee-for-service to provide patients with allergy shots, which are less costly than medications. After the availability of an OTC, however, capitated physicians are less likely to provide these shots, as they are no longer the least costly. OTCs are instead the most cost effective form of treatment for an insurance plan, since the patient pays completely out-of-pocket for them.

Similarly, for the acid reflux group, physicians under capitation are more likely to provide the older OTC medication Zantac to their patients as this is least costly.

Once Prilosec moves to the OTC market, capitated physicians have another option for treatment that is just as cost effective for the insurance company since the patient remains fully responsible for the cost of the drug.

Overall there also seems to be some evidence of brand loyalty amongst patients when drugs move to the OTC market. In both markets, there is a decrease in the overall use of prescription medications after the availability of an OTC, indicating that patients follow these drugs to the OTC market, even though it may be more costly.

Importance of Study

The pharmaceutical industry has recently seen the switch of several top selling drugs from the prescription to the over-the-counter drug market. Traditionally, drugs available over the counter were less effective than prescription medications. Rx-only and OTC drugs, therefore, could only be considered as imperfect substitutes for each other. Even those brands that moved their products from the prescription market tended to have reduced dosages as OTCs. This changed in 2002 when, for the first time, a prescription drug product became available to the public on an over the counter basis and was of equal strength and effectiveness as those in the same class that remained prescription-only.

Little research to date has addressed how the change in prescription status affects the use of a drug, or other competing drugs in the same class with equal effectiveness, when it moves to the over-the-counter market. While other researchers have studied physician incentives in regards to brand-name versus generic drug prescriptions, few have studied the incentives physicians face when deciding between prescription and OTC substitutes. Even those studies that have examined prescription versus OTC drugs were done when the two markets were not as comparable. OTCs

and prescriptions drugs for these studies could have been used as compliments rather than substitutes for one another.

Healthcare resource utilization can potentially be made more efficient with access to OTCs that are equal in strength and effectiveness to prescription-only counterparts. The availability of these drugs on the OTC market can create an effective sorting system in which those patients with less severe symptoms can self treat allowing for quicker, less expensive therapy; and preventing unnecessary physician office visits.

Purpose and Scope of Research

The purpose of this study is to examine how patients and physicians change their behavior after the availability of an OTC drug that is chemically equivalent to its prescription counterparts. Specifically, this study first intends to examine whether those patients that have less severe symptoms, utilize OTC drugs to self-treat, as a substitute to physician office visits. This could potentially increase the overall severity of the patient case-mix seen in physician offices after the availability of an OTC drug. Second, the study also focuses on whether or not physicians change their prescribing behavior when a drug switches from prescription to OTC class, and how this varies by the drug class being considered and the reimbursement method to physicians. Patient level data was used from the National Ambulatory Medical Care Survey (NAMCS) from the years 1997 – 2004 to study the effects of this switch. The allergy/antihistamine and the acid reflux drug classes are the two categories being examined since both have witnessed recent movements of blockbuster medications from the prescription-only to the OTC market in 2002 and 2003 respectively.

Key Issues

The following section discusses the important factors that are considered in this research.

Physician Incentives and Reimbursement

All players in the health care industry are affected by the switch of drugs from prescription to over the counter status. The physician is perhaps in the most important position, however, since he/she is integral in determining whether or not a patient receives a prescription. Physicians' incentives are an important aspect to examine when studying the effects of OTC switches as they are in this vital position. As owners and partners of private practices, physicians have a financial incentive to maximize their own profits, but at the same time, they must balance their intentions with patient welfare. As an agent for his/her patients, the physician's choice of a drug for a patient's ailment should not be influenced by its OTC versus Rx status, from a chemical perspective, even though physician authorization is required only for prescription drugs. Financial motives, however, may affect the decision between prescription and OTC medications as there could be an impact on physician profits.

A switch in regulatory status may also entail a change in the cost to the patient depending on their insurance coverage. It is therefore important for patients to understand their full range of options for medications and the implications of the physician's choice.

Pharmaceutical companies must also analyze the incentives of physicians as they are the gatekeepers for prescription medications. The makers of drugs can determine the best strategies to promote and sell their products when patent expirations near for their own drug or when other drugs in the class move to the OTC market by understanding how a physician may change his/her prescribing pattern when these changes occur.

As providers of health insurance coverage, both government and private insurance companies can employ certain techniques to align the incentives of the physician with those of the third part payer, especially in regards to prescribing

behavior. In fact, rather than fully reimburse physicians for all costs of care, some insurance companies use discounted reimbursements, capitated payments, and other controls to monitor the drug consumption decisions made by physicians. These companies also use annual reviews to either reward or penalize physicians based on their prescribing behavior. Figure 1.1 shows the extent to which these measures are used to control physician decisions. As can be seen, almost all companies use at least some form of cost control, with most requiring physicians to adhere to some practice guidelines or undergo drug utilization review; and over ninety percent requiring physicians to get prior authorization for medication choice. From 2001 onwards, as depicted in the figure, all HMO's implement some form of prescription control. While the use of financial incentives declined after 1998, it steadily remained a control method for over twenty percent of HMO's. Second opinion is the least used control method amongst these managed care organizations.

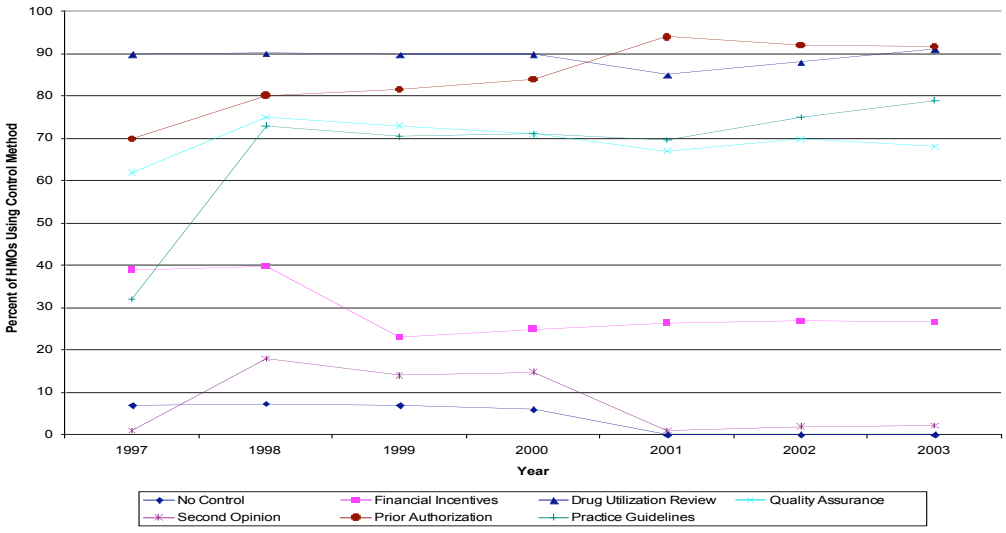

Figure 1.1

Control Methods Used by HMOs to Influence Physician Prescribing Behavior

(Kaiser Family Foundation, 2006)

Capitation

Increases in health care expenditures created a restructuring of the industry that was led by cost-conscious managed care organizations (MCOs) beginning in the 1980s. In the new environment, these organizations attempted to curb the effects of moral hazard, or over utilization, by making physicians financially accountable for their decisions. Traditionally, physicians were completely unattached to the third party payers since they received full reimbursements without any incentives to reduce costs. Physicians made their treatment and health care decisions based on what they thought was appropriate for the patient and were not at all financially responsible for providing medical care. This led to an increase in moral hazard since physician revenues increased with the higher utilization of resources.

In order to create a more efficient use of resources, managed care organizations created a system in which the physician was now financially responsible for his/her treatment decision. MCOs developed protocols for physicians to follow and even began controlling treatment options, thereby decreasing physician autonomy. Managed care companies, however, vary in the amount of financial responsibility they place on the physician. It is under capitation that physicians are most financially responsible for their treatment decisions.

According to the Centers for Medicare and Medicaid Services, capitation is the physician payment method in which a set dollar amount per patient per unit of time is paid by insurance companies to cover services without regard to the actual number of services provided. That is, an insurance company pays the physician a set amount; all services utilized by the physician for the patient during the period are deducted from that payment. While the use of capitation has decreased in recent years, this method of payment is most likely to align physician incentives with those of the insurance companies, as physicians bear some financial responsibility for their decisions. This

method of reimbursement can vary in the extent to which physicians are held responsible. Some companies allow physicians to only take the administrative costs of a patient visit out of the fixed payment, while the company covers the cost of tests, medications, and other services. Other companies require physicians to deduct all services from the fixed payment. Figures 1.2 and 1.3 depict the extent to which capitation has penetrated the physician market. It is possible for a physician to reimbursed by both FFS and capitation simultaneously, as he or she could have patients under both types of insurance plans.

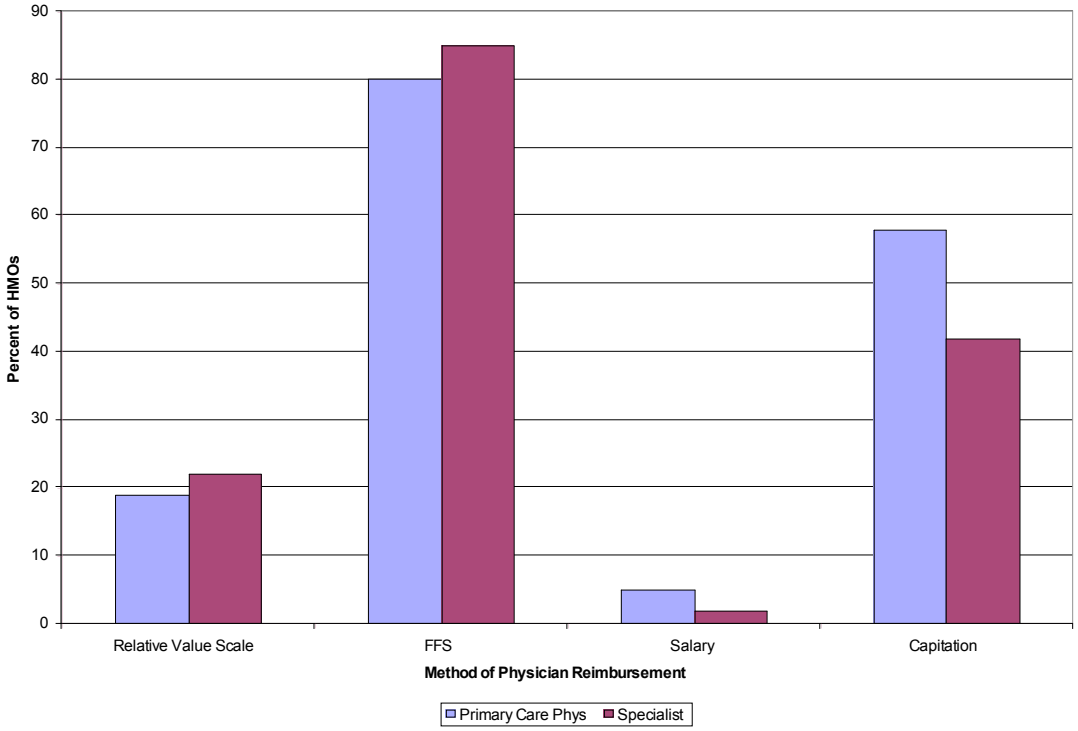

Figure 1.2

Method of Physician Reimbursement by HMOs in 2001

(Kaiser Family Foundation, 2006)

According to Figures 1.2 and 1.3, capitation seems to be relevant for both specialists and primary care physicians, but to a lesser extent for specialists.

Capitation for both types of physicians is the second most used method of physician reimbursement, with over fifty- percent of HMO's using some form of capitation for primary care practices. The majority of pediatricians face capitation as their method of reimbursement, while both general internal medicine and family practice have capitation rates for nearly 50% of their field.

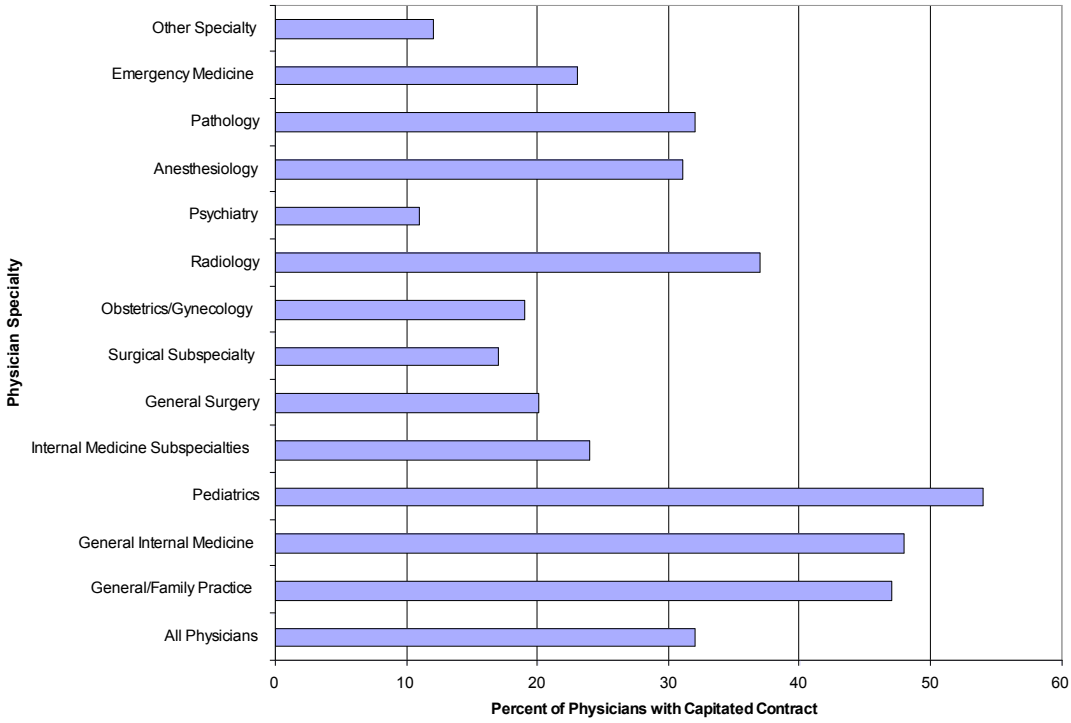

Figure 1.3

Percent of Physicians with Capitated Contracts by Specialty in 2001

(Kaiser Family, 2006)

Capitation is compared with Fee-for-Service in the work here to examine the impact of financial incentives on physician prescribing behavior. The incentives under capitation are to minimize the use of resources in order for the physician to maximize profits. FFS physicians, however, can increase profits by maximizing resource use. Under the context of prescribing behavior, this study examines how

capitated and FFS physicians differ in their prescribing behavior. This analysis is then further carried to examine how these physicians differ in prescribing behavior, once a low cost OTC becomes available in the market that is of equal strength and effectiveness as prescription-only drugs. By providing an OTC drug to their patient, physicians can minimize further office visits for the same illness, since the patient no longer has to get physician approval for refills. Providing a prescription drug, however, increases the likelihood that a patient will return to a physician's office, since the patient will need refills and/or physician monitoring. Using OTCs, therefore, can limit the amount of resources used, which may be beneficial to capitated physicians.

Patient Case Mix

According to the theoretical model described later, it is predicted that patients will have the opportunity to self-treat with an OTC, and therefore the only patients seen in physician offices are those who were not successful with the OTC or those who were not able to properly diagnose themselves, perhaps because of co-morbidities. Also, those patients that have the relevant illness on a long term basis are likely to be seen in physician offices for disease management.

It is therefore hypothesized that the case mix of patients with a related diagnosis seen in physician offices will become more severe after the availability of an OTC medication for a particular class of drugs. Measuring patient severity is difficult without knowing the exact nature of a patient's symptoms or the results of patient exams and tests. Other researchers have utilized measures such as Ambulatory Care Groups (ACGs) and Chronic Disease Scores (CDS) to adjust for patient case-mix. With ACGs, resource use is predicted using ambulatory visit diagnoses. CDS uses the category of drugs prescribed to identify chronic comorbid conditions (Hillman et al, 1999).

Some researchers have used time spent with the physician, defined as the number of minutes the physician spends face-to-face with the patient, as a measure for severity, where an increased time spent indicates a higher severity of illness. It has often been suggested that a greater amount of time spent with a patient indicates greater physician effort (Rice, 2004). While time spent with the physician could very well shed light on the severity of the patient, this measure can be influenced by many other factors that are not related to severity. For example, physicians may spend more or less time with a patient simply because of changes in reimbursement methods rather than the nature of the patient's illness. Also, it is when patients first have symptoms that time spent with the physician could be greatest. It is in these initial visits that the physician takes time to understand the patient's symptoms and educates the patient about the illness. Time spent therefore, could be an indication of the start of an illness for a patient, in which case the severity may still be low. Also, those that have chronic conditions are thought of having a higher severity. Time spent with chronic patients, however, does not necessarily have to be higher, since these patients are most likely being managed, rather than first being diagnosed with the illness. Time spent with the physician is therefore tested here, to simply better understand what happens amongst patients and physicians once an over the counter drug is available, rather than to predict changes in case-mix severity.

The number of diagnostic tests ordered could also be an indicator for the complexity of a patient's illness since physicians use these tests as tools in the diagnosis process. When patients have many symptoms that could lead to a variety of illnesses, physicians utilize diagnostic tests to help discern between them. Again, however, the most testing could be done when patients first present with symptoms in the physician's office. It is during this initial time period that the physician could still be in the diagnosis process and utilizes testing to help determine the patient's illness.

The total number of diagnostic tests therefore would not necessarily indicate a higher severity, but rather the early part of an illness. Total testing is also examined here to better understand the effects of an OTC becoming available in a class, but it is not used as a measure of severity.

To better understand changes in severity, this study analyzes the use of specialist physicians before and after the availability of an OTC medication to indicate any changes in patient case-mix. The use of a specialist indicates that the patient has symptoms that can no longer be effectively treated by a primary care physician and instead need to be more aggressively handled by a physician trained in the area (Diette et al, 2001).

Finally, this study examines the nature of the patient's condition to estimate severity. The nature of the illness is categorized by the length of time the patient has had symptoms. Acute patients are defined as those having symptoms for less than three months; chronic routine are those patients with symptoms for more than three months; and chronic flare-up includes those patients that have had the illness for more than three months, but their symptoms have suddenly been exacerbated. As described by Rice (2004), chronic conditions can be considered as more severe and more costly than acute ones because they require a greater use of medications and a longer time period for treatment. According to the hypotheses of this study, if acute patients can be successfully treated with OTC medications, these patients will no longer see their physicians, thereby increasing the overall severity of the patient case mix seen in physician offices. Chronic flare-up patients are expected to act similarly to acute patients, since their conditions may also be short-term.

Regulatory Status of Drugs and Policy Impact

The regulatory status of drugs determines the extent of access patients have to the medication. To obtain prescription drugs, patients must first go through

physicians, whereas OTC medications can be accessed directly, without prior authorization. As more medications for more illnesses, move to the OTC market, patients will increasingly be able to self treat. This could create an efficient mechanism to sort between patients with mild conditions from those with higher severity. If all patients first use OTC medications, some will be treated effectively and will not have to see a physician at all. Others, however, will not be treated successfully by the OTC and will have to see a physician for further diagnosis. The availability of OTC medications creates a system in which unnecessary physician visits can be avoided, thereby decreasing health care costs. This could impact the decisions of the Food & Drug Administration, when determining which drugs and which drug classes should be available without physician approval. The downside of OTC availability is an important factor in this decision making process as well. With increased access, patients could over-utilize medications, or could even take these drugs incorrectly if they misdiagnose themselves.

Significance of Pharmaceutical Market Analysis

The medical drug market has become an increasingly important component of the health care industry, which further provides reason for increased research in this area. In 1999–2000, according to a survey done by the National Center for Health Statistics, 44.3 percent of Americans of all ages reported using at least one prescription drug during the month in which the survey was conducted. During the same period the percent of individuals who reported using three or more drugs in the past month was almost 17 percent. More than 60 percent of adults age 45–64 years and more than 80 percent of adults age 65 years and over reported taking at least one prescription drug during the month in which the survey was conducted between 1999-2000. In 2002, national expenditures on prescription drugs were over $162 billion and grew over 15% from the amount spent the year before (National Center for Health

Statistics, 2004). Figure 1.4 shows the percent of National Health Expenditures spent on prescription drugs.

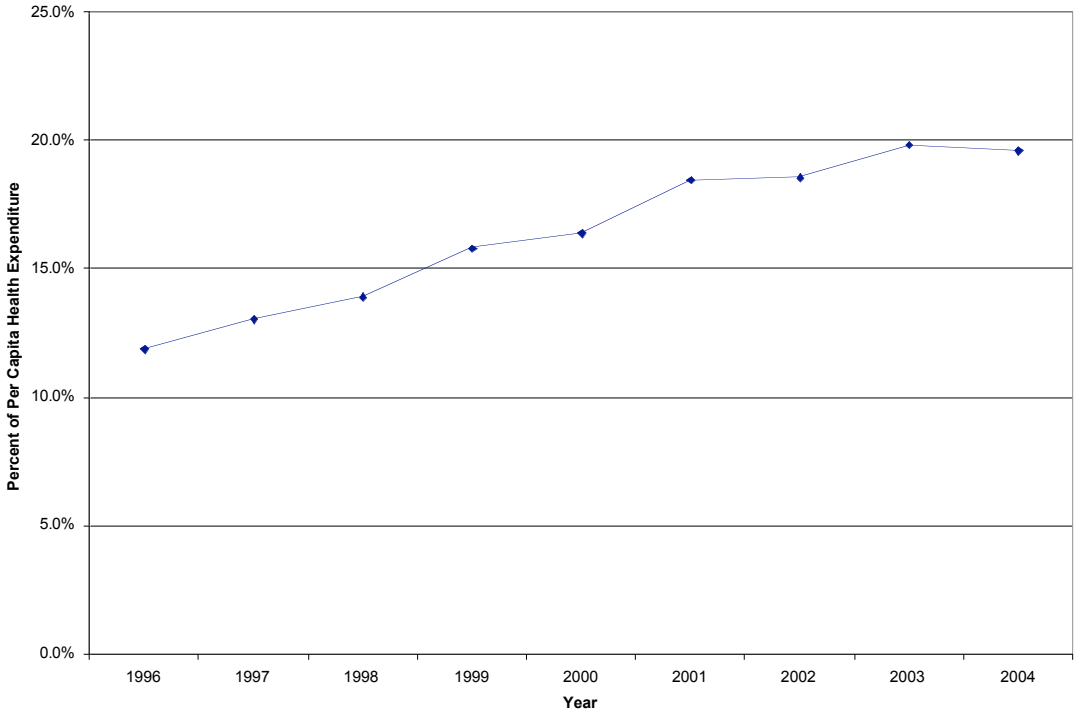

Figure 1.4

Percent of per Capita National Health Expenditures Attributable to Prescription Drugs (MEPS, 2006)

These expenditures should progressively increase as the use of drugs continues to rise. As some blockbuster drugs come off patent, there may be a leveling off of prescription drug expenditures since the cost of these drugs should decline. Other new drugs, however, will still be introduced at higher prices, off setting the patent expiration effect. Figures 1.5 shows the percent of the U.S. population that has a prescription expense. Figure 1.6 depicts the mean out-of-pocket cost paid by patients amongst those that have a prescription expense. The two figures provide different perspectives on the pharmaceutical market and its trends.

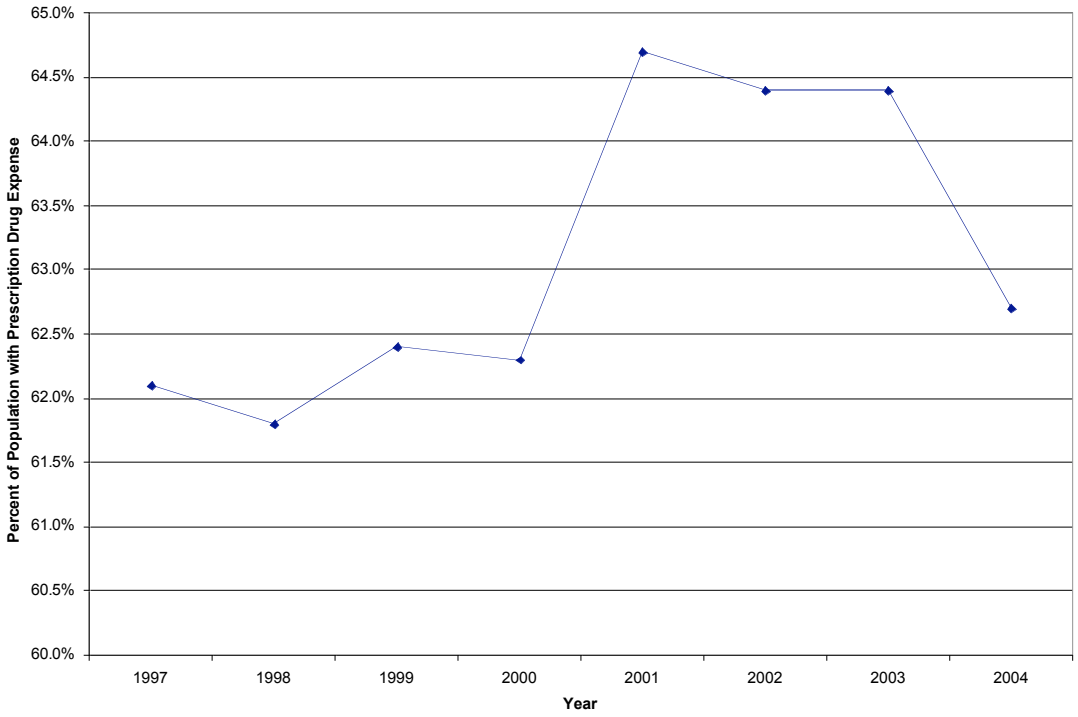

Figure 1.5

Percent of Population with a Prescription Expense

(MEPS, 2006)

While the percent of the population that has a prescription expense seems to be leveling off from 2000 – 2003, and even falling in 2004, the actual out-of –pocket expense for patients seems to be on the rise, as depicted in Figure 1.6. These two figures indicate the possibility that drug prices have increased. Also, these graphs could be implying that amongst those patients that have a prescription expense, more patients are using multiple drugs in their therapy. If this were true, an increase in the percent of people with a prescription expense would not be seen, but an increase in the total cost of medications for each individual would be found. Figure 1.6 shows that amongst those with a prescription expense, individuals spent over $1000 per year on medications in 2004 compared to approximately $600 in 2000.

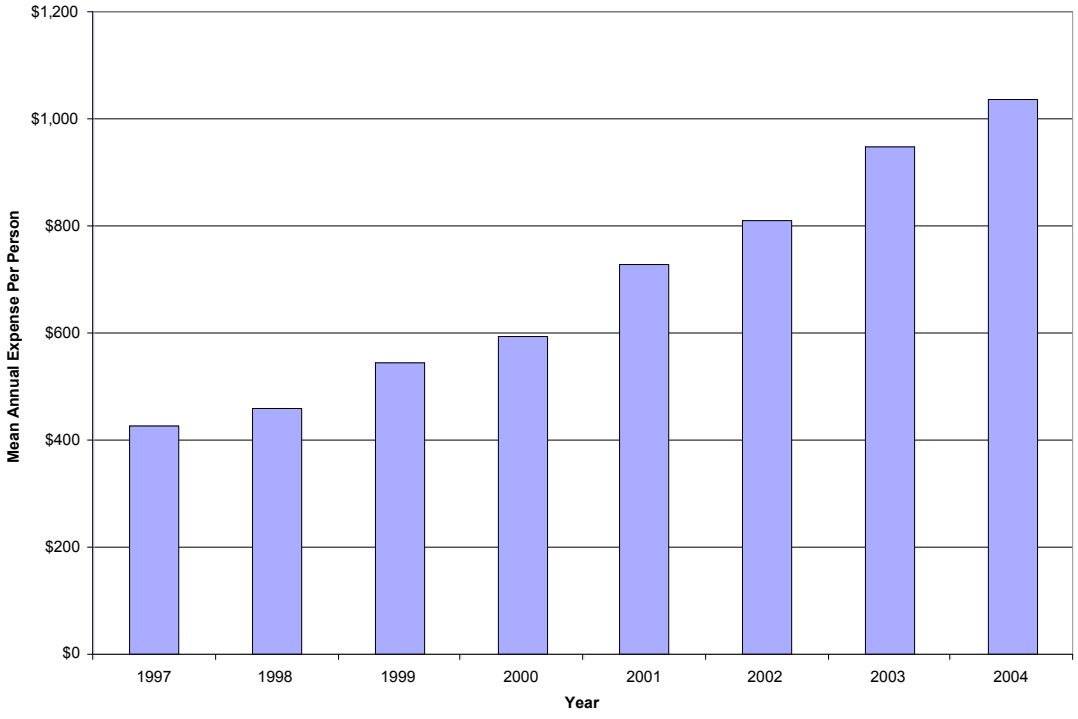

Figure 1.6

Mean Out-of-Pocket Expense for Population with Prescription Expense

(MEPS, 2006)

CHAPTER 2

BACKGROUND

Players in the Health Care Industry

The health care market in the U.S. has many players acting with varying interests. Patients are the primary consumers of health care, but physicians often act as agents for them in their consumption decisions. The majority of U.S. patients do not pay the full price of all the products and services in the health care industry at the point of consumption because of insurance. Because patients do not necessarily face the marginal cost of these services, there can be a moral hazard tendency to over consume.

While physicians are suppliers of health care services, they are consumers as well. Physicians provide their skills and services to patients and charge a fee, but, as mentioned earlier, they must simultaneously act as an agent on behalf of patients and their interests. As owners of private practices or even as employees of managed care companies, physicians must balance business interests as well, by minimizing costs. In this position physicians must provide adequate care at the least possible cost.

The U.S. government through the services of Medicare and Medicaid and private insurance companies are the major providers of health insurance in this country. These organizations do not consume any health care services directly; however, they are the major payers of all health care products. As third party payers, the main incentive for insurers is to minimize excess costs.

Pharmaceutical companies are players in this industry as well. Most of these companies are public and therefore, in order to meet shareholder goals, they must maximize profitability. To accomplish this, drug companies engage in heavy marketing directly to the consumer, but most of all to the physician. Pharmaceuticals also attempt to find the most innovative medication for each type of illness to sell in

drug markets with patent protection. These companies engage in heavy research and development efforts to find the newest products, obtain patents, and gain FDA approvals. By getting a patent for the product, these corporations can protect themselves from competition and can set their prices in a monopolistic way. According to the Congressional Budget Office, as of 1994, the patent for a prescription drug lasts 20 years from the date of filing. The 20 years of exclusivity includes the period in which the drug moves through FDA trials, and therefore amounts to an average of 11.5 years of marketing time (CBO, 1998).

Once a drug loses patent protection, generics are able to enter the market and create a great deal of competition, driving down prices. At times, pharmaceuticals are able to extend the profit life of prescription products as they lose patent protection by turning to the over the counter market. As they switch a drug to OTC status, pharmaceutical companies can take advantage of the brand name associated with their product and can continue to make profits from it. In addition, the Drug Price Competition and Patent Restoration Act of 1984 (Hatch-Waxman) allows for a 3 year patent extension of those drugs switched from prescription only to over-the-counter status, if the company has been required to provide additional clinical trials for the switch to be evaluated. This extension is also given to those products in which a pharmaceutical firm can find a new indication for use when the drug moves to the OTC market (Harrington, 2002).

When competing in the OTC market, however, pharmaceuticals must also face increased price elasticity. That is, since patients generally pay for the full cost of OTC medications completely out-of-pocket, they will be more sensitive to differences in price. For this reason, pharmaceutical companies are not able to price their medications as high in the OTC market as compared to when the drug was prescription-only.

Insurance companies that provide drug coverage are also in a position to push for the switch of prescription drugs to over the counter status. Traditionally, most insurance companies have not covered OTC products within their prescription drug plans. Therefore, as they are looking for ways to reduce costs in the prescription drug market, insurance companies can petition the FDA to convert a drug from the prescription to the OTC market. Also the company can save costs when people self-medicate and thereby decrease their trips to physician offices.

Policy Analysis and the Pharmaceutical Industry

There are many public policy issues concerning the pharmaceutical industry as well. In 2003 the Medicare Modernization Act (MMA) was initiated to provide drug coverage for the Medicare population to ease the financial burden of prescription drug spending, especially for those with low incomes. Under this plan, in January 2006, Medicare began paying for outpatient prescription drug coverage through private drug plans. With the recent start, there is considerable interest in understanding how the new benefit could affect the out of pocket costs beneficiaries face. According to a Kaiser Family Foundation report, in 2006, the Congressional Budget Office (CBO) estimates that Part D participants will spend, on average, $792 out of pocket for prescription drugs (excluding premiums), which is 37% less than the $1,257 they would have spent in the absence of the law.

In another area of pharmaceutical policy, in 2004, a group of senators introduced a bill that would allow the re-importation of prescription drugs from other nations. The Pharmaceutical Market Access and Drug Safety Act would allow U.S. residents to re-import as much as a 90-day supply of prescription drugs from Canada for personal use from only Canadian pharmacies that have been approved by the Food and Drug Association (FDA). Those in favor of the bill argue that there is no reason why Americans have to pay more for their medications than people in other countries.

Those opposed to the bill feel that re-importation will prevent the FDA from being able to monitor the quality of drugs entering the U.S. and will thereby open the door for unapproved medications that could be potentially harmful to patients. The bill has not been passed into law, and therefore it is still illegal for anyone other than a drug manufacturer to bring pharmaceuticals into the US.

Advertising has also been at the center of public policy recently. Before 1997, pharmaceutical companies had to provide all of the risk information associated with a drug during a television advertisement. This requirement increased the length of the advertisement, making them impractical. In 1997, the FDA issued a new guidance allowing pharmaceutical companies to meet requirements by presenting the major side effects, either in audio or in audio and visual form, and by telling consumers where to find additional information, including how or where to obtain the approved product labeling. According to the General Accounting Office from 1997-2001 spending on advertising increased from $1.1 billion to an estimated $2.7 billion. Meanwhile, spending on total promotion increased from $11.0 billion to an estimated $19.1 billion. This rapid increase caused a great deal of debate as to the true effect of advertising. Those in favor of direct-to-consumer advertising claim that these ads provide information to consumers by making them aware of conditions and the treatments available. These advertisements encourage patients to see their physicians and get proper care in a timely manner. On the other hand, those opposed to advertising claim that these ads create unnecessary demand for pharmaceutical products. People see ads and think they have conditions that they may not in fact have; patients then demand these brand name products from their physicians. According to the opposition, this wastes valuable physician time and physician autonomy, especially when the physician has to explain to the patient why they do not need a particular drug.

U.S. Drug Approval Process

Before a drug can even enter the prescription or OTC markets, it must be approved by the Food and Drug Administration (FDA). According to the FDA, a legal drug is a substance used in the diagnosis, treatment, or prevention of a disease or as a component of a medication. In 1938, the Food, Drug, and Cosmetic Act was passed, requiring for the first time that drugs be cleared by the FDA before being marketed for patient use. Under this act, all new drugs had to be proven as safe for human use and had to have the labeling specifications required by the act.

Drug companies formally propose that the FDA approve a new drug for sale in the United States with a new drug application (NDA). An NDA includes data collected from various research trials and analyses. Specifically they must provide sufficient results to prove the safety and effectiveness in treating, preventing, or diagnosing a specific disease. Decisions that the FDA must make include:

- Whether or not the drug is safe and effective for its proposed use.
- Whether the drug's proposed labeling is appropriate.
- Whether manufacturing methods are adequate to preserve the drug's strength, quality, and purity.

The research and development process for drug companies is very complicated, time-consuming, and expensive. In addition, it is never guaranteed that a successful product will be the end result. Thousands of chemical compounds are made and tested in hopes of finding one that can make it through the approval process. According to FDA estimates, it takes approximately eight and a half years to study and test a new drug before it can be approved for the general public. This approximation includes laboratory and animal testing, as well as clinical trials on human subjects.

Drugs are developed in many different ways. In some instances, pharmaceutical companies themselves decide to develop a new drug for a specific

medical condition. Scientists may choose to investigate an interesting line of research, or findings from university and government research may point the way for drug companies to follow their own research. In all cases, new drug research begins with an understanding of how the body functions, normally, as well as abnormally. This level of understanding allows researchers to determine how a drug might be used to prevent, cure, or treat a medical condition. Sometimes scientists can find the correct compound quickly, but usually thousands must be screened first.

In the U.S., it is estimated that bringing a prescription drug to market costs between $300 million and $600 million, and takes approximately 10-15 years. One in five thousand compounds that enter preclinical testing actually proceeds to human testing, and around 20% of those that enter clinical trials actually make it to the market (Paul, 2001).

Pre-Clinical Research

Before the approval process even begins, companies are required to first undergo pre-clinical research to show that a drug is reasonably safe for initial small scale studies. It is during this stage that sponsors evaluate a drug's toxic and pharmacological effects. The results of these tests are then used in the Investigational New Drug (IND) application required to be submitted to the FDA before testing can begin on human subjects. This application lays out all the information known about the drug to date and it begins the official dialogue between the FDA and the pharmaceutical company. According to the FDA, sponsors of drug applications have various options for fulfilling these requirements. Depending on whether a compound has been marketed previously or even studied before, companies can compile data from past laboratory studies on the compound; they can compile data from previous clinical testing or marketing of the drug; or companies can undertake new pre-clinical studies.

Animal testing generally begins in this pre-clinical phase to measure the toxicity of a drug and examine the chemical breakdown of it in vivo. Animal testing can be short term, lasting a few weeks to a few months. Long term animal testing, however, can even last several years, at times running concurrently with human testing in order to learn about the long term effects of a drug. All of the data in this phase is used to determine if it is safe to proceed with human/clinical trials.

Clinical Trials

The goal of clinical trials is to obtain safety and effectiveness data for each drug. The clinical trials part of the process is divided into three phases. Phase 1 is the initial introduction of the investigation. Here, tests are usually conducted on approximately twenty to eighty healthy volunteer subjects to determine the metabolic and pharmacologic actions of the drug in humans; any side effects associated with increased doses; and gain early evidence on effectiveness.

In Phase 2 researchers conduct controlled clinical studies on several hundred people to obtain data on the effectiveness of the drug in those patients with the target disease. Many short-term side effects are often found in this phase. This phase can take several years to complete and costs between $20 million and $40 million (Paul, 2001). The studies in this phase also determine the dosage levels and frequency of administration at which this level of effectiveness is reached safely.

Phase 3 includes expanded controlled and uncontrolled trials. After evidence from Phase 2 has been found indicating that a drug is effective, Phase 3 trials begin to gather more information about the effectiveness and safety of a drug to create an overall benefit-risk relationship. Physicians monitor patients closely in this phase of trials in order to confirm the effectiveness of the product and also to identify and adverse reactions. Because Phase 3 trials are conducted on several hundred to several

thousand people, they provide an adequate basis for extrapolating the results to the general public.

Occasionally, the FDA conditionally approves a product, in which case, it requires companies to conduct Phase 4 trials. This additional research is generally conducted to measure the compounds impact on particular patient subgroups or to provide a clearer picture of benefits. Companies can begin marketing their products while they are in the process of conducting Phase 4 trials.

NDA Review

After Phase 3 of the Clinical Trials stage is complete and successful, an NDA is submitted for review. After careful review of data from all of the research trials, the FDA decides whether or not the drug labeling, or the official instructions for use, is acceptable. The FDA then has an inspection of manufacturing sites and areas where significant clinical trials were performed. If those are found to be in satisfactory condition, the NDA is generally approved, after which only the sponsor of the NDA can market the drug. Pharmaceutical companies are still required, after approval, to continue to submit periodic reports to the FDA regarding all serious adverse reactions and quality control problems (FDA, 2005).

Prescription & OTC Drugs

The distinction between prescription and over-the-counter (OTC) drugs was first established in 1951 with the Durham-Humphrey amendments to the Food, Drug, and Cosmetic Act which defined the types of drugs that could only be safely used with medical supervision (FDA Food and Drug Law History, 2005). Later, all drugs, both those that did and did not require physician authorization, were required to be proven safe and effective with the passing of the Kefauver-Harris amendments in 1962. In 1972, the OTC Drug Review was started to evaluate OTC product ingredients to ensure safety, effectiveness, and labeling standards. Formally, a prescription drug is

any drug or medicine requiring physician authorization before it can be purchased or obtained. OTC drugs on the other hand are available to consumers without a prescription from a physician. Like prescription medications, however, these drugs also undergo an approval process and are monitored by the FDA. According to the FDA, OTC drugs generally possess the following characteristics (Mossinghoff, 1999):

- Benefits outweigh risks.
- Potential for misuse and abuse is low.
- Consumers can use them for self-diagnosed conditions.
- They can be adequately labeled.
- Health practitioners are not needed for the safe and effective use of the product.

OTC Approval

The FDA's review of OTC drugs is primarily handled by Center for Drug Evaluation and Research's (CDER) Division of Over-the-Counter Drug Products. The FDA has been evaluating the ingredients and labeling of some drugs since many OTC products have been marketed to the public even before laws were passed requiring proof of safety and effectiveness. This FDA project is part of "The OTC Drug Review Program" which is intended to establish OTC drug monographs for each class of products.

OTC drug monographs include information on acceptable ingredients, doses, formulations, labeling, and testing, and they are continually updated to add additional ingredients and labeling as needed. Those products that already conform to a monograph can be marketed without pre-approval from the FDA. Those drugs that do not conform to the monographs, however, must undergo separate reviews and must gain approval through the New Drug Application (NDA) process, which is the same

process for approving prescription drugs. New ingredients that enter the OTC market for the first time also must use the NDA process.

The OTC Drug Review evaluates OTC product ingredients and initially categorizes a drug as Category I, II, or III. Category I drugs are generally recognized as safe and effective for the claims given by the sponsor. Category II drugs are recognized as generally unsafe and ineffective, while Category III drugs are those with insufficient data to allow for a final classification. The FDA evaluates the findings from this review to either approve or reject a drug for OTC marketing (FDA, 2005).

Prescription to OTC Reclassification

Thirty percent of new OTC drugs that were put on the market between 1975 and 1994 were originally prescription-only drugs. Since the OTC Drug Review was initiated, more than 40 product ingredients have been switched from prescription to OTC status.

According to Mahecha (2006), "The US Food and Drug Administration defines an Rx-to-OTC switch as over-the-counter (OTC) marketing of a drug product that was once a prescription (Rx) drug for the same indication, with the same strength, dose, duration of use, dosage form, population and route of administration". There are three sponsors that can apply for the reclassification process from prescription to OTC. First, manufacturers can create a supplement to the original New Drug Application (NDA) if post-marketing evidence from prescription-only sales shows that the drug can be used safely without physician supervision. Second, after a drug has already been sold on the prescription-only market the FDA itself can file a petition for reclassification if it has been determined that prescription status is not necessary for safe use of a drug. Third, any interested party (such as patients, physicians, or insurance companies) that feels an Rx-to-OTC switch would be appropriate can file a citizen petition asking the FDA to consider changing a drug's status (CDER, 2006).

The majority of switches, however, are initiated by the parent company of the drug in question since the manufacturer has the most access to data that can determine whether or not a switch is appropriate.

Drugs must meet certain criteria before the FDA will consider such reclassification. The indications for use as an OTC drug must first be similar to the prescription indications, and the OTC drug must allow for easy diagnosis and monitoring by the patient. Next, the drug must have positive adverse-event and drug-interaction profiles, relatively low toxicity, as well as a low potential for abuse. Finally, the drug must not have characteristics that make it impractical for OTC use (FDA, 2005). Figure 2.1 shows the number of OTC approvals and Rx-to-OTC switches per year. According to the figure, 1996 had the most switches/new approvals. This year had high profile switches in products from drug classes including:

- Acid Reflux – (Zantac, Axid)
- Smoking Cessation – (Nicorette, Nicotrol, Nicoderm)
- Hair Growth – (Rogaine)
- Anticandidal – (Femstat, Monistat, Gyne-Lotrimin) (Soller, 2000).

Financing Drug Development

Drug manufacturers are faced with increasing costs for drug development. The Southern Medical Association estimates that the cost for developing and marketing a single pharmaceutical product has risen from $54 million in the 1970s to greater than $800 million in 2000 (Spruill, 2005).Many companies therefore try to extend patent life as long as possible to prevent any threats of competition that may drive revenues down. Table 2.1 shows the change in profits after patents have expired for a few major drugs. Drugs such as Claritin have a decrease in profits of nearly ninety – percent.

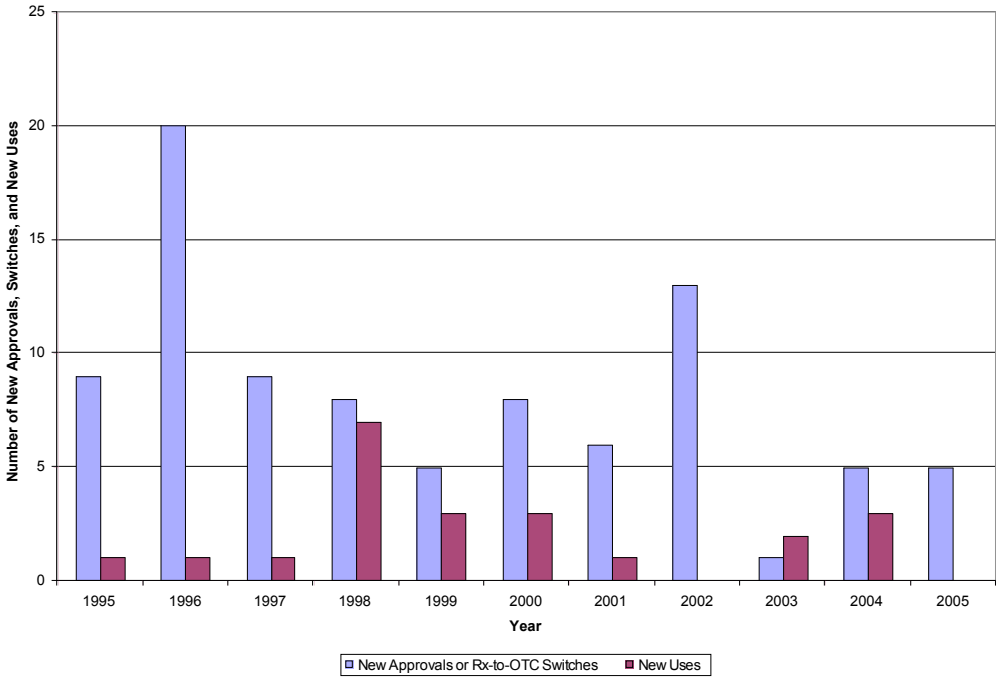

Figure 2.1

OTC New Approvals, Rx-to-OTC Switches, and New Uses by Year

(CDER, 2005)

Table 2.2 provides recent revenues for drugs with upcoming patent expirations. Many drugs facing patent expiry are switched to the OTC market to protect revenues from generic competition. When a drug patent is about to expire, the company submits a switch request in the hopes that brand recognition and loyalty cultivated among prescription customers will transfer to the over-the-counter market. As mentioned earlier, The Hatch-Waxman Act of 1984 added another incentive: granting 3 additional years of market exclusivity to drug makers if they perform the extra clinical trials required to gain over-the-counter approval or if they create new indications for use (Reynolds, 2002). Even if a drug does not receive the exclusivity extension, it still may be worthwhile for drug companies to move their products to the

OTC market to capitalize on their brand name. In addition, companies can use the OTC market for these, older drugs, and open the prescription-only market for other new products they may have in the class, that are still under patent protection.

Table 2.1

Annual Revenues Before and After Patent Expiration and Generic Drug Entry (Spruill, 2005)

Brand Name	Manufacturer	US Sales (pre-patent expiration)	US Sales (post-patent expiration)	Year Expired
Claritin	Schering-Plough	> $3 Billion	$370 Million	2002
Prozac	Eli Lilly	> $2.9 Billion	$480 Million	2001
Pepcid	Merck	$755 Million	$110 Million	2000

Table 2.2

Blockbuster Drugs Facing Patent Expiration (Generic Drugs, 2006)

Brand Name	Manufacturer	Common Uses	Revenues in 2003 (in - billions)	Year of Expiration
Prevacid	TAP	GERD, Peptic Ulcers	$3.5	2007
Imitrex	Glaxo-SmithKline	Migraine Headache	$1.1	2007
Zyrtec and Zyrtec D	Pfizer	Allergies	$1.4	2007
Depakene and Depakote	Abbott	Seizures	$0.7	2008
Effexor and Effexor XR	Wyeth	Depression	$2.1	2008

Some manufacturers sell their drugs on both the OTC and prescription markets simultaneously, also known as dual status. According to the FDA, "Dual status is defined as having the same molecule and the same brand name simultaneously in the Rx and OTC markets, but with a different strength or indication from one to the other." The three year market exclusivity available in the OTC market would still apply to those drugs with dual status, however, according to the FDA, this status is still not that well known or practiced by US domestic Rx marketers (CDER, 2006). While, dual regulatory status could potentially extend the market exclusivity and allow for utilization of brand recognition, it could also cause companies to spread their resources too thin over the two markets since competition would exist from both prescription and OTC drugs (Goldfarb, 2002).

OTC Market

Many patients use OTC drugs as their first attempt at treatment for illnesses. Some feel that the switch from prescription to OTC status of drugs drives down the cost of healthcare, especially for insurers since they generally do not cover the cost of OTC drugs. Almost all OTC medicines can be purchased for well under $20, while the average price of a prescription drug is closer to $40 (CHPA, 2005).

According to a 2005 AC Nielsen report, in 2004, OTCs accounted for over $15 billion in sales in the U.S. retail market, excluding Wal-Mart. Wal-Mart is excluded from this figure because of the unavailability of data from the company. In 2001, the Consumer Healthcare Products Association (CHPA) reports, "More than 700 medicine products available over-the-counter today use ingredients and dosages that were available only by prescription less than 30 years ago." In the same year the CPHA estimated that there were more than 100,000 OTC products with approximately 1000 active ingredients used in them in the market. In 2003, the CHPA stated, "Since 1976,

almost 80 ingredients, dosages, or indications have made the 'switch' from prescription to OTC status" (CHPA, 2005).

From 1976 to 1989, the FDA approved 39 Rx-to-OTC switches and 20 switches just between 1990 and 1996. Some of the switched products during this time period include Smoking Cessation products, such as Nicorette; Children's Advil, Children's Motrin, Orudis KT, and Actron all for pain relief; Femstat 3 for treating vaginal yeast infection; Pepcid AC, Tagamet HB, Zantac 75, and Axid AR for heartburn; and Rogaine for promoting hair growth (Ling, 2002). Figure 2.2 depicts the total sales for OTC medications by year.

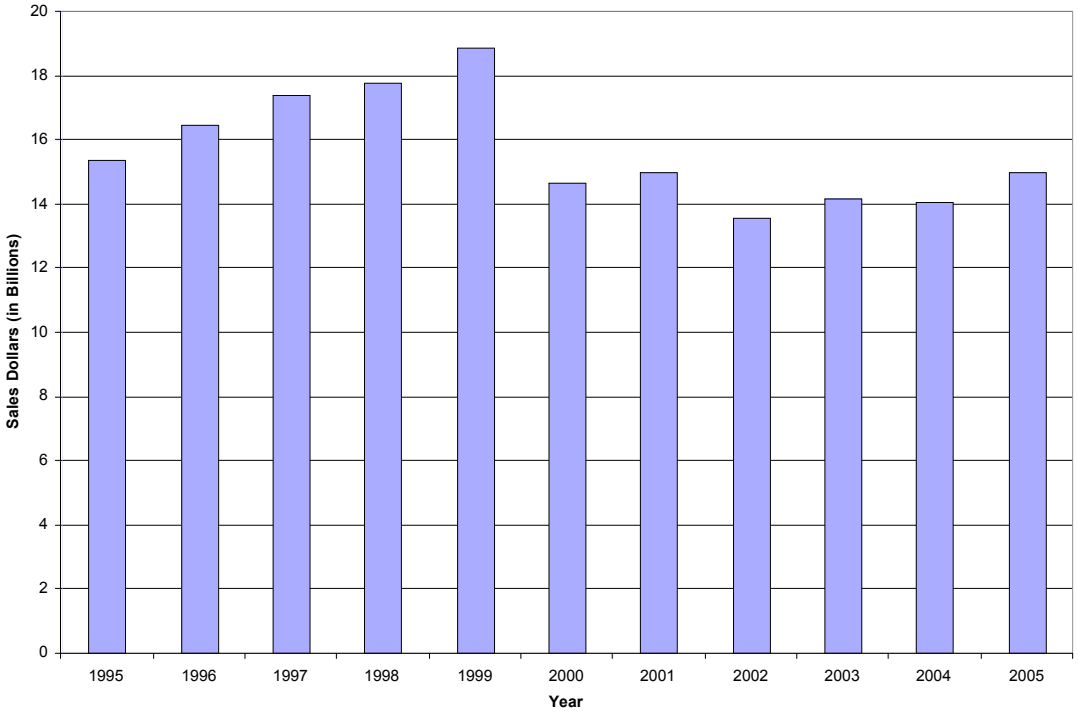

Figure 2.2

OTC Retail Sales by Year (excluding Wal-Mart) (CHPA, 2006)

The OTC industry, as seen above, accounted for over $18 billion in sales in 1999 at the peak, but continued to have sales well over $12 billion afterwards. This

market, however, is limited to only a few drug categories, as not all are appropriate for sale without physician approval.

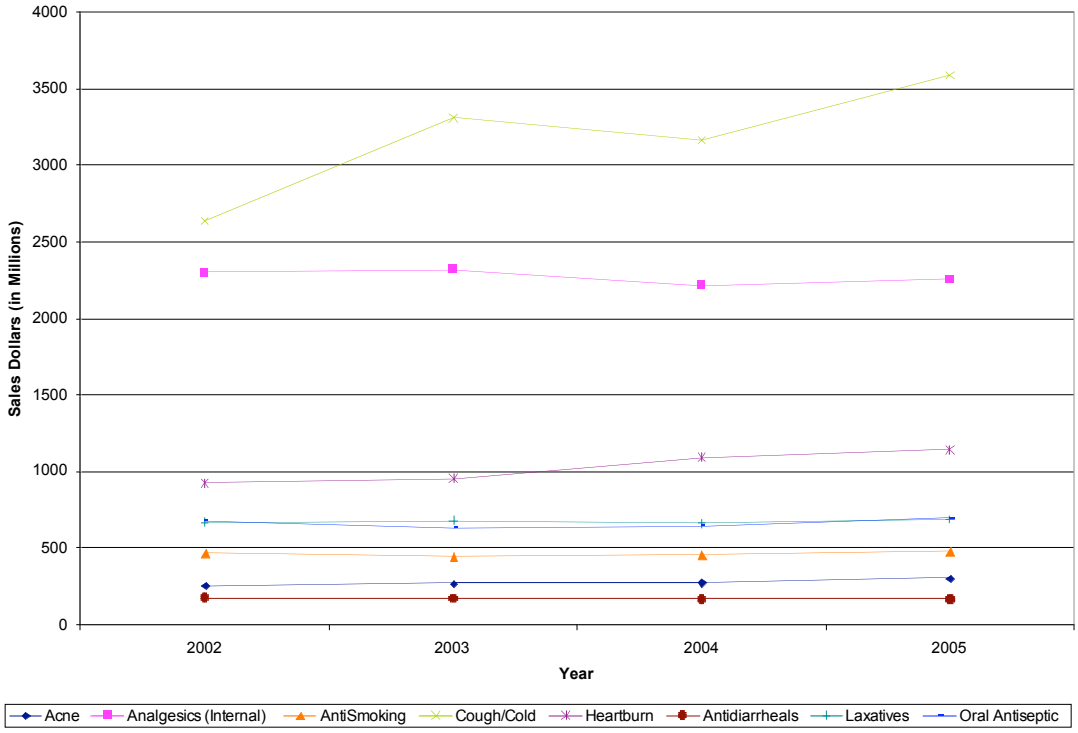

Figure 2.3

OTC Sales by Category (in Millions) (CHPA, 2006)

Sales are broken down by drug class in the Figure 2.3. As this figure shows, the cough and cold category had the most sales with a general upward trend from 2002 – 2005 and over $2.5 billion in sales. While sales of OTC healthcare products continued to be strong in 2004, they were slightly less than that of 2003. The pressures to recall certain COX-2 prescription painkillers and the ephedra ban deterred many consumers from buying as many medications. Also, there was a decrease in major product innovations which constrained the growth of many types of OTC products. Digestive remedies, medicated skin care, eye care, wound treatments, and other products, however, continued to increase in 2004 (The-Infoshop, 2005).

Key Drug Switches

The December 2002 switch of Schering-Plough Corp's Claritin (loratadine) into the OTC market was one of the biggest ever. In this case, the manufacturer was not the one to lobby the FDA for the switch. Instead, California-based WellPoint Health Networks, a third-party insurer, requested the FDA to switch the product because they claimed to spend millions on prescription Claritin annually.

Claritin, a top prescription performer, was the first non-sedating formula in the OTC market. First generation antihistamines, generally caused drowsiness. The active ingredient of Claritin, loratadine, is considered a second generation antihistamine, and has non-sedating properties. The American College of Allergy Asthma and Immunology (ACAAI) estimates that 44% of allergy patients using OTC products switch medications because of dissatisfaction with first generation antihistamine products. Second generation products are, however, more expensive than the first generation counterparts. Generic diphenhydramine (Benadryl's active ingredient) or chlorpheniramine (ChlorTrimeton's active ingredient) cost $3 to $4 for 24-30 tablets, whereas the same number of Claritin tablets, in the OTC market, can cost a patient between $18 - $19.

Schering-Plough was denied the 3 year Hatch Waxman exclusivity period because of the company's delays and lack of planning. Therefore, Claritin was soon followed to the OTC market by competitors. Wyeth Consumer Healthcare's loratadine product, Alavert, is on store shelves and has a suggested retail price of $27 for a 48 count package (www.drugstore.com). The OTC sales of Claritin have been successful with first year sales totaling nearly $400 million and a market share of 50% in the allergy market.

Prilosec, the world's most prescribed drug from 1996 – 2000, was also a major switch into the OTC market. H2Antagonists such as Zantac and Tagamet were the

antacid products in the OTC market, while the more effective proton pump inhibitors (PPIs) were available by prescription only. The mechanism of PPIs is different from earlier products in that they work by shutting down proton pumps in the stomach that produce acid. Prilosec was the first of the PPIs to switch to the OTC market.

A licensing agreement between Astra-Zeneca and Proctor & Gamble was created and the two companies conducted the switch of Prilosec jointly. A great deal of debate took place between these companies and the FDA regarding claims, usage, and the risk for more serious conditions, such as ulcers and gastroesophageal reflux disease to go undiagnosed. After collaboration between the two sides, however, Prilosec was approved for OTC sales in June 2003. Prilosec was also given the 3 year Hatch Waxman market exclusivity and the first year of OTC sales were nearly $300 million (Mahecha, 2006). This extension applies only to the drug moving into the OTC market. All other drugs, under the same name, that have not switched markets, are not granted this period of exclusivity.

In the cases of both Claritin and Prilosec, the parent pharmaceutical company had new prescription-only products ready to be launched at the same time as the switch of the older drugs into the OTC market. Both companies shifted their advertising expenses towards the promotion of their newer medications in order to move patients from the older drug to the new one. In the case of Claritin, Schering-Plough attempted to convert patients from using Claritin to their new prescription product Clarinex. Astra-Zeneca had the newer PPI, Nexium, ready to take over the prescription market once Prilosec became OTC. Schering-Plough was not as successful at moving patients to the newer medication because neither patients nor physicians found any major differences between Clarinex and the over the counter Claritin. Astra-Zeneca was, however, more successful at moving patients to Nexium. In fact, in Prilosec's first advertising campaign the drug became known as the "purple

pill". After Prilosec's movement to the OTC market, Astra-Zeneca referred to Nexium as the "new purple pill" symbolizing the replacement on the prescription only market.

Areas of Debate

There are three classes of drugs in which there is much debate as to whether or not OTC status should be approved. Emergency Contraception was the major topic of debate in June 2000, when the FDA had to decide whether to sell emergency contraceptives over the counter. Women's-health advocates said that the move is overdue since the drug was available without prescription in the United Kingdom and Canada. Opponents, however, argue that over-the-counter emergency contraception could discourage use of conventional birth control methods. The FDA has just recently approved the OTC status of this drug, with some restrictions. Emergency contraception will only be available to those individuals 18 years or older. Also, the drug will not be stocked on store shelves, but rather behind pharmacy counters.

Antimicrobials were denied OTC status in December 1998 largely because of fears of antiviral resistance. While there were no major concerns for individual safety, The Infectious Disease Drug Committee indicated that it would not support the over-the-counter availability of antimicrobials because of the serious threat of antibiotic resistance.

Statins, used to lower cholesterol levels, were also denied OTC status. The FDA issued a guideline stating that lowering of cholesterol levels is not an appropriate indication for over-the-counter approval because physician monitoring is required. Most OTC products are for conditions that patients can generally detect easily. Hypercholesterolemia, however, may not be a condition patients can diagnose on their own, and therefore require physician supervision. Concern existed in regards to the OTC sale of these drugs because of the possibility of improper use. That is, those

individuals that do not need to lower their cholesterol may take these drugs unnecessarily. In addition, these medications are not recommended for use by women who are pregnant. The availability of statins on the OTC market would create the risk that women who were unaware of their pregnancy may take the drug and potentially harm themselves or their babies.

CHAPTER 3

PREVIOUS LITERATURE

This study examines how both patients and physicians react to a change in prescription status of a drug. The first section of this chapter examines physician incentives, generally, not related to prescribing behavior, but to other physician decisions. The second part of this chapter examines the impact of incentives on physician prescribing behavior. The research to date that has focused on prescribing behavior utilizes the standard principal agent model. In terms of the research done here, such a model would indicate that the physician's choice of a drug for a patient's ailment should not be influenced by simple its OTC versus Rx status, but rather the effectiveness of the medication for the patient. The third section examines the literature comparing the use of prescription and OTC drugs.

The model in this study also predicts that patient will also react to the availability of an OTC medication. That is, those patients with less severe conditions should choose to self-treat, leaving only those with more severe illnesses in physician offices. The final section of this chapter examines how severity has been measured in previous studies.

Physician Incentives

Barros et al (2003) create a model to test hospital production in which they define the output produced by the hospital as the health status of the patient. These authors also use physicians as the major decision makers of resource allocation. The hospital based physician must balance decisions between acting as a perfect agent for the patient and as an agent for the hospital, whose objective is to restrain hospital spending. Their model contains the utility functions of physicians and uses the expected health status of patients, resource allocation, and hospital financing policy as arguments. Their evidence shows that for physicians employed by hospitals, budget

setting methods and possession of third party payers are important predictors of resource use. Also, the authors conclude that resource use is important in predicting the final health status of the patient.

Both Glied et al (2002) and Melichar (2007) examine the effect of financial incentives on physician behavior, with respect to the amount of time a physician spends with a patient. Glied et al use the NAMCS to investigate the effect of managed care on physician time spent with the patient, while Melichar distinguishes between managed care and capitation. Glied et al find a negative relationship between the percent of patients under HMOs seen by a physician and the average length of time that physician spends with a patient. These authors do find an increased use of other services during a visit when there are a greater percentage of managed care patients in a practice. This may indicate that physicians, who have a higher number of managed care patients, substitute other services for length of visit time. Melichar, however, finds that it is capitation, and not just HMO status, that affects the amount of time physicians spend with patients.

Physician Prescribing Behavior

The theoretical framework used in this study models physician behavior as resulting from an objective function in which fee-for-service physicians have the incentive to provide prescriptions in order to increase the number of repeat patient visits which thereby increases physician profit. The model developed here also indicates that capitated physicians can maximize profits by providing OTC medications in order to minimize resource use.

Prescribing incentives are modeled as the outcome of a production function. The hypotheses drawn from this are tested by regressions in which indicators for providing a prescription are dependent on patient characteristics, insurance status, and the availability of an OTC drug for a particular diagnosis.

Bradford et al (2004) used a similar model in studying the impact of direct-to-consumer advertising on physician prescribing behavior. Their output measure was the number of prescriptions for COX-2 inhibitors (used for treatment of osteoarthritis). The authors used the flow of patients with osteoarthritis as an input to capture the patient demand function for office visits. Patient demand, as explained by the authors, is influenced by the price of office visits, patient characteristics and the exposure to advertising. This study found that direct-to-consumer advertising of certain drugs increase prescriptions for that drug as well as others.

In another study of prescribing behavior, Iizuka (2004) examines physician-patient agency in the prescription drug market of Japan. Doctors in Japan provide diagnostic services to patients and dispense drugs as well. This creates an incentive to induce demand since doctors can choose drugs based on the extent of profit they obtain, rather than safety or cost. The data used in this paper indicate that physicians' choices for drugs are significantly affected by the profit margin they earn.

In a 1998 paper on prescribing behavior, Stern and Trajtenberg use the theory of physician agency to examine the implications of physician authority in pharmaceutical prescribing decisions. According to their article physicians' expertise in prescribing relies on two assets: diagnostic skills and information about drugs. The authors define concentration of prescribing behavior as the degree of variation in drugs that physicians use. That is, those physicians that use a wide range of drugs or vary their choice of drugs by patient, for a particular illness, are not very concentrated. Those that choose their prescriptions amongst the same few medications, for most of their patients, are considered to have a concentrated portfolio of drugs. They find substantial variation in the degree to which physician prescribing is concentrated and this concentration is correlated with observable drug characteristics. These authors use the NAMCS survey to find that physicians who are concentrated in their

prescribing portfolio tend to prescribe those drugs with high levels of advertising, low prices, and high market shares. These features allow highly concentrated physicians to invest the minimum required resources to provide care for patients with the least overall harm.

Hellerstein, in her 1998 article, studied how physicians decide to give patients either generic or trade-name drugs. She specifically tests whether or not physicians are more likely to give generic drugs, because they are less expensive, to those patients without drug coverage. The author explains that if there were no costs to physicians for prescribing drugs, physicians would act as perfect agents for patients. There are, however, costs to the physician such as the time cost of learning about new drugs. Therefore, physicians may choose a prescription based on what is more convenient for them, rather than what is best for the patient. This paper utilizes the 1989 NAMCS survey. While the author does find that physicians are important agents in the prescription decision, she is unable to decipher why some physicians are more likely to give generics than others. The only statistically significant finding regarding insurance in this paper showed that physicians with a large proportion of HMO patients are more likely to give out generic prescriptions. As the author explains, this may be due to cost control methods implemented by managed care companies which make physicians somewhat financially responsible for their prescribing decisions. The author concludes that it is not the individual patient's insurance type that determines the physician's prescribing behavior, but rather the distribution of insurance types across all patients that the physician sees.

There are many studies that focus on how managed care influences prescription choices amongst physicians. In general, the majority of the studies that explore issues with managed care and prescribing behavior focus on the decision between brand name drugs and generics. The following articles, examine the financial

incentives of physicians to some extent, but they either look at a drug category as a whole, when one product in it moves to the OTC market or they examine the financial incentives of the patient and the physician in general prescribing, without examining a specific drug class.

Managed Care Incentives

Hillman et al (1999) estimated the impact of patient financial incentives on the use of prescription drugs while physicians had differing payment mechanisms. The study included some physicians who were compensated fee-for-service through the Independent Practice Association (IPA) model, while others were reimbursed by capitation under network-model Health Maintenance Organizations (HMO). Under IPAs physicians did not bear financial risk for medications, whereas with HMOs physicians did bear risk for their prescribing decisions. The results from this study show that higher patient copayments for prescription drugs are associated with lower drug spending in models in which physicians are not at risk for drug costs. Higher copays for patients do not, however, have much effect in models where physicians bear some financial risk for prescribing behavior. A limitation of this study is that it uses claims data and therefore the authors are not able to determine what the physician prescribed and how this may have differed from what was actually provided in the pharmacy. This is especially important since some plans and some states allow the pharmacist to fill the prescription with the lowest cost drug. If this is the case, the effect of financial incentives for the physician may be ambiguous.

Mortimer (1998) used the NAMCS from 1991 – 1993 and marketing data from IMS America to determine the demand characteristics of prescription drugs and how they are influenced by types of insurance. The author uses two therapeutic markets: antidepressants and beta blockers; and creates a mixed logit model that estimates the probability of a drug being prescribed. The explanatory variables in this paper include

drug characteristics; patient and physician characteristics; and average drug price. The main explanatory variable used here, however, is the interaction of drug price and insurance type, such as HMO, Medicaid, or Private Insurance. The author finds that managed care is effective in increasing a physician's awareness of drug costs. The results of this paper show that demand for drugs in managed care sectors is more price elastic than in other sectors. Interestingly, this author finds demand in the self-paid sector to be the least price elastic.

Prescription to OTC Switch

The following studies examine changes, once a drug moves from the prescription to the OTC market. While this literature is helpful in guiding the hypotheses of this study, little research thus far has examined how physician prescribing behavior is affected by OTC switches. In fact, even amongst most of those studies in which prescription and OTC drug use is analyzed, the markets for the two sets of drugs were different than what is being studied here. Previously, OTC and prescription drugs were not considered as substitutes for one another, as the prescription drugs were always stronger. This study adds to the literature by being able to utilize the unique situation in which equivalent drugs exist on the prescription and OTC market simultaneously. In the research here Claritin and Prilosec attained OTC status while therapeutic equivalents remained Rx only.

Andrade et al (1999) indicate that in the setting of managed care organizations, there were reductions in the prescriptions for H_2 receptor antagonists given to patients with chronic conditions after the availability of some OTC versions of these products. This suggests that physicians are under certain pressures in a MC setting to alter prescribing behavior when drugs go OTC. It was during this time, though, that Proton Pump Inhibitors entered the market, and therefore the study may fail to capture the movement physicians made to the newer, more effective drugs. Since this study

looked only at managed care and did not compare to FFS, the two effects are possibly confounded.

In her 1989 article titled "Substitution Between Prescribed and Over-the-Counter Medications" Leibowitz became one of the first to research OTC use in an experimental setting. Leibowitz used data from the Rand Health Insurance Experiment in which patients were assigned to health insurance plans with varied levels of medical cost sharing. The experimental design allowed the author to not only examine patients with different relative out-of-pocket payments for prescription drugs compared to OTCs, but she also was able to study areas in which access to physicians services were varied. This article hypothesizes, as do others described later, that OTC drugs may be used as a substitute for prescription drugs and/or a substitute to formal medical care, i.e. physician office visits. With the data from this experiment, Leibowitz hypothesized that those with less generous health care plans, that is, those plans that required higher out-of-pocket copays, would substitute OTC medications for prescription ones. Also, the author hypothesized that OTC drugs would be a substitute for physician office visits for those that did not have convenient access to physicians, as well as for those with high wages, in order to spend their time at work, rather than at a physician office. Similarly, when medical care is less available, for example with uninsured patients, OTC drugs should be used as substitutes as well.

An interesting finding of this article was that there were infrequent purchases of OTC drugs overall: on average less than one purchase per-person per-year. The author suggests that this may be consistent with high levels of OTC use if these drugs are purchased in large quantities and stored for later use. In terms of health insurance difference, Leibowitz found that with drug coverage, participants purchased more prescription and over-the-counter medications. Those patients facing cost sharing purchased fewer OTC drugs than those in the free plan. Females, children, and those

patients with more education were more likely to buy OTC drugs. In general, this study found no evidence of substitution between OTC and prescription drugs. While this article is an important one because of its key experimental design, it was also conducted in a time where the drugs available by prescription were generally not in competition with those available OTC. Prescription drugs were stronger and more effective than the OTC products. Since 2002, however, the situation in some drug markets has changed considerably. The availability of equivalent drugs on the prescription and OTC market could potentially lead to a different result if this study were conducted today.

Hollenbeak in his 1999 *Health Affairs* article used a game theory model to determine the optimal time, in relation to generic competition, to switch a drug from the prescription to OTC market. He determines that switching of drugs occur if the probability that an application will be approved by the FDA is strictly positive and the OTC market is characterized by first-mover advantages. He shows that firms switch their products into the OTC market in response to the threat of generic competition when patents are close to expiration. Pharmaceutical firms know that if they do not switch into the OTC market first, the generic may initiate the switch and become the first mover.

Harrington (2002) found that the conversion of prescription products to OTC availability can have an impact on prescription drug benefit costs and on total health care costs. According to Harrington, in 2000, the U.S. was estimated to spend $19.1 billion on OTC drugs expanding from $10.2 billion in 1991. While approximately 600 of the currently available OTC products were available only by prescription 20 years ago, less than 2 cents of every dollar spent annually on health care in the U.S is spent on OTC drugs. Harrington also estimates that almost $13 billion a year is saved by consumers when they use medications switched from prescription only to OTC

status. Furthermore, she finds that, 63% of total U.S. OTC sales in 1996 were from prescription to OTC switched products. She illustrates that for those patients with drug coverage, out-of-pocket payments for prescription drugs were less than the prices for OTC products. She also found that OTC approval was associated with elevated medical service use.

In their 2002 review of literature, Shih et al proposed that according to economic theory a firm that is protected by a patent will price aggressively in the OTC market. The OTC markets will likely be more elastic, however, due to a lack of insurance coverage. Therefore, drug manufacturers would be likely to charge a lower price in the OTC market.

In his 1992 article, Temin analyzed data from the cough and cold drug market and hypothesized that once a drug in this category moves to OTC, the number of people seeing physicians for the common cold should decrease since they can self medicate. In fact, even those that have more serious conditions will be able to ease some of their symptoms by using more readily available medications, and will therefore delay any trips to the physician's office. On average, Temin found that physician visits for the common cold fell by 110,000 a year and he estimated the savings plus the consumer surplus from this to be $770 million.

Shiffman et al (1997) tried to estimate the impact of allowing nonprescription sales of nicotine replacement therapies in the U.S. using sales and marketing data before and after the OTC switch of these products. These authors found that since 1996, when the sale of nicotine medications went to the OTC market, utilization of these products increased by 152% compared to when these medications were available by prescription only. They find that the increased availability of nicotine medications have significantly increased the number of former smokers.

Thorndike et al (2002) also examined whether or not the change in nicotine replacement therapy sales to the OTC market, from prescription only status, affected smoking cessation. These authors found no significant change over time in the proportion of smokers who used nicotine replacement therapy. They did, however, find racial and ethnic differences in the use of these products in the OTC market. According to these results, fewer non-Whites used nicotine replacement therapy after the switch to OTC, while the proportion of Whites using these products did not change significantly. They therefore concluded that there appear to be other barriers to the use of nicotine replacement products besides access to a physician among minority smokers.

Many other papers have looked at the impact of switching drugs from prescription only to OTC status in specific product markets. Temin also examined the hydrocortisone market in 1983 and found that the switch of these drugs increased consumer surplus in the years immediately after the switch. Gurwtiz et al (1995) examined the vaginal antifungal agent market and found that the number of prescriptions fell by 6.42% creating an annual savings of $42,528 in medication costs. These authors did not find any significant change in the number of physician visits.

Lipsky and Waters (1999) also researched the vaginal antifungal product market and found that the use of these agents have increased since their conversion into the OTC market. According to this article, sales of these agents were about 13.7 million units per year as prescription products and jumped to more than 25 million units per year once the agents started moving into the OTC market. These authors list patient autonomy and reduced health care costs as advantages of the switch of drugs from prescription to OTC status. The authors include the potential for unnecessary use of the agents as well as the development of resistant strains of bacteria causing infections as disadvantages of the switch of products into the OTC market.

Kalish et al (1997) found negligible differences in health care costs between Rx and OTC drugs for treatment in initial episodes of dyspepsia or acid reflux when examining the market for H_2 receptor antagonists. Andrade et al (1999) did find an annual savings of $187,212 for managed care plans in medications costs for chronic treatment of dyspepsia when looking at the same market in 1999. These authors found a decrease in the number of prescriptions by 1.5 prescriptions per chronic user after the OTC products were introduced and they did not find significant changes in the number of physician visits.

Ling et al (2002) examined the impact of direct-to-consumer advertising and physician oriented marketing on the sales of prescription and OTC versions of antiulcer medications. These authors find spillover effects of marketing for Rx drugs on same brand OTC versions. They also find that marketing intensity increases with order of entry in the OTC market and that demand elasticities are dependant on order of entry. Ling et el also mention that since OTC products are primarily "experience" rather than "search" goods, brand loyalty is strong, and therefore, perceived switching costs may be high.

Patient Severity

The theoretical model of this study predicts that the severity of patients in physician offices should decline after the availability of an OTC medication. This is because those patients with less severe symptoms should be able to successfully self-treat with the OTC. Since these patients drop out of the sample in physician offices, the overall case mix of patients should become more severe. Severity is a difficult characteristic to measure without knowing the exact nature of the illness, other problems the patient may be having, tests results, and other specifics about the patient. Nonetheless, other researchers have tried to measure severity using indirect methods.

Severity can be defined differently depending on the discipline of the healthcare provider. Physicians for example may categorize severity based on the impact a disease has on physiology, while a therapist may instead use functionality or activities of daily living to determine the severity of an illness. There are three components that are most used in the measurement of severity, including:

1. Functional ability of individual to conduct daily activities of living.
2. Cost to society
3. Physiologic, morphologic, and biologic derangements

Many computerized programs have been developed in an effort to standardize severity measurement. Some of these programs include Acute Physiology and Chronic Health Organization System, the Computerized Severity Index, Disease Staging, MedisGroups, and Patient Management Categories. The basis for all of these programs is either physiology or resource use (Petryshen et al, 1995).

Many of these measures calculate severity based on the likelihood of a death for patients already admitted to hospitals. MedisGroups uses clinical data to predict the probability of an in-hospital death and creates a score based on sixty-four disease groups. Physiology scores also calculate severity using clinical data, but for patients in intensive care units. Disease stating, another measure, predicts the probability of an in-hospital death using the discharge summary. Finally, All Patient Refined Diagnosis Related Groups utilizes patient discharge summaries as well, but to estimate total hospital charges, rather than the probability of death (Iezonni, 1995).

While Rice (2004) examines the differences in quality of care between managed care and fee-for-service physicians, she also examines the intensity of treatment provided by the physician. It is assumed here that greater treatment intensity is needed for patients with more severe symptoms. A similar model is therefore used here to assess changes in patient case mix after the availability of an

OTC. Rice analyzes the NAMCS data for 1997 – 2000 and uses five instruments to measure the intensity of treatment including: consultation length (measured in minutes of physician and patient contact time); number of physical exams; number of tests; number of imaging procedures; and prescriptions ordered. The author finds that, compared to FFS physicians, those physicians under managed care spent less time with their patients, ordered fewer physical exams, and prescribed fewer medications, but they also ordered more tests and imaging procedures. She finds that overall FFS physicians provided slightly more intense treatment. Rice distinguishes between acute, chronic routine, and chronic flare-up patients, and determines that acute are the least severe, while chronic patients have a higher severity of illness.

Hillman et al (1999), as described earlier, study the impact of patient financial incentives on the use of prescription drugs given varying physician payment mechanisms. In their research, the authors adjust for patient case-mix by using Chronic Disease Scores (CDS). The authors compare the use of Ambulatory Care Groups (ACGs) and CDS and found that CDS was more appropriate. ACGs use ambulatory visit diagnoses while CDS uses drug categories to identify comorbidities. The authors chose CDS because it explained more variation in drug spending for their data. CDS is also based on filled prescriptions indicating that the physician and the patient both felt that the illness was serious enough to treat with medication. In addition, CDS identifies comorbid conditions in those patients without ambulatory visits since patients can fill prescriptions without actually seeing a provider. While the data used here does not allow for this level of analysis of prescriptions, the article provides insight on how case-mix can be measured.

Glied et al (2002) also examine treatment intensities in their work studying the effects of managed care on physician behavior. Similar to the model used by Rice (2004), these authors use four measures for treatment intensity including: length of

visit; number of tests ordered; number of medications ordered; and whether a return visit was scheduled by the physician. Using the NAMCS 1993 – 1996, the authors find that on an individual level, patients under managed care receive less intense treatment as compared to FFS.

CHAPTER 4

THEORETICAL MODEL

The following theoretical model is used to draw testable implications about how physicians' prescribing behavior reacts to the movement of prescription medication to the over the counter market. The interactions of three main players in the health care industry are modeled, including: patients, insurance companies, and physicians to anticipate physician prescription behavior under two different reimbursement schemes.

Patients

In this model, patients seek care, advice and prescription authorization from physicians. There are two main types of patients; *Type I* has an illness and sees a physician for consultation, advice, and treatment. *Type II* also has an illness, but it may have just occurred recently and may be short term. These patients would have otherwise needed to see a physician, but after the availability of an OTC, they can choose to self-treat rather than spend the time or money on a physician office visit. When a drug moves from prescription to over-the-counter status, *Type II* no longer has to see the physician. Since *Type II* patients may have conditions that are temporary, they can bypass the physician and self treat using the OTC market. Let θ represent patient severity and assume that $(\theta)_I > (\theta)_{II}$ since *Type I* requires physician expertise for diagnosis. The severity of *Type I* patients is also higher because their illnesses are likely to be long term, requiring lengthier periods for treatment and a greater use of resources. In addition, it is possible that *Type I* patients are also likely to have co-morbid conditions, making diagnosis more difficult. Patients with more comorbidities or those with symptoms that are more difficult to diagnose may require a greater number of health care resources for diagnosis since their conditions may point to multiple illnesses. Some *Type I* patients may have initially tried to self-treat with

OTC medication, but were unsuccessful. For these patients, their conditions could have been complex or severe enough such that OTCs did not work; or they may have misdiagnosed their conditions because of other co-morbidities. After a drug moves to OTC status, the probability that *Type II* patients will see the physician is 0 since they can now self-treat. Therefore only *Type I* is seen in physician offices and this shifts the distribution for the severity of cases seen in physician offices towards the right once a drug moves OTC, a testable hypothesis.

Given the above assumptions, the movement of a drug to the OTC market creates an efficient sorting system for the health care industry. Since those patients with less severe conditions should self-treat, only those patients that need to see physicians should actually make office visits. This system can eliminate unnecessary physician visits, thereby reducing the cost of care. If all patients use OTC medications as their first method of treatment, those with less severe conditions are successfully treated with these drugs, while those with more severe conditions can later see a physician. In addition, the patients with more severe conditions could at least accomplish a temporary relief of symptoms until they can directly see their health care providers.

Insurance Companies

Insurance companies are profit maximizing entities. Physician prescribing behavior enters the per patient profit function for fee for service contracts as follows:

$$\pi_i = P - C(q)$$

where P is the premium revenue and C is the cost of treatment, which is a function of the amount of medical services consumed, q. In this case, only the use of medications as consumed medical services is considered, thus:

$$q = z$$

where z = the number of medications used. z is defined as:

$$z = p + otc$$

where p is the total number of prescription medications and otc is the total number of OTC medications. Thus, $C(z)$ is the cost of medications; $C(p)$ is the cost of prescription medications and $C(otc)$ is the cost of over the counter medications. Therefore per patient profits are equal to:

$$\pi_i = P - C(p) - C(otc)$$

It is assumed that $C(otc) = 0$ since insurance companies do not cover OTC drugs, which gives us per patient profits as:

$$\pi_i = P - C(p)$$

Some insurance companies create contracts with physicians to align their incentives with those of the company by giving only fixed payments per patient per year. This puts the physician at financial risk for all care provided. In these, most extreme cases of capitation, the profit function per patient for the insurance company is:

$$\pi_i = P - a$$

where a is the capitated fixed payment per patient. This remains unchanged regardless of whether a prescription or OTC drug is provided since the payment made to the physician is always a. The incentives of the insurance company will enter into understanding physician prescribing behavior in the next section.

Physicians

The physician market is different from any other type of business in a number of important ways. For example, while physicians have financial incentives to maximize profits, they are also concerned for their patients' health. Third party payers set prices and try to influence treatment decisions, but yet physicians are able to induce their own demand to a certain extent because of the asymmetry of knowledge between the physician, patient, and third party payer.

It is assumed that the only care provided by physicians is that of providing medications. Here, physicians are thought to be interested both in their own profits, π_{pz}, and the benefits to patients, B_z. Where z is the proportion of medications given to patients and is normalized to 1.

The physician maximizes the following utility function:

$$Max\ U[\pi_p(z), B(z)]$$

assuming:

$$z = \sum (x + (1\text{-}x))$$

where x = fraction of OTC drugs and $1\text{-}x$ = fraction of prescription drugs

As agents for their patients, and because they are bound by their ethical code, physicians typically care about patients and their welfare. In addition, physicians can maximize their own profits when they perform well and create good reputations. This then affects the number of new patients coming in for office visits, the loyalty of established patients, as well as the number of referrals from other colleagues, all of which directly impact physician profits.

The balance between health care utilization and physician profits depends on the reimbursement arrangement between the physician and the insurance company. With Fee-For-Service arrangements, profits are maximized when maximum health services are provided. Under capitation, however, the minimization of resources leads to profit maximization.

A physician's profits per patient visit, assuming Fee-for-Service, are given by:

$$\pi_{pz} = R_z - C_z$$

where R_z is revenue per patient visit and C_z is the time cost of providing medications per patient visit. Since no financial burden is placed on the physician for either prescription or OTC drugs other than the time cost of seeing the patient, the equations for both prescription and OTC medications are the same.

Under capitation the profit equation per patient visit is given by:

$$\pi_{pz} = a - C_p$$

where a is the per member per month fixed capitation payment to the provider from the insurance company; and C_p is physician costs which can be broken down into costs of the visit, $C(N)$, and costs of providing medications, $C(z)$.

That is:

$$C_p = C(N) + C(z)$$

Therefore physician profits are also depicted as:

$$\pi_{pz} = a - C(N) - C(z)$$

Providing a prescription drug to a patient will count against physician profits under a capitated arrangement since the physician will have to deduct these costs from his/her fixed payment. Providing an over the counter drug, however, will not be deducted, because they are typically not covered by health plans, and will instead allow the physician to keep more of the fixed payment.

The cost of medications can be further divided into the costs of prescription and the cost of over-the-counter drugs. Therefore:

$$C_z = C_x + C_{1-x}$$

For prescription drugs only, capitated physician profits per patient are:

$$\pi_p = a - C(N) - C(1-x)$$

The capitated profits from over the counter medications are:

$$\pi_{px} = a - C(N) - C(x)$$

where $C_x = 0$ for the physician since the cost of OTCs are fully paid for by the patient. Therefore:

$$\pi_{px} = a - C(N)$$

For the purposes of this paper, the utilization of health care services is examined by looking at specific drugs in both the prescription and over-the-counter

markets. The incentives for providing either a prescription or OTC drug are also determined by the legal characteristics of each. Since the physician can require future office visits with prescription drugs, choosing these medications can directly impact revenue. Physicians can induce demand for office visits by asking patients to come in for monitoring or by requiring an office visit to get refills.

OTC medications, however, do not require physician authorization. Therefore when a physician advises a patient to take and OTC drug, the patient is not obligated to come back to the physician for treatment of the same illness. Instead, patients can purchase OTC drugs on their own and self treat that particular illness.

This theory assumes that there is an asymmetry of information between physicians and patients. Physicians know which drugs are appropriate for their patients and they also know which drugs are substitutes for one another. While patients may find drugs for their illness sold on the over the counter market, they may not know that these drugs are equivalent in strength and/or effectiveness as their prescription counter parts. Even if patients do have this information, they may still prefer the prescription drug to the OTC one, if they have insurance. With drug coverage patients could have lower out of pocket costs since they are usually responsible for modest copay with a prescription drug while they would instead be required to pay the full retail price of an OTC.

Fee for Service Plans

Physicians maximize utility by maximizing the number of office visits, under a fee for service reimbursement scheme:

$$Max\ U[\pi_{px}, B_x]$$

where π_p is the physician profit per patient from providing medications, and B is the benefit to the patient from medications, and x is the total number of OTC medications.

Physician profits per patient are determined by the revenues, *R*, per patient visit minus the cost of per patient visit, *C*, times the total number of office visits, *N*. As a physician provides more OTC drugs the likelihood for further visits is less since the patient does not have to come in for refill visits. In addition, the physician does not have to induce further visits in order to monitor the patient for adverse effects of the prescription drug. Therefore, assuming

$$N = f\left(\frac{1}{x}\right)$$

where N is the number of office visits and x is the proportion of OTC medications provided:

$$N = f(x^{-1})$$

$$dN = -f'(x^{-2})\,dx$$

$$\frac{dN}{dx} = -f'\left(\frac{1}{x^2}\right)$$

assuming $f'(1/x^2) \geq 0$

$$\frac{dN}{dx} \leq 0$$

The above equations prove *N* and *x* to be inversely related. Therefore, as a physician provides more OTC medications, there should be a decrease in patient visits.

The profits for a FFS physician are as follows:

$$\pi_p = N[R - C]$$

where, again, the number of patient visits, *N*; *R* is the amount of revenues from a visit, and *C* is the cost of a visit. The derivative with respect to N is:

$$\pi_p = N[R - C]$$

$$\delta\pi_p = [R - C]\,\delta N$$

$$\frac{d\pi_p}{dN} = [R - C]$$

assuming $[R - C] \geq 0$

$$\frac{d\pi_p}{dN} \geq 0$$

As expected, the above equations show that physician profits and patient visits are positively related. That is, as a FFS physician has more patient visits, s/he should expect more profits.

Claim 1:

For FFS physicians:

$$\frac{d\pi_p}{dx} \leq 0$$

For all patients, the FFS physician is more likely to provide a prescription drug in order to bring that patient back into the office and generate more revenue. Also, many insured patients have drug coverage in their insurance plans and not only prefer prescription medications, but expect them. By providing a prescription, physicians can satisfy their patients, who may then refer their friends and family to this physician, again to generate more revenue. Therefore, assuming:

$$N = f\left(\frac{1}{x}\right)$$

and thereby:

$$\frac{dN}{dx} \leq 0$$

The following can be modeled:

$$\pi_p = N[R - C]$$

$$\pi_p = f\left(\frac{1}{x}\right)[R - C]$$

$$d\pi_p = [R - C]\left(-f'\left(\frac{1}{x^2}\right)\right)dx$$

$$\frac{d\pi_p}{dx} = [R - C]\left(-f'\left(\frac{1}{x^2}\right)\right)$$

assuming $[R - C] \geq 0$ (With zero fixed costs and zero economies of scale.)

$$\frac{d\pi_p}{dx} \leq 0$$

Therefore, as a FFS physician provides more OTC drugs, s/he can expect fewer patient visits which will lead to fewer physician profits as well. It can, therefore, be understood that a FFS physician stands to maximize profits, by providing patients with prescription drugs, rather than OTC.

Capitated Plans

Physicians under capitation similarly maximize their utility function:

$$Max\ U[\pi_p(x), B(x)]$$

Physician profits for the capitated physician are the fixed capitated payment, *a*, minus the cost of office visits, minus the total cost of prescription drugs. The cost of providing OTC drugs is zero, as described earlier, and is therefore not included in the following equation.

$$\pi_p = a - C(N) - C(1-x)$$

where *a* is the capitated payment and $(1-x)$ is the proportion of prescription drugs; When deriving the profit function with respect to *N* the equation is:

$$\pi_p = a - C(N) - C(1-x)$$

$$\delta\pi_p = (-C)(\delta N)$$

$$\frac{d\pi_p}{dN} = -C$$

assuming $C \geq 0$

Incentives under capitation are to minimize utilization of resources. Therefore, an increasing number of office visits leads to decreasing physician profits.

Claim 2:

For capitated physicians:

Under capitation, the physicians have the incentive to provide OTC drugs for all of their patients, since patients will not have to return to the physician for refill authorization. By providing an OTC drug, the physician can minimize the costs deducted from his fixed payment for the patient since the patient can self medicate without coming in for an office visit; and the cost of this medication will not be deducted from the fixed payment.

Taking the derivative of the capitated physician's profit function with respect to x, the fraction of OTC medications (with *1 – x* equal to the fraction of prescription drugs):

$$\pi_p = a - C(N) - C(1 - x)$$

$$\delta\pi_p = -C(-1))\delta x$$

$$\delta\pi_p = C(\delta x)$$

$$\frac{d\pi_p}{dx} = C$$

assuming: $C \geq 0$

As physicians in a capitated arrangement provide more over the counter drugs, they can reduce the number of office visits for each patient. That will allow physicians with this style of reimbursement to maximize utility as resource utilization is minimized, and profits are therefore increased.

Hypotheses

In summary, the following are testable hypotheses from this model.

1. After a medication in a particular class of drug moves over the counter, the overall case mix of patients physicians see in their offices will have higher severity.
2. In an attempt to maximize profits, FFS physicians will provide prescription drugs instead of over-the-counter substitutes for patients.
3. Capitated physicians will minimize costs and patient visits by advising patients to take more over-the-counter medications, thereby maximizing profits.

CHAPTER 5

EMPIRICAL MODEL

The reaction to the availability of an OTC medication of both physicians and patients is empirically modeled here. The first section of this chapter outlines the analysis for the physician group, while the second section examines changes in the patient case mix seen in physician offices.

Physicians

The theory established in the previous chapter portrays physicians as profit maximizing entities. This model provides a link between the likelihood that a physician orders a prescription or over-the-counter drug for his/her patients and physician profits, depending on how they are reimbursed for their services. The following empirical model studies how physicians differ in their prescribing behavior based on capitation versus FFS, both before and after the availability of an OTC.

How Number of Prescriptions Impacts Revenues

When physicians provide patients with prescription drugs, those patients must visit the physicians' offices repeatedly in order to get refills; to be monitored for side effects; or to change to another type of prescription medication for that particular illness. Therefore, by advising patients to take a prescription medication, physicians increase the number of visits from those patients. When providing over-the-counter medications, however, physicians cannot impact future visits as directly since patients do not need physician approval to get these drugs. Instead, patients can bypass physician offices and obtain these medications on their own.

Capitated Versus FFS Physicians

The financial incentives for capitated physicians are very different from those of non-capitated physicians. Non-capitated physicians generally receive payments on a fee-for-service scale from third party payers. Therefore, as the number of services

provided increases, the payments these physicians receive increase as well. Capitated physicians, however, receive a fixed payment for their services, generally per member per month. The capitated physician then must deduct any services provided from this fixed amount. This creates financial risk for the physician, and creates the incentive to minimize costs. A capitated physician, thus, will prefer, in terms of profit motives, to minimize the number of future patient visits. By providing more over-the-counter drugs, in place of prescription counterparts, the capitated physician can decrease the likelihood of repeated patient visits for the same illness.

Capitated physicians also face the incentive to minimize the cost of care by providing the lowest cost form of therapy. Amongst medications, these physicians would be responsible for the cost of prescription medications. OTC medications, however, are paid fully by the patient. This thereby creates a greater incentive amongst capitated physicians, as compared to FFS, to provide these drugs.

There are variations in the degree to which physicians are held financially responsible under capitated arrangements. In some cases, only the administrative costs for an office visit are deducted from the capitated payment, while the insurance company pays for all other treatments. In other cases, however, the total cost of care including: prescription medications, lab tests, and other exams, may be deducted from the capitated payment. For the purposes of making predictions from the model here, however, it will be assumed that under capitation physicians are held fully financially responsible for their prescription decisions. Under drug plans for both capitation and FFS, patients face copays for their prescription drug use. It is assumed here that patients under both types of plans face similar drug coverage and copays; and therefore no differences in these are modeled here.

The model used here compares how capitated physicians vary in their prescribing decisions from FFS physicians. The two types of reimbursement methods

are also compared before and after the availability of an OTC medication. Table 5.1 helps depict how this will be empirically tested.

Table 5.1

Capitation vs. FFS Before and After OTC

	FFS	Capitation
After OTC	A	B
Before OTC	C	D

Where A = FFS After OTC availability

B = Capitation After OTC availability

C = FFS Before OTC availability

D = Capitation Before OTC availability

The equation that has been set up to estimate physician behavior when a drug moves from prescription to over the counter is as follows:

$$Y = \beta_0 + \beta_1 \text{Capitation} + \beta_2 \text{AfterOTC} + \beta_3 (\text{Capitation} * \text{AfterOTC}) + \beta_4 X_i + \beta_5 U_j + \varepsilon$$

Where Y = The likelihood of a prescription in the drug class being examined

Capitation = Physician with capitated payments in the Before OTC period

AfterOTC = FFS Physicians in the After OTC Period

Capitated*AfterOTC = Capitated Physicians in the After OTC Period.

X_i = Patient Characteristics

U_j = Physician Characteristics

Both B and D from the above table include capitation while B and A include the after OTC period. The interaction of Capitation and AfterOTC is, therefore, depicted by B. Hence, the only variable missing from the table is C. The regression therefore uses this variable, FFS in the Before OTC, period as the comparison group.

Predictions of Physician Behavior

For both the allergy and acid reflux class, the above regression is carried out such that Y is first equal to the likelihood of any prescription in the drug class. The analysis is further carried where Y is then equal to the likelihood of being prescribed one of each of the other competing brand name drugs in the class.

Capitated physicians are expected to utilize the least costly form of treatment as compared to FFS. Before the availability of an OTC drug, capitated physicians may use prescriptions at least as much as FFS, since medications could be less expensive than other forms of treatment, depending on the illness category. Amongst medication choice, it is expected that capitated physicians will use older prescription products more than FFS in the before OTC period, as these should be less expensive than the newer medications.

After an OTC is available, it is expected that those FFS physicians that previously utilized the drug that changed status, will now use other medications that remain prescription-only, in order to maximize their own profits. That is, FFS physicians will redistribute their patients towards one of the other brands in the category that remain on the prescription market, rather than use the new OTC drug.

The expectation is that capitated physicians will be more likely than FFS in the after OTC period to use the new OTC medication. OTCs are less expensive and therefore, can be used by capitated physicians to minimize costs, especially since physicians would not be held financially responsible for providing these drugs to patients. In the after OTC period, it is therefore expected that capitated physicians should decrease their usage of all prescription drugs. Some of these physicians that previously used other brand name medications are expected to switch their patients to the new OTC. A decrease in the likelihood of all prescription medications should be

expected for capitated physicians, after the availability of an OTC as compared to FFS.

Patient Severity

The second part of this study examines how patients change their behavior after the availability of an OTC. That is, this research questions if patients that have less severe symptoms choose to self-treat after the availability of an OTC, as a substitute to visiting physician offices. If there is a change in patient behavior, a noticeable change should also occur in the case mix of patients seen in physician offices. It is hypothesized in this model that because those with minor symptoms can self treat, only those with more severe conditions will be seen in physician offices after the availability of an OTC.

Severity, here, is measured using the length of time a patient has had symptoms. Acute patients are defined as those that have had symptoms for less than three months. Chronic routine patients include those that have had symptoms for more than three months, while chronic flare-up includes those with symptoms that have lasted for more than three months, but are suddenly exacerbated. It is assumed that acute patients are the least severe of the three types, since their symptoms have been occurring for the shortest time period. Chronic conditions are thought of as being more severe since there is generally a longer time spent on treatment and an increased probability of long-term medication use.

The likelihood of a visit to a specialist physician is also used as a measure for severity. With an increase in severity of patient case mix, specialists may be utilized more after the availability of an OTC. Primary care physician may also have a decreased threshold in referring patients to specialists, since many patients may have already tried the OTC drug that is chemically equivalent to the prescription-only products, which would have otherwise been used as the first line of treatment.

In the empirical model here, we use the type of patient as the dependent variable, and examine the impact on the number of office visits from each of these patient types after of availability of an OTC.

The model used is as follows:

$$Y = \beta_0 + \beta_1 \text{AfterOTC} + \beta_2 X_i + \beta_3 U_j + \varepsilon$$

Where Y = Type of patient (Acute, Chronic Routine, or Chronic Flare-up) or Specialist Physician

After OTC = the period after which an OTC is available in the drug class

X_i = Patient Characteristics

U_j = Physician Characteristics

This model allows for the comparison of the patient type before and after the availability of an OTC. That is, this model aims to predict the likelihood of a physician office visit from an acute, chronic routine, or chronic flare-up patient after an OTC is available, to compare with the before OTC time period. This model is then repeated using just specialist physicians, rather than all physicians to determine if there are any changes amongst this group.

Severity Predictions

Before the availability of an OTC drug in the class, all patients have to see physicians to get treatment for the related illness. After the availability of an OTC, it is expected that those with more minor symptoms can self-treat with OTC medications, in place of physician office visits. Those patients who have severe conditions and know of the available OTC treatment may delay a physician's office visit to instead attempt self-treatment first. Only when self-treatment is unsuccessful, should these patients be seen in physician offices. Therefore, the patients seen in physician offices are those that were unsuccessfully treated with the OTC, or those that must have physicians manage their illnesses because of higher levels of severity.

The expectations from the above model, therefore, are that acute patients, who have the least severe symptoms, should be less likely to come to physician offices after the availability of an OTC. There are no expectations for any changes in the likelihood of chronic routine patients in physician offices since these patients may be regularly monitored by the physician because of their higher severity. Chronic flare-up patients may be also less likely to see a physician when there is an OTC available since their conditions are short term and may also be temporary.

Specialist physicians are more likely to see patients with more severe symptoms than primary care physicians. It is, therefore, expected that the impact on patient severity of an OTC may be less amongst these physicians since they are not likely to see patients with minor conditions even before an OTC is available due to self-treatment. There may be an increase in visits to specialists, however, if there are more referrals to these physicians from primary care.

In summary, it is expected that the AfterOTC variable will have a negative impact on the likelihood of acute patient visits, and possibly a negative impact on visits from chronic flare-up patients. If the severity of patient case mix has increased, the number of visits to specialist physicians is also expected to increase.

Additional Empirical Analysis

Time spent with the physician, and the total number of diagnostic tests, are also examined in this study. Both of these variables are used as dependent variables in regressions similar to those done in the severity section. That is, both of these variables are examined to determine the effects of the availability of an OTC.

Therefore the model used for these is as follows:

$$Y = \beta_0 + \beta_1 \text{AfterOTC} + \beta_2 X_i + \beta_3 U_j + \varepsilon$$

Where Y = Time Spent with Physician or Total Number of Diagnostic Tests

After OTC = the period after which an OTC is available in the drug class

X_i = Patient Characteristics

U_j = Physician Characteristics

There are no expectations for these variables since it is not clear as to how these variables may be affected by changes in patient case-mix. While higher levels of both time spent and number of diagnostic tests could indicate an increase in patient severity, these variables could also be higher during the early diagnosis period of an illness when severity may still be low. In addition, changes in these variables could result because of other factors not related to patient severity such as changes in reimbursement amounts. These two variables are, therefore, being used just for exploratory purposes to better understand the effects of OTC availability.

Potential Limitations

The analysis done here does not include models for the actual drug that has moved to the OTC market. Since over the counter drugs are available without authorization from physicians, there should be a general decline in observations of those drugs that have changed status. In addition, while the NAMCS instructs physicians to include all types of medications on the survey form, physicians may feel that since OTC drugs are available without a prescription, that they do not need to include them in their survey. Because of these factors, it may not be possible to determine if capitated physicians actually move towards the OTC since these observations may not be recorded.

While severity is attempted to be measured here, it is very difficult to actually determine patient severity without knowing further details of the patient's condition. In fact it may be possible that a patient comes to a physician's office with severe symptoms even during the early part of the illness, i.e. when the patient would still be considered acute. In general, however, even when an acute patient becomes a chronic one, the early stages of the illness are thought to be the least severe.

CHAPTER 6

DATA

In order to fully examine the effect on patients and physicians of drugs moving from the prescription to over the counter market, the data used would ideally provide information about all drugs prescribed and the severity of patients before and after the change in regulatory status. This would allow for the examination of whether physicians are making their decisions based on profit motives or simply because severity of patients is different in each time period. Also, it would be ideal to have data that included the extent of detailing (pharmaceutical advertising to physicians) and direct-to-consumer advertising for each drug and how that changes when a drug moves from prescription to over the counter status. Data that followed patients from the physician's office to the drug store would be helpful as well since it would be possible to directly examine not only what physicians recommend, but also what patients actually purchase. Finally, ideal data would follow both patients and physicians over time to adequately see long-term effects. No such ideal data set exists, thus the data source used is now described, along with its relative strengths and weaknesses.

National Ambulatory Medical Care Survey (NAMCS)

The National Ambulatory Medical Care Survey (NAMCS) for the years 1997 – 2004 is used to test the implications of the theoretical model proposed here. The NAMCS is a national survey conducted through the CDC's National Center for Health Statistics annually from 1973 to 1981, in 1985, and every year since 1989. The survey was administered to physicians, rather than patients. Physicians were randomly assigned to a 1-week reporting period, during which data for a random sample of visits were recorded by the physician. Data were obtained on patients' symptoms, physicians' diagnoses, and medications ordered or provided. The survey also provides

statistics on the demographic characteristics of patients (e.g. gender, age, race, insurance type) and services provided, including information on diagnostic procedures, patient management, and planned future treatment. The NAMCS focuses on outpatient care since hospital-based physicians are excluded from the sample. The survey allows physicians to list up to six medications prescribed to a patient during an office visit, including both prescription and OTC drugs. Later years actually allow for eight drugs to be recorded, but for comparison purposes these last two drug entries were dropped from analysis. In total, before any exclusions, each year of data (1997-2004) contains over 20,000 patient records.

Advantages of Using NAMCS

- The NAMCS provides data from physicians directly. This is an important feature when examining physician incentives, since physician decisions and intentions are recorded and do not have to be extrapolated from other sources.
- The NAMCS collects data on health insurance status of patients. This creates data that can be used to compare utilization rates for patients enrolled in managed care plans versus other types of health insurance.
- The NAMCS contains detailed information on demographics, diagnoses and laboratory testing which can be used to examine the change in the case mix of patients after drugs move to OTC status.

Descriptive Statistics

Restricting the data to only those patients with any insurance coverage allows for the clean comparison of the effects of Fee-for-Service against those of capitation, regardless of whether the patient is publicly or privately insured. This limits the data to only those patients with either: Private Insurance, Medicare, or Medicaid. In some of the specifications, the data are further restricted to only those patients with the diagnosis relevant to the drug class being examined. Before limiting the data by

diagnosis, however, the summary statistics show that the insured NAMCS sample averages slightly over 20,000 patient visits per year. The data consists of 57.5% females and 87.1% white patients, with an average age of 46.1 years. The majority of the insured patients (63.7%) have private insurance, while 26.5% have Medicare and 9.8% have Medicaid. Approximately 26.3% of physicians accept capitated payments and the majority of capitation is seen through private insurance (as opposed to Medicare or Medicaid).

The summary statistics show that 58.1% of patients see a specialist and 85.1% are established patients (i.e. not new patients). Physicians provide medications for their patients in over 62% of visits. Prescription drugs are provided in 56.1% of visits, while OTC medications are provided in 10.4%. It should be noted that prescription and OTC medications can be provided both as substitutes and as compliments. Therefore, a person receiving a prescription drug could also receive an OTC drug at the same time and vice versa.

Physicians spend an average of just over 19 minutes with each patient. It should be noted, however, that physicians bill insurance companies using a tiered structure of time spent with the patient. Therefore a skew in the reported amount of time spent with the patient that follows the billing schedule for reimbursement can be expected.

In terms of severity, as measured here, 32.8% of patients reported having acute conditions. Chronic routine patients made up 33% of physicians office visits and 9.5% were from chronic flare-up patients.

The following figures provide further insight into the nature of physician office visits amongst the insured population in the NAMCS 1997 – 2004 data for the entire sample, as well as for the two drug classes considered here: allergy and acid reflux.

For all of the figures, it should be noted that Claritin, in the allergy class, is an OTC in 2003 and 2004; while Prilosec, in the acid reflux class, is an OTC in 2004.

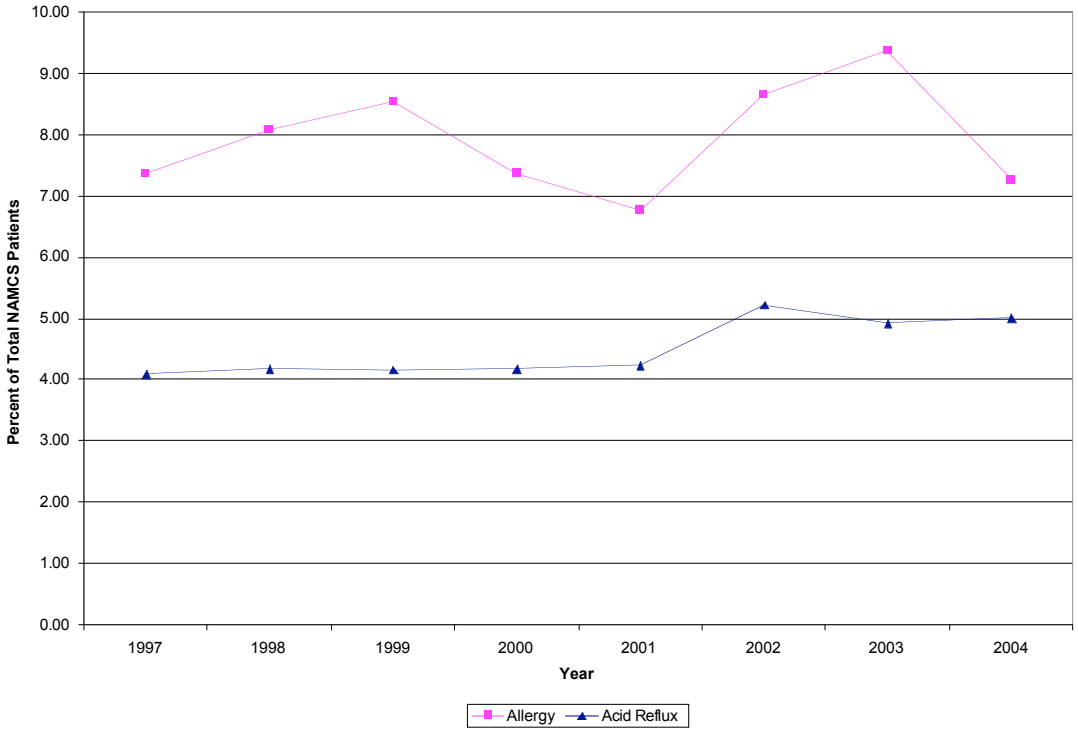

Figure 6.1

Percent of Patients with Diagnosis – Total Insured NAMCS Sample 1997 – 2004

Figure 6.1 shows the percent of patients in the insured NAMCS sample for each of the diagnoses analyzed here. According to this figure there is an increase in the percent of patients with an allergy diagnosis after 2001 and then a decline after 2003. The decrease in visits for those patients in the allergy sample, after 2003, could be an indication of patients using Claritin OTC as a substitute to physician visits.

Prilosec moves to the OTC market at the end of 2003, but this graph does not provide any indication of a decrease in visits from this market. From 1997 – 2001 there seems to be very few changes in the number of patients coming in to physician offices for an acid reflux related diagnosis. While, an increase in the acid reflux group

is seen after 2001 but then declines after 2002 and then levels off. These changes, however, are slight, providing little conclusive evidence of a change due to the OTC status of Prilosec.

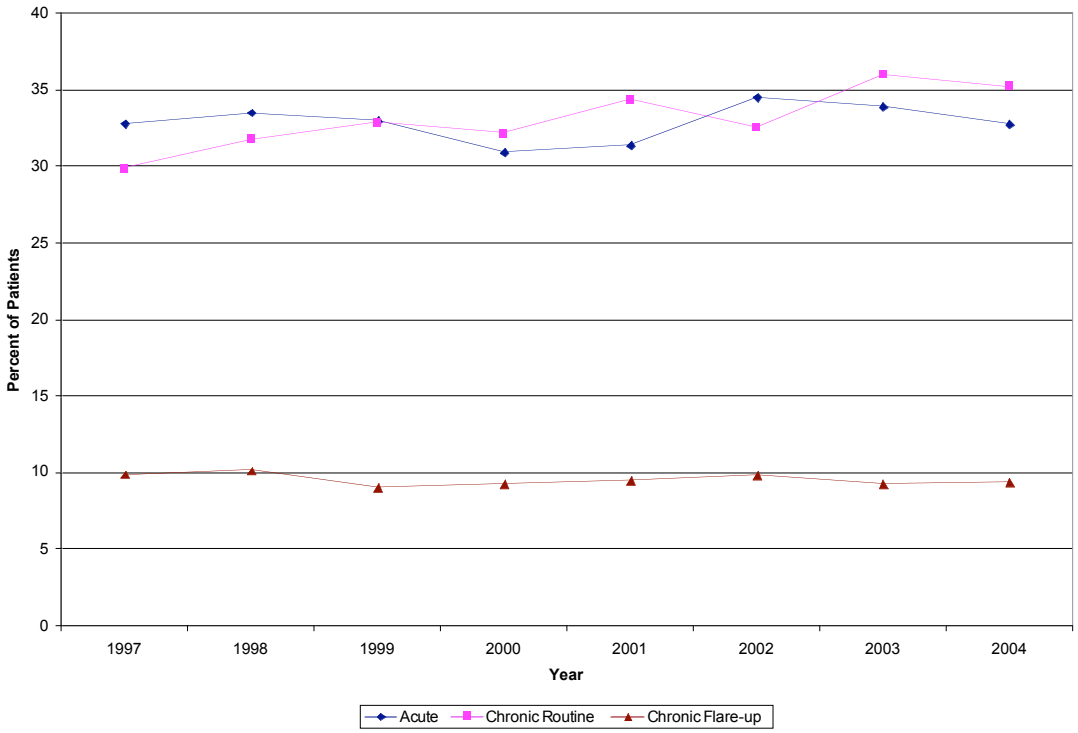

Figure 6.2

Type of Patient Visit – Total Insured NAMCS Sample 1997 – 2004

Figure 6.2 depicts the type of patient (acute, chronic routine, or chronic flare-up) per year for the general population. The figure shows a slight increase in acute patients after 2001, but then levels off. Chronic routine has a slight increase after 2002, but no major changes are seen in any of the groups. This is as expected since these trends are for the general population and not the specific class associated with the drug moving to the OTC market. The number of visits from chronic flare-up patients seems to change only slightly over the years from 1997 – 2004. Again, while this graph is shown for descriptive purposes, no changes are expected in the severity

of the entire sample, since they should not be influenced by the availability of an OTC in one specific drug category.

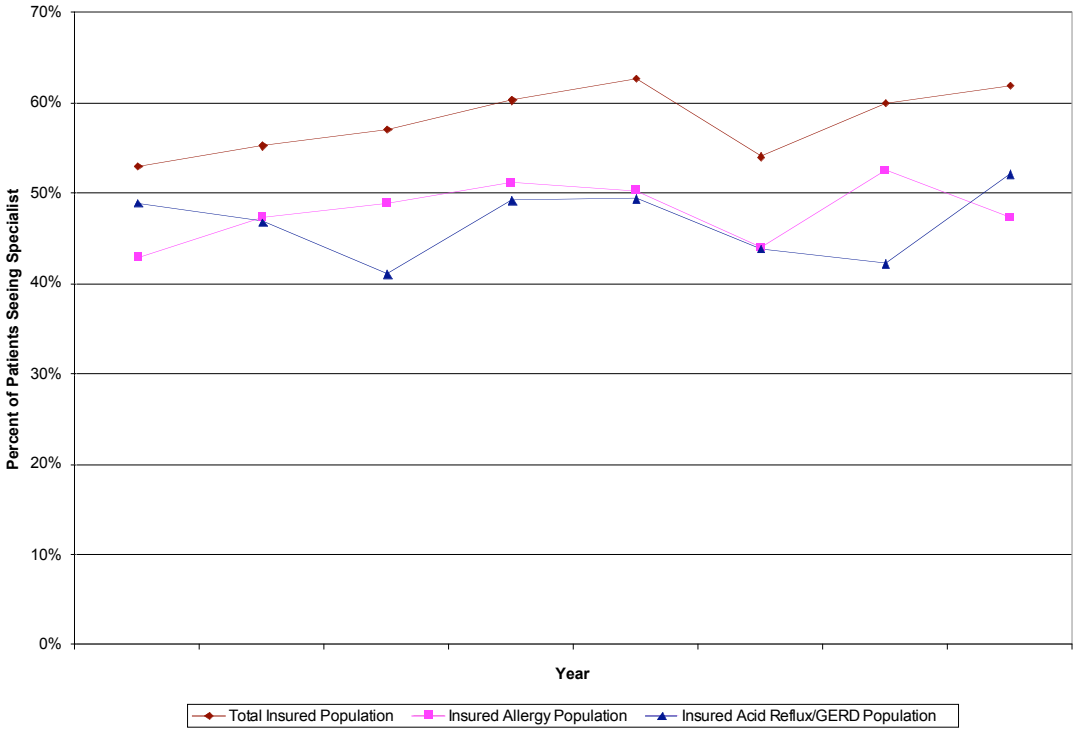

Figure 6.3

Percent of Patients Seeing a Specialist Physician by Diagnosis – Insured NAMCS 1997 – 2004

In the analysis of patient severity, the use of specialist physicians is also used. Figure 6.3 depicts the percent of patients seeing a specialist physician, under both the allergy and the acid reflux diagnosis categories, as well as for the entire insured population.

The Allergy group does have an increased percentage of specialist visits in 2003, the year following the Claritin OTC switch, but then this decreases in 2004. Similarly, the Acid Reflux group has an increased percentage of specialist visits in

2004, the year after the Prilosec OTC switch. There is, however, a general increasing trend of seeing a specialist, as seen with the Total Insured Population line, after 2002.

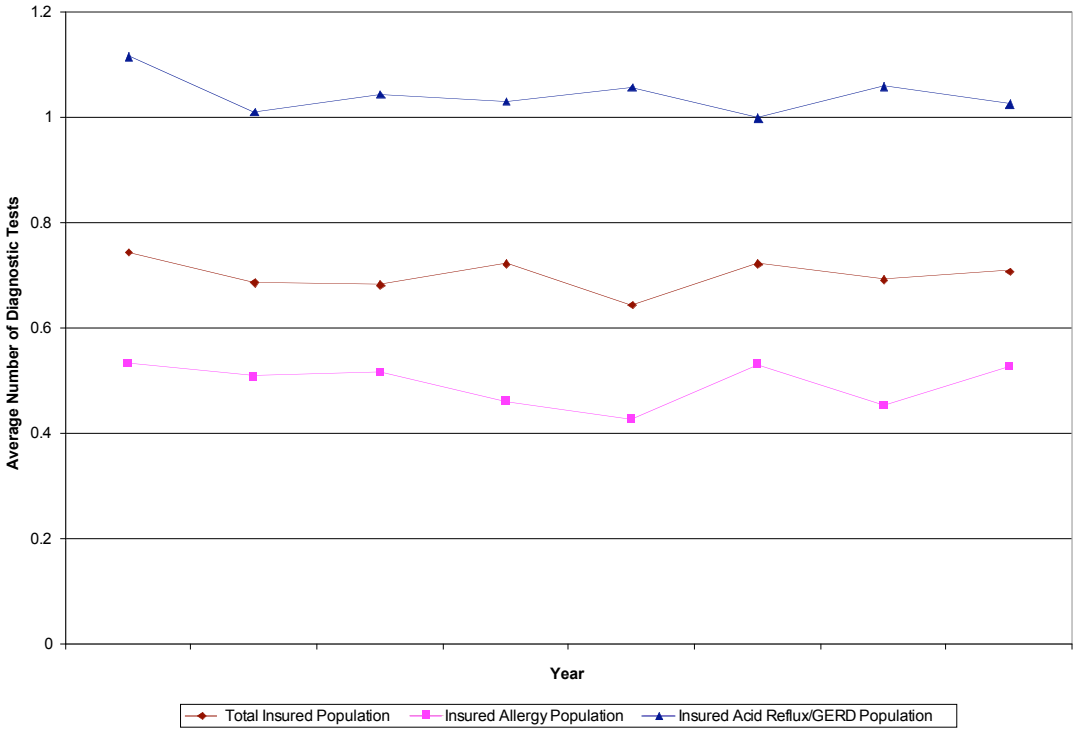

Figure 6.4

Average Number of Diagnostic Tests per Patient by Diagnosis – Insured NAMCS 1997 - 2004.

Figure 6.4 depicts the average number of diagnostic tests ordered per patient for the entire insured NAMCS sample. This graph provides the average number of tests for the entire NAMCS sample as well as by diagnosis group (allergy or acid reflux). The average number of tests could provide insight into the severity of patients if one assumes that as the number of tests increases, a patient is likely to have more severe conditions. This is not the assumption utilized here. Instead, the average number of tests is only used to help examine what happens, in general, after a drug in a category moves to the OTC market. The only expectation for this variable is that no

changes should be seen amongst the entire insured NAMCS sample, since the entire population should not have any changes when a drug in a specific class is given a different regulatory status. The only changes, therefore, should be seen amongst those populations that are related to the drug class in which an OTC is newly available.

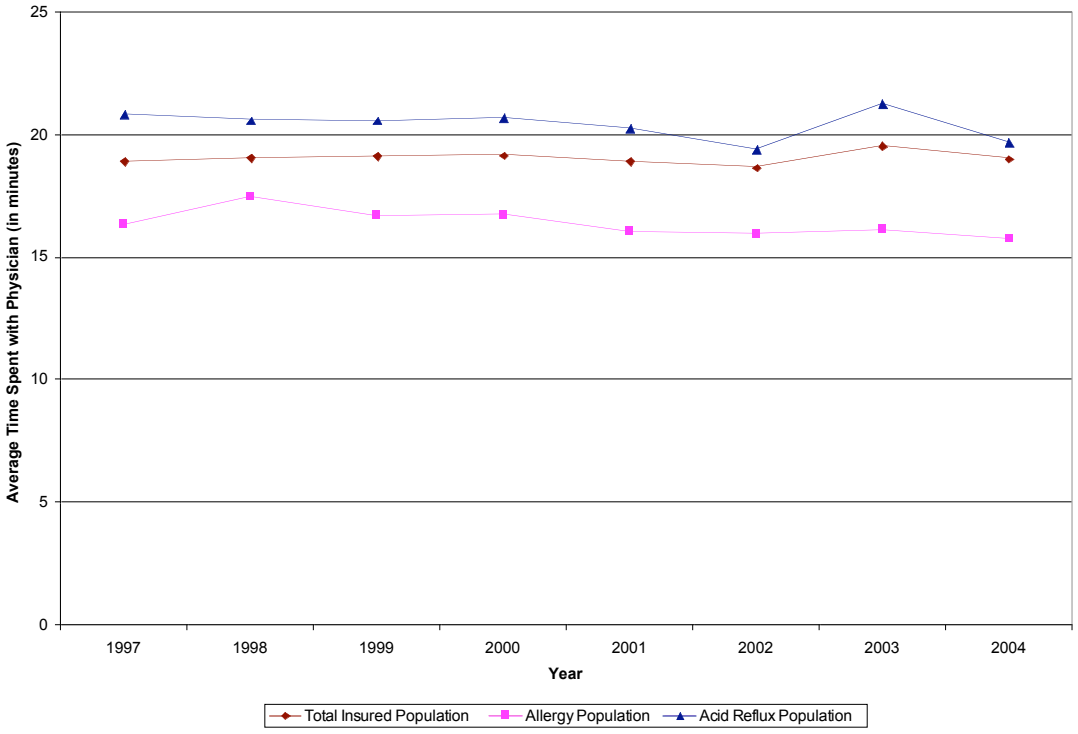

Figure 6.5

Average Time Spent (in minutes) with Physician by Diagnosis Group – Insured NAMCS 1997 – 2004

Figure 6.5 depicts the average amount of time spent with the physician, in minutes, by year. As mentioned earlier, some studies indicate that an increase in time spent indicates an increase in severity of patients. While, this is not used as a measure of severity in this research, time spent is included in the analysis just as an exercise to see if there are any changes after the availability of an OTC. There is a peak in time spent with acid reflux patients in 2003 after which there is a decline. There is a slight

increase in time spent with the allergy group also after 2002. The total population remains unchanged as expected. These trends overall do not depict any major changes in time spent after the availability of an OTC.

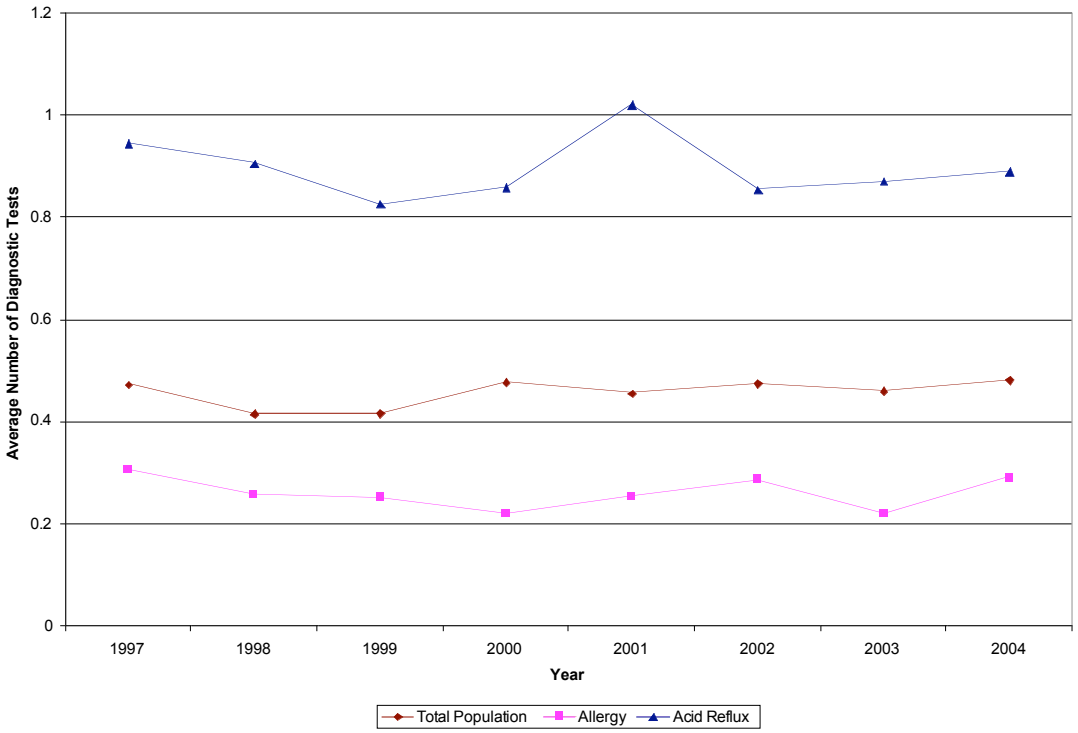

Figure 6.6

Average Number of Tests per Patient by Diagnosis Group Specialist Physicians – Insured NAMCS 1997 – 2004

Figure 6.6 depicts the average number of tests ordered by specialist physicians. There is a peak of tests done in 2001 for acid reflux patients, and then this trend levels off. Others remained relatively unchanged indicating no real effect of OTC availability.

Due to the possibility that primary care physicians are more likely to refer patients to specialists after the availability of an OTC because of an increase in patient

severity, visits to specialist physicians are further analyzed as well. Figure 6.7 depicts the average time spent with a specialist physician.

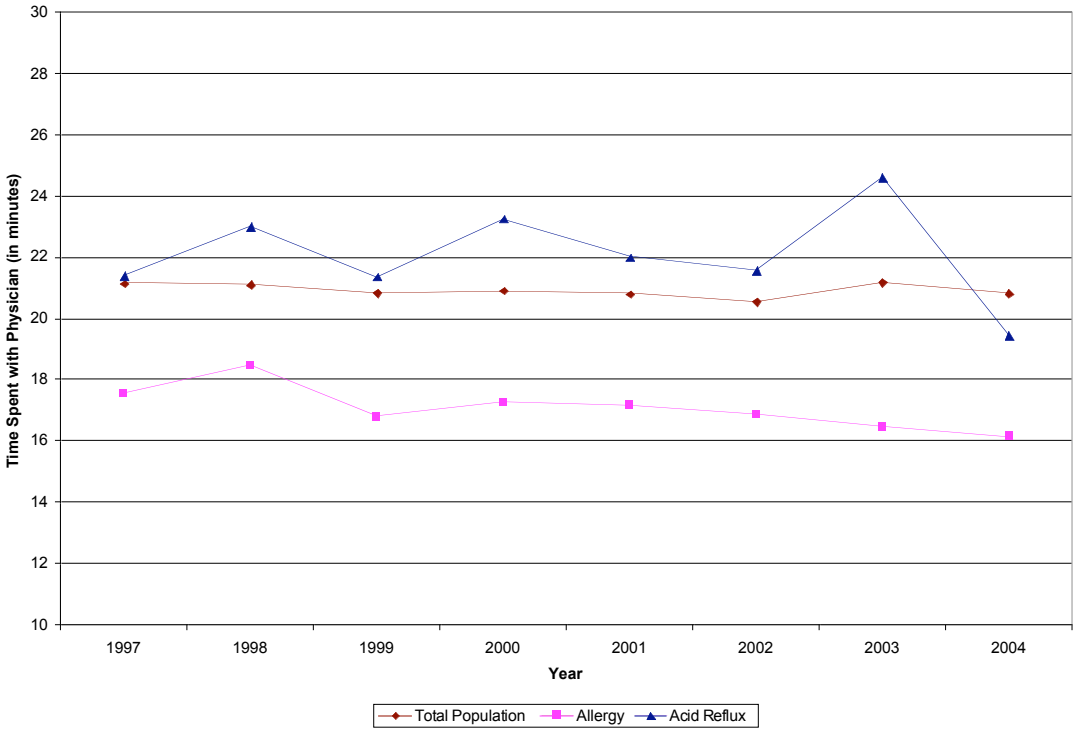

Figure 6.7

Average Time Spent (in minutes) with a Specialist Physician by Diagnosis Group - Insured NAMCS 1997 – 2004

No conclusions can be formulated for the allergy or total population groups from Figure 6.7. Acid reflux patients have an increase in time spent with a specialist physician from 2002 – 2003, and then a decrease in 2004. While this could imply a change in patient severity, it could also indicate other changes, such as a different reimbursement schedule for the amount of time physicians spend with patients.

In terms of drug use, the percentages of patients receiving medications by population are examined in Figures 6.8 and 6.9. Figure 6.8 shows the percent of

patients receiving a prescription medication by diagnosis group while Figure 6.9 depicts the usage of OTC medications.

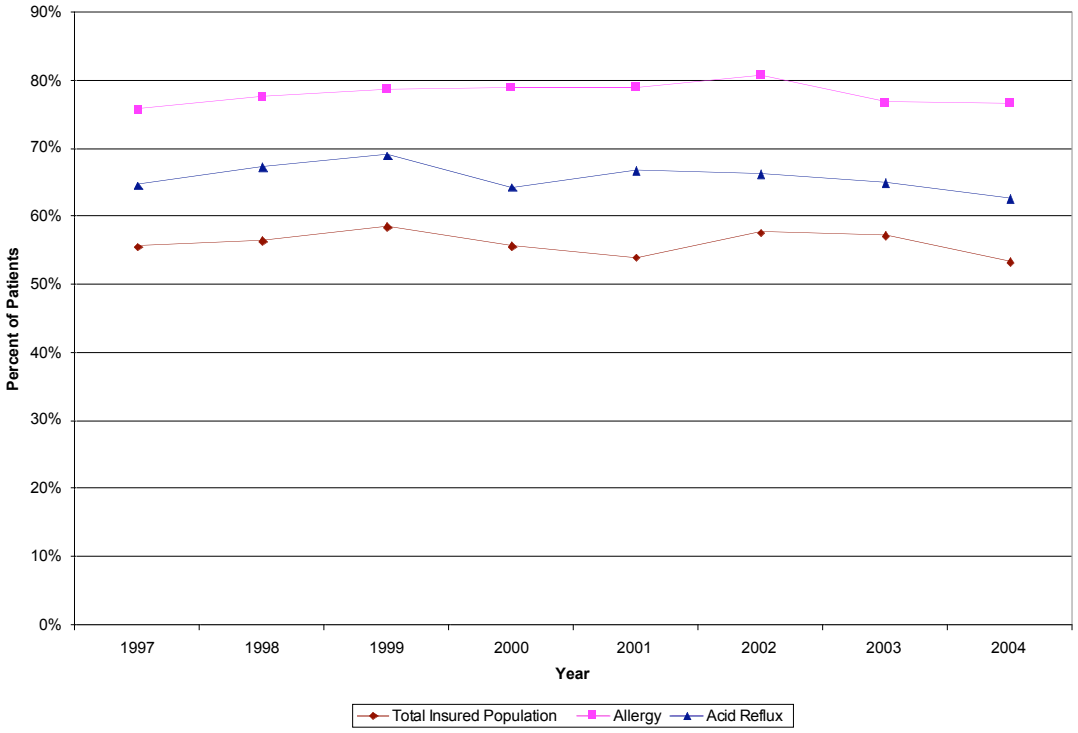

Figure 6.8

Percent of Patients Receiving a Prescription Medication – by Diagnosis Group

NAMCS 1997 – 2004

There are no major changes in prescription drug use over the years from Figure 6.8. The majority of physicians are FFS and therefore, overall, physicians are not expected to change their prescribing habits drastically after the availability of an OTC. Instead only those FFS physicians that prescribed the medication that is now OTC are expected to switch to another prescription-only product. In the allergy group, there is a slight decrease in the use of prescriptions after 2002, which may indicate that some physicians are using the OTC drug instead of prescription-only ones.

Figure 6.9 shows that there is a decrease in OTC use for acid reflux patients from 2001 – 2003, but then levels off in 2004. OTC use increases in the allergy group after 2002.

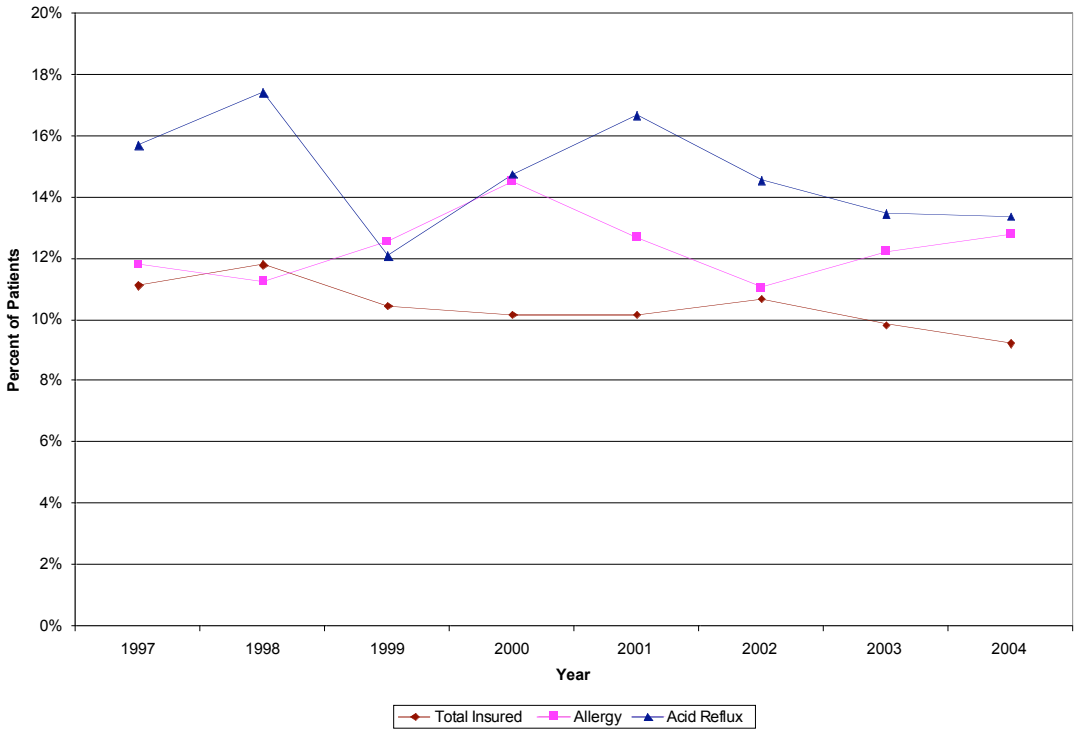

Figure 6.9

Percent of Patients Receiving an OTC Medication - by Diagnosis Group NAMCS 1997 – 2004

Table 6.1 provides the summary statistics for the NAMCS data used. In the regressions conducted, the samples consisted of insured patients only from 1997 – 2000, and 2003 – 2004. The years 2001 and 2002 were dropped from the analysis because the capitation variable is missing for these years. The capitation variable is the one indicating whether or not the physician is under any influence of a capitated reimbursement system.

Tab1e 6.1

Descriptive Statistics - Entire Insured Sample NAMCS 1997-2000, 2003-2004

	Frequency	Percentage	Mean	Standard Deviation	Min	Max
Year						
1997	19869	16.37				
1998	19219	15.84				
1999	17252	14.22				
2000	23030	18.98				
2003	21252	17.51				
2004	20741	17.09				
Total Obs.	121363					
Gender						
Female	69791	57.51				
Male (omitted group)	51572	42.49				
Age			46.12	25.10	0	100
Race						
White	105682	87.08				
Black	11260	9.28				
Asian	3775	3.09				
Other (omitted group)	646	0.53				
Hispanic Ethnicity						
Yes	9157	7.51				
No	112206	92.45				
Paytype						
Private Insurance	77311	63.70				
Medicare	32130	26.47				
Medicaid (omitted group)	11922	9.82				
Primary Care Physician?						
Yes	42228	34.79				
No	79135	65.21				
Specialist?						
Yes	70525	58.11				
No	50838	41.89				
Allergy Specialist?						
Yes	898	0.74				
No	120465	99.26				

Table 6.1 (Continued)

Gastro Specialist?						
Yes	1452	1.19				
No	119911	98.81				
Patient Referred for this visit?						
Yes	27790	22.90				
No	93573	77.10				
Has patient been seen here before?						
Yes	103257	85.08				
No	17493	14.41				
Missing	613	0.51				
Were Any Medications Provided?						
Yes	75186	61.95				
No	46177	38.05				
Total Number of Medications			1.36	1.57	0	6
Were any Prescription Drugs Given?						
Yes	68045	56.07				
No	53318	43.93				
Were any OTC Drugs Given?						
Yes	12635	10.41				
No	108728	89.59				
Were any Allergy Prescriptions Given?						
Yes	3011	2.48				
No	118352	97.52				
Was Allegra Given?						
Yes	900	0.74				
No	120463	99.26				
Was Zyrtec Given?						
Yes	871	0.72				
No	120492	99.28				
Was Clarinex Given?						
Yes	121226	99.89				
No	137	0.11				

Table 6.1 (Continued)

Were Allergy Shots Given?						
Yes	120803	99.54				
No	560	0.46				
Allergy OTC Available						
Yes	41801	34.44				
No	79562	65.56				
Claritin OTC Market Share			0.03	0.04	0	0.098
Were any Gastro Prescriptions Given?						
Yes	2233	1.84				
No	119130	98.16				
Was Nexium Given?						
Yes	256	0.21				
No	121107	99.79				
Was Prevacid Given?						
Yes	785	0.65				
No	120578	99.35				
Was Protonix Given?						
Yes	196	0.16				
No	121167	99.84				
Was Zantac Given?						
Yes	716	0.59				
No	120647	99.41				
Gastro OTC Available						
Yes	20540	16.90				
No	100823	83.08				
Prilosec OTC Market Share			0.03	0.07	0	0.185
Major Reason For Visit						
Acute Problem	39792	32.79				
Chronic Problem, Routine	40101	33.04				
Chronic Problem, Flareup	11557	9.52				

Table 6.1 (Continued)

Preventive Care (omitted group)	16785	13.83				
Pre/Post Surgery	10742	8.85				
Missing	2386	1.96				
Region						
Northeast	25027	20.62				
Midwest	27190	22.40				
South	41915	34.54				
West (omitted group)	27231	22.44				
Metro. Stat. Area						
MSA	101645	83.75				
Non-MSA	19718	16.25				
Solo Practice?						
Yes	47157	38.86				
No	74206	61.14				
Employment Status of Physician						
Owner	89870	74.05				
Employee	25465	20.98				
Contractor (omitted group)	4602	3.79				
Missing	1426	1.17				
Capitation Payment Accepted?						
Yes	31889	26.28				
No	89474	73.72				
Capitation by Insurance Breakdown (Percent are of total Capitated Pop.)						
Private Insurance Capitation	21630	67.83				
Medicare Capitation	6815	21.37				
Medicaid Capitation	3444	10.80				
Total	31889					
Total Number of Tests			0.70	0.92	0	7
Total Number of Tests with Allergy Specialist			0.42	0.58	0	4

Table 6.1 (Continued)

Total Number of Tests with Gastro Specialist			0.81	0.76	0	7
Time Spent with Physician (in minutes)			19.11	12.60	0	240
Time Spent with Allergy Specialist			18.89	17.47	0	120
Time Spent with Gastro Specialist			23.93	14.60	0	120

CHAPTER 7

ALLERGY CLASS ANALYSIS

Allergies are a condition in which one's immune system overreacts to a substance in the environment. This disease is one of the most common in the United States, affecting more than 50 million people. Allergies rank sixth in leading causes of chronic disease and approximately $18 billion are spent annually in treatment and diagnosis. Common allergies include: plant pollens, mold spores, foods, insects, and animal products. The symptoms associated with allergies can greatly affect patients' life styles and can be a concern for employers as well. According to a previously mentioned study, productivity losses associated with a diagnosis of allergic rhinitis were estimated to be $601 million (Crystal-Peters, 2000).

Antihistamines are medications used in the treatment of allergies. While no cure exists for allergies, antihistamines are used to relieve patients of allergy symptoms such as itchy, watery eyes; sneezing; and congestion. These medications are available on both the OTC and prescription drug markets. Examples of antihistamines include:

- OTC Market: Benadryl, Claritin, Chlor-Trimeton, Dimetane and Tavist
- Prescription Market: Clarinex, Allegra, and Zyrtec

Allergy Shots

Allergy shots, also known as immunotherapy, are another form of treatment for allergy symptoms. With immunotherapy, patients are injected with a serum containing the substances they are specifically allergic to so that their immune response and tolerance can be built. While allergy shots are not available for all types of allergies or patients, they are considered as one of the most effective forms of treatment for severe allergies (Haines, 2006). Allergy shots are, however, time intensive for the patient as they have to, at least initially, receive weekly injections. In

order to build immunity, the patient later receives shots once per month in a maintenance cycle, which can last for several years. Because of the time requirements for allergy shots and because it often takes several months before any relief is realized from these injections, this therapy is most appropriate for chronic patients.

The cost of allergy shots is less than that of medications for both patients and insurance companies. A study in the April 2000 issue of *Research Reviews* showed that patients generally pay $1200 in out-of-pocket costs for year-round drug treatment of allergic rhinitis. Another study, however, shows that a patient would pay only $800 for the first year of allergy shots. Because the first year has the most number of shots in order to build up the patient's tolerance, it is also the most expensive. This study calculates that in later years, once the patient had reached maintenance and shots were given less frequently, the costs drop to between $170 and $290 per year. Since allergies are a chronic condition, the cost difference between drug therapy and immunotherapy can add up to significant amounts in the long term (Kirchheimer, 2003).

Antihistamine Market

There are two main categories of antihistamines: first generation and second generation. First generation antihistamines, such as Benadryl, are effective in the treatment of allergy symptoms; they are widely available and are generally inexpensive. Second generation antihistamines, such as Claritin, are also effective, but are more expensive than the first generation counterparts. For example, generic diphenhydramine (Benadryl's active ingredient) or chlorpheniramine (ChlorTrimeton's active ingredient) cost $3 to $4 for 24-30 tablets, whereas the same number of Claritin OTC tablets can cost a patient $20 or more (Drug Store, 2005).

The main differences between these two types of drugs, other than prices, however, are in their side effects. While, first generation antihistamines are effective,

they also contain very strong sedating effects. This is due to their lack of selectivity for the proper chemical receptors in the body. This reaction is so effective, it is a characteristic used in many OTC sleeping aid medications (Gleason et al, 1998). In fact, a study testing the driving capabilities of subjects showed that taking common, over-the-counter antihistamines can impair a person's ability to drive, even more so than being legally drunk (Tracey, 2000).

In addition to the driving concerns that result from the use of first generation antihistamines, there are productivity concerns as well. Other authors have found that when first generation allergy medications were used and an assessment of productivity was considered, the estimated loss in productivity ranged between $2.4 billion to $4.6 billion. The results from the 1995 National Health Interview Study showed that "the most significant productivity losses resulted not from absenteeism but from reduced at-work productivity associated with the use of sedating OTC antihistamines" (Crystal-Peters, 2000). Therefore, while first generation antihistamines have lower retail prices for consumers, the costs of taking these medications can be far greater to patients, employers, and society.

Second generation antihistamines are far more effective at locating the proper receptors and therefore, have greatly improved sedation effects of their earlier counterparts. Consumers can gain greater access to these medications, at possibly lower prices, with the movement of these drugs to the OTC market. This could allow for dramatic reductions in the productivity losses and driving hazards that are caused by the use of first generation anti-histamines.

Claritin

As described in Chapter 2, the December 2002 switch of Schering-Plough Corp's Claritin (loratadine) into the OTC market was initiated by the third part payer,

Wellpoint, who argued that the drug was just as safe as other OTC antihistamines (Goldfarb, 2002).

Claritin's patent was to expire on December 19, 2002, and on November 27th of the same year, the FDA approved Claritin, a top prescription performer, as the first non-sedating formula for the OTC market (FDA Orange Book, 2006). Schering-Plough was denied the 3 year Hatch Waxman exclusivity period because of the company's delays and lack of planning. Therefore, after Claritin's December 2002 OTC launch, it was soon followed to the market by private-label and value versions of loratadine in January and April 2003, respectively. The OTC switch of Claritin was successful with first year sales totaling nearly $400 million and a market share of 50% in the allergy market (Mahecha, 2006).

Schering-Plough attempted to keep their place in the prescription-only second generation antihistamine market by launching their new drug, Clarinex in January 2002. This new drug was designed to work faster and last longer than the older Claritin. However, the company had little time, less than one-year in fact, to convert the Claritin patients to Clarinex because of delays in Clarinex approval (IMS Health, 2003).

When Claritin made the switch into the OTC market, many insurance companies dropped their drug coverage for all antihistamines. These third party payers argued that there was an effective, low price antihistamine in the OTC market, and therefore patients should utilize that drug, rather than the more expensive, prescription counterparts (Kirchheimer, 2003).

According to the magazine *Drug Topics*, "total sales of antihistamines dropped 28.5% in 2003 following a 9.7% increase for 2002". While the top performing drugs still had some growth in sales from the previous year, this change had dropped

substantially. Allegra grew 21.5% in 2002, but only 4.3% in 2003. Zyrtec has a 10.4% increase in sales in 2002, with only 6.5% in 2003 (Gebhart, 2004).

Figure 7.1 depicts the percent of worldwide sales for each of these drugs. Much of the decrease in antihistamine sales described above seems to be stemming from Claritin according to Figure 7.1. When Claritin moved to the OTC market, its price dropped also, decreasing total sales dollars and percent market share. The other three drugs in the class increase in percent market share over the years. Claritin's market share begins to fall rapidly even 2001, before the OTC movement.

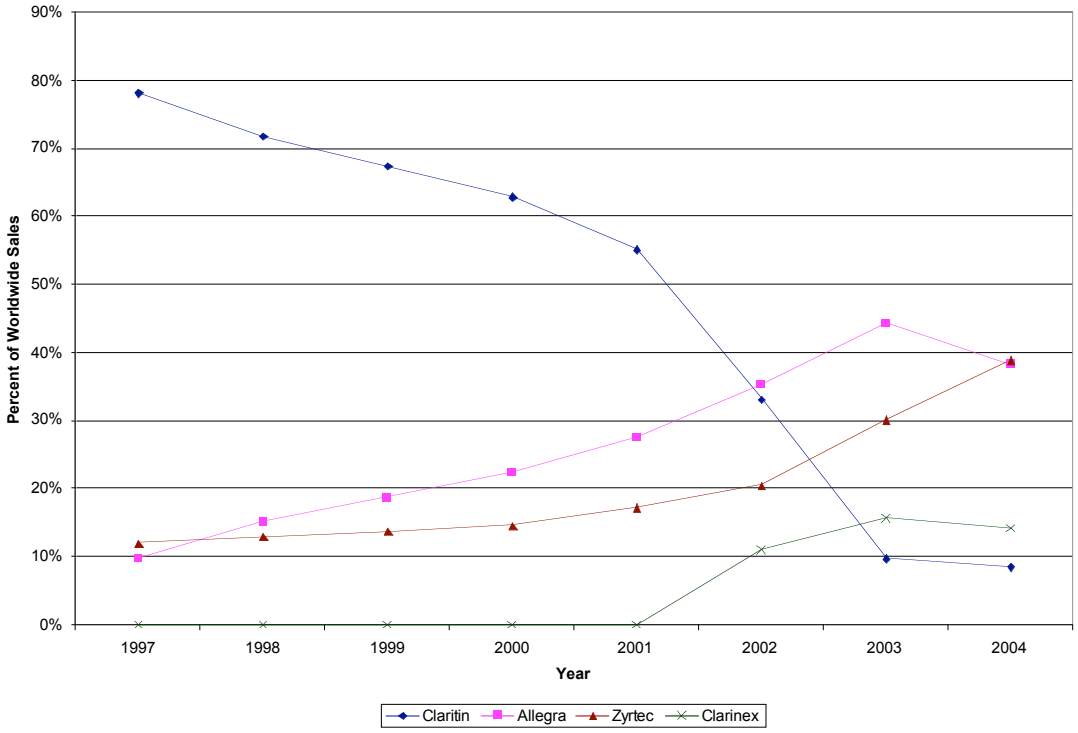

Figure 7.1

Percent of World Wide Sales per Year – Antihistamine Class

Allegra initially emerges as the market leader after Claritin's decline. By 2004, however, Zyrtec catches up and seems to have equal market share. Clarinex remains in the third position with less than twenty-percent market share.

The companies that produced second generation antihistamines engaged in heavy marketing efforts directly to consumers. Figure 7.2 shows the dollar amount spent on direct-to-consumer advertising, using Competitive Media Reports (CMR) data for the years 1997 – 2002 and Neilsen data collected from *Med Ad News* for 2003 and 2004.

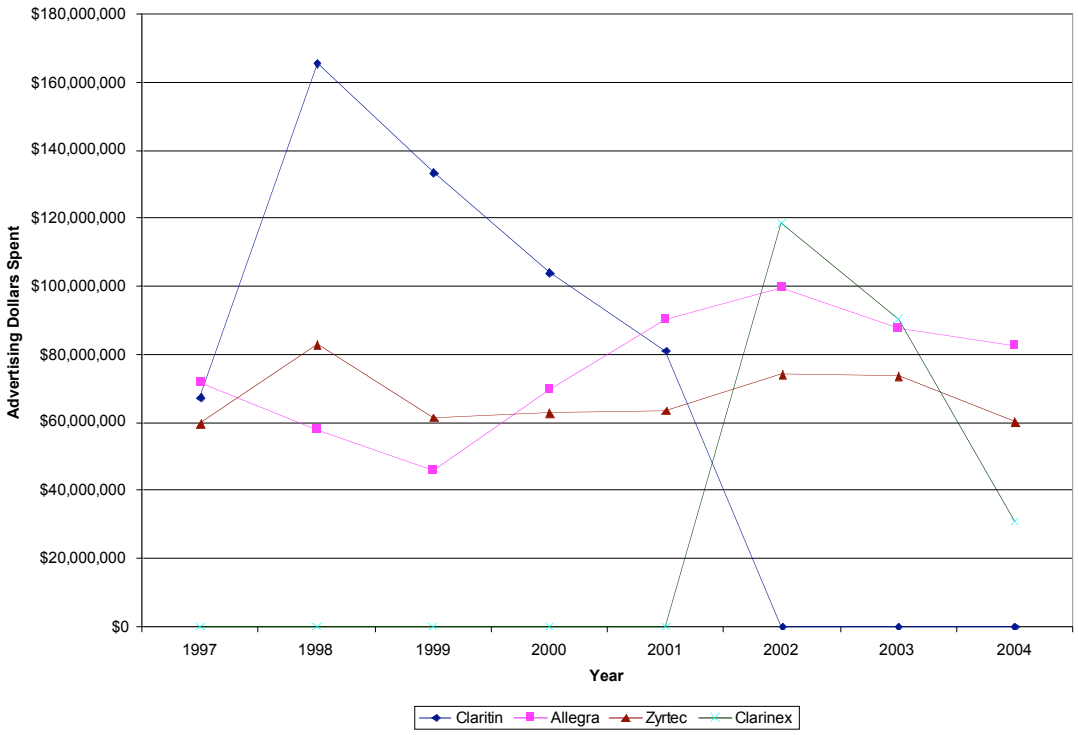

Figure 7.2

Advertising Dollars Spent per Year by Drug – Antihistamine Class

The data from *Med Ad News* does not include advertising information for most OTC. Therefore, the advertising data for Claritin is missing for the years 2003 and 2004, when it is sold in the OTC market. It is in 2002, however, when Claritin is still prescription that the advertising drops to nearly zero. In fact, Schering-Plough begins to slow down the advertising of Claritin from 1998. Also in 2002, the advertising for Clarinex, the new second generation antihistamine from Schering-Plough, is initiated.

Allergy/Antihistamine NAMCS Data

For the analysis of the allergy/antihistamine market, the NAMCS 1997 – 2000, 2003 – 2004 is used. The entire data set is examined, first, to study the use of allergy drugs because approximately half of the prescriptions for these medications were given to patients with non-allergy diagnoses. Due to the nature of the NAMCS, in that diagnoses are very specifically defined, it was not possible to find any one non-allergy diagnosis that dominated these prescriptions.

The data was then limited to only those patients with an allergy diagnosis. The data was also restricted, both for the entire population as well as the allergy population, to just those with some form of health insurance. This is done so that the effects of capitation and FFS can be clearly compared, without drawing in comparisons with the uninsured group.

This data, when restricted to the insured allergy group, provides a total sample of 9,692 allergy patient visits, averaging slightly over 1600 allergy patient visits per year. Nearly 58% of the allergy sub-population is female, while over 86% is white, and the average age is 37.5 years (somewhat younger than the average age for the entire NAMCS sample). Private insurance covers 74.4% of the patients, while 15.1% are covered by Medicare, and 10.5% by Medicaid. Capitated reimbursement is accepted by 27.7% of physicians and nearly 86% of allergy patients received a medication at their visit. While 77.4% received a prescription drug, 12.6% received an OTC, and fewer than 18% of the patients were given an allergy prescription. When describing their major reason for visit, 47.4% claimed to have an acute problem (symptoms occurring for 3 months or less); nearly 29% had chronic routine problems; and 13.3% had flare-ups of chronic conditions.

The following figures are first used to examine the allergy diagnosis in the NAMCS sample. Figure 7.3 shows the number of prescriptions for each allergy drug

for the total NAMCS population. Figure 7.4 shows the number of prescriptions for each allergy drug as well, but for the group diagnosed with an allergy condition.

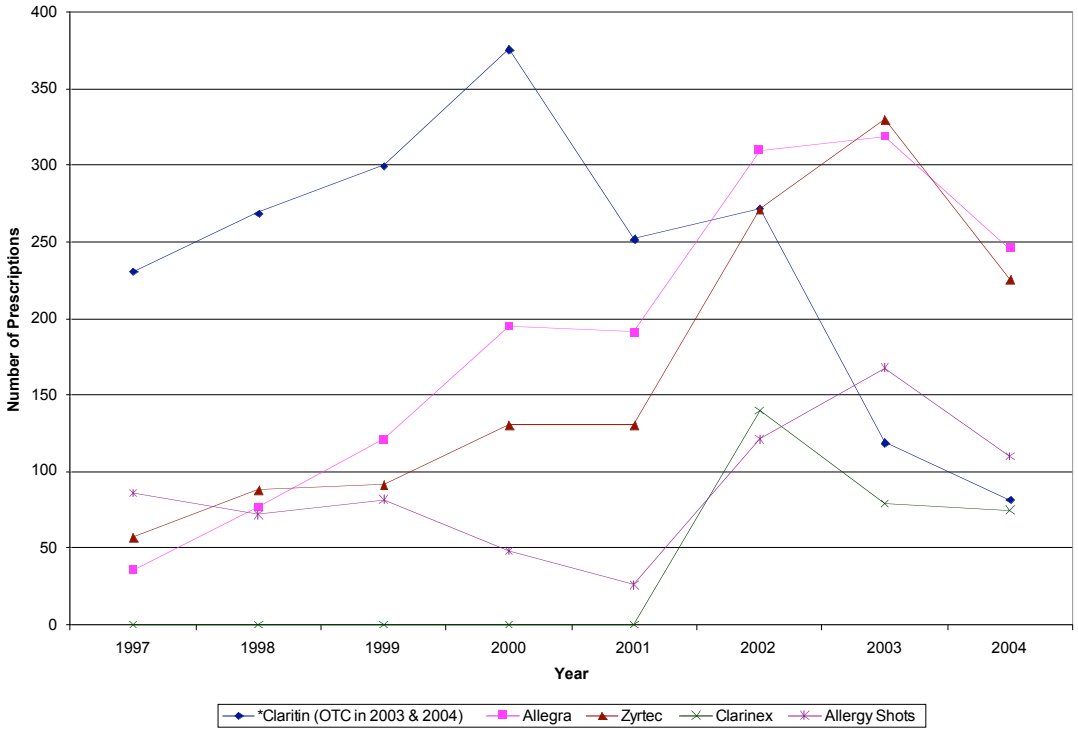

Figure 7.3

Number of Prescriptions by Allergy Drug – Total Insured NAMCS Sample

As was depicted in the figure showing the market share of world wide sales, this figure also shows that Claritin dominates the market until 2001. In 2002, Allegra takes over as market leader, with the most number of prescriptions, but Zyrtec soon catches up in 2002. Allergy shot use was found to increase steadily after 2001 and then declines in 2004. In this last year of data, however, allergy shots are still used more than either Claritin or Clarinex.

In both Figures 7.3 and 7.4, Claritin is classified as an OTC medication in the years 2003 and 2004; in all others it is a prescription. The two graphs provide the number of prescriptions by allergy drug; the first being for the entire insured sample

and the second is for the insured sample with an allergy related diagnosis. The two figures follow nearly the same patterns, with more prescriptions overall for the total insured sample.

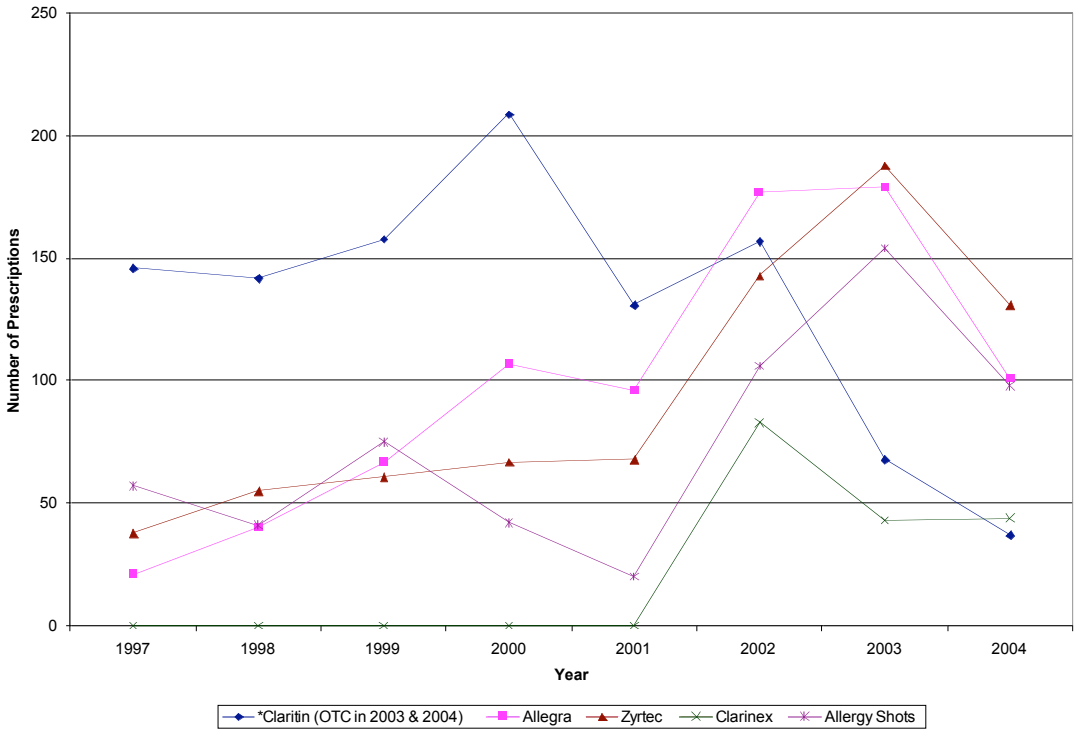

Figure 7.4

Number of Prescriptions by Allergy Drug – Allergy Sample

To measure severity in the allergy group the use of allergy shots is examined. This treatment is most often used for patients with severe allergies since the full benefits from this treatment are normally realized only after many months. Therefore, as the case-mix of patients becomes more severe and the patients seen in physicians' offices possess chronic symptoms, a greater utilization of allergy shots should be noticed. Figure 7.5 shows the percent of patients receiving allergy shots, for the entire NAMCS population and for the allergy related diagnosis sample.

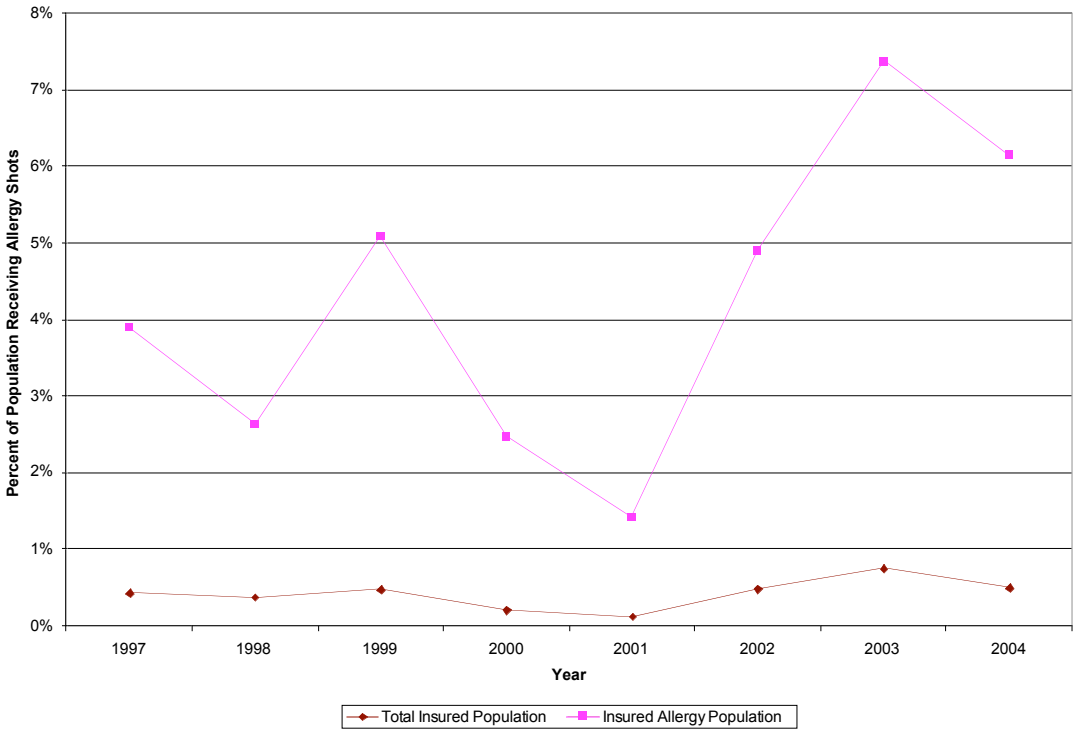

Figure 7.5

Percent of Population Receiving an Allergy Shot – NAMCS 1997 – 2004

An increase in the use of allergy shots is found in both groups after 2001. The allergy group peaks its use of allergy shots in 2003, the year following the Claritin OTC switch. The percent of patients getting an allergy shot then declines in 2004. Between 2001 and 2003, the percent of patients receiving allergy shots more than doubled amongst those with an allergy related diagnosis. Physicians may have felt the need to use allergy shots increasingly after 2001 because the types of patients coming into their offices may have become more severe. Also, after the switch of Claritin to the OTC market, many insurance companies dropped coverage of all antihistamines. For this reason, there may have been an increase in the use of allergy shots amongst allergy patients, since this form of treatment was still covered under most insurance

plans. Later, there was a backlash against insurance companies and many returned antihistamines to their drug coverage plans.

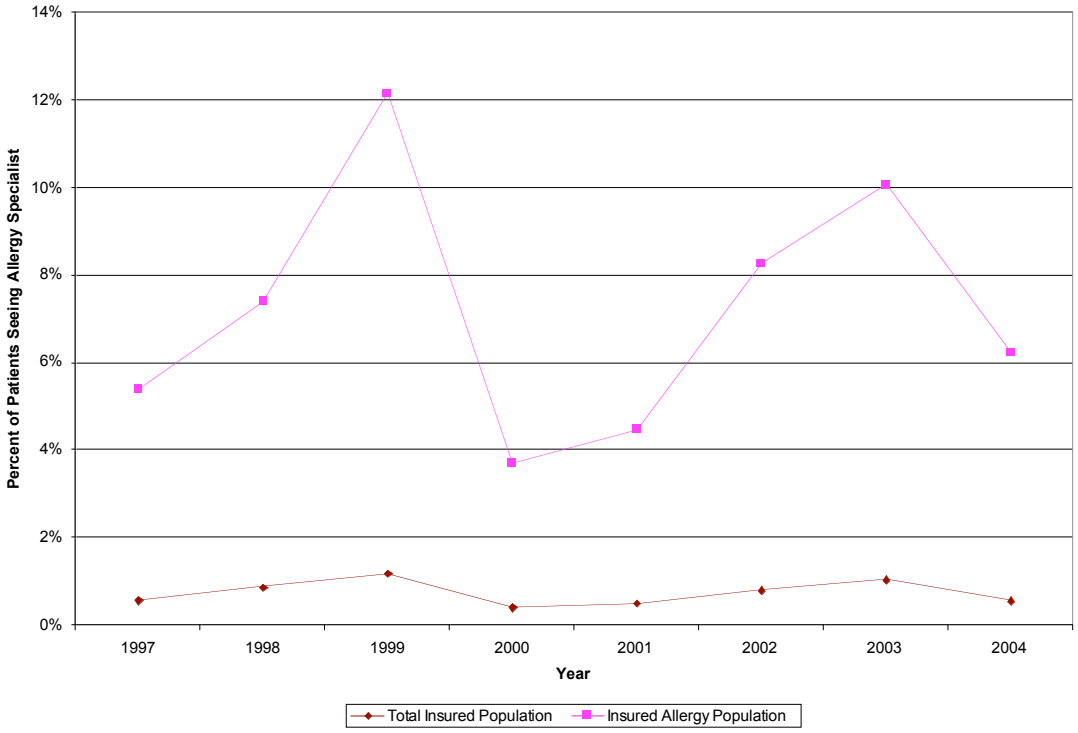

Figure 7.6

Percent of Patients Seeing an Allergy Specialist - NAMCS 1997 – 2004

In another attempt to examine severity the use of allergy specialists is examined. Figure 7.6 depicts the percent of patients in both the total insured population and the insured allergy population who see an allergy specialist.

While a peak in the use of allergy specialists is found in 2003 (the year after the Claritin switch) the percent of visits to allergy specialist begins to decrease there afterwards. It is expected that the use of an allergy specialist should increase with an increase in the use of allergy shots, since these physicians provide the injections in the majority of cases. Severity is not expected to change for the entire population, as the availability of an OTC in a drug class should only affect the relevant diagnosis group.

In order to analyze patient severity, the nature of the patient's illness is used, which categorized as acute, chronic routine, and chronic flare-up. Figure 7.7 depicts the trend in visits for each of these types of patients for the allergy sample.

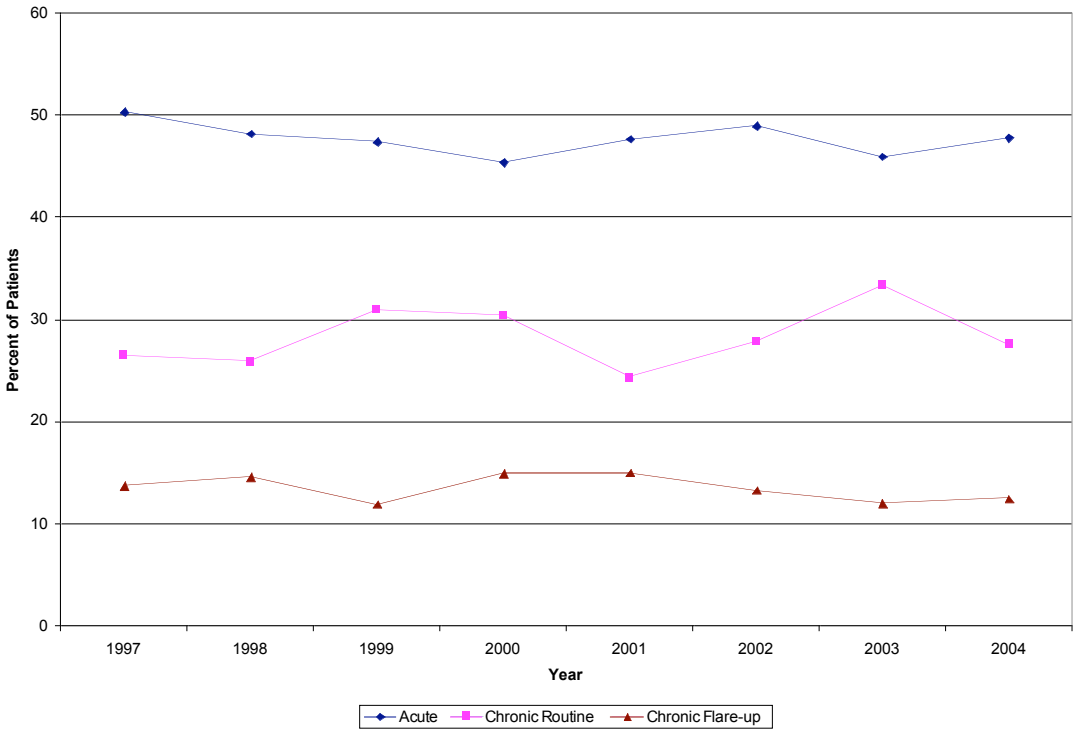

Figure 7.7

Percent of Visits by Type of Patient – Allergy Sample

NAMCS 1997 – 2004

While the number of visits from chronic routine patients seems to decrease after 2003, visits from acute and chronic flare-up patients seem to have minimal changes. The number of acute patients increases slightly, while the number of chronic flare-up patients seems to change only slightly.

In Figure 7.8 the type of patient seen in the offices of allergy specialists is depicted. This figure shows an increase in chronic routine patients amongst specialist

and a decrease in both acute and chronic flare-up patients, especially after 2002, the year in which Claritin moves to the OTC market.

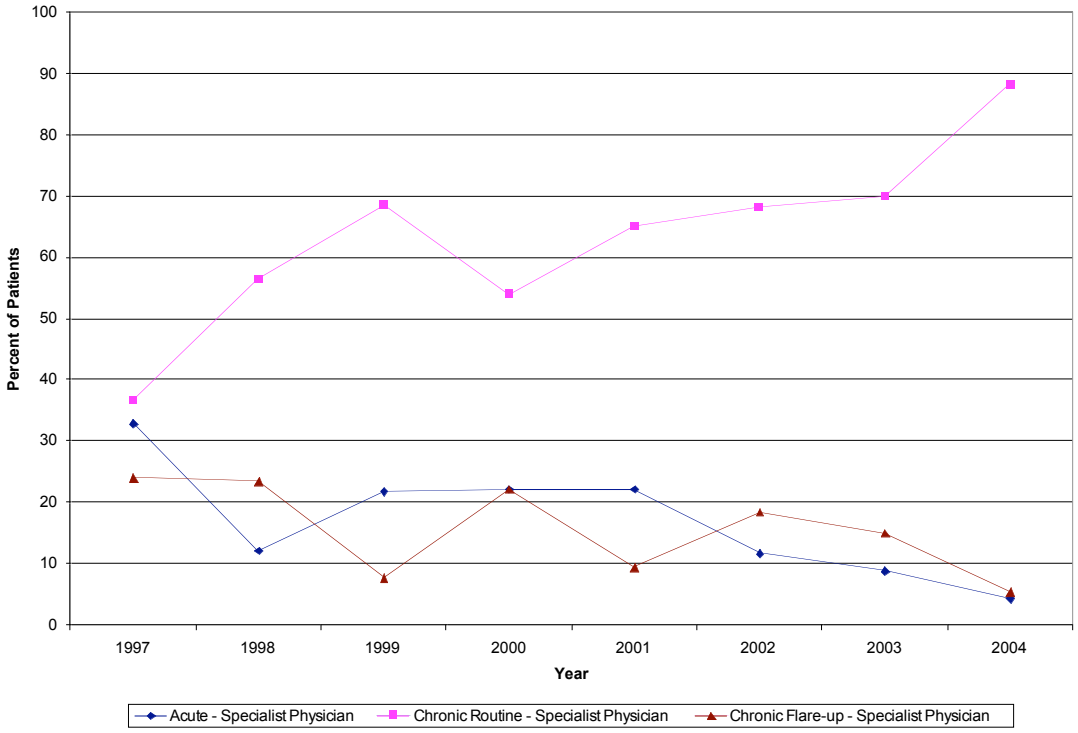

Figure 7.8

Percent of Visits by Type of Patient amongst Specialist Physicians– Allergy Sample

NAMCS 1997 - 2004

As expected, there is a decline in visits from acute and chronic flare-up patients that may be due to self treatment. Their conditions could be temporary, thus, they may be substituting Claritin OTC for a physician's office visit.

Table 7.1 provides the descriptive statistics for the allergy group. The capitation variable was only available for the NAMCS survey in the years 1997 – 2000 and then again in 2003 – 2004. Therefore, 2001 and 2002 are dropped from the actual regression analysis done later.

Table 7.1

Descriptive Statistics - Allergy Insured Sample NAMCS 1997-2000, 2003-2004

	Frequency	Percentage	Mean	Standard Deviation	Min	Max
Year						
1997	1464	15.11				
1998	1555	16.04				
1999	1473	15.20				
2000	1700	17.54				
2003	1993	20.56				
2004	1507	15.55				
Total Obs.	9692					
Gender						
Female	5605	57.83				
Male (omitted group)	4087	42.17				
Age			37.45	24.41	0	100
Race						
White	8343	86.08				
Black	906	9.35				
Asian	385	3.97				
Other (omitted group)	58	0.59				
Hispanic Ethnicity						
Yes	789	8.14				
No	8903	91.86				
Paytype						
Private Insurance	7207	74.36				
Medicare	1471	15.18				
Medicaid (omitted group)	1014	10.46				
Primary Care Physician?						
Yes	4449	45.90				
No	5243	54.10				

Table 7.1 (Continued)

Specialist?						
Yes	4726	48.76				
No	4966	51.24				
Allergy Specialist?						
Yes	722	7.45				
No	8970	92.55				
Patient Referred for this visit?						
Yes	1587	16.37				
No	8105	83.63				
Has patient been seen here before?						
Yes	8247	85.09				
No	1405	14.50				
Missing	40	0.41				
Were Any Medications Provided?						
Yes	8311	85.75				
No	1381	14.25				
Total Number of Medications			1.98	1.49	0	6
Were any Prescription Drugs Given?						
Yes	7504	77.42				
No	2188	22.58				
Were any OTC Drugs Given?						
Yes	1217	12.56				
No	8475	87.44				
Were any Allergy Prescriptions Given?						
Yes	1699	17.53				
No	7993	82.47				

Table 7.1 (Continued)

Was Allegra Given?						
Yes	488	5.04				
No	9204	94.96				
Was Zyrtec Given?						
Yes	526	5.43				
No	9166	94.57				
Was Clarinex Given?						
Yes	80	0.83				
No	9612	99.17				
Were Allergy Shots Given?						
Yes	462	4.77				
No	9230	95.23				
Allergy OTC Available						
Yes	3467	35.77				
No	6225	64.23				
Claritin OTC Market Share			0.03	0.04	0	0.098
Major Reason For Visit						
Acute Problem	4596	47.42				
Chronic Problem, Routine	2848	29.39				
Chronic Problem, Flareup	1286	13.27				
Preventive Care (omitted group)	501	5.17				
Pre/Post Surgery	282	2.91				
Missing	179	1.85				
Region						
Northeast	1934	19.95				
Midwest	2186	22.55				
South	3564	36.77				
West (omitted group)	2008	20.72				

Table 7.1 (Continued)

Metro. Stat. Area						
MSA	8145	84.04				
Non-MSA	1547	15.96				
Solo Practice?						
Yes	3830	39.52				
No	5862	60.48				
Employment Status of Physician						
Owner	7063	72.87				
Employee	2186	22.55				
Contractor (omitted group)	352	3.63				
Missing	91	0.94				
Capitation Payment Accepted?						
Yes	2616	26.99				
No	7076	73.01				
Capitation by Insurance Breakdown (Percent are of total Capitated Pop.)						
Private Insurance Capitation	2008	76.76				
Medicare Capitation	284	10.86				
Medicaid Capitation	324	12.39				
Total	2616					
Total Number of Tests			0.49	0.74	0	7
Total Number of Tests with Allergy Specialist			0.39	0.51	0	2
Time Spent with Physician (in minutes)			16.48	11.05	0	240
Time Spent with Allergy Specialist			19.21	17.97	0	120

Antihistamine Results

As mentioned earlier, in the theoretical model chapter, the case mix of patients is expected to become more severe after the availability of an OTC drug. Also, capitated physicians are hypothesized to provide OTC medications to minimize costs, and thereby maximize profits. For the allergy group, only the second generation antihistamine market is examined. Claritin is the drug that moves to the OTC market in 2002, while Allegra, Zyrtec, and Clarinex are the drugs in the prescription-only market. Also included are allergy shots as an alternative therapy to antihistamines.

The following cross tabulations are used to help frame the predictions of the effect of an OTC medication for the allergy group, using the means calculated from the NAMCS data.

In the first table (7.2), the probability of receiving each drug, before and after the availability of Claritin OTC, is shown. The second table (7.3) also depicts the probability of receiving each drug, before and after Claritin OTC, but broken down by reimbursement type. Both of these tables are for the entire, insured NAMCS sample. Tables 7.4 and 7.5 repeat the probabilities shown in tables 7.2 and 7.3, but for the allergy diagnosis sample.

Tables 7.2 and 7.4 show that there is an increase in prescriptions for each brand of antihistamine. There is also an increase in the use of allergy shots amongst patients from both the entire NAMCS insured population, as well as the allergy population. Amongst the allergy group, there is an overall decrease in the use of allergy prescriptions in general. When broken down to individual drugs, however, the tables show that there are increases in the use of Allegra, Zyrtec, Clarinex, and allergy shots. This could indicate that even though the use of other drugs increases, other patients have followed Claritin to the OTC market. For the entire insured population, there is also an increased use of allergy prescriptions.

Table 7.2
Probability of Receiving Allergy Prescription Medication Before and After

	Pre-Claritin OTC	Post-Claritin OTC	Difference
Allergy Prescription	2.45%	2.54%	0.09%
Allegra	0.55%	1.11%	0.56%
Zyrtec	0.47%	1.19%	0.72%
Clarinex	n/a	0.33%	0.33%
Allergy shots	0.37%	0.64%	0.27%

Table 7.3
Probability of Receiving Allergy Prescription Medication Before and After Claritin OTC Event, By Capitation Status - Total Insured NAMCS Sample

	A	B	C	D	
	Pre-Claritin OTC FFS	Post-Claritin OTC FFS	Pre-Claritin OTC Capitated	Post-Claritin OTC Capitated	Difference in Difference (D-C)-(B-A)
AllergyRx	2.41%	2.64%	2.72%	2.45%	-0.50%
Allegra	0.53%	1.15%	0.69%	1.07%	-0.24%
Zyrtec	0.48%	1.22%	0.40%	1.17%	0.03%
Clarinex	n/a	0.37%	n/a	0.29%	n/a
Allergy shots	0.35%	0.93%	0.48%	0.39%	-0.67%

Note: In both of the above tables, samples consist of all insured patients in the NAMCS 1997-2000, 2003-2004.

Table 7.4
Probability of Receiving Allergy Prescription Medication
Before and After Claritin OTC Event - Insured Allergy Sample

	Pre-Claritin OTC	Post-Claritin OTC	Difference
Allergy Prescription	17.65%	17.31%	-0.34%
Allegra	3.87%	7.12%	3.25%
Zyrtec	3.61%	8.68%	5.07%
Clarinex	n/a	2.31%	2.31%
Allergy shots	3.49%	7.07%	3.58%

Table 7.5
Probability of Receiving Allergy Prescription Medication Before and After Claritin OTC Event, By Capitation Status - Insured Allergy Sample

	A	B	C	D	
	Pre-Claritin OTC FFS	Post-Claritin OTC FFS	Pre-Claritin OTC Capitated	Post-Claritin OTC Capitated	Difference in Difference (D-C)-(B-A)
AllergyRx	17.65%	17.90%	17.70%	16.73%	-1.22%
Allegra	3.74%	7.63%	4.69%	6.64%	-1.94%
Zyrtec	3.70%	8.57%	3.05%	8.79%	0.87%
Clarinex	n/a	2.52%	n/a	2.10%	n/a
Allergy shots	3.72%	10.15%	1.99%	4.08%	-4.34%

Note: In both of the above tables, sample consists of all insured allergy patients in the NAMCS 1997-2000, 2003-2004.

FFS physicians are expected to continue providing prescription medications to their patients to ensure repeat visits. Once Claritin moves to the OTC market, it is expected that FFS physicians will be more likely to move away from prescribing this drug, and will instead provide Allegra, Zyrtec, or Clarinex. If the case mix of patients does become more severe, as predicted, it is also expected that FFS physicians will be more likely to prescribe allergy shots since this therapy is used on more severe cases of allergies. In both the entire insured sample, as well as the allergy diagnosis sample, the tabulations above show an increased probability that FFS physician will provide each of the brand name prescriptions. These physicians are also more likely to provide allergy shots after the availability of Claritin OTC for both samples.

Capitated physicians, before the availability of an OTC, are expected to provide the least costly form of treatment. Other studies have shown that using allergy shots can amount to lower costs per year than using medications. Because of this, it is expected that cost-minded capitated physicians will be more likely than FFS physicians to utilize allergy shots as opposed to prescription medications. Once Claritin moved to the OTC market, insurance companies generally dropped coverage for Claritin and in some cases, all antihistamines. Hence, it is expected that capitated physicians will be more likely than FFS physicians to move from providing allergy shots to their patients, to instead providing the OTC medication. That is, while no OTC's are available, capitated physicians choose the lowest cost of treatment by providing allergy shots since these are less expensive than prescription medications. Once Claritin moves to the OTC market, and insurance companies no longer pay for Claritin, or even all antihistamines, capitated physicians choose the lower cost treatment for the insurance provider which, in this case, is antihistamines. It is also expected that the capitated physician will be less likely to provide Allegra, Zyrtec, or

Clarinex than FFS physicians, as these drugs are more expensive for insurance companies when they are included under drug coverage.

The difference in differences columns in Tables 7.3 and 7.5 allow for the comparison of the effect of OTC availability on capitation versus the effect on FFS. If the effect of the availability of an OTC is the same for both groups, the difference in the change between these two will be zero. The results are not zero and therefore, indicate that one group is more affected by the availability of an OTC than the other.

The tables mentioned above show that under capitation there is a decreased likelihood that physicians will provide allergy prescriptions and allergy shots to the total insured NAMCS sample. For the allergy sample, the tables show a decreased use of allergy prescriptions amongst capitated physicians.

Table 7.6 provides the prescription drug regression results for the entire insured NAMCS population. The first three independent variables will be the focus in the analysis of the results. The results in Table 7.6 show that before the availability of an OTC, for the entire insured population, capitated physicians are more likely than FFS to provide allergy shots. This is as expected since allergy shots are the least costly form of treatment. After the availability of an OTC, FFS physicians are more likely to use allergy shots, than before. This could be a result because FFS physicians are shifting costs from the patient to the insurance company. Because many companies dropped coverage for antihistamines, FFS physicians are alleviating patients from paying the full cost of prescriptions, and are instead providing allergy shots, which would be covered under insurance plans as an office visit and, thus, would have lower copays.

Table 7.6

Allergy OLS Regression Results for Entire Insured Sample NAMCS 1997 – 2004

(Note - Regressions exclude years 2001 and 2002)

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5
	Allergy RX	Allegra	Zyrtec	Clarinex	Allergy Shots
Capitated Visit	0.001 [0.002]	0.001 [0.001]	-0.001 [0.001]	0 [0.000]	0.003*** [0.001]
AllergyOTC	-0.018*** [0.003]	-0.004** [0.001]	0.004*** [0.001]	0.004*** [0.001]	0.009*** [0.001]
Capitated Visit * AllergyOTC	-0.003 [0.002]	-0.002* [0.001]	0.001 [0.001]	-0.001 [0.000]	-0.008*** [0.001]
Private Insurance	0.008*** [0.002]	0.004*** [0.001]	0.001* [0.001]	0 [0.000]	0.003*** [0.001]
Medicare	0.001 [0.002]	0.002 [0.001]	0 [0.001]	0 [0.000]	0.002* [0.001]
Female	0.004*** [0.001]	0.002*** [0.001]	0.002*** [0.000]	0 [0.000]	0.001** [0.000]
White	0.005 [0.006]	0.005 [0.003]	-0.002 [0.003]	-0.002 [0.001]	-0.001 [0.003]
Black	0.005 [0.006]	0.004 [0.003]	-0.003 [0.003]	-0.001 [0.001]	-0.002 [0.003]
Asian	0.009 [0.007]	0.008** [0.004]	-0.002 [0.004]	0 [0.001]	0 [0.003]
Hispanic	-0.001 [0.002]	0 [0.001]	-0.002* [0.001]	0 [0.000]	0 [0.001]
Age	0.000*** [0.000]	0.000*** [0.000]	-0.000*** [0.000]	0.000** [0.000]	0.000*** [0.000]
Age^2	-0.000*** [0.000]	-0.000*** [0.000]	0.000*** [0.000]	-0.000** [0.000]	-0.000*** [0.000]
Acute	0.024*** [0.001]	0.006*** [0.001]	0.006*** [0.001]	0.001*** [0.000]	-0.003*** [0.001]
Chronic Routine	0.013*** [0.001]	0.002*** [0.001]	0.005*** [0.001]	0.001* [0.000]	0.007*** [0.001]

Table 7.6 (Continued)

Chronic Flare-up	0.024*** [0.002]	0.005*** [0.001]	0.008*** [0.001]	0.001*** [0.000]	-0.002** [0.001]
Pre/Post Surgery	-0.004** [0.002]	-0.002* [0.001]	0 [0.001]	0 [0.000]	-0.004*** [0.001]
Northeast	0.003** [0.001]	0 [0.001]	0 [0.001]	0 [0.000]	0.003*** [0.001]
Midwest	0.005*** [0.001]	0.001 [0.001]	0.002** [0.001]	0 [0.000]	0.008*** [0.001]
South	0.011*** [0.001]	0.002*** [0.001]	0.003*** [0.001]	0 [0.000]	0.005*** [0.001]
New Patient	-0.006*** [0.001]	-0.001* [0.001]	-0.001 [0.001]	0 [0.000]	-0.004*** [0.001]
Physician Owner	0.007*** [0.002]	0.001 [0.001]	0.001 [0.001]	0.001 [0.000]	0.003*** [0.001]
Physician is Employee	0.010*** [0.002]	0.003*** [0.001]	0.001 [0.001]	0.001 [0.000]	0 [0.001]
MSA	0.001 [0.001]	0 [0.001]	0 [0.001]	0 [0.000]	0.001 [0.001]
Time Trend	0.004*** [0.000]	0.002*** [0.000]	0.001*** [0.000]	0 [0.000]	-0.001*** [0.000]
Observations	121363	121363	121363	121363	121363
R-squared	0.01	0	0	0	0.01

FFS physicians in the after Claritin OTC period are less likely to provide prescriptions in general and less likely to provide Allegra, but are more likely to provide Zyrtec and Clarinex than before an OTC. Because of the decreased likelihood in overall prescription use, after OTC availability, the results indicate that some physicians are shifting their patients to other, prescription only drugs, while others are perhaps utilizing Claritin OTC.

After the availability of an OTC, capitated physicians are less likely than FFS to provide allergy shots. This i0s also along with the expectations stated earlier, since allergy shots are no longer the least costly form of treatment.

Because the dependent variables in this analysis are all binary, probits were also conducted. The results of these estimations are found in Table A.1. in the Appendix section. Marginal effects were also found for these estimations with results in Table A.3. Both the probit results and the marginal effects follow along the same lines as the OLS regressions above with similar significant results and the same signs of the coefficients. The marginal effect results show that under capitation, physicians are less likely to provide Zyrtec, by 0.1%, but more likely to provide allergy shots, than FFS by 0.1% before Claritin OTC. After the availability of an OTC, FFS physicians are 1.5% less likely to provide prescriptions and 0.4% less likely to provide Allegra to patients. FFS phys0icians are, however, more likely to provide allergy shots in the post OTC period by 0.4%. Capitated physicians are 0.2% less likely than FFS to provide Allegra and 0.1% less likely to provide allergy shots, after the availability of an OTC.

In other results, private insurance patients are more likely than Medicaid to get any allergy prescription, as well as Allegra, Zyrtec, and allergy shots for the entire population. Medicare is more likely than Medicaid to get allergy shots. Females were more likely to get allergy prescriptions, Allegra, Zyrtec, and allergy shots as well. Acute patients are less likely than preventive care patients to get allergy shots, as expected since this form of treatment is normally used for those with more severe conditions. Chronic routine patients are more likely to get allergy shots, while those with flare-ups are less likely to get shots than preventive care patients.

The regression results found in Table 7.7 repeat the same analysis as from Table 7.6. These results, however, are for the insured sample with an allergy related diagnosis.

Table 7.7

Allergy OLS Regression Results for Insured Allergy Sample NAMCS 1997 – 2004

(Note - Regressions exclude years 2001 and 2002)

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1 Allergy RX	2 Allegra	3 Zyrtec	4 Clarinex	5 Allergy Shots
Capitated Visit	0.005 [0.014]	0.014* [0.008]	-0.006 [0.009]	0 [0.003]	0.005 [0.008]
AllergyOTC	-0.120*** [0.022]	-0.033*** [0.013]	0.027** [0.013]	0.022*** [0.005]	0.071*** [0.012]
Capitated Visit * AllergyOTC	-0.013 [0.019]	-0.020* [0.011]	0.007 [0.011]	-0.005 [0.005]	-0.054*** [0.010]
Private Insurance	0.022 [0.013]	0.011 [0.008]	0.003 [0.008]	0.001 [0.003]	0.013* [0.007]
Medicare	0.014 [0.019]	0.009 [0.011]	-0.007 [0.011]	-0.001 [0.005]	0.017* [0.010]
Female	0.012 [0.008]	0.006 [0.005]	0.012** [0.005]	0 [0.002]	0.002 [0.004]
White	0.054 [0.050]	0.028 [0.029]	0.018 [0.030]	-0.024** [0.012]	-0.011 [0.027]
Black	0.067 [0.051]	0.034 [0.029]	0.005 [0.031]	-0.02 [0.012]	-0.027 [0.027]
Asian	0.064 [0.053]	0.052* [0.031]	0 [0.032]	-0.015 [0.013]	-0.002 [0.028]
Hispanic	0.001 [0.014]	0.005 [0.008]	-0.012 [0.009]	-0.003 [0.003]	0.007 [0.008]
Age	0.004*** [0.001]	0.003*** [0.000]	-0.001*** [0.000]	0.000*** [0.000]	0.001*** [0.000]
Age^2	-0.000*** [0.000]	-0.000*** [0.000]	0.000** [0.000]	-0.000** [0.000]	-0.000*** [0.000]
Acute	0.021 [0.015]	0.016* [0.009]	-0.013 [0.009]	0.002 [0.004]	-0.106*** [0.008]
Chronic Routine	0.014 [0.016]	0.011 [0.009]	-0.012 [0.010]	-0.001 [0.004]	0.009 [0.009]
Chronic Flare-up	0.053*** [0.018]	0.016 [0.010]	0.003 [0.011]	0.003 [0.004]	-0.098*** [0.010]

Table 7.7 (Continued)

Pre/Post Surgery	-0.094***	-0.023	-0.037**	-0.004	-0.120***
	[0.027]	[0.015]	[0.016]	[0.006]	[0.014]
Northeast	0.009	-0.01	-0.003	0	0.031***
	[0.012]	[0.007]	[0.007]	[0.003]	[0.007]
Midwest	0.018	0	0.008	0.002	0.074***
	[0.012]	[0.007]	[0.007]	[0.003]	[0.006]
South	0.063***	0.013**	0.016**	0.003	0.048***
	[0.011]	[0.006]	[0.006]	[0.003]	[0.006]
New Patient	0.014	0.007	0.017***	0.001	-0.047***
	[0.011]	[0.006]	[0.007]	[0.003]	[0.006]
Physician Owner	0.025	0.005	-0.001	0.001	0.023**
	[0.019]	[0.011]	[0.011]	[0.004]	[0.010]
Physician is Employee	0.032	0.018	-0.007	0.002	0
	[0.020]	[0.011]	[0.012]	[0.005]	[0.011]
MSA	0.021*	0.004	0.004	0.001	0.009
	[0.011]	[0.006]	[0.006]	[0.003]	[0.006]
Time Trend	0.024***	0.015***	0.004*	0.001	-0.003
	[0.004]	[0.002]	[0.002]	[0.001]	[0.002]
Observations	9692	9692	9692	9692	9692
R-squared	0.02	0.03	0.02	0.02	0.11

In the allergy diagnosis sample, capitated physicians are more likely than FFS, in the before OTC period to provide Allegra. After the availability of an OTC, FFS physicians decrease their overall use of allergy prescriptions and Allegra, but increase the use of Zyrtec and Clarinex. Again, because of the decreased likelihood in overall prescription use, after OTC availability, the results indicate that some physicians are shifting their patients to other, prescription only drugs, while others are perhaps utilizing Claritin OTC.

FFS physicians are also more likely to provide allergy shots after the availability of an allergy OTC. Again, this could be due to FFS physicians shifting costs away from the patient and towards the insurance company. As described before, since many companies dropped coverage for antihistamines, FFS physicians provide allergy shots to patients, since these are still covered under their health plans. The

patient, hence, does not have to bear the full cost of a prescription, but can instead pay the copay amounts associated with shots.

Capitated physicians are less likely than FFS to provide allergy shots for this population, after the availability of an OTC. Again, this is as expected since allergy shots are no longer the least costly form of treatment. After the availability of Claritin OTC, capitated physicians are also less likely than FFS to provide Allegra.

The probit and marginal effects results for the allergy sample are found in Tables A.2. and A.4., respectively. According the table from the marginal effects estimations, none of results for the pre-OTC capitation variable are significant. In the post-OTC period, FFS physicians are 10.8% less likely to give out prescriptions and are 3.6% less likely to prescribe Allegra; however, these physicians are more likely to give allergy shots by 1.9%. After the availability of Claritin OTC, capitated physicians, compared to FFS, are less likely to prescribe Allegra by 1.5% and less likely to provide allergy shots by 0.6%.

Both private insurance and Medicare patients are more likely than Medicaid to get allergy shots. Females are more likely to get Zyrtec in the allergy group and whites are less likely to get Clarinex. With this sample as well, acute patients are less likely than preventive care to get allergy shots, as are chronic flare-up patients.

Severity Results

It is expected that after the availability of an OTC, the overall case-mix of patients seen in physician offices will be of higher severity. The measures used to examine severity include: seeing a specialist physician; and the nature of the condition (acute, chronic routine, and chronic flare-up). Both time spent with the physician/specialist as well as total number of diagnostic tests are also examined, but are not used as measures of severity. The severity of patient case-mix is expected to change only for the allergy diagnosis sample, since the drug moving to the OTC

market is relevant to this group only. Therefore, the analysis done for severity is only conducted on the allergy group. The following cross tabulations are used to frame the expectations from the severity analysis.

Table 7.8

Probability of Patient Type/Severity Indicators Before and After Claritin OTC Event - Insured Allergy Sample

Note: Sample consists of all patients in NAMCS 1997-2000, 2003-2004, limited to those with insurance but not limited to those with an acid reflux indication

	Pre-Claritin OTC	Post-Claritin OTC	Difference
Allergy Specialist Seen	7.16%	7.96%	0.80%
Acute	47.74	46.84	-0.90
Chronic Routine	28.53	30.92	2.39
Chronic Flare-up	13.94	12.06	-1.88
Time Spent with Physician	16.86	15.80	-1.05
Total Number of Diag.Tests	0.50	0.46	-0.05
Time Spent with Allergy Specialist	22.12	14.49	-7.63
Total Number of Diag.Tests Allergy Specialist	0.40	0.37	-0.03

According to the above table, allergy specialists are more likely to be seen after the availability of an OTC. Acute patients and chronic flare-up are less likely to make physician office visits as expected, since these patients can self-treat. Chronic routine patients have an increased likelihood to make a physician office visit after the availability of Claritin OTC. Time spent and total number of diagnostic tests decrease amongst all physicians as well as amongst specialists, after the availability of an OTC. While there were no expectations for these two variables, they are included to examine the effects in physician offices after the availability of an OTC.

Table 7.9 provides the results for the variables used in the patient severity regressions from only the allergy sample since severity of the non-allergy group is not expected to change after the availability of an OTC in the allergy drug class.

Table 7.9
AllergyOLS Severity Regression Results for Insured AllergySample NAMCS 1997 – 2004
(Note - Regressions exclude years 2001 and 2002)
Standard Errors in Brackets
*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5	6	7
	Allergy Specialist	Acute	Chronic Routine	Chronic Flareup	Acute Specialist Physician	Chronic Routine Specialist Physician	Chronic Flareup Specialist Physician
AllergyOTC	0.029** [0.014]	0.023 [0.028]	0.009 [0.025]	-0.034* [0.019]	0.118 [0.077]	-0.118 [0.101]	-0.059 [0.081]
Private Insurance	0.007 [0.009]	0.033* [0.017]	-0.026* [0.016]	-0.001 [0.012]	-0.004 [0.046]	0.037 [0.060]	0.001 [0.048]
Medicare	0.002 [0.013]	0.005 [0.025]	0.011 [0.023]	0.002 [0.017]	-0.11 [0.071]	0.116 [0.092]	-0.011 [0.074]
Capitated Visit	-0.038*** [0.007]	0.086*** [0.013]	-0.083*** [0.011]	-0.006 [0.009]	-0.071* [0.038]	-0.053 [0.049]	0.104*** [0.040]
Female	0.004 [0.005]	0.023** [0.010]	-0.014 [0.009]	0.004 [0.007]	-0.021 [0.027]	0.011 [0.035]	0.02 [0.028]
White	0.064* [0.033]	0.011 [0.064]	0.005 [0.059]	-0.033 [0.045]	-0.963*** [0.338]	0.866* [0.442]	0.102 [0.356]
Black	0.061* [0.034]	-0.025 [0.066]	0.022 [0.061]	-0.019 [0.046]	-0.966*** [0.341]	0.890** [0.445]	0.096 [0.358]

Table 7.9 (Continued)

Asian	0.049 [0.036]	0.126* [0.069]	-0.066 [0.063]	-0.063 [0.048]	-0.868** [0.344]	0.770* [0.449]	0.124 [0.361]
Hispanic	0.011 [0.010]	0.005 [0.019]	-0.015 [0.017]	0.012 [0.013]	0.022 [0.043]	-0.048 [0.056]	-0.003 [0.045]
Age	0 [0.000]	-0.007*** [0.001]	0.006*** [0.001]	0.001** [0.001]	-0.002 [0.002]	0.003 [0.003]	-0.003 [0.002]
Age^2	0 [0.000]	0.000*** [0.000]	-0.000*** [0.000]	0 [0.000]	0 [0.000]	0 [0.000]	0 [0.000]
Acute	-0.021** [0.010]						
Chronic Routine	0.118*** [0.011]						
Chronic Flare-up	0.039*** [0.012]						
Pre/Post Surgery	-0.041** [0.018]						
Northeast	0.005 [0.008]	0.024 [0.016]	-0.038*** [0.014]	0.011 [0.011]	0.054 [0.041]	-0.125** [0.054]	0.088** [0.043]
Midwest	-0.044*** [0.008]	0.037** [0.016]	-0.031** [0.014]	0.009 [0.011]	0.074 [0.048]	-0.298*** [0.062]	0.179*** [0.050]
South	-0.009 [0.007]	0.027* [0.014]	-0.018 [0.013]	-0.003 [0.010]	0.102*** [0.036]	-0.167*** [0.047]	0.058 [0.038]
New Patient	0.013* [0.007]	0.105*** [0.014]	-0.085*** [0.013]	0.011 [0.010]	0.311*** [0.036]	-0.390*** [0.047]	0.069* [0.038]

Table 7.9 (Continued)

Physician Owner	0.041***	-0.062**	0.079***	-0.050***	0.125	0.386***	-0.168*
	[0.013]	[0.024]	[0.022]	[0.017]	[0.093]	[0.121]	[0.097]
Physician is Employee	0.013	0.012	0.014	-0.074***	0.218**	0.405***	-0.277**
	[0.013]	[0.026]	[0.024]	[0.018]	[0.103]	[0.135]	[0.109]
MSA	0.054***	-0.079***	0.059***	0.023**	0.192**	-0.039	0.03
	[0.007]	[0.014]	[0.013]	[0.010]	[0.080]	[0.104]	[0.084]
Time Trend	-0.004	-0.011**	0.007	0.004	-0.039**	0.066***	-0.013
	[0.003]	[0.005]	[0.005]	[0.004]	[0.016]	[0.020]	[0.016]
Observations	9692	9692	9692	9692	722	722	722
R-squared	0.08	0.05	0.04	0.01	0.18	0.18	0.05

The main variable of interest from these equations is allergy OTC. This variable is an indicator for when Claritin moves to the OTC market. The above results show that there is an increased likelihood, after the availability of an OTC, for allergy patients to see a specialist physician. There is also a decreased likelihood of chronic flare-up patients making a physician office visit. This is consistent with the earlier hypothesis that these patients may try to self-treat their temporarily exacerbated symptoms rather than see a physician. It was expected that acute patients would be less likely to make physician office visits in the after OTC period. The resulting coefficient is positive, which is not as expected, but this result is not significant.

It was also found that specialists are less likely to be seen under capitation than FFS. Acute patients are more likely to be seen and chronic routine are less likely to be seen under capitated plans than under FFS. Acute patients are less likely to be seen by specialists, as expected since this group is thought to have less severe symptoms.

Tables A.5 and A.6. show the results from the probit and marginal effect estimations for severity. According to these results, after the availability of an OTC, there is a 2.5% increase in the likelihood of seeing a specialist physician and a 3.2% decrease in the likelihood of a Chronic Flare-up patient seen in the physician's office.

Table 7.10 provides the results of the regressions examining time spent with the physician and the total number of diagnostic tests ordered. Again, because the effect of OTC is only expected on the allergy diagnosis, only this group is being studied.

The results for allergy OTC in these regressions are not significant for physicians in general, nor are they significant for specialist. Interestingly, capitated physicians are likely to spend less time with patients than FFS and are more likely to order tests. This perhaps indicates that capitated physicians substitute time spent with diagnostic testing.

Table 7.10

Time Spent and Diagnostic Tests Regressions NAMCS 1997 – 2004 Allergy Sample

Note – 2001 and 2002 are excluded from these regressions.

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4
	Time Spent with Physician	Total Number of Diag. Tests	Time Spent with Specialist Physician	Total Number of Diag. Tests Specialist Physician
AllergyOTC	-0.525 [0.611]	-0.03 [0.040]	-4.187 [3.155]	-0.146 [0.108]
Private Insurance	0.313 [0.381]	-0.100*** [0.025]	1.263 [1.871]	0.071 [0.064]
Medicare	0.199 [0.548]	-0.048 [0.036]	-2.42 [2.894]	-0.103 [0.099]
Capitated Visit	-0.765*** [0.276]	0.078*** [0.018]	1.244 [1.569]	-0.101* [0.054]
Female	-0.462** [0.223]	0.017 [0.015]	-2.045* [1.086]	-0.015 [0.037]
White	0.185 [1.417]	-0.139 [0.092]	5.557 [13.892]	0.438 [0.476]
Black	0.831 [1.459]	-0.038 [0.095]	6.401 [13.987]	0.495 [0.479]
Asian	-1.055 [1.514]	-0.08 [0.098]	5.8 [14.088]	0.414 [0.483]
Hispanic	-1.103*** [0.412]	0.021 [0.027]	-3.567** [1.758]	-0.100* [0.060]
Age	0.046*** [0.017]	0.024*** [0.001]	0.034 [0.092]	0.011*** [0.003]
Age^2	0 [0.000]	-0.000*** [0.000]	0 [0.001]	-0.000** [0.000]
Acute	-2.153*** [0.442]	-0.441*** [0.029]	-3.342 [2.972]	0.063 [0.101]
Chronic Routine	-2.289*** [0.463]	-0.566*** [0.030]	-5.290* [2.713]	0.019 [0.092]

Table 7.10 (Continued)

Chronic Flare-up	-0.188 [0.512]	-0.494*** [0.033]	3.355 [2.922]	0.268*** [0.100]
Pre/Post Surgery	-1.322* [0.766]	-0.808*** [0.050]	-7.346 [10.176]	0.371 [0.349]
Northeast	-0.872** [0.346]	-0.006 [0.023]	-6.030*** [1.682]	-0.393*** [0.058]
Midwest	-3.564*** [0.341]	-0.018 [0.022]	0.536 [1.983]	-0.002 [0.068]
South	-1.290*** [0.307]	-0.006 [0.020]	-4.802*** [1.496]	-0.161*** [0.051]
New Patient	5.906*** [0.313]	-0.128*** [0.020]	25.516*** [1.572]	0.311*** [0.054]
Physician Owner	-1.369** [0.536]	-0.018 [0.035]	-6.462 [3.971]	0.008 [0.134]
Physician is Employee	-0.466 [0.566]	0.128*** [0.037]	2.146 [4.404]	0.099 [0.149]
MSA	0.228 [0.306]	-0.063*** [0.020]	7.295** [3.311]	-0.138 [0.113]
Time Trend	-0.011 [0.114]	-0.007 [0.007]	0.332 [0.642]	0.056** [0.022]
Observations	9690	9692	721	722
R-squared	0.06	0.11	0.44	0.19

Allergy Market Discussion

The change in regulatory status of Claritin from prescription-only to OTC spurred many changes in the antihistamine drug class. While Clarinex was launched by Schering-Plough as an attempt to capture the prescription market share of Claritin, it was unable to fully accomplish this. Both Allegra and Zyrtec had increased market shares after the Claritin switch, as expected.

One of the most interesting results of this analysis came with the Allergy Shots regressions. Allergy shots, before the availability of any OTC products, were the lowest cost of treatment according to other studies. After the movement of Claritin to the OTC market, insurance companies no longer covered this drug and in fact many stopped coverage for antihistamines altogether.

As was proposed, capitated physicians had the incentive to reduce the cost of care in order to maximize their profits. For this reason, according to these results, capitated physicians were found to be more likely to provide allergy shots than FFS before the availability of an OTC. After the availability of an OTC, capitated physicians were less likely than FFS to provide allergy shots, while FFS was more likely in the after OTC period to provide shots than before. Capitated physicians, therefore, seem to reduce the use of allergy shots once an OTC becomes available because these are no longer the lowest cost treatment. From these results, capitated physicians seem to act as an agent for the insurance company by shifting costs away from the payer, to the patient. FFS physicians, however, act as an agent for patients, by protecting them from the full cost of prescription medications when providing allergy shots in the after OTC period.

The results for the severity regressions indicate that specialists are more likely to be used after the availability of an OTC. This measure indicates that perhaps severity has increased, as specialists are more likely to deal with severe patients than primary care physicians. Also, the results indicate that, in the post OTC period, those patients with chronic conditions are likely to self-treat, as opposed to visiting a physician's office when their symptoms are exacerbated.

CHAPTER 8

ACID REFLUX CLASS ANALYSIS

Acid reflux, or heart burn, is characterized by a burning discomfort in the throat or chest, caused by the presence of acid in the esophagus. Infrequent acid reflux is typically caused by various types of foods or drinks. Frequent or chronic heart burn is generally due to permanent changes in the barrier between the esophagus and the stomach. Gastroesophageal reflux disease (GERD) can be defined as heartburn that occurs more than twice a week, and can lead to more serious health problems (NDDIC, 2005). These complications include:

- Esophageal Narrowing – In this condition, cells in the lower esophagus are damaged due to acid exposure which leads to the formation of scar tissue. The scar tissue then narrows the food pathway and can interfere with swallowing.

- Esophageal Ulcer – With this condition, stomach acids create an open sore by eroding tissues in the esophagus.

- Barrett's Esophagus - Although uncommon, this disease is caused by repeated and long-term exposure to stomach acid and causes a cellular change associated with an increased risk of esophageal cancer (Mayo Clinic, 2005).

Treatments for acid reflux or GERD range from simple lifestyle changes to the use of medications, and even surgery in more extreme cases. Physicians often initially recommend patients to adjust particular parts of their lifestyle in order to alleviate symptoms of acid reflux. These changes include: avoiding alcohol; avoiding cigarettes; losing weight; eating smaller meals; wearing loose fitted clothing; and raising the head of a bed 6-8 inches so that the patient is not lying flat, but rather at an

angle. Physicians also advise patients to make dietary changes and avoid certain foods. These foods include: citrus products, such as oranges and lemons; chocolate; drinks with caffeine; fried foods; garlic and onions; mint flavorings; spicy foods; and tomato-based products (NDDIC, 2003).

Surgery is not a common treatment for acid reflux or GERD, but it remains an option for those who have other complications; for those who do not want to remain dependent on medications; or for those who cannot tolerate these drugs. Fundoplication is the most common of surgeries and involves tightening the lower esophageal sphincter to prevent stomach acid from moving into the throat/esophagus. Endoluminal gastroplication is another form of surgery in which stitches are sewn into the stomach, near the weakened sphincter to strengthen it and prevent the flow of acid into the esophagus. Finally, the stretta procedure uses radiofrequency energy to melt tissues within the esophagus that contain the weakened valve (Mayo Clinic, 2005).

Acid Reflux Medications

The use medication is the most common form of treatment for acid-reflux/GERD. Drugs in this category are widely available and include both over-the-counter and prescription-only products. Antacids, one of the oldest acid reflux medications, neutralize stomach acids and usually provide quick-relief. These are OTC products and are generally used by those with mild or occasional heart burn problems. Some familiar antacids include: Maalox, Mylanta, Rolaids, and Tums.

Histamine-2 (H-2) Antagonists, also known as H-2 Receptor Blockers, reduce the production of acid, instead of acting as neutralizing agents like Antacids. These drugs do not act as quickly as their earlier counterparts; however they do provide longer relief. Some brand names included in this category are: Tagamet, Pepcid AC, Axid, or Zantac. H-2 Antagonists are readily available in the OTC market.

Proton pump inhibitors (PPIs) are the youngest of acid-reflux medications; they are long-acting; and the most effective. These drugs work by blocking the production of acid and thereby allow time for the esophageal tissue that has been damaged by stomach acids, to heal. Common brands of PPIs include: Prilosec, Nexium, Prevacid, and Protonix (Mayo Clinic, 2005).

Prilosec

Prilosec, the world's most prescribed drug from 1996 – 2000, was a major entrant into the OTC market in 2003. H-2 Antagonists such as Zantac and Tagamet, along with antacids were the products already in the OTC market, while the more effective proton pump inhibitors (PPIs) such as Prilosec and Prevacid were available by prescription only. Because the drug was approaching patent expiration, Astra-Zeneca made Prilosec the first of the PPIs to switch to the OTC market (Goozner, 2004).

Rx-to-OTC switches can be less profitable for companies that are solely involved in the prescription-only market. Therefore, some of these companies create partnerships for OTC marketing with companies that have the infrastructure and expertise to market the drug as a consumer product. In order to ensure a successful switch, Astra-Zeneca, the parent company of Prilosec, created a licensing agreement with Proctor & Gamble and the two companies conducted the switch of Prilosec jointly (Mahecha, 2006). Both companies worked closely to develop the clinical data needed for the Rx-to-OTC switch and because of Procter & Gamble's success in bringing consumer health care products to market, it handled the marketing and distribution of Prilosec OTC in the U.S. and Puerto Rico (National Heartburn Alliance, 2002).

A great deal of debate took place between these companies and the FDA regarding claims, usage, and the risk for more serious conditions, such as ulcers and

gastroesophageal reflux disease to go undiagnosed. Eventually Prilosec was approved for OTC sales on June 20, 2003. Prilosec was also given the 3 year Hatch Waxman extension, giving it market exclusivity until June 20, 2006 (FDA Orange Book, 2006). The first year of Prilosec OTC sales were nearly $300 million (Mahecha, 2006).

Astra-Zeneca attempted to transition patients off from Prilosec, even before it was moved to the OTC market, to their younger prescription-only PPI, Nexium, which still had patent protection. The parent company of both these drugs had intensive DTC and detailing promotions to move people to the "new purple pill". These advertising efforts were successful as can be seen by the market shares of these medications. Prilosec had 40% of the market share for worldwide sales of PPIs in 2002, the year before it moved into the OTC market. Nexium took over some of this by claiming a 30% market share in 2003. Although it had switched to the OTC market, Prilosec still maintained nearly 20% of the market even after 2003.

Overall, PPIs performed well in terms of sales, even after the switch of Prilosec. Total sales for this category were up by 11.6% and made PPIs the top selling drug class for 2003. Individually, drugs also performed well: Prevacid was up 9%; Nexium was up 54%; and Protonix was up 52% (Gebhart, 2004).

Figure 8.1 shows the percent of market share of worldwide sales for each PPI and for Zantac, an H2 Antagonist. Zantac is included because, even though it is an OTC for all years included, it is one of Prilosec's major competitors, especially in the earlier years of the graph. The percent market share of Prilosec peaks in 1999. After 2001, Prilosec's percent market share declines substantially per year. This is the same year in which Nexium is introduced. By 2003, Nexium becomes the market leader, followed by Prevacid. While Protonix is the newest of the Proton Pump Inhibitor class, its market share remains below 20% for the entire time period depicted in the figure.

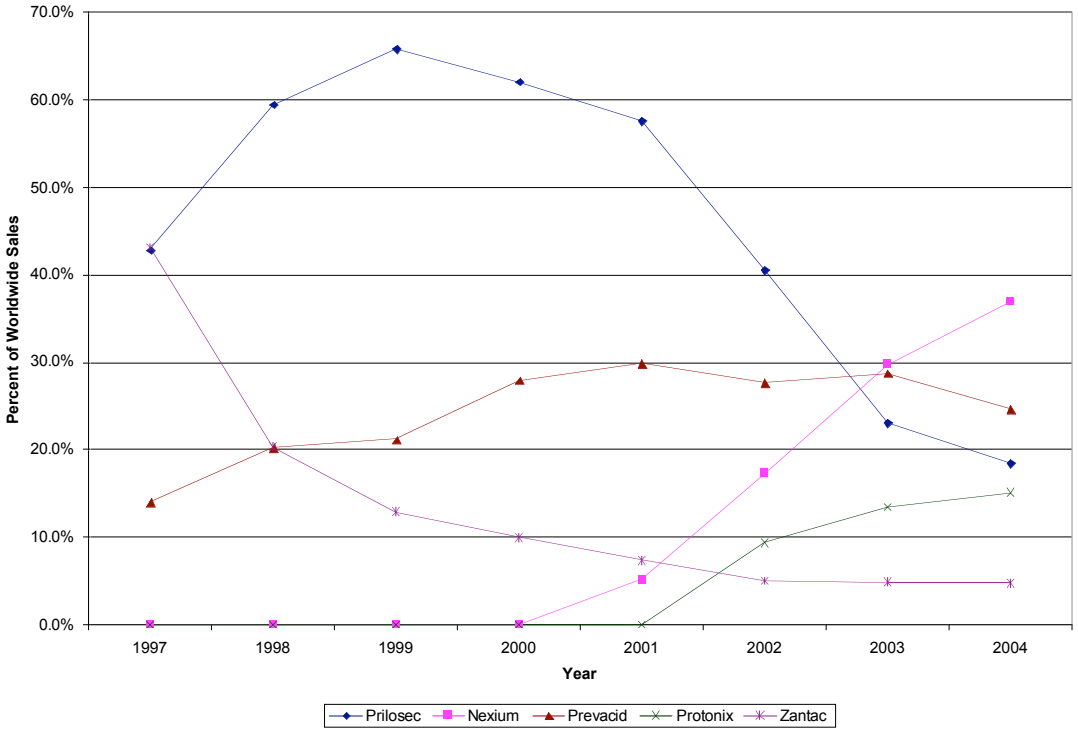

Figure 8.1

Percent of Worldwide Sales by Drug - Acid Reflux Class

The companies that make these medications are well known for their heavy advertising efforts. Figure 8.2 shows the direct-to-consumer advertising amounts for each of the PPIs, along with the advertising for Zantac. Since Zantac is an OTC medication throughout the time period of this analysis, the regulations for advertising of this drug are different from those of prescription medications. In addition, it is generally less expensive to advertise OTC medications because of these more relaxed rules for advertising. The data from Figure 8.2 was collected through CMR and *Med Ad News,* which does not include most OTC drugs. Therefore, the advertising amount for Prilosec OTC in 2004 is missing from the data. Astra-Zeneca seems to begin the complete phase out of Prilosec between 2000 and 2001. The company reduces its

advertising of Prilosec to nearly nothing in this time period and instead begins its promotion for Nexium in 2001. Interestingly, this replacement occurs two years before Prilosec actually moves to the OTC market.

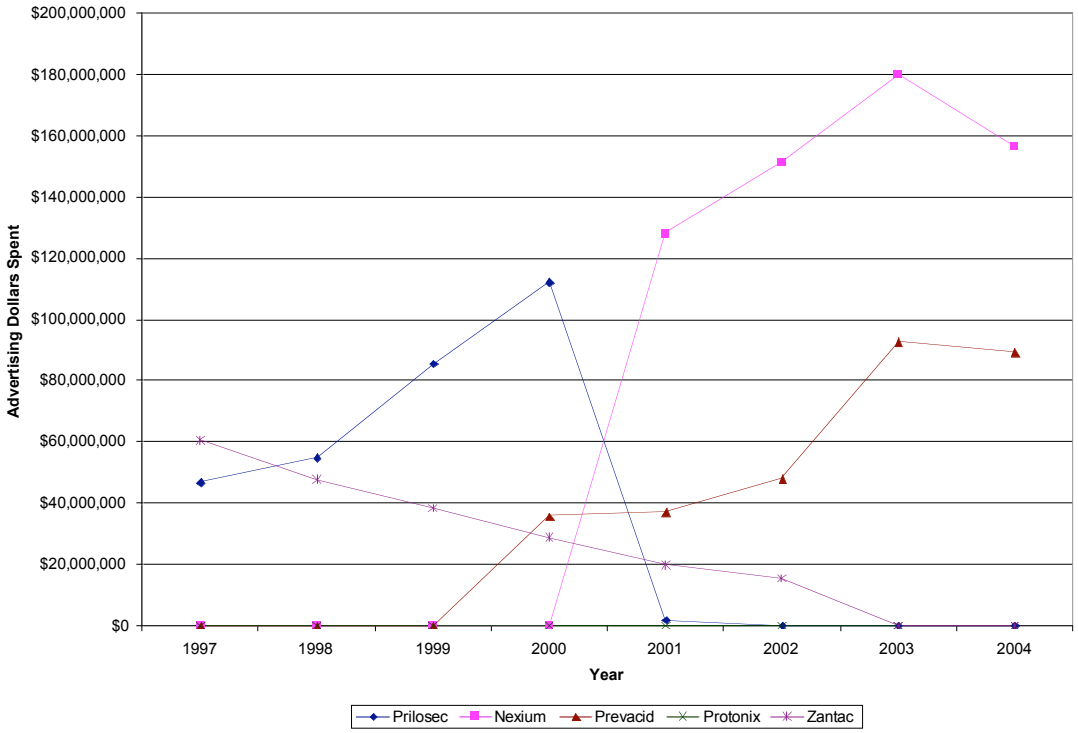

Figure 8.2

Advertising Dollars Spent per Year by Drug – Acid Reflux Class

Acid Reflux NAMCS Data

For the analysis of the acid reflux/GERD market, the NAMCS 1997 – 2000, 2003 - 2004 is used again. As was done with the allergy group, the entire data set was first used to examine the use of acid reflux drugs because approximately half of the prescriptions for these medications were given to patients with non-acid reflux diagnoses. Because of the nature of the NAMCS, in that diagnoses are very specifically defined, it was not possible to find any one non-acid reflux diagnosis that dominated these prescriptions.

The data was then limited to only those patients with an acid-reflux or related diagnosis. The data was also restricted, both for the entire population as well the acid-reflux population, to just the insured. This is done so that the effects of capitation and FFS can be compared clearly, without drawing in comparisons with the uninsured group.

This data, when restricted to the insured acid reflux group, provides a total sample of 5,386 acid reflux patient visits, averaging over 800 acid-reflux patient visits per year. Nearly 57.8% of the acid reflux sub-population is female, while over 85.4% is white, and the average age is 49.5 years, slightly older than the average for the entire population. Private insurance covers 60% of the patients, while 29.2% are covered by Medicare, and 10.8% by Medicaid. Capitated plans were accepted by 27.4% of physicians. Over 70% of acid-reflux patients received a medication at their visit. While 65.3% received a prescription drug, 14.4% received an OTC, and approximately 17% of the patients were given an acid reflux prescription. When describing their major reason for visit, 45.1% claimed to have an acute problem (symptoms occurring for 3 months or less); over 30% had chronic routine problems; and 13% had flare-ups of chronic conditions.

The following figures are first used to examine the acid reflux diagnosis in the NAMCS sample. Figure 8.3 shows the number of prescriptions of each acid reflux drug for the total NAMCS population. Figure 8.4 shows the number of prescriptions for each acid reflux drug as well, but for the group diagnosed with an acid reflux condition. For each of these graphs, it should be noted that Prilosec is classified as an OTC drug only in 2004.

Prescriptions for Prilosec peak in 2000 and then begin to fall in 2001, the same year Nexium enters the market. Nexium overtakes Prilosec in number of prescriptions in 2002. Prevacid has the most number of prescriptions in the NAMCS from 2002 –

2004. Prescriptions for Zantac fall in 2004, as expected since this is when Prilosec is OTC and creates direct competition with Zantac, in the same market.

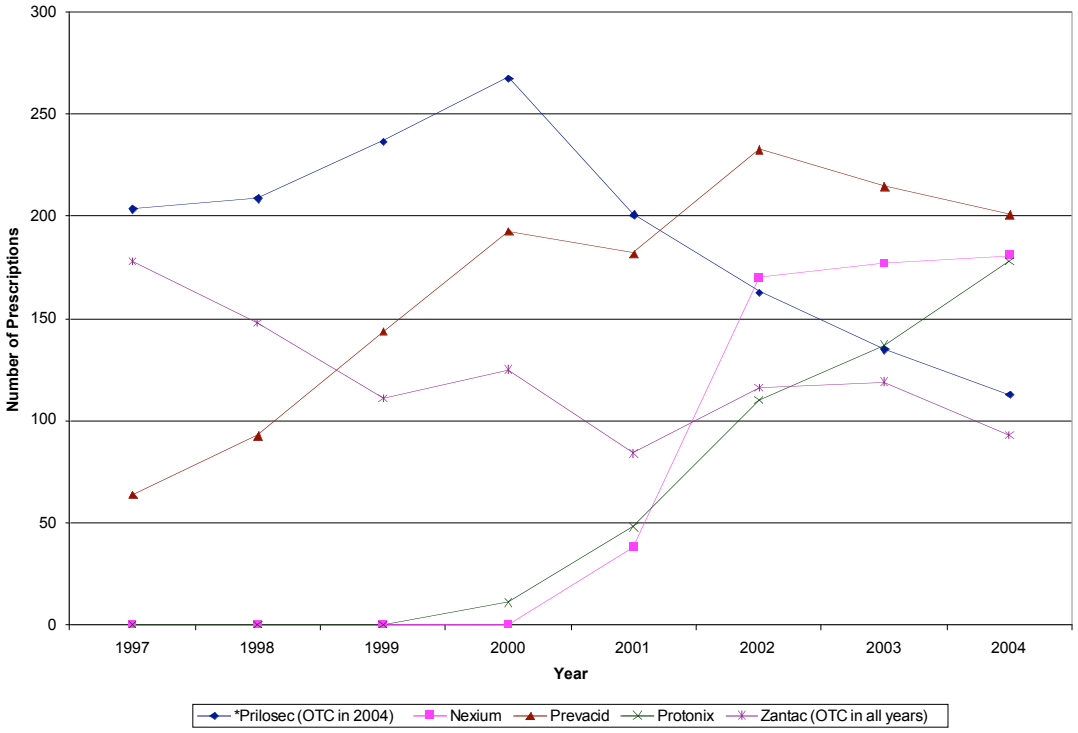

Figure 8.3

Number of Prescriptions by Drug NAMCS 1997 – 2004 Total Insured Sample

Both Figures 8.3 and 8.4 seem to follow similar patterns. Physicians are found to decrease the use of Prilosec for acid reflux patients earlier than they do for all other patients, as the prescriptions for Prilosec for the acid reflux group peak in 1999, while they peak in 2000 for the total sample. Just as with the entire insured NAMCS sample, Prevacid has the most prescriptions from 2002 – 2004 for the group with an acid reflux related diagnosis. All prescriptions decrease from 2003 – 2004, but Zantac has the steepest decline, after having reached a peak in 2003 for the acid reflux diagnosis group. Amongst both populations, Protonix continues a steady increase in number of prescriptions after its introduction in 2000.

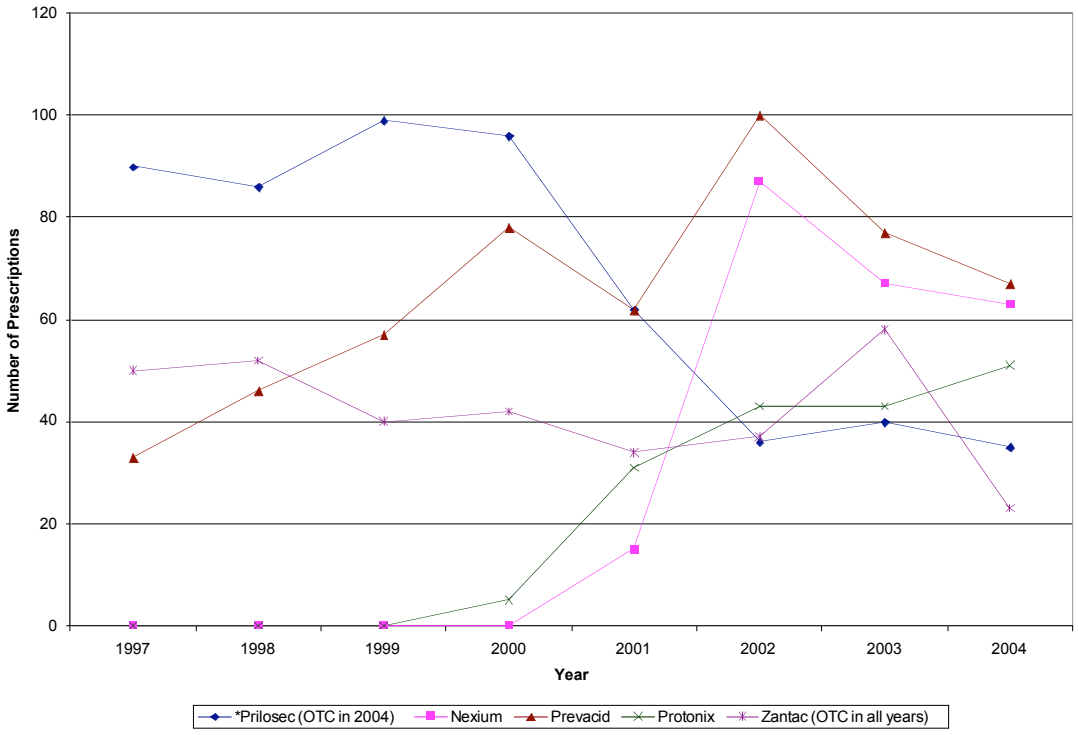

Figure 8.4

Number of Prescriptions by Drug NAMCS 1997 – 2004 Acid Reflux Sample

To examine severity for this market the percentage of patients that see a gastrointestinal specialist are analyzed. These percentages are for both the entire, insured NAMCS sample, as well as for the acid reflux sample, and are depicted in Figure 8.5.

The percentage of patients seeing a gastrointestinal specialist for the general insured NAMCS population does not seem to change much. This percentage for the acid reflux/GERD population, however, fluctuates over the years. An increase in the use of gastrointestinal specialists is found in 2004, the year after Prilosec moved to the OTC market, an indication that perhaps severity has increased. This is the only year of data after the switch takes place, however, making it difficult to formulate any concrete conclusions from this result.

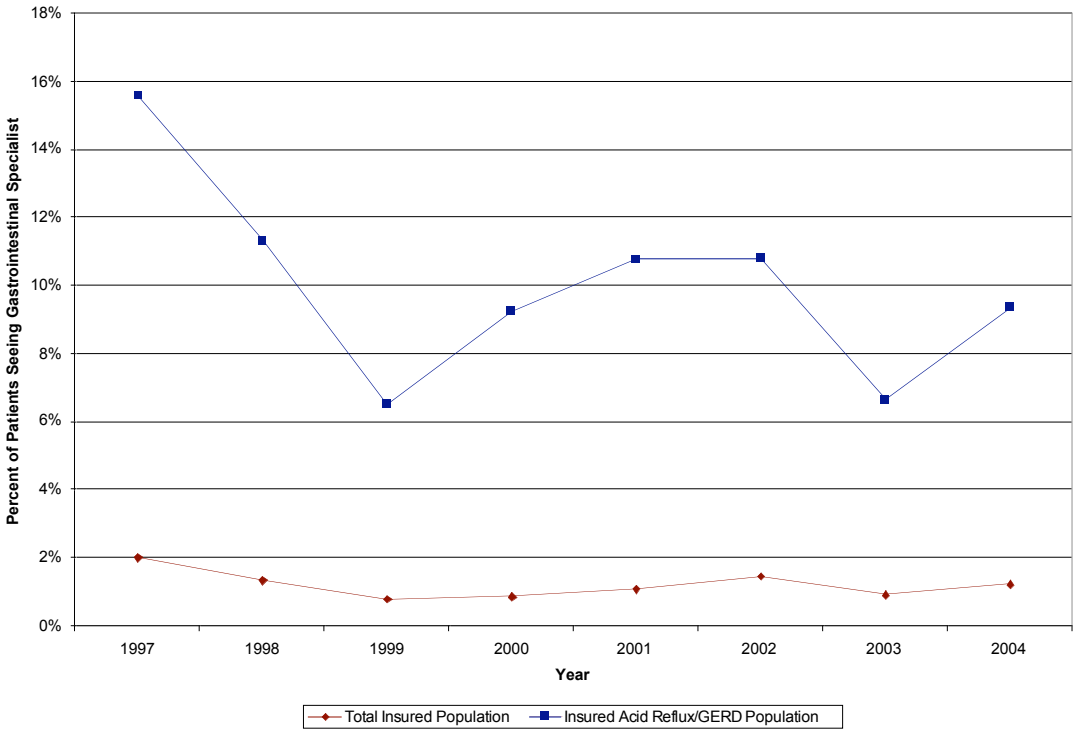

Figure 8.5

Percent of Patients Seeing Gastrointestinal Specialist by Diagnosis Group – NAMCS 1997 – 2004

Severity is also measured using the nature of the patient's illness, which includes acute, chronic routine, and chronic flare-up. Acute patients are assumed to have the least severe conditions since their conditions are short term and may in fact be temporary. Chronic routine patients are assumed to be more severe because their conditions have lasted over a longer time period and they are likely to have utilized more resources in diagnosis and treatment. While chronic flare-up patients are expected to have severe conditions, they may act more similarly to acute patients since their conditions are also likely to be short term or temporary.

Figure 8.6 depicts the trend in visits for each of these types of patients for the acid reflux group. This graph indicates an increase in the number of visits from

chronic routine patients between 2003 and 2004. Also, Figure 8.6 indicates a decrease in the number of visits from acute patients after 2002, and especially after 2003, when Prilosec moves to the OTC market, while chronic flare-up remains unchanged.

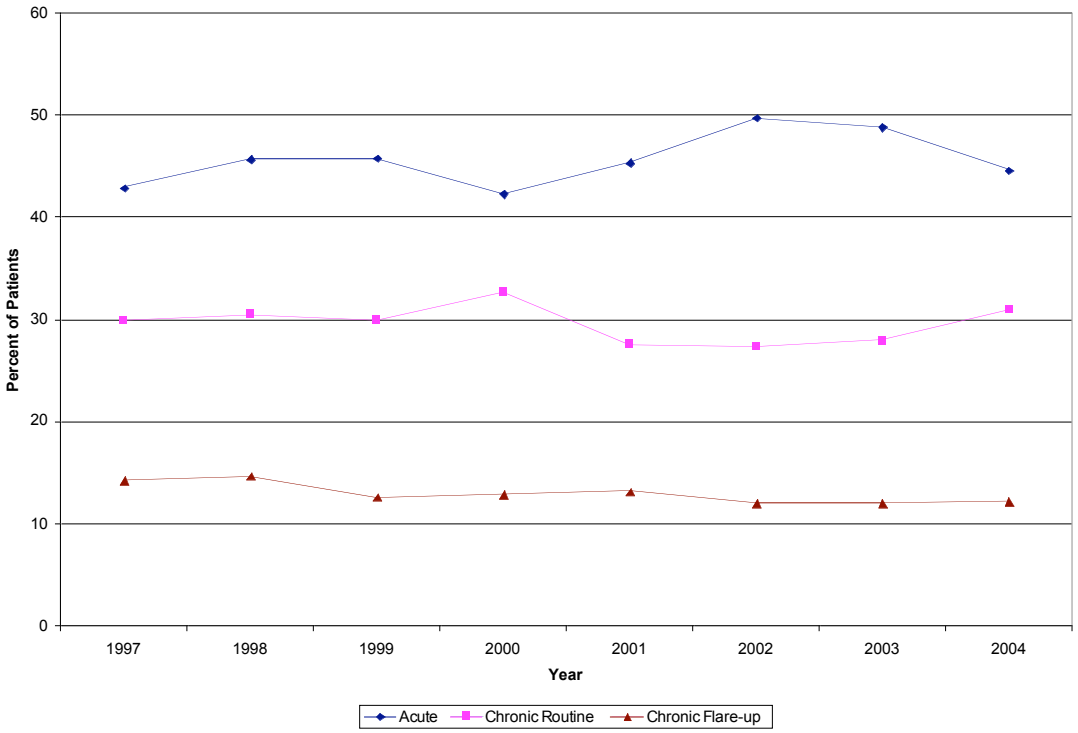

Figure 8.6

Percent of Visits by Patient Type – All Physicians – NAMCS 1997 – 2004 Acid Reflux Sample

Figure 8.7 also depicts office visits by patient type, but for specialist physicians. Office visits to specialists by patient type in the above graph vary greatly year by year. While it is difficult to make any conclusions from this figure, there is a decrease in acute patients seen in specialist offices after 2003, when Prilosec becomes available on the OTC market. There is also a leveling off of chronic flare-up patients after this time period as well, following an increase between 2002 and 2003. Visits from chronic routine patients increased in 2004.

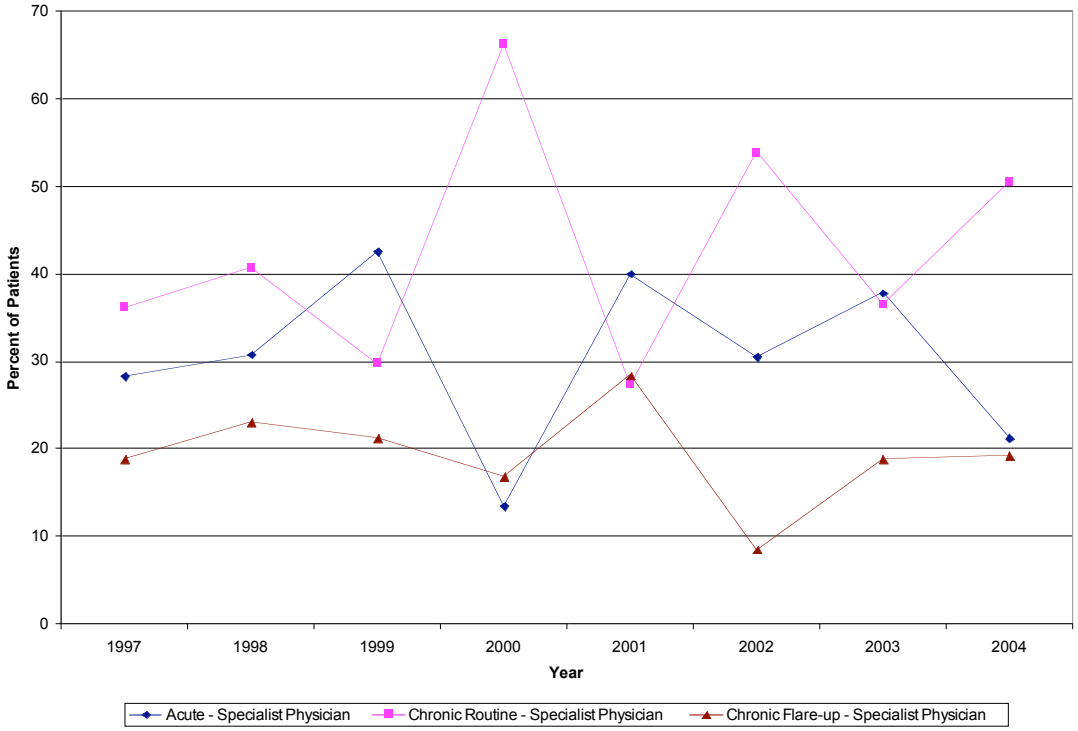

Figure 8.7

Percent of Visits by Patient Type – Gastrointestinal Specialists – NAMCS 1997 – 2004 Acid Reflux Sample

Table 8.1 provides the descriptive statistics for the acid reflux group. The data used for these statistics reflect the same data used in the regression analysis conducted later. The capitation variable asks whether or not the physician accepts capitated payments. This variable was only available in the NAMCS survey for the years 1997 – 2000 and then again for the 2003 – 2004 surveys. The capitation variable was not included in the 2001 and 2002 surveys, and therefore these years are dropped from the actual regression analysis done later. For this reason, these two years are also not included in the descriptive statistics table.

Table 8.1

Descriptive Statistics - Acid Reflux Insured Sample NAMCS 1997-2000, 2003-2004

	Frequency	Percentage	Mean	Standard Deviation	Min	Max
Year						
1997	815	15.13				
1998	803	14.91				
1999	720	13.37				
2000	962	17.86				
2003	1047	19.44				
2004	1039	19.29				
Total Obs.	5386					
Gender						
Female	3112	57.78				
Male (omitted group)	2274	42.22				
Age			49.45	23.61	0	100
Race						
White	4601	85.43				
Black	517	9.60				
Asian	236	4.38				
Other (omitted group)	32	0.59				
Hispanic Ethnicity						
Yes	430	7.98				
No	4956	92.02				
Paytype						
Private Insurance	3233	60.03				
Medicare	1570	29.15				
Medicaid (omitted group)	583	10.82				
Primary Care Physician?						
Yes	2701	50.15				
No	2685	49.85				

Table 8.1 (Continued)

Specialist?						
Yes	2514	46.68				
No	2872	53.32				
Gastro Specialist?						
Yes	527	9.78				
No	4859	90.22				
Patient Referred for this visit?						
Yes	1318	24.47				
No	4068	75.53				
Has patient been seen here before?						
Yes	4442	82.47				
No	922	17.12				
Missing	22	0.41				
Were Any Medications Provided?						
Yes	3778	70.14				
No	1608	29.85				
Total Number of Medications			1.79	1.80	0	6
Were any Prescription Drugs Given?						
Yes	3517	65.30				
No	1869	34.70				
Were any OTC Drugs Given?						
Yes	777	14.43				
No	4609	85.57				
Were any Gastro Prescriptions Given?						
Yes	918	17.04				
No	4468	82.96				

Table 8.1 (Continued)

Was Nexium Given?						
Yes	109	2.02				
No	5277	97.98				
Was Prevacid Given?						
Yes	339	6.29				
No	5047	93.71				
Was Protonix Given?						
Yes	75	1.39				
No	5311	98.61				
Was Zantac Given?						
Yes	256	4.75				
No	5130	95.25				
Gastro OTC Available						
Yes	1036	19.24				
No	4350	80.76				
Prilosec OTC Market Share			0.04	0.07	0	0.185
Major Reason For Visit						
Acute Problem	2430	45.12				
Chronic Problem, Routine	1635	30.36				
Chronic Problem, Flareup	702	13.03				
Preventive Care (omitted group)	314	5.83				
Pre/Post Surgery	193	3.58				
Missing	112	2.08				
Region						
Northeast	952	17.68				
Midwest	1285	23.86				
South	2043	37.93				
West (omitted group)	1106	20.53				

Table 8.1 (Continued)

Metro. Stat. Area						
MSA	4390	81.51				
Non-MSA	996	18.49				
Solo Practice?						
Yes	1956	36.32				
No	3430	63.68				
Employment Status of Physician						
Owner	3891	72.24				
Employee	1261	23.41				
Contractor (omitted group)	170	3.16				
Missing	64	1.19				
Capitation Payment Accepted?						
Yes	1478	27.44				
No	3908	72.56				
Capitation by Insurance Breakdown (Percent are of total Capitated Pop.)						
Private Insurance Capitation	986	66.71				
Medicare Capitation	340	23.00				
Medicaid Capitation	152	10.28				
Total	1478					
Total Number of Tests			1.04	1.02	0	7
Total Number of Tests with Gastro Specialist			0.76	0.68	0	6
Time Spent with Physician (in minutes)			20.52	12.93	0	240
Time Spent with Gastro Specialist			24.47	15.23	0	120

Acid Reflux Results

As mentioned earlier in the theory section, the case mix of patients is expected to become more severe after the availability of an OTC drug and capitated physicians are hypothesized to provide OTC medications to minimize costs, thereby maximizing profits. For the acid reflux group, Proton Pump Inhibitors, as well as one H2 Antagonist, Zantac, are examined. Prilosec is the drug that moves to the OTC market in 2003, while Nexium, Prevacid, and Protonix are the drugs in the prescription-only market. Zantac, an OTC in all years of data, is included because of its strong market share and competition with Prilosec.

The following cross tabulations are used to help frame the predictions of the effect of an OTC medication for the acid reflux group.

Table 8.2, the probability of receiving each drug, before and after the availability of Prilosec OTC, is shown. Table 8.3 depicts the probability of each prescription, before and after Prilosec OTC, but broken down by reimbursement type. Both of these tables are for the entire insured NAMCS sample. Tables 8.4 and 8.5 repeat these analyses, but for the insured acid reflux population.

Table 8.2 indicates that there is a decreased likelihood of acid reflux prescriptions in general, after the availability of Prilosec OTC. This table also shows a decreased likelihood of Zantac being prescribed in the post OTC period. This is expected, since once Prilosec is on the OTC market, it competes more directly with Zantac and may take some of its market share. Table 8.4 also shows that there is a decrease in the likelihood of receiving any acid reflux prescription or Zantac after the Prilosec OTC period for the acid reflux group. This table also indicates that Prevacid is less likely to be prescribed after the availability of an OTC amongst those patients with an acid reflux related diagnosis.

Table 8.2
Probability of Receiving Acid Reflux Prescription Medication
Before and After Prilosec OTC Event - Total Insured NAMCS Sample

	Pre-Prilosec OTC	Post-Prilosec OTC	Difference
GastroRx	1.84%	1.83%	-0.01%
Nexium	0.12%	0.67%	0.55%
Prevacid	0.64%	0.66%	0.02%
Protonix	0.09%	0.53%	0.44%
Zantac	0.65%	0.30%	-0.35%

Table 8.3
Probability of Receiving Acid Reflux Prescription Medication Before and After Prilosec OTC Event, ByCapitation Status - Total Insured NAMCS Sample

	A	B	C	D	
	Pre-Prilosec OTC FFS	Post-Prilosec OTC FFS	Pre-Prilosec OTC Capitated	Post-Prilosec OTC Capitated	Difference in Difference (D-C)-(B-A)
GastroRx	1.83%	1.78%	1.88%	1.86%	0.03%
Nexium	0.08%	0.63%	0.27%	0.69%	-0.13%
Prevacid	0.63%	0.68%	0.69%	0.65%	-0.09%
Protonix	0.05%	0.50%	0.22%	0.55%	-0.12%
Zantac	0.65%	0.33%	0.66%	0.27%	-0.07%

Note: In both of the above tables, sample consists of all insured patients in NAMCS 1997-2000, 2003-2004.

Table 8.4

Probability of Receiving Acid Reflux Prescription Medication Before and After Prilosec OTC Event - Insured Acid Reflux Sample

	Pre-Prilosec OTC	Post-Prilosec OTC	Difference
GastroRx	17.70%	14.29%	-3.41%
Nexium	1.17%	5.60%	4.43%
Prevacid	6.51%	5.41%	-1.10%
Protonix	0.87%	3.57%	2.70%
Zantac	5.45%	1.83%	-3.62%

Table 8.5

Probability of Receiving Acid Reflux Prescription Medication Before and After Prilosec OTC Event, By Capitation Status - Insured Acid Reflux Sample

	A	B	C	D	
	Pre-Prilosec OTC FFS	Post-Prilosec OTC FFS	Pre-Prilosec OTC Capitated	Post-Prilosec OTC Capitated	Difference in Difference (D-C)-(B-A)
GastroRx	17.60%	15.67%	18.10%	13.21%	-2.96%
Nexium	0.81%	5.52%	2.57%	5.66%	-1.62%
Prevacid	6.37%	6.18%	7.04%	4.80%	-2.05%
Protonix	0.64%	4.19%	1.79%	3.09%	-2.25%
Zantac	5.21%	1.77%	6.37%	1.89%	-1.04%

Note: In both of the above tables, sample consists of all insured acid reflux patients in NAMCS 1997-2000, 2003-2004.

FFS physicians are expected to continue providing prescription medications to their patients to ensure repeat visits. Once Prilosec moves to the OTC market, it is expected that FFS physicians will be likely to move away from prescribing this drug, and will instead provide more Nexium, Prevacid, or Protonix. In the entire insured sample, the tabulations in Table 8.3 show an increased probability that FFS physicians will provide each of the brand name prescriptions, except Zantac. FFS physicians are likely to provide less Zantac in the post OTC period, as expected, since Prilosec OTC may be used as a substitute.

Amongst the acid reflux sample, as shown in Table 8.5, FFS physicians are more likely to provide Nexium and Protonix to patients in the post OTC period. The table shows that the use of Prevacid decreases after the availability of an OTC, as does the use of Zantac and acid reflux prescriptions in general.

Capitated physicians, before the availability of a Prilosec OTC are expected to provide the least costly form of treatment. Amongst the drugs analyzed here, it is expected that in the before Prilosec OTC period, these physicians will be more likely to provide patients with Zantac since this is an OTC drug already, and is likely to be the least expensive.

Once Prilosec moves to the OTC market, it is also expected that the capitated physician will be even less likely to provide Nexium, Prevacid, or Protonix. Also, these physicians are likely to decrease their use of Zantac, since they can now substitute with Prilosec OTC.

Tables 8.3 and 8.5 above show that under capitation, there is a decreased likelihood of acid reflux prescriptions, in general, after the availability of Prilosec OTC for both groups. Capitated physicians are likely to increase their use of Nexium and Protonix in the after OTC period, while they are likely to decrease their use of Prevacid and Zantac.

The difference in difference columns in Tables 8.3 and 8.5 allow for the comparison of capitation before and after Prilosec OTC with FFS before and after Prilosec OTC. If there are no differences in their reaction to the availability of an OTC, the change between the two groups should be zero. The table shows that the difference is not zero, indicating that the two groups are reacting to the availability of an OTC differently.

Table 8.6 provides the prescription drug regression results for the entire insured NAMCS population. The first three independent variables will be the focus in the analysis of the regression results.

The results show that before the availability of an OTC, for the entire insured population, capitated physicians are more likely than FFS to provide Zantac, as expected since this the least costly form of treatment amongst these medications. Capitated physicians, however, are also more likely than FFS to provide Nexium and Protonix than FFS before the availability of Prilosec OTC. This was unexpected since Protonix is the youngest of the PPI medications, and is likely to be the most expensive.

After the availability of an OTC, it was expected that FFS physicians would be more likely to use any of the other prescription medications, since they should transition patients from Prilosec to one of the other prescription-only products. The results show that FFS physicians in the after Prilosec OTC period are less likely to provide prescriptions in general and less likely to provide Prevacid. These physicians, however, are more likely to provide Nexium and Protonix than before Prilosec OTC. Because of the decreased likelihood in overall prescription use, after OTC availability, the results indicate that some physicians are shifting their patients to other, prescription only drugs, while others are perhaps utilizing Prilosec OTC.

Table 8.6

Acid Reflux OLS Regression Results for Entire Insured Sample NAMCS 1997 – 2004

(Note - Regressions exclude years 2001 and 2002)

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5
	Gastro RX	Nexium	Prevacid	Protonix	Zantac
Capitated Visit	0.001 [0.001]	0.001* [0.000]	0 [0.001]	0.001** [0.000]	0.002*** [0.001]
GastroOTC	-0.006*** [0.002]	0.001* [0.001]	-0.002** [0.001]	0.002*** [0.001]	0.001 [0.001]
Capitated Visit * GastroOTC	0.001 [0.002]	0 [0.001]	0 [0.001]	0 [0.001]	-0.002* [0.001]
Private Insurance	-0.003** [0.001]	0 [0.000]	-0.001* [0.001]	0 [0.000]	-0.002** [0.001]
Medicare	-0.001 [0.002]	0 [0.001]	-0.001 [0.001]	0 [0.001]	-0.001 [0.001]
Female	-0.001 [0.001]	-0.001** [0.000]	0 [0.000]	0 [0.000]	-0.001 [0.000]
White	0.002 [0.005]	-0.001 [0.002]	0.002 [0.003]	0.001 [0.002]	0.004 [0.003]
Black	0.002 [0.005]	-0.001 [0.002]	0.002 [0.003]	0 [0.002]	0.005* [0.003]
Asian	0.008 [0.006]	0 [0.002]	0.005 [0.003]	0.001 [0.002]	0.006* [0.003]
Hispanic	0.002 [0.002]	0 [0.001]	0.001 [0.001]	0.001*** [0.000]	0 [0.001]
Age	0.001*** [0.000]	0.000*** [0.000]	0.000*** [0.000]	0.000*** [0.000]	0.000*** [0.000]
Age^2	-0.000*** [0.000]	-0.000** [0.000]	-0.000*** [0.000]	0 [0.000]	0 [0.000]
Acute	0.006*** [0.001]	0.001 [0.000]	0.003*** [0.001]	0 [0.000]	0.001** [0.001]
Chronic Routine	0.008*** [0.001]	0.001** [0.000]	0.003*** [0.001]	0.001 [0.000]	0.002** [0.001]

Table 8.6 (Continued)

Chronic Flare-up	0.010*** [0.002]	0.001 [0.001]	0.005*** [0.001]	0 [0.000]	0.002** [0.001]
Pre/Post Surgery	-0.005*** [0.002]	0 [0.001]	-0.001 [0.001]	-0.001 [0.000]	-0.002** [0.001]
Northeast	0.003** [0.001]	0.001 [0.000]	0.001 [0.001]	0 [0.000]	0 [0.001]
Midwest	0.003** [0.001]	0 [0.000]	0.002*** [0.001]	0 [0.000]	0.001 [0.001]
South	0.005*** [0.001]	0.002*** [0.000]	0.001** [0.001]	0 [0.000]	0.001** [0.001]
New Patient	-0.006*** [0.001]	-0.001*** [0.000]	-0.001** [0.001]	0 [0.000]	-0.002*** [0.001]
Physician Owner	0 [0.002]	0 [0.001]	0.001 [0.001]	0 [0.001]	-0.003*** [0.001]
Physician is Employee	0.004** [0.002]	0 [0.001]	0.003*** [0.001]	0 [0.001]	-0.001 [0.001]
MSA	-0.003*** [0.001]	-0.001** [0.000]	0 [0.001]	0 [0.000]	0.001** [0.001]
Time Trend	0.001*** [0.000]	0.001*** [0.000]	0.001*** [0.000]	0.001*** [0.000]	-0.001*** [0.000]
Observations	121363	121363	121363	121363	121363
R-squared	0.01	0	0	0	0

After the availability of an OTC, capitated physicians are less likely than FFS to provide Zantac to their patients. This was as expected, since capitated physicians can now choose the lowest cost of treatment with either Zantac or Prilosec, as both OTCs are usually not covered under most drug policies.

The probit and marginal effects estimations for this sample are found in Tables A.7. and A.9., respectively. According to the marginal effects, capitated physicians are 0.2% more likely to provide Zantac to their patients than FFS in the pre-OTC period. After the availability of Prilosec OTC, FFS physicians are 0.4% less likely to provide prescriptions and 0.2% less likely to prescribe Prevacid. Also, capitated physicians are 0.2% less likely to provide Zantac in the post-OTC period.

In other results, private insurance patients are less likely to get acid reflux prescriptions than Medicaid. Patients with private insurance are also less likely to receive Prevacid or Zantac. Females are less likely to get Nexium, while black and Asian patients are more likely to get Zantac than Native Americans. Acute patients are more likely to get acid reflux prescriptions, Prevacid, and Zantac as compared to preventive care patients. Chronic routine patients are more likely that preventive care to receive all drugs except Protonix. Chronic flare-up patients are more likely to receive acid reflux prescriptions as a whole. They are also more likely get Prevacid and Zantac.

Table 8.7 provides the results of the prescription drug regressions for the acid reflux diagnosis group. These results show that before the availability of an OTC, for the entire insured population, capitated physicians are more likely than FFS to provide Zantac. Again, this is as expected since this the least costly form of treatment amongst these medications.

The Gastro Rx regression results in both tables 8.6 and 8.7 show no evidence that capitated physicians are less likely to provide prescription drugs overall after the availability of an OTC. This is not as predicted from the theory proposed earlier. However, since these physicians are more likely to utilize Zantac, they are already more likely to provide an OTC product to their patients, and therefore the availability of Prilosec OTC is not expected to change their behavior in regards to other prescription drugs. Instead Prilosec provides more competition to Zantac, and capitated physicians should be found choosing between these two.

None of the results for the after OTC period are significant for FFS or capitated physicians. It is hypothesized that for those already diagnosed with acid reflux, physicians may not be as motivated by profit with patients in this class because

the illness and complications associated with acid reflux and GERD can be more serious.

Table 8.7

Acid Reflux OLS Regression Results for Insured Acid Reflux Sample NAMCS 1997 – 2004

(Note – Regressions exclude years 2001 and 2002)

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5
	Gastro RX	Nexium	Prevacid	Protonix	Zantac
Capitated Visit	0.004 [0.015]	0.005 [0.006]	0.001 [0.010]	0.001 [0.005]	0.018** [0.009]
GastroOTC	-0.034 [0.023]	0.007 [0.009]	-0.013 [0.015]	0.008 [0.007]	-0.019 [0.013]
Capitated Visit * GastroOTC	-0.032 [0.028]	-0.003 [0.010]	-0.016 [0.018]	-0.012 [0.009]	-0.018 [0.016]
Private Insurance	0 [0.017]	-0.003 [0.006]	-0.003 [0.011]	-0.004 [0.005]	-0.007 [0.010]
Medicare	-0.007 [0.021]	-0.004 [0.008]	-0.009 [0.014]	-0.007 [0.007]	0.007 [0.012]
Female	-0.024** [0.010]	-0.005 [0.004]	-0.004 [0.007]	0.002 [0.003]	-0.002 [0.006]
White	0.032 [0.066]	0.004 [0.025]	0.032 [0.043]	0.026 [0.021]	0.035 [0.038]
Black	0.021 [0.068]	0.004 [0.025]	0.031 [0.044]	0.025 [0.021]	0.04 [0.039]
Asian	0.078 [0.070]	-0.003 [0.026]	0.058 [0.046]	0.022 [0.022]	0.062 [0.040]
Hispanic	-0.006 [0.019]	0.005 [0.007]	-0.009 [0.013]	0.009 [0.006]	-0.008 [0.011]
Age	0.007*** [0.001]	0.001*** [0.000]	0.003*** [0.001]	0.001** [0.000]	0.001 [0.000]
Age^2	-0.000*** [0.000]	-0.000* [0.000]	-0.000*** [0.000]	0 [0.000]	-0.000* [0.000]
Acute	-0.002 [0.020]	0.001 [0.007]	-0.004 [0.013]	0.006 [0.006]	-0.036*** [0.011]

Table 8.7 (Continued)

Chronic Routine	0.060***	0.005	0.017	0.012*	-0.022*
	[0.020]	[0.008]	[0.013]	[0.006]	[0.012]
Chronic Flare-up	0.039*	0.01	0.017	0.003	-0.031**
	[0.023]	[0.009]	[0.015]	[0.007]	[0.013]
Pre/Post Surgery	-0.025	0.004	-0.032	0.004	-0.043**
	[0.032]	[0.012]	[0.021]	[0.010]	[0.018]
Northeast	0.031*	0.005	-0.003	0.006	0.009
	[0.017]	[0.006]	[0.011]	[0.005]	[0.010]
Midwest	0.008	-0.004	0.002	-0.004	0.004
	[0.016]	[0.006]	[0.010]	[0.005]	[0.009]
South	0.035**	0.014**	-0.008	0.002	0.007
	[0.014]	[0.005]	[0.009]	[0.005]	[0.008]
New Patient	-0.054***	-0.013**	-0.001	-0.004	-0.023***
	[0.014]	[0.005]	[0.009]	[0.004]	[0.008]
Physician Owner	-0.036	-0.005	0.026	-0.006	-0.036**
	[0.025]	[0.009]	[0.017]	[0.008]	[0.015]
Physician is Employee	-0.022	-0.009	0.027	-0.003	-0.031**
	[0.027]	[0.010]	[0.018]	[0.008]	[0.015]
MSA	-0.011	-0.001	-0.007	0.001	0.012
	[0.013]	[0.005]	[0.009]	[0.004]	[0.008]
Time Trend	0.004	0.009***	0.003	0.006***	-0.003*
	[0.003]	[0.001]	[0.002]	[0.001]	[0.002]
Observations	5386	5386	5386	5386	5386
R-squared	0.03	0.04	0.01	0.02	0.01

Acid reflux/GERD, as described earlier, can lead to more serious problems such as ulcers and even cancer. Hence, it is expected that physicians will be more cautious with the acid reflux/GERD patients, and will in fact prefer to monitor them closely. Physicians may choose to maintain the treatments that have been successful for their patients rather than move them to other medications that may not work as well for them, simply for profit reasons.

The results from the probit and marginal effects estimations for the acid reflux sample are found in Tables A.8. and A.10. These tables show that capitated physicians are 1.4% more likely to provide Zantac to their patients than FFS in the pre-OTC period. After the availability of an OTC, FFS physicians are 2.5% less likely to provide Zantac.

In the acid reflux sample, the results show that females are less likely to get a prescription. Acute patients are found to be less likely to get Zantac than preventive care, as are chronic routine and chronic flare-up. Chronic routine patients are more likely to get prescriptions in general and are more likely to get Protonix. Chronic flare-up patients are more likely to get acid reflux prescriptions than preventive care.

Severity Results

It is expected that after the availability of an OTC, the overall case-mix of patients seen in physician offices will be of higher severity. The measures used to examine severity include: seeing a specialist physician; and the nature of the condition (acute, chronic routine, and chronic flare-up). It is assumed that if conditions become more severe in the patient population seen in physician offices after the availability of an OTC, there may be a greater use of specialists. This is because these physicians may be more equipped to handle complicated cases than primary care.

Acute patients are defined here as having the least severe conditions, since their symptoms have only been present for a short time period (i.e. less than three months). Chronic routine patients have had symptoms for a longer time and have most likely used more resources in their diagnosis and treatment. These patients are therefore considered to be more severe. Chronic flare-up patients, while they may have severe conditions, they are expected to act similarly to acute patients since their symptoms could also be temporary.

Time spent with the physician/specialist as well as total number of diagnostic tests is also examined. These two variables are not used as measures for severity, but rather to provide insight into the changes in physician offices, if any, after the availability of an OTC. The severity of patient case-mix is expected to change only for the acid reflux diagnosis sample, since the drug moving to the OTC market is relevant to this group only.

Table 8.8

Probability of Patient Type/Severity Indicators Before and After Prilosec OTC Event - Insured Acid Reflux Sample

Note: Sample consists of all patients in NAMCS 1997-2000, 2003-2004, limited to those with insurance and those with an acid reflux indication

	Pre-Prilosec OTC	Post-Prilosec OTC	Difference
Gastro Specialist Seen	9.84%	9.56%	-0.2800%
Acute	45.22	44.69	-0.53
Chronic Routine	30.21	30.98	0.77
Chronic Flare-up	13.22	12.26	-0.96
Time Spent with Physician	20.75	19.55	-1.20
Total Number of Diag.Tests	1.05	0.99	-0.05
Time Spent with Gastro Specialist	26.38	16.21	-10.16
Total Number of Diag.Tests Gastro Specialist	0.82	0.51	-0.31

Table 8.8, used to frame the expectations for severity results, indicates that there is a decreased likelihood of specialist visits after the availability of Prilosec OTC. Both Acute and Chronic Flare-up patients are less likely to be seen in physician offices after the availability of Prilosec OTC, which is in line with the expectation that these patients will self-treat. Chronic routine patients have an increased likelihood of an office visit in the post OTC period according to the table above. Time spent and total number of diagnostic tests decrease amongst all physicians as well as amongst specialists, after the availability of an OTC. Table 8.9 provides the results for the variables used in the patient severity regressions. Only the acid reflux class of patients is used since a change in severity is only expected amongst patients with a diagnosis relevant to the class in which an OTC has become available.

Table 8.9

Acid Reflux SeverityRegression Results for Insured Acid Reflux Sample NAMCS 1997 – 2004

(Note - Regressions exclude years 2001 and 2002)

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5	6	7
	Gastro-intestinal Specialist	Acute	Chronic Routine	Chronic Flare-up	Acute Specialist Physician	Chronic Routine Specialist Physician	Chronic Flareup Specialist Physician
GastroOTC	0.041*** [0.014]	-0.039* [0.023]	0.021 [0.021]	0.009 [0.016]	-0.066 [0.070]	-0.027 [0.079]	0.003 [0.068]
Private Insurance	-0.015 [0.014]	0.046** [0.023]	-0.069*** [0.021]	0.004 [0.016]	0.05 [0.064]	-0.138* [0.072]	0.094 [0.062]
Medicare	-0.012 [0.017]	0.028 [0.028]	-0.077*** [0.026]	0.041** [0.019]	0.099 [0.075]	-0.132 [0.084]	0.06 [0.072]
Capitated Visit	0.002 [0.010]	0.051*** [0.017]	-0.017 [0.015]	-0.029** [0.012]	0.002 [0.050]	0.059 [0.055]	-0.076 [0.048]
Female	0.006 [0.008]	0.024* [0.013]	-0.021* [0.012]	0 [0.009]	0.038 [0.037]	0.014 [0.042]	-0.038 [0.036]
White	-0.018 [0.052]	-0.237*** [0.086]	0.197** [0.080]	-0.011 [0.060]	-0.400* [0.242]	0.552** [0.271]	-0.233 [0.233]
Black	-0.071 [0.053]	-0.214** [0.089]	0.170** [0.082]	0.002 [0.061]	-0.349 [0.255]	0.480* [0.285]	-0.197 [0.244]

Table 8.9 (Continued)

Asian	0.037 [0.055]	-0.134 [0.091]	0.129 [0.085]	-0.027 [0.063]	-0.145 [0.254]	0.223 [0.283]	-0.334 [0.243]
Hispanic	0.011 [0.015]	0.052** [0.025]	-0.026 [0.023]	0.006 [0.017]	-0.149** [0.071]	0.06 [0.079]	0.052 [0.068]
Age	0.002** [0.001]	-0.009*** [0.001]	0.007*** [0.001]	0.003*** [0.001]	0.001 [0.004]	-0.012** [0.005]	0.007 [0.004]
Age^2	0 [0.000]	0.000*** [0.000]	-0.000*** [0.000]	-0.000*** [0.000]	0 [0.000]	0.000** [0.000]	0 [0.000]
Acute	-0.001 [0.015]						
Chronic Routine	0.082*** [0.016]						
Chronic Flare-up	0.087*** [0.018]						
Pre/Post Surgery	0.056** [0.025]						
Northeast	-0.009 [0.013]	0.011 [0.022]	-0.031 [0.020]	0.026* [0.015]	0.106 [0.069]	-0.099 [0.077]	0.012 [0.066]
Midwest	-0.023* [0.012]	0.035* [0.021]	-0.085*** [0.019]	0.039*** [0.014]	0.205*** [0.070]	-0.258*** [0.079]	0.005 [0.068]
South	0.053*** [0.011]	0.034* [0.019]	-0.056*** [0.017]	0.025* [0.013]	0.235*** [0.055]	-0.353*** [0.061]	0.064 [0.052]
New Patient	0.077*** [0.011]	0.153*** [0.018]	-0.115*** [0.016]	-0.027** [0.012]	0.303*** [0.042]	-0.202*** [0.047]	-0.023 [0.040]

Table 8.9 (Continued)

Physician Owner	0.022	0.014	-0.02	-0.02	0.175*	-0.388***	0.123
	[0.020]	[0.033]	[0.031]	[0.023]	[0.102]	[0.114]	[0.098]
Physician is Employee	0.043**	0.038	-0.04	-0.028	0.272**	-0.532***	0.189*
	[0.021]	[0.035]	[0.032]	[0.024]	[0.107]	[0.120]	[0.103]
MSA	0.009	-0.037**	0.040**	0.006	-0.011	-0.03	0.058
	[0.011]	[0.017]	[0.016]	[0.012]	[0.052]	[0.058]	[0.050]
Time Trend	-0.010***	0.001	0.001	-0.002	0.009	0.004	0.001
	[0.002]	[0.004]	[0.003]	[0.003]	[0.011]	[0.012]	[0.010]
Observations	5386	5386	5386	5386	527	527	527
R-squared	0.05	0.06	0.05	0.01	0.18	0.17	0.04

The main variable of interest from these equations is gastro OTC. This variable is an indicator for when Prilosec moves to the OTC market. The above results show that there is an increased likelihood, after the availability of an OTC, for acid reflux patients to see a specialist physician. There is also a decreased likelihood of acute patients making a physician office visit. This is consistent with the earlier hypothesis that these less severe patients may try to self-treat. Also, from the probit and marginal effects tables (A.11. and A.12.) it can be seen that acute patients are 0.41% less likely to visit a physician's office in the post-OTC period.

In other results, private insurance patients are more likely to be acute patients than Medicaid and less likely to be chronic routine. Medicare patients are also less likely to be chronic routine than Medicaid, but are more likely to be chronic flare-up. Under capitation, patients are more likely to be acute and less likely to be chronic flare-up.

Table 8.10 provides the results of the regressions examining time spent with the physician and the total number of diagnostic tests ordered. Again, because the effect of OTC is only expected on the acid reflux diagnosis, only this group is being studied.

The results show that time spent with the physician decreases after the availability of Prilosec OTC. The decrease in time spent after Prilosec OTC is especially strong amongst specialist physicians. Specialists are also found to be less likely to use diagnostic tests after Prilosec OTC. Under capitation, there is less time spent with the physician than under FFS. This is true for both physicians in general, as well as specialists. Both private insurance and Medicare patients are more likely to spend time with the specialist than Medicaid.

Table 8.10

Time Spent and Diagnostic Tests Regressions NAMCS 1997 – 2004

Acid Reflux Sample

Note – 2001 and 2002 are excluded from these regressions.

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4
	Time Spent with Physician	Total Number of Diag. Tests	Time Spent with Specialist Physician	Total Number of Diag. Tests Specialist Physician
GastroOTC	-1.459**	-0.009	-15.222***	-0.249**
	[0.572]	[0.045]	[2.115]	[0.107]
Private Insurance	0.714	0.005	3.771*	-0.078
	[0.574]	[0.045]	[1.937]	[0.098]
Medicare	0.722	0.024	4.567**	-0.004
	[0.700]	[0.055]	[2.249]	[0.114]
Capitated Visit	-0.818*	0.044	-2.565*	0.036
	[0.421]	[0.033]	[1.488]	[0.076]
Female	-0.045	-0.026	-1.315	0.066
	[0.339]	[0.027]	[1.124]	[0.057]
White	0.346	-0.065	-32.360***	-0.226
	[2.183]	[0.172]	[7.297]	[0.371]
Black	-0.181	0.077	-33.745***	-0.025
	[2.244]	[0.177]	[7.656]	[0.389]
Asian	-2.279	-0.109	-35.801***	-0.012
	[2.315]	[0.182]	[7.623]	[0.387]
Hispanic	-1.242*	0.057	4.565**	-0.138
	[0.635]	[0.050]	[2.126]	[0.108]
Age	0.153***	0.037***	0.378***	0.021***
	[0.027]	[0.002]	[0.132]	[0.007]
Age^2	-0.001***	-0.000***	-0.003***	-0.000**
	[0.000]	[0.000]	[0.001]	[0.000]
Acute	-3.919***	-0.578***	0.697	-0.202
	[0.644]	[0.051]	[2.864]	[0.146]
Chronic Routine	-3.119***	-0.728***	0.067	-0.406***
	[0.671]	[0.053]	[2.791]	[0.142]
Chronic Flare-up	-3.109***	-0.688***	-2.786	-0.353**
	[0.755]	[0.059]	[2.907]	[0.148]

Table 8.10 (Continued)

Pre/Post Surgery	-5.620*** [1.066]	-1.077*** [0.084]	-3.987 [3.780]	-0.492** [0.192]
Northeast	0.995* [0.553]	0.094** [0.044]	-4.672** [2.068]	0.487*** [0.105]
Midwest	-2.917*** [0.526]	0.023 [0.041]	-11.719*** [2.143]	0.154 [0.109]
South	-1.367*** [0.476]	0.01 [0.038]	-9.053*** [1.695]	0.436*** [0.086]
New Patient	9.449*** [0.450]	0.007 [0.035]	12.215*** [1.328]	-0.008 [0.067]
Physician Owner	-1.803** [0.837]	0.065 [0.066]	-0.498 [3.083]	0.096 [0.157]
Physician is Employee	-1.14 [0.885]	0.086 [0.070]	1.982 [3.281]	0.026 [0.167]
MSA	0.387 [0.444]	0.055 [0.035]	-1.107 [1.570]	0.157** [0.080]
Time Trend	0.149 [0.092]	-0.009 [0.007]	2.008*** [0.325]	-0.019 [0.017]
Observations	5383	5386	527	527
R-squared	0.11	0.12	0.37	0.19

Amongst gastrointestinal specialists, the results show strong differences in time spent with the physician between races. White, black, and Asian patients are all likely to spend less time with the specialist than Native Americans, while Hispanics are likely to spend more time. According to Stancioiu (2005), as well as other researchers, H – pylori infections, associated with ulcers and cancer, are highly prevalent in both Native American and Hispanic communities. Thus, there is likely to be an increased amount of time spent with the specialist physician for these two groups.

Acid Reflux Market Discussion

With the switch in prescription status of Prilosec, the acid reflux/GERD market saw the gradual phasing out of one drug, with the replacement of a newer one. Years before Prilosec was to lose patent protection, Astra-Zeneca began to transition patients off of the older drug and over to Nexium, the "new purple pill" in order to maintain

the market share it had with Prilosec. Prevacid, Protonix, and Nexium all begin to take over market share from Prilosec as it gets closer to the OTC switch. Surprisingly, Zantac, the oldest of these drugs and an OTC, maintains a steady market share throughout the years.

The analysis found that capitated physicians are more likely than FFS to use Zantac and this is consistent with the hypothesis that these physicians utilize the lowest cost treatment. Not all of the changes in prescribing behavior that were expected after Prilosec moved to the OTC market, however, were found. As mentioned earlier, this may be due to the serious complications that can potentially occur in patients with acid reflux related illnesses. Physicians may choose to provide prescription drugs for the purpose of being able to monitor patients and prevent any serious complications that can occur when the illness is untreated. There is an overall decrease in the use of prescriptions for the total insured sample, indicating that some physicians are just shifting patients from Prilosec to one of the other medications, while others increase their usage of Prilosec after it is OTC. Amongst capitated physicians, strong changes may not have been seen because they were already utilizing the OTC drug Zantac. Therefore, the effect of Prilosec's change in regulatory status was not as much on other prescription medications, as it was on Zantac.

When examining severity the results indicate that there is a decrease in physician office visits from acute patients, who are less severe, as was expected. This result indicates that these patients perhaps choose to self treat, rather than make a physician office visit. It was also found that there is an increased likelihood of specialist visits after Prilosec OTC, which supports the hypothesis of an increase in the severity of patient case mix after the availability of an OTC.

CHAPTER 9

CONCLUSIONS

The goal of this study was to examine the reaction of physicians as well as patients to the availability of an OTC medication that is chemically equivalent to its prescription-only counterparts. Amongst physicians, the differences in prescribing decisions between fee-for-service and capitated were studied. These physicians were then compared by reimbursement type before and after the availability of an OTC. Patient reactions were also examined by analyzing the change in case mix of patients seen in physician offices after the availability of an OTC.

The main findings from this study were:

- Capitated physicians choose the least costly form of treatment and shift the responsibility of costs towards patients.
- FFS physicians cost shift away from patients by providing treatments that are covered by third party payers.
- There is an increased use of specialists after the availability of an OTC, indicating a higher severity of the patient case-mix.
- Patients with less severe conditions make fewer physician office visits after the availability of an OTC, causing the overall patient case-mix in offices to become more severe.
- There is a decreased use of prescriptions overall after the availability of an OTC, indicating brand loyalty as patients follow drugs to OTC market.

The results show some evidence of physicians under capitated plans cost shifting towards the patient, and away from the insurance company and/or themselves. Capitated physicians are found to utilize the least costly form of treatment before the availability of these new OTCs, and then shift away from those treatments after the

new OTCs are available, as these become the least costly form of care. In the acid reflux class, these physicians are significantly more likely than FFS to provide Zantac, an OTC and the least costly form of treatment, to their patients. By providing Zantac, the physician puts the responsibility of payment solely on the patient, in most cases, thereby reducing costs for the insurance company.

In the allergy market, capitated physicians are found to be significantly more likely to provide allergy shots to their patients before the availability of an OTC, as these are the least costly form of treatment. Once an OTC becomes available, capitated physicians decrease their usage of allergy shots, perhaps because the OTCs are of even lower cost. As mentioned earlier, FFS physicians significantly increase their use of allergy shots after Claritin moves to the OTC market, perhaps because of an increase in severity. This may also have been the result of FFS physicians attempting to cost shift away from patients. By providing allergy shots, these physicians save their patients the total out-of-pocket costs associated with OTCs, since shots are still covered under most health plans.

There is also some evidence of patients with less severe conditions decreasing physician office visits after the availability of these new OTC drugs. This indicates that perhaps these patients are using the medications as a substitute to physician care. Amongst the acid reflux group, those patients with acute conditions have a statistically significant decrease in the likelihood of making a physician office visit after Prilosec moves to the OTC market. In the allergy group there is a significant decrease in the likelihood of seeing chronic flare-up patients in physician offices. There is also evidence of an increase in the use of specialist physicians after the availability of an OTC. In both the allergy as well as the acid reflux group there was a significant increase in the use of specialist physicians. Both sets of these results indicate that the overall severity of the patient case mix seen in physician offices, after the availability

of an OTC, is higher. In addition, amongst the allergy group, FFS physicians are found to be more likely to provide allergy shots after the availability of an OTC, also indicating that severity may have increased.

Finally, in both the allergy and acid reflux groups, overall prescriptions for the class decrease after the availability of an OTC medication. This indicates that patients are brand loyal to medications in these groups and follow the drugs to the OTC market. That is, those patients on Claritin or Prilosec prefer to continue with these drugs, even though they are on the OTC market, rather than switch to another prescription-only medication.

Patient Case Mix

The theoretical model developed here shows that the patient case mix seen in physician offices should be more severe after the availability of OTC medications, since those patients with milder conditions can self-treat. Empirically, changes in severity are measured by examining the use of specialist physicians; and the nature of the patient's illness, based on the length of time the patient has had symptoms. It was hypothesized that if the patient case mix worsens, more patients will be seen by specialists since these physicians are better equipped to manage more severe patients.

Acute patients were defined as those having symptoms for less than three months. Both chronic routine and chronic flare-up patients are considered to have more severe symptoms than acute because their illnesses are long term and require more time and medication for treatment. Once an OTC becomes available, it was expected that acute patients will self treat and will no longer need to see the physician. This would drive up the severity of the patient case mix in physician offices. Chronic flare-up patients are also less likely to make physician office visits after the availability of an OTC because they may recognize that their symptoms are temporary.

These patients may, therefore, choose the OTC treatment rather than make an office visit.

As mentioned earlier, there was some evidence of an increase in patient severity seen in physician offices from both the allergy and acid reflux analyses. In both result sections, there was an increased use of specialist physicians. Acute patients were less likely to make physician office visits when Prilosec moved to the OTC market. In addition, chronic flare-up patients were less likely to make an office visit after the OTC switch of Claritin.

Capitation vs. FFS

The theoretical model developed here also provides the differences in financial incentives faced by fee-for-service physicians versus those under capitation. Under this model it can be seen that fee-for-service physicians have the most to gain with the repeated visits of patients. As the number of visits increases, so does the FFS physician's profits since they are not financially liable for any costs. These physicians are most easily able to induce these visits by providing prescription drugs to their patients. That is, when a prescription-only drug moves to the OTC market, the model suggests that FFS physicians that formerly provided that drug will instead switch to another competitor medication that remains on the prescription-only market. These physicians choose prescription drugs because patients must return to the office for refills and physicians can further increase the number of return visits by asking patients to come back for monitoring reasons.

The capitated physician, on the other hand, sees a decrease in profits with an increased number of office visits. These physicians become financially responsible for the care of patients because of the prepaid method insurance companies utilize. Therefore, as the capitated physician sees patients more, a greater amount is deducted from the prepaid amount, decreasing profits. In order to minimize costs, it was

expected that capitated physicians will utilize the least costly form of care and limit the number of repeat visits. When a drug becomes available in the OTC market, it was hypothesized that capitated physicians could decrease patient office visits by providing this drug instead of prescription-only ones. By advising patients to take an OTC medication, the physician can reduce the number of repeat visits since these patients can self-treat in the future. These patients also do not have to come back for refills or monitoring since the FDA deems these medications as safe.

The major finding of this study shows that capitated physicians, amongst both drug classes, choose the least costly form of treatment. In the allergy market, when choosing between prescription drugs only and allergy shots, the capitated physician treats patients with allergy shots, as these are the more cost-effective option for the insurance company. Once Claritin moves the OTC market, the cost of antihistamines falls for insurance companies, as most no longer cover Claritin, and some drop coverage for all antihistamines. After the availability of OTC Claritin, capitated physicians decrease the use of allergy shots since they are no longer the most cost-effective. In the acid reflux class, as well, capitated physicians are found to be more likely than FFS physicians to choose Zantac, the lowest cost form of treatment before Prilosec OTC. By utilizing Zantac, capitated physicians are less likely to change their behavior in relation to prescription medications (Gastro Rx), since they are already using an OTC. Instead, these physicians may substitute Prilosec OTC for Zantac.

Overall, the results of this study indicate that physicians under a capitated system are acting as agents for the insurance companies to shift the cost of therapy from the third party payer to the patient. Even amongst FFS physicians, there is a decrease in the use of prescription drugs overall, after the availability of an OTC, leading to the conclusion that patients are brand loyal and follow the medications to

the OTC market, even though it may cost them more, as OTCs are generally not included in drug coverage plans.

Policy Implications

The empirical results from this study suggest that capitation is an effective tool for aligning physician incentives with those of the insurance company when dealing with illnesses that are not life threatening. In addition, the availability of an OTC may be an efficient mechanism to sort patients by severity. When an OTC is available, both acute and chronic flare-up patients are less likely to be seen in physician offices. Both of these types of patients have symptoms that are short term. While acute patients have had their symptoms for less than three months, chronic flare-up also consists of patients who are possibly having a temporary increase in severity. The availability of an OTC allows these patients to self treat. If the self treatment is successful, resources are saved including the time and cost of an office visit. If the OTC treatment is not successful, the patient can at least receive some level of temporary relief until he/she is able to see a physician. The downside of this, however, is that those patients that self treat, but actually should see a physician, may be delayed unnecessarily. Also, there is the chance that patients could incorrectly diagnose themselves and thereby attempt self treatment with the wrong type of medication. Finally, the availability of an OTC, because of more convenient access, increases the likelihood that patients will utilize these medications even when not necessary.

Limitations of This Study

Severity. While it was attempted to understand changes in severity for the entire sample of the data, it was not possible to directly measure it. Without more detailed information on symptoms, diagnoses, and patient histories, the changes in the

severity of patient case-mix, if any, cannot be gauged before and after the availability of an OTC medication.

Clinical Effects. The analyses for the two drug classes produce somewhat differing results. While some significant changes in physician behavior are found under the allergy class, the results are weaker with the acid reflux class. This difference could be the result of the differing characteristics of each category. That is, antihistamines and other allergy drugs are generally considered as medications in which the quality of a patient's life is improved, but the drug is not necessary for survival. With acid reflux, however, conditions can worsen in patients causing further complications such as ulcers and even cancer. For this reason, physicians may feel it necessary to maintain regular visits with acid reflux patients, so that they can continue to monitor the illness and prevent progression into something more serious.

Patient Drug Co-pays. By using the NAMCS, it is not possible to determine how much patients actually pay out-of-pocket for their medications, which may influence physician incentives. It is very likely that physicians make their medication choices based on what the patient requests or what is least expensive for the patient. Without knowing the cost each patient faces, this portion of physician incentives cannot be analyzed.

Extent of Capitation. While the NAMCS does ask physicians whether or not they accept capitated payments and whether or not that particular patient visit was from a capitated plan, it does not ask the extent to which the physician is capitated. Under capitation some physicians can face plans in which they are minimally financially responsible for their decisions while others are fully financially responsible for their therapy choices. There is a vast array of capitated contracts; however, using the NAMCS the degree to which each physician faces capitation cannot be determined.

Strength of Sample. The OTC switch of Claritin took place in December 2002, while Prilosec entered the OTC market in mid-2003. The NAMCS data includes the years 1997 – 2004. This allows only 2 years in the case of Claritin and 1 year in the case of Prilosec for analysis. Because of the short time period available after the switch of these drugs, the analyses may not be capturing the full effects from the move into the OTC market. While those patients that were already on Claritin and Prilosec most likely followed the drugs closely, other patients, new to these drug classes may not have been aware of the availability of these medications without physician approval. Therefore, changes in patient case-mix could perhaps be captured more accurately with later years of data.

Recommendations for Future Work

As the FDA allows more drugs to move from the prescription-only to the OTC market, further work can be carried on analyzing the effects of these switches and how they vary with the diagnosis class. For even the drugs analyzed here, long term studies can be carried out to determine the true impact of the availability of OTC drugs on costs and patient access.

Future research can also examine if patients are truly sorted by severity once an OTC is available, by utilizing data that captures the magnitude of the illness. Patient health outcomes with this sorting mechanism could also be examined, to determine if patients are better or worse off with access to more medications on the OTC market.

When examining physician prescribing behavior, a key factor for future work would be to incorporate the physician's exposure to detailing. In addition, more insight into the exact nature of physician reimbursement plans would be ideal since physicians are influenced by the incentives set up in these contracts.

Finally, more information on patient characteristics would be optimal. Such data would include factors such as the employment status of the patients, their exact health plans and drug coverage, and their education. Patient information is important because physicians are not only influenced by their own incentives, but also the preferences of their patients.

APPENDIX

TABLE A.1. ALLERGY PROBIT REGRESSION RESULTS – TOTAL INSURED

NAMCS SAMPLE 1997 – 2000; 2003 – 2004

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5
	Allergy RX	Allegra	Zyrtec	Clarinex	Allergy Shots
Capitated Visit	0.024 [0.030]	0.083* [0.050]	-0.099* [0.060]	-0.061 [0.059]	0.205*** [0.064]
AllergyOTC	-0.322*** [0.045]	-0.319*** [0.073]	0.115 [0.076]	N/A	0.637*** [0.097]
Capitated Visit * AllergyOTC	-0.061 [0.040]	-0.117* [0.062]	0.075 [0.069]	N/A	-0.505*** [0.081]
Private Insurance	0.134*** [0.029]	0.235*** [0.055]	0.071* [0.042]	0.105 [0.110]	0.295*** [0.069]
Medicare	0.002 [0.039]	0.158** [0.067]	-0.048 [0.061]	0.037 [0.142]	0.180** [0.087]
Female	0.071*** [0.016]	0.093*** [0.026]	0.106*** [0.026]	0.041 [0.059]	0.070** [0.034]
White	0.094 [0.119]	0.308 [0.237]	-0.093 [0.146]	-0.32 [0.254]	-0.168 [0.218]
Black	0.083 [0.121]	0.255 [0.241]	-0.147 [0.152]	-0.149 [0.265]	-0.269 [0.225]
Asian	0.143 [0.126]	0.444* [0.245]	-0.13 [0.165]	0.022 [0.280]	-0.091 [0.242]
Hispanic	-0.014 [0.031]	0.003 [0.049]	-0.074 [0.049]	-0.096 [0.115]	-0.001 [0.068]
Age	0.007*** [0.001]	0.027*** [0.002]	-0.013*** [0.002]	0.014*** [0.005]	0.009*** [0.003]
Age^2	-0.000*** [0.000]	-0.000*** [0.000]	0.000*** [0.000]	-0.000*** [0.000]	-0.000*** [0.000]
Acute	0.436*** [0.027]	0.352*** [0.044]	0.351*** [0.044]	0.319*** [0.110]	-0.702*** [0.079]
Chronic Routine	0.268*** [0.029]	0.165*** [0.046]	0.268*** [0.046]	0.229** [0.112]	0.380*** [0.045]

Table A.1. (Continued)

Chronic Flare-up	0.452***	0.307***	0.420***	0.356***	-0.250***
	[0.033]	[0.054]	[0.054]	[0.128]	[0.080]
Pre/Post Surgery	-0.239***	-0.184**	-0.211**	-0.462	N/A
	[0.050]	[0.076]	[0.088]	[0.294]	
Northeast	0.058**	-0.036	0.007	0.039	0.486***
	[0.026]	[0.041]	[0.042]	[0.095]	[0.077]
Midwest	0.092***	0.034	0.085**	0.033	0.836***
	[0.025]	[0.039]	[0.041]	[0.097]	[0.073]
South	0.189***	0.105***	0.166***	0.142*	0.641***
	[0.023]	[0.035]	[0.036]	[0.083]	[0.072]
New Patient	-0.109***	-0.065*	-0.022	-0.101	-0.967***
	[0.023]	[0.035]	[0.036]	[0.086]	[0.147]
Physician Owner	0.128***	0.125	0.066	0.443	0.303***
	[0.042]	[0.076]	[0.068]	[0.318]	[0.096]
Physician is Employee	0.186***	0.210***	0.069	0.449	0.062
	[0.044]	[0.078]	[0.071]	[0.323]	[0.104]
MSA	0.017	0.012	-0.014	0.231**	0.027
	[0.022]	[0.036]	[0.036]	[0.114]	[0.048]
Time Trend	0.071***	0.126***	0.045***	-0.005	-0.063***
	[0.008]	[0.014]	[0.014]	[0.058]	[0.018]
Observations	121363	121363	121363	41801	110621

TABLE A.2. ALLERGY PROBIT REGRESSION RESULTS – INSURED

ALLERGY SAMPLE NAMCS 1997 – 2000; 2003 – 2004

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5
	Allergy RX	Allegra	Zyrtec	Clarinex	Allergy Shots
Capitated Visit	0.023	0.151*	-0.083	-0.085	0.015
	[0.057]	[0.089]	[0.094]	[0.098]	[0.132]
AllergyOTC	-0.458***	-0.484***	0.181	N/A	0.709***
	[0.086]	[0.130]	[0.128]		[0.162]
Capitated Visit * AllergyOTC	-0.059	-0.201*	0.087	N/A	-0.423***
	[0.076]	[0.110]	[0.112]		[0.156]
Private Insurance	0.086	0.129	0.036	0.002	0.152
	[0.055]	[0.092]	[0.073]	[0.178]	[0.108]
Medicare	0.068	0.173	-0.074	-0.081	0.226
	[0.080]	[0.124]	[0.116]	[0.252]	[0.144]
Female	0.042	0.058	0.117***	0.016	0.048
	[0.031]	[0.047]	[0.045]	[0.098]	[0.057]
White	0.259	0.457	0.138	-0.614*	-0.294
	[0.225]	[0.427]	[0.278]	[0.361]	[0.324]
Black	0.304	0.506	0.018	-0.466	-0.529
	[0.230]	[0.432]	[0.287]	[0.385]	[0.338]
Asian	0.292	0.678	-0.064	-0.224	-0.175
	[0.237]	[0.439]	[0.303]	[0.405]	[0.366]
Hispanic	0.001	0.036	-0.101	-0.164	0.074
	[0.057]	[0.085]	[0.081]	[0.190]	[0.109]
Age	0.019***	0.043***	-0.010***	0.022***	0.024***
	[0.003]	[0.004]	[0.003]	[0.008]	[0.005]
Age^2	-0.000***	-0.000***	0	-0.000**	-0.000***
	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]
Acute	0.086	0.181*	-0.093	0.082	-1.783***
	[0.063]	[0.102]	[0.083]	[0.203]	[0.127]
Chronic Routine	0.055	0.137	-0.089	-0.064	-0.07
	[0.066]	[0.106]	[0.088]	[0.215]	[0.079]
Chronic Flare-up	0.201***	0.186	0.039	0.158	-1.168***
	[0.072]	[0.114]	[0.095]	[0.228]	[0.125]

Table A.2. (Continued)

Pre/Post Surgery	-0.494***	-0.324	-0.447**	-0.247	N/A
	[0.128]	[0.202]	[0.189]	[0.419]	
Northeast	0.032	-0.143*	-0.025	0.018	0.629***
	[0.050]	[0.076]	[0.072]	[0.168]	[0.119]
Midwest	0.071	-0.007	0.07	0.157	1.118***
	[0.049]	[0.072]	[0.069]	[0.160]	[0.112]
South	0.240***	0.120*	0.142**	0.19	0.879***
	[0.043]	[0.063]	[0.061]	[0.141]	[0.109]
New Patient	0.051	0.063	0.142**	0.063	-1.299***
	[0.042]	[0.061]	[0.059]	[0.134]	[0.191]
Physician Owner	0.099	0.103	-0.001	0.28	0.356**
	[0.078]	[0.135]	[0.112]	[0.438]	[0.180]
Physician is Employee	0.126	0.228	-0.045	0.33	0.057
	[0.082]	[0.140]	[0.119]	[0.447]	[0.191]
MSA	0.084*	0.042	0.03	0.072	0.051
	[0.044]	[0.066]	[0.063]	[0.164]	[0.082]
Time Trend	0.096***	0.184***	0.050**	0.136	-0.037
	[0.016]	[0.026]	[0.024]	[0.097]	[0.031]
Observations	9692	9692	9692	3467	9410

TABLE A.3. ALLERGY MARGINAL EFFECT REGRESSION RESULTS –

TOTAL INSURED NAMCS SAMPLE 1997 – 2000; 2003 – 2004

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5
	Allergy RX	Allegra	Zyrtec	Clarinex	Allergy Shots
Capitated Visit	0.001 [0.002]	0.001 [0.001]	-0.001* [0.001]	0 [0.000]	0.001*** [0.000]
AllergyOTC	-0.015*** [0.002]	-0.004*** [0.001]	0.002 [0.001]	N/A	0.004*** [0.001]
Capitated Visit * AllergyOTC	-0.003 [0.002]	-0.002** [0.001]	0.001 [0.001]	N/A	-0.001*** [0.000]
Private Insurance	0.006*** [0.001]	0.003*** [0.001]	0.001* [0.001]	0.001 [0.001]	0.001*** [0.000]
Medicare	0 [0.002]	0.003** [0.001]	-0.001 [0.001]	0 [0.001]	0.001* [0.000]
Female	0.004*** [0.001]	0.001*** [0.000]	0.002*** [0.000]	0 [0.000]	0.000** [0.000]
White	0.004 [0.005]	0.003* [0.002]	-0.002 [0.003]	-0.003 [0.004]	-0.001 [0.001]
Black	0.004 [0.007]	0.005 [0.006]	-0.002 [0.002]	-0.001 [0.001]	-0.001* [0.000]
Asian	0.008 [0.008]	0.011 [0.010]	-0.002 [0.002]	0 [0.002]	0 [0.001]
Hispanic	-0.001 [0.002]	0 [0.001]	-0.001 [0.001]	-0.001 [0.001]	0 [0.000]
Age	0.000*** [0.000]	0.000*** [0.000]	-0.000*** [0.000]	0.000*** [0.000]	0.000*** [0.000]
Age^2	-0.000*** [0.000]	-0.000*** [0.000]	0.000*** [0.000]	-0.000*** [0.000]	-0.000*** [0.000]
Acute	0.026*** [0.002]	0.006*** [0.001]	0.006*** [0.001]	0.003** [0.001]	-0.002*** [0.000]
Chronic Routine	0.015*** [0.002]	0.003*** [0.001]	0.005*** [0.001]	0.002* [0.001]	0.002*** [0.000]
Chronic Flare-up	0.033*** [0.003]	0.006*** [0.001]	0.010*** [0.002]	0.004* [0.002]	-0.001*** [0.000]

Table A.3. (Continued)

Pre/Post Surgery	-0.010*** [0.002]	-0.002*** [0.001]	-0.003*** [0.001]	-0.002*** [0.001]	N/A
Northeast	0.003** [0.001]	-0.001 [0.001]	0 [0.001]	0 [0.001]	0.003*** [0.001]
Midwest	0.005*** [0.001]	0.001 [0.001]	0.001** [0.001]	0 [0.001]	0.007*** [0.001]
South	0.010*** [0.001]	0.002*** [0.001]	0.003*** [0.001]	0.001 [0.001]	0.004*** [0.001]
New Patient	-0.005*** [0.001]	-0.001* [0.000]	0 [0.001]	-0.001 [0.001]	-0.002*** [0.000]
Physician Owner	0.006*** [0.002]	0.002* [0.001]	0.001 [0.001]	0.003* [0.001]	0.001*** [0.000]
Physician is Employee	0.010*** [0.003]	0.004** [0.002]	0.001 [0.001]	0.005 [0.005]	0 [0.000]
MSA	0.001 [0.001]	0 [0.001]	0 [0.001]	0.001*** [0.001]	0 [0.000]
Time Trend	0.004*** [0.000]	0.002*** [0.000]	0.001*** [0.000]	0 [0.000]	-0.000*** [0.000]
Observations	121363	121363	121363	41801	110621

TABLE A.4. ALLERGY MARGINAL EFFECT REGRESSION RESULTS –

INSURED ALLERGY SAMPLE NAMCS 1997 – 2000; 2003 – 2004

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5
	Allergy RX	Allegra	Zyrtec	Clarinex	Allergy Shots
Capitated Visit	0.006 [0.014]	0.013 [0.008]	-0.008 [0.009]	-0.004 [0.005]	0 [0.003]
AllergyOTC	-0.108*** [0.019]	-0.036*** [0.009]	0.019 [0.014]	N/A	0.019*** [0.007]
Capitated Visit * AllergyOTC	-0.015 [0.018]	-0.015** [0.007]	0.009 [0.012]	N/A	-0.006*** [0.002]
Private Insurance	0.021 [0.013]	0.01 [0.007]	0.004 [0.007]	0 [0.009]	0.003 [0.002]
Medicare	0.017 [0.021]	0.016 [0.012]	-0.007 [0.010]	-0.004 [0.011]	0.005 [0.004]
Female	0.011 [0.008]	0.005 [0.004]	0.011*** [0.004]	0.001 [0.005]	0.001 [0.001]
White	0.059 [0.046]	0.028 [0.019]	0.012 [0.023]	-0.047 [0.040]	-0.008 [0.011]
Black	0.085 [0.071]	0.059 [0.068]	0.002 [0.029]	-0.016* [0.008]	-0.006** [0.003]
Asian	0.083 [0.074]	0.094 [0.090]	-0.006 [0.027]	-0.009 [0.013]	-0.003 [0.005]
Hispanic	0 [0.014]	0.003 [0.007]	-0.009 [0.007]	-0.007 [0.007]	0.002 [0.002]
Age	0.005*** [0.001]	0.004*** [0.000]	-0.001*** [0.000]	0.001*** [0.000]	0.000*** [0.000]
Age^2	-0.000*** [0.000]	-0.000*** [0.000]	0 [0.000]	-0.000** [0.000]	-0.000*** [0.000]
Acute	0.022 [0.016]	0.015* [0.009]	-0.009 [0.008]	0.004 [0.010]	-0.057*** [0.006]
Chronic Routine	0.014 [0.017]	0.012 [0.010]	-0.008 [0.008]	-0.003 [0.010]	-0.001 [0.001]
Chronic Flare-up	0.054*** [0.021]	0.017 [0.012]	0.004 [0.010]	0.009 [0.014]	-0.011*** [0.002]

Table A.4. (Continued)

Pre/Post Surgery	-0.097*** [0.019]	-0.020** [0.009]	-0.031*** [0.008]	-0.009 [0.012]	N/A
Northeast	0.008 [0.013]	-0.011** [0.005]	-0.002 [0.007]	0.001 [0.008]	0.021*** [0.006]
Midwest	0.018 [0.013]	-0.001 [0.006]	0.007 [0.007]	0.008 [0.009]	0.053*** [0.011]
South	0.062*** [0.012]	0.010* [0.005]	0.014** [0.006]	0.01 [0.007]	0.026*** [0.005]
New Patient	0.013 [0.011]	0.005 [0.005]	0.015** [0.007]	0.003 [0.007]	-0.012*** [0.002]
Physician Owner	0.024 [0.019]	0.008 [0.010]	0 [0.011]	0.012 [0.015]	0.006** [0.003]
Physician is Employee	0.033 [0.022]	0.021 [0.014]	-0.004 [0.011]	0.02 [0.032]	0.001 [0.004]
MSA	0.020** [0.010]	0.003 [0.005]	0.003 [0.006]	0.003 [0.007]	0.001 [0.001]
Time Trend	0.024*** [0.004]	0.015*** [0.002]	0.005** [0.002]	0.007 [0.005]	-0.001 [0.001]
Observations	9692	9692	9692	3467	9410

TABLE A.5. ALLERGY SEVERITY PROBIT RESULTS – INSURED ALLERGY SAMPLE NAMCS 1997 – 2000; 2003 – 2004

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5	6	7
	Allergy Specialist	Acute	Chronic Routine	Chronic Flareup	Acute Specialist Physician	Chronic Routine Specialist Physician	Chronic Flareup Specialist Physician
AllergyOTC	0.268**	0.059	0.02	-0.156*	0.516	-0.279	-0.26
	[0.117]	[0.072]	[0.076]	[0.089]	[0.381]	[0.304]	[0.339]
Private Insurance	0.035	0.084*	-0.083*	-0.005	-0.049	0.129	-0.014
	[0.074]	[0.045]	[0.049]	[0.058]	[0.236]	[0.185]	[0.212]
Medicare	-0.005	0.012	0.026	0.008	-0.581	0.362	-0.095
	[0.111]	[0.065]	[0.068]	[0.081]	[0.373]	[0.290]	[0.333]
Capitated Visit	-0.348***	0.222***	-0.258***	-0.026	-0.426*	-0.186	0.490***
	[0.058]	[0.033]	[0.035]	[0.041]	[0.228]	[0.160]	[0.183]
Female	0.037	0.060**	-0.043	0.014	-0.096	0.029	0.109
	[0.043]	[0.027]	[0.028]	[0.033]	[0.132]	[0.109]	[0.128]
White	0.594	0.031	0.01	-0.152	-7.830***	6.765***	4.378***
	[0.415]	[0.167]	[0.180]	[0.202]	[0.535]	[0.487]	[0.539]
Black	0.57	-0.063	0.06	-0.087	-7.815***	6.819***	4.361***
	[0.420]	[0.172]	[0.186]	[0.208]	[0.575]	[0.512]	[0.569]
Asian	0.47	0.329*	-0.217	-0.304	-7.397***	6.446***	4.514***
	[0.428]	[0.179]	[0.194]	[0.219]	[0.618]	[0.570]	[0.636]

Table A.5. (Continued)

Hispanic	0.048 [0.072]	0.013 [0.049]	-0.048 [0.053]	0.059 [0.060]	0.101 [0.209]	-0.16 [0.176]	-0.01 [0.201]
Age	-0.004 [0.003]	-0.017*** [0.002]	0.019*** [0.002]	0.007** [0.003]	-0.009 [0.011]	0.009 [0.009]	-0.016 [0.011]
Age^2	0 [0.000]	0.000*** [0.000]	-0.000*** [0.000]	0 [0.000]	0 [0.000]	0 [0.000]	0 [0.000]
Acute	-0.326*** [0.096]						
Chronic Routine	0.721*** [0.092]						
Chronic Flare-up	0.308*** [0.101]						
Pre/Post Surgery	-0.818*** [0.273]						
Northeast	0.055 [0.063]	0.064 [0.041]	-0.120*** [0.044]	0.049 [0.051]	0.177 [0.227]	-0.372** [0.175]	0.397* [0.204]
Midwest	-0.460*** [0.072]	0.096** [0.040]	-0.101** [0.043]	0.04 [0.050]	0.391* [0.231]	-0.878*** [0.192]	0.732*** [0.214]
South	-0.069 [0.056]	0.071* [0.036]	-0.057 [0.038]	-0.016 [0.046]	0.450** [0.186]	-0.522*** [0.152]	0.262 [0.179]
New Patient	0.158*** [0.058]	0.270*** [0.037]	-0.251*** [0.040]	0.052 [0.045]	1.103*** [0.156]	-1.077*** [0.146]	0.286* [0.160]
Physician Owner	0.479*** [0.130]	-0.161** [0.064]	0.259*** [0.071]	-0.200*** [0.073]	5.581*** [0.196]	1.224*** [0.379]	-0.818** [0.417]

Table A.5. (Continued)

Physician is Employee	0.197	0.03	0.054	-0.321***	5.942	1.280***	-1.304***
	[0.138]	[0.067]	[0.075]	[0.079]	[0.000]	[0.421]	[0.473]
MSA	0.824***	-0.204***	0.178***	0.112**	0.787*	-0.1	0.156
	[0.096]	[0.036]	[0.039]	[0.046]	[0.442]	[0.309]	[0.354]
Time Trend	-0.049**	-0.028**	0.023	0.015	-0.177**	0.189***	-0.069
	[0.022]	[0.014]	[0.014]	[0.017]	[0.075]	[0.062]	[0.069]
Observations	9692	9692	9692	9692	722	722	722

TABLE A.6. ALLERGY SEVERITY MARGINAL EFFECT RESULTS – INSURED ALLERGY SAMPLE NAMCS 1997 – 2000; 2003 – 2004

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1 Allergy Specialist	2 Acute	3 Chronic Routine	4 Chronic Flareup	5 Acute Specialist Physician	6 Chronic Routine Specialist Physician	7 Chronic Flareup Specialist Physician
AllergyOTC	0.025** [0.012]	0.023 [0.029]	0.007 [0.026]	-0.032* [0.018]	0.098 [0.079]	-0.103 [0.113]	-0.054 [0.068]
Private Insurance	0.003 [0.006]	0.034* [0.018]	-0.028* [0.017]	-0.001 [0.012]	-0.009 [0.043]	0.048 [0.070]	-0.003 [0.046]
Medicare	0 [0.010]	0.005 [0.026]	0.009 [0.023]	0.002 [0.017]	-0.076** [0.034]	0.123 [0.090]	-0.02 [0.066]
Capitated Visit	-0.027*** [0.004]	0.088*** [0.013]	-0.084*** [0.011]	-0.006 [0.009]	-0.063** [0.028]	-0.069 [0.061]	0.124** [0.053]
Female	0.003 [0.004]	0.024** [0.011]	-0.015 [0.010]	0.003 [0.007]	-0.017 [0.024]	0.01 [0.040]	0.023 [0.027]
White	0.037** [0.017]	0.012 [0.066]	0.003 [0.061]	-0.034 [0.048]	-0.989*** [0.003]	0.903*** [0.014]	0.294*** [0.032]
Black	0.075 [0.076]	-0.025 [0.068]	0.021 [0.065]	-0.018 [0.041]	-0.289*** [0.028]	0.586*** [0.027]	0.933*** [0.013]
Asian	0.06 [0.073]	0.130* [0.069]	-0.069 [0.058]	-0.055* [0.033]	-0.155*** [0.017]	0.427*** [0.022]	0.898*** [0.012]

Table A.6. (Continued)

Hispanic	0.004 [0.007]	0.005 [0.019]	-0.016 [0.017]	0.013 [0.014]	0.019 [0.040]	-0.06 [0.067]	-0.002 [0.043]
Age	0 [0.000]	-0.007*** [0.001]	0.006*** [0.001]	0.001** [0.001]	-0.002 [0.002]	0.003 [0.003]	-0.003 [0.002]
Age^2	0 [0.000]	0.000*** [0.000]	-0.000*** [0.000]	0 [0.000]	0 [0.000]	0 [0.000]	0 [0.000]
Acute	-0.029*** [0.008]						
Chronic Routine	0.084*** [0.014]						
Chronic Flare-up	0.033** [0.013]						
Pre/Post Surgery	-0.038*** [0.005]						
Northeast	0.005 [0.006]	0.025 [0.016]	-0.040*** [0.014]	0.011 [0.011]	0.033 [0.045]	-0.140** [0.068]	0.095* [0.054]
Midwest	-0.033*** [0.004]	0.038** [0.016]	-0.034** [0.014]	0.009 [0.011]	0.083 [0.057]	-0.338*** [0.071]	0.206*** [0.072]
South	-0.006 [0.005]	0.028* [0.014]	-0.019 [0.013]	-0.003 [0.010]	0.084** [0.036]	-0.193*** [0.056]	0.058 [0.041]
New Patient	0.015** [0.006]	0.107*** [0.014]	-0.081*** [0.012]	0.011 [0.010]	0.289*** [0.052]	-0.409*** [0.051]	0.068 [0.042]
Physician Owner	0.036*** [0.008]	-0.064** [0.025]	0.085*** [0.022]	-0.045*** [0.017]	0.325*** [0.027]	0.460*** [0.125]	-0.23 [0.141]

Table A.6. (Continued)

Physician is Employee	0.019	0.012	0.019	-0.062***	0.979***	0.337***	-0.160***
	[0.015]	[0.027]	[0.026]	[0.014]	[0.003]	[0.067]	[0.030]
MSA	0.047***	-0.081***	0.058***	0.023**	0.084***	-0.036	0.031
	[0.003]	[0.014]	[0.012]	[0.009]	[0.025]	[0.108]	[0.064]
Time Trend	-0.004**	-0.011**	0.008	0.003	-0.031**	0.069***	-0.015
	[0.002]	[0.005]	[0.005]	[0.004]	[0.013]	[0.023]	[0.015]
Observations	9692	9692	9692	9692	722	722	722

TABLE A.7. ACID REFLUX PROBIT REGRESSION RESULTS – TOTAL

INSURED NAMCS SAMPLE 1997 – 2000; 2003 – 2004

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5
	Gastro RX	Nexium	Prevacid	Protonix	Zantac
Capitated Visit	0.009	-0.022	-0.003	0.093	0.107***
	[0.026]	[0.067]	[0.038]	[0.075]	[0.038]
GastroOTC	-0.123***	-3.181***	-0.125**	-0.105	0.023
	[0.042]	[0.095]	[0.059]	[0.090]	[0.075]
Capitated Visit * GastroOTC	0.017	0.071	-0.003	-0.057	-0.164*
	[0.051]	[0.092]	[0.073]	[0.102]	[0.092]
Private Insurance	-0.090***	-0.027	-0.098**	-0.102	-0.128***
	[0.035]	[0.093]	[0.049]	[0.092]	[0.049]
Medicare	-0.043	-0.108	-0.06	-0.14	-0.100*
	[0.039]	[0.105]	[0.057]	[0.105]	[0.057]
Female	-0.011	-0.074	0.01	0.062	-0.036
	[0.018]	[0.046]	[0.026]	[0.051]	[0.027]
White	0.096	-0.131	0.205	0.134	3.724***
	[0.144]	[0.267]	[0.240]	[0.343]	[0.098]
Black	0.079	-0.119	0.189	0.03	3.770***
	[0.147]	[0.276]	[0.244]	[0.355]	[0.104]
Asian	0.225	-0.037	0.352	0.272	3.832***
	[0.152]	[0.300]	[0.249]	[0.364]	[0.115]
Hispanic	0.047	-0.069	0.021	0.239***	-0.026
	[0.036]	[0.096]	[0.053]	[0.078]	[0.057]
Age	0.039***	0.037***	0.029***	0.030***	0.013***
	[0.002]	[0.006]	[0.003]	[0.006]	[0.002]
Age^2	-0.000***	-0.000***	-0.000***	-0.000***	-0.000**
	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]
Acute	0.181***	0.134	0.199***	0.052	0.101**
	[0.033]	[0.089]	[0.048]	[0.089]	[0.046]
Chronic Routine	0.211***	0.155*	0.194***	0.099	0.112**
	[0.032]	[0.086]	[0.048]	[0.086]	[0.045]
Chronic Flare-up	0.268***	0.177*	0.293***	0.043	0.141**
	[0.038]	[0.103]	[0.056]	[0.111]	[0.056]
Pre/Post Surgery	-0.093**	-0.064	-0.049	-0.134	-0.175**
	[0.045]	[0.125]	[0.068]	[0.132]	[0.070]
Northeast	0.070**	0.147*	0.047	-0.005	-0.012
	[0.028]	[0.081]	[0.042]	[0.075]	[0.043]

Table A.7. (Continued)

Midwest	0.077***	0.089	0.115***	-0.097	0.047
	[0.028]	[0.083]	[0.040]	[0.079]	[0.042]
South	0.108***	0.307***	0.084**	-0.009	0.077**
	[0.025]	[0.072]	[0.037]	[0.068]	[0.038]
New Patient	-0.138***	-0.194**	-0.078**	-0.105	-0.114***
	[0.028]	[0.080]	[0.040]	[0.081]	[0.043]
Physician Owner	0.001	0.013	0.094	-0.026	-0.141***
	[0.043]	[0.150]	[0.070]	[0.156]	[0.054]
Physician is Employee	0.091**	0.047	0.182**	0.088	-0.034
	[0.046]	[0.157]	[0.073]	[0.162]	[0.058]
MSA	-0.067***	-0.139**	-0.001	-0.116*	0.065*
	[0.023]	[0.062]	[0.036]	[0.069]	[0.038]
Time Trend	0.022***	3.198***	0.031***	0.256***	-0.050***
	[0.005]	[0.061]	[0.007]	[0.028]	[0.008]
Observations	121363	121363	121363	121363	121363

TABLE A.8. ACID REFLUX PROBIT REGRESSION RESULTS – INSURED

ACID REFLUX SAMPLE NAMCS 1997 – 2000; 2003 – 2004

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5
	Gastro RX	Nexium	Prevacid	Protonix	Zantac
Capitated Visit	0.023	-0.002	0.007	-0.05	0.157*
	[0.062]	[0.141]	[0.080]	[0.154]	[0.083]
GastroOTC	-0.113	-3.464***	-0.09	-0.177	-0.343**
	[0.094]	[0.198]	[0.122]	[0.177]	[0.169]
Capitated Visit * GastroOTC	-0.17	0.009	-0.145	-0.142	-0.139
	[0.116]	[0.195]	[0.152]	[0.216]	[0.207]
Private Insurance	0.014	-0.091	-0.011	-0.105	-0.057
	[0.076]	[0.177]	[0.096]	[0.179]	[0.102]
Medicare	-0.003	-0.101	-0.051	-0.186	0.085
	[0.088]	[0.201]	[0.115]	[0.210]	[0.124]
Female	-0.095**	-0.14	-0.028	0.05	-0.022
	[0.042]	[0.097]	[0.055]	[0.106]	[0.061]
White	0.144	0.142	0.335	4.619***	4.496***
	[0.291]	[0.481]	[0.446]	[0.569]	[0.215]
Black	0.1	0.158	0.326	4.555***	4.554***
	[0.298]	[0.502]	[0.455]	[0.590]	[0.233]
Asian	0.312	-0.177	0.523	4.418***	4.746***
	[0.306]	[0.576]	[0.461]	[0.628]	[0.237]
Hispanic	-0.022	0.063	-0.092	0.219	-0.078
	[0.082]	[0.170]	[0.112]	[0.171]	[0.119]
Age	0.039***	0.035***	0.027***	0.024**	0.007
	[0.004]	[0.010]	[0.005]	[0.011]	[0.005]
Age^2	-0.000***	-0.000**	-0.000***	0	-0.000*
	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]
Acute	-0.002	-0.039	-0.038	0.191	-0.331***
	[0.085]	[0.197]	[0.109]	[0.249]	[0.104]
Chronic Routine	0.243***	0.068	0.129	0.401	-0.188*
	[0.086]	[0.199]	[0.111]	[0.249]	[0.107]
Chronic Flare-up	0.173*	0.18	0.131	0.12	-0.271**
	[0.095]	[0.218]	[0.123]	[0.284]	[0.125]
Pre/Post Surgery	-0.085	0.035	-0.332	0.217	-0.444**
	[0.138]	[0.312]	[0.206]	[0.369]	[0.206]
Northeast	0.123*	0.183	-0.025	0.154	0.076
	[0.069]	[0.174]	[0.090]	[0.166]	[0.098]

Table A.8. (Continued)

Midwest	0.039	-0.133	0.017	-0.182	0.037
	[0.067]	[0.180]	[0.084]	[0.179]	[0.095]
South	0.147**	0.319**	-0.064	0.017	0.061
	[0.060]	[0.154]	[0.078]	[0.153]	[0.086]
New Patient	-0.225***	-0.390**	-0.014	-0.139	-0.287***
	[0.059]	[0.152]	[0.073]	[0.151]	[0.094]
Physician Owner	-0.147	-0.086	0.282*	-0.232	-0.262**
	[0.101]	[0.371]	[0.166]	[0.325]	[0.129]
Physician is Employee	-0.098	-0.225	0.290*	-0.133	-0.213
	[0.108]	[0.385]	[0.172]	[0.338]	[0.138]
MSA	-0.045	-0.079	-0.058	-0.007	0.126
	[0.054]	[0.137]	[0.071]	[0.152]	[0.083]
Time Trend	0.018	3.510***	0.023	0.321***	-0.026
	[0.012]	[0.121]	[0.015]	[0.052]	[0.016]
Observations	5386	5386	5386	5386	5386

TABLE A.9. ACID REFLUX MARGINAL EFFECT REGRESSION RESULTS – TOTAL INSURED NAMCS SAMPLE 1997 – 2000; 2003 – 2004

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5
	Gastro RX	Nexium	Prevacid	Protonix	Zantac
Capitated Visit	0	0	0	0	0.002***
	[0.001]	[0.000]	[0.001]	[0.000]	[0.001]
GastroOTC	-0.004***	0	-0.002**	0	0
	[0.001]	[0.000]	[0.001]	[0.000]	[0.001]
Capitated Visit * GastroOTC	0.001	0	0	0	-0.002**
	[0.002]	[0.000]	[0.001]	[0.000]	[0.001]
Private Insurance	-0.003**	0	-0.001*	0	-0.002**
	[0.001]	[0.000]	[0.001]	[0.000]	[0.001]
Medicare	-0.001	0	-0.001	0	-0.001*
	[0.001]	[0.000]	[0.001]	[0.000]	[0.001]
Female	0	0	0	0	0
	[0.001]	[0.000]	[0.000]	[0.000]	[0.000]
White	0.003	0	0.002	0	0.017***
	[0.004]	[0.000]	[0.002]	[0.000]	[0.001]
Black	0.003	0	0.003	0	0.790***
	[0.006]	[0.000]	[0.005]	[0.000]	[0.028]
Asian	0.01	0	0.008	0	0.862***
	[0.008]	[0.000]	[0.008]	[0.001]	[0.025]
Hispanic	0.002	0	0	0.000*	0
	[0.001]	[0.000]	[0.001]	[0.000]	[0.001]
Age	0.001***	0	0.000***	0.000***	0.000***
	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]
Age^2	-0.000***	0	-0.000***	-0.000***	-0.000**
	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]
Acute	0.007***	0	0.003***	0	0.001**
	[0.001]	[0.000]	[0.001]	[0.000]	[0.001]
Chronic Routine	0.008***	0	0.003***	0	0.002**
	[0.001]	[0.000]	[0.001]	[0.000]	[0.001]
Chronic Flare-up	0.012***	0	0.006***	0	0.002**
	[0.002]	[0.000]	[0.001]	[0.000]	[0.001]
Pre/Post Surgery	-0.003**	0	-0.001	0	-0.002***
	[0.001]	[0.000]	[0.001]	[0.000]	[0.001]
Northeast	0.003**	0	0.001	0	0
	[0.001]	[0.000]	[0.001]	[0.000]	[0.001]

Table A.9. (Continued)

Midwest	0.003*** [0.001]	0 [0.000]	0.002*** [0.001]	0 [0.000]	0.001 [0.001]
South	0.004*** [0.001]	0 [0.000]	0.001** [0.001]	0 [0.000]	0.001** [0.001]
New Patient	-0.004*** [0.001]	0 [0.000]	-0.001** [0.001]	0 [0.000]	-0.001*** [0.000]
Physician Owner	0 [0.001]	0 [0.000]	0.001 [0.001]	0 [0.000]	-0.002** [0.001]
Physician is Employee	0.003* [0.002]	0 [0.000]	0.003** [0.001]	0 [0.000]	0 [0.001]
MSA	-0.002*** [0.001]	0 [0.000]	0 [0.001]	0 [0.000]	0.001* [0.000]
Time Trend	0.001*** [0.000]	0 [0.000]	0.000*** [0.000]	0.000*** [0.000]	-0.001*** [0.000]
Observations	121363	121363	121363	121363	121363

TABLE A.10. ACID REFLUX MARGINAL EFFECT REGRESSIONS – INSURED

ACID REFLUX SAMPLE NAMCS 1997 – 2000; 2003 – 2004

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5
	Gastro RX	Nexium	Prevacid	Protonix	Zantac
Capitated Visit	0.006	0	0.001	0	0.014*
	[0.015]	[0.000]	[0.009]	[0.001]	[0.008]
GastroOTC	-0.026	0	-0.01	-0.001	-0.025**
	[0.021]	[0.000]	[0.013]	[0.001]	[0.010]
Capitated Visit * GastroOTC	-0.038	0	-0.015	-0.001	-0.011
	[0.024]	[0.000]	[0.015]	[0.001]	[0.015]
Private Insurance	0.003	0	-0.001	-0.001	-0.005
	[0.018]	[0.000]	[0.011]	[0.002]	[0.009]
Medicare	-0.001	0	-0.006	-0.001	0.008
	[0.021]	[0.000]	[0.013]	[0.001]	[0.011]
Female	-0.023**	0	-0.003	0	-0.002
	[0.010]	[0.000]	[0.006]	[0.001]	[0.005]
White	0.033	0	0.032	0.017**	0.136***
	[0.063]	[0.000]	[0.035]	[0.008]	[0.010]
Black	0.025	0	0.046	0.906***	0.977***
	[0.077]	[0.000]	[0.077]	[0.101]	[0.006]
Asian	0.085	0	0.086	0.922***	0.972***
	[0.094]	[0.000]	[0.101]	[0.096]	[0.003]
Hispanic	-0.005	0	-0.01	0.002	-0.006
	[0.019]	[0.000]	[0.011]	[0.002]	[0.009]
Age	0.009***	0	0.003***	0.000*	0.001
	[0.001]	[0.000]	[0.001]	[0.000]	[0.000]
Age^2	-0.000***	0	-0.000***	0	-0.000*
	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]
Acute	-0.001	0	-0.004	0.002	-0.028***
	[0.020]	[0.000]	[0.013]	[0.002]	[0.009]
Chronic Routine	0.061***	0	0.016	0.004	-0.015*
	[0.022]	[0.000]	[0.014]	[0.004]	[0.008]
Chronic Flare-up	0.044*	0	0.016	0.001	-0.020***
	[0.026]	[0.000]	[0.016]	[0.003]	[0.007]
Pre/Post Surgery	-0.02	0	-0.030**	0.002	-0.027***
	[0.031]	[0.000]	[0.014]	[0.005]	[0.008]
Northeast	0.031*	0	-0.003	0.001	0.007
	[0.018]	[0.000]	[0.010]	[0.002]	[0.009]

Table A.10. (Continued)

Midwest	0.009 [0.016]	0 [0.000]	0.002 [0.010]	-0.001 [0.001]	0.003 [0.008]
South	0.036** [0.015]	0 [0.000]	-0.007 [0.009]	0 [0.001]	0.005 [0.008]
New Patient	-0.050*** [0.012]	0 [0.000]	-0.002 [0.008]	-0.001 [0.001]	-0.021*** [0.006]
Physician Owner	-0.036 [0.026]	0 [0.000]	0.030* [0.016]	-0.002 [0.004]	-0.025* [0.014]
Physician is Employee	-0.023 [0.024]	0 [0.000]	0.038 [0.025]	-0.001 [0.002]	-0.017* [0.010]
MSA	-0.011 [0.013]	0 [0.000]	-0.007 [0.009]	0 [0.001]	0.01 [0.006]
Time Trend	0.004 [0.003]	0 [0.000]	0.003 [0.002]	0.003*** [0.001]	-0.002 [0.001]
Observations	5386	5386	5386	5386	5386

TABLE A.11. Acid reflux SEVERITY PROBIT RESULTS – INSURED Acid reflux SAMPLE NAMCS 1997 – 2000; 2003 – 2004
Standard Errors in Brackets
*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5	6	7
	Gastrointestinal Specialist	Acute	Chronic Routine	Chronic Flare-up	Acute Specialist Physician	Chronic Routine Specialist Physician	Chronic Flareup Specialist Physician
GastroOTC	0.288***	-0.103*	0.069	0.047	-0.206	-0.086	0.015
	[0.089]	[0.060]	[0.063]	[0.076]	[0.240]	[0.225]	[0.249]
Private Insurance	-0.104	0.122**	-0.208***	0.022	0.192	-0.409*	0.383
	[0.087]	[0.060]	[0.064]	[0.079]	[0.252]	[0.214]	[0.250]
Medicare	-0.076	0.071	-0.229***	0.184**	0.329	-0.4	0.268
	[0.101]	[0.074]	[0.076]	[0.093]	[0.280]	[0.243]	[0.283]
Capitated Visit	-0.003	0.133***	-0.058	-0.143**	0.013	0.164	-0.287
	[0.064]	[0.044]	[0.047]	[0.057]	[0.168]	[0.158]	[0.177]
Female	0.042	0.063*	-0.066*	0.001	0.138	0.042	-0.15
	[0.051]	[0.036]	[0.037]	[0.044]	[0.132]	[0.121]	[0.131]
White	-0.136	-0.639***	0.667**	-0.053	-1.179	6.116***	-0.814
	[0.326]	[0.236]	[0.277]	[0.289]	[0.791]	[0.594]	[0.768]
Black	-0.518	-0.578**	0.586**	0.007	-0.954	5.932***	-0.697
	[0.339]	[0.242]	[0.283]	[0.297]	[0.832]	[0.624]	[0.812]

Table A.11. (Continued)

Asian	0.174 [0.342]	-0.362 [0.250]	0.447 [0.290]	-0.156 [0.310]	-0.278 [0.828]	5.144*** [0.605]	-1.283 [0.828]
Hispanic	0.058 [0.093]	0.138** [0.066]	-0.075 [0.071]	0.025 [0.084]	-0.753** [0.326]	0.158 [0.232]	0.231 [0.250]
Age	0.017*** [0.005]	-0.022*** [0.003]	0.023*** [0.003]	0.016*** [0.004]	0.002 [0.016]	-0.034** [0.014]	0.026 [0.016]
Age^2	-0.000** [0.000]	0.000*** [0.000]	-0.000*** [0.000]	-0.000*** [0.000]	0 [0.000]	0.000** [0.000]	0 [0.000]
Acute	0.012 [0.115]						
Chronic Routine	0.557*** [0.113]						
Chronic Flare-up	0.559*** [0.122]						
Pre/Post Surgery	0.409** [0.161]						
Northeast	-0.06 [0.087]	0.027 [0.058]	-0.095 [0.060]	0.131* [0.074]	0.450* [0.268]	-0.291 [0.219]	0.074 [0.244]
Midwest	-0.168** [0.084]	0.092* [0.055]	-0.253*** [0.057]	0.184*** [0.070]	0.790*** [0.261]	-0.727*** [0.225]	0.024 [0.261]
South	0.336*** [0.070]	0.091* [0.050]	-0.161*** [0.051]	0.120* [0.064]	0.906*** [0.216]	-1.005*** [0.181]	0.246 [0.194]
New Patient	0.449*** [0.061]	0.395*** [0.046]	-0.354*** [0.051]	-0.128** [0.060]	0.950*** [0.142]	-0.609*** [0.141]	-0.088 [0.150]

Table A.11. (Continued)

Physician Owner	0.181	0.041	-0.063	-0.092	0.967*	-1.090***	0.55
	[0.132]	[0.088]	[0.091]	[0.104]	[0.495]	[0.342]	[0.422]
Physician is Employee	0.309**	0.106	-0.13	-0.133	1.265**	-1.515***	0.788*
	[0.139]	[0.093]	[0.097]	[0.111]	[0.508]	[0.361]	[0.436]
MSA	0.064	-0.099**	0.125**	0.025	-0.044	-0.106	0.243
	[0.068]	[0.046]	[0.049]	[0.057]	[0.174]	[0.166]	[0.193]
Time Trend	-0.064***	0.002	0.003	-0.009	0.028	0.014	0.004
	[0.014]	[0.010]	[0.010]	[0.012]	[0.037]	[0.034]	[0.038]
Observations	5386	5386	5386	5386	527	527	527

TABLE A.12. Acid reflux SEVERITY MARGINAL EFFECT RESULTS – INSURED Acid reflux SAMPLE NAMCS 1997 – 2000; 2003 – 2004

Standard Errors in Brackets

*significant at 10% **significant at 5% ***significant at 1%

	1	2	3	4	5	6	7
	Gastrointestinal Specialist	Acute	Chronic Routine	Chronic Flare-up	Acute Specialist Physician	Chronic Routine Specialist Physician	Chronic Flareup Specialist Physician
GastroOTC	0.047***	-0.041*	0.024	0.01	-0.061	-0.034	0.004
	[0.016]	[0.023]	[0.022]	[0.016]	[0.067]	[0.087]	[0.067]
Private Insurance	-0.015	0.048**	-0.072***	0.005	0.059	-0.160*	0.1
	[0.013]	[0.024]	[0.022]	[0.016]	[0.076]	[0.083]	[0.064]
Medicare	-0.011	0.028	-0.077***	0.040*	0.105	-0.153*	0.074
	[0.014]	[0.029]	[0.025]	[0.021]	[0.092]	[0.091]	[0.081]
Capitated Visit	0	0.053***	-0.02	-0.029***	0.004	0.065	-0.071*
	[0.009]	[0.017]	[0.016]	[0.011]	[0.052]	[0.063]	[0.041]
Female	0.006	0.025*	-0.023*	0	0.042	0.016	-0.041
	[0.007]	[0.014]	[0.013]	[0.009]	[0.040]	[0.047]	[0.036]
White	-0.021	-0.249***	0.195***	-0.011	-0.43	0.712***	-0.268
	[0.054]	[0.087]	[0.065]	[0.063]	[0.290]	[0.032]	[0.287]
Black	-0.055**	-0.213***	0.220**	0.001	-0.200**	0.695***	-0.135
	[0.025]	[0.080]	[0.111]	[0.062]	[0.100]	[0.023]	[0.103]

Table A.12. (Continued)

Asian	0.028 [0.061]	-0.138 [0.090]	0.167 [0.114]	-0.03 [0.054]	-0.078 [0.208]	0.700*** [0.024]	-0.189*** [0.051]
Hispanic	0.009 [0.014]	0.055** [0.026]	-0.025 [0.023]	0.005 [0.018]	-0.177*** [0.053]	0.062 [0.092]	0.067 [0.078]
Age	0.002*** [0.001]	-0.009*** [0.001]	0.008*** [0.001]	0.003*** [0.001]	0.001 [0.005]	-0.013** [0.006]	0.007 [0.004]
Age^2	-0.000** [0.000]	0.000*** [0.000]	-0.000*** [0.000]	-0.000*** [0.000]	0 [0.000]	0.000** [0.000]	0 [0.000]
Acute	0.002 [0.017]						
Chronic Routine	0.094*** [0.022]						
Chronic Flare-up	0.107*** [0.029]						
Pre/Post Surgery	0.076** [0.037]						
Northeast	-0.008 [0.012]	0.011 [0.023]	-0.032 [0.020]	0.028* [0.017]	0.153 [0.098]	-0.111 [0.080]	0.02 [0.068]
Midwest	-0.023** [0.011]	0.037* [0.022]	-0.084*** [0.018]	0.040** [0.016]	0.281*** [0.099]	-0.257*** [0.068]	0.006 [0.070]
South	0.051*** [0.011]	0.036* [0.020]	-0.055*** [0.017]	0.025* [0.014]	0.271*** [0.061]	-0.379*** [0.063]	0.065 [0.051]
New Patient	0.079*** [0.013]	0.157*** [0.018]	-0.113*** [0.015]	-0.025** [0.011]	0.325*** [0.050]	-0.227*** [0.049]	-0.023 [0.039]

Table A.12. (Continued)

Physician Owner	0.025	0.016	-0.022	-0.02	0.250**	-0.414***	0.131
	[0.017]	[0.035]	[0.032]	[0.023]	[0.102]	[0.116]	[0.089]
Physician is Employee	0.050**	0.042	-0.044	-0.027	0.441**	-0.481***	0.243
	[0.025]	[0.037]	[0.032]	[0.021]	[0.176]	[0.080]	[0.148]
MSA	0.009	-0.039**	0.042***	0.005	-0.014	-0.042	0.06
	[0.009]	[0.018]	[0.016]	[0.012]	[0.055]	[0.066]	[0.044]
Time Trend	-0.009***	0.001	0.001	-0.002	0.009	0.006	0.001
	[0.002]	[0.004]	[0.003]	[0.003]	[0.011]	[0.013]	[0.010]
Observations	5386	5386	5386	5386	527	527	527

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